Towards Developing CAD/CAM Solutions in the Retention of Extra-Oral Facial Prosthetics

Within the Discipline of Design

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Abstract

In the production of removable facial prosthetics, Computer-Aided Design and Manufacture (CAD/CAM) is being increasingly explored. This PhD thesis investigates the application of CAD/CAM in the design and production of components that retain the prostheses to the anatomy. Conventional methods of hand-crafting the retention elements are well established but little research has considered producing these elements using CAD/CAM. A fully digital prosthetic workflow has not yet been developed, and the efficacy of using CAD/CAM for retention mechanism design and fabrication remains unclear.

This study firstly focuses on defining the requirements for designing extra-oral prosthesis retention mechanisms, by mapping the various stages of conventional practice and obtaining the opinions of practicing clinicians. Secondly, the qualitative findings are applied to develop a fully CAD/CAM process using existing technologies. Scanning, reverse engineering, design and fabrication technologies are trialled and samples of bar-clip mechanisms are produced. The final stage focuses on developing objective methods to evaluate aspects of bar-clip design previously limited to subjective evaluation, and to make an initial comparison of conventional and CAD/CAM bar-clip mechanisms. This focuses on measuring surface and dimensional quality, accuracy of fit and clip retention forces.

This study provides an increased knowledge-base of current prosthetic practice; CAD/CAM prosthesis production and evaluation methods; and insight into the attitudes of clinicians towards the integration & implementation of CAD/CAM.

The thesis demonstrates that CAD/CAM can be used to design, produce, and integrate bar-clip retention mechanisms in all aspects of the prosthesis production workflow. Digital measurement methods allow an objective evaluation of the important aspects of bar-clip mechanism design, identifying a number of inaccuracies/design flaws that current evaluation techniques fail to identify. The study concludes that the overall CAD/CAM workflow is not yet appropriate for clinical practice but there is potential in the newly developed processes and this drives future work.

Keywords: Maxillofacial Prosthesis, CAD/CAM, Extra-Oral, Retention Mechanism

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Declaration

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

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This thesis is the result of my own investigations, except where otherwise stated.
Other sources are acknowledged by giving explicit references. A bibliography is appended.

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Glossary of Terms & Abbreviations

3D Systems	Company that provides consumer and industrial 3D printing and manufacturing solutions
Abutment	Component that connects to bone implant and protrudes through the skin
AM	Additive Manufacturing
BAHA	Bone Anchored Hearing Aid
Bar Structure / implant framework	Retention component that connects to abutments and holds clips within prosthesis in place
CAD	Computer Aided Design
CAM	Computer Aided Manufacturing
CMM	Coordinate Measurement Machine
CNC	Computer Numerically Controlled
CT	Computer Tomography scanning. A medical scanning method that produces sliced, pixel computer images.
DMLS	Direct Metal Laser Sintering. An AM process that builds in metal.
Extra-oral	External to the oral cavity
EnvisionTEC	Company that provides 3D printing solutions
FCubic	Company that provides metal 3D printing using ink-jet technology
FDM	Fused Deposition Modelling
Haptic	The sensation of touch
IAA	International Anaplastology Association
IMPT	The Institute of Maxillofacial Prosthetists & Technologists
Intra-oral	Internal to the oral cavity
ISMR	The International Society for Maxillofacial Rehabilitation
Laser Cusing	Laser melting with metals by Concept Laser
Materialise	A software developer and supplier of Additive Manufacturing services based in Belgium
Maxillofacial (surgery)	Surgical speciality concerned with the diagnosis and treatment of diseases affecting the mouth, jaws, face and neck.
MPT	Maxillofacial Prosthetist and Technologist
MRI	Magnetic Resonance Imaging. Medical scanning technology.
Objet	Objet Geometries RP system that manufactures in a photopolymer.
Osseointegration	A fixed, bone anchored retention method for attaching external or oral prostheses.
Palatal Obturator	A prosthesis that closes a cavity in the roof of the mouth
PDR	The National Centre for Product Design & Development Research, Cardiff Metropolitan University
Precision Attachment	Retention systems used in dentistry
RE	Reverse Engineering
RP	Rapid Prototyping
RPD	Removable Partial Denture framework
SLA	Stereolithography Apparatus
SLM	Selective Laser Melting. An AM process that builds in metal.
SLS	Selective Laser Sintering
Solidworks	Computer-Aided Design software by Dassault Systemes
STL	STereoLithography file format. Defines 3D volumes in faceted triangles.
Sub-structure / base-plate / clip structure	The component that combines an acrylic casing and multiple clips for use in bar-clip retention mechanisms
Watertight CAD model	No holes or geometric overlaps in the CAD model (manifold)

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Chapter 1: Introduction

1.1 Context

As a consequence of tumour surgery, congenital deformities, trauma or other damaging diseases, a portion of the head or face is often left missing. When reconstructive surgery is inappropriate, the missing tissue can be restored by artificial means, through the use of a Removable Maxillofacial Prosthesis. As well as restoring the anatomy and camouflaging the defect, this method of treatment can aid the psychological rehabilitation of the person in attempt to restore his/her appearance. This, in essence, is the work of a Maxillofacial Prosthetist and Technician (MPT).

Maxillofacial Prosthetics (called Anaplastology in some parts of the world), is associated with artificially replacing injured parts of the face, but people also use a removable prosthesis to restore fingers, hands, feet, toes, breasts, and portions of the head. All kinds of removable facial prostheses are worn. Artificial eyes, noses and ears are most common, but larger portions of the face can also be restored this way. The design processes involved in the field of Maxillofacial Prosthetics are traditionally craft-based, but in recent years the field has shown an increasing interest in Computer Aided Design and Manufacture (CAD/CAM).

CAD/CAM technologies are well-established means of designing, prototyping and manufacturing products in many different industries. The development and adoption of these technologies is growing quickly in the patient-specific medical device industry. Such devices are individualised to the requirements and anatomical form of the patient. Removable prostheses are a good example, but other devices include customised implants, personalised splints and burns masks. There is significant scope for research and commercial application of using CAD/CAM in patient-specific devices, particularly in the field of extra-oral Maxillofacial Prosthetics, where adoption has been slower compared with dental technology and facial implantology.

In extra-oral removable Maxillofacial Prosthetics, there are limited standards controlling the levels of quality and accuracy in the design and fabrication processes (Eggbeer, 2008). This is especially true with regards to the customised mechanisms that are used to retain the removable prostheses to the anatomy. Methods of creating prosthesis retention mechanisms rely on MPT judgement, experience and skill through the application of various manual hand crafting techniques, analogous to processes in jewellery making. Figure 1 shows a typical prosthesis retention mechanism and ear prosthesis.

Figure 1: Prosthesis retention mechanism and prosthesis

The craft-based nature of retention mechanism fabrication means that inaccuracies can be introduced during the process, which can subsequently be the cause of implant and prosthesis failure. Processes are required that should reduce complications and number of patient visits to the hospital. An opportunity exists to explore the use of CAD/CAM technologies for the design and manufacture of prosthesis retention mechanisms, and to evaluate the processes against conventionally used methods.

This thesis concentrated on the amalgamation of two aspects – *extra-oral prosthesis retention and CAD/CAM technology*. It focused on using CAD/CAM to create, integrate and evaluate the intricate retention components involved in the prosthetic assembly. Very little research has been conducted focusing on this application of CAD/CAM, and this PhD generated new knowledge in this area.

To allow an appropriate application of CAD/CAM, a thorough understanding of the conventional retention mechanism design and fabrication process was required, and which aspects influence part performance. Appropriate CAD/CAM technologies were identified, trialled and compared to conventional practice.

Research in maxillofacial prosthetics is broad and covers science, art, design, engineering and psychology. A literature review was conducted so that the existing state of knowledge could be established, and gaps in the existing research and possible avenues for the PhD study could be identified. This provided initial direction for the PhD study and allowed research objectives to be devised.

The thesis began by reviewing the existing literature, which covered Phase 1 of the research (Chapters 1, 2 and 3). Chapter 1 provides an overview of the Maxillofacial Prosthetics field, state of conventional practice, and the primary research trends within this subject. Chapter 2 focuses on providing a review of bone-anchored retention, including how the various features and performance indicators of retention mechanisms have been evaluated in previous literature. Chapter 3 provides a review of CAD/CAM technologies in the area of Maxillofacial Prosthetics, particularly highlighting where CAD/CAM has been adopted in retention mechanism design and fabrication. Chapter 4 describes how the information obtained in the literature review was used to form a research plan. This chapter explains the overall research approach and lists the individual study methods used within the PhD.

Phase 2 (reported in Chapter 5) of the research focused on capturing in-depth data from MPTs specifically about retention mechanism design and fabrication, and about their processes and requirements. This chapter provides an account of in-depth interviews, an international survey and observations of MPT practice, all of which were conducted with practicing MPTs.

Chapter 6 documented the methods and findings from Phase 3 of the research. This phase was exploratory in nature, and was focused on trialling the available CAD/CAM technologies for obtaining novel retention mechanism samples. This phase also allowed a fully digital prosthetic process to be developed.

The final phase of the research focused on the technical characterisation of the obtained retention mechanism samples, reported in Chapters 7, 8 and 9. Firstly, chapter 7 focuses on methods to measure the surface and dimensional quality of the retention mechanism samples. Chapter 8 focuses on developing a method to measure accuracy of fit of the components and Chapter 9 describes a process to measure the retention forces produced by traditional and experimental retentive clips. All results from the individual studies are presented in each of the relevant chapters.

Chapter 10 reflects on the overall research approach, and discusses the study methods, limitations and findings in relation to the research objectives devised. Chapter 11 consolidates the PhD study outcomes and findings, and provides recommendations for future work.

1.2 Maxillofacial Prosthetics

Maxillofacial prosthetics became a specialist profession after the First World War, due to the many soldiers who were left disfigured. In March 1916, Francis Derwent Wood established a mask-making unit for facial disfigurement, which focused on helping soldiers who had been facially disfigured during combat. Wood described his craft (Alexander, 2007):-

> *"I endeavor by means of skill I happen to possess as a sculptor to make a man's face as near as possible to what it looked like before he was wounded…. The patient acquires his old self-respect, self assurance, self-reliance…takes once more to a pride in his personal appearance."*

There have been significant developments in technology, surgical technique and improvements in cancer treatment and detection in the last decade (Bibb et al., 2010). This has led to an increased number of patients with large post-surgical defects that require prosthetic rehabilitation, and therefore the demand for maxillofacial prosthetics is increasing. However, with increased patient numbers and a lack of investment, the Maxillofacial Prosthetics field is faced with challenges. There are a decreasing number of professionals entering the field and access to prosthetic services can be difficult for some patients. Prosthetic treatment currently relies on technically complex, time-

consuming, craft-based techniques, but the training required for the application of new technologies is limited and requires costly specialist courses. These challenges must be tackled in order to meet healthcare and patient demands (Eggbeer et al., 2012b).

Bibb et al. (2010) made a rough estimation that collectively about 64,000 prostheses are needed a year in developed countries. Watson et al. (2006) used a survey to estimate 4359 extra-oral prostheses were provided in the UK in 2002. Of the 98 UK-based maxillofacial laboratories that were sent the survey, a response rate of 63% was achieved. This means that the true number of prostheses could be much higher - without key figures provided from every laboratory in the UK, the number is difficult to gauge. Bibb et al. (2010) noted a potentially large demand for facial prostheses in developing countries, but this demand is unmet and could offer valuable opportunities for the prosthetics market.

1.2.1 The Maxillofacial Prothetist & Technician (MPT)

The profession of Maxillofacial Prosthetics is governed by three main bodies – The International Anaplastology Association (IAA), The International Society for Maxillofacial Rehabilitation (ISMR) and The Institute of Maxillofacial Prosthetists & Technologists (IMPT). The three organisations provide platforms for the discipline of Maxillofacial Prosthetics, to oversee training and education, and to provide advice for patients, professionals and governmental groups. The bodies also act as forums for research and innovation through the coordination of conferences, seminars and publication, for the development of the profession and practice. Other charitable organisations, which support the rehabilitation of facially disfigured people, 'Let's Face It' for example, connects people with disfigurements to resources for recovery.

The work of MPTs involves constructing a variety of artificial anatomical features. MPTs also fabricate customised implants and surgical devices for the reconstruction, substitution or re-positioning of bony tissues. The work mostly involves craft-based methods to accommodate the array of challenging patient-specific cases. Watson et al. (2005) conducted a UK survey to obtain an overview of staff profiles and their work.

Findings revealed that laboratories did a variety of work, Maxillofacial Prosthetics occupying 47% of the work week, the rest being orthodontics and dental prosthetics.

Maxillofacial Prosthetics requires an interdisciplinary team effort, which involves the contribution of specialist skills and knowledge from MPTs, Maxillofacial surgeons, dentists, speech therapists, physiotherapists and digital design specialists. The treatment of maxillofacial defects requires cooperation and coordination between those treating the defect, and those responsible for the rehabilitation and emotional wellbeing of the patient. The interdisciplinary, patient-centred approach is important to treating such patients and the skills of the various specialists are complimentary. The MPT plays many roles, including adopting a supporting role to the patient. Watson et al. (2006) conducted a survey which referred to the relationship between the MPT and patient. 89% of the respondents said that they build a relationship with their patients. Eggbeer (2008) collated the responsibilities and key skills needed as an MPT:

- Understanding of anatomy and physiology (especially the head and neck)
- Understanding of materials and lab techniques
- Artistic ability (for sculpting, crafting and colour matching prosthetic items)
- Understanding of indications for prosthetic rehabilitation
- Understanding of surgical processes
- Understanding of psychological issues

The MPT plays an advisory role to the maxillofacial surgeon, and supports other specialities such as plastic surgery and neurosurgery. Communication between the MPT and surgeon, especially regarding pre-operative patient assessment is paramount, but this relationship has not been described in depth in the literature.

1.2.2 Indications for Prosthetic Rehabilitation

Worthington and Brånemark (1992) advocate that prosthetic reconstruction provides a good alternative to reconstructive surgery, where the cavity cannot be sealed permanently. In malignant cases for example, it is important not to close areas where a tumour may reoccur. Surgical processes, unlike prosthetic solutions, are often difficult

to reverse. The surgeon may already be working with distorted, low quality or scarred anatomy. However, Wolfaardt et al. (2003) stated that autogenous reconstruction and prosthetic reconstruction should be seen as complimentary, not as '*competing approaches'*. A number of researchers (Worthington and Brånemark, 1992; Maller et al., 2010; Wilkes and Wolfaardt, 1994; Thorne et al., 2001; Goiato et al., 2009b) have presented indications for extra-oral prosthetic reconstruction over surgical reconstruction. These include:

- Major cancer extirpation
- Potential tumour reoccurrence
- Severely compromised or underdeveloped tissue
- Size or location of the facial defect
- Failed autogenous reconstruction
- Previous radiotherapy treatment or poor operative risk
- Surgeon's training, experience and tradition
- Psychophysical conditions of the patient
- Patient preference
- Patient ability to maintain the prosthesis and patient lifestyle

The psychological benefits and lifestyle improvements of prosthetic reconstruction have been documented (Sela and Lowental, 1980), and it is a process which allows full control over colour, shape and position of the new anatomy. However, prosthetic reconstruction can also have complications. Mantri et al., (2011) suggested that prostheses can cause irritation of the tissue site, especially when prostheses can not be cleaned properly or when using adhesives. Prostheses also require periodic remake, which requires multiple patient visits.

1.2.3 Classification of Maxillofacial Prostheses and associated components

Medical devices are classified according to the risk they pose on the patient. The classification of custom medical devices is regulated by the Medical Devices Directives 93/42/EEC (MHRA 2006; 2008). The classification rules are broad, and are designed to be flexible to accommodate the continual developments in medical technology. The

directives act as guidelines for the design and manufacture of medical devices, including Maxillofacial Prostheses.

Maxillofacial prostheses are a *'replacement or modification of the anatomy*' (MHRA 2006). They are classified as custom-made medical devices which, according to the MHRA, do not pose significant risks to the patient. A custom-made medical device is a device that (MHRA 2006):-

> *a) Is manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design;*
>
> *b) Is intended for the sole use of a particular patient.*

In the classification of maxillofacial prostheses, there is no information focusing on the individual components of the device, rather it concentrates on the overall assembly. Some prostheses protrude deeply into the face, and many of the custom-made components sit on screw-like implants, which are anchored into the bone. There is little specific information regarding these individual components, which may have a direct influence on the success of the prosthetic treatment.

There is a large crossover between implantology, dental technology, maxillofacial prosthetics, and limb prosthetics. These categories rely on different design criteria but share similarly designed components and fabrication processes. Stock components and materials are often manipulated to form custom-made devices, but there is lack of guidance to inform new technology developers of the technical requirements involved in the development of such devices (Eggbeer, 2008).

1.2.4 Removable Maxillofacial Prosthesis Designs

The various prosthesis designs have been well documented. They have been largely documented by illustrating cases from clinical practice. Many textbooks (Brånemark and de Oliveira, 1997; Taylor, 2000; Thomas, 2006) describe the various types of prosthetic solutions available, and many journal articles describe methods of creating prostheses. Nasal (Goiato et al., 2009c), auricular (Demir et al., 2010), orbital (Khan et al., 1994), and large complex (Nandini and Chandrasekharan, 2003) cases have been

described, as well as combination intra/extra oral prostheses (Brignoni and Dominici, 2001). The literature provides many case reports that allow an understanding of the various types of prostheses available. This thesis deals primarily with extra-oral (external to the oral cavity) prosthetics, and an understanding of the available solutions is required.

Nasal prostheses (nose) are required when part of/all of the nose or the mid-face is removed, see figure 2. These prostheses often extend across the face and sometimes include lips or eyes. Airflow is often required within the prosthesis so that moisture does not build under the prosthesis whilst breathing. This is a very mobile part of the face, and often the margins (edges of the prosthesis) that sit on the upper lip and cheeks are lifted, which causes the prosthesis to be noticed. These prostheses are often retained to the anatomy by magnets, bar-clip structures that extend across the cavity, or eyeglasses.

An *orbital prosthesis* (eye region) is required when the orbit, including the eye, is surgically removed, see figure 3. An ocular unit is often provided, held in place by the silicone prosthesis. These prostheses are commonly retained by magnets, bar-clip structures, and eyeglasses. Sometimes, the shape of the orbital cavity is utilised as a means of retention. Prominence of facial expressions and blinking in this region means that creating realistic orbital prostheses is challenging.

Figure 2: Nasal prosthesis

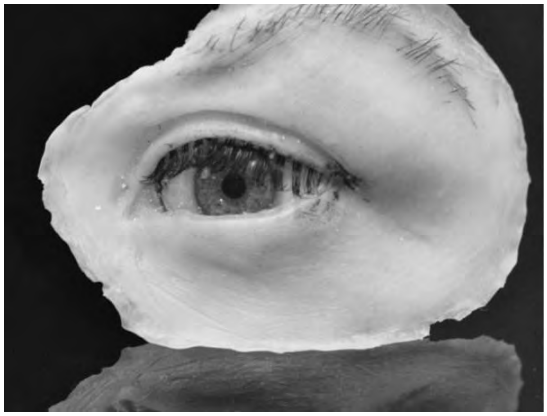


Figure 3: Orbital prosthesis

The fabrication of an *auricular prosthesis* (ear) can often be created by mirroring the opposing healthy ear, but many are also provided for people who have congenital

deformities where both ears are affected (bilateral defects), see figure 4. This is one of the main challenges in designing auricular prostheses, when there are limited landmarks available for positioning the ears. The anterior margins of the ear are often a challenge to camouflage due to the movement created by the Temporal Mandibular Joint. These prostheses sometimes even need to combine a hearing aid or retain glasses. Auricular prostheses are commonly retained to the anatomy by bar-clip structures, magnets or studs, which sit on implants anchored into the bone. Adhesives are also used to retain auricular prosthesis, especially for patients with limited dexterity, or where implant prognosis is poor.

Figure 4: Auricular Prosthesis, clips bonded within the body

The various methods of prosthesis retention will be described in Chapter 2.

1.2.5 The prosthesis production process: An overview

The generic stages involved in designing and fabricating facial prostheses for the rehabilitation of defected facial anatomy have been documented in a number of articles and textbooks (Taylor, 2000; Thomas, 1994; 2006). Wolfaardt et al. (2000) described the implant-based prosthetic process as;

> *'stepwise, protocol-driven process, involving multiple disciplines, which can seem complex and sometimes confusing to staff and patients.'*

Wolfaardt stated that the process needs to be structured and well maintained. The manual crafting techniques vary largely in the literature, so it is challenging to see

consistency in the process and identify literature that provides depth on all stages of the process. The general stages involved in the process were collated and are described below. Some of these stages are described in further detail later in the literature review.

Prosthesis production process

1. Patient consultation (plan prosthetic treatment and requirements)
2. CT Scan (obtain data)
3. Plan implant sites and create surgical drilling guide (can be done using virtual planning software)
4. Surgery – implants placed into the bone
5. Osseointegration of implants and healing process (6 weeks)
6. Take a silicone impression of the healthy and defected site (obtain anatomical surface and locations of implants by using impression copings)
7. Create Dental Stone replica of the anatomy with replica abutments placed in stone
8. Design of the retention mechanism (bar and clip / magnet /studs etc)
9. Sculpt the prosthesis wax pattern (process of sculpting and fitting, can be based on mirrored healthy anatomy)
10. Plaster mould production, with placement of retention structures
11. Boil out the wax pattern to leave a negative of the pattern
12. Colour matching (Patient present, process of mixing colours to match patient's skin)
13. Pack the mould with silicone, prime the female retention structure and cure
14. Remove prosthesis, trim excess material
15. Try the fit to the patient and apply appropriate retention forces (if adjustable)
16. Extrinsic colouring, detailing (eyebrows, eyelashes etc)

The process of creating the associated retention attachments has not been described fully in depth in the literature. Some literature describes the process of fabricating retention mechanisms, but it is generally vague and does not provide a critical view on the process. The most detailed schematic is provided by Bergström (1997), but even this does not describe or critique the process in depth, or discuss the variety of possible routes in the process, and the associated issues with the various techniques. The detailed

processes used to create the retention assemblies have been overlooked, with disregard to the significance of the sub-stages in the process. A critical analysis and detailed breakdown of the techniques used to craft retention mechanisms is needed to inform practitioners, researchers and technology providers.

1.2.6 Prosthetic materials

A large number of materials have been trialled in soft tissue prosthetics, including latex, gelatine, natural rubber and silicones. Methacrylates and silicones have particularly established themselves in prosthetics. Mantri et al. (2011) & Maller et al. (2010) provided a historical review of the evaluation of soft tissue replacement materials. No information was provided, however, on the evolution of retention mechanism materials in the extra-oral literature, although dental materials have been described comprehensively (Craig et al., 2004). Surveys (Andres, 1992; Montgomery and Kiat-Amnuay, 2010) have been conducted to gauge an understanding of MPT preference in prosthetic materials, and to determine the most frequently used materials and perceived properties of an ideal material. The technical properties of soft tissue replacement materials have been tested by some researchers, focusing on tear strength, hardness, and surface roughness (Bellamy et al., 2003).

There is a divide in the literature focusing on materials used for the soft tissue elements (prosthesis body) and retention elements (bar structures etc). Literature describing the retention mechanism materials is more associated with implant frameworks for *intra-oral* applications. Cast noble alloys (gold, palladium, silver, platinum), cast base metal alloys (Cobalt Chrome), milled titanium frameworks and Zirconium frameworks were described as being materials well suited to dental frameworks. The important factors associated with materials used in fixed implant frameworks for intra-oral applications were reviewed by Drago and Howell (2012) but limited research exists providing material requirements for fabricating *extra-oral* mechanisms.

1.3 Research in Maxillofacial Prosthetics: Overview

The quality of the existing research and research trends in Maxillofacial Prosthetics has been described by some researchers (Al Mardini, 2009; Eggbeer, 2008; Wolfaardt et al., 2003). There has previously been a lack of coherent direction for research in this field, but some researchers have attempted to provide future direction. A recent workshop report (Eggbeer et al., 2012b) discussed a research strategy for facial prosthetics. The report concluded that research in this field needs to move towards evidence-based practice, focusing on the improved efficacy of prosthetic procedures and improved economic performance. The drivers for change were identified – including the need to increase accuracy and consistency in practice; improve materials; decrease invasiveness of procedures; reduce surgical and laboratory time and costs; and reduce training time for MPTs. This report suggested that current practices urgently need to be evaluated so that a foundation of data on conventional practice can be established.

1.3.1 Case studies focusing on craft techniques and clinical results

Al Mardini (2009) reviewed the current trends in prosthetic rehabilitation of the head and neck area and found that the literature is abundant with case reports describing new craft techniques through case study articles. Preceding this, Wolfaardt et al. (2003) also stated that the majority of the literature were case reports. Wolfaardt et al. indicated that within this literature, only 4% (between 1995-1998) were controlled studies and were still considered to be at the lowest level in the hierarchy of strength of evidence. Al Mardini (2009) recognised that evidence-based research focusing on the evaluation of the craft techniques is limited, and the advancement of the scientific methodology in this field remains inadequate. Eggbeer (2008) also stated that most of the literature in this field focused on single case studies that provided minimal critical evaluation of the entire treatment process. Recognising that case study methods are a dominant feature in the literature is important, and shows that this is an integral part of the dissemination of research in this field. However, robust scientific methodologies must also be introduced in the field to strengthen the evidence obtained in practice.

Case study dissemination is important in Maxillofacial Prosthetics, but this research must be accessible to practitioners. No database of extra-oral case studies exists and this makes accessing this research in a coherent manner difficult. Single case study techniques and outcomes must be easily accessible to practicing MPTs if the research is to be of value.

The previous dissemination of prosthetic techniques and processes in many cases is the presentation of a craft technique, as conducted by the MPT, describing the generic stages of the process and presenting the final prosthesis as the result. Therefore, this case study literature tends to contain a lack of in-depth information on the process, its idiosyncrasies and issues. Following this, research has not yet been presented describing the process of fabricating extra-oral retention mechanisms from an observational approach. This would allow in-depth data focusing on current practice to be captured.

1.3.2 Subjective evaluation of prostheses

In the literature, measuring the overall success of a maxillofacial prosthesis has been mainly a subjective task, focusing on the overall satisfaction of the patient and subjective evaluation of the final result by the MPT. As recognised by Eggbeer (2008), some aspects of prosthesis design and production are difficult to quantify, where there are no formalised quantitative testing methods available.

An improved quality of life for a patient is ultimately the main goal of prosthetic rehabilitation. However, in a literature review article by Goiato et al. (2009b) it was highlighted that studies on changes in perceived quality of life after prosthetic rehabilitation are limited. This may be complicated to quantify however, because the psychological impact of losing part of the face is different for every patient, and the severity of injuries varies considerably.

A handful of surveys have been conducted to gauge the attitudes and opinions of patients about their prostheses (Chang et al., 2005; Hooper et al., 2005; Markt and Lemon, 2001; Schoen et al., 2001b). Survey parameters have focused on various aspects of prosthetic reconstruction - aesthetics (colour & shape), retention, home care

(maintenance), longevity, cost, prosthetic use and general quality. Schoen et al. (2001b) also evaluated the functional comfort of the prosthesis (based on a rating scale), the psychological acceptance of the prostheses (by using Linear Analogue Self-Assessment method), and conducted a clinical assessment on the condition of the surrounding tissues. The articles concluded that patients are generally satisfied, but the areas in which they would like improved performance are the colour stability of the prostheses, prosthesis longevity and improved retention mechanisms.

A small number of studies (Hatamleh et al., 2010; 2011) have focused on MPT attitudes and opinions about their work. However, these studies have offered little depth on the opinions of MPTs about their processes, retention components, and toward the integration of CAD/CAM into the prosthetic process. No in-depth interviews have previously been conducted to obtain this information, and this may offer a deeper insight into MPTs views.

To measure the success of a prosthesis, many factors need to be considered. Standardised patient questionnaires can be provided, and a clinical assessment must be performed. But these methods essentially provide qualitative data, and offer little on the quantifiable, technical performance of the associated components. Although a valuable source, the opinion of person (patient or MPT) cannot be relied on fully to evaluate the technical aspects of the designs, which essentially require more accurate measurement techniques. A more scientific approach is needed to allow objective evaluation methods, to accompany and compliment the existing subjectively driven methods.

1.3.3 Adoption of CAD/CAM technologies - overview

The digital revolution has changed the way we live, work and think. The beginning of the new 'Information Age' has influenced a huge variety of industries. Medicine and healthcare has been heavily impacted by changes brought by computing technologies. A new wave of customised products and services, borne by advances in design technologies, are catering for the needs of individuals on a mass scale. Such technologies are replacing, supporting and complimenting many traditional techniques

of customising products and the benefits of using these technologies are becoming increasingly clear.

The ability to translate a real object into digitised data, manipulate its form and manufacture a new object with almost boundless geometric possibilities has become a hot topic in recent years. For example, Additive Manufacturing (AM) is being utilised to cater for mass customisation for the general population, where companies like Shapeways (Shapeways Inc.) provide an online platform for people to upload and sell 3D printed designs of their own.

The medical device industry has benefited from this shift in thinking, moving from mass-production to mass-customisation of many products. Many medical devices can now be designed and manufactured digitally to suit an individual patient's needs using specialised computer programmes and advanced manufacturing processes.

Patient-specific digital design services have evolved to improve processes and services in surgery and healthcare. 3D design and prototyping agencies can process medical scan data and manufacture a 3D model of the patient's anatomy (typically 3D printed). Some hospitals have purchased their own additive manufacturing machines to produce models in-house. However, more complex CAD/CAM procedures require a collaborative effort using the expertise of designers, engineers, technologists and clinicians (Sugar et al., 2004). Such services focus on being patient-centred, where products are individualised to fit the patient's anatomy or condition.

There has been an increasing interest in using CAD/CAM methods as a means of creating Maxillofacial prostheses but it is still difficult to gauge the extent of the benefits (Eggbeer et al., 2012a) or even what is fully possible with the available technologies. This provides significant research and commercial opportunities in this field. Despite the increasing interest in CAD/CAM, the quantity of research exploring the use of these technologies in Maxillofacial Prosthesis production is still relatively low, and some aspects of prosthesis design remain almost untouched.

The concept of designing and fabricating extra-oral retention mechanisms by using CAD/CAM has been discussed by some researchers (Eggbeer, 2008; Ciocca et al.,

2010a; de Crescenzio et al., 2011) but this area is largely unexplored and this thesis aims to capitalise on this gap in the research. The state of the art in CAD/CAM prosthesis production was described by Bibb et al. (2010), and an initial design specification was provided to guide technology developers in this field. This specification should be reviewed and updated, because on-going technology developments mean that such guidelines may become outdated within a short period of time. Research in CAD/CAM in facial prosthetics is discussed in more detail in Chapter 3.

1.3.4 Requirements for successful prostheses

Measuring the success of a prosthesis is difficult, and relies on a number of factors. Prosthesis success can be considered from the point of view of the patient, those who are close to the patient (family members etc), and those who fabricate it (MPT, designer). Thomas (2006) stated that a prosthesis must achieve '*realistic aesthetics, functional retention and stability*'. dos Santos et al. (2010) indicated that a successful prosthesis relies on knowledge concerning '*principles of facial harmony, colour mixture, adaptation, retention, prosthesis weight, durability and biocompatibility'*, and that these factors are directly related to material selection. dos Santos et al. (2010) also suggested that successful implant-based prostheses rely on factors concerning the planning of placement of implants, and it was noted that a good connection is needed between the prosthesis body and the retentive elements. Despite a general understanding of these criteria, these lists lack specific technical data, and only a few researchers have attempted to quantify these aspects. This will be discussed later in the literature review.

Determining the success of a prosthesis requires more than asking a patient if they are satisfied, although of course, this contributes largely to the concept of success. As suggested by Brånemark et al. (1985), the patient's appraisal of a prosthesis is important, but he/she may have compromised bone or soft tissue, which is non-obvious to the patient. Brånemark et al. highlighted the importance of using criteria to establish the appropriateness of the tissue for tissue-integrated prosthetic rehabilitation. Measurable criteria should also apply to the use of new materials, processes and designs used in extra-oral prosthetic components. Many of the techniques used in practice have been

adopted from dental applications, but in extra-oral prosthetics, a different set of requirements is required.

Literature (Parel et al., 1986; Thomas, 2006) defining a criteria for successful prostheses tend to regurgitate information from earlier research. Eggbeer (2008) highlighted that few studies had evaluated prostheses in terms of their technical performance, and the majority of research studies concentrated on evaluating qualitative aspects of prostheses. The vague nature of the initial attempts at quantifying prosthesis success led Eggbeer (2008) to conduct further work at attempting to define the success of a prosthesis, and attempted to quantify performance aspects previously indicated as influential on prosthesis performance. Eggbeer focused firstly on the process (time and economic impact) and secondly on the final prosthetic result (quality of the edges, positional accuracy, prosthetic form, soft surface texture, fit between the components, fit to the surrounding anatomy). Eggbeer recognised that some factors are impossible to quantify, but some quantifiable aspects have not yet been studied and this provides direction for future research.

This work by Eggbeer contributed toward the development of a set of target specifications for the use of CAD/CAM technologies for the fabrication of soft tissue prosthetics (Bibb et al., 2010). However, there are gaps in this target specification, which mainly centre upon the design and integration of the retention mechanisms. This provides an opportunity to explore and quantify some of these aspects. The requirements for extra-oral prosthesis retention mechanisms are discussed in chapter 2.

1.4 Chapter Summary

Chapter 1 provided an overview of Maxillofacial Prosthetics, the responsibilities of the MPT, and the various types of prosthesis available. The conventional prosthetic process was described in a general context, but this also reflects the nature of existing literature. The literature review identified that current literature does not provide a critical view of current practices, and evaluation techniques are primarily subjective – two important considerations for this PhD study.

An overview of the research trends within the field of Maxillofacial Prosthetic was provided, showing that case studies often focus on documenting the overall craft process and the clinical outcome, but do not integrate an objective approach to evaluating designs. A growing theme in research is the adoption of CAD/CAM technologies - this topic will be discussed in further depth in Chapter 3.

Chapter 2: Prosthesis retention

2.1 Prosthesis retention

This chapter presents a literature review on aspects of bone-anchored prosthesis retention. Laney (2007) provided a definition of retention as;

> *'The capacity of a removable prosthesis or dental restoration to maintain its intended position in function, or its resistance to displacement' (Laney, 2007).*

In extra-oral, maxillofacial prosthetics, many design and fabrication techniques have been adopted and adapted from dental specialties to create intricate retention systems (called Precision Attachments in dentistry). Examples of commonly used precision attachments in intra-oral applications include studs, clips, snaps, magnets and press-fitting designs (figure 5), which have been described thoroughly in textbooks (Jenkins, 1999; Preiskel, 1979). Many of the principles in *intra-oral* and *extra-oral* retention are similar, although many of the key design requirements differ, due to the functional and biological differences in the oral environment.

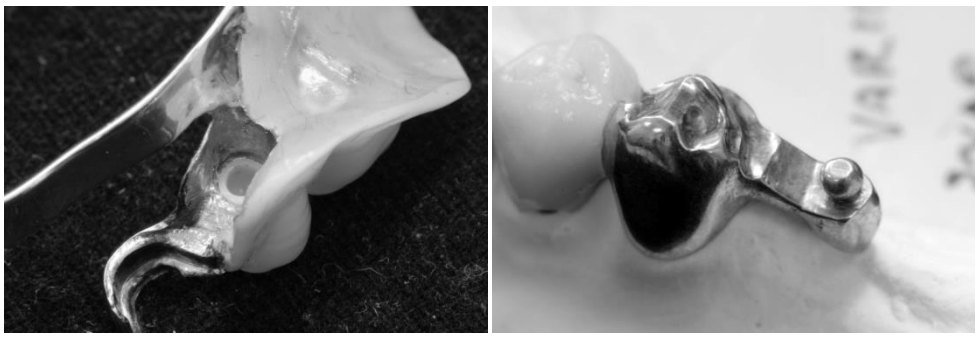


Figure 5: Dental precision attachment (female and male components)

Commonly used retention methods applied in extra-oral Maxillofacial Prosthetics include the use of anatomical undercuts (Mantri et al., 2011), mechanical means of retention such as eyeglasses, adhesives, and implant-anchored components such as magnets, bar structures and clips, all of which have been previously described in

textbooks (Brånemark and de Oliveira, 1997; Thomas, 2006). Other methods include the use of mushroom fastener buttons (Lemon et al., 2005) and studs (Moller, 2003).

Anatomical undercuts

Tissue undercuts can be used to provide retention without adhesives or mechanical components (Parel, 1980). A variety of case-specific solutions have been presented using this method, for example, Goveas et al. (2012) created an intra-nasal stent to retain a silicone nasal prosthesis, by using the shape and form of the defected anatomy. The utilisation of a palatal obturator can also be used as a means of retention. In severe cases where the defect removes the oro-nasal separation and also affects the extra-oral facial features, an intraoral-extraoral combination prosthesis can be fabricated. Pruthi et al. (2010) and Patil (2010) successfully used an obturator as the primary means of retention.

Some complex facial deformities in patients even require a combination of implant-based retention methods and the utilisation of anatomical undercuts – retention is not limited to one method. Retention may involve using a combination of techniques using engineered components and anatomically shaped structures.

Medical Adhesives

Medical grade adhesives or double sided sticky tapes can be used to retain a prosthesis, and are often used in cases where patient dexterity or surgical prognosis is poor. However, skin reactions, prosthetic discolouration, poor edge adhesion, and loss of retention, are some of the issues associated with using adhesives (Nerad, 1991; Seals et al., 1989). Adhesives require manual application to the skin, a task which can be time consuming and difficult to manage, especially for people with limited dexterity.

2.2 Bone-anchored retention

In 1979, titanium, cylindrically-shaped, threaded implants were placed in the mastoid region of the skull to retain a removable auricular prosthesis (Taylor, 2000). These implants are permanently integrated to the bone (called osseointegration) underneath the location of the prosthesis. Today, this process has become the state of the art and commonplace method used to retain dental prostheses, hearing aids and extra-oral facial

prostheses. The implants act as anchors for attaching the retention components, which can retain the prostheses to the anatomy (Worthington and Brånemark, 1992). These retention components include magnets, gold bars and clips analogous to some items of jewellery.

The aim of applying bone-anchored implants into prosthetic applications is to provide a reliable, stable and safe means of anchorage which can endure the patient's lifetime, with limited complications (Brånemark et al., 1985). The main benefit of implant-based retention is that it provides a secure fixation and allows a more predictable placement of the prosthesis than other methods. Implant-based retention tends to be more appropriate than adhesive when a patient is susceptible to adhesive-skin irritations or has usability issues due to limited dexterity. The increased use of implant-based prosthesis retention has meant a decreasing dependence on adhesives and anatomical undercuts but does not completely replace these methods.

The procedure of placing an implant only requires minor surgery (dos Santos et al., 2010), but the impact of losing part of the face is already huge – to undergo further surgery may be difficult for some patients. Implants can also be difficult to place when the supporting bone has been removed or modified during the initial surgical procedures.

Brånemark et al. (1985) defined osseointegration as a '*direct structural and functional connection between ordered, living bone and the surface of load-carrying implant*'. This means that the bone adheres to the oxide surface of the implant, and therefore integrates to the implant. Titanium is particularly desirable as an implant material because of its mechanically strong nucleus and its biomechanically advantageous surface oxide. To allow the protrusion of an implant through the skin, a biological barrier is needed between internal and external environments.

A healthy bone-implant interface is strong. For example, Brånemark et al. (1985) noted that when a fracture has occurred to the implant or bone due to loading, the bone-implant interface remained undamaged. Research statistically reviewing the number of successful implants in the various regions of the skull, in both non-irradiated and

irradiated bone is plentiful (Jacobsson et al., 1988). The literature shows that implants can fail to integrate with the bone, and the potential reasons are listed:

- There are risks using implants in irradiated bone – these tissue sites can develop necrosis and this can affect the success of the bone-implant integration. If the bone is already in poor condition, implants may not integrate at all. (Schoen et al., 2001a)
- There is a risk of infection where the abutments protrude through the skin. Regular cleaning of this area is required so that infections do not affect the implants. (Eggbeer, 2008)
- The success of an implant can be effected by the surgical technique (dos Santos et al., 2010)
- The design of the retention mechanism – a low and equal distribution of force on the implants is required, so that the implants are not overloaded. (dos Santos et al., 2010)

Therefore in a general sense, the success of the implants depends on the appropriate design and fabrication of the other prosthetic components, the quality of the soft and hard tissues, and decisions during the pre-operative planning stages and surgical skill.

2.2.1 Implant placement and considerations

The most commonly-used prosthesis implant systems (Federspil, 2009) are screw-type implants which are placed as individual pieces into the bone (e.g. Brånemark system (Nobel Biocare Services AG), ITI Straumann system (Institut Straumann AG)). These are typically commercially pure titanium, or titanium-zirconium alloy. They are usually designed with flanges and an internal thread for the abutment. The abutments protrude through the skin. Another popular implant method is the Epiplating System (Medicon, Tuttlingen, Germany), which incorporates a titanium plate system that protrudes through the skin. It is rarely used in the UK, although common in Europe. The plates are often bent to conform to the anatomical shape. This thesis will concentrate on the use of the most commonly used system in the UK, the screw-type.

The number and positioning of the screw-type implants varies depending on the location and size of the defect, quality of the surrounding bone (Schoen et al., 2001a), and the desired retention system (Laurito et al., 2012). Laurito highlighted a direct correlation between the number of implants and design of the prosthesis.

The surgical technique of placing implants has been well documented (Brånemark et al., 1985; Gumieiro et al., 2009), but limited studies have looked at the accuracy of the final implant position in comparison to the planned position. The placement of implants depends highly on the quality and availability of the soft and hard tissues, and therefore the ideal implant location might not be possible. Digital methods of implant placement planning using CAD software are also becoming widely used, and are discussed in Chapter 3.

Rangert (1993) offers generalised guidelines for implant placement and there are recommended implant sites for each prosthesis type. For example, an auricular prosthesis usually requires 2 or 3 implants, usually placed in the temporal bone approximately 20mm from the ear canal opening, sitting at 8 and 11 o'clock on the right side and 4 and 1 o'clock on the left side. The distance between the implants should be at least 15mm (Bergström, 1997).

2.2.2 Bone-anchored retention mechanisms

There are many types of retention mechanisms available in dental applications, but only few have been established within the field of extra-oral prosthetics. The main implant-based retention systems used in extra-oral prosthetics are the 'Bar-clip' system, magnets, studs and mushrooms. Many designs have been clinically trialled and experimented in labs, with varying results. Retention preferences of MPTs have been explored in some survey studies (Hatamleh et al., 2010; Rubenstein, 1995), which concluded that the method of retention depends on the location of the prosthesis, and that the mechanisms are an integral factor for the success of the prosthesis. The main factors that differentiate the different retention systems are:

- Retention force
- Adjustability

- Size and shape (therefore space required within prosthesis)
- Where the mechanism sits in relation to the implants
- Abutment design

The simplest systems are stock components that connect directly to the abutments with no further manipulation. Although some of these components can be integrated into customised frameworks, usually they are connected to the implants as isolated components. Magnets, studs and mushrooms are used this way – one component connecting directly to the implant, and its partnering component bonding directly into the prosthesis (or rigid substructure that forms part of the prosthesis).

2.2.2.1 Magnetic retention

Magnets are used most in nasal prostheses (Hatamleh et al., 2010), where lateral/shearing forces are lowest. Magnets come in varying shapes and sizes, and have been discussed in the literature (Maeda, 2005). There are many types – flat, dome, cushion, and rigid, usually manufactured by Computerised Numerical Control (CNC) micro machining. The magnet assembly comprises of a closed-field, Platinum-Iron (PtFe) or Neodymium Iron Boron (NdFeB) magnet, placed within a stainless steel or titanium casing and coating, so they remain inert and non-corrosive. A partnering magnetic abutment (keeper) is screwed directly into the implant.

Magnets (figure 6) can provide retention of 0.5kg – 1kg, and the breakaway forces have been tested in some research studies (de Sousa and Mattos, 2008; Nestle et al., 1999). The number of magnets relies on the number of placed implants, but they can also be integrated into customised bar structures for extension across the cavity. Magnets allow a self-localization, automatic seating on the abutment and easy access for hygiene control – beneficial for patients with low dexterity (Chung et al., 2003). However, the retention forces of magnets are non-adjustable and are prone to accidental dislodgement. Despite this, lateral dislodgment can be beneficial because the supporting structures are protected from unwanted forces (Goiato et al., 2009a).

Notable recent developments have included the O-ring magnet by Technovent (Technovent Limited, Wales), which incorporates a ring that offers back-up retention

force if the magnets are disengaged. The o-ring does not act as a means of retention, but it adds a level of security to the system, which is useful for lateral/shearing forces that may disconnect the prosthesis (especially in auricular cases). Other developments in magnetic systems make use of concave/convex keepers for self-centring (e.g. Steco Magnetic Attachments, (SIC invent AG, Switzerland)). In dental applications, some magnets allow for movement and shock absorbing functions (e.g. MAGFIT, (Aichi Steel Corporation)). Shock absorbing and resilient designs are less important in extra-oral prosthetics where prostheses are not subject to high forces from mastication.

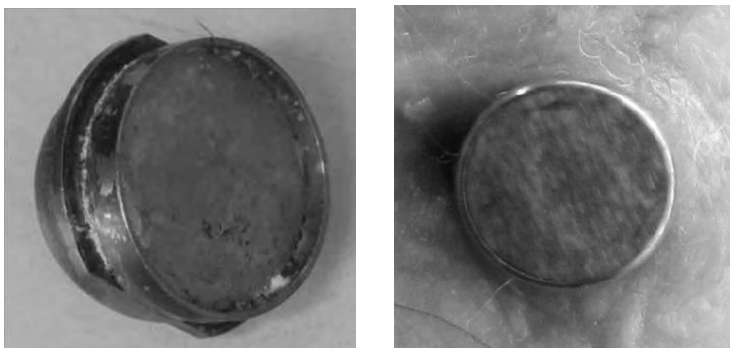


Figure 6: Magnetic keeper and abutment

2.2.2.2 Studs and mushrooms

The stud assembly comprises of a ball and socket assembly - the ball component usually connects to the implant and the socket is bonded to the prosthesis. When attached, the ball sits in the socket and can provide a degree of movement (Goiato et al., 2009a). This resilient system is used less than other retention mechanism designs (Rubenstein, 1995), but can be advantageous when freedom of movement is required.

Mushroom attachments consist of a mushroom-shaped abutment that sits in isolation on the implant. The shape of the mechanism provides retention to the prosthesis, where it must be squeezed into mushroom shaped cavities in the silicone. These components can be obtained pre-formed in noble metals or custom-made by casting and laser welding to standard abutments (Edwards and Farnell, 2004). This simple system is used rather infrequently, and literature describing or evaluating this system is limited.

2.2.2.3 Bar-clip system

The bar-clip system (Figure 7) has been adopted directly from prosthetic dentistry, and is fabricated using stock clips (called riders) and sections of gold circular bar, hand-crafted into individualised frameworks by laser welding, soldering, bending and polishing. The bar and clip system is the most commonly used system in auricular prostheses, where shearing forces are common (Hatamleh et al., 2010). This system is compact, allowing it to be fitted into small spaces, and variable retention can be applied.

Figure 7: Bar-clip mechanism

A cross-section of the bar-clip assembly in situ is shown and labelled in Figure 8.

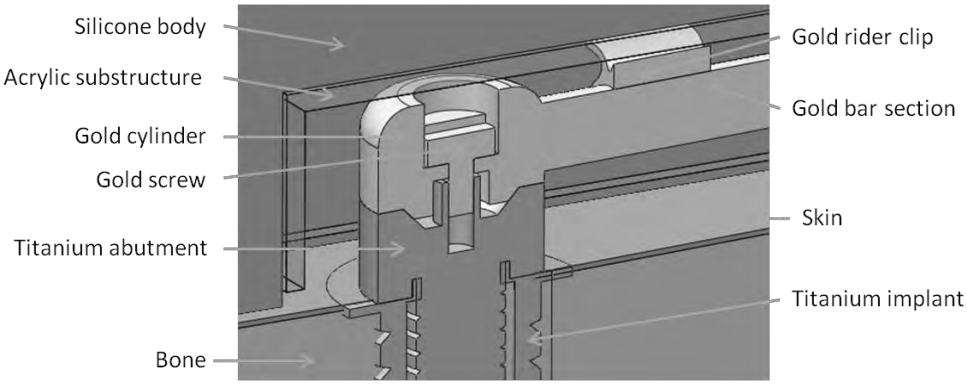


Figure 8: Cross section of bar-clip assembly

By hand-crafting bar structures from stock components, a number of different designs can be created (figure 9), depending on the needs of the patient, and the size, location and complexity of the defect. Complex frameworks can be fabricated, which have been illustrated in a number of textbooks (Brånemark and de Oliveira, 1997; Taylor, 2000).

Figure 9: Various bar structure designs

However, a number of issues are involved in the conventional design and fabrication process of prosthesis retention components (Eggbeer et al., 2006b). Patients are required to make a number of visits to the hospital during the design process. This can involve a lot of waiting and can be costly for both patient and the prosthetic rehabilitation team. Replacement or repair of components can also be difficult for this reason. It is currently necessary to take a physical impression of the anatomy, which requires physical contact with sensitive areas of the face.

Manipulating the gold bar structure requires precision by bending, welding and soldering – and mistakes can be costly (dos Santos et al., 2010). The process requires a significant amount of expertise and skill to achieve good results and if it is completed to a poor standard, it can result in implant failure, which may require further surgery. This problem is often accentuated in larger, more complex facial prosthesis cases.

The retention clips are manually altered according to patient requirements but this means that retention forces cannot be predicted easily (Eggbeer et al., 2006b). Bar-clip structures have a tendency to wear over time and clips must be adjusted to compensate.

Bergström (1997) and Wolfaardt et al. (2000) described some key design elements that should be taken into consideration, but limited technical evidence or design theory was provided to back-up these guidelines. Recommendations in the literature tend to stem from MPT experience rather than evidence-based research. Some of the design recommendations for bar-clip systems are listed below, but it must be noted that these recommendations are somewhat ambiguous:

- Placement of the clips as close and parallel as possible to the abutments.

- Non-linearity of the bar structure to reduce rotational dislodgement.
- Bar structure should follow the contours of the prosthesis.
- 2mm space required left between the skin and acrylic plate for airflow.
- 8-10mm bar-arm maximum length to avoid bending movement to the fixtures.

2.2.2.4 Bar and clip fabrication

Fabrication techniques of bar-clip structures are well established, although time consuming and laborious (Eggbeer, 2008). The process has been described in literature (Bergström, 1997; Wolfaardt et al., 2000) but even in some more recent key textbooks (Thomas, 2006) the details of the process have been largely overlooked andlimited information on some of the recently adopted technologies (such as the use of laser welding) is provided.

Laser welding has become a common and well-established method of fabricating bar frameworks in intra and extra-oral prosthetics. Laser welding guidelines (Besimo and Rohner, 2008) offer generic information on using the technology, but donot describe or analyse common practice. A deeper understanding of all aspects of extra-oral bar structure fabrication is required.

Bergström (1997) described the impression stages, creation of the working model, soldering technique of the bar, and clip structure fabrication. The bar-clip fabrication process is described in the following stages (Bergström, 1997):

1. Fit impression copings to the patient's abutments.
2. Take an impression of the site, capturing the anatomy and abutment positions.
3. Remove the impression and screw abutment replicas to impression copings.
4. Set the impression in dental stone.
5. When the dental stone has set, the impression copings are unscrewed and impression removed. This leaves a working model.
6. A drawing of the desired bar structure shape is drawn onto the model.
7. Gold cylinders are screwed on to the model and bar pieces soldered/laser welded onto the cylinders.

8. Retention clips are placed on the bar and an acrylic plate is formed around the clips.
9. The wax prosthesis model is fitted to the base-plate for optimal position, and the wax ear is then casted in Silicone.
10. The surface of the base-plate is roughened and cleaned with acetone.
11. Primer is applied to the base-plate and it is bonded into the silicone prosthesis

With the continuous introduction of new materials and techniques, up-to-date information is required on this process. This provides opportunity to observe and critique the process and provide further insight into any recent developments.

2.3 Relevant forces associated with retention

Although the loads applied in extra-oral prosthetics are relatively low in comparison to intra-oral prosthetics, the loading effect of various extra-oral retention mechanism designs on the implants and tissues should not be overlooked because it cannot be fully predicted in current practice. The three types of loads associated with extra-oral implant-based retention mechanisms, that are discussed in the literature are:

- Required forces of the retention mechanism to retain the prosthesis
- Functional loads generated during use – in extra-oral prosthetics, this relates to attachment/removal forces of the prosthesis (Faulkner and Berg, 1998; Miller et al., 2004).
- Loads generated by misalignment of prosthetic components (accuracy of fit/ passivity)

2.3.1 Retention forces

The retention forces of various magnetic retention systems for prosthetic applications have been measured in a number of articles. Nestle et al. (1999) used force transducers and strain gauges to examine how various factors, including height, form and angle, affect the retention forces produced. In extra-oral prosthetics, some researchers (de Sousa and Mattos, 2008) evaluated the performance of magnets before, during and after

prolonged use – they remained unaffected by repetitive testing, showing little loss of retention.

Retention forces of different mechanical retention systems have also been measured (de Sousa and Mattos, 2008; del Valle et al., 1995). del Valle et al. (1995) used a tensile/compression loading machine to measure the different mechanical and magnetic systems (including ball and sockets, gold bar and clips, magnets) by pulling the male component from the female component in the vertical direction. The test was designed to represent the disengagement of a typical auricular prosthesis. Tests were also done from an angle, which most represented a shearing force. The clip tests involved tests after 'activation' (adjustment) of the clip using the 'activation tool', and an inactivated clip. The limitation of this study was that no indication was given as to how much 'activation' was applied, and based on no particular criteria. The clip was 'activated' but what this meant with regards to clip gap size is unknown. It suggested that small degrees of clip adjustment (0.15mm) produce large increases in retention force, but these force values were unclear. de Sousa and Mattos (2008) concluded the bar-clip system is able to provide higher retention forces than magnetic systems on the market.

Miller et al. (2004) used various techniques to remove the prosthesis by hand (pulling with 3 clips aligned, pulling from one side, combination of twisting and pulling), and the loads were measured using strain gauges. This technique, although mimicking a real life situation, lacked control and consistency in the detachment action. Three clips were used, but no information was offered on the degree of clip adjustment and differences between each clip. This would have been an important aspect influencing the force during detachment.

The range of retention force values produced by the bar-clip at varying levels of adjustment has not yet been defined in the literature. If new clip mechanisms are to be designed, it is important that a retention force range is determined to inform new technology developers. This prompts further work, which will be addressed in this PhD study.

Studies (Wichmann and Kuntze, 1999) exist in the dental literature to analyse the problem of wear in retention components. Mechanical wear simulators (e.g. loaded

rocking machine) have been previously used to simulate movement in the oral environment and to determine the differences in retention forces after prolonged use of various attachment systems. This method was used by Wolf et al. (2009), Bayer et al. (2007) and Breeding (1996) to evaluate wear in various attachments used in dental prostheses. No studies have focused on extra-oral wear simulation, where loads are much lower and mastication affects the movement in the attachment components differently.

Bayer et al. (2007) stated that wear appears in all attachment systems, but ones that are adjustable (e.g. rider clips) allow compensation for changes in retention forces. The significance of evaluating wear in adjustable mechanisms is unclear. The clinician simply adjusts the clip when there is a loss of retention, so worn clips can always be adjusted to compensate for loss of retention.

2.3.2 Structural performance of implant-frameworks

Applying a high load to cantilever framework designs may have negative effects on the components, implants, or the surrounding tissue. Bergström (1997) advises that the bar should not extend more than 8-10mm as to reduce bending movement to the fixtures. Some earlier research (Rangert, 1993; Rangert et al., 1989) presented intra-oral guidelines and design rules for the use of the Brånemark implant system, and discussed the various types of loading and clinical situations associated with implant frameworks. The biomechanical effects of loading produced by implant frameworks remains unclear, and Rangert et al. (1989) stated that it is bone quality that determines the degree of leverage that should be applied to the cantilever designs. In extra-oral prosthetics, the forces can be exerted from various angles, but there is no direct mastication involved, so there is less force through the implant.

The optimal implant framework design was discussed by Glantz (1985). Glantz provided means of predicting the deformation of intra-oral framework designs, by looking at the relationship between applied forces on a framework with the modulus of elasticity of the material, and the width, height and length of the framework. That is, with an increase of force on a framework with a longer cantilever length, the more likely there is to be a deformation of the framework. The fatigue limit of Brånemark

Implant System components are about 300N axial tensile load and 60Ncm bending moment (Rangert et al., 1989).

Dental literature exists (Duyck et al., 1999; Takeshita et al., 2011) focusing on structural analysis of various attachment designs, but it is difficult to apply these findings to extra-oral prosthetics because the environment, tissues and forces are different. In reality, evaluating the structural behaviour of unique hand-crafted designs is challenging because every case is different with its own set of variables. The combination of craft processes and subjective assessment means that the structural behaviour of cantilever designs cannot be predicted easily. Virtual simulation tools could significantly improve prediction of performance, but there are many complex variables associated to each case. Firstly, the typical forces associated with fitting and retaining extra-oral prostheses must be determined; otherwise simulation conditions cannot be generated. This means that there is an opportunity to determine the applied retention forces of clip designs, which could feed into future studies simulating the biomechanical and biological effects influenced by the retention forces. However, measuring the biomechanical aspects of prosthetic rehabilitation is outside the scope of this PhD study.

2.3.3 Loading generated by misalignment of components

Tensile, compressive and bending forces produced by inaccurate retention components can result in biological complications or mechanical failures of the prosthesis components and implants (Kan et al., 1999). This can include screw loosening, bone loss, soft tissue alterations and loss of osseointegration (de Torres et al., 2011). The importance of an accurate fit between retention frameworks and implant abutments has been highlighted in both the intra and extra-oral literature - a passive fit is advocated so that lower forces are produced which can be distributed evenly to the individual implants (Kruth et al., 2005).

Some researchers have studied the loading effects of framework misalignment on craniofacial implants. In a study by Miller et al. (2004), implant frameworks in situ were connected to strain gauges, and the generated forces of the applied misfit were recorded. de Torres et al. (2011) used photo-elastic analysis to measure the stresses in

the implants caused by vertical misfits in dental implant frameworks, which is particularly useful for complicated geometry or loading conditions.

2.4 Accuracy of fit

Some researchers have attempted to define an acceptable accuracy of fit (also called passivity) between retention bar frameworks and the implant abutments. This relates to the gapping between the bar-copings and abutment fitting surfaces, indicated in Figure 10.

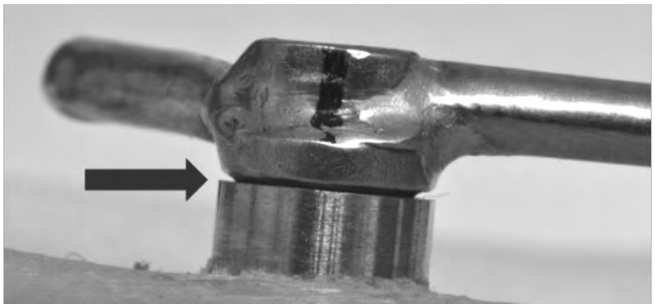


Figure 10: Accuracy of fit

Brånemark (1983) defined an acceptable passive fit at the 10µm level because this would enable bone maturation and remodeling. Assif et al. (1996) added that the implant-bone interface allows only limited movement of around 10µm. However, Jemt (1991) suggested that an acceptable fit is at ≤150µm, or when the fit does not cause any long-term clinical complications. The latter statement provides a limited indication of an acceptable accuracy of fit since the value of 150µm in fact, corresponds to half the distance between Nobel Biocare prosthetic screw threads, but this value is misleading if other systems' screws are used, and is rarely noted in the literature. In other dental literature, Riedy et al. (1997) and Jemt & Lekholm (1998) suggested that a gap size between implant framework and abutments should not exceed 40µm, but reasons for this value are unclear.

Kan et al. (1999), Laurito et al. (2012) and Abduo et al. (2010) acknowledge that although the suggested values are used as a reference, they are still of empirical origin, and the concept of 'passivity' is still poorly understood. The definition of a passive fit in

implant frameworks needs more exploration - distortions can occur in the x, y and z axis (Nicholls, 1977) but measurement techniques fail to consider all of the axes, and angulations. Figure 11 illustrates a side view of the fit of a 2-coping bar structure, typically connected at one side to expose the vertical (dy) and horizontal (dx) misfits. The angulation (θ) however cannot be easily understood from this angle, as it only considers the angle in one plane.

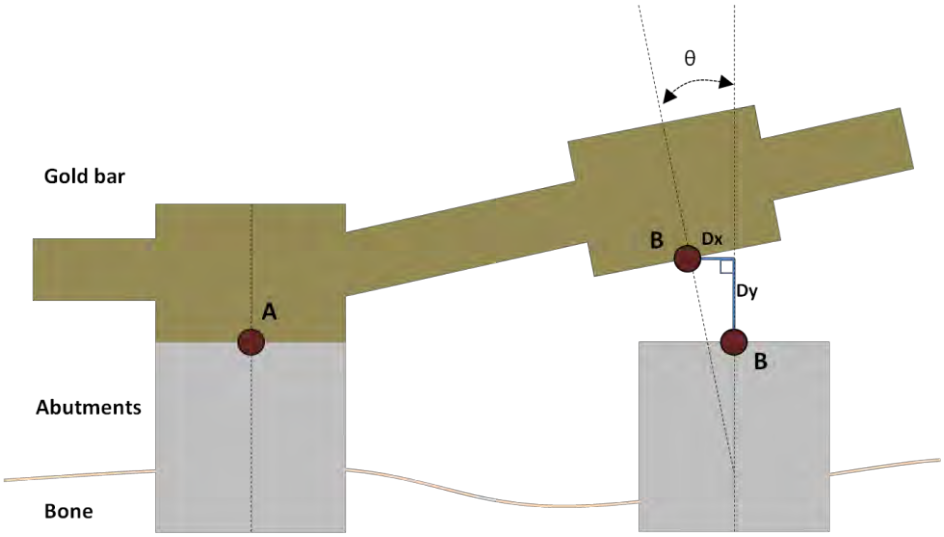


Figure 11: Fit of bar structure to abutments

Some researchers have suggested that obtaining a perfect passive fit is impossible, and even unnecessary (Sahin and Cehreli, 2001). However, this statement also lacks evidence to conclude that even the smallest of misfits do not influence the bone or components. Riedy et al. (1997) asked;

> *"What precision of fit is achievable in clinical practice, and is the fit different when frameworks are fabricated by different techniques?"*

The accuracy of fit of implants frameworks fabricated by different techniques must be compared, and benchmark values must be obtained. These values do not yet exist for conventionally made extra-oral retention frameworks.

2.4.1 Ensuring passivity

Numerous studies in the dental literature have investigated the various parameters that can affect the accuracy of fit of dental bar structures. These factors include:

- Impression accuracy and materials used (Lee et al., 2008)
- Master cast (working model) accuracy and materials used (Vigolo et al., 2000)
- Machining tolerances by the manufacturers of the stock components (Ma et al.,1997)
- Accuracy of the various framework fabrication processes (Cheshire and Hobkirk, 1996; Carr et al., 1996)
- Framework rigidity (Jemt, 1991)
- Ability of the screw to close the gap between abutment and bar (Kan et al., 1999)
- Increased tightening torque of the screw (Moraes et al., 2005)

Soldering/welding an implant framework requires experience and skill, but some distortion can arise during this laboratory process. A small distortion can be magnified if the structure is long (Preiskel, 1979), therefore distortions can increase with larger structure spans. These distortions can affect the accuracy of fit between the bar structure and abutments. To minimise the risk of misfit, many techniques have been used during framework fabrication. Precautions to minimise the chance of misfit have included the use of verification jigs and reference castings, sectioning the frameworks, and various impression techniques.

2.4.2 Methods for measuring accuracy of fit

Some publications have described the clinical and in-vitro methods of measuring the accuracy of fit of implant frameworks, particularly in intra-oral applications. A comprehensive review of the various methods was published by Abduo et al. (2010), some of which are described below.

2.4.2.1 Qualitative methods

Discomfort

If the patient experiences discomfort when the screws are being tightened, this has been known to indicate an unacceptable level of misfit (Yanase et al., 1994). However, this

method is highly ambiguous, relying on direct patient feedback or observed response, but discomfort could be also be caused by a number of other possibly unidentifiable reasons.

Alternate finger pressure

This involves seating the framework on the abutments, and applying finger pressure to either implant. Rocking in the framework implies a misfit (Henry, 1987).

Direct vision and microscopes

Magnifying the area under inspection can be used to look for gaps. This technique depends on the ability of the clinician to identify misfit, and in fact, Carr and Toth (1995) reported inconsistency for determining misfits <95µm. The lighting conditions and angle of vision affect MPT judgment on gap sizes (Tan et al., 1993).

Tactile sensation

This involves using a probe and feeling the gaps between the framework and abutments (Yanase et al., 1994). The success of this technique also depends on the size of the probe tip - if it is bigger than the gap size between the abutment and framework coping. This method can also be influenced by how the framework has been fabricated – burring or roundness of edges can make measurement difficult.

Disclosing media

Disclosing media (such as wax or impression paste) of a known thickness can be used on the mating surfaces of the abutment and framework coping. By tightening the framework to the abutments, the pressure imprinted in the disclosing media can be observed (Yanase et al., 1994). Cheshire and Hobkirk (1996) measured the vertical and horizontal misfits by sectioning the imprinted disclosing media and taking measurements of the cross-sections using a travelling microscope. However, this method also fails to accommodate 'negative vertical misfit'.

One-screw test

Jemt (1991) and Tan et al. (1993) advocated the one-screw test to evaluate framework fit, and this test is often used to compliment direct vision and tactile methods. In this test, the framework is seated on the abutments, and one screw is tightened to 10Ncm.

The vertical misfit between the opposing coping and abutment is observed. Millington and Leung (1995) highlighted that focusing on vertical misfit is limited – that horizontal and angular misfits can also exist in implant frameworks. The 'bottoming out' concept (negative vertical misfit) is also an issue, because this cannot be observed by 'eyeballing'. Spazzin et al. (2009) suggested that the one-screw test is ambiguous even with the aid of a microscope.

Screw Resistance test

In this test by Jemt (1991), screws are tightened one at a time, until resistance is encountered between the screw and the framework. When less than half a screw-turn is needed to tighten the structure to a torque of 10-15Ncm, the fit can be deemed acceptable. If more than half a screw-turn is needed, this is considered a misfit. Therefore, misfits can be calculated with regards to the over or under rotations of the screw. An issue with this method is that it is based on the principle that half a screw turn relates to closing a gap of 150µm, based originally on the thread size of the Nobel Biocare screw (Nobel Biocare Services AG). Retention systems with different screw thread dimensions would require different test parameters, as highlighted by Kan et al. (1999), and this could be problematic.

Radiographs and Scanning Electron Microscopy

Radiographs have been used to check for fit of dental abutments, copings and frameworks (Kan et al., 1999). The radiograph must be taken as perpendicular as possible to the abutment-framework interface, otherwise overlapping components may hide misfits. Moraes et al. (2005) used Scanning Electron Microscopy to qualitatively evaluate the fit of copings to dental abutments, but this method was only able to identify irregularities and gapping at the marginal contour of the interface.

The main issue with the qualitative methods is that they rely on the subjective assessment of the MPT, which is limited to the accuracy of the human eye. Also, the measurement techniques are limited to identifying vertical gapping, but can offer little insight to inaccuracies in other axes or potential overlapping misfit (negative vertical misfit).

2.4.2.2 Quantitative methods

Cathetometer

Miller et al. (2004) was able to quantify vertical misfit of implant frameworks by using the one-screw test with a cathetometer - a traditional measurement instrument consisting of a Vernier scale and telescope for measuring vertical distances, and accuracy specified at ±10μm. However, using this device for measuring misfits at the 10μm level (Brånemark, 1983) would not suffice.

Periotest instrument

The Periotest instrument is an ultrasonic vibrating probe that repetitively taps the test object, and tests for stability. Some researchers have explored its use to measure the gapping in the framework-abutment interface (May et al., 1996).

Digital Scanning and virtual measurement

Coordinate Measuring Machines (CMM) have been used in a number of research studies in dental literature (Al-Fadda et al., 2007; Kwon et al., 2011; Lee and Cho, 2011; Sierraalta et al., 2012) to determine the three-dimensional orientation of implant abutments and framework cylinder features. Non-contact scanning methods have been also been trialled, such as laser videography (Riedy et al., 1997) and optical fringe projection scanning (Tahmaseb et al., 2010), but the accuracy compared to CMM scanning is often lower. The intricacy of the abutments make them difficult to capture by scanning directly, so in dental applications, cylindrical registration elements can be connected to the abutments for the determination of the implant locations. The implant position coordinates (x, y, z) and vector directions (i, j, k) can be exported as into CAD software, where the position of the framework cylinders can be compared and the accuracy of fit can be quantified. Drago et al. (2010) provided a volumetric (x*y*z) determination of misfit using this method. Despite these developments, measurements of angular misalignments still remain absent in the literature.

High accuracy testing methods need to be developed and clinically adopted to determine misfits in extra-oral frameworks. Through the use of scanning, and digital matching methods, the accuracy of fit of bar structures against the working models can be measured in a virtual environment - therefore eliminating screw preload

discrepancies and allowing consideration to misfit parameters that are otherwise very difficult to measure (such as overlapping).

2.5 Surface finish / quality

Finishing and polishing techniques are used to remove excess material and to smooth roughened surfaces. The quality of surface finish plays an important role in the functionality of retention components. In applications that rely on close tolerances and high fitting accuracy, it is important to be able to quantify how much material has been removed, because this will affect the dimensional accuracy of the part. This is especially important on fitting surfaces and mechanical interfaces.

Surface finishing and polishing processes for intra-oral retention components have been described in dental technology textbooks (Craig et al., 2004) but have not yet been described in depth for extra-oral prosthetic components. Many of the techniques have been adopted directly from dental technology, but no literature has justified why extra-oral components need the similar abrasive sequences, when the components function in a different environment. The achievable surface quality of an appliance depends on numerous factors, including the type of abrasive used, the type of material being abraded, and the speed and force applied during the abrasion process. For intra-oral components, ideal surface roughness values have been proposed (Craig et al., 2004), but these values are also required for extra-oral components. There have been limited studies evaluating the surface roughness values of extra-oral retention mechanism materials, especially for some of the newer materials and concepts when using AM processes and materials.

In intra-oral hard surfaces, the range of surface roughness is found to be wide and the surface finishing treatments (e.g. polishing, glazing, and brushing) is material dependent (Bollen et al., 1997). It has been suggested that every dental material needs its own finishing treatment. This means that finishing treatments for new manufacturing processes and materials in implant-frameworks (e.g. AM) must be developed. Any imperfections in implant-frameworks may lead to complications during patient use, such as bacterial colonisation, which could affect the healthy tissue and the integration of the implants to the bone (Saba, 2001). However, the importance of a smooth surface

finish for extra-oral bar structures is unclear because, in fact, they are rarely in contact with the surrounding tissues.

Control of bacterial adhesion and retention to different materials and human tissues is important in biomedical applications, and it is a complicated process that is governed by many factors. Scheuerman et al. (1998) suggested that irregularities on a material's surface promote bacterial adhesion because the depressions in a rougher surface offer favourable sites for bacterial colonisation.

Bacterial adhesion has shown a direct positive correlation with surface roughness (Scarano et al., 2004) and some studies have particularly concentrated on the correlation between surface roughness and bacterial adhesion in intra-oral applications. It has been suggested for intra-oral applications a surface roughness above Ra = 0.2µm results in an increase in bacterial accumulation (Bollen et al., 1997), but interestingly a study by Taylor et al. (1998) showed that surface roughness values Ra≥1.86µm of Polymethylmethacrylate (PMMA) showed a reduction in bacterial adhesion. However, this could be associated with the properties of the specific materials selected for the studies.

Further research is needed to characterise and measure the surface roughness values in extra-oral retention mechanisms. The existing literature does not offer enough information on whether the currently applied surface finishes are appropriate for discouraging bacterial adhesion, ensuring functional fitting surfaces, for passivity of components and minimisation of wear. No studies to date have been conducted measuring the surface roughness values for extra-oral retention frameworks, and this data is required if new processes are to be proposed. Furthering this, no surface finishing techniques have been recommended for creating smooth, anti-bacterial surfaces in AM components. This is an opportunity to develop initial surface finish requirements for AM processes in retention mechanism fabrication, based on current practice (state of the art).

2.6 Chapter Summary

Chapter 2 provides an overview of bone-anchored retention, current systems and fabrication methods in practice. The review shows that detailed stages of current fabrication methods have not been fully documented and this prompts further investigation. The chapter also reviews how the functional aspects of retention mechanisms are evaluated in current practice and how they have been measured in the research literature. For example, the review shows that a number of methods are available to evaluate the accuracy of fit of implant frameworks in clinical practice, which rely on visual and tactile feedback. The fit of implant frameworks has also been measured using digital methods in the research literature, but the definition of fit remains unclear. The review suggests that measuring the performance of the technical features of retention mechanism design requires an objective approach in research to support the subjectivity in practice. In the development of new mechanism concepts, this must be addressed.

Chapter 3: CAD/CAM in Maxillofacial Prosthetics

3.1 CAD/CAM in patient-specific applications

This chapter presents a literature review on the application of CAD/CAM in Maxillofacial Prosthetics.

CAD/CAM's application in the production of patient-specific medical devices has been reviewed in many research articles (Daniel and Krassimir, 2010; Giannatsis and Dedoussis, 2009; Gibson et al., 2006) and demonstrated in many patient-specific products and services. This has included the use of CAD/CAM for the production of models based on patient CT and MRI data, models for surgical planning, surgical drilling and cutting guides, scaffold structures, radiation shielding masks, burns pressure masks, patient-specific implants, customised hearing aids and prosthesis moulds.

Customised implants and surgical guides are typically designed using patient scan data (CT, MRI). Such devices can subsequently be manufactured directly from the digital data using Additive Manufacturing, a process that builds objects in an additive manner; building up two-dimensional layers of material until a three-dimensional object emerges. Implants produced in this way have been successful, where typically rough surface finishes from AM can support soft tissue and promote bone growth (Mazzoli et al., 2009a).

The field of dentistry and fixed prothodontics have been quick to adopt and utilise the benefits of CAD/CAM technologies. Such examples include intra-oral scanning, digital design packages and manufacture of dental crowns, bridges and implant frameworks. Nevertheless, dentistry still relies on many manual, hands-on techniques and many applications are yet to be digitalised commercially and clinically. For instance, the integration of CAD/CAM in the creation of Removable Partial Denture (RPD) frameworks is still in the early stages of development. Early attempts at digital RPD

design and manufacture by Eggbeer et al. (2005), Bibb et al. (2006) and Wu et al. (2006) showed promising results. A more recent study by Wu et al. (2012) proposed a dedicated CAD package for the design of RPD frameworks, but to achieve this much work is still needed to develop a less complicated and efficient process.

The perceived benefits of using CAD/CAM include an improved surgical outcome, reduced time in surgery (therefore reduced healthcare costs), increased accuracy of fit to the anatomical form, reduced risks for the patient (e.g. infection, anaesthesia), and the ability to test designs before even making contact with the patient (Eggbeer et al., 2012b). However, with an increasing demand for high-precision products, the limitations of CAD/CAM must be understood.

Adoption of CAD/CAM technologies has been slower in extra-oral Maxillofacial Prosthetics than in dental applications. Researchers (Eggbeer, 2008; Bibb et al., 2010; Ciocca et al., 2010c) have recognised an increasing interest in using digital methods as a means of creating Maxillofacial prostheses. Maxillofacial Prosthetics has been influenced by major developments in digital technology, especially by the introduction of scanning technologies such as Computed Tomography (CT) and Magnetic Resonance Imaging (MRI). Although the field of Maxillofacial Prosthetics has been generally slow on the adoption of digital technologies, some specific digital processes have become established in practice. These processes have been primarily associated with the early stages of the prosthetic rehabilitation process, but despite this, no standardised model exists for digitally designing and manufacturing prostheses and their associated components. Bibb et al. (2010) stated;

> *"The full benefits of digital technologies will only be achieved through the adoption of an appropriately devised, implemented and evaluated workflow".*

Many people in developing countries do not have access to treatment at all. This is a real-life issue that urgently needs addressing, and Bibb et al. noted that new digital technologies might be able to provide rapid, low cost methods of creating facial prostheses. The main benefits of using digital technologies in Maxillofacial Prosthetics have been identified (Eggbeer, 2008) as;

- Increased speed of production

- Reduced cost to health service or other provider
- Increased quality, predictability and reproducibility
- Ability to work collaboratively online

3.2 CAD/CAM technologies: an overview

Within the discipline of patient-specific medical device design, an array of different technologies (software and hardware) is used, which can be divided into 3 main categories – *Reverse Engineering, Design, and Manufacturing.*

3.2.1 Reverse engineering

Reverse Engineering is the process of taking the data obtained from the physical object and translating this into the CAD environment – from the physical into the digital realm. Reverse Engineering (RE) is an established part of the product design process, and is used in many applications. RE is often used to produce a copy of an object, to create a cross-sectional profile of an object, the re-engineering of a product, or to capture design constraints within which a new part must fit (i.e. a buck).

The RE process involves methods of data capture, data processing and surface creation of an object. Traditionally, objects can be measured by using standard measuring tools (Vernier Callipers etc) and the measurements can be used to replicate their shape.

3.2.1.1 3D data capture

This involves the initial capturing process of the surface or form of a physical object before translating the data into the virtual environment. The techniques used to capture objects have become a critical part in the engineering process, especially when the CAD data of the object is unavailable. This is essentially the first stage of reverse engineering an object. 3D scanning can be categorised into contact and non-contact methods.

Contact methods use a probe to touch or drag along the surface of an object, which can capture single point data or continuous surface data of an object. Contact methods to

directly capture the anatomical form of a patient are inappropriate, due to the mobile and soft nature of the facial tissues.

Non-contacts methods have been developed to capture the internal and external geometries of an object. CT, MRI and Cone Beam Computed Tomography (CBCT) have made significant differences in medicine and healthcare, as well as being used for industrial purposes, such as inspecting internal flaws in engineered assemblies.

Whilst CT, MRI and CBCT techniques are required for scanning internal structures of objects, surface-scanning techniques can be used to scan the external form of an object. A variety of non-contact surface scanning technologies are available, including laser-based scanners, optical structured white light scanners and Stereophotogrammetry. The devices vary in resolution, scanning speeds, processing speeds, usability and portability. The various methods of data capture have been described in a number of review articles and textbooks (e.g. Robert, 2010).

3.2.1.2 Reverse Engineering Software

Scan data is usually exported in either point cloud data (a series of x, y, z points) or a triangulated mesh (STL (STeroLithography) file format), and this scan data represents the general shape of an object. The data must be imported into an appropriate software package for processing and manipulation. Understanding the '*design intent'*, and manipulating the scan data so that it represents the original object is the key to successful RE. Many software packages are available for dealing with scan data, and they share the same goal - to take imperfect scans and generate watertight CAD models.

Medical-specific software solutions can be used to process sliced scan data (CT and MRI). For instance, Mimics (Materialise NV) is an established software for the processing and segmentation of anatomical scan data for the production of 3D digital anatomical models. Other various RE software solutions have been described in a number of review articles and textbooks (e.g. Sokovic et al., 2005).

3.2.2 Computer Aided Design

Industry standard CAD packages that use 3D parametric solid modelling play a huge role in today's industrial design process. These packages deal very well with geometric data, engineering tasks, assemblies and consumer product design. However, other CAD software has evolved to deal with complex surfaces typically required in design using patient anatomical data.

Digital sculpting software such as *Geomagic Freeform* (3D Systems) allows the user to design and sculpt in a virtual clay, and utilises force-feedback technology, where the user can physically feel the clay using a haptic feedback device. This software allows designers to mimic modelling techniques used in the physical world of sculpture, model-making and industrial design. Evans et al. (2005) evaluated this program for conducting typical product design tasks. Due to the tactile nature of the system, it is often described as a very intuitive package, but as Evans noted, this tends to focus on the simplistic carving tools, and the more complex design tools are rather unintuitive in comparison with many conventional CAD packages (Evans et al, 2005). Despite these issues, the technology is now established in many areas, and in particular, dental technology and patient-specific implant design have benefited from its tools, which are especially useful for designing components that fit to the anatomy accurately (Bibb et al., 2002; Mazzoli et al., 2009b).

3.2.3 Computer Aided Manufacturing

Computer Aided Manufacturing (CAM) covers a broad range of technologies, but can be divided into subtractive manufacturing and additive manufacturing. These technologies may be competing with each other in some contexts, like for example in the manufacture of patient-specific implants.

In Subtractive Manufacturing (SM), material is successively removed from a block until the desired shape is reached. The CNC machining process has been described thoroughly in the literature (Schmid and Kalpakjian, 2000) and is a well-established technology. Although well developed, it has its limitations when dealing with complex geometries. Creating tool paths and preparing the process can be very time consuming,

and often requires expert machinists. Ideal CNC machining projects are when a specific material or very high tolerances are required. For higher complexity components, when subtractive manufacturing does not suffice, Additive Manufacturing can be used as an alternative route.

3.2.3.1 Additive Manufacturing

Additive Manufacturing (AM) (also called Rapid Prototyping, Layer Manufacturing, Solid Freeform Fabrication and 3D Printing) is a process which builds objects in an additive manner, building up two-dimensional layers of material until a three-dimensional solid objects emerges. The term Additive Manufacturing tends to concentrate on the use of this process for the manufacture of 'end-use' components.

AM technologies can broadly be categorised as photo-polymerisation, filament deposition, 3D polymer jet printing, lamination, and powder sintering (Hollister and Bergman, 2004) - all of which have been thoroughly described in textbooks and research literature (Wohlers, 2009). AM technologies can produce a variety of functional and aesthetic results, depending on the process parameters, material and design of the component. Parts can be built in many materials including plastics, rubber-like materials and metals. Metal AM machines can build fully dense parts in titanium, cobalt chrome, stainless steel and noble metals such as gold. Researchers have shown possibilities to build functionally graded materials (Hascoet et al., 2011), and even nanostructures (Ivanova et al., 2011). An overview of the possible AM materials is presented in Table 1 (Reeves, 2009).

Metallic Materials	Polymeric Materials	Ceramic Materials	Organic Materials
Aluminium	ABS	Alumina	Waxes
Titanium	Polyamide (nylon)	Zirconia	Tissue / cells
Tool & Stainless Steel	PEEK	Silicon Carbide	
Inconel	Ceramic loaded epoxies		
Cobalt Chrome	Filled PA	Silica (Sand)	
Copper	Thermosetting epoxies	Plaster	
Gold / Platinum	Polycarbonate	Graphite	
Aluminium loaded polyamide		Beta-Tri calcium Phosphate	
Hastelloy	Polyphenylsulfone		
	Polyetherimide		

Table 1: Additive Manufacturing Materials (Reeves, 2009)

AM allows a level of geometric freedom superior to many other conventional processes, which is why it has become particularly useful in the fabrication of complex anatomical, freeform shapes, which are almost impossible to manufacture in any other way. AM enables the production of complex geometries such as complex honey mesh structures, variable wall thicknesses, structures inspired by organic or biological forms, non-linear holes, and multi-material components. This has inspired a new way of thinking, and 3D design and manufacture has taken a leap forward in possibilities. Designs can be driven by the structural requirements, rather than the limitations set by conventional manufacturing processes (Wohlers, 2009).

AM is a process very well suited to low volume production, building complex and lightweight components, minimising waste, eliminating tooling costs, simplifying supply chains, and reducing inventory and capital investment (Wohlers, 2009). These benefits are the core drivers to the adoption of AM, and can offer many new opportunities for designers, businesses and entrepreneurs. AM allows for objects to be manufactured on demand, and caters very well to personalised products. The technology has been adopted in many applications where low-volume customisation is important, such as patient-specific medical devices.

Despite this new found geometric freedom, AM does have its limitations, and many products are not suited to AM. A number of challenges relating to materials, processes and applications still remain. Areas for development have been identified by a number of researchers (Campbell et al., 2011; Kinsella, 2011). These areas include material development and characterisation; process development, control and optimisation; development of testing procedures and monitoring; predictive modelling of AM parts; AM part performance and standardisation; development of design tools and software.

AM components can show mechanical limitations, poor surface finish, and lower part accuracy than many subtractive methods. These limitations must be understood by engineers and designers, so that AM can be harnessed for what it is capable of, and used appropriately. The AM field offers many opportunities for research and development, highlighted by the many areas described.

In some applications, AM models must undergo post-build processes, so that the manufactured outcome is more appropriate for function. The post-processing and surface finishing of AM models is being explored, and many processes are still in their infancy. Depending on the application, components may need thermal treatments, coating, or machining, especially when high tolerances are required for coupling components.

Metal coatings can be applied to non-metal AM model surfaces by electroplating (or electroforming), to alter the structural and/or aesthetic appearance of the component. Many materials (including organic objects) can be electroformed, and 'Metalise it' (3DDC Limited) commercial metal coating service was set-up specifically for AM components. A variety of AM processes (SLA, SLS, FDM, Perfactory, Objet etc) can be coated with a variety of metals. This application has become commonplace for creating functional prototypes and testing models. Such processes are established in jewellery design but are unexplored in Maxillofacial prosthetics.

3.2.4 Geometric and surface analysis of AM models

Some researchers have attempted to understand the process limitations of various AM process. For instance, the limitations of Selective Laser Melting was evaluated by Kruth (2005) and Vandenbroucke & Kruth (2007) through the dimensional, mechanical and chemical properties of benchmark models, which incorporated sharp and rounded corners, overhangs, sloping planes, cylinders, holes and thin wall sections. Thomas (2010) also conducted a series of design experiments and dimensional analysis, to develop a set of design rules for the SLM process. Charmeux et al. (2007) used visual inspection, analysis of dimensional accuracy by optical measurement system, and metallographic analysis to evaluate the accuracy and feasibility of AM casting models. These studies have shown that a variety of measurement techniques are feasible for the dimensional analysis of AM models.

Surface roughness value 'ranges' exist for many manufacturing and finishing processes, such as casting, sawing, milling and finishing processes such as polishing and grinding. Average surface roughness values (Ra) have been noted in numerous metrology and engineering textbooks, as shown in Table 2 (Bewoor and Kulkarni, 2009).

Conventional Processes	Material, details	Common Ra Range (µm)
Turning & Milling	Metallic, N/S	0.32-25
Abrasive jet machining	Metallic, N/S	0.1-1.6
Ultrasonic machining	Metallic, N/S	0.2-3.2
Chemical machining	Metallic, N/S	0.2-6
Investment Casting	Metallic, N/S	1.6 - 3.2
Die Casting	Metallic, N/S	0.8 – 3.2
Grinding	Metallic, N/S	0.063 - 5
Polishing	Metallic, N/S	0.04 - 0.16
Lapping	Metallic, N/S	0.012 - 0.16
Super-finishing	Metallic, N/S	0.16 – 0.32

Table 2: Ra (average surface roughness) ranges for conventional processes (Bewoor and Kulkarni, 2009).

Some studies have attempted to quantify surface roughness characteristics of various AM processes. As AM parts are structured by layers, some AM processes share the common surface characteristic of 'stair-stepping'. This means that the layer thickness affects the surface roughness of a component. However, layer thickness is not the only factor that affects surface roughness in AM models – AM parts also exhibit 'secondary geometric attributes' described as 'micro-topography', shown in work by Reeves and Cobb (1995).

Campbell et al. (2002) noted that the surface roughness could be predicted using theoretical calculations for some AM processes which exhibit the typical 'stair-stepping' effect (e.g. SLA, FDM, LOM). Other AM processes (Z402 3D Printer) showed unpredictable results because of other process variables that influenced the surface roughness (Chryssolouris et al., 1999). In fact, the 'stair-stepping' effect did not appear to be the main factor influencing surface roughness. This means that measurement instrumentation must be used to determine true surface roughness values of AM components.

Build orientation can also affect the surface roughness of an AM part, where the surfaces meet support material, or where the 'stair-stepping' effect possesses different characteristics at different build angles. To overcome the variable roughness qualities produced by build orientation, some researchers (Cheng et al., 1995; Lan et al., 1997) developed build orientation strategies, but Campbell et al. (2002) suggested that many AM components require low surface roughness only for particular features. For

complex mid-face prosthesis retention bar structures, an optimized build orientation would be very difficult to achieve, because of the potentially obscure angles of the fitting surfaces that the bar structures may possess. Campbell et al. (2002) developed a visualisation system for determining the surface roughness of an AM model in the virtual environment pre-manufacture, as an aid to optimising build orientation. Such a visualisation tool would be useful for processes where the surface roughness cannot be easily understood.

A limited number of studies have attempted to determine surface roughness ranges for metal AM components. Some researchers have presented roughness values for SLM components (Vandenbroucke and Kruth, 2007) and others have studied the roughness of metal castings from AM casting shells and patterns (Charmeux et al., 2007). The inkjet FCubic process did not suffer from the stair-stepping effect (Charmeux et al., 2007) but roughness values were higher. SLM component roughness values were high, but finishing techniques used in another study (Vandenbroucke and Kruth, 2007) allowed for reduced roughness values. Ranges of surface roughness values of various AM processes are presented in Table 3, based on the existing literature. Ippolito et al. (1995) in particular, compared surface roughness values of AM processes to conventional manufacturing techniques.

Non-metal AM Processes	**Material, layer thickness**	**Ra Range (µm)**	**Reference**
SLA (3D Systems)	SLA5530 epoxy 0.10mm layers	1.7-4.3 approx	(Pal and Ravi, 2007) (Ippolito et al., 1995)
SLS (DTM)	Polycarbonate Nylon	15.3-16.6 14.8-18.4	(Ippolito et al., 1995)
FDM (Stratasys)	ABS P400, P300, P200 0.25mm layers	1.2-18	(Pal and Ravi, 2007) (Ippolito et al., 1995)
LOM (Helisys)	Paper (LPH Series) 0.20mm layers	2.4 - 4	(Pal and Ravi, 2007) (Ippolito et al., 1995)
SDP (Invision)	PVC Foil 0.165mm layers	4.4 (approx.)	(Pal and Ravi, 2007)
OBJ ET Eden 260	Fullcure 720, 16µm layers	14.6 (approx.)	(Pal and Ravi, 2007)
OBJET Eden 350V	FullCure 720,16µm layers	0.84	(Udroiu and Mihail, 2009)
Solid Ground Curing (Cubital)	G-5661 Polyester Resin. Undefined	5-9.8	(Ippolito et al., 1995)
Metal AM Processes	**Material, layer thickness**	**Ra Range (µm)**	**Reference**
SLM (M3 Concept Laser)	Ti-6Al-4V (as processed, glass blasted, ultrasonic ceramic filed)	Top 18, 12, 10 Side 20, 13, 11	(Vandenbroucke and Kruth, 2007)
SLM (M3 Concept	Co-Cr-Mo (as processed, glass	Top 15, 12,	(Vandenbroucke and

Laser)	blasted, ultrasonic ceramic filed)	7 Side 15, 8, 5	Kruth, 2007)
FCubic Direct Shell Process (DSP)	Zirconia shell, cast in Alu and Zinc	4.5-6.2 approx.	(Charmeux et al., 2007)
Thermojet (3D Systems) SPI Pattern Master (Sanders Prototypes Inc.)	Cast in Alu and Zinc	0.8 – 5.2 approx. 1-3 approx.	(Charmeux et al., 2007)

Table 3: Ra surface roughness ranges for various AM processes

The complex geometry of customised medical devices means that build orientation will continue to be an issue, but stair-stepping is only one parameter associated with surface roughness. Build resolution does not necessarily represent surface roughness. Surface roughness values of AM components must be inspected post-build, to verify the part's accuracy in reflection of the design intent.

3.3 CAD/CAM in Maxillofacial Prosthetics

Since the late 1990s, a series of studies have been conducted exploring the use of CAD/CAM in extra-oral maxillofacial prosthetics, where the digital capture of the anatomy, digital design of the prosthesis form and digital manufacture of the prostheses has been trialled. One of the earliest studies in this area by Chen et al. (1997) used laser scanning, CAD software and wax milling for prosthesis design and production. Many technology limitations were noted from this study, and this prompted a number of research studies focusing on how CAD/CAM could be integrated into the prosthetic process.

Recent research studies (Bibb et al., 2010) have shown promising outcomes, but CAD/CAM techniques have not yet been fully adopted in clinical practice. These studies have tended to concentrate on the application of technology, rather than providing a clinically successful outcome (Eggbeer, 2008), and in fact, only a limited number of studies (Eggbeer et al., 2012a) have created a clinically acceptable prosthesis. However, this is related to clinical acceptance as indicated by the MPT.

Some aspects of extra-oral digital prosthesis design remains almost untouched, and limited studies report using digital technologies for every aspect of implant-based prosthesis production. However, Bibb et al. (2010) report that CAD/CAM can be used

for every aspect of prosthesis design, but despite this, a fully integrated prosthetics-specific software/hardware solution does not yet exist. The current CAD/CAM workflow forces the technologies to be used in isolation - this is complex, time consuming and unintuitive. Similarly to Wu et al. (2012), who proposed a dedicated CAD package for the design of Removable Partial Denture (RPD) frameworks, researchers have also advocated for a dedicated CAD package for extra-oral prosthetics. The CAD/CAM process, even in its current state of complexity, is neither complete nor realistic for practical adoption.

The concept of designing and fabricating *extra-oral retention mechanisms* by using CAD/CAM has been studied by only a small number of researchers. Although CAD/CAM processes of dental retention mechanisms have been developed, this area remains largely unexplored in extra-oral soft tissue prosthetics.

In 2010, Bibb et al. (2010) presented the state of the art in digital prosthesis production, and a design specification was presented to help guide technology developers in this field. This research provided a step forward in identifying the appropriate technologies, and key characteristics of prosthesis design. However, further depth is needed on why components have evolved this way, so that the appropriate CAD/CAM technologies can be considered. The work conducted by Bibb et al. was a useful step in directing research of CAD/CAM in Maxillofacial Prosthetics, highlighting areas for further research.

With regards to evaluating the prosthetic process (rather than the final outcome), previous studies have focused on timing the prosthetic process (MPT time & patient visits), and recording the economic impact of the digital process (Bibb et al., 2010; de Crescenzio et al., 2011). Other aspects have also been recorded - the material volume, and machine build time (Ciocca et al., 2010c), and these aspects have been compared to the conventional processes.

3.3.1 Implant planning and placement

Commercial software (e.g. Surgicase Anaplastology Module, Materialise NV) allows the MPT to import CT images so that surgery can be planned and simulated and identify ideal sites for implant placement by displaying vital structures, bone volumes, and bone

densities. Various implant sizes are provided and subsequently the position of the prosthetic implants can be planned. Following this, a surgical drilling guide can be designed based on the plan, and the data can be sent to the manufacturer for production of the guide (Wolfaardt et al., 2000). The software also allows mirroring of anatomy so that the ideal prosthesis position can be planned. However, the software provides limited functionality; no tools are available for designing the subsequent prosthesis components.

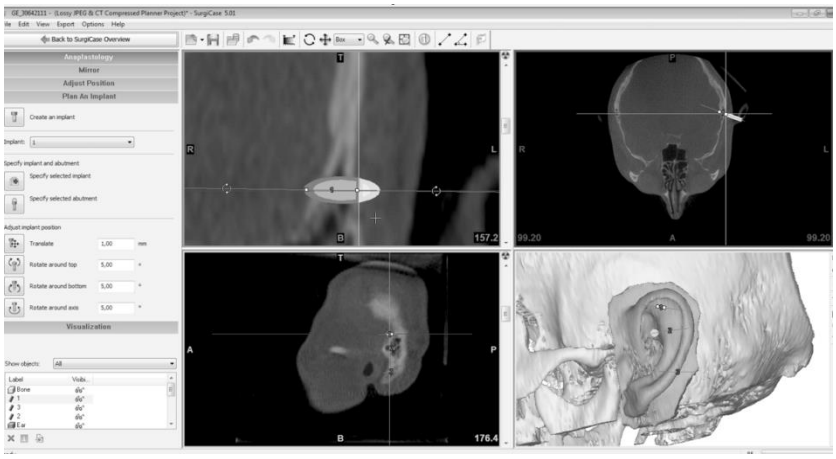


Figure 12: Materialise Anaplastology Wizard

Numerous studies (Bibb and Eggbeer, 2009; di Giacomo et al., 2005; Reitemeier et al., 2012) have focused on the planning and placement of implants for extra-oral prosthetics using CAD/CAM techniques. However, no studies have explored basing the design of retention mechanism or framework directly on the surgical plan (placement of the implants). This may be difficult because the initial plan and the final implant positions can change, especially when the condition of the bone is poor and the implant positions must be compromised.

3.3.2 Capturing implant locations and surrounding surfaces

For the design of an implant-based prosthesis, key features need to be captured - the implant locations, the internal tissues and the surrounding external surfaces. Data must be captured from mobile anatomy, including complex textures and incoherent surfaces (like hair), and the sharp edged detail of the abutments. Medical scanning (CT, MRI and

CBCT) is able to capture the internal and external geometries, and is an essential step for planning the implant positions. CT data has also been used to design the prosthetic form in a number of studies (Bibb et al., 2010; Verdonck et al., 2003; Jiao et al., 2004; Subburaj et al., 2007), and MRI data can also be used (Coward et al., 1999; Schievano et al., 2010) as a means of capturing the anatomical form.

Additional surface detail is required to capture the implant positions post-operatively. Verdonck et al. (2003) used two CT scans, one pre-operatively, and one post-operatively to capture the implant locations and tissue changes. Verdonck suggested that X-ray-based scanning techniques are inappropriate for second stage scanning due to cost and prolonged radiation. Therefore, alternative 3D surface scanning methods have been explored, such as Photogrammetry (Sabol et al., 2011), laser surface scanning (Ciocca et al., 2007), and optical structured light scanning (Runte et al., 2002). Some studies (Cheah et al., 2003; Eggbeer, 2008) have concentrated on comparing scanning technologies for Maxillofacial Prosthetics, and other studies (Bell et al., 2003; Coward et al., 2005) have focused on measuring the accuracy of scanning methods that are able to capture skin topography or dental models.

Photogrammetry scanning has shown potential for anatomical surface capture (Eggbeer et al., 2012a), and it has been adopted in a clinical environment for body and facial scanning by numerous hospitals and organisations – its 'multi-camera set-up' means that all angles can be captured without the need to move around the patient. It captures the data in a matter of seconds, which also makes it particularly useful for mobile anatomy. However, its application capturing intricate abutment features is limited (Eggbeer, 2008).

Davis (2010) and Eggbeer (2006; 2008) described the main technology requirements for surface scanning technologies for Maxillofacial Prostheses. These include:

- Repeatability, accuracy and speed
- Ability to capture surface texture and colour
- Capture the size and contours of the object
- To be unaffected by environmental factors, such as bad lighting conditions
- Ability to capture a high level of detail, such as the fine edges of the abutments

Some of the limitations of surface scanning have been noted in the literature (Bibb et al., 2000; Cheah et al., 2003; Eggbeer, 2006). The main challenges associated with capturing mobile anatomy, incoherent surfaces (like hair), sharp edges and highly reflective surfaces (abutments). Kai et al. (2000) noted how areas hidden by the scanner's line of sight are difficult to capture, and handheld scanners have been developed to overcome this, as well as multi-camera set-ups that capture every angle of the head. Despite this, Eggbeer (2008) noted that these new developments still struggle to capture all features, such as wrinkles, behind the ears and within the nostrils. Eggbeer also noted that the procedure of processing data produced by these scanners is often time consuming and complex, due to the messy nature of the data. Chandra et al. (2005) used handheld surface scanning to capture the anatomy, but reported that no time-savings were obtained over conventional processes. However, researchers have continued to search for solutions and technology developments in this area. No studies have found the perfect non-contact 3D scanning solution.

Previous studies by Eggbeer (2008) and Bibb et al. (2010) utilised an Action Research (AR) approach to evaluate the potential of non-contact surface scanning to capture a patient's anatomy. A plaster model of the patient was used to overcome the issue of mobile anatomy. Subsequently, Eggbeer and Bibb et al. used a contact touch probe scanner (Roland Pix-30) in their studies to obtain the implant positions. It was concluded that non-contact 3D scanning technologies were not able to capture all the details needed for an implant-based facial prosthesis design, and by introducing a plaster model, unwanted steps were introduced into the process. Therefore, further work is needed in this area.

Limited studies in extra-oral prosthetics have attempted to simplify the intricacies of the abutment so that implant positions can be determined. Eggbeer (2008) explored the manipulation of magnetic abutments for implant recognition – the abutments were coated with white paint, and after a high resolution scan of the abutments model, the data was imported into Magics software (Materialise NV). In the STL file format, data was trimmed across the surface of the magnet abutment, leaving a remaining flat top surface. In Freeform, the centre of this surface was located manually (automatic alignment tools were not available), and subsequently the bar structure could be

designed. This is a complicated and inaccurate process, and so further tools are needed in this software for determining the abutment positions and the alignment of the components.

Ciocca et al. (2010a) also acknowledged that one challenge in particular was to obtain an accurate representation of the implants in the digital process. Ciocca et al. took a laser scan of the implant framework in situ (on the patient), and used Boolean operations to determine the position of the bar. This relies heavily on having a pre-fabricated bar structure to scan, and therefore this does not provide an ideal solution.

To capture the implant, it is important to record the position of the implant in three dimensions, and this is traditionally done with impression material. In dental technology, digital techniques have been developed to capture the location of the abutments set in the dental stone master cast. A cylindrical registration pin (called a locator) is screwed to the abutment on the master cast. The pin is captured by touch probe scanning, and subsequently the data can be used to determine the position of the implants (Kucey and Fraser, 2000).

A study by Kruth et al. (2005), somewhat overlooked in extra-oral prosthetics literature, presented a digital workflow for the design and manufacture of a dental implant framework. After taking a conventional impression of the oral cavity, 'registration cylinders' were attached to the abutments on the stone model, which were scanned (non-contact optical scan) to determine the locations of the implants. Using the point data generated from the optical scan of the registration cylinders, the top plane and cylinder surface were translated to the known dimensions of the registration cylinders. Subsequently, the implant framework was digitally designed using this data, and the framework was produced by SLM.

This concept has not yet been translated to extra-oral prosthetics, where using a refined method of a similar nature could potentially address some of the challenges with CAD/CAM described earlier in the literature review.

3.3.3 Prosthesis 'body' design and manufacture

CAD/CAM methods have been developed for the design and fabrication of a silicone prosthesis body. These techniques, although not fully adopted in clinical practice, have also been translated successfully into workshops (Eggbeer et al., 2012b) focusing on the use of digital design in Maxillofacial Prosthetics. These techniques have concentrated on importing CT and/or surface scan data into digital sculpting software Geomagic Freeform (3D Systems, Inc.), and sculpting the prostheses form in the virtual environment. Similar techniques have been used in other patient-specific applications, such as custom implant and surgical guide design, as described earlier in the literature review.

Early research involved manufacturing anatomical models using SLA, SLS, FDM and LOM processes (Bibb et al., 2000; Chen et al., 1997; Coward et al., 1999; Kai et al., 2000). This research concentrated on using the AM models so they could be transferred into wax patterns for moulding. Later research showed that prosthesis wax patterns could be manufactured directly using Thermojet wax 3D printing (3D systems, Inc.), subsequently incorporating this into a conventional mould for final prosthesis production (Chandra et al., 2005; Verdonck et al., 2003; Reitemeier et al., 2004; Sykes et al., 2004).

This work prompted Eggbeer (2008) to publish a PhD exploring the potential of digital technologies in Maxillofacial Prosthetics. During this time, Eggbeer conducted a series of case studies and experiments, led by a case study and action research approach, focusing on the application of scanning technologies, integration of skin textures and incorporation of retention mechanisms into digital prosthesis production. The research led to multiple outcomes, which have guided current research in CAD/CAM Maxillofacial Prosthetics. A key element to their work was the exploration of using Geomagic Freeform Haptic sculpting software (3D Systems, Inc.) for various aspects of prosthesis design.

Freeform has been successfully applied in numerous research studies for the design of the prosthesis form (Eggbeer, 2008; Eggbeer et al., 2012a; Eggbeer et al., 2006c; Verdonck et al., 2003; Sykes et al., 2004). However, a number of researchers have noted

that bilateral facial defects (absence of facial features on both sides) present significant challenges in prosthesis design because the anatomy cannot be mirrored. Researchers Wu et al. (2008) and Ciocca et al. (2010a; 2010b; 2010c) have attempted to overcome this issue through the use of a digital anatomical library, where digital facial features can be imported into the CAD model of the patient's scanned face. One study (Mueller et al., 2011) focused on using statistical modelling (200 face scans) for the design of a mid-face prosthesis, a novel idea which may have useful application when a large number of scans are available.

More recent studies (Eggbeer et al., 2012a; Eggbeer and Evans, 2011) have shown that prosthesis mould tools can be designed in Freeform successfully. CAD/CAM mould tool production was initially explored by Cheah et al. (2003), but the techniques were very time consuming, complex, and could not address design subtleties for realistic looking prostheses. More recent research has successfully used CAD and AM to design and manufacture rather complex prosthesis moulds. Removable prosthetic breast moulds have been produced (Eggbeer and Evans, 2011) by using Freeform and SLA, and the digital techniques have been translated to facial prosthesis moulds (Eggbeer et al., 2012a) by using high resolution 3D printers (Projet 3D Systems). Other researchers have used design software *Geomagic Studio* (3D Systems Inc.) and *Rhino3D* (Robert McNeel & Associates) for mould design and utilised *ZCorp* 3D printing, SLA and FDM for mould production (Bi et al., 2013; Ciocca et al., 2009; Ciocca et al., 2010a; Ciocca et al., 2010b; de Crescenzio et al., 2011; Liacouras et al., 2011). Fantini et al. (2013) added a mock bar framework into the design of the mould and positioned the clip substructures into the mould for over-moulding. This could be considered the closest step to considering all retention components into the design of the mould.

de Crescenzio et al. (2011) highlighted that the surface roughness of AM prosthesis moulds should be considered, but no benchmark surface roughness values were provided. de Crescenzio et al. suggested that the stair-stepping effect of AM should be minimised by optimising build orientation. However, due to the many other AM machine parameters that can effect surface finish, optimising build orientation may provide no improved solution for the surface finish of complex prosthesis moulds. Consideration must be given to selection of technology for mould production and guidelines/design rules should be developed to aid in prosthesis mould production.

CAD/CAM mould production techniques have been influenced by techniques in conventional prosthetic practice. In the conventional process, to create a pressure fit of the prosthesis to the anatomy, MPTs often apply abrasion to the stone mould on areas where the margins will be moulded. Abrasion of this surface means that material is removed so that the margins can be extended too. Eggbeer et al (2012a) applied this technique in the CAD environment using Freeform, whilst designing the prosthesis mould. Some of the virtual clay could be sculpted away in a similar way to the traditional process, but by using a 'tolerance map', the exact amount of material removed could be controlled. Wolfaardt (1996) suggested that the conventional method is ambiguous and subject to inaccuracies - this further supports the benefits of applying this method in the digital environment where the level of material removal and accuracy can be controlled. However, conventional or digital methods have not yet allowed the applied pressure (pressure fit) to be quantified.

No CAD/CAM technology exists that is able to directly produce a clinically acceptable prosthesis body in the appropriate materials. Nevertheless, a small number of studies have attempted to manufacture the prosthesis body directly using additive manufacturing. Mueller et al. (2011) used Selective Laser Sintering (SLS) in polyamide powder to manufacture a mid-face prosthesis. Despite proving that the form could be manufactured, clinically the outcome was poor, due to the colouring and hardness of the prosthesis. Eggbeer et al. (2012a) compared indirect prosthesis production (AM mould with conventionally packed silicone) with direct manufacture of a nasal prosthesis using Objet 26a Shore material. Although the AM model was clinically unviable, due to the limitations of the technology and materials, the qualitative attributes of the prosthesis - position, shape, colour and edge quality, was comparable to the indirect method. This showed potentially promising results for using AM in the future. The ability to build components in variable hardness / functionally graded materials using AM techniques (such as Objet Multijet Printing or Oxman's (2010) Variable Property Rapid Prototyping (VPRP) patented process) offers significant possibilities in prosthesis production but the materials are not yet appropriately developed for clinical use. These processes could be used to build the prosthesis and clip substructure as 'one' – when the technology is well developed for clinically acceptable components, this may also be an exciting prospect.

3.3.4 Retention mechanism design and manufacture

In 2003, Verdonck et al. (2003) used two CT scans, one pre-implant planning to capture the prosthesis site, and one post-implant placement to capture the implant location. This has been considered as the first attempt at considering the retention components in the digital design of a prosthesis (Eggbeer, 2008). However, as noted by Eggbeer, the limited resolution of CT scanning '*would not have been able to define fine detail necessary to establish exact angle and fitting surfaces of abutments'*. Following this study, some researchers have given consideration to the implant positions and retention mechanism design in digital prosthesis production, shown in Table 4.

Author, year	Prosthesis & Retention	Reverse engineering process (anatomy & implant capture and processing)	Retention mechanism design and manufacturing process
(Verdonck et al., 2003)	Orbital	**Scanning:** CT of anatomy, CT of implants **Software:** Mimics + Freeform	**CAD:** Freeform - registration 'posts' to define implants, Boolean subtract virtual 'posts' to create cavity in prosthesis **CAM:** N/A
(Eggbeer et al., 2006a) (Bibb et al., 2010; Eggbeer, 2008)	Auricular Magnetic	**Scanning:** Structured white light scan of stone model with magnets fitted **Software:** Polyworks, Spider (Alias)	**CAD:** Freeform - Boolean subtract virtual magnets to create cavities **CAM:** N/A
(Ciocca et al., 2007)	Auricular Bar-clip	**Scanning:** Laser scanner Scanned bar structure on model **Software:** Rapidform XOR	**CAD:** Rapidform XOR **CAM:** Substructure only, AM Substructure placed in mould
(Eggbeer et al., 2006b) (Bibb et al., 2010; Eggbeer, 2008)	Auricular Bar-clip	**Scanning:** Structures white light of stone model with magnet keepers fitted for simplification of abutment **Software:** Polyworks, Spider (Alias), Magics	**CAD:** Magics & Freeform to identify abutments and design bar structure. Freeform for clip structure. Boolean subtract clip structure to create cavity in prosthesis. **CAM:** Bar structure - SLM-100 316L Stainless Steel (50µm layers), grit blasted, polished Clip structure - SLA & Perfactory
(Ciocca et al., 2009)	Nasal Eyeglasses substructure	**Scanning:** Laser Scanner **Software:** Rapidform XOR	**CAD:** Rapidform XOR **CAM:** SLA substructure, placed in ZCorp mould, over-moulded.
(de Crescenzio et al., 2011)	Auricular Bar-clip	**Scanning:** Laser Scanner Retention bar structure fitted on patient **Software:** Rapidform	**CAD:** Rhino **CAM:** FDM Substructure without clips placed in AM mould, over-moulded, clips glued in post build.
(Ciocca et al., 2010a)	Bilateral Auricular Bar-clip	**Scanning:** Laser Scanner, scanned with pre-fabricated bar in situ **Software:** Rapidform XOR	**CAD:** Rapidform XOR, Boolean operations for implant bar replication. Digital ear library. **CAM:** FDM ABS clip substructure

			& mould, conventional silicone packing with substructure placed in mould. Clips glued in post build.
(Ciocca et al., 2010b)	Nasal Bar-clip	**Scanning:** Laser Scanner, scanned with pre-fabricated bar in situ **Software:** Rapidform XOR	**CAD:** Rapidform XOR. Digital nose library **CAM:** FDM ABS clip substructure & mould, conventional silicone packing with substructure placed in mould. Clips glued in post build.
(Ciocca et al., 2010c)	Nasal Eyeglasses substructure	**Scanning:** Laser Scanner **Software:** Rapidform XOR	**CAD:** Rhino 4.0 **CAM:** FDM, Placed in FDM mould & overmoulded
(Bibb et al., 2010; Eggbeer, 2008)	Nasal Magnetic	**Scanning:** Laser Scan of stone model with magnets fitted **Software:** Pixform	**CAD:** Freeform for substructure **CAM:** SLA substructure with bonded magnets
(Bibb et al., 2010; Eggbeer, 2008)	Individual bar structure	**Scanning:** Roland Pix-30 touch probe of stone model with screw abutments **Software:** Undefined	**CAD:** Freeform – set plane top abutment surface, extrude and Boolean subtract for copings. **CAM:** Bar structure – SLM100 cobalt Chrome (30, 50µm layers), hand polished
(Fantini et al., 2013)	Nasal Bar-clip	**Scanning:** Laser scanning (NextEngine Desktop) & of model (Konica Minolta VI-9i) with pre-fabricated bar in situ **Software:** Rapidform XOS2	**CAD:** Framework 'reconstructed' in Rhino 4.0. Digital nose library. Designed bar structure into digital mould. **CAM:** FDM ABS clip substructure & mould, conventional silicone packing with substructure placed in mould on mock bar structure. Clips glued in post build.

Table 4: Extra-oral studies considering retention mechanisms

Hatamleh and Watson (2012) noted that '*technology is only practical when it can be shown to improve clinical outcomes'*. However, the research articles listed in the table showed limited steps forward in relation to clinical feasibility of the technology. The challenges revolving capturing abutments and translating this to the retention mechanism design within a prosthesis still remains a clinical challenge. It should also be important to consider the wider improvements and implications of digital prosthesis design, not limited to improved clinical outcomes, but also considering the reductions of costs, patient visits and optimisation of associated surgical, design and production processes.

3.3.4.1 Clip/substructure design and fabrication

A few recent research studies (Ciocca et al., 2009; Ciocca et al., 2010c) have involved building simple structural frameworks (substructures) for eyeglasses-retained prostheses

using AM (FDM). Undercuts and holes were featured in the substructure design, so that the silicone could adhere strongly to it. Subsequently the structures were incorporated into an AM prosthesis mould, where they could be integrated within the silicone prosthesis. These studies illustrated the potential of using CAD and AM to create simple substructures of limited functionality.

Subsequent studies (Ciocca et al., 2010a; de Crescenzio et al., 2011; Fantini et al. (2013) showed that challenges remained, particularly with regards to creating clip-substructures, (which have functional clips within the structure). In these studies, the rider clips were not fabricated by AM, but rather they were glued into the substructure manually. This contradicts the argument for digitally designing and producing these components, and shows that a solution does not yet exist in CAD/CAM for clip structure fabrication.

Previous to these research articles, Eggbeer (2008) attempted to fabricate clip-substructures by CAD/CAM. Eggbeer designed the clip component using Freeform CAD, which could not provide an ideal solution. Freeform does not deal well with accurate placement of components, although it was well suited to the surfaces following the shape of the anatomy. Eggbeer fabricated the clip-substructure by SLA (DSM Somos, 10110 epoxy resin, 0.1mm layers), and a Perfactory (Enviontec) substructure was also manufactured. There was no indication as to what retention forces were applied. His research showed that it was not viable to design and fabricate clips using AM. Eggbeer suggested that more work needs to be conducted in this area, and a retention range should be defined, which has not yet been concluded for bar-clip mechanisms.

3.3.4.2 Bar structure / implant framework design and fabrication

A number of researchers (Bibb et al., 2010; Ciocca et al., 2010b; Eggbeer, 2008; Verdonck et al., 2003) have indicated that more research is required in the development of extra-oral prosthesis bar structures.

Eggbeer (2008) published the first (and only) attempt at fabricating an auricular bar-structure by using CAD/CAM. In this study, a CMM scan of a dental stone model with

abutments was taken. The data was imported into Freeform, where the structure was digitally crafted and exported and subsequently manufactured by Selective Laser Melting (SLM-100 – MTT Technologies) at 0.05mm layers. The bar was grit blasted and polished using conventional techniques. The design was regarded clinically acceptable in a following publication (Bibb et al., 2010) but no quantitative technical evaluation was conducted to measure its technical performance. No quantitative values were provided on structural integrity, dimensional accuracy, surface roughness or accuracy of fit of the component. The abutment fitting surfaces were described by the author as 'poor'. Information was not provided about the post-processing or polishing techniques. Assessment was primarily based on the qualitative aspects of the design, but no quantitative values were provided to support the subjective assessment. This however, reflects the nature of current practice, where evaluation procedures are limited to subjective evaluation.

The build strategy for using the SLM process for dental implant-frameworks was discussed by Kruth (2005). The build position of the framework in the bed was considered, for improved fitting surfaces and a reduced stair-stepping effect. The stair-stepping effect was noted as a potential issue for producing gapping on the abutment/framework interface. Implants angles in dental applications do not vary more than about 10 degrees. However, in extra-oral frameworks, implants are often placed and designed at a range of angles, especially in larger mid-face defects. The concept of using an optimised build orientation for predictable fitting surfaces is therefore much more difficult for extra-oral frameworks.

Kruth (2005) determined that the angle of the build influenced the gap size produced between the surfaces, due to changes in the step sizes. The fitting gaps were measured at values of 18 to 37µm, which are within range of the acceptable accuracy of fit of 40µm suggested by Riedy et al. (1997). However, these values are rather misleading, because the size of the gaps produced by the stair-stepping effect does not correspond well to defining 3-dimensional accuracy of fit.

Many of the technical aspects of retention mechanism designs have either been ignored or evaluated subjectively with little scientific rigour. The technical performance of the retention mechanisms (e.g. accuracy of fit, surface roughness) must be measured

quantitatively to allow an objective and appropriate comparison with conventionally made bar and clip mechanisms. There is a large gap in the research in this area. This provides a significant opportunity to test similar and alternative manufacturing processes for producing bar structures, and evaluate their mechanical properties quantitatively.

3.4 Literature Review Summary

3.4.1 Prosthetic practice

In this literature review, an overview of the Maxillofacial Prosthetics field is provided and methods of prosthesis retention are described. The general requirements for successful prostheses have been discussed in the literature (Wolfaardt et al. 2003; Eggbeer, 2008) but the specific criteria for successful retention mechanisms have not been fully developed.

The conventional process of designing, fabricating and integrating the retention mechanism is inherently a craft process, adopted from dental technology, which requires experience and understanding of various materials, tools and techniques. The overall traditional prosthetic process has been documented in a number of textbooks and case studies, and studies (Hatamleh et al., 2010) have attempted to gauge MPT preferences in prosthetic materials and retention systems. However, inadequate information or analysis has been provided in the process of creating the retention mechanisms, or why the designs have evolved this way. Textbooks (Brånemark and de Oliveira, 1997; Taylor, 2000) have tended to overlook many of the details associated with retention mechanism design, usually focusing on the overall workflow. Many of the individualised mechanism solutions are designed arbitrarily and evaluated empirically, without the support of laboratory measurement techniques. Further depth is needed to understand and gauge current practice and to critically analyse the processes used.

3.4.2 Current state of CAD/CAM extra-oral Maxillofacial Prosthetics

The main CAD/CAM technologies used in patient-specific applications are described in this literature review. These technologies include data capture devices, reverse engineering, CAD and CAM. Studies focusing on measuring the technical quality of AM are reviewed, and it is noted that a limited number studies have looked at measuring the surface and dimensional quality of AM components.

The state of the art in using CAD/CAM in Maxillofacial Prosthetics are discussed in the literature review. Some technologies have already established themselves within the prosthetic rehabilitation process, such as medical scanning (CT, MRI), digital surgical planning software and surgical guide production by AM. Other technologies are becoming increasingly utilised in prosthetics, such as non-contact surface scanning for capturing complex surfaces and Freeform Sculpting software for mirroring anatomy and sculpting prosthetic forms. Recent years have seen CAD/CAM used in various a number of research studies, which have included the use of a digital anatomy library, digital design and AM of prosthesis moulds and simplistic substructures. However, these studies continue to fall short in capturing the implant positions, accurate design and manufacture of retention bar frameworks, and quantitative testing methods for novel designs.

Previous articles (Bibb et al., 2010) have shown that CAD-based technologies can, in theory, be used to design every component of a prosthesis. The primary shortcoming in the research is the union of all aspects of the process into one fully streamlined digital process. The ideal digital pathway has not yet been defined and consequently, a single software solution that interfaces with CAD/CAM does not exist to enable the efficient production of prostheses and their associated retention mechanisms.

The current state of digital implant-based prosthesis design and production is illustrated in Figure 13.

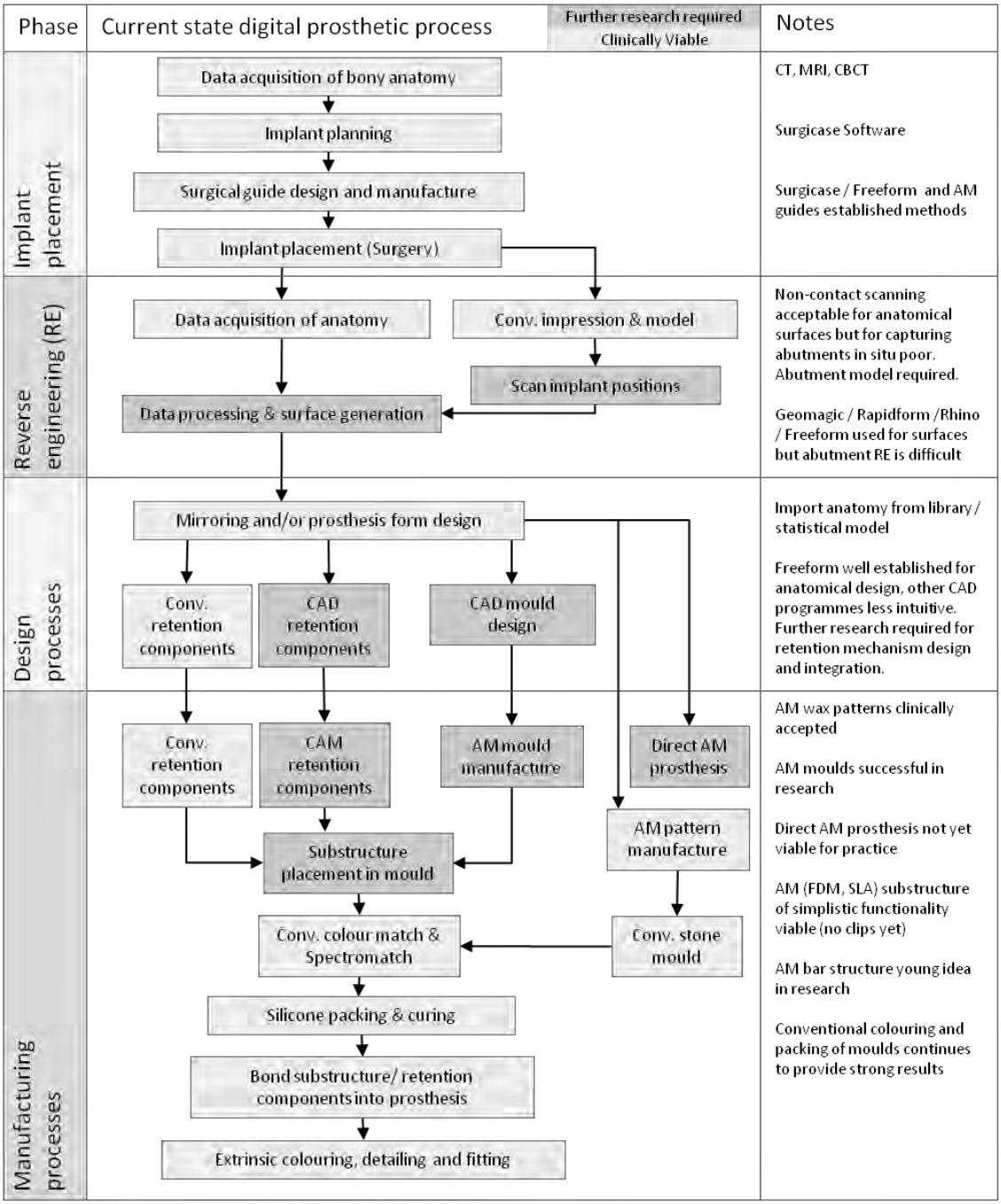


Figure 13: Current state: Digital prosthetic process

Limited studies are available comparing CAD/CAM retention mechanisms with conventionally made mechanisms. Previous to Eggbeer (2008), no studies had focused on using CAD/CAM in extra-oral bar structures, although studies had explored this topic in dental technology (Kruth et al., 2005). However, extra-oral frameworks must be designed under a different set of requirements, and therefore new processes may not necessarily be adopted directly from the dental field.

3.4.3 Requirements for Maxillofacial Prostheses

The design requirements for extra-oral prostheses, based on the previous literature can be divided into aesthetic factors, materials requirements, clinical factors, and functional factors.

Aesthetic requirements (Eggbeer, 2008)

- Accurate shape and form (likeness to anatomy)
- Accurate position in relation to the contra lateral side or anatomical landmarks
- Accurate colour and texture match to anatomy
- No visible gaps of prosthesis edges (fit of margins)
- Subtle blending of prosthesis margins to skin (margin thickness measured at 40μm – 130μm)

Material requirements

Silicone body (Bibb et al., 2010; Hooper et al., 2005)

- Light, biocompatible and easy to clean; able to colour match and accept intrinsic and extrinsic colouration; mouldable and easy to work with
- Technical properties: 20 -30 Shore A hardness, >500 % elongation at break, >16kN/m tear strength, 4.8N/mm^2 tensile strength.

Retention mechanisms (Bibb et al., 2010)

- Biocompatible, non-corrosive, hydrophobic
- Compatible with materials of other components (inert)
- Smooth surfaces / able to be polished
- Wear resistant (1,460 cycles a year)
- Stiffness and hardness approximately equal to or greater than 18 carat gold
- Clips hardness approx. 150 kg/mm^2 (equivalent 18-carat gold)
- Able to bond clip structure to the prosthesis body
- Components must resist hot water at 908°C during mould release
- Water sorption of components ≤0.6 mg/cm^2

Clinical requirements

- Comfortable, positive psychological impact on patient, ability to clean/maintain, able to put on and take off (caters to patient's needs and ability).

- No tissue irritation, successful and long-lasting bone-implant integration

Functional requirements (Bibb et al., 2010; Taylor, 2000)

- Stability (does not fall off due to the weight of the prosthesis or dynamic movement)
- Appropriate, long-lasting and adjustable retention
- Good fit of prosthesis to anatomy (pressure fit needed)
- Prosthesis disengages before breakage of components (e.g. fatigue limit of Brånemark Implants – about 300N axial tensile load and 60Ncm bending moment (Rangert and others 1989)).
- An accurate fit of bar structure to abutments (Brånemark, (1983) defined at the 10µm level, Jemt (1991) defined at ≤150µm)
- Sufficient to build 1.3mm diameter holes with sharp detail (tolerances undefined)

3.4.4 Identification of Technologies

The requirements for data capture devices, reverse engineering software, CAD packages and manufacturing processes were reviewed. As Eggbeer (2006) suggested, suitable CAD packages for Maxillofacial Prosthetics must provide tools for precisely aligning geometric shapes as well as the manipulation of complex anatomical forms. The various components must be manufactured in suitable materials to withstand the functional aspects of use. The technologies required for prosthesis design and fabrication must include:

- Non-contact scanner that can capture abutments and anatomy.
- Software for reverse engineering and to process scan data for use.
- CAD software for prosthesis, mould and retention mechanism design.
- Manufacturing technology that can produce acceptable prosthesis patterns, moulds and retention components.

The requirements and potential technology options for the various prosthetic stages must be explored further. Data needs to be obtained on whether some of the alternative,

digital processes can match the designs created by MPTs, but firstly benchmark values must be determined on the technical performance of the conventionally made retention mechanisms. To date, some of these processes have only been evaluated subjectively, and this provides opportunities for further research.

3.4.5 Research direction

The literature review suggests that more research is required on the aspects listed below. These aspects can be used to develop research questions/objectives for guiding this PhD study. However, this PhD study cannot address all of these aspects, but the most appropriate research topics are defined in chapter 4.

- A critical review of retention mechanism fabrication processes and broader understanding of key design requirements.
- Benchmark values of technical aspects of conventionally-made retention mechanism designs including:
    - Acceptable accuracy of fit of retention components
    - Acceptable surface roughness range of prosthesis bar frameworks
    - Dimensional tolerances of customised retention mechanisms
    - Range of retention forces of clips in bar-clip system
    - Structural properties of cantilever framework designs
    - Biomechanical effects of different framework designs
- Force values required for ‘pressure fit’ of prostheses
- Non-contact digital methods for capturing abutment positions, and linking this stage to design of retention mechanism and prosthesis.
- CAD/CAM technology identification for designing and fabricating bar-clip mechanisms.
- Clinical and technical feasibility of using CAD/CAM for designing, manufacturing and integrating the retention components into the wider prosthetic process, including MPT opinions on CAD/CAM.

Chapter 4: Research Methodology

In this chapter, the overall research model, research methods and research tools are described. The individual study methods are described in more depth in their corresponding study chapters.

4.1 Literature review approach

The literature review concentrated on two aspects – extra-oral prosthesis retention, and CAD/CAM technology. It demonstrated that an understanding of both aspects is required, for these areas to be combined. The literature review confirmed that very little research has been conducted in this application of CAD/CAM, and this PhD seeks to capitalise on this.

A thematic approach was taken to conduct the literature review, focusing on combined literature in the fields of *Maxillofacial Prosthetics*, *Prosthesis Retention* and *Computer-Aided Design and Manufacture*.

The following steps were taken to ensure the relevant literature was sourced, organised and cited in the appropriate manner.

1. Mind-map key research categories for literature search.
2. Develop initial literature themes based on key textbooks, and discussions with field experts (both clinical and technology experts).
3. Identification and selection of key search engines and research databases to search. (Google Scholar, Scopus, Pubmed, ScienceDirect, Emerald)
4. Develop search strategy - choose search terms based on literature themes. Search databases and search engines using Boolean logic search strategy. Example search query:

(Maxillofacial OR Auricular OR Extra-oral OR Craniofacial OR Bone-anchored OR Implant-based OR nasal OR Implant-retained) AND (Prosthetics OR Prosthesis OR

Prostheses) AND ("Rapid Prototyping" OR "CAD" OR "CAM" OR "RP" OR "CAD/CAM" OR "Rapid Prototyped" OR "Computer Aided Design" OR "Computer Aided Manufacture")

5. Obtain research articles focusing on relevance. References that could not be sourced via university subscriptions to journals and databases were sourced through Inter Library Loans (ILL).
6. Obtain citation from databases and import to Endnote (Thomson Reuters) reference organisation software. Group references thematically by digitally tagging and linking to original digital copies.
7. Set email alerts in Google Scholar and Science Direct for newly published articles using relevant search themes. This ensured an up-to-date, continuous literature review throughout the PhD.

Literature was also sourced through using the reference lists published in key research articles. This formed a key part of identifying previously cited literature, and developing an understanding of the important studies in this subject. Review articles were also particularly useful in identifying past research studies. Following the initial literature review, other relevant literature was reviewed continuously throughout the PhD study.

To identify gaps in the literature, the definition of originality was taken into consideration. Originality in research can be defined as many different things (Phillips, 2000), and the most applicable definitions for this PhD study are listed:

- Being cross-disciplinary and using different methodologies.
- Using techniques/design methods that people in the discipline have not looked at before.
- Taking a particular technique and applying it to a new area.
- Adding to knowledge in a way that has not been done before.

4.1.1 Research objectives and approach

Within the constraints of the PhD, not every aspect identified in the literature review could be explored. Therefore, this PhD concentrated on aspects of the design process

and evaluating retention mechanism performance. In consideration of the topics covered in the literature review, the research question that guided this PhD is:

> To what extent can CAD/CAM be used to produce customised Maxillofacial prosthesis retention mechanisms, and what are the challenges associated with using such a strategy?

A series of research objectives were devised based on the guiding research question and the gaps identified in the literature review:

1. *Gain insight into the process of fabricating extra-oral prosthesis retention mechanisms, define design considerations and criteria, and explore MPT perspectives on using CAD/CAM in prosthetic processes.*
2. *Explore how CAD/CAM can be used to design, fabricate and integrate the retention mechanisms into the prosthetic processes.*
3. *Develop quantitative testing methods to evaluate and compare selected technical aspects of conventionally made and novel CAD/CAM mechanisms.*

These objectives required an approach that not only described the practice and opinions of MPTs, but the technical performance of current and new retention mechanism designs. Therefore, this PhD was concerned with both narrative and numeric data.

In the design of the research methodology, the key scientific processes of observation, classification, measurement and communication were considered. To form an understanding of the clinical and technical needs in retention mechanism design, descriptive studies were required to observe and classify the design and fabrication process. It was noted early on that this would require qualitative research application for a deeper understanding of the subject. For the exploration of using CAD/CAM technologies in this field, a period of developmental work was required, to create CAD-based samples and gauge how far the digital process could be taken. It was planned that the samples would need to be evaluated quantitatively by measuring the physical characteristics of the samples, which would satisfy an identified gap in the research. The process also needed to be evaluated, and this could be completed qualitatively. The

combination of these aspects were used to contribute toward the development of CAD/CAM solutions in extra-oral retention mechanisms.

4.1.2 Mixed method research

The development of technologies in this field is growing rapidly, but to properly evaluate the application of these technologies in the field of prosthetics, the design requirements must be understood further and testing methods must be developed to evaluate part performance. For this reason, a mixed method approach was chosen.

A mixed method research approach involves the mixing of quantitative and qualitative methods. Mixed method research can be defined according to Tashakkori and Teddlie (2008) as:

> *"…research in which the investigator collect and analyzes data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or program of inquiry"*

…and Onwuegbuzie & Johnson (2006) believe that,

> *"…the goal of mixed research is not to replace quantitative or qualitative research, but it is to utilise the strengths of two or more approaches by combining them in one study…"*

Qualitative research is appropriate when the goal is to *observe* and *describe,* and by nature, the data collection, data analysis, and data interpretation stages are iterative (Onwuegbuzie and Leech, 2006). Mack et al. (2005) suggests qualitative methods can be effective to decipher '*the complex reality of a situation'* and it offers a way of obtaining a deeper understanding of a social context or task.

> *"Qualitative research consists of collecting evidence, particularly providing culturally specific information about the beliefs, opinions and behaviours of people."(Mack et al., 2005)*

Qualitative research is an effective type of research for presenting information on people's experiences and how they feel about a particular issue. It is a process of

'understanding' a subject where the researcher develops a... *"complex, holistic picture, analyzes words, reports detailed views of informants, and conducts the study in a natural setting" (John, 2012)*

Quantitative research is more focused on the collection and analysis of numerical data and statistics (Charles and Mertler, 2002), whereas qualitative research takes a broad outlook to describe a particular phenomenon and is mostly subjective in nature. Quantitative research is objective in nature and takes a more narrow approach to answer a particular question. It is possible to use quantitative methods to give rigid, unambiguous and verifiable expression to qualitative concepts. The details of quantitative measurement and analysis can be described thoroughly, and the results are objective, so they do not rely on people's opinion, therefore the results may be replicated. Of course, the insights gained from the results may differ or develop every time the experiment is replicated. The researcher decides which variables to investigate, and must choose the most appropriate measurement instruments.

The mixed method approach is pragmatic in nature, that is, it holds the belief that research methods should be mixed when it is appropriate. In this PhD study, a fully qualitative or quantitative approach would not have been appropriate to fulfil the research objectives, and the gaps identified in the research provided impetus to use a mixed method approach. The multifaceted composition of the research question was also an influential driver for the decision to use a mixed method approach. Greene et al. (1989) suggested five justifications for using mixed methods research.

Triangulation (seeking convergence and corroboration of findings from different methods that study the same phenomenon)
Complementary (i.e. seeking elaboration, illustration, enhancement, and clarification of the findings from one method with results from the other method)
Development (i.e. using the findings from one method to help inform the other method)
Initiation (i.e. discovering paradoxes and contradictions that lead to a re-framing of the research question)
Expansion (i.e. seeking to expand the breadth and range of inquiry by using different methods for different inquiry components).

The mixed method approach was not only used to triangulate the results within the descriptive research (survey, interview, observational), but to expand the depth of understanding about the design process and to inform the subsequent phases of research so that appropriate research avenues could be pursued. Collins et al. (2006) also suggest rationale for mixing or combining qualitative and quantitative methods, one being '*Significance Enhancement'*, that is, to assist in developing richness of data and amplifying usefulness of findings.

Quantitative and qualitative research methods can be combined in a number of ways regardless of which has priority in the research. The mixed method research approach tends to be iterative and interactive (Onwuegbuzie and Johnson, 2006). Quantitative and qualitative research methods can be combined sequentially, in parallel or concurrently. In this PhD study, the individual studies remained autonomous in nature, until the interpretation stage of the research phases. Therefore, although the data collection methods in each phase of the work were conducted in parallel (collected separately with little attempt at integrating the inferences into one), the conclusions were combined into a 'coherent whole' at the end of each phase, (otherwise known as 'concurrently' combining mixed method research). In this PhD study, the inferences were integrated after each phase of the research. Onwuegbuzie & Johnson (2006) explain that in concurrent mixed research, *'inferences are made on both sources of data in an integrated manner.'* Tashakkori and Teddlie (2010) coined this as '*meta-inference'*, illustrated in Figure 14.

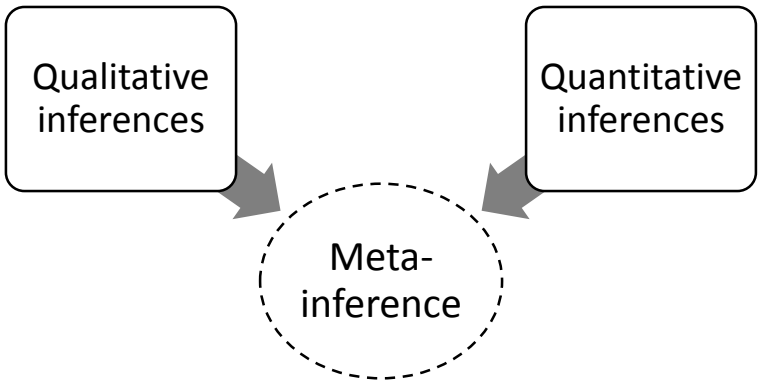


Figure 14: Parallel mixed method approach with integrated inferences.

The research findings produced during the PhD study were a combination of those from the independent qualitative and quantitative elements, and of those that transpire as inferences after each research phase. Tashakkori and Teddlie (2008) express that when inferences are combined, *'the two provide a more complete meaning, a Gestalt that is bigger than the sum of its parts'.*

To conclude, mixed method research should follow what is known as the '*fundamental principle of mixed research*' (Johnson and Turner, 2003)**,** which involves the mixing and combining of quantitative and qualitative approaches, that have '*complimentary strengths and non-overlapping weaknesses'*. However, the strengths and weaknesses of qualitative and quantitative research must firstly be understood so that the researcher is in a position to apply this strategy.

4.1.3 Validity in mixed research

Research validity refers to the confidence a researcher can have in making certain conclusions. Evaluating the validity of mixed method research can be quite complex, and even counterproductive, because of the conflicting ideas between quantitative and qualitative researchers' beliefs. The concept of validity in quantitative research is accepted but it is often disliked by qualitative researchers. However, qualitative and quantitative researchers agree on the usefulness of the concept of triangulation, to corroborate and unite findings from various methods that study the same research issue, as explained by Tobin and Begley (2004):

> *'Inquirers are thus not using triangulation as a means of confirming existing data, but as a means of enlarging the landscape of enquiry, offering a deeper and more comprehensive picture.'*

An important stage for a mixed method researcher is to combine the various sets of inferences generated by the various parts of the study, and to ensure a good quality of inferences. (Tashakkori and Teddlie, 2008) describe the quality of inferences being related to design quality and interpretive rigour. They suggest mixed method inferences must incorporate many of the standards of quality from qualitative and quantitative approaches. The validity of the qualitative inferences is based on credibility and trustworthiness, and the validity of the quantitative inferences deals with an appropriate use of statistics and minimising bias. The key driver for this PhD's research validity was

to ensure rigour, suitability and good design of the individual study methods to generate appropriate inferences that are aligned with the research objectives.

The involvement and opinions of practicing MPTs was an important asset to ensuring validity and good research design. The dissemination of the findings during the course of the PhD was also considered important for assessing the quality of the research.

4.2 Research Model

This PhD research study consisted of 4 phases. These phases were devised to answer the overall guiding research question and meet the individual research objectives.

Phase 1 – Literature Review

The literature was reviewed to gain an understanding of what had previously been achieved in this field, and to identify the gaps in the research. A thematic approach was taken to source the relevant literature and following this initial filtering process, the literature was continuously and iteratively reviewed throughout the course of the PhD.

Phase 2 – Descriptive Research Studies

The aim of this phase was to meet research objective 1. This involved seeking insight and understanding into the prosthetic design process by conducting in-depth interviews, observational studies in the prosthetic laboratory, and a survey with a series of MPTs. Triangulation of the three research methods means that the validity and strength of the inferences were enhanced. This phase provided a foundation of knowledge to inform the subsequent phases of work. This work also allowed conventionally made retention mechanism samples to be obtained.

Phase 3 – CAD/CAM process trials and development

To meet research objective 2, this phase was exploratory in nature and focused on two aspects. The first aspect was to identify and trial the appropriate CAD/CAM technologies for the development of a complete CAD/CAM prosthetic process. The second aspect focused on generating a series of CAD/CAM-based retention mechanism samples. MPT feedback was sought on the conceptual CAD/CAM process.

Phase 4 – Evaluative Research

The aim of this phase was to meet research objective 3 – to evaluate the conventional and CAD/CAM samples obtained in the previous phases. The quantitative methods used in this phase focused on the technical measurement of the key features and was supported by qualitative data where possible.

These phases provided a framework for the overall research model of the PhD, mapped in Figure 15. The research model guided the subsequent chapters of the thesis.

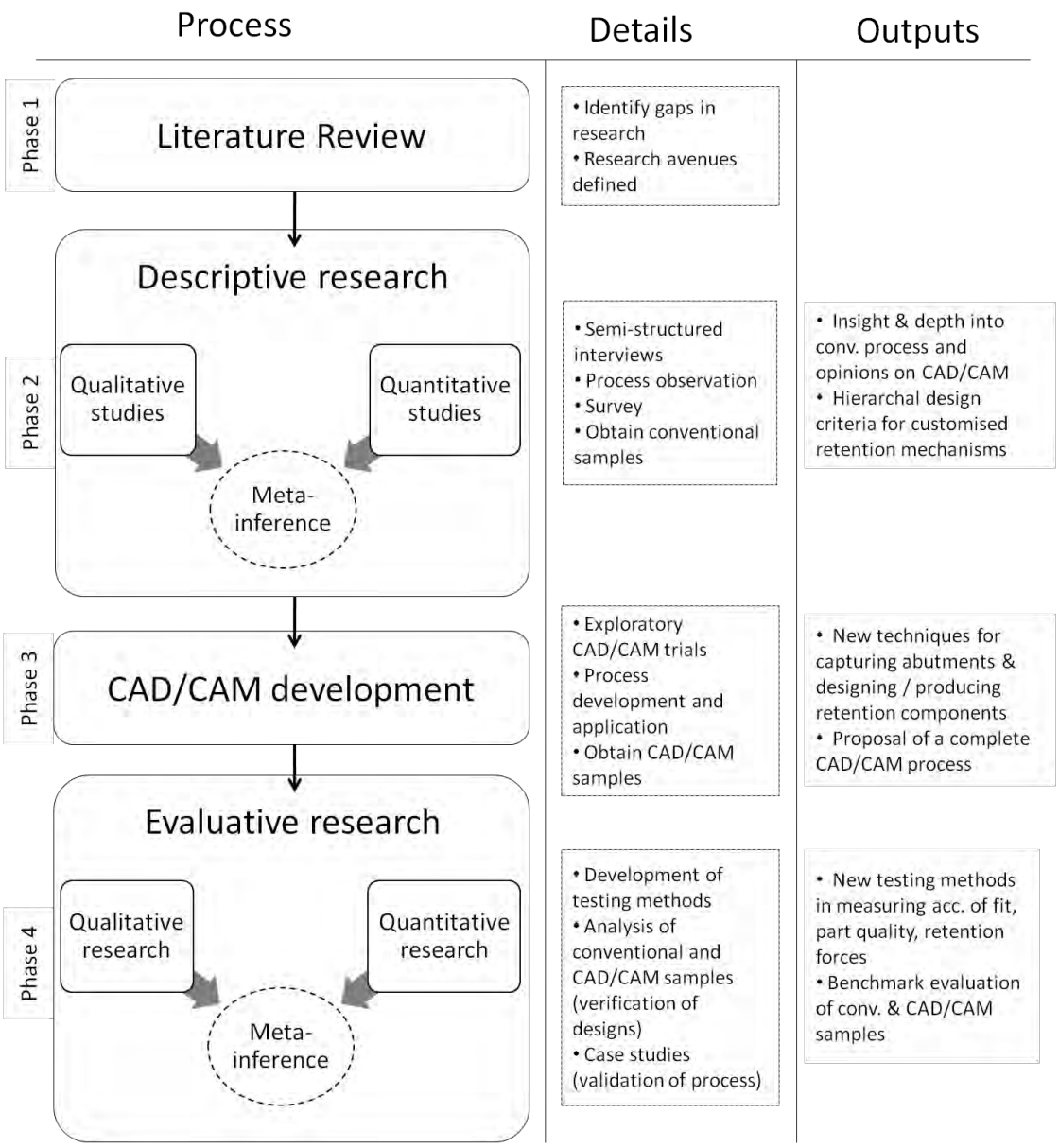


Figure 15: PhD Research Framework

4.3 Research methods

A number of research methods were used in this PhD study to satisfy the research objectives. The methods are described in this section.

4.3.1 Descriptive research methods

The following descriptive research methods were chosen for research phase 2:

- Survey *(qualitative & quantitative questions)*
- In-depth interviews *(qualitative)*
- Process observation *(qualitative)*

There are limitations and advantages to each method, but by using a combination of all three methods, a complimentary approach can be taken, where the weaknesses of one method can be compensated by the other (triangulation).

Surveys are useful for collecting opinion from the general population or community (Babbie, 1973), require minimal time to complete and costs mainly include printing and postage. Surveys however can potentially require a long wait for responses, and can be difficult to control whether respondents interpret the questions wrongly. Although allowing for both quantitative and qualitative data, it can be difficult to encourage additional comments. In-depth interviews can overcome some of the limitations posed by surveys.

Interviews are *'appropriate for collecting data on an individual's personal histories, perspectives, and experiences'* (Mack et al., 2005). Interviews can be time consuming to conduct but there is an instantaneous exchange of data, and the interviewer can explain questions and encourage further comments if required. The data obtained through interviews is qualitative and relies on the interviewer's interpretation of the data. Interviewer bias can influence the responses or analysis, so every attempt to reduce bias should be made. Usually, costs are related to travel, participant time and reward.

Observational studies (or naturalistic enquiry) are '*appropriate for collecting data on naturally occurring behaviours in their usual contexts'* (Mack et al., 2005). Like interviews, they are more informal than surveys and allow instantaneous exchange of data through personal contact. Observational work can be time consuming to complete but can allow for discussion and the observer can explain questions. Observations provide a more objective approach than interviews, but where discussion occurs, bias may influence data. Both qualitative and quantitative data can be obtained through observations. This method tends to focus on documenting actual operations and impacts of a process over a period of time. In the context of Maxillofacial Prosthetics, this will be the day-to-day processes that occur within the laboratory.

4.3.2 Evaluative research methods

The evaluative methods focused on technical comparison of the conventionally-made and experimental samples. As described in the literature review, assessment of practice and in many research studies has been limited to subjective evaluation. Subjective evaluation is considered important in the context of patient-specific design, but to measure the technical aspects of designs, it can not be used alone.

Quantitative research is appropriate when a focused research question needs answering or a hypothesis needs testing. A disadvantage to quantitative research is it presumes that the investigator understands a research issue well enough to reliably measure it. This is particularly important when analysing and interpreting quantitative data. To overcome this, experts in the field of metrology, microscopy and mechanical measurement (Cardiff University and Renishaw Plc) were consulted to support and facilitate the most appropriate methods of measurement.

The performance criterion identified in the literature review and data obtained in Phase 2 defined the appropriate evaluative studies. Individual measurement methods had to firstly be developed to allow the evaluation of the conventionally-made and CAD/CAM samples. Following this, the measurement studies concentrated on producing an initial set of data to provide insight into the performance of the samples, so that a comparison

of conventional practice vs. CAD/CAM could be made. The approach is illustrated in Figure 16.

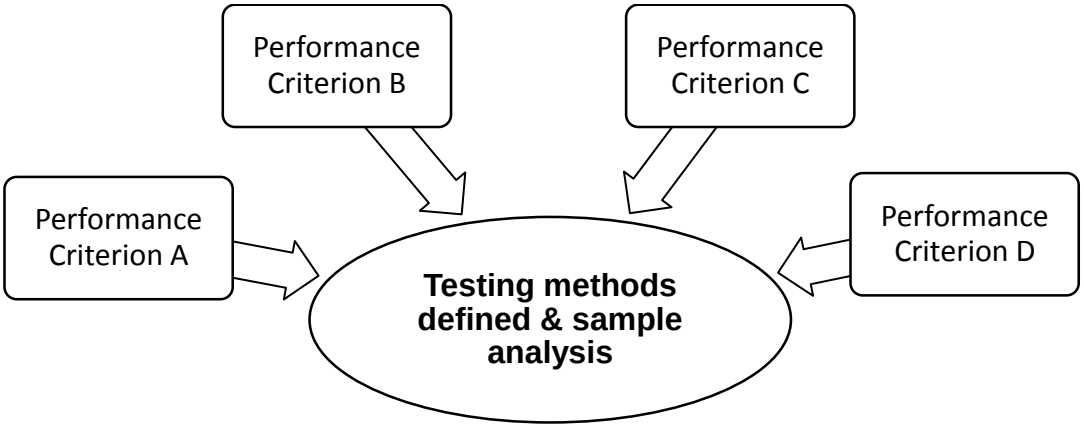


Figure 16: Measurement study approach & outcome

In each evaluative study, the same sequence was followed to measure the samples. The sequence is illustrated in Figure 17.

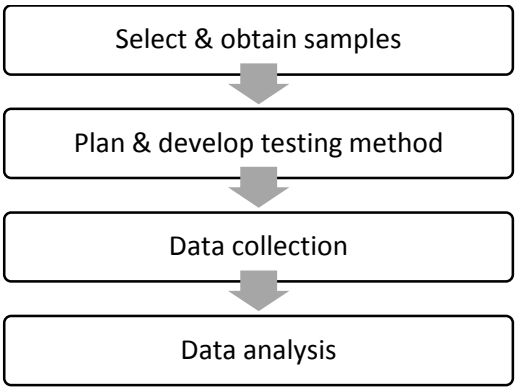


Figure 17: Measurement testing sequence

The evaluative studies defined methods and provide indications for future measurement studies in the topic of prosthesis retention mechanisms. The technicalities and detailed steps in the studies are described more thoroughly in each of their own chapters.

4.4 Instrumentation

4.4.1 Descriptive research tools

A combination of hardware and software was used to enable the descriptive research methods:

Hardware:

Nikon D90 digital camera with macro lens: 12.3 megapixel resolution**,** IS0 200-3200 range. Sigma 70-200mm f2.8 Lens, with macro feature.

Sony ICD-PX333 Digital Voice Recorder: 72 hrs battery life

Software:

SPSS (IBM®): Statistical analysis software

NVivo8 (QSR International Pty Ltd): Qualitative data analysis software

4.4.2 Evaluative research tools

4.4.2.1 Qualitative tools

A digital microscope was used to qualitatively inspect the samples:

Dino-Lite Digital Microscope: AM4113/AD4113 series. Adjustable focus and magnification. Optical magnification rate: 20x-90x, 200x. 1.3 megapixel resolution.

4.4.2.2 Quantitative measurement tools

The instruments used to quantitatively measure the samples included:

Digital Vernier Calliper

For making prompt measurements in the workshop environment, a Mitutoyo Digital Electronic Vernier Calliper was used, corresponding to the calibration standards met at PDR, Cardiff Metropolitan University. The range of the calliper reached 150mm, accuracy ±0.02mm, and repeatability ±0.01mm.

Coordinate Measurement Machine (CMM)

Using Incise touch probe technology (Renishaw Plc), measurements could be taken of cylindrical components. Using this method, it was possible to export the 3 dimensional coordinates from the accompanying software. These figures tell the user the exact vector coordinates of cylindrical components in space.

Virtual measurement (CAD software)

Measurements were made using Solidworks (Dassault Systemes) design engineering software. This software was used for importing 3-dimensional coordinates produced from the Coordinate Measurement Machine and making measurements. Within this software the measurement tool was utilised to pick points on virtual components and measure the distances between them. The software was also used to trace surface scan data using the integrated sketch tools, and subsequently measurements could be taken.

Microscopy

Microscopy measurements were taken in the Mitutoyo Metrology Laboratory, Cardiff University, School of Engineering of the retention mechanism samples. The two aspects that were measured were surface roughness and dimensional accuracy.

Surface roughness

To measure the surface roughness of the test samples, a MicroXAM White Light Interferometer was used, with accompanying MapVue EX surface mapping software (ADE/Phase Shift).

Dimensional accuracy

To measure the dimensional accuracies of the test samples, An ACCEL Quick Vision Pro (Mitutoyo) microscope with QuickVisonPAC accompanying measurement software was used.

Mechanical force measurement

To determine the retention forces applied by bar and clip mechanisms, a Servocon Systems universal testing machine with Systemes MTS software was utilised at Cardiff School of Engineering.

4.5 Patient Model

Consideration was taken into the appropriateness of using patient cases for the development of new techniques. As the efficacy and risks associated with the experimental processes in the early stages of this PhD were unknown, it was decided that a patient replica model should be designed and fabricated.

The model represented a patient without an ear – a typical auricular prosthesis case. This model was used throughout the PhD study, to ensure consistency in obtaining samples and allowed repeatability during experimental testing procedures.

A volunteer's face was scanned using a handheld laser scanner (Handyscan), and the data was imported into the virtual sculpting software, Geomagic Freeform (3D Systems, Inc.). The scan data was used to create a full head, and one ear was removed (figure 18). In the CAD environment, abutments were placed in the defected site under the guidance of an experienced MPT, so that real abutment replicas could be placed in the final physical model in the correct location and depth.

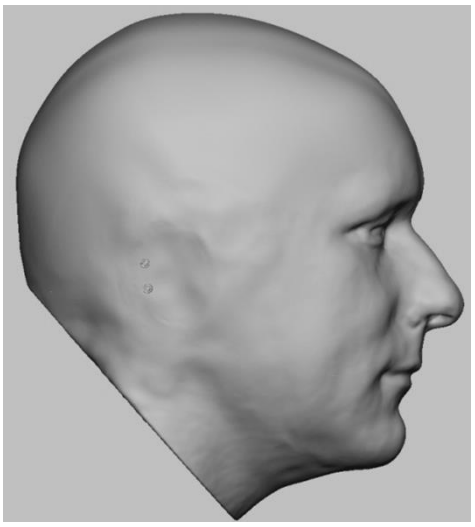


Figure 18: CAD model of defected side, virtual abutments placed

The head model was cropped to a smaller portion, around the auricular region, and utilised a reinforced design to ensure stability. The model was exported in the STL file format for manufacture - produced using Stereolithography (SLA 250, 3D Systems), White Flex 9420EP (DSM Somos) light curing polymer resin (figure 19). Post manufacture, screw-type abutment replicas (Cochlear, Vistafix) were bonded into the holes securely (figure 20). The model was labelled to ensure its correct orientation.

Figure 19: Model of a portion of a patient's head for bar and clip retention

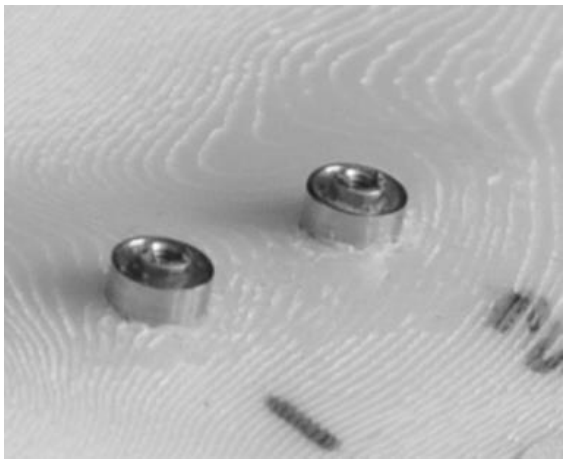


Figure 20: Abutments bonded into model

4.6 Ethics

The PhD study involved NHS staff at various stages of the research through interviews, participant observation and surveys. The ethical implications were considered and ethical approval was sought from Cardiff Metropolitan University Ethics Committee. The studies were concerned with collecting opinions and information about the design process only, meaning the data collected was non-personal, non-confidential and non-sensitive. Therefore the research had no ethical implications regarding confidentiality or impact on working practices for the participants. The School Ethics Committee granted ethical approval and further ethical reviews were not required.

4.7 Summary

This PhD research study was divided into 4 phases, and a combination of qualitative and quantitative methods was used. The mixed method approach was used to triangulate

the results within the descriptive research, to expand the depth of understanding about the design processes and to inform the subsequent phases of research. The validity of the mixed inferences was concerned with triangulation, and using reliable, well-established methods with expert consultation.

This PhD is concerned with narrative, exploratory and numeric data. The first chosen research methods included in-depth interview, observations and surveys – these methods formed the descriptive research phase to gain insight into current MPT practice and opinions. Exploratory research was conducted to trial the potential technologies and this fed the development of a conceptual CAD/CAM process. Subsequent research methods focused on developing and using technical measurement to evaluate samples obtained from traditional practice and novel CAD/CAM processes. The individual study methods will be described in their own chapters.

The findings are to be disseminated in the form of conference papers, research posters, articles and the final thesis. The research will have practical application within the clinical laboratory, but further research should to be conducted to implement the proposed ideas, so that all risks can be reduced for the patient and MPT. The research outcomes may also be useful for commercial application, for the utilisation of existing technologies or development of new technologies in this field.

Chapter 5: Descriptive Research

5.1 Overview

This study chapter describes current practice and presents the opinions of MPTs on the production of extra-oral retention mechanisms. To do this, research objective 1 was divided into specific study objectives, based on the identified gaps in the literature.

- *What is involved in current state-of-the-art processes for retention mechanism fabrication?*
- *What are the design requirements for extra-oral retention mechanisms, and how are the various performance parameters evaluated?*
- *What are MPT opinions of integration of CAD/CAM in prosthetic processes?*

5.2 Sample selection

The inclusion criteria for the survey included all practicing or training MPTs who were members of a recognised Maxillofacial Prosthetics body or organisation.

For the interviews and observations, the inclusion criteria consisted of the following:

- Candidates must regularly undertake prosthetic reconstructing including retention components;
- Candidates must have over 4 years experience in fabricating retention mechanisms, of different types for various facial prostheses. Experts were consulted to define the appropriate experience level.
- Candidates were chosen based on their willingness, enthusiasm to participate and openness - they must feel comfortable with participating in a semi-structured interview and open to sharing their experiences, opinions and reflecting on the practice;
- Candidates must also be chosen based on being accessible around the required timescale.

5.3 Descriptive research methods

5.3.1 Method A: Survey

This survey aimed to capture data from the community of practicing MPTs. The main themes of the survey focused on preferences in conventional methods of retention and associated fabrication processes; timescales for fabrication processes; evaluation methods; and opinions on CAD/CAM in prosthesis retention. Therefore, the survey questions asked participants to:

- Define their favoured methods of retention
- Rate the influential factors for choosing and designing retention systems
- Define their checking and evaluation procedures
- Estimate the length of time to design and fabricate a 'bar and clip' mechanism
- Rate the importance of various factors involved with 'bar and clip' mechanism design
- Rate the potential benefits that CAD might offer in retention mechanism design

An online pilot survey was firstly conducted with 5 members of the International Anaplastology Association (IAA) to assess the relevance and appropriateness of the proposed survey questions. The survey design was refined accordingly and finalised in collaboration with a three experienced MPTs. The finalised survey questions can be viewed in Appendix IV. Following the pilot study, 175 surveys were distributed to members of the Institute for Maxillofacial Prosthetists and Technology (IMPT), via the 2011 Spring Newsletter (this represents the population of the IMPT). 26 usable surveys were returned from prosthetic rehabilitation laboratories around the UK and France (answered in Q1), which represented a 15% response rate. Survey completion dates varied between the 21st March to 20th July 2011. Quantitative data obtained from the surveys were analysed using SPSS statistical analysis software (IBM®), and the qualitative answers were transferred to qualitative data analysis software NVivo8.

The results of the surveys were combined with the results of the qualitative data to form the initial research findings that informed the subsequent studies.

5.3.2 Method B: In-depth interviews

The interviews were used to gain a greater understanding on MPT requirements for designing retention mechanisms, depth on the design and manufacturing process, clarity on how MPTs evaluate their processes and their attitudes towards the potential integration of CAD/CAM technologies in this process.

A semi-structured interview was designed in relation to the gaps identified in the literature. Interview questions were developed through collaboration with an expert MPT (over 10 years experience) and an expert in qualitative methods (Cardiff Metropolitan University) in order to ensure questions were appropriate, robust, and to capture all of the necessary data. The finalised interview questions can be viewed in Appendix II and covered the following key topics:

- The definition of prosthesis retention success;
- The retention mechanism design process;
- Checking and evaluation procedures;
- User requirements in mechanism design;
- The integration of Computer Aided Design (CAD) into the prosthetic process.

A pilot interview was conducted with an established MPT (over 10 years experience). The pilot interview highlighted that the method worked well in encouraging the participant to share past experiences and opinions. A voice recorder was essential, so that the interviewer could give their full attention to the MPT and conversation could flow. The pilot study revealed that note-taking altered the nature the participant interacted with the interviewer – it interrupted the interview, often halting the free-flowing thoughts of the participant. Further changes could be made to the interviews questions based on the insight from the pilot.

Following the pilot interview, a further seven MPTs were interviewed, from three different prosthetic rehabilitation laboratories around the UK - Queen Elizabeth

Hospital, Birmingham; Worcestershire Acute Hospital; and Morriston Hospital, Swansea. The sample size for the interviews was reached when the same themes, issues, and topics emerged sufficiently from the interviewees.

All MPTs were interviewed for between 50 minutes and 1 hr 20 minutes. All interviews were recorded in a quiet environment using a voice recorder with the permission of the MPT being interviewed. Following the interviews the recordings were transcribed into Microsoft Word. The researcher took care so that any personal information in the recordings would not be identifiable.

The interviews were read by the researcher and transcribed. Transcriptions can be viewed in Appendix II. After the interview recordings were transcribed, the transcriptions were reviewed in detail using qualitative data analysis software (NVivo8), and themes emerged in the data. This is known as *thematic analysis*. As a theme emerges, a code is assigned to that element of the document. Codes help index the key themes while maintaining the context in which the themes occur. Text segments are accumulated with other segments that have been given the same code. It is the researcher's interpretation of the data which determines whether the codes reflect the same concept and if they have been grouped appropriately. Existing codes can be refined and new codes can be identified in an iterative fashion. Using this coding system seeks to reduce 'confirmation bias', when the investigator is vulnerable to interpret or note occurrences that align with their expectations. The evolution of the thematic coding structure ultimately feeds into the qualitative findings report.

To summarise, thematic analysis follows a process of filtering the codes into overall themes by merging categories together and organising them into hierarchical groups. Themes can be defined as *'recurrent unifying concepts or statements about the subject of inquiry'* (Curry et al. 2009).

5.3.3 Method C: Observations

In the literature, information documenting the issues with the conventional retention mechanism design process is limited and although textbooks have described the process stages, the descriptions lack depth and critique. For this reason, an observational method

was required to capture the craft process in further detail than previously documented in the literature.

In order to document the process of retention mechanism design procedures, MPTs were observed and recorded in a lab-based environment. The main task was to capture and document the process, and the most appropriate way of doing this was by the researcher immersing himself amongst the clinicians, spending multiple hours observing the process (it was recognised that the act of observation in itself could affect the outcomes), and thoroughly questioning the various tasks and techniques that were being used. Where possible, the 'patient replica model' was used for consistency in the study. This also allowed a series of conventionally-made bar-clip samples to be obtained.

Six MPTs from three prosthetic rehabilitation laboratories around the UK (hospitals defined in previous section) participated in the study. The interview participants were asked if they wished to participate in the observational study following the interview – this was logistically and financially more viable. The sample size was reached when the same techniques, methods, themes, issues and emerged sufficiently from the observational study.

One work day was spent with each participant in his or her own natural work environment. To avoid introducing any form of bias and to minimise disruption to the process the observational research did not include formal questioning, and video filming was not used due to the potential to capture sensitive patient information. The processes were documented using unobtrusive techniques - field notes were taken and a voice recorder was used to record the participants' passing thoughts and comments, which were later transcribed (see Appendix III). The work was photo-documented so that the design process could be captured. Transcriptions and notes were reviewed in detail using qualitative data analysis software (NVivo8), and a thematic coding structure was developed, similarly to the interviews. The photos were used to support the thematic analysis of observations.

The observed process was separated into three phases:

***PHASE 1*:** Impression of the anatomy and abutment capture
PHASE 2: Retention bar design and fabrication
PHASE 3: Clip structure design and fabrication

In each phase, the following aspects were documented:

- Process stages and techniques
- Evaluation procedures during the fabrication process
- Issues, obstacles or uncertainties
- Any relevant passing thoughts and comments
- Time taken to complete the process phases
- Materials and tools used

The equipment used was a Nikon D90 DSLR camera, 8gb memory card, voice recorder x 2 (one back up), note pad, and a semi-structured question sheet to prompt discussion.

5.4 Descriptive Research Results

This section describes the results from the MPT survey, semi-structured interviews and observations of the process. Quantitative results from the survey are presented and following this, the various themes and sub-themes that developed iteratively through the qualitative data analysis are described.

5.4.1 Summary of individual study findings

5.4.1.1 Survey – summary of results

- The 'Bar and Clip' system was overall the most favourable method of retention because it was believed the system was the most retentive and most reliable.
- Patient dexterity was the highest influence on the choice of retention but other factors were also considered highly influential, such as positioning of the implants and patient lifestyle.
- The estimated time to fabricate a bar-clip mechanism varied largely (min. ≈ 60 minutes, max. ≈ 600 minutes) but reasons for this were unclear.

- All the proposed factors relating to retention mechanism design were suggested to have some importance, but it could not be clearly concluded from the results if there was a clear hierarchical order of importance, despite the natural hierarchy provided due to the nature of the question.
- The one-screw test was the most recognised method in current practice for evaluating accuracy of fit, and this is fully subjective.
- Mixed opinions were provided by the survey respondents in relation to the proposed benefits of using CAD/CAM in this field.

5.4.1.2 Semi-structured interviews – summary of results

A number of themes were developed from the interviews transcripts. A summary of the main results is provided in this section, and the individual themes are discussed in further depth throughout this chapter.

Data showed that the importance of understanding the patient was a primary topic for the MPTs in the process of designing implant-retained prostheses. It was clear that the MPTs put the patient at the forefront of the process, and this also included building a strong relationship with the surgeon to allow a greater understanding of the clinical needs. The process was described as one that relies on communication between MPT, patient and a number of other technical and clinical personnel.

As part of the thematic analysis of the interview data, a series of considerations for bar-clip fabrication were identified that were suggested to contribute to the success of bar-clip retention devices. These were categorised as clinical factors, mechanical factors, biological factors and factors associated with the design process (see Table 5). The factors will be discussed in more detail in the subsequent sections of this chapter.

BIOLOGICAL / BIOMECHANICAL	CLINICAL
• Modes of infection • Irradiated bone • Recurrence of cancer • Quality of bone-implant integration • Forces on bone-implant interface	• Patient lifestyle • Patient dexterity • Patient psychological state • Condition of hard and soft tissues • Prosthesis location on face • Patient history and future surgical plans
MECHANICAL	**PROCESS**
• Retention strength • Surface smoothness of components • Modularity of components • Components fitting within the prosthetic envelope • Loading transferred to implants and bone • Structural properties • Accuracy of fit between components • Stability (anti-shearing & rotational), and can withstand anatomical movement • Component longevity and resistance to damage • Application of pressure fit on margins • Path/nature of prosthesis attachment	• Efficiency, stages in process for MPT and patient • Flexibility in design methods and ability to compromise • Potential modes of contamination • Accuracy of processes, tools and materials • Invasiveness – patient comfort

Table 5: Considerations for bar-clip fabrication

The interviewees discussed the various factors that are evaluated in conventional bar-clip retention. The main elements included fit of prosthetic components, applied levels of retention and surface quality of the components. It was suggested that all elements are evaluated subjectively in current practice.

Mixed opinions were also provided by the interviewees whilst discussing the proposed benefits of using CAD/CAM. Some MPTs believed the use of CAD/CAM brings no benefits at all, some interviewees suggested it could bring a number of benefits, and others were uncertain about what the future could hold for the field of Maxillofacial prosthetics.

5.4.1.3 Observations – summary of results

The conventional fabrication processes were captured and the overall stages are summarised below.

Phase 1 – Anatomy and implant capture

- Impression copings fitted to abutments
- Silicone impression material applied to anatomy
- Remove from patient, apply abutment replicas to impression
- Create model by pouring dental stone to impression and around abutment replicas
- Leave to set, trim, wash

Phase 2 – Design of bar structure

- Place gold copings on working model
- Cut gold bar pieces to size and laser weld them to the copings
- Smooth joints and apply gold solder, smooth the joints
- Polish the bar, check accuracy of fit on model

Phase 3- Design of clip structure

- Position gold clips on bar structure
- Sculpt wax under the bar for the formation of the clip base plate
- Apply light cure sheet and gel on to wax 'buck', cure
- Remove the clip structure and boil out the wax
- After creating the silicone prosthesis body based on a wax master, bond the clip base plate into the prosthesis with primer.

By mapping the process, it could be seen that despite the overall objectives remaining the same, the MPTs' methods were inconsistent and relied on varied techniques to satisfy the design aims, derived from experience rather than scientific evidence. A number of themes were also developed from the observational study transcripts the individual themes are discussed in further depth throughout this chapter.

The qualitative data provided insight into how the various requirements are met through the various bar-clip design features. The data suggested that traditional designs are able to satisfy many requirements, but despite this, some of the applied design methods conflict with some of the proposed requirements.

The data allowed the conventional process to be characterised. The process was observed to provide not only a patient-specific solution, but also to be conducted in an

MPT-specific manner, where outcomes rely on the judgment and personal preferences of the MPT.

The process was observed to be dominated by idiosyncratic craft methods, which was perceived to allow an open, flexible process but allowed a number of opportunities for inaccuracies difficult to identify, given the nature of the evaluation techniques.

The themes developed from the interview data and observational study transcripts were consolidated and are elaborated in subsequent sections of this chapter (a number of synergies were identified that allowed an appropriate consolidation of themes).

5.4.2 Initial numerical results

From the survey, it was found that the 'Bar and Clip' system was confirmed as the most favourable method of retention (Q2). 69% respondents preferred bar and clip for auricular prostheses compared to 19% for magnetic systems. 12% of respondents preferred other methods such as titanium studs and mushroom style abutments. Respondents who favoured the 'bar and clip' believed the system was the most retentive and most reliable.

Survey respondents were asked (Q3) to rank on a Likert-type scale a list of potential influences (0- not influencing their choice at all, 5- a high influence on their choice of retention). Results revealed that patient dexterity was the highest influence on the choice of retention as seen in Figure 21. All factors were considered influential to some degree ($x>3$) but the standard deviation shows that there was a range of opinions within the sample.

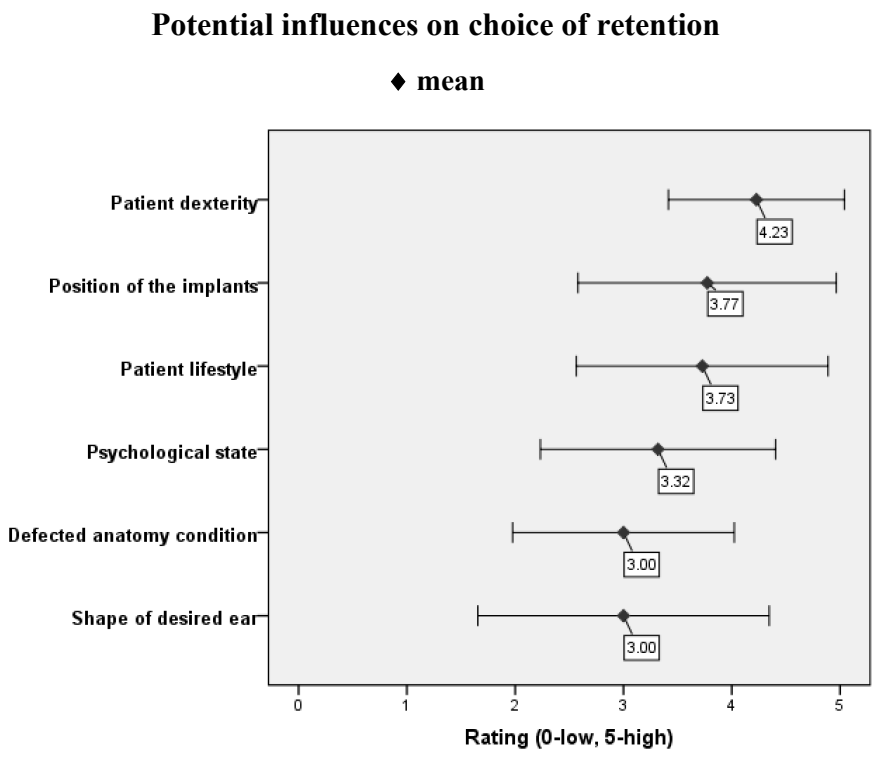


Figure 21: Influences on retention mechanism choice and design, ± 1 Standard Deviation

The survey asked (Q5) how much time is required to fabricate a bar-clip mechanism. However, it is important to note that the survey asked the MPTs to estimate the time required. Actual time required to fabricate a bar-clip mechanism was therefore recorded in the observational study. The results are shown in Figure 22.

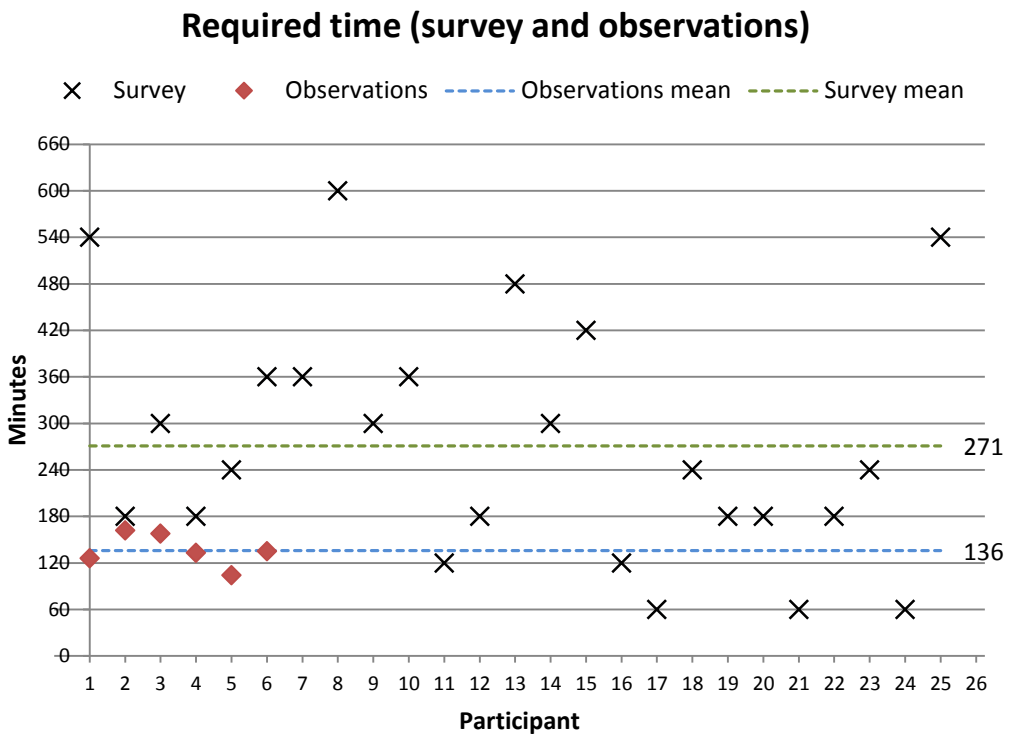


Figure 22: Time required for bar-clip fabrication

It can be seen that the survey mean yields a 135 minutes difference to the overall process time recorded in the observations. The mean time estimated from survey responses was 271 minutes (n=25). 50% of the responses were between 180-360 minutes, with a standard deviation of 155 minutes. This is a large time difference between respondents, and although reasons for this are unclear, a potential reason might be due the various sub-processes involved – this might have made it difficult to define times for the overall process.

In the observational studies, the three phases of bar-clip fabrication were timed individually, and the results are displayed in Figure 23. It can be noted that the distribution of time between phases are fairly consistent – phase 2 always requiring roughly the combined amount of time for phase 1 and 3. (Phase 1 mean =26 min, phase 2 mean = 60 min, phase 3 mean = 26 min).

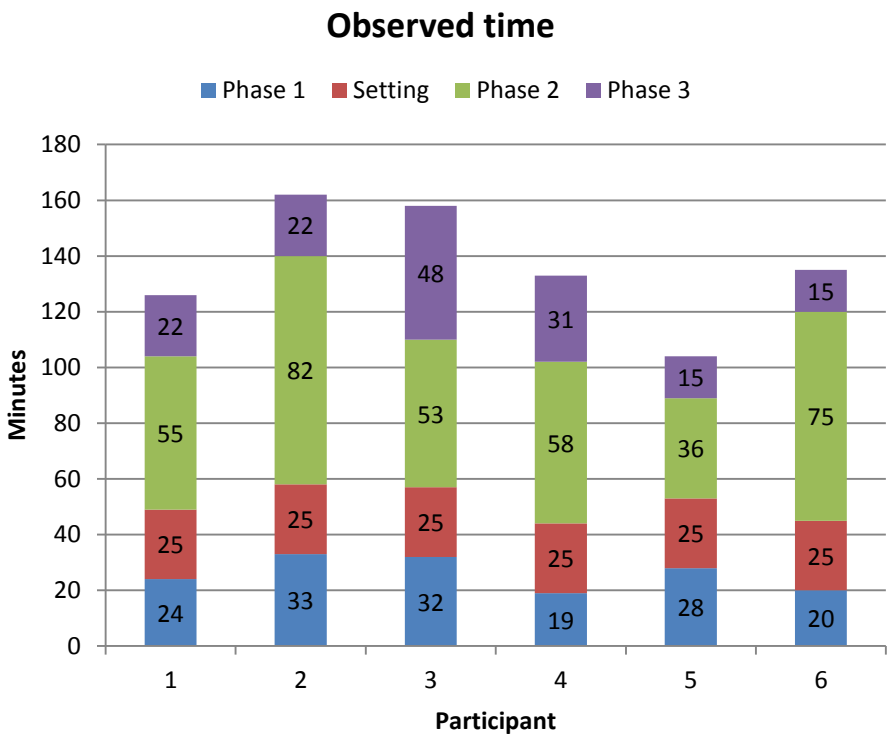


Figure 23: Time required for phases of bar-clip fabrication

5.4.3 Process mapping

The observational study generated an abundance of images and notes describing the various stages of the fabrication process. This also provided an understanding of the various routes the MPT could choose within the process. Some example images are illustrated in Figure 24 and the workflow is mapped in the subsequent flowcharts, shown in figures 25 to 27.

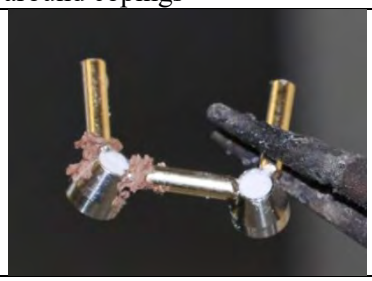
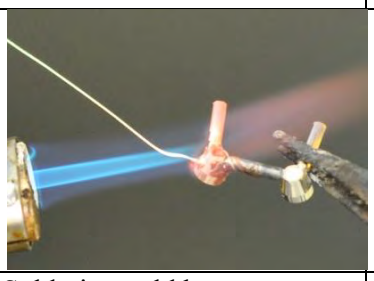
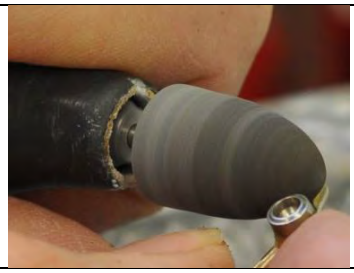
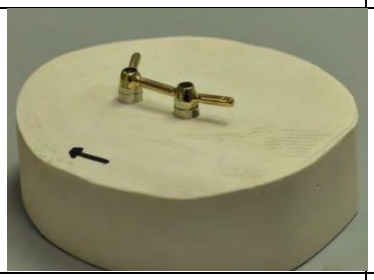
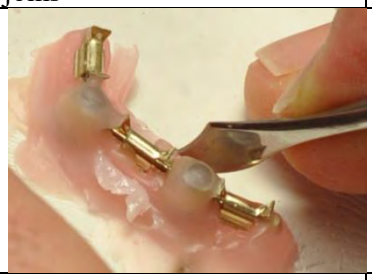
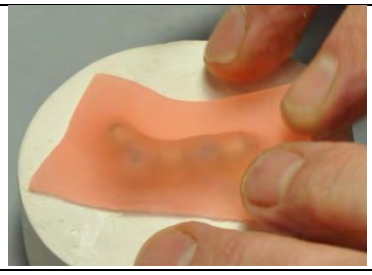
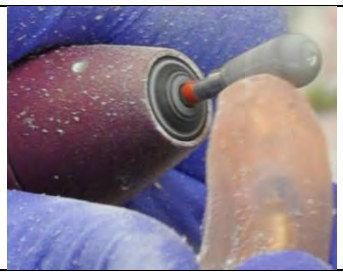
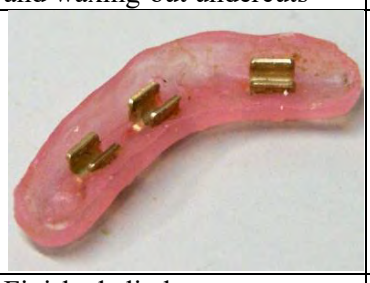
Impression copings fitted	Light cure and thread applied to copings	Impression material applied around copings
		
Model of anatomy and abutments from impression	Retention bar design and cutting gold bar pieces to size	Applying flux and anti-flux for soldering gold bar structure
		
Soldering gold bar structure	Laser welding bar structure joins	Grinding gold bar structure
		
Gold bar structure fitted to stone model	Clips fitted to bar structure and waxing-out undercuts	Light cure sheet applied over waxed-out bar structure
		
Grinding the clip base	Finished clip base	Clip base bonded into prosthesis

Figure 24: Images illustrating conventional process

Workflow Phase 1 – Impression of the anatomy and abutment capture

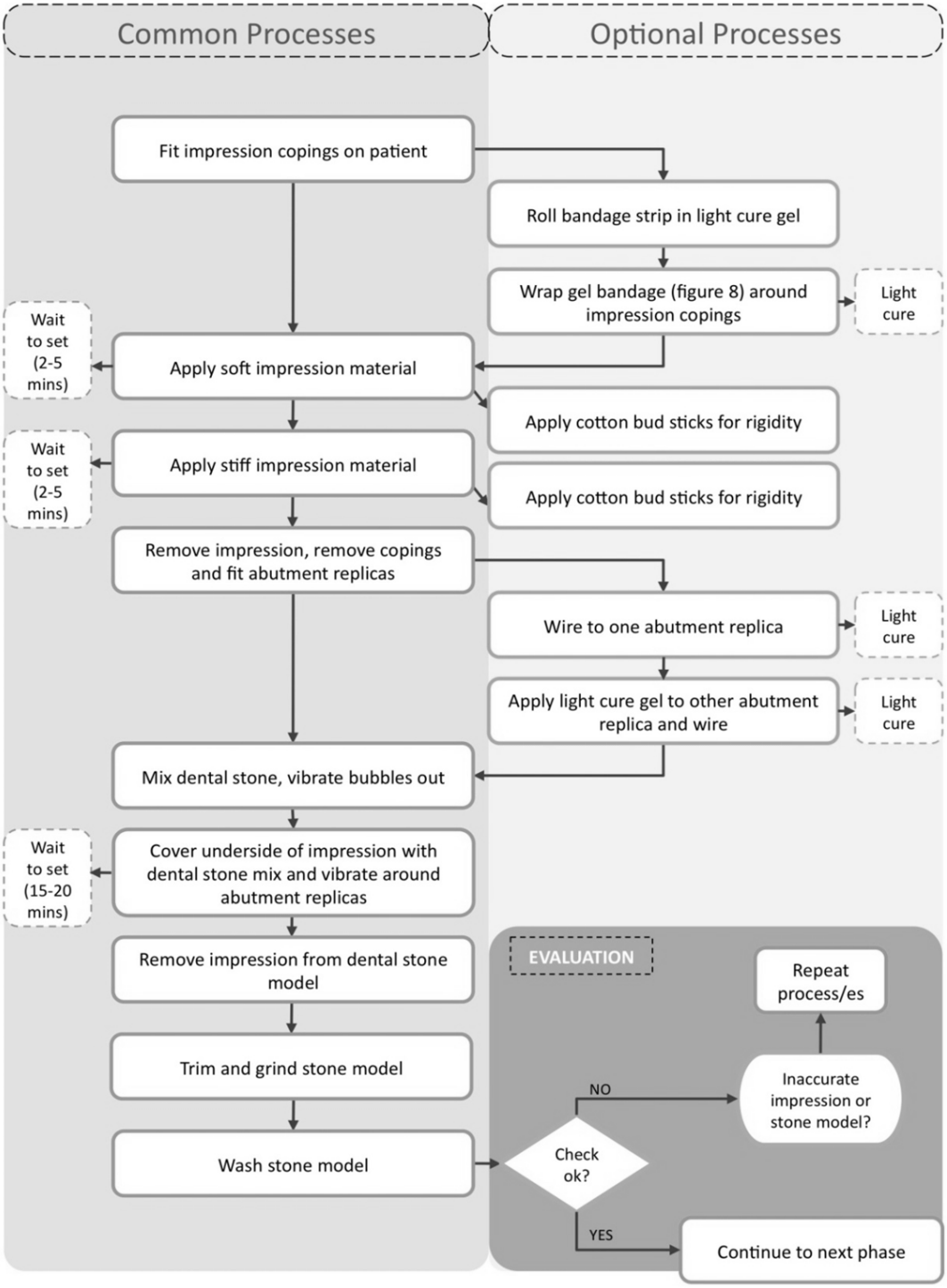


Figure 25: Phase 1 flowchart – Impression

Workflow Phase 2 – Retention bar fabrication

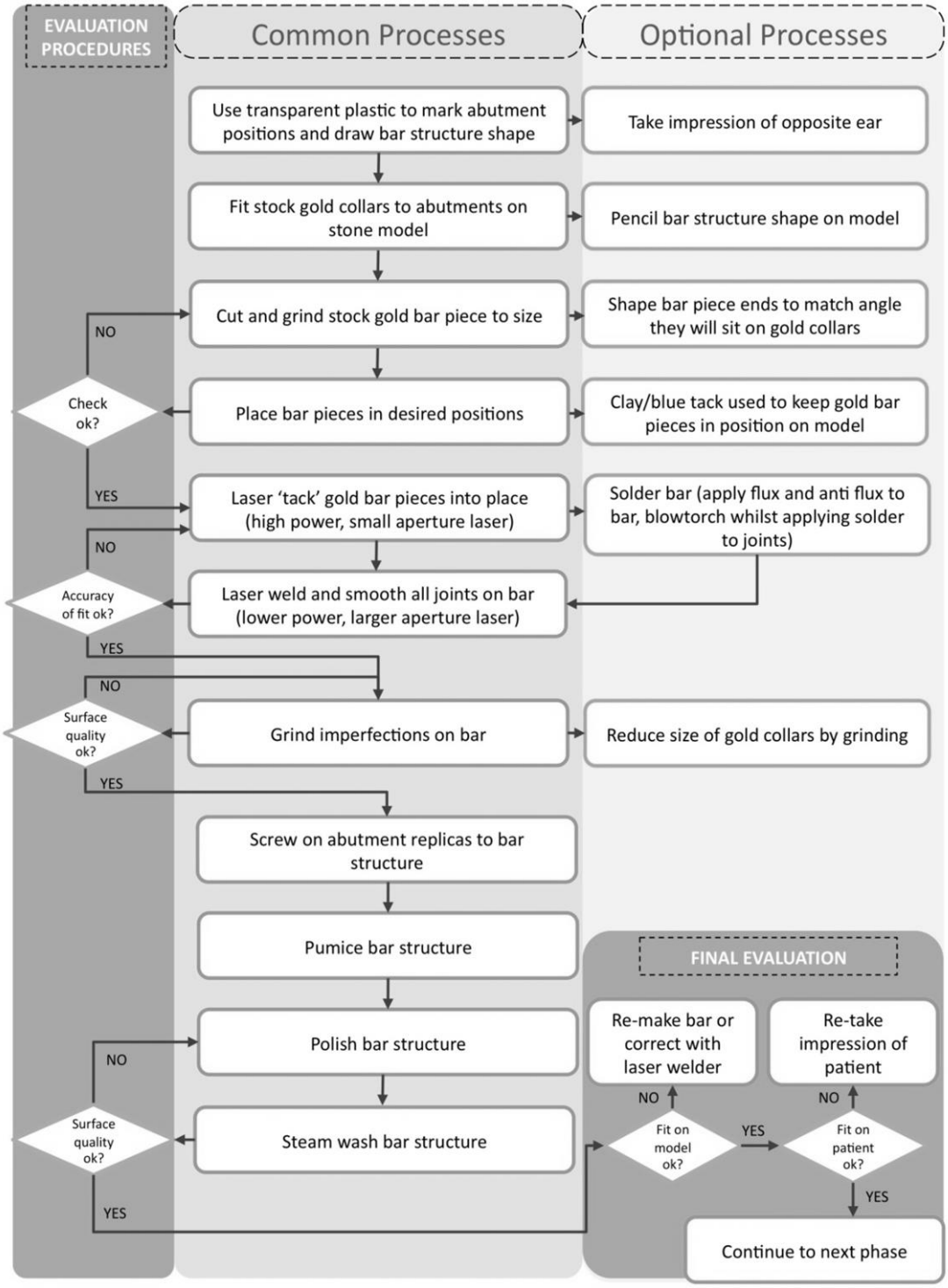


Figure 26: Phase 2 flowchart - Retention bar design & fabrication

Workflow Phase 3 – Clip Structure Fabrication

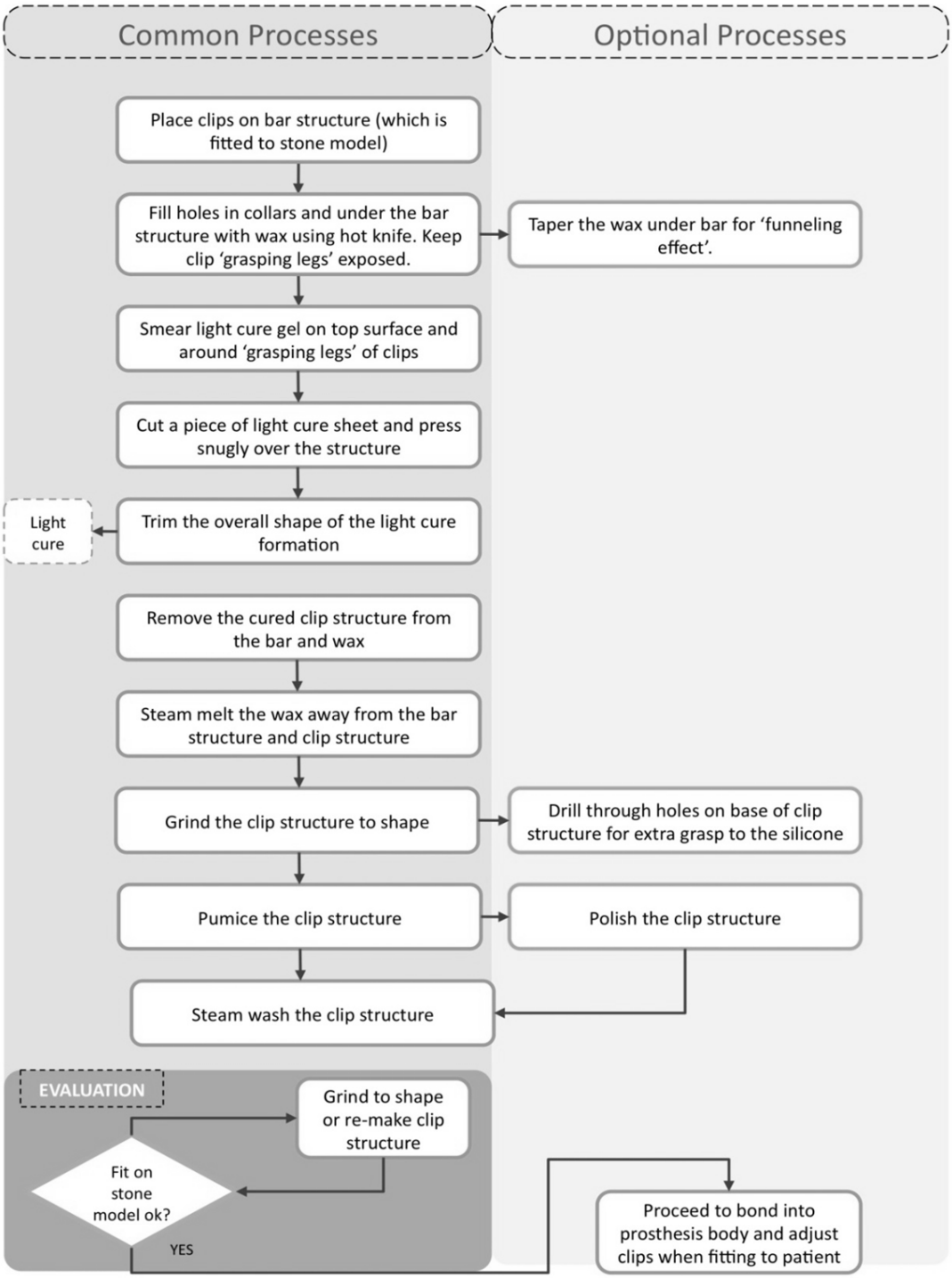


Figure 27: Phase 3 flowchart - Clip structure design & fabrication

Current components, process materials & tools

The various elements used to construct the bar-clip mechanism are listed and described in Table 6.

Part	Quantity needed	Manufacturers and Details
Gold Round Bar	Several pieces: Depend on number of implants and shape of prosthesis	Stock extruded round bar by Cendres+Métaux (Cendres+Métaux SA, Biel-Bienne) **OR** Cochlear Vistafix® gold bar (Cochlear Bone Anchored Solutions AB, Sweden) • Diameter 1.8, 1.9 mm, 2mm initial stock bar length options 20, 100, 200 mm. • 18k (75%) Gold • Bar cut or bent to size • Laser welded/gold soldered, easily polished
Gold Cylinders	Matches number of implants	CNC Micro-machined Cochlear Vistafix® (Cochlear Bone Anchored Solutions AB, Sweden) • Multiple heights, typically 4 mm for extra-oral prosthetics • 18k (75%) Gold • Can be ground to size
Rider Clips	Usually one per bar piece but depend if higher retention strength is needed	Metal stamped rider clips (Cendres+Métaux SA, Biel-Bienne) **OR** Cochlear Vistafix® clips (Cochlear Bone Anchored Solutions AB, Sweden) • Clip dimensions: Typically 2.75 x 3.5mm, 2mm internal diameter • 18k (75%) Gold • Retention tags of the clip retain the clip in the acrylic substructure • Retention force ranges unknown
Acrylic Sub-structure	One – to contain the clips and bond into prosthesis	Triad® light curing materials - photo-sensitive polymer sheet and gel (DENTSPLY International, Inc) • Moulded around the clips with then UV light cured
Abutments	Matches number of implants	CNC Micro-machined Titanium (E.g. Nobel Biocare, Cochlear, Straumann) • Typically an outside diameter of 4mm with a raised rim • Raised 2mm diameter centre • 1mm diameter threaded hole is located in the centre
Gold Screws	Matches number of implants/ abutments	Gold screw Unigrip (Cochlear Bone Anchored Solutions AB, Sweden) • CNC Micro-machined • 18k (75%) Gold

Table 6: Components of the bar-clip assembly

Table 7 lists the various materials and tools used in the process, noted from the survey and observational study. Consequently, this list represents tool and material preferences in current practice.

Phase 1 (impression)	Phase 2 (bar structure)	Phase 3 (clip structure)
Materials		
Aquagel (water based gel to stop sticking to the hair) Dental floss or bandage Steel wire in some cases Light cure gel (Triad Gel, Clear Colourless, DENTSPLY International Inc.) Epiform flex soft silicone impression material or M517 Coform soft dental impression material (Principality) Epiform solid silicone impression material Cotton buds or tongue depressors Impression copings, guide pins Abutment replicas (described in table 5) CrystaCal-R (Dental stone) or plaster Water	Gold cylinders (3 or 4mm) (described in table 5) Gold screws compatible with gold cylinder (described in table 5) 14 carat gold bar (1.8, 1.9, 2mm diameter) (described in table 5) Plastemene - This is firmer clay – to hold the bar pieces in place during laser welding Gold solder (750Y, Flow temperature 745'C) or gold wire For gold soldering - flux (Oxynon, DeguDent) and anti-flux (NEY, The J.M. NEY Company) Abutment replicas (described in table 5) Pumice Polishing wax, Water	Anutex Dental Wax Gold clips (described in table 5) Light cure sheet (Triad TranSheet, Visible Light Cure Material, DENTSPLY International Inc.) Light cure gel (Triad Gel, Clear Colourless, DENTSPLY International Inc.) Unifol Acetone Household Solvent (Care) Pumice Water
Tools		
Laser welder to tack UV Light cure machine Spatula Torque driver. Vibrating machine for plaster Scalpel Grinding machine Steamer	Cochlear component- specific screwdriver Dremmel and various cutters and burrers Strong Cutters (plyer style) Laser Welding machine with Argon gas Pumicer Polisher Steamer	Bunsen burner and hot-knife UV Light cure machine Pumicer Steamer

Table 7: Current practice materials and tools

5.4.4 Thematic analysis findings

From the qualitative data emerged a series of thematic maps, refined iteratively from the coding process. The thematic data from the surveys, interviews and observations were amalgamated – and where possible, common and uncommon themes have been identified. The consolidated thematic map is presented in Figure 28, which is translated directly into topics for discussing the findings.

Transcriptions, survey answers and observations					
Bar-clip design		Bar-clip fabrication		Design validation	CAD/CAM
Design requirements	Meeting the design requirements	Nature of process	Process idiosyncrasies	Evaluation procedures	Positivity
Clinical factors	Bar –clip characteristics	Patient-specific process	Ensuring quality	Subjectivity	Uncertainty
Biological factors		Communication	Error		Negativity
Mechanical factors		MPT-specific process			
Process factors		Invasiveness			
		Empirical process			
		Open, flexible, creative			
		Compromise			

Figure 28: Themes and sub-themes of qualitative data

5.4.4.1 Theme 1: Design requirements and considerations

Findings revealed that there are many factors that contribute to the success of bar-clip retention devices. These can be described as clinical factors, mechanical factors, biological factors and factors associated with the design process. It is the combination of these factors that create successful or unsuccessful retention for a patient (figure 29). Overlooking one or more of these factors means that something may have to be compromised in the prosthetic outcome.

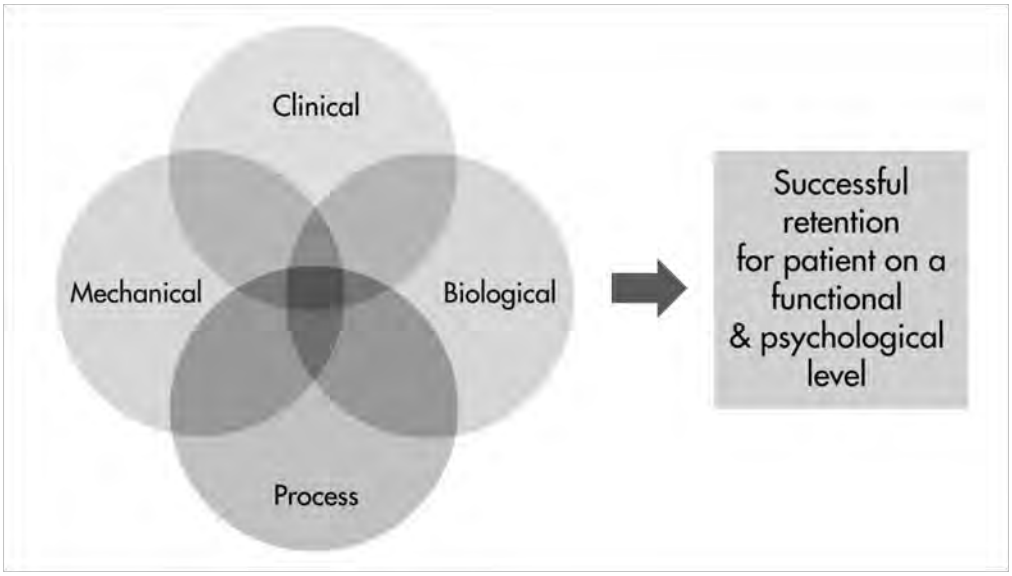


Figure 29: The critical factors for successful retention

5.4.4.1.1 Clinical factors

These factors relate to the direct observation of the patient. The interviews highlight the importance of considering the clinical issues in every prosthetic rehabilitation case, and this is the initial part of the rehabilitation process.

Some patients may find it difficult to attach/detach their prosthesis and this might be for example, the result of poor dexterity. The interviews reflected that the prostheses should always be designed to accommodate usability factors:

> *"The usability of a prosthesis will depend on the patient, their ability to take it off and put it on, that really should be worked out before the patient is considered for an implant retained prosthesis. That would affect the design process."*

These main clinical factors influencing retention mechanism design were mentioned on numerous occasions in the qualitative data, and can be listed as:

- Patient lifestyle (e.g. plays sport? Is the patient unhygienic?)
- Patient dexterity (can the patient put the prosthesis on/off and clean it?)
- Patient psychological state (e.g. is the patient able to look after the implant site?)
- Condition of hard and soft tissues (e.g. irradiated bone? Skin conditions?)
- Prosthesis location on face (is the surrounding anatomy regularly moving?)

- Patient history and future surgical plans (will the patient receive further surgery?)

The following extract from an interviewee reflects how the retention mechanism must be altered according to a person's facial movement:

> *"The considerations are facial movement, if somebody has got massive movement in the ear, which means you've got to put more pressure on the edge, otherwise that's just going to gap when they talk, so you increase the retention…"*

And the effects of limited manual dexterity was also discussed:-

> *"You may find that especially in an elderly patient or a patient with not great manual dexterity, you may find they may have trouble attaching a bar and clip prosthesis, which might count as a failure…."*

Knowing the patient's ability to keep the prosthesis clean, regardless of shape or size of the prosthesis, is crucial. It is vital for patients to be able to look after their prosthesis and retention elements, and quite often the retention mechanism will be designed according to the patient's ability to maintain it. For example, somebody with arthritis might have difficulty cleaning a bar and clip structure, so magnets could be used as an alternative solution. The interviewees commonly believed that the prosthesis or implants could fail following poor maintenance, allowing bacteria to colonise the components.

The retention mechanism must allow the prosthesis to overcome mobile anatomy, stabilizing rotational and lateral shearing forces. The required stability of the prosthesis is affected largely by the anatomical features of the defect and surrounding area. Thickness of soft tissue can affect the prosthesis stability, as highlighted by one interviewee:

> *"….or there's too much soft tissue around it pushing the prosthesis off."*

The retentive elements should be designed to accommodate this. The shape and form of the anatomy plays a fundamental role in prosthesis retention.

5.4.4.1.2 Mechanical factors

The mechanical functionality of the retention mechanism contributes to prosthesis success. The following factors associated with mechanical functionality were discussed in the qualitative data:

- Retention strength
- Surface quality of components
- Modularity of components
- Components fitting within the prosthetic envelope
- Loading transferred to implants and bone
- Accuracy of fit between components
- Stability (anti-shearing & rotational), and can withstand anatomical movement
- Component longevity and resistance to damage
- Application of pressure fit on margins
- Path/nature of prosthesis attachment

The interviewees emphasised the importance of fitting the prosthesis securely so that it blends naturally to the rest of the face. The retention mechanism plays a large role in allowing this to happen. The MPT must design the mechanism so that it can apply pressure on the edges of the prosthesis:

> *"Technically what you're trying to do is put pressure on the front edge… (otherwise) the front would lift and a gap would form."*

The patient must be provided with confidence and reassurance - the retention mechanism plays a large role in meeting this requirement. The bar-clip mechanism is designed so that there is only one possible position for the prosthesis, with one path of insertion. This makes the prosthesis easy to locate, and the click sound from the action of attachment provides reassurance that the prosthesis is in the correct position.

> *"…with bar and clip that substructure will only fit in one position, it will not fit anywhere else. Once the patient knows it's on then it's on, it's rigid, it's on."*

> *"…the beauty of the bar and clip, you can hear it click, once it's there, job done."*

The MPT must apply appropriate levels of retention for the prosthesis, and once in place, the retention mechanism must maintain its stability. Essentially, if a retention

mechanism fails to do this, it has failed to do its primary job. A person with limited dexterity may not be able to remove a prosthesis if retention is too strong, and on the other hand, if the prosthesis is too loose, the person is may worry about it being noticed in public. One interviewee discusses this in the following extract:

> *"If they're not happy with the positioning or fit, if they're worried that they're going to lose it, then they're not going to wear it. They want something that's going to be secure and see them through the day."*

The longevity of the retention components contributes to the mechanical success of the prosthesis. This depends on the materials, and if the mechanism has been fabricated accurately and carefully.

> *"They (bars structures) need to last the life of the prosthesis."*
>
> *"…if anything gets damaged, like the collars, the more chance there is for failure."*

5.4.4.1.3 Biological factors

As described in the literature review, the implants used with these systems can sometimes fail to integrate with the bone, and the main reasons for failure (lose integration with the bone) were discussed by the interviewees.

> *"That's probably the main reason for implant failure…infection…"*
>
> *"… in kids, the most common form of extra-oral implant failure is infection; in adults it is infection and necrotic bone through radiotherapy."*

The participants strongly emphasised reasons for implant failure as:

- Infection
- Irradiated bone
- Recurrence of cancer
- Bad integration or not enough contact with bone

However, participants also discussed other possible reasons for implant failure, which derived from factors influenced by design of the retention mechanisms.

Interviewees suggested that unwanted forces could be produced, for example, from a poor accuracy of fit of retention components. This may cause discomfort for the patient, and was suggested that this may also influence the success of implant integration.

> *"…if you made a bar and it's not passive, then you're inviting implant failure."*
>
> *"…if the bar is not passive then it is not fitted. End of. That's it. That is a golden rule…"*

The importance of an accurate fit of retention components to the abutments was emphasised on a number of occasions, but suggested levels of misfit to cause implant failure could not be provided, and evidence of a poor accuracy of fit as a contributor to implant failure was limited.

Retention device design as a mechanism contributing to implant failure was discussed, but with a degree of uncertainty. There was also difficulty in backing up these statements with scientific evidence, also reflecting many articles in the literature.

Awareness of the associated biological factors for prosthesis success is important for MPTs, but how the design of the retention mechanism may contribute to biological or biomechanical failures needs to be understood further – MPTs could not provide depth of information regarding this topic. This may require further discussion with experts in material science.

5.4.4.1.4 Factors associated with the design process

The key requirements related to the process were identified in the qualitative data:

- Efficiency, minimal steps in process for MPT and patient
- Flexibility in design methods and ability to compromise
- Low levels of contamination to ensure compatibility with human tissue and other components
- High level of accuracy

The current prosthetic design process relies on MPT skill, experience and the available laboratory-based equipment (see Table 7). The specific tools and methods used to create

retention mechanisms affect the prosthetic outcome. The factors associated with the process are important to consider, and an understanding of the workflow and material limitations/qualities is crucial if comparable processes are to be devised.

To ensure biocompatibility in the components, manufacturing processes should be controlled effectively. In the conventional process, many of the processes, like for example, laser welding, soldering, polishing and grinding may influence the material properties when heat is introduced.

> *"…whether you are laser welding or joining, you are introducing heat into the process, and with soldering you're introducing another alloy"*

In the interviews, there was some discussion about how some methods in the process can introduce a level of inaccuracy, related to human error and tools. As an example, the following extract highlights how one MPT believes that either soldering or laser welding techniques can introduce inaccuracies in joint welds and positioning. The outcome of this is that components may not fit together accurately.

> *"You've got to be very careful when you're soldering that when you invest (solder) it nothing moves at all. With laser welding, when you're joining the two parts together, you make sure that you do it evenly to make sure that you're not getting any movement there…"*

MPTs require accurate and flexible methods in the process so they can ensure the essential design criteria is met – this, as discussed later in this chapter also relies on the ability to measure the processes accurately. However, although flexibility was identified as a requirement, efficiency was also considered important. The MPTs talked about the importance of minimising the stages in the process for both patient and MPT.

> *"We need to be able to scan, send, boom – to make it an effective process…It's all about making their experience as streamlined as possible really."*

5.4.4.2 Design hierarchy of importance

The surveys and interviews attempted to identify which of the design considerations were the most important. Survey participants were asked to rank on a Likert-type scale the importance of a variety of considerations identified in the literature review and from

personal discussions with MPTs. The data indicates which factors respondents believe to be the most important and the least important whilst designing the 'bar and clip' mechanism, illustrated in Figure 30.

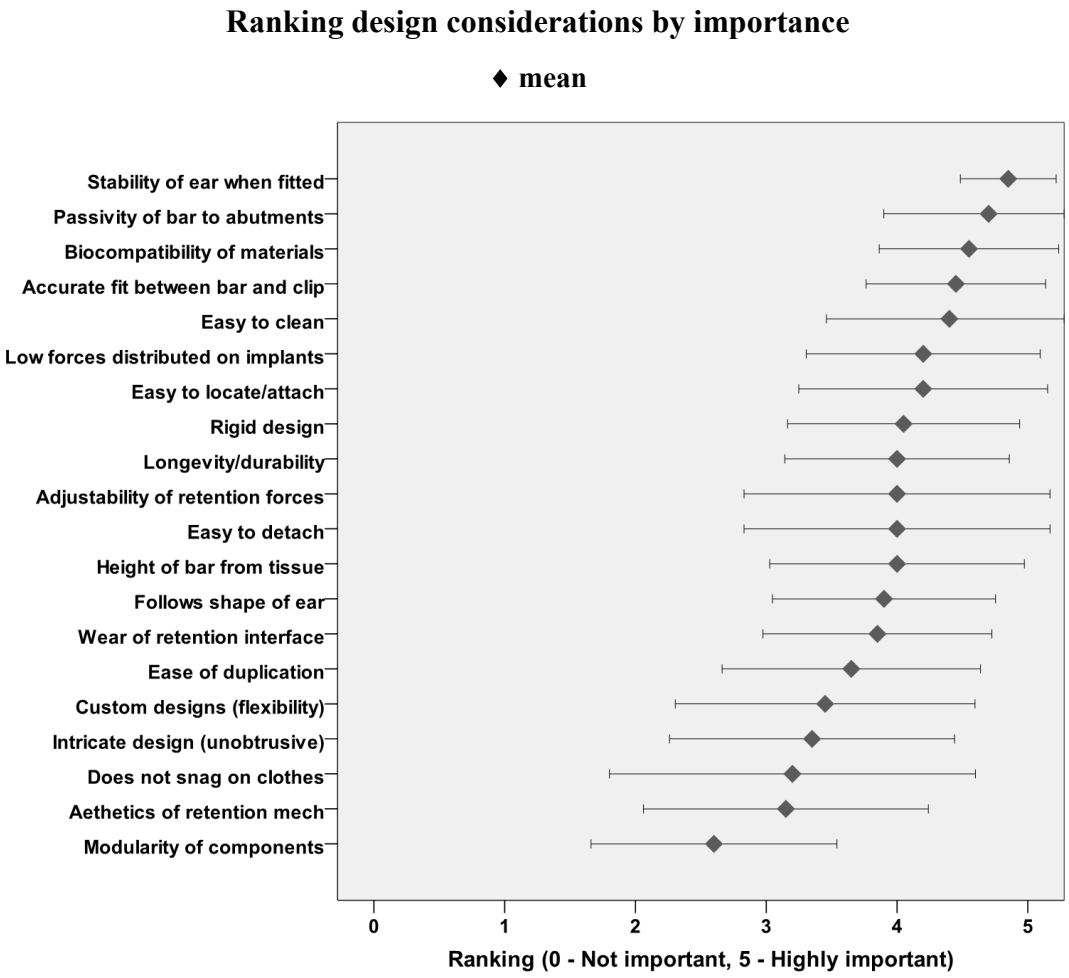


Figure 30: Importance of factors to the success of retention mechanisms ± 1 Standard Deviation

The assumption that a hierarchy of importance exists in retention mechanism design was confirmed by the completion of the survey question. However, there may be no clear hierarchy here, in consideration that there is little difference between results. However, the main finding here is that none of the elements listed were considered unimportant. The results showed that many of the factors were of similar importance and many of the factors were not ranked lower than 4/5. The highly rated factors have a smaller standard deviation, meaning the MPTs were in greater agreement for those aspects.

Modularity and intricacy of components was considered less important than anticipated. This goes contrary to current practice, where retention mechanisms are fabricated from a number of intricate 'modules'. This suggests that MPTs do not necessarily require modularity or intricacy of components, even though existing fabrication techniques have evolved this way.

The interviews provided opinions on the various design requirements, and this was combined and consolidated with the survey results. In the knowledge that all proposed elements were of importance, a design criteria hierarchy was developed by categorising the design requirements into desirable, important and imperative criteria (Figure 31).

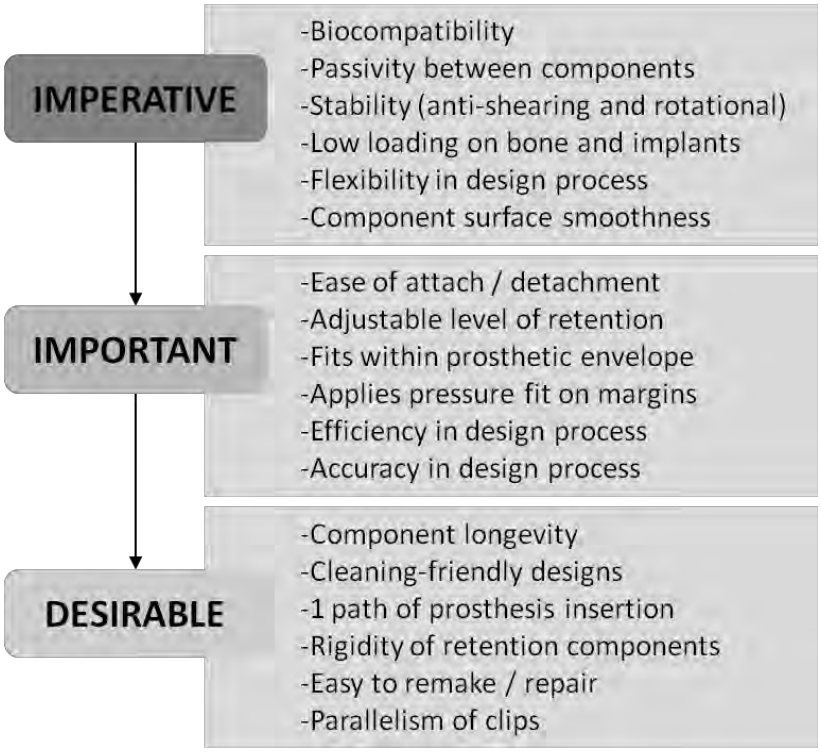


Figure 31: Design criteria hierarchy for prosthesis retention mechanisms

This hierarchy could be used as an indicative model for new proposed solutions in prosthesis retention mechanism design, where designs could be validated according to the listed requirements.

5.4.4.3 Theme 2: Meeting the design requirements

The factors influencing the success of the prosthesis are directly reflected in the design of the bar-clip mechanism. The clinical and technical requirements must be met by the final design of the mechanism – the various characteristics of the conventional bar-clip designs exist to meet these criteria. The data obtained in the descriptive studies provided information on how the requirements are met through bar-clip design. For example, one participant explained that the substructure is designed like a 'funnelled trough' rather so that it is easier for the patient to locate the correct position. This is especially important for patients with low dexterity. Aspects and features of current bar-clip designs are listed.

Materials

- Flexible yet tough clip material (adjustable retention)
- Rigid bar material (rigidity, stability)
- Light cure substructure able to bond to silicone (stability,
- Malleable materials (Gold, light cure)
- Anti-microbial material (Gold)
- Safe, inert materials (Gold, Titanium)

Bar structure

- Polished bar structure
- Good accuracy of fit between abutments and bar
- Length of abutments & collars
- Bar-structure arm length
- Bar structure arm angles (non-parallel)
- Welded bar-structure joins
- Height of bar structure
- Rigidity of bar

Clip structure

- Accuracy of fit between clips and bar
- Trough-shaped substructure
- 'Click' noise feedback

- Adjustable retention (clips)
- Number of clips
- Location of clips on bar (close to collars if possible)
- Parallelism of clips
- Accuracy of fit between substructure and prosthesis

Other

- Trough like design - 1 path of insertion for easy prosthesis location
- Modularity of components (flexibility to customise)
- Mechanism position within prosthesis
- Selective abrasion of models (for pressure fit)
- Shape of retention mechanism (Compact in size and follows anatomy)

Despite the current bar-clip designs satisfying a number of the design requirements, some design features conflicted with the requirements. For example, to ensure retention stability, the design of the bar has evolved to be non-parallel in shape, to oppose shearing and rotational forces. However, MPTs also desire parallel positioning clips, but this is unachievable with most bar shapes.

The data showed that the MPTs desire an easy to repair/remake retention mechanism. Current practice does not allow this fully – if a mechanism breaks, the entire assembly must usually be re-constructed. The MPTs suggested that it is not important for mechanism designs to be intricate or modular. However, current designs are both intricate and modular. Therefore it could be suggested that in some aspects, the design requirements and current practice conflict with one another.

5.4.4.4 Theme 3: Process characteristics

The qualitative data confirmed existing knowledge defined in the literature review on many aspects of the process, but also provided insight on the nature of the prosthetic process previously not reported in the literature.

5.4.4.4.1 Patient-specific process

All interviewees highlighted continually throughout the study that retention mechanism design is patient-specific, driven by the needs of the patient. Every patient is different and therefore each patient has different requirements. As one MPT explained, *"It's all down to individual design"*. The patient requirements must be specified early so that the appropriate method of retention can be chosen for the patient.

> *"We have a guy with really bad Parkinson's and that's an issue. And in this case you'd go for a magnet instead of a bar. Specific patient needs. All these things are custom made. Nothing is off the shelf."*

The design process is patient-led, and the requirements of the patient must be clear from the beginning. The choice of retention is often based on patient lifestyle and patient ability.

The bar structure is designed according to the anatomical form, implant positions, the size of the prosthetic envelope and shape of the prosthesis. Each MPT explained that the bar structure can be designed in many shapes and sizes, and it is crafted by customising and combining stock components – a standardised bar structure design does not exist. The following extracts illustrate how the bar structure is customised:

> *"You've got the universal 4mm copings, they used to come in 3 and 4mm but we said we'd rather have one size that we can cut"*

> *"If for instance the implants are further back, you might put the bar in front, or vice versa, best to put it down centrally, because any stress goes down the centre of the implant"*

> *"If it's a smaller ear, you don't tend to put a top piece on. You can even make a little T piece in the middle and that would stop the rotation. There's many ways you can do it."*

5.4.4.4.2 Communication

The ability to produce patient-specific designs is largely based on the communication between the patient and MPT. Sometimes a patient's ability to communicate is hindered by their facial disfigurement, but it is vital that the MPT captures the patient's needs. Communication at the prosthesis fitting stage is important too – the patient must feel

comfortable with the applied retention forces. Lack of communication may result in un-maintained or misused prosthesis components, which can cause further complications.

> *"You ensure that you educate the patient on how to look after it."*
>
> *"That's probably the main reason for implant failure…infection…you've got to make sure you educate the patient."*

MPTs stated that the design process of creating implant-based retention mechanisms requires the input of multiple disciplines. Knowledge of the patient's anatomy is needed to perform both surgical and lab-based tasks. There is a large crossover in the rehabilitative work by surgeon and MPT – the surgeon relies on the knowledge and experience of the MPT and conversely. This design process of implant-based systems bases itself on this relationship. For example, when the location of an implant is compromised, the MPT must work with the surgeon to formulate alternative solutions. Both surgeon and MPT must have a clear understanding of one another's work, their capabilities, resources and limitations – and be flexible to devise appropriate solutions for the patient.

> *"You work together in the theatre with the surgeon and the stent, and make sure (the implants) they go where you want for the best prosthetic outcome."*
>
> *"……it's got some arrows so the surgeon knows which way up it goes and how it fits in. And you're there to advise. Then you ask them to put the implants in along the lines……"*

The role of the MPT becomes one of an advisor during the surgical procedures. Together they must plan the surgery based on the desired prosthetic outcome, as would a designer and toolmaker collaboratively planning the production of a new product.

5.4.4.4.3 MPT-specific process

Every observational study participant followed roughly the same process, with the same overall principles, direction and goals, expecting to achieve similar prosthetic outcomes. However, each process varied in the individual techniques used. Each prosthetic outcome relied on MPT skill, experience and preferences to different materials, tools and processes.

For example, the aim of the impression taking process was to accurately capture the anatomy and placement of the impression copings. However, there was some variance in the techniques. Some MPTs used multiple layers of impression material with cotton bud sticks or tongue depressors placed within the impression for rigidity. One MPT added a wire structure to the abutment replicas to ensure passivity. There was little consistency in practice between the MPTs, but the overall goal to produce an accurate impression was the same. The variance amongst MPT processes is highlighted in the mapped process workflows (Figure 25, Figure 26, Figure 27). One study participant articulates this:

> *"You could give ten prosthetists the same job to do and they would all be different."*

5.4.4.4.4 Empirical process

Maxillofacial Prosthetics relies heavily on an in depth knowledge of materials and craft techniques, and therefore the prosthetic outcome highly depends on the skill and experience of the clinician. What works, and what does not, comes with experience. The experiential nature of the process is highlighted in the following extracts:

> *"You can use CroForm (impression material), which is good for a particularly hairy patient, because it doesn't take the hair off."*

> *"Go half way up the clips with the wax, because you need a space around the clips to be able to tighten or loosen the clips."*

This knowledge is gained through experience, by working with numerous patients, shadowing other clinicians and using a variety of different techniques, tools and materials. Some techniques work for one MPT but may not suit another. Trusting that each technique produces a good result is extremely important. However, measuring success of the work relies on the experience of the MPT, and consequently is highly subjective. One MPT talks of the impression taking technique:

> *"Difficult to tell how accurate it is, they rely on the accuracy of it but don't really know how accurate."*

When using materials that are in contact with human tissue, the clinician must know that they are safe. This is, to some extent, also experiential, because guidelines are

vague. The MPTs are aware of some of the exothermic effects of some of the impression materials during the curing process, as highlighted in the following extract.

> *"To a degree you get some exothermic reaction, so you have to be careful when curing the gel on a patient…you don't want to burn the patient."*

Some further examples of how using the various materials require experience and understanding are listed:

- Sometimes putting boiling water on the stone model can make it crack because the abutments expand much quicker than the stone.
- Light cure needs acetone on its surface because it does not cure on surface - non-cured light cure is a great inhibitor to silicone so you have to make sure you clean it or trim it off.
- Gold conducts heat very well but it potentially contracts when cooling. This may be problematic for the fabrication of the bar structure.
- Rigidity of the clip base-plate material is important, otherwise the clips move.
- This impression silicone is a soft material that can move around after it has been applied to the tissue. It has its benefits and limitations.

5.4.4.4.5 Craft domination

The element of craft dominates this process. Every MPT in the observational study used a pencil to draw their bar structure design on the stone model. This is a primitive yet key part of the design process. It is quick, easy, cheap, and uses a basic principle of design – to sketch the idea before spending time fabricating the product. However, this does not offer any insight into the structural properties of the proposed bar design. The design is essentially based on the shape and size of the prosthesis, the form of the defected anatomy and the position of the implants. The design is purely founded on shape and form, with no regard to engineering principles.

The craft element of this process provides opportunity to give attention to detail. Some examples of this are described below.

- A concave is ground into the tips of the gold bar pieces, so that they can sit snugly on the copings to help the join.
- Sometimes a couple of holes are drilled through the base plate so that the silicone can pass through it and 'grasp' the plate.
- A layer of wax sheet is sometimes placed under the bar when waxing-out for the creation of the base plate. This puts a space under the base plate, a neat way of doing it because this stops the base plate touching the skin.

However, as this process relies on MPT craft skills, a number of common issues were observed and their consequences listed (Table 8):

Craft-based issue	**Consequences**
Light cure gel can potentially creep down the screws of the impression copings	It makes them difficult to release.
The impression material can take out hair quite easily when removed. The patient is often asked to wrinkle their face to release the impression	It may be uncomfortable.
The CrystaCal dental stone is a viscous, messy material when pouring and needs to be vibrated to remove the air bubbles within.	The dental stone can contract/expand if there is air within it.
Intricate components (e.g. impression copings and guide pins) are fiddly	As they are small, it is important to ensure they are not lost within a patient's defect.
The light cure gel is a sticky, viscous material until cured. After curing it can remain adherent.	If the light cure is not cured correctly, it might stick to the patient's skin.
The patient and prosthetist are exposed to this light on numerous occasions during the process.	The UV light is intense, and direct eye contact should be avoided.
Positioning and cutting the gold bar pieces to size can be quite fiddly. They need to be trimmed, grinded to angle the ends to fit onto the copings, which can be rather slow and care needed not to trim too much.	The bar piece will require lots more solder to fill the gaps in the join.
The gold gets hot when grinding or laser welding. The pieces are comparatively small to the cutting tools.	The pieces can be difficult to hold.
It is quite easy to get solder into the screw holes if you do not have anti-flux in there.	This can obstruct the fitting surface of the screws. Solder/weld the screws to the copings, which is difficult to rectify.
The gold pieces are very small, sometimes making the process of laser welding difficult to deal with.	It can injure the fingers

Laser welding requires skill and experience to avoid making mistakes	It can affect the passivity of the bar structure
You need to make sure you wax out around the clips so they can expand, a common mistake is not waxing out around the clips and then	The clips can not open up.
Need to make sure there are no bits in the clips (no light cure etc). Make sure it clips down properly and make sure it's not touching anywhere (the tissue).	Affects the alignment of the clips. The clips can touch the tissue.
The bar structure shape is incorrect	It protrudes outside the prosthetic envelope.
The process of 'waxing-out' the bar structure to make the clip base-plate can be rather laborious.	Takes time and is laborious.
Bending the bar structure	Re-make or repair using laser welder.

Table 8: Craft process issues and consequences

5.4.4.4.6 Open, flexible, creative

The process must be flexible so that it can satisfy every patient's needs. The individual techniques within the overall the process are changeable and adaptable. Adapting and selecting alternative materials is also possible, as long as the result is clinically acceptable. Some comments by the participants suggest that materials or processes are subject to user-specific application. Terminology such as '*tend to'*, '*like to'*, is used, as if the processes and materials are founded on personal preference.

> *"I tend to use the harder silicone on first"*
>
> *"For our models I always use CrystaCal. Some people like a bit of plaster too to give it extra body. I don't like mine too runny. If it's runny it's weaker as well. You just mix it until it looks and feels right..(however)…there is a set ratio for mixing they recommend because it can expand."*

It was unclear how the processes and materials are regulated and controlled. Flexibility in the process allows the MPT to choose the materials and techniques most suited to their skill, experience, style and to their patient's needs. This process is very open to change, especially useful when something must be modified.

As discussed in the literature review, the Medical Device Directive (MDD) does not provide specific guidelines for MPTs in extra-oral prosthetic processes. Rather, it outlines the requirements for custom medical devices in general. Manufacturer

recommendations for materials and equipment tend to offer initial guidance for MPTs, in for example technical data sheets or manuals. However, recommendations discussed in the qualitative data seemed to stem from MPT experience. Formalised recommendations for the processes either do not really exist, or at least were not used in the design of the retention components during the observational study. Design recommendations were discussed in a casual manner and seemed rather ambiguous.

> *"The idea is that each spot that you make cover the previous spot by 70%, so you have a laser weld overlap of 70%. And that guarantees that you have a full weld underneath. We've changed a few things on the recommendation sheet for the laser welder."*

5.4.4.4.7 Compromise

Many of the interviewees suggested that every facial prosthetic design procedure has some degree of compromise. Every case is a matter of balancing design parameters. For example, this may include:

- Aesthetics **VS** Fit
- Implant location **VS** Poor quality bone
- Soft tissue condition **VS** Height of bar
- Height of bar **VS** Aesthetic Outcome
- Retention strength **VS** Patient lifestyle/ability

The ability to compromise was emphasised repetitively by the study participants. Due to the individuality of each case, it may be impossible that any of the requirements are ever perfectly met. The following interview extract highlights an experience by one MPT:

> *"…a current case is a child with 2mm thick skull so it's very difficult. Fixtures of this length probably won't work if they're this big. So then you have to change the implant position..."*
>
> *"(but)… if the implants aren't perfectly placed, you can get over that with a different shaped bar"*

This necessity to modify stock components, because they are not always the appropriate shape, requires flexibility in the design and fabrication process. This is satisfied partly

by the chosen materials and the modularity of the bar-clip component system (having a range of stock components of various sizes).

> *"Gold, it's malleable, it's easy to keep clean, it's easy to polish, All of those things are important."*

> *"You've got the universal 4mm copings, they used to come in 3mm and 4mm but we said we'd rather have one size that we can cut"*

The MPTs have to accept the best possible outcome they can achieve, but compromising does not necessarily mean a poor prosthetic outcome.

> *"I think it could've been a slightly different angle on the arm, it might be a bit too angular and it might interfere with the ear a bit, but it should be ok."*

5.4.4.5 Theme 4: Process idiosyncrasies to ensure accuracy

5.4.4.5.1 Taking the patient impression

The overall goals of the impression stage are clear – to capture a high level of detail from the anatomy and determine and maintain accurate abutment positions.

> *"If your impression isn't right then it won't be passive on the patient."*

> *"Wow, look at that detail on the impression, you could pick up a fingerprint!"*

Findings suggested that this stage of the prosthetic process can be uncomfortable for some patients, especially when the impression material must touch sensitive areas of the skin, or in large facial cavities.

A range of techniques are used within in this initial stage, and they rely highly on MPT preference. As observed, the numerous techniques within the impression method included impression layer combinations, splinting of the abutment replicas using light cure wire, and placing tongue-depressors / cotton-buds within the silicone. None of the observed processes were identical.

Some of the MPTs were more conscious of how their techniques would affect the prosthetic outcome than others. One MPT used one layer of soft impression silicone to take the impression, whilst others reinforced their impression with cotton buds. A

simplistic approach required fewer steps in the process, but it was unclear to what level of accuracy the various techniques could achieve, without technical measurement.

One observed participant used a complex approach, firstly by covering medical bandage with light cure, wrapping it around the impression copings in a figure of 8, and curing the light cure for rigidity. Two layers of soft and hard impression material were used, and cotton buds were incorporated for further rigidity (Figure 32).

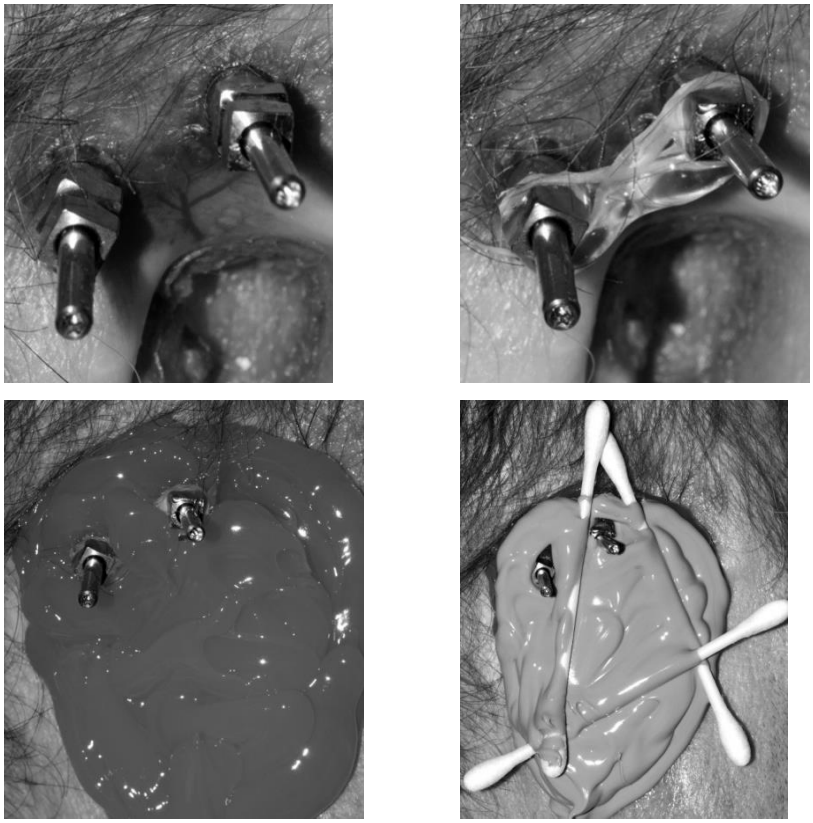


Figure 32: Impression sequence

After obtaining and removing the silicone impression, a piece of wire was laser tacked to one abutment replica, and light cure was applied to bond the opposing abutment replica to the wire (Figure 33). The MPT explained that this technique was used to ensure rigidity within the stone model – to ensure passivity of the abutments.

> *"The way you do it with a lot of the orbital ones, we use steel wire tack welded on to the analogues for stability. Especially on the bigger ones."*

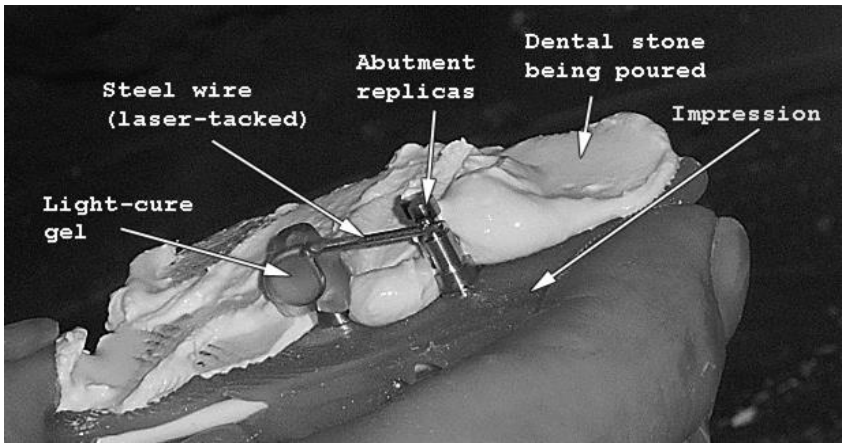


Figure 33: Ensuring passivity of the abutment replicas

In agreement with the literature, the study participants suggested that a high accuracy of fit in the bar structure is important to achieve. However, findings revealed that there are number of process idiosyncrasies which could influence the accuracy of fit. These had not been described in the previous literature.

5.4.4.5.2 Welding

The MPTs suggested that the sequential procedure of welding the bar structure can affect its accuracy of fit.

> *"When you weld this on, when you tack, you want to do opposite sides. If you start firing loads of tacks onto one side out of proportion, you're going to get contraction from that. You can over tighten one side. You want to spread the force. Once you've tacked it, you want to spread the metal. You can always tweak it slightly by laser welding parts of the weld and it can right itself."*

One of the study participants emphasised the importance of welding the bar-collar joints in as few 'hits' as possible, so not to warp the desired position of the arms (it can especially cause a problem if the arms are positioned using wax, where the laser heats up the wax and it droops).

Also emphasised was the importance of pursuing a 'welding sequence' whilst laser welding the gold bar sections to the gold copings. The MPT described the first sequence as a '*North-South-East-West weld*', which involves sequentially tacking opposing sides of the bar-collar join. The second sequence relates to the order of joins to weld. The

MPTs explain that it is important to completely finishing one weld before moving onto the next, shown in Figure 34.

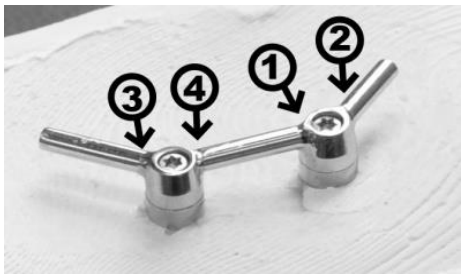


Figure 34: Laser welding sequence 2

The 'welding sequence' is a systematic method so that the MPT can maintain control in the process - aiming to apply equal and symmetrical welds on each side of the join, so bar sections do not distort from the desired position. Any distortion may result in misalignment between the bar and abutments.

> *"The outer arm doesn't matter too much if it's a bit 'out' because it's only got one connection point anyway. It's the middle bar that really matters for passivity. The last weld you do is the crucial one!"*

This sequence also allows the MPT to trace which weld might have distorted the bar, so the MPT can return to that particular weld and alter it. It is important that there is no gapping between the bar and coping before it is laser tacked/welded. This can also contribute to pulling the bar to a different angle to thus distorting the design. One participant explains that laser welding contracts the gold, which consequently puts force through the join.

This process requires a skilled and steady hand, and a good understanding of the capabilities and limitations of the laser welder. An inexperienced user might find it difficult to control the distortion that the welder applies to the bar.

> *"…so with this weld it's tacked at completely the wrong angle, the power was probably too high…"*

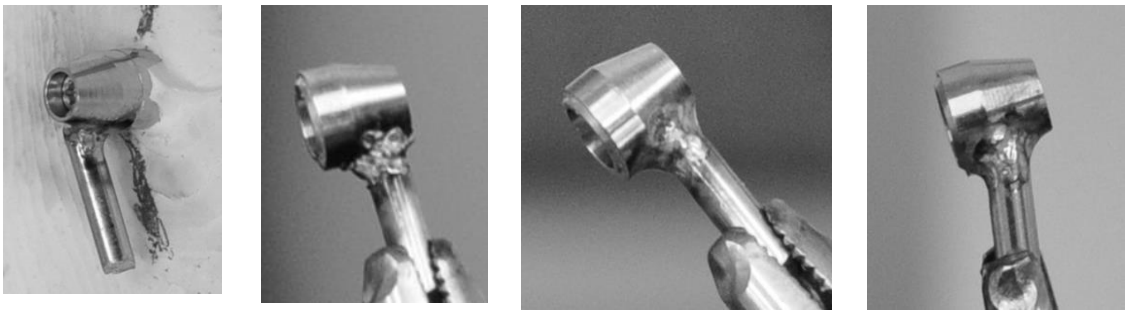
However, the applied angles of the bar sections were not measured during practice. In fact, the 'accuracy' of the bar shape can only relate to the initial design intent, based on a rough sketch on the stone model without consideration to engineering rules or

technical recommendations. To an extent, the welding process determines how the bar pieces sit on the copings, regardless of design intent.

> *"With an ear it's not too bad if you do get some distortion, you can usually work out where it is and correct it. It's when you have a multi-unit bar, perhaps an orbit or nose when you've got 4 different implants being linked up. That's when this method is really important, finish one gold collar completely…if you do one at a time, you know which one is the problem."*

5.4.4.5.3 Surface smoothing

Each study participant discussed the required surface smoothness of the bar structure at the various stages of the process, and how they achieve this using the various tools. It was observed that the laser welder was used not only to join the bar pieces to the copings, but to smooth the joins too. This was achieved by increasing the aperture of the laser so it would spread the material (usually solder is added) around the join. Most often, they would completely finish one weld before moving onto the next, smoothing the weld straight away (Figure 35).



1. *Laser tack in place*
2. *Laser weld add solder*
3. *Widen aperture, smooth*
4. *Final smooth*

Figure 35: Tacking & smoothing the join

The MPTs aim to create a neat join, without any pitting.

> *"I just spotted some pits, so I used the welder to get rid of them. Pits are just a breeding ground for bacteria so we must get rid of them."*

By looking closely at the bar structures produced, it could be seen that newer laser welding techniques produced more desirable results than traditional soldering. Figure 36 Figure 37 illustrate the difference between a soldered join and laser welded join.

Figure 36: Soldered and polished bar

Figure 37: Laser welded and polished bar

The MPTs took time to polish the bar structures in the final stage of bar fabrication. Some of the MPTs discussed the possibility of over-polishing the bars. Subsequently, this can affect the fit of the clips on the bar. However, no attempts were made to measure the dimensions of the polished bar sections during this stage. Nevertheless, the consequences of over-polishing were discussed.

> *"Careful not to take to much material off during finishing processes. Preserve as much of the original detail as you can because the clips might loosen if you polish the bar too much."*

> *"I've seen so many people polish these away and you lose the symmetry of the bar, bit that dip in and out. You only really want to pumice where you welded, you don't want to affect anything else. You've smoothed it on the laser welder."*

Looking closely at one of the produced bar structures (Figure 38), it appears quite misshapen from over-polishing.

Figure 38: Over-polished bar

The MPTs all believed that polishing the bar discourages bacterial colonisation. However, quantifiable levels of surface smoothness were not provided. The MPTs simply check visually for a…

> *"…a satin finish, so getting rid of any discolouring".*

There was inconsistency and conflicting views amongst the MPTs whether the clip substructure should be polished. The majority believed they should not be polished, but only pumiced. The rougher surface of the clip plate was believed to offer a stronger bond to the silicone prosthesis body, and polish would inhibit the silicone bond – but there were conflicting views on this.

> *"…we don't polish them as such, we abrade them with pumice…there are those who say you want it as smooth as possible, so you get maximum contact but there is the argument that the more surface roughness you have, your surface area is greater… but if it is rough, you're not guaranteed to get your material into every nook and cranny…"*

In the observational study, it was noted that the process of polishing the retention components appeared difficult. On numerous occasions the bar was snatched out of the hands of the MPT, through the force of the polishing wheel (Figure 39). Gold is malleable so care must be taken not to distort the bar during these stages. In fact, on one occasion, the bar structure bent and no longer fitted to the abutments – the MPT had to re-make the bar.

Figure 39: Polishing the bar

5.4.4.5.4 Parallelism

The concept of parallelism was discussed on numerous occasions by the MPTs. This relates to the bar sections, and positioning of the clips. The MPTs try to ensure that the bar pieces are placed so that they are in parallel planes to each other, so that the clips can engage properly at the same time.

> *"You sort of want all your pieces of bar at the same level otherwise they might not engage at the same time properly"*
>
> *"…but I want to get it (the bar) as parallel as I can. I just want to spend the time to get the job right. What you're looking for is it to slot in nicely to position."*
>
> *"You want to make sure all your clips are pointing in the same plane. If you had one pointing wrongly, you wouldn't be able to locate it properly"*

However, the concept of parallelism is limited to the accuracy of the craft methods, skill and judgment by eye. The anatomy and implant locations often determine the positioning of the bar sections. Therefore, this theoretical design requirement may even be impossible to achieve in some cases – theory and everyday practice is conflicting here. As an example, two retention bars produced in this study are presented (Figure 40), and it is quite clear (even by eye) that the bar pieces are far from parallel. However, whether this makes any difference to the engaging success of the clips is unknown.

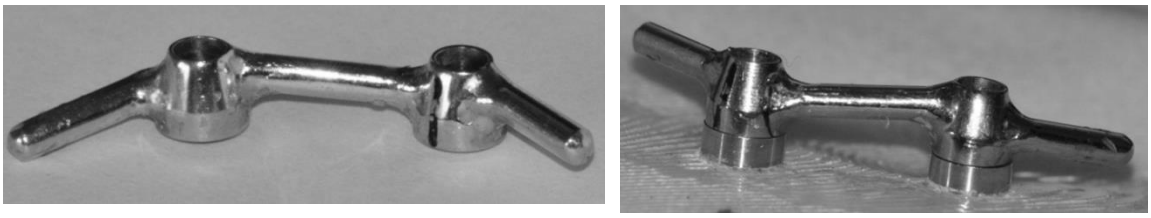


Figure 40: Examples of non-parallel bars

5.4.4.5.5 Clip positioning

Clip positioning is another topic where there was disagreement amongst those interviewed. The suggested 'rule-of-thumb' by the MPTs was to position the clips as close to the abutment as possible. It was suggested that if the clips were positioned further away, they could influence the forces applied to the implants during attachment / detachment (relating to bending moments).

This theory was presented by a number of the MPTs, but in reality, the potential forces could not be measured in practice. The effects of various clip positions and the associated forces were considered empirically, and applied only according to the described 'rule of thumb'.

> *"There were some arguments (referring to literature without specific reference), that you should always place the clip as close as possible to the cap. Wherever you put the clips, you're still pulling against the length of the implant."*

5.4.4.6 Theme 5: Design Validation / Evaluation procedures

5.4.4.6.1 Diagnosing errors

One MPT describes the process as *"...fiddly but not really tricky. It's not complicated*". Some of the observed stages involved messy processes (Figure 41 and Figure 42), for instance the application of impression silicone on the patient's anatomy, pouring the dental stone to the impression, applying flux for soldering, and applying wax for moulding.

Figure 41: Applying the dental stone to the impression

Figure 42: Applying soldering flux to the bar structure

From the observational work, it could be concluded that diagnosing errors in the prosthetic process is difficult. Potentially, an error can go un-noticed until the fitting the prosthesis to the patient. During one of the studies, the MPT detected an issue where the abutments appeared to have been positioned incorrectly, but precise reasons for this mistake were unclear, although it may have been the influence of being observed.

> *"I'm just wondering if the abutment replica has moved there. That doesn't look as if it's as high as the other one. I'm checking on the accuracy here. I wouldn't be able to tell though until I've made the bar… So I'm going to make a gold bar now that might not even fit. I should start again on the model…"*

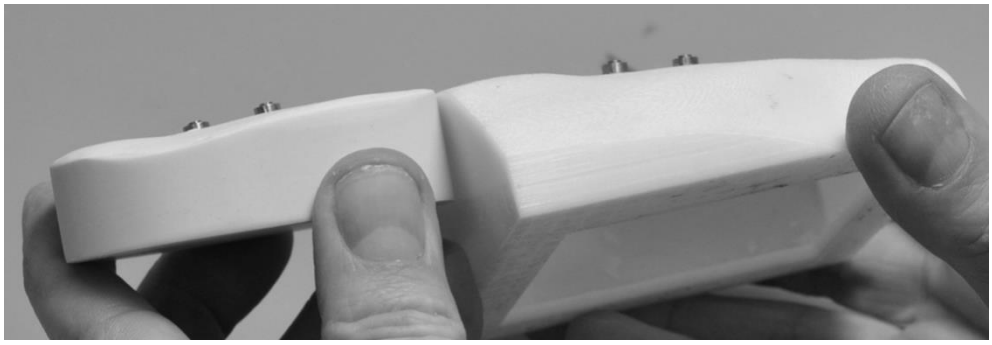


Figure 43: Comparing the stone model to the mock-up patient model

A series of potential mechanical complications were noted from the qualitative data. These include complications through prolonged patient use or accidental damage, for example:

- Damaged bar or clips through fracture

- Unintentional bending of gold bar through trauma
- Clip structure base-plate peeling away from silicone
- Damage to the surfaces of the abutments or gold collars

….and complications during the design process and fabrication process, for example:

- Over-contraction of welds
- Over-polished bar so that clips no longer fit correctly
- Abutment replicas or impression copings moving whilst creating the impression and working model

5.4.4.6.2 Evaluation procedures in practice

The specific aspects of the retention mechanisms that were evaluated during the observational studies and identified in the qualitative data focused on:

- Levels of retention
- Accuracy of fit between prosthetic components
- Surface quality of various locations on the bar structure
- Fit of the prosthesis on the patient – positioning, pressure on margins

Further details on the procedures used to evaluate these aspects are described in Table 9, and supported by extracts of the qualitative data.

Factor	Checking procedure
Fit of the prosthesis on the patient	Looking for gapping on the prosthesis margins, this is a method of evaluating the fit. By interpretation of patient satisfaction on a functional and aesthetic level. If the patient is not satisfied with the fit, the MPTs can re-look at the design of the system. *"When you try it on the patient and they are happy with the result."*
Ensuring appropriate levels of retention	By feel and through experience by performing task such as pulling, as explained by one study participant below. Adjustments are made accordingly. *"I just test it by pulling it really. So what do you consider then when finalizing the retention? Personally, if you pull it, you want their head to come with it! You don't want it to go pop and come off really easily, most patients wouldn't want that. It should be quite solid, you can test it in the mould as well. You get to know how it feels really, I've never measured it in Newtons or anything like*

	that. You get to know how solid it feels."
Passivity between prosthetic components	A combination of inspecting components by visual means and by performing the 'one screw test' to feel the resistance through the gold screws. Looking for gaps between components may or may not be with the aid of a microscope. The following extracts illustrate this procedure: *"I always test it by putting a screw in one side and leave the other side free. Have a look at it under the magnifier on the laser welder and you want to make sure there is absolutely no spring there at all,"* *"I always check it under the magnifier on the laser welder and it magnifies quite a lot. You can see what might look passive in your hand……..(but with the laser welder) you can magnify it quite a lot and you might get a bit of discrepancy there."* The passivity of the components were also validated by the reaction of the patient. If the patient experiences pain when the bar structure is screwed on, then it is a clue that there is an inaccuracy of fit between the bar and abutments: *"We have had patients complaining of pain and we've looked at the passiveness of the bar and there has been a visual discrepancy. You'd probably guess a ¼mm or something like that."*
Surface quality of welded areas	By looking through the laser welder microscope, and evaluation based on MPT's own interpretation of whether the surface quality is a high enough standard. This is highlighted by one interviewee: *"…making sure that when you're making the bar you've welded it properly, no little gaps and things like that. I normally look by eye to check, using the laser welder to look through, when you're tacking it, you want to make sure there's no holes, when you're actually putting the gold on by welding it together, you want to make sure it all flows in to every little bit."*

Table 9: Subjective checking procedures in the retention mechanism craft process

The survey asked MPTs how they evaluated the accuracy of fit of bar structures during practice, and the results are presented in Figure 44. Survey findings confirmed that MPTs checking regimes of accuracy of fit are fully subjective, and no respondent evaluates this aspect quantitatively. A small number used a microscope to look for gapping between the abutments and bar, and answers suggested that the one-screw test is a recognised method in practice.

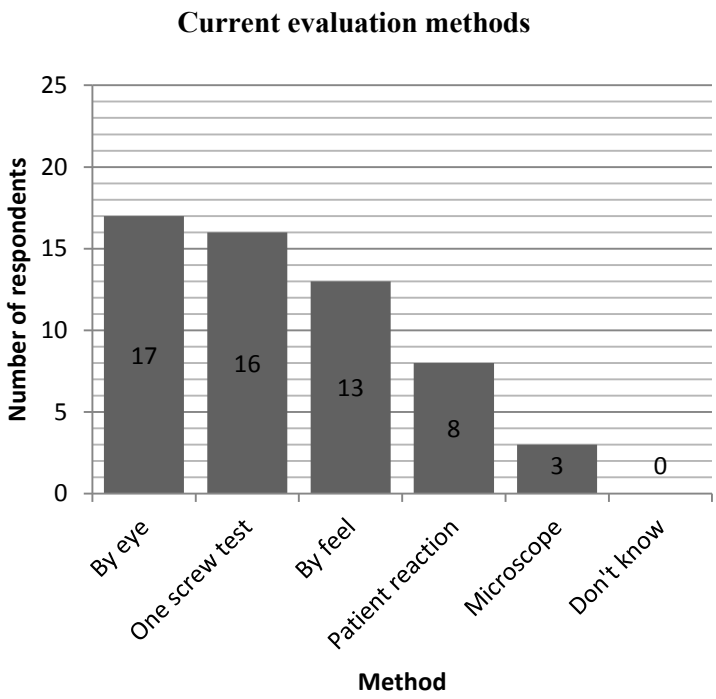


Figure 44: Evaluation methods in practice

Table 10 presents a summary of the tasks associated with trying to achieve accuracy, the possible errors in these tasks and the procedures used to evaluate the work. The summary was developed from the findings of the qualitative research methods.

Stage	Tasks	Aims of tasks	Possible errors	Evaluation procedures
Impression and stone model	Soft/hard layer combinations Cotton bud sticks in silicone Light cure '8' wrap Laser tack and light cure wire	Capturing & maintaining anatomical features accurately & high level of detail Capturing & maintaining the abutment locations accurately	Uncured impression material Abutment replicas moving Flexibility of impression material Accuracy and structural integrity of impression and model materials Distortion in splinting of abutment replicas	Feeling impression material (test if cured) Inspecting by eye
Bar structure fabrication	Welding sequences Tacking and smoothing of joins Bar design Polishing sequences	Accuracy of fit (passivity) Surface smoothness Anti-rotational stability	Distortion in welding, through over-tacking Applying too much solder Pitting in joins	Inspecting by eye with / without microscope
Clip	Waxing around	Space for adjustability of	Excess material around	Tactile

substructure fabrication	clips Placement of clips on bar	clips Parallelism of clips (in same plane)	clips Movement in clips whilst fabricating enclosing substructure	feedback Inspecting by eye

Table 10: Summary of tasks, errors and evaluation procedures

5.4.4.7 Theme 6: Opinions on CAD/CAM

Findings confirmed that CAD/CAM is not currently being used to fabricate extra-oral retention mechanisms in practice. The perceived benefits of CAD/CAM have been discussed in many disciplines. Survey participants were asked to rate some of these potential benefits for implant-based designing retention mechanisms. Figure 45 illustrates the results.

There were mixed responses - the standard deviation shows a large variance in answers, some respondents suggesting no benefit at all and others highly ranking the potential benefits. The mixed responses contributed to a mean in all aspects circling around 3/5 for using CAD/CAM in this area.

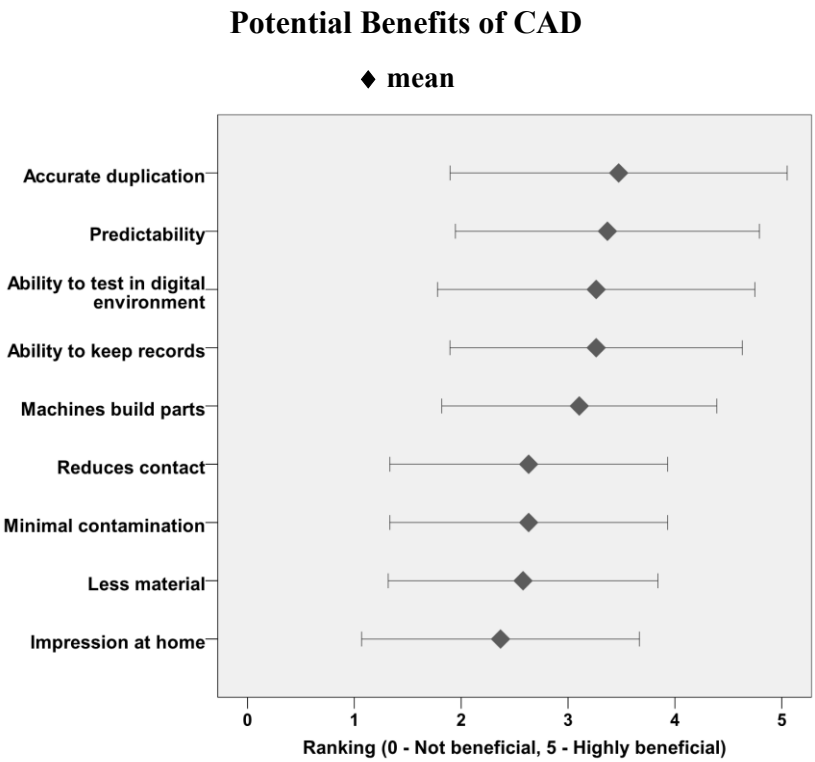


Figure 45: Ranking the potential benefits of CAD (± 1 Standard Deviation)

The qualitative data also revealed that there were mixed feelings about the concept of integrating CAD technologies into maxillofacial prosthetic design processes.

The interviewed MPTs were generally open-minded and optimistic for utilising CAD/CAM methods in the process of designing and manufacturing retention mechanisms, but were aware of a number potential obstacles facing the adoption of these technologies. One obstacle seldom discussed in the literature was the willingness and acceptance of using CAD/CAM by established MPTs, and this issue was raised a number of times in the qualitative data:

> *"…we have to go down that road. It is the future… (but) a lot of people don't want to adopt it because they are frightened of the unknown."*
>
> *"There are plenty of prosthetists out there at the moment, who are approaching retirement age who have worked in a particular way for their entire life, who may not be too keen on going over to entirely new system at this point in their career. It depends how forward thinking they are and how keen they are in incorporating those systems in their day to day work as oppose to things they've been brought up with and working with all their life."*

There was a sense of inevitability from a number of the interviewees, and a number of the perceived benefits were discussed. Efficiency, reducing time for the MPT and patient was a common theme, as well as potentially improving the accuracy and quality of components.

> *"It'll probably save quite a lot of time for some people"*
>
> *"If you can do things on-screen in CAD it's far better than to do it on the patient."*
>
> *"… referring to the substructure or to the bar, the advantage of CAD/CAM in that respect would be accuracy and dependency…"*

Some negative feelings towards using CAD/CAM were expressed. Potentially high costs were associated with CAD/CAM, and this pre-perception was mainly linked to initial investment and training –costs considered difficult to justify. Three interviewees discussed how the implementation of CAD/CAM could de-skill MPTs. Two of the interviewees expressed that they do not wish for CAD/CAM to replace the craft methods, but preferably compliment the current methods.

> *"Inevitably it de-skills you in certain aspects, makes life easier, but there is a degree of de-skilling"*

A number of the participants believed that the quality of the technologies is not yet good enough to implement, or would not ever be able to provide a good enough solution.

> *"The stuff I've seen within bar construction is the sintered stuff and it's been pretty bad. That should change soon. The sintered stuff has to be passive; the stuff I've seen hasn't been great."*
>
> *"The computer isn't going to tell you where all the soft tissue movements are."*
>
> *"…we'll still have to have some artistic license to finish them off, but some of the processes will be taken out, or done in a different way"*

Limited knowledge, skills and experience in using CAD/CAM meant that many of the MPT participants were uncertain of its future.

> *"And I don't really know how far down the line that CAD technology is with regards to manufacture of moulds to create a prosthesis. My knowledge of those technologies is a little bit short."*
>
> *"I'm just wondering where it's going to lead…"*

The opinions were grouped into three categories – positivity toward CAD/CAM, negativity toward CAD/CAM and feelings of uncertainty. The specific points are listed in Table 11.

Attitude	**Discussed aspects**
Positivity	• Efficiency - saves MPT time • Forward thinking and welcoming of new solutions • Reduces patient chair time, increase flexibility • Increased accuracy, predictability, duplication • Complimentary to craft process • Increased accuracy in evaluating work
Negativity	• High cost of investment, difficult to justify • Low availability of technologies • Believe that the technology is not yet good enough • See it potentially devaluing and de-skilling MPTs • Negative pre-perceptions of CAD/CAM
Uncertainty	• Limited understanding of CAD/CAM - could not really comment • Unsure of willingness of other MPTs to accept and adopt

Table 11: MPT Attitudes toward CAD/CAM

5.5 Chapter summary

A breadth of data was obtained by using survey, interview and observational methods. These methods showed a good capability for capturing in depth information on the design and fabrication process and the opinions of MPTs about their work. The observational study revealed the variations between MPTs' processes, materials and tools that allowed the MPTs to fabricate bar-clip retention devices. The nature of current practice was described, and through the qualitative data, a series of considerations for bar-clip fabrication were identified for bar-clip retention design.

The importance of the various considerations was discussed in the interviews and survey. This provided some insight to which design requirements were the most important for bar-clip designs. A design criteria hierarchy was developed, based on the initial information from the survey and from the author's interpretation of the qualitative data. Table 12 shows the imperative category of design criteria. This provided an indication to the most important aspects, but these design criteria should be continuously reviewed and updated in further research.

Design criteria	**Sub-criteria / details**
(Bio) Compatibility	Materials (inertness)
	Tissues (biocompatibility)
Accurate fit of components	Abutment-collar fit
	Clips on bar
	Substructure within silicone
	Margins on anatomy (pressure)
Smooth surfaces	Discourage bacteria
	Mechanical interfaces
Low loading on bone and implants	Minimum cantilever effect
	Accuracy of fit of components
Flexibility in design process	To overcome compromises in implant placement or anatomical condition
	Patient-specific solutions
Stability (anti shearing and rotational)	Appropriate retention forces
	Shape of bar-clip mechanisms

Table 12: Imperative Design Criteria

Table 13 summarises the considerations for successful retention, the requirements for bar-clip mechanisms and how the requirements are met through conventional bar-clip mechanism design.

	Requirements	Design considerations	Meeting the requirements
Imperative	Biocompatibility and component compatibility	Process contamination Material selection Surface roughness	Appropriate materials and processes (certified/standards) Inert materials (Gold, Titanium)
	Accurate fit between retention components	Accuracy of design processes Surface smoothness	Accuracy of fit (passivity) Polishing of bar Parallelism of clips
	Stability (anti-shearing & rotational)	Anatomical movement Location of prosthesis	Bar-structure arm length Bar structure arm angles (non-parallel) Rigidity
	Low loading transferred to implants and bone	Length of bar-structure arms (levering forces) Rigidity Material selection	Short bar structure arms Clip situated close to collars Good accuracy of fit between abutments and bar
	Ability to make customised designs	Material selection Flexibility in design methods Shape of anatomy and prosthesis	Component modularity Creative craft techniques Malleable materials (Gold, light cure) Unique bar-clip shapes
	Discourage bacteria and infection	Surface smoothness Material selection Gapping and cracks Designed to be cleaned	Space between implants Existence of space within prosthesis Height of bar structure Length of abutments & collars Accuracy of fit between components (no gapping) Surface smoothness Anti-microbial material (Gold)
Important	Ease of use and provides confidence	Path/nature of prosthesis attachment	1 fixed location of prosthesis 1 path of insertion Trough-shaped substructure Rigidity of bar 'Click' noise feedback
	Caters to patient lifestyle and ability	Retention method Strength of retention	Adjustable clips
	Adjustable retention	Adjustable clip design	Flexible clip material Number of clips (retention level)
	Components fitting within the prosthetic envelope	Size and shape of mechanism Appropriate amount of clips	Mechanism placed within deepest parts of prosthesis (if possible) Mechanism components are small Modularity of components
	Pressure fit of prosthesis margins	Anatomical movement Location of prosthesis	Selective abrasion of models Shape of retention mechanism
	Efficient, accurate techniques and equipment	Selection of techniques and tools	Established processes and new technologies (e.g. laser welder)
Desirable	Component longevity and resistance to damage	Material selection Design of the bar structure	Rigidity Laser welding and soldering bar-structure joins Polishing of bar Placement of clips Adjustability of retention
	Able to clean	Location of implants Height of bar structure Surface smoothness	Plenty of space between bar and skin Implants at a distance apart Polished bar structure

		Length of abutments & collars	
	Easy to remake/repair	Flexibility in design methods	Modularity of components Creative craft techniques

Table 13: Requirements, considerations and meeting the requirements

There were many opportunities for unforeseen errors in the process of fabricating bar-clip mechanisms. Many sub-stages and idiosyncrasies have evolved to achieve 'accuracy', but rely highly on the accuracy of the components, MPT hand-skill, associated processes, equipment, materials, and evaluation techniques. Measuring the success of the retention device consists of whether the 'aspects of design' meet the defined requirements. In both literature and practice, limited measurable definitions exist in a number of the technical parameters of bar-clip design.

These aspects particularly include ranges of retention forces, accuracy of fit of bar-implant connections, and characterising of surface and dimensional qualities of bar-clip components, which are all related to aspects of the imperative design criteria. Therefore, these elements are not only some of the most important aspects of bar-clip design, but also rely fully on subjective techniques in their 'technical' evaluation. This must be addressed.

The MPTs expressed various opinions on the concept of using CAD/CAM in prosthetic processes. Despite some scepticism, the MPTs showed enthusiasm and a sense of '*we must try it to keep up'*. If CAD/CAM is technically feasible for this process, technology providers must be able to convince MPTs that the process can offer similar or improved results. Therefore, this must involve a technical evaluation of a variety of CAD/CAM samples, and comparing the results with conventionally made models.

This chapter contributes to the direction of the PhD study in the subsequent chapters. The following topics will be the focus of the evaluative phase (Phase 4) for developing objective evaluation methods to compare the conventionally-made and CAD/CAM samples.

- Characterisation of surface and dimensional qualities
- Accuracy of fit of bar-implant connections

- Ranges of retention forces

Chapter 6: CAD/CAM process development

6.1 Overview

The literature review showed that the most relevant CAD/CAM technologies for facial prosthetics concerns surface data capture devices, reverse engineering & design software, and manufacturing technologies. Previous literature concluded that a single technology platform could not provide a solution for every stage of design and fabrication. Therefore to achieve all of the design and fabrication stages mapped in Chapter 5, a range of CAD/CAM technologies must be used. Based on this knowledge, this chapter explores how the available technologies can be used to create a fully digital process, and provides Phase 4 with a series of CAD/CAM based bar-clip samples.

For the purpose of this study it would be unrealistic to trial every piece of CAD/CAM technology on the market. An initial technology identification list was devised to filter a large portion of the CAD/CAM technologies on the current market. Through consideration of previous studies in the literature, availability, time constraints and budget (some engineering software can cost as much as £20,000), some technologies could be appropriately selected for use in this PhD study. The technologies were categorised as *data capture, design and reverse engineering software, and manufacturing*.

The necessity of obtaining samples provided impetus to address other challenges that were identified in the literature review. The literature review identified that some stages of bar-clip production have not been completed successfully by using CAD/CAM. This means that a fully digital process does not yet exist. These stages were identified as:

Phase 1 – Combined anatomy and implant capture directly from patient
Phase 2 – Accurate design of bar structure in virtual environment
Phase 3- Accurate design of clip structure in virtual environment
Phase 4 – Full integration of bar-clip mechanism into the mould using CAD/CAM

Therefore the challenges that were presented for this stage of research consisted of the following:-

1. Define a method to capture a patient's facial anatomy and define the location of the abutments using scanning technologies and reverse engineering software.
2. Design a bar structure and clip structure using CAD software based on scanned data.
3. Integrate the retention mechanism into the design of a prosthesis mould.
4. Obtain a range of samples of bar-clip mechanisms manufactured by CAM.
5. Propose an ideal process for CAD/CAM bar-clip design and fabrication.

6.2 Technology requirements

Based on the considerations for successful retention (Figure 29) and literature review, a number of technology requirements were identified. The general process requirements are reiterated below.

- Efficiency, minimal steps in process for MPT and patient
- Flexibility in design methods and ability to customise designs easily
- Low levels of contamination to ensure compatibility with human tissue and other components
- Accuracy of processes, tools and materials
- Minimal invasiveness – patient comfort

The specific technical requirements in previous literature focused on describing conventional bar-clip mechanisms, or recommending CAD/CAM technologies before the realisation of a fully digital solution. Therefore for this exploratory stage, only the general process requirements were considered, because this allowed wider scope for experimentation with novel solutions.

To accompany the requirements, the stages in the conventional prosthetic process were also used as a reference for creating a comparable CAD/CAM process. The next sections will discuss the selected technologies and processes followed.

6.3 Phase 1: Data Capture

In previous literature, the abutments could not easily be captured in previous studies due to their typically intricate form and reflective surfaces. Abutment also vary in the level they protrude out of the skin. Despite some attempts to address this issue, it is yet to be resolved.

Some initial non-contact scanning trials were conducted to validate the existing knowledge that the abutments could not be captured sufficiently. As figures 47 & 48 show, non-contact surface scans do not always pick up the data required because the surfaces are too reflective, or cannot define the shape of the abutments accurately due to the lower working resolution.

Figure 46: Abutments in model

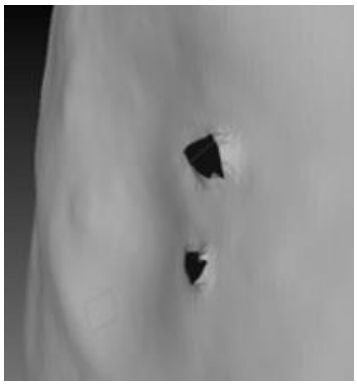


Figure 47: Handyscan, exposed abutments

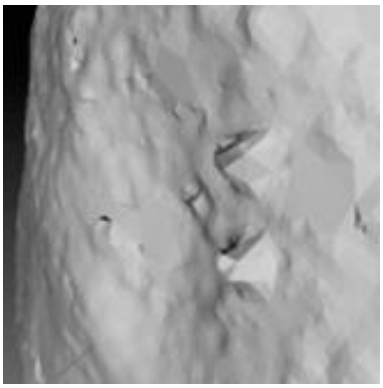


Figure 48: 3DMD, exposed abutments

In dental applications, cylindrical registration scanning locators can be connected to the abutments on the stone models and their locations determined using CMM touch probe scanning. Following this, the scanning locators can be reverse engineered and translated to the abutment positions. As described in the literature review, this concept has not yet been applied to extra-oral prosthetics, especially through using non-contact scanning techniques.

Inspired by these techniques, oversize cylinders were designed for non-contact scanning of the extra-oral abutments. The scanning locators were designed to screw on to the abutments (Figure 49), to simplify and increase the scanning surface area. The prototype

locators were designed in Solidworks (Dassault Systemes) and manufactured using Projet 3D (3D Systems) printing at the highest resolution setting (16µm), and sprayed in a matte grey colour to reduce the reflectivity as much as possible.

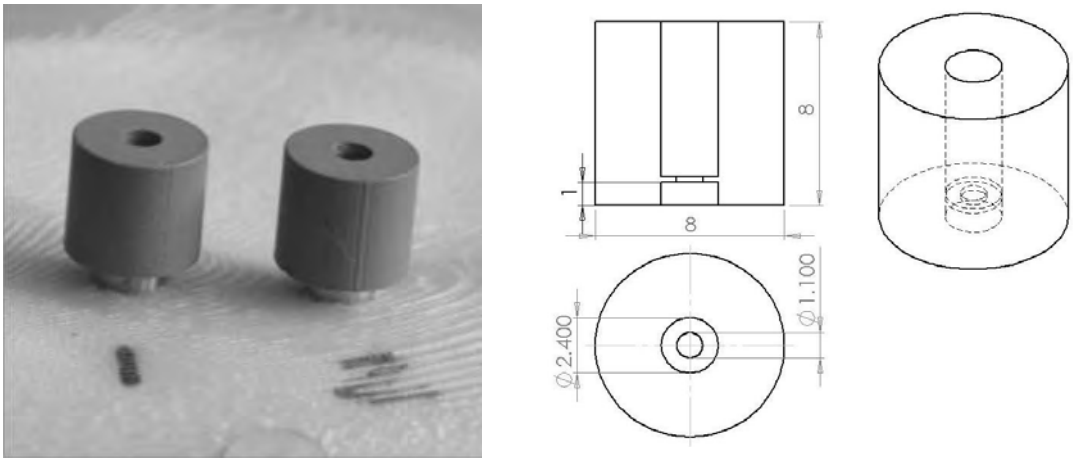


Figure 49: Scanning locator design

A series of trial scans were conducted using three scanning devices, which are currently being utilised in either prosthetics or similar fields. The key selection criterion was scan quality of both the anatomy and scanning locators, which could be used as the foundation for subsequent reverse engineering tasks. The scans were performed at the highest resolution possible.

- **Artec Handheld Scanner**: Used to scan custom seating surfaces at the Rehabilitation Engineering Unit, Morriston Hospital
- **3DMD Photogrammetry Scanner**: Used regularly in prosthetic applications at the Medical Illustration Department, Morriston Hospital
- **Creaform Handyscan laser scanner:** Used in a number of research studies and industrial applications by the Medical Applications Group, PDR

The results of the scans are shown respectively in Figure 50, Figure 51, Figure 52 and Table 14:

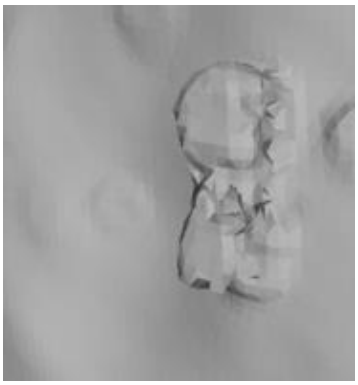


Figure 50: Artec scan data

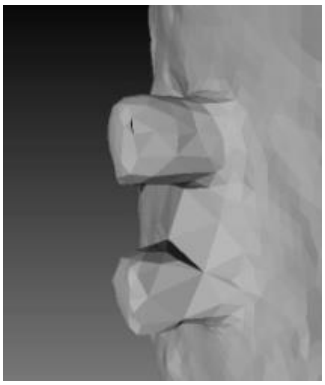


Figure 51: 3DMD scan data

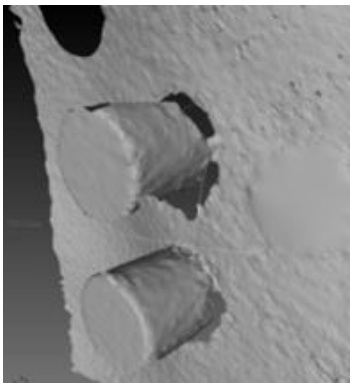


Figure 52: Handyscan scan data

	Scanning Time	Anatomical surface	Scanning locators
Artec *(scan res. 0.5mm)*	9 minutes	Good. Smooth surface with minimal holes.	Distorted shape & many holes Fill-hole function merged cylinders. The outcome is a messy result that cannot be used for RE.
3DMD Photogrammetry *(scan res. 0.2mm)*	Seconds	Very lumpy and spiky around the abutments.	Higher definition on one side than the other, due to shadowing effect of camera eye-line, resulting in inconsistent results. Facets too large so cannot be used for RE.
Creaform Handyscan *(scan res. 0.1mm)*	15 minutes	Smooth surface and able to capture detail.	Well-defined. Can be used for RE.

Table 14: Results of data capture device trials

All of the scanners had the capability to capture the anatomical surface. However the surface data representing the scanning locators varied in quality. The 3DMD and Artec produced either messy or indefinable surfaces. The Handyscan laser scanner provided satisfactory results – the scanning locator surfaces and edges were clean and easily definable. This data could be used in the next stage of the process (reverse engineering).

The Handyscan surface scanning procedure is described:

1. Reflective dots applied
2. Custom screw-on scanning locators applied to abutments
3. VX Elements Software used with scanner
4. Perform auto – configuration on scanning locators

5. Capture location points (reflective dots)
6. Capture surface - scan thoroughly abutment locators, anatomy can be scanned more quickly
7. Save facets to file
8. Facets saved as STL file

The outcome from this section suggests that the ideal scanner for this application would combine the capture speed of the 3DMD and the scanning resolution of the Handyscan. An armamentarium of data capture devices exist on the market today, but of the devices trialled in prosthetics research, it is believed that no ideal solution yet exists. The scanning locators can overcome this, which is explained further in the following section.

6.4 Phase 2: Reverse Engineering & Design

6.4.1 Reverse Engineering

The cylindrical locators provided more useful surfaces for non-contact scanning than the abutments, and of the scanning devices trialled, the Handyscan laser scanner provided the most promising and usable surface data for the next stage:- Reverse Engineering (RE).

This phase focuses on defining the scanning locators. If the data is prepared sufficiently, it should be possible to design the retention mechanism based on the reverse engineered scanning locators, and the prosthesis mould integrating these features.

Generating surfaces from scan data relies on the accuracy of the scanning device, the quality of the scan data and method of translating the data into workable surfaces. It is particularly challenging to produce an accurate representation of a geometric feature from scan data, and even impossible if the data is of low quality.

A number of software solutions were used to attempt to complete this workflow, which are listed.

- Geomagic Freeform (3D Systems)
- Geomagic Studio (3D Systems)
- VX Elements & Powershape (Delcam)
- Solidworks (Dassault Systemes)
- 3-Matic (Materialise NV, Belgium)

Through using the locators, it gives an opportunity to deal with larger and simplified surfaces rather that attempting to deal with the intricacy of abutments. This is an important part of the RE process. Through trialling various software, it was shown that a number of RE methods are available.

The scan data (.stl) was imported to each software (with exception to VX Elements, which dealt directly with the scanning procedure), and the available tools were utilised. The key tasks were to define the raw scan data of the locators as geometric entities of known dimensions, and subsequently replace the locators with stock collar components in the correct position, as if they were sitting on the abutments.

6.4.1.1 Manual positioning

Freeform has been used in a number of research studies for prosthesis design, but the challenge of accurately defining the locations of the abutments had not been overcome.

As shown in Figure 53, the STL data from the Handyscan laser scanner was imported into Geomagic Freeform, where an attempt at defining the scanning locators was made. It was quickly noted that only manual positioning techniques could be used, and this meant that the software could not provide an ideal method.

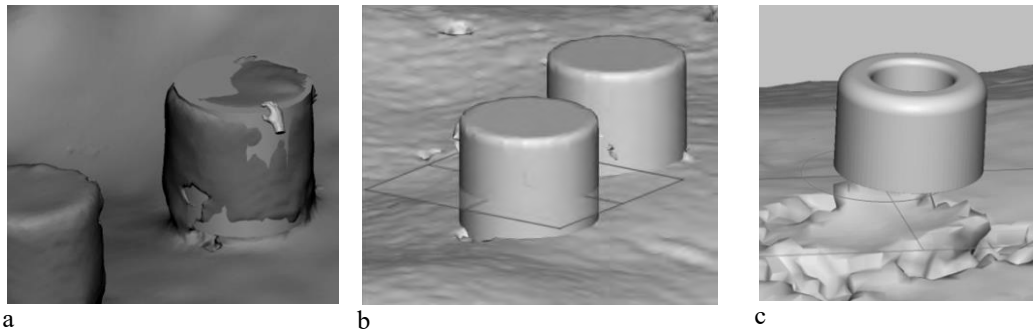


Figure 53: Freeform procedure for abutment determination

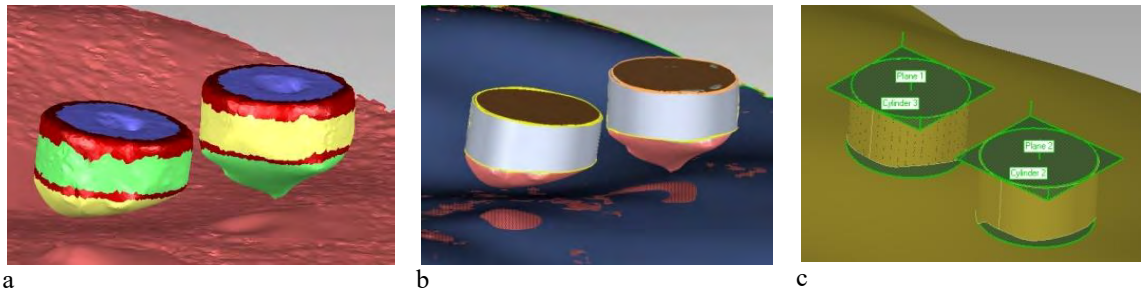
Notes: *(a) Manual positioning of cylinders; (b) Plane defined; (c) Manual positioning of the collars into position on the plane*

6.4.1.2 Best fit registration

A number of software solutions provided tools to select regions of scan data and translate these regions into geometric entities. In Geomagic Studio, VX Elements and 3-Matic, this involved slightly different techniques but essentially the same principles were applied. The procedure involves selecting a region of scan data (facets) on the top surface of the locator, followed by the appropriate facets on the side surface of the locator. The flat top surface and cylindrical side surface must firstly be identified within the scan data, and this can be challenging if the quality of the data is poor.

The top surface represents the maximum height of the locator (i.e. distance from the abutment connection) and the side surface represents the direction the locator is pointing (the vector). The groups of facets can be used to position geometric entities of known dimensions (cylinders, planes) to the best possible fit.

In Geomagic Studio, regions of the scan could be highlighted by using a 'paint' style selection tool and the regions were categorised to the desired elements (freeform surface, cylinder, plane). The regions could be translated to surfaces, stitched and exported as parametric entities (Figure 54). In this case, the top plane and cylindrical surface were treated separately.



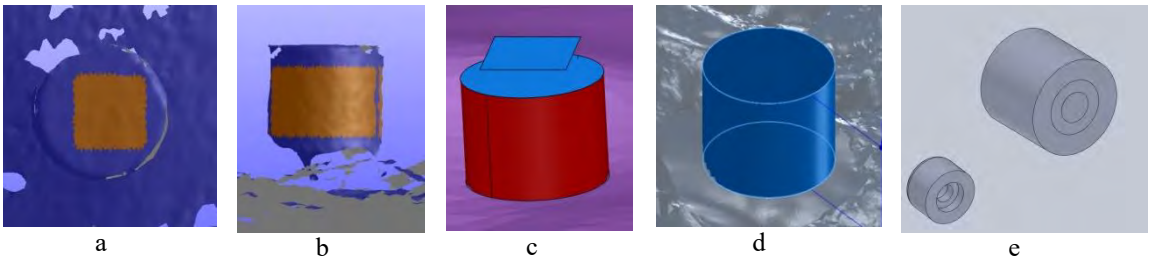
a b c

Figure 54: Geomagic Studio RE procedure

Notes: (a) Selecting regions on scan data; (b) Assigning geometric surfaces and edges to regions; (c) Stitched surfaces and parametric entities (planes, cylinders)

In VX Elements, the facets on the top surface were selected, and a plane was assigned to these facets by using a best-fit method. The side surface facets were then selected, and a cylinder was assigned to these facets to define its direction. The geometric entities (plane, cylinder for each locator) could be exported in the IGES file format, for processing in subsequent software.

Using Powershape (Delcam) software, the IGES entities were imported so that the planes and cylinders could be connected and translated to workable surfaces. Using Solidworks (Dassault Systemes), the surfaces could be converted to parametric solids. Pre-designed stock collars could be imported and aligned to the centre of the bottom surface (abutment/collar interface), and the locators could be removed, leaving the collars in the desired position. The process is illustrated in figure 55.



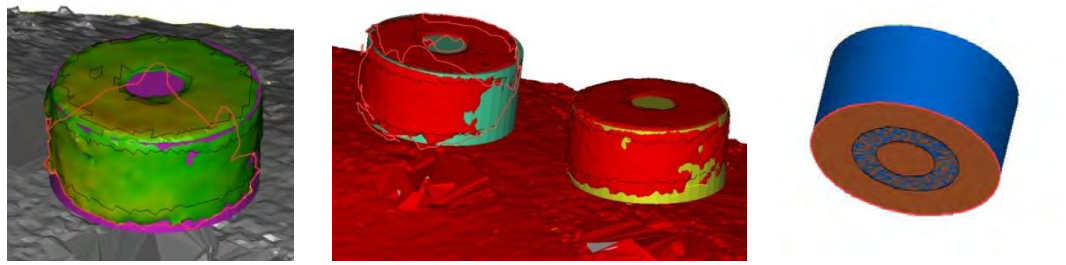
a b c d e

Figure 55: Reverse engineering sequence for the scanning locators

Notes: *(a) Top surface facets; (b) Side surface facets; (c) Distance and direction defined; (d) Planes and cylinders connected; (e) Positioning collars*

In 3-Matic, a more automated approach was available - after selecting the desired regions, pre-defined cylinders (representing the locators) were positioned in one action using the 'Global Registration' tool. Pre-designed collars could be imported, aligned to

the desired position, and the locators could be removed - essentially 'replacing' the locators (Figure 56).



a b c

Figure 56: 3-Matic RE procedure

Notes: (a) Selecting facets; (b) Best fit of cylinders to facets; (c) Alignment of collars

6.4.2 Design of retention components

Through the completion of the reverse engineering procedure, the foundation was provided for designing the implant framework. The next steps in the process involved:

1. Completion of the bar structure design
2. Design of the clip structure
3. Integration of the assembly into the design of the mould and prosthesis

A significant challenge remains to design both retention mechanism and prosthesis form in the same software. A combination of Solidworks and Freeform was chosen to complete these stages, and the process was taken as far as possible with the available tools. The stages in the process are described (and illustrated in figure 57 and 58):

1. Decide how the bar structure should be designed (length and angle of arms). This can be achieved by importing a photograph of the desired anatomy into Solidworks and sketching the shape of the bar in relation to the size shape of the anatomy.
2. Import stock components (gold caps) and replace the cylinders with them (move body, translate, mate components using correct reference features, hide cylinders.)

3. Connect the cylinders with 2mm diameter cylinder section, create arms at appropriate angles and lengths according to prosthetic envelope.
4. A 0.5mm fillet feature was applied the ends of the arms and joints, so that there would be no sharp edges on the outer surface of the bar structure.
5. Import stock clips (these were designed only to fit, but retention forces unknown).
6. Position in desired position on bar structure (move, mate etc)
7. Connect all clips by swept base from one to the next.
8. Extrude cut the desired shape then extrude a new shape for top surface of the clip-structure.
9. Create new shape - Convert entities, offset entities, extrude down toward surface. Extrude cut top, fillet edges.
10. Create over-moulding features for silicone to integrate with the part.

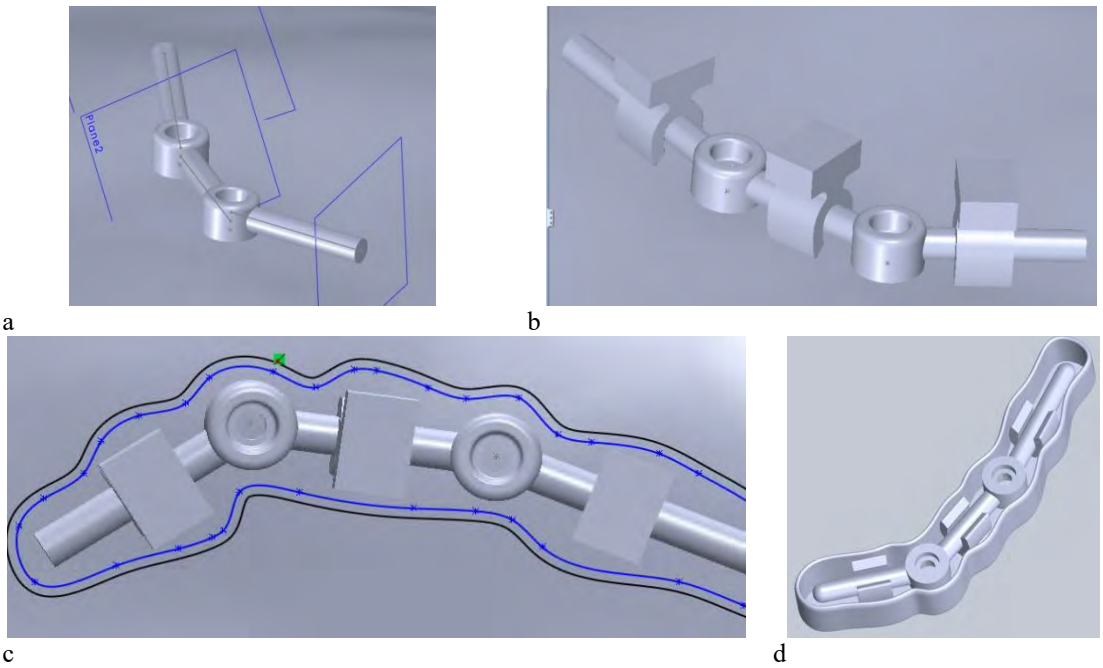


Figure 57: Stages of bar-clip design

Notes: (a) Creating bar sections; (b) Placement of clips; (c) Substructure design; (d) Final assembly

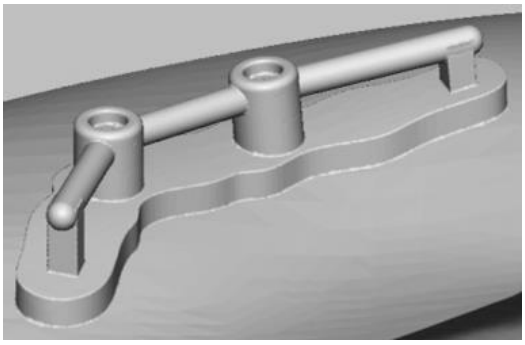
The bar and clip structure was exported in the STL file format (configured to highest resolution STL: 0.005968mm deviation, 0.5° angle) for manufacture.

6.4.3 Mould design

The bar structure was modified in Solidworks to be incorporated into the mould design. This involved designing features that allowed the bar structure to integrate into the anatomical surface. The defected anatomy with integrated bar structure represented the bottom part of the mould. This was achieved in the following steps.

1. The anatomical scan data (under the bar structure) was translated to a thickened surface.
2. The bar structure was combined with the surface by extruding the collars through the surface. Structural tabs were added to strengthen the arms.
3. The part (combined bar structure and thickened surface) was exported as an STL and imported into Freeform at a high resolution.

This involved mirroring the desired anatomy (auricular) in Geomagic Freeform, positioning the new facial feature into the desired position, and sculpting it to the desired form. The desired ear shape was taken from the patient model described in Chapter 4. A subtraction of the defected anatomical surface from the new anatomical shape enabled an accurate fit. The new anatomical feature surface was used to offset a separate part – which created the hollow mould. Split lines were created and guiding features to ensure correct assembly. The auricular prosthesis required a 3-part mould.



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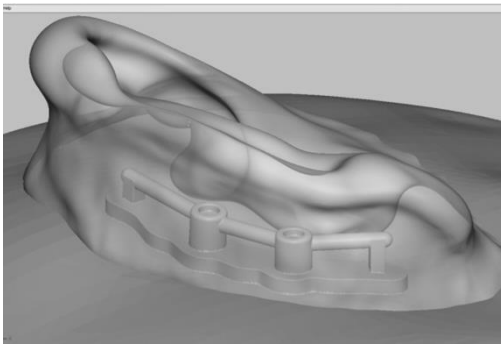

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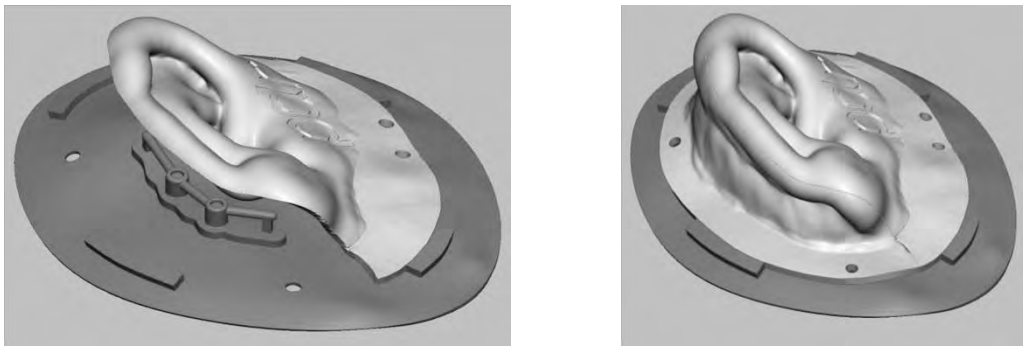


c d

Figure 58: Auricular prosthesis mould design

Notes: *(a) Mock retention bar structure; (b) New ear sculpted and located; (c) Mould design exposing mock bar underneath; (d) Final 3 part mould design*

6.5 Phase 3: Manufacturing

A number of manufacturing methods were used to produce the various components in the prosthetic assembly. This section presents these methods.

Technologies were selected for the production of trial bar-clip retention mechanisms, based on the following generic criteria:

- Must fully or partly use Computer-Aided Manufacture (indirect or direct CAM)
- Process must be able to produce biocompatible materials (but biocompatible components not necessarily required for this study)
- Sample production must fit within the financial restraints of the PhD study
- Process must be able to produce a component in size and shape of a typical auricular bar-clip assembly.

6.5.1 Bar-clip sample manufacturing

Conventional prosthesis bar structures are laser welded or soldered from stock gold pieces. This section describes how Computer Aided Manufacturing methods were identified and utilised for the production of bar-clip mechanism samples.

The literature suggests that CAM can be used to create bar structures, but limited technical data has been presented in using CAM processes in this application. The technical capability of many manufacturing techniques (especially AM) is provided by the manufacturer in promotional or commercial literature. Conclusions could not be made based on these references, because they are not usually peer-reviewed and often do not provide the scientific evidence to support the claims. This provided an opportunity to source new data to provide indicative evidence of the technical performance of the selected processes. A series of experimental bar structures were manufactured, so that technical measurements could be performed using these components in subsequent chapters.

The manufacturing methods were chosen in consideration of the available data in literature, technology appropriateness, relevance and availability. The process requirements identified in the previous chapters also influenced the selection of the manufacturing technologies. A selection of formative, subtractive and AM techniques were considered, but not every available technology could be trialled within the time and financial constraints of the PhD.

Biocompatible materials were used where possible, but could not be obtained for all of the CAD/CAM samples. However, substitute materials were used where required and expert advice was obtained where possible. An example CAD/CAM bar structure is illustrated in Figure 59.

Figure 59: Direct Metal Laser Sintered (DMLS) bar structure sample

A list of all the obtained bar structure samples is provided below. Images of the samples are provided in Appendix VI.1.

Rigid bar structure samples	Acronym
Dental investment cast from RP master (Cardiff Met.)	DentCast
Solidscape 3D wax print, layers 13µm. Induction cast (CoCrMo)	
Jewellery investment cast from RP Master (Jewellery Industry Innovation Centre, Birmingham)	JewlCast
Solidscape 3D wax print, layers 13 µm. Centrifugal cast (Brass)	
Selective Laser Melting (SLM Solutions)	SLM
Titanium (TiAl6V4), Layer thickness 30µm	
Mlab Laser Cusing *(*Concept Laser Gmbh)	LasCus
Remanium star CL (CoCrMo), layer thickness 50µm	
Direct Metal Laser Sintering (EOS DMLS)	DMLS
Cobalt Chrome (CoCrMo), layer thickness 40µm	
Inkjet Metal Printing (Fcubic)	FCubic
Stainless Steel (316L), resolution 20µm	
Electrodeposited AM master (Morganic Metal Solutions)	Electro1
3D Systems Projet EX200 base, layer 16µm	
Electroformed Copper coating of 100µm thickness	
Electrodeposited AM master (3DDC)	Electro2
3D Systems Projet EX200 base, layer 16µm	
Electroplated Copper coating of 100µm thickness	
Incise® Dental Milling (machining) - Zirconia (Renishaw Plc)	Zirc
Zirconium dioxide using Incise® Dental Miller	
CNC Machined PEEK (Invibio Biomaterial Solutions)	PEEK
PEEK-OPTIMA (Polyether ether ketone) 250-500m/min cutting speed	

Bar structure non-rigid samples	Acronym
Objet Connex 500 (PolyJet Matrix™ Technology)	a. Obj ABS
ABS-like digital material (fabricated from FullCure®515 and ®535). Layer thickness 30µm (IPF Rapid Prototyping)	b. Obj Dur
DurusWhite - simulated polypropylene material, layer thickness 28µm (HK Rapid Prototyping)	c. Obj Vero
VeroWhite - rigid opaque material, layer thickness 30µm (Loughborough University)	
Stereolithography (SLA-250) (3D Systems)	a. SLA 25

Accura 25 – simulated polypropylene material, layer thickness 100µm (3D Systems) Accura Xtreme – ABS-like material, layer thickness 100µm (3D Systems)	b. SLA Xtr
Perfactory Digital Dental Printer (EnvisionTec Gmbh) RCP30 Ceramic filled photopolymer - PP type material). Pixel Size 30 µm, Dynamic Voxel Resolution in Z (material dependent) 25µm	Perf
Selective Laser Sintering (SLS) (3D Systems) Duraform EX – simulated polypropylene material, layer thickness 100µm	SLS
Vacuum Cast from 3D printed master (PDR) 3D Systems Projet EX200 base, layer 16µm Vacuum cast in Polypropylene-type material (MTT)	VacCast

Two experimental clip structures were manufactured by AM to gain an initial understanding of the feasibility of the processes. The first trial clip structure was produced by Direct Metal Laser Sintering (EOS DMLS) in Cobalt Chrome (CoCrMo) at a layer thickness of 40µm, shown in Figure 60a. The outcome suggested this process was inappropriate for clip fabrication because the stiffness of clips was too high, meaning the bar structure was unable to be inserted without damaging one of the components.

The second trial clip structure (Figure 60b) was produced by 3D printing (Projet 3D printer (3D Systems) using Projet EX200 photopolymer material on Extreme High Definition (XHD) setting (layer thickness 16µm). This clip structure was flexible enough to engage with the bar, and although not intended for real clinical use, it was noted that this process could be used for producing experimental clip designs later in the PhD study.

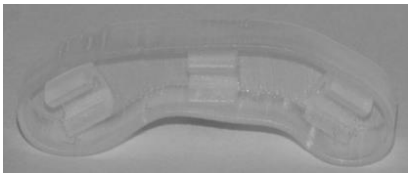
a b 

Figure 60: Sample CAM bar-clip mechanisms (a. DMLS, b.Projet)

6.5.2 Mould and prosthesis manufacture

The mould components were manufactured following methods of mould-production by Eggbeer et al. (2012a). Parts were 3D printied on a Projet 3D printer (3D Systems) using Projet EX200 photopolymer printing material on Extreme High Definition (XHD) setting (see figure 61). The wax supports were melted away and the parts were degreased. They were manufactured so that the prosthesis-touching surface was orientated upwards, where the wax supports were not produced. This ensured a smoother surface finish.

Figure 61: 3D printed prosthesis mould

Similar to methods by Fantini et al. (2013), the female retention element (clip structure) was attached to the mould on the integrated bar structure. The mould was assembled, and an industrial rubber material was poured into the moulds, penetrating the over-moulding features on the clip structure. The mould was clamped and put into the oven to cure. The prosthesis was removed from the mould, and it could be seen that the clip structure was successfully over-moulded into the prostheses. The result is shown in figure 62.

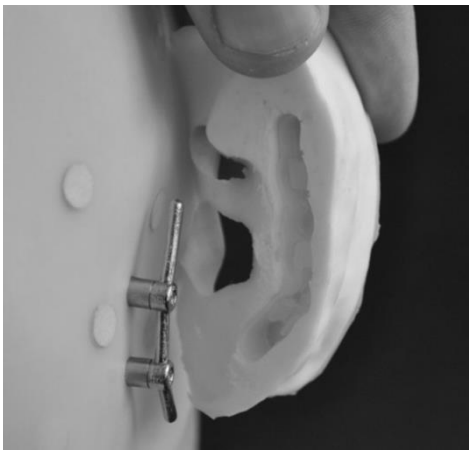


Figure 62: Over-moulded prosthesis and electroformed bar structure

6.6 CAD/CAM process evaluation

This chapter presented the first attempt at documenting a fully CAD/CAM process of bar-clip mechanism design and production. As an initial source of feedback on the feasibility of this process, an interview was conducted with a leading MPT at Morriston Hospital, Swansea. Time constraints did not allow further interviews to be conducted. The transcript can be viewed in Appendix V.

The MPT was guided through the process and each stage was described in detail. Following this, the samples of retention mechanisms, moulds and prostheses were presented and an interview was conducted to complete the session.

The interview was semi-structured and the researcher allowed open responses to each question. The main aim of the interview was to gain feedback on the early-stage CAD/CAM process, allowing the MPT to reflect on the various stages, and whether it would be appropriate to use in a clinical environment. The interview was used as an early evaluation of the conceptual process, and to gain further understanding of how the CAD/CAM process may be applied in a clinical setting.

6.6.1 MPT feedback: results

A number of positive observations were noted by the MPT about the process. The limitations and issues involved in the process in its current state were also discussed. The results are presented in Table 15.

Stage	Issues, limitations & challenges	Positive observations
Scanning	Handheld laser scanner relies on user experience and skill. The patient must be static for the duration of the scan, potentially difficult in long scanning times. Although less invasive than traditional impression techniques, reflective stickers must be applied to sensitive regions of the anatomy for scanning.	The scanning procedure is non-invasive
RE & CAD	The CAD process is perceived as challenging for a non-CAD expert. For clinical application, the ease of use of this process must be considered. Without sufficient scan data, the RE and CAD stages cannot be conducted. At present, there is no control over the adjustability of the clips It is important to define the accuracy of the components. No library of retention components available yet.	The patient is not required in the clinic. Reduces patient chair time. CAD process is defined and replicable. The work of MPTs is fragmented by nature; CAD could allow control over this process, which reduces pressure on the MPT. The process may provide a safer outcome through possibility of simulation.
Manufa-cture	The mould is not transparent enough when colour matching – idea to develop clear moulds Currently limited in choice of clinically acceptable materials and processes	Ability to make components lighter, and smaller. Able to reduce patient visits by re-produce components easily. Likes the idea of a flexible bar structure.

Table 15: MPT observations

The MPT suggested a number of ideas to improve the process, and discussed the future of using CAD/CAM in this field. The importance of defining the limitations of the digital process was highlighted.

> *"It's important to see how far we can go – we need to stop doing the simplest cases as trials. We need to do a difficult, large midface"*

The MPT believed that a computerised design process potentially creates an element of disconnection with the patient – the MPT requires sufficient patient contact to achieve the desired prosthetic outcome.

> *"We spend a lot of energy on the complex cases, those are the people you want to help – and it's during those the cases, the patient really needs to be there."*

The MPT discussed the conflict between automation and creativity. The MPT stated that the ability to be creative in this process is important, but a streamlined process that saves time and money is also a requirement. It was suggested that if automation exists in this process, there must also be elements where the MPT/designer is provided with freedom to manipulate designs creatively. The MPT worried that automation may be applied in the wrong stages, which could hinder this process.

6.6.2 The 'ideal' CAD/CAM process

To summarise the chapter, the process in its current state was mapped in the following flowcharts (figures 63 to 66), and ideal processes are presented where possible. The flowcharts were developed in consideration of the MPT feedback and initial experiences during the developmental process.

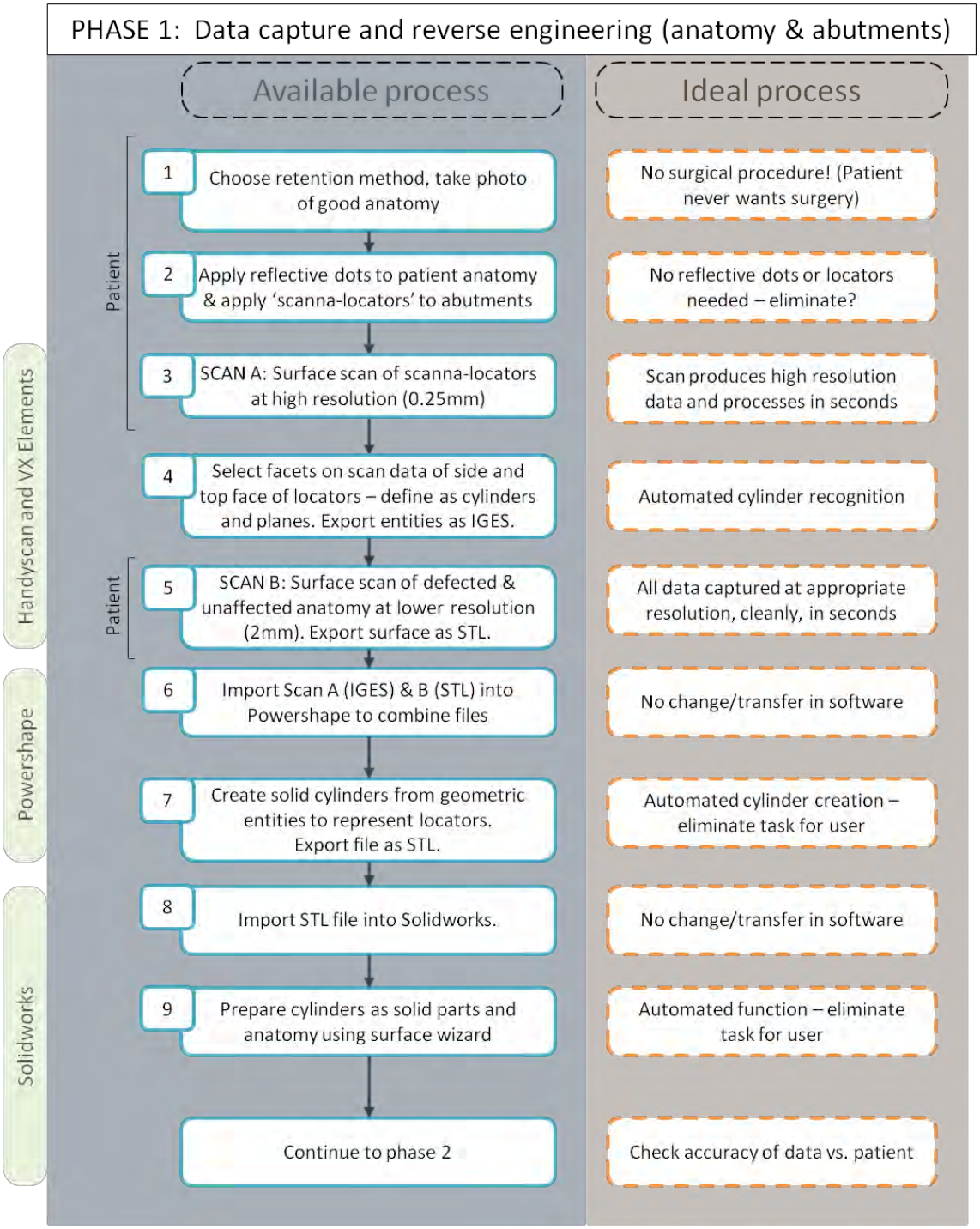


Figure 63: Phase 1 - 'Ideal' process

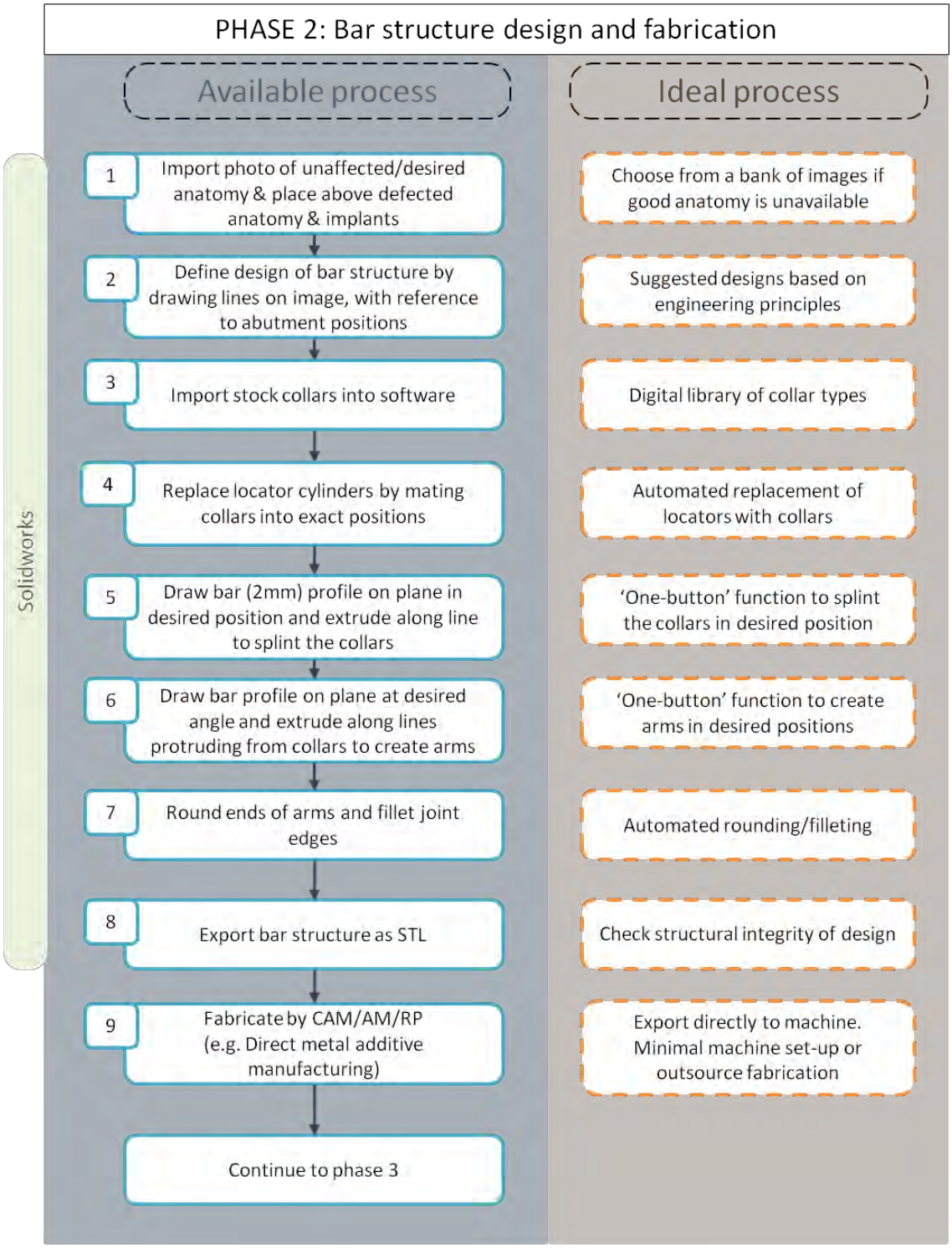


Figure 64: Phase 2 - 'Ideal' process

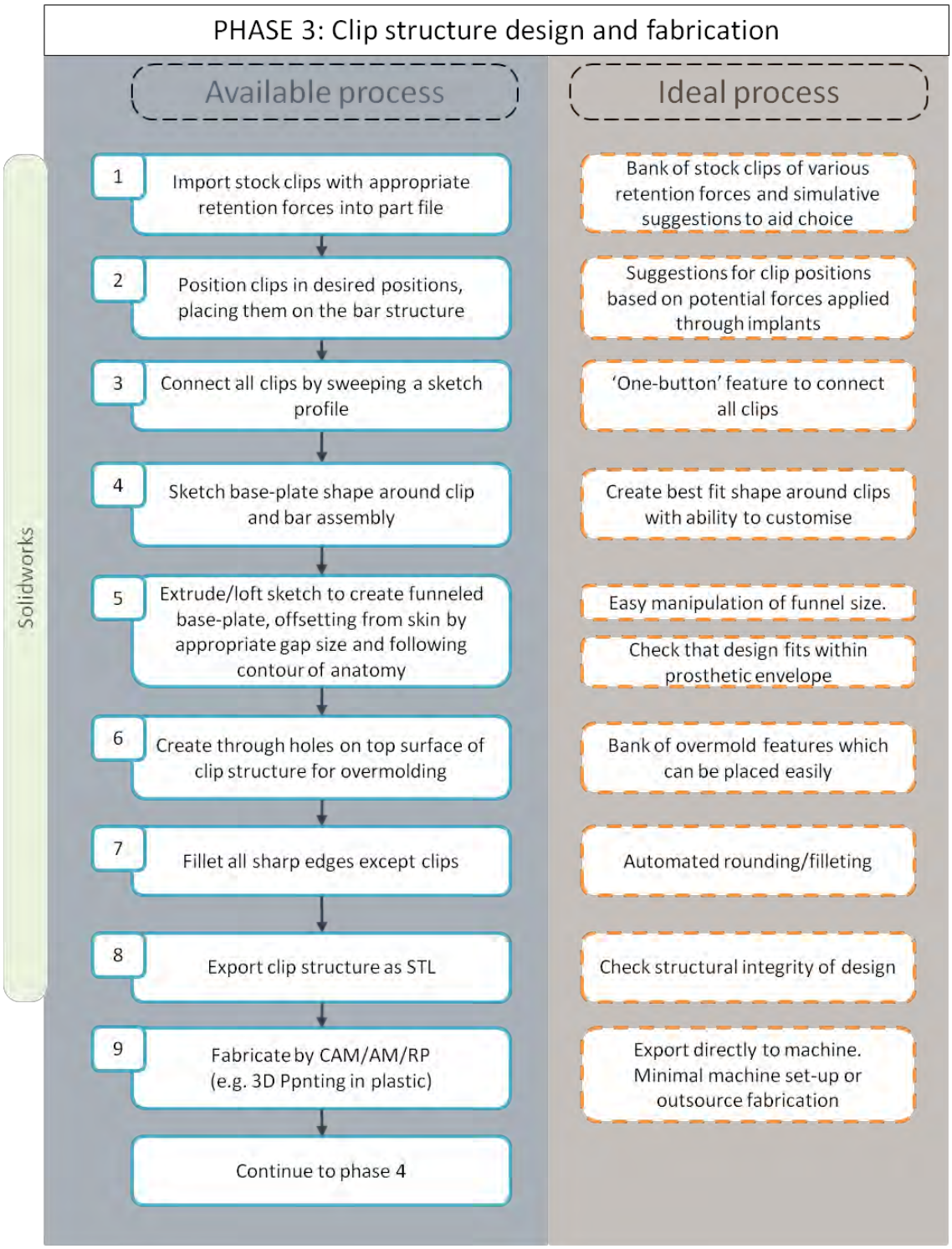


Figure 65: Phase 3 - 'Ideal' process

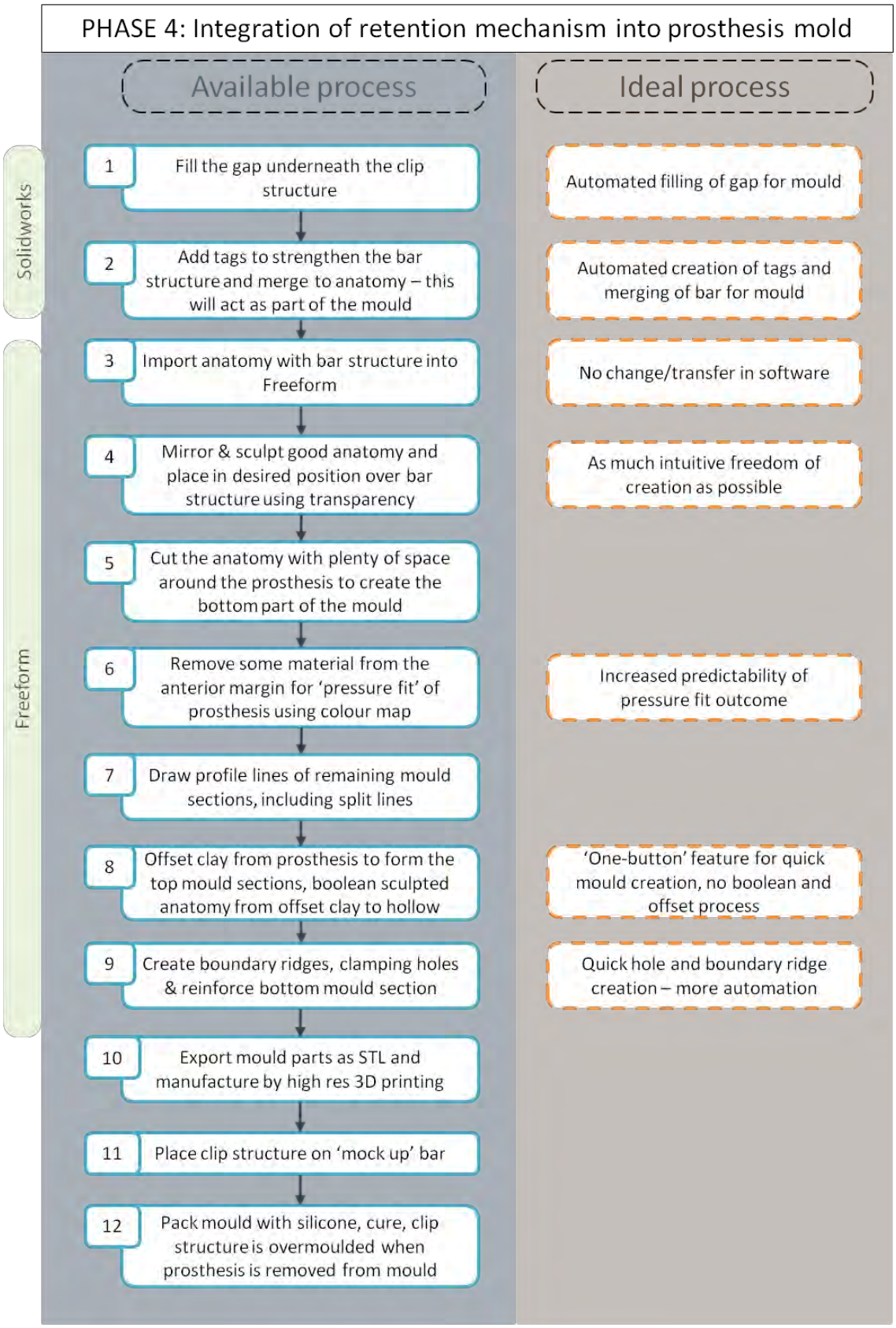


Figure 66: Phase 4 - 'Ideal' process

6.7 Chapter summary

The aim of this phase of work was to obtain samples, and the work also provided a number of new methods for capturing abutments, digitally designing, manufacturing and integrating the retention mechanism into the prosthesis mould. New process stages were developed which use CAD/CAM to create prostheses with the successful integration of an implant-based retention mechanism. The novel CAD/CAM processes developed in this phase can be defined as:

Development 1: Abutment capture
Capturing the implant locations by using non-contact surface scanning, customised surface scanning locators and reverse engineering techniques. Defining the scanning locators as 'cylinders' from the captured scan data.

Development 2: Translating abutment positions to bar design
Accurately replacing the 'cylinders' with pre-defined abutment collars. Completing the design of the bar structure based on the position of the collars.

Development 3: Design of the clip structure
Accurate placement of the clips, and design the clip structure based on the clip positions, bar design and prosthetic envelope.

Digital method 4: Full integration of bar-clip into AM mould
Fully integrate the retention mechanism into the design and manufacture of the prosthesis moulding process by 3D printing the mould with mock bar structure and over-moulded clip structure in situ (no gluing clips in post moulding).

Following the MPT feedback, the conceptual process was mapped in phased flowcharts, and an initial 'ideal' process is proposed. A series of bar structures for bar-clip mechanisms were also obtained from a variety of manufacturing process. The samples were selected based on generic criteria, focusing on the available technologies that had not previously been trialled in this application. These samples will be studied in the next Chapters - 7, 8 and 9.

Chapter 7: Surface and dimensional quality

7.1 Overview

The craft process of designing and fabricating retention bar structures involves laser welding, soldering, grinding and polishing, all of which require skill and experience to produce a high quality result. The components must accurately assemble to one another and the surface properties must discourage bacterial growth. This was identified in both the literature review and observations, and considered as part of the imperative design criteria.

The design requirements for prosthesis retention mechanisms must be met by the production process. As identified earlier in this thesis, the traditional design and manufacturing processes associated with retention bar and clip mechanisms are rather messy and intricate, and there are many stages within the process where errors may be introduced.

Conventional bar structures are polished during the fabrication process, so that they reduce wear in the clips and discourage bacterial colonisation. The common design intent is to polish them until they are "*smooth and reflective".* The level of applied surface smoothness is based on the subjective judgment of the MPT, and although a microscope is often used for visual checking of the welds, the true surface roughness values are unknown. A more accurate approach is needed to ensure consistent, safer and improved results.

The functioning quality of an engineered component is highly dependent on the quality of its surface and dimensional accuracy (Palani and Natarajan, 2011). The measurement of geometric features and roughness is very important in engineering, especially when concerned with the mating/fitting of components. The accuracy of the geometric features can also influence wear on moving parts. These factors are particularly important in the retention components of a facial prosthesis. They are crucial in providing an appropriate connection of the prosthesis to the implants and facial anatomy. Facial prosthetics is most often dealing with subjective measurements taken

by eye or by hand. There are tools available which can help reduce the uncertainty, increase the accuracy and quantify measurements. To observe lower than *mm* level means that a laboratory microscope is the minimum requirement. Existing imperfections below this level must be identified, and the appropriate measurement devices must be utilised to capture and quantify them.

This chapter focuses on measuring the dimensional accuracy and characterising the surface quality of the conventionally-made and CAD/CAM samples.

7.1.1 Dimensional accuracy and working tolerances

The accuracy of dimensional features is crucial when dealing with fitting assemblies, and it can also influence wear on moving parts. Dimensional features can include width, diameter, straightness, flatness, parallelism, roundness, circularity, etc. (Bewoor and Kulkarni, 2009). Some of these factors such as straightness, are dimensionless, and can be defined as qualitative aspects of the component. However, the process of inspection can quantify these aspects so that components can be compared quantitatively.

No research studies have attempted to specifically determine acceptable tolerance zones for retention mechanism bar structures – perhaps because of the lack of control over these aspects due to the craft nature of the work. An acceptable tolerance zone for the various dimensional features of prosthesis bar structures must be defined if developing new concepts (figure 67).

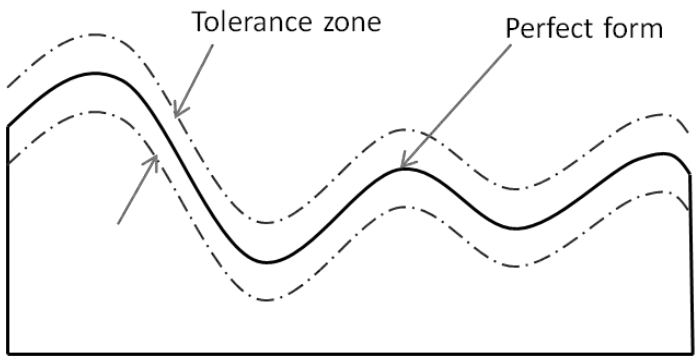


Figure 67: Tolerance zone of a component

There are no standards for working tolerances in extra-oral bar structure fabrication. The main factors that determine an 'acceptable tolerance zone' for bar and clip mechanisms have only been suggested empirically in the literature, (e.g. a smoothly polished surface) and therefore this study takes an engineering approach to describing the working tolerances of conventional bar designs. The tolerance zones need to be determined for a number of features on the bar structures associated with quality – hole geometries, clip fitting interfaces, and surface finish.

The classification of fit for the various components has not been specified in the research or manufacturing literature, although it is believed by the author that a clearance fit is needed for the holes to fit the abutments and screws. Distorted geometries may therefore result in an inaccurate fit to the corresponding components.

7.1.2 Surface quality

The characteristics of a surface can be described by lay, form, waviness and roughness and flaws (Bewoor and Kulkarni, 2009). Lay is the direction of the pattern that exists on a surface which is determined by the manufacturing process. Form is the general shape of a surface, which can be effected by process that might change the general geometry of the surface (like for instance, stress patterns in a component or if it is clamped too tightly). Waviness comes from imbalances or instabilities in the machine or work process, like for instance, vibrations of the machine. Surface roughness can be described as a '*measure of the finely spaced surface irregularities'*. This also comes from the inherent action of the manufacturing or surface finishing process. Flaws can be categorised as irregularities that occur in random individual locations, at varying distance from each other. Random scratches or pits can be classed as flaws. (Bewoor and Kulkarni, 2009)

It can be said that roughness is superimposed on waviness, which is superimposed on form. This may be a particularly important point when dealing with layer manufactured components, where it has been suggested that there is a secondary 'micro' surface roughness on the z surfaces of the layers. The difference in roughness, waviness and form can be seen in Figure 68.

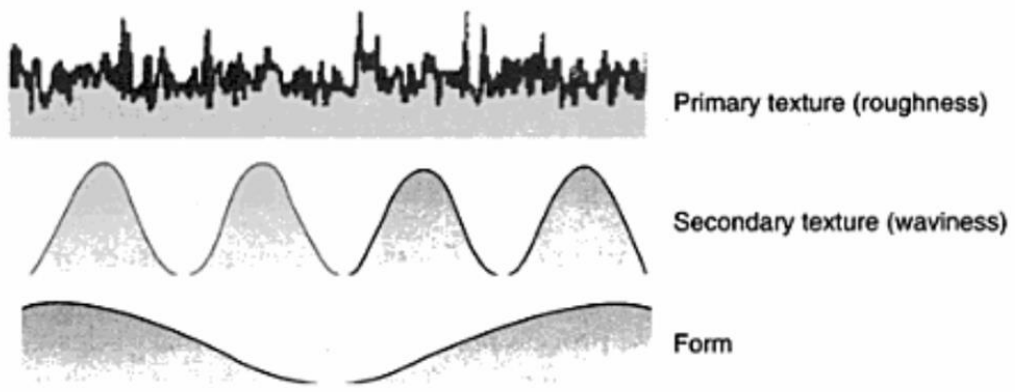


Figure 68: Roughness, waviness and form (Bewoor and Kulkarni, 2009)

7.2 Method

Samples of the conventionally-made bar structures and CAD/CAM bar structures were used in this study, which were obtained as described in the earlier phases of the PhD study.

Observations and measurements were taken of the retention mechanism samples in the Mitutoyo Metrology Laboratory Cardiff University, School of Engineering. The two aspects studied in this chapter were surface roughness and dimensional accuracy. To measure these aspects, it was possible to take two approaches:

- Visual inspection of the surfaces and geometric features. This is a process of qualitative observation.
- Direct instrument measurements, a quantitative approach which deals with obtaining numerical values to describe the surface and dimensional features.

7.2.1 Visual inspection

Subjective inspection was performed on all samples. The surfaces and dimensional aspects of the components were inspected qualitatively to attempt to identify dimensional flaws and surface defects. Surface roughness measurements can sometimes disregard imperfections in the surface and so simple microscope observations are an important part of analysing the quality of the components. Observations were taken

with a *Dino-Lite Digital Microscope.* Images using the microscope were used to identify larger pits, scratches, and other larger surface imperfections. The images were used to understand the surface quality of the various processes visually, and to support the quantifiable values.

Qualitative inspection can include information on characteristics or irregularities of the surface that cannot be described numerically. Patterns on the surface can be described, which can often be representative of a particular manufacturing process. The qualitative aspects can be useful to support the quantitative data.

7.2.2 Surface roughness measurements

Surface roughness can be measured by contact or non-contact methods. Contact methods involve dragging a stylus across the surface of a component. Non-contact instruments means that the surface is not altered during the measurement process, which means improved reliability during multiple measurements of the same location.

Surface roughness measurements were taken only on the metallic samples. There were two reasons for this. Firstly, the polymeric and ceramic bar structures could not be measured due to the limitations of the selected machine. The metallic bars offered enough reflectivity to detect their surfaces, whilst the polymeric and ceramic bar structure surfaces were too faint or transparent to detect. This meant that only the metallic bar structures could be measured for surface roughness using the available interferometer (MicroXAM White Light). A contact stylus device would not have been appropriate because the hard stylus may scratch the surfaces, 'build-up' burrs of resin and produce errors or inconsistent results. Another difficulty with some of the AM non-metallics was the nature of the support structure, by visual inspection, not all of the support material could be removed for sufficient measurement (this is highlighted in the dimensional accuracy results especially). This may affect the results.

7.2.2.1 Instrumentation

To measure the surface roughness of the test samples, a MicroXAM White Light Interferometer (KLA-Tencor) (Figure 69) was used, with accompanying MapVue EX

surface mapping software (ADE/Phase Shift). This is a non-contact device, which means that the surface is not altered by the downward force of a stylus tip with other contact-based (destructive) methods. This is especially important when taking multiple of measurements of softer materials like gold, where scratches can occur easily - measurements can be skewed by the scratches produced by the stylus tip.

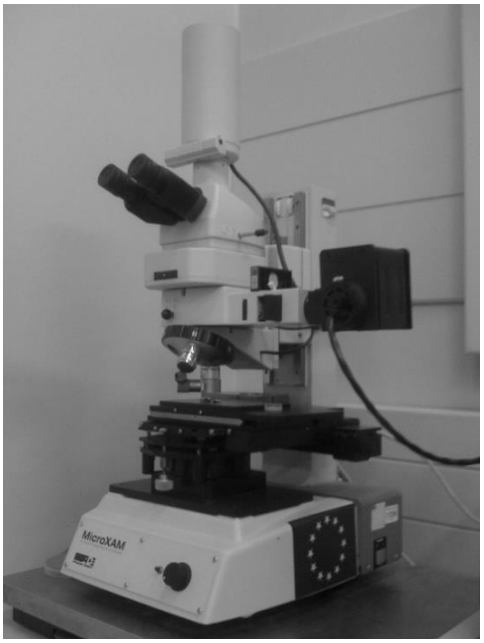


Figure 69: MicroXAM White Light interferometer

White light interferometry is a well-developed measurement technique for optical measurements. The system works by coherence peak sensing, where the fringe pattern of a component's surface changes in relation to its topography. The instrument was used to measure different locations on the bar structure samples. The locations of interest are illustrated in Figure 70 and Figure 71. By focusing on the surface of the part at its highest point (in z axis), the machine moves vertically, processing images at 30 frames/sec (rolled sheet analysis). The sequence of images is captured from the deformed fringe patterns, and the component's surface topography is generated. Therefore, a series of images are generated that produce a topographical representation of the component in a particular location, and this can give the user an understanding of its surface roughness through topographical imagery and numerical data (typically Ra). The analysis software can automatically remove the curvature of the bar to calculate the roughness.

Machine set-up

Scanning parameters:

- Accuracy at nanometre level
- Noise threshold: 0.03
- Scan length (depth): 50µm (0.050mm)
- Magnification: 10x (2x5)
- Rolled Sheet set up:
- High pass filter ON
- Filter cut off: 800µm (0.800mm)

Mask set up

- Mask 1 length: 801.9µm
- Mask 2 length: 797.5µm, width 192.8µm

Roughness Parameters

- Ra

7.2.2.2 Surface roughness parameters

There are a number of parameters that can describe the surface roughness of a component (Leach, 2001). This study focuses on Ra values, which relate to average surface roughness.

The Ra value can be described as the *'arithmetical mean deviation of the assessed profile',* or in other words, the average roughness of a given surface. This is an important and probably the most commonly used parameter for surface roughness. Ra is obtained by calculating the average height of all the peaks and troughs of a surface, from the mean line within a sampling length. Ra averages the surface profile, so actually it might not describe everything about the topography of a component's surface. Surfaces can have the same Ra value, but they can actually be quite different. Ra is not so useful for detecting the presence of single extreme peaks or valleys, which will only have a small influence on the value, and the Ra value does not provide direct insight into the shape or cause of a surface's imperfections.

7.2.2.3 Filtering

A surface profile can be described by its form, waviness and roughness, each descending in size respectively. Filtering can be used to reject irrelevant or insignificant information. A roughness filter can be used when measuring a surface to isolate the smaller wavelengths associated with roughness. This means that the longer wavelengths associated with form and waviness are filtered and this allows the roughness to be observed in isolation. A *low pass* filter rejects short wavelengths, such as frequencies associated with roughness, and a *high pass* achieves the opposite – rejects the longer wavelengths associated with form and waviness and preserves the shorter roughness wavelengths. A high pass filter was therefore used to preserve the roughness of the samples.

7.2.2.4 Measurement points/locations

The machine could be used to measure different locations on the bar structure (top and bottom). m1, m3, m4 and m6 are the surfaces around the joint areas between the collar and bar. m2 and m5 are in the central area of the bar structure. The locations were chosen because they are interacting with the clips, and also the welded areas on the joints are prone to pitting and imperfections. Each bar sample was measured in these locations, providing 6 measurements per bar. Cut off length is the length of the measurement taken across the surface in focus. A longer cut off length means an average value over a longer surface. A cut off length of 800µm and a scanning depth of 50µm was chosen so that an appropriate portion of the sample could be observed in the critical areas.

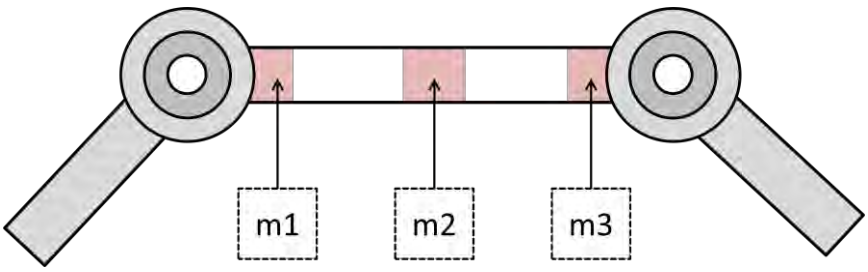


Figure 70: Surface roughness zones of interest top surface

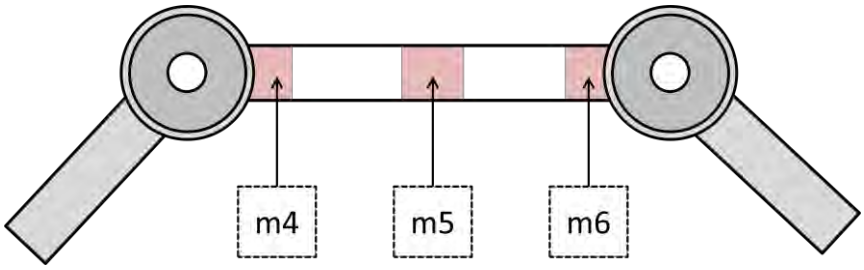


Figure 71: Surface roughness zones of interest bottom surface

7.2.3 Dimensional accuracy measurements

7.2.3.1 Instrumentation

To measure the dimensional accuracies of the test samples, An ACCEL Quick Vision Pro (Mitutoyo) microscope (Figure 72) with QuickVisonPAC accompanying measurement software was used.

Figure 72: ACCEL Quick Vision Pro Microscope

Two light settings were used to focus on sections of the retention bar structure samples. For open features where light could pass beyond the feature, a stage light was used (from below) which produced a contrasting, silhouetted image (Figure 73). For closed

features where light could not pass beyond the feature, a coaxial light was used (light from the top) which produced a clear image of the surfaces (Figure 74).

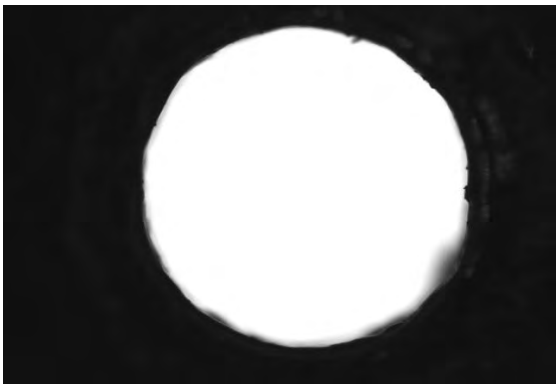


Figure 73: Stage light (from below)

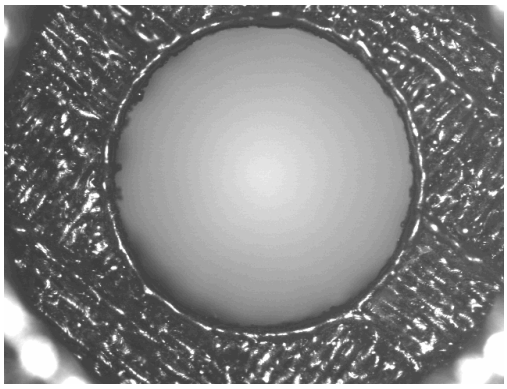


Figure 74: Coaxial light (from above)

Machine set up

- Magnification: 2,500x
- Machine accuracy x=5µm, y=6µm
- Lights: Stage & Coaxial
- Auto-focus applied after location defined

7.2.3.2 Parameters

The microscope was used to measure the dimensional accuracy of key geometric features on the samples. The features measured are illustrated in Figure 75, H1, H2, H3 and H4 deal with the circularity and diameter of the holes. S1 and S2 focuses on the straightness of the long bar section at each side. L1, L2, L3 deal with the width of the bar at three locations along the length of the middle bar section. The data could be compared to the samples true values (original proposed designs) to gauge and quantify the accuracies.

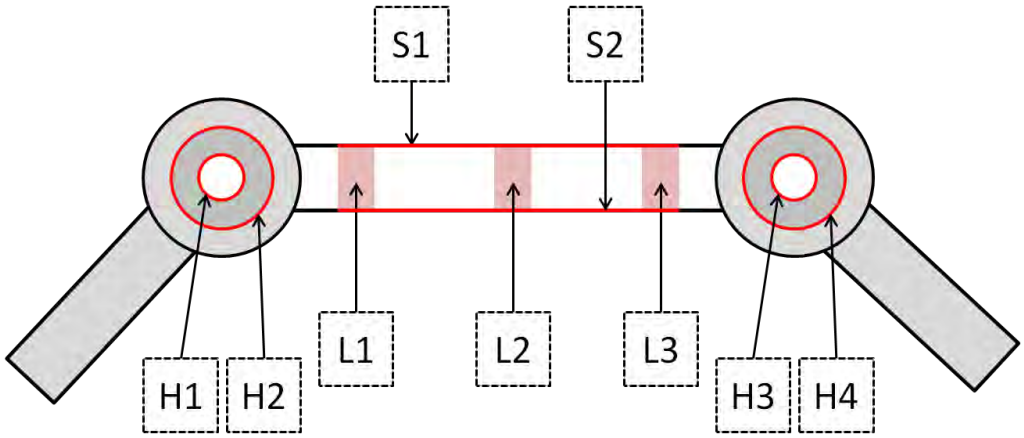


Figure 75: Dimensional measurement parameters

The measurement of the diameter and circularity of holes and shafts is an important aspect to manufacturing functional components. The diameter hole can be measured and compared to its theoretical value i.e. the intended design. However, the diameter of a hole or shaft provides a limited description of accuracy. The diameter of a hole at two different points could be measured at the same value, but this may not mean that the hole is circular. The accuracy of form is equally as important as the dimensional accuracy of the features, and without circularity, the parts may not fit or function during use. Error of circularity can be quantified by determining the difference between the maximum profile and the minimum profile of the fabricated hole. Width and straightness of the bar sections are also important aspects to measure, because these areas on the bar will have direct contact with the rider clip. In conventional practice, inaccuracies may be overcome by the manual adjustment of the clip, but this is approach cannot control wear or misalignment of components.

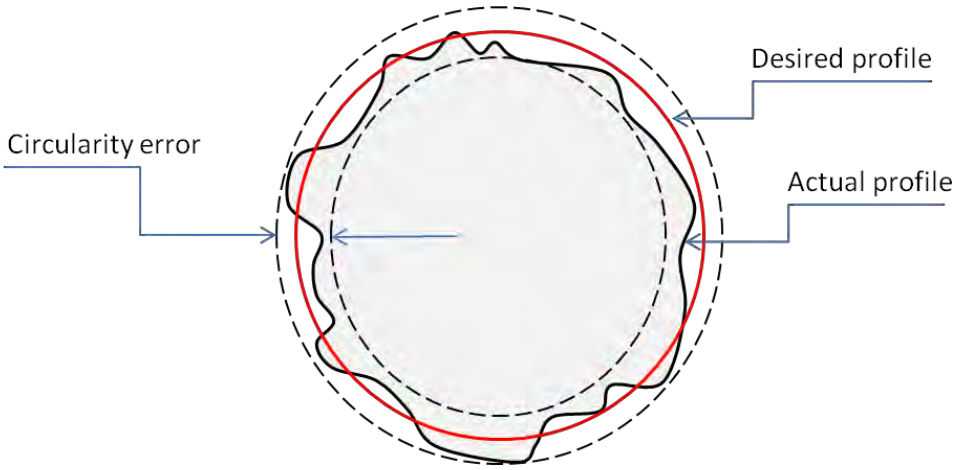


Figure 76: Circularity of a hole

The theoretical dimensional values of the geometric features of the CAD model and conventional bar structure are presented in Table 16 (differences in dimensions relate to the screw diameter and design of the clips). The dimensional values of the conventional structure are based on the manufacturer's suggested dimensions. Important to note that these are theoretical values, the 'design intent' of the manufacturer, and these will be used as comparable values to determine the accuracy of the actual manufactured samples. The CAD bar structure values describe the virtual model dimensions, which will also be used to determine the accuracy of the actual manufactured samples later in this chapter. Perfect circularity/straightness is 0. Values >0 describe the degree of out-of-circularity / straightness.

	Design intent	
Feature	**Conventional bar structure**	**CAD bar structure**
H1, H3 Hole diameter	1.55mm	1.5mm
H2, H4 Hole diameter	3mm	2.5mm
H1,H2,H3,H4 Hole Circularity	0mm	0mm
L1, L2, L3 width	1.9mm	2mm
S1, S2 Straightness	0mm	0mm

Table 16: Theoretical dimensional values for conventional and CAD bar structures (design intent)

7.2.3.3 Measurement process

To obtain the values for the various geometric parameters the components were measured by selecting a series of points on the edge of the shape where the component was fully contrasting the light. In some cases this was achieved manually and in some cases automated, but this depended on the quality of the contrasting image.

It can be seen in Figure 77 and Figure 78, that the general area under focus (the edge of the shape in focus) was highlighted. In Figure 77 the red circles enclose the circular silhouette of the hole. Points along the edge of the hole were then selected automatically. As more points are selected, the shape is described to a higher level of accuracy. Figure 78 shows the edge of the bar feature, where a series of points could be selected along the contrasting edge. This was conducted along the entire length of the bar and the straightness was recorded.

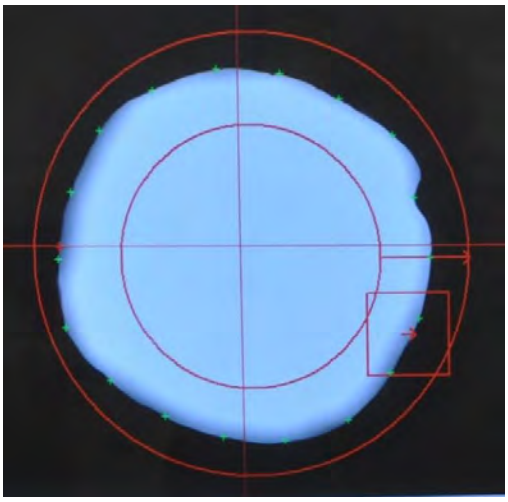


Figure 77: Circularity and diameter of hole features

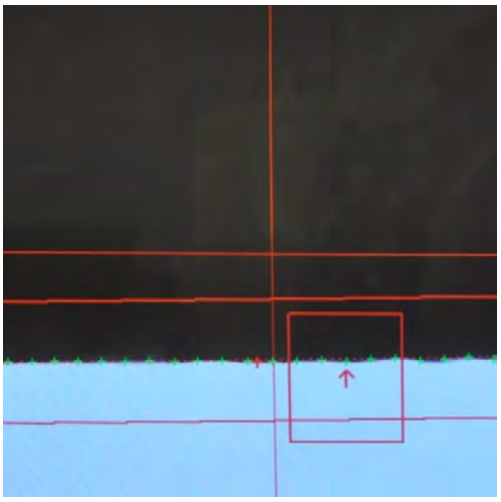


Figure 78: Straightness and width of bar length

Some of the potential errors should be considered when evaluating the geometric accuracy of the parts. . Two influencing factors of error during the measurement process were:

- Rounded edges on the holes – vague edge representation.
- Support structure or flashing impairing on measurement. i.e. choosing points on unwanted material – misleading edge representation.

Care was taken to overcome these errors by seeking expert guidance in identifying the edges, and eliminating any samples that were impaired by too much support structures / flashing.

7.3 Qualitative Results

A series of qualitative observations were made on the bar structure samples to support the quantitative data. Inspecting the components by eye is useful for making conclusions on patterns and defects regarding form and surface /irregularities.

7.3.1 Conventional sample characteristics (those fabricated by MPTs)

A smooth, complete weld may have imperfections that are difficult to be seen by eye, and especially due to the reflectivity of the polished material, these imperfections may be difficult to trace and be misleading (Figure 79). Many of the samples were presented with incomplete welds and excess solder on critical areas of the structure.

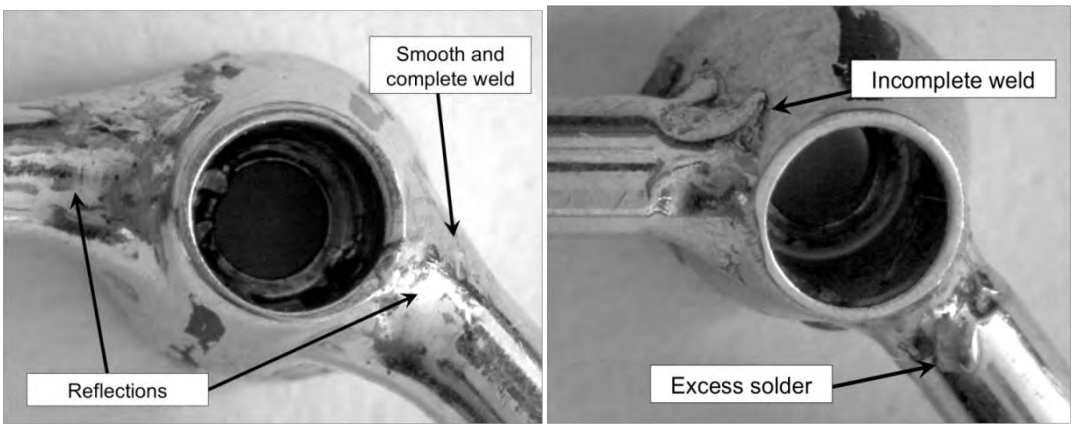


Figure 79: Conventional bar structure characteristics (bar section width ≈ 2mm)

The conventional samples showed a general surface smoothness, but all of the samples displayed prominent irregularities that could be identified by eye. Pitting especially occurred on the welded joins (see Figure 80) and this could potentially present regions for bacterial growth.

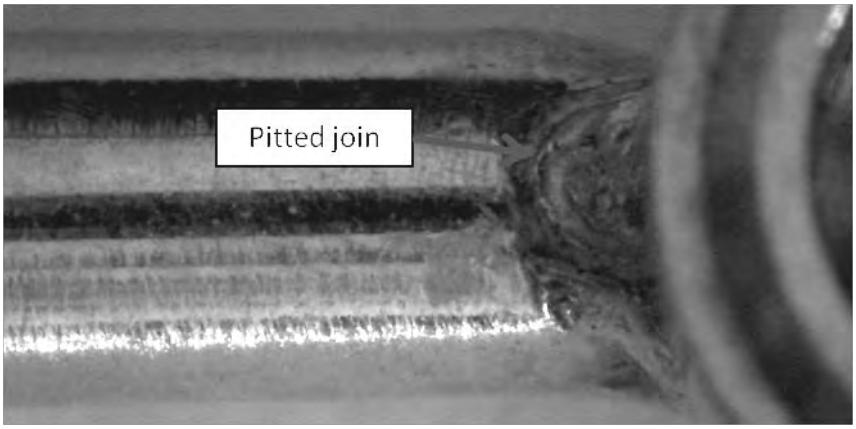


Figure 80: Incomplete and pitted join

The conventional samples varied in quality - the edges of the abutment-collar interface were well defined on some of the samples, but appeared misshapen on others, as illustrated in Figure 81.

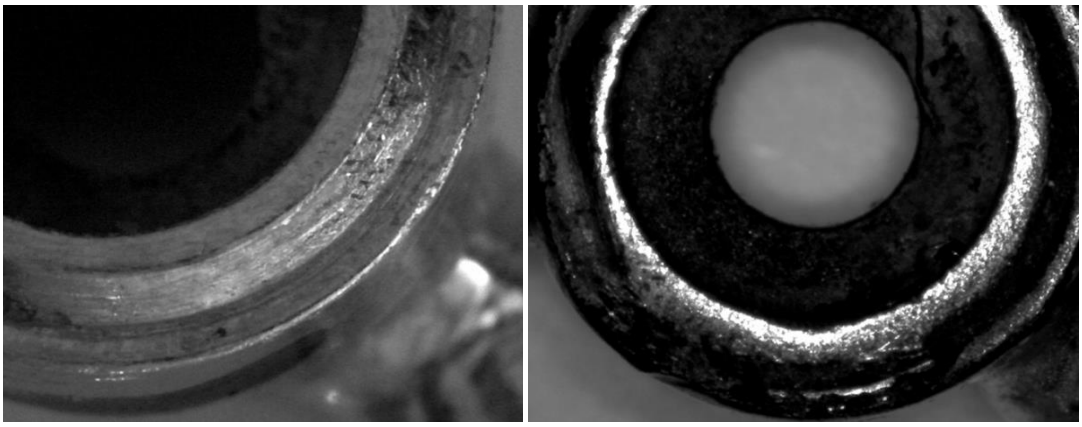


Figure 81: Well-defined and misshapen edges

Other regions of the bar structure also appeared misshapen, such as the cylindrical bar sections and top facing entry holes, as illustrated in Figure 82.

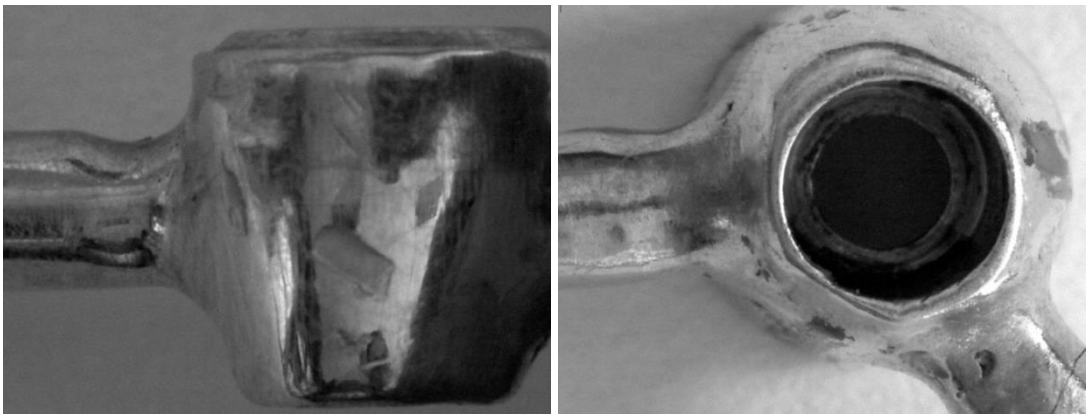
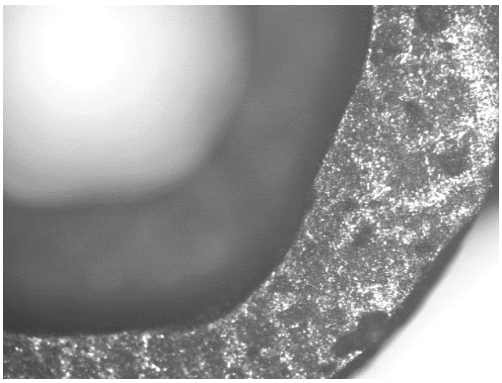
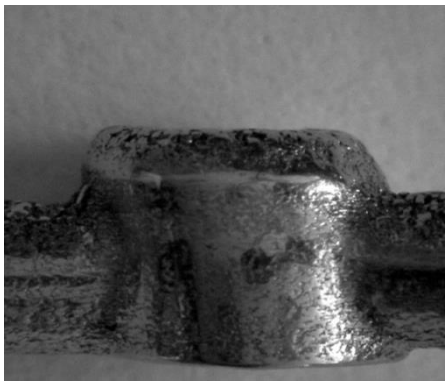


Figure 82: Misshapen regions on the samples

7.3.2 CAD/CAM sample characteristics

7.3.2.1 Misshapen geometric features

The examples in figure 83 highlight issues with the overall form that may affect the performance of the bar structures.

a.  b. 

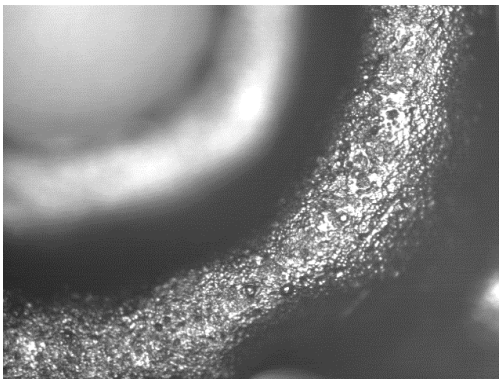
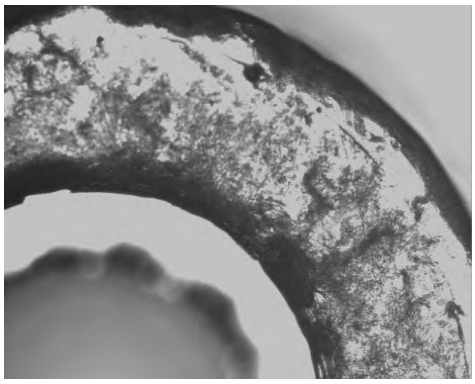
c.  d. 

Figure 83: Misshapen features

Notes: a) DMLS - prominently misshapen hole; b) MLab laser cusing- general distortion and inconsistency in build; c) 3DDC electroplated - rounded edges; d) Morganics electroformed - rounded edges

In figure *a* and *b*, distorted geometric form can clearly be seen. Figure *b* displays an extreme amount of distortion, appearing as if there has been a large shift in the horizontal build during AM. Figures *c* and *d*, show an idiosyncrasy of wrapping or 'growing' material around another object – the edges are no longer prominent, they have been 'drowned' in material and there is no longer fine definition of the edge. This is particularly important for the integrity for functional fitting surfaces.

7.3.2.2 Hand finishing required

Some of the samples would require hand finishing in order to achieve an acceptable level of quality. Examples of this are shown in Figure 84. Images *a* and *b* illustrate the bubbles produced during the casting processes. Even after polishing the brass sample (*b*), a bubble remains within one of the fitting holes, out of reach of the polishing. The flashing (unwanted excess material from production method) would require removal by using specialised hand tools - such methods are already being used in the conventional process. Sprue flashing is illustrated in figures *c* and *b*. Excess material could cause complications and inaccuracies in the fit of the mating components, and potentially provide breeding grounds for bacteria.

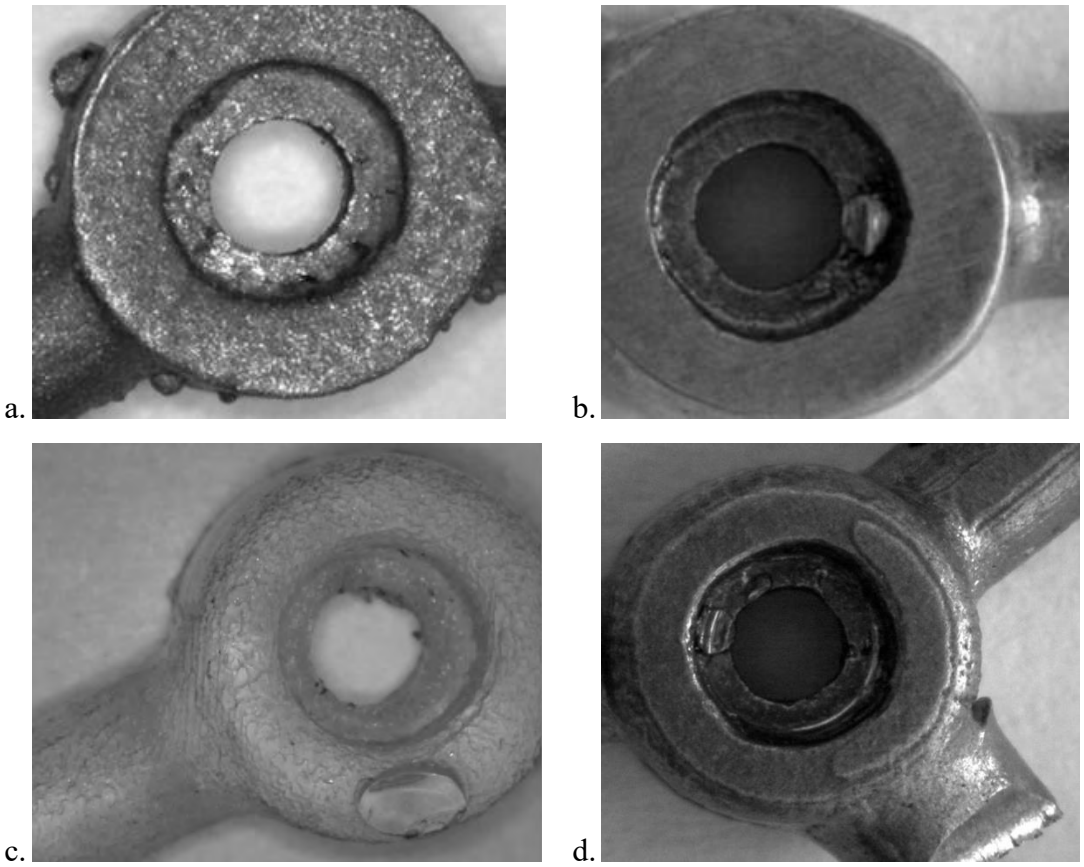


Figure 84: Samples requiring hand finishing

Notes: a. Dental Investment Cast – bubbles on outer surface need removal, b. Polished cast brass – bubbles inside screw holes difficult to remove, c. Vacuum Cast –sprue flash needs removal, d. Cast brass –sprue flash needs removal

7.3.2.3 Additive manufacturing - 'stair-stepping' effect and roughness variability

The characteristic stair stepping affect in AM models was observed. As seen in figure 85, the effect was prominent on some of the samples. There were clear ledges on the surface of the component, but this may not describe the true surface roughness of the component. The ledges may contribute to the roughness value of the component, assuming the layer thickness is within the range of surface roughness measurement (unfiltered, or disregarded as waviness). The secondary surface finish can be examined in Figures *a* and *b*. This lies between the layer ledges. In figure *a*, the secondary surface of the SLA component appears smooth, but possesses a significant stair-stepping structure. Such components may provide promising results, if the stair-stepping affect can be reduced. The surface roughness values of the samples may depend on both the

stair-stepping affect and the secondary roughness. Individual values need to be determined for the roughness values of both primary and secondary roughness.

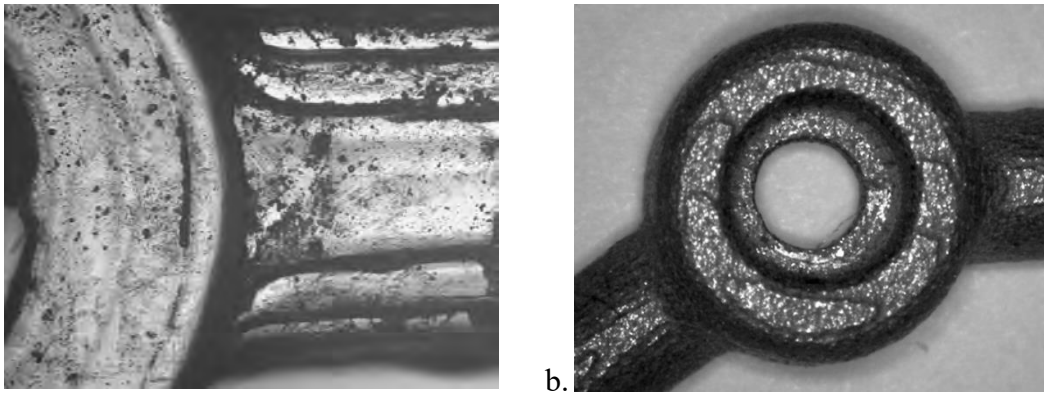


Figure 85: Stair-stepping effect of AM

Notes: a. SLA extreme resin – stepped profile; b. FCubic – stepped profile and distinguishable from secondary roughness

The variability in texture was also observed in a number of the AM samples. The Laser Cusing sample clearly displayed this characteristic, shown in figure 86. Based on observations noted in previous literature, it can be suggested that this characteristic may be directly related to build orientation. This can mean that varying surface orientations may adopt their own unique surface textures.

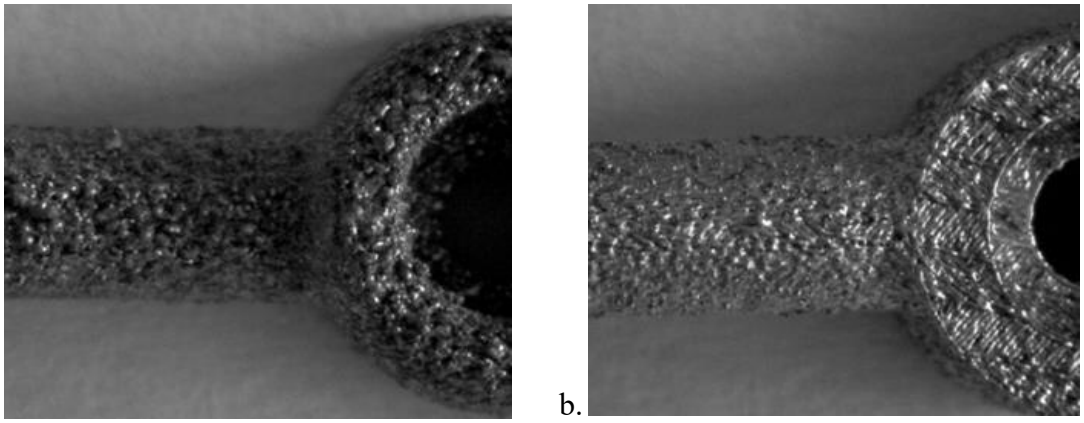


Figure 86: Laser Cusing roughness variability

Notes: a. Laser Cusing Top surface, b. Laser Cusing Bottom surface

7.3.2.4 Prominent texture and patterns

The Mlab Laser Cusing samples demonstrate the significant texture patterns of additive manufacturing (Figure 87). Figure 87*a* shows the unpolished sample, where a cross-hatched pattern dominates the surface. Figure 87*b* shows the sample post-polishing, where it is evident that the texture is not removed. The main peaks have been flattened but pits of various sizes remain clearly on the surface. Also important to note, is that the polishing method could not reach the inner surfaces, and these surfaces could not be smoothed at all.

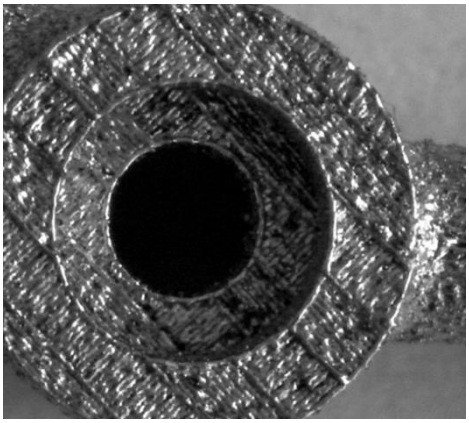
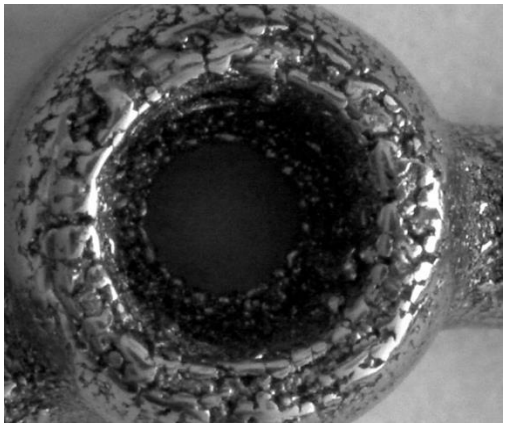
a.  b. 

Figure 87: Texture and patterns

Notes: a. Unpolished laser cusing – Prominent grooved texture, b. Polished laser cusing – Prominent grooved texture not removed

The Objet ABS-like sample exhibited surface characteristics that appeared as what could be described as 'flaky' (Figure 88a). The edges of the layers appear jagged, and the horizontal surfaces appear relatively smooth. This means that this will particularly affect vertically facing surfaces. The flakiness caused by the inaccurate edges of the layers may affect the dimensional integrity of the sample. Other samples displayed 'graininess' (SLM sample, Figure 88b). The exhibited surface characteristic may provide ideal conditions for harbouring bacteria; therefore the appropriateness of the surface finish, even before assigning a surface roughness value, should be questioned.

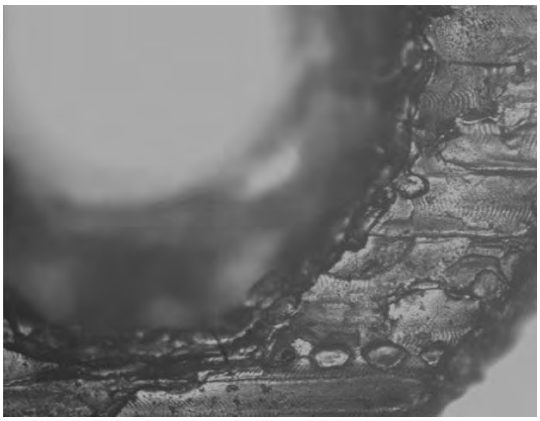
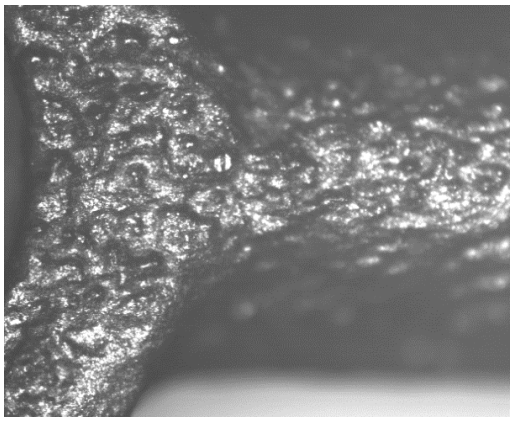
a.  b. 

Figure 88: Poor surface finish

Notes: a. Objet ABS-like – flaky surface, b. SLM – Highly pitted surface

7.3.2.5 Promising visual results

Some samples offered promising results by the initial qualitative inspection, for example the CNC milled Zirconia sample (figure 89).

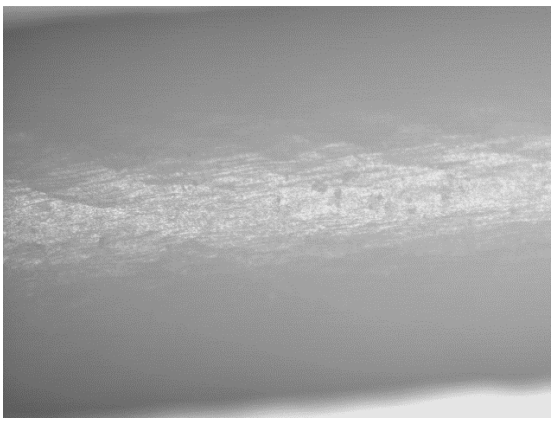
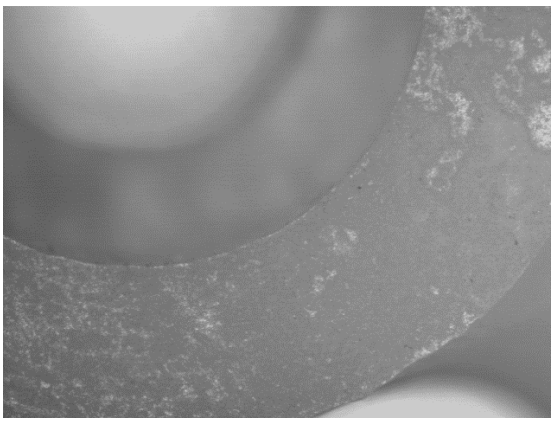
a.  b. 

Figure 89: Milled Zirconia

Notes: a. Smooth cuts and non-pitted, promising surface; b. Visually sound geometry

Without measuring the surface roughness, a significant difference can be seen between this sample and some of the metal additive manufacturing surface finishes. This surface appears very smooth. The Ra value of this sample could not however be measured in this study due to the limitations of the machine, but this value should be determined in future studies. The geometric integrity of the part was also visually promising, as shown

in the hole and wall thickness appearing to be consistent. This is also shown by the Envisiontec Perfactory sample (Figure 90). The definition for this part is high, and offers very desirable geometric integrity. The elimination of welding/soldering means reduced risk of incomplete joins with an improved filleting between part sections. This can clearly be seen in Figure 90.

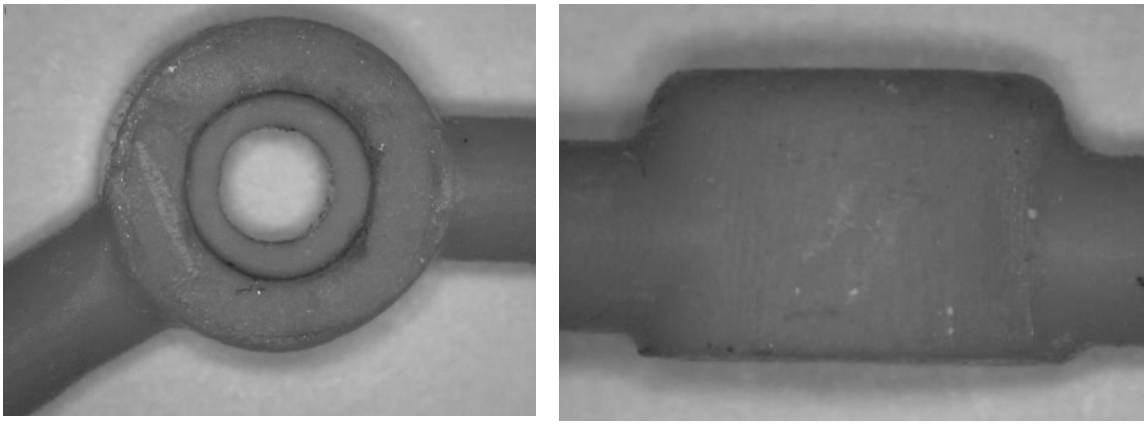


Figure 90: Envisiontec Perfactory - high definition and stable geometry

An interesting characteristic of the electroformed/plated samples (Figure 91) was that the edges had been rounded due to the nature of the process of 'growing' material on the AM parts. This characteristic may be desirable if the elimination of sharp edges is required.

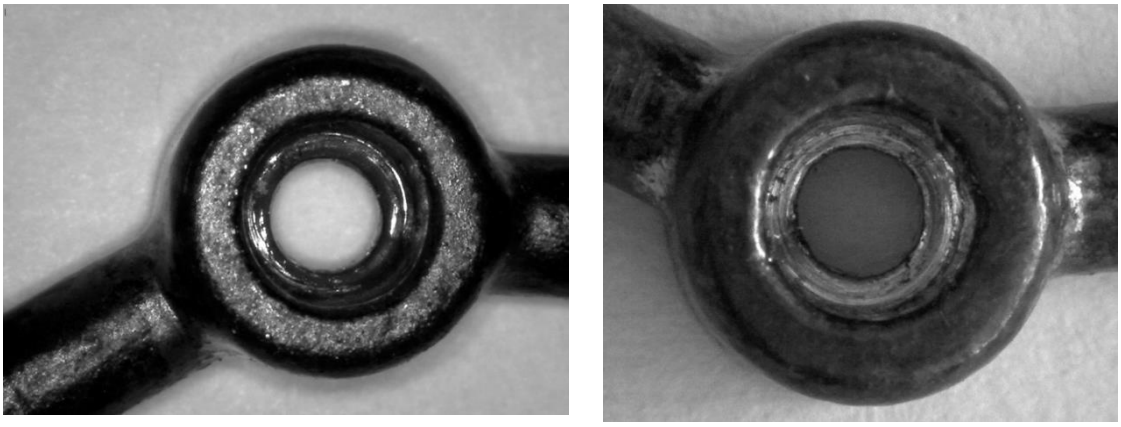


Figure 91: Electroformed samples (3DDC & Morganics) – visually smooth surfaces and no edges

The qualitative characteristics of the samples are summarised in Table 17.

Sample Group	QUALI observations
Conventional	Some prominent pitting and scratches around welds Noticeably unfinished welds, also excess solder present Highly polished, reflective surfaces, well defined edges of copings Samples varied in fabrication quality
Cast	Post processing required to remove flashing caused by air bubbles and sprues Stair stepping affect present
CNC machined	Zirconia: Smooth surfaces, well defined edges and geometric features PEEK: An irregular form on the bar length, tool cuts visible
Electroformed	'Drowning-out' of edges, uneven coatings of material Appearance of smooth surfaces, but varied on location – some features were highly pitted and inconsistent.
AM metal	Varied results (process dependent) Stair stepping effect prominent on some samples Part orientation determined nature of surfaces Some metal AM (Laser Cusing) largely deformed features and highly pitted FCubic sample most visually promising of AM metals
AM polymer	Varied results (process dependent) Support material could not be fully removed on every sample Stair-stepping effect very prominent on some samples, could not be seen on others Part orientation determined nature of surfaces Polymer samples dimensionally stable in appearance

Table 17: Qualitative characteristics of sample groups

7.4 Quantitative results

The individual measurement values of the surface roughness and dimensional accuracies of all samples can be viewed in Appendix VI. The results are described in this section.

7.4.1 Average surface roughness (Ra)

Five conventional bar samples were measured and one sample was used for each of the CAD/CAM processes. Every bar was measured on three locations on each side,

providing six measurements per sample. The measurement locations can be referred to in Figure 70 and Figure 71. Figure 92 shows the standard deviations (illustrated by lines) and mean values (of six measurements) of Ra values for all samples.

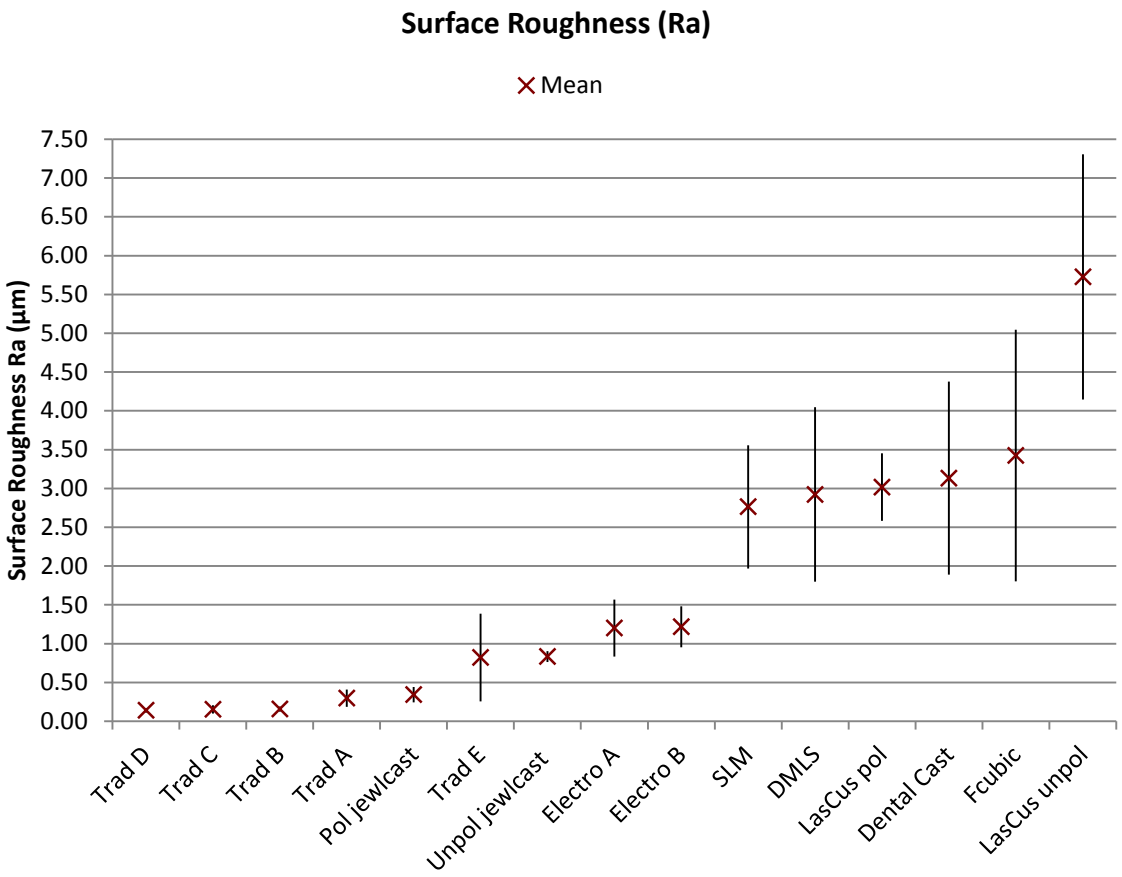


Figure 92: Surface roughness (Ra) mean (6 measurements per sample) ± 1 Standard Deviation

The highest Ra value measured at 8.76µm for the unpolished Laser Cused bar structure, whereas the lowest Ra value obtained was 0.1µm by traditional bar structure 4. The mean values and standard deviations for four out of five of the traditional bars were smaller than all of the CAD/CAM bars, suggesting higher quality surfaces (smoother) across the various locations on four of the traditional samples. The exception was traditional bar E, which even showed a larger standard deviation than the electroplated samples (electro A, B) and the polished laser cusing sample (LasCus pol). The range (min - max) of Ra measurements for the five traditional samples varied between *0.1 – 1.51 µm*.

The jewellery cast samples (unpol jewlcast, pol jewlcast) also show consistent results by displaying small standard deviations in comparison with the other CAD/CAM bars. By polishing the jewellery cast sample, the Ra value is brought close to the values of the traditional bars. The electroplated/formed samples offered promising results, and their mean also fell within the range measured on the traditional samples.

The standard deviation of measurements for SLM and DMLS samples was similar, and in fact, the mean values of SLM, DMLS and Fcubic were similar to the dental cast sample. This meant that these AM processes can match Ra values of an unpolished dental cast bar, without extra surface finishing. This is an important finding because many have advocated casting as a well-suited alternative for dental bar structure fabrication.

The mean value of the traditional bar structures lies at 0.31µm but the highest Ra value was measured at 1.51µm. This suggests that the Ra values of the traditional bars may coincide with bacterial colonisation (some literature suggested a reduction of bacterial adhesion at Ra ≤0.2µm or ≥1.86µm), but how this translates clinically must be further investigated, and consideration must be given to the relatively little evidence supporting these figures.

To support the qualitative data seen in Figure 86, there was a clear difference in Ra values in the top and bottom surfaces on the AM samples, presented in Figure 93. As an example, the unpolished laser cusing sample was measured at Top=4.80µm, Bottom=6.65µm. This corresponded well with previous research which focused on the effect of build orientation of AM components on surface roughness. The traditional samples showed less variability on either side of the bar samples, where differences were measured at the 0.1µm level. Further investigation is required to determine the impact of these differences in bar structure design.

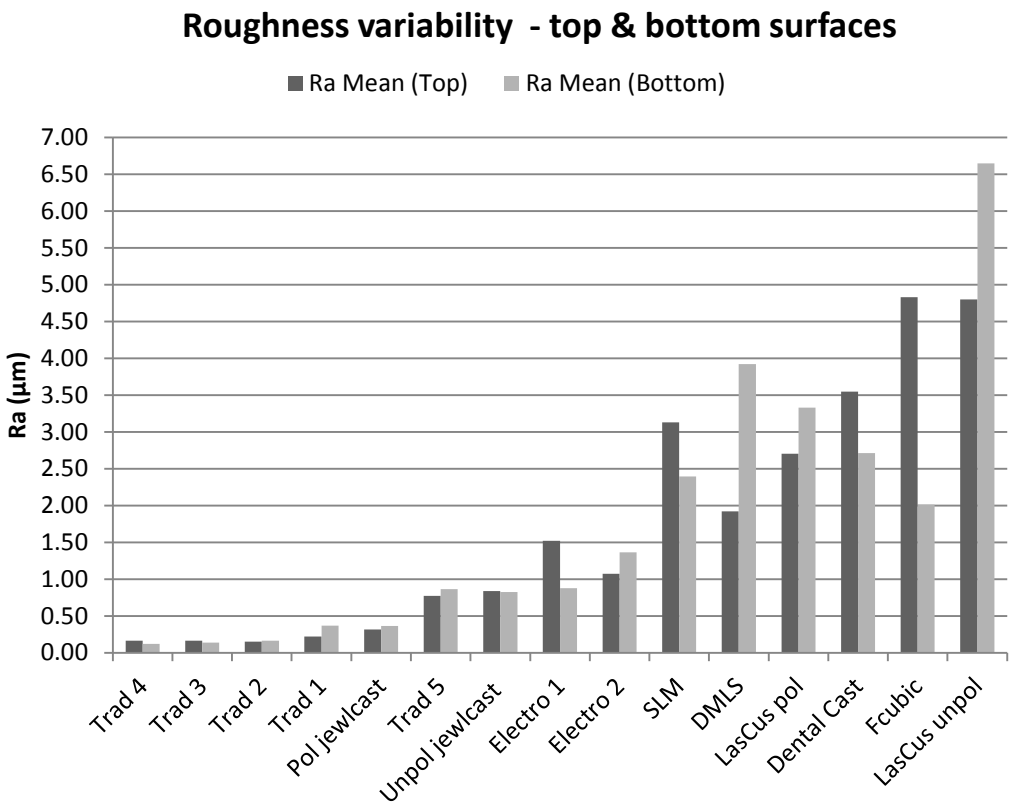


Figure 93: Roughness (Ra) variability - top and bottom surfaces (3 measurements per side)

In conclusion, these qualitative and quantitative results provide an initial indication of the surface roughness characteristics of the various processes, and show that conventional fabrication and polishing techniques provide a smoother surface finish than the CAD/CAM samples. Further investigation must be considered into surface finishing techniques for the CAD/CAM bars, and a higher number of samples of the most promising processes must be analysed.

7.4.2 Dimensional accuracy

Selected AM samples (*SLA Accura25, Objet PP, SLS DuraEX, Objet Vero*) were excluded from the analysis because the visual obstruction of excess AM support material could not allow the component's edges to be defined clearly. However, the results of the available dimensional measurements are presented.

Firstly, the benchmark tolerance limits set by the traditional bar structures were defined. Following this, the CAD/CAM samples were evaluated to determine if they could provide comparable geometric accuracy. All accuracy results can be viewed in

Appendix VI, which were obtained by subtracting the measured value from the theoretical value defined earlier in Table 16.

2 values were considered in the development of the benchmark tolerance limits.

- The mean dimensional values for all conventional bar features (e.g. all through-holes).
- The single largest ± value (high value = low accuracy) from the 5 conventional samples for each parameter.

The results are presented in Table 18.

Benchmark tolerance limits (*µm*):		
Geometric features	**A:** Mean of all trad. samples	**B:** Max. single measurement
Diameter of through-holes	± 10 µm	± 40 µm
Circularity of though-holes	± 20 µm	± 50 µm
Diameter of blind-holes	± 50 µm	± 92 µm
Circularity of blind-holes	± 30 µm	± 60 µm
Bar section width	± 60 µm	± 110 µm
Bar section straightness	± 120 µm	± 290 µm

Table 18: Benchmark values (defined by conv. samples)

Table 19**Error! Reference source not found.** presents how the CAD/CAM bar structures performed compared to the benchmark tolerance limits set by the conventional bar structures. The table shows the comparison of the ***mean value*** of all features from individual CAD/CAM samples (e.g. all through-holes per sample) vs. ***mean value*** of all features from all conventional samples (e.g. all through-holes from all samples).

xμm	CAD/CAM accuracy value falls within benchmark tolerance limit (≤x)
xμm	CAD/CAM accuracy value falls outside benchmark tolerance limit (≥x)

	AM							Cast			Milled	
Parameter	SLM	DMLS	LaC pol	LaC unpol	FCubic	Elect.	Env.	JCpol	JC unpol	Dent Cast	Zirc.	PEEK
Ø thru	10	10	80	60	20	20	30	90	110	70	110	50
Ø blind	240	50	210	230	180	60	30	60	120	70	200	30
Circ. thru	40	50	60	50	40	40	50	60	60	50	30	80
Circ. blind	120	140	50	50	90	90	70	60	90	130	30	90
Bar width	30	50	60	20	90	20	60	150	50	80	10	130
Straightness	180	110	50	140	70	110	70	30	70	220	80	510

Table 19: Mean value CAD/CAM feature accuracy vs. Mean value Conventional feature accuracy (μm)

The overall results show that when comparing the CAD/CAM samples to the mean benchmark tolerance limits, the CAD/CAM samples do not achieve good hole accuracy comparable to the conventional samples. However, the CAD/CAM bar section accuracies (width & straightness) are comparable to the benchmark values. This suggests that polished areas of the conventional bars provide achievable benchmark tolerances for CAD/CAM fabrication. The DMLS sample shows the most promising result overall (4/6 parameters ≤ x).

7.5 Chapter summary

This chapter focused on evaluating the surface roughness and dimensional tolerances of conventionally-made bar structures and a variety of CAD/CAM-made bar structures. The selected measurement methods provided an initial indication of the technical characteristics associated with conventional fabrication, direct AM, casting AM components, electroforming AM components and milling. Both qualitative and quantitative data was used to support the study. The quantitative measurements provided two sets of results. Firstly benchmark tolerance limits for predefined parameters, (set by the conventionally-made samples (Table 18)) were presented. Secondly these values were used as to determine if the CAD/CAM processes could achieve comparable dimensional accuracies.

In conclusion, the results show that conventional fabrication and polishing techniques provide lower average roughness (Ra) than the CAD/CAM samples, but they also show that the surface and geometric integrity of the features do not match the true design intent of the MPT. All conventional bars were influenced by pitting, incomplete welds, and over-polishing/grinding in the clip regions. This meant that the conventional samples varied in quality, and shows that the design requirements defined by the MPTs during phase B are not fully satisfied with current methods (i.e. highly polished surface finish, eliminate pitting and produce complete welds, no over-finishing of bar sections).

The CAD/CAM bars also varied in quality. Cast bars, Milled, Electroplated and Additively Manufactured all produced varying results, smost of which were of a lower quality in terms of surface roughness and geometric accuracy than the conventional bars. The findings indicated that some of the bar samples however achieved promising results, showing that technically CAD/CAM could be used to achieve similar results to conventional methods. However, further work must be conducted to determine the precision of the CAD/CAM processes, due to the low volume of samples.

The dimensional tolerances may have been influenced by a number of factors for the various samples. However, the specific causes could not be pinpointed from the quantitative data, but some of the suggested factors are listed below in consideration of the qualitative data.

- Excess material, e.g. un-removed support material or flashing
- Surface irregularities
- Too much material removed during processing (cutting or polishing)
- Too much material added during processing (plating or AM layers)
- Warping of part during fabrication

All of the CAD/CAM processes measured would require further surface finishing or processing to reduce their surface roughness values within the benchmark roughness range. Further investigation must be considered into surface finishing techniques for the CAD/CAM bars, and a higher number of samples of the most promising processes must be analysed. This can help to inform future studies in retention mechanism design and CAD/CAM technical research studies.

Chapter 8: Accuracy of fit

8.1 Overview

An accurate fit of the bar structure-abutment interface was identified as an imperative design requirement earlier in the thesis. However, varying definitions of an acceptable accuracy of fit for abutment/bar structures have been suggested in the literature review. Methods of measuring accuracy of fit vary between practice and research. Abudo et al. (2010) published a thorough overview of the main methods (in vivo and in vitro) of measuring accuracy of fit, as described in the literature review. Few methods are able to measure the fit quantitatively, one of them will be used in this study, which has not yet been attempted in the extra-oral literature.

Distortions in implant frameworks can occur in the x, y, and z axis (Nicholls, 1977) but many measurement techniques fail to consider all of the axes. As noted in the literature and qualitative research phase, the parameter that is usually assessed in clinical practice, is the vertical gapping between the abutment and framework, and this relies on the accuracy of the human eye. However, a number of research studies in dental applications (described in the literature review) have used Coordinate Measuring Machines (CMM) to measure misfits (misalignment accuracy) in horizontal dimensions too. This technique has also not yet been properly translated to extra-oral retention bar frameworks.

The intricacy of the abutments makes them difficult to capture by scanning directly, so cylindrical registration elements can be connected to the abutments for the determination of the implant locations. As described in the literature review, the implant positions can be measured this way by CMM and the positional and directional coordinates can be exported (x,y,z, i,j,k). Following this, a virtual '*one-screw test'* can be conducted.

Therefore, this study focuses firstly on developing a CMM method to determine the accuracy of fit of extra-oral retention bar structures. Secondly, the conventionally-made

samples will be measured and provide a benchmark for comparison with the CAD/CAM bar samples.

8.2 Samples and models

8.2.1 Patient replica model

A model of a portion of a patient's head was designed using Geomagic Freeform (3D Systems Inc.) and manufactured by SLA (3D Systems Inc.). The model represented a missing right ear, with two implant abutments placed typically for the retention of an auricular prosthesis. The position and depth of the abutments were validated by MPTs at Morriston Hospital, Swansea. The abutments were bonded securely into the model and labelled. This model (figure 94) was used to represent a patient consistently throughout this study.

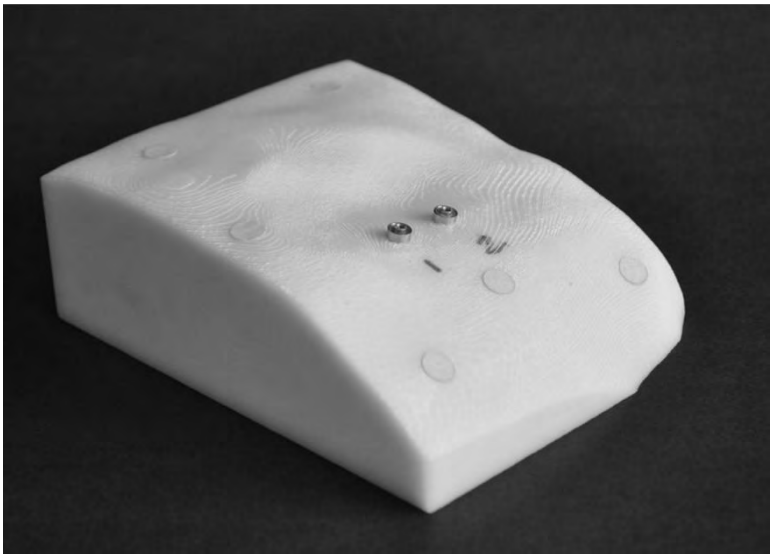


Figure 94: Plastic replica of patient's defected auricular region

8.2.2 Conventionally-made samples

The patient replica model was taken to 3 UK-based Maxillofacial Prosthetics laboratories. Four MPTs were asked to use the model to take a conventional impression

of the patient model, and produce a dental stone abutment-model (figure 95) – this process is described in detail in Chapter 5. Four stone abutment models were obtained.

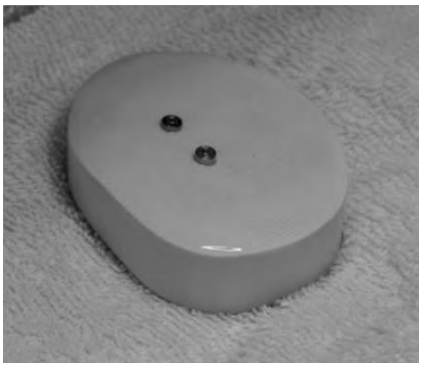


Figure 95: Dental stone model with abutments set in place

Using the abutment models, the MPTs were asked to fabricate a bar structure (same as used in Chapter 7), using their typically known conventional methods. Therefore, each conventionally-made bar structure was designed based on the patient replica model (figure 96).

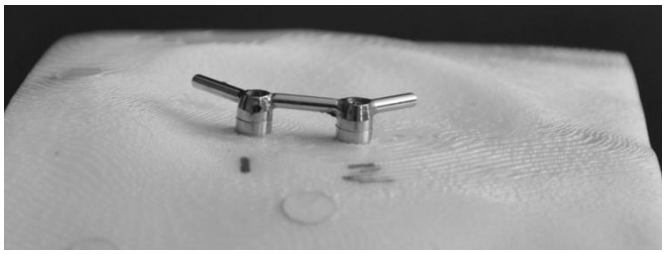


Figure 96: Conventionally-made bar structure fitted to patient replica model

8.2.3 CAD/CAM samples

The CAD/CAM bar structure was designed using processes described in Chapter 6, and used the previously reverse engineered positions of the abutments on the patient replica model. Samples used in this measurement study are listed.

1. **Dental investment cast from RP master (Cardiff Met.)**
   Solidscape 3D wax print, layers 13µm.
   Induction cast (CoCrMo)
2. **Jewellery investment cast from RP Master (Jewellery Industry Innovation Centre, Birmingham)**
   Solidscape 3D wax print, layers 13 µm.
   Centrifugal cast (Brass)
3. **Selective Laser Melting (SLM Solutions)**
   Titanium (TiAl6V4), Layer thickness 30µm
4. **Mlab Laser Cusing (Concept Laser Gmbh)**
   Remanium star CL (CoCrMo), layer thickness 50µm
5. **Direct Metal Laser Sintering (EOS DMLS)**
   Cobalt Chrome (CoCrMo), layer thickness 40µm
6. **Inkjet Metal Printing (Fcubic)**
   Stainless Steel (316L), resolution 20µm
7. **Electrodeposition on AM master (Morganic Metal Solutions)**
   3D Systems Projet EX200 base, layer 16µm
   Electroformed Copper coating of 100µm thickness
8. **Electrodeposition on AM master (3DDC)**
   3D Systems Projet EX200 base, layer 16µm
   Electroplated Copper coating of 100µm thickness
9. **Incise® Dental Milling (machining) - Zirconia (Renishaw)**
   Zirconium dioxide using Incise® Dental Miller
10. **CNC Machined PEEK (Invibio Biomaterial Solutions)**
    PEEK-OPTIMA (Polyetheretherketone) 250-500m/min cutting speed

Samples obtained previously that were more flexible by nature (e.g. Envisiontec) were excluded from this study - the tactile nature of the selected measurement technique meant that these samples were inappropriate for use. Therefore, only the higher rigidity samples were chosen for this study.

8.3 Instrumentation

8.3.1 Coordinate Measuring Machine (CMM)

A CMM is a device that can measure the location of a 3-dimensional object in space. It consists of a stylus with a touch-sensitive tip, which is connected to a movement-sensitive sensor. When the tactile tip comes in contact with the surface, the machine generates point coordinates, which represent a point on the surface of the object. The object being measured must be secured, usually by clamping the piece to a stable surface. This means that this method is not suitable for mobile, soft or flexible surfaces, because they can be distorted during contact with the stylus tip - generating inaccurate readings.

In dental applications, the touch probe method has been used to capture the positions of implants on dental stone models. Cylindrical registration elements (scanning locators) are attached to the abutments (in the stone model) and the stylus takes measurements of the locators to determine their position in the volumetric space of the machine. Using this data, dental bridges and frameworks can be designed in the virtual environment, and can subsequently be sent for manufacture (usually by milling). Renishaw's *Incise* dental package (Renishaw Plc), offers a simplistic scan and design process, which can be easily executed by non-CAD experts. Designs of dental components (such as copings, bridges and frameworks) can be designed in a virtual environment, and the data is usually streamlined to Renishaw's accompanying milling service in a variety of dental materials.

Using touch probe technology, measurements could be taken of cylindrical components. From the obtained locator positions, it was possible to export the 3-Dimensional coordinates (x,y,z & i,j,k) from the accompanying software. These figures tell us the positional and directional coordinates of cylindrical components in space, illustrated in Figure 97.

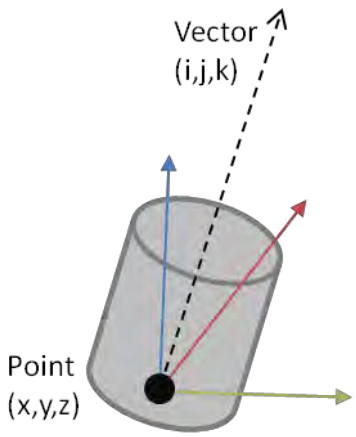


Figure 97: Cylinder location (x,y,z) and angulation (i,j,k)

The machine was used to firstly determine the locations of the abutments on the patient replica model and stone models (figure 98). Following this, the locations of the cylindrical copings of the retention bar structures were recorded.

Figure 98: Incise dental scanner

Machine set up

- Machine accuracy: 5-10µm (ISO 9001)

- Calibration procedure through accompanying software, with 6mm diameter calibration ball assembly
- Probe module: SM25-1
- Stylus A: 1mm diameter x 30mm long, effective working length 22.5mm
- Stylus B: 3mm diameter x 30mm long, effective working length 22.5mm

The machine accuracy determined the level of accuracy of fit that could be defined – for this reason Jemt's (Jemt 1991) definition of an acceptable fit was used (≤150µm), and Brånemark's (Brånemark, 1983) definition of 10µm was considered inappropriate in relation to the measurement method.

8.3.1.1 Accompanying Software

Through the accompanying Incise software and the locators on the abutment model, the implant frameworks are able to be measured – following the same procedure for the design of a dental framework (Figure 99). An administrative version of the software was used for the purpose of this research study so that the coordinates could be exported. Spatial coordinates x, y, z describe the position of the central point of the top surface, and vector coordinates i, j, k describe the direction the axis of the cylinder is pointing.

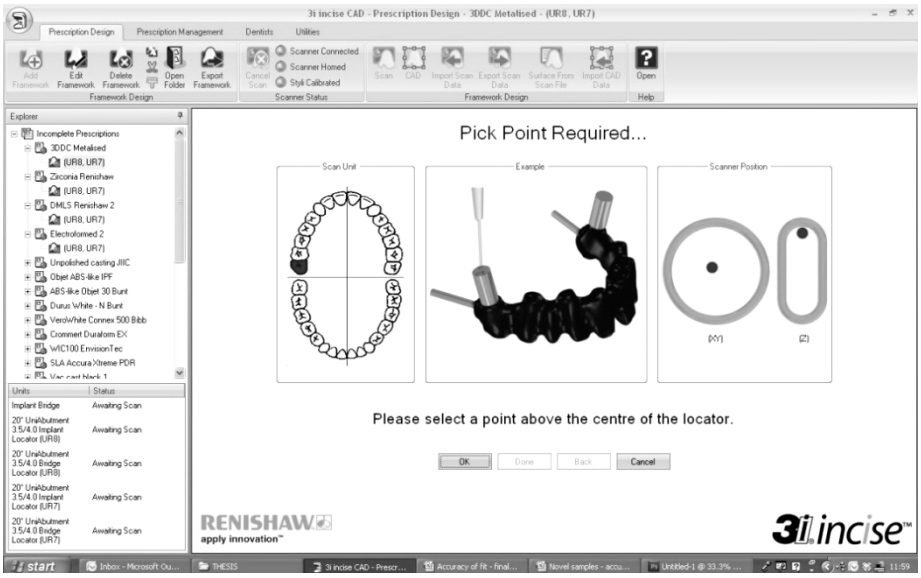


Figure 99: Incise software

8.3.2 Custom scanning locators

Due to the intricacy of the abutments, cylindrical registration elements (scanning locators) must be connected to the abutments for the determination of the implant locations.

Two 'scanning locator' designs were used – one for the abutment models, and one for the implant frameworks. To ensure consistent measurements, the locators were labelled to match the abutments i.e. locator 1 was always used with abutment 1. The length and diameter of the custom locators were measured ten times with a Digital Vernier Calliper, and the mean value was calculated.

Abutment model custom locators

One-piece, Projet 3D-printed (Projet 3000HD plus (3D Systems), EX200 photopolymer, 16µm layers) cylindrical elements were designed to sit accurately on the abutments and be screwed into place (figure 100).

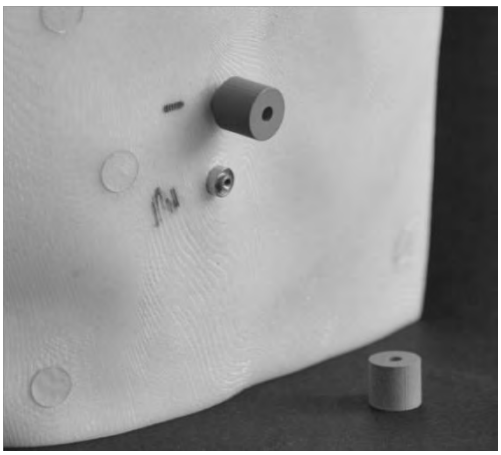


Figure 100: Abutment model scanning locator

Locator	A	B
Length (mean)	8.00mm	7.99mm

Implant framework custom locators

This design used a standard abutment replica, assembled with a 3D-printed (Projet 3000HD plus (3D Systems), EX200 photopolymer, 16µm layers) cylindrical element that fitted tightly over the underside of the abutment replica. This way, the implant framework could be accurately screwed to the abutment replica (figure 101).

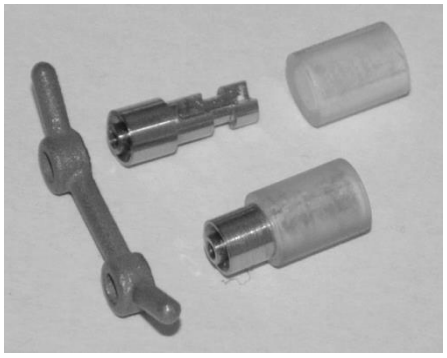


Figure 101: Implant framework custom locator

Locator	A	B
Length (mean)	12.02mm	12.03mm

8.3.3 Study limitations

Coordinate Measurement Machine (CMM)

Topographical variations within the abutment-bar interface (e.g. from stair stepping effect of AM) cannot be measured with this method.

Software

Within the Incise software procedure, the vector and surface interception is not exact. A line is created along the vector with a set number of points in. This process looks for the closest point in the line to the top surface and the line is segmented at this point. The estimate error for this software process is 2µm.

Locators

The scanning locators were additively manufactured (Projet 3000HD plus (3D Systems), EX200 photopolymer, 16µm layers). This was best possible technology

available within the scope of the PhD, but more precision-engineered locators could be used in future studies.

There was potential movement within the bar structure locators because of their 2-part assembly, but the extent of this could not be measured. A recommendation for further studies using this technique is to use more appropriate 1 part scanning locators.

Therefore the potential known error in this measurement process was determined at ±14µm. (CMM = max 10µm, software = max 2µm, digital Vernier Calliper measurements of locator length = max 2µm).

8.4 Measurement Procedure

The first task was to capture the location of the abutments which had been bonded into the patient replica model and of the abutments set in the dental stone. Following this the locations of the cylindrical elements of the implant frameworks were captured. Both data sets could subsequently be compared to determine accuracy of fit.

8.4.1 Scanning procedure

The models were each mounted in the *Incise Dental Scanner* with the scanning locators attached. The abutment models were clamped securely into place, and the implant frameworks were secured to the scanning bed by applying hot wax – this ensured no distortion was taking place through clamping. The scanner was directly linked to Incise software which displayed the data. Each scanning locator position was measured three times and the means were calculated. The dataset can be seen in Appendix VI. The procedure was as follows:

1. Calibrate the CMM, following the calibration procedure presented in the Incise software.
2. Mount the 6mm calibration ball to the scanner bed.
3. Attach stylus B (3mm diameter) to the scanner.
4. Initiate calibration (stylus scans the calibration ball).

5. Secure the patient replica model or implant framework to the scanner bed, with appropriate scanning locators connected to the abutments/copings.
6. Open new case (treat as dental model)
7. Begin scan procedure for each abutment/coping (Figure 102).
8. Position stylus manually at point above top surface of scanning locator 1.
9. Stylus records 10 points on the top surface.
10. Position stylus manually on side surface of cylindrical scanning locator 1
11. Stylus scans vertical surface in a circular fashion, recording direction and diameter of locator.

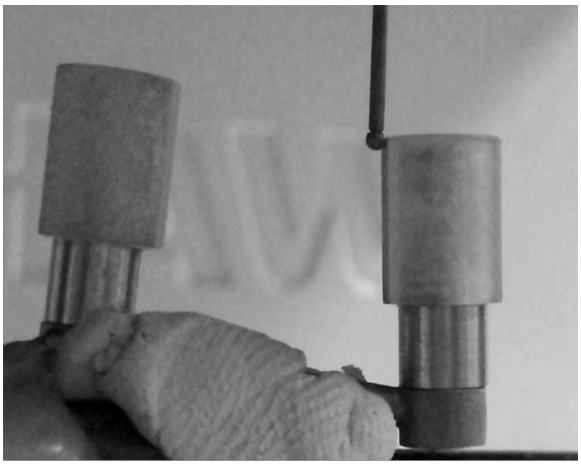


Figure 102: Scanning locators and stylus during scanning procedure

12. Repeat steps for abutment/coping 2.
13. Export coordinates from Incise software to Microsoft Excel file - 'x, y, z' and 'i, j, k' coordinates are provided. These coordinates provided the location of each scanning locator in 3D space relative to each other (the model must not be moved between scans). The central point of the top surface is provided by 'x, y, z' and 'i, j, k' provides information on the vector direction of the locator.
14. The 'i, j, k' figures must be converted to angles, therefore Inverse Cosine ($Cos^{-1}z$) must be calculated for each figure.

8.4.2 CAD Measurement procedure

Virtual measurements were made using Solidworks (Dassault Systemes) design engineering software. This software was used by importing the (xyz, ijk) data generated from the Incise system and subsequently virtual scanning locators could be created. The Solidworks measurement tool was utilised to determine:

- Distance between the two scanning locators points (distance AB),
- Vertical discrepancy (Dy)
- Horizontal discrepancy (Dx)

The procedure conducted in Solidworks was as follows:

1. Sketch circle on the top plane of 5mm diameter (although diameter irrelevant).
2. Extrude circle to create parametric cylinder of length of specified locator (cylinder represent the locator). See locator measurements.
3. Create reference point in centre of bottom face of cylinder.
4. Rotate cylinder to vector direction based upon reference point created in previous step. This involves the input of 'i,j,k' angular values previously obtained and calculated.
5. Create 3D-sketch of point using 'x,y,z' coordinates previously obtained.
6. Move cylinder to position of 3D-sketch point (relative to reference point)
7. Scanning locator A is in position. Repeat procedure for scanning locator B.
8. Create a sketch point on the centre of the connecting surface of cylinder A (bottom surface).
9. Create a line which projects from the sketch point on cylinder A towards the centre point of the connecting surface of cylinder B, but along the axis of the surface A.
10. Create a new World Coordinate System (WCS) on sketch point A (origin of line). The x-axis of the WCS must match the vector direction of cylinder A, and y-axis must match the sketch line which is projecting toward cylinder B. Central cylinder face A is the set as origin (0,0,0).
11. Using the Solidworks 'measure tool', measure from centre of cylinder face A to centre of cylinder face B, in relation to new WCS.

12. Note distance Dx, and Dy. Dz = 0 because measurements are taken with reference to x and y axes.

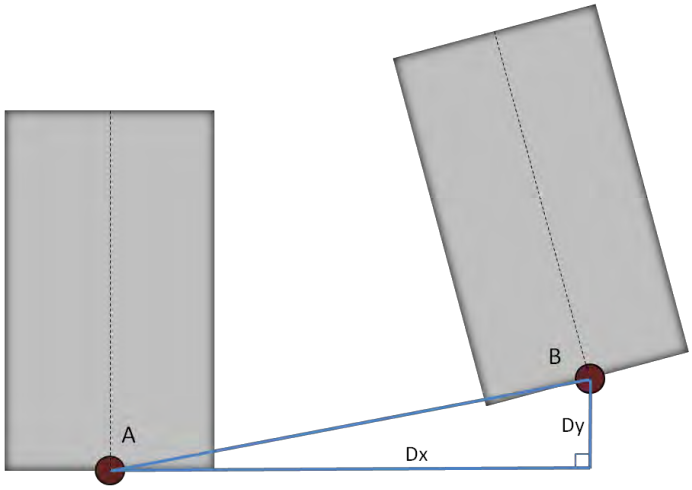
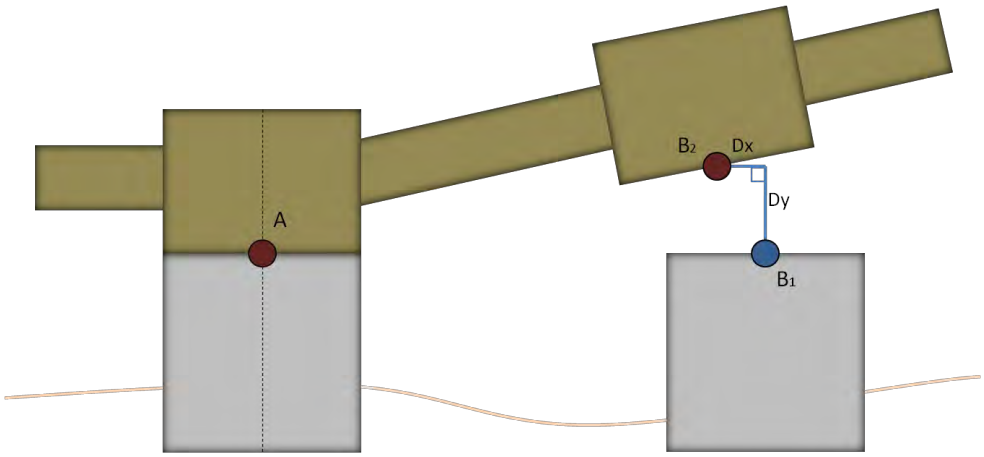
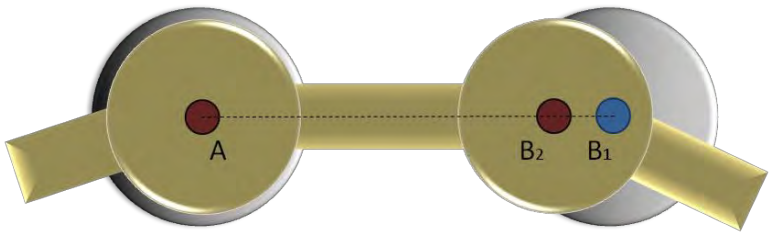


Figure 103: Determining relative positions of scanning locators

To determine the accuracy of the stone models, their data obtained through the described method was compared to the data of the patient replica model (figure 103). The differences between models provided insight into accuracy. Secondly the accuracy of fit of the implants was determined by subtracting their Dx/Dy values from the patient replica abutments, as illustrated in Figure 104 (Δ Dx, Δ Dy = Coping positions (Dx, Dy) - abutment positions (Dx, Dy)).



a. Side view



b. Top view

Figure 104: Accuracy of fit calculation (Δ Dx abutments/copings, Δ Dy abutments/copings), side & top views

This is essentially a simulated one-screw test, where the best possible fit is considered (with no rotation around point A). The origin for abutment A (0,0) matches the origin for coping A (0,0), and the distortion levels can be described by calculating the differences between points B_1 and B_2 (Dx, Dy). If the bar were rotated around A, the distances Dx, Dy may increase and describe an irrelevant situation. For a perfect accuracy of fit, the implant framework values should match the patient model. Using this matching method means that no distortion occurs from physically connecting the framework to the abutment, where vertical fit overlaps (seen in Figure 104) can not be easily identified.

8.5 Results

8.5.1 Measurement method

The digital measurement method provided insight into the vertical and horizontal misfits in the abutment model and bar structures in comparison to the plastic replica model. In conventional methods (e.g. one-screw test), gapping can be identified between the bar and abutments, but this does not describe misfit in the overlapping (–ive) vertical direction. Results showed that the CMM method could identify vertical discrepancies in both directions (±), as presented in Figure 105.

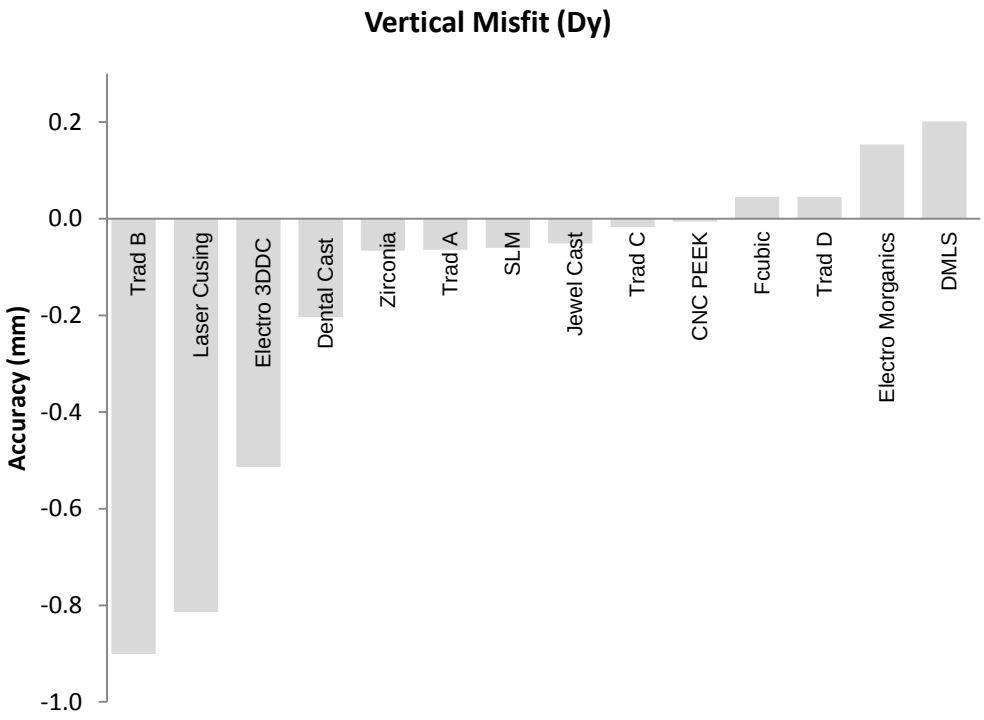


Figure 105: Vertical Misfit (Dy)

This measurement technique exposes vertical misfits that current subjective techniques may not identify. However, to define the general accuracy of fit of the components, the extent of the misfit is noted rather than the direction of the misfit. The accuracy values presented in the next sections represent the deviation from the patient model (patient model = 0, accuracy of samples = deviation from 0). Deviations are stated as + values, focusing on the extent of the deviation rather than its direction (– or +).

8.5.2 Abutment models

The results of the abutment models measurements are shown in Table 20. The comparable differences are presented – this describes the accuracy of the models compared to the original patient replica model. The patient model measured at Dy = 0.216mm and Dx = 12.408mm.

	Accuracy (deviation from patient model in mm)	
Models	Δ Dy	Δ Dx
Stone Model A	0.076	0.055
Stone Model B	0.007	0.018
Stone Model C	0.019	0.063
Stone Model D	0.264	0.080
Mean	0.092	0.054

Table 20: Accuracy of stone models compared to patient model

Therefore, the accuracy of the stone models (mean) can be defined as:

Dy (Vertical accuracy): 92µm

Dx (Horizontal accuracy): 54µm

The mean value of the abutment models is within the clinically acceptable range defined in the literature at ≤150µm. However, it is difficult to determine in this study, the root cause of the existing inaccuracies produced. The influential factors may be caused by:

- Impression technique / material
- Splinting techniques
- Dental stone production / material properties
- Measurement error (±14µm)

Further work is needed to pinpoint the degree of influence of each of these areas.

8.5.3 Conventional implant frameworks

The results for the conventionally-made implant frameworks comparing to the patient replica model are described in Table 21.

	Accuracy (deviation from patient model in mm)	
Model	**Δ Dy**	**Δ Dx**
Bar A	0.064	0.011
Bar B	0.901	0.059
Bar C	0.017	0.059
Bar D	0.046	0.045
Mean	**0.257**	**0.043**

Table 21: Conventionally-made implant implants compared to plastic replica

The accuracy of fit of the conventionally-made bar structures (collectively) can be defined as:

Dy (Vertical accuracy of fit): 257µm *(42µm excluding B)*
Dx (Horizontal accuracy of fit): 43µm

The mean Dy (vertical misfit 257µm) is not necessarily representative of the bar structures, because excluding bar structure B, the mean is reduced to 0.042mm (42µm), which is well within the clinically acceptable value (≤150µm). Model B is however, an important model to consider, because it is an example of the potentially larger error (Dy=901µm) that may occur using conventional production techniques. Horizontal misfit (Dx) for all conventionally-made bars is within the clinically acceptable value set at ≤150µm.

The accuracy of the conventionally-made implant frameworks was compared to their partnering stone abutment models.

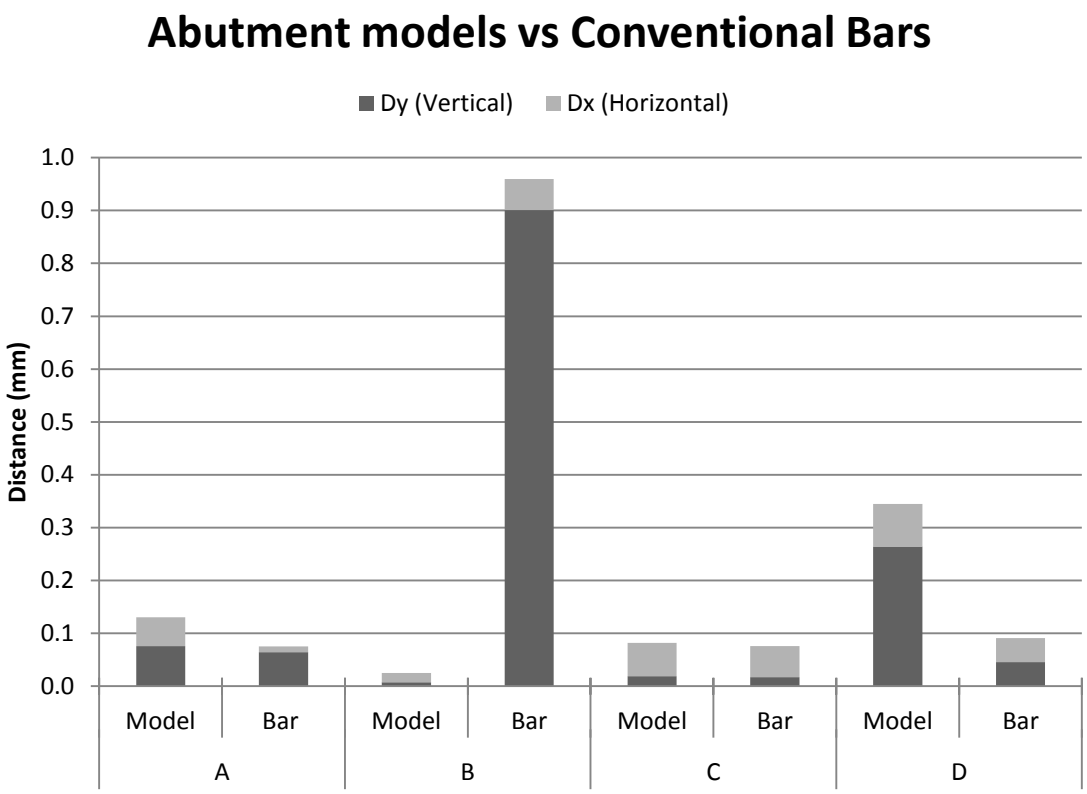


Figure 106: Comparing stone models to conventionally-made bars

Horizontal discrepancy (Dx) is consistent throughout the samples, no large (clinically unacceptable) discrepancies in horizontal fit occur between the stone models and bar structures.

Larger discrepancies occur in the vertical fit (Dy) between the stone models and bar. For example, samples B (stone model = 0.007µm, bar = 0.901µm) presented a large degree of misalignment, suggesting that the error originated during the production of the bar. However, diagnosing precisely why the discrepancies are present is difficult – but this may be due to factors relating to the material, or factors relating to distortion during the fabrication process.

8.5.4 CAD/CAM implant frameworks

The results for the CAD/CAM implant frameworks comparing to the patient replica model are described in Table 22.

	Accuracy (deviation from patient model in mm)	
Model	**Δ Dy**	**Δ Dx**
CNC PEEK	0.006	0.186
Fcubic	0.045	0.001
JewlCast	0.051	0.068
SLM	0.06	0.267
CNC Zirc	0.066	0.018
Electro (Morg.)	0.154	0.059
DMLS	0.202	0.062
DentaCast	0.204	0.359
Electro (3DDC)	0.513	0.057
LasCusing	0.814	0.304
Min.	**0.006**	**0.001**
Max.	**0.814**	**0.359**

Table 22: CAD/CAM implant frameworks

Mean values for the accuracy of fit for the CAD/CAM bars do not apply, as each manufacturing process is different and needs to be treated individually. There are no clear trends in the CAD/CAM results because they are one-off measurements (single sample per process). However, many of the CAD/CAM samples produced a horizontal fit (Dx) within the clinically acceptable range of 150µm - FCubic, Jewlcast, CNC Zirc, Electroform, DMLS, 3DDC). In terms of vertical misfit (Dy), the milled samples (CNC PEEK, CNC Zirconia), metal AM samples (FCubic and SLM), and the JewlCast sample all perform comparably with the higher performing traditional samples (A, C, D). The highest and lowest performing samples were are noted below:

The highest performing CAD/CAM bars:

Dy (Vertical accuracy of fit): CNC PEEK (6µm)

Dx (Horizontal accuracy of fit): FCubic (1µm)

The lowest performing CAD/CAM bars:

Dy (Vertical accuracy of fit): Laser Cusing (814µm)

Dx (Horizontal accuracy of fit): Dental Cast (359µm)

8.6 Chapter Summary

This chapter focused on defining a method to describe the accuracy of fit of retention bar structures to implant abutments. A CMM was used to capture the positional and directional coordinates of the abutments set in the stone models and the the bar structures. Custom cylindrical locators were used to allow the CMM to capture the coordinates. CAD software was used to measure the distances between the cylindrical features in the vertical and horizontal axes, providing a quantitative evaluation of fit.

This method had not been used previously in measuring the accuracy of fit for extra-oral retention mechanisms, and the study showed that the method could allow the fit of the bars to be evaluated in the virtual environment. The method allowed potential issues with conventional methods (e.g. hidden vertical overlaps) to be identified and provided an insight to a higher degree of accuracy than methods in practice (i.e. by feel and eye). The developed test method allowed valuable insights into retention component fit, but should be trialled further to understand its limitations and applicability in clinical practice.

The measurements of the conventional stone models showed that the set positions of the abutments provided an acceptable level of accuracy for the production of the bar structure. The measured values describing the accuracy of the impression and stone model technique must be considered in future work concerning digital scanning methods.

The horizontal and vertical fit of four of the five conventional bars (excluding bar B), were within 50µm. This means the conventional bars mostly achieved the clinically acceptable fit ≤150µm defined in the literature. Some of the CAD/CAM bars were able to compete with the conventionally-made bars in both vertical and horizontal accuracy of fit, and also provided a clinically acceptable fit ≤150µm. Distortion occurred more in the vertical axis, than horizontal in many of the bar structures – and this may have been influenced by material distortion along the bridging bar section. In the CAD/CAM samples, horizontal misfit may have originated from the absence of an alignment ridge on the abutment/coping interface.

Chapter 9: Retention forces

9.1 Overview

A typical retention clip structure for bar-clip systems consists of multiple clips at varying angles. The retention forces applied to each individual clip can not be well predicted, especially because the clips are adjusted manually, with no measurement tool. Also the prosthesis can be inserted more ways than one, which makes predicted attachment and removal forces difficult.

As discussed in the literature review, some studies have measured the retention forces of various prosthesis retention systems. Polypropylene Hader clip components for dental prostheses claim to provide 0.6kg (white), 0.8kg (yellow) and 1kg (red) retention forces (commercial literature) – these clips sit within a metal housing and can be replaced when worn or replaced when lower/higher retention forces are required. However, the range of retention forces applied by gold 'rider clips' in the extra-oral bar-clip system has been largely overlooked, although as described in the literature review, Del Valle et al. (1995) looked at differences in retention force after applying 0.15mm in clip activation. This requires more work to define the retention force ranges of the commonly used gold rider clip.

The conventional 'rider clip' for bar-clip retention systems is illustrated in Figure 107. Typically the arms are bent manually outwards/inwards to alter the retention forces of the clips. Unlike many clip designs that are retained by a friction-fit, the bar is retained mechanically - once the bar has passed the locating lips at the ends of the arms, the bar is retained obstructively, without relying on friction to secure it in place.

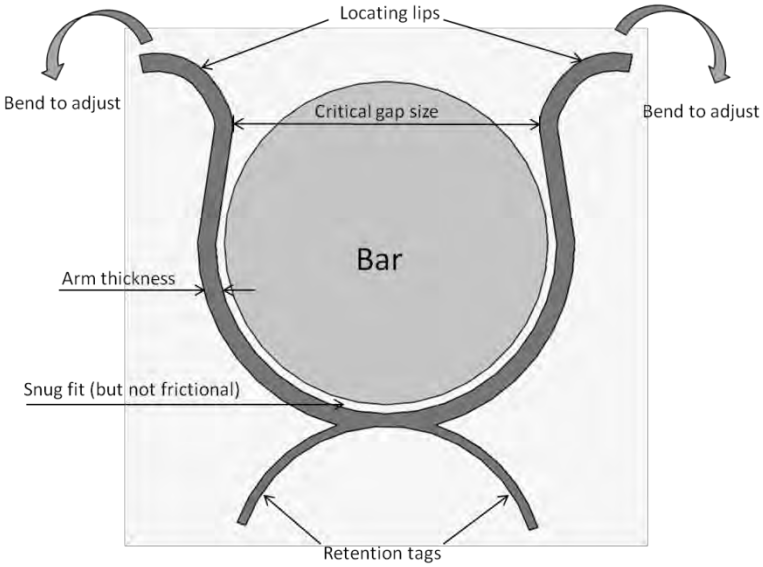


Figure 107: Rider clip functionality

Three factors were suggested to affect the retention forces of a clip through a personal discussion with a representative employee from Cochlear (Cochlear Ltd.).

- The size of the gap
- The thickness of the arms
- Stiffness of clip material

This chapter focuses firstly on determining the typical clip dimensions, when adjusting the retention clip for a patient. Secondly the retention forces were measured at the various adjustment levels. Experimental clips were designed in Solidworks (Dassault Systèmes Solidworks Corp.), and manufactured by high resolution 3D printing. Their retention forces were compared to the conventional rider clips.

9.2 Experimental design

9.2.1 Conventional clip specimens

Three MPTs were asked to adjust a series of rider clips for an auricular prosthesis. Three clips were used, which were conventionally bonded into a light cure acrylic

structure (figure 108). Each clip was adjusted manually by the MPT twice, with a clip adjustment tool.

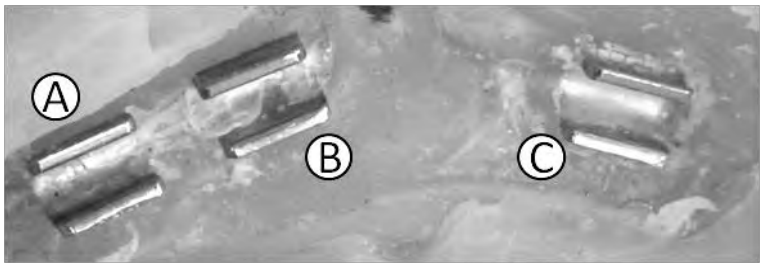


Figure 108: Position of the clips

The first adjustments were made in relation to a patient who needs the 'minimum' amount of retention (light retention applied), this was to represent someone with an inactive lifestyle, or perhaps someone with limited dexterity. The second adjustment was made in relation to a patient who requires the 'maximum' amount of retention (strong retention applied), which would represent an active person. Measurements of the clip critical gap sizes were taken with a digital Vernier calliper to the nearest 0.01mm.

The results are presented in Table 23.

	Minimum required retention			**Maximum require retention**		
MPT	Clip A	Clip B	Clip C	Clip A	Clip B	Clip C
1	1.73	1.83	1.67	1.65	1.68	1.65
2	1.84	1.75	1.76	1.64	1.68	1.58
3	1.82	1.8	1.68	1.64	1.64	1.62
Mean	1.80	1.79	1.70	1.64	1.67	1.62

Table 23: Minimum required retention (mm)

Following this, three individual, isolated rider clips were set in separate light cure blocks, taking care not to allow light cure acrylic to encroach any portion of the inner clip (see figure 109).

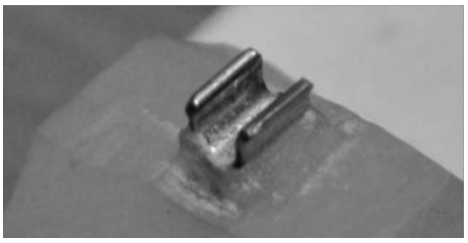


Figure 109: Gold clip set in light cure block

The gap sizes determined from the initial MPT adjustment measurements were used to inform the gap sizes in the clips used in the retention force measurements. Three gap sizes were used during the tests – narrow (1.60mm), mid (1.70mm), wide (1.80mm). The clips were adjusted manually and measured by Digital Vernier Calliper.

9.2.2 CAD/CAM clips

Three sets of experimental clips were designed using Solidworks (Dassault Systèmes), and two design elements varied on the clips – arm thickness and critical gap size (figure 110).

Arm thickness was anticipated as an influential factor on retention forces. Therefore experimental Clips A-D were designed with a varying arm thickness (0.5, 1, 1.5, 2mm) with consistent gap size of 1.7mm (mean of conventional clip gap size). Clips E-I were designed with varying gap size (1.61, 1.66, 1.76, 1.80, 1.86mm) and consistent arm size of 1mm.

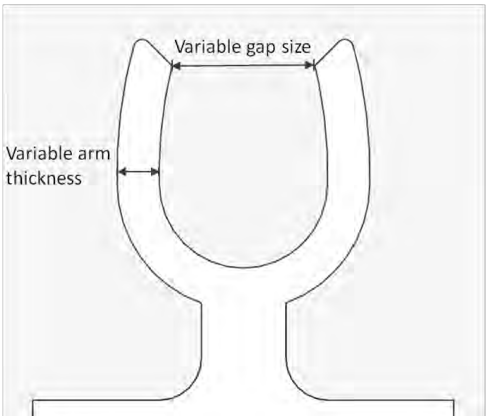


Figure 110: Design elements of CAD clip

The intricate design required a durable rigid material that allowed for a degree of flexibility for the bar piece to enter between the arms. Therefore, three test bases consisting of all clip sizes were fabricated by Projet 3D printing (Projet 3000HD Plus, XHD setting, 16µm layers, resolution 750x750x1600dpi, accuracy of 25-50µm). This process was chosen because of its ability to print high definition components in an appropriate plastic-like material (3D Systems Projet EX200 base) – this material was promoted by the manufacturer to suit functional testing applications.

9.2.3 Instrumentation

To determine the retention forces applied by traditional stock rider clips, and CAD/CAM clips, a universal testing machine (Servocon Systems) with accompanying software (Systemes MTS) was utilised at Cardiff School of Engineering. This machine was used to determine the uni-axial removal and attachment loading forces between the test clip specimens and a sample bar piece.

Machine set up

- Load cell: 100N
- Actuator: 5kN
- Displacement distance: ± 4mm
- Displacement speed: 0.2mm/sec

A customised sample mount was designed in Solidworks (Dassault Systèmes) and 3D printed (Projet 3000HD Plus, 3D Systems) to securely retain an untouched piece of stock gold bar of 1.9mm diameter (Cochlear Ltd) attached to the testing load cell. The bar piece was measured ten times with Vernier calliper before and after testing and no dimensional difference was detected. The same bar and mount was used through the study to eliminate variation error and ensure consistency in this part of the assembly. The custom mount and test assembly is illustrated in Figure 111.

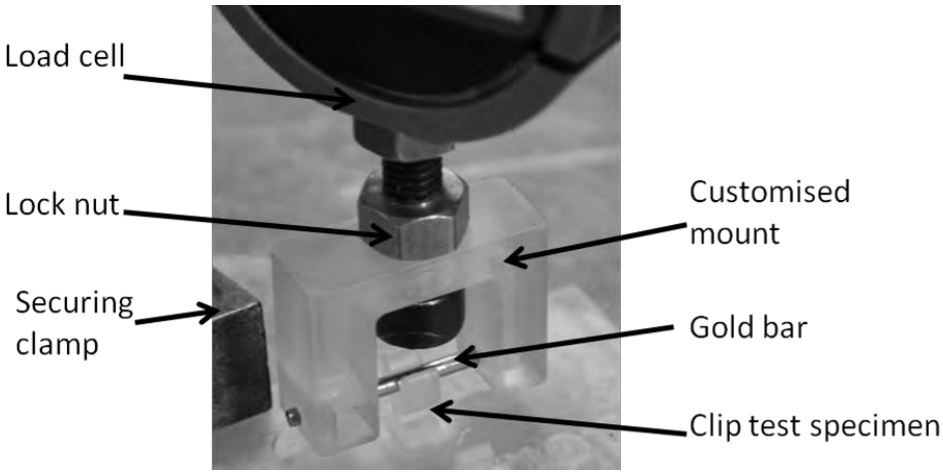


Figure 111: Test set-up

The clip test pieces were clamped to the lower bed/base of the testing machine. The male bar component was lowered by the machine to engage with the female clip component. When the bar piece completed the attachment/removal action, the test was complete.

After piloting the system by hand, some key testing parameters were taking into account. The negative loading of the clip, relating to the bottoming out forces of the bar within the clip were considered by ensuring that the start/end position of the bar piece did not touch the bottom of the clip. The bar was essentially 'loose' within the clip when secured. When the loading values started to increase after the bar had entered the clip, it could be seen that the bar was touching and pressing against the bottom of the clip.

The overhanging lips at the end of the clip arms were also taken into account. A direct, vertical motion entering and exiting the clip was important – any misalignment could affect the results of the test. This was ensured by clamping the test piece with the bar secured within the clip, so the bar essentially self-aligned.

The attachment and detachment of each clip was measured three times (six measurements per clip), and each category of clip was measured three times, which equates to nine tests per clip category for removal and nine tests per clip category for attachment. The data generated by the machine during the tests was imported into

Microsoft Excel. The peak loads for the attachment and detachment of the components were able to represent the retention forces applied by the mechanisms.

9.3 Experimental results

A measurement of a gold rider clip sample is compared to an experimental CAD/CAM sample in Figure 112. Points in the measurement process are highlighted and are described.

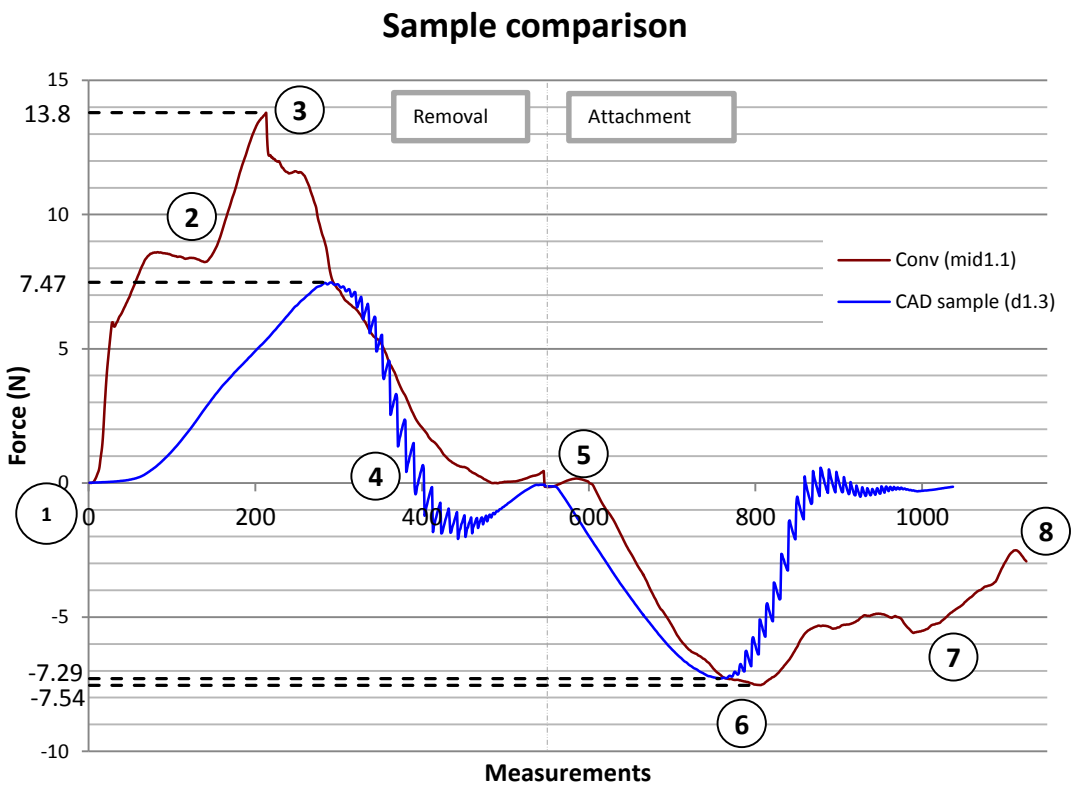


Figure 112: Comparison of conventional clip sample (mid1.1) and CAD clip sample (d1.3)

1. Start of test – bar is in position within the clip. Bar begins to rise vertically.
2. This change may be from the movement of the bar along the form of the inner clip.
3. Peak retention force the moment before bar is released.
4. Bar is on its way out of the clip, the noise in the CAD sample may relate to the bar being completely free, where no force is being measured, but the vibration from the releasing action of the bar-clip is recorded.

5. The bar is freely in position above the clip. The vertical lowering of the bar is initiated.
6. The peak retention forces related to attachment can be observed.
7. The conventional bar clip system does not allow freedom between the bar and inner surface of the clip, therefore there will be continued forces here as the bar is lowered further.
8. The bar is 'bottomed-out' in the clip – any further lowering means an increase in force.

Individual values of the force measurement tests are shown in Appendix VI, and an overview is presented in Figure 113. The mean peak forces represent attachment and removal over nine tests per clip category. Standard deviation (± one SD) for each clip category is also shown.

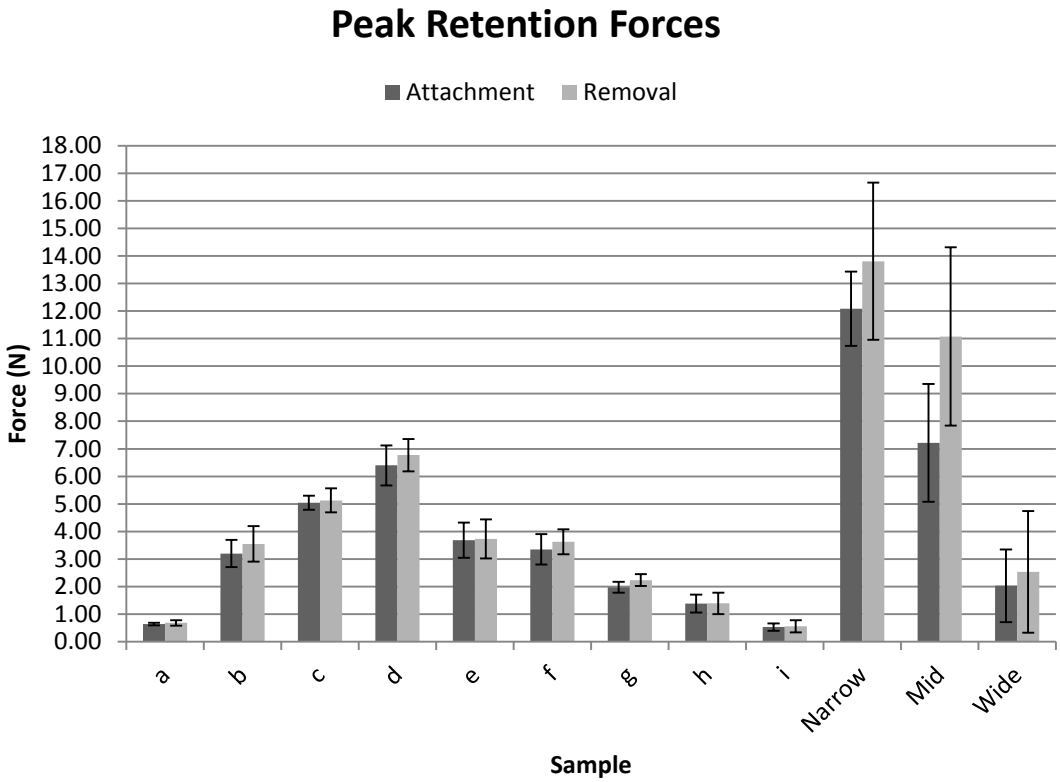


Figure 113: Peak retention forces (± 1 Standard Deviation)

Notes: (a,b,c,d - varying arm thickness (0.5, 1, 1.5, 2mm) with consistent gap size of 1.7mm, e,f,g,h,i - varying gap size (1.61, 1.66, 1.76, 1.80, 1.86mm) with consistent arm thickness of 1mm.

Maximum retention force recorded was 18.75N for removal of gold rider clip 2 'narrow'. Lowest retention force recorded was 0.19N for attachment of gold rider clip 2

'wide'. Additionally, the mean range of retention forces produced for gold clips (minimum and maximum gap size) is 2.53N - 13.81N. This suggests that the conventional gold rider clips offer larger retention ranges than this study's CAD/CAM clip designs. Therefore, further design work is required to match the ranges produced by the conventional clips.

CAD/CAM sample *g* (arm 1, gap 1.76) and *gold clip wide* (gap 1.80) are comparable in mean removal retention force (g=2.24, gold wide = 2.53), even though their designs differ. This shows that CAD/CAM designs do not necessarily need to replicate the conventional geometry, to produce similar results (although designs will vary when the materials are different)

Despite these findings, it can be concluded from the results that attachment and removal forces differ in the conventional clips to a higher extent than the CAD clips. All experimental CAD/CAM clips have a smaller standard deviation than the conventional gold clips, and therefore offer more consistent and predictable results than the conventional gold clips.

By decreasing the gap size, the retention forces can be increased. A gap size of 1.61mm (sample *e*) resulted in a mean removal retention force of 3.73N. However, this does not translate directly to the gap sizes of the gold rider clips - a gap size of 1.60mm produces a mean removal retention force of 13.81N.

By increasing the 'arm thickness' in the CAD/CAM clips, the retention forces could be increased. An arm thickness of 2mm offers a mean retention force of 6.77N. This is useful finding – this confirms that the retention forces are influenced by arm thickness, and this could be used in future clip designs.

Within the results of the CAD/CAM samples, sample *b* (arm 1, gap 1.7), *e* (arm 1, gap 1.61), are comparable in mean removal retention force (b=3.55N, e=3.73), despite 0.09mm difference in gap size.

9.4 Chapter summary

A mechanical testing machine was used to measure the attachment and detachment forces of currently used conventional rider clips (state of the art), and additively manufactured clips of varying geometry. This provided a range of retention forces that could be compared, to determine whether the experimental CAD/CAM clips could match the performance of the conventional clips.

A range of retention forces was presented for the conventional gold rider clips (2.53N - 13.81N). This described the ranges typically used in a three clip auricular prosthesis, In future studies, ranges of retention forces should also be measured for other categories of extra-oral prostheses (e.g. nasal, orbital).

The experimental AM clips provide a more consistent peak retention force and a smoother attachment/removal action than currently used gold rider clips. However, the gold rider clips provided a higher degree of retention and a wider range than the experimental CAD/CAM clips. Further work must be conducted for the CAD/CAM designs to generate comparable retention forces for the maximum required retention, but the designs could be used for the 'minimum – middle' range retention requirements.

Adjustment of retention forces is not possible with the CAD/CAM designs. The forces of CAD/CAM designs rely on accurately designed elements – this can not be changed after the clip is produced. However, as seen in the results of the conventional clips, manual adjustment equates to inconsistency in retention forces. This design challenge should also be considered in future work.

Smaller gap sizes and thicker arms equate to higher retention forces. However, arm thickness is limited to the available space within the prosthetic envelope. This must be considered if larger arm thicknesses are to be used for higher retention forces. Attachment forces are lower than removal forces for conventional clip designs. Identifying reasons for this also require further exploration, but this could be due to the different angles encountered upon insertion and removal.

Chapter 10: Discussion

10.1 Introduction

Previous literature suggested that CAD/CAM could provide a promising alternative route for extra-oral prostheses design and manufacture. Most research focusing on this topic however had largely ignored the intricate retention assemblies involved in prosthesis manufacture, which play a key role in the success of prosthetic rehabilitation. The concept of whether CAD/CAM is appropriate for retention mechanism fabrication is inconclusive on several aspects, and this PhD study aimed to address this. Based on the identified gap in knowledge, the guiding research question for this PhD study asked:-

> *Can CAD/CAM processes be used to match MPT practice in extra-oral prosthesis retention mechanism design and fabrication?*

To answer this question, further research was firstly required in understanding the requirements for designing extra-oral prosthesis retention mechanisms and how successful retention could be defined clinically and technically. Secondly, the previous use of CAD/CAM in this topic was identified, and showed that further research was needed to develop new CAD/CAM solutions with existing technologies. Thirdly, a comparison of conventionally-made retention mechanisms with novel CAD/CAM mechanisms was required to determine how well CAD/CAM could match conventional practice. The identified topics were translated into three research objectives that were used to guide the study.

1. *Gain insight into the process of fabricating extra-oral prosthesis retention mechanisms, define design considerations and criteria, and explore MPT perspectives on using CAD/CAM in prosthetic processes.*
2. *Explore how CAD/CAM can be used to design, fabricate and integrate the retention mechanisms into the prosthetic process.*
3. *Develop quantitative testing methods to evaluate and compare selected technical aspects of conventionally-made and novel CAD/CAM mechanisms.*

This chapter describes to what degree the PhD thesis met the research objectives, and discusses the findings, methods and study limitations.

10.2 Methodology

To answer the initial research question and to reflect the multi-faceted nature of Maxillofacial Prosthetics, multiple avenues were pursued in this PhD study. Research in the field of Maxillofacial Prosthetics requires a multi/inter-disciplinary approach, involving engineers/designers, clinicians (surgeons, MPTs, speech therapists), clinical scientists, manufacturing experts, and materials scientists. Clinicians and technical experts were consulted during the design of the research methodology and during the individual studies, and consequently, a mixed method approach was taken, focusing on both the qualitative and technical aspects of retention mechanism design. The PhD study focused on the application of design research methods to gain insight into MPT work processes and define essential requirements for retention mechanism design. This was used to inform further studies, exploring how CAD/CAM could be used to create a fully digital process, and objectively comparing conventional and CAD/CAM retention components.

The combination of design research, technology trials and measurement, provided strength to this PhD study and allowed a diverse approach to answering the initial research question. The combination of the selected study methods formed a holistic approach for studying aspects of retention mechanism design, and to meet the research objectives, an overly narrow approach could not be justified. This point was essential to the larger justification for the overall research design.

As identified in the literature review, many research studies in Maxillofacial Prosthetics have focused on either the technology or the clinical outcome by subjective assessment, and only few address both. This research approach focused on bridging clinical knowledge and technical measurement in the topic of prosthesis retention.

10.3 Research objectives & findings

The main findings were summarised within the respective chapters. This section will synthesize the findings of the PhD thesis and discuss to what extent the work met the individual research objectives.

10.3.1 Findings relating to Objective 1

Gain insight into the process of fabricating extra-oral prosthesis retention mechanisms, define design considerations and criteria, and explore MPT perspectives on using CAD/CAM in prosthetic processes.

In research phase 2, surveys, interviews and observations were conducted to address research objective 1. The methods were used to expand the breadth and range of information about retention mechanism design, prosthetic laboratory processes and MPT attitudes toward CAD/CAM technologies. The chosen methods allowed the objective to be met sufficiently, providing a large data source which helped to inform the subsequent studies.

10.3.1.1 Current practice

A number of insights into the conventional process were obtained through using user-based research methods. The surveys, interviews and observations provided enough evidence to show that there are many sub-stages, MPT-specific idiosyncrasies and opportunities for inaccuracies within the conventional process. Many of which had not been described in the previous literature. This collection of insights is important for future process and product development.

The design considerations and requirements for successful retention were captured. No formalised model existed in the previous literature describing the requirements. The research concluded that multiple elements require consideration for successful retention, including clinical, mechanical, biological factors and factors relating to the process. Designs rely on balancing these aspects for successful retention, but these aspects cannot always be satisfied in every case – so there will often be compromises in the design of the prosthesis assembly. This research could be especially useful for new

product development, where essential requirements must be met to gain regulatory approvals and meet standards.

Measuring the success of the retention device consists of whether the 'aspects of design' meet the defined requirements. In both previous literature and practice, limited measurable definitions exist in bar-clip design. The findings showed that subjectivity was not limited to checking techniques only, empirical methods were used throughout the duration of the fabrication processes, and that there are many opportunities for error in this process. Findings showed that the prosthetic outcomes rely highly on the accuracy of the components, MPT hand-skill, the processes, equipment, materials, and evaluation techniques. Many idiosyncrasies were identified in the processes that were largely overlooked in the literature. These could be particularly influential on the final prosthetic outcome, but have not been fully considered in the previous literature. It could also be concluded from the findings that MPTs' fabrication methods were inconsistent, despite common design intent. The definition of 'clinically acceptable' continues to be unclear in many aspects. Currently, MPT opinion is paramount, and drives this process.

10.3.1.2 MPT Perceptions and practicality of CAD/CAM

CAD/CAM has already been adopted in some aspects of Maxillofacial Prosthetics, in for example; surgical planning, creating surgical drilling guides, fabricating medical models and designing and fabricating patient-specific implants. Although research studies have shown promise for digital technologies in these aspects, they are yet to be adopted in regular clinical practice. These aspects primarily include the design and fabrication of soft tissue facial prosthetics and their retention mechanisms. Publications that have used CAD/CAM to create prosthesis moulds and simplistic retention sub-structures (Bibb et al., 2010; Ciocca et al., 2007; 2009; 2010a; 2010b; 2010c; de Crescenzio et al., 2011; Eggbeer, 2008; Fantini et al., 2013) do not represent common practice, and without investment in the technologies, these processes are inaccessible to many clinicians.

The opinions of MPTs had not been collected in previous literature concerning using CAD/CAM for retention mechanism design. It was identified that current opinions on

using CAD/CAM were mixed. Despite some scepticism and uncertainty, the MPTs also showed enthusiasm and an obligation to 'keep up' with technological advancements. Technology providers may face a potentially challenging situation to convince MPTs that the CAD/CAM can offer similar or improved results to conventional methods.

Little previous research has explored the impact of new CAD/CAM technologies on the MPT practice, and the findings from phase 2 suggested that MPTs are uncertain about what the future might hold. A paradigm shift has begun to take place – a number of commercial organisations employ CAD designers to design patient-specific medical devices; previously this would have been the responsibility of the MPT only. Care must be taken that a comprehensive understanding of prosthetic processes is paramount for any technology developer/service provider in this field. Discussions with clinicians in this PhD study highlighted the danger of becoming disconnected with the patient using CAD/CAM. This must be considered in the design of a new digital prosthetic process. The MPT spends a lot of energy on the complex cases, and it's during those cases, the presence of the patient and creative freedom is increasingly required.

The prosthetic process has been developed over years of iterative craft-experimentation and it's important not to dismiss this creative element. The current craft-based process is flexible and adaptive, allowing the MPT to alter designs according to the patient's needs. The retention mechanism, a rather simple device, is the result of a system filled with complexity, but the management of this complexity requires attention. As highlighted in the literature review, Wolfaardt et al. (2000) described the prosthetic process as:

> *'a stepwise, protocol-driven process, involving multiple disciplines, which can seem complex and sometimes confusing to staff and patients.'*

It is important to manage the complexity of this process and to simultaneously control the accuracy of the work. This must be considered in the development of a complete CAD/CAM process for prosthesis and retention mechanisms, and perhaps the integration of new technologies could help manage this complex process.

The interview participants believed CAD/CAM should be complimentary to the existing craft-processes, and to simply replace the craft processes without consideration to the

key clinical and process criteria could be disruptive. A number of perceived benefits of CAD/CAM in Maxillofacial Prosthetics have been discussed in previous articles (Eggbeer et al., 2012b) and by the MPTs in Phase 2, but its potential benefits for satisfying the continuously increasing regulatory requirements has been largely overlooked. In commercial development of custom medical devices, the regional regulatory requirements can vary, and increased control through digitisation in future patient-specific device development may become a higher priority.

The developed CAD/CAM process in Chapter 6 is essentially linearly replicating the conventional process in a virtual environment. This does not take advantage of all of the possibilities of CAD/CAM. The relationship between creativity and automation must be considered in the development of such a process. In its current state, each stage requires significant manual input, which does not consider the expertise or skill-set of today's MPT. Elements where creativity plays a large part must offer a degree of freedom in defining designs. On the other hand, it is suggested that many of the steps in the process need not be laborious; rather development should focus on automating these aspects. This may significantly reduce the number of steps in the CAD/CAM process, and help to ensure that these tasks are regulated, consistent and accurate.

Currently, clinicians are not trained in complex CAD/CAM. This requires an industrial designer or engineer, but typically engineers lack clinical knowledge or experience. Therefore, to design prostheses using CAD/CAM, it must be considered how both the technical and clinical aspects can be addressed to develop an ideal solution. Specific design guidelines for conventional processes tend to derive from textbooks which generally overlook many sub-processes. Regulatory requirements may become tighter and increasingly reviewed in the future, and so all of the overlooked sub-processes must be considered in the development of this process.

10.3.2 Findings relating to Objective 2:

Explore how CAD/CAM can be used to design, fabricate and integrate the retention mechanisms into the prosthetic process.

In phase 3 of the research, an exploratory approach was taken so that samples could be obtained and CAD/CAM technologies trialled, to address objective 2.

An important part of this research was identifying the appropriate technologies for designing and fabricating the samples. An abundance of available technologies meant identifying the appropriate technologies for the study was challenging. Either no data or only commercial, promotional literature was available. Only a few research articles stated the technology requirements for prosthesis components. Many of the technology requirements were unknown, and only a few processes had been trialled in previous literature.

This prompted a number of samples to be manufactured from various manufacturing processes. This also required new trials of software and scanners, to design the appropriate components. This exposed the opportunity to develop an entirely digital workflow.

Previous literature (Bibb et al., 2010) highlighted that CAD/CAM can be used to design all of the components to make a bar-clip retained prosthesis. However, the literature review identified that gaps existed that prevented a fully digital process, with little evidence showing the technical feasibility of the presented methods. The work in response to objective 2 confirmed that existing CAD/CAM technologies could be used in every aspect of retention mechanism design and manufacture. A new CAD/CAM workflow was developed and mapped to illustrate that the conventional workflow could be replicated in the digital environment. This meant developing new solutions to overcome some of the challenges identified in the previous literature.

The work showed that although technology limitations prevent an ideal solution, the available CAD/CAM technologies could be combined with new solutions (developed within this PhD) to create a complete CAD/CAM process.

10.3.2.1 Data capture and Reverse Engineering

Previous research (Eggbeer, 2008) suggested that the abutment features were too intricate and reflective to capture through non-contact scanning. The work in Phase C showed that non-contact hand-held laser scanning, with the aid of custom cylindrical scanning locators and reverse engineering software methods could be used to digitally

capture the abutments' 3-dimensional positions. This was a breakthrough for extra-oral applications.

Surface scan data of a geometric element requires reverse engineering to match the design intent - messy scan data can not always be processed by the design software or operator. Raw scan data is merely a freeform representation of the geometry in focus, made up of facets, analogous to draping a creased paper cloth over a feature. The facets need to be defined as a recognisable feature, for example, a cylinder of a specified height and diameter. Subsequently, providing sufficient data is a fundamental part of the process to advance the overall CAD workflow. The work showed that some surface scanning technologies (Artec, 3DMD) which are becoming increasingly recognised in extra-oral prosthetics, could not provide sufficient data to allow the abutments to be captured. The laser scanning process however provided enough data to capture the scanning locators so that the facets could be translated into geometric entities, and therefore providing a foundation for designing the retention components. However, the handheld laser scanner struggled to capture the subject when movement occurred. .This could cause a shift in the scan data, which would result in the true position of the locators being difficult to define. A shift in the data would affect its accuracy and consequentially introduce errors in the design process. The scanning locator method was a successful 'proof-of-concept' but further research is required to optimise the process. Future generation scanning technologies that could ensure accuracy regardless of instability, vibrations, thermal variations, or operator skills, could particularly improve the techniques used in this research study.

The RE processes developed to define the abutment locations used multiple software packages (e.g. VX Elements, Solidworks, 3-Matic, or Geomagics Studio) but these were laborious and unintuitive. More intuitive and economically viable ways to define the geometric entities are required, especially to provide a practical solution for in-clinic use.

During the PhD study, a patent search was conducted for the developed process of capturing the abutments, and it showed a promising opportunity for commercial development. A patent was published by Lawitschka et al. (2012) which describes the process of using non-contact scanning to capture polyhedral locators (called scanning

bodies) for determining the position of dental implants. The method was described for *intra-oral* prosthetics, and therefore an opportunity still remains to develop a similar process for *extra-oral* prosthetics.

10.3.2.2 Computer-Aided Design

The processes developed in the study showed that bar and clip structures could be designed using industry standard CAD. Digital assembly methods allowed a coincident fit between critical elements (i.e. mating functions). This level of fit cannot be ensured in conventional craft methods. The retention assembly could also be integrated into the prosthesis mould in a way that had not been achieved in previous literature. The method also allowed the clip structure to be placed accurately into the printed CAD/CAM mould for over-moulding into the prosthesis body. This technique could provide direction for future studies using CAD/CAM for indirect prosthesis manufacture.

Within the design software trials that were conducted, Solidworks was easily and accurately used to achieve engineering/design specific tasks, and Freeform was superior in dealing with complex and creative surface manipulation. However, in agreement with Bibb et al. (2010), no software was identified that could perform all the required tasks in one streamlined workflow. An element of compromise existed for every software solution. For example, where accuracy and control was dominant, the ability to manipulate freeform surfaces was more difficult. The current necessity to alternate between software packages is not ideal. This is complicated and may produce inaccuracies. The work showed that bar-clip mechanisms can be designed and integrated into CAD mould designs sufficiently, but the work especially highlighted the need for a single technology platform to provide a holistic approach to implant-retained mechanism design, which could feed research and commercial application.

10.3.2.3 Integration of freeform and geometric elements

Similarly to prosthesis retention mechanisms, many other patient-specific applications require the integration of patient-specific and off-the shelf components, and there is currently a gap in the available technology that addresses this. CAD/CAM patient-specific implants (e.g. cranial closure) have proven successful clinically and

commercially, and the next step is to apply this knowledge to load bearing and more complex assemblies, which would mean a considerable step forward in medical device design and manufacture. Extra-oral prostheses are examples of such assemblies, but many other applications require similar design processes, such as customised orthopaedic implants, spinal straightening systems and orthodontic devices. Applying this knowledge to more complex devices present a whole new set of challenges, which, like prosthesis retention mechanism development, require a collaborative and innovative approach from specialist clinicians, researchers and engineers to develop new solutions.

The planning and surgical stages were given very little consideration during this study. On reflection of the PhD work and knowledge of conventional practice, these areas are hugely influential on the design of prosthesis and retention mechanism. The conceptual CAD/CAM process, like the conventional process, is linear by nature. However, there is an opportunity here to take advantage of CAD/CAM to provide iterative and adaptable design methods by integrating prosthesis assembly design from the very beginning within the stages of surgical planning.

Highlighted in the literature review, the Anaplastology software solution by Materialise NV focuses on planning prosthetic cases, specifically allowing the planning of implant positions and mirroring of anatomy. However, the software currently does not allow further development of the prosthetic assembly. The work has highlighted that the process must be developed further to fully integrate the planning and design stages, focusing on simplifying the engineering-led tasks, providing the ability to define specified accuracies, and providing freedom of creativity at specific stages for surgeon and/or MPT input. A workflow is proposed in Figure 114 illustrating how retention mechanism design could be integrated at various stages of the CAD/CAM process, including the preoperative planning stages, where retention mechanism design has mostly been overlooked.

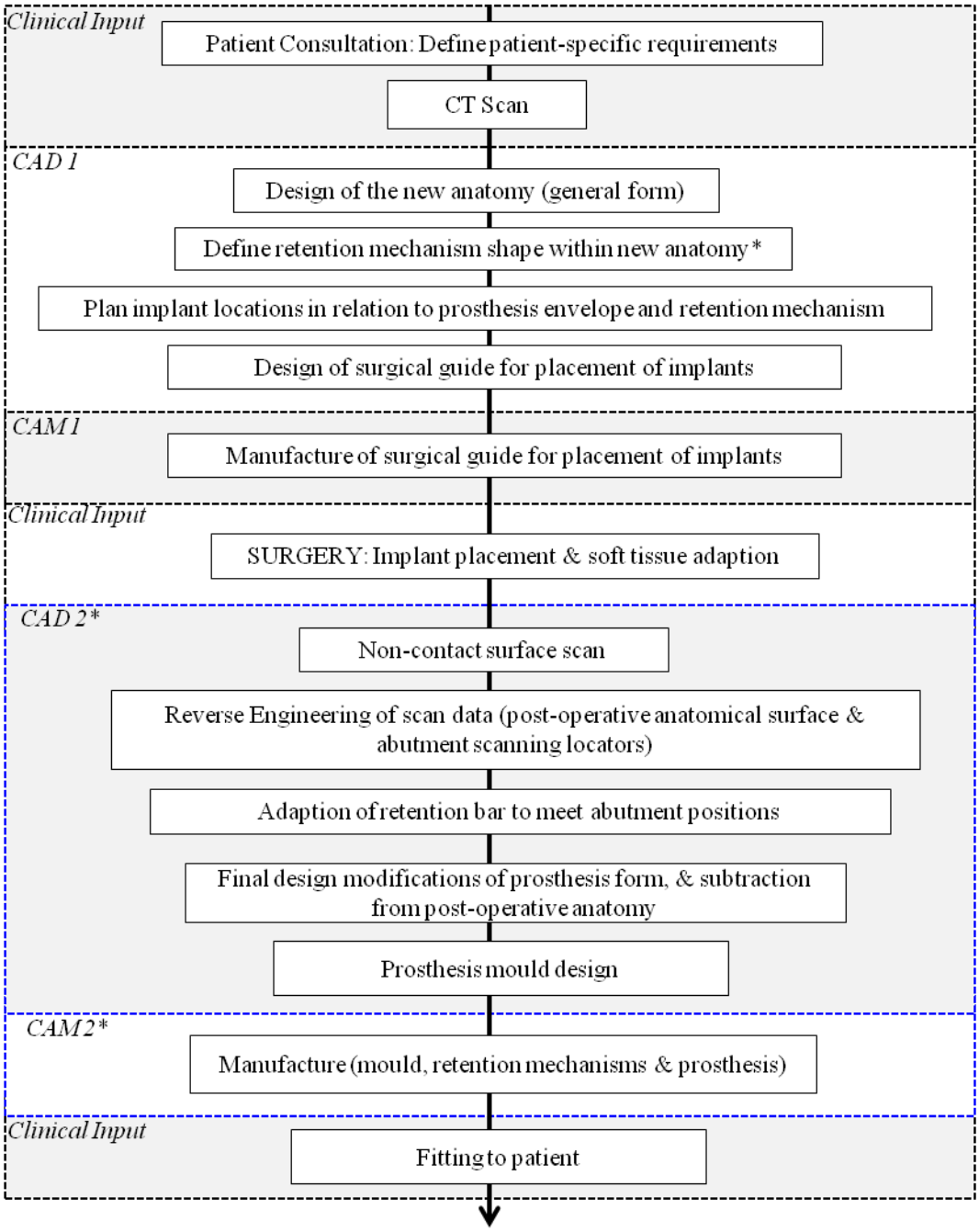


Figure 114: Proposed CAD/CAM workflow, integrated with virtual planning (covered within PhD)*

The proposed CAD/CAM workflow allows the general design of the retention mechanism within the preoperative planning stages to be defined and final design adjustments to be conducted post-operatively to overcome compromises in the position of the implants. The conventional process would not be able to provide this solution, because designs are more difficult to adjust once they have been hand crafted.

10.3.3 Findings relating to Objective 3

Develop quantitative testing methods to evaluate and compare selected technical aspects of conventionally-made and novel CAD/CAM mechanisms.

In phase 4, quantitative measurement-based methods were utilised to meet objective 3. The first task of this phase was to define testing methods to measure some of the technical aspects of bar-clip designs. From the literature review and descriptive research phase, key technical performance indicators were identified. Established measurement technologies were used where possible to measure the samples, and testing methods were developed. Conventional samples were measured and compared to selected CAD/CAM samples.

The MPTs' design intent (defined in Chapter 5) is to produce a bar structure with a high quality surface finish, eliminate pitting and produce complete welds, all of which without removing excess material from the bar through over-finishing. Chapter 7 showed that in reality, by using conventional processes, these goals could not be fully achieved. MPTs aim to provide a 'passive' fit between bar structure and abutments, but the research showed that subjective checking techniques cannot easily identify misfits in all directions (overlaps) and focus on gaps only within the range of the human eye. Retention forces of the conventional clips were analysed and found that accurate application of forces is challenging - this means that applied forces are unpredictable, and rely fully on the experience of the MPT.

The findings of this phase indicated that some of the CAD/CAM bar samples achieved promising results in some aspects, but were quite poor in others. A number of characteristics were identified in the various CAD/CAM samples, suggesting that some of the selected CAD/CAM processes would not be appropriate for fabricating bar-clip mechanisms. This information could be useful to help guide future research studies in this area.

10.3.3.1 Surface & dimensional quality

Pitting, imperfections in welding regions and misshapen features featured on all of the conventional bars. Also, the subjective checking techniques used during the process

were not entirely sufficient for identifying all of the present imperfections on the bars. However, all of the conventional bar structures obtained were deemed clinically acceptable by the MPTs.

Surface design must be considered in medical components where potential bacterial colonisation of prosthetic components could affect the healthy tissue and the integration of the implants to the bone (Saba, 2001). It was suggested that an acceptable range of surface roughness for a reduction of bacterial adhesion could be Ra ≤0.2µm (Bollen et al., 1997) or ≥1.86µm (Taylor et al. (1998). The mean Ra values of the conventionally-made bar structures were recorded 0.31µm, but the highest Ra value was measured at 1.51µm. This suggests that the Ra values of the traditional bars could coincide with Ra ranges relevant for bacterial colonisation, but this must be further investigated. Edwards and Rutenberg (2001) explained that bacteria are understood to adhere more to grooved surfaces compared to flat surfaces because the contact area is larger. This may not bode well for some of the additively manufactured components which are inherently grooved because of their layered structure.

In dental applications, an array of surface finishing methods and materials exist to produce surfaces of varying smoothness (Bollen et al., 1997), but only a few have been adopted in conventional extra-oral prosthetics and none have yet been established in CAD/CAM extra-oral prosthetics. A highly polished conventional prosthesis bar structure is required so that bacterial colonisation is discouraged. Alternative CAD/CAM processes must also fulfil this requirement. It has been suggested that every dental material needs its own finishing treatment. In consideration of the varied results obtained from the various CAD/CAM samples, it is suggested that specific finishing treatments for new CAD/CAM processes and materials in extra-oral bar structures must be developed – simply adopting surface finishing techniques used in conventional practice may not provide sufficient outcomes. Additionally, limited research exists on application-specific surface finishing in the field of Additive Manufacturing. This presents an opportunity to use CAD/CAM technologies to apply accurate, controlled and automated finishing techniques for CAD/CAM manufactured bar frameworks.

10.3.3.2 Accuracy of fit

One of the challenges with current practice is the inevitable subjectivity in evaluating fit of the bar structures to the abutments, and there will always be variability in anatomy, tissue condition and patient psychological state too, which can all influence the outcome. However, as a noted in the literature review, the accuracy of fit of the bar structure / abutments was recommended at ≤150µm by Jemt (1991), at ≤40µm by Riedy et al. (1997 Dec) and Jemt & Lekholm (1998), and at the 10µm level by Brånemark (1983). However, as observed in Phase 2 of the research, MPTs did not quantitatively measure the gaps between the copings and abutments – all MPTs judged the fit by feel and by eye. The study showed that a degree of misalignment existed in all bar-abutment assemblies in both horizontal and vertical axes. One of the conventional bars was -0.9mm vertically misaligned (overlap), but was perceived as clinically acceptable by the MPT. The CMM method allowed an objective approach at measuring the accuracy of fit, and such vertical inaccuracies could be more easily identified.

In relation to Jemt's (1991) definition of an acceptable accuracy of fit of ≤150µm, the conventional bars and a number of CAD/CAM bars were deemed clinically acceptable. However, this definition says little about misalignment in 3-dimensions and how this translates to the forces transferred to the bone/implants. As mentioned in the literature, Kan et al. (1999), Laurito et al. (2012) and Abduo et al. (2010) acknowledge that the recommended values for fit are still of empirical origin, and the concept of 'passivity' is still poorly understood. Some researchers in the dental field had considered 3-dimensional implant framework misalignment. Drago for example, considered volumetric misfit (x*y*z), but this can be somewhat misleading, because it does not pinpoint the exact distribution of misfit. This chapter therefore focused on individualising the measurements, so that vertical and horizontal misalignments could be identified. In future studies, consideration should also be given to angular misalignment because this can also influence the forces transferred to the implants and bone. However, this remains a challenge because the relevant angles have not been defined.

Identifying the source of discrepancies in fit is challenging. Bar structures may be influenced by a number of factors relating to the material, design, distortion during the

fabrication process, or handling. Observations in Phase 2 could help provide some insight into process related factors influencing the accuracy of fit.

10.3.3.3 Retention forces

Current methods for adjustment of multiple conventional clips rely on tactile feedback from fitting the prosthesis. The findings from Chapter 9 showed that by using these methods, the conventional clips were less predictable in the application of retention forces compared to the experimental AM clips. The highest load shown in the conventional rider clips was higher than expected (clip '2 narrow' = 18.75N). This means that the delivery of force to the implants could be higher than anticipated during clinical practice, but nevertheless, the conventional clips allowed a wider range of retention forces and adjustability compared to the CAD/CAM designs in this study.

In this study, a 3-clip prosthesis was fitted and the individual clips were adjusted. Individual clips may have been over-adjusted to compensate for an under-adjustment of a sibling clip in the same assembly. The results showed inconsistency in gap sizes within the clips, which translated directly to attachment/detachment force values. Therefore, manual adjustment is one of the reasons for clip force inconsistency in the conventional samples. Observations in Phase 2 suggest there could also be other reasons for this. In Chapter 5, it was noted how often the light cure acrylic encroaches and/or enters the inside of the clip. Flexure of the clips could be influenced by this encroachment of the substructure material. Excess material within the clip prevents an accurate fitting interface between bar and clip. These issues could influence the effectiveness of the clip, limit adjustment, or cause misalignment issues to the overall assembly. Caution was taken in this study to prevent this, but in practice this could pose technical and clinical issues.

In a previous study, Breeding et al. (1996) suggested that the retention forces of rider clips decreased after the first removal, and then continued to decrease during following removals. In this PhD study, the gold rider clips produced the opposite effect in the removal process of some of the samples (e.g., '2 narrow' = 12.44, 17.38, 18.75), and do not occur in the attachment process, or any of the CAD/CAM tests. Further research is required to discover why these changes occur.

Loading for bone remodelling has been explored in many research articles, but the loads applied to the bone influenced by aspects of retention mechanism design has seldom been looked into. As explained in the literature review, the potential inaccuracies produced by craft-fabrication of retention frameworks may have direct influence on the forces transferred to the implants and bone. Forces might originate from distortions in the implant framework, clip structures, misfit of fitting surfaces, and retention forces applied. The levering (momentary) forces on more complex mid-face bar structures are especially challenging to predict. Measuring the transferred forces and biomechanical affects of aspects of retention design was outside the scope of this PhD, but the author sees this as a fruitful research avenue to pursue for future work.

The work showed that clips can be manufactured by AM to produce middle range retention force strengths, comparable to conventional clips. Further clip geometries and materials need to be explored to achieve the higher retention strengths of the conventional clips.

10.4 Research methods: limitations

10.4.1 Bar-clip samples

10.4.1.1 Cost / sample size

Conventionally-made gold bar structures were calculated at around £300 each. Consequently only a limited number of samples could be obtained within the financial constraints of the PhD.

The cost of samples was also a limitation for the CAD/CAM samples, and therefore low quantities of samples were obtained for each process. Cost was also a limiting factor in obtaining samples in the desired materials for every process. Therefore substitute materials were used where possible, e.g. brass instead of gold. Also, obtaining multiple samples for the selected manufacturing processes could not be financially justified where technical data in the literature was limited. In consideration of this, research phase 4 focused on creating an initial overview of the appropriateness of the selected

samples. Measurement of the individual samples therefore could only provide indicative results on the technical performance of the processes. The data provided information about the individual samples, but multiple samples must be obtained to provide valid and significant data about the technical nature of the manufacturing processes.

10.4.1.2 Control of manufacturing processes

For obtaining the CAD/CAM samples, expert suppliers were used with experience in configuring parameters to achieve the optimum manufacturing results. The samples were requested at the optimal quality settings for each manufacturing process. However, further research is necessary to ensure that all of the process parameters can be clearly defined, so that the relationship of specific parameters and component quality can be understood. This is especially true for the AM samples, where less data is available in the literature.

10.4.2 Measuring surface roughness

Surface roughness measurements were taken only on the metallic samples. There were two reasons for this. Firstly, the polymeric and ceramic bar structures could not be measured due to the limitations of the machine. The metallic bars offered enough reflectivity to detect their surfaces, whilst the polymeric and ceramic bar structure surfaces were too faint or transparent to detect. This meant that only the metallic bar structures could be measured for surface roughness using the available interferometer (MicroXAM White Light). A contact stylus device would not have been appropriate because the hard stylus can scratch the surfaces, 'build-up' burrs of material and produce errors or inconsistent results. Another challenge of the AM non-metals was the nature of the support structure, by visual inspection, not all of the support material could be removed for sufficient measurement - this is highlighted in the following section especially.

10.4.3 Measuring dimensional accuracy

There was some difficulty when manually examining the holes that required the use of the coaxial light (from above). The precise location of the edge of the hole was

sometimes unclear, especially where the edges were slightly rounded. As highlighted in Figure 115 and Figure 116, two potential edges could be selected and this was down to the interpretation of the operator. The view was taken that the inner edge of the darker ring described the edge of the hole (Figure 116) – but the light was reflected inwards making it appear as a darker ring.

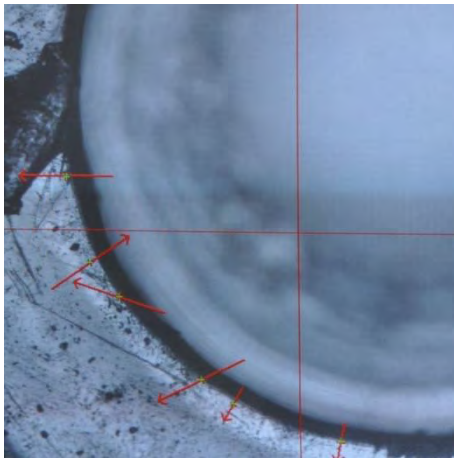


Figure 115: Edge detection 1

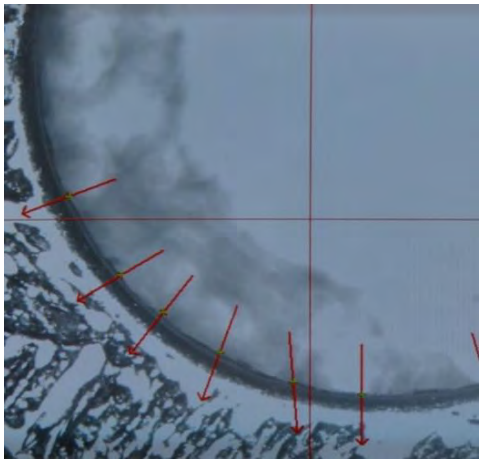


Figure 116: Edge detection 2

There was also some difficulty with detecting the edges of the holes on some of the components where RP support structure could not be completely removed or flakes of material were hanging over the true edges (as seen in Figure 117). This meant that fewer points could be selected and it was important to select points on the most prominent contrasting edges. Stage light and coaxial lighting could be utilised to ensure accurate selection of the edges.

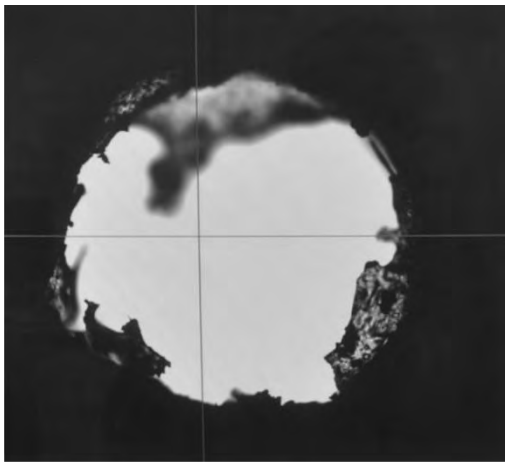


Figure 117: Stage light - overhanging flakes of support material (Objet Polyjet AM)

10.4.4 Measuring accuracy of fit

Using the CMM method is a lengthy process and the requirement for high investment could pose difficulty for clinics to adopt this technique as part of everyday practice. However, it offers a more accurate approach to measuring fit tolerances than conventional current techniques which rely mainly on 'eye-balling' and the experience of the MPT. Therefore the CMM method represented repeatability and accuracy that was necessary for this research, but perhaps not appropriate for application in a clinical setting.

A degree of error was identified in the measurement machine, the software and the manufactured components. By stacking these individual errors, the degree of measurement error could be approximated. Coordinate Measurement Machine (CMM) accuracy was defined at 5-10µm. Within the Incise software procedure, the vector and surface interception is not exact. A line is created along the vector with a set number of points in. This process looks for the closest point in the line to the top surface and the line is segmented at this point. The estimated error for this software process is 2µm. Therefore the potential known error in this measurement process was determined at ±14µm. (CMM = max 10µm, software = max 2µm, and digital Vernier Calliper measurements of locator length = max 2µm). Where consideration is given to Brånemark's (1983) definition of an acceptable accuracy of fit at the 10µm level, this would require an alternative measurement method of measurement.

10.4.5 Measuring retention forces

In the process of measuring retention forces of the clips, the bar and clip attachment motion was conducted perpendicularly. In a real situation however, there are various modes of prosthesis insertion and removal – which means that the bar could be fitted/removed to the clip at varying angles. As de Sousa and Mattos (2008) suggested, this could lead to deformations of the bar-clip interface, which would lead to faster loss of retention and clinical longevity. For the representation of a real situation, the various angles of insertion/removal need to be considered in the set-up of future research studies focusing on measuring retention forces.

10.5 Application of research

As an initial validation of the PhD research, the developed CAD/CAM concepts were applied to two patient cases within the Maxillofacial Clinic, under the supervision and responsibility of an experienced MPT. Conventional prostheses were also created as the primary method of treatment for the patients. No personal information was gathered or devices provided for the patients to use. These case studies were used to apply the PhD findings to the clinical environment, for scoping the feasibility of future case studies, and to fuel further publications.

The cases in focus were of a bar-retained auricular prosthesis (2 implants) and a magnet-retained mid-face prosthesis (4 implants, ocular piece). The CAD/CAM processes developed in this PhD were used. Figure 118 shows the abutment scanning locators in situ in the auricular region. The locators were scanned using the handheld laser scanner and the scan data was processed following methods described in Chapter 6 (VX Elements, Solidworks).

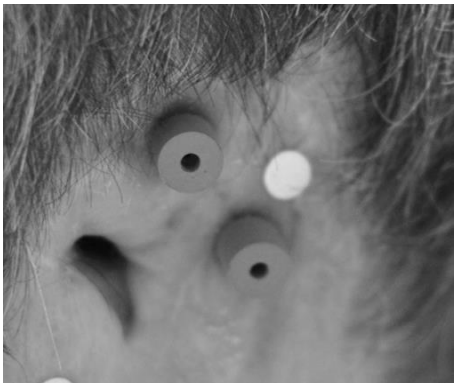


Figure 118: Scanning locators applied to abutments on auricular region

The retention mechanism assemblies were designed in Solidworks, and the prosthesis bodies were digitally sculpted in Geomagic Freeform (3D Systems). Mould designs were designed allowing the incorporation of the retention assemblies. The final moulds were manufactured using Projet 3D printing (Projet 3000HD Plus in XHD Mode). Clip and magnet substructures were produced by Stereolithography, SLA 250-50 (3D-Systems) in Accura ClearVue resin (3DSystems) with a 0.15mm layer thickness. The

auricular bar structure was produced by Laser Melting (Renishaw AM250 machine, Renishaw Plc, UK) in dental grade CoCr alloy. The retention components were placed in the moulds in position. Figure 119 shows the magnets positioned within the mould ready for the substructure to be connected into position. The prosthesis silicone was poured into the moulds and cured. The retention mechanisms were subsequently over-moulded into the prosthesis bodies in the desired position. The trials were used to highlight the obstacles and benefits of using the CAD/CAM process in the clinical environment, but no final prostheses were provided to the patients – this was considered to be too risky for a patient because the materials chosen were not for clinical use.

Figure 119: Mid-face prosthesis mould prototype with magnet mechanism

After trialling the methods with the MPTs, the suggested benefits using CAD/CAM for this process were listed:

- Less invasive than traditional methods.
- Potentially easy and accurate duplication of components.
- Potential for easy data transfer and collaborative online design sessions.
- Reduction of process materials, and therefore potential reduction in longer terms costs and patient clinic time.
- Increased flexibility in working routine, through enabling more on-screen work.
- The ability to re-iterate design stages, reduce opportunities for human error and trace error within the CAD environment.

- Potentially an increase of control over retention forces of clips.
- Increased possibilities for intricate/difficult designs, and increased manufacturing options using RP.
- Possibilities to perform engineering simulation/tests on designs before manufacture and patient fitting, ensuring safer & more robust designs.

The response from the MPTs involved in these cases was positive, and by guiding the clinician through the process, feedback could be given on each stage of the process in the context of a clinical environment. The case studies reflect that this process is achievable in a clinical environment, but the process must be developed and optimised to meet all the necessary user requirements (i.e. efficient, accurate, flexible, safe, user-centred), and to provide a practical and realistic solution for in-clinic adoption.

Chapter 11: Conclusions & Future Work

This concluding chapter summarises the contributions to knowledge, recommendations for future work, and main conclusions.

11.1 Contributions to knowledge

The PhD thesis has been able to fill some of the gaps identified in the previous literature and provided contributions to knowledge in the fields of Maxillofacial Prosthetics, CAD/CAM and custom medical device design. The research is also relevant to some aspects of Dental Technology, where similar approaches are used in research and practice. The individual contributions to knowledge are listed in this section.

Contributions to knowledge from Phase 2:

- An in-depth and critical review of conventional retention mechanism design and fabrication by mapping current processes and collating clinical and technical considerations. As a result of this knowledge, the requirements for customised retention mechanisms were defined and organised into a hierarchy of importance (Table 13).
- An insight to MPT views on current processes and prospect of using CAD/CAM in extra-oral facial prosthetics.

Contributions to knowledge from Phase 3:

- A complete CAD/CAM process workflow presented including novel sub-processes: -
    - Determination of abutment positions by using laser scanning, novel surface scanning locators and reverse engineering.
    - New CAD techniques developed for designing bar-clip mechanisms and full integration to prosthesis moulds.

- A range of novel digital manufacturing methods used for producing bar-clip mechanisms, previously not explored in this application (Appendix VI.1).
- A proposed 'ideal' CAD/CAM process workflow presented, which could be used for future process development (Figure 114).

Contributions to knowledge from Phase 4

- A quantitative approach at evaluating the surface and dimensional quality of extra-oral bar structures.
- A digital method for measuring the accuracy of fit of extra-oral bar structures by using touch probe CMM and custom scanning locators.
- A set of benchmark values for conventional and CAD/CAM extra-oral bar-clip mechanisms in surface roughness, dimensional tolerances, accuracy of fit and clip retention forces (Table 19, Table 21, Table 22, Figure 113).

11.2 Recommendations for future work

The work in this PhD thesis leads to a series of topics that could drive future research studies and avenues for practical or commercial application of CAD/CAM in Maxillofacial Prosthetics. These topics are described in this section.

11.2.1 Understanding clinical practice

There has been a tendency for researchers exploring CAD/CAM in facial prosthetics to focus either on the ability of the technology or the clinical outcome of case studies. Future research in this field should go beyond this - it should also consider the clinical environment, the nature of practice, and the opinions of those who have direct contact with patients. This was an important aspect of Phase 2 of this PhD study, and it raised some important topics about the current state of thinking in using CAD/CAM in this field. It is recommended that future research consider the role of the CAD/CAM designer & MPT in future prosthetic rehabilitation, and the impact of using CAD/CAM in a clinical environment.

It is also recommended that future work involves continuously evaluating the state of the art in everyday practice, staying up-to-date on practical and technical developments. The instructional literature must be updated regularly so it can inform future researchers of developments comprehensively and easily.

11.2.2 CAD/CAM process optimisation

Prosthetic treatment is a continuous improvement process, where efforts in research and practice seek incremental improvement over time. However, with no existing CAM/CAM process in place in everyday practice, the potential introduction of an optimised fully digital process could provide a 'breakthrough' improvement all at once. This will require the appropriate development of each stage in the conceptual process defined in this thesis. For this to become achievable, the following areas must be addressed and taken forward.

- Improved scanning methods for capturing both intricate geometric components and freeform surfaces on mobile subjects – high quality data output with speed of Photogrammetry and flexibility of handheld scanning.

- Ease of transition and efficiency in translating captured data to usable elements for designing prosthetic components. Reverse Engineering methods must be considered in future work.

- A method to integrate surgical planning with design of retention mechanism, prosthesis and mould, with fewer transitions between software packages. This must consider the design interoperability of freeform and geometric elements within the prosthetic assembly.

- A streamlined software solution that addresses both efficiency and freedom of creativity should be considered. A combination of automated and open stages within the process should be considered.

- CAD/CAM solutions must consider how the involvement of the patient can be preserved, so that communication between MPT and patient is sustained throughout the rehabilitation process.

This list provides impetus for further research in the context of both technology and user-based challenges. This highlights an opportunity for not only academic research studies but could also drive commercial opportunities and feed practical application.

11.2.3 Technical recommendations for retention mechanism design and fabrication

The technical evaluation of retention mechanism production should be more clearly defined in future work. The acceptable range for accuracy of fit of the bar-abutment interface remains unclear. This PhD explored the use of CMM touch probe to measure the accuracy of fit, but it is not simple, especially with introduction of three or more abutments. Defining a clinically acceptable range for 3-dimesnional fit is complicated - more clarity is required on this.

The PhD findings correspond with key areas identified for AM development. These areas are particularly focused on describing AM part performance, and development of testing procedures for measuring AM part performance. The data produced from measuring the AM samples can be used as an initial attempt to present values for dimensional accuracies and surface roughness for the selected samples. In the current literature, this information is limited, must be updated in parallel to technology developments, and relies largely on manufacturers' promotional literature. This provides an opportunity to expand on this knowledge base in further work.

Some of the selected manufacturing technologies showed promising results for producing the retention components. However, the range of potential available CAD/CAM materials and processes is expanding quickly. AM technologies may be particularly useful for facial prosthetics, especially where multiple materials of varying properties can be produced simultaneously, for example, using *Objet Geometries PolyJet Printing* to produce clip structures integrated into the prosthesis form. It is

recommended that future research continue to seek, identify and explore technologies that are well suited to facial prosthetics.

Further research is recommended focusing on the technical and biomechanical factors of the most appropriate CAD/CAM samples in this PhD study. It is crucial to ensure that any potential risks for the patient can be eliminated - the CAD/CAM samples within the PhD remain conceptual, and should not be considered for human use without rigorous testing of material, process and biocompatibility. For example, the electroplated samples must be tested further in consideration to wear, galvanic corrosion and biocompatibility, aspects that this PhD could not cover.

Research in CAD/CAM fabrication should also concentrate on application-specific surface finishing processes, in the context of extra-oral retention mechanisms, finishing processes that can produce highly accurate, controlled surfaces that discourage bacterial colonisation. The varying surface roughness levels of AM components and their relationship with bacteria colonisation should be explored.

11.3 Main conclusions

The overall research question asked: -

> *To what extent can CAD/CAM be used to produce customised Maxillofacial prosthesis retention mechanisms, and what are the challenges associated with using such a strategy??*

In consideration of the findings and research question, the research can be summarised by a number of conclusions:

Building a successful extra-oral prosthesis assembly relies on a satisfying a framework of mechanical, biological, clinical and process requirements. Current conventional methods can address this, but they are full of idiosyncrasies and relies fully on the opinion of the MPT to determine the clinical feasibility of the device.

Existing CAD/CAM technologies can be used to complete all necessary stages of retention mechanism design, manufacture and integration into the prosthesis. However

the CAD/CAM process in its current state is impractical for clinical use and to meet all the identified requirements.

The functions and features of extra-oral retention bar-clip structures can be measured objectively using quantitative methods. The methods used provided valuable insight into the technical performance of bar-clip mechanisms, exposing inaccuracies and design flaws that current checking methods cannot easily identify. Phase 4 also showed that the technical performance of the selected CAD/CAM processes do not match conventional bar-clip production in every aspect. Therefore, caution must be applied in attempting to replace these methods in the clinical environment without further scientific research.

To summarise, a range of factors influences the feasibility of using CAD/CAM in extra-oral prosthesis retention mechanisms; it is not limited to assessing the technical aspects of replicating conventional practice with new technologies. The technical requirements must be met and be measurable, but its practicality in the clinical environment and its suitability for patient care must be considered and challenged. MPT opinions must be considered in the development of new products and processes in this field, but the opinions of MPTs must be supported with technical data. This work has shown that there is potential for CAD/CAM technologies in the context of extra-oral retention mechanism design process, fabrication, and evaluation, and this drives future work.

11.4 Publication Plan

The following journal articles will be submitted/published in the relevant international scientific journals post submission of the PhD thesis.

- Daniel, S. & Eggbeer, D. (2014). *A CAD/AM process for maxillofacial prostheses bar-clip retention.* Rapid Prototyping Journal. Emerald. *IN REVIEW*
- Daniel, S., Eggbeer, D. & Evans, P. *Current practice in Maxillofacial Prosthesis bar-clip retention mechanism production and MPT opinions of CAD/CAM: A qualitative study* (e.g. The Journal of Prosthetic Dentistry)
- Daniel, S., Eggbeer, D., Brousseau, E. & Littlewood, E. *An evaluation of dimensional accuracy, surface roughness and fit of CAD/CAM retention bar*

structures for Maxillofacial Prostheses. (e.g. Rapid Prototyping Journal, Emerald)

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Appendices

Appendix I: List of publications, presentations & other relevant work

Publications

- Daniel, S. (2012). *Design Technologies in Facial Reconstruction.* Annual Research Review, Cardiff Metropolitan University, Vol 1 (2). (15 research projects selected across the University)

- Daniel, S., Eggbeer, D., Millward, H. & Evans, P. (2010). *Development of Design Criteria for Maxillofacial Prosthesis Retention Mechanisms.* Proceedings of 11th National Conference on Rapid Design, Prototyping & Manufacture. Jacobson, D., Bocking, C.E. & Rennie, A.E.W. (eds.). High Wycombe: CRDM Ltd. p109-116.

- Daniel, S. (2012). *An Observational Study of the Maxillofacial Prosthetic Craft Process. Conference for emerging art and design researchers.* Extended Abstract. Wales Institute for Research in Art & Design (WIRAD) Conference, Cardiff.

Conference Presentations

- Daniel S*, Eggbeer D, Evans P. Design Criteria Hierarchy for Bone-Anchored Auricular Prosthesis Retention Mechanisms. (2011). 4th International Conference in Advanced Digital Technology in Head and Neck Reconstruction. Freiburg, Germany. *Presented

- Daniel, S.,* Eggbeer, D., Millward, H. & Evans, P. (2010). *Development of Design Criteria for Maxillofacial Prosthesis Retention Mechanisms.* 11th National Conference on Rapid Design, Prototyping & Manufacture. Lancaster University. *Presented

- Daniel, S. (2012). *An observational study of a Maxillofacial prosthetic craft process.* Extended Abstract. Conference for Emerging Art and Design Researchers. WIRAD Conference, Cardiff.

Conference Posters

- Daniel, S. (2010). *Digital Technologies in Maxillofacial Prosthesis Retention Mechanisms.* 3rd Academic Associate Poster Symposium. 4th May. University of Wales Institute, Cardiff.

- Daniel, S. (2011). An IMPT Survey: *The design and manufacture of retention mechanisms for auricular prostheses.* Poster at 25th Scientific Congress of The Institute Of Maxillofacial Prosthetists and Technologists. 7th-9th September, 2011. Birmingham, UK.

- Daniel, S. (2012). *Design Technologies and Facial Injuries: Digital Design in Maxillofacial Prosthesis Attachments.* Academic Poster at the University of Wales Research Students' Conference. Cardiff.

- Daniel, S. (2012). *An Evaluation of Surface Roughness and Accuracy of Fit of Rapid Prototyped Retention Bar Structures for Maxillofacial Prostheses.* Academic Poster at the 21st Symposium of the International Association for Surgical Prosthetics and Epithetics. 5-7th October 2012. Heidelberg, Germany

Workshops (assistance)

- Digital Technologies in Facial Prosthetic Rehabilitation. 25th Scientific Congress of The Institute Of Maxillofacial Prosthetists and Technologists, Birmingham, UK. 2011. Workshop tutors included Dr. Dominic Eggbeer (PDR/CARTIS), Peter Evans (Morriston Hospital/CARTIS)

- An Exploration of Digital Technologies in Facial Prosthetic Rehabilitation. 4th International Conference in Advanced Digital Technology in Head and Neck Reconstruction, 2011. Freiburg, Germany. Workshop tutors included Rosemary Seelaus (IRSM), Ben King (IRSM Canada), Dr. Dominic Eggbeer (PDR/CARTIS), Peter Evans (Morriston Hospital/CARTIS).

Other relevant information

During my time at Cardiff Metropolitan University, I undertook a number of commercial activities for The National Centre for Product Design & Development Research (PDR). This included patient-specific medical modelling and various design / engineering projects.

Appendix II: Interview transcripts, question sheet, participatory form

Participant Information Sheet

PhD Project Title

Novel design solutions in maxillofacial prosthesis retention mechanisms

Aim of this study

This study aims to gather valuable information from prosthetists and technicians from various prosthetic rehabilitation laboratories around the UK. The research is specifically seeking information on the design and fabrication process of implant-based extra-oral prosthesis retention mechanisms.

Why is the research being undertaken?

This study is one stage of a 3 year PhD based at the Medical Applications Group at The National Centre for Product Design and Development Research (PDR) in Cardiff, Wales. PDR's research focuses on the development of new knowledge, new technologies and new systems and practice in rapid product design and development.

Who is undertaking the research?

Steffan Daniel will be undertaking the research. Steffan is in his second year of his PhD study based in the Medical Applications Group at the National Centre for Product Design & Development Research.

Who is funding the research?

The study is funded by the Medical Applications Group within The National Centre for Product Design and Development Research and the PhD funding is supported by The University of Wales Institute, Cardiff.

How will the data be gathered?

Ethnographical study methods will be used for this research and we are not seeking to collect any sensitive data on you. A mixture of observational and semi structured interview techniques will be used to gather data.
Permission will be sought before any notes are taken or recording of audio.

Timescale of the Study

The overall timescale of the study is expected to last between 2-3 months. This includes the pre-study organisation, piloting the study, conducting the sessions with the prosthetists, collating and analysing the data.
Actual time that each participant will be involved in the study will about 1 day each in total.

Why have you been asked?

Volunteers are required for this research study from the field of maxillofacial prosthetics so that expert opinion can be gathered and practice can be analysed. It is entirely voluntary – there is no obligation of any kind to join the study and you will not discriminate in any way against if you decide not to take part.

What would happen if you join the study?

If you join the study you will be asked to design and fabricate a typical retention mechanism that will be used to retain an auricular prosthesis.
The study begins with an introduction that aims at giving you a brief overview of the research. Following this, you will then be asked to proceed to create a retention mechanism using the model of the head portion provided or a patient (depending on circumstances).
The exercise will be recorded by note taking and photographed. Key points and thoughts as you are working will be described in the notes.
Once the exercise is complete, you will be interviewed using a semi structured interview style. The purpose of this interview is to gather as much insight into your experiences and process as possible.
During the interview you will be encouraged to be analytical of your own process and discuss the process others might take.

Are there any risks?

We do not foresee any immediate risks to the participants of the study. If you decide to join the study you can change your mind and stop at any time. There are no penalties for stopping.

What happens to the data collected from the study?

The data from the study will be disseminated in an international conference paper and/or journal paper and be included in a final PhD thesis.

Are there any benefits from taking part?

By taking part in this study you will be given the opportunity to use your feedback and opinions on the currently used processes of creating and designing maxillofacial prosthesis retention mechanisms.
The expected benefits of this research is to contribute technically and clinically to the field of maxillofacial prosthetics by exploring and evaluating novel design solutions for today's process of designing and fabricating retention mechanisms.

How we protect your privacy

All data collected from the study will be handled in accordance with the Data protection Act. Any consent forms and written documents will be retained by the principle investigator for a period of at least 5 years in a secure location within UWIC. The documents will be made available for the purpose of inspection. Digital data such as audio recordings and video and notes taken will be kept on a password protected computer.

YOU WILL BE GIVEN A COPY OF THIS SHEET

If you require any further information about this project then please contact:

Steffan Daniel
Tel: 029 2041 6692
Email: stdaniel@uwic.ac.uk

Dominic Eggbeer
Tel: 029 2041 6703
Email: deggbeer-pdr@uwic.ac.uk

PLEASE NOTE: By taking part in the study implies consent to participate.

Participant Consent Form

Participant Name:

UWIC PARTICIPANT CONSENT FORM

Title of Project: Novel Design Solutions in Maxillofacial Prosthesis Retention Mechanisms

Name of Researcher: Steffan Daniel

Participant to complete this section. Please initial each box.

1. I confirm that I have read and understand the information sheet dated ..... for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my relationship with UWIC, or my legal rights, being affected.

3. I understand that relevant sections of any of research notes and data collected during the study may be looked at by responsible individuals from UWIC for monitoring purposes, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I provide consent for the taking of photos and video recording of my participation within the study .

5. I agree to take part in the above study.

_____ _____

Name of Participant Date

Signature of Participant

_____ _____

Name of person taking consent Date

_____

Signature of person taking consent

Interview Transcript - Pilot Study *10/11/10*

Section 1 – Prosthesis success

1. ***What for you makes a successful auricular prosthesis?***

When you try it on the patient and they are happy with the result. The colour matches, the edges blend in, that's what makes a successful prosthesis. Whether it holds in place correctly. If the patient's happy. You can take it on or off easily. You sometimes won't know whether a prosthesis is successful there and then. It's only really in use when you find out if a prosthesis is successful or not. You might not know when you're making it or when you fit it, a couple of weeks later, the patient might come back and say 'this is great ' or….'I can't get this thing on'.

2. ***How do you think the retention mechanism affects the overall success of a prosthesis?***

It's important to the patient. As long as they can put it on and it stays on. No patient wants implants, they just want a prosthesis that stays in place. Something they put on, it's secure and stays in place. That's really what the success of it is really.

3. ***What are the main reasons you must duplicate a prosthesis bar and clip retention mechanism? What effect does this have on the overall function of the prosthesis?***

You very rarely need to duplicate the bar because the way we work, you take the bar off and it's used on the mould. You need to make a new base plate each time the patient comes in (for a replacement prosthesis). Sometimes we re-use the patient's base-plate. Generally we re-make it when they come in. Because they might keep that existing prosthesis and we make a second spare one for them.

4. ***What process do you follow for the duplication of a bar and clip prosthesis? Does this have its advantages or any complications?***

- *Duplicating the base plate*

To duplicate a baseplate, we replace the bar in the mould, put the clips on the bar, add a light cure gel/acrylic, set that off then that's the base plate duplicated. It's repeating the whole process.

- *Duplicating the Bar*

That would be tricky. It's almost impossible to duplicate the bar accurately enough to use it. We did develop a technique in 1990 duplicating the bar, but even that was tricky. As the base plate fits so well, and you might have a little solder out of place, it's not going to be….if you try and duplicate any 3D object, to that degree of accuracy, it's very difficult.
You could make a duplicate bar for the patient or a 'second' bar for the patient but it won't necessarily be a duplicate. You could make a new base plate on it but the base plate will only fit that bar. It's unlikely you will make a bar that most base plates will fit. You would always make a bar with a substructure to go with it. They go hand in hand.

5. ***What are usually the reasons a retention mechanism might fail to do its job?***

Usually, it fails to do its job because,

- With magnets if it's not enough magnetic retention or there's too much soft tissue around it pushing the prosthesis off.
- With clips, they might need adjusting or tightening. In rare cases, you might need to add another clip to make it more secure. The good thing about the clip is because they are gold, they can be adjusted.

6. ***How might you overcome the potential of implant failure in the design of prostheses and their retention components?***

If the implant failed in an ear case it's very difficult to overcome that because you've only got two fixtures. We've done designs using eyeglasses and magnet and then changing to a V shaped bar on the retaining implant. But because the cylinder swivels, once it becomes loose, the prosthesis won't fit in the correct position. Makes it very difficult. If you've got a prosthesis for an eye, you can put in another fixture. For an ear it's almost impossible to get round. When you've got several fixtures for a midface defect, you could get away with it.

7. ***How might you diagnose the cause of implant failure?***

It's very difficult to diagnose why an implant fails, and sometimes it might fail and you haven't noticed it's failed because it could be a third implant and it's supported by two others. You take the bar off and you don't know it's failed. Sometimes you know if the patients' had a bash on it, then that might be a reason or if they're on a certain amount of drugs, if it's radiotherapy, which could be the reason. They might get a bit of bleeding and a dull ache, but it's fairly pain free – sometimes they come out and they don't even realise.

8. ***When adjusting the retention forces, what is considered when finalizing the retention force?***

Whether the patient can put it on or off. Sometimes I change the retention forces. Initially when putting the prosthesis on, I might keep the retention force fairly low, when you talk about bar and clip. You can't change it with magnets but they don't have a lot of issues with putting magnet ones on because they pull into position. So, dealing with bar and clip, keep the retention force fairly low so it's easier for them to put the prosthesis on and then maybe tighten it up slightly later. When they get used to it…otherwise they feel they've got to force it.

Section 2 – User Requirements and Mechanism design

9. ***What in your opinion are the requirements in the design of a retention mechanism for a maxillofacial prosthesis?***

- To be easily attached and detached
- Long lasting
- Inert
- Easily cleanable
- Adjustable
- Repairable
- Robust – got to last a reasonably long time

10. ***Could you rank the factors which you feel are the most important (most important at the top and least important at the bottom)?***

1. To be easily attached and detached
2. Inert
3. Adjustable
4. Easily cleanable
5. Long lasting
6. Repairable
7. Robust – got to last a reasonably long time

11. ***How do you think any of these performance factors may be difficult to measure/evaluate as part of the process?***

No problem with evaluating these factors. You'll know through experience with the patient whether they are good or not. You would just know.

12. ***How would you normally check the retention mechanisms so that they can be passed as clinically acceptable?***

You would normally take the prosthesis on and off, put it on, take it off. Ask to do some facial movements. If it's displaced you know it needs some adjustment. If they can't get the prosthesis on, then they need adjustment.

13. ***Are there any established standards or testing methods for the evaluation of these performance factors? Could you tell me your thoughts on them?***

No standards of these testing methods. Each patient is different at the end of the day. You wait to see and adjust it to the patient's lifestyle. Couldn't really have a standard because you can't say one child has

20Ncm to take this on or off. That one child might be sedentary or the next child might play rugby and then it'll come off straight away. So it really goes with lifestyle.

14. ***How might you test for usability of the prosthesis for the patient?***

Testing it only really comes with feel, taking it on or off and making sure they're happy. The usability only really comes with time and they can go away, try it out. Most struggle when they first try it but then after a while it becomes second nature. We don't get any patient who can't put it on or take it off. Might struggle in the beginning but then after a month it's usually ok.

15. ***Is passive fit in bar structure designs important to you? Why? How do you ensure there is a high level of passivity? To what level do you know the accuracy of fit?***

I think passive fit of the bar construction is one of the most important factors because if you don't have that passiveness, when you tighten it up, you're putting a strain on one or more of the implants which could lose you that fixture, which could lead to failure. That's one thing we've always done is solder the bar, try it onto the model, try it back on the patient, very carefully tightening it down to right tightness and making sure there are no gaps appearing as you tightening it down. You tighten one down, making sure there is no gap appearing on the other side. We have had problems in the past with non-passive bars so that's very important really.

It is purely by eye (you know the accuracy of fit). I don't think you know to a high degree, or to a sufficient degree how accurate bar fits really. It is purely down to a visual check, you just tighten it down and see if it moves. If you looking at it on the patient and it is a particularly difficult area, maybe in an orbit or it's an ear with a lot of hair around, it's difficult to see. All your trying to look at is the distance/gap between the cylinder as you tighten it down and the other cylinder between the bar. It's probably not a very scientific way of doing it. It seems to work but we don't know that… In theory a poor fitting bar, a non-passive bar could cause problems to the fixture. In theory it would be pulling on the fixture. If you tighten one down, they would certainly be pulling at each other. Now they might move through the bone physically and re-adjust themselves….we don't know…but it could also cause pain for the patient and lead to infections etc.

16. ***Have you experienced any complications with bar structure mechanisms that do not have a high level of fit?***

We have had patients complaining of pain and we've looked at the passiveness of the bar and there has been a visual discrepancy. You'd probably guess a ¼mm or something like that. You can see when you tighten one side of the bar down, you can see it bouncing on the bottom, there was a gap occurring that we hadn't noticed, and that's caused problems for the patients. The technique for making the bar is open to distortion. Although we've changed our techniques, both are not perfect by any means, they could distort.

17. ***What do you think of the concept of functional loading on implants by applying designs that are essentially 'mis-fitted'?***

I think that's only been looked at in an oral situation but I don't think that's been looked at in an extra-oral situation. I think all prostheses must provide some loading to a bar because the edge is compression fitted, so often you would fit the edge with the patient maybe, with their mouth open, so when they close their mouth the edge stays in contact, otherwise what can happen if you fit it in the passive state, when they open their mouth there's a gap. We've often fitted the prosthesis like that. So there is micro-movements there, now how much of that is transferred to the ear, to the bar through to the prosthesis is difficult to estimate, because you're dealing with silicone and each ear is going to be different. You're dealing with a flexible material, so how much is being transferred is difficult. If you look at the success rate of the implant in the mastoid area – 96/97% success rate, we must be doing something right, so I don't think there is necessarily a need to look at loading. What you might get by that (loading) is an extra deposition of bone and overgrowth of tissue, so it could go the other way.

18. ***How is the mechanism designed to accommodate for cleaning and hygiene?***

We always, whenever possible, we raise the bar above the tissue by around about 5mm, or as high as we can get it to be honest within the confines of the design of the ear, we use to have 3 and 4mm cylinders

but now we've got only 4mm cylinders to use. So now we would raise that bar above the tissue around about 4mm I suppose. What we try to ensure is that you can get a cotton bud underneath so that the patient can clean around it. We try to ensure that the soldering is neat and tidy so that it doesn't pick up debris. In older patients we would try and raise the bar a little higher. Just to make it easier for them to clean really because their dexterity is not so good. Because the ear is bigger, you've got the possibility for raising the bar higher. You want the bar parallel to the skin because when the patient is asleep you don't want the bar kicking out, or catching on the bed clothes or when they're putting their clothes on. We advise patients to take their prosthesis off every time they go to sleep. Some patients don't but we advise patients to do that. So we try and design the bar so that's parallel to the tissue so that when they take their clothes off or sometimes you can curve the end of the bar so that's a smooth passage.

19. ***What effect might surface roughness have on the mechanism? Between the bar and abutments, and between the bar and clips?***

- Between the caps and the abutments:

You really wouldn't want surface roughness there because anything that would manage to hold bacteria wouldn't be a good thing, so you really want a higher polished surface as possible.

- Between the bar and clips:

The nature of the clips – the clips are designed to curve around the bar, and a lip on them to catch onto the bar. By roughening the bar you would improve the retention. I suppose the danger is that you might make it a surface that can pick up bacteria, not so easy to clean. We try and have everything so it's pretty smooth and clean.

20. ***Are there ever any complications with screw loosening? What might be the cause of this?***

Because a screw is gold we don't often have a problem with screw loosening. We probably see the patients twice a year. Once for a check up and once for a new prosthesis. Very rarely we get patients coming in with a screw loose. When you tighten them down, because they're soft yellow gold you get that 'bite' with the metal so they generally don't come loose.

21. ***Why are bar structures shaped so that there are protruding 'arms' on each side?***

The design of the bar structure is to really support your prosthesis so that you might have…One is to stop rotation, an angled arm to stop this. If you just have a single piece between two implants, say a straight bar, what would happen is you get a rotation effect, because you have round clips too. By adding the bar to the two ends, you add stability. Often your implants will be quite high up but the bottom, the 'lobe' to your prosthesis will be down to the cheek. If you retain high up and you've got nothing but silicone down to the cheek, then you're going to lose edge pressure. The bar gives you that stability and it spreads the load so that the prosthesis gets the support all the way down. You can do that with the base plate a little bit by extending the base plate a little bit. If you increase the size of the base plate you make the ear more stable. With the arms extending from the bar you get a more stable prosthesis. A general rule is that the arms aren't any longer than the span between the implants so you get too much leverage on the fixture. It's got to be enough for 1 clip at least. I don't usually make the arms much longer than 3 clips length. Depends on the shape of the ear. For older people when you have a big lobe coming down, you might make the bar longer to give it that support.

22. ***What are the advantages of using bar structures over magnets? When and why would a prosthetist choose to use magnets?***

With magnets, they're very off and on. You can't adjust the magnet really. There little tips and tricks you can do to, like sleeving the magnet. You can change the size of the magnet but it's really just off and on retention. By using a bar and clip, if you want to have more clips you can, if you want to have a longer bar you can, if you want to change the area of your retention, say in the orbit or the nose or a large midface defect you might want support in different areas. If you're using a magnet, you're only going to get direct support and the rest is by the base plate. With a bar structure you're sharing that support. You can spread it around the bar structure. Also with a bar you're bracing the other implant. With the magnet, although it's very off and on, the force is directly onto that fixture, but with a bar you can share that force between all of them. So you might have say, 3 fixtures and you want to share them but one might be 3mm long, one is 5mm and one is 10mm, you don't want to put all that force on the 3mm one and you might want to share it on the other two because they're longer fixtures. You can't do that with magnets.

23. ***What determines the implant positions (xyz planes and distance from each other)?***

In an ear: One, surgically it's going to be the availability of bone. Secondly is you want to be in thickest part of the ear, within the anti helix, you try to position your implants, within that area so your bar structure and base plate all fits into that. You want them far enough apart so that the patient so that the patients can clean between them. So you don't want them too close together once you get your gold cylinders on and you can't fit a bar inbetween them or you can't fit a clip in between. You want them far enough apart to do that. And you want them as parallel as possible. **Are the implant positions effected by the design of the bar structure?** I would be considering the design of the prosthesis but I wouldn't necessarily consider the bar design first. I would consider the implant locations in relation to the prosthesis, and then I would design my bar around that. So you might think, there's my perfect ear position but there's no bone there – a current case is a child with 2mm thick skull so it's very difficult. Fixtures of this length probably won't work if they're this big. So then you have to change the implant position to where it can be compromised.

Section 3 – The Design Process

24. Where in the process do you believe there to be a high level of accuracy?

You don't really know. I presume the implant location when you do the impression should be accurate enough. We don't feel there's a problem. We're not losing implants, we're not getting patients constantly talking about having pain, we're not getting bars fracturing so whether there's a high degree of accuracy is debatable but certainly the degree of accuracy we're working with seems to be suitable for what we're making. We're only connecting generally 2 implants so there is a margin for error, but when you start to connect 3 or 4 then you might get problems. You're generally only connecting over a small span of 2cm at the most. When you start to make large spans, that's where you start to find problems. Then would we certainly consider milling something. It's only going to be as accurate as your impression at the end of the day. We did make a large bar structure for one guy with a large midface defect and that was very difficult (horrendous) to make. We don't make them very often fortunately for the patients. We lost implants on one case with a large midface defect. We would like to try a milled bar with him. Interestingly with his gold bar there is some flex, the same gold as we use for the ear. There is some flex in it – that's quite interesting. Should you have flex? Because it's a midface, you've got those masticatory forces. In your skull you've got some flex, it's not a perfectly rigid structure, there is flexing in the skull and the bones move. So do you want in your retention system a perfectly hard rigid thing, when you've got masticatory forces, maybe in the ear it doesn't matter, but do you want that bit of give so you're not pushing direct hard forces onto those implants? I don't know. Mastication forces are high.

25. Where in the process do you believe there to be inaccuracies introduced (if at all)?

Probably all the way through. There's nothing to check it. Depends what you call inaccuracies? I don't know how accurate the impressions are…but it doesn't seem to be a problem….

26. At which stages in the process do you perform any 'checking' procedures?

When you take the impression, you check that the impression copings in the impression are set. That they're not moving, you move them with a screwdriver and make sure that they're set within the impression. Sometimes if you don't get enough bite registration paste around there then they can be floating around in there, and if you don't notice that then you could get inaccuracies. When you put the copings on you check that the pins are tight. Cast the impression, take it off. When you make your bar, you check that that's passive before you solder it, then you solder it, put it back on then check again to what we feel is passive. Then you put it back on the patient and check that it's passive on the patient. That's all visual really.

27. What are the benefits of multiple part assemblies? (Abutments, spacers, caps, bars)

The benefit of that is flexibility. If you've got all those components you can do different designs. It's the flexibility. There aren't a huge number of components compared to some dental assemblies. The more bits, the more bits to go wrong.

28. Do you apply any design techniques that are personal to you? Any idiosyncrasies/habits that others may use or may not know of?

One of the design techniques is turning the end of the bar down so it doesn't catch the patient. Angling the bar, making sure it's parallel so it doesn't catch on clothing. I used to make bars curved so it was more aesthetic. When the patient took their ear off there was a curved bar the same sort of shape to the ear but then I found it didn't work because the ears popped off. The clips were meant for a straight bar so I gave up on that one. It looked good but it was useless because he clips were straight so they didn't stay on.

29. ***Have there been any recent developments in the design or fabrication process that you are particularly aware of?***

In the design process we have 3D planning now so that's changed things. The only change really is milled bars. It's already been done orally so the ears are the next step for us, to have milled titanium bars rather than the wrought gold bars, which should increase the degree of accuracy that patients have in their bars. We tend to follow what happens dentally I suppose, because that's where all the research and money goes and there's more cases. (NAME) was talking about it recently so it won't be long before milled bars come. We could be doing it tomorrow; it's just a matter of sitting down and doing it. The companies are there and they're happy to do the work. Maybe not just the bar but maybe milling the gold cap as well, and the abutment. So maybe you'll have a screw that goes straight down onto the fixture. At the moment you've got fixture, abutment, cap. In theory you could mill the gold cap and abutment in one, so you could screw directly on the fixture then. A variation of abutment design. Which might improve things, or might not improve things, we don't know yet. It would be worth trying.

30. ***Do you follow any particular guidelines or regulations for the manufacturing methods?***

We use standard materials, standard gold bar – a high degree of gold so that we know that the purity is there. We try to keep the materials the same, so gold clips, gold bar, so you don't get any different reactions between metals. The rules really were set down by Branemark a long time ago, we don't make the span of the bars too long so that are lower forces on implants. We try and keep it off the tissue so that you can clean around them.There are no hard and fast rules really, as long as the materials you use are suitable.

Section 4 – Computer Aided Design Processes

31. ***What is your experience of Computer Aided Design (CAD) in the design process of creating prostheses? Do you currently use any CAD processes in any prosthesis design processes?***

What we tend to do now in our working practice, we don't really look at the bar design when we're placing the implants, we leave that until the implants have been placed. But we tend to do is I would, make the bar, make the base-plates, paint that with a little bit of tip-ex and carbon, mix those together and place that on the base plate so it's like a matte grey colour, put that back on the patient, send them off to be scanned and then reposition the ear over the top of that, then do a Boolean operation so then send that to (NAME) to get the ear pattern made. The only downside of that is not having a wax machine. You have to duplicate whatever comes back in 3D. Duplicating one surface of an ear is not so bad. You pour the silicone into the top but duplicating two surfaces is difficult. It's a bit of a pain. That's how we go about it at the moment. That does save a lot of time, especially for orbits.

32. ***What obstacles may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

Cost is the main one. You've got to be a busy unit to justify it, and even a busy unit finds it hard to justify. You consider how many patients you're treating which is never huge numbers and if you are a prosthetist that is doing a fair number you can already carve pretty quickly. I've got to weigh up my time, e.g. If I've got an ear there then it's in plaster. We've got to spray it then scan it in two axes, that might take a while. Then we've got to put those scans together, then take it through Freeform, then edit it, send it to (NAME) for making it with SLA, send it back to me, then I'll duplicate that into some silicone impression material. Pour that up in wax and there's my ear. You consider the length of time those processes take. I could carve an ear in half a day. As no ear is exactly the same as the other one it doesn't matter that it's not a perfect replica. That's what you've got to weigh up. If you're not a busy unit, it's hard to justify the cost. Those are the limiting factors. We need to be able to scan, send, boom – to make it an effective process.

33. What benefits may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?

It's almost an advantage for those not doing a lot of work who are not so well practiced in carving etc. It's easier for them to send off to have an ear made rather than spending 2 days to carve an ear, whereas it takes me 1/2 a day to carve an ear. It's almost better for them. It's predictability and also the fact there is less patient time involved. If you can do things on-screen in CAD it's far better than to do it on the patient. If you're referring to the substructure or to the bar, the advantage of CAD/CAM in that respect would be accuracy and dependency, it might be that I make a bar, try it on and it's not passive, if we can streamline the thing and you can CAD/CAM that bar, and you know it's going to be passive then it's better for the patient, and it's better and saves work for us. Once it's been sent off and it's being milled, I don't have to make and solder the bar. Another advantage would be that what we normally do, when a patient comes in for a remake, we take the bar off them, we put it in the mould, they wait, we colour match it and they wait while that's processed and we fit it in the afternoon. I need the patient's bar. If you were CAD/CAMing, I could have a duplicate I could put in the mould. I have tried various methods of doing this but it's never really worked. But if you could CAM/CAM it and put it in the mould, we wouldn't need the patient. So in theory, a patient could wear their existing ear, come for a colour match and I could post it out to them. Or they could come in another day for a fitting; they don't have to be there on that day. Make us more flexible and it would be better for patients. It could actually make a big difference.

Revised & Final Interview Questions

***Name:* …… *Date:* ……**

Dictaphone x 2

Subject: *The design and manufacture of retention mechanisms for auricular prostheses.*

Aim*: To obtain your expert opinion, gain insight on your experiences and design process, why you follow this process and how you evaluate it.*

Note: *Take as little or as much time as you like for each question, and there is no right or wrong answer!*

Section 1 – Prosthesis success

1. What for you makes a successful auricular prosthesis?
2. How do you think the retention mechanism affects the overall success of a prosthesis?
3. What are common reasons a 'bar and clip' mechanism might fail to do its job?
4. How might you diagnose the cause of implant failure? How do you think a prosthesis might affect this? (mention 'compression fitting forces' and 'misfit forces')
5. How might you overcome the potential of implant failure in the design of prostheses and their retention components?
6. Are larger mid-face prostheses more likely to fail than auricular prostheses? Why is this?

Section 2 – The Design Process

7. How might you define the levels of accuracy in the design and fabrication process? Do you believe there to be inaccuracies introduced at any point in the process affecting the success?
8. What are the benefits of multiple part assemblies? (Abutments, spacers, caps, bars) Is 'modularity' important to you?
9. Do you apply any design techniques that are personal to you? Any idiosyncrasies/habits that others may use or may not know of?
10. What process do you follow for the duplication of a bar and clip prosthesis? Does this have its advantages or any complications?
11. Is there any part of the process you feel particularly frustrated about conducting?
12. Have there been any recent developments in the design or fabrication process that you are particularly aware of?

Section 3 – Checking Procedures

13. How would you normally check the retention mechanisms so that they can be passed as clinically acceptable? (When would this usually be?)
14. Do you perform any 'technical' checking procedures? (When would this usually be?)

15. Are there any established standards or testing methods for the evaluation of the 'performance' of retention devices?

16. How might you test for the usability of an auricular prosthesis for the patient? How is this different to other facial prostheses?

Section 4 – User Requirements and Mechanism Design

17. What are the main considerations when finalizing the retention forces of the retention mechanisms? Is there a retention force 'range' that you work within?

18. Is passive fit in bar structure designs important to you? How do you ensure there is a high level of passivity?

19. Have you experienced any complications with bar structure mechanisms that do not have appropriate levels of fit?

20. How might you define (or evaluate) an appropriate accuracy of fit for bar structure mechanisms?

21. How is the mechanism designed to accommodate for cleaning and hygene?

22. What effect might surface roughness have on the mechanism? Between the bar and abutments, and between the bar and clips?

23. Are there ever any complications with screw loosening? What might be the cause of this?

24. Why are bar structures shaped so that there are protruding 'arms' on each side? Is there a specific length and angle the protruding arms should be?

25. What determines the implant positions (xyz planes) and their distance from each other?

26. What are the advantages of using bar structures over magnets in auricular prostheses? Have you experience of using any other devices?

27. Why are bar designs rigid? Could this affect the surrounding anatomy in any way?

28. What is the importance of the currently used materials in bar structure mechanisms?

29. Please rate the importance of the following factors for a bar and clip mechanism for an auricular prosthesis, and expand on your thoughts. (1 Not important →5 Very important)

FACTOR	**RATING** *(1 Not important →5 Very important)*				
Changeable/custom designs (flexibility)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Adjustability of retention forces	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Accurate fit between male and female components (e.g. bar and clip)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Equal forces distributed on implants	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Stability of ear when fitted	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Biocompatibility of materials	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Height of retention mechanism from tissue	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Mechanism longevity/durability	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Passive fit of components to abutments (e.g. bar to abutment)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Aesthetics of retention mechanism when exposed	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Ease of duplication	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Good wear properties of clips and bar interface	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Many components (Modularity)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Intricate	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Easy to clean	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Rigid design	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Easily attached/detached	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Follows the shape of the ear	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Does not snag on clothes	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Section 5 – Computer Aided Design Processes

30. What is your experience of Computer Aided Design (CAD) in the design process of creating prostheses? Do you currently use any CAD processes in any prosthesis design processes?

31. What obstacles may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?

32. What benefits may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?

33. Is there anything else you think is important to the success of an auricular 'bar and clip' mechanism?

Interview Transcript Participant 1 - 24/1/11

Section 1 – Prosthesis success

1. ***What for you makes a successful auricular prosthesis?***

When someone doesn't notice it when they walk down the street. That's what your aim is ultimately. When someone walks past you and they wouldn't notice there is anything different about their ear to the other side, so they wouldn't give it a second glance. That's my idea of it being successful.

2. ***How do you think the retention mechanism affects the overall success of a prosthesis?***

We use 98% of ours are retained by clips and bar; we don't tend to use magnets with ears. I've found they can get knocked off a lot more easily, once you use that magnetism, you lose the hold then and they can get knocked off. We have still got a couple of patients who use glue which does hold on pretty well, I think once you've put the glue on, they're not going to fall off very easily…but it's messy and that tends to make it more difficult as well. So I tend to always go for a bar and clip mechanism.

3. ***What are common reasons a 'bar and clip' mechanism might fail to do its job?***

If the clips are too loose….sometimes the clips can be loosened too much and that can cause them to drop off. If they're too tight, they might not be able to take them on and off easily enough. Occasionally you can get a fracture of one of the clips, or you can get one of the clips coming out of the acrylic. It doesn't happen very often but it can do, if it got knocked then it could cause the base to snap because you've got the clips within the acrylic base, and that's a possibility if it got knocked on there. We have had cases of people being hit on the bar and that can distort the bar slightly and that can stop them fitting as well. It doesn't happen very often though, it's quite rare. That'll happen to other ones as well but then you haven't got the bar there then. It's still going to cause the ear to fall off but then they would be able to replace that, but if you damage the bar in any way then it wouldn't be able to fit, it would have to come back, you'd have to go through the process again.

4. ***How might you diagnose the cause of implant failure? How do you think a prosthesis might affect this? (mention 'compression fitting forces' and 'misfit forces')***

I found that you'll try and put something on and it won't tighten, so it will just spin, spin and spin. Normally they just haven't integrated….we've had one that's happened 20 years down the line…and you think they're sound and then suddenly one has come out. And normally it will just come out, if it's half secure then it's still in there. It might be that we take the abutment off and you feel that it's loose and they do just come out, and they will come out clean…I have had a couple which have come out with a little bit of bone…you don't really know why it's happened but that's what has happened in the past. But normally it'll just spin round, some people might get recurrent infections, butt hat doesn't always cause failures though. Some people are more susceptible of having infections but there is that tracking because you've got the implant through the skin, it can get infection going down there and it may be that there is an infection that can cause it to break down which can cause it to come out. But I don't know exactly what that could be.

5. ***How might you overcome the potential of implant failure in the design of prostheses and their retention components?***

You have to make sure your bar is completely passive when you making it. If you made your bar and it wasn't passive then that could cause it to fail because you're putting stress on the implants then which would…if you're tightening up something that isn't quite passive then you can imagine it's just going to torque those abutments slightly and that could cause them to fail. I haven't really come across anything that could cause it personally. Some people think that if you splint them they will make them more secure, other people don't. That's all based on other people's evidence, on papers etc. I haven't come across it really.

6. ***Are larger mid-face prostheses more likely to fail than auricular prostheses? Why is this?***

Large face ones are normally on patients who are oncology patients. Some may have had radiotherapy, which can cause the implants to fail more readily than an auricular, that may be trauma or congenital or

oncology, which means the bone may be more secure, whereas if they've had radiotherapy they may get osteo-radio necrosis, where the bone starts to break down. So you do tend to get more failures in facial ones but more for that reason really. ***What about with more complex bar structures, has that effected anything?*** I haven't noticed anything. Sometimes you use magnets for orbits and things like that. I haven't had particular problems with it. I think as long as your bar is made to fit completely passively then there shouldn't be a problem there. It's more to do with the bone itself than it being the structure put on it.

Section 2 – The Design Process

7. ***How might you define the levels of accuracy in the design and fabrication process? Do you believe there to be inaccuracies introduced at any point in the process affecting the success?***

There's always some inaccuracy within taking the impression, following it through. You try and minimize these by making sure you take your impression and everything's completely passive. With an ear, if you've got 2 implants in there, when we're taking the impression we'll normally splint the 2 together, so you put the impression coping son and then you'll splint them together with light cure. Light cure is non-expanding as well so that should be completely passive. It shouldn't expand or contract. When you take your impression off you've then got your impression of that firmly in it, so when you then make your model that should be pretty accurately represented in your model. When you're dealing in things like wax, you pour the wax up and it can reduce in size. If you're duplicating one that you've done in the past, you can get slight shrinkage in the wax but then you can compensate for that by just adding to it to make it bigger. You can cancel out some of the inaccuracies. You've got some inaccuracy in plaster but you can argue that they are so small they it wouldn't really make a difference to the end product. In the silicone there's no expansion or contraction with that.

8. ***What are the benefits of multiple part assemblies? (Abutments, spacers, caps, bars) Is 'modularity' important to you?***

Yes it makes it much better then. You can make it all yourself by hand. You know which inaccuracies you've got then by doing it yourself. Bars you couldn't really do…I know you can mill them but I haven't actually tried that so I can't compare it to what I do at the moment. I think it's good that you can put all these parts together rather than just having one part.

9. ***Do you apply any design techniques that are personal to you? Any idiosyncrasies/habits that others may use or may not know of?***

Not especially. Because I've been taught here, you take little bit of other people who have taught you. There's nothing special that I do that would be any different to anyone else I think. People do things in different ways but the end result always looks the same. Some people make their mould slightly different but I haven't noticed anything major that would be different.

10. ***What process do you follow for the duplication of a bar and clip prosthesis? Does this have its advantages or any complications?***

I don't duplicate bars so…I'd make one bar and you'd make your prosthesis on there and then you'd make another one and you'd make a separate prosthesis on there so they wouldn't fit on your first bar so you've basically got 2 separate ones rather duplicated ones. But the bar would fit in the same mould so it would it would just be the bar that would be different. So you've got 2 bars and you can use those 2 bars in the same mould. So your ear would end up looking the same, it would just be the bar that would be slightly different. That's more from just making them by hand. Everything as close as possible looking so that the patient finds it easier to put it on but I don't tend to duplicate a bar. You just have to make it up again from scratch. So they'll always be slight differences between them. It's a bit more time consuming I suppose. The good thing about it is for the patient, because you've always got a spare one, although if you could duplicate them you would have the same thing, you've always got something there, so you haven't got to go through the whole process again with the patient once you've made it twice. You can still make it up in the same way. As long as you make the bar pretty similar the patient shouldn't have a problem either in fitting it. They soon get used to the slight difference in shape etc, it might be that it's just your angles are slightly different on the opposing side, it shouldn't make a big difference really.

11. ***Is there any part of the process you feel particularly frustrated about conducting?***

I still enjoy it all. Every little bit is different and because we do the whole lot, it's not like you're just churning out the same thing the whole time, and because you're doing all those different stages I think it makes it better rather than frustrating. Because you do it all the way through, you're not thinking 'oh I've got to all of that again' so you sort of do different processes all the time and it's quite nice to do it like that. Making the bases is sometimes a bit tedious doing those, but they don't take very long, 10 minutes or so and it's not too difficult. I still enjoy doing the waxes and mixing the colour. It's more waiting for plaster to dry, if you're trying to do it in short time scale, waiting for the plaster to set, you can't do it too early or anything like that, so you want to make sure everything is fully set…..It's more time space in-between things that can get frustrating but there's not anything you can do about that. You've got lots of little stage that you have to go through to get to the end result.

12. ***Have there been any recent developments in the design or fabrication process that you are particularly aware of?***

Some people are milling bars now. We got to this implant stage then the process has been pretty similar since then really. There's different silicones coming on the market that can make it a bit different, you can make an ear but it's softer and there are silicones you can buy to make the lobe softer than the helix. They're compatible because they're all the same, you're just using a different catalyst to make the Shore hardness slightly softer. I don't tend to do that personally because it's more time, you've got to mix up little bits of both. Whether patients would prefer that, that's another question. But I don't tend to do that. That's part of the development process though, before you would use just the one silicone. And they are developing more silicones that are softer and flexible, especially for noses and things like that more than ears really. A lot of patients say it feels a bit hard and you want it to be quite flexible so we can use different types of silicone to make them more flexible. We always have our favourite that you back and use all the time, but there are other ones. We've got a few here. If someone reacts to one, we can use another one. You've got a bit of flexibility in that.

Section 3 – Checking Procedures

13. ***How would you normally check the retention mechanisms so that they can be passed as clinically acceptable? (When would this usually be?)***

With an ear you would physically tug it to make sure that it's not going to pop off. I always get the patient to feel if it is to secure to them. Different patient will have different ideas how they want it to fit. I'll always ask for their opinion as well on how tight or loose it is. Some patients might want it to be a bit looser, depending on their manual dexterity might not be quite so good and they want to get it on a bit easier. Others will want them really tight so it clunks on and then they've got that security that it's not going to fall off. I do it that way really in terms of retention.

14. ***Do you perform any 'technical' checking procedures? (When would this usually be?)***

I always want to make sure you have done everything properly really. That you use decent clips, that they're properly fitted into the acrylic, that the acrylic is solid, no cracks. The base is actually bonded into the silicone as well, that's quite an important one. We used to have problems with that in the past. You take it off a few times and it starts to peel away from the base which is going to affect the fit and everything ten. We haven't had that problem so much recently because we have different primers now. You cover the base with a primer and that what causes the silicone to bond with the acrylic then. If you didn't put that on they wouldn't bond together. You need that primer for the 2 to bond together. That's a really important part of it, if you haven't got that then it's failed really. If someone's going to take their ear off 5 times and it starts peeling out, then it's not the best way really. As long as you follow your procedure through properly, make sure that your base is completely clean, I mean I acetone them, get rid of any grease, completely de-grease them and then you put your primer on, usually leaving it for 20 minutes for it to evaporate. It normally opens up the pores on the acrylic and then when you pack the silicone on it should bond. That should be bonded for the life of the prosthesis basically. To get it out you'd have to literally cut it out if you ever wanted to get it out. That's one of the most important things really. We did have some instances a while ago where it wasn't working. Some primers are incompatible with some silicones and that. Some that are platinum based. Some companies' primers might not work with other companies' silicone. You've just got to make sure your using the right ones. It would be more person error than equipment error I'd say.

15. ***Are there any established standards or testing methods for the evaluation of the 'performance' of retention devices?***

I don't know. Other than making sure things fit and making sure that when you're making the bar you've welded it properly, no little gaps and things like that. I normally look by eye to check, using the laser welder to look through, when you're tacking it, you want to make sure there's no holes, when you're actually putting the gold on by welding it together, you want to make sure it all flows in to every little bit. Otherwise if you've got a little air space underneath it could cause it to fracture or something like that. You've got to take a bit of time to make sure that you get every last bit covered. And you should be able to see that through the laser welder microscope. You just have to do each bit slowly so you can actually see it hasn't just covered over a hole. You can always blast it again with another shot and sometimes you'll see it open up into a hole. You can then fill it in. That can affect it as much as it might snap as it won't be as strong if it has any air holes inside. And you don't want any porosity. You don't normally get porosity on there but you can get porosity if you solder them sometimes, if you don't put enough flux on there as well. I think it might oxidise it and that can make it weaker as well. Some people solder them and you still want to look at that under the microscope to make sure you haven't got any porosity in there, so plenty of flux and not heating it up too much. You also want to make sure the clips are solid as well.

16. ***How might you test for the usability of an auricular prosthesis for the patient? How is this different to other facial prostheses?***

You probably want to test their tear strength if you're using a new silicone because they are taking them on and off quite a lot. You want to make sure the edges aren't going to tear if they pull an edge. More so on say an orbit, because they're a lot more difficult to get off and they might stretch. Some silicones have a bit of stretch in them and if you pull them too much, stretch an edge, which could stop them from fitting properly. More on orbits than anything else. Noses and ears are a lot easier to pull off, orbits are a bit more difficult to get off sometimes because of the nature of the way they are so you'd probably find that more with those. You want to make sure that what you use is decent.

Section 4 – User Requirements and Mechanism Design

17. ***What are the main considerations when finalizing the retention forces of the retention mechanisms? Is there a retention force 'range' that you work within?***

I've never thought about it really. I just test it by pulling it really. ***So what do you consider then when finalizing the retention?*** Personally, if you pull it, you want their head to come with it. You don't want it to go pop and come off really easily, most patients wouldn't want that. It should be quite solid, you can test it in the mould as well. You get to know how it feels. I've never measured it in Newtons or anything like that. You get to know how solid it feels. You'd know if the clips were too loose if it came off too easily. Without much force of pulling, you can tighten the clips up to get that bit more retention then. You've got to make sure you put enough clips on there for retention but you don't want to put to many clips on there. I put 3 on for an ear. If one were to shear or something like that, you've still got two on to hold it. We had one this morning, one of the clips had broken and there was only 2 clips in there anyway so it was just rocking around. You need at least 2 decent ones to keep it on there. And you also need to make sure they're on different angles as well. If you had a bar that was too straight, you might have a bar that would start to rotate. Even if it's got 3 clips on there. If they're not opposing each other enough, it could start to rock…that's probably quite an important thing to consider when you're designing your bar as well. Apart from getting exactly where you want it to be in the ear, you want it to make sure you have opposing sort of angles so that when you do put it on you have the retention left from that as well as from the clips, so that's quite important really.

18. ***Is passive fit in bar structure designs important to you? How do you ensure there is a high level of passivity?***

Yes. Because we laser weld them, you have to make sure you're spot on with the laser welding. The same with soldering really, you've got to make sure that when you put the gold collars onto the abutments, you want to make sure they're torqued completely onto the thing, so you've got that full fit on there, then you want to make sure there's no movement, when you're soldering you might get a bit of movement, because most people wax them on. You've got to be very careful when you're soldering that when you invest it that nothing moves at all. With laser welding, when you're finally joining the two parts together that you make sure that you do it all evenly around to make sure that you're not getting any movement there. I

always test it by putting a screw in one side and leave the other side free. Have a look at it under the magnifier on the laser welder and you want to make sure there is absolutely no spring there at all, so when you screw down one side, the other side even though it's not screwed down it's still fitting on the abutment replica on there. That's how I'd do it. You'd do the same with soldering, you'd check it on one side then the other side to make sure there is absolutely no spring there. Even the slightest amount means that when you torque those 2 sides on there is going to be a bit of stress within that then. It's going to want to fit passively, so you're either going to get stress in the bar or worse, stress into the abutments and then into the fixtures then. You've got to make sure they're completely passive. I'd always make sure of that. That's one of the most important things because you don't want the fixtures to fail, because you're back to square one then.

19. ***Have you experienced any complications with bar structure mechanisms that do not have appropriate levels of fit?***

I've occasionally found one, very rare though. As most have been made here, everyone here knows how they should be made and hopefully makes them properly. I've had occasional ones where they have broken, because of maybe how they have been fabricated in the past, maybe there was a bit of porosity or something. But first of all I do make sure they have been made completely properly. Then you don't get those problems in the future then.

20. ***How might you define (or evaluate) an appropriate accuracy of fit for bar structure mechanisms?***

Same as before, just making sure they are completely passive. I always check it under the magnifier on the laser welder and it magnifies quite a lot. You can see what might look passive in your hand, might not be under the magnifier, you can magnify it quite a lot and you might get a bit of discrepancy there. Even having a bit of plaster over the abutment replica when you cast it, checking for things like that is quite important, so when you're getting that passive fit completely onto the abutment rather than onto something else. Making sure there is nothing stopping the screws going in or anything like that. So when I put the screw in it will torque completely. So you want it to torque to that certain level. Which I think you do about 15N/m or something like that. That's what I do.

21. ***How is the mechanism designed to accommodate for cleaning and hygene?***

You want a decent space underneath the skin. Probably about 3mm. You don't want a huge amount of space because you don't want to compromise the prosthesis. But at the same time you don't want the bar to be touching the skin either. Sometimes you've got to make a balance between the two. You want to be able to get under there. We normally provide them with a really soft toothbrush. They're designed for cleaning around bars, they're like a baby's toothbrush. And then you should be able to get under there to brush anything away. If the bar was too close to the skin you wouldn't be able to do that. If they were to get any infection, it might cause the skin to swell and then push against the bar, which will then make it worse because it's touching it. Sometimes you get instances where the skin will grow up, because you've taken some away the skin starts to grow up the collars, and sometimes we'll have to change the abutments to accommodate for that. And re-make the bar to then bring it out so that you've then got space again to do that, so you always need space to get around and clean it. But there will still be people who don't clean it.

22. ***What effect might surface roughness have on the mechanism? Between the bar and abutments, and between the bar and clips?***

You want to make sure your bar is nice and shiny. I don't know how it affects it as such but I mean the clips are ready made. You want to make sure the bar is highly polished. For cleaning purposes too. You don't want any rough areas because that would mean that you've ground the bar and the clips might not fit quite so well if you've got rough areas. The clips are designed to fit on the bar how it is before you've done anything to it. So you want to do as little as possible to that bar. So there shouldn't be any rough areas on there. If you've fabricated it properly then you shouldn't need to do anything to the bar, other than polish it. Just to bring up to its shine again. So if you had a rough area rubbing up against the clip, that could start wearing the clip which would then make both the bar and the clip weaker then.

23. ***Are there ever any complications with screw loosening? What might be the cause of this?***

Sometimes you can get debris building up in the screws. If someone hasn't been for a while and they don't clean very well. You can just get skin cells there, if you've had an infection or anything like that, it just fills up with all that sort of stuff. So you just need to pick it out. You can get screws shearing…sometimes you'll go to take the screw out and it just won't do anything or you'll just get the head of the screw off and you're left with the thread of the screw just in there. For this we use a technique with a cotton bud. I think you put it in there and twist it the opposite way. The fibres of the cotton bud will grab onto the screw. Takes a bit of time but then you can work the screw out, it has worked with a few instances. If the screw shears basically you can't take it off then because the thread is still within the abutment. You just have to work at it until it comes out. It's quite difficult. You could take the other one out. You would be unlucky if it happened to both at the same time. If that did happen to us, you'd not be sure if we had a dodgy batch or something. If it wasn't too tight you could work it out. It would depend on how much the screw was torqued in I suppose. Once the screw is loose then you can work it out, but it's just that initial bit where it's really tight.

24. ***Why are bar structures shaped so that there are protruding 'arms' on each side? Is there a specific length and angle the protruding arms should be?***

It's for retention basically. Like I said before, if they're all straight, if you imagine you've got something in a straight line and you put 3 clips in, you've got rotation there, because the clips will all be facing the same direction you can rotate something around it. The reason with the ears they're designed like that, hopefully the fixtures have been put in where we've asked them to put them. There's like a set distance from the meatus, the angles where you should put them and the distance back, which should then fall within the deepest part of the ear. Ideally you want a bar so they're like a 'C', or an angled 'C'. It's for both retention purposes and the best design is to hide it in the ear to get the best result when you're carving your ear up. So 2 reasons really. As long as you've got the angulation the length doesn't need to be too long. You only want it a clip length, certainly at the top, you can bring it down slightly at the bottom. If someone's got a long ear, then you want that retention at the bottom so you could make it longer. But the retention at the bottom, when they're putting the ear on the retention point is further down. So if you'd imagine you've got all your clips up the top half you've got nothing down there, so you might get a bit of movement. It would depend on each case really on how you make them. You don't want them too long so that they protrude obviously, but you can make it as long as you can make it to give the retention better. So the top would normally be quite short and then the bottom one could be slightly longer. That's what I would normally do. You want that retention on the lobe as well because that's quite a movable area down there, if someone is moving or talking, that's where a lot of the movement is. At the top you don't get as much movement. You get more movement round the top of your jaw, so you want to bring that retention down so you've got something holding it so when it moves it's keeping it together.

25. ***What determines the implant positions (xyz planes) and their distance from each other?***

How their other ear is. I'll always do a template for them. I think it's about 11 o'clock and 4 o'clock or something like that, and what you do is draw a template on the other side and then draw a line backwards so that your implants would go within the deepest parts of the ear, so then you transfer that to the other side. Then the implants come through. So you draw around the one side with the patient's ear that we've got, and then you transfer that to the other side. You determine where the meatus should be. You've got the two models, one of the patients side with the ear and one of the defected side. You mark where the implants should be on the template, flip it over and then you'd see where those implants should be. Then you mark it on the model. Then you make a template over that, and we put drill holes through where the implants should be. Then when the surgeon is in theatre they can put that template on and he knows where to drill the holes to put the implants in which would be the ideal position in terms of us making the best ear for the patient. And their distance then, probably just less than an inch I suppose. It's more for hiding it in the ear. You don't want them too close together because if you want to be able to put a couple of clips in the middle you could. It's more for getting the best result in terms of making a prosthesis. It also depends on how big the patient's ear is. If a patient didn't have either ear you'd go for a set distance, I think it's about ¾ inch.

26. ***What are the advantages of using bar structures over magnets in auricular prostheses? Have you experience of using any other devices?***

Retention really. I know some people still use magnets on them but I found they retain a lot better with a bar rather than a magnet, because you've only got to touch the ear with magnets, and once you lose that initial sort of initial bite with a magnet you lose the retention. You'd only have two magnets on there if there are only two implants which you pretty much always have with an ear. If there's only 2 magnets, if

you lose one magnet then the other one is going to go as well. So they are a lot less stable. A lot less than a bar retained one. If you jump into a swimming pool then it's going to come off. I find the retention isn't good enough for an ear. If you took your jumper off it might fly off. I think the patients want more security than that. You can get collars that go down further and the magnets can be lipped but still…once you lose the magnetism then it's gone then. I don't like them for ears personally.

27. Why are bar designs rigid? Could this affect the surrounding anatomy in any way?

So that you're not going to get any movement within the implants. You want it to be completely firm. You want no movement at all, any movement can torque the implants, which is going to make it less secure. You want it permanently fixated to the bone. You don't want any torquing of those implants. You don't want the abutments to move, which could then cause the fixtures to move. They shouldn't move but you don't want to torque them in any way because that could then cause a failure. When you're constantly moving something in the bone then it's not going to be secure in there.

28. What is the importance of the currently used materials in bar structure mechanisms?

I don't know really, we've used titanium a couple of times for a bar. I don't know how much it costs, I don't know if it's a cost thing or not, as gold is going up in price now too. ***Do you like working with gold?*** The collars a gold, and obviously the implants are titanium but they are pretty compatible so they're not going to affect it. Gold doesn't tend to affect the skin or anything like that, because you've got no nickel content within this gold, not like earrings or that type of gold. It's 14 carat I think. You've got a bit of rigidity, you wouldn't want to use 18 carat or 22 carat because that would be too soft. 9 carat is quite hard. I don't know why we specifically use 14, but that's what it's always been. Titanium is very rigid. Gold is a really easy material to use, you can solder it easily, weld it easily. With the clips, because it's gold, you've got that bit of movement there. If it was too rigid, rather than flexing slightly to be able to get over the bar, they might just snap or damage the bar if you didn't have exactly the right amount. So you want that bit of flexibility so you can push it over the bar and then it would grab onto it, if it was too rigid, you wouldn't be able to do that. You would push it on and rather than flexing over, it would grate against the bar. You probably wouldn't get the same retention then. You can also adjust the clips in this way and they find their own level then. If you take a gold clip on and off a certain amount of times they find their own level of fit. Sometimes patients come back to get their clips tightened again. Over time they loosen up a bit. Some like them really tight, others are happy with that level they find. It's just the right level of spring in there.

29. Please rate the importance of the following factors for a bar and clip mechanism for an auricular prosthesis, and expand on your thoughts. (1 Not important →5 Very important)

FACTOR	**RATING** *(1 Not important →5 Very important)*
Changeable/custom designs (flexibility)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Adjustability of retention forces	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Accurate fit between male and female components (e.g. bar and clip)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Equal forces distributed on implants	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Stability of ear when fitted	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Biocompatibility of materials	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Height of retention mechanism from tissue	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Mechanism longevity/durability	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ They need to last the life of the prosthesis really. Bars normally last longer than the prosthesis anyway.
Passive fit of components to abutments (e.g. bar to abutment)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Aesthetics of retention mechanism when exposed	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ They shouldn't be exposed that often. Most patients would wear them all the time. It's important but it's not as important as say having a passive fit.
Ease of duplication	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ You should be able to do it.
Good wear properties of clips and bar interface	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Many components (Modularity)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Intricate (fine in detail)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Easy to clean	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Rigid design	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Easily attached/detached	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Follows the shape of the ear	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Does not snag on clothes	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

Section 5 – Computer Aided Design Processes

30. ***What is your experience of Computer Aided Design (CAD) in the design process of creating prostheses? Do you currently use any CAD processes in any prosthesis design processes?***

I haven't personally at all. We have used it here more for the reconstruction of ears. Where you flip the other side and end up with an exact duplicate. It has been used for that here. We've had quite a few made in that way here. We've made in wax through CAD. It's more about trying different things out. I haven't had any experience of it really.

31. ***What obstacles may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

I suppose when you make it, it's made to that rigid design, and the wax that they use (RP) is different to the wax that we use, so then we have to duplicate it into our own wax. And they still need to be adapted to the shape of the head because the defected side will be different. So you get you get your template but you'll still have to adapt it to fit on the other side. You still have to pretty much go through the same processes, it's just cutting out that original part of carving out the ear from scratch but you would still have to adapt it anyway. It probably doesn't save you an awful lot of time by doing it at the moment.

32. ***What benefits may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

I suppose you're getting an instant replica of the other side. So maybe if you weren't as good at carving….So you've got that duplication already there. So you might not have to adapt it quite so much than if you'd carved it up from scratch. It'll probably save quite a lot of time for some people in that respect. You have got that shape there ready, and the height could be correct so it could be beneficial in that way.

33. ***Is there anything else you think is important to the success of an auricular 'bar and clip' mechanism?***

No, pretty much what we've talked about, making sure it's passive. Making sure it falls within the shape of the ear so the ear can be made as best as possible. If the design of the bar is wrong you are then compromising the design of the ear, which sometimes you can't help it…if they can't put your implants in the exact place that would be best for us personally then you have to compromise a bit from that perspective.

Interview Transcript Participant 2 – 06/01/2011

Section 1 – Prosthesis success

1. ***What for you makes a successful auricular prosthesis?***

Firstly and most importantly whether the patient is happy with it at the end of the day and it functions in the way in the way you want it to function for them and they want it to function for themselves. To me that is the key. It looks right, it fits ok. Sometimes the actual aesthetics of it might not be perfect in your eye, but for the patient it's great and the patients relatives. That's the key, patient happiness and usability if you like. That would be my end result. Whether it's technically correct along the way it might not be and might be compromised but if it's usable and the patients are happy and it has the aesthetic disappearance if you like when it's fitted is the best way of putting it.

2. ***How do you think the retention mechanism affects the overall success of a prosthesis?***

In certain cases it's quite critical. I showed you that case this morning with the magnets, where we thought that would be a nice way of retaining it but actually now in the longer term it won't be as good because of the way the tissues have resorbed. So I think the actual retention mechanism is key to a good end result.

3. ***What are common reasons a 'bar and clip' mechanism might fail to do its job?***

I think if you've got a patient who's got dexterity issues is probably the main one. Other countries tend to use magnets more. That case this morning, that would have been ideal I think if we could have got the other magnet in, a hard tissue issue. Operation time, we're going to have to revert to bar and clip. Having worked in another unit the bar and clip does seem the most popular. The only downside to that is if you have a patient that does have dexterity issues and has trouble on the side with the prosthesis fitting. Other than that, they seem pretty solid, stopping lateral movement and if it's knocked it does hold it really well. In my experience, the ones that we've made have worked really well. They hold glasses on the patient; we've even made it so you can have a hearing aid fitted into it. And that worked really well. The bar and clip seems to be the most stable in my experience at the moment but we want to move and have a go with magnets because they've been proved with their retention strength, and I'd like to have a crack at that next. But the patient choice on that is key. It's nice to have a few different options. So you can think actually for this one we'll use magnets, if you have a dexterity issue and you're not overly active then perhaps magnets would be good, but for someone who is a bit more active, good dexterity, wears glasses perhaps, then a gold bar and clip might be a better option just to help with holding it on and with the accidental knocking and stuff like that. It's nice to have a few choices in your technical basket, so you can use what you think would be suitable for each patient rather than thinking only bar and clip, you could think magnets could be nice for this one. I think it's good to have both, but bar and clip seems to be the most popular at the moment. Whether it's a historical thing, or the fact that magnets are developing. There have been a lot of developments in magnets over at Technovent. It's a matter of patient choice and having those options.

4. ***How might you diagnose the cause of implant failure? How do you think a prosthesis might affect this?***

Implant failure hopefully is diagnosed before you put the bar and clip on. At the stage where the implants are exposed, hopefully you're working along side the surgeon, to work out if an implant's on it's way out. You tend to listen to them, they tend to tap them and listen for a really nice solid sound or you can put an abutment in and…you can just sort of tell. If it's necessary, you can x-ray it up and see if it's actually integrated really well so hopefully by putting a bar and clip on won't actually cause implant failure. You want to make sure your implants are well integrated before you put the bar and clip on it. If they're not, I suggest you leave the prosthesis fitting until you know that the implants have integrated well. I wouldn't like to put a bar and clip on the job and cause implant failure. That comes down to design and not stressing them. Once an ear's on, it's passive. It's not got any forces on it, it clips on and sits there and there's no sort of torque action on there or anything like that. Implant failure, it shouldn't occur. Good care once you've fitted the prosthesis, good hygiene and regular consultation initially just to make sure you're not getting infection around it. And that's all part of the process of telling them of looking after the implants. If they've got any problems they need to call and come in and we'll do a swab and we can give them antibiotics, or the process of monitoring it to make sure that doesn't happen. We've had a couple of

patients that do have who have trouble with healing because of their disease. Their tissue healing was inhibited so we kept a really close eye on it. The guy is fine now so once you get into the routine of cleaning and looking after it should be fine. I would be disappointed if my prosthesis causes an implant to fail. We like to make they are well integrated before we put the prosthesis on. Once it's on it should work. It shouldn't be anything a bar or prosthesis design that causes that implant to fail, that's why it has to be so passive and no torque and so on. I haven't come across that yet but if we did, I'd have to go back and critically analyse what we did and where it went wrong if it was something that we did caused it to fail. Not with the patient, but you'd have a multidisciplinary meeting and work out what caused it. If it was caused by what you had done, the way you make and design stuff that that wouldn't occur. You work together in the theatre with the surgeon and make sure they go where you want for the best prosthetic outcome.

5. ***How might you overcome the potential of implant failure in the design of prostheses and their retention components?***

I think we have covered that really. You should when you put your bar on, make sure that it's really passive. And even after you've welded it and you go to refit it onto the working model and it doesn't fit really passively, then I would cut a joint and re-position it and re-weld it to make sure it's passive. Because occasionally when you go to laser welding, there is a chance because of the way the weld packs you can get small movement, so you try and alleviate that. If you do get slight movement and you're not happy with the passivity, I have cut the joint before and then re-weld it, to get that really pure and passive fit of that bar to the implant, so there is no stress on the abutment joint. When you're screwing it in you know there's no stressing, and that's just techniques as well and care. It's taking that extra 5 minutes on it. The extra 5 minutes that you give it, makes it looks 5 minutes better. It goes from "that'll do" to "that's nice". That's how I tend to do all my welding. If I'm not happy I'll change it until I'm content with what I've produced. I'd like to find most people are like that.

6. ***Are larger mid-face prostheses more likely to fail than auricular prostheses? Why is this?***

That's a really tough one. We haven't had any large mid-face prostheses here but the ones I worked on in (NAME) when I was there, they worked fine. Because of the method of retention and bar design, especially if you've got an orbital prosthesis that's held on around the orbits or nasal, you might use a combination of a bar and magnet. You've got to have this flexibility in mind when you're making these things for the patient. You might combine different techniques to get a nice fit. With the implants, going back to a previous question, you want to make sure the implants are nicely integrated. You might get an infection in implants, not through our prosthetic design or bar design it's just patient specific. The ones that I've seen, I haven't seen any that have caused an implant fail through the prosthesis or technical design, it was more a patient issue. I can't speak of great experience there because I haven't got it. From ones I have seen in (NAME), if there were implant failures, it was more patient issue rather than technical design issue. One of them was from the recurrence of cancer.

Section 2 – The Design Process

7. ***How might you define the levels of accuracy in the design and fabrication process? Do you believe there to be inaccuracies introduced at any point in the process affecting the success?***

The way we try and look at things here is the outcome at the end of it, so you see your patient at the early consultation stage with the consultant and he'll tell you what the problem is and what he's going to probably do surgically and then you will look at your prosthetic outcome and we try and work backwards. If you're going to have a total removal of the ear we'll say right what we'll do is reproduce the prosthesis so they've got their natural balance and that they can wear their glasses, we'll start at that point and work backwards. We'll ask if we are going to use magnets? A bar and clip? We'll look at problems related with each. Make sure they're going to use implants. We'll make a stent so the implants are placed where we want them to go. Go to theatre with the surgeon; make sure the stent is in the right place, because it can be easily moved so that's marginally inaccurate, potential for inaccuracy there. Then we'll make sure the implants go in and then they'll put the flap overt and close it up. We should be quite happy that they've gone in where we want. Once, we couldn't put a 3rd implant in because of bone quality, so we had to do 2 instead. That slightly alters your (original) design but not a lot. It just means you might have to run a slightly longer cantilever arm on your gold bar. We had one occasion when we went to theatre and they didn't plan to do implants and we to do a sort of….how could you describe it…there's a rule…a 25mm rule where you can put your implants from the auricular meatus (your ear hole). It's trickier to do but you

look and you decide where you want it and you hope you're in the right place. On the whole that's how we do it. When they come back, they'll have the implants exposed, put healing caps on, they go away for a couple weeks. When they come back and we'll do an impression with silicone and impression copings. We use silicone in two stages, perhaps a soft one around the implants and soft tissue then back it with a harder silicone. Pour that up and then make a gold bar. One case we actually got them back in because they were local, once we'd made the gold bar, got them back in for a 5 minute appointment, put the abutments on, and made sure that the gold bar was passive because we felt that there might have been a little bit of movement and we weren't sure if our impression was as accurate as we would have liked. So we got them back in quickly, popped the gold bar on and once were happy that it was really passive and fitted then we sent him away while we made the light cure matrix and wax up. As it's not as busy as some of the larger central units perhaps we can afford that little bit of flexibility in time. Whereas in busier units, you might not have that time, you might get them in and it might not be that passive and it cuts you back a stage. When I worked in (NAME) it all worked quite well. But because we're a smaller unit we can afford that little bit more time not much because time is money but it saves time in the long run, because we know it fits at that stage. And then we'll carry on and process it as a normal process, make the gold bar, make the light cure matrix with the clips, do the wax up, get them in, fit it, make sure the aesthetics are good, if not you can adjust it there and then. Take it back to the lab and process it. You might do a colour match at that stage if you're confident. And if you're not happy, you have to tell them that there's no point going any further, go back a stage and re-do it. Silicone and colour is quite a black art. Some guys are great at it but I'd probably find that trickier. I find it difficult but my success has been quite good. I tend to concentrate that little bit more on the colour. Give me some metal work and ask me to make something, then I'll like that. I find the artistic stuff a little bit trickier, but that's something you can overcome. When it fits, it fits…you get no gapping…you can't really see a join line….and you look at them at a glance and you can't tell you've got a prosthesis on….to me that's the end game, and that's my accuracy. If you're not happy, you stop and you get it until you're happy with your accuracy and it's those little bits of detail, whether you change the wax work or you go back and make a new bar…you do what you need to do to get as best you can.

8. ***What are the benefits of multiple part assemblies? (Abutments, spacers, caps, bars) Is 'modularity' important to you?***

The way the implant systems have been set up, is designed for the modularity, not so much for the user, obviously these companies have set these things up with technical input. The system we use here is Straumann, which is great, but they've stopped supplying the parts as easy as they did, and now we have to order them in advance. We were thinking of going down the Branemark system. In the components they're a little bit tidier and smaller, not so bulky, which then gives you more prosthetic flexibility, because you can then make a smaller light cure matrix, which then allows you a greater depth of silicone, which gives you a nicer prosthetic rehab, rather than thin silicone so you working on less margins. By having a modular system it means you can just get components in and you can be a couple of steps ahead. If you had only 1 complete part, you'd have to wait for the patient to come in and use that. But with the modular system, if we're happy with the aesthetics of the silicone mould, I can then make a new gold bar, pack an ear, so when they come in we've got a silicone prosthesis that we can fit to the patient that we can extrinsically tint up, take their gold bar off, and re-use that. In some labs they might give the patient a couple of prostheses to go away with, so you've got longevity of use and wear. Having components does mean you can go steps ahead. If you'd have a couple of units in a smaller environment they'd use a similar system, and you'd need a component, you could borrow a component, while you're getting a supply. If you haven't got the supply of the components, you can ring up another unit and say, "can I have a gold cap for the Branemark system?"…it gives a bit of manufacturing flexibility amongst units that get on and work together. I don't know whether there's a cost implication because that's the system you use, you've got the screws and the gold caps…as long as you know how they function, what torques to put on the screws and stuff, I can't really see there being an issue with that. That's how it's been done for a long time, and until someone comes up with a system or method of manufacture that's better than that that offers the same benefits, then that'll have to be looked at. But at the minute, the system that is in place provides enough benefits and flexibility for a decent outcome for the patient.

9. ***Do you apply any design techniques that are personal to you? Any quirky techniques/habits that others may use or may not know of?***

I wouldn't have thought so. I suppose that all comes down to mentoring, you go through your training and you get mentored by certain people and you tend to take their style of manufacture, not necessarily as the way to do but as a good standard method of manufacture, it gives you a good manufacturing outcome. And when you're dealing with Titanium and Gold, especially if you're doing internal implants, you need

a good standard of manufacture that's going to be implanted into somebody. The manufacturing process has got to be pretty perfect. If you take those from people and they are successful, then you're going to keep using them. I might have done something, which is slightly different, but it gives you the same consistent outcome, I think it all comes from your mentoring and your learning process. It might be regional, the slight design differences. There's a similarity across the board I'd imagine, little bits you might learn from your mentor, which might be slightly different from somebody else's style. It's a stylization. My mentoring has been done by a couple of people on the welding for instance and I'd imagine my style is quite similar to theirs. The experience they have is vaster than mine but the manufacturing style and the outcome is the same.

10. ***What process do you follow for the duplication of a bar and clip prosthesis? Does this have its advantages or any complications?***

I'd be worried if the bar broke, because they might have injuries. There's a chance of it fracturing at the weld site, a potential. I'd have a look at it on the patient, look at the fit. It would be difficult to get a good impression. I'd be tempted to say 'let's go back a stage', get their bar, put it on their original model, have a look at the fit on the original model, see if there is any distortion and if necessary go back a stage, and manufacture a new bar…just because there might well have been other issues with the structure. If it had taken a knock and fractured…you might be able to take the bar off putting it on the model and re-welding it. If not I'd be tempted to go back to square one and make a new bar matrix and prosthesis that way. Duplicating a bar in position is quite difficult for the accuracy. We've got a few denture patients that have to have new dentures made for them and getting an accurate impression of a bar is quite tricky. (NAME's) got a little technique for doing it and it worked quite well. Yeah I would tempted to go back and make a new bar, because if there were any other issues and check the implants are ok. ***What is (NAME's) technique that you mentioned?*** We get some silicone putty and putty out underneath the bar. What you will do is take a soft silicone impression with putty filling in the voids underneath the bar, so you block out the bar with the putty and take a silicone impression over the top of it, so you've got the bar and abutment cavity, when it comes out you'll take out the little bits of putty you blocked out with and place it in your impression, it's a bit of a fiddle but it works. And then you'll pour your model into that, so you get a model then of the bar with the blocked out areas already, and then you can put your clips on the plaster bar and make a wax one over that. It's a little bit tricky and a little bit fiddly but it works, or it has worked, for the patient we chose to do it for, it worked and he had a couple that worked quite nicely. If you've got an auricular prosthesis and you've got a bar that's broken, then I'd be tempted to take it off, put it on the original model, have a look at the distortion on that. If it was minor, I'd probably just be tempted just to tidy the weld joint up if it was at a weld and re-weld it. I'd be shocked if it were anywhere else, just because to bend and fracture a bar anywhere else I'd be worried about the trauma that the patient had occurred. You just have to assess each patient individually and you have to decide on your action plan individually as well. I don't think you can have a 'this is what I do for all of them', because everybody's different and each appliance is slightly different so you have to treat each one as an individual. For one you might just think ' I'll re-weld that' and quickly re-weld it and fit it and it all clicks back nicely or you re-make it because you're a bit worried about it. The duplication part of it is quite tricky – you've got to get an accurate impression that's not going to distort at all, you want it passive, and to get that it could be quite a difficult job, partly because we've never had to do it, and I've not had to think about that problem and solution to it. Trying to get an impression of a bar accurately and then remove it all and get it accurate afterwards would be quite tricky. That's why it's important to keep your original models.

11. ***Is there any part of the process you feel particularly frustrated about conducting?***

Not really. As long as you've got your components, you've got your gold; it's quite a straight forward process making a gold bar. Making sure it's passive. It slots on and off without any interference at all. Getting the impression's quite straight forward. If you're not happy with it you can take the components out and do it again until you're happy. It's got to be accurate. And individual as well.

12. ***Have there been any recent developments in the design or fabrication process that you are particularly aware of?***

Not really. In the time I've been doing it, the process has been fairly consistent, through the whole of my learning period. I think the process is better not because of laser welding rather than soldering. You've got less chance of metal damage and all those other little issues occur in accuracy. And laser welding there's the speed. It's quite quick and accurate. If you're not happy you can stop, cut off, start again. Soldering, you've got to invest, get accuracy and that. For the time I've been doing the job, the

manufacturing process has been similar; well it's been exactly the same really. I was brought up using the laser welder during my training period so I didn't have to solder, but I can and would've soldered. But to me, laser welding is the way forward. But there have been no major developments.

Section 3 – Checking Procedures

13. ***How would you normally check the retention mechanisms so that they can be passed as clinically acceptable? (When would this usually be?)***

You do it as you're going along really. I'd make my gold bar, then I'd put my gold clips on my gold bar, make my light cure matrix…and at that stage you can see if it's going to be nice and retentive because it will fit nicely to your bar, there's no gapping around your model, so it's accurate. If I'm happy with it at that stage, then I'm happy to take it on to the next stage of the wax up, incorporating it into the wax up. So then, you'd check that on the patient. So you'd put your gold bar onto the patient, click your wax up onto your gold bar, on the patient, and you can tell there whether it's going to be retentive. Sometimes it might be too retentive, so you can adjust it a bit. Really I would check the retentive capability of the prosthesis all the way along. If it's too retentive you can just ease your gold clips apart, you might a little bit more retention on one area and you can just adjust it. I would check the retention from the minute I've made my light cure matrix and then all the way through to the final prosthesis. So there's probably 3 or 4 little stages where you check your retention, and then you can tell them that it might become a little bit loose with use, because the gold flexes, and if it does, they can pop in and we can tighten it back up for them.

14. ***Do you perform any 'technical' checking procedures? (When would this usually be?)***

Probably more by experience, you can feel if it's going to be retentive or not. When you've got your light cure matrix, you can see, 9 times out of 10 you have to pop it off with a tool or an instrument just to lift it off initially and you can tell at that stage if it's going to have enough retention. It's more of an experiential type thing rather than technical testing. When you're working with it, you put your wax up on and off whilst you're making it and you just sense whether or not it's going to be retentive and you just get a feel for how it's going to fit onto the patient as well, whether it's going to fit on the top slightly or the bottom or whether it's going to go straight on or slightly at an angle, and you can pass that information to your patient. And then they go off and they find their own way of fitting them anyway. It's a lot easier sometimes to ask them to remove it when they come in because they've got their own technique that they're comfy with. So you sort of check all the way along really, so there's no definite technical way…or I haven't got one, whether somebody else has, I don't know…it's more of a 'if it feels ok'.

15. ***Are there any established standards or testing methods for the evaluation of the 'performance' of retention devices?***

Not that I know of. I've not seen a technical standard that's been written. When you fit it to the patient, you can give it a bit of a shove and a pull to see that it's not going to fall off, and you can let the patient have a little go, just to prove to them it's not going to just drop off in the shop, one of our patients had his drop off in the shop because he didn't fit it properly. I'd imagine a lot of patients have little experiences like that; he just hadn't clicked it on tight enough that was all. If they've got glasses you make sure they can get their glasses on and off without it coming loose and stuff like that. If they wear a hat, make sure it doesn't affect things and stuff like that. You almost have a feel for it. You can tell when you click it on if it's going to be troublesome or not.

16. ***How might you test for the usability of an auricular prosthesis for the patient? How is this different to other facial prostheses?***

I've got a couple of patients, both have glasses, we just adjust their glasses to fit if we need to, everything's comfortable for them, the aesthetics of it are good, it stays on, it's retentive… and the patients' happy with the way it looks. It's retentive, it functions the way they want it to function, it gives them back their facial aesthetics…they're the sorts of things you look at. All prostheses you make sure they fit well and they're not going to fall off, it doesn't stand out and looks natural. Some function, like you can breathe through it. That's a tricky question because that's all part of the manufacturing and finishing process – it's fit for purpose and what it's designed and made to do. And like we said, if there's any time during that process that you feel it's not right, you stop and make it right, so when you click it

on for that final time, the patient says, "yeah that's cool!" When people don't realise that someone is wearing one, that for me is when things are right, and that's what you're trying to achieve for all of them. Even if you have a hearing aid fitted to it, it's made so the hearing aid fits into the prosthesis. You want them to have what they had before they had their ear removed.

Section 4 – User Requirements and Mechanism Design

17. ***What are the main considerations when finalizing the retention forces of the retention mechanisms? Is there a retention force 'range' that you work within?***

Not really no. With magnets, you have to look for the firmest magnets you can use, partly because the forces that act on prostheses. With a gold bar and clip, I don't think that's such an issue because it's a fairly solid, retentive fixation. And I suppose that sort of thing comes with experience. We're slightly weary of using them because we're not sure of how their retentive capabilities act (magnets). It's an experience thing. With the gold bar and clip, they've been used for a long time, on lots of different sorts of patients, those with special needs or those that haven't, and they function well. The retention capabilities are there, they are an inherent part of the design. And I'd imagine that comes with years of it being used in that way and passed down. The more we might use magnets, the more we might learn about them. But again that would be a patient choice thing. So if someone is a bit less dextrous but they can click it on and we know that any dislodging forces aren't going to dislodge it, then that's good. So yeah, there isn't really a 'range'. If it fits well and the patient likes the fit, you feel confident in it that it's right. The actual range of retention would be hard to quantify to be honest. It comes down to feel and experience rather than set figures. Some might want it tighter than others. And then you can think if you use a bar or a magnet, and that's a dexterity thing too.

18. ***Is passive fit in bar structure designs important to you? How do you ensure there is a high level of passivity?***

Yes. If the bar is not passive, it may be putting stress into the implant. Although the appliance itself is passive and doesn't function, I think if you can reduce any forces into your implants then that is almost essential. When we're making dentures, the fit is passive. It clicks on, there's very little torquing. There are no forces that will be detrimental to the implant. You take that technical consideration to an auricular prosthesis with a bar and it fits passively, when you put your passive, non functioning ear on, you're not going to set up any stresses or strains. You're hoping to give those implants longevity. Although everything's passive and non-functioning, you still don't want torquing into those implants. You want them to be passive. Any detrimental forces into the implant could cause it to fail.

19. ***Have you experienced any complications with bar structure mechanisms that do not have appropriate levels of fit?***

Once, we made a bar that didn't quite fit right. It fitted on the model well but didn't fit the patient. We thought maybe the model had shrunk or something so it was back to square one. The patient has been through enough treatment to understand that wouldn't do it unless you have to. A bar cracked once too, the weld failed. We couldn't quite work out why but we put it back on the model, re-welded and put it on the patient and it fitted passively and we were happy. That was when I worked at (PLACE). Here at (PLACE) I haven't had that yet.

20. ***How might you define (or evaluate) an appropriate accuracy of fit for bar structure mechanisms?***

I think again that's an experience thing. You can tell if it's fitting passively. If it's catching. When you torque it, if it doesn't fit properly, you can see that it doesn't fit properly. You can see when you're tightening it up, if it's coming down passively, on the Branemark you can see if it's passive even before you put the screws in. So you know if it's going to fit. The Straumann are slightly trickier because of the conical shape of them. But because they are conically shaped, if it doesn't fit passively straight away, you can tell straight away, even before you put a screw in. And you get a feel, if you're putting it on or off, if it's catching. And that's probably experience. If necessary you'll cut the bar and fit it in 2 parts…I suppose you evaluate it through experience. A lot of technical skills and knowledge mentored down. You learn first hand if it's not right and you critically analyse why, or what you've done, then you think I'm going to cut it, re-join it, and try again. You just have the feeling, and you can see. And the patient might feel it and say something, especially if we're doing an intra-oral case. They'll get a sensation – some of

them are quite sensitive, especially after radiotherapy or treatment. They may be hypersensitive to pressure, and they'll tell you if it's a bit tight. It might not seem it to you, but they will pre-warn you.

21. How is the mechanism designed to accommodate for cleaning and hygiene?

Gold bar – you give them instruction on how to keep it clean. After the initial fit, you'll probably get them back in after a month for a review, see how they're getting on and you can help them with anything. But you give them instruction on cleaning the appliance, bit of warm soapy water and a brush, like a soft toothbrush or a shaving brush to clean around their bar. When you get them back for a review, a lot of the time you take the bar off, and steam clean it, re-polish it and re-fit it. Same as the ear, you can steam clean out the matrix, if it's grubby. And tell them to keep it cleaner. Re-iterate the reasons why. You can design the bar so it's quite high from the tissue like we did with one guy with bad tissue. Prosthetically it can reduce the silicone, which can give a few aesthetic issues, but we get around them. It allows the bar to stand off the tissue, which makes it easier to clean. Which means you don't get infection as much. For others, you try and get the bar quite low down because it gives you that prosthetic flexibility. So for people with tissue problems, e make the bar quite high off the tissue, but it means they can get under it easy with a brush, keep it clean and not come back with any infections. Otherwise you try and get it quite low down because it gives you more aesthetic flexibility for the silicone thickness and the colour. Silicone and tissue quite like each other whether it's the moisture… and it keeps things clean and tidy, around the implant and abutment. As long as you keep that clean, everything seems to be ok. For some people then, you get it high, but on the whole you try and get it low down for aesthetic flexibility, especially for shading.

22. What effect might surface roughness have on the mechanism? Between the bar and abutments, and between the bar and clips?

We try and make everything as clean and as tidy as you can. Doesn't seem to have a great effect on the retention between the clip and the bar when it's highly polished, because the clips designed to flex up and over it and grip underneath it. The matrix itself is as highly polished as you can get it, that helps alleviate debris sticking to it and doesn't make any difference to the retention fit. On the external finish of the matrix, you polish it and treat it with a primer so the silicone sticks to it so that's not an issue. And the bar itself is polished so it's easier to clean, aesthetically more pleasing than a dull bar and again, because of the way the clips work, doesn't have any effect on the retention. If it were rough, you'd probably end up with more dextrous sticking to it, and if they're not overly clean as a person, you might find they get more infections. I don't think the roughness makes any difference to the retention because the clips are designed to slot up and over a bar anyway. With a magnet, you've got that magnetic retention anyway. With the bar, whether it's rough or smooth, it's a mechanical retention anyway, it just helps keep it clean which helps alleviate infection.

23. Are there ever any complications with screw loosening? What might be the cause of this?

Yeah we did have one patient whose screw seemed to work loose. We couldn't quite work out why. We applied the correct torque. So we just changed the screw and that seemed to stop it. Whether it was a slight manufacturing error in the screw. I don't know, you can't put it down. So we changed the screw, torqued it in and it seemed to be fine. If the abutment comes loose, it's an area for infection. You can't really know why that would happen.

24. Why are bar structures shaped so that there are protruding 'arms' on each side? Is there a specific length and angle the protruding arms should be?

Not as far as I know. You have them to provide the retention, so the prosthesis sits where you want it to sit. If you were to have a short bar and a long bar, you may well have potential for a cantilevering force, but you try and get them as horizontal as you can and I'll explain why we did what we did. On this one (shows example), one arm is slightly longer than the other. As far as I know and read, there is no set distance and length you'd make it. As you can see, the lower part i.e. where the lobe would be is lightly longer. This guy had a particularly large pinna - he's quite an old gentleman. We had a hard tissue issue on the lower part, so we only managed to put 2 implants in, quite well spaced actually…which is fortunate because of the large ear. We had a few aesthetic issues with the matrix because it's so close to the border. I put the bar on this side of the caps (anterior), because if I'd fitted it in the middle, we'd have to compromise on the aesthetics. Because the implant positions were compromised because of hard tissue issues, it was a little bit of a wing and a prayer to be honest, but we pulled it off. He's also got poor tissue healing. There were a couple of compromises. This bar is quite high off the tissue as well. The gold bar

piece was designed on the inside because it gave us more aesthetic capabilities. We were a bit concerned that there might be a slight 'tipping' force on it. Once it was on, it was passive. The clips are fairly tight to the angles. So if there is any torquing force, it's less distance from the implant to the point of force. We put it quite tight to the angle. If there were any forces, they would be alleviated, that was our thinking. This result was good and the patient was quite pleased. Then we fitted a hearing aid to it. In some prostheses you know that the arm going down the lobe is going to be much longer, than the arm at the top of the helix. It shouldn't make a difference because once it's clipped on, it's all passive, and it has non-functioning forces on it.

25. What determines the implant positions (xyz planes) and their distance from each other?

There is no set position, but there is an arc around the meatus. I think it's 25mm (from the meatus). With this case (shows example) there was a bit of a compromise because of hard tissue condition. You can make your implant stent, like a drilling guide that fits into the meatus, it's got some arrows so the surgeon knows which way up it goes and how it fits in. And you're there to advise. Then you ask them to put the implants in along the lines (of the stent). If necessary you get the wax up ear, put it on and say "right I want an implant there and there, you get a big drill, make your stent, cut it off so you've got your drill holes, usually in the thickest part of the prosthesis. With this case, because of some issues the implants are positioned a few mm too posterially, but it worked. Then the matrix was made to help support the prosthesis against the tissue. The patient is still fine and it's still functioning well. With everything, there are guides, but everybody is slightly different. You might get a bit of hard tissue on one person that's ace, but on another person the hard tissue is just not up to the job.

26. What are the advantages of using bar structures over magnets in auricular prostheses? Have you experience of using any other devices?

My experience in using magnets is quite minimal so it's a difficult question to answer. Pretty much all the ones I've done have been on bar and clip and they seem to function really well. They are retentive, they seem to withstand dislodging forces well, and if the patient is a spectacle wearer, they withstand the spectacles tying to dislodge the prosthesis. With modern magnets I can't see there being much of an issue but until I use them a lot, I couldn't comment further than that. But we will use them, especially the small, super-power magnets that are available from Technovent. In my experience I've always used gold bars and clips, and they've worked really well, and until I've got experience with magnets, I can't really comment on them. But it's another tool in your toolbox for giving the patients a good outcome.

27. Why are bar designs rigid? Could this affect the surrounding anatomy in any way?

I don't really know why they're rigid to be honest. The rigidity I would imagine adds to the retention. Although if it was spring-loaded it might do…the fact that it's rigid might stop the tissue being damaged because there aren't any (functional) forces acting on the tissue and everything is passive. Which is what you're looking for, if it was flexible, you may find your prosthesis ends up with gapping and that won't look as natural when little gaps occur. The bar and clips are made of metal and you need that rigidity for the retentive function of it and stiffness. I suppose you could say stiffness and rigidity adds retention. You've got the rigidity of the metal and the function of the clips together, gives that retention.

28. What is the importance of the currently used materials in bar structure mechanisms?

Well, gold is a really inert metal. You could use Titanium, which is also inert. Gold is also used because it's got flexibility, it can spring in and out for a given period of time until it work hardens and breaks, or loosens so we can re-tighten it up. It's nice to keep clean. It's also aesthetically quite nice to look at. When you haven't got the prosthesis on, it's a bit like a piece of jewellery. It's a nice material to use from a technical point of view. The laser welding to the gold is really nice and clean and is not likely to lead to infections. Over a period of years, they found that that's the best material for the job, at this time, because of its properties and its function. I'd imagine that's come from experience. Over a period of a number of years they found gold bar and gold clips to be the best materials to work together for the retention that you require.

29. Please rate the importance of the following factors for a bar and clip mechanism for an auricular prosthesis, and expand on your thoughts. (1 Not important →5 Very important)

FACTOR	RATING *(1 Not important →5 Very important)*

Changeable/custom designs (flexibility)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Adjustability of retention forces	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Well the whole idea is that you make it so it stays on! If you need to loosen it you can just adjust it slightly.
Accurate fit between male and female components (e.g. bar and clip)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Equal forces distributed on implants	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Stability of ear when fitted	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Biocompatibility of materials	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Height of retention mechanism from tissue	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ That has a lot to do with the aesthetic outcome of the prosthesis. The Straumann abutments compared to the Branemark ones are quite bulky. But you can cut 2 or 3mm off the top of those. You can put the gold bar as tight to the tissue as you want really dependant on your abutment.
Mechanism longevity/durability	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Passive fit of components to abutments (e.g. bar to abutment)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ I can't really change the fit of the cap to the abutment, which really comes down to the manufacturer not you. The bar as a whole to the abutment though is a key part; you don't want any torque in that.
Aesthetics of retention mechanism when exposed	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ The patient might not like a gold bar on the side of the head, but I can't tell you that until it's fitted. So to me it's not that important. It must do a good job and it's relatively nice looking.
Ease of duplication	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Good wear properties of clips and bar interface	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Many components (Modularity)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Well you just get the parts and put them together.
Intricate	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Easy to clean	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Rigid design	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Easily attached/detached	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Follows the shape of the ear	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ That's how I manufacture it and where my implant position is.
Does not snag on clothes	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Well if you wear one of these that's one of the risks.

Section 5 – Computer Aided Design Processes

30. ***What is your experience of Computer Aided Design (CAD) in the design process of creating prostheses? Do you currently use any CAD processes in any prosthesis design processes?***

Thinking about it, we probably don't use CAD much for creating auricular prostheses. It's quite limited at the minute with regard to auricular prostheses. We've used some CAD for positioning some orbital implants for one guy. But fairly limited at the moment.

31. ***What obstacles may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

I would imagine there to be a cost implication. Knowledge and skills. Actually having the technologies available. And I don't really know how far down the line that CAD technology is with regards to manufacture of moulds to use, to create a silicone prosthesis. My knowledge of those technologies is a little bit short.

32. ***What benefits may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

There probably would be. You could certainly use it to aid your implant design. There's probably a higher chance of getting everything correct when using software and technology. But present time you use skills and knowledge, rather than defined accuracy of a computer program. As it becomes more accessible, I can see it being more useful. Especially when you can mirror ears across and then look at implant position and make a stent using CAD. Maybe make an SLA mould of a prosthesis, you could even make a bar I'd imagine. This is where you come in. You could probably cut a bar from a gold chunk. But then you've got cost implications and all the rest of it. However, I can see it being beneficial for the future. Perhaps in 5 years time it might be the way it's done. It might be the combination of using the technology and skill. I'm sure it will benefit, especially if you can get your implant position.

33. ***Is there anything else you think is important to the success of an auricular 'bar and clip' mechanism?***

I think we've covered everything really. As long as you take your time, look at everything critically, if it's not right then go back and analyse why it's not right, even if it might sort of look right.

Interview Transcript Participant 3 – 6/1/2011

Section 1 – Prosthesis success

1. ***What for you makes a successful auricular prosthesis?***

Patient satisfaction. Successful retention and the aesthetics. If the patient is satisfied with it and they are able to manage it quite well, including the implant area and the abutments…if we're using an implant retained prosthesis. Which we tend to. Patient satisfaction covers a lot of it, and obviously I have to be satisfied that the patient is going to be able to manage it and there's going to be some good life in it as well. We did one the other day with a middle part of the ear. We made an acrylic substructure with a magnet in it that fitted in behind the ear located in with adhesive and then the prosthesis clipped into that. The patient and his wife was shown how to use it, they though it was fantastic, he could wear his specs, an important consideration. Told them how to look after it. In terms of its success is if they wear it and they're happy with it.

2. ***How do you think the retention mechanism affects the overall success of a prosthesis?***

It gives the patient confidence if you've got simple and successful retention. For ear prostheses particularly here, we will use implants. The reason for that is because it's more definitive. It's easier for the patient and gives greater life to the prosthesis as oppose to adhesives and all those things gives the patient confidence. Implant retained auricular prostheses; they're going to position them in the right place every time. The prosthesis will only fit in one place, or it should. You shouldn't ever be in a position where you could position it in even a slightly different position. In the fabrication process, you should be getting it in the right place. You should be getting the symmetry all done all at the wax trial stage. The physical symmetry…then the visual symmetry, the colours when you pack it, before fitting it you should have everything in its place. Splitting up implant retained prostheses, you've got bar and magnets. Magnets, psychologically a little bit more accepting for the patient but seeing as though they spend most of their time covered up…I would still that bars are three-dimensionally more stable. Magnets are fine, they're nice and strong but they only give you retention in those particular areas. With the bar you have the option to cantilever. You've got that lateral resistance for any displacing forces. So the retention mechanism and the overall success of the prosthesis…yeah it's that foundation of confidence I think…in patient and practitioner. If you've got that right, you should be able to put the rest of it right.

3. ***What are common reasons a 'bar and clip' mechanism might fail to do its job?***

Common reasons would be a break down in the bond between the acrylic substructure and the silicone. Clips can fail but they can be replaced. Poor placement of implants but that's not necessarily restricted to bar and clips. Like I said you can always cantilever your bar and clips either side of the abutments. I think that's probably it.

4. ***How might you diagnose the cause of implant failure? How do you think a prosthesis might affect this? (mention 'compression fitting forces' and 'misfit forces')***

Implant failure….I mean anything can get infection. You can get infections. In terms of the prosthesis, if you made a bar and it's not passive, then you're inviting implant failure. Magnets are…any substructure that is joined as one has got to be passive. So if you're using magnets, for whatever reason you want to join them up, you've got to make sure they're sitting passively. If they're not joined up then you've got a silicone prosthesis on top of it and it's going to give. The desire with everything you do with implants is to fit everything directly onto the implant as passive…and accurate. That's probably the main reason for implant failure…infection…you've got to make sure you educate the patient. Looking at hygiene and care of the transmucosal area particularly about the implants. In some designs of magnetically retained prostheses where there's a preference to bring the silicone right down and around the neck of the implant, you've got make sure that that's going to be able to be maintained and kept hygienic. Those are the areas where I would expect a prosthesis design to affect implant failure. In other prostheses like a nasal prosthesis where perhaps you're not choosing the best bone. Length of implants…with the Straumann system we've been using, sometimes you can use narrow intra-oral type implants so you've got a longer implant to use. Particularly up in the nasal bone region. We had a case where the patient had magnets for a nasal prosthesis. The tendency with a nasal case was to disengage the superior magnet first and then most of the pulling pressure was on that. Whereas it was more of torquing, twisting, almost shearing force, on the two which were on the roof of the mouth and nose area. Because we used a craniofacial

short type implant, in the end the guy took his nose off and the implant was still attached to the magnet. So perhaps that could be a design of retention, maybe the bar could've been better if you have poorer bone…magnets might not have been the most appropriate method to use. Actually it's proved since, because we didn't replace the implant, and that was 8/9 years ago and the patient is still successfully managed the prosthesis on the 2. So it was proved that it was unnecessary in the first place. Implant failure might not be the end of the world. With a nasal prosthesis, and 10 years ago, you're looking at a triangular pattern of implant placement and it might be that that's actually not that necessary.

5. ***How might you overcome the potential of implant failure in the design of prostheses and their retention components?***

Well if you've got a single structure that's going to contact all implants, you have to make sure that's passive, and fits well. You ensure that you educate the patient on how to look after it. If you're having silicone fitting around it that that's fitting hygienically and that the prosthesis has been fabricated in a way that you've got nice smooth silicone around it, not rough. And the design of your sub-structure as well, that you're not asking the implants to do something that they can't. There is design implications in cantilevering implants, but I'm not sure that's such a consideration in extra-oral cases where there are definite loads, where it is purely retention and not so much function, you could probably push those limits a bit but it's always worth bearing in mind if you have a whole load of bar springing around, you want to support it as much as you can.

6. ***Are larger mid-face prostheses more likely to fail than auricular prostheses? Why is this?***

There's a tendency to assume that they will, because the nature of the defect of whatever prosthesis you're putting onto it is going to be more complex. Having said that, if you apply good enough criteria for implant placement and appliance prosthesis design, you should be able to reduce that, I wouldn't say eliminate it. Ears are a lot more straight forward, you've got different areas and different qualities of bone, so with obturator components especially, you're taking into account part function, transfer forces, it does get a lot more complex. So the natural assumption would be yes, they do tend to fail more because there's a lot more going on. There's more weight, an ear prosthesis doesn't weigh a lot, it's out of the way on the side of the head, it's easily visible, easily inspected, in theory easy to keep clean. With mid-face you've got that nasal, sometimes oral, orbital communication, so you're into different types of hard and soft tissue. So I'd guess there are more factors stacking up to go wrong.

Section 2 – The Design Process

7. ***How might you define the levels of accuracy in the design and fabrication process? Do you believe there to be inaccuracies introduced at any point in the process affecting the success?***

Well you're starting off with an accurate impression, so you've got to make sure your impression technique is accurate and satisfactory. You can check that but only by subsequently seeing what you've made, if it fits. You don't have to go right to finish, with a bar you do…Defining the levels of accuracy...with implants that's quite straight forward, it'll either fit accurately or it won't. With a bar it tends to spring a bit. Magnets are a bit more difficult if you're bonding them directly to silicone. If you're doing a bar for an ear, with the bar, you make the bar and on top of that you make the acrylic substructure with the clips in and then you do your wax up in the next phase. At that next appointment you can check the fit of the bar, you can see what's going on before you put the ear on. With magnets, it's all covered up. You get a feel for it. And you can do your best to check but without that visual element. You can't really fully satisfy yourself. The only thing you can do is get 2 more magnets and maybe cheaper transfer magnets, join them together and when you get your patient back separately from you trying, you check the fit. So then you're doubling up on components. But with what you're actually making you can't really see what you're doing. You could use a couple of magnets and keep them to check the fit, have a set of used ones, 2 or 3, but you'd need to join them together with acrylic. We've tried laser welding but I don't know what it is with magnets, they don't quite like it. But that's what you'd need to do. I guess it's that experience of knowing. You know if something's not quite right. With the bar, you don't have to rely so much on your experience or your sense, from the very first time I made a bar I could see if it fitted or not. You know, when you're screwing it down there's some resistance or not. You know. It's a little bit more ambiguous with magnets. But like I say, if you're not joining them together, ultimately the silicone forgives that but in terms of how you feel about it as a practitioner, you want it to fit accurately.

8. ***What are the benefits of multiple part assemblies? (Abutments, spacers, caps, bars) Is 'modularity' important to you?***

The Straumann implant system is a transmucosal coping which your gold bar is screwed straight to the abutment. The only problem with the Straumann system is you don't have anything to brace the integrated component when you're trying to undo things or when you do things up, and in some cases you can actually de-integrate it (implant) without that protection. I'm not that familiar with the Branemark system but I know that element is built in so maybe the extra components… With casting a bar up you've got contraction issues and obviously accuracy of how the copings fit to the abutments. I would much prefer to buy gold coping. They're more expensive but I know they're going to fit much better onto the abutments and then it's a process of how you're going to join them together, whether it's by soldering or laser welding and you've just got to make sure that how you do it they remain passive. With multiple components you can completely finish one join and then move onto the other, so you're not addressing the whole bar in one go. You can just address one joint. But still, whether you are laser welding or joining, you are introducing heat into the process, and with soldering you're introducing another alloy. Heat expands, and then it contracts. We tend to use the laser welder, and you have to do one joint at a time before moving onto the other.

9. ***Do you apply any design techniques that are personal to you? Any idiosyncrasies/habits that others may use or may not know of?***

I wouldn't say so no, other than the completely bespoke nature of what we're doing. Everybody's different and everybody would do it slightly differently but no I don't think so.

10. ***What process do you follow for the duplication of a bar and clip prosthesis? Does this have its advantages or any complications?***

Well, we tend to keep the original models. So providing we are happy with that bar fitted in the first place, you could use that. You would also need to consider why the bar broke because if you're not happy with the reasons…if you think it might be the designs then you might need to consider starting again. I would think in a lot of cases, you're looking at making another bar. As we don't deal with the same sort of volume as places like (PLACE) or (PLACE), we would probably re-make the prosthesis, because we don't have many bar fractures at all, not enough to effect it. If you've got a bar, then you've got a prosthesis with clips with an acrylic matrix in. Unless you can make or repair your bar exactly the same, then you're going to compromise the fit of the prosthesis onto it no matter what you do really. You might get away with it but the numbers that we deal with, there's really no need to try and get away with it. Or even if you were doing a lot you shouldn't get away with it, because everything's got to fit properly. Unless there was a way of making the same bar so you had a back up then you'd need 2 bars and 2 individual matrices that fit within the mould, or start again.

11. ***Is there any part of the process you feel particularly frustrated about conducting?***

No, not really. If you could guarantee the fit of the bar and if you could guarantee the fit of the prosthesis, that's really what we're trying to do. If you can guarantee the lifespan for colour, the aesthetics, the whole process to be successful, to build more guarantees into it. In affect that would be nice but that's probably the essence of what we do anyway. That's the challenge to do what we're doing. You're always trying to better it. Personally I don't get frustrated by anything. I probably would do if I'm trying to make a bar and I couldn't get it to fit for whatever reason, constantly colouring it up, you know, having to re-do things…I know anecdotally from colleagues, if you follow the fabrication process from start to finish it's rewarding. If you bodge bits and go back and re-do things it's frustrating.

12. ***Have there been any recent developments in the design or fabrication process that you are particularly aware of?***

I mean there's the jigs and stuff for placing implants that PDR are doing. There's the CAD /CAM bars that PDR has explored. It's not an area that I'm aware that there's been a great deal of movement, when talking about bars and implants and magnets and stuff.

Section 3 – Checking Procedures

13. ***How would you normally check the retention mechanisms so that they can be passed as clinically acceptable? (When would this usually be?)***

In terms of retention for an implant retained prosthesis, be it a magnets or a bar…the bar is visual and manual…you can check it on the model and check it on the patient. You can feel if it's not fitting passively. With magnets it's a bit more difficult, you can always have a separate matrix just to check that your impression is accurate. If you're talking about adhesives, then not every patient's compatible. Adhesive is acceptable, but you know there are different skin types and to be honest, unless they're aware that they've got an issue, it's sort of trial and error really, when they come back to say what it's done.

14. ***Do you perform any 'technical' checking procedures? (When would this usually be?)***

As technical as it is, it's that visual check, throughout the whole manufacturing process. As far as I'm aware, if you're in doubt to whether there's a gap in a coping and an abutment or not, you can try and pass something fine into what you perceive to be a gap. I don't know… we always feel that we should be able to establish whether something is accurate or not.

15. ***Are there any established standards or testing methods for the evaluation of the 'performance' of retention devices?***

I don't think so. If in doubt you normally get a colleague in to have a check. Other than what I've already mentioned, there's nothing that I'm aware of. You can see as you go to screw in the second screw, if the bar starts to move, you can feel it, and you can see it. If the bar's moving even the slightest bit then it's not passive, in order to fully close the screw up. It's going to feel different to the first one, because there's going to be resistance. When you fully engage one screw, you can see from the other coping(s) and if you can't necessarily see, when you come to doing the final half turn on the screw, then you will see or feel some resistance, and it will feel different to the first one. And then you can always screw it down fully on your model, and as you start to unscrew the other one, again, you'll feel that it's unscrewing with some resistance. And you should be able to see if there's any slight movement. That's exactly what you're looking for. Or any difference in the connection between the coping and the abutment. If you're still getting resistance from unscrewing your screw and that is changing then you know that it's not passive. That's exactly it.

16. ***How might you test for the usability of an auricular prosthesis for the patient? How is this different to other facial prostheses?***

They're going to use it for retaining spectacles and cosmetics. If they're a rugby player, you're probably going to advise them not to play with it on. It may be that a magnetic retained prosthesis is safer in terms of the abutments when the patient's not wearing it if they're coming into contact. I know there are issues for people who do a lot of swimming with the chlorine, but that's mainly the effect it has on the colours in the silicone, the bleaching effect. I don't know how you would test that really. You would always make sure, with any appliance really, that it is removable, any prosthesis that's removable whether it's a denture, obturator, or a facial prosthesis, they are able to insert it and remove it successfully. Not just that they know how to do it, but particularly in elderly people there is an element that they are able to do it. That the physical dexterity is there to insert, remove and look after what it is you've supplied them with. So that's pretty much a clinical thing really… that you know what to ask them. I would have to confess that I don't routinely ask our patients, particularly in the case of ear prostheses about their lifestyles. You know a bit about them anyway through clinical records. Here a lot of them are elderly gentlemen, it's a rural community and a lot of people spend their time outdoors and so our skin cancer rates are increasing quite a lot here so what we focus in on is whether a bar would be more difficult for them to look after and whether or not they are going to be active enough to demand the most secure form of retention over what they might be able to look after. I don't know, it might be a wrong assumption to look at abutments for a magnetic retained prosthesis as oppose to a bar and think well, they're much more straight forward, you know, little studs popping through the skin… and they'd be easy to look after. I mean you've still got to look after them and whether there is a great deal more care for something like that than a bar, I don't know really, I wouldn't think that there is really. Do they live on their own…mentally are they able to look after…have some control over what you've done when they go away because it's completely out of your hands. We had a patient come back, an auricular case, who came back and had descended quite rapidly to some state of dementia, and so we just took everything off. Because they were losing them, not looking after them, unfortunately the decision is probably better for that person to not have an ear than to have a bar for them to look after, you're making them a prosthesis every week because they keep throwing them away. Other than that, lifestyle…we don't tend to see many young, active people here. If

they're born without ears or with congenital defects or as young people they've had cancer, geographically Birmingham take a lot of that, all of it congenital defects, everything goes into Birmingham children's' Hospital. That's why we tend to get a lots of older farmers with big hairy coloured ears that are quite easy to colour up because you can just chuck everything in. Doing little kids ears is difficult; it's a lot more difficult to match the colours because you've got less to work with. What we're looking at is to expand what we do and work closer with other units. A sort of hub and spoke sort of arrangement and we're quite happy with that, it can't be any other way really. Our patient type is probably a little bit different to some of the 'super-centres' really. All the clefts born here go to Birmingham Children's Hospital, there's a degree where if you were doing less than 13 a year then you have to give them up. You've got to be doing enough to keep your skill levels up. You've got to have other colleagues that can peer review or assess what it is you're up to.

Section 4 – User Requirements and Mechanism Design

17. ***What are the main considerations when finalizing the retention forces of the retention mechanisms? Is there a retention force 'range' that you work within?***

In terms of bars and clips, if you're going to fit an ear, it's going to clip on….you can tighten the clips a little bit but I would be quite happy with that sort of visual, manual feeling. So if the patient's able to clip it on, insert it and remove it…we don't really have anything technical, anything measured that we would apply. Choice of size of magnet, I think Technovent have just come up with another magnet that is slightly stronger but… it's that lateral, shearing, displacement force you're trying to operate against. And they've got those O-rings as well as the magnet in the abutment. Again it's just experience and feel, the more retentive a magnet is, the more you're asking of the bond between the metal and the silicone.

18. ***Is passive fit in bar structure designs important to you? How do you ensure there is a high level of passivity?***

When you're making a bar, it's the primary consideration I would think. You'd screw one of them up tight once you've made it. In terms of the fabrication process, I would rather have pre-made components and join them together. Some people maybe particularly gifted in casting stuff and are more happy to do that. That's just how I would prefer to do it. I know that pre-fabricated copings are going to fit nicer on the abutments. And the way we do it, you can finish one join and then concentrate on the final one. So you know where your problem's going to be. And in terms of checking it, you would screw it in and if you can't determine any movement or any gaps, that's how you satisfy yourself, if it's passive. If it were not then I wouldn't expect that level of accuracy in passiveness is going to affect anything that the integration couldn't overcome. I would've expected there to be a massive problem if that was the case. As technicians, technologists and prosthetists, we have the skill level to establish to a satisfactory point that things are passive.

19. ***Have you experienced any complications with bar structure mechanisms that do not have appropriate levels of fit?***

Yes. I have cast bars before. That has worked and in some cases it hasn't. Initially, quite a few years ago, it was probably a cost consideration, that if you routinely cast the bars yourselves, the plastic copings you could buy to burn out or wax up yourself would be cheaper, but the number of mis-casts and re-makes we quickly realised that having something more definitive in terms of pre-fabricated copings and the gold bar being better made cancel each other out. Then all you've got to consider is how you join the components together. Your soldering or welding techniques.

20. ***How might you define (or evaluate) an appropriate accuracy of fit for bar structure mechanisms?***

Exactly how I've explained to you. If you cannot see and cannot feel any gaps or any sense of resistance by screwing down one then screwing down the other and then maybe unscrewing the first screw…just spending that time clinically and in the workstation. What we do in the lab is dependant on the accuracy of the impression so you are building in a step, a possibility for compromise of fit, because you can't weld it when it's on the side of the patient's head really. If in the lab you are happy with the impression, and what you've done in the lab, you've still got to satisfy it clinically up to that level, and if there's any doubt, you really need to go back to the impression stage again.

21. How is the mechanism designed to accommodate for cleaning and hygiene?

You want to make sure that your bar-structure has got enough space. You don't want it sat right on the soft tissues. So you need enough space to clean around the patient, to get something to physically clean around it. With prosthesis body, I like to leave a little bit of a gap to allow air in. You should be trying to get a sealed area but will be at body temperature, dark with some moisture in it which is ultimately what you are trying to avoid. So that would be the other thing, to allow some gap for ventilation.

22. What effect might surface roughness have on the mechanism? Between the bar and abutments, and between the bar and clips?

In as much as you're happy with how passive it fits, you've got to be as happy with how well you've finished it. Your metal work should be as highly polished as you can get it, to the point where it shouldn't even be a consideration. Acrylics and silicones are a different mater altogether. I mean you can polish acrylics. Silicones are porous anyway so not matter how close you look, you'll find roughness. You're just trying to finish it to as neat and to as clean as possible. Stuff will stick to it; you want to discourage bacterial growth.

23. Are there ever any complications with screw loosening? What might be the cause of this?

Intra-oral bars and stuff we used to get quite a bit of a problem with the kit we used…it's because you're putting them under a lot of pressure, there's a lot of movement going on with those implants. Extra-orally, if you haven't screwed them up properly then they may come loose, it's not a problem we've tended to have really, with the Straumann system that we use, you get a little torque wrench with it. I know there are torquing mechanisms for the Branemark system and you just torque it. I would imagine if it's not passive it will just work itself loose, and depending on how much load you put on it. If you've got a complex mid-facial prosthesis that's supporting an obturator as well then you're going to get a lot more forces and a lot more directions on it. We don't tend to experience that as a big issue.

24. Why are bar structures shaped so that there are protruding 'arms' on each side? Is there a specific length and angle the protruding arms should be?

The cantilever arms are there to give that extra retention and stability. The reason they're shaped as they are is to fit into the prosthesis and if you had a straight bar you create a pivot, a rotation, so angling the bars contradicts that and stops that from happening.

25. What determines the implant positions (xyz planes) and their distance from each other?

Ultimately if you haven't got the right bone, you can't put an implant in it. So bone quality and bone determines where your implants go. Moving back a stage from that, your planning of the surgical side of things, let's say an ear, if you've got a pre-existing ear, you know where the thickest parts, the anti helix are, where you want your implants to fit into the prosthesis best, so you would develop a stent of some sort that fits…a lot of our cases are for ears, particularly from disease, patients have had wedge resections, biopsies, so we've got a good idea and we have access to the patient prior to surgery so we've got some idea where we want those implants to go, so we can determine that. If the bone quality is not there, then you are starting to have to accept compromise. The distance from each other, again, you don't want them right up close to each other, the point of it is to create that 3-planed anti-rotational substructure within the confines of what your ultimate prosthesis is going to look like, you can determine how far apart. You can't put them infinitely apart, just where it fits in with the shape of the prosthesis really.

26. What are the advantages of using bar structures over magnets in auricular prostheses? Have you experience of using any other devices?

The advantages are…you do get a more 3 dimensional stability and a sort of lateral resistance.

27. Why are bar designs rigid? Could this affect the surrounding anatomy in any way?

It's rigid because for a bar, the bar isn't the retention, the clips are the retention and you need to clip something over it. Which means its flexibility is within the clips arms and the bar needs to resist that flexibility in order for it to engage an undercut. And remain retentive. In the same way the abutments for a magnets or some of the mushroom techniques are metal, or hard, whatever is the engaging part has got to be softer than the bit it is engaging in order for it to physically resist it enough in order to engage. If

you have a soft bar, you would never be able to get metal clips over it, and you'd have to have softer clips I would've thought.

28. What is the importance of the currently used materials in bar structure mechanisms?

Gold and titanium. Gold's got good biocompatible properties. It's quite a nice material to use, it's quite forgiving as oppose to titanium. We've not ever tried to use titanium bars. Don't know why we've not tried it; we've always just used gold. It's quite a traditional thing. I think all the components are more readily available, I don't know really, I don't know if there are titanium clips, if there are then I couldn't think of a reason why you couldn't use titanium copings, bar and clips. That flexibility that we talked about, Gold is good at that, it's got those flexible properties, maybe because of the copper element…not sure…they are only alloys…the nature of an alloy is that you can put in what you want whilst trying to retain the biocompatible properties. You can put in what you want to serve a purpose, there is softness to gold, and I'm not sure how flexible titanium clips would be. I know there was an issue getting hold of titanium rod at the correct thickness to accommodate the gold clips. I mean I can't believe that hasn't been overcome. That part of engaging the undercut of the bar, maybe gold is a much better material doing that.

29. Please rate the importance of the following factors for a bar and clip mechanism for an auricular prosthesis, and expand on your thoughts. (1 Not important →5 Very important)

FACTOR	**RATING** *(1 Not important →5 Very important)*
Changeable/custom designs (flexibility)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Adjustability of retention forces	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ You've got to be able to do it!
Accurate fit between male and female components (e.g. bar and clip)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Equal forces distributed on implants	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ The forces you're going to exert on an ear prosthesis is through putting it on and taking it off in theory. It's important but I'm not sure if it's an issue.
Stability of ear when fitted	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Biocompatibility of materials	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ If it's not biocompatible, you're wasting your time.
Height of retention mechanism from tissue	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ If you're able to modify within the materials that you've got, that's the important thing. You can't have the clips hitting the soft tissue so the height is very important, not so much the level of the height but the existence of a space.
Mechanism longevity/durability	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Passive fit of components to abutments (e.g. bar to abutment)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Aesthetics of retention mechanism when exposed	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ I wouldn't say they were insignificant because some patients it is an issue.
Ease of duplication	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Good wear properties of clips and bar interface	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Many components (Modularity)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ With what we've got at the moment in terms of casting or soldering or welding then I would much prefer to do it that way. It's very important to me but that's not to say it's definitive. If we could come up with a different way of fabricating bars that didn't involve that…it's only important to what we've got at the moment.
Intricate	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ You don't have a lot of room to play with so it is important, you can't fit bulky items into a prosthesis.
Easy to clean	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ If they can't do that then it will fail.
Rigid design	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ In terms of what we've got available, it's got to be more rigid, even if it's only slightly than what you're using to get your retention through engaging the undercut. To me that's a bit black and white.
Easily attached/detached	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Follows the shape of the ear	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ If you haven't got the bone quality, you can't put implants in so sometimes you have to compromise. If you were starting off in an ideal world you'd have that as a gold standard so a 5.
Does not snag on clothes	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ If that's how you've designed it, sometimes people just have to make allowances. In order for the success of a prosthesis, you design something that plain. Sometimes you have to make modifications; you can't cover all your

	bases. But it is a consideration. Where you've ended up with the skin being really tight onto the bone, which is what you're trying to get but in some cases you do get a bit more thickness. Everything seems to stand up; you can turn down the ends of the bar if you've got the room. You can build it in as a consideration.

Section 5 – Computer Aided Design Processes

30. ***What is your experience of Computer Aided Design (CAD) in the design process of creating prostheses? Do you currently use any CAD processes in any prosthesis design processes?***

In cases like ear prostheses I don't. What I'm aware of…I did the Mimics course down at Cardiff. The ins and outs of placements, getting the depth, mirroring, all that sort of stuff. It is fabulous but the numbers and the cost of it. The numbers of the cases that we do and the complexity of them. We can achieve what we're happy with and what the patients are happy with without it (CAD). But I'm aware of it and if everyone had affordable access to it then I think it would probably be one of those things we'd all be using. I don't think it's exclusive; it doesn't exclude you being able to do something.

31. ***What obstacles may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

It's cost of hardware…in terms of SLAs and manufacturing things in that way then yeah it's cost. In terms of hardware I'm not sure if the cost of the actual fabricating is, I know at PDR if you're going to put some models through then you're going to want to fill the table up. It's more cost effective. But I don't know what the actual physical cost of creating a model would be. In terms of the market side of things, what we get from it, it offsets cost, theatre time, accuracy, stuff like that, not talking about prostheses here. Some custom made implants would be made, plates and bars etc for reconstructions, but I'm not sure how much it actually costs to make in terms of materials etc. I suppose I don't need to know. If it costs us £250 and we're happy with it then… I guess what you're buying is not just raw materials, you're buying people's skills, their knowledge and training, it all comes at a cost. If we invested in the hardware and it was affordable then the day to day costs might be affordable too.

32. ***What benefits may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

You're getting more knowledge, more information. Things like the mirroring, you're getting bone depths from the scans prior to going in there. Without 3D imaging gives us the inability to see it on a screen and you're not taking that into theatre, so there's benefits then, fewer surprises on the day. Accuracy…cost aside…the ability to make templates. You're building more assurances into the process as you go along. Quite how much of an advantage that is ultimately I don't know. But if they're there and you're able to build them in then perhaps you should be building them in.

33. ***Is there anything else you think is important to the success of an auricular 'bar and clip' mechanism?***

Guaranteed accuracy really. Once you've got that accuracy, the compatibility which you should have beforehand. The durability…if you're going to go to the trouble of making something, you want it to last.

Interview Transcript Participant 4 – 11/01/2011

Section 1 – Prosthesis success

1. ***What for you makes a successful auricular prosthesis?***

A successful auricular prosthesis is a prosthesis that the patient himself is fully satisfied with. The number one thing that we would be looking for is patient satisfaction and ultimately we haven't succeeded in our goal unless that patient is as satisfied as he possibly can be with that patient. Obviously you've got technical aspects that you'd look at in terms of the success of a prosthesis, like whether it's a good fit, whether the colour is accurate, whether you're happy with the shape of the moulding of the prosthesis but basically what it all boils down to is whether the patient is happy with the final outcome.

2. ***How do you think the retention mechanism affects the overall success of a prosthesis?***

Greatly….because if the patient isn't happy with the quality of the retention, then ultimately they're never going to be happy with the quality of the prosthesis. If they're going to be concerned that it's going to fall off every 5 minutes, they really need to know that the prosthesis is going to fit securely, it's not going to go anywhere, it's going to stay exactly where it's put. So ultimately it's a critical factor in the outcome of the prosthesis. If anything, most of the complaints, if we had had any complains at all, it's been due to the retention system. Fewer failures, more concerns. If anybody does come back being concerned about anything it is with the level of retention. We've had patients who've had magnetically retained prosthetics, who've gone over to bar and clip, because they prefer the enhanced retention offered by that system.

3. ***What are common reasons a 'bar and clip' mechanism might fail to do its job?***

Fracture of the base-plate. Damage to the clips themselves, damage to the bar. Another consideration is the manual dexterity of the patient. You may find that especially in an elderly patient or a patient with not great manual dexterity, you may find they may have trouble attaching a bar and clip prosthesis, which might count as a failure If they are unable to wear it or unable to take it on and off themselves. So it's more of a failure in their inability to wear it rather than a failure of the mechanism itself.

4. ***How might you diagnose the cause of implant failure? How do you think a prosthesis might affect this?***

Probably not. I can't really see that the prosthesis would affect the failure rate of implants in any shape or form in most cases. Unless it was applying extremely adverse torque to the implant, say for example you manufactured a bar that wasn't passive on the model, and was applying a massive torquing force then you may have a situation where it could disrupt the implants but it would really have to be something substantially wrong. It should never get to that stage to begin with, to affect the stability.

5. ***How might you overcome the potential of implant failure in the design of prostheses and their retention components?***

Well more than anything, it's making sure that all the components are passive on the model when you are actually soldering the bar. The last thing you want is to be applying a torquing force. You've just got to ensure everything is passive. A lot of the time, soldering your bar in a passive state and then screwing each of the screw when they're on the model, to make sure you're not getting any form of torquing force, looking at it carefully to make sure it doesn't rock in any way, shape or form, or if it seems to spring away from the model. It just needs to be completely passive. As for the prosthesis itself, as long as the bars are ok there shouldn't be any reason why the prosthesis would cause an adverse reaction.

6. ***Are larger mid-face prostheses more likely to fail than auricular prostheses? Why is this?***

Yes and no. You obviously have the complexities of a larger mid face prosthesis. It depends what you refer to as failure really, whether you're referring to a failure from a patient standpoint to fully rehabilitate them or whether you're looking at a failure from a retentive standpoint. With a sufficient bar and clip structure there's no reason why you shouldn't have a mid face prosthesis that should fail but in saying that, yes there is all the more likelihood that it could depending on the bar complexity that you construct and depending on the weight of the prosthesis. The other aspect if failure is the likelihood of the patient

experiencing satisfactory rehabilitation, you've got all the more scope for the prosthesis not living up to their expectations in terms of restoring their original appearance. With an ear it's much more easily hideable. ***What about in terms of passivity of fit, is there more chance of a larger mid-face prosthesis being less successful?*** In terms of implant failure I wouldn't have said so, it depends on the quality of the bone the implants are placed into to begin with. As long as the substructure is properly made and you've taken the necessary precautions, there shouldn't be any reasons why it would cause the implants to fail. The only difference may be in by making a more complex structure you have more chance of it applying a torquing force purely because of the amount of stress you build into it when you're manufacturing it. As long as you take care when you're producing the substructure there shouldn't be any reason why it should make the implants any more likely to fail. If you do encounter a higher degree of failure with a larger mid-face prosthesis, it's probably due to the poor bone quality, or the level of radiotherapy treatment or chemotherapy treatment that the patient's undergone to reach that stage. You'll often find they'll have to take away so much bone that there's vey little remaining to satisfactorily position the implant, so that you might to be an issue with large mid-face defects. Depending on the position of the implants and how far the extent of the prosthesis and base plate and retentive clips are away from the nearest implant, you could get torquing forces transmitted through the substructure itself. If you can imagine you've got the implants positioned say for example in the orbital ridge and nothing below to support the substructure, you haven't got any cheek bone, you haven't got your zygoma, you haven't got the maxilla on that side…you've really got nothing there in terms of hard bone to support a substructure so you may find your entire appliance is supported by a substructure running off implants only in the upper portion of the face, so you an imagine when you're clipping something on and off, you're getting more of a rotational torquing force on those implants than you would if you had a lower implant to support it. We ideally don't like to have a situation whereby the area of affect of the prosthesis upon removal and positioning is too far away from the positioning of the implants, we don't want that rocking effect. As much as the bar structure and substructure is a rigid structure, you can of course apply torque to it. If I was pressing against my cheek and the implants we're quite up in the orbital ridge and you've got quite a lot of scope for torquing on those implants. You've got quite a large cantilever effect.

Section 2 – The Design Process

7. ***How might you define the levels of accuracy in the design and fabrication process? Do you believe there to be inaccuracies introduced at any point in the process affecting the success?***

Well there can always be inaccuracies, depending on user error, depending material qualities, depending on any number of factors really. We try our best to ensure that everything is as accurate as possible, used laser welding techniques and soldering techniques, ensuring that everything is passive on our models by using good quality impression materials, making sure that our models are as accurate as possible to begin with…but at each step there is a possibility for an inaccuracy….distortion of the impression, incorrect placement of the lab analogues. All of those things should be diagnosed before the bar actually gets fitted to the patient. If there's a chance that it isn't going to fit, it should be picked up along the lines. If you had a bar that wasn't in a passive state, then you actually analyse that on the model. There are potential inaccuracies with every step of the process, you've just got to be very careful and minimize those inaccuracies by using the best techniques possible and just following the best practice you can really.

8. ***What are the benefits of multiple part assemblies? (Abutments, spacers, caps, bars) Is 'modularity' important to you?***

It can be, in a lot of cases we've had patients transfer from one system to another. Especially if you've got modularity at the abutment level, you can have a situation where a patient is fairly dissatisfied with a magnetic retention system and they can quite easily be transferred over to an alternate abutment system. You've also got systems whereby you might have a bar encroaching on the soft tissues. If you've got overly short abutments, you can always replace those with longer abutments to raise the bar further away from the tissue level. And of course each piece is replaceable, you haven't got a situation where if one piece gets damaged you don't have to replace the entire lot, you can actually replace a part of a system, rather than replacing all of it. So it does have its advantages, the modular system.

9. ***Do you apply any design techniques that are personal to you? Any quirky techniques/habits that others may use or may not know of?***

Not especially, most of my training's come from (NAME) so I probably follow a lot of (NAME's) technique. Other than that I can't really think of anything that's personal to me. I do have a bit of a habit of assembling n entire bar using soft ribbon wax before actually laser welding everything. It does have the potential to move but it is pretty time saving. As oppose to assembling everything with plaster or a longer setting time material, it just helps to position everything where I want it so I can see the layout of the bar before actually going any further. Other than that I can't think of anything particularly personal to me.

10. ***What process do you follow for the duplication of a bar and clip prosthesis? Does this have its advantages or any complications?***

We frequently have to duplicate the prosthesis itself, in that we have laboratory abutment replicas within the patient's mould which allows us to position the patient's bar within the mould and duplicate the prosthesis as an exact copy, re-making the base-plate and clip section. It's very rare that we would have to duplicate the bar itself, in doing so you would probably be better off re-making the bar from scratch. Unless the patient has a history of having had several prostheses they use as spares, by the time you actually make up a bar which is an exact copy of the original, which is unlikely to be that exact to begin with, you're probably better off starting from scratch and re-making a new bar and going from square one, knowing that you have a system that works perfectly well with new prosthetics but not necessarily with the old ones. It's not that much hassle to make a patient a spare prosthesis anyway, that's standard practice. If a bar was damage to such a level that you would have to replace the bar itself then you are probably better off starting again. As for duplicating the prosthesis itself, it's just a matter of re-making the base plate. Give them new gold clips. You've already got the locations within your mould to position everything so that's not an issue at all. That's just our standard working protocol. We make duplicates regularly.

11. ***Is there any part of the process you feel particularly frustrated about conducting?***

No, to be honest I think the process is pretty straight forward, I can't think of anything…. One thing I think patients feel potentially frustrated about is the fact that they have to come for a colour match each time they come in for a duplicate. Most patients would prefer a system whereby they could phone up and say "I need a new one" and we can send it out to them in the post. To be honest it keeps us on our toes and makes sure that we're doing everything to the best of our ability. Otherwise you could be sending out duplicates that are ok but not great and really not ever seeing the outcome, whereas if we have the patient here every time, we can always monitor the condition of their implants, monitor the condition of their bar, check that nothing is untoward, and also it keeps us on our toes to make sure that our colour match is accurate to their skin tone at that particular time. If we did have a system where we could send them out on a pre-existing colour sample…they might have got a tan in the meantime…they might have faded quite substantially…you don't know what their skin type is like at that moment in time so you just make sure that everything is the best it possibly can be for that situation.

12. ***Have there been any recent developments in the design or fabrication process that you are particularly aware of?***

The biggest development that I can think of is the CAD/CAM systems. I've seen examples of ceramic based bars, zirconia type bars which are like an all in one piece which are very strong and very light, as far as I know they are not in mainstream use at the moment, but you can see that the development of things like that will be on the horizon. At the moment I think most people will be using the standard gold cylinder, gold bar system so to an extent there's a case of 'if it ain't broke, don't fix it'… People go along with things they've been using for a long time because they work perfectly well, there's no overt reason to fix them. Most people will be able to make a pretty good bar and clip system in a fairly straight forward manner. Ok the components are costly but at the end of the day they work very well and you don't hear any reports of any problems with them, so it's standard procedure, there is scope for potential CAD/CAM systems but as far as I'm aware at the moment most people are using the traditional methods.

Section 3 – Checking Procedures

13. ***How would you normally check the retention mechanisms so that they can be passed as clinically acceptable? (When would this usually be?)***

Everything we make is made to MDD (Medical Device Directive) standards. So everything is based on existing protocol written up according to the latest journal information based on what is considered as the

standard procedure. Anything we make should be passed as…it's all biocompatible and we know that the materials that we use are safe for patient use, so there shouldn't be any reason why anything we make shouldn't be suitable for patient usage. Any potential discrepancy could be backed up in a court of law because it is actually manufactured to what is common practice specification. The MDD provide a set of guidelines, which essentially say what you can and can't do, and you have to work within those guidelines. It's more of criteria for safe and functional design rather than anything else because prosthetists need scope for flexibility if they are coming up with novel solutions. You can't really have set criteria, there must be flexibility within the guidelines otherwise prosthetists can't get on and do what they need to do for novel and successful outcomes. Every case is different after all.

14. ***Do you perform any 'technical' checking procedures? (When would this usually be?)***

The only thing we check is the passivity of the bar and screwing each of the abutments to make sure there isn't a visible rock and to make sure there isn't any spring in the bar that could cause torque on the implants. Other than that we don't apply any particularly scientific checks on them. It's more visual checks to make sure that everything's to the required standard.

15. ***Are there any established standards or testing methods for the evaluation of the 'performance' of retention devices?***

Not that I'm aware of.

16. ***How might you test for the usability of an auricular prosthesis for the patient? How is this different to other facial prostheses?***

I think this is quite a broad question in that the usability really depends on the satisfaction with the prosthesis really. Any prosthesis that goes out of the door we ensure that the patient is capable of fitting it on and off before they leave, so they have a good practice session before we send them off, especially if they're a new patient, not so much if they're existing patients who are pretty much dab-hands, they'll pick up the prosthesis and put it straight on. Particularly with new patients we will tend to keep them for a little while just to make sure that they're happy with the retention system, they can fit it on and off without any difficult, if they themselves can't then they have a partner who can, maybe they have a carer who is capable of doing it. The most important thing is that they are able to wear it to begin with. The other thing is their personal perception of it, how it effects their life, we have people who wear their prosthesis only to go out and about, they don't wear them in the house at all, that could be for comfort reasons, that could be because they don't feel the need to wear it with their immediate family but as for usability itself, the most important thing is that they're able to control the prosthesis so to speak. That they feel capable of taking it off and cleaning it and maintenance but really we don't have many problems at all. It is very important to ensure that they're happy, that's the most important thing. As long as they are comfortable with the removal and positioning of the prosthesis then they will wear it. It's just that they have to be comfortable with it themselves and it's important to make sure they are before they leave.

Section 4 – User Requirements and Mechanism Design

17. ***What are the main considerations when finalizing the retention forces of the retention mechanisms? Is there a retention force 'range' that you work within?***

I don't think I could quote any figures off the top of my head…the main consideration is that the actual prosthesis isn't going to fly off at the slightest nudge. The one thing that will concern patients most is if they feel that they've got a prosthesis which is going to come away far too easily. The most important thing to consider is that your retention system is going to be incorporated within the prosthesis affecting the overall aesthetics of the prosthesis. There will be occasions where that's completely unavoidable where the bar is in a position that is very difficult to hide or the ear is particularly small the bar is shaped so that it is difficult to hide within the structure. But one of the main considerations is to make it as aesthetic as possible to camouflage that bar. It should always be manufactured with aesthetics in mind but first and foremost you are looking at a level of retention which would make the patient comfortable to go out and about and not have to worry about the fact that their prosthesis is going to come off at any given time. With the standard gold clips, we never really have a problem with the level of retention. As long as the base plate is made properly and the clips are securely fastened to the bar when the base plate is made you know that you'll get a system that will hold the prosthesis in place. And as long as the bar is

sufficiently designed to correctly accommodate the number of clips necessary to hold the prosthesis in place. You will tend to find with a larger prosthesis or with a prosthesis that has a longer span, you will need more clips so you will need a longer base plate to be able to prevent it from rocking, to allow it to clip in place and remain solid. Especially relevant when you have a prosthesis that has a fitting edge quite a long way from the point of retention. You might want to extend your bar slightly further in order to give it more retention to allow the fitting edge to fit down more securely. What you find tends to happen. If you've got a short base-plate and a long prosthesis you'll tend to get a lot of silicone, which is free to move. If you've got a rigid plate and a rigid bar within it, it tends to keep it in the position that it's made. ***Would you adjust the mechanism according to the patient's lifestyle?*** Potentially yes, it is a potential factor. If you've got an elderly lady sitting at home watching TV all day and not moving around much, the level of retention may not be as critical as someone who works as a builder or an active sportsman. So you do tend to find you adjust the retention according to personal preference as well, we have some people who prefer the prosthesis to be slightly loose because they worry about the potential of breaking it. Not really an issue but ultimately if they feel concerned about the possibility that they will break it, it's better that they feel comfortable. And also we have people who like the retention system to be very tight. It's always a possibility to tighten up the clips slightly following processing to make the prosthesis as tight as they want it. We've got people who go to extremes either way. There does tend to be an average value. You get people who are perfectly happy with the clips in their default position and they're happy to go away with the prosthesis in its standard configuration, they don't need any adjustment to the clips or retention at all, they're happy with it as it is but obviously we'll get the minorities who will sway either way. Sometimes you may need to adjust an individual clip if they feel one is too tight or one is too loose. Sometimes through the fault of the manufacturer they might have slight discrepancies. One will be tighter than another, so it's all a matter of personal preference more than anything. And their lifestyle does come into it as well.

18. ***Is passive fit in bar structure designs important to you? How do you ensure there is a high level of passivity?***

Yes. After we finish making the bar, everything is tightened down onto the model originally in the first place. We make sure that when we solder everything, all the components are kept as passive as they possibly can be. When we finish laser welding and soldering everything, we tend to undo one of the screws holding the bar in place and look carefully to see if there's any rock or any sign of tension within the bar which should result in a gapping between the cylinder and the abutment replica. If we do see any sign of torquing forces, we'll probably cut the joint and re-solder it to make sure we get the bar as passive as possible. We've called it the one-screw test.

19. ***Have you experienced any complications with bar structure mechanisms that do not have appropriate levels of fit?***

Not really to be honest. As long as they're made carefully and as long as you follow the procedure you normally use and keep an eye on what you're doing then…no we haven't had any problems. The biggest potential for a problem is if the abutment replicas are positioned in the wrong place when the implant is being taken to begin with…that is entirely possible, say for example one of the replicas moves slightly the impression isn't quite set, but that would be more down to operator technique than anything, as long as the impression is taken properly, everything is allowed to set properly and the impression is closely examined upon removal from the patient, you should be fairly confident that everything is going to fit perfectly at the end.

20. ***How might you define (or evaluate) an appropriate accuracy of fit for bar structure mechanisms?***

As accurate as possible. You don't want anything less than optimum accuracy. Anything that's going to affect the implants in any way, shape or form, you don't want any torquing forces on those implants over any length of time. You don't want it to have an orthodontic affect on them to be applying a gradual, small force. I mean there's nothing worse than that over a long space of time for causing a bit of trouble. You just want the fit to be absolutely perfect if possible. Anything less than that really shouldn't be accepted.

21. ***How is the mechanism designed to accommodate for cleaning and hygiene?***

Usually we make sure the bars are spaced well off the tissue so the patient can get a cleaning mechanism, whether it is a brush or cotton wool bud underneath the bar for cleaning. Most of our patient's don't find

it a problem whatsoever. The biggest problem with cleaning, especially in teenagers, if the soft tissue tends to build up during their growth spurt and tends to encroach on the bar, and we do incorporate that into our designs by making sure that the bar is well elevated from the tissues. If that does become a major problem, they'd be either looking at revision of their tissues, to smooth everything out again, lessen tissue contact with the bar or we'd be looking at making a bar with longer cylinder to raise it further off the tissue to allow them space for cleaning. There's always scope to make things as easy as possible. The bar itself is a fairly shiny item. It doesn't have many little corners or areas of detail. We try to make our soldering as smooth as we possibly can. It would be possible just to laser weld the bars and leave them exactly as they are but we tend to find it gives a slightly rough finish so we'd prefer to solder over the laser weld to make sure all the surface are smooth as possible to prevent the accumulation of debris and tissue. The smoother everything is and the further the gap between the bar and the tissue the better it is for cleaning ultimately.

22. ***What effect might surface roughness have on the mechanism? Between the bar and abutments, and between the bar and clips?***

It could cause for the potential for accumulation of debris and the potential for heightened infection rates because any small amount of roughness is enough to harbour microbes, if you've seen the tiny little pits that microbes can accumulate in, you really don't want any roughness at all if possible. You want that surface to be as smooth as you can possibly get it to make cleaning as easy as possible and to stop microbial build up.

23. ***Are there ever any complications with screw loosening? What might be the cause of this?***

Not that I'm aware of. We do occasionally get a patient coming in where the screws have loosened very slightly but it's absolutely fractional to be honest, it's marginal. I've not known it to ever be a problem. Maybe through taking on and off the prosthesis, those forces are play really, each time the prosthesis is clipped on and off there's obviously a reaction along the length of the bar and the subtle vibration of positioning things may eventually work it loose. It's also possible if the patient works with heavy machinery with vibrations running through their body may affect the tightness of the screws, but to be honest we've never come across anything with cause for concern. In the time I've been working here, most of the screws that I've tested have been very tight upon the patient walking into the clinic room. We always check that they're sufficiently tight before the patient leaves and they usually come back in a similar state.

24. ***Why are bar structures shaped so that there are protruding 'arms' on each side? Is there a specific length and angle the protruding arms should be?***

Usually to prevent rotational forces. The last thing you want to happen is for the ear to fit perfectly but rotate very easily. What we tend to do is give the arm structures to prevent rotational forces to allow grip in multiple planes. What you find tends to happen is if you don't have those arms and you just have a flat bar you tend to find that the clips do rotate quite easily around the bar and that the fit does tend to be compromised. They'll rotate a little bit too easily and pull away too easily. The length and angle does vary on the prosthesis, it varies on the individual and it does vary depending on the aesthetic result. We do design the bar in such a way to incorporate them within the aesthetics of the prosthesis so we try to hide the bar as well as we possibly can. No that can have a bearing on the angulation of the arms. There's no distinct angle. I'm sure somebody has tried to come up with one but ultimately there's no point in obeying a particular angle that's ideal for retention if the bar is going to make the prosthesis look ugly. That you can't hide it sufficiently within the confines of the prosthesis. So the angles that we produce vary entirely based on our analysis on how much space we've got to play with and the angles that we can comfortably fit.

25. ***What determines the implant positions (xyz planes) and their distance from each other?***

Bone quality is one important factor. Ideally you'd want a sufficient length of bar to be able to fit, for an ear, 3 gold clips. So you'd be looking at an area that has excellent bone quality. You'd also be looking at the optimal position based on the patient's opposite ear. You don't want the implants to be positioned in such a way that they're in perfectly good bone but you've got a position that's absolutely impossible to discreetly hide your base plate. Ideally you'd want your implants to be essentially behind the thickest part of your ear so looking at the anti-helix area to try and fit them in under the most bulbous part of the ear where you've got plenty of room for your base-plate to be happily hidden. You don't really want them in a situation where they are going to be encroaching and making your base plate a little bit too obvious. So

there are multiple considerations, the bone quality is a very important one because ultimately you don't want your implants to pull out all too easily, or the bone to fail or the integration to be compromised, but you should be looking at positioning them in an ideal location. It can't always be done, especially in patients that have poor bone quality in exactly the area that you're looking to work and there are ways around that. Potentially you could have a situation whereby you need to lengthen the base-plate and hide the retentive section with artificial hair. There could be a situation whereby you need to elongate the base plate and potentially hide it behind the structure of the ear itself….which may compromise the aesthetics of the ear slightly but ultimately if you can get it in the most bulbous part of the ear, that is preferable.

26. ***What are the advantages of using bar structures over magnets in auricular prostheses? Have you experience of using any other devices?***

You do tend to get much better retention with the bar structure. You do tend to find the patients that do have the bar are more confident than patients that have magnets. Whether that's a psychological factor because with the magnets we can use more retentive magnets, such as the O-ring system that do provide an extremely sufficient level of retention. You wouldn't really ever encounter many problems with the O-ring and lipped magnet systems. But somehow we do tend to find that the patients who do have the bar and clip system do tend to feel a bit more confident and more comfortable with the level of retention that it offers. On the flipside, they are more difficult to clean and you do tend to encounter the problem that…for elderly patients they might have more trouble fitting their prosthesis, whereas with the magnets they're pretty much self-locating. They'll find their own level and lock themselves into position. With the bar and clip you tend to have to have the dexterity to be able to position your prosthesis and the strength to be able to put it into position.

27. ***Why are bar designs rigid? Could this affect the surrounding anatomy in any way?***

As long as everything is passive it shouldn't affect the surrounding anatomy at all. The bar structures are rigid because if you had anything that was flexible you'd tend to find that the clips wouldn't fit very well. You would be pushing against them and the bar would be moving away as you were trying to push the clips into position. What we find is that a rigid structure makes it much easier to push everything into position. We have had situations in the past whereby in our moulds we've used silicone materials in place of laboratory analogues and a fitting location for a bar. So rather having the bar in the mould during processing, we have a silicone replica. And we find it is very difficult to rely on the position of the clips because of the level of movement. You tend to find that they degrade quite quickly to. We haven't found the level of rigidity that we use much of a problem. The only place I could see it being an advantage is if the patient was to knock the bar and then maybe it would flex with impact as oppose to torquing the implants or fracturing but…with the prosthesis in place that should be an event that should be a few far and between to be honest.

28. ***What is the importance of the currently used materials in bar structure mechanisms?***

The biocompatibility for a start, the fact that the materials are extremely safe, tried and tested. We know that they work well. The advantage of the bar being gold as well as it being a fairly soft metal, so that if any torquing forces are applied, the likelihood is that the bar will break before the implants are torqued to a level to actually destroy the structure or to compromise the implants. So even though it's strong enough for what we need, you tend to find if it was to take a severe impact, it would potentially destroy itself rather than destroy the implants. You've also got the situation whereby you don't get any galvanic reaction with gold. You don't want a dissimilar metal, which would potentially cause shocking pain to the patient. That's something that is important to be aware of. Or anything that could cause an allergic reaction. Gold is very inert. Even when the skin is rubbing against it. It will cause soreness obviously but you don't get any dermatitis or anything like that. The materials are biocompatible.

29. ***Please rate the importance of the following factors for a bar and clip mechanism for an auricular prosthesis, and expand on your thoughts. (1 Not important →5 Very important)***

FACTOR	**RATING** *(1 Not important →5 Very important)*				
Changeable/custom designs (flexibility)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Adjustability of retention forces	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Accurate fit between male and female components (e.g. bar and clip)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Equal forces distributed on implants	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Stability of ear when fitted	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ If it isn't stable the patient's not going to want to wear it! It needs to be spot on really. If they're not happy with the positioning or fit, if they're worried that they're going to loose it, then they're not going to wear it. They want something that's going to be secure and see them through the day.
Biocompatibility of materials	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ You just can't compromise on a lot of these things at all.
Height of retention mechanism from tissue	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Depends on the situation.
Mechanism longevity/durability	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ It is an issue but the patient will be coming back every 12-18 months anyway, so if there was any situation whereby it's starting to wear, we could replace it. Ideally we would want it to be a 5. You would want it to last a long time. They don't want to do that every time they come back. If the component was to fail, we would be able to replace it on a regular basis.
Passive fit of components to abutments (e.g. bar to abutment)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Aesthetics of retention mechanism when exposed	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ That'll be more important to some than it will to others because some of our patients don't tend to wear their prosthesis around the house. They wouldn't want anything to look ugly on the side of their head. They don't happen to look particularly ugly. They almost look like a shiny piece of jewellery. It's not the most important factor but it should have some consideration.
Ease of duplication	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Good wear properties of clips and bar interface	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ There's nothing more annoying for a patient finding out that they break too easily or wear out quickly. They want them to last them. If they've got a nice prosthesis that they're happy with, I know of a patient that only comes back every 2 ½ years. They're typically paler skin, they don't need a prosthesis all that often. It will be quite annoying for them to have to come back because it's broken rather than being dissatisfied with the appearance of it. Ideally we only really wish our patient to come back when they are dissatisfied with the appearance rather than it failing on them. Obviously the materials have a finite lifespan. Silicone discolours, it only lasts so long, but ultimately you want it to last as long as the colour and aesthetics lasts, so the longer the better.
Many components (Modularity)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Intricate	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Something that is fine in detail? I would say it's pretty important because the smaller the mechanism is the more conveniently you can disguise it. A lot of the time you'll tend to find that the bulkier the components are that you're using, the less scope you've got for hiding it within the prosthesis. The only downside to that is if the mechanism becomes so small it begins to impact on the level of retention that you're getting. You wouldn't want it to compromise on the function of the device. You'd want it to be as functional as possible but as small as possible.
Easy to clean	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Rigid design	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ It really depends on how you define importance, because if you could come up with a flexible design, which was as retentive and was as suitable as current designs that we've got, it really wouldn't make all that difference. It isn't vital that is all that rigid. I think the rigidity is a convenience at the moment because that's the way the system works. If there was a flexible system that works just as well, it'll be just as convenient, potentially more convenient because I say, it would bend with the patient, if they took a knock, so I wouldn't say the rigidity is the most important factor, it's an important factor as the system stands but not necessarily important for the future development of the system, it depends on how things progress. So I don't think that's one I can really give an answer to, because I don't think the rigidity in itself is of a defining factor. If a miracle material came along that was rigid when you want it to be and not when you don't then it would be an entirely different scenario.
Easily attached/detached	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ The patient needs to be extremely comfortable with it.
Follows the shape of the ear	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Preferably yes. You want really want it to.
Does not snag on clothes	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ You find that a lot of the bars tend to if you get them caught but most of our patients learn to be careful when they're taking their clothes of that they pull the jumper over to make sure it doesn't snag. At the moment with the designs we've got, it's fairly impossible to come up with a design that won't snag in any way. Usually it doesn't cause much of a problem. We don't get many patients complaining about this.

Section 5 – Computer Aided Design Processes

30. ***What is your experience of Computer Aided Design (CAD) in the design process of creating prostheses? Do you currently use any CAD processes in any prosthesis design processes?***

Personally I don't at the moment but as a unit we do. We incorporate a lot of CAD based design in a lot of our prosthetics. Even in terms of duplicating ears from one side to another, flipping over the patterns that we need. We do use it a lot. Most of our implant placement and guide work is done by CAD systems too. So pretty much everything involves some CAD system. I don't work on the computer systems myself much at the moment because I'm not trained in the software, but in the future I'm hoping to have more training it. So yeah…if there's not use in it already there is a lot of potential for CAD to be incorporated in it. I mean it's pretty much revolutionized the process of flipping an ear from one side to another whereas everything used to have to be carved by hand, we can at least now, even if it's not the most accurate fit in the world, we can at least get a building block based on a CAD based reversal of the existing ear. It just cuts out a lot of the work and some of the in-between stages really.

31. ***What obstacles may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

As far as I can see, the biggest obstacle is cost…at the moment…for most units. We're quite a large unit and we're lucky in that we've got access to a lot of systems, our involvement with PDR…we're near enough as well so that we can phone up, find out information, come down for a visit, see what goes on, and we learn as we go along. Whereas more outlying units may have the problem with costing, if they do enough prosthetics to warrant the costing to begin with… One of the things you do find is that MaxFac Units are not solely MaxFac Units, there are only a few in the country which concentrate and have dedicated technicians who focus entirely on maxillofacial prosthetics. We're one of those, looking at places like Birmingham, Kings, Glasgow, have people who focus entirely on facial prosthetics. A lot of the smaller units specialize in orthodontics and do prosthetics as a sideline so it's incorporated into their daily work but isn't necessarily the mainstream of their daily work. Unless they could incorporate those CAD/CAM systems into their other areas of their daily work, it would be very difficult justifying paying out the money for the software and the hardware necessary to carry out CAD/CAM based work. I think the costing is the larger obstacle. Also the training. The time out that they would need to train up their staff to follow through each of the processes is an obstacle. There are plenty of prosthetists out there at the moment, who are approaching retirement age who have worked in a particular way for their entire life, who may not be too keen on going over to entirely new system at this point in their career. It depends how forward thinking they are and how keen they are in incorporating those systems in their day to day work as oppose to things they've been brought up with and working with all their life.

32. ***What benefits may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

The potential for quicker prosthetics manufacture. In the future, you could imagine patients would spend less time in the chair. Ultimately you have to think about the patient's comfort. The less time they need to spend sitting in that chair having wax try ons, colour matches etc, the better really. You want them to think that they can come in, have something made as quickly as possible and then get out the door. Although the service that we provide is invaluable to the patient, in their eyes we're a means to an end. They just want the end product; they don't necessarily want to sit all day in a chair getting tired and sore…. The less time it takes to get things processed and the less time in the chair the better. It's all about making their experience as streamlined as possible really.

33. ***Is there anything else you think is important to the success of an auricular 'bar and clip' mechanism?***

I think we've just covered pretty much everything!

Interview Transcript Participant 5 – 09/12/2010

Section 1 – Prosthesis success

1. ***What for you makes a successful auricular prosthesis?***

A Successful auricular prosthesis is a prosthesis that they're happy with, in their day-to-day life, and are pretty unaware of.

2. ***How do you think the retention mechanism affects the overall success of a prosthesis?***

I think it gives them confidence, if you've got retention, you can have confidence in that prosthesis staying in place.

3. ***What are common reasons a 'bar and clip' mechanism might fail to do its job?***

I suspect it has to be badly made, or poor implant placement. I think bar and clip doesn't fail where we've wanted to use bar and clip and certainly on an odd occasion, I've tried magnets on an ear and the patient's decided on a bar in the end. I can't imagine why they would fail other than those two reasons – not greatly made, poor implant placement, implant failure I suppose you can say. We enjoy great success with bar and clip for an auricular.

4. ***How might you diagnose the cause of implant failure? How do you think a prosthesis might affect this?***

Obviously any superstructure you fit needs to be passive. You don't want to unduly load implants, the need to be passive in the auricular area, but if your bar is not passive, that can cause issues. So you need good impression technique, good materials, there's no point having a good technique if your materials aren't good. You need to give consideration to skin care. So you don't want to be traumatizing skin, particularly around the abutment. Once an implant is integrated, the highest cause of failure is infection. Certainly for us here, the auricular area is the only area where we use flanged implants. What we've found with flanged implants is it's not unknown for there to be a chronic infection without symptoms. It has happened that the first symptom is that the implant has failed. When it comes out you can see that there has been a chronic infection there. And because it's under a flange, it's been left untreated. Years ago we used to send every failed implant off for analysis, but they don't want them anymore. I would think, the vast majority of cases, it's infection. Very, very rarely trauma to the area. If it's not integrated from the start. Another thing we have is in heavily irradiated patients, it might actually be that the bone breaks. You've maintained integration but the bone around that integrated area breaks. You can usually challenge if that's the case because there would be good bone on the implant and it might even come away with a good chunk of bone. ***How do you think a prosthesis might affect this?*** Undue stress on the implant. Like I say, poorly made bar, not really easing the skin area, poor ventilation in a patient that might have skin problems, I mean you can have bad ventilation. I don't think there is any typical reason that we could come up with for implant failure, no toxics or anything like that they produce.

5. ***How might you overcome the potential of implant failure in the design of prostheses and their retention components?***

Firstly if we were concerned there was potential for failure, we'd put more implants in at then initial stage. There are cases where you know the risks are increased if they're having radiotherapy, if they're smokers, that sort of thing, although that's been discredited now…So if it was a case with high risk i.e. potential for failure, we'd put more implants in the initial stage. After then, what happens is that when one ideally placed implant fails, you use another implant that's less ideally placed. You're just moving the compromise for aesthetics really. What makes this question slightly ambiguous is the inclusion of 'potential'….we look at the possibilities of failure in the future and it's just a balancing act. If they're likely to lose fixtures, you put more in. If it's in a young fit patient that's having an ear, and you're drilling into a perfectly healthy temporal mastoid region, we'll just put 2 in. And if 1 fails, we try and come up with a temporary solution, I had one recently, an oncology patient, she lost a couple and she's down to one now and we managed to get it to stay on with just one magnet and she'll be coming in the next few weeks to have more put in. Like I say, it's a compromise. If you have to alter your retention, it's a compromise either in retention strength or aesthetics. That's the compromise.

6. ***Are larger mid-face prostheses more likely to fail than auricular prostheses? Why is this?***

A few years ago I would've said yes because in a heavily irradiated midface we used to use small craniofacial implants, we don't really use very long length implants. We have to my knowledge only lost implants in 1 patient in the mid face and that was due to bone complexities, where the bone actually came away. Long implants we tend not to use. The success rate in mid-face is very good, and if we've lost any in the last few years it would be that 1 patient through bone complexities. Or continual disease process. Either resulting in implants being in diseased bone and coming out or having to be removed in a larger resection. So the success rate is very good in the midface.

Section 2 – The Design Process

7. ***Do you follow any particular guidelines or regulations for the manufacturing methods?***

We do as a matter of protocol and certainly we encourage all the surgeons that we go to theatre with to understand the core requirements. In the unlikely event, certainly in the hospital, we're always there. But if you were to go somewhere else where they do not have access to that service…so they understand where it's coming from. So from a teaching perspective…yes…we follow the original guidelines set by what used be Nobel Biocare and is now Cochlear so it's 15 – 18mm from the centre of the external meatus. The other guidelines we follow is ensuring that those implants are placed in an area that can develop within the prosthesis. And you do that as closely as you can. With just a standard case it's not a problem, you can always do it, if you're talking about a large temporal section, then that can be tricky. So you just go as close as you can.

8. ***How might you define the levels of accuracy in the design and fabrication process? Do you believe there to be inaccuracies introduced at any point in the process affecting the success?***

No. I don't actually because we wouldn't allow….the only things you can measure as accurate are implant placement, bar, fitting the implants correctly, and the rest is down to interpretation. We don't do mirrored ears you know. I suppose you can say if you've got one bigger than the other then that's an inaccuracy. It's a hard thing to define. The mechanical side, you can measure it, you can know it's accurate or not…but certainly anyone who gets trained here is told if the bar is not passive then it is not fitted. That's it. That is a golden rule. So it has to be passive.

9. ***What are the benefits of multiple part assemblies? (Abutments, spacers, caps, bars) Is 'modularity' important to you?***

It is, it gives you that flexibility, and there is always the chance that if something is not quite right, you can address that in the next 'module' if you like. So if the implants aren't perfectly placed, you can get over that with a different shaped bar. What else would I say, I've been brought up on it, and that's what I do, and that's where we enjoy our success is using that system.

10. ***Do you apply any design techniques that are personal to you? Any quirky techniques/habits that others may use or may not know of?***

I like using the light cure, base and impression taking, base construction. Whereas traditionally here they use cold cure for bases or….think they just use silicone for impression taking. Whereas I rigidly locate the abutments with light cure. The only thing that's changed with the design of the bar is that I never bent the bar I always cut it. Because I think there is a small chance that you'll put a stress in there, whereas if it's cut then you know it's not going to try and unfold, there is no elastic memory there. That's something that I do, and where I do bend the bar, I always try and heat it to remove any….you can actually do it using the laser welder, zap the joints and I suppose it realigns all the crystal structure. It's probably complete and utter nonsense but it's just something that struck me as a good thing not to have bends if you can avoid them. We still stick quite closely to the Gothenburg technique… developed I think in the late 70s, and we're used to following that technique.

11. ***What process do you follow for the duplication of a bar and clip prosthesis? Does this have its advantages or any complications?***

We always keep a box for each patient with his or her original model in. You know if we've done it correctly or not. It's a good check. If a bar is broken we will usually suspect that there has been trauma.

And if not, then the bar hasn't been made properly, has it? That's one thing, the steps you go through, when you're welding it, you're not just welding a little bit around the outside, and you're welding it through and through. Some people have a problem with bars breaking and effectively it's because they just join the bit they can see, which is a wafer thin bit of gold. So you have to get your weld well into the joint. But if it looks as if the bar is defected then it's practically trauma. Self-description. Whether it's because an implant's failed and it's traumatized, pressing that bar, and the joints is not good. If the bar were repairable then I would re-do it on a model that we had. I'd check the implants and the abutments, just to make sure what's gone wrong. You could do that could easily, because quite often our patients have two bars. They have one that they're wearing and when they need others, we've got a bar and we can make….when they come in you just change the bar. So you could do an early check with the other bar to see if there's been any movement to the abutments or the implants. And then for some reason, maybe it's been knocked and it's broken, you can just repair it and stick them on their way. Obviously if it's an implant failure, either trauma or infection, we get them on the waiting list. Get some more implants.

12. ***Is there any part of the process you feel particularly frustrated about conducting?***

Not really. It's part of that beautiful mix that we have which is technical, an engineering side of it, and then later on you go on to the carving, the sculpting and the art side of it. I think it's quite a nice process, making ears is quite a nice thing….beautifully finished gold bar, it's like a little bit of jewellery isn't it. It's less frustrating now we have something like the laser welder. When you used to have to solder them, that was frustrating, waiting for materials, so actually having the laser welder has removed one of the frustrations I certainly had. It's actually made making certain bars possible, because it was almost impossible with the old system to make certain bars. Like that nose we saw, because they're all converging. You have to cut out the back where the collar is…I say if you can actually get the thing on and off….whereas before you'd have to use bits of wax to hold these bits together, investing, soldering, and then if it didn't fit, you'd have to perhaps grind it out of there, it was a lot more effort and very difficult to do.

13. ***Have there been any recent developments in the design or fabrication process that you are particularly aware of?***

I suppose if you really wanted to, you could have it milled. These days, it's a very straight forward process, there's a lot of kit around that would allow you to scan the area and then get a bar milled. That's something we should probably try just to see. The laser welder, and other things, the fact that we use long dental implants has made a big difference for these cases where they have a large temporal resection. Because we actually put long dental implants, if you like, sideways into the skull, rather than perpendicular to it. The benefit of that is you've got the longer implants, often you'd take at least the apex of that implant out so it's outside the field of radiation so it gets good bone. But they are dental implants, they're not a new invention, they're old stuff that we just found a new use for. I know the day will come when they drop dental technology from our trade and it would be a big shame because that's what gives us our strength. The hand skills you get from making snappers allows us to do our job.

Section 3 – Checking Procedures

14. ***How would you normally check the retention mechanisms so that they can be passed as clinically acceptable? (When would this usually be?)***

I use a microscope. Always have done. I use the one in the laser welder now. It's just easier. But even when we soldered, we had a tabletop microscope, not a really high definition one or anything, but one that shows up your polishing and that allows you to check visually that it's passive, it's like anything you do, if you're honest you can say yeah that's passive or actually 'no it isn't'. So I use that for the bar, that's probably it. But then of course that's duplicated on the patient, you know, put the patient under the microscope. You can then truly see if it's passive or not. ***So when you put it back on the patient, what is it that you usually do to test that it's right?*** We torque the screws to the agreed setting. I don't tend to take one screw out then put it on the other but you can see if it's not right, if there is premature contact somewhere, that's absolutely what you're looking for.

15. ***Do you perform any 'technical' checking procedures? (When would this usually be?)***

I feel like I've pretty much covered that in the last question.

16. ***Are there any established standards or testing methods for the evaluation of the 'performance' of retention devices?***

Not to my knowledge. Because it's such a subjective thing whether it's successful or not. Because ultimately everything we do, the marker for success is - is it right for the patient, does it allow the patient to get on and have a good life, not be constantly concerned about their prosthesis….if it was always falling off, they wouldn't have the confidence, and we'd see that as marker for failure. I think it's more the fluffy things isn't it, where it's difficult to do without the technique that you like.

17. ***How might you test for the usability of an auricular prosthesis for the patient? How is this different to other facial prostheses?***

Well they've got to be able to take it off. We've got patients that can't take their own prostheses off and on, in which case somebody else needs to be taught how to do it. It's little things, if you got a poor old dear that's got arthritic hands as well. It's all being good to make it so when you put it on there is a big reassuring clunk…but she's got to be able to fit it. So you might lose some of the clips a little so it's not so difficult to take off and put on. One of the measures of success in this is if they can properly look after it, it's no good just sitting there and 6 months later you haven't taken it off which we've had, a few people who haven't taken it off, not 6 months but I had one on a 4 week review. We went through everything how to take it off, clean it, and normally I see them 2 weeks after fitting, for the first time, and he came in about 4 weeks later and I said "how you getting on with it, you managed to clean it well?", he said "yeah I did it like you said, when I wash my hair etc" well he did but only cleaned it on the outside, he hadn't taken the thing off! Whether that was my communication, whether it's what he got in his head…. It was actually, underneath all the muck, really healthy, but could've gone the wrong way, he's fine now. He got it into his head that he didn't have to take it off. We have a process with an amputee, where they come and see us and we explain to them what it's all about, how it fits, all before the operation. About maintenance you know, because in this hospital we have surgical reconstruction as the other option. Prosthetic reconstruction is not the only option. If they felt they didn't want the prosthesis to be taken off and on, then we would refer them on to autologous reconstruction. So the measure of success is if they can get on and use it, manage it, and if they are not capable, there is somebody, whether it's a professional carer or relative.

Section 4 – User Requirements and Mechanism Design

18. ***What are the main considerations when finalizing the retention forces of the retention mechanisms? Is there a retention force 'range' that you work within?***

Not anything that's calibrated by. It's just feel, I have to say. The considerations are facial movement, if somebody has got massive movement in the ear, which means you've got to put more pressure on the edge, otherwise that's just going to gap when they talk, so you increase the retention, it's not scientific at all. Often with kids, because they're so adaptable anyway, they don't mind if you clunk it on, and they'll be running around and you don't want it knocked off. But with older patients like I say, you reduce it somewhat, to make it usable for them. It's not scientific if I'm honest. What you might find is some figures in the dental regions. I suspect that the companies would have info on that, how much force it takes to pull off one of their clips the bar. There are more factors than just the clips.

19. ***Is passive fit in bar structure designs important to you? How do you ensure there is a high level of passivity?***

I think it's absolutely fundamental to what we do. I actually went to a lecture a few years ago where a guy said you could allow up to 1mm for a non-passive bar or a collar. Afterward, a colleague was doing a workshop on orbital impression taking. I said to her, 'why didn't you pick him up on that?' and she said 'why didn't you?' That's it - it was absolutely not based on anything. Does that show his inability to make a bar? If a bar is not passive, there's a reason for it. And it's a reason you can overcome. Otherwise people wouldn't be able to make passive bars. With laser welding, you know, we had to change the way we made bars; you have to finish one weld, before you do another one. You finish it completely. As soon as you go back to that bar, if you haven't completed it and you've started another one, and the bar becomes impassive, you don't know where it is. So you need to go back and correct it.

20. ***Have you experienced any complications with bar structure mechanisms that do not have appropriate levels of fit?***

Some of the very large mid-face cases. It's not unknown to have to remake part of that structure. Because a very large impression is very difficult to get off, and make a model of, having it completely accurate. I've got to say with ears, we make hundreds of them, so we should know what we're doing when it comes to making bars for these. I think we've only got one patient who has magnets, out of 200 odd patients with ears, it might even be 300 now. ***Why does that person have magnets?*** It's not my patient, but I think they have Parkinson's.

21. ***How might you define (or evaluate) an appropriate accuracy of fit for bar structure mechanisms?***

I would evaluate it under a microscope on the model; evaluate it on the patient visually. If you're going down the wrong line, and it isn't passive, you can tell when you're tightening it. It feels different. We would be looking for no movement, if you like, that collar is flat on the abutment, it's not torquing it, it's not putting it under any stress at all. That's really it. It's either passive or it isn't. And you aim to have it passive. That's the bottom line really. If you put any load on it that it's not designed for, it could jeopardize it in the long term. When we want to put 2 implants into a patient, we want those to last all of their life.

22. ***How is the mechanism designed to accommodate for cleaning and hygiene?***

You got to have enough space below the bar. Your skin has to be thin. Up until when we take impressions, and beyond it if you have a problem, but up until then, it's very much a partnership between surgeons and prosthetists. You need somebody who is able to do proper skin thinning. You want it non-hair bearing. And that's a dual thing, because that's for us to say at the time. If its hair bearing, we don't want that. So it's important this close relationship. So it needs to be non-hair baring, non-mobile, thin tissue. There needs to be enough space between the bar and the tissue. But then you want to ensure that the bar falls within that prosthetic envelope. Things that are put inside or by the body need to be finished immaculately and polished to a very high standard. The more polished they are, the easier they are to clean. There is less chance you're going to get infection. You've got to educate you patient on maintenance. It's not a burden, but it's really important. Then the issue with the instruments, they all get their little blue toothbrushes to clean around the abutments. Like I say that chap who didn't take his ear off…I failed somewhere, at the very least not to enforce, or to check that he was aware.

23. ***What effect might surface roughness have on the mechanism? Between the bar and abutments, and between the bar and clips?***

One is, it's going to get dirty easily, and retain fluids from the body or from dirty fingers, and it's going to keep that on the surface. It would wear the clips more readily. As an abrasive. If there was damage to the face of the collar onto the abutment, in any way that might mean it's not passive. If you've got a dent in it, either side of those dents you might have raised areas. So it's important that things are kept pristine.

24. ***Are there ever any complications with screw loosening? What might be the cause of this?***

A strange one, don't know if other units have found this but we've had particular patients that keep coming back with the loose screw. We torque them to factory settings. To a degree, when we get people back for an early review, we torque them a bit more because you get stretch in the screws. We've had a couple of individuals who keep coming back with loose screws. We change the screws so it's not defected material. I have no idea what that's about. It's not positioning, it's not angulations. Just one of those things I can't explain. Maybe they use earphones and listen to the radio too much. I don't know.

25. ***Why are bar structures shaped so that there are protruding 'arms' on each side? Is there a specific length and angle the protruding arms should be?***

No. Again it's accommodated within the prosthetic structure. It's there to give 3-point retention so that the ear doesn't rotate on the bar. The only reason why we'd have a bent bar. The chances are if you didn't need a bend, you'd probably get away with a couple of clips on a straight piece of bar between 2 implants. But we do it to stop it flapping. Technically what you're trying to do is put pressure on the front edge. And if you didn't stop it rotating, the front would lift and a gap would form. So that's technically it.

26. What determines the implant positions (xyz planes) and their distance from each other?

Firstly anatomy of the individual patient. And secondly the length you need to use for a bar and clip, between those implants. So too close, you wouldn't be able to fit a bar and clip in, and if they were too far apart, they would probably fall outside that prosthetic envelope. So it's down to the anatomy of the patient, some people have big ears, some people have small ears, so you have to accommodate that, and then putting them within that envelope.

27. What are the advantages of using bar structures over magnets in auricular prostheses? Have you experience of using any other devices?

My personal point of view, I think the security of them. Magnets are fantastic but once that bond has gone, then it's just gone. There are no warnings. Very clever closed field magnets, they've only got to be marginally apart and that's them gone. People seem to like the reassuring click of a bar. They know when it's on and off. And we have very few problems with them, very few problems at all. So it's personal preference, and patient preference more importantly.

28. Why are bar designs rigid? Could this affect the surrounding anatomy in any way?

I think it's historical. Traditionally we though it was a good idea to splint implants. I think it's since been proved that's not the case but so long as having rigidly splinted doesn't cause problems then I don't know what the clever people say about that to be honest. We do alter the rigidity of the bar, in somewhere like the orbits, where you're crossing a natural suture, some people can get symptoms if you bridge that. You know, you're trying to bridge something that's designed to have that sort of flexibility in it. We have had people who have got sort of head aches and various symptoms from that. That's one we are aware of in the orbit. Of course, in an ear unless you're really far away from the ideal position, then you wouldn't come across any sutures. And the same with the nose, we tend to place implants into the nasal bone and into the maxilla…..those are rigidly splinted and we don't have a problem with that. We don't really have people coming back with pain or symptoms with that. If you go across a suture line, naturally occurring suture line and you bridge that, you can get symptoms. You can get pain. Discomfort…because you're rigidly splinting an area that is designed to have give. We have had those symptoms. Difficult to find that in an auricular unless you've got a really large section, it would be difficult to find sutures to cross there. The down side I suppose of rigidly splinting them is if you get trauma to one (implant) you get trauma to both. If one is failing, it can fail without symptoms until it's led to the next one to fail. Overall we don't have a big issue with splinting. ***Do you think that rigidity helps with retention at all?*** I think it probably gives a reassuring noise and feel to the retention. I think it's probably more of a confidence and reassuring thing if it's rigid, for the patient and for us. Like I say, it's historical for us. They just know when it's on and they know when it's not. And they don't have to look. Magnets a great because they find their own way, but a lot of our patients feel they don't hear that 'tappy' click with them, it doesn't feel as reassuring. The rigid bar thing has come from our roots which is dentistry, the Dolder bar.

29. What is the importance of the currently used materials in bar structure mechanisms?

They are readily available. They are produced commercially to a high standard. Specifications made to say you've got consistency of material. Readily accepted by the body. Relatively easy to use. The most important aspects are, accepted by the body, that they don't cause any problems to the patient. Consistency of material for use.

30. Please rate the importance of the following factors to the success of a bar and clip mechanism for an auricular prosthesis, and expand on your thoughts. (1 Not important →5 Very important)

FACTOR	RATING *(1 Not important →5 Very important)*
Changeable/custom designs (flexibility)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ It's got to be for that patient, it's not like buying a good pair of shoes you can take off a shelf. The whole ethos of what we do is patient care, nothing fits all.
Adjustability of retention forces	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ We don't need to address that so often.
Accurate fit between male and female components (e.g. bar and clip)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Equal forces distributed on implants	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ For an auricular I don't think it matters, because the forces are so low compared to what an implant can take, that if you're saying that there is a bit more load on the

	bottom one than the top one. I don't think it's important because the forces are so low, the forces are not damaging, whether they are equal or not. If you had a large midface, maybe they've lost their whole palette, the forces are massive, forces of mastication are massive compared to putting an ear on, you would be wanting to look after your implants, and you would be concerned to spread that load evenly. And that comes from your design of the bar structure and where you take those forces. We use the same principles as sculptors when it comes to facial reconstruction. In a larger facial yeah quite important. An implant can take a very little load and remain healthy, it can take a very high load and remain healthy. So between the two I don't think it really makes a difference. If you were talking about putting lateral forces on them or torqueing forces on them then you can argue that you want that reduced.
Stability of ear when fitted	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Biocompatibility of materials	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ It's no good having a beautifully made ear if they're going to come back with some nasty reaction. If it's not biocompatible, effectively it's failed. So it's an imperative. It's the first requisite isn't it?
Height of retention mechanism from tissue	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ You have some leeway in that.
Mechanism longevity/durability	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ It's something we're aiming for but you do have some flexibility in that. I'd rather the prosthesis looked great and only lasted a year, rather than lasting 3… It means having quality prosthesis.
Passive fit of components to abutments (e.g. bar to abutment)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Aesthetics of retention mechanism when exposed	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ That's aimed at individual patients, some couldn't care less what it looked like when it was off. It's important for job satisfaction too, a nice finished gold bar.
Ease of duplication	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Good wear properties of clips and bar interface	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Many components (Modularity)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ I think it's great that we've got all these different bits, because it allows us to accommodate difficulties. I think it's good. It allows us to make a decent prosthesis. If we didn't have the flexibility of those different components, there are a number of occasions where you would struggle.
Intricate	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ I think it's important because if it weren't intricate you wouldn't be able to include it within that prosthetic envelope. If it were big, you'd struggle to hide it. You'd have to compromise somewhere. The fact that it's intricate allows us to make a better artificial bit, a more realistic prosthesis.
Easy to clean	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Rigid design	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ If we would have something that wasn't rigid, we would be able to accommodate. I suppose it gives security. Are magnets rigid? I suppose it stops rotation, the legs to put pressure on.
Easily attached/detached	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ It's important but it's not imperative.
Follows the shape of the ear	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ If it isn't, then you will have to compromise
Does not snag on clothes Suppose this is my WILDCARD!	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Well it will…Because you have an open end at the bottom. People do it.

My criteria is – are you going to be able to do a decent prosthesis. If it's tricky to put on, a real pain, really bad….but if it's just tricky to put on then it's not the end of the world, if it looks great and it's on then you can live with that. If it snags your jumper, then just take a bit of care, but it's not the end of the world. Whereas there are certain things like, being passive that are an absolute must. There is never a time where not being passive is good. There is no reason for it not being passive. Every prosthetic item we do, whether it's a cranioplasty or an ear or an eye, it is a compromise. And there are certain standards you need to set even before you set out. But there are things that make that compromise bigger…if it's difficult to clean then….you might still get a great result….you wouldn't say because it's difficult to clean it's deemed as useless, you could love it but it's difficult to clean, well then you can address that. I think it's degrees of compromise with our job. And you reduce that compromise down as much as you can. There are certain things you can't compromise on, like passivity is one. The engineering over art.

Section 5 – Computer Aided Design Processes

31. ***What is your experience of Computer Aided Design (CAD) in the design process of creating prostheses? Do you currently use any CAD processes in any prosthesis design processes?***

Yes. We build our own models for a lot of what we do. I've tried for facial prosthetics; we've used them a lot for things like prosthetic joints. We use Surgicase, software to export our STL files, to manipulate the DICOM and Export files.

32. ***What obstacles may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

I think it's going to be great. It's something that we are going to have to do. For facial prosthetics, we're going to have to do, it's a bit like electronic colour matching…not because it can necessarily make that better. It's just the natural process. And what we find is that we'll become dependant upon it. So I think it's inevitable that we have to go down it. So I'm sure (NAME) is the same, he could mix the colour better than a Spectrograph/match, but it's inevitable that we go down this route. I'm sure (NAME) can carve a better ear than a wax pattern made by a 3D printer, but it's important that we do because in 20 years time we will be using this technology as part of our training; it won't be like I am. We will sit at computers, and bang out prosthetics on a printing machine. Every ear you look at the materials for RM and Prototyping and it's just fantastic. 10 years ago it was unthinkable. I think it's natural progress. Inevitably it de-skills you in certain aspects, makes life easier, but there is a degree of de-skilling.

33. ***What benefits may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

I suspect that will take a lot of the guess-work out, perhaps remove the need to think more. It would probably mean more accurate prosthetics. I think it means that a lot of the skills that we have will eventually go. It's natural progression. At the moment it's fun for us but next generation will be brought up with it and won't know anything else. You might find that in the future you might get a medical illustrator doing our job. Being an old cynic I'm just wondering where it's going to lead! We talked the other day about getting this Spectromatch, not because we want to, but because you have to keep moving don't you and keep trying stuff. If we don't then who is?

34. ***Is there anything else you think is important to the success of an auricular 'bar and clip' mechanism?***

I think other than the technical side, then the education of the patient and the management of expectation of the patient. Whatever prosthesis it is, it's important that they know what they're going to have. Even down to the bar and clip. I have a pamphlet, which shows them the bar, and clip, I don't think it ever shows the magnets. You could say we're taking an option away from them, and I suppose we have but we don't have many problems with them. We don't have any problems that using magnets would solve. Keep them optimistic. Bar and clip does a very good job for ears.

Interview Transcript Participant 6 – 29/11/2010

Section 1 – Prosthesis success

34. What for you makes a successful auricular prosthesis?

It is purely having patient satisfaction purely because I can make a prosthesis fit and then think it doesn't look great but a patient think it's absolutely fantastic, so you always makes things better. Some patients even ask if a prosthesis can be tinted darker than what they need. If that's what they want then that is patient satisfaction.

35. How do you think the retention mechanism affects the overall success of a prosthesis?

Retention's massive. Hence why we moved away from adhesives to implants. The retention mechanisms are paramount to the psychology to the patient. It's not just a case hanging a base plate on a bar; you have to take into account, masticatory forces. If at first you fit a prosthesis and it pops off because of masticatory forces, then you can change the design of the bar, and you can change how far you bring your base plate down so you can have more silicone. Retention mechanism is paramount.

36. What are common reasons a 'bar and clip' mechanism might fail to do its job?

Incorrectly designed bar and poorly made bar. Too many distributed forces. You have to allow the wax up to compensate. It's not all one way traffic. You have to allow a patient to turn their head, maybe more skin here, or more pressure there, there are a lot of aspects you have to take into consideration. The main failure is not allowing to distributed forces within the soft tissue and poorly designed arms. You don't want the 2 arms parallel to each other, as soon as there's a lifting force from the front it's going to pop off. You almost want opposing forces. ***Do you think the craft nature of the process naturally makes the arms on different planes?*** Yeah because you have to take the soft tissue into account – it all depends what the anatomical soft tissue is like as well. There are so many different factors. Getting something retentive straight away is difficult. Orbits are a lot easier because there's not as much soft tissue around. Auricular are far more difficult for this reason.

37. How might you diagnose the cause of implant failure? How do you think a prosthesis might affect this? (mention 'compression fitting forces' and 'misfit forces')

A prosthesis? No. I'd say the main cause of implant failure is infection and necrotic bone. Because we are a large regional centre here for oncology, a lot of the extra-oral implants that we put in would be for this. Rhinectomies, a lot of these implants go in, they will be post radio-therapy fields. So basically, you put an implant into a dead bit of bone anyway. Especially in kids, the most common form of extra-oral implant failure is infection; in adults it is infection and necrotic bone through radiotherapy.

38. How might you overcome the potential of implant failure in the design of prostheses and their retention components?

You would try and use a longer implant than you would, because with an auricular implant you use a 3mm-4mm, but with in an orbit, you use an intra-oral implant, 10, 12, 14mm. So if you get through the field of radiation, that's great. But the most common form is infection and necrosis.

39. Are larger mid-face prostheses more likely to fail than auricular prostheses? Why is this?

Yes. Again, a lot more prone to infection and a lot more prone to irradiated bone. Especially in the mid-face, because if you're chopping something out of the mid-face, there are so many different areas, open tissues, and so much more bacteria within that field so a lot of the mid-face prostheses will have a through connection to the oral cavity, and the oral cavity is just a breeding ground. The mid-face is a lot more prone to failure. ***Do you think misfit might affect the success?*** It can contribute to implant failure because if you're if you're loading an implant 3 months after it's been inserted, you're putting a non passive fit on it, you can affect the osseointegration of the implant. If you're having an opposing force on it….yeah definitely. Passivity of the bar is paramount. If you see it's not passive then don't fit it. You're taken 2 steps backward, and you're putting the patient in pain. You always know if it's not passive, and they know as well, if you tighten it and they flinch. That's one sign that it's not passive, if it hurts the patient. If you make it on the model and it's passive but not passive on the patient, then start again. Just

start again. There's not point having a passive bar on the model without it being passive on the patient, because there's been movement somewhere down the line. You're chasing a moving target.

Section 2 – The Design Process

40. How might you define the levels of accuracy in the design and fabrication process? Do you believe there to be inaccuracies introduced at any point in the process?

In the design of the bar, the only inaccuracies you can sometimes encounter is as if, we re-use lab analogues, sometimes they might have been hit with a hammer or that kind of thing. The lips on the lab analogues may have been damaged, and can affect the passiveness. Our unit, we have over 400 prosthetic patients. With laser welding, you can over compensate with something fitting really accurately, just trying to make something fir too accurately, you can over-cook it. A pitfall is having faulty equipment, not faulty, stuff that's just been used and used. That's definitely something that can happen. You can make something more passive on the damaged side but then that throws everything out. You can have one collar slightly on an angle, but again with the screws you can over shoot a screw and that will over torque. If you're torque settings are wrong, or over torque manually a screw, you splaying the edges of the collar as well. The minutest can stop a fitting edge of a prosthesis fitting, something microscopic as that. The line between success and failure is huge. The main thing is with the design is human error. It's trying to cut corners I would've though, because we all try and do it. If I have a patient that's travelled down from Aberdeen or somehwhere, and something's not quite right, to save them coming back tomorrow, you try everything to make things more realistic. The main fault of the bar would be down to human error. Even if you were to do it on a computer.

41. What are the benefits of multiple part assemblies? (Abutments, spacers, caps, bars) Is 'modularity' important to you?

It is. There aren't any benefits really…because every single stage is a stage that can go wrong, that's the thing. Passivity is one thing – if anything gets damaged, like the collars, the more processes there are involved, the more chance there is for failure. If you're fixing a bar. There is that flexibility, but it's having all those pieces available to you. Some place might just order in a bit of gold bar and copings and do it that way, if they mess it up, they're stuffed. We've got half a million pounds stock so it's easier to do. With all the multi-units and components, yes there are more stages to go wrong but yes you can correct one single stage rather than back track the whole way.

42. Do you apply any design techniques that are personal to you? Any idiosyncrasies/habits that others may use or may not know of?

I like my bars central to the copings, but some people like to play them around the back. I like to keep my bar as high as possible on the copings; some people like to take them lower. They say that might affect the strength of the arms. Everyone has their own little quirky ways. With the base plate it's different things, some people might chop the base plate a lot higher for the silicone to go under for the silicone to breath, but you don't know with that base plate until you try it on the patient. You go against things you've seen and you know have worked. I might not be able to do it a way another prosthetist does it. It's one of those things.

43. What process do you follow for the duplication of a bar and clip prosthesis? Does this have its advantages or any complications?

i) Duplicating the baseplate/substructure

If you can see exactly where it is fractured. If the bar is broken on the actual weld, could almost marry the part back together. The only problem with that is the substructure might not fit on. You can do that though. If someone has really broken their bar, you can make a temporary repair of it but ultimately have to make a new bar, because especially if it's the weld, there's a possibility it could go again. You can't fit that new substructure into an old prosthesis. We give a patient 2 prostheses, so those prosthesis will only fit that bar. You know that substructure is going to fit the bar, you've got your mould. You're not making a new mould or doing the whole waxing up process, because you've got your mould.

ii) Duplicating a bar structure

If someone has broken their bar and I know it is passive, I would go back to the master impression that we poured up, and we would fix it on the master mould.

44. Is there any part of the process you feel particularly frustrated about conducting?

No not really…I think the most tedious thing is making the mould, doing the plaster work. The most tedious thing is if you come to fit it and it doesn't fit. You have to start from scratch. Re-do the impression, everything. You can put hours and hours into something that doesn't fit, that's the most frustrating. Doing it again is just another job that adds on to the back of the train. Frustrating can be coming to fit the bar and it's not passive. It can be something as trivial as putting light cure around your analogues when you take your impression, or using the wrong impression material, tiny stuff like that.

45. Have there been any recent developments in the design or fabrication process that you are particularly aware of?

Within the bars? No, all the components are still the same. We used to get 3/4mm collars (caps), so you could determine the height of the collar for your prosthesis. They used to have an apron that used to duck in and out, now they're all conical. So that's changed. Within the design process, it's pretty much the same since the early 90s. The only thing that's changed is the normal and multi unit implant- only the second stage goes in. From conventional to multi unit, and conical collars. Each design is different though to each individual patient. The wheel hasn't been re-invented though as far as we can see.

Section 3 – Checking Procedures

46. How would you normally check the retention mechanisms so that they can be passed as clinically acceptable? (When would this usually be?)

With the base the substructure, by fitting them on the patient, when you've constructed your bar, put it on the patient. Put your substructure on, if that's fine, then you can do your wax up. So try on the substructure and the bar before you do your wax up. You can just go bar, base, wax. It is important that they can see it going on, that it's passive, retentive, check all the soft tissue movements, check if they're enough clearance between the tissues. So if that's fine then that's clinically acceptable.

47. Do you perform any 'technical' checking procedures? (When would this usually be?)

If you put your finger under the front and give it a little tweak and it bounces off, you know that your angles aren't right. You can change the leg of one of your bars. You could make a substructure and give it a little flick and will want to bounce off in a strange way, there is almost too much force in there, so you know in that way. You put the substructure on, it fits on great, and think of the masticatory forces and then could pop off. So you got to compensate for people doing that. The base plate could be fine with movement of the jaw that way, but the other way it might pop off. So then you could move your bar lower down, and move the force further down. Having more silicone further down where the soft tissue is as well.

48. Are there any established standards or testing methods for the evaluation of the 'performance' of retention devices?

I think that the only established method is making sure it doesn't pop off. And that it can stand he forces against it. The one screw test – if this works then yeah. You can get away with a slight bit of movement, if you do screw gradually 2 screws at the same time that would be fine but if you screw one side down and the other nose up, it's like putting a springy floor board down. You can't just crank it into place, it doesn't work like that. The one screw test is the way to do it though, or keep your finger on it. That's tried and tested. In the design – if you have a U shape of a tube a rod, which slides beautifully up and down – if you have that with your bar, it'll just lift up. If you have it slightly 'off', there will be opposing forces. You want to take into account tissue thickness, length of the second stage abutment. If you make it really retentive, especially for a midface, again it all depends on the dexterity of the patient. You can have the prosthesis where you can clip the left side first then the second side in, that's your path of insertion and knowing which way for retention it goes in. We had a patient in last week, massive midface defect, obturator and midface. The carers came in and said he couldn't get his prosthesis on. Showed him how to put it on again, and it went on fantastically. He's had a left sided stroke since we fitted it– he could do it with his left hand normally, but can't use his right hand properly, so we're going to have to go back to the drawing board with that one. So again, you can design a bar that goes on like that, if he was using his left hand properly. But now we're going to have to design it so it slides on instead. The angle of the clips

determines the path of insertion the prosthesis goes in like a partial denture. Trial and error – the patient has to use it first.

49. ***How might you test for the usability of an auricular prosthesis for the patient? How is this different to other facial prostheses?***

Make sure they can get it on. Some of the auricular prosthesis will be from burns patients. And they might only have tiny digits so they might not be able to get a hand around it. If they have a carer, we will always show them how to put in on. There's more to it than whacking it on and away we go. We will always make them having a go at putting it on. We have a guy with really bad Parkinson's and that's an issue. And in this case you'd go for a magnet instead of a bar. Specific patient needs. All these things are custom made. Nothing is off the shelf. With the auricular there is so much more soft tissue movement. Up and down, lateral of the jaw, masticatory movement, you've got the temporalis muscle. With midface is like that too, because you're chasing a moving target. But with orbital, you've only got a smile, there's not much going on. Once it's all settled down, you haven't got a lot. Auricular for usability, it's definitely the more challenging, there are just more aspects you have to put in the bag.

Section 4 – User Requirements and Mechanism Design

50. ***What are the main considerations when finalizing the retention forces of the retention mechanisms? Is there a retention force 'range' that you work within?***

Force – not scientifically no. As I mentioned with the bar and clip, you know they are in unison, if they engage that's fantastic. With magnets, that's a different kettle of fish, you can have magnets and clips that culminate one another. With the clip and bar, that's designed for you. You can put too much force on a prosthesis. Your magnets alter in polarity, whereas your bar and clip, if it's home it's home. You can incorporate more pressure from the prosthesis from your wax up. If you put too much pressure on the wax, your edge will curl. If you overcompensate on your wax, it will have too much pressure on the soft tissue which alters the retention force of the magnet. You can make something fit beautifully but you can introduce more opposing forces on the soft tissue, so the magnets keepers don't fit perfect. That's the beauty of the bar and clip, you can hear it click, once it's there, job done.

51. ***Is passive fit in bar structure designs important to you? How do you ensure there is a high level of passivity?***

Passive fit is paramount. That's got to be your gold standard. You wouldn't buy a car door if the door didn't fit.

52. ***Have you experienced any complications with bar structure mechanisms that do not have appropriate levels of fit?***

Yeah I've experienced that and that can be introduced through faults in the impression, the plaster work, the equipment, there's quite a few factors that can be incorporated into that. Because there are so many stages you have to go through, everyone has encountered that. We've encountered a whole different array of structures when we got the laser welder because it changed how we did it, we had to go down the whole structure again with the multi unit stage has a stud on top of it. It's not just two halves going into one. Again you have to think about your insertion of the bar, if it's a complex orbital one, you scoop out one side of the coping so it slides over the stud. So you're cutting half the surface area away of your coping, you almost incorporate a non passive fit, once its on and screw it down, it looks like its not passive because half the coping is missing. The larger defect, how parallel the implants are, so again there are loads of different aspects you have to take into account and consideration during the design procedures.

53. ***How might you define (or evaluate) an appropriate accuracy of fit for bar structure mechanisms?***

Passiveness.

54. ***How is the mechanism designed to accommodate for cleaning and hygiene?***

Again, having your gold bar high up the coping, you can allow for something to get underneath it. All comes down to manual dexterity, sometimes you get grubby patients, and they're not going to clean it. You can incorporate a certain amount into the design for cleaning. You're limited in your design what you can do with it. If your soft tissue is thickening up, you can have a soft tissue reduction, or change the height of the 2nd stage abutment to make it higher, or even laser weld 2 coping on top of each other. We had a guy who came in 6 ft 3, won't have skin reduction. He's reaching now for a 3rd coping on top. What happens when the soft tissue starts coming up, it starts enveloping the bar like jelly. The soft tissue will grow around it and swallow up the bar. You are limited to the design mechanism to how much you can incorporate the cleaning into it because you want it retentive as well. A lot of them will get a relative to clean it. A lot of them will be able to clean it because they'll have the dexterity, maybe in the shower.

55. ***What effect might surface roughness have on the mechanism? Between the bar and abutments, and between the bar and clips?***

You down want any impurities on the bar and clip. Flick the light cure gel off the bar and clip, it can creep in there. You down want any roughness on the bar at all. For infection, cleanliness and fit of substructure too.

56. ***Are there ever any complications with screw loosening? What might be the cause of this?***

There haven't been many, because you torque the screw. You can't have non-rotational screw. Once its torqued up, it sorts of overstretches the screw. We don't get a lot of screws coming loose but if we do, it's because of sports. We've had bent bars because of a football to the side of the head. It's fairly uncommon.

57. ***Why are bar structures shaped so that there are protruding 'arms' on each side? Is there a specific length and angle the protruding arms should be?***

No. It's all down to individual design. Due to the position of the implants, some designs, you can't put a top bar on, you make a longer bar with the 2 clips at the bottom. So you distribute the force. It's the implants which are taking the force. You just want to distribute the force evenly, that's why we have 3 clips, because we distribute the force. Evenly spread the load.

58. ***What determines the implant positions (xyz planes) and their distance from each other?***

When we plan the implant position, we take a drawing from the other side, with all the landmarks; you want to measure it all up. Scar tissue could determine it. Hemifacial microsomia could determine it. Quality of bone. Most of all it's the quality of bone. Especially the craniofacial and the Hemifacial microsomia cases, nothing is symmetrical. You can plan implant prosthesis, and you go into surgery, the mastoid bone is so airy. In an ideal world you want to go where you planned it but sometimes you have to throw the rulebook away. There are so many factors.

59. ***What are the advantages of using bar structures over magnets in auricular prostheses? Have you experience of using any other devices?***

Retention. If it's poor manual dexterity, you could use magnets, but 9/10 would go bar because it's so much more retentive. The patient psychologically gets more….it's like a comfort thing of hearing it click on. A psychological thing. Magnets will displace before a clip one.

60. ***Why are bar designs rigid? Could this affect the surrounding anatomy in any way?***

Again it's down to retention because with bar and clip that substructure will only fit in 1 position, it will not fit anywhere else. Once the patient knows it's on then it's on, it's rigid, it's on. With something that's flexible, you've almost got more scope for someone to struggle to put something on. You're putting more force on the implant than you want. And with the bar and clip, it only fits in one position and the patient knows that. They are not introducing any excess of forces that shouldn't be there. It's a rule book for them. Sometimes we get a patient who comes back and the substructure is smashed because the have lost patience. 9/10 patients, if you set tem down the road with magnets or bar, they would come back with a bar every time. We've got patients who've had magnets in for years and years. (NAME) uses a lot of magnets. When it all came about, the chosen form was magnets, and now the bar has come along and it's worked, a lot of people were going down the route of the bar. Patients who you've taken off magnets and introduced them to bar, they say 'why haven't I had these years ago?'. Mainly retention.

61. What is the importance of the currently used materials in bar structure mechanisms?

Gold is a non-ferrous metal, you can MRI and CT with a bar on. Even with the magnets on you can CT. There is no scatter if you have secondary CT images. All the materials are compatible and marry up, the titanium and gold components are all compatible.

62. Please rate the importance of the following factors for a bar and clip mechanism for an auricular prosthesis, and expand on your thoughts. (1 Not important →5 Very important)

FACTOR	RATING *(1 Not important →5 Very important)*				
Changeable/custom designs (flexibility)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Adjustability of retention forces	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Accurate fit between male and female components (e.g. bar and clip)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Equal forces distributed on implants	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Stability of ear when fitted	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Biocompatibility of materials	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Height of retention mechanism from tissue	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Mechanism longevity/durability	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Passive fit of components to abutments (e.g. bar to abutment)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Aesthetics of retention mechanism when exposed	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
	It doesn't matter at all really does it?				
Ease of duplication	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Good wear properties of clips and bar interface	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
	Some clips may fracture so yeah it's important				
Many components (Modularity)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Intricate	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Easy to clean	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Rigid design	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Easily attached/detached	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Follows the shape of the ear	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
	Nobody's ears are the same!				
Does not snag on clothes	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Section 5 – Computer Aided Design Processes

63. What is your experience of Computer Aided Design (CAD) in the design process of creating prostheses? Do you currently use any CAD processes in any prosthesis design processes?

The stuff I've seen within bar construction is the sintered stuff and it's been pretty bad. That should change soon. The sintered stuff has to be passive, the stuff I've seen hasn't been great. The sintered stuff is quite fragile like the cranioplasty examples too. I think milling would be better than sintering. With the software, we have software that we're using, it's not really used for implant placement stents. Purely because there are so many of them going through. We tried to do a facial library but that's gone really quiet. The use of computers is on the up, but you still have to manually do the wax up on the patient. The computer isn't going to tell you where all the soft tissue movements are. You can thermojet something in wax but it's hard. The images that it can generate to tell you what it would like is fantastic but you still have to do it manually on the patient. You can cut certain things out with a PC, but a computer generated bar, if that's not passive, it's not going to be able to take an impression, well it could scan, and recreate where the implants are, but predominantly you still have to do the impression. It's a never ending circle. Ask me in 5 years time. At the moment, there is room for improvement definitely.

64. What obstacles may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?

I don't think it's an obstacle but we have to go down that road. It is the future. We have to get on that bus, otherwise we miss it. A lot of people don't want to adopt it because hey are frightened of the unknown. It's changed how we practice and I think there are good things to come.

65. What benefits may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?

Limitless. Computer software generation software will never end. You always want better. But it's a money industry.

66. Is there anything else you think is important to the success of an auricular 'bar and clip' mechanism?

There's not a lot more to put into it. The most important thing with the bar, and can't stress this enough, is it being passive.

Interview Transcript Participant 7 – 09/12/2010

Section 1 – Prosthesis success

1. ***What for you makes a successful auricular prosthesis?***

One that is aesthetically pleasing to both the eye and the patient and has a retention that doesn't impinge on the lifestyle activities of the patient.

2. ***How do you think the retention mechanism affects the overall success of a prosthesis?***

It's very important because that will affect the confidence of the patient as a wearer, in terms of what they feel able to do with the prosthesis. It's very important that the retention is a key element, as is the aesthetics in the overall success rate and satisfaction of the prosthetic wearer.

3. ***What are common reasons a 'bar and clip' mechanism might fail to do its job?***

The only reason the bar and clip system, which is a well tried and tested system would fail would be an inadequate design, i.e the design hasn't taken into account the retention forces that's required from the retention, or it would be lack of adjustment or incorrect technical procedure in construction. Normally it would be very unlikely that you would have retention problems with a bar and clip system, which is far more reliable than any other system in terms of retention.

4. ***How might you diagnose the cause of implant failure? How do you think a prosthesis might affect this? (mention 'compression fitting forces' and 'misfit forces')***

In terms of implant failure, its highly unlikely implant failure would be caused by any retention mechanism. Problems with Implants tend to go into 2 categories. Category number 1 would be the implant failure – which happens sporadically. It can be a failure of osseointegration initially, but that's not necessarily implant failure, that's the failure of osseointegration initially. We can have an implant failure at any time during a patient's lifetime. Even as long as we have had implant failures after 20 years. Generally, most problems with implants are related to soft tissue. It can be that soft tissue could cause a reaction that goes down to the implant, but generally there are 2 categories of complications. One is the implant in or out, and the other is skin complication. ***Does the skin complication cause infection then does it?*** It can cause infection, but it would have to be very severe to cause implant failure.

5. ***How might you overcome the potential of implant failure in the design of prostheses and their retention components?***

I think it's important to mention that patient hygiene is important. It has been mentioned that patients who have magnetic retention for auricular prostheses have less skin problems. And that could be deemed as correct. Some patients find the cleaning regime easier. Doesn't necessarily mean you're going to get less implant failure but you might get more implant failures because the implants are stressed as individuals as opposed to being splinted by a bar. Generally speaking, that shouldn't really be a reason for poor skin condition, that's generally a cleaning issue. Saying that the skin condition improves with magnets just means that it's easier to clean. If the patient pays particular attention with the bar, there same situation should arise.

6. ***Are larger mid-face prostheses more likely to fail than auricular prostheses? Why is this?***

Midface implants are more prone to failure because generally speaking the best success rate is in the mastoid bone, and they're generally shorter implant. There is a difference in the bone between the mid face, between the maxilla and mandible, all the bone around the face is different. Retention in terms of implant failure tends to be better if the implants are in good bone, with maximum bone contact. Mid face we always use intra-oral implants because they always have more bone contact, so the success rate goes up because you use longer implants to a level that is fairly comparable with the mastoid bone, but not quite as good because there are more failures in that area. Sometimes in the nasal region, the bone can be a little bit deficient. Generally you can up the success rate of the implants by using longer fixtures. You have to be very careful when you're comparing mid-face to mastoid because quite often mid-face defects may have bone trimmed away; the patient may have been irradiated. Generally we put implants in before radiation here. It doesn't necessarily follow elsewhere and that would grossly affect the success rates.

You get a much higher success rate if the implants are in before the radiation starts. You can't compare the two. You can't compare post-radiated implant insertion to pre. You're talking about two different things.

Section 2 – The Design Process

7. ***How might you define the levels of accuracy in the design and fabrication process? Do you believe there to be inaccuracies introduced at any point in the process affecting the success?***

All implant in terms of prosthetic planning should be planned by the person who is going to make the prosthesis in conjunction with the surgeon. If we are doing a case where there are no difficulties in terms of receptions to be encountered then in theory, the implants can really go in the place they have been designed to go in by the prosthetist. That responsibility depends on the prosthetist making a template which those implants went as close to the area as required. And that would be the success. The first design stage is identifying where the implants are going to go and make sure the implants go in that place. There may be instances where the bone may not be as good in that area and they may have to move from that place, but that should be the starting point and that could be decided in theatre. ***What about the rest of the design process as you make the mechanism?*** Going back what I just said in terms of the design process, there are numerous methods of designing the implant position and you can take CT scans, you can make bone level templates, all of those have limited amount of success or make a difference but generally it's very rare you cant get the implants in the mastoid bone in the area you want. So I would suggest that CT in every case would not be necessary.

8. ***What are the benefits of multiple part assemblies? (Abutments, spacers, caps, bars) Is 'modularity' important to you?***

The design stage moves. Once you've got the implants in situ and you've put the abutments on. The length, depth and height of the abutments are quite important. And that would depend on the skin thinning in the surgical procedure. That needs to be observed, if that procedure isn't adequately done, then you can immediately do something straight away, in terms of the skin will be too close to the top of the abutment. So before you move to that stage, you need to make your soft tissue is done. Important factor number 1 is getting the implants in the right place, Factor number 2 is getting the skin adequate around the abutment and then we move to bar and retention design after that. ***How do you think having different components/multiple part assemblies would affect that stage?*** Well in terms of that stage we haven't really got that much in terms of multiple assemblies, we have various heights of abutments. In theory you should be able to do every single auricular prosthesis with a 4mm high abutment, it's just that simple. If you have to use one higher, that means your skin is thicker, then you have to ask yourself why your skin is thicker. It can thicken over time in terms of patients who have had prostheses for a long time, it can thicken, and that's a perfectly natural process. It may require putting longer abutment on at some stage, but you should be looking at getting the skin thin enough to use a 4mm abutment. ***Have you ever had to add collars on top on of collars before?*** No, generally we are more likely to put a longer abutment on, this is more sufficient, the longest you can get is about 7mm. Rather than trying to build up the collars, You actually want to move the abutment away from the skin, not necessarily the collar.

9. ***Do you apply any design techniques that are personal to you? Any quirky techniques/habits that others may use or may not know of?***

In terms of design, with the bar structures, you have lots of different options in terms of how you design the bar around the abutments which you don't have if you use magnetic retention or ball jointed retention, of which I never tend to use on an auricular prosthesis, I'm not that keen. Although there maybe a case for magnet retention on patients that have a very sedentary lifestyle. They might find it easier to apply the prosthesis. Apart from that it would always be bar and clip. In terms of what you can do, you can put the bar at the front of the collar, at the side of the collar, between the collars, to enable you to move the retention area or the bar or the disguise the bar under the prosthesis in a more favourable way, Dependant on the implant position. If you've got an implant that is too high, it's maybe that you don't include an upper arm from the abutment, or a small child, you may exclude it.

10. ***What process do you follow for the duplication of a bar and clip prosthesis? Does this have its advantages or any complications?***

We tend to always make 2 prostheses for a patient, so the patient will go away with 2 prostheses. If I have a problem with the prosthesis, if there's any major issues, normally but not exclusively, it's related to the clips within the prosthetic component. So you have a spare prosthesis and if you needed to repair or make another one then you would take the bar off and you would put that into your mould. For long standing patients, we would have a second one, so we would run with being fitted with 2 prostheses. Another bar made, that would enable us to have 2 more prostheses made when they are due to be sapped over. Or we do it in one visit. Otherwise it's very difficult to make another. It's very difficult to completely duplicate the bar. It's probably technically possible now with different scanning things etc, but in theory if you have a long standing patient and they're going to have a prosthesis for the rest of their life, having a second bar is not really that much of an expensive option, and minimises clinical work time…dramatically.

11. ***Is there any part of the process you feel particularly frustrated about conducting?***

Only the difficulty in duplicating a bar exactly. That's a little bit difficult. And that's kind of an issue I suppose, which is why I mentioned having 2 bars. If you've got a very complex mid face one, it's actually very difficult.

12. ***Have there been any recent developments in the design or fabrication process that you are particularly aware of?***

There are lots of uses of digital technology in terms of everything from CT planning to depth of bone, to digital scanning of auricular, say left side to reproduce a right side, there are lots of uses of digital technology in that area, and that is useful but basically doesn't really take us any further. It just gives us different ways of doing certain things. You can actually, if you're not careful you can swap laboratory bench-time to computer time, which causes not quite as beneficial as it seems. It's just doing things in a different way.

Section 3 – Checking Procedures

13. ***How would you normally check the retention mechanisms so that they can be passed as clinically acceptable? (When would this usually be?)***

That would be done, by experience in clinic. It maybe on the first fitting of a prosthesis, it may well be that the retention clips are not fully maximized in terms of their retentive qualities until a week or so later, when we assure that the patient can fit the prosthesis in an adequate way, and then we may modify and tighten the clips. We would review them in a week. Any problems with a prosthesis are going to occur virtually instantly, in terms of taking it off and putting it on. If they can't do that quickly then there will be a problem. It doesn't happen very often I have to say but you need get them back straight away, otherwise it could damage the prosthesis, which is why sometimes I don't fully tighten them. I make it retentive but not retentive enough to say go diving off a swimming pool, first time round, but second time round though.

14. ***Do you perform any 'technical' checking procedures? (When would this usually be?)***

Technical procedures on review, I would check with a torque driver the abutments. I would check the skin condition. I would check the level of retention between the bar and clips. ***What would you usually do there?*** Between the bar and the clips, that would be based on experience and feedback from the patients. Based on what the patient's activities are. A patient with a very sedate lifestyle, you don't need massive retention but if someone was say in their 20s doing a lot of activities, water parks and that sort of thing, then yes you would have to make sure it was very tight.

15. ***Are there any established standards or testing methods for the evaluation of the 'performance' of retention devices?***

The established pattern would be from the patient themselves, because they are in a far better position to actually communicate any retentive problems than we are, living with a prosthesis on a day to day basis. So I would always listen to what the patient said, what they were doing with a prosthesis, whether they were having any problems, how often you need to see them to adjust it, that sort of thing. If the patient has 2 prostheses then in theory they can post 1 back. That can be adjusted without the patient. Which is quite important because if you have patients living a long way away, which we have.

16. ***How might you test for the usability of an auricular prosthesis for the patient? How is this different to other facial prostheses?***

The usability of a prosthesis will depend on the patient, their ability to take it off and put it on, that really should be worked out before the patient is considered for an implant retained prosthesis. That would affect the design process. If the patient has an arm missing, we would have lots of soldiers with multiple limb loss, so we would have to think very carefully, about how that is going to be applied, about how they are going to look after that. It doesn't mean that they would be excluded from that process, but we would have to work that out. It may well be in some cases, somebody with very bad arthritis, and it may well be in those patients which are generally quite as active but not exclusively, then we may think of a different form of retention, but only based on that criteria, in terms of their day to day use of prostheses.

Section 4 – User Requirements and Mechanism Design

17. ***What are the main considerations when finalizing the retention forces of the retention mechanisms? Is there a retention force 'range' that you work within?***

Not really, to be perfectly truthful, in terms of bar and clips, no. It is totally dependant on the adjustment of the clips. Hopefully the bar hasn't been over polished, because you can reduce the bar obviously, or grind the bar. So, in theory if you do a lot of work on the bar then you might need to adjust the clips to take into account the condition of the bar metal as it's been polished. Generally speaking you would adjust the clips in such a way that it would give adequate retention. You can tell that by taking it off and on. That's based on patient feedback.

18. ***Is passive fit in bar structure designs important to you? How do you ensure there is a high level of passivity?***

In theory a bar that's fitted between abutment should always be passive otherwise you are using the bar as a orthodontic appliance, and you can actually move the implants, and might even give some individual pain, if the implants are under tension, That can happen. If you take accurate impressions of the copings and highly sophisticated, modern impression tools, that's unlikely to be an issue and is rarely an issue. I can't say it's never happened but it is fairly unlikely.

19. ***Have you experienced any complications with bar structure mechanisms that do not have appropriate levels of fit?***

If they didn't have great fit, then you'd have to go back and retake the impression and re-do it, or re-section the bar and re-solder it, if it's under tension. You would know as soon as you'd try and put it on, if it's not down properly, then you need to re-look at your technique for impressions. It can be much more complicated on complicated mid-face structures, very rarely is it a problem on flat mastoid bone.

20. ***How might you define (or evaluate) an appropriate accuracy of fit for bar structure mechanisms?***

Only by visually looking. We don't really do any other method. Simply by visually looking, you can feel as screw the bar down. There isn't really any sophisticated method of doing that. In terms of 'do we need to do that?' The answer is probably - the more problems you have, the more you need to evaluate things. If you have very rare problems then there isn't anything that's done that's doing the patients any problems, there's not much point in following it up. On an individual patient, if they have continual pain, then obviously you would check much more carefully. You can get sporadic or undefined pain from implants for no apparent reason but very rare would you have it.

21. ***How is the mechanism designed to accommodate for cleaning and hygiene?***

It would depend on the ability to get underneath the bar. If the skin is thickening and it becomes very close the bar then obviously then you have an inability to clean underneath the bar or it becomes more difficult. You have to be aware of that. If that's the case, you may have to modify, to actually thin the skin, if it's a problem, or raise the bar away from the skin so you could clean under it. Different patient have different skin problems and some patients will have continual rumbling shall we say, not necessarily serious skin problems but they will have sporadic skin episodes from time to time. Other patients will have no problem with any skin whatsoever, even if they wear the prosthesis 24/7. It's quite case

dependant, not even cleaning dependant as we originally first though, some patients just have more problems with skin than others, its just that simple.

22. ***What effect might surface roughness have on the mechanism? Between the bar and abutments, and between the bar and clips?***

Surface roughness will mean that it's more difficult to clean and that will obviously mean that part of the prosthesis or structure will be more difficult to clean.

23. ***Are there ever any complications with screw loosening? What might be the cause of this?***

Very rare. Can't think there is any screw loosening problems on a bar prosthesis. I can't think that has ever been a problem. I suspect if it has, that would because the screw hasn't been torqued down properly. It's happened to magnets in orbits. I've seen that before. That's presumably how the patient cleans around it and by loosening it, cotton buds and things. But screws…no.

24. ***Why are bar structures shaped so that there are protruding 'arms' on each side? Is there a specific length and angle the protruding arms should be?***

Yes. The bar design is dependant...if you had a completely straight bar with one clip on it, you could properly get sufficient retention to hold that prosthesis on. What you wouldn't get, is anti rotational resistance. That's what you have the arms for. Not necessarily increase the retention, but to reduce the rotation. That's why. If you have no arm on top, if it's a very small ear, or the implant's high, you have an arm on the bottom, which has a sufficient length to get a clip on, that in theory would be enough to stop the rotation. If you had a very long straight bar, not suggesting you design it this way, you have a very long span between 2 implants and you make the bar in a V shape that would be sufficient for retention with no rotation, you wouldn't need arms at all. The reason you have the arms is to help with the rotation and also to hide that area underneath the thickest part of the prosthesis. In terms of length of the arms, you need to get one clip on it. Unless it's a very big prosthesis, which I suspect would only be in some kind of school based surgery, where you've actually removed the mastoid bone and your implants are in a completely different place. Then sometimes then you may need to put a slightly longer arm on. In a straight forward auricular congenital case, as long as you can get 1 clip on, then that's enough. And actually it makes it neater; you don't really want long arms.

25. ***What determines the implant positions (xyz planes) and their distance from each other?***

To disguise them in the thickest part of the prosthesis. That's the whole key to where the implants go. If they're not in the widest part, the deepest part of the prosthesis – taking the meatus as your centre point, you have 10 past 5 and 10 to 7, depending on which side, that's where you want the implants to be, about 18-20mm from the meatus. Using a clock as your guide, at 10 past 5 and 10 to 7. On a congenital case, you quite often haven't got a meatus, so you have to mark that yourself in your planning. Generally speaking that would be the case. Too far back and you have to put a step in the prosthesis, to far forward and you're into your carving, so it quite crucial.

26. ***What are the advantages of using bar structures over magnets in auricular prostheses? Have you experience of using any other devices?***

It can have a low profile if needed, by that I mean height. It can be adapted to be very flexible in planning a retentive structure. The retention can be at a distance from the implant, so it can be designed into an extended defect. The bar can be behind or in front or between implant abutment collars, so carving the prosthesis is not compromised by the bulk of bar. Retention using bar structures are very resistant to dislodging forces. This system offers adjustable retention too….being manual does not require other components or change of components. The disadvantages are as follows. Bar structures can be more difficult to replace or remake prostheses without the original bar. There are more technical processes used to make them than magnetic systems, for example soldering, welding, and polishing. And this also means there is additional metalwork on the patient. And lastly a disadvantage over magnets is cleaning around abutments gives more restricted access.

27. ***Why are bar designs rigid? Could this affect the surrounding anatomy in any way?***

No. Only if it's across a suture line, which wouldn't happen in a mastoid. If you had a bar in a growing orbit then you would have to be a bit more careful. Probably wouldn't make any difference in terms of that, as bone is pretty elastic and it may grow around the implant but you may inhibit the growth so you would have to watch that. ***So why are they rigid?*** They're rigid because you can get firm retention and location. If they were not so rigid, you would probably have more difficulty actually locating the clips on, it's a friction clip, so if your bar moves as you try to put the clip over it, it would make it very difficult to work.

28. What is the importance of the currently used materials in bar structure mechanisms?

The materials used are generally speaking, are easy to keep clean, and are easy to solder or weld. That's the main criteria. They don't have to be particularly strong because they're in quite small tensions but they have their ideal properties for what we use them at the moment. Not to say we can't look at others, other materials, because obviously we do. Gold, it's malleable, it's easy to keep clean, it's easy to polish, All of those things are important.

29. Please rate the importance of the following factors for a bar and clip mechanism for an auricular prosthesis, and expand on your thoughts. (1 Not important →5 Very important)

FACTOR	RATING *(1 Not important →5 Very important)*
Changeable/custom designs (flexibility)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Adjustability of retention forces	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Accurate fit between male and female components (e.g. bar and clip)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Equal forces distributed on implants	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Stability of ear when fitted	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Biocompatibility of materials	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Height of retention mechanism from tissue	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Mechanism longevity/durability	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Passive fit of components to abutments (e.g. bar to abutment)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Aesthetics of retention mechanism when exposed	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Ease of duplication	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Good wear properties of clips and bar interface	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Many components (Modularity)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Intricate	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Unobtrusive is a better word for that I think. Intricate almost sound like 'tiny'. So I can't really answer that.
Easy to clean	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
Rigid design	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 4 in relation to the bar and clip but if we're talking magnets then you probably couldn't say that. Because you could have the magnets floating in the silicone, so instead of having a rigid base, you could have a floppy base that would drop on. It would still be held within the silicone but it wouldn't be rigid.
Easily attached/detached	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Well that's what you don't want isn't it? If it's easy to detach then that means it comes off easy so that's kind of a strange question really. You want it able to be located by the patient but you don't want it to come off in a straight forward way. So that's almost contradictory, you want it to go on in one position only and not come off in any other position. So you want it to locate but you don't want it to easily come off. Which is different. So just saying it's easy to put on and off means it just drops off. You need a sort of twisting action to take it off. Easy to locate, but not necessarily easy to move unless desired to move. That's the whole purpose of it isn't it. You want it to locate in only one format and only one way, so it lines up correctly but you absolutely don't want it to come off. It's got to be usable. You want it to come off in a set pattern, in a certain movement. It should take no more than a second to take off, but you can't knock it and it comes off. We're trying to avoid it coming off easily. You've got those two things…
Follows the shape of the ear	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ The bar and clip design is dependent on the shape of the prosthesis that is going to fit over it. That's the whole key of it isn't it. The position of the implant, the design of the retentive structure is key to what it looks like, so it's really important.
Does not snag on clothes	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Well the prosthesis - that almost needs to say not easily dislodged, with whatever you're doing. Needs to be re-worded I'd say.

Section 5 – Computer Aided Design Processes

30. ***What is your experience of Computer Aided Design (CAD) in the design process of creating prostheses? Do you currently use any CAD processes in any prosthesis design processes?***

Yes. We have access to all the new technology in terms of digital technology. We have our own rapid prototyping machine; we're going to get our own laser scanner. We have 3D imaging, we have CT stuff. All of which is very interesting at the moment. With the exception of planning, and a couple of occasional cases, doesn't enable us to do anything we couldn't previously do in the subject that we're talking about now.

31. ***What obstacles may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

Cost. Cost effectiveness. Time. Cost per case. We do use digital technology, but has it made the process easier, more efficient and cheaper at this moment in time…no. But in the future I have no doubt it will.

32. ***What benefits may there be for prosthetists to adopt CAD technologies as part of their current process of creating prostheses?***

I think it's an evolutionary process, which means we'll be eventually for the first time be moving away from traditional craft based skills, to having modular, ready made components which will be used as opposed to being made from scratch. That will be the biggest stage, which we would be able to cut out some stages at some stage with modular parts. We'll still have to fit them, we'll still have to have some artistic licence to finish them off, but some of the processes will be taken out, or done in a different way. That's what I'm hoping to do with digital technology, take out some stages to make it faster and stronger, at this moment in time we're not quite there.

33. ***Is there anything else you think is important to the success of an auricular 'bar and clip' mechanism?***

Yes. I would like to see it less intrusive I suppose. I would quite like to see a retention system that didn't rely on skin penetration components. Whether that's possible or feasible in the future is a possibility. I mean no implants. I mean magnets under the skin, or improved surgery. I mean prosthetics is only one method in reconstructive body parts and I would like to see other methods used along side it.

Appendix III: Observational study transcripts

Observational Study Notes/Transcript - Pilot

Impression taking stages

1. Tighten abutments on model
2. Out impression coping squares on
3. No release agent on this model because it is an SLA, on skin they use a releasing agent.
4. Apply impression material: first M517 Soft from Coform Principality. Don't need too much, just to cover where the ear would be.
5. Apply the second impression material on top. This is a bite registration (dental) silicone.
6. Feel it after a few minutes – normally gets a bit warm. Subjectively feel when it's ready by tapping on top. Doesn't think the heating of the silicone whilst curing affects anything.
7. When the impression material has set, undo the guide pins (which are in the impression copings) and when you hear the click, it's undone – slightly fiddly.
8. Take the impression off the 'skin' /model, by checking that the impression copings are engaged with the harder silicone. This is important.

Advantages
- Quick
- Easy for patient, they are sitting upright in a chair
- The material is stable for long periods, don't have to pour it up straight away

Disadvantages
- Slightly flexible material
- Difficult to tell how accurate it is, they rely on the accuracy of it but don't really not how accurate.
- Doesn't expect it to be as accurate as plaster because of the flexibility…

Locating abutments
1. Take to the plaster casting room.
2. Apply de-bubbliser on the impression – this reduces the surface tension of the silicone
3. Mix some plaster
4. Silicones are designed to hold their shape, the effect of the plaster heating whilst curing shouldn't effect the distortion of the silicone.
5. Put a blob of plaster on the table, and lay the impression on top, press lightly to ensure that the impression is sitting snugly to the plaster.
6. Clean the edges of the plaster shape and let it set.

Design and creation of the bar structure - (including checking procedures)

- Take our wax ear and then we'd put it on the patient and then what we would do is match up so that you're looking at symmetry. Hold that up to the patient, looking at the other ear if there is one and making sure that you position the ear, especially looking at the lobe and the top of the helix, putting it in the correct position. If you've got a tragus on the model, as a flat surface, it's more difficult to position , then we would take some measurements form the tragus to the nose. Sometimes takes 2 people, one to hold, one to look. If the tragus is there, it's pretty much set, and you can't change that.
- Then you look to design the bar. Pencil it onto the plaster. Have the impression we've taken, look at it on the patient and say right, have a straight piece inbetween. If for instance the implants are further back, you might put the bar in front, or vice versa, best to put it down centrally, because any stress goes down the centre of the implant. Reduces the rotational forces. The middle one is going to be fairly set.
- You want the angles to be fairly acute. The greater that angle, the less chance you going to get of rotation. If you design your bar straight, there's a chance you're going to get some rotation around that.
- There are various designs. Often we don't put a top piece on, often in children where the implant comes up here. Where the ear is smaller, you don't tend to put a top piece on. You can even

make a little T piece in the middle and that would stop the rotation. There are many ways you can do it.

- Looking at three angles, that follows the contour of the ear. You want to be able to get a clip on there, so make it long enough for a clip. There were some arguments by Wolfaart where you should always place the clip as close as possible to the cap. Why have a long bar you know? If you put them at the end of the arms you will get more torque I suppose. What's happened is that we've seen a large success rate – 99%. We don't lose a lot. The success rate of the implants in the mastoids is high.
- Wherever you put the clips, you're still pulling against the length of the implant.
- Put the gold caps on. We've designed our bar. Putting the clay under where the bar is meant to sit. (Plastemene) This is firmer clay – it will hold in place when you laser weld it. You're only going to tack it. There is various ways of doing this. Some people like to do it with acrylic pattern resin and then solder it. This is what we find is the quickest way and probably the most accurate. Start on the side arms, then do the middle piece. Some people cut the gold bar with a cutting disc, but I tend to use cutters. Lightly slots in. You should really do the middle one first. It's fiddly but not really tricky. It's not complicated.
- Just going to take the end off it with a burr.
- So going to laser weld that now. (Just to tack the arms onto the caps)
- How do you know when the thing is attached? You can see the metal.
- Sandblasting. Doesn't give too much texture, the solder will go over that anyway.
- Gold soldering. Put on the solution (flux and anti flux) to help the solder flow and also to detract the solder from the edges of the caps. Helps with the oxides on the gold.
- It's quite easy to get solder into the screw holes if you don't have anti-flux in there.
- The solder just drips over, not really applying very much. Heat it up first, then just pop the solder over it, then the flux helps the solder flow.
- You don't not want a huge amount of solder on there, there aren't huge forces on the bars.
- The gold shouldn't distort because we laser weld it as well.
- Put it back on the model, check if it is passive. You tighten that one down, check the gap to see if there is any movement. You test both of them, if there is any issues with it not being passive, then it will bounce. What do you do if it we do find it isn't passive and bouncing, then we you re-do the bar. What we would do is cut it and solder it. What you can also do is tighten both screws, then you warm it with the flame and that passifies the whole thing. That's a bit risky but you can do that. Using the heat to let it find its own level. What you can get is the plaster exploding or the screws welding themselves in. Of course that doesn't mean that it's accurate, it's accurate on the model. But then you have to try it on the patient to really know. At this stage you try it on the model, then we go and polish it up, then once it's polished up then you try it on the patient. Unless you have doubts at this stage, then you try it on the patient. You probably only really check it at one stage.
- Then we go and burr it up.
- It's not really about changing dimensions of the bar – because they're set. You don't really want to take too away. It's quite a labour intensive process.
- I use the burr to round off the end of the bar. The polishing is mainly for the rest of it. We avoid the underside of the caps. What some people do is screw a pair of replica abutment in the end of the caps to act like a stopper to protect the underside of the bar.
- Depending on the burr you use it's not really going take off a lot of material. But really depends on the burr. The better polishing we do, the more high value it is to the patient. Looking for a satin finish. Getting rid of any discolouring.
- Then we polish it (wax wheel), pumice wash and blow and dry.
- Then we try it on the (patient) model. 2nd stage check? Would do the 1 screw test on the patient too. It could be passive on your model but if your impression isn't right then it won't be passive on the patient.
- Evaluation of fit - perfectly passive, but with a tiny gap, checks with a microscope. He gets touchy if there is a gap there.
- When you use gold, (used 2nd hand gold here) it's un-dented and comes out a bit fresher.

Alignment of the clips and creation of the substructure

- Try the bar on the patient; if it's ok, you put it back on the model, then that's when you make the substructure.
- Position clips on bar (x3).

- Bunsen burner on. Put a bit of wax on the surface of the plaster model so that the substructure is off the tissue, just to make sure it is not touching.
- Put more wax, blocking out the undercuts. Need to make sure you wax out around the clips so they can expand, a common mistake is not waxing out around the clips and then they can't open up!
- The substructure is designed like a trough rather than a flat so that it feeds in to the bar, to make it easier for the patient to locate it. You also cover the screws up so you don't get any acrylic in there.
- A bit of gel – more liquid than the sheet acrylic but it bonds around tightly. Gets in the gaps. The sheet were going to use is light cure. Easily mouldable. Moulds around the wax then trimmed. Cures with light.
- Trim it with a burr, tidy it all up.
- Wash it with pumice, and wash over.
- You make sure there are no bits in the clips (no light cure etc). Scrape it out. Make sure it clips down properly and make sure it's not touching anywhere (the tissue). Try it on the patient.
- What we might do is paint it grey and then scan it. Put the scan into a digital model, print a wax ear using a CAD file.

Observational Study Transcript, Participant 1 – 25/01/2011

(No patient - Used replica model)

Stage 1: Impression taking and locating abutments

Making a light cure bandage…some people use dental floss. Basically you just squirt a bit of gel onto the bandage. There's no getting around the stickiness. This is what holds the analogues together. You do a figure of eight for stability really. You don't want it down on the skin but you want to get underneath it. Horrible stuff this. If you were to leave it out it would cure, that's why everything is in black, the top and the packet etc. As long as it's kept in the box it's ok, it'll last. Reinforce this with a bit more gel. (Puts it in under light cure machine with light guard). All ready – it just takes 10-20 seconds. It's very intense light, you don't want to look into it really.

(Starts putting on silicone impression material) I tend to use the harder silicone on first, because there's no real undercut here so it'll come off fine. It still picks up all the same detail. I do quite a wide impression so that if you're going to do a wax up, you've got a base. They are dental impression materials, that's what they were for originally. So I put the cotton buds in the impression too for added stability. It's 2 part silicone and it mixes it together, then 1 part acts as the catalyst. On the patient I would probably put Aquagel on them first, which is just a water based gel to stop it sticking to the hair. Might be slightly quicker on the patient to set because of the heat from the patient. I would just give it 5 minutes or so now to set, you can tell when it's set because it just feels rubbery. It's always going to be set against the skin first, so if the outer part is set then the rest is going to be set. I don't pull them out completely (the guide pins). So you can see it's picked up all the detail, there are few air-holes but that's ok because as long as it's stable.

So now to make the plaster model. I know Pete tethers the lab analogues together but I don't do that. Gloves on. For our models I always use CrystaCal. Some people like a bit of plaster too to give it extra body. I don't like mine too runny. If it's runny it's weaker as well. You just mix it until it looks and feels right. There is a set ratio for mixing they recommend because it can expand, especially in dental applications. But we always get accurate results with the ratio that we choose from experience. Make sure all the surface is covered. If you just plopped it into the plaster you might get air bubbles so I spread it on and shake it first to make sure the whole surface is covered. Just make sure the impression covers everything you want. If you play with plaster too much it can end up flat, so it's important that you don't touch it much. Plaster heats up, but CrystaCal heats up less because it's a stone. You use it as a backing. You never use it as a direct material to a patient. Plaster can suck moisture out of things as well. It's usually silicone or alginate on a patient, and then using plaster or CrystaCal as a backing material to make models. Then you cut out the excess. Then you just leave it to set for 15-20 minutes.

Stage 2: Designing and making the bar

You get some collars, put them on the model. What we'd do is have a template. That was drawn from the good ear and would be drawn on the side on the patient. That's the ideal placing for the implants in red dots on the (plastic, transparent) template. If we've got the actual position of the implants are a bit off so you can see it's not the ideal but not a million miles off. You can't accurately orientate the ear. You can mark where the meatus is, and the implants. So the implants should be in the deepest part of the ear. Your model is pretty much the ideal really. So the pieces of bar should go at these angles (positioning them on the SLA ear), following the shape of the ear. So we'd take the impression of the bad side before the implants are in. And then after the implants are in obviously. So we've got our 14 carat gold, and you want good contact between the bar and the collars, so I would grind the bar a bit. So I tend to grind it on an angle too. To match the angle of the collar where it will sit (the angle of the bar basically). You want to bring it quite low down on the collar but not too low because you'd be in danger damaging the bottom of the collar. The middle piece is always the most difficult. I normally cut it too long and then grind it down to size. It's easier to hold it with the pliers than with your fingers sometimes, it's a bit fiddly with your fingers. So just doing little by little grinding it down. It gets hot though. So you just want it to snugly slot in. Some people just bend one piece of bar around. But then you use a lot more material, it's bulkier, you'd imagine you've got gold sticking out the back. Sometimes if the implants are too far forward, you could do it because then it enables you to move the bar back a few millimetres. Then again I'd still probably used 3 pieces and just weld them further back. The better contact you get initially (before welding), the better it is. If you have to add more solder because you have gaps, then that's a weak point.

So I would do the arms first here. (Start tacking the bar onto the collars now.) So you make sure the collars are tight. So I completely finish one weld before moving onto the next. So I'll completely smooth it off straight away. I don't to worry about going around sequentially on these ones (the arms), because it sort of doesn't matter much if they're a bit out. But you really have to be careful on the last ones joining them together. I still do it anyway because it gets you in the habit of doing it sequentially. So then you can use the gold wire (solder) for filling around then. You have to be careful you don't weld the screws to the copings! And keep your fingers out of the way of the laser! So you can see you've got gold all the way around, and then smooth it off by increasing the focus, and so the power is less intense because it's over a wider area. So I have the focus as wide as possible when I want to smooth the weld off. I can never remember my setting though! With this setting I can blast it as much as I want because it's not powerful, but it might change the angulation of the bar slightly, but you can blast it back on the other side. Even without pumice and polish it's finishes pretty smooth. That's the first one. It doesn't take that long to do but you've got to spend some time getting it right. So with this weld it's tacked it at completely the wrong angle, the power was probably too high. So let's do it again. You sort of want all your pieces of bar at the same level otherwise they might not engage at the same time properly. Once it's securely tacked you can take it off the model and do the rest, and get underneath it. You can't get underneath it if it's on the model. So then you tack it all the way around. The least amount of solder on the better, you don't want it bulky. The P number on the laser welder is set at infinity so when you put your foot on the pedal it will pulse the laser. It saves you having to pump your foot. If you put too much solder on, it takes more to flatten it down. That arm might be a bit too far down but it's fine. Now we just need to do the middle one. So when you attach it to the first one it's not too bad but when you attach it to the second one (collar) you have to be careful. I've tacked that once at the top and because it's difficult to get in there, I'm going to take it off the model to continue the welding. So you can see that's got loads of contact between the bar and collar. That's the sort of contact you want, you don't want gaps between the bar and the collar. So that's that one done and now we have to link them together. This is where you really have to do the opposing welds. So you're always go to the opposite sides to weld. I go around and I do 8 spots there. If it doesn't need any solder I'll still do a spot there, just to make sure. I've got enough solder on there, now we just need to smooth it off. Quick polish now and burr the ends of the bar. What I do is put abutment replicas on to protect the fitting edge of the collars when you're grinding or polishing. Especially if you slip and go onto the fitting edge. Pumice, Polish, Wash, Steam.

Stage 3: Alignment of the clips and creation of the base-plate

You want to make sure all your clips are pointing in the same plane. If you had one pointing wrongly, you wouldn't be able to locate it properly. You only need a very thin layer of wax around the collar. And then thicker around the bar. Go half way up the clips with the wax, because you need a space around the clips to be able to tighten or loosen the clips. Put some wax in the holes of the collars too. So you want to cover the bar even if it's just a thin layer so it's not going to have any contact with the acrylic so there will be no stress put in the bar. So you only want the clips exposed. You don't want a massively thick layer of wax (on top of the bar between the clips). Then you can just square it all off to make it neat. I have the shape of the cavity square, so as long as you can fit a tool in there to adjust the clips. Blow torch it a bit just to smooth it off.

So put a bit of light cure gel around the clips first, there are tiny holes in those bits on the clips, you get the light cure gel through those holes to secure the bond. Then get a bit of light cure sheet. Feels horrible this stuff. I try and get it where I want it to finish then you won't have to trim it at all then. So put that in the light cure machine and that's done. I'll just trim the edges. You can take the stickiness of the light cure off with acetone. I'll just buff the other side, and it can always be trimmed down more if you need to when you come to fit it on the patient. That's it. One base.

Observational Study Transcript, Participant 2 – 25/01/2011

(No patient - Used replica model)

Stage 1: Impression taking and locating abutments

There's the patient's skull prepared with the impression copings. It's a slightly different system to the one we use but it's pretty much the same, just different components. The principals are the same across the board. So I'm going to put on an impression material, Epiform Flex first and then back it with Epiform solid and that will give me a solid based impression. And because I need to leave the screw holes free, I can work the impression materials around to keep the holes free. I'm using a spatula here today to spread the materials. So this is using the Branemark system today. We're thinking of transferring to this system because we were really struggling to get hold of the components with the Straumann.

You want a good wide base so you get the whole area. We have done this in Alginate before but it's not so strong so you have to back it. This (silicone) is a really nice soft material and you can move it around after you've put it down to make sure you get all the detail you want. It moulds to the head nicely. Nice thing is as well it releases from the tissue quite well. So I wait for the soft silicone to set first before backing it with the much firmer material. If this was on a patient I would use a bit more material, maybe a cm more around the side. You can get some sort of clips that clip onto the implant and cover it with little nodules but these are the screw in copings are really accurate, even for intra-oral, they give you much greater accuracy because you know they lock in tight. So for when a patient comes in it would set a bit quicker because of the heat from the head. This one seems a bit cold so might take a bit longer.
So you can look at that (the other ear), at say I know the size and where it should sort of be. This impression material is great because it's soft and moves well but when it sets, it sets really hard. Some people would break up some tongue depressors and put them in there as well for extra stability. But this hard material gives you a firm base anyway. I need those screw holes open so I can unscrew it. We use the flex for a lot of applications, I brought it back to here after I'd worked at (NAME). You can use CroForm, which is good for a particularly hairy patient, because it doesn't take the hair off.
So if you feel that now, that's much firmer. Now you unscrew your pins. And you gently ease it off the patient's head. It's got a few little marks on it but you can take them off with a scalpel. That's a real definitive fit actually, they're really good. So now get that poured up in plaster.
So you unscrew that, quite a neat little system this. Good little screws! Get a scalpel now. Wow, look at that detail on the impression, you could pick up a fingerprint! Just going to trim the model up now, there's not really enough on the anterior but it's enough to make an ear anyway.

During the visual check
I'm just wondering if the abutment replica has moved there. That doesn't look as if it's as high as the other one. I'm checking on the accuracy here. I wouldn't be able to tell though until I've made the bar! The abutments are different heights but in the impression they are the same. I wonder if one wasn't seated down quite right. Or I haven't got one of the guide pins screwed in properly. Yep, that's definitely lower… So I'm going to make a gold bar now that's might not even fit. I should start again on the model really. Not happy with that. I'm going to re-make the plaster model, otherwise it's pointless. So one of the pins wasn't quite tucked in somehow. I wonder if we got deceived by the plaster. So unfortunately if it doesn't fit, you might not realise until you come to fitting the gold bar. I think the abutment replica wasn't completely seated all the way down.

Stage 2: Designing and making the bar

Happy with our working model now. And now we'll construct the gold bar. You wouldn't usually recycle gold caps for different patients, but you might do it for the same patient. You know, it's not really on using the same pieces for different patients. Get some gold bar, recycle some if you need to. But make sure it is sterilized and cleaned.
So I'm just going to tidy up the edge, watch your eyes! I would put it on, between the copings, mark where I need to cut it and then it might be a bit big but we can work that back. Everyone has their own technique, but gold can get hot. So it doesn't force its way in but it's sort of friction grip fitted and then it'll mean laser welding it will be a lot easier. What I'll do is tack it on each end, then take it off and weld it free hand. Burring it now. It's a bit more brutal with the burr but it gets you there a bit quicker. It's really close now. Sometimes you get a little burry edge, but I want to get it as parallel as I can. I just want to spend the time to get the job right. What you're looking for is it to slot in nicely to position. Now I'm going to weld that. So I've got the argon gas on, (NAME) made a little adaptation with the tube so you

can get the argon gas right in there, so you can eliminate any contamination. I'm just trying to get the settings right, as I've been doing other things with the machine. I need to turn it up a bit as I didn't quite have enough power on to tack. So that's just tacked together. So I'm going to add the other 2 pieces and then I'll give it another little tacking then hold it in my hand then go around and weld around it. So I'm just rounding the bar slightly inward so it fits onto the copings nicely. Oh dear, I just caught the bar there slightly which is a bit of a bummer. The arm is a bit long but then I'll ease it back. Then I'll get another bit for the bottom sorted out now. Basically it's (the bar) big enough to get a clip on and all 3 bar pieces are about the same size so they don't have a big cantilever effect. Watch out for your fingers, it could take about 4-5 months to heal up because it'll go all the way through. So before welding it, I check it on the model to see if it's all good. That looks fine, the lower arm could've been a little longer from a perfectionist's point of view. Ok so then I move onto welding the whole thing. Now that that's been welded, it just needs rubbing up now. And tidy it up.
So I've just trimmed it back and now I'm polishing it up the bar. Some people use gloves but I find that dangerous. I'm trying to make it look as nice as I can. If these were made in titanium, they might not wear as quickly as the gold bar. So now I just clean it up with a bit of washing up liquid, and wax it up. That on arm is slightly pointed upward but should be ok. It might be a bit too angular and it might interfere with the ear a bit but hey it should be ok.

Stage 3: Alignment of the clips and creation of the base-plate

Get some gold clips and put them in the right place. Get some wax. I'm already critically analysing this as I'm making it. Bunsen burner on. So when that bit is over the top there will be a space. To be honest, I would probably cut off that arm that is rising up too much and do it again. I think it could probably lean down a bit. Anyway we'll make do. I'll get a good bit of wax on it. Some people might put a block of wax under here just to save a bit of time. There's a big gap under that arm, I'm not happy with that, might cause me problems. I'll need a big dollop of wax under there. In terms of making these, I'm still quite a new boy at these, compared to say, (NAME). I just need to put a smidge of wax on the clips. Hopefully nothing leaks underneath but light cure is quite a liquid material. Unifol, an emulsion type separating material. You get the pink sheet of light cure and light cure gel. I put the gel on each of the clips. It just gets in there and flows around the clips nicely. And then I cut the pink sheet and if it's cold it's a little bit stiff. You can warm it in your fingers. You can adapt it carefully over, like so, cut around and peel it off and adapt it down, if the gel squeezes out it's no drama. It helps to support that area if you put a little bit of extra material in the middle. You can just cut it right around but I'll just leave a bit of sheet through the middle. You can always cut it off if you don't want it. It all depends on the person you're making it for. So just pop it in the light cure machine for 2 minutes.

My critical analysis of it is my upper helix arm needs to be angled a bit further down. I design it in a 3D way to make sure it fits into the thicker part of the ear. If the patient's got a longer lobe, you might extend the arm a bit further down to give it a bit more support further down. I will visually design it according to how it needs to be. I might add a bit of light cure if you need a bit more support somewhere. But you want as much silicone as you can, but if you can get a nice shaped bar it does help. And you want the margins so they smooth in, so they are made invisible. That's the challenge. You want your matrix as small as possible really, but someone else might say you need a much bigger one for more stability.

So now I take the structure light cure matrix off and just give it a boil in the steamer to get rid of all the wax. Now I just trim up the matrix. Watch out for the dust. Just giving it all a nice even thickness. And you can just thin that edge down and make it nice, rounded and smooth. Get a little bit of light cure gel and add to where the clip is a little bit exposed. Trim and polish it. Give it a nice even finish with the diamond burr. You can't put it on any other way (actually it can because the distance is the same either way). So you can just run over the fitting surface slightly just to remove any flashing. It's important that you're not too rough. So then you give it a pumice, a little polish and a wash. Make sure there's no little bits. When you put your primer on, you know you get your polished surface…with a pumiced surface, what may look smooth is actually rough, with a polished surface when you put the primer on you get more surface area so you get a better bond. That's the thought behind polishing it.
So then to finish I check it if it fits again. On the working model, then on the patient. You'd try it on the patient. Seems to fit fairly passively. That's alright, you'd get away with that, the arms is slightly short and it'll be going into the thick bit of the ear. A couple of things I'm not so happy with but it'll work.

Observational Study Notes, Participant 3 – 11/01/2011

(Patient case- Nasal)

No voice recording taken due to patient preference.

Stage 1: Impression taking and locating abutments

No notes or images taken as patient didn't feel comfortable with this stage.

Stage 2: Designing and making the bar

- Feel it's very expensive if you get things wrong. There should be a training kit for practicing prosthetists, maybe with copper bar, or cheaper materials that they can train with.
- Trimming gold to right size – worried about wasting gold
- Laser welding
- Need to get the tacking done in as few hits as possible. The heat can make the wax supports droop (heats up wax and can affect the position of the bar)
- Polishing the bar using a variety of dremmels etc
- You could give 10 prosthetists the same job to do and they would all be different.
- Preserve as much of the original detail as you can because the clips might loosen if you polish the bar too much.
- Flux around joins. Pumice and plaster in the screw holes. Avoid solder going in.
- Gold conducts heat very well, potentially contracts when cooling. Hardens and contracts, don't know if this is a good idea.
- Finishing the bar takes a surprising amount of time.
- TIME TAKEN: 1hr 15

Stage 3: Alignment of the clips and creation of the base-plate

Notes and images

- Rigidity of the baseplate holding clips important, otherwise the clips move back.
- Leaves the baseplate rough (just pumiced) so that the silicone attaches more successfully.

Observational Study Transcript, Participant 4 – 09/12/2010

(No patient - Used replica model)

Stage 1: Impression taking and locating abutments

I push the coping guide pins through and apply a light cure gel to this. Light cure gel is pretty stable – that's why I'd use it on the copings. I'm effectively making a bit of rope to wrap around the copings. You could just laminate it but you something very strong. Top tips, don't get any light cure down the screws! To a degree you get some exothermic reaction, so you have to be careful when curing the gel on a patient, you can kill bone with a 2 degree increase in temperature. Plus you don't want to burn the patient. Do the light in short bursts if you have to do a thin section. Now we take a soft tissue impression. This would just be used really as an anatomical guide. It would identify the meatus, identify any anatomical shapes. That's it. The most important part of this procedure is the localization of the abutments. The impression is an aid to be honest. It tells us exactly the height of the skin and any anatomical landmarks, such as the tragus and meatus. Any tags on the skin that might be around. And you want to encompass that. This impression material is very soft, I only bother with this for any ear. All our carvings are done on the patients, not on the models. Put the reinforcement sticks (cotton buds) in. The elastic memory bumps in after the initial set. That'll go off in a bit. You just feeling it and you know when it's set. Take it off now. The beauty of the impression materials, is that they're like thick whipped cream, they just sit there. They don't flow, they're great in the mouth, the orbits, they're very safe.
To get it off you tell the patient to wrinkle their face and it starts to come off.

For the next step, I will put a bit of wire between the abutments. In stones, you can get a bit of expansion or contraction, with this system you get a box section, perfectly rigid. Keeping a little gap between the second analogue and wire. All passive. If it's touching there's a chance it could be 'grabbing'. Acetone over the light cure gel. Acetone sets the light cure off. Now we're mixing the plaster in a vacuum. It's a relatively new machine. When I'm mixing the plaster, you're not worried about air bubbles, because the model is used purely to make the bar, it's nothing to do with the skin. Wait for it to set now.

Stage 2: Designing and making the bar

You've got the universal 4mm copings, they used to come in 3 and 4mm but we said we'd rather have one size that we can cut. I'd probably drop the bar down and cut the top of the collars off. With a real patient you know about and are responsible for the thickness of the skin and the height of the abutment. If you were to place the bar at the top of the copings that would be a big gap so I would drop them down a bit to be honest. You want an oxygen, muck free environment. I used to do a lot of welding with titanium, and I'd have a bowl of water and I'd cool it, but of course what you're doing is introducing contamination with anything that is in the water and that can affect the strength in the weld. There should more than enough strength in the gold to be ok.

Just putting a bit of a concave into the end of the gold and a little bit of an angle, because the collars are conical shaped. I need a jig to do this because it gets so hot on your fingers. It's a great conductor of heat, gold. When you're laser welding, you don't want massive gaps because as you zap it, it shrinks and it can pull and distort it, so you want it reasonably close. You can slowly drop the gold down. It took the company about 8 years year make these collars. I'd assume they'd have the same process in (NAME) as us. Once you've gone too far with the bar, you won't be able to pull it back. What I'll do, I'll start welding one joint and finish it completely before moving onto another joint. And then you know if there are any distortions and where they are. On the free end you don't have to worry about it distorting (because it only has 1 connection point). So now I'm changing the focus on the laser welder so it's a wider focus so it can sort of finish the weld in a polished way. By changing the focus you don't go so deep, so you're using the same energy but in a wider area. Quite often you don't need to any trimming or anything with a good laser welder. The idea is that each spot that you make cover the previous spot by 70%, so you have a laser weld overlap of 70%. And that guarantees that you have a full weld underneath. We've changed a few things on the recommendation sheet for the laser welder. I've just added in extra gold there on the joints and I'm just smoothing it out. I think it's 14 carat gold. So you're flooding it with inert gas to keep the weld clean. It's an absolute necessity with titanium, not so much with gold but titanium oxidises. If you get titanium wrong you can actually see it crackle and you have to cut it out and replace it with new material.

With an ear it's not too bad if you do get some distortion, you can usually work out where it is and correct it. It's when you have a multi-unit bar, perhaps an orbit or nose when you've got 4 different implants

being linked up. That's when this method is really important, finish one gold collar completely…if you do one at a time, you know which one is the problem. The ends of the bar are virtually flat. Where your gold clip ends is where your bar should end. I just make it so it's not sharp.
These are just old abutment replicas I've cut off and all they serve to do is to protect the surface of the gold caps. So you don't abrade it when you're polishing. These things are quite beautifully engineered and then it's easy to destroy them. So now I'll just give it a quick polish.

Stage 3: Alignment of the clips and creation of the base-plate

This (layer of sheet wax) just puts a space under the base plate, a neat way of doing it because you don't want the base plate touching the skin. You only thing you want touching the skin is the edge of the prosthesis. This isn't a fine science or anything. Just making sure I've put enough around the clips. Removing any undercuts, and you make it so it just wants to feed down, so there's no doubt at all. This dental wax carves so nicely. We've tried all sorts. We just use light cure sheet next. Light cure is a favourite of ours, we use it an awful lot. So the gel material and sheet is the same material but they behave very different. They aren't ideal for everything. But they're very stable. So popped it in the light cure machine for 2 minutes. The Objet machine pretty much uses the same stuff if you think about it. The nice thing about lying a sheet down is on your model is that you haven't contaminated your model and you don't have to boil it off. Sometimes if you put boiling water on your model it can crack and if you think about it, the abutments are going to expand so much quicker than the plaster. Just going to clean these parts off, just getting the wax off really. You see, this light cure material doesn't cure on the surface and non-cured light cure is a great inhibitor to silicone so you have to make sure you clean it off really or trim it off otherwise you might have small amounts kicking around and you might not know it. You can buff it with pumice but then don't polish it. You see when you polish something you get peaks and troughs and you tend to knock the peaks off and bits fall in the troughs. What's not filled in by the peaks is filled in by the polish and think it forms a barrier between the polish and the material. So we don't polish them as such, we abrade them with pumice. I think there is some science to it, there are those who say you want it as smooth as possible, so you get maximum contact but there is the argument that the more surface roughness you have, your surface area is greater. Supposing if it is rough, you're not guaranteed to get your material into every nook and cranny. When you come to try it on and do the wax up, then you can trim it more if you want to. Because patients can hear this so well so they know exactly when it is on. Magnets are easy and these might be a bit difficult to start but once they've had it a week or two they love this. They love this reassuring clunk. Clips are better for us.

Observational Study Transcript, Participant 5 – 29/11/2010

(Patient case - auricular. Used patient for impression, but the rest of the process to be done without patient)

Stage 1: Impression taking and locating abutments

Notes only (patient preference)

- Dental floss around impression coping squares, set in light cure gel. This was to stabilize the copings (locations of the abutments). This is more accurate this way because maintains passivity. On bigger cases they would often use steel wire and laser spot weld all of the anchors so they don't retract.
- UV light cure this (on patient)
- Apply impression material (Soft body impression material – Epiform Flex) onto patient defect. A 2 part system. This picks up detail.
- Apply second impression material - harder silicone. This for stability.
- Apply cotton buds for extra stability.
- Leave to set for 4-5 mins
- A light touch to check if it is cured
- Take the impression pins out (these were set at the ideal torque with a torque driver)
- Take impression off, patient tells us that it is not at all uncomfortable.
- Patient uses a badger hair shaving brush
- Said that you don't want to clean it too much, this can also irritate it.
- Cotton buds are often too hard and too hard, patient doesn't really like them.
- When putting the prosthesis back on, uses Vaseline to set the margins down.
- Noticed that over time the margins do tend to corrugate and warp.

Stage 2: Designing and making the bar

Transcript (Patient not required)

"Now you've got your working model. And you would have your opposing side impression. Take 2 gold cylinders. Gold screw unigrip. The white gold cylinders go on. The only time you would have the opposing ear is to plan the implants. And so if it's pre-implant, you draw it on the blank. If you've got a meatus and a tragus you can record all that. You've got all the landmarks. You line up the tragus. You've got the opposing side before even going into surgery. And that working ear, the opposing side, allows you to carve to that opposing ear.

I'm just measuring roughly how far to go, just so you know roughly where to position it. What you want to do with a clip bar is have opposing forces. So if you've got two legs of the bar that are in the same plane as each other, there is going to be a displacement force, you have them on a slightly different angle, you'll be able to get rid of that. But you've still got to remember they've got to get it off. You want to try and eliminate any displacement forces. It's following the contours and you want it in the deepest part of the ear…in an ideal situation…sometimes you can't do it. You don't want to plan for your bar to come out the front.
I was just using the dremmel to round off (take off the burr) the end of the bits of bar. The important thing is with the welding is that you don't blow a hole through the caps and weld the screw into the coping. This is just like spot welding. A lot of the time you would get soft tissue overgrowth so you can compensate for that with the height of the bar. Also, you have to remember to allow the bar to be long enough to get the clips on. When you weld this on, when you tack, you want to do opposite sides. If you start firing loads of tacks onto one side out of proportion, you're going to get contraction from that. You can over tighten one side. You want to spread the force. Once you've tacked it, you want to spread the metal. This is actual gold wire, in theory it acts like your solder. Got to check it hasn't gone through the wall there! It's a bit ferocious. The beauty of this is that you weld and you don't need solder at all. There's almost no need to smooth it off either. Takes a bit of practice getting used it, once you do though, it becomes the best bit of kit you've ever seen. The gas you use on this is argon. Zap it on each arm, you have to eliminate every weakness that's in it. So…check if it's passive on the model .It might not be passive if it doesn't fit. You can set the setting higher, and re-go it with a stronger force. Go back into where you welded. You can always tweak it slightly by laser welding parts of the weld and it can self-right itself. You can utilize it with a patient. So now you put the lab analogues back on and it's ready to

be pumiced and polish. All it needs now is a quick pumice and polish, you don't need to go overboard. Job done. The more you start pumicing and polishing these things, you've got your clip and I've seen so many people polish these away and you lose the symmetry of the bar, bit that dip in and out. You only really want to pumice where you welded, you don't want to affect anything else. You've smoothed it on the laser welder.
At 26 minutes, (end of the process) Stefan drops the bar and bends it. The bar itself just bends, doesn't affect the welds. The beauty of the laser welder is how easy it is to fix the mechanism. If one comes back broken. You can fix them if they're broken. But it's often quicker to make them from scratch.

Stage 3: Alignment of the clips and creation of the base-plate

Transcript (patient not required)
The thing about the legs as I mentioned earlier, being not parallel to each other is important. By displacing those forces, if there is masticatory forces, if they're all lined up the same, they'll just pop off, what we tend to do is put 2 clips on the bottom leg. Usually 3 clips is enough, but depending on the position of the implants and the masticatory forces, having 4 clips is so much better. When you're covering it in wax, all you want is the gold clips to contact the gold. Sometimes the clips can crack out of the base plate, if this happens, scrap it. Once the base-plates start breaking, the light cure material just fragments, it's better to just make a whole new ear. The idea of the wax is that the substructure is an apron over the top, so you're just blocking out the bar so you're not getting any undercuts under the bar, when it comes off it follows the apron all the way down. By covering half a clip, when you process the base-plate, sometimes when they're new clips they can be too tight, so they're going half way up here, it allows you to have the scope to disengage the clips. It gives you a bit of scope for movement. This design will only fit in one position. If the clips engage then that's the job done. So, now we put some light cure gel on top, then it's ready to go into the light cure machine. The design gives it a bit of rigidity (that flap). Now it's cured, we trim, pumice and wash it.

Appendix IV: IMPT survey

Dear Maxillofacial Prosthetist,

I am a 2nd year PhD student based at the National Centre for Product Design and Development Research at the University of Wales Institute, Cardiff. My research involves evaluating the potential of using Computer Aided Design as part of the process of creating implant-based maxillofacial prostheses.

Attached to this edition of the IMPT newsletter is a survey seeking expert information from all UK based MPTs. I would be most grateful if you could complete the survey and send it back to me using the enclosed self-addressed envelope. Further details can be seen below:

Project Summary:

This survey seeks information specifically on the design of ***retention mechanisms for implant-based auricular prostheses***. Participants are required for this research study from the field of maxillofacial prosthetics so that expert opinion and quantitative data on clinical practice can be obtained.

The expected benefit of this research is to contribute technically and clinically to the field of maxillofacial prosthetics by exploring and evaluating today's solutions for designing and fabricating retention mechanisms. The analysis of the results of the study will be published in the IMPT Journal for your information.

The questionnaire should take about 15 minutes to complete.

Are there any risks involved?

The research involves a questionnaire-based interview, and we are not seeking to collect any sensitive data from you. We do not think that there are any significant risks associated with this study. However, if you do feel that any of the questions are inappropriate then you do not have to answer. Furthermore, you can change your mind and withdraw from the study at any time.

All the information we get from you is strictly confidential and there is an option for anonymity. We will keep your name and any personal details completely separate from the other questionnaire forms. Your personal details and your finished questionnaire will be kept at secure locations within UWIC. When we have finished the study and analysed all the information, all the forms used to gather the data will be destroyed.

If you require any further information about this research then please feel free to contact me directly.

Kind regards,

Steffan Daniel
UWIC Tel: 02920416692
Email: stdaniel@uwic.ac.uk

PTO

Survey for Maxillofacial Prosthetists on the Retention of Implant-Based Auricular Prostheses

1. **You are not required to answer this question if you wish to remain anonymous.**

Survey Completion Date (dd/mm/yy):	Name:
Hospital/Company:	City/Town:
Role:	
Email Address:	

2. **Please tick your most favoured method of retention for AURICULAR cases.**

Bar and Clip	☐	Magnetic	☐
Magnet/Bar & Clip Combo	☐	Medical Adhesive	☐
Other (Please state)			

Why do you favour this method?

3. **Please rate how the following patient considerations influence the final choice of mechanism design for an auricular prosthesis. (1 low influence → 5 high influence)**

Shape of the desired ear	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Defected anatomy condition	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Position of the implants	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Patient dexterity	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Patient lifestyle (e.g. sporting)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Patient psychological state	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Other (Please state) ……	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

4. **If using a bar structure for retention, how would you check for a 'passive fit' between the bar and abutments? (Select all that apply)**

By eye – checking for gaps	☐	By 'feel'	☐
Microscope	☐	Patient's reaction when fitted	☐
One screw test	☐	Don't know	☐
Other (please specify)			

5. **On average for a unilateral case, how many hours does it take to design and create an auricular retention mechanism? (From impression taking through to the bonding of the sub-structure/baseplate)**

1-2 ☐	2-3 ☐	3-4 ☐	4-5 ☐	5-6 ☐	6-7 ☐
7-8 ☐	8-9 ☐	9-10 ☐	10+ ☐		

6. **Please rate the importance of the following factors for a *bar and clip mechanism* for an auricular prosthesis. (1 Not important →5 Very important)**

FACTOR	RATING *(1 Not important →5 Very important)*				
Changeable/custom designs (flexibility)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Adjustability of retention forces (increase/decrease)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Accurate fit between male and female components (e.g. bar and clip)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Equal forces distributed on implants	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Stability of ear when fitted	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Biocompatibility of materials	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Height of retention mechanism from tissue	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Mechanism longevity/durability	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Passive fit of components to implant abutments (i.e. bar structure to abutment)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Aesthetics of retention mechanism when exposed	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Ease of duplication	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Good wear properties of retention interface (e.g. bar and clip)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
The number of components (Modularity)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Intricate design (unobtrusive)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Easy to clean	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Rigid design	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Easy to locate/attach	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Easy to detach	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Follows the shape of the ear	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Does not snag on clothes	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Other? (please specify)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

7. **Please describe any complications you may have experienced in the following stages of designing and fabricating a *'bar and clip' auricular retention mechanism*.**

Designing and positioning the bar structure (deciding on bar shape, length, angles etc)
Fabricating the bar structure (welding, soldering and finishing)
Alignment of the clips and bar and incorporation into to the substructure (baseplate)

PTO

8. **Please describe any complications you may have experienced in the following stages of designing and fabricating a '*magnet retained' auricular retention mechanism*.**

Choosing the appropriate magnetic system/components

Alignment of the magnetic components and incorporation into to the substructure (baseplate)

9. **How do you think it might be appropriate to introduce *Computer Aided Design (CAD)* into this process of designing retention mechanisms?**

10. **Please rate the following factors to which degree CAD might be of benefit to you, with regards to designing *implant-based retention mechanisms*.**
(1-Not beneficial, 5 -Very beneficial)

FACTOR	RATING (1-Not beneficial, 5 -Very beneficial)				
Accurate duplication of components	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Ability to take impression at patient home	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Minimal contamination during design process	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Less 'material' needed (reduces impression materials)	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Reduces contact with human tissue	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Machines build the parts	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Ability to keep records of design actions	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Predictability of final outcome	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Ability to test designs in a digital environment	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

11. **Do you have any further thoughts on the success of retention mechanisms for implant-based auricular prostheses?**

Thank you for your time!

Appendix V: CAD/CAM process feedback - transcript

CAD/CAM Prosthetic Process Interview – Transcript 02/05/2012

1. **On a scale of 1 – 10 (1 being complicated, 10 being easy), how easy were the different stages in the process?**

   a. ***Anatomy capture***

I've never particularly got on well with the Handyscanner. When we used it before I found it sensitive to light and things but I think it could be down to user. I'd give it an 8, it looks quite easy really.

   b. ***Abutment capture***

Give that an 8 too.

   c. ***Reverse engineering (defining abutment positions and creating clean anatomical surface)***

5. It's difficult to know without doing it. It's essentially only basic CAD/CAM processes isn't it?

   d. ***Design of retention bar / magnet structure***

7.

   e. ***Design of clip base plate***

Probably a bit more difficult for me, say 5.

   f. ***Design of RP prosthesis mould with integration of retention mechanisms***

Shouldn't be a problem. 6.

   g. ***Manufacture of components***

You send them away don't you… So 10 then I suppose.

2. **On a scale of 1 – 10 (1 being inappropriate, 10 being appropriate), how appropriate were the various stages in the process for doing what you need to do?**

Do you mean can I think of a better way of doing it? I think it's difficult to not rate it as a whole process rather than individual stages. I'm thinking of the patient in this too. When you were describing it, I was trying to think in my head, how would I do that in the clinic, and I don't see any problems. There will be problems, like hair and where you can stick the little white sticky tags and things like that. But I think it was overall pretty appropriate.

3. **What did you find particularly useful in the process?**

What am I gaining then? I think flexibility. Being able to work at your leisure on computers, so you can be doing that at any time. Once you've captured your data, you're reducing the patient's chair time. Once they've gone away, you don't need them anymore. But now…part of that they spend the day with us. You know, we make the bar, they try it on, we make the base plate, they try it on etc. That would be saved.

4. **What didn't you find useful?**

There may be an issue with that disconnection with the patient. You're going from where you're heavily involved with the patient where they're there for all the processes. When you need the patient there and how the patient fits into these processes.

5. **Which parts of the process could you see beneficial to the**

   a. **patient**

I think the ability to re-make the bar and re-make the mould easily could save a lot of patient time.

   b. **clinician**

The idea of being able to design the components on screen at your leisure than being under pressure whilst the patient is there to get it sorted. I think the idea of having a choice of materials, giving a choice of how you deal with it, having that time on screen to design your bar. I think it's that flexibility really. I think what's also useful could be say to have that choice of say, flexible materials which could be really useful in some cases – that could be really useful, having different materials to cater for different patient needs. The other thing is, if you break anything, you can re-make it can't you. Whereas at the moment. If we have a plaster mould, and it cracks after a dozen times, you've got to re-make it. The patient's got to come back in and we have to re-make it for the patient.

6. **Can you see any disadvantages to using this process over the traditional craft process?**

I think when you're making your ear, I'd worry that some of the detail isn't quite there on these things. The sharpness of the carving isn't quite there as if you've hand carved it. So perhaps your aesthetic

qualities you're not quite getting with CAD yet. I mean that will improve no doubt, but at the moment it's not quite not there. I would've carved it down a bit further, but these are minor things.

7. **What would you like to see in the process that isn't already there?**

I'm not sure if the mould is within what you're looking at but I think the mould could be improved. I think there could be some mileage in making these materials completely clear for moulding. It's already quite good semi-clear but if it was transparent it would be very useful. Especially for matching the colour.

8. **The levels of accuracy can be defined in various stages of this process – do you feel this is important?**

Yes I do.

9. **If this process were integrated into a streamlined, semi-automated piece of software, would that be good/appropriate/improve life?**

It might be good. Sometimes when you work between packages it's quite nice because there's flexibility of working between packages. Once you've got everything streamlined into one package, if you want to move onto another package, say you've got an improved area in another package, you can't move out or take advantage of another package. **So could you say you'd want some of those elements to be automated and some of those to be very open to give you that ability to be creative?** Or through that automated process, have a way out at any point to go into your creative software. If you could export at any point then that would be useful.

10. **Do you think that to follow this process, a lot of CAD experience/training is needed?**

Yeah I think you might need it. Or would you just employ somebody who does it?

11. **Is there anything in this process you may see as complicated for clinicians, not coming from a CAD background?**

I think you might find some of the processes there you might find challenging for a person with a non-CAD background. I'm looking at it thinking 'yes I can probably do that' and I've had quite a lot of experience. I'm not a CAD expert by any means but I've had some experience so if you look at MIMICS, that's written for non-CAD people isn't it so…I think there might be some issues. But not issues you shouldn't be able to get around.

12. **What aspects of the process would you like to see automated and which should be kept as manual as possible?**

I suppose the obvious one to be automated is the abutment capture. The skin capture and the abutment capture. The manual parts would be the bar and the clip plate design. They would be semi-automated. You want the position and extension of the arms of the bar to be manual, and then the creation of the bar you would want to be automated. 'That's where I want it, now make me a bar'. The clips, you want to put them where you want, you don't want that to be automated. But then I suppose you can put the clips on then it could tell you 'please adjust' (for better positioning based on engineering principles), you adjust, then 'please create base plate'. **So you would like it if the software could indicate if you need to adjust something (clips) if they are putting too much stress on the implants for example?** Yes, that could work.

13. **Do you think there should be controlled levels of adjustability with the stock components? How would you feel if they were interchangeable parts from a library of stock components?**

I think it would have to be. They're either on or off, so you would have to have some control over that. So you would choose a clip that was a bit stronger maybe that might be better.

14. **Would you be more satisfied knowing the accuracies and forces can be measured and controlled to a high level?**

I think so yeah. In what way could you do that? **So if you choose a clip, you know that that design you've chosen from a library of clips will give a certain amount of force. Would you be satisfied with that?** Yes I think that would be good.

15. **What would make you happier about the process/es?**

Don't know really. What I would worry about is the automation, having more automation in the bar design and things, you would want more automation in the capture. It's got to be a pretty smooth process doesn't it. To save you time.

16. **Are there aspects of the traditional process that you would like to combine with CAD process, but not eliminate? – are there aspects you think should not be done using CAD?**

No not really. As long as they can produce the same result I wouldn't have an issue. It's important to be able to make sure that the patient is happy, rather than just taking a scan and saying 'right, here's your bar, here's your ear, bye'.

17. **On a scale of 1 – 10 (1 being not useful, 10 being useful), how useful is the:**

   a. ***Scanning process***

I think it could be very useful, it just gives you that flexibility with the patient. Also, tele-working, tele-medicine – you can't just think about your own work environment…what about in a country where they've had the implants, they want an ear for that patient, they can take a scan and send you that data. If we do work with somebody in India say, that could work well.

   b. ***Designing bar and clip / magnet structure in CAD***

That's very useful I think. Having that time and ability. We tend to evaluate things by eye and so on, especially if you can measure those forces, it could become a much safer process.

   c. ***RP Mould***

I think very useful. If you look at a plaster mould, it is big and heavy. This is very light and you can reproduce it at any time that you want. A few design issues but you know. The ability to re-make it. I think there might be issues with the fact that it becomes quite soft when you heat it up. Other than that, it's light and easy to store, we have big boxes at the moment for our moulds. Or you might be able to get to a stage where you rapid prototype the mould for the patient to pack the ear in and then throw it in the bin afterwards. **So a disposable mould, it doesn't necessarily have to be that material (Projet 3D printed), it could be something else.** It did cross my mind earlier whether it would be worth coating the mould in a metal, which would make it strong and heat resistant maybe, it may not deform under heat then. It would also make the mould quicker to use, because the heat would go through the mould better. This is a step toward being able to rapid prototype a prosthesis.

   d. ***Over-moulding substructure***

I'd have to see that I think. It would be whether that could hold in the prosthesis. The down side of that would be if it does come out of the prosthesis on the patient, how do you get it back in? You'd have to make a new prosthesis. If that does rip-out at any point…it's not likely to rip out, but if it does, you won't be able to get it in again. You can't see it in there if you've broken the silicone or not. **So are you saying that the adhesive bond you have with traditional base-plates in prostheses can be broken at a particular force – that it is important that the bond is broken before the silicone is ripped, so that it doesn't ruin the prosthesis?** Yes. It's pretty good though but I think there might be a few issues.

   e. ***Manufacture of components using CAD/CAM-based machines***

Very useful. Because of the repeatability of it. We've struggled for years really, you know, we can't duplicate a bar accurately so being able to do that is very exciting. If a patient breaks a bar, you just print another one off. It's a whole different way of thinking about it really.

18. **If process could be repeated so that the same results could be achieved time after time, do you see that helping your practice?**

Yes definitely.

19. **What do you feel that the process has not achieved/ can not achieve?**

When we talked about the fine detail on the prosthesis, I don't think we've quite got there yet. Maybe we haven't looked at it well enough yet. I know (NAME) did some work on textures and so maybe that needs to be looked at. See how good this mould process can be, how accurate it can be. We're looking at a lot of young ears at the moment, perhaps we need to look at a really old, crusty, greasy, detailed ear and see how the whole process handles that, not a simplified ear. The challenge is also then to try and produce that detail on an old crusty ear. **What about the design of the retention mechanism? Is there anything you feel like it couldn't achieve there?** No, I think it's brilliant. On a subjective level, I feel that it's an acceptable process to follow. I think it's really good, can't wait to try it. There will be hiccups. Once you start to roll it out to different patients, that's when you start find the issues. You never know, if you try this process on a larger midface defect, it might start coming into it's own. I was lecturing in Cardiff on Friday and one of the things I was saying was that we really want to help the big midface defects because that's where you're spending a lot of energy and time. You're spending a lot of time on trying to get things right. And you're spending a lot of time with the patient. The patient really needs to be there. If

you can do it on something simple like an ear, well can it be done on something complex? See how far you can go with it. When you have a network of bars on more than 3 implants, that's really challenging. They're the patients you're really going to help.

20. Can you see any benefits in the various stages of the process?

The flexibility of working away from the patient. The non-invasiveness of the scanning process for not having to use any silicone. You're saving money there, about £50 a tube, that's quite expensive you know…. you're probably saving £50-70 in materials, plus your time. If you're just scanning, it could be very useful. And having the data there. You think of the process at the moment – the patient comes in, you take an impression, and take an impression of their other ear, then you've got to carve it up. These are all stages you can save on.

21. Can you see any challenges in the various stages of this process?

I think there's that remoteness from the patient and learning to work in completely new way, and thinking about working in this way and acquiring your data in the right places. They're going to be the challenges. You've got to figure out where you're going to get your data and when and what you need to move on in the process. Because if you haven't got it then you can't do it. But there are advantages too.

22. Which samples (models) do you see as promising? Why?

I like the Zirconia, the Envisiontec flexible bar, the FCubic could be useful and the plated bars. I know there are a few other flexible ones in there but it's whether they are flexible and they break, or if they are flexible and they go back to way were before, and those are two quite different things.

23. How successful do you feel this digital process is at this stage? What needs more work and why?

Moulding. We need to do that together, you need to run it through, see it, so you can see what we need.

24. What do you see as the next step in the development of this process?

A patient trial. Packing some of the moulds with silicone to see how the plate integrates into that. Making sure that's all good. I'm confident with the capture you've showed me. Maybe you need to roll on and do a 3 component model, maybe you need a model with an eye, and see how your process might need to change doing an eye.

25. Could you see yourself adopting some of these processes? Which ones if yes/no?

Yes. Definitely. I'd adopt all of it.

26. Is there anything else you would like to add?

I think it's really exciting. It's a bit mind blowing all the metals and plastics you've got there – the Zirconia and the flexible one and… I'm normally pretty good at spotting issues but I can't see any major problems. I think your pressure edges and that can be worked out. I think there's mileage in doing several captures, say 3DMD captures or scans, maybe with your mouth open and closed so you can analyse where the maximum movement is. You could use the scan of the abutments and then match it to a series of scans from the 3dmd perhaps. Would that be possible? We need to set some time aside for you to come up to do some colour matching with those moulds. I certainly think you're going in the right direction. It would be easy to get side-tracked by different designs but it may be more about process. You could try mushrooms and slots but these designs work and they have evolved over the years. You could come up with invariable designs on that but not get you anywhere. I'm not sceptical about this in any area. Over the years we've put the key pieces in place so now it seems as if everything is in place. I think you've done a lot of work, gone about it in a sensible way. I think you could've said let's do some buttons, do this design or that design but by sticking to the bar design and having that tenacity to say right I want it to fit onto that, I think you've done well. Just one thing I think about the Technovent magnets, the way they are now, because they have the ridge around them, it's a retention lip and it's very good.

Appendix VI: Images of samples and Data tables

Appendix VI.1 CAD/CAM samples - images

Rigid bar structure samples	Images
Dental investment cast from RP master (Cardiff Met.) Solidscape 3D wax print, layers 13µm. Induction cast (CoCrMo)	
Jewellery investment cast from RP Master (Jewellery Industry Innovation Centre, Birmingham) Solidscape 3D wax print, layers 13 µm. Centrifugal cast (Brass)	
Selective Laser Melting (SLM Solutions) Titanium (TiAl6V4), Layer thickness 30µm	
Mlab Laser Cusing (Concept Laser Gmbh) Remanium star CL (CoCrMo), layer thickness 50µm	
Direct Metal Laser Sintering (EOS DMLS) Cobalt Chrome (CoCrMo), layer thickness 40µm	
Inkjet Metal Printing (Fcubic) Stainless Steel (316L), resolution 20µm	
Electrodeposited AM master (Morganic Metal Solutions) 3D Systems Projet EX200 base, layer 16µm Electroformed Copper coating of 100µm thickness	
Electrodeposited AM master (3DDC) 3D Systems Projet EX200 base, layer 16µm Electroplated Copper coating of 100µm thickness	
Incise® Dental Milling (machining) - Zirconia (Renishaw Plc) Zirconium dioxide using Incise® Dental Miller	
CNC Machined PEEK (Invibio Biomaterial Solutions) PEEK-OPTIMA (Polyether ether ketone) 250-500m/min cutting speed	

Bar structure non-rigid samples	Acronym
Objet Connex 500 (PolyJet Matrix™ Technology) ABS-like digital material (fabricated from FullCure®515 and ®535). Layer thickness 30µm (IPF Rapid Prototyping)	Obj ABS
DurusWhite - simulated polypropylene material, layer thickness 28µm (HK Rapid Prototyping)	Obj Dur
VeroWhite - rigid opaque material, layer thickness 30µm	

(Loughborough University)	
	Obj Vero
Stereolithography (SLA-250) (3D Systems)	SLA 25
Accura 25 – simulated polypropylene material, layer thickness 100µm (3D Systems)	
Accura Xtreme – ABS-like material, layer thickness 100µm (3D Systems)	SLA Xtr
Perfactory Digital Dental Printer (EnvisionTec Gmbh)	
RCP30 Ceramic filled photopolymer - PP type material). Pixel Size 30 µm, Dynamic Voxel Resolution in Z (material dependent) 25µm	
Selective Laser Sintering (SLS) (3D Systems)	
Duraform EX – simulated polypropylene material, layer thickness 100µm	
Vacuum Cast from 3D printed master (PDR)	
3D Systems Projet EX200 base, layer 16µm	
Vacuum cast in Polypropylene-type material (MTT)	

Appendix VI.2 Surface Roughness Measurement results

Roughness measurements (µm)												
Sample	**Top side**						**Bottom side**					
	Ra			**Rz**			**Ra**			**Rz**		
	m1	**m2**	**m3**	**m1**	**m2**	**m3**	**m4**	**m5**	**m6**	**m4**	**m5**	**m6**
Traditional 1	0.27	0.22	0.18	1.15	0.63	1.01	0.41	0.24	0.46	1.4	1.53	1.71
Traditional 2	0.15	0.12	0.18	0.92	0.72	0.92	0.13	0.15	0.21	0.65	0.74	1.15
Traditional 3	0.26	0.11	0.13	1.27	1.03	0.67	0.13	0.13	0.16	0.56	0.64	0.76
Traditional 4	0.16	0.15	0.18	0.76	0.82	1.15	0.13	0.13	0.099	0.8	0.62	0.5
Traditional 5	1.51	0.49	0.32	5.43	2.34	1.65	1.51	0.81	0.28	3.63	11.79	1.45
Electroformed 1 (Morganics)	1.42	1.5	1.65	3.91	4.23	4.6	1	0.78	0.86	3.43	2.52	2.97
Electroplated 2 (3DDC)	1.08	0.85	1.29	3.73	4.77	4.67	1.55	1.46	1.08	6.56	5.06	4.83
Jewellery Cast (Polished)	0.2	0.41	0.34	1.05	1.67	1.69	0.39	0.25	0.46	2.43	1.68	2.77
Jewellery Cast (Unpolished)	0.81	0.94	0.77	2.85	3.92	2.91	0.86	0.75	0.87	3.65	2.99	3.96
Dental Cast	1.78	4.25	4.62	7.4	11.63	16.37	2.24	3.84	2.06	9.03	10.66	9.51
Laser Cusing (polished)	2.73	3.07	2.31	12.62	10.78	8.88	3.13	3.38	3.48	8.96	9.48	13.17
Laser Cusing (unpolished)	4.53	4.88	4.99	12.73	12.01	11.63	8.76	5.06	6.13	18.88	9.64	12.38
Metal Inkjet (FCubic)	4.51	4.28	5.71	13.77	13.83	23.45	1.88	1.96	2.2	10.01	8.37	11.32
SLM	4	3.06	2.33	12.13	10.2	6.53	3.11	2.34	1.74	20.09	16.18	15.22
DMLS	1.74	1.67	2.35	14.8	16.07	15	3.82	3.92	4.03	14.36	18.9	14.8

Table 24: Ra and Rz values (µm)

Appendix VI.3 Dimensional Measurement Results

Model	H1Ø	H2Ø	H3Ø	H4Ø	L1	L2	L3	H1o	H2o	H3o	H4o	S1	S2
A. Trad Gold 1	0.00	-0.02	0.00	0.06	-0.05	-0.06	-0.08	0.01	0.06	0.01	0.03	0.06	0.06
B. Trad Gold 2	0.02	0.04	0.04	0.04	-0.02	-0.03	-0.08	0.01	0.03	0.00	0.04	0.09	0.09
C. Trad Gold 3	-0.01	0.04	-0.01	0.05	-0.03	-0.02	-0.01	0.05	0.01	0.02	0.02	0.06	0.10
D. Trad Gold 4	-0.01	0.05	0.00	0.05	-0.05	-0.08	-0.10	0.02	0.01	0.01	0.01	0.29	0.21
E. Trad Gold 5	0.03	0.09	-0.01	0.08	-0.09	-0.09	-0.11	0.01	0.03	0.05	0.05	0.16	0.13
F. CNC Peek	-0.05	-0.03	-0.05	-0.02	0.04	0.27	0.07	0.05	0.11	0.12	0.07	0.67	0.35
G. SLM	0.01	0.21	0.01	0.28	-0.02	-0.02	-0.03	0.01	0.12	0.07	0.12	0.17	0.18
H. Electro Morg	-0.03	-0.08	-0.01	-0.09	0.03	0.03	0.03	0.03	0.04	0.03	0.08	0.17	0.10
I. JewlCast Pol	-0.10	-0.05	-0.09	-0.07	-0.15	-0.15	-0.15	0.06	0.07	0.06	0.04	0.02	0.05
J. JewlCast Unpol	-0.12	-0.12	-0.11	-0.12	-0.04	-0.04	-0.05	0.06	0.09	0.06	0.09	0.04	0.10
K. Envisiontec	0.02	0.03	0.04	0.02	-0.06	-0.05	-0.07	0.06	0.06	0.03	0.08	0.07	0.07
L. VacCast	-0.25	0.00	-0.19	-0.07	0.01	0.00	0.05	0.15	0.11	0.14	0.11	0.78	0.37
M. DMLS	-0.01	-0.01	-0.01	-0.09	-0.05	-0.06	-0.05	0.05	0.20	0.05	0.08	0.17	0.05
N. SLA Xtrem	-0.14	0.31	-0.19	0.31	0.04	-0.04	-0.01	0.03	0.08	0.08	0.07	0.11	0.41
O. SLS DuraEX	-0.07	-0.04	-0.10	-0.15	-0.09	-0.10	-0.10	0.06	0.16	0.07	0.11	0.18	0.10
P. SLA Accura25	0.04	0.04	0.03	0.05	-0.11	-0.12	-0.12	0.03	0.15	0.03	0.03	0.06	0.06
Q. Objet Vero	-0.19	-0.04	-0.25	-0.08	0.15	0.13	0.22	0.04	0.13	0.07	0.09	0.12	0.12
R. DentCast	-0.07	0.07	-0.07	0.06	0.06	0.06	0.11	0.05	0.13	0.04	0.13	0.32	0.12
S. Mlab Pol	-0.07	0.21	-0.09	0.21	-0.05	-0.06	-0.06	0.05	0.04	0.06	0.06	0.07	0.03
T. Mlab Unpol	-0.07	0.23	-0.05	0.23	-0.02	-0.01	-0.03	0.06	0.07	0.04	0.04	0.09	0.19
U. CNC Zirco	-0.11	0.20	-0.11	0.20	-0.01	-0.01	-0.01	0.01	0.03	0.04	0.04	0.06	0.11
V. Objet PP	0.06	0.35	0.03	0.40	0.08	0.10	0.05	0.05	0.14	0.07	0.11	0.09	0.16
W. Obj ABS	0.06	0.21	0.05	0.11	-0.09	0.01	0.04	0.07	0.13	0.09	0.15	0.14	0.15
X. Electro 3DDC	-0.01	-0.04	-0.04	-0.04	-0.02	0.00	0.00	0.06	0.15	0.03	0.11	0.06	0.10
Y. FCubic	-0.03	0.17	-0.01	0.19	0.09	0.09	0.09	0.05	0.09	0.03	0.09	0.05	0.08

Table 25: Accuracy values (mm) of components (comparing to theoretical designs)

Appendix VI.4 Accuracy of fit study - CMM raw data

Abutment Stone Models & Plastic Replica						
Model A						
Abutment 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Set 1	11.973083	21.258854	-5.642020	-0.000228	-0.043145	0.999069
Set 2	11.961720	21.312431	-5.638610	-0.002170	-0.050322	0.998731
Set 3	11.946668	21.288009	-5.641300	0.001588	-0.045222	0.998976
mean	**11.960490**	**21.286431**	**-5.640643**	**-0.000270**	**-0.046230**	**0.998925**
Inverse Cosine				90.01546986	92.6497283	2.656934056
Abutment 2						
Set 1	-0.424884	19.963140	-5.814400	-0.004348	-0.049824	0.998749
Set 2	-0.424362	19.979836	-5.815825	-0.003669	-0.051203	0.998682
Set 3	-0.449190	19.975241	-5.816674	-0.003180	-0.050256	0.998731
mean	**-0.432812**	**19.972739**	**-5.815633**	**-0.003732**	**-0.050428**	**0.998721**
Inverse Cosine				90.21382835	92.89053755	2.898138938
Model B						
Abutment 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Set 1	8.537335	10.442533	1.335091	0.159463	0.078298	0.984094
Set 2	8.685403	9.883705	1.612161	0.148374	0.084409	0.985322
Set 3	9.352672	10.759194	1.234767	0.125396	0.058045	0.990407
Mean	**8.858470**	**10.361811**	**1.394006**	**0.144411**	**0.073584**	**0.986608**
Inverse Cosine				81.696827	85.78013335	9.387419322
Abutment 2						
Set 1	-3.750400	10.344960	1.387573	-0.021697	-0.001291	0.999764
Set 2	-3.592763	10.045623	1.488232	-0.035975	0.007782	0.999322
Set 3	-2.890378	12.271366	0.841981	-0.058584	0.003467	0.998276
Mean	**-3.411180**	**10.887316**	**1.239262**	**-0.038752**	**0.003319**	**0.999121**
Inverse Cosine				92.22088214	89.80983496	2.402502703
Model C						
Abutment 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Set 1	-0.344418943	-6.79162741	15.4543467	-0.05831717	-0.020535028	0.99808687
Set 2	-0.354961634	-6.78526068	15.4508324	-0.058441818	-0.020721361	0.9980757
Set 3	-0.355353	-6.79001045	15.4495335	-0.058636185	-0.02077056	0.9980633
Mean	**-0.351577859**	**-6.78896618**	**15.45157087**	**-0.058465058**	**-0.02067565**	**0.99807529**
Inverse Cosine				93.35171237	91.1847119	3.555412245
Abutment 2						
Set 1	0.401328772	5.60090542	15.6685791	-0.06469563	-0.021357402	0.9976765
Set 2	0.388966262	5.5947566	15.6666832	-0.06474708	-0.021548215	0.997669041
Set 3	0.385200918	5.596597	15.6658287	-0.0647639	-0.021690132	0.997664869
Mean	**0.391831984**	**5.597419673**	**15.66703033**	**-0.064735537**	**-0.021531917**	**0.997670137**
Inverse Cosine				93.71166855	91.23378332	3.911894908
Model D						
Abutment 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Set 1	-2.762616	7.718699	-22.975955	0.056136	-0.021951	0.998182
Set 2	-2.741308	7.709687	-23.001545	0.053148	-0.022388	0.998336
Set 3	-2.766971	7.729003	-22.999191	0.050555	-0.025615	-
mean	**-2.756965**	**7.719130**	**-22.992230**	**0.053280**	**-0.023318**	**0.998259**
Inverse Cosine				86.9458347	91.33614409	3.381427224
Abutment 2						
Set 1	-12.959826	0.500807	-22.767197	0.052370	-0.021536	0.998396
Set 2	-12.899794	0.501634	-22.793720	0.047244	-0.021068	0.998661

Set 3	-12.917908	0.493167	-22.793257	0.050192	-0.018946	0.998560
mean	**-12.925843**	**0.498536**	**-22.784725**	**0.049935**	**-0.020517**	**0.998539**
Inverse Cosine				87.1377449	91.17562	3.097530759
Model E						
Abutment 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Set 1	9.588559	16.178536	-18.544755	0.031009	-0.002069	0.999517
Set 2	9.177351	16.075832	-18.546248	0.031184	0.002902	0.999509
Set 3	9.223778	16.038897	-18.549399	0.029879	0.008116	0.999521
mean	**9.329896**	**16.097755**	**-18.546801**	**0.030691**	**0.002983**	**0.999516**
Inverse Cosine				88.24125905	89.82908644	1.782698213
Abutment 2	**X**	**Y**	**Z**	**I**	**J**	**K**
Set 1	1.508735	6.554477	-18.063990	0.004723	0.025085	0.999674
Set 2	1.845127	6.471994	-18.078849	0.003137	0.025442	0.999671
Set 3	1.190605	6.663675	-	-0.004381	-0.027932	-
mean	**1.514822**	**6.563382**	**-18.071420**	**0.001160**	**0.007532**	**0.999673**
Inverse Cosine				89.93353688	89.56844411	1.465289177
Plastic Replica						
Abutment 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Set 1	-0.222035	-11.392728	-2.893474	0.007224	0.005662	0.999958
Set 2	-0.243810	-11.417475	-2.905317	0.009387	0.007971	0.999924
Set 3	-0.205721	-11.403186	-2.934819	0.009583	0.006258	0.999934
mean	**-0.223855**	**-11.404463**	**-2.911203**	**0.008731**	**0.006630**	**0.999939**
Inverse Cosine				89.499744	89.620126	0.632856
Abutment 2	**X**	**Y**	**Z**	**I**	**J**	**K**
Set 1	12.119581	-10.265085	-3.101621	0.008953	0.003234	0.999955
Set 2	12.127265	-10.203041	-3.115851	0.009664	0.000348	0.999953
Set 3	12.144747	-10.283745	-3.152843	0.011069	0.004923	0.999927
mean	**12.130531**	**-10.250624**	**-3.123438**	**0.009895**	**0.002835**	**0.999945**
Inverse Cosine				89.433049	89.837566	0.600926

Table 26: Raw CMM data - Abutment Stone Models & Plastic Replica

Conventional bar samples						
Repeatability tests	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	12.6887836	0.5437108	29.627594	0.003868096	-0.021220878	0.999767363
Measurement 2	12.7175446	0.6141995	29.6295586	0.002411255	-0.019201772	0.9998127
Measurement 3	12.7007017	0.585468233	29.6276855	0.000467502	-0.019599535	0.999807835
Measurement 4	12.7009268	0.591862559	29.6270485	0.001551406	-0.020690085	0.999784768
Model A						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	4.138915	6.536373	28.8092155	0.037130944	-	0.9993001
2	4.138896	6.536483	28.8064137	0.037569173	-0.004357048	0.999284565
3	4.141663	6.53628874	28.8062553	0.037512932	-0.004381632	0.999286532
Mean	**4.139824667**	**6.53638158**	**28.80729483**	**0.03740435**	**-0.00436934**	**0.999290399**
Inv. Cosine				87.85638856	90.25034554	2.15859131
Locator 2						
Measurement 1	15.364296	1.173136	28.51464	0.057847768	0.037810106	0.9976092
2	15.3656988	1.175405	28.5127869	0.05790164	0.03798428	0.9975994
3	15.3688345	1.17859936	28.5128136	0.057812337	0.0377368	0.997614
Mean	**15.36627643**	**1.175713453**	**28.5134135**	**0.057853915**	**0.037843729**	**0.997607533**
Inv. Cosine				86.68336291	87.83119616	3.964124014

Model B						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-3.32140374	8.305968	6.14899063	0.060161285	-0.054976713	0.9966736
2	-3.31865287	8.307572	6.15059566	0.06002588	-0.05511526	0.996674061
3	-3.31695652	8.30903	6.150916	0.060148757	-0.054995112	0.9966733
Mean	**-3.319004377**	**8.307523333**	**6.15016743**	**0.060111974**	**-0.055029028**	**0.996673654**
Inv. Cosine				86.55375999	93.15452451	4.674571415
Locator 2						
Measurement 1	7.66380072	3.34412217	6.996397	-0.057995945	0.090318985	0.9942228
2	7.66646671	3.34990072	6.99778271	-0.05803597	0.0903275	0.9942197
3	7.669552	3.34906936	6.99830151	-0.058153808	0.09021967	0.9942226
Mean	**7.666606477**	**3.347697417**	**6.99749374**	**-0.058061908**	**0.090288718**	**0.9942217**
Inv. Cosine				93.32857428	84.81978296	6.162359332
Model C						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-1.491384	9.820771	4.75246334	-0.05031088	-0.037325878	0.9980359
2	-1.49391246	9.820947	4.75228	-0.05027086	-0.03739465	0.9980353
3	-1.489159	9.820747	4.75262356	-0.050265465	-0.037386347	0.9980359
Mean	**-1.491485153**	**9.820821667**	**4.752455633**	**-0.050282402**	**-0.037368958**	**0.9980357**
Inv. Cosine				92.8821848	92.14158221	3.591804205
Locator 2						
Measurement 1	9.077293	3.37007713	5.10958862	-0.050041713	-0.034699243	0.9981442
2	9.076652	3.37050986	5.109376	-0.05002476	-0.034755997	0.9981431
3	9.080554	3.373424	5.109915	-0.050090324	-0.03480927	0.9981379
Mean	**9.078166333**	**3.371336997**	**5.10962654**	**-0.050052266**	**-0.034754837**	**0.998141733**
Inv. Cosine				92.86898236	91.99170658	3.493485648
Model D						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	0.07115975	-1.79817557	29.96105	0.040873848	-0.009276731	-
2	0.075307816	-1.79748166	29.9623	0.04061139	-0.009347932	0.999121249
3	0.07335189	-1.79338956	29.96169	0.04065285	-0.009542545	0.999127746
Mean	**0.073233783**	**-1.797828615**	**29.961675**	**0.040712696**	**-0.009312332**	**0.999121249**
Inv. Cosine				87.66668946	90.53356503	2.402162343
Locator 2						
Measurement 1	11.9001541	1.41252017	29.91494	-0.003882894	-0.026476763	0.9996419
2	11.929101	1.39530635	29.6130333	-0.006588763	-0.023724843	0.999696851
3	11.9276867	1.39721382	29.61227	-0.006677191	-0.023851944	0.9996932
Mean	**11.9189806**	**1.401680113**	**29.71341443**	**-0.005716283**	**-0.024684517**	**0.999677317**
Inv. Cosine				90.32752067	91.41446231	1.455584265
Model E						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	0.266090274	0.683019638	29.8070374	-0.004348896	0.017843783	0.9998314
2	0.260765046	0.6836649	29.80415	-0.003927157	0.017662818	0.9998363
3	0.223520249	0.6831682	29.8072338	-0.004004525	0.017758997	0.9998343
Mean	**0.25012519**	**0.683284246**	**29.8061404**	**-0.004093526**	**0.017755199**	**0.999834**
Inv. Cosine				90.23454242	88.98264858	1.043993229
Locator 2						
Measurement 1	12.7230368	0.544479251	29.6262741	0.003856252	-0.021182466	0.9997682
2	12.7226858	0.544491768	29.6253815	0.003908264	-0.02126723	0.999766231
3	12.68446	0.5459896	29.6283417	0.003897695	-0.021258935	0.9997664
Mean	**12.71006087**	**0.544986873**	**29.62666577**	**0.003887404**	**-0.021236211**	**0.999766944**
Inv. Cosine				89.7772676	91.21683674	1.237018542

Table 27: Raw CMM data - conventional bar samples

CAD/CAM samples						
Repeatability tests	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	1.48932493	-1.19839668	6.07321072	-0.004035588	0.001840574	0.999990165
Measurement 2	1.455283	-1.22220731	6.074357	-0.006487267	0.00539958	0.9999644
Measurement 3	1.47221887	-1.14832747	6.07416725	-0.004034259	0.000283078	0.999991834
Measurement 4	1.47062	-1.21227729	6.07422638	-0.002989093	0.002658911	0.999992
SLM solutions						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-6.667356	-3.09097362	5.02361774	0.011252804	-0.023306554	0.999665
2	-6.665765	-3.08872771	5.028474	0.011444452	-0.023242157	0.999664366
3	-6.660027	-3.08528686	5.03284645	0.011341343	-0.023383962	0.9996622
Mean	**-6.664382667**	**-3.088329397**	**5.02831273**	**0.0113462**	**-0.023310891**	**0.999663855**
Inv. Cosine				89.34989668	91.33573666	1.485638428
Locator 2						
Measurement 1	4.199254	2.73647022	5.364216	-0.015736152	-0.060330056	0.998054445
2	4.195402	2.740325	5.368783	-0.015275407	-0.060471214	0.9980531
3	4.20082	2.74515724	5.373294	-0.01545676	-0.060500313	0.9980485
Mean	**4.198492**	**2.74065082**	**5.368764333**	**-0.015489439**	**-0.060433861**	**0.998052015**
Inv. Cosine				90.88751497	93.46471636	3.576851909
Dental Cast						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	0.815416336	7.008565	5.39143658	-0.009858498	-0.05004586	0.9986983
2	0.8104445	7.00554228	5.39108	-0.01058819	-0.04983695	0.9987013
3	0.808562338	6.996936	5.390607	-0.010516054	-0.049905065	0.9986986
Mean	**0.811474391**	**7.003681093**	**5.391041193**	**-0.010320914**	**-0.049929292**	**0.9986994**
Inv. Cosine				90.59135531	92.86192765	2.922513908
Locator 2						
Measurement 1	3.02928042	-5.17290068	5.062252	-0.007636156	-0.018613959	0.9997976
2	3.0205555	-5.16741228	5.06201839	-0.008130751	-0.018680869	0.999792457
3	3.0226655	-5.173794	5.061922	-0.008190251	-0.018697899	0.9997916
Mean	**3.02416714**	**-5.171368987**	**5.06206413**	**-0.007985719**	**-0.018664242**	**0.999793886**
Inv. Cosine				90.45755286	91.06944439	1.163319039
Polished JIIC						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	5.39450026	-3.45344257	4.832552	-0.020391798	-0.015587556	0.999670565
2	5.39034128	-3.45430946	4.83079052	-0.020264402	-0.015378392	0.9996764
3	5.38918352	-3.44691586	4.83051872	-0.02020803	-0.015420132	0.9996769
Mean	**5.391341687**	**-3.451555963**	**4.83128708**	**-0.020288077**	**-0.015462027**	**0.999674622**
Inv. Cosine				91.16250094	90.88594419	1.461650365
Locator 2						
Measurement 1	-6.25544643	0.9661599	4.64102	-0.024143603	-0.01457262	0.9996023
2	-6.254311	-	4.6405344	-0.024157276	-0.014375194	0.9996048

3	-6.26179838	0.9652044	4.640169	-0.024101604	-0.014417263	0.999605536
Mean	**-6.25718527**	**0.96568215**	**4.640574467**	**-0.024134161**	**-0.014455026**	**0.999604212**
Inv. Cosine				91.38291984	90.82824083	1.612067664
PEEK Invibio						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-5.933495	1.34059739	5.153611	-0.014835735	-0.020923408	0.999671042
2	-5.931427	1.3277421	5.14981	-0.014786919	-0.021048578	0.999669135
3	-5.93248367	1.32629347	5.14810467	-0.014983136	-0.021188408	0.999663234
Mean	**-5.932468557**	**1.33154432**	**5.150508557**	**-0.014868597**	**-0.021053464**	**0.999667804**
Inv. Cosine				90.85193925	91.20636376	1.476885589
Locator 2						
Measurement 1	5.35120773	-4.160986	5.15440655	-0.004458002	-0.027644739	0.999607861
2	5.35056067	-4.188043	5.15082	-0.004901414	-0.027480882	0.9996103
3	5.353205	-4.181151	5.14969254	-0.005065462	-0.027335297	0.9996135
Mean	**5.3516578**	**-4.176726667**	**5.151639697**	**-0.004808293**	**-0.027486973**	**0.999610554**
Inv. Cosine				90.27549596	91.57508593	1.599098992
Mlab Cusing middle						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-5.342219	3.036397	5.43038559	-0.036420047	-0.065445155	0.9971913
2	-5.325428	3.03734827	5.43959045	-0.036663696	-0.0655217	0.997177362
3	-5.34476757	3.031948	5.444002	-0.03649734	-0.06536804	0.9971936
Mean	**-5.337471523**	**3.03523109**	**5.43799268**	**-0.036527028**	**-0.065444965**	**0.997187421**
Inv. Cosine				92.09331021	93.75240216	4.298251647
Locator 2						
Measurement 1	4.557797	-4.636803	5.55559349	-0.063937254	-0.072003976	0.9953529
2	4.549645	-4.634437	5.56343	-0.064127296	-0.07220387	0.9953262
3	4.55284834	-4.637316	5.568923	-0.06412131	-0.07215667	0.995330036
Mean	**4.553430113**	**-4.636185333**	**5.56264883**	**-0.064061954**	**-0.072121505**	**0.995336379**
Inv. Cosine				93.67299481	94.13584859	5.535644367
Electroformed 1						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	1.784574	-7.902546	4.908387	-0.001792447	-0.025423797	0.999675155
2	1.77893639	-7.899516	4.9085207	-0.001122662	-0.025442889	0.9996757
3	1.774782	-7.9038806	4.908266	-0.000936338	-0.025373334	0.9996776
Mean	**1.779430797**	**-7.901980867**	**4.908391233**	**-0.001283815**	**-0.02541334**	**0.999676152**
Inv. Cosine				90.0735572	91.4562339	1.458209627
Locator 2						
Measurement 1	0.431252629	4.68645334	5.18960762	0.017724803	0.004961531	0.9998306
2	0.4351718	4.6838975	5.189536	0.018074552	0.005104228	0.99982363
3	0.432817459	4.682756	5.189502	0.018194957	0.005173868	0.999821067
Mean	**0.433080629**	**4.684368947**	**5.18954854**	**0.017998104**	**0.005079875**	**0.999825099**
Inv. Cosine				88.96872892	89.70894335	1.071618263
DMLS Renishaw 1						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-4.287	4.054083	5.11558247	-0.029587872	-0.010774881	0.999504149

2	-4.292683	4.05171	5.11391926	-0.029581843	-0.010528075	0.99950695
3	-4.27728271	4.04406929	5.114813	-0.029641667	-0.011278968	0.999496937
Mean	**-4.285655237**	**4.049954097**	**5.114771577**	**-0.029603794**	**-0.010860641**	**0.999502679**
Inv. Cosine				91.6964203	90.62228113	1.807066062
Locator 2						
Measurement 1	3.61714435	-5.714258	5.15222263	0.003762129	-0.053766344	0.9985465
2	3.620955	-5.708709	5.15119934	0.003834889	-0.053832274	0.998542666
3	3.62147713	-5.716924	5.15036774	0.003554064	-0.05373389	0.998549
Mean	**3.619858827**	**-5.713297**	**5.151263237**	**0.003717027**	**-0.053777503**	**0.998546055**
Inv. Cosine				89.78702955	93.08271105	3.090041082
Crommert Accura 25						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-2.33381987	6.711139	5.18457127	-0.065469556	-0.03445353	0.9972596
2	-2.3242712	6.705675	5.18286228	-0.06631013	-0.034724288	0.997194648
3	-2.333262	6.71020269	5.18141651	-0.06598952	-0.035183005	0.9971999
Mean	**-2.330451023**	**6.709005563**	**5.18295002**	**-0.065923069**	**-0.034786941**	**0.997218049**
Inv. Cosine				93.77985479	91.99354712	4.274773436
Locator 2						
Measurement 1	4.54319525	-3.93178368	5.00115776	-0.037987806	-0.08368548	0.9957679
2	4.54219866	-3.9317894	4.999898	-0.038238686	-0.083542384	0.995770335
3	4.53900433	-3.93412256	4.99895763	-0.03842818	-0.083394244	0.9957754
Mean	**4.54146608**	**-3.932565213**	**5.000004463**	**-0.038218224**	**-0.083540703**	**0.995771212**
Inv. Cosine				92.19027635	94.79211483	5.271069599
Vac Cast black 1						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	7.46693945	-2.57393622	5.396187	-0.004445525	-0.05097313	0.9986901
2	7.46152163	-2.57210064	5.393792	-0.004405302	-0.051207267	0.9986783
3	7.46055269	-2.57442355	5.392706	-0.004323131	-0.051274497	0.9986752
Mean	**7.46300459**	**-2.573486803**	**5.394228333**	**-0.004391319**	**-0.051151631**	**0.9986812**
Inv. Cosine				90.25160485	92.93205213	2.942895494
Locator 2						
Measurement 1	-3.56314087	-8.493595	4.9557457	-0.03733794	-0.044289097	0.998320758
2	-3.56595	-8.490905	4.9536314	-0.037242644	-0.044149168	0.998330534
3	-3.56482625	-8.493638	4.9529686	-0.037288245	-0.04408596	0.9983316
Mean	**-3.56463904**	**-8.492712667**	**4.954115233**	**-0.037289609**	**-0.044174742**	**0.998327631**
Inv. Cosine				92.13703267	92.53185018	3.314089465
SLA Accura Xtreme PDR						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-5.90057468	1.66541183	5.247658	-0.034723043	-0.048751894	0.9982072
2	-5.893026	1.67128134	5.24768734	-0.0346933	-0.048961215	0.998198
3	-5.892255	1.67191648	5.247244	-0.034734786	-0.048757184	0.9982065
Mean	**-5.895285227**	**1.66953655**	**5.24752978**	**-0.034717043**	**-0.048823431**	**0.9982039**
Inv. Cosine				91.98953983	92.7984891	3.43453472
Locator 2						
Measurement 1	5.85763	-2.63588762	5.51396751	-0.04273086	-0.048258506	0.997920454
2	5.85384369	-2.62620473	5.51353	-0.042790465	-0.04856893	0.9979028

3	5.856216	-2.62780237	5.513337	-0.0428719	-0.04860463	0.9978976
Mean	**5.855896563**	**-2.629964907**	**5.513611503**	**-0.042797742**	**-0.048477355**	**0.997906951**
Inv. Cosine				92.45287918	92.77863689	3.707687366
WIC100 EnvisionTec						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-3.503009	5.86106157	5.215578	-0.09615671	0.017321633	0.9952155
2	-3.54311681	5.93413639	5.195616	-0.09136707	0.007399171	0.9957898
3	-3.53608274	5.915867	5.198107	-0.092292026	0.008747005	0.995693564
Mean	**-3.52740285**	**5.90368832**	**5.203100333**	**-0.093271935**	**0.011155936**	**0.995566288**
Inv. Cosine				95.35186733	89.36079869	5.397367155
Locator 2						
Measurement 1	7.203513	0.6276981	5.26888752	-0.025146144	-0.046599496	0.9985971
2	7.20025539	0.624716341	5.2675705	-0.025414936	-0.047088984	0.998567343
3	7.200338	0.6238138	5.26693058	-0.025552278	-0.047412984	0.9985485
Mean	**7.201368797**	**0.625409414**	**5.2677962**	**-0.025371119**	**-0.047033822**	**0.998570981**
Inv. Cosine				91.45381404	92.69583406	3.063432837
Crommert Duraform EX						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-3.8042016	-6.272685	5.09251976	-0.08466153	-0.00815453	0.9963764
2	-3.78854656	-6.26470566	5.09083843	-0.084088996	-0.007957299	0.996426463
3	-3.798212	-6.26678228	5.08710575	-0.08363237	-0.007942281	0.996465
Mean	**-3.79698672**	**-6.268057647**	**5.090154647**	**-0.084127632**	**-0.008018037**	**0.996422621**
Inv. Cosine				94.82586218	90.4594046	4.847855446
Locator 2						
Measurement 1	-0.6084106	5.78317928	5.512973	-0.08892572	0.003357943	0.9960326
2	-0.6013586	5.77805042	5.510147	-0.08859021	0.003180646	0.9960631
3	-0.604091465	5.77311039	5.50857449	-0.088542946	0.002831245	0.996068358
Mean	**-0.604620222**	**5.778113363**	**5.51056483**	**-0.088686292**	**0.003123278**	**0.996054686**
Inv. Cosine				95.08803494	89.82104906	5.09121346
VeroWhite Connex 500 Bibb						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-3.37333	8.468793	5.18867874	-0.06375469	-0.015619918	0.9978434
2	-3.37795615	8.469822	5.184868	-0.06437561	-0.01599654	0.997797549
3	-3.37597442	8.46329	5.18314266	-0.06468861	-0.016115004	0.9977754
Mean	**-3.375753523**	**8.467301667**	**5.185563133**	**-0.06427297**	**-0.015910487**	**0.99780545**
Inv. Cosine				93.6851101	90.91164222	3.796556135
Locator 2						
Measurement 1	-8.092677	-3.16193748	4.76576042	-0.069823675	-0.024163347	0.99726665
2	-8.100347	-3.16362548	4.762244	-0.06998429	-0.02381253	0.997263849
3	-8.102751	-3.159371	4.760007	-0.07016416	-0.02366199	0.9972548
Mean	**-8.098591667**	**-3.161644653**	**4.762670473**	**-0.069990708**	**-0.023879289**	**0.997261766**
Inv. Cosine				94.01345352	91.36831254	4.24103698
Durus White - N Bunt						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-1.29199767	-5.99783373	5.043338	0.001012348	-0.061784994	0.998088956

2	-1.286725	-5.99748373	5.04707432	0.001810533	-0.06253465	0.998041153
3	-1.288905	-5.99760628	5.04982853	0.0018731	-0.06267835	0.998032033
Mean	**-1.289209223**	**-5.997641247**	**5.04674695**	**0.001565327**	**-0.062332665**	**0.998054047**
Inv. Cosine				89.91031333	93.57371538	3.574985257
Locator 2						
Measurement 1	0.09067887	6.61273241	5.39966965	0.043462567	0.027204055	0.998684645
2	0.100211918	6.604288	5.402417	0.044225384	0.027677866	0.9986381
3	0.08746904	6.605746	5.40590668	0.044426747	0.027802639	0.9986257
Mean	**0.092786609**	**6.607588803**	**5.402664443**	**0.044038232**	**0.02756152**	**0.998649482**
Inv. Cosine				87.47597889	88.42064123	2.978082384
ABS-like Objet 30 Bunt						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-4.456643	2.84641886	4.98431873	-0.003889548	0.007952628	0.99996084
2	-4.459505	2.84460068	4.98185539	-0.004271118	0.007536551	0.9999625
3	-4.465374	2.846392	4.980891	-0.004448124	0.007404152	0.9999627
Mean	**-4.460507333**	**2.845803847**	**4.98235504**	**-0.00420293**	**0.007631111**	**0.999962013**
Inv. Cosine				90.24081086	89.5627653	0.49940916
Locator 2						
Measurement 1	1.59400284	-8.13357449	4.872367	-0.001201736	-0.02054981	0.9997881
2	1.59189665	-8.146427	4.870161	-0.001530866	-0.020501886	0.999788642
3	1.59114027	-8.148414	4.86922	-0.001655459	-0.020445168	0.9997896
Mean	**1.592346587**	**-8.142805163**	**4.870582667**	**-0.001462687**	**-0.020498955**	**0.999788781**
Inv. Cosine				90.08380582	91.17458588	1.177637878
Objet ABS-like IPF						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-2.055258	7.436754	5.00223637	-0.024066899	0.00032991	0.9997103
2	-2.053718	7.46892166	5.007721	-0.024405738	0.000178948	0.999702156
3	-2.05571485	7.43853474	5.01116276	-0.0242754	0.000306048	0.999705255
Mean	**-2.05489695**	**7.448070133**	**5.007040043**	**-0.024249346**	**0.000271635**	**0.999705904**
Inv. Cosine				91.38952138	89.98443646	1.389609688
Locator 2						
Measurement 1	-3.17792273	-5.077815	4.74719334	-0.039259695	-0.044971228	0.998216569
2	-3.16912317	-5.073182	4.754506	-0.039409097	-0.04494276	0.998212
3	-3.1659143	-5.077939	4.7582407	-0.03943503	-0.044999167	0.9982084
Mean	**-3.170986733**	**-5.076312**	**4.753313347**	**-0.039367941**	**-0.044971052**	**0.998212323**
Inv. Cosine				92.25619991	92.57752077	3.426469544
Unpolished casting JIIC						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	4.48578167	2.97587633	10.0579166	-0.053406846	0.010576641	0.998516858
2	4.475881	2.975409	10.0596914	-0.052813828	0.010839142	0.9985456
3	4.48168564	2.971437	10.0604277	-0.053474814	0.010851054	0.998510242
Mean	**4.481116103**	**2.974240777**	**10.05934523**	**-0.053231829**	**0.010755612**	**0.998524233**
Inv. Cosine				93.05140139	89.38373694	3.11314932
Locator 2						
Measurement 1	-6.34270573	-3.228755	9.660302	-0.05047137	0.02477609	0.998418152
2	-6.34760952	-3.22585344	9.661804	-0.050502352	0.024816096	0.9984156

3	-6.34282637	-3.227258	9.663354	-0.050513376	0.024729224	0.9984172
Mean	**-6.34438054**	**-3.227288813**	**9.66182**	**-0.050495699**	**0.024773803**	**0.998416984**
Inv. Cosine				92.89442137	88.58042041	3.22431594
Electroformed 2						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-1.20754087	-6.40980244	9.71155548	-0.03389703	-0.022817735	0.9991648
2	-1.20793009	-6.407445	9.710537	-0.03403548	-0.022729004	0.999162138
3	-1.22922969	-6.39961433	9.710346	-0.03383472	-0.022932727	0.999164343
Mean	**-1.214900217**	**-6.40562059**	**9.710812827**	**-0.03392241**	**-0.022826488**	**0.99916376**
Inv. Cosine				91.94398388	91.30797503	2.343329545
Locator 2						
Measurement 1	1.49526727	5.75051832	10.0890884	-0.016926538	-0.01578196	0.9997322
2	1.5011425	5.756731	10.0882483	-0.016750515	-0.016361343	0.9997258
3	1.49632311	5.758879	10.0884666	-0.01688462	-0.016266452	0.999725163
Mean	**1.497577627**	**5.755376107**	**10.0886011**	**-0.016853891**	**-0.016136585**	**0.999727721**
Inv. Cosine				90.96570254	90.92459835	1.337071274
DMLS Renishaw 2						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	0.062301736	-6.516351	9.789459	-0.002036206	-0.038541544	0.999254942
2	0.06330964	-6.51627	9.786978	-0.001630212	-0.03875665	0.9992474
3	0.066756815	-6.52086	9.786136	-0.001644155	-0.038739435	0.999248
Mean	**0.06412273**	**-6.517827**	**9.787524333**	**-0.001770191**	**-0.03867921**	**0.999250114**
Inv. Cosine				90.10142453	92.21670845	2.219026027
Locator 2						
Measurement 1	1.3434881	5.97181845	10.3163528	0.014748333	-0.03391734	0.999315858
2	1.34813321	5.97041273	10.3121977	0.014983688	-0.033860635	0.999314249
3	1.34903753	5.970716	10.3119926	0.014856014	-0.033891577	0.9993151
Mean	**1.34688628**	**5.970982393**	**10.31351437**	**0.014862678**	**-0.033889851**	**0.999315069**
Inv. Cosine				89.14839992	91.94211731	2.120732213
Zirconia Renishaw						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-1.65344715	-8.417828	9.17807	-0.016864158	-0.019071095	0.9996759
2	-1.65068078	-8.402802	9.178987	-0.016642833	-0.01918991	0.99967736
3	-1.65939808	-8.406881	9.178963	-0.01651664	-0.018946588	0.9996841
Mean	**-1.65450867**	**-8.409170333**	**9.178673333**	**-0.016674544**	**-0.019069198**	**0.99967912**
Inv. Cosine				90.95542527	91.09265079	1.451511792
Locator 2						
Measurement 1	-5.53711939	3.33816075	9.381584	-0.019203907	-0.010643829	0.999758959
2	-5.53910446	3.34884262	9.382619	-0.018911036	-0.01056953	0.999765337
3	-5.53173828	3.34606051	9.38263	-0.019111622	-0.01036995	0.9997636
Mean	**-5.535987377**	**3.344354627**	**9.382277667**	**-0.019075522**	**-0.01052777**	**0.999762632**
Inv. Cosine				91.0930132	90.60320793	1.248410195
3DDC metalised						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	-2.81988621	6.02150631	9.500868	-0.033023585	-0.027246516	0.9990831

2	-2.82420874	6.015093	9.499893	-0.032648347	-0.027318798	0.9990935
3	-2.81576061	6.00998831	9.499798	-0.032714494	-0.027030503	0.9990992
Mean	**-2.819951853**	**6.015529207**	**9.500186333**	**-0.032795475**	**-0.027198606**	**0.999091933**
Inv. Cosine				91.8793793	91.55855753	2.441908836
Locator 2						
Measurement 1	4.53431368	-4.28424025	9.437201	-0.014668288	-0.040104162	0.99908787
2	4.53458643	-4.286747	9.436458	-0.014719807	-0.040122923	0.9990863
3	4.536236	-4.286911	9.436174	-0.014613872	-0.040165875	0.999086142
Mean	**4.53504537**	**-4.285966083**	**9.436611**	**-0.014667322**	**-0.040130987**	**0.999086771**
Inv. Cosine				90.84040578	92.29995381	2.448840695
Fcubic						
Locator 1	**X**	**Y**	**Z**	**I**	**J**	**K**
Measurement 1	6.754476	-0.07186882	9.551553	-0.036373913	-0.01832576	0.999170244
2	6.761737	-0.055052042	9.553429	-0.036526613	-0.01782279	0.99917376
3	6.75238657	-0.06728786	9.552522	-0.036588736	-0.017863022	0.9991708
Mean	**6.756199857**	**-0.064736241**	**9.552501333**	**-0.036496421**	**-0.018003857**	**0.999171601**
Inv. Cosine				92.09155539	91.03160076	2.332316037
Locator 2						
Measurement 1	-3.72472334	-6.88960028	9.194904	-0.027343169	-0.018647509	0.9994522
2	-3.732902	-6.88758039	9.194829	-0.027447281	-0.018517025	0.999451756
3	-3.72347736	-6.898882	9.195077	-0.02752385	-0.018225651	0.999455
Mean	**-3.727034233**	**-6.89202089**	**9.194936667**	**-0.0274381**	**-0.018463395**	**0.999452985**
Inv. Cosine				91.57228465	91.05793472	1.895208725

Table 28: Raw CMM data – CAD/CAM samples

Appendix VI.5 Retention force values

		Attachment											
		Varying Arm Thickness				Varying Gap Size					Gold clips		
		a	b	c	d	e	f	g	h	i	Narrow	Mid	Wide
Test 1	1	0.57	2.79	5.30	7.28	3.73	2.95	1.71	0.98	0.36	11.14	7.54	2.94
	2	0.58	2.84	5.31	7.39	3.70	2.92	1.74	0.98	0.37	11.09	7.53	3.07
	3	0.59	2.86	5.25	7.29	3.68	2.94	1.76	0.97	0.37	11.21	7.48	3.11
Test 2	1	0.68	2.99	4.62	5.70	4.35	3.02	1.98	1.68	0.66	11.24	4.96	0.19
	2	0.69	2.90	4.74	5.69	4.43	3.03	2.00	1.70	0.67	11.22	4.44	0.24
	3	0.66	2.88	4.81	5.68	4.44	3.04	2.01	1.71	0.68	11.28	4.44	0.41
Test 3	1	0.66	3.82	5.17	6.32	2.96	4.07	2.18	1.47	0.58	14.20	9.34	2.83
	2	0.67	3.85	5.11	6.20	2.93	4.12	2.19	1.47	0.56	13.66	9.44	2.77
	3	0.68	3.88	5.04	6.05	2.91	4.04	2.18	1.48	0.54	13.76	9.74	2.69
Min		0.57	2.79	4.62	5.68	2.91	2.92	1.71	0.97	0.36	11.09	4.44	0.19
Max		0.69	3.88	5.31	7.39	4.44	4.12	2.19	1.71	0.68	14.20	9.74	3.11
Mean		0.64	3.20	5.04	6.40	3.68	3.35	1.97	1.38	0.53	12.09	7.21	2.03
SD		0.05	0.49	0.26	0.73	0.64	0.55	0.19	0.32	0.13	1.35	2.14	1.32

		Removal											
		Varying Arm Thickness				Varying Gap Size					Gold clips		
		a	b	c	d	e	f	g	h	i	Narrow	Mid	Wide
Test 1	1	0.56	2.95	5.36	7.42	3.62	3.10	2.02	0.90	0.27	11.70	13.80	4.16
	2	0.57	3.04	5.43	7.67	3.62	3.18	2.03	0.91	0.27	11.31	13.39	6.13
	3	0.56	3.04	5.33	7.47	3.63	3.20	2.01	0.90	0.26	12.30	12.88	4.97
Test 2	1	0.62	3.12	4.56	6.28	4.60	3.53	2.17	1.78	0.77	12.44	6.32	0.20
	2	0.76	3.30	4.55	6.22	4.59	3.52	2.19	1.80	0.77	17.38	10.07	0.21
	3	0.74	3.31	4.55	6.25	4.60	3.51	2.19	1.81	0.77	18.75	9.46	0.21
Test 3	1	0.77	4.32	5.54	6.65	3.16	4.14	2.46	1.46	0.65	10.61	6.03	1.44
	2	0.77	4.42	5.44	6.50	2.92	4.24	2.52	1.47	0.63	14.48	13.68	2.79
	3	0.78	4.43	5.39	6.46	2.87	4.20	2.54	1.48	0.60	15.32	14.09	2.69
Min		0.56	2.95	4.55	6.22	2.87	3.10	2.01	0.90	0.26	10.61	6.03	0.20
Max		0.78	4.43	5.54	7.67	4.60	4.24	2.54	1.81	0.77	18.75	14.09	6.13
Mean		0.68	3.55	5.13	6.77	3.73	3.62	2.24	1.39	0.55	13.81	11.08	2.53
SD		0.10	0.64	0.44	0.58	0.71	0.46	0.21	0.39	0.22	2.85	3.23	2.21

Table 29: Clip peak retention forces