The Computer Aided Design and Fabrication of Facial Prostheses

Within the discipline of Design

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Abstract

Maxillofacial prosthetics is a specialised profession that seeks to meet the needs of patients with various degrees of facial deformity by restoring aesthetic and functional portions of missing tissue using artificial materials. The maxillofacial prosthetics specialty is relatively small compared to other healthcare professions and technological developments are often denied to them, as commercial companies cannot recoup the investment required from such a small market. Therefore many of their practices are inherently labour intensive, requiring inordinate amounts of skill and training to become competent.

Faced with increasing case numbers and a reduced number of new prosthetists entering the profession, there is urgency to update techniques in order to improve efficiency. The need to embrace technological development is clear.

The profession has a long and well-documented history of adopting, adapting and improving on existing technologies found in industry. For example, Computer Aided Design (CAD) and Rapid Prototyping (RP) have been successfully used for many years to assist maxillofacial surgery. However, the application of these technologies for soft tissue prostheses has proved more complicated and very few people have concentrated research efforts in the area.

This research critically evaluates and develops the current capabilities of technologies that may be used to assist in the production of soft tissue facial prostheses. Case study, action research methods were used to critically evaluate technologies in terms quality, economics and clinical viability. Technological limitations have been challenged and case studies in this thesis incorporate gradually more complex aspects of prosthesis design, such as implant retention mechanism design and fabrication and texture creation. Conclusions on the current capabilities, limitations and required future developments are made. The research culminates in a specification, against which developers may measure their technologies and towards which they may develop them to meet the needs of the profession and UK health service.

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Glossary of terms

3D Systems	A USA based company who produce Stereolithography equipment.
3D Studio software	3D CAD software for animation and rendering. By Discreet (part of Autodesk inc.).
AAA	American Anaplastologists Association.
Anutex	A type 1 baseplate or modelling wax by Kemdent. As used for carving prosthesis patterns in the Maxillofacial Laboratory at Morriston Hospital.
ArtCAM	Jewellery design CAD software. By Delcam
Auricular	Ear
Autopolymerising acrylic	Can also be called self or cold cure acrylic. Typically provided in a powder with a separate liquid component. The powder consists primarily of a polymer with approximately 1% peroxide to initiate a reaction. The liquid is principally a monomer with inhibitor to prevent it polymerising. [Craig *et al*, 1996]
Baseplate wax	Baseplate waxes are typically 70-80% paraffin based or commercial cerecin with small quantities of other waxes and additives [Craig *et al*, 1996]. Type 1 is typically used for prosthesis patterns. It is pliable, easy to form and sticks to itself well, making it ideal for shaping prosthesis patterns. They are typically specified by ISO standard 15854:2005.
Boolean	Boolean logic mathematical code which governs logical functions (true/false). Developed by George Boole in the mid-19th century. Used in CAD solid modelling to unite two parts, subtract one from another or create a new part passed upon the intersection of two others.
Breuckmann	Manufacturer of 3D digitising equipment. Known for the Opto TOP-HE, DermaTOP, FaceScan and BodySCAN ranges.
C	Carbon
CAD	Computer Aided Design
CEREC	A system for the fabrication of ceramic dental restorations using CAD/CAM technology. By Sirona
CNC	Computer Numerically Controlled machining.
Comet 250	Steinbichler 3D digitiser.
COMPRU	Craniofacial Osseointegration and Maxillofacial Rehabilitation Unit. Based at the University of Alberta, Canada.
Cosmesil	Maxillofacial prosthesis rubber. By Principality Medical.
CT	Computer Tomography scanning. A primarily medical scanning method that produces axial slice, pixel computer images.
Cyberware	Manufacturers of 3D digitising equipment and software developers.
Delcam	CAD / CAM software developer
Dental stone	Typically a gypsum-based plaster that is mixed as a dry powder with water to form a low viscosity slurry, which sets hard. Dental stone replicas are often worked on for initial shaping of a prosthesis pattern. Dental stone is also commonly used as the mould material since it picks up high levels of detail.
DSM Somos	Developer of Stereolithography and other materials.
Exenteration	Removal of the entire contents of the orbit, including the extraocular muscles.
Haptic	The sensation of touch.
Haversian (haversian canal)	The network of channels in bone that contain blood vessels and nerves.

EOS GmbH	Electro Optical Systems. A German based producer of rapid prototyping machines.
EnvisionTec	RP machine manufacturer. Known for the Perfactory machine.
Faro	A Swiss based company who design and manufacture reverse engineering equipment such as scanners and measuring arms.
FDA	Food and Drugs Administration.
FDM	Fused Deposition Modelling. An RP process that builds in plastic
Fe	Iron metal
Flask	A typically metal alloy case or tube used to bolster dental stone mould sections.
Flasking	The process of converting a wax pattern into a mould using a flask.
FreeForm	A CAD package manufactured by SensAble Technologies Inc.
Helisys inc.	USA based manufacturer of the LOM RP system.
IMAlign	Software used to align point cloud data from 3D digitisers. By InnovMetric Software Inc.
IMPT	Institute for Maxillofacial Prosthetists and Technologists.
InduraCast	The build material used in the Solidscape RP process.
InSpeck	Manufacturer of 3D digitising equipment. Known for the Mega Capturor.
ISMR	International Society for Maxillofacial Rehabilitation
Kemdent	Supplier of dental wax materials based in the UK.
Konica-Minolta	Manufacturers of digital equipment such as cameras and 3D digitisers. Known for the Vivid range of digitisers.
LOM	Laminated Object Manufacture. An RP process that builds in paper.
Magics	STL manipulation software by Materialise.
Materialise	A software developer and supplier of rapid prototyping services based in Belgium.
Maxillofacial (surgery)	Surgical specialty concerned with the diagnosis and treatment of diseases affecting the mouth, jaws, face and neck.
Mimics	Software for reading in CT/MRI data and outputting 3D CAD data for integration in other software or RP technologies.
MPT	Maxillofacial Prosthetists and Technologist
MRI	Magnetic Resonance Imaging. Medical scanning technology.
N	Nitrogen
NURBS	Non-Uniform Rational B-Spline. Mathematical representations of 3D geometry that can accurately describe any shape from a simple 2D line, circle, arc, or curve to complex 3D organic free-form surface or solid.
O	Oxygen
Objet	Objet Geometries RP system that manufactures in a photopolymer.
Obturator	A device to replace a missing pallet. Designed to allow swallowing, speech and normal opening and closing of the mouth.
Osseointegration	A fixed, bone anchored retention method for attaching external or oral prostheses.
Osteomalacia	Softening of the bones caused by a deficiency of vitamin D.
Perfactory	Envisiontech RP machine that builds in a photopolymer material.
Phantom Desktop	A haptic interface developed by SensAble Technologies.
Photopolymerizable	A liquid resin that will undergo a state change when exposed to a given

	wavelength of light.
Photogrammetry	The technique of measuring objects (2D or 3D) from photogrammes.
Photoshop	Digital image manipulation software by Adobe Systems Inc.
Pixform Pro	A version of Rapidform reverse modelling software sold with the Roland DG, LPX-1200 scanner.
Principality Medical	Manufacturers of medical products. Known for Cosmesil silicone rubber.
Profilometry	A method of measuring micro surface topography, such as skin texture.
QuickCast	A Stereolithography build style used for components that will be cast.
Raindrop Geomagic	Software used in the processing of point cloud data from 3D digitisers. By Raindrop Geomagic Inc.
Rhabdomyosarcoma	A rhabdomyosarcoma is a type of cancer, specifically a sarcoma (cancer of connective tissues), in which the cancer cells are thought to arise from skeletal muscle progenitors
Rapidform	Software used in the processing of point cloud data from 3D digitisers. By Inus Technology Inc.
Rhino 3D	Rhinoceros 3D CAD software. NURRBS surface modeller. By Robert McNeel & Associates.
Roland DG	Manufacturers of electronic equipment. Known for the LPX range of 3D scanners.
RP	Rapid Prototyping.
RPD	Removable Partial Denture framework.
SensAble Technologies	Software developers. Known for the FreeForm CAD package.
SimPlant	Implant planning software by Materialise (Belgium)
SL	Stereolithography
SLA	Stereolithography Apparatus
SLC	Selective Layer Contour file format. Defines 3D objects by successive cross-sections taken at ascending Z intervals.
SLM	Selective Laser Melting. An RP process that builds in metal. By MCH-HEK, Germany.
SLA-250	A 3D Systems Stereolithography machine.
SLA-500	A 3D Systems Stereolithography machine.
SLS	Selective Laser Sintering. An RP process.
Solidscape	Solidscape inc. manufacturer of RP machines.
Spider	Software used in the processing of point cloud data from 3D digitisers. By Alias-Wavefront Inc.
Steinbichler Optotechnik	Manufacturers of 3D digitising equipment. Known for the Comet range of scanners.
STL	STereoLithography file format. Defines 3D volumes in faceted triangles.
SurgiGuides	A custom, patient-specific surgical guide produced by Materialise (Belgium) from Simplant software data.
Technovent	Manufacturers / suppliers of maxillofacial lab and surgery products such as implant fixtures and facial prosthesis silicones
ThermoJet	A 3D Systems RP system that builds in a wax material.
Ti	Titanium metal.
TJ-88 and TJ-2000	Wax materials for the ThermoJet RP machine.
TMJ	Temporal Mandibular Joint. Joint between the mandible (jaw bone) and the temporal bone at which the mouth opens and closes.
TPM	TriPropylene glycol Monomethylerther. Solvent used to clean Stereolithography parts.
Tube pedicle	A tube pedicle is a flap of skin sewn down its long edges, with one end left attached to the site of origin, the other is attached to the site to be grafted

UV	Ultraviolet light spectrum.
Voxel	A volumetric pixel. Voxels are commonly used to display medical imaging data (such as CT and MR) by stacking pixel images with depths equal to the slice thickness.
ZBrush	CAD package for animation and rendering. By Pixologic, Inc
Z-Corp	An RP systems that builds from a powder substrate.
ZEdit	A software tool designed to apply colour to CAD objects. Specifically designed for Z-Corp RP systems.

Chapter 1 - Introduction

Interest in the application of advanced computer-based technologies to medical applications has grown dramatically in the last decade. This has been driven by increased accessibility to high performance, computer-based technologies. Upon its initial conception, Computer Aided Design (CAD), Rapid Prototyping (RP) and surface scanning technologies in particular were only available to large companies and research organisations, typically in the wealthy and competitive aerospace and automotive sectors. As these technologies became more commercialised and affordable, bureau services began adopting them, making them more widely available.

The National Centre for Product Design & Development Research (PDR) in Cardiff was formed in 1994. PDR exists as a commercial and academic research centre for product design and manufacture with expertise in product and graphic design, RP, batch manufacturing, Computer Numerically Controlled (CNC) machining, reverse engineering and other industrial fabrication processes. PDR also undertake research into the design process, how it may be implemented and knowledge transfer, particularly within small companies.

The Medical Applications Group (MAG) in PDR was formed in 1998 with the task of adopting, developing and evaluating the application of product development technologies to medicine and rehabilitation.

MAG's work initially focussed on utilising existing software tools, medical, and surface scanning methods and engineering production methods such as RP to generate replicas of anatomical forms. It was quickly realised that maxillofacial surgeons were particularly interested in new technologies and techniques, most likely due to the complex nature of head anatomy and complex nature of surgical techniques. Once medical modelling had become an established and accepted process, the service was commercialised and made available to maxillofacial units nationwide. In 2006, over 200 models were provided to the UK National Health Service (NHS).

The complexity of human anatomy brings about many challenges for technologies designed for the creation, manipulation and production of geometric components. Overcoming these challenges is best achieved with clinical and technological expertise. Soon after MAGs conception, a research collaboration with the maxillofacial unit at Morriston Hospital was formed. Since then, the collaboration has pioneered and developed many successful applications of advanced design and manufacturing technology in the field of head and neck reconstruction and rehabilitation. In 2006, the Centre for Applied Reconstructive Technologies in Surgery (CARTIS) was established, providing a formal relationship between the two centres. CARTIS was established with 4 primary objectives:

- To become the pre-eminent UK centre for the research, development and application of advanced technologies in medicine
- To develop long-term international collaborations
- To provide specialised teaching and training in advanced technologies in medicine
- To assist in the transference of new techniques and approaches into clinical practice

The research described in this thesis began in March 2003. The researchers in MAG all came from a product design background, so there was a lot to learn about the fundamentals of anatomy, current research into the application of digital technologies for medical purposes and its challenges. MAG already had significant research expertise in the design of prostheses, where new technologies were beginning to replace conventional methods in clinical application. There was however a need to develop techniques and ensure their clinical focus. Amongst the areas that represented a significant challenge was soft-tissue facial prosthetics. The unique challenges of designing something as visible as a portion of face that required subtle detailing to appear realistic had eluded the capabilities of technology.

Facial prosthesis production is a highly specialised profession where the skills required occupy both science and craft. When compared to other medical specialties facial prosthesis production also represents a relatively small sector within the UK and indeed the worldwide health service. Figures quoted by the patient group, “Let’s Face It” stated that around 20,000 people in the UK

have a facial prosthesis (1:2900 pt/pop ratio) [according to personal communications with M Cutler, fellow of the Institute of Maxillofacial Prosthetists and Technologists, 25th November, 2005]. Each case is unique and a bespoke, fitted and colour matched device is provided to each patient making the production processes labour intensive. The production techniques used are also decades old. Although the techniques used for each case share similarities, they also involve unique challenges.

In order to establish maxillofacial prosthetics as a high value service within the health sector and for it to compete with the many other specialities for investment, the introduction of new, more efficient and high-value techniques must be introduced [Wolfaardt, *et al*, 2003]. It is recognised that for the profession to meet patient expectations whilst achieving healthcare service and budgetary targets, investment in advanced technologies must be considered.

The world-wide maxillofacial prosthetics field is faced with a number of challenges that must be tackled in order to meet patient and health service expectations. The challenges include:

- Increased patient numbers with few new staff entering the profession
- Lack of significant investment from industry and the government

A high proportion of patients requiring facial prostheses are cancer survivors. Survival rates of cancer patients have dramatically improved with advances in surgical techniques and treatment technologies, which has led to increased demand for prostheses. At the same time in the UK, it has been recognised that the number of newly qualified Maxillofacial Prosthetists and Technologists (MPTs) is only matching or is less than the number retiring, so fewer people are doing more work. This cannot be sustainable [Wolfaardt, *et al*, 2003].

Maxillofacial prosthetics is also a relatively small, comparatively low-value specialty within the healthcare systems. This means that it does not attract significant investment from industry and therefore lacks funding for research and development.

Some research groundwork had already been undertaken by MAG and other groups world-wide. A review of previous literature highlighted an increasing interest in digital methods, but the quantity of literature was still very low. Most of the literature centred on single case studies and gave little critical evaluation of the entire treatment process. Complex, yet fundamental aspects of prosthesis design such as texture detail and implant retention mechanisms had not been considered. A link between subjective assessment and quantified performance had also not been made. Economic implications had only been loosely considered in previous literature although this was clearly an important issue within a health care system. Much more in-depth development was required to ensure technologies and techniques were objectively evaluated and developed to meet the needs of the profession. This was backed up by the clinical experiences of the Maxillofacial lab at Morriston Hospital.

The application of digital technologies to soft-tissue facial prosthetics within the UK National Health Service (NHS) was therefore chosen as the area for this doctoral research.

Unlike previous research, case studies and experiments in this thesis incorporates gradually more complex aspects of prosthesis design, such as implant retention mechanism design and fabrication. Other, previously unexplored aspects important to digital prosthesis design including texturing are also evaluated.

This thesis evaluated a comprehensive range of appropriate and commercially available technologies. The results of multiple case studies and experiments were used to identify a specification, against which developers may measure their technologies and towards which they may develop them. The research in this thesis is presented in 8 chapters, beginning with a review of the maxillofacial prosthetics profession and current practices. Chapter 3 reviews computer-aided technologies and their application in facial prosthetics. The research methodology is described in chapter 4 and is followed by the results of a survey into current techniques within the UK NHS. Case studies and experiments are written up in chapter 6 and further discussions are

provided in chapter 7. Conclusions are made and future work is discussed in chapter 8. The target specification is also presented at the end of chapter 8.

Ch 2 – Maxillofacial Prosthetics

This chapter provides an introduction to the background of modern facial prosthetics, details on the profession and representing organisations, facial anatomy and conventional methods of prosthesis production including the techniques and materials used.

2.1 - Background

Maxillofacial prosthetics is a specialised profession that seeks to meet the needs of patients with various degrees of facial deformity by restoring aesthetic and functional portions of missing tissue using artificial materials. The practice of restoring lost tissue with prosthetic replacements precedes surgical attempts and even with recent advances in surgery there still remain many cases where prosthetic rehabilitation is more suitable and desirable to the patient involved. Figure 2.1 shows a case requiring an orbital prosthesis.

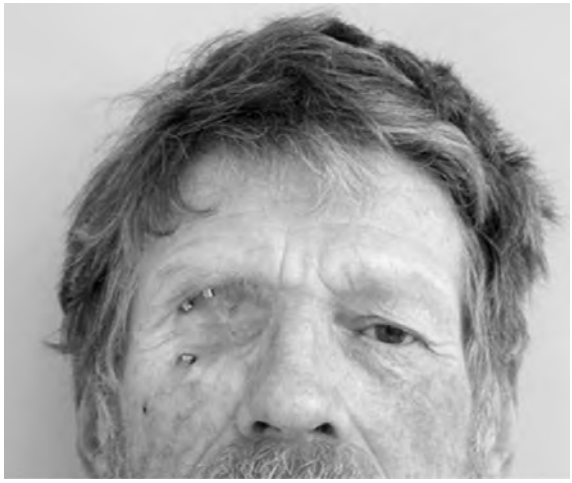


Figure 2.1. A patient with implants requiring an orbital prosthesis

Maxillofacial Prosthetists and Technologists (MPTs) treat a wide range of patients with conditions resulting from cancer treatment, traumatic injury (such as vehicle accidents), congenital deformity and other diseases that cause significant tissue damage. Not all of the work undertaken by MPTs is facial; it also includes fingers, hands, feet, toes, breasts and nipples since the construction

techniques involved are similar. MPTs are also typically involved in fabricating surgical guides, cranioplasty plates (figure 2.2), obturators and other custom head and face related devices. In many cases, they will also be involved with planning maxillofacial surgery.

Figure 2.2. A titanium cranioplasty plate on a stereolithography, replica skull model

Maxillofacial prosthetics has a history dating back hundreds of years, but became a specialist profession after the First World War when many soldiers survived with terrible facial injuries. This history is intertwined with the development of pioneering plastic surgery techniques. From 1914-1918 a pioneering plastic surgeon named Harold Gillies founded a team of facial surgeons, dentists, anaesthetists, radiologists, medical illustrators and sculptors [Kemp, 2004]. In 1916 the Queen's Hospital, dedicated to the application of pioneering techniques in facial reconstruction, opened in Sidcup to deal with the vast numbers of casualties created by the war. Pioneering techniques such as tube pedicles, muscle transfer, cartilage implants, splints and prostheses were developed. Slightly later in 1918, Francis Derwent Wood and Anna Coleman Ladd provided face mask production service for facial burns patients. From a London and Paris base, 67 masks were produced in 1918, and 153 in 1919 [Kemp 2004]. Masks were designed from portraits of the patient and produced on a plaster mould of the face. Features were hand painted on and the thin mask held in place with clips. They were notoriously uncomfortable.

In 1939 Archibald McIndoe (cousin of Harold Gillies) moved to the Queen Victoria Hospital, East Grinstead. He became the founder of the infamous 'guinea pigs club' who's selected members had suffered facial disfigurement from war wounds. Patients were provided with revolutionary treatment plans for burns therapy and by the end of World War Two there were 649 members.

The more modern history of facial prosthetics is discussed in chapter 2 part 5.

The demand for facial prosthetics has dramatically increased with the improved detection and surgical intervention of cancer, which can leave patients with significant portions of missing facial tissue. Major UK units such as Morriston Hospital in Swansea, Queen Elizabeth in Birmingham and Queen Victoria in East Grinstead provide facial prostheses to between 10 and 20 new patients per year. There are approximately 7 major units in the UK that provide these numbers of facial prostheses and many more smaller units that undertake work less frequently. Based upon these approximate figures for major units and excluding smaller units, between 70 and 140 new facial prostheses are provided to UK patients per year.

Realistic though prostheses can initially appear there are limitations in achieving a lifelike appearance since they are not living tissue. Prostheses will not tan or change colour when the surrounding anatomy does and it will remain static when the rest of the face moves. They will therefore be detectable upon close inspection.

2.2 - Profession details

2.2.1 – Representing organisations

Maxillofacial prosthetics is a relatively small sector when compared with other specialist medical professions. Figures quoted by the Institute of Maxillofacial Prosthetists and Technologists (IMPT) [in letter from M Cutler, 11th May, 2004] say there are 104 *recognised* units carrying out maxillofacial prosthetics and technology in England, Northern Ireland, Scotland and Wales. All

are NHS units except for 3 military establishments. In addition, there are an estimated 17 units carrying out maxillofacial prosthetics and technology that are not recognised/known to the IMPT. Estimate costs for the UK NHS to provide maxillofacial prosthetics are difficult to accurately establish, but are around £6.7-8.2 million per year. Costs in other countries are even more difficult to estimate, especially where the service is provided on a private basis or where the discipline is split into sub-categories.

There are three main organisations and institutes looking after the interests of the profession: The IMPT, the American Anaplastology Association (AAA) and the International Society for Maxillofacial Rehabilitation (ISMR). The IMPT is UK based with members in 20 countries. There are 205 practicing MPTs in England, Northern Ireland, Scotland and Wales, of which seventeen are *recognised* trainees below full membership level (Student IMPT/ Associate IMPT) (in 2005). There are an estimated additional 25 MPTs carrying out maxillofacial prosthetics and technology (either as qualified/unqualified staff or as trainees) that are not registered with or known to The IMPT. The IMPT also has 81 overseas members based in countries such as Australia, Brunei, Canada, Denmark, Eire, Germany, Hong Kong, India, Israel, Lebanon, Netherlands, New Zealand, Norway, Saudi Arabia, Singapore, South Africa, Sweden, Switzerland and USA.

The AAA is based in North America and has around 180 members. There are however many practicing prosthetists that are not registered, which makes establishing an accurate number very difficult.

The ISMR are an American based organisation who are committed to the advancement of the art and science in maxillofacial rehabilitation. There are around 150 members, most of which are based in North America, Asia and Europe. Specialities encompass: surgery, prosthodontics, speech pathology, anaplastology, dental oncology and radiation oncology. The ISMR organise biennial conferences and research programs with the aim to advance the education and development within the field. They also run outreach programs to provide rehabilitation in areas of the world that would not otherwise benefit.

2.2.2 - Training and skill requirements

UK

A prosthetist provides a service and product that must meet a number of demands, ranging from the technical and functional to the aesthetic and psychological. The skills required in prosthetic rehabilitation must therefore extend from the artistic and craft based, to interpersonal, clinical and scientific. In a working document (revised 23rd May, 2003) produced by the IMPT outlining fitness to practice, a practicing MPT will have undertaken a formally recognised course in dental technology, which may be one of the following: City & Guilds Final Certificate, BTEC ONC/OND, first degree BSc. In addition, the IMPT suggest that one or more of the following, formal qualifications should also have been attained by practicing MPTs: City & Guilds advanced Certificate (Maxillofacial), HNC/HND incorporating four maxillofacial units, University diploma in maxillofacial prosthetics & technology, IMPT Membership examination. Two years post qualification work should also be undertaken before obtaining fully qualified status.

In addition to the specific educational requirements, practicing MPTs are expected to adhere to a high standard of practice and develop their skills through continual professional development courses.

General MPT skill requirements include:

- Thorough understanding of anatomy and physiology, especially of the head.
- Good understanding of materials and techniques used in the lab.
- Artistic ability for carving and shaping prostheses, cranioplasty plates and implants.
- Good understanding of the conditions resulting in the need for maxillofacial rehabilitation.
- A good understanding of maxillofacial surgical techniques.

Patient well being must remain paramount, so the prosthetist and techniques employed should be sympathetic to their pre-conditions and requirements. An understanding of psychological issues relevant to the reconstruction of an individual's face is important in order to understand their expectations and improve communications. Patient expectation is likely to be different depending on whether their defect was acquired or is congenital. Patient's with acquired defects are likely to have an idea of what their face looked like before, whereas those with a congenital deformity are not likely to have any preconceptions and may be happier with smaller improvements. Cancer patients may be dealing with uncertainty over their future.

Each of these factors will contribute to the overall success of the prosthesis and should therefore be considered with the introduction of any new technique.

Other Europe

Training across Europe differs. Generally, a dental based background is required.

There are two training options in the Netherlands for maxillofacial technicians and maxillofacial prosthdontists. A technician will train whilst working in an institute, whereas a prosthodontist will train whilst working at a dentist, dental school.

In Sweden, a facial prosthetist will have a dental technician background. There is no specific training in Scandinavia for maxillofacial prosthetics other than short course workshops. Some prosthetists opt to undertake a course abroad, including in the UK.

USA

There is no separate or distinct college level course curriculum for anaplastology (the American name for maxillofacial prosthetics) according to the AAA (website last accessed in April 2007) and

a common route is through a related degree/certificate such as medical illustration and dental technology. In general, anaplastology training is subsequent to another degree and is art rather than dental technology based.

Japan

There is no formal training in Japan. Any training is typically undertaken on a private basis.

2.3 - Functions of the maxillofacial anatomy

2.3.1 - Nose

Function

The nose performs a number of functions: it warms air as it enters the body, filters dust and germs, provides a fluid outlet, modulates acoustics, humidifies the air entering the lungs, provides the sense of smell, gives a small degree of expression and provides a platform for glasses.

Anatomy

The nose is made up of the nasal bones, cartilaginous tissue (upper and lower lateral cartilage) and skin. The cartilage forms the hard ridge vertically in the centre and forms the rhinion (osseocartilaginous) junction with the nasal bone. The alars form the visible nostrils with the central columella. The columella forms an angle with upper lip of around 90 degrees in males and 100 degrees in females.

Figure 2.3 shows the topographic anatomy of the nose.

a. Columella

b. Root

c. Bridge

d. Ala

e. Apex – tip

f. External nares

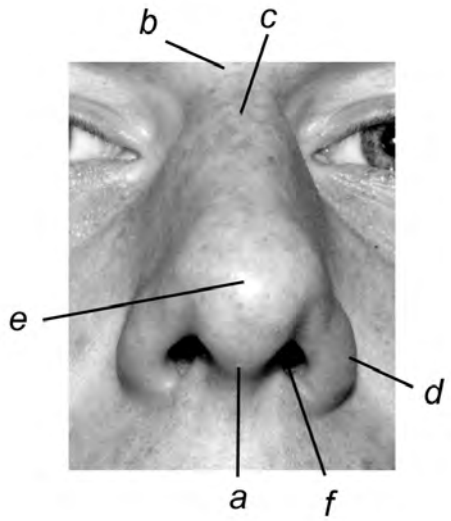


Figure 2.3. Topographic anatomy of the nose

2.3.2 - Ear (auricular)

Function

The outer ear (Pinna) acts to funnel sound through the auditory canal towards the ear drum. This acts as an amplifier with both ears required to help detect the location of a sound.

Anatomy

Figure 2.4 labels the key topographical landmarks of the ear.

a. Lobule

b. Antitragus

c. Tragus

d. Helix

e. Antihelix

f. Crus of helix

g. Cavum concha

The pinna is made up of elastic fibrocartilage covered by perichondrium and skin. The skin over the lateral aspect of the ear is tightly adhered to the perichondrium whereas on the medial surface, it is more loosely attached. The auricle is attached to the tympanic (portion of the temporal bone on the lateral aspect of the skull) by extension of the auricular cartilage into the cartilaginous external canal, by three ligaments, poorly developed muscles, skin and subcutaneous tissue.

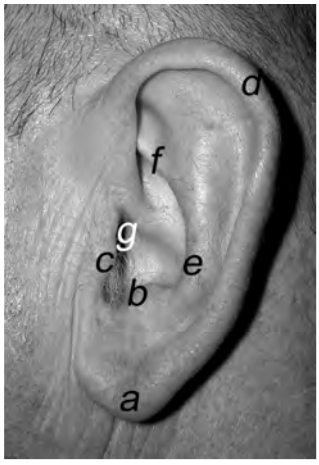


Figure 2.4. Topographic anatomy of the ear

Malformations of the Pinna may be caused by:

1. Atresia – absence of the pinna
2. Aplasia – pinna develops abnormally
3. Microtia – abnormally small pinna

The ear may also be missing due to traumatic injury or removal due to cancer.

2.3.3 - Eye

Surgical considerations

Surgical removal of the eye falls into three categories: Evisceration, enucleation and exenteration. Evisceration involves removal of the contents of the globe, leaving the sclera and possibly the cornea in place. A spherical implant is used to reconstruct the shape of the eyeball. Enucleation is the removal of the entire contents of the globe after the extraocular muscles and optic nerve have been severed. An implant is inserted to restore the contours. Exenteration of the eye involves removing the entire contents of the orbit, including the extraocular muscles. This may be due to a malignant on non-malignant disease, trauma or infection. The defect is normally covered with an external prosthesis. Ideally the patient's natural eyebrows should be left intact in their original position to retain realism in the post-prosthetic result [Parr *et al*, 1983].

Anatomy

Figure 2.5 labels the eye.

a. Medial canthus
b. Eyebrow
c. Palpebrae – eyelids
d. Eyelashes
e. Lateral canthus
f. Pupil
g. Iris
h. Sclera

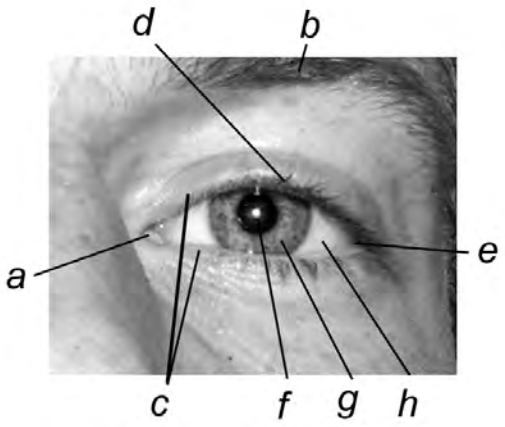


Figure 2.5. Topographic anatomy of the eye

2.3.4 - Gross facial anatomy

The visible, superficial facial anatomy is influenced by the underlying structures and is highly mobile. A number of structures make up facial features. The deepest of these is the bony anatomy, which together with the cartilage provides a framework of rigid structures that support the overlying soft tissues. Muscles in the intermediate layers interact with the bony and overlying soft tissue layers and are highly mobile. The outer skin surfaces and fatty tissue form the textures and skin softness. The highly mobile nature of the soft facial layers makes prosthesis fitting extremely difficult.

Facial proportions and topography are an important aspect to consider when designing a facial prosthesis and a high degree of subjective judgement is necessary when establishing the correct position and protrusion of a prosthesis; achieving perfect symmetry may not always produce the best result.

2.3.5 - Texture and wrinkles

Texture and wrinkles may be important features to create a lifelike prosthetic outcome. Micro-topography such as texture and wrinkling are formed on a number of levels. Visible skin texture

may be classified according to the orientation and depth of the lines. Primary and secondary lines form a pattern on the skin surface and are only noticeable on closer observation. They often form a criss-cross, polygon pattern reaching 20-200µm in depth [Piérard, 2004]. The back of the hand often shows a good example. Their prominence often increases with aging. No grading scales appear to have been widely adopted. Visible wrinkles are more prominent and are a result of cellular structural changes beneath the visible skin surface. They are not simply a deepening of shallow lines. It has been suggested that the term wrinkle should apply when an extension of the skin perpendicular to the axis of the skin surface change leaves a marked line representing the bottom of the wrinkle [Griffiths, 1992, cited by Piérard *et al*, 2003].

Wrinkles may be classified in four categories according to Piérard *et al*: Atrophic, elastotic, expressional and gravitational. Atrophic wrinkles are caused by the decreased elasticity in the skin and may be attributed to aging. Elastotic lines become progressively more permanent and develop particularly on sun exposed areas such as the cheeks, upper lip and neck. They tend not to disappear when the skin is stretched. The skin becomes more rigid and forms a cobblestone like pattern. Expressional wrinkles are formed by the forces exerted by facial muscle movement. They gradually become more permanent with repeated contractions of the skin. Typical examples are frown lines on the forehead and crows feat at the corner of eyes. Gravitational wrinkles include sagging and folding of the skin caused by the forces of gravity. They are exacerbated by the loss of skin elasticity due to aging and are most prominent in areas of thick skin.

Lemperle *et al* (2001) developed an assessment scale that was subsequently used to assess and quantify deep facial wrinkles. Wrinkles from various facial locations were graded from 0-5 by dermatologists. 0 was described as no wrinkles and 5 very deep wrinkles, redundant folds. Following the visual grading, the wrinkles were then measured using profilometry and the results correlated. This produced a graded wrinkle scale table with associated depth of wrinkle values for the various facial locations. Using this scale, a nasolabial wrinkle (side of the nose) with a grading of 1 would correlate to a wrinkle depth of <0.2mm and a grading 5 would be greater than 0.81mm depth.

These figures may be used to identify methods of applying texture in a computer environment.

2.4 - Prosthesis types

2.4.1 – Introduction

By their nature, facial prostheses are individually custom made and may be combined with a facial part and/or an obturator.

2.4.2 - Obturators: Obturators are required where part of or the whole maxilla (that forms the upper jaw and mouth pallet) has been removed. They are designed to allow swallowing, speech and normal opening and closing of the mouth and must therefore provide a tight seal between the mouth and nose. These are individually made for each patient and at each stage of their treatment. They may be a solid plastic material, hollow box or multiple-part. Materials used include polymers, metals and gutta-percha (a natural material that expands to form a tight seal).

2.4.3 - Orbital: In cases of full exenteration of the orbital content, a silicone prosthesis is the only solution to restore the facial aesthetics. Orbital prostheses are constructed of multiple components; the main body of silicone matched to the patient's skin tone and texture, an eye unit (typically acrylic), eyelashes and where required, a sub-structure enclosing the retentive clips or magnets. A prosthesis will not move or blink which makes the eye an extremely difficult part of the anatomy to recreate, especially since it is involved in so many facial expressions. As with any prosthesis, realism is added by applying textures, colour and other fine details to match the patient's surrounding tissue. The edges are also 'feathered' (made extremely thin) and contoured to press against the surrounding tissue and blend in as best as possible. Facial expressions are highly pronounced around the orbits, which causes further difficulties when trying to achieve an accurate fit without the margins lifting. Implant retention provides the most accurate and secure result since

this keeps the prosthesis pressed down around the margins. Glasses are often worn by the patient to further disguise the margins.

2.4.4 - Nasal: Nose prostheses are a common choice to replace either part of, or the entire nose. Plastic surgery may also be an option in some cases. In more pronounced cases, nasal prostheses are combined with a part facial prosthesis and extend across parts of the cheeks. Many of the same construction and retention techniques as orbital prostheses are employed, with implant retention being the preferred method.

Like the orbit, the nose is very prominent and difficult to disguise on the face, which makes achieving a realistic result very important. The area around the nose is also highly mobile which makes it very difficult to hide the margins. Fine feathered edges are again used to blend the silicone into the surrounding anatomy, but these may be easily lifted when the mouth and cheeks move. Dimpled textures and flocking may be combined with individual colour matching to achieve a realistic result.

2.4.5 - Ear (auricular): Ears are arguably the simplest facial prosthesis to construct, but still require much practice to achieve an accurate match to the contralateral (opposite unaffected side) side. Movement around the Temporal Mandibular Joint (TMJ) (where the jaw rotates around) can cause the anterior margins to become detached from the surrounding tissue. Hair brushed behind the prosthesis can sometimes be used to disguise the margin, but this is not always satisfactory. Careful design of the margins must take tissue mobility into account at the early stages of construction. Positioning a prosthesis may also be limited by remnant of existing ear, especially in cases of congenital deformity. Measurements of the ear in relation to other anatomical landmarks may be made in order to establish the correct position and protrusion, but in some congenital cases where the face is significantly asymmetrical, this becomes difficult. Where the prosthesis is to be implant retained, it is vital to establish the correct position of the implants in relation to the potential retentive components within the proposed prosthesis. The thickest parts of the ear

typically house a sub-structure which incorporates retentive components. In general, the tips of ears are level with the eyebrow.

2.5 - Current prosthetic construction techniques

2.5.1 - Introduction

Although facial prosthetics has a long history that dates back hundreds of years, technological advances have been relatively slowly adopted. Many of the fundamental techniques used today were developed during the First and Second World Wars to deal with the high number of casualties with facial wounds. Even with the widespread introduction of silicones in the 1980's, the construction methods changed very little and are still in use today.

Literature published by Laney as early as 1979 describes prosthesis construction techniques that are still used in laboratories today. More recent books by Thomas (1994), McKinstry (1995) and Taylor (2000) describe very similar construction techniques, but refer to the application of new silicone materials and improved methods of retention such as Osseointegrated implants (Chapter 2, part 5.4). A similar trend is shown with journal publications. Guerra and Canada (1976) discussed a method of producing metal-faced moulds. Sooudi and Green (1984) also discussed a very similar technique. Zini *et al* (1978) discussed simplified mould construction techniques for facial prosthetics a similar technique was discussed by Wolfaardt *et al* (1983).

Authors such as Barron *et al* (1983) and Parr *et al* (1983) discussed aspects of prosthesis construction that are very similar to the techniques discussed much later by authors such as Rommerdale (1990a,b,c), Wolfaardt and Coss (1996a), Cheng *et al* (2002), Sykes and Sukha (2003) and Hecker (2003).

2.5.2 - Processes

Although the processes have been developed over a long period of time, prosthesis production processes are labour intensive and require an inordinate amount of time and skill to achieve a result that is judged aesthetically satisfactory by the prosthetist. The techniques also require a lot of training to become competent. Lengthy, multiple visits are required for the patients, which often involve long periods of sitting and waiting. The outcome is also largely dependent on the individual prosthetist's experience and skill. The basic construction stages have been described in many books and papers (cited throughout this chapter).

Although the fabrication process may be adapted in order to accommodate the patients' clinical condition and individual wishes, the fundamentals of the process remain the same. The production process for either adhesive retained or implant retained prostheses is shown in figure 2.6. Additional stages of implant planning, surgery and a healing period are required where implant retention is used. Additional fabrication of retention components is also required over adhesive retained prostheses. Section 2.8.4 provides further details on osseointegrated implants.

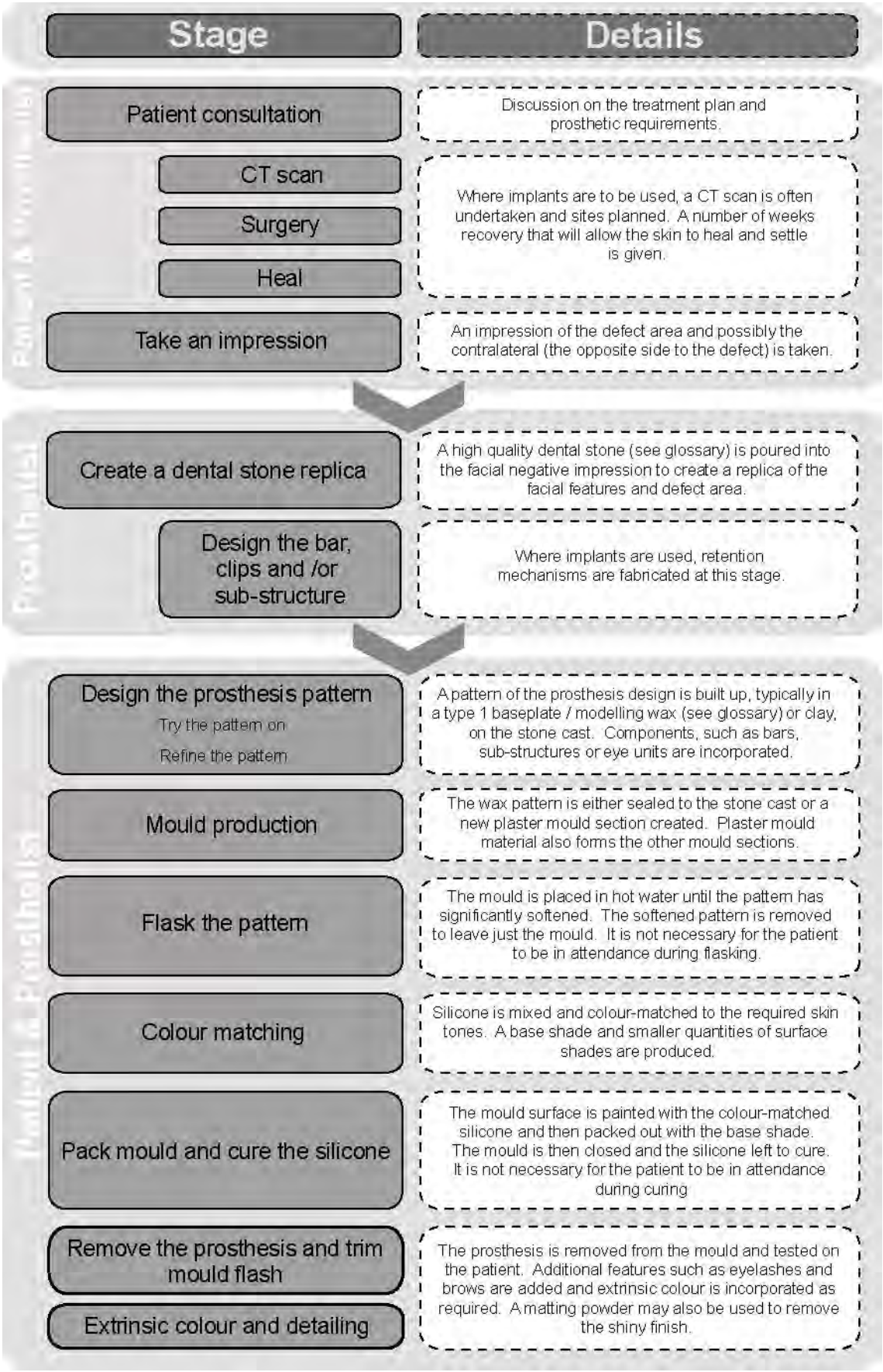


Figure 2.6. The conventional prosthesis production process.

In addition to the published literature, a questionnaire was sent to training and practicing UK based MPTs in order to gauge their current practices, awareness and opinions of emerging technologies. The results of this may be seen in chapter 5.

2.5.3 – Stages of production in detail

Initial consultation and treatment planning

A treatment plan is undertaken to establish the type and purpose of the prosthesis to meet the patient's needs. A plan will involve consultation with the referring surgeon, establishing the patient's medical history and an examination of the defect area. This will help to determine diagnosis, prognosis, last date of surgery and purpose of referral. Understanding the medical history will also help to identify any issues that may cause treatment complications such as allergies. Sensitive areas should be identified in a physical exam so they may be avoided when taking an impression. This stage may also identify suspicious lesions that may require further investigation. The chosen prosthesis solution will be based upon a number of factors, including:

- The necessary longevity
- The patient's ability to maintain the prosthesis
- The location on the face and tissue mobility
- The patient's lifestyle

Facial impression taking

Achieving an accurate cast of a defect area is vital to ensure that the resulting prosthesis has a good fit and marginal integrity [Pow and McMillan, 2000, Kubon *et al*, 2000, Kubon and Anderson, 2003, McKinstry, 1995]. Reitemeier *et al* (1999) suggests that an inconspicuous prosthesis is characterised by its close fit and that the precondition to achieving this is to obtain an impression that is a true reflection of the defect in both detail and accuracy. Since impression techniques and materials vary, it is important to consider how the choice will affect the final prosthetic outcome [Kubon and Anderson, 2003]. The prosthetist must also consider how different facial expressions, tissue distortion and even the physiological position will affect the fit and marginal integrity and

therefore how best to record this [Woolfaardt and Coss, 1996a, Pow and McMillan, 2000]. The importance of an accurate impression has been discussed by Reitemeier *et al* (1999). A study comparing the accuracy of impression methods and seating positions concluded that the patient should ideally be seated upright (the natural position the prosthesis is viewed in). Clinically significant displacements of between 0.6mm and 1.1mm were measured between seated and reclined positions. Ultimately the fit and marginal accuracy of a static prosthesis will always be compromised due to dynamic tissue movement.

The process of impression taking may be very distressing for the patient, especially in the case of orbital defects where the eyes and possibly the nostrils are covered. An impression is normally taken 6-8 weeks following surgery when the tissue has had time to recover and dressings have been removed. The basic process may be described as follows:

1. The patient should be seated in a natural position to minimise tissue distortion and towels may be placed to protect clothes.
2. Areas of undercut and orifices may be blocked with Vaseline gauze or cotton wool. Vaseline should be coated over areas of hair such as moustaches, eyebrows and eyelashes.
3. The impression area may be masked off to avoid spillage, using for example sticky back foam tape.
4. A flexible impression material is poured or syringed over the defect site. A second layer of stiffer material may then be used to stabilise the impression.
5. The impression is removed and a dental stone material poured to create the positive model soon after.

Variations on these basic techniques have been suggested, with differences including: the use of custom impression trays to add rigidity to the impression material [Wolfaardt and Coss, 1996a] and alternative material combinations [Kubon *et al*, 2000, Kubon and Anderson 2003].

A range of impression materials are available, including:

Alginate (irreversible hydrocolloid). Alginates are mixed with water prior to being used and then poured over the impression area. A layer of gauze followed by plaster is typically applied to stiffen and strengthen the cast. They tend to be messy and relatively inaccurate compared with other impression materials and are commonly used for larger areas.

Plaster of Paris. This is rarely used as an impression material due to the long sent times, but is often used to back a flexible impression.

Silicone putty with a rubber base. This provides good detail, but has a low strength and is also expensive.

Polyether. Polyether-based impression materials are typically combined with silica filler and plasticiser to give a higher tear strength than alginate materials with excellent reproduction of detail (Wassell *et al,* 2002). They also have a short set time that gives it a relatively short working time.

Polysulfide. This has a high tear strength and is easier to pour than elastomer materials. It does however have a relatively low dimensional stability, long set time and unpleasant odour.

Polysiloxane (condensation cure silicones). These may be syringed around into place, are very accurate and set quickly, but are relatively flexible and must be supported by a stiffer material.

Poly vinyl siloxane (addition cure silicone). This may be syringed and is used to support a softer silicone elastomer impression material.

Impression taking with osseointegrated implants

Obtaining an impression and constructing an osseointegrated (see section 2.8.4 for details) retained prosthesis represents a further challenge due to the difficulty in recording the exact location of abutments and copings that will ultimately provide fixation for the prostheses. An implant-retained prosthesis must also incorporate clips or magnets and a sub-structure, adding to its complexity.

The prosthetist and surgeon must collaborate before surgery to establish optimum implant sites that meet both the aesthetic requirements of the prosthesis and the technical and anatomical constraints of surgery. It is recommended that the prosthetist be present during surgery to advise in cases where the ideal implant sites are not possible and a compromise must be reached [McKinstry, 1995]. The process of obtaining an impression with osseointegrated implants may be surmised as follows:

1. Any epithelial debris must first be removed from around the abutment base.
2. The magnetic keepers are screwed into the abutments.
3. The abutments may be kept steady using a stiff material, such as an addition cure silicone or light cure acrylic.
4. An impression material is then syringed around the abutments and backed up by a stiffer material.
5. Once set, the impression is carefully removed and a spare set of keepers screwed into brass abutment replicas. This assembly is then carefully placed into the impression material.
6. A stone impression is then poured as normal, thus recording the exact implant position.

Where copings are used, they must be kept stable in order to record the exact position without distortion. One technique is to use a firm rubber impression material, injected around the base of the copings, engaging the undercuts. Softer impression materials are then used as normal, taking care not to cover the top of the coping screw. Figure 2.7 shows an impression being taken. Once the composite impression is set, the copings are unscrewed carefully and the assembly lifted away. Replacement brass replica abutments are then assembled to the impression copings and a dental stone cast is poured as normal.

Figure 2.7. An impression being taken of an auricular defect. Metal posts protrude though the impression material and record the position of the implants.

Obtaining an impression presents a number of challenges. These include the displacement of soft tissue, especially around the orbits [Pow and McMillan, 2000, Kubon *et al*, 2000] and movement of the abutments [Seals *et al*, 1989, Kubon and Anderson, 2003]. An accurate recording of the abutment locations is required to achieve an accurate fit for the retentive components.

Pattern carving

The materials used tend to be similar for each prosthesis type, but the techniques differ and will be discussed according to prosthesis type. Type 1 baseplate/modelling relatively soft wax, which is paraffin or cerecin based is most commonly used in the UK, but in some cases, clay is preferred. Anutex modelling wax (Kemdent, UK) is typically used in the Maxillofacial Lab at Morriston Hospital.

Orbital: the wax pattern is typically carved on the stone model created from the impression and checked on the patient during its construction. Where the prosthesis is retained by implants, a sub-structure is created first to provide a secure interface between the final silicone material and retentive components. Circular section bar and clip mechanisms are popular since they are very compact. A bar is constructed on the plaster replica with the recorded abutment locations in an inert material such as 18k, hard Gold. Soldering techniques are used to join lengths of bar and the cylinder components together. Where a bar arrangement is used, the area between the bar underside and skin is blocked off to provide a gap between the prosthesis surface and skin. The retentive clips are located on the abutments and a sub-structure is formed over the top by hand in an autopolymerising acrylic (see section 2.6.3 and glossary). The hardened acrylic sub-structure is then trimmed to create a gap between it and the skin surface. Where magnets are used, these are either embedded directly into the silicone, or encased in a similar sub-structure as described for bar and clips.

Baseplate / modelling wax is typically used to form the bulk of the prosthesis and define the contours first. The eye unit is mounted via a recess in the rear of the pattern and may be loosely fixed to allow rotation and fine adjustment. The aesthetic outcome is highly reliant on the correct positioning of the eye unit, which must be given the correct angle of gaze, depth and inter-pupillary distance in order to look natural [Thomas, 1994, Guerra *et al*, 1992]. A combination of Vernier gauges, flexible tape measures and judgement are used to ensure the correct placement of the eye unit, which makes ocular prostheses more time consuming and complicated than other prosthesis types. It is generally accepted that the exact eye unit positioning is open to interpretation by the prosthetist and may only be finalised with the wax pattern in place on the patient (figure 2.8). It should therefore be kept mobile within the wax pattern until finalisation.

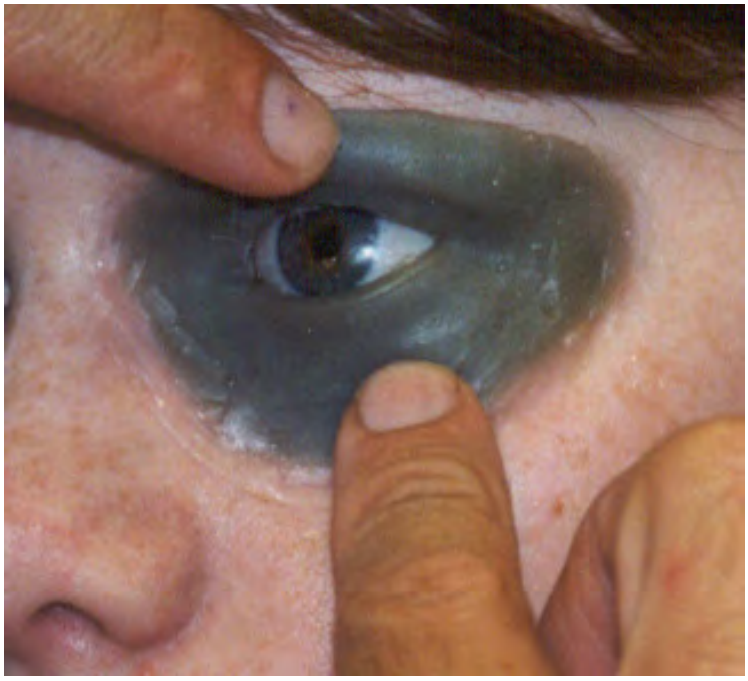


Figure 2.8. Testing the pattern fit and ocular unit position

The sub-structure is built in to the prosthesis and the wax edges sealed to the plaster replica towards the edge of the prosthesis if the stone is being used as one mould part. The edges may also be contoured to press against the face in a freehand manner and a new mould half constructed to accommodate the altered contours.

Nasal: the carving techniques used are similar to those used in orbital and Auricular prostheses. Either clay or a combination of sheet and bead dental wax is commonly used to hand craft the nasal shape, which is gradually refined to add detail and realism (figure 2.9).

Figure 2.9. Shaping a nasal prosthesis in clay

An autopolymerising acrylic shell sub-structure is often used to support the retentive components that clip to implant abutments (figure 2.10). This may be only a few millimetres below the outer silicone surface. Stippling using a toothbrush or orange peel may be used to create the appearance of skin texture. The edges are thinned out and often contoured to press lightly against the face to form a good seal.

Figure 2.10. A sub-structure shell, incorporating gold clips.

Auricular: techniques are again similar to those used in other prosthesis types. Where a sub-structure is used, it must be designed within a very limited space at the thickest points of the ear. Fine edges are created by either sealing the wax to the plaster replica or in a free hand manner. Figure 2.11 shows an ear prosthesis pattern being measured for accuracy.

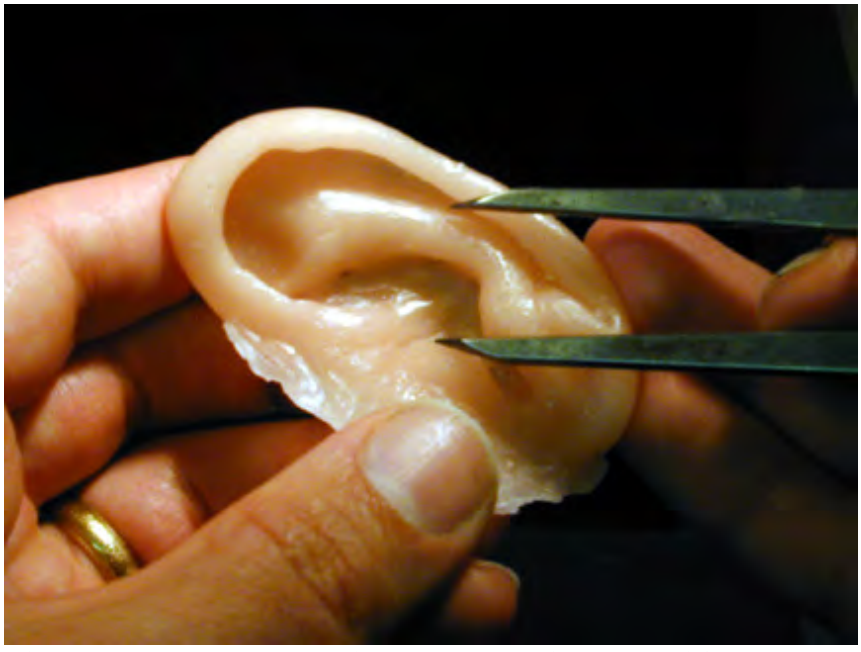


Figure 2.11. An ear prosthesis wax pattern being checked for accuracy.

Mould construction

The most common mould material used is dental stone due to its low cost, high accuracy and ease of use. The two most common techniques used to produce a mould are flasked and flaskless. Flasks are used to retain the material and strengthen the mould, but are not always required. Flasks can either be brought off the shelf or custom manufactured using materials such as PVC drain pipe [Chambers *et al*, 1996], plastic tubs [Thomas, 1994] or metal [Guerra and Canada, 1976]. These methods tended to be more complicated and expensive than dental stone techniques whilst not providing any significant advantage. One flaskless technique observed uses adhesive backed paper or thin plastic sheet to form a custom-sizable round container, into which the stone may be poured (figure 2.12). This is a cheap, fast and flexible method. Figure 2.13 shows a two-part mould for an orbital prosthesis.

Figure 2.12. First part, flaskless moulding for a nasal prosthesis

Figure 2.13. A completed, two-part orbital prosthesis mould.

2.6 - Prosthetic materials

2.6.1 – Prosthesis body material requirements and development

According to Laney (1979), biocompatibility (although non-allergenic may be a more appropriate description) is a major prerequisite for a prosthetic material. Materials must also be easy to work with, provide adequate resistance to chemical and mechanical wear whilst maintaining patient comfort and providing a realistic, natural appearance. Bellamy and Waters (2005) noted the following processing and functional properties for the ideal prosthetic material:

- Low viscosity
- Low weight
- Ease of colouration
- Chemically and environmentally stable
- Ease of adhesion to living tissues without sensitivity to the host tissues
- Good physical properties such as tear and abrasion when moulded to thin edges.
- Ease of cleaning

These are indeed significant demands. Various materials have been used throughout the history of facial prosthetics. Extremely early examples of prostheses were manufactured in materials such as leather and even silver and were mechanically retained by straps and external clips. Early

examples include A. Pare (1510-1590) who used materials such as silver, paper and leather to fabricate prostheses and obturators [Kemp, 2004] and T. Brahe (1546-1601) who had a gold/silver nose. Material technology has seen significant development since these early days. Flexible materials such as latex, vinyl plastisols and polyurethane polymers have been used [Laney, 1979], but the most commonly used prosthesis construction material used today is silicone. Silicone was developed for maxillofacial application late 1970s [Laney, 1979] and was in widespread use for prosthetics by the late 1980s. It is currently the material of choice since it can be easily colour matched, the physical properties can be altered to speed up or slow down curing, reduce the hardness to allow the prosthesis to comply with changing facial expressions and be more comfortable to wear, does not cause an allergic reaction and can be moulded easily [Thomas, 1994 and in conversations with Mark Waters, Principality Medical, Newport, UK, 2004].

Silicone is available in two basic forms: Condensation cure (one or two part) and platinum (addition) cure. The mixture of base polymer, additives and fillers may be altered in order to achieve different physical properties, but there are limitations that should also be considered.

Condensation cure. Condensation cure silicones use a base polymer and a tin catalyst which react to form the end product. A water and alcohol by-product is produced by the reaction (hence condensation cure). This results in a minimal shrinkage.

Platinum cure. Platinum cure silicones use a platinum complex as a catalyst. No by-product is produced, which means there is no shrinkage.

2.6.2 – Prosthesis body material properties specification.

Shore hardness values are typically around A20-A30, percentage elongation at break approximately 500%-650%, tear strength approximately 90-110ppi and tensile strength approximately 4.8 N/mm^2 [Factor II Inc.]. Each prosthesis case will require slightly different material properties, so the values quoted above are only an indication. The properties of the basic material may be altered in

many different ways depending on the requirements. A silica filler material is typically used to add strength to the material and varying the characteristics and quantity of this alters the properties. The silica forms a hydrogen bond within the cross-linked polymer structure, but does not actually react. Varying the actual polymer type, length and cross-link density also alters the stiffness, elasticity and strength. Introducing a hydride functional cross linker will give a foaming effect, whereas adding an un-reactive fluid will give gel properties. Adding a suppressant to the catalyst will slow the curing reaction allowing the material more time to be worked [in conversations with Mark Waters, Principality Medical, Newport, UK, 2004].

2.6.3 –Sub-structure material

Sub-structures which hold clips or magnets are typically fabricated in an acrylic dental base material, more commonly called autopolymerising, self-cure or cold-cure acrylic. These materials are typically provided in a two-part powder and liquid base and are described in textbooks [Craig *et al*, 1996]. When the two components are mixed, a polymerisation reaction occurs and the mixture hardens. The processed material has an elastic modulus of 3,800 MPa, Knoop hardness of 15Kg/mm^2 (147 MPa), Tensile strength of 55 MPa, water sorption (24hrs) of 0.6mg/cm^2 and demonstrates good tissue compatibility.

2.7 - Colouring

Colour matching is one of the more artistic and challenging aspects of prosthesis construction and requires the prosthetist to rely on their individual sense of colour to achieve a realistic result [Cheng *et al*, 2002]. Realistic colour matching was also highlighted as one of the most challenging aspects of facial prosthesis design in the survey. Achieving the correct colour match may take many attempts, during which the patient should be present. The correct result may also look different under various light conditions (metamerism), for example daylight compared to indoor lighting, so multiple prostheses may be required to accommodate a patient's lifestyle. The effects of metamerism have been studied [Leow *et al*, 1999] and difficulties in achieving a single colour matched prosthesis for all conditions identified. Achieving an accurate colour match may also be

made more difficult where a skin graft or flap of a different colour to the surrounding tone is present.

Colours are typically custom mixed with the clear base silicone and assessed against a patient's surrounding skin. The colours are either a dry earth pigment suspended in light silicone oil, or in the form of rayon flocking. Tiny amounts of pigment can dramatically alter the appearance of the prosthesis in relation to the surrounding skin tone. A different colour is typically required for the various areas of the prosthesis and each colour mix is applied to its appropriate area of the mould. Approximately colour matched, bulk silicone is used to fill the main body of the prosthesis. Figure 2.14 shows a mould being coloured.

Figure 2.14. Colouring the mould.

Once cured, trimmed and fitted, extrinsic colouring may also be used to enhance the aesthetic appearance.

Prosthesis colour change due to exposure to environmental conditions over time has been identified as the primary cause for facial prosthesis replacement [Hooper *et al*, 2005].

2.8 - Fixation methods

2.8.1 - Introduction

A wide range of retention methods are available for different applications and individual case requirements. Modern techniques have dramatically improved in comparison to early examples where visible external mechanical fixings such as sprung steel head bands, straps that located around the ears and head or attachments to glasses were often used. These techniques are rarely used in modern facial prosthetics and have been replaced with less visible, more reliable and aesthetically pleasing alternatives. The two most popular are:

- Direct skin contact adhesives and the use of natural undercuts
- Osseointegrated implants coupled with magnets and/or clips

Alternative methods such as mechanical fixings to glasses are also used where there is no other choice, but are normally limited to temporary prostheses. Further methods may also be considered where obturators are used.

The choice of retention will depend on the patient's physiological condition and personal wishes. There are several patient preconditions that should be considered before the retention method is decided upon [Worthington & Brånemark , ch. 7]:

- Age
- Sex
- Malabsorption syndones
- Metabolic bone, Rheumatic and hormonal diseases
- Coagulation disorders (anticoagulant drugs)
- Alcohol abuse
- Tobacco smoking
- Allergic reactions to adhesives

Lifestyle and previous treatments are also likely to influence the most suitable method. An active sports person or child is likely to require a strong and reliable fixation method that will prevent accidental loss, whereas somebody who has just undergone significant amounts of surgical treatment may not wish to have further surgery required to place implants. Congenital absence of the ear may also for example make the positioning of implants more difficult and the aesthetic result may suffer as a consequence. The patient's ability to look after an implant area and prevent infection should also be evaluated since it will involve a lifetime commitment.

There are also advantages and limitations of adhesive and implants are discussed in the following sections.

2.8.2 - Mechanical retention

Although rarely used in modern prosthetics, mechanical retention by means of attachment to external devices may still be required in certain cases. Options for external fixings include attachments to glasses, headbands or straps. Glasses may be effectively used to retain nasal and ocular prostheses where the tissue is particularly poor and unsuitable for adhesives. Although not as widely available, polymethyl methacrylate (acrylic) frames are preferred since they allow a good bond with commonly used prosthetic materials. Mechanically fixed prostheses should be very lightweight to avoid dislodging and the need for further retention.

2.8.3 - Adhesive retention

Up until the introduction of Osseointegrated implants (see section 2.8.4 for details), adhesive retention provided the simplest, most aesthetically pleasing and best fitting results. This was due to the closer fit that allowed the blending of a finer, feathered edge over previous methods of crude, mechanical retention. Adhesives are available in two common forms: liquid (for example a silicone or acrylic-based) or double-sided, medical grade tape. The choice is again down to

individual case peculiarities and may also depend on a patient's allergic reaction. Adhesive choice will also depend on the prosthetic material it will bond.

Acrylic resin adhesives: These are made up of an acrylic resin in a water solvent, which when evaporated leaves a rubber-like substance.
Silicone adhesives: These are typically Room Temperature Vulcanising (RTV) silicones dissolved in a solvent or water. When the solvent evaporates, a sticky residue is left behind. Silicone adhesives are resistant to weathering and moisture, but have a relatively low adhesive strength.

Direct adhesives available include:

- Dow Corning 355 medical adhesive. It may be painted on with a brush.
- Cosmedica PSA 1. This may also be painted on thinly.
- Factor II, Secure B and BT series. Available in either brush or spray on in varying adhesive levels.
- Cosmesil G series adhesives. Available in a two-part, platinum cure cartridge system or paint on water based.

Adhesive retention may be preferred where the bone has insufficient vitality or depth to support the load of implants or where a tight radius prevents holes being made. Patients who have undergone radiotherapy often exhibit reduced bone growth in the treated area that will reduce the possibility of proper osseointegration (see section 2.9 for details). This is also true for patients with diseases such as osteoporosis or osteomalacia (see glossary). Although implants may provide the best method of retention, patients may not wish to undergo further surgery, in which case, adhesives are likely to provide the next best solution.

There are however a number of limitations to adhesive retention methods. Skin movement around the prosthesis may cause it to work loose and the margins to become visible with certain facial expressions. This is especially a problem for auricular and some orbital prostheses where movement at the temporal mandibular joint, forehead and cheeks is extensive. This movement

should be accounted for early on in the impression taking and sculpting stages where the patient may be asked to show different facial expressions to determine tissue displacement that may affect the prosthesis margins. Where the movement is excessive, adhesive methods may become unsuitable, or if no alternatives are possible a strong version should be used.

Since adhesives may not be applied all the way to the thin edges of a prosthesis, techniques have been developed to improve marginal fit and adhesive retention. These include modification of the working mould by selective abrasion to further extend the feathered prosthesis margins and use of petroleum jelly to improve their adhesion. These methods are ambiguous and subject to inaccuracies [Wolfaardt *et al*, 1996b].

Another drawback with adhesives is the high amount of cleaning and constant removal required which tends to damage the margins and cause degradation of the silicone and extrinsic colouring. This means that prostheses may have to be replaced every 6-8 months. Cleaning is required to prevent moisture build up and infection and must be carried out daily, which for some patients can be frustrating and difficult.

Some patients also experience an allergic reaction to the adhesives used, which can ultimately lead to infection and further treatment if not detected in time.

Adhesives may also limit the patient's sense of security due to worries about it falling off and perhaps being lost if not noticed [Parel and Brånemark, 1986].

2.8.4 - Osseointegrated implants

Osseointegrated implants form a fixed, bone anchored retention method for attaching external or oral prostheses and is defined by Prof. Brånemark as "a direct contact between living, haversian bone and the loaded implant surface." The result is an abutment which is permanently attached to the patient's bone, but that protrudes though the skin to make contact with retentive components

within the prosthesis. Abutments typically have an outside diameter of 4mm with a raised rim, recess and a raised 2mm diameter centre. A 1mm diameter, threaded hole is located in the centre. Figure 2.15 shows an abutment. Implant retention is still considered state of the art today.

Figure 2.15. A replica abutment embedded in a replica cast. The outside diameter is 4mm.

Osseointegration occurs where the body accepts the direct contact between bone and implant. The technique has been developed over a forty-year period, primarily by Prof. P. I. Brånemark and associates who use inert, commercially pure titanium. The alloy is made up of:

Ti	–	99.75%
Fe	–	0.05%
O	–	0.1%
N	–	0.03%
C	–	0.01%
Others	–	0.06%

It is the chemical inertness of titanium and the high dielectric constant of the oxide coating that means bone grows around the implant rather than rejecting and shrinking away from it.

The stronger retention offered can provide significant functional and aesthetic advantages in facial prostheses including improved accuracy and a better marginal fit that is affected less by soft tissue movement that would otherwise allow the prosthesis to move with facial expressions [Seals *et al*, 1989, Wolfaardt *et al*, 1996b]. Rare earth magnets can provide around 500g – 1kg break away force and clips even more depending on how they are adjusted. It also means that prostheses must not rely on engaging undercuts and skin contact, resulting in reduced irritation and chances of accidental dislodging. A study of adhesive methods concluded that bond strength significantly decreased during the period of one day perhaps due to body movements and perspiration [Kiat-amnuay *et al*, 2001]. It was also noted that patients with dry skin (a side effect of localised radiotherapy) also found that adhesives became irritating.

A range of fixation methods that utilise osseointegrated implants are available and include magnets, balls and bar with clip arrangements. A bar and the clips for an auricular prosthesis are shown in figure 2.16a and b. These retention methods are highly accurate and are generally easy for the patient to use since they do not rely on the regular application of adhesives and careful adjustment to achieve the correct positioning. They also allow the inclusion of aeration channels, which are an important feature to reduce the possibility of infection caused by debris and sweat build up around the fitting surface of a prosthesis [Wolfaardt *et al*, 1996b]. In addition, the retentive forces may be altered to suit specific patient needs by altering the magnet types and clip tightness.

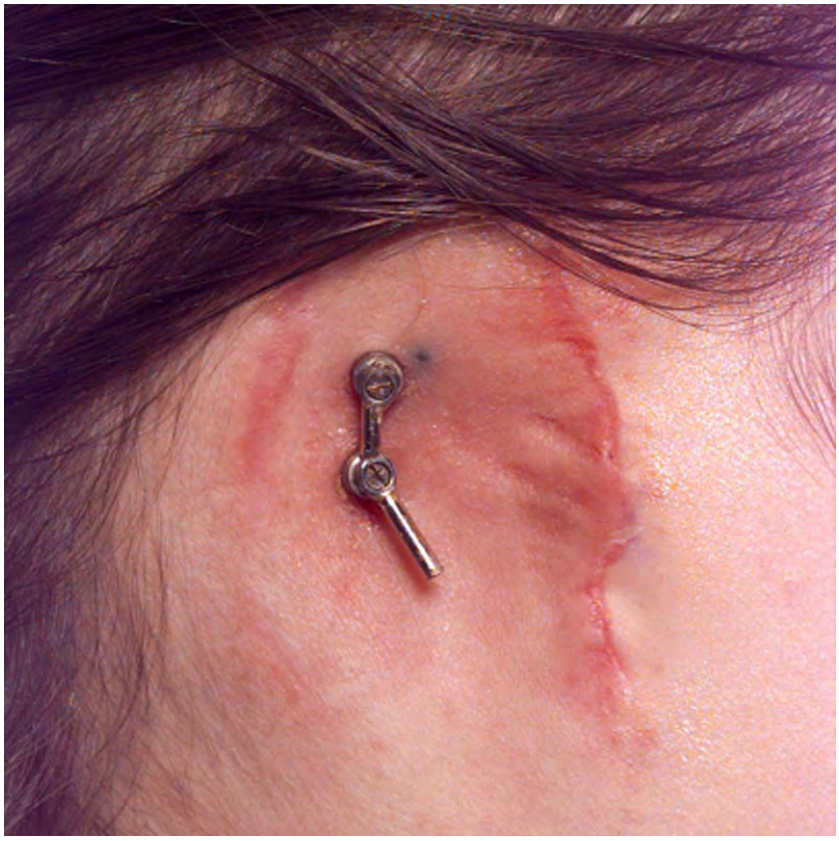


Figure 2.16a. A bar for an auricular prosthesis.

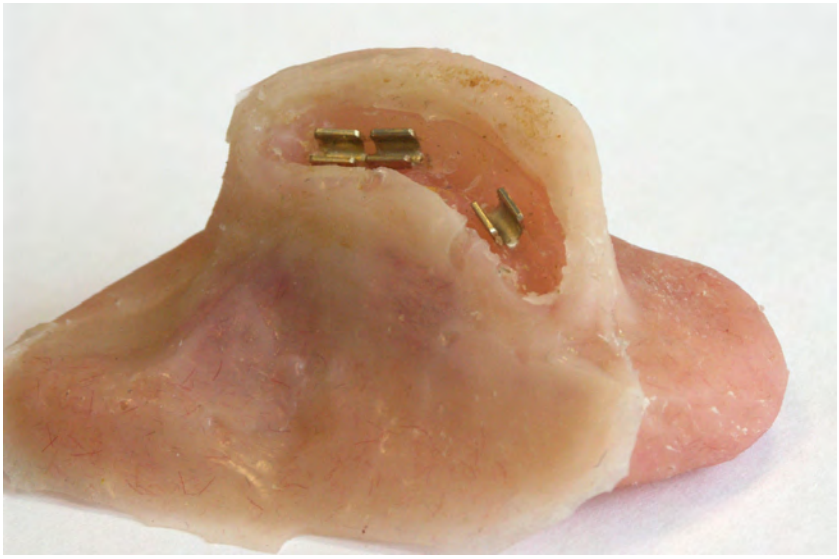


Figure 2.16b. Clips embedded within the fitting surfaces of an auricular prosthesis

Where a bar and clip system is used, close tolerances are required between components. What constitutes a 'satisfactory' bar fit has been discussed [Kan *et al*, 1999], but no standard has been adopted. Brånemark (1983) suggested that a passive fit should exist on the 10µm level, whereas Jemt (1991) suggested that misfits smaller than 150µm were acceptable. A conclusive and

commonly adopted method of evaluating fit also remains undecided and clinical methods typically rely on 'eyeballing' and testing for a rocker action in the frame.

There are however drawbacks and implants are not always the best solution. Additional surgery, that may appear daunting to a patient who has already undergone significant trauma, is required, so some are reluctant. Some patients are put off by the retention abutments that poke through the skin and are highly visible when their prosthesis is not worn. For some, physiological and lifestyle preconditions as listed in chapter 2, part 8.1 may reduce the suitability of implants. Advantages and disadvantages of implant retention are summarised in table 2.17.

Advantages	Disadvantages
Secure fixation that allows an improved prosthetic fit	Requires further surgery that may be daunting for the patient
Allows for better designed prostheses that reduce the chances of irritation	Not always suitable where bone vitality is reduced
	There is an ongoing risk of infection where the abutments protrude through the skin, therefore daily cleaning is required.

Table 2.17. Advantages and disadvantages of implant retention

2.9 - The Osseointegration Process

The fixing of implants requires careful planning between surgeon, prosthetist and patient and surgical techniques that prevents excessive heat being generated during drilling of the bone site [Worthing and Brånemark, 1992]. Bone temperature should not be raised above 43 ^{0}C in order to maintain its vitality. MPTs typically work with surgeons to plan the implant locations pre-operatively. Software packages such as Simplant (Materialise) may be used to plan the sites digitally and transfer this information to produce a physical guide that may be used during surgery. Other methods include producing a skin mounted guide. Ideally the prosthetist should still be present during the surgery to assist and advise [Thomas, 1994]. A slow speed drill and depth limiter is used to drill 3-4mm holes that are then countersunk and threaded with a titanium screw tap. The implant fixtures are then inserted into the holes and the implants internal threads covered before the skin flap is replaced and sutured. In a two-stage operation the implants must then be left to osseointegrate with the bone for 4 to 6 months, during which time loading should be avoided.

After the 4-6 month period, the original suture line is re-opened and subcutaneous tissue removed to prevent the free skin movement around the implant site. The abutment is then screwed into the implant thread and a healing cap placed into the abutment thread. The area on the skin surface around the abutments is pressure dressed for around seven days. After removal and a 3-4week period, impressions may be obtained and normal prosthetic construction processes used.

The process of placing osseointegrated implants is illustrated in figure 2.18.

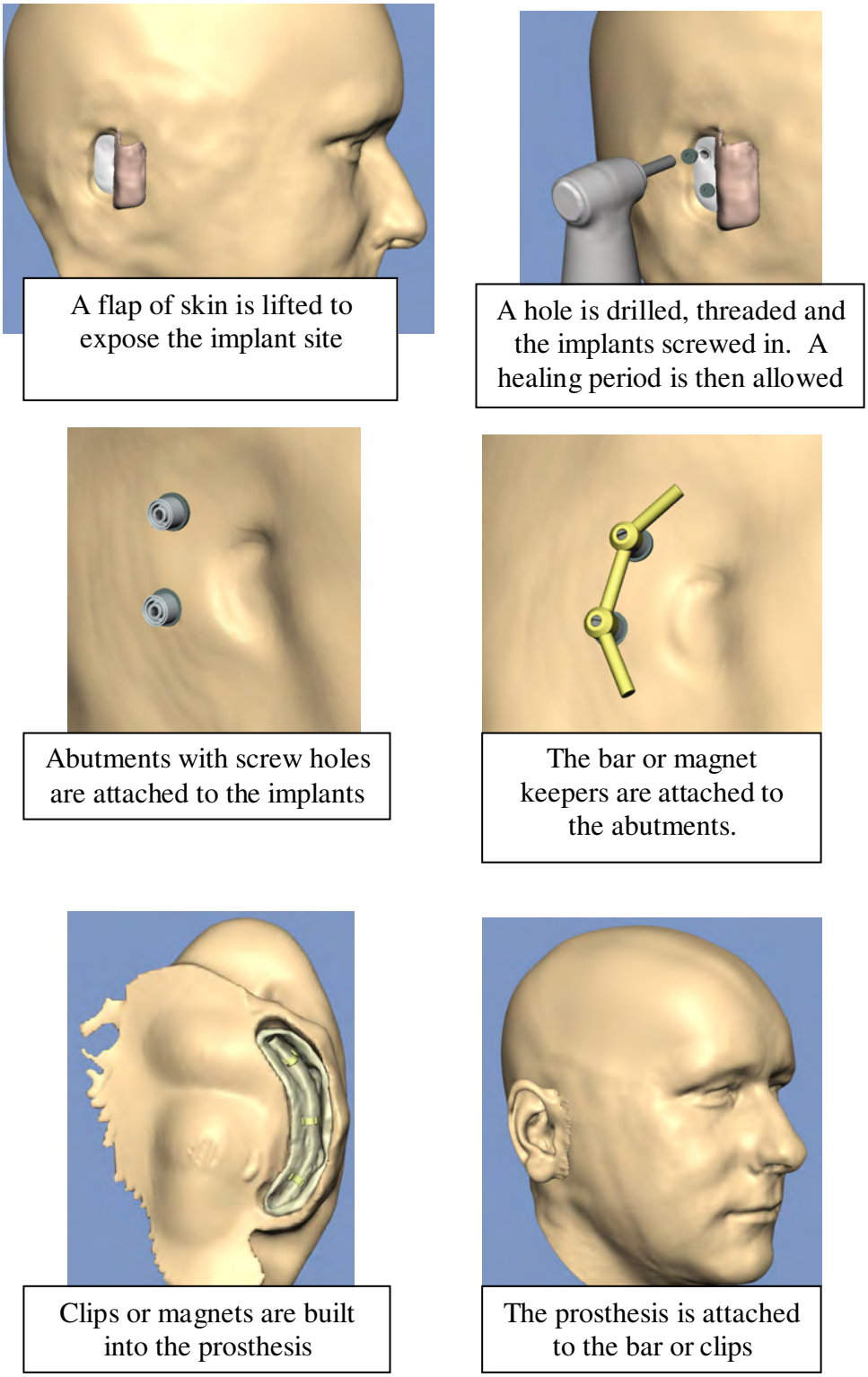


Figure 2.18. The process of placing osseointegrated implants for attaching an auricular prosthesis.

2.10 - Measuring prosthesis success

Many factors determine prosthesis success, including:

- The position and protrusion of the main prosthesis and features [Guerra *et al*, 1992].
- Colour match to the surrounding skin [Thomas, 1994, Cheng *et al*, 2002].
- Static and dynamic blending of the edges to the surrounding skin [Wolfaardt and Coss, 1996a, Aziz *et al*, 2003].
- Texture [Cheng *et al*, 2002].
- Homogeneity – veins, freckles, spots, marks etc. [Thomas, 1994].
- Fit of the retentive components [Seals *et al*, 1989, Kan *et al*, 1999].
- Retention and ease of application strength to suit patient needs [Parel *et al*, 1986].
- Wear resistance and colour retention [Hooper *et al*, 2005].
- Ease of cleaning and maintenance [Bellamy and Waters, 2005, Hooper *et al*, 2005].

Literature discussing the success of facial prostheses may be broadly broken down into two categories: social/psychological impacts and quality/functional. Research that focuses on the social/psychological impacts typically use questionnaires and interviews to rate the patients' feelings [Lowental, 1982, Newton *et al*, 1999, Chang *et al*, 2005, Hooper *et al*, 2005], but do not consider the technical aspects that make a prosthesis successful. Relatively few studies concentrate on evaluating the quality/functional outcomes of prostheses using quantitative measurement. This means that although it is understood that success is highly dependant on the factors listed above, the relationship requires further investigation. Sykes *et al* (2004) attempted to employ quantitative measurement techniques to identify the differences between an auricular prosthesis produced using conventional methods and one mirrored using digital technologies. Quantifiable findings were then correlated against subjective assessment. This is one of few studies that have attempted to apply quantitative techniques to what has traditionally been subjectively assessed.

Other studies have attempted to measure more quantifiable aspects of prosthesis characteristics using experimental methods. This has included the measurement of impression material performance [Reitemeier *et al*, 1999], adhesive performance [Kiat-Amnuay *et al*, 2001], the

mechanical evaluation of retention systems [Del Valle *et al*, 1995] and silicone material properties [Veres *et al*, 1990]. Whereas these studies do not consider whether a prosthesis is aesthetically correct, they do ultimately provide information on performance aspects that are part of the over all success and have led directly or indirectly to improvements.

Subjective feedback may also result in scientific development. Often a prosthetists' description of a problem or need in non-technical terms may be translated to technical requirements by a technology or material developer. For example; silicone material properties may be adjusted to alter the end results on the basis of feedback such as the material is too tacky.

2.11 - Conclusions of current prosthetic construction techniques

Although the techniques employed in prosthetic construction utilise relatively low value technologies derived from practices that are decades old, they have also been suitably developed over this period to cope with the patient specific demands. By their nature, facial prostheses are one off and custom made, which may preclude many methods of automation typically used in areas of engineering design and manufacture. Each case requires a unique treatment approach that will often rely upon a subjective opinion, assessment and design with the patient present. Hand carving, colour matching by eye and other craft based techniques, although laborious are well adapted at coping with these situations.

Although adaptable, the laborious nature of prosthesis design can cause significant inconvenience and trauma to patients who are likely to have already undergone invasive treatment. This is not desirable and consequently, any technique that reduces patient consultation time and uncomfortable procedures would be of benefit. In addition, reducing clinic time is also likely to benefit the prosthetist and others involved in treatment and therefore have a positive economic impact.

Conventional techniques rely heavily upon practice and skill, which makes achieving a satisfactory result difficult without years of training. Some of the techniques employed are also messy and in

some cases, inaccurate. Impression taking can distort the tissue, especially in soft and highly mobile areas, or with patients who have soft skin. Orbital impressions also rely on the healthy eye being closed, so an accurate comparison is not available when carving the prosthesis.

Areas where digital technologies may offer advantages therefore include:

- Increased speed of production.
- Reduced cost to the health service or other provider.
- Increased quality, predictability and reproducibility.

The introduction of computer-aided techniques to professions such as product, engineering and graphic design has been revolutionary in improving the efficiency and capabilities of services. Chapter 3 will provide an introduction to computer-aided, digital technologies and discuss how they have been applied to maxillofacial prosthetics and surgery.

Chapter 3 – Digital Technologies in Prosthetics

The purpose of this chapter is to review technologies that have been used within the scope of the thesis both on a day-to-day and research basis. It will also outline the principles, history and current research into the application of digital technologies to medical modelling and maxillofacial prosthetics.

3.1 - Introduction to Digital Technologies

3.1.1 - Overview

Digital technologies may be used to describe many different processes, which all centre on the application of computers. The development of digital technologies has traditionally been driven by high value industries such as aerospace and automotive engineering design. These industries are able to invest money in return for increased profitability. As bureau services adopted digital technology, this provided increased access for other industrial sectors. More recently, the technologies discussed in this chapter have become increasingly affordable and therefore accessible to smaller organisations, individuals, universities and colleges.

Four main technologies are considered in this research: Non-contact surface digitising, medical scanning, CAD and RP. These will be briefly discussed before the history of their application in facial prosthetics is reviewed.

3.2 - Scanning

3.2.1 - Non-contact Surface Digitising

Non-contact surface digitising techniques may be likened to taking a digital photograph that records the surface of an object in three dimensions. Surface information of an object is captured in the form of a large number of points, with each point in space corresponding to a point on the captured object's surface. Points are stored as x-y-z coordinates in a computer and when grouped together are termed a point cloud. The more points there are describing a surface, the more

definition will be described. Although the technology was initially developed to meet the needs of engineering design it has also found application in the arts, history and medical sectors. Typical applications include:

- Reverse engineering of surfaces for integration into CAD systems. This may be useful where no original CAD data exists or where complex surfaces have been produced by hand, but are difficult to replicate using CAD.
- Quality and inspection of production parts.
- The acquisition of surfaces to incorporate into a sculpture.
- Capture and recreate data for the movie or animation industry.
- Documentation of art works.
- Digitising dental study models [Bell *et al*, 2003].
- Recording facial morphology [Kau *et al*, 2004].
- Planning surgery and augmentations [Marshal *et al*, 1998, Coward *et al*, 2002].
- Digitising anatomy for anthropometrical / ergonomic studies [Kuo and Chu, 2005].
- Digitising anatomy for prosthesis / orthodontic design [Hajeer, 2004, Bibb *et al*, 2006]

Laser and white light surface digitising are two of the most common forms of non-contact scanning and the techniques. These are both light based methods and work by measuring distortions in patterns created on the scanned object. Software applications are required to translate the point cloud information to a usable file format that may be integrated into a CAD program. Figure 3.1 illustrates the process.

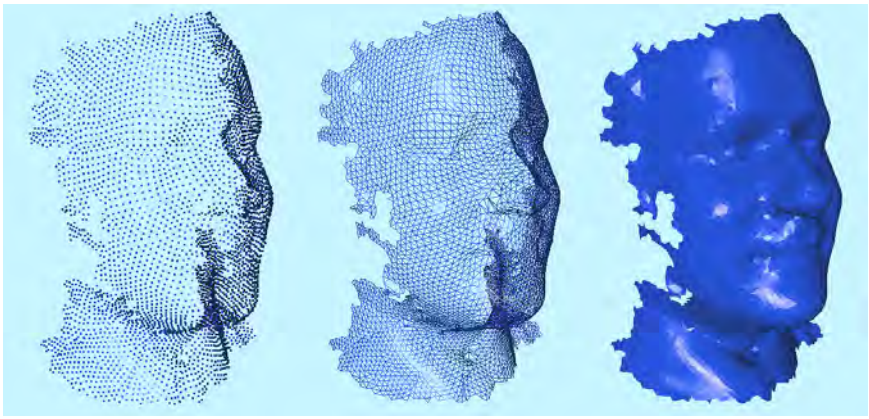


Figure 3.1. Illustration of the point cloud to surface process

Whilst both techniques are capable of providing very highly detailed information, there are limitations. Only areas within the line of sight of the capture camera may be digitised. This means multiple overlapping scans are often required to capture an entire object or surface and sophisticated software is required to align the data. Figure 3.2 demonstrates this.

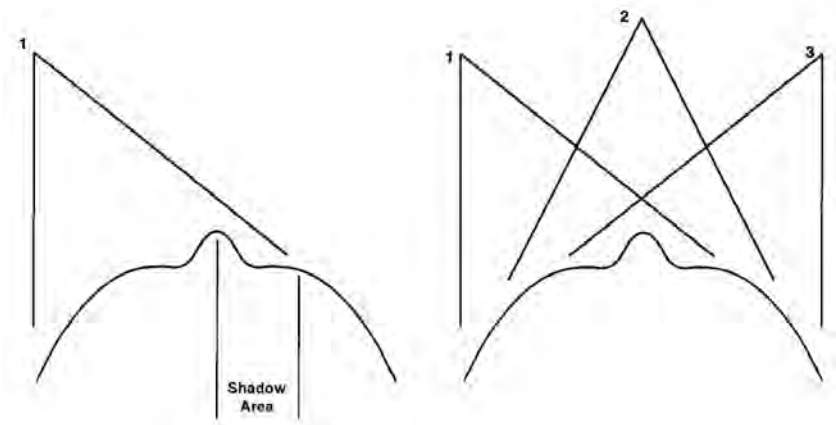


Figure 3.2. An axial cross section through the nose area, demonstrating the need for multiple scans to capture the entire face.

Highly reflective and non-coherent surfaces (such as hair) are also difficult to digitise [Bibb *et al*, 2000] and result in missing surfaces and noise, which can distort the true surface of the object. Figure 3.3 shows a portion of face with holes in the data where the eye and eyebrow should be. There are also other missing patches of data from reflective surfaces or areas hidden from the line of sight. Software is again required to overcome these problems.

Figure 3.3. Holes in scan data due to reflective surfaces, hair and areas hidden from the line of sight. Data from the Handyscan 3D.

The random nature of point cloud data obtained from multiple non-contact scans also means that geometric shapes are not defined by accurate numbers and reference points. For example, an edge that is known to be straight and sharp on the physical object may be represented by points that do not lie exactly along it, resulting in a jagged representation. The faithful representation of geometry is therefore generally a function of the number of points describing it. This means that loss of geometric detail and edges becomes a greater problem when dealing with small objects, which must be described by very high density of points. Figure 3.4a shows a magnetic keeper with a diameter of 4mm on a replica defect cast and b shows the results after scanning with a structured light based digitiser (Steinbichler Comet 250) and converting to the STL file format. Although the keeper has sharp edges and a flat surface, the process of scanning and STL conversion has resulted in a rough surface with jagged edges.

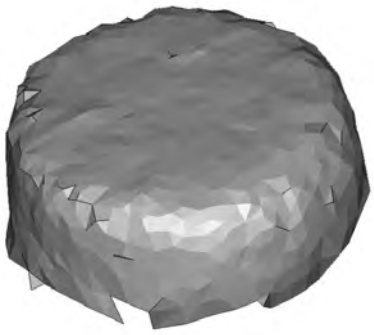


Figure 3.4a (left). A magnetic keeper.
Figure 3.4b (right). A scanned magnetic keeper converted to an STL file.

3.2.2 - Medical Scanning

Computer Tomography scanning

Computer Tomography (CT) scanning was first developed by Godfrey Hounsfield of EMI Laboratories, England in 1972. Tomography is derived from the Greek word "tomos", meaning slice and "graphia" meaning describing. The technology was first clinically available by around 1974-76 as a head only scanner and at a later date as a whole body scanner.

CT works by focussing x-rays through the body and detecting the signal on the opposite side. Scans are obtained in a series of slices, which may then be reconstructed to form a three-dimensional image. Each slice is displayed as a grey-scale, pixel image (much like a digital photograph), which highlights internal and external anatomical detail as different shades. Images are typically 512x512 pixels, but some more modern scanners have an increased resolution of 1024x1024 pixels. Figure 3.5 shows an axial image though the head.

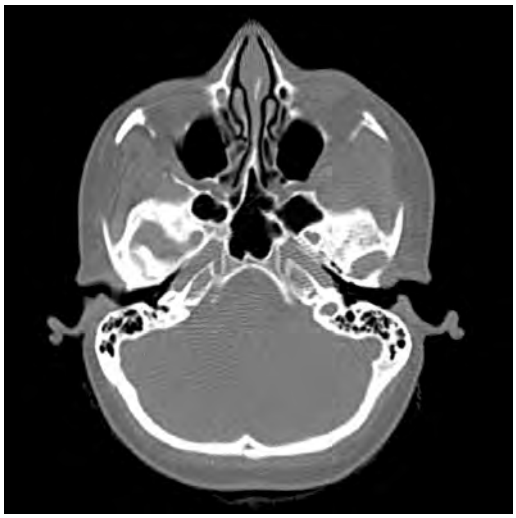


Figure 3.5. A CT image through the head.

CT images are extremely useful as a visualisation and diagnostic tool. CT is particularly good at highlighting bone structures, which appear as bright white in the slice images. Bone densities are easily segmented by selecting the correct Hounsfield or grey scale value, but it is more difficult to distinguish between different soft-tissue types.

Early scanners produced very poor quality, low-resolution images when compared with modern versions. Modern scanners also have much faster capture times than their predecessors and provide a much more detailed image that shows the contrast between tissue types much more clearly. Pixel sizes are typically around 0.25mm to 0.5mm depending on the area focused upon.

Slice thicknesses may be varied, but may be as thin as 0.5mm with modern scanners. The radiation dose does however increase with thinner slices, so a compromise between the required detail and safety must be reached. Slices of 1mm give accurate results for areas of skull, in particular thin bones in the orbital and ethmoidal areas.

Three-dimensional reconstructions may be created by stacking the slices in order to form a volume or surface data set. The quality of reconstructed three-dimensional images is determined by a combination of pixel size and slice distance. Small pixels and thinner slices produce a higher resolution image that will provide clearer information of small details. Conventional CT is however still unable to capture enough detail to pick up textures and wrinkles on the skin surface since sharp detail is lost. This is demonstrated in figure 3.6.

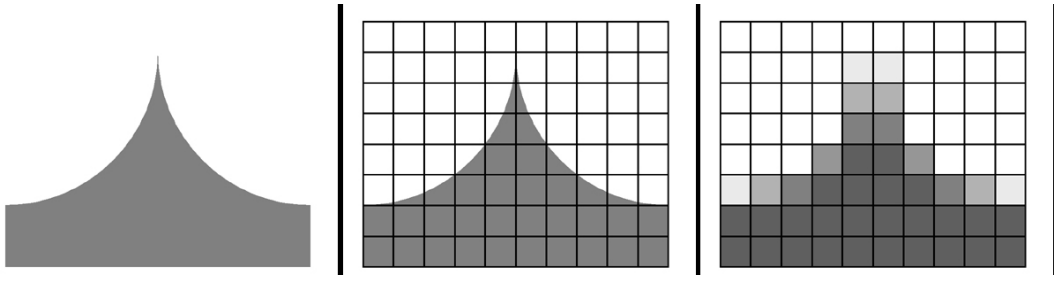


Figure 3.6. The left image represents an example of sharp geometry. The middle image demonstrates the effect of pixilation. The right image demonstrates the resulting blurred edges shown in CT slice data.

A new type of CT scanning called Cone Beam offers increased resolution over conventional scanning and is design particularly for scanning portions of the head. It also gives a far reduced dose of radiation and may therefore provide a more suitable solution for post-surgical, diagnostic scanning. Figure 3.7 shows a cone beam CT slice from a Xoran Technologies, i-CAT scanner.

The data has a slice distance of 0.25mm and a pixel size of 0.25mm. The increased resolution may make it more suitable for capturing soft-tissue details, but the data shows a pixilation effect when three-dimensional reconstructions are generated (Figure 3.8a). This may however be smoothed out to some degree (Figure 3.8b).

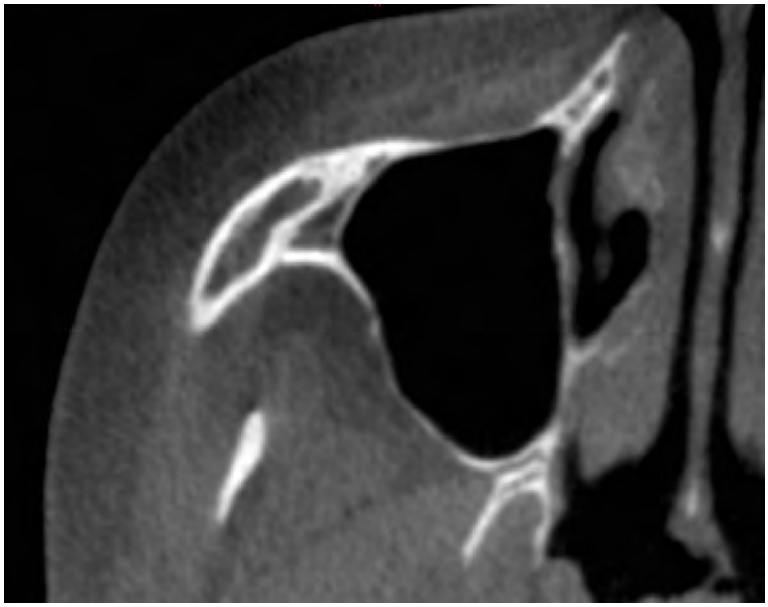


Figure 3.7. Sample data from an i-CAT, cone beam CT scanner. Close up of the maxillary sinus area. 0.25mm pixel size.

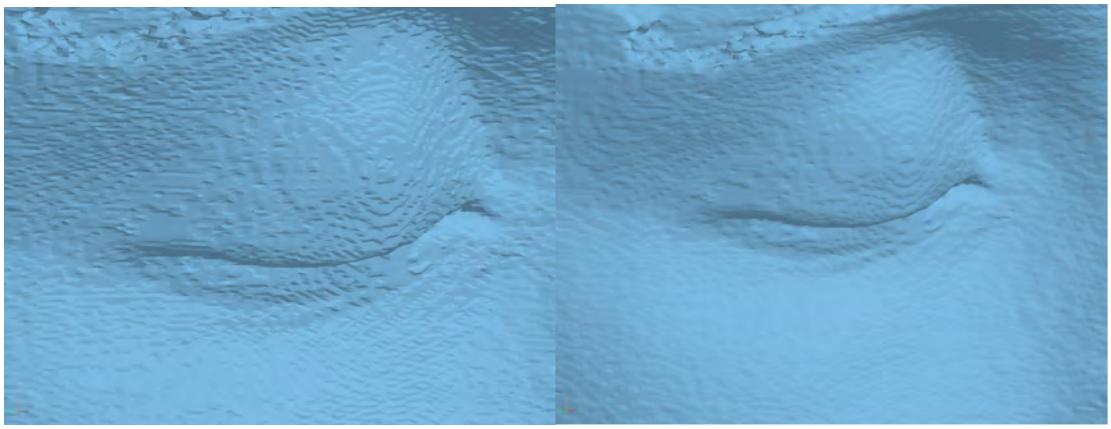


Figure 3.8a (left) and 3.8b (right). Three-dimensional reconstructions from the i-CAT cone beam scanner.

Magnetic Resonance imaging

Magnetic Resonance (MR) imaging is another technology commonly used in hospitals as a visualisation and diagnostic tool. Pixel based slice images, similar to CT are produced and may be

reconstructed to produce a three-dimensional representation. Figure 3.9 shows a typical MR image through the abdomen.

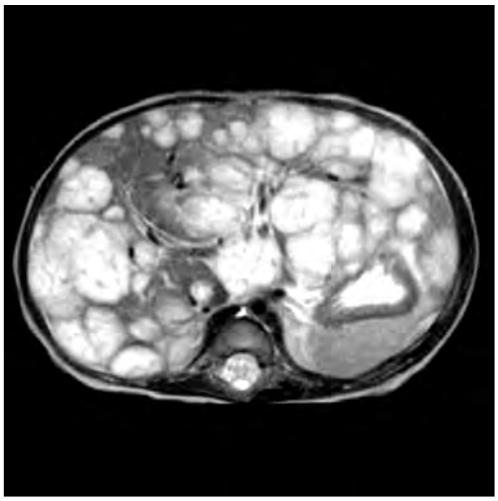


Figure 3.9. A typical MR image through the abdomen.

MR works by aligning molecules in the body using magnetic fields, using radio waves to temporarily disrupt the molecule alignment and timing how long it takes the molecules to return to their aligned state. Depending on what is being looked for, the scan settings may be altered to highlight different tissue types more clearly. T1 weighting highlights fatty tissue as bright white, but cerebrospinal fluid (CSF) and cysts as dark grey. T2 weighting highlights cysts and CSF as white, but fatty tissue as dark grey.

There are key differences between MR and CT. MR is generally more sensitive than CT at showing the difference between soft-tissue types and is a particularly useful tool for detecting the early stages of abnormalities in soft-tissue. MR does not expose the patient to potentially harmful radiation, which also makes it an ideal outpatient scanning method. Scan times are however much longer than CT and require the patient to lay still from anything up to half an hour making it a less useful tool in trauma cases or with uncooperative patients who are unwilling or unable to lay still for long periods. Due to the longer scan periods, the slice thicknesses are typically in the order of 3-5mm making it less suitable for capturing fine three-dimensional detail. CT is also better at highlighting bony anatomy and also tends to give a better definition between skin and air than MR. MR is also an expensive technology to operate, partially due to the long scan times.

As with any advanced technology, MR scanning techniques are constantly improving by reducing scan times and improving image definition. This is also likely to lead to operative cost reductions.

3.3 - Computer Aided Design - CAD

Three-dimensional CAD was pioneered by the product development / engineering sector and helped to revolutionise the ways in which products were developed by improving accuracy, communication and the ability to visualise products and components before manufacture. CAD is based upon defining geometries and relationships between geometries. For example, lengths, angles and curves are relatively simple to define in two-dimensional geometry. Three-dimensional CAD describes surfaces and enclosed volumes, typically defined from original two-dimensional data. Features are added to an original component by defining their geometry and the relationship between them with dimensions. The completed component is typically described by many construction stages, geometries and features with their own construction history and constraints. Figures 3.10a-c demonstrates the stages from a 'wireframe' model, to a fully rendered model of a product assembly.

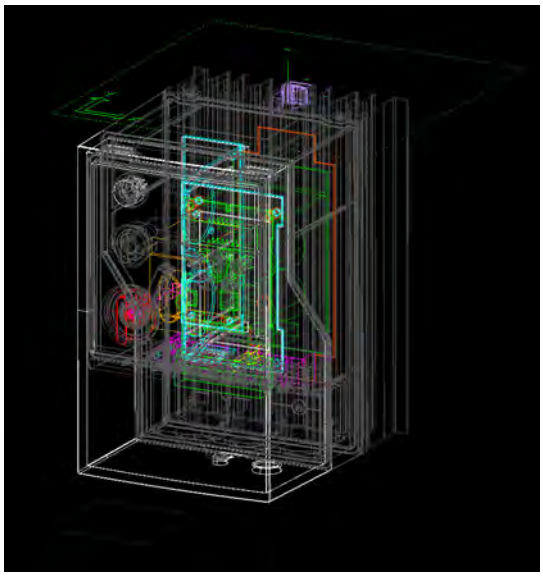


Figure 3.10a (left). A 'wireframe' model of a CAD assembly.
Figure 3.10b (right). Basic solid model rendering of the same assembly.

Figure 3.10c. Full rendering of the same assembly shown in 3.10a and 3.10b.

Utilising three-dimensional CAD also provides access to many advanced manufacturing technologies such as Computer Numerically Controlled (CNC) and RP that are capable of turning designs into parts in a short timescale. Working within a three-dimensional CAD environment has helped industry to dramatically reduce product time to market, spot mistakes earlier and allow departments within an organisation become more involved in the development process. The improved repeatability and inherent accuracy of CAD and associated manufacturing technologies has improved the efficiency of many manufacturing processes.

As with many new technologies, CAD was initially very expensive and only accessible to wealthy organisations with large research and development budgets. The cost has significantly reduced since its first introduction making it more accessible to smaller organisations or individuals. The widespread application of CAD has also allowed the associated technologies to develop and reduce in price.

More recently, non-conventional CAD software have revolutionised the way in which geometries may be defined. Developers such as SensAble Technologies and Pixologic have produced software capable of defining and manipulating more anatomical forms that conventional CAD is not able to handle.

FreeForm (SensAble Technologies) is unlike conventional CAD software. Shapes may be designed and modified arbitrarily by the user with tools analogous to those used in physical handcrafting. Rather than a mouse, the user interface with the software is provided by a stylus [Phantom Desktop haptic interface; SensAble Technologies Inc.] that incorporates positioning in three-dimensional space and allows rotation in all axes. In essence, the stylus translates hand movement to the virtual sculpting environment. Force feedback (haptic) sensations (for example, when the virtual tool contacts the model) in relation to the tool position within the sculpting environment are fed through to the user with the result mimicking handcrafting. Although the software does not rely as heavily on mathematically defined and constrained geometry as engineering CAD, precision is ensured by accurately definable sculpting tools and precise measuring techniques. The computer model of the object being worked is referred to as 'clay' by the software, but may also be thought of as a digital version of the wax used when designing a prostheses pattern in the lab. The clay may be handled in a similar way as the physical methods. Roughly defined shapes are gradually refined in order to produce the higher levels of detail required in the finishing stages. Shapes can be viewed from any angle, clay added to the model and measurements in any direction established in precise ways. A protective mask or 'buck' setting may also be used to protect a model from inadvertent carving.

The range of tools available within FreeForm allow clay to be modelled and shaped in many different ways, including ones that would not be possible if shaping by hand using conventional methods. These include carving with various shaped tools, tugging, building up areas by attracting clay towards the tool, indenting, embossing, creating groves, Boolean cutting, addition and intersect options (see glossary or Mullineux, 1986 & Jones, 1992 for descriptions) etc. In addition, undercuts may be analysed, views from many different angles established, guide planes placed to

assess anatomical positioning and images rendered to look more realistic. One of the most significant advantages that digital design offers is the ability to save work, undo operations that were not successful, and produce multiple copies if required.

Z-Brush (Pixologic) is similar in style to FreeForm, but does not provide the haptic feedback or as wide a range of manipulation tools.

3.4 - Rapid Prototyping (RP)

3.4.1 – Overview

Rapid Prototyping is term used to describe a set of technologies that build physical parts directly from three-dimensional computer data. Traditionally it is used to produce small numbers of parts that are used either for prototypes or as patterns in downstream manufacturing processes, although more recently material and process improvements have allowed more functional parts to be produced. This has led to the term Rapid Manufacturing (RM). Perhaps a more accurate term for these technologies is layer additive manufacture, since they all build parts in a layer-by-layer basis.

RP has become the most widely adopted description.

3.4.2 - Principles

There are a number of key differences between RP and other manufacturing methods. RP processes are additive; they build parts as opposed to remove material like machining processes. They also require no tooling unlike mass manufacturing processes, but are actually extremely slow in building compared to many other production techniques. It is the layer-by-layer nature of the process that allows RP to build parts that would otherwise be impossible. Internal detail and undercut features are extremely difficult to create using moulding or machining techniques, but are

simple for RP since it is not limited by tool paths, draft angles and many other manufacturing constraints.

Although many RP technologies exist, they all share similar principles. CAD geometry is sliced into layers that are then physically recreated by the RP process. A sliced circular profile is demonstrated in figure 3.11. RP technologies are differentiated by the materials and processes used to create the layers. Various methods are employed and result in parts with extremely different properties.

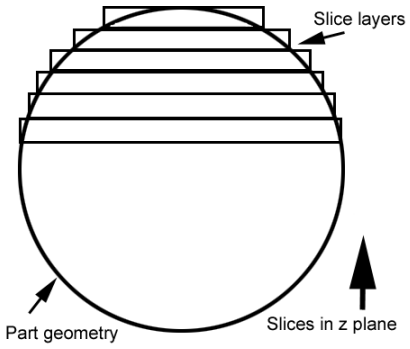


Figure 3.11. The effect of layering in RP produced parts

3.4.3 - RP history

RP technologies were first developed in the late 1970s and early 1980s by C. Hull at Ultra Violet Products, H. Kodama at Nagoya Prefecture Research Institute and A. Herbert at 3M [Jacobs, 1992]. These individuals worked independently, developing similar systems that built parts layer-by-layer in ultraviolet cured resin. It was Hull that developed the first patent in 1986 and formed 3D Systems with R. Freed [Jacobs, 1992]. They named their process StereoLithography (three-dimensional printing). Kodama and Herbert's research ceased when funding ran out. The first commercially available RP machine called the SLA-1 (**S**tereo**L**ithography **A**pparatus) was sold by 3D Systems in 1987 and a partnership with Ciba-Geigy was formed to develop resins specifically for the process. Hull and Freed were also responsible for developing the STL (derived from **ST**ereo**L**ithography) file used to represent three-dimensional digital parts before RP manufacture. Development of the technology led to the 1989 release of the SLA-250 machine, then the larger

and faster SLA-500 (eight times the build volume of the 250) and more recently the Viper. By 1994, stereolithography was the most popular RP technology in the global market [Jacobs, 1996].

Since the advent of the first SLA machine, other manufacturers developed mimicking technologies, but due to patent restrictions were unable to sell in America and Europe. Many alternative technologies by other manufactures have also been introduced and have become highly successful in the market place. Some of the most popular RP technologies are summarised in table 3.12.

RP technology	Description	Build material
StereoLithography (SL)	3D-Systems manufactured. Polymerises a liquid substrate to a solid form.	Epoxy or acrylate resins
Selective Laser Sintering (SLS)	DTM or EOS manufactured. Sinters a powder material to a solid object.	Various plastics, ceramics and some metals. Typically nylon.
Laminated Object Manufacture (LOM)	Helisys manufactured. Stacks layers of paper to form the solid object. No longer manufactured.	Paper
ThermoJet printing	3D-Systems manufactured. Inkjet style printing of a wax material. No longer manufactured	Wax polymer
Solidscape printing	Solidscape manufactured. Selective deposition of molten wax.	Wax polymer
Fused Deposition Modelling	Statasys manufactured. Extrudes fine plastic layers.	ABS, Polycarbonate
Objet printing	Objet Geometries manufactured. Uses ink jets to deposit photopolymer layers that are then cured.	Un-disclosed Photopolymer
Perfactory	Envisiontec manufactured. Polymerises a liquid substrate.	Acrylate photopolymer
Z-Corp 3D printing	Selectively binds a powder base material. Can also build in colour.	Plaster and starch
Selective Laser Melting (SLM)	MCP manufactured. Melts metal layers from a powder substrate.	Stainless steel, chrome cobalt, titanium and other metal alloys.

Table 3.12. Some common RP technologies

When considering the choice of RP technology for engineering and product development applications, there are a number of factors that will determine the best solution, including: material physical properties, ability to post finish, achievable accuracy and ability to build small detailed features. Each RP technology has unique advantages and limitations so the choice of process will primarily be dictated by the end application. There is no one process that will suit all needs.

More recently, many RP technologies have become financially and technically accessible to smaller organisations, universities and colleges. This has led to their more widespread adoption for both engineering and medical purposes.

3.5 - File Formats used with RP

3.5.1 - The STL file

The STL file has become the *de facto* standard throughout the RP industry for the transfer of 3D data since its inception for the first SLA-1 machine. It is freely available and therefore all major CAD software supports the format.

The STL file describes triangles that make up three-dimensional geometry. It is a representation of the original CAD data. The file contains information on which side faces outwards and the co-ordinates of each triangle point. Since triangles have straight edges, curved surfaces of CAD geometry are approximated by a series of interconnecting flat, triangular surfaces. This means the STL file accuracy compared to the original CAD model geometry is directly proportional the number of triangles that define it. Planar surfaces are exactly accurate since they can be defined by triangles. The number of triangles is directly related to the STL files size, but although this may increase the preparation time, it will not have an effect on the part build time. Figure 3.13 shows the result of facets on a curve which may show up on the final model.

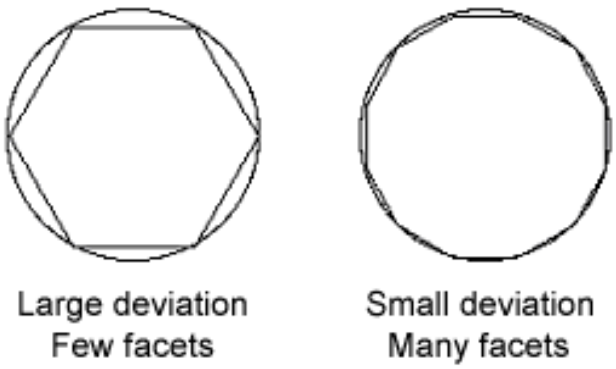


Figure 3.13. The effect of facets on a curve

In order to reflect the required part accuracy, most CAD software allows the deviation or resolution to be user defined using different techniques. Two popular methods are to define the percentage of chord length or absolute deviation from the true curve (figure 3.14 and 3.15).

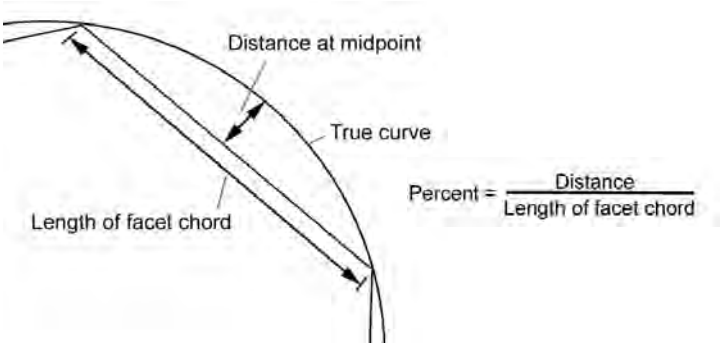


Figure 3.14. Percentage deviation

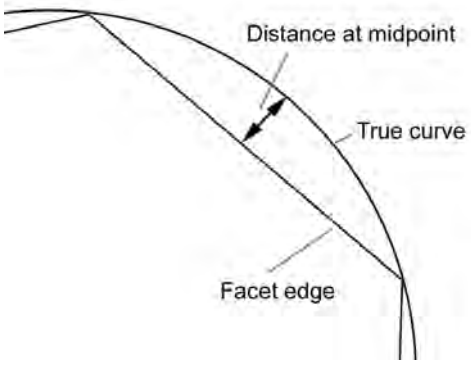


Figure 3.15. Absolute deviation

STL files also have the ability to describe the component surface in colour. Using this option assigns a red, green, blue colour value to each triangle representing the objects surface. This allows RP technologies such as the ZPrinter 310 plus (Z Corporation) to physically reproduce the colour in the physical model.

3.5.2 – The Selective Layer Contour (SLC) format

The SLC format defines the 3D geometry in a series of slices, much like CT scan data. The model volume is represented by layer contours stacked in the z axis distinguished by polylines that define internal and external surfaces. Since no approximation of curved surfaces is made, SLC generates smoother curved surfaces that represent the original data more accurately. Of course, there will be

a degree of approximation since the data is vector based, but SLC produces a smaller, more efficient file size when compared with STL. Although a common link between CT data and the stereolithography process, the SLC format is otherwise relatively uncommon and very few software packages use it, therefore it has limited application in the exchange of data.

3.6 – Digital technology in medical modelling and prosthetics

3.6.1 - Overview

The application of digital technologies in the production of accurate models of patient anatomy was revolutionised by the widespread introduction of CT scanning in the 1980's. It was quickly realised that by stacking the series of two-dimensional images produced, a three-dimensional representation could be displayed and fabricated. In order to create physical three-dimensional models from CT data, thin aluminium plates were cut to the contour of each CT slice and stacked in order [Rhodes M, 1985, Vannier *et al*, 1983, Mankovich 1985. All cited by Swaelens and Kruth, 1993]. Although this may now be considered crude, the principles remain the same today. With the advent of RP technologies, principally Stereolithography and specifically designed software such as Mimics (Materialise), the accurate and rapid production of physical models of patient bony anatomy became more widespread [Swaelens and Kruth, 1993]. The techniques of physical model production were predominantly used to make bone models, but as early as 1993 it was reported that it may be possible to apply these technologies to soft-tissue modelling [Swaelens and Kruth, 1993]. Today, there are a range of advanced technologies available that allow the accurate capture, representation, manipulation and reproduction of both soft and hard tissue anatomy. The application of these technologies will be explored in the following sections.

3.6.2 - CT scanning and RP for bone models

1972-1979

With the advent of CT scanning in the early 1970's imaging of the body was revolutionised. Within the space of five years, research was focussed on the generation of 3D images from CT slice data [Herman and Liu, 1977].

1980-1990

Research into the visualisation of 3D models continued throughout the early to mid 1980's, but there was also increased interest in the fabrication of physical models from reconstructed CT slice data. According to Swaelens and Kruth (1993) and Santler *et al* (1998), Alberti was the first to publish the idea of making 3-dimensional models from CT data in 1980. Considering that some of the first published work on 3-dimensional visualisation from CT data was only presented in 1977 by Herman, Alberti's idea was extremely ambitious and initially rejected by commercial developers according to Swaelens and Kruth (1993). Despite this, the production of physical models from CT slice data was presented by Marsh and Vannier (1983) and by Rhodes (1985) (both cited by Swaelens and Kruth, 1993). The techniques presented were extremely crude compared with current technology and relied upon cutting out and stacking sheets of aluminium according to the individual slice layers. Concurrently, other techniques were also being used to produce physical models, the most popular being machining. At this time machining was an established technology, especially in other areas of engineering and manufacture whereas rapid prototyping (in particular Stereolithography) was relatively new and had certainly not been exploited to a great degree in the medical sector.

More pioneering work was however underway by the end of 1980's. Toth *et al* (1986) published some of the earliest attempts at using computer and machining technologies to manufacture corrective prostheses for craniofacial reconstruction. The techniques relied upon CT scanning and

3-dimensional imaging, photography and milling in order to produce alloplastic implants, templates for fashioning autogenous bone grafts, modelling tissue removal and implant prosthesis design. Although rudimentary, this was perhaps the first step towards computer assisted prosthesis design.

Mankovich *et al* (1990) and Palser *et al* (1990) (cited by Swaelens and Kruth, 1993) separately were some of the first to produce a model from CT data using Stereolithography in 1990. The processes employed were however time consuming and provided limited detail resolution compared with current practices. This was due to the inability to interpolate smoothing layers between the original CT slice thickness. Arguably one of the most significant research outcomes in relation to current directions was published by Evenhouse (1990) (Cited by Swaelens and Kruth, 1993). Stereolithography was used to produce a mirrored ear as a pattern for producing the contralateral prosthesis. This may be the first ever computer assisted design of an ear prosthesis.

As computer aided tools were developing in areas of surgery and prosthetics, so they were in other medical sectors, especially dentistry. Some authors had already begun to explore the application of optical, surface scanning in the fabrication of dental components such as inlays [Grimm, 1989 & Leinfelder *et al*, 1989]. Optical scanning methods would later become a key tool in the acquisition of facial data for computer aided prosthesis design. The Biomaterials Clinical Research, School of Dentistry, University of Alabama had developed a system [CEREC] that utilised optical scanning technologies coupled with CAD and machining method to produce ceramic dental components, which by 1990 had been in clinical application for around three years [Mormann *et al* 1990].

1991-2000

During its establishment as the favoured tool for physical model production, RP has been evaluated against other manufacturing methods such as CNC machining [Klein *et al* 1992 & Santler *et al*, 1998]. Although Klein *et al* based his study on now outdated manufacturing technologies, his arguments conclude that RP methods are more appropriate to produce fine details, undercut and internal structures prominent in the skull, with the major draw backs of RP being the technological

cost and time involved. Pioneering research in the early 1990s by the Catholic University of Leuven, Belgium, focussed on improving the computational and technical hurdles faced by RP technologies. Here, interface software technologies were being developed with the aim of reducing the processing requirements, improving slice interpolation, data manipulation and file generation for the RP process. The techniques took advantage of advances in CT scanning technologies such as continual spiral scanning which dramatically reduced scan times and therefore reduced movement artefact. Two software modules were developed: MIMICS and CT-Modeller. MIMICS gave the ability to select the required tissue by means of adjusting the greyscale value, edit the slice images to remove artefact caused by metal objects and segment the data into areas of particular interest. For the time, this was a revolutionary and powerful tool. The data outputted from the MIMICS module was translated to the CT-Modeller, which provided the tools necessary to build a Stereolithography model. This included the ability to interpolate between the relatively thick CT slices to generate smooth contours. A method of support generation was also developed and coupled with the MIMICS module. A spin off company formed from research undertaken at the University of Leuven called Materialise was formed in around 1990. The software developed there would quickly become one of the most widely used to prepare medical models for building using RP technologies.

At around the same time in Germany, Klein *et al* (1992) published work [in German] of a Stereolithography produced skull. This however used a relatively inefficient technique compared with those developed at the University of Leuven.

The first applications of non-contact surface digitising were also being explored in the late 1980s and early 1990s by authors such as Moss *et al* (1987), Cutting *et al* (1998), Topper and Fernie (1990), Marshall *et al* (1990) and Bhatia *et al* (1994). Research focussed on imaging techniques for orthopaedic prostheses, facial morphological work but the application to maxillofacial prostheses was left unexplored until later.

By 1993, methods of RP produced models were becoming increasingly refined, driven by research at the University of Leuven [Swaelens and Kruth, 1993], yet the processes were still not in widespread use. From 1992 until 1995 most research into the application of RP technologies for medical modelling was centred in Belgium, Australia and Germany. In 1995, Wehmoller *et al* applied CAD/CAM technologies typically utilised in industrial engineering practices to assist the design of implant prostheses. The benefits cited were strikingly similar to those identified in modern approaches: the ability to create complex forms in materials suitable for implanting and the non-contact nature of the process.

At around 1996 the first selectively colourable Stereolithography material was utilised by Materialise. Still in use today, this allows areas of model to be coloured in order to highlight specific details that improve visualisation for planning. It is also certified as a low toxicity material (FDA 23, USP Class 6), which makes the parts produced suitable for handling under theatre conditions.

The application of MR data to produce models of soft-tissue was first reported by Swann in 1996. Although pioneering, the techniques described highlighted a number of problems due primarily to the thick slices of the MR scan and translation of data to a suitable format for RP manufacture. Mehta *et al* (1997) compared MR, CT and ultrasound scanning for the generation of finite element CAD models and concluded that resolution was an important consideration when selecting an appropriate technology. Although physical models were not produced, CT scanning was demonstrated as the most appropriate technology for capturing both bone and soft-tissue due to its higher resolution. Few others have considered the use of MR scan data, possibly for some of the reasons highlighted by Swann (1996) or lack of requirement given that CT has become relatively routine in cases where bony defects require highlighting..

3.6.3 - Applications in soft-tissue prosthetics

The current interest in advanced technologies to soft-tissue prosthesis design may be traced back to around 1997. An overview of recent research into the application of digital technologies in soft-tissue prosthetics is shown in table 3.16.

Author / year	Prosthesis type	Technologies	Issues addressed
Chen *et al*, 1997	Orbit	**Scanning** - Surflacer VMR-301 (UNISN) **CAD** - NURBS (Kubota Computer) **RP** - SLA (SOUP-600PA) - CNC machining (Roland CAMM-3)	**Novelty:** First to use laser surface scanning, specifically for soft tissue prosthetics. Used CAD to design the prosthesis and milling to produce a wax model pattern (not clinically applied though). Limitations with milling fragile wax and undercut surfaces were noted. **Limitations:** Limited ability subtly contour realistic details using the CAD surfacing methods.
Coward *et al*, 1999	Ear	**Scanning** - MRI **CAD** - Unknown **RP** - SL A silicone tool was created from the SL ear and used to create the wax pattern	**Novelty:** MRI Scanning (no radiation, can capture undercuts, but slow). **Limitations:** Required the production of silicone tools to produce a wax pattern.
Chua *et al*, 2000 Nanyang Tech. Uni.	Ear	**Scanning** - Laser surface **CAD** - DUCT (Delcam) - CopyCAD (Delcam) **RP** - SL - SLS - FDM - LOM Vacuum casting was also used to create the final prosthesis	**Novelty:** Compared a range of RP methods. First to design and fabricate a tool using digital methods and compare this to in-direct tool fabrication. **Limitations:** A polyurethane prosthesis was provided. This could not have been accurately colour matched as is typically required to make a realistic prosthesis.

Gebhardt, 2000	Ear	**Scanning** - CT **CAD** - Unknown **RP** - 3D printing (not described in detail)	**Novelty:** Recognition and in-depth discussion of clinical implications. **Limitations:** No detail provided on methods used.
Bibb *et al.* 2000	Orbit / face	**Scanning** - Structured white light **CAD** - Polyworks **RP** - LOM	**Novelty:** In depth discussion of the limitations of surface scanning. **Limitations:** CAD not used to design the prosthesis pattern.
Zeilhofer *et al*, 2000	Nasal	**Scanning** - Ultrasound **CAD** - N/A **RP** - Stereolithography	**Novelty:** first to use ultrasound to acquire facial contours with potential to assist in prosthesis design. **Limitations:** No prosthesis was designed.
Bibb *et al.* 2002	Cranioplasty plate	**Scanning** - CT **CAD** - FreeForm **RP** - Stereolithography	**Novelty:** First to apply FreeForm, sculpting CAD. **Limitations:** Used for cranioplasty contouring, not a facial prosthesis.
Runte *et al*, 2002	Orbital	**Scanning** - Structured white light (Topometric sensor head, GOM) **CAD** - Rhinoceros (R. McNeel) **RP** - SLA	**Novelty:** Used CAD to visualise asymmetries. First to consider obturator design and incorporate this into a digital prosthesis design. **Limitations:** Additional stages were required to generate the wax patterns (not elaborated on in the paper).
Cheah *et al*, 2003a. Nanyang Tech. Uni. Singapore. Part 1 of research.	Ear Nose	**Scanning** - Facia Laser Surface scanner (UCL) - ATOS (GOM) **CAD** - Surfacer (Imageware) **RP** - SLS - SGC Silicone mould tooling and vacuum casting used to produce the final prosthesis	**Novelty:** Comparison between multiple RP and CAD technologies. First to compare digital tool design and fabrication against digital pattern design and fabrication. **Limitations:** Lacking in clinical focus, especially on details of final prosthesis production. Extensive time using surface modelling CAD software would have been required to digitally design a mould, especially for an ear.
Cheah *et al*, 2003b. Nanyang Tech. Uni. Singapore. Part 2 of	Forehead	**Scanning** - Polhemus FastScan **CAD** - Surfacer (Imageware) **RP**	

research.		- SLS - LOM Vacuum casting used to create the final prosthesis	
Verdonck, *et al* 2003a&b	Orbital	**Scanning** - CT **CAD** - FreeForm (SensAble) **RP** - ThermoJet (3D Systems)	**Novelty:** First to consider implant placement planning. First to use FreeForm CAD for prosthesis form design. First to use ThermoJet wax printing. **Limitations:** Although implant retention was incorporated, the structures were not designed in CAD or fabricated using RP. The method also required CT data.
Reitemeier *et al*, 2004	Orbital	**Scanning** - Structured white light (kolibri method by Fraunhofer Institute **CAD** - Surfacer (Alphacam) **RP** - ThermoJet	**Novelty:** Application of non-contact scanning, CAD and ThermoJet to produce a pattern. **Limitations:** conventional, surface modelling CAD used to design the prosthesis form. No mention of implant retention mechanisms.
Tsuji *et al*, 2004	Facial	**Scanning** - Surflacer, laser digitiser **CAD** - Basic CAD software to mirror **Production** - Milling (Roland miller) in wax	**Novelty:** An alternative method for creating wax patterns based on mirroring the unaffected side and incorporating the affected contours was developed. **Limitations:** This was a lengthy and unintuitive method.
Sykes *et al*, 2004	Ear	**Scanning** - Breuckmann Optotop white light **CAD** - FreeForm **RP** - ThermoJet	**Novelty:** First to use optical scanning, FreeForm and ThermoJet production together. First to provide statistical comparisons between a conventionally produced pattern and digital version. **Limitation:** compared the plaster cast, not the final prosthesis. Did not consider implant retention. No detailed breakdown of time provided.
Chandra, *et al*, 2005	Ear	**Scanning** - Polhemus Fastscan **CAD** - Simple mirroring **RP** - ThermoJet	**Novelty:** First to use a handheld scanner, allowing the capture of undercuts more easily. **Limitations:** Indirect scan of a replica cast. Didn't incorporate implant retention mechanism.

Table 3.16. Summary of past research into the application of digital technologies in soft-tissue, facial prosthetics.

As computer technologies have improved, so has the ability to capture, represent, manipulate and re-create anatomical forms. Whilst RP became an established technology in the production of bony medical models, research began to plateau as other, arguably more challenging areas for investigation were identified. This was reflected in work from Japan by Chen *et al* (1997). Chen *et al* were one of the first to introduce the concept of non-contact surface digitising, CAD tools and RP fabrication in the design of soft-tissue facial prostheses through a patient case study. This research cited the advances made and benefits advanced technologies had brought to other areas of medical applications and therefore applied similar processes. As in previous work related to the production of bone models, this research identified RP as the most suitable production method for complex anatomical forms, primarily due to its ability to build thin and undercut sections that would not otherwise be possible. Conventional, engineering CAD surfacing software was used to generate the prosthesis pattern based upon a method of copying and mirroring information from the unaffected side of the face. This identified one of the major technological limitations that more recent work has also cited. Facial asymmetry meant that the mirrored anatomy would not simply fit the defect and it was difficult to manipulate the design sufficiently to accommodate the required contours. Although the principles and potential benefits were clearly identified in this research, it also highlighted some of the major difficulties that make the digital prosthesis design challenging.

Since 1998, the Nanyang Technological University at Singapore have been instrumental in applying advanced technologies in areas of soft-tissue prosthetics. An early study by Chua *et al* published in 1998, aimed to identify a suitable link between laser surface digitising and rapid prototyping methods with a view to developing the techniques for clinical application. References were made to research undertaken by the National Research Council of Canada and University Hospital of Knappschaftskrankenhous, Germany, where CAD and milling technologies were being used to store and manufacture anatomical models derived from CT data. In a critique of this work, Chua *et al* stated that "since the CT data is relatively inaccurate, the fabricated implant would not be precise." This statement was however unsupported by a reference to previous work or proven during his study and more recent research by Coward *et al* (2005) suggested that CT, MR and optical scanning produces acceptable results for auricular prostheses. Instead of CT scanning, laser

surface digitising was used in two studies to capture the facial and breast surfaces, which in turn highlighted many practical limitations. The scan times were around seven seconds, which in photographic terms and when compared with modern technologies is a very long time, during which the subject is likely to move slightly, distorting details [Bibb *et al*, 2000]. Complex and time-consuming methods of point cloud to surface file conversion were also employed, which made the process inefficient. It may however be considered that the problems experienced at the scanning stages were primarily due to technological limitations of the time rather than the fundamental ideas behind the technique. Two commercially available engineering design software packages were used to represent the surface data, DUCT and Pro-Engineer. Whilst able to represent relatively complex surfaces and mirror data to create contra-lateral models to assist prosthesis production, no mention of contour manipulation was made. This may not have been necessary for the case studies highlighted, but as Chen *et al* (1997) noted, this would be necessary in many facial prosthesis cases. Whilst Chua *et al* (1998) successfully identified potential methods of capturing and re-creating anatomical topography, the techniques used did not represent an intuitive solution for clinical applications due to their complex and time consuming nature.

More recent research published in 2000 [Chua *et al*, 2000] from the same authors and university went further towards identifying and testing technologies that may be used to assist soft-tissue prosthesis production. Two different approaches based upon the techniques developed in the 1998 research were applied to a prosthetic ear case. Route one produced a prosthesis pattern and route two produced an RP mould for the final prosthesis production. The authors anticipated that surgery to place an implant would take place following the production of a prosthesis. This approach is not typically used since the soft-tissue contours will alter dramatically after surgery and during healing, so a previously designed prosthesis would be unlikely to fit. Despite this, laser surface digitising was used to capture anatomy required for digital ear prosthesis construction. The scanner was only able to capture surfaces within the line of sight and consequently areas of undercut such as behind the ear could not be digitised. It was also necessary to remove scatter and invalid point data to produce a smooth surface. These two operations required significant amounts of CAD remodelling to achieve a realistic result.

Once the digital scan impression was acquired, RP techniques were used to create a mould and patterns directly. In the first method, four RP processes were compared: SL, SLS, LOM and FDM. These RP processes produced parts with varying levels of surface finish, but significantly, none of them would have integrated well with conventional wax or clay sculpting techniques easily. Modifying the pattern to blend into the surrounding anatomy and define wrinkles and textures would have been very difficult. The SL and FDM patterns in particular would also have required hand finishing in order to remove the stair step effect. This would add another process stage. Issues of de-lamination were also experienced with the LOM models. The RP patterns were used to create a two-part silicone tool into which the polyurethane prosthesis material was vacuum cast. This was a time consuming stage with took four hours for the silicone mould to cure. It would also have been difficult to control the colour of the prosthesis. The second method of prosthesis production considered direct mould manufacture from the digital design. Whilst this did remove the silicone tool stage, it required a lengthy process of CAD manipulation using software better suited to engineering applications. The RP moulds produced were also expensive compared to conventional plaster versions and it would have been difficult to remove the effects of stair stepping in the internal mould cavity surfaces.

This research placed much emphasis on the application of engineering based technologies, but appeared to lack clinical focus. No in-depth consideration was given to the fitting, colouring and minor modifications required to produce a realistic result and the CAD methods employed would have not provided an intuitive solution to a prosthetist.

Coward *et al* (1999) published a more clinically orientated approach that also provided considered arguments for the technologies employed. The work was continued from his previous research (1997) that utilised laser surface scanning and CNC milling to generate an auricular prosthesis pattern. Shortcomings in the previous research (inability to capture all of the ear and difficulty in machining complex forms) were identified and solutions addressed in the 1999 research. Magnetic resonance imaging was chosen as the capture method despite the long times required for the patient

remain motionless. Coward *et al* dismissed CT scanning due to the radiation exposure unless it was also required for implant planning. Custom designed software was used to mirror the healthy ear, plan the location and produce a file of the mirrored ear combined into the defect side (digital design of the prosthetic solution). Both a model of the prosthetic solution and defect side without the ear were fabricated using stereolithography. The prosthetic solution stereolithography pattern was used to create a three-part, silicone mould. In order to form a wax trial pattern that would fit the patient's defect, the model of the defect side was placed inside the mould and material poured in through a sprue hole to cover it. Conventional finishing methods were used to adapt the pattern for implants and to alter the margins to achieve a good fit.

Coward's *et al* research showed a good understanding of the clinical needs and addressed the issues of poor data capture and subsequent CAD remodelling required that hindered other processes. Issues of pattern modification and subsequent integration with current techniques were also considered, but the choice of RP technique may not have been the most appropriate. The process of achieving a wax pattern was lengthy and the process could have been improved. Further recommendations and suggestions for the process including the integration of laser scanning to capture post surgical topography of the defect side were identified and good comparisons with conventional carving techniques made. Shortcomings of this research that have been addressed in more recent research, including the use of laborious and expensive methods to create a wax pattern. This was however balanced by the good clinical focus and consideration of the need to integrate the techniques with current practices.

Bibb *et al* (2000) reported on the application of non-contact scanning and RP to assist the production of soft-tissue prostheses. The research aimed to identify and evaluate the effectiveness of the technologies and apply them in a patient case study. Many of the limitations previously identified were also highlighted by Bibb *et al*. These included the inability of non-contact scanners to capture areas hidden from the line of sight, covered by hair or highly reflective. All of these features exist on the body and are especially prominent on the face. In order to overcome these issues, four, multiple overlapping scans were required to cover the required anatomy of both orbits.

These required the subject to remain still for periods of around forty seconds each time. Slight movements still produced some noise and distortions in the data. According to the author (in personal communications), point cloud data alignment and subsequent surface data interpolation was difficult and time consuming at the time, but is likely to have improved with developments in hardware and software.

Zeilhofer *et al* (2000) discussed the application of 3D-ultrasound to capture soft-tissue facial data, in particular, the nose. Adapted software and hardware were used to capture data and Stereolithography used to reproduce the forms to assist operation planning. Although models were successfully built from the data little information was provided on the process details, in particular how the data was converted to a usable file format. In addition, no figures on the accuracy or qualities of the data produced were provided. No other work relating to the application of ultrasound in maxillofacial prosthetics has been published since.

Custom software developed at the University of Münster was used by Runte *et al*, (2002) to triangulate and calculate a surface STL file derived from fringe pattern scanning. The scanning technology used was also able to capture a greyscale image of the face and wrap this around the model. This acted as a useful visualisation tool. As in previous research, Runte *et al* (2002) identified that simply mirroring anatomical forms in order to create a prosthesis is not possible in many cases due to facial asymmetry. A commercially available, software program developed for industrial design was used to adjust the contours of the mirrored pattern. Whilst this would have allowed adjustment to the overall contours, fine details and feathered edges would have been difficult to achieve due to the limited number of control points used to define the surfaces. These are the same limitations faced by much of the prior research. A two-part, obturator and prosthesis were designed and initially manufactured using Stereolithography for test fitting on the patient. Another process was required to convert the design into a wax suitable for further adjustment using conventional techniques. Building directly in a wax material would have avoided this stage.

Although this research identified potential benefits and limitations of the techniques utilised, the case study failed to capitalise on the most appropriate technologies available. As in previous research, the choice of design software would have provided limited ability to manipulate complex forms and define realistic details that make a prosthesis convincing. The choice of RP process also meant that additional process stages were required to achieve the final result. Runte *et al* was however the first to identify the potential to capture and reproduce colour models and use CAD to estimate asymmetries. Although at the time, no suitable technology existed to achieve this, it was an ambitious goal to recognise at the time.

2002-present

A more appropriate method of manipulating anatomical forms that addressed many of the limitations identified in previous research was applied by Bibb *et al*, (2002) to assist in the design of a cranioplasty plate. The potential to apply the techniques in facial prosthesis design were identified. In the 2002 study, CT scan data was used to acquire the shape of a cranial defect. The digital sculpting package, FreeForm (discussed in Ch3, section 3) was used to fill a skull defect and design a cranioplasty plate. The software enabled a much more arbitrary and unconstrained method of manipulating complex, anatomical forms and overcame many of the CAD constraints identified in past research. The cranioplasty plate pattern was designed on screen in a manner analogous to the more traditional, tactile skills used by prosthetists. The ability to design and alter shapes in this freehand manner was revolutionary and highlighted a technique that would be much more suitable for clinical application than those used in previous research. Once the design was completed within a digital environment, the master pattern was fabricated using Stereolithography for the final plate fabrication. The results were accurate and the research identified many benefits, including the decreased manufacturing time and material use, cleanliness and minimal usage of materials and equipment. The potential to transfer the application of the techniques discussed to facial prosthesis design were noted.

Following on from the previous 1998 and 2000 research, Cheah *et al* from the Nanyang Technological University went on to investigate a range of advanced technologies in the construction of different prostheses. Earlier research highlighted the difficulty in capturing areas of undercut using non-contact surface digitising. In an attempt to overcome these problems, a number of competing technologies were compared and CAD remodelling techniques were developed. The research made reference to CT and MR scanning, but focussed primarily on the non-contact scanning due to practical and ethical issues of exposing patients to harmful radiation unnecessarily. It was however noted that further investigation into tomography was required, CT scan data could be used to acquire surface topography.

Four different capture methods were studied: Facia Laser Surface Scanner, ATOS (GOM), Polhemus FastScan and Minolta VIVID 700. This gave a good comparison between some of the more appropriate scanning methods available, but the research still highlighted the issue of poor capture in areas of undercut or reflective surfaces. Methods of reconstructing the poor data were developed, but like the previous study, did not make an intuitive solution for inexperienced CAD users. The CAD software compared all highlighted limitations in their ability to manipulate and reconstruct complex anatomical forms such as nostrils. This would have made cases with significant asymmetry very time consuming. The conventional CAD used would also have struggled to represent forms where surfaces joined at acute angles making the definition of fine-feathered edges extremely difficult.

Two methods of prosthesis construction, similar to those tested before were studied: direct and indirect mould construction. The indirect method involved the production of various prosthesis patterns using RP technologies and the subsequent production of a silicone tool and use of vacuum casting techniques to produce the final prosthesis. The direct mould production method used CAD to design the tool and RP to produce it. The RP processes chosen were SL, SLS, SGC and LOM. Each of these processes produce parts in a hard, difficult to manipulate material. As in the previous study, it would be difficult to manipulate the pattern contours and add textures to blend the design into the patient's surrounding anatomy. How this was achieved was not discussed. Using vacuum

casting techniques to produce the prosthesis would also have given the same issues as previous research (length of mould production and curing time, difficulty in localised colour matching and location of retentive elements). These issues were also not discussed.

Although the authors showed good understanding of the technological and clinical issues in the application of their new techniques, many shortcomings were still not addressed from their earlier research in 1998 and 2000. The process was not shown in great detail through to the final fitting and the prostheses case studies did not stretch the capability of the chosen CAD techniques in the manipulation of forms. In addition, little consideration was given to the methods of retention, final colouring and texturing of the prostheses and how these stages would integrate into the proposed techniques.

Some of the limitations experienced in previous research were addressed by Verdonck *et al* (2003a&b). An implant retained orbital prosthesis case study was used as a basis to develop a treatment protocol using CAD and RP technologies. In this study, the prosthesis was designed to accommodate the implants, but two CT scans were required in the design process. As identified by Cheah *et al* (2003) this may not be justifiable in many cases due to radiation exposure. The second, post operation CT was used to refine the original pre-operation design and account for the tissue alterations and final abutment locations. Although CT data may be used to capture topography, the limited resolution would not have been able to define fine detail necessary to establish the exact angle and fitting surfaces of the abutments. Although this was not discussed, this may have resulted in a potential degree of error when the virtual impression posts were placed in the computer environment.

FreeForm was chosen to design the prosthesis pattern. This represents an intuitive and effective method of manipulating shapes and a manner analogous to conventional hand sculpting techniques, making it more appropriate for prosthesis design and allowing fine fitting edges and details to be easily created.

ThermoJet RP manufacture was used to produce a pattern directly in a wax material suitable for further modification using conventional techniques. Building directly from CAD data in a suitable wax material eliminated the need to take an impression and mould wax that had been required in past research. This was a fundamental step in reducing the time taken to fabricate a pattern and integrating the digital processes into conventional finishing techniques.

Verdonck's 2003 research successfully addressed many of the issues that had hindered past research, including: the unsuitability of conventional CAD software for manipulating anatomical forms and the necessity to convert RP patterns to a wax material for further modification. Addressing these issues proved that digital technologies could have a place in a laboratory and that suitable technologies existed. Future possibilities including the potential to incorporate digital sub-structure design and the direct manufacture of a prosthesis directly from a CAD software environment were also noted, although it was also realised that further research would be required.

Although FreeForm CAD and ThermoJet RP technologies had been identified as key suitable technologies for the design and fabrication of facial prosthesis patterns, further research was required to develop the techniques and integrate them into the prosthesis construction process. Non-contact scanning methods also required further development to successfully integrate them in to the prosthesis production process.

Reitemeier *et al* (2004) studied the application of a self-calibrating, fringe projection scanning system to assist the design of an orbital prosthesis. A multi-camera set up allowed the complete face to be captured in one operation, thereby eliminating the need for the patient to remain motionless for long periods. No information was however given on the quality of data outputted and how much gap filling was required.

Sykes *et al*, (2004) was the first to attempt a direct comparison between conventionally and digitally produced prostheses. Optical scanning, FreeForm modelling and ThermoJet wax printing were used in the digital method. These technologies may be considered state of the art based upon

the evidence of previous research. Blinded observers rated a conventionally carved ear against a digitally mirrored version and the results were used to identify statistical significance. Statistically significant differences in favour of the digitally designed ear were found in terms of shape and aesthetics, but not for anatomy, size or resemblance to the original cast. Although only based on a single case, this study provided a benchmark for comparing two methods of production. However, one limitation was that the observers rated against a replica cast of the contra-lateral ear rather than rating the appearance of the prostheses in situation. A symmetrical prosthesis is not always the ideal aesthetic solution, so a more realistic rating would be achieved if each of the prostheses were rated in situ. This would also allow important aspects such as edge quality and position to be compared. Sykes *et al* also concluded that a limitation of digital technologies was the necessary expense and suggested that were are many other applications which could benefit.

A clinically critical perspective of the application of digital technologies was provided by Chandra *et al* (2005). Both an auricular prosthesis and a burns splint were produced using digital methods. A highly portable, handheld scanner was chosen for its manoeuvrability to capture behind the ear. Data was processed, 'cleaned' and mirrored using commercially available software then produced using ThermoJet printing. Rather than attempting to fit the mirrored ear, the pattern was modified to fit a pre-made bar structure. This effectively saved the need to digitise the defect site. It was found that although the time spent sculpting an ear was reduced, this was offset by the additional stages of scanning and data manipulation. As with previous studies, it was concluded that additional work was necessary to streamline the processing of scan data. Although Chandra *et al* provided a sound rationale for their choice of technologies, this study did not progress from previous work by other authors. No accurate quantification or comparisons of time or quality appropriateness was given.

Ch 3.7 - The development of associated technologies in other related medical applications

During the same period that advanced technologies were being developed to specifically assist facial prosthesis production, other, related medical specialties were also exploring the potential benefits. Dental applications have been at the forefront of CAD and CAM technology development. Applications have included custom surgical guides to assist implant placement (for example, SurgiGuides by Materialise. See glossary), crown and bridge design and fabrication (for example, the CEREC system by Sirona. See glossary), and more recently Removable Partial Denture (RPD) framework design [Williams *et al*, 2004, Eggbeer *et al*, 2005, Bibb *et al* 2006]. The mass market appeal of dental applications has led to the development of specific software and hardware, something maxillofacial prosthetics is unlike to benefit from.

Whereas single tooth restorations and surgical guides have become relatively mainstream commercial activities, more complex appliances such as RPD frameworks remain in the research stages of development. Like soft-tissue prosthetics, this is partially due to technological limitations [Williams *et al*, 2004].

Ch. 3.8 – Conclusions

Research to date highlights the difficulties and peculiarities that make the application of digital technologies to facial prosthetics challenging. The challenges faced may be broadly categorised as technological limitations and financial constraints. In addition, the introduction of new technologies and techniques would require changes to current treatment protocols, physical working environment and training requirements. This makes the need to select and apply the most appropriate technologies crucial if techniques are to be clinically and economically viable and adopted by the profession.

Technological limitations were apparent in many of the techniques described in the literature. One of the most frequently identified limitations was with non-contact scanning. Although able to accurately capture three-dimensional geometry, surface scanning is unable to capture areas that are hidden from the line of sight, such as behind the ears, nose and areas of wrinkles around the eyes. All non-contact scanning methods also struggle to capture hair and reflective surfaces such as eyes. The technique therefore relies upon complex and in many cases, time consuming methods of reconstructing areas of missing data. The software used to align, fix and output suitable data that may be imported to CAD software for further manipulation is also often complicated to use. It appears that to date, no ideal scanning solution has been identified.

Further constraints are also apparent where conventional, engineering CAD was used to manipulate the data and design a prosthesis. Whilst mirroring anatomy is relatively simple, adjusting the form to fit the contours of the defect site often proved more challenging. The application of FreeForm in more recent research provided a solution to this problem and must therefore be considered state of the art.

Methods of producing the final prosthesis could be categorised as production of a mould to produce the prosthesis and production of a pattern that could be used to produce a mould. Whilst both of these techniques had merits, the production of a pattern in suitable wax is often the desired solution for the prosthetist. Designing a mould for a complex prosthesis such as an ear would be extremely difficult and time consuming in CAD. In addition, adjustment of the pattern during test fitting and mould before curing is often essential to provide the best possible fit to the surrounding anatomy, but to avoid additional stages, it is most efficient to produce the pattern directly in wax. Direct wax production was used in two cases, the most common technique being ThermoJet printing.

Whilst many of the prostheses were implant retained, very little information was given as to the methods of designing and incorporating retentive components. Verdonck *et al* (2003a) noted that it might be feasible to incorporate retentive component design into the digital process, but that further research would be required.

Only more recent research has directly compared the outcomes of conventional techniques with digital. Whilst earlier research mentioned timesavings made, none quantified differences between the two methods. Economic issues are extremely important and are especially complex within the National Health Service. There may be a number of reasons why economics were under-explored in the past literature:

- It is difficult to compare new techniques with those established for many years.
- In order to identify statistical significance, many studies would be required. The number of patients and access to technologies may be limited.
- Many aspects of prosthesis production are determined by the individual prosthetists skill and speed. An accurate comparison is therefore difficult.

Where comparisons on aesthetic outcome were made, they relied on subjective assessment, which was in turn used to identify any statistical significance. This may be the most suitable method when assessing aesthetic outcome, but does not provide a solution for measuring *why* a prosthesis is successful.

Very little consideration was given to the impact on patients. Although the end result may be the same as if a prosthesis was produced conventionally, there is a likely impact on the clinic time and cost implications for the patient. A method of considering patient impact is therefore important.

Measuring the success of prosthesis delivery is extremely difficult for a number of reasons:

- The relatively small number and low frequency of cases.
- All prostheses are different; there are a wide range of patient preconditions. Techniques must adapt to fit individual case peculiarities.
- There are no standard methods of measuring the economics of production or the success in terms of quality (those factors listed in section 2.10).

This is highlighted in past research where studies have predominantly used subjective assessment techniques to identify the success or failure of a technique (discussed further in chapter 2).

Those providing medical treatment or therapies are increasingly required to select and justify their methods and simply basing selection on personal experience is not adequate [Anderson, 2000, Jacob, 2000]. Choosing the most appropriate treatment for patients should ideally be based upon a thorough review and understanding of how methods described in research may be applicable to the practitioners' circumstances as well as their knowledge of existing practice. A balanced and scientifically justified approach to choosing a methodology is important [Concato *et al*, 2000 & 2004].

Chapter 4 - Methodology

This chapter describes the methods used, a rationale for their selection and illustrates the research model. Specifics of case study criteria are also discussed later in the chapter.

4.1 - Introduction

4.1.1 – Novelty

Previous work in the application of digital technologies in the design and construction of facial prostheses (summarised in table 3.16) has been limited in scope. The ad-hoc trials to date have not provided a common clinical and economic perspective on the effectiveness of digital technologies; they have concentrated on either clinical aspects [e.g. Coward *et al*, 1999, Gebhardt, 2000, Runte *et al*, 2002] or the technology [e.g. Chen *et al*, 1997, Chua *et al*, 2000, Cheah *et al*, 2003a&b], overall prosthesis form design using FreeForm [e.g. Verdonck, *et al* 2003a&b, Sykes et al, 2004] or other engineering CAD software, explored direct mould production [e.g. Cheah *et al*, 2003a] and utilised various RP techniques to fabricate the basic prosthesis form [e.g. Chandra, *et al*, 2005]. Fundamentally important aspects of clinical and economic efficiency and, design and construction, such as texture detailing and implant retention mechanisms have not yet been fully explored. Comprehensive evaluation of the efficacy of digital technologies in the capture of facial anatomy, the design and fabrication of facial has therefore not been undertaken.

Employing a comprehensive approach and gathering sufficient data from multiple case studies and experiments will allow more robust conclusions to be drawn. In particular, from this data it should be possible to evaluate the effectiveness of digital technologies, develop new methods and identify recommended approaches that may be employed in different prosthetic rehabilitation situations. For the first time, this study will attempt to assess the economic implications of employing digital technologies. Based upon the evidence, a new target specification will be developed to guide future technology development. In addition, a future strategy model will be presented based upon the ideal application of digital technologies to meet patient and health service needs.

4.1.2 - Research Aim

The aim of this study is to identify and validate the potential benefits of digital, computer aided technologies in the design and fabrication of facial prostheses in terms of time, cost, clinical and aesthetic results.

4.1.3 - Objectives:

1. Establish the current state of the art in facial prosthetics, including recognised current best practice, delivery time and cost data and patient satisfaction.

2. Review the current research in the application of CAD and RP technologies in head and neck reconstruction; specifically soft tissue applications.

3. Explore, develop and evaluate CAD and RP techniques in the design and fabrication of facial prostheses through applied case studies and experiments.

4. Review cases studies to establish optimal routes for the design and fabrication of facial prostheses within the limits of the technology currently available to the MPT profession.

5. Review the findings to identify areas for future technological development.

6. Develop and disseminate specifications or standards towards which technologies may be developed or assessed in order to meet the future needs of the profession.

4.2 - Proposed methods

Within the scope of this thesis, the introduction of new technologies and techniques did not impact the final prosthesis delivery since conventional methods were required to achieve a clinically acceptable result. Ultimately, the introduction of new technologies will impact on laboratory methods, but this research aimed to assess the technology, not to alter the clinical outcome and delivery of prostheses to patients. The degree to which technology is likely to impact the prosthesis delivery process is discussed.

4.2.1 – The mixed method approach

Given the applied nature of prosthesis production and relatively small sample population, mixed research methods were used. The primary method chosen was case study and Action Research (AR). Case study and AR methods are utilised primarily in the field of social science (e.g. teaching, anthropology), but involves techniques ideally suited when dealing with small sample numbers and where the methods must adapt to changing situations. The participatory approach lends itself to direct involvement and collaboration and is therefore likely to produce realistic and valid results. Yin (2003) describes a case study as an "empirical inquiry that: investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident." McNiff *et al* (1996) summarises AR to have the following characteristics:

- It leads to knowledge
- Provides evidence to support the knowledge
- Makes explicit the process of enquiry through which the knowledge emerges
- Links new knowledge with existing knowledge

The overall research aim was broken down to form separate case studies and/or experiments with more specific aims. Each of these studies had their own research design. The first stage was to identify what to measure. This in turn led to specific case study research/experiment aims. Stage

two involved choosing the relevant data to capture. A literature review was undertaken prior to each case study in order to identify recognised methods of measurement or evaluation used in practice or that have been validated by relevant scientific research. Using recognised methods of measuring and evaluating results would help to improve the construct validity of each study and would allow a fair comparison with conventional methods, which could be used as a benchmark. Decisions on the methods of data capture and analysis methods were then made. Case studies were developed based upon the evidence gathered in previous studies. This iterative approach is illustrated in figure 4.2.

Four methods were used according to their suitability:

Questionnaires: A descriptive survey questionnaire was used to determine current practices, the awareness of digital methods and the need for development in UK prosthetics labs. Since no statistical analysis of the data was required, open questions were asked in order to maintain flexibility in the responses. A closed survey using a five-point rating scale was used in case study 6e since the aim was to statistically analyse the results to identify significant differences in observer opinions.

Pilot studies: Pilot studies were used to develop the techniques and gain a greater understanding of the issues before continuing with case studies. Findings from the pilot studies were also used to indicate methodology modifications and develop new theories that could be tested through case studies or experiments. Pilot studies used cases that were easily accessible and represent the 'typical' scenario or the trial of a previously unused method that required further development before measurable studies could be carried out.

Case studies: Single case studies were used to test an existing theory, a unique or a typical case. Multiple studies were used to validate the findings from a single study by simply replicating the methods to other cases. Results were obtained by measuring single (or where possible, multiple) aspects of prosthesis construction using alternative methods.

Experiments: In addition to straightforward case study research design, aspects of experimental design were used. Experimental design was chosen for three situations:

1. Where more accurate results could be obtained by controlling the environment and only measuring specific aspects without the influence of extraneous factors that may introduce bias to the results.
2. In order to validate the findings of a case study or to help develop a case study method before it was applied.
3. Where it was not possible or ethical to involve patients.

4.2.2 - Subjective validation methods

Subjective assessment of the process and final prosthesis were used to validate the findings of quantitative results. Although it may be argued that opinion based evidence is subject to a high degree of bias the success or failure of a prosthesis may ultimately be determined by the patients feel about un-measurable aspects such as comfort and aesthetics. The prosthetist and other clinicians involved with the delivery or a prosthesis may also express valid opinions on the usability of particular techniques, which although are not measurable, may influence its viability and must therefore be considered. Three primary subjective aspects were commented upon:

1. Usability / clinical viability of the process or technology
2. Benefits / limitations to patient, prosthetist and health service
3. Prosthesis performance: comfort, aesthetics and function

Prosthesis success factors identified thought the literature are listed in chapter 2, section 10. These factors may be re-categorised as quality aspects and linked to subjective assessment criteria. This is shown in table 4.1.

Quality Aspects	Subjective assessment	Rated by
Fit	Comfort / appearance	Patient Prosthetist
Accuracy		
Resolution	Appearance	Patient Prosthetist
Texture		
Colour homogeneity		
Mechanical and material properties	Application and removal (function)	Patient Prosthetist

Table 4.1. Prosthesis quality aspects linked to subjective performance characteristics

Opinions from both the patient and prosthetist were recorded, however it may be considered that the prosthetist is likely to provide a more objective and constructive view due to their experience. A patient may only have ever seen one prosthesis, but could provide important feedback on comfort and fit.

4.3 - Research Model

Stage 1 – Undertake a research literature review to discover what has been done previously, critically appraise it and to identify the current 'state of the art' as a comparitor.

Stage 2 – Identify the data to capture.

Stage 3 – Decide upon the capture methods – develop case study and experimental research designs.

Stage 4 – Undertake case studies / experiments

Stage 5 – Evaluate the results and develop a new case study / experiment

Stage 6 – Develop a specification towards which technology may be developed

Figure 4.2 illustrates the iterative, action research design.

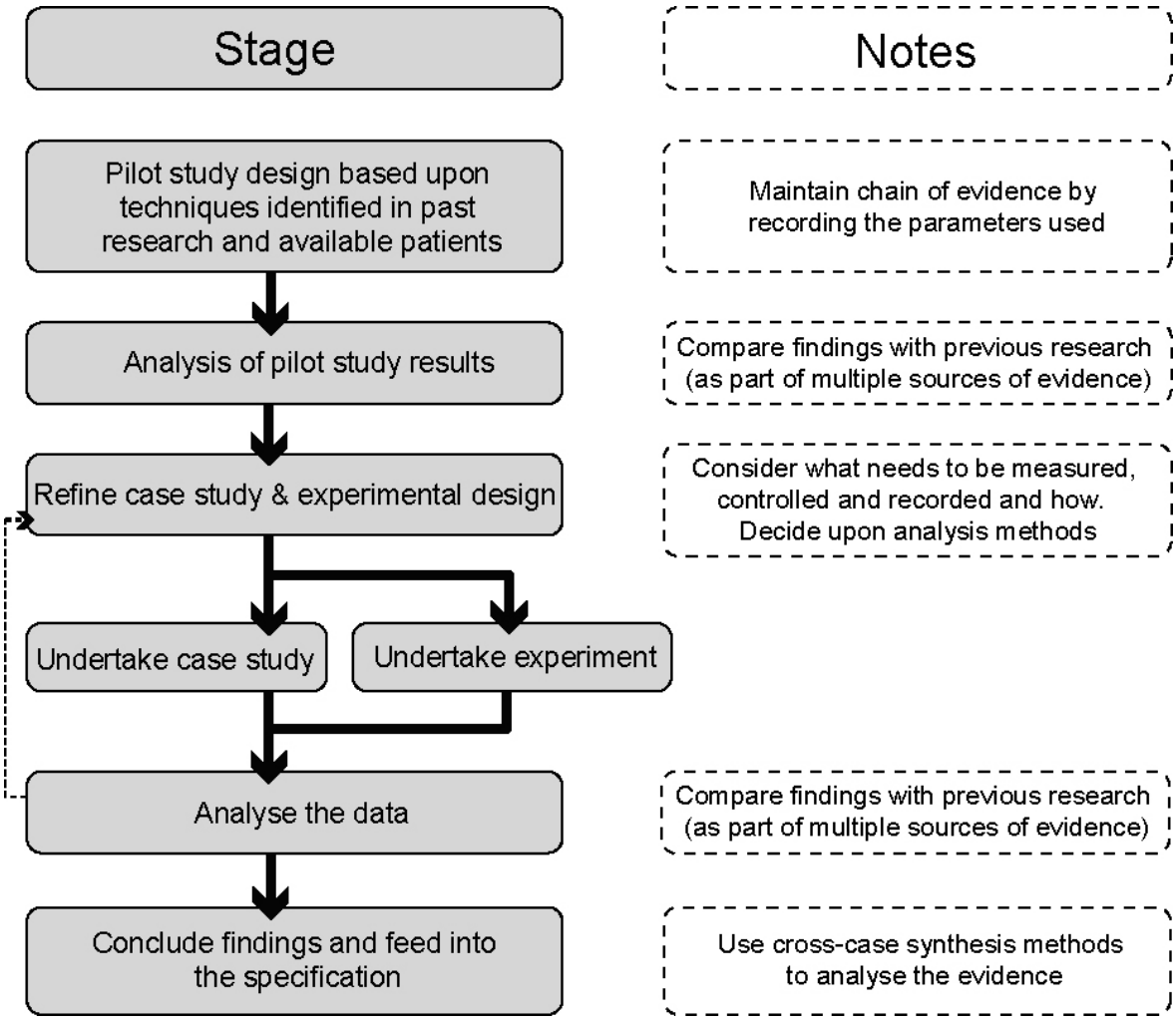


Figure. 4.2. The proposed feedback process of case study, action research

4.4 – Methods of assessing bias and validity

A number of methods were used to ensure the research validity:

1. Identification of converging, multiple sources of evidence.
2. Involvement of practitioners to assist in case study selection, design and results analysis.
3. Consideration of alternative perspectives.

The identification of multiple converging sources of evidence helped to improve construct validity. Evidence was gathered from:

- Literature reviews
- Case study data (participant observation and supplied data from practitioners using conventional methods)
- Experimental data (results from controlled experiments, measuring single variables to validate findings of case study data)
- Peer reviews
- Questionnaires
- Interviews

Having those involved with prosthesis production and delivery review the findings of each case study helped to ensure construct validity and also provided insight to external validity based upon their alternative perspectives and experience. In addition, publishing the results of case studies in peer reviewed journals and presenting findings at conferences provided further opportunity for a wider audience to assess and comment upon the findings.

By linking empirical data to predicted outcomes and alternative perspectives, the degree to which the techniques may applied to other types of prosthesis cases were concluded

4.5 – Case study categories

4.5.1 – Introduction

There are numerous factors that determine the success or failure of a facial prosthesis and past research has highlighted the difficulty of measuring these (discussed in chapter 2, part 10). This research broke the measures of success down into aspects that were evaluated using case study and experimental design. These factors were identified through the literature review and consultation with prosthetists at Morriston Hospital, Swansea.

The two primary categories are defined as:

1 – Economic

2 – Quality

These two categories are closely linked, but were considered independently due to the rapidly changing nature of costs and associated performance of technologies. Where suitable, consideration were also given to the subjective opinions of the prosthetist and patient.

4.5.2 - Economics

Growing pressures on financial resources means that the adoption of new technologies into health care systems such as the UK National Health Service faces many challenges. Significant emphasis is placed upon making informed decisions that are based on the objective assessment of potential new technologies and it is clearly important that this thesis considers the economic impacts.

Determining the cost of prosthesis production to a public health system such as the NHS is extremely challenging and this is reflected in the limited published literature on the subject. One study by the maxillofacial unit at Morrison Hospital, Swansea [Hooper *et al*, 2005] price the provision of an orbital or auricular prosthesis at £1000-£1500 excluding remakes and repairs. Few details on how this figure was obtained were published. This is likely due to the vast range of factors that affect costs and how they are accounted for when measuring prosthesis production.

According to Sachdeva (2001), in a cost benefit analysis, cost can be classified as direct, indirect and opportunity. Direct costs relate to during hospital stay and after discharge. Indirect costs include overheads (which includes the cost of technology). Opportunity costs include aspects such as potential loss of earning for the patient in the future. Sachdeva (2001) also suggests that benefits may be considered objectively and subjectively. Objective measures include aspects such as length of patient stay (or treatment) functional outcomes and validated health related quality of life tools. Subjective measures include patient satisfaction and perception in quality of care. Direct costs, such as materials and staff may be relatively easily measured, but a cost model will become far more complicated when considering prosthesis production within the entire treatment process, including indirect over-heads and technology costs, lost opportunity costs such as travel and loss of patient earnings. In addition, there is no health service wide standardised method of measuring cost, therefore each department is subject to its own unique interpretation on what to include and exclude. The custom nature of prosthesis production also means that the cost attributed to one prosthesis is unlikely to be exactly the same as another and is also likely to vary between prosthetists based upon their speed, experience and techniques. In addition, technology cost varies between manufacturers and over time, and its use in a hospital environment is not likely to be limited to one department or specialty. This would make quantifying an accurate figure for the cost of technology infeasible.

Sachdeva (2001) suggested that the application of quantifiable outcome-based methodologies provides an objective basis to answer four crucial questions: 1) should an organisation invest in new technology? 2) If so, what are the associated benefits and risks of this capital investment? 3) What is the likely impact on patient outcomes as a result of adopting this technology? 4) What is the return on investment? Methods of accurately answering these questions would require a complex evaluation tool that considers the influence at a macro level (impacts at county policy, country and international level). Decisions on the most suitable methodology for measuring technology impacts depend on proposed study scope, required complexity, resources

Economic issues in this thesis were considered within the scope of individual case studies. Results from these studies were used to identify how economic issues may be applied to a broader context and in turn answer:

- What the likely benefits of adopting the technologies are
- What the likely risks are
- What the likely patient outcomes are
- What the likely departmental outcomes are

This helped to determine the value of adopting digital technologies.

Economic aspects were broken down into two categories:

1 – Cost

2 – Time (patient and prosthetist)

Although undoubtedly linked, differentiating between these issues helped to more clearly identify areas of strength and weakness in the techniques applied and helped identify external validity.

It is also important to consider the priority of cost and time associated with people and equipment in prosthesis production, including: the patient, prosthetist, other clinical staff, surgeon, technology operator and the equipment used. It may not be the case that the quickest solution to prosthesis delivery is the most cost effective if it utilises primarily expensive techniques and staff.

4.5.3 - Quality

Quality issues require careful consideration due to the variety that affect the outcome of a prosthesis. Historically, measures of a successful prosthesis have primarily relied upon subjective, qualitative assessment of the final result, however for the purpose of this research it is necessary to identify and develop quantifiable methods. Quality aspects were broken down into the following categories:

- Fit
- Accuracy

- Resolution (capture, handling and reproduction)
- Texture and micro surface finish
- Strength and mechanical characteristics (materials and retention)
- Colour and homogeneity

Each of these categories was tested using case studies and experiments. Consideration to validated research designs published in journal and textbook literature was given. However, where no techniques have been described, or none were suitable, methods used by related specialties or engineering were applied.

Fit

Overall prosthesis fit is generally described as good marginal integrity where the edges of the prosthesis blend naturally into the surrounding skin and there is no visible gap. Fit is typically assessed by eye and the result is determined by how well the edges are blended into the skin at the wax pattern stage. Edges that do lift may be stuck down to some degree using petroleum jelly. Marginal fit is extremely difficult to achieve in areas of significant facial movement, such as the mouth and jaw joints (typically where the anterior margin of an auricular prosthesis blends into the skin). To some degree, good fit is determined by an accurate impression, although hand adapting of the wax pattern is required in most cases anyway.

Fit is also defined by the interface between retentive surfaces and the skin or abutments and between the various prosthesis components. To date, published literature describing methods to measure the marginal fit of prostheses is minimal, therefore techniques must be developed or adapted from other related literature. Very little has been published on methods of measuring the interface between various prosthesis components. A limited number of publications describe methods of measuring the fit between abutments and cylinder components, but these are predominantly describing oral applications [Riedy *et al*, 1997, Kan *et al*, 1999, Lie and Jemt, 1994, May *et al*, 1997]. Suitable methods identified in this literature were applied to comparing how well conventional and RP produced bars fit.

Accuracy

Accuracy was described as the ability of a technique or technology to capture or produce objects with the desired level of overall dimensional tolerance. Accuracy concerns the overall shape and dimensions of the object as opposed to fine detailing, which was considered as resolution or texture.

Prosthesis accuracy as a whole is difficult to measure due to the complex, anatomical forms and the soft-tissue interface. However, past research has identified accuracy issues as important in order to achieve a good marginal fit between the prosthesis and skin [Reitemeier, *et al* 1999, Wolfaardt *et al*, 1996a] and studies have measured the accuracy of various impression techniques. More recent studies have compared the accuracy of various alternative methods that are able to capture skin topography, such as structured light, CT and MRI [Coward *et al*, 2005]. Research has also been carried out in areas such as dentistry to evaluate the accuracy of various optical and contact digitising methods [Bell *et al*, 2003].

Resolution & texture

Resolution was defined as the ability of a technology to reproduce or record fine detail. This relates to aspects of prosthesis production such as capturing small features in a scan, adding texture or producing thin edges. Conventionally, aspects such as texture are judged subjectively by the clinician, but there is particular interest amongst the cosmetics industry to validate and quantify skin texturing and wrinkles [Lemperle *et al*, 2001]. The ability of digital technologies to capture, create and reproduce high-resolution details such as texture and fine edges has not been widely discussed, especially in relation to facial prosthetics. Given the importance of texture and wrinkling in achieving a realistic result, it should be considered when developing new techniques. A series of studies were developed to evaluate the ability of technologies to capture, manipulate and produce textures to the required level of detail and to identify future requirements.

Strength and mechanical characteristics

This covers both the material properties of the prosthesis components and the mechanical interaction between them. There is much interest in the mechanical properties of silicone prosthesis material, which must meet demanding specifications. There is currently no RP technology capable of producing directly in a material suitable for wearing as a prosthesis, but a limited number are able to produce in a rubber-like material (Objet, impregnated Z-Corp, SLS). Where RP technologies show potential, they were used as a benchmark to identify the developments necessary to make them clinically viable.

Mechanical interfaces such as between clips and bars were tested using standard engineering techniques or those developed by related specialties such as dental technology or orthodontics [Williams *et al*, 1995, Kan *et al,* 1999].

Colour and homogeneity

This is an area where digital technologies are unlikely to even closely match what is currently possible using conventional techniques due to fundamental limitations with capturing, manipulating and reproducing patient matched colour in three-dimensions. The measurement of colour and homogeneity is highly subjective and the matching process itself extremely time consuming and dependent on many environmental conditions [Leow *et al*, 1999] (discussed in Chapter 2, sections 3 & 4). There are however a limited number of technologies capable of producing colour parts. Where suitable these were used as a benchmark against which future specifications were developed.

4.6 - Case study selection

4.6.1 – Sample population

Suitable case studies were selected primarily by the Maxillofacial Unit at Morriston Hospital, Swansea. This helped to ensure impartially in those selected by reducing the influence of the researcher and also ensure cases were suitable. Morriston are a large, busy regional unit that provide a broad range of prostheses and therefore have many cases to select from. They also have an established history of embracing new technologies and encouraging research. Where suitable case studies could not be provided from Morriston, other major units were contacted.

4.6.2 - Cases to exclude

Certain types of cases were excluded from this research: those under the age of consent, the extremely ill, those undergoing treatment such as radiotherapy or those unable or unwilling to provide consent. Children were excluded due to the difficulty in obtaining consent, potential difficulty in their compliance and rapid growth, which could invalidate the results and make measuring difficult. Prosthesis production techniques are not altered by patient age and if anything they are more technically challenging in adults due to the presence of facial hair and greater skin texturing. Patients who were extremely unwell or undergoing treatment for diseases such as cancer were also excluded due to the increased potential for their circumstances to alter dramatically and the potential of the introduction of new technologies to increase the treatment time. This research did not attempt to compare the effects of technology and techniques on different on-going patient conditions and sought to avoid the influence of treatments by selecting patients who were stable.

4.6.3 - Selection criteria

Three criteria were used when choosing case studies:

1 – Facial prostheses

2 – Consenting adult

3 – Stable condition

The clinician initially identified potentially suitable cases based upon these criteria. The results of the literature review were also used to identify and filter out techniques that had been reported to be unlikely to work.

4.7 - Case study classification

Facial prosthesis complexity may be defined according to many different factors, including

- Size / extent
- Retention mechanism
- Location on the face
- Patient age
- Skin texture and details
- The pre-conditions (trauma, congenital, etc.)

For this reason, case studies that accurately represent the types of cases that are carried out in a prosthetics lab, including the more challenging were chosen. Case study selection also depended on the patients' being willing to cooperate and on their availability.

Experiments were more structured and carried out based upon the findings or needs of the case studies.

4.8 – Summary

This chapter discussed the proposed methodology and the rationale behind case study selections. The following two chapters present the results the questionnaire sent to UK prosthetists, the case studies and experiments. The case studies and experiments in chapter 6 are presented in the order of development; the findings from previous studies were used to guide the development of the subsequent study.

Chapter 5 – Questionnaire: review of current practice

5.1 – Introduction

An open question survey was used to establish:

- The range of techniques used in the UK.

- How these compare to the literature.

- Understand inter-hospital variation.

- Identify particular areas of difficulty experienced.

- Gauge the current understanding and application of computer technologies.

The questionnaire was sent to 20 practicing and training MPTs who were members or associate members of the IMPT. This provided 13 replies. The questionnaires may be found in the appendix. The prosthesis construction process is described in chapter 2 part 5.

5.2 - Results

5.2.1 - Impression techniques

Ear impression

Materials used:

- Syringe able, addition cure silicone.
- Putty for complex parts
- Alginate with stent backing
- Dental alginate with a compound backing.
- Alginate supported with quick setting plaster. Standard technique.
- Alginate with acrylic / plaster backing
- Silicone impression material (Epiflex)

Impression materials listed: Provil MCD, Exafast NDS, Epiform – flex/solid. Also Cavex normal set, Bayer, UK. Silicone elastomer (president, light body coltene, UK).

Patient seated upright in a chair. Large syringe or icing funnel used detail of the ear, then backed with compound. Plastic ring used to contain the impression area.

Ear – implant retained

Impression copings placed in position and bridged together using light cure base material. Alginate syringed onto the defect site and around the copings. A second application of alginate applied by stent composition with adhesive bond and an access hole for the impression copings. Lab analogue abutments screwed into impression copings prior to casting.

A damn may be used to contain the impression area.

Nasal

Many of the materials and techniques cited were the same as with auricular cases.

Vaseline gauze used to protect air passages. Alginate syringed on to peripheral boundary of defect site. A second application of alginate applied supported by stent composition with adhesive bond.

Build up in layers using a spatula to spread the material. A heavier body silicone or Epiform - solid used to back the impression.

Orbit

As above

Orbit – implant retained

Transfer magnets positioned on implants and bridged together using light cure base material. Alginate syringed onto the defect site and surrounds the transfer magnets. Second application of alginate applied supported by stent composition with adhesive bond. Lab analogue abutments with attached analogue cap positioned on to the transfer magnets prior to casting.

5.2.2 - Impression conclusions

The techniques and materials mentioned were similar for each prosthetist. The material and technique choice depended on the individual case requirements and the same materials were often used for auricular, nasal and orbital defects. All of the materials and techniques mentioned are established throughout the profession, but were individually tailored to each case requirement by selecting the most appropriate materials and methods.

The use of optical, surface scanning and CT as tools to acquire soft tissue contours was mentioned, but the techniques had not been used by the respondents.

5.2.3 - Methods of achieving symmetry

- Cast or mirror image of contra-lateral side combined with measurements.
- Mirror image with patient. Place prosthesis on and off patient.

Carve wax by eye, then use callipers to take different measurements. If auricular – take an impression of opposite side and use as a mirror image for defect site. Patient is present after carving the first trial.

For nasal and orbital – callipers used to take measurements. Patient presence is necessary in order to refer to the opposite side with orbital prostheses.

Measurements with divider ruler and calliper. Try to copy the opposite side.

Stereolithography models used in craniofacial deformity cases. Patient photographs are useful.

A plaster copy of the opposite ear is trimmed back anatomically from the upper junction of the helix to the lower junction of the lobe with the anterior margin trimmed back to the tragus. Modelling wax is adapted and sealed to the rear of the cast, then additional wax is added to form a mirror image using metric gauge callipers to transfer anatomical landmarks from the plaster cast. Profile and horizontal alignment of the wax pattern is determined directly on the patient.
Nose – the most effective way of applying symmetry for a nose is to use wax transfer copy from donor pattern. The wax pattern is adapted to the plaster cast and symmetry is determined directly on the patient using a vertical facial midline transfer.

Implant retained orbital prosthesis – a modelling wax base is adapted to the model cast and over the magnet components, then trimmed to the peripheral border. Symmetry of the eye unit is determined directly on the patient using a transparent ruler that has calibrated 1cm square grids and a small spirit level attached to it. The edge of the ruler is contoured at the centre allowing it to be positioned on the nasal bridge. The eye unit is positioned using ribbon wax with the papillary level adjusted in relation to the position determined by the transfer measurement of the calibrated ruler.

Natural artistic eye. Nobody is symmetrical, so achieving perfect symmetry is not critical.

Nasal - Impression taken of opposing ear and cast in stone to copy dimensions.

5.2.4 - Symmetry conclusions

The use of a contra lateral impression and standard measuring devices to obtain dimensions were commonly employed. These techniques have been discussed in reference materials [Thomas, 1994, McKinstry 1995]. The use of photographs was mentioned, but the presence of the patient

was highlighted as being more important during the test fitting stages. It was also noted that achieving perfect symmetry is not ideal since nobody is symmetrical.

The use of physical models was also mentioned, but was not common.

5.2.5 - Mould and flasking techniques

- Metal or plastic flasks.
- Plaster and dental stone (e.g. Crystacal D by British Gypsum or Velmix by Kerr Dental Laboratory Products).
- Epoxy.
- 2/ 3 part flask with spacer technique to reduce flashing.

Standard lost wax process in a plaster mould.

Moulds made in white Velmix, within an aluminium flask. Wax pattern flasked (supported on the fitting side), then left to set. A wax sheet is put over plaster area and cut away from wax pattern to leave a boarder (creates nice edges to prosthesis and reduces flash). Plaster (stone) cold mould sealed and then pattern tapped. 2 part moulds. 3 parts for auricular (the helix is supported with stone. This is a separate stage).

Where appropriate, metal dental flasks with larger maxillofacial flasks available. On occasions a plaster coffin (custom made plaster flask) will be used. Moulds for facial prostheses cast in white Velmix and a spacer used to avoid flash. For more permanent moulds, epoxy from Factor II will be used.

For lager prostheses magnetic ring formers will be used, but lack of support for the mould under compression can cause the mould to fracture.

5.2.6 - Mould / flasking conclusions

The materials and techniques discussed were all established techniques. The most common mould material was dental stone/plaster with metal flasks. 2 part moulds were used for nasal and orbital prostheses, but a three-part mould was used for auricular prostheses.

Epoxy was used as a mould material by one prosthetist where longevity is required.

5.2.7 - Materials and techniques for the final prosthesis

Materials used:

- Newsill, Technovent, Factor II + others depending on the situation.
- Silicone paste colours for intrinsic and extrinsic colour.
- Sealed with diluted Room Temperature Vulcanising (RTV).
- Intrinsic pigments with flocking/fibres.

Implant components by Branemark, Technovent and Entific.

Technovent platinum cure silicone elastomer/catalyst. Shore hardness A24, ratio 10:1. Can be cured at room temperature for 24 hours or rapid heat curing at 110^0c for 2 hours (used when rapid replacements are required).

Factor II Realistic A-588v. Shore hardness A12, A19, A29 (the hardness options are liked).

Factor II Silicone elastomer A-2000. Shore hardness A20 with A-304 primer.

Factor II intrinsic and extrinsic colour.

O.P.S. ocular products.

Individual colours are mixed starting at one point on the anatomy and worked around. The colours are packed into the mould individually and blended into each other. Extrinsic pigments are added during the final test fitting to achieve a better lifelike colour.

Intrinsic colour matching is carried out in daylight conditions or with an optional daylight simulating source. The basic colour is determined by matching a range of previously cured silicones to the patients' basic skin tone. The basic colour is enhanced using additional pigments and various coloured nylon flock to produce character. A fine layer of clear silicone is applied over the surface of the mould to allow adhesion of long vessels and veining character before placing silicone into the mould using fine tapered spatulas and fine brushes. Rapid and bench cure methods are used. These techniques are standard in the MPT profession, but may have been modified slightly.

5.2.8 - Materials and techniques conclusion

The most widely used silicone elastomers were produced by Technovent and Factor II. Different versions were used according to the individual requirements. Colour matching was carried out using both intrinsic and extrinsic tinting and flocking was commonly used to add the extra realism of veins/capillaries. Although much research has been published into the effect of lighting conditions to the appearance of prostheses, the importance of using natural daylight was only mentioned by one person. This prosthetist used pre-cured silicone samples to establish a colour match under daylight (or simulated daylight). Few other prosthetists went into detail of their colour matching techniques.

Neither the finer points of sculpting or addition of skin texture were discussed.

5.2.9 - Skill acquisition and published references

Most of the prosthetists suggested that their techniques had been developed through experience and witnessing other people's work, but the Thomas book (1994), Prosthetic Rehabilitation was also cited as a reference.

5.2.10 - Challenging aspects of the process

Challenging aspects highlighted included:

- The labour intensive nature of the work.
- The high skill level required.
- The reliance on compliant patients – can cause significant trauma.
- Wax carving, particularly of nasal and orbital prostheses. Orbital prostheses were highlighted as particularly difficult due to the amount of anatomical features and the difficulty in achieving symmetry, assessing the correct aperture of the upper eyelid and gaze of the eye unit. Nasal prostheses are central in the face and very noticeable.
- Colour matching. One person highlighted that this is particularly difficult to match ethnic groups.
- The realistic addition of flocking to create the illusion of a blood supply.
- Psychological rehabilitation of the patient was highlighted by one person.

Inconveniences highlighted included:

- The number of visits required, especially if the patient finds travelling difficult.
- Obtaining impressions causes stress and inconvenience to patients.
- The long time scales.

Aspects which take/waste the most time:

- Mould making
- Carving and trailing
- Remakes of prostheses to match patients changing skin colour.

5.2.11 - Recommended state of the art techniques

- Construction of maxillary obturators using data from CT/MRI and wax deposition RP technology. Being able to cut out the impression procedure of obturators construction would be of great benefit.
- Study the accuracy of colour matching in digital photography. This would be useful for matching iris and skin tone colours, allowing the preparation of pre-matched skin tones, thereby reducing the patient time at the clinic. This would also be useful in cases where the patient is unable to attend clinic.
- A computer generated colour matching system.
- Digital design. As presented by Verdonck (2003b). This must provide real benefits, not simply replicate what is currently done, but using computer technologies. It must remove stages from prosthesis construction.
- Direct mould construction from CAD.

Digital / computer aided technologies are shown to be of interest, as long as they are both accurate and time saving. The two main areas of interest highlighted are: digital colour matching technologies and digital prosthesis/mould/obturators design and manufacture.

5.3 - Questionnaire conclusions

The results of this questionnaire provided an indication into the techniques employed in UK prosthetics labs. Current technologies were for the most part similar to those described in currently available textbooks, with a small number of respondents actively modifying and developing their own techniques.

The need to reduce inconvenience to the patient was highlighted, with the primary concerns being lengthy and the high number of visits required to complete a prosthesis. The distress caused by impression taking was also highlighted as a concern.

There is an awareness and interest in emerging digital technologies, but they are not in widespread application. The responses demonstrate a need to critically evaluate digital technologies to ensure that the needs of patients and the profession are met.

Chapter 6 – Case studies introduction

6.1 - Introduction to the case studies

Case studies were selected based upon the criteria highlighted in section chapter 4, section 6.

The case studies were undertaken as the need to explore different aspects of prosthesis construction became apparent. The pilot study was used to evaluate the current state of the art and identify areas for further investigation. This demonstrated that CT data could be used to capture the anatomy, that the prosthesis form could be designed using FreeForm and that ThermoJet printing could be used to produce usable patterns for conventional finishing. Three subsequent studies were undertaken to explore the application of optical scanning technologies, skin texture and incorporation of implant retention mechanisms. Case study 2 identified significant limitations in the ability to design and fabricate bar structures. Experiment 2 utilised newly available technologies to address these limitations and develop new techniques. Case study 3 incorporated the techniques pioneered in the previous studies and developed them further to present the new state of the art. As the digital techniques became more established, further analysis of the economic implications and differences compared to conventional methods was possible. A review study of scanning methods used throughout the study was included at the end.

6a - Pilot study. Adhesive retained, orbital prosthesis

6a.1 - Introduction & objectives

The pilot study aimed to evaluate suitable technologies identified in the literature review and direct the development of future case studies.

6a.2 - Research design

Study type: A single, clinical case study was used evaluate the clinical viability of the chosen techniques compared to conventional methods.

Data capture & analysis techniques: Subjective assessment of the final clinical result, notes on the effectiveness and limitations of the technique and the approximate construction time compared to conventional methods were recorded.

Validity control: The study was undertaken with a qualified and highly experienced prosthetist to ensure that the techniques being used were valid and appropriate. This also reduced the likelihood of false reporting.

6a.3 - Case details

A 21year old female had undergone exenteration of the left eye and surrounding soft-tissue following a rhabdomyosarcoma at 7years old. Further surgery, radiotherapy and chemotherapy were needed to complete the treatment over a period of three years. This had consequently hindered the natural growth and development of the left orbital region. She presented with a particularly poor, adhesive retained hard acrylic prosthesis and was keen to improve the aesthetics and method of retention.

It was decided to construct a new adhesive retained prosthesis immediately and also plan for craniofacial implants in the future. Due to the reduced bone in the orbit and limited space available, it was decided to use three-dimensional CT scans to plan the positions of the osseointegrated implants. 254 CT slices, with a 512x512 pixel resolution and a 0.468mm pixel size were taken. There was no gantry tilt.

The same CT data was then used to aid the design and construction of the adhesively retained prosthesis described. The only additional requirement for the CT scan was that the patient was scanned with her eye open.

6a.4 - Materials and methods

Data formatting: Mimics software was used to read in the CT slice data from the recent scan, segment the patient's facial detail and generate a three-dimensional computer model of the anatomy in the highest quality STL file format. Due to the limited resolution of the CT data, fine surface detail such as wrinkles were not shown. The STL data was imported into FreeForm version 7 using the 'buck' setting. This protected the original anatomy from carving, but allowed material to be added.

CAD: An area of the unaffected right eye was selected based on the extents required for the prosthesis side. This was then copied and recreated as a new piece that would form the basis of the prosthesis and that could be worked on separately from the rest of the model. The new piece was then laterally inverted around the midsagittal plane to create the basic shape required for the prosthesis pattern (figure 6a1).

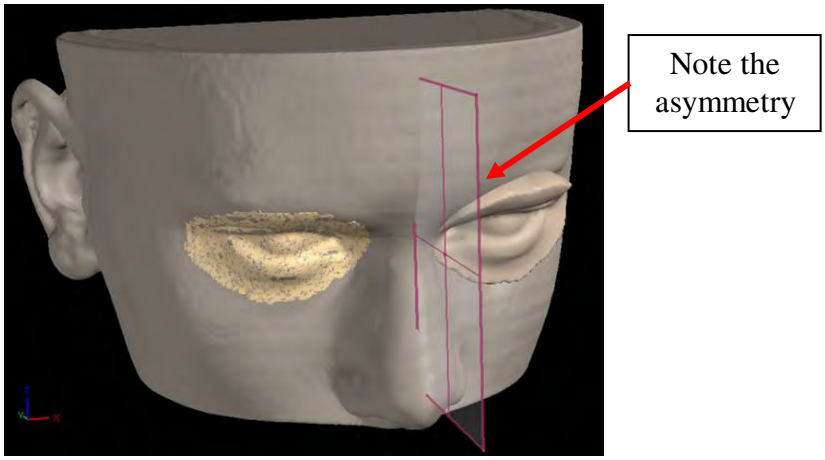


Figure 6a1. Mirroring the selected area

The originally selected piece was then deleted leaving just the prosthesis pattern and anatomy models. Construction planes were created in 3D model space and used as a reference to assist in the accurate alignment of the prosthesis in relation to the unaffected side. These planes were located across the pupils to assess depth and in the midsagittal plane to compare midline deviation (figure 6a2). However, the prosthesis pattern did not immediately fit to the patient model highlighting the asymmetry of the face.

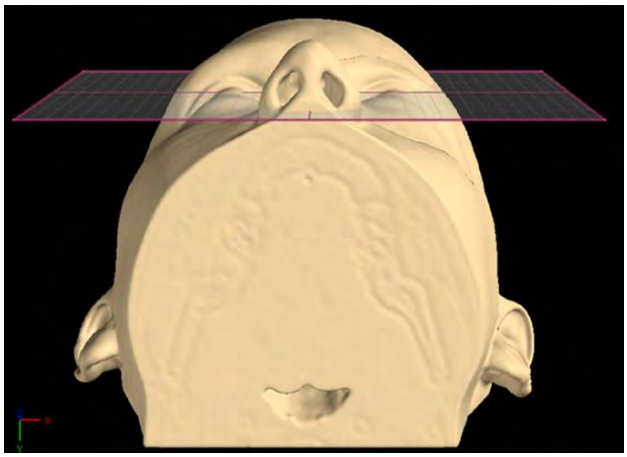


Figure 6a2. Using guide planes to locate the pattern

With the prosthesis correctly aligned, discrepancies in the fit were corrected using 'attract' and 'add clay' tools. In order to create thin edges to the pattern it was combined into the original model resulting in a single piece, the prosthesis clay was then blended into the surrounding buck anatomy

using ‘carve’, ‘smooth’, ‘tug’ and ‘smudge’ tools until the result was judged aesthetically correct. Figure 6a3 shows the result.

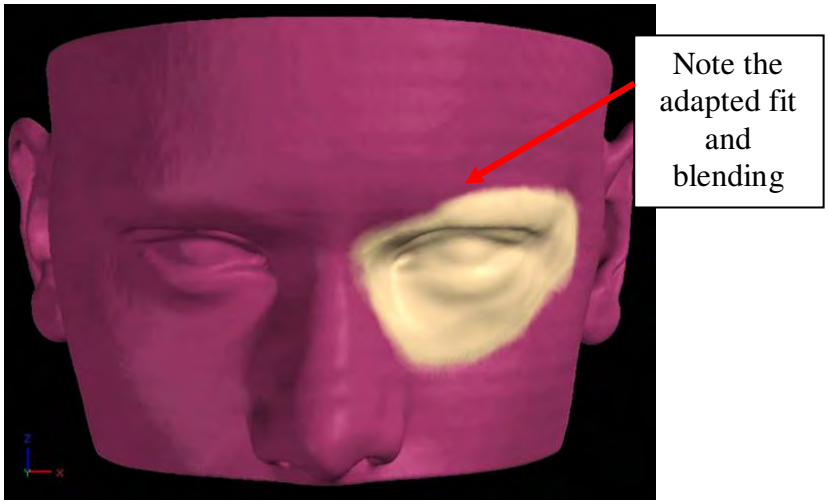


Figure 6a3. The blended in result

The surrounding buck anatomy was then subtracted using the Boolean method (any areas of clay that touched or overlapped the buck model was removed) [The Boolean method is described by Mullineux, 1986 and by Jones, 1992], leaving just the prosthesis pattern design. Up until this stage the clay was relatively roughly defined by FreeForm in order to minimise computer memory usage. This meant that fine levels of detail were not easy to define and thin edges appeared jagged. It was therefore necessary to refine the clay, which had the effect of smoothing out jagged edges and allowing finer levels of detail (such as wrinkles) to be crafted.

Material was removed from the back of the pattern to reduce the amount of hand carving required to fit the acrylic eye unit. The detail around the eye was protected from carving and editing using the ‘paint on mask’ tool.

The completed prosthesis design was then exported as an STL file suitable for manufacture using RP methods.

Fabrication: A 3D Systems ThermoJet machine was chosen to fabricate the wax prosthesis pattern. The wax material has similar physical properties to that typically used in the prosthetics

laboratory and is therefore suitable for hand finishing and moulding [Verdonck *et al*, 2003, Sykes *et al*, 2004]. The down facing surfaces of parts built on the ThermoJet have a poor, rough finish due to the supports that are used to attach them to the machine bed. The pattern was orientated so the fitting surface faced downwards, ensuring the best finish was the one on show. Figure 6a4 shows the up and down facing surfaces. Given that that the fitting surface was also likely to require alterations, this was the best option.

Figure 6a4. The down facing (left) and up facing (right) of the ThermoJet pattern

The ThermoJet machine took approximately two and a half hours to manufacture a single prosthesis pattern that would retail for approximately £35 (based on a material price of £130/kg and £10/hr running cost. Running cost = £25. The pattern weight was 12g with 20% added for waste material. Material cost calculated at £1.90. Material cost + running cost = £26.90. Profit added at +30%. Total = £34.97). The completed pattern required careful removal from the build platform using sharp pointed tools once it had hardened at room temperature.

Fitting & pattern modification: The pattern fit was checked on the patient and the final extent of the edges determined. The fit was excellent but it was decided that the patient's natural eyebrow should be used, so the wax was reduced in that area.

Wax between the eyelids was cut away to allow positioning and sealing of the acrylic eye from the back in the traditional way. The rear of the pattern was smoothed with a hot knife and the fit was improved by relining with a low viscosity silicone impression material (Figure 6a5). Thin edges

were added to the ThermoJet pattern and contoured to the surrounding tissue using pink dental wax and heated sculpting tools.

Figure 6a5. Lining the rear of the ThermoJet pattern with impression material

Mould making & final fit: The final wax pattern was removed from the patient and moulded in a flaskless two-part plaster mould using established techniques. Some caution was needed when boiling out the wax from the mould as it has a higher melting point than standard baseplate/modelling waxes at around 70°c to soften and 85-95°c melt (baseplate, type 1 wax has a softening temperature of approximately 35°c and a melting point of around 60-63°c). Removal of the wax before it is fully softened could damage the final detail of the mould.

Traditional techniques were used to prepare the mould, colour match the silicone and pack the mould.

Figure 6a6 shows the final result.

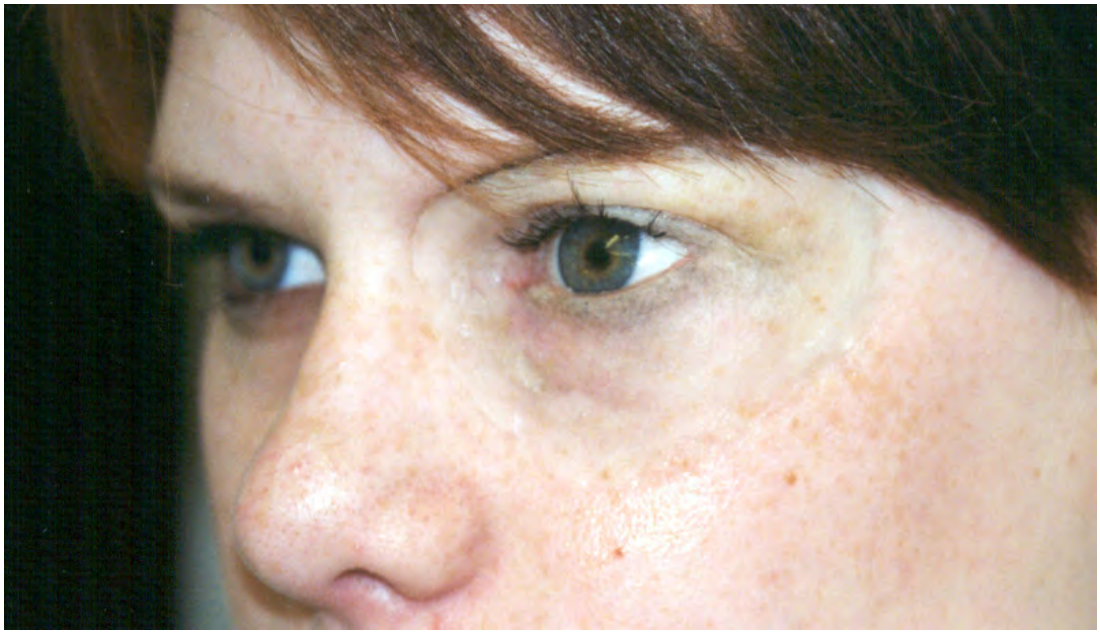


Figure 6a6. The completed prosthesis

6a.5 - Discussion

The CT data available in this study provided adequate information on facial contours to allow prosthesis pattern design. It also captured undercut details, eyes and areas of hair without problems. Wrinkle details, small folds and fine textures were not visible in the reconstructions generated from the CT data due to the relatively low resolution. This meant it was necessary to add detail at later stages of production. Where CT scan data is not available, optical scanning methods may be used to capture surface topography, however previous studies have highlighted difficulties in capturing areas around the eyes, hair, reflective surfaces and undercuts [Bibb *et al*, 2000]. Further studies explored these methods.

Positioning of the wax prosthesis pattern on the patient is traditionally difficult and time consuming. This was relatively simple using FreeForm since it could be viewed from any angle far more easily than when working with a patient in clinic. Guide planes set up in the digital environment also helped to quantify the location of the eye in relation to the midline and contra-lateral side.

A high-resolution setting was necessary to achieve thin edges on the digital pattern. However, the Boolean subtraction to separate the face from the pattern caused jagged edges that would not reproduce faithfully in fabrication. It was therefore necessary to smooth the edges. The ruler functions in FreeForm were used to measure the edge thickness of the final pattern (figure 6a7). Thicknesses were in the order of 0.3 – 0.5mm.

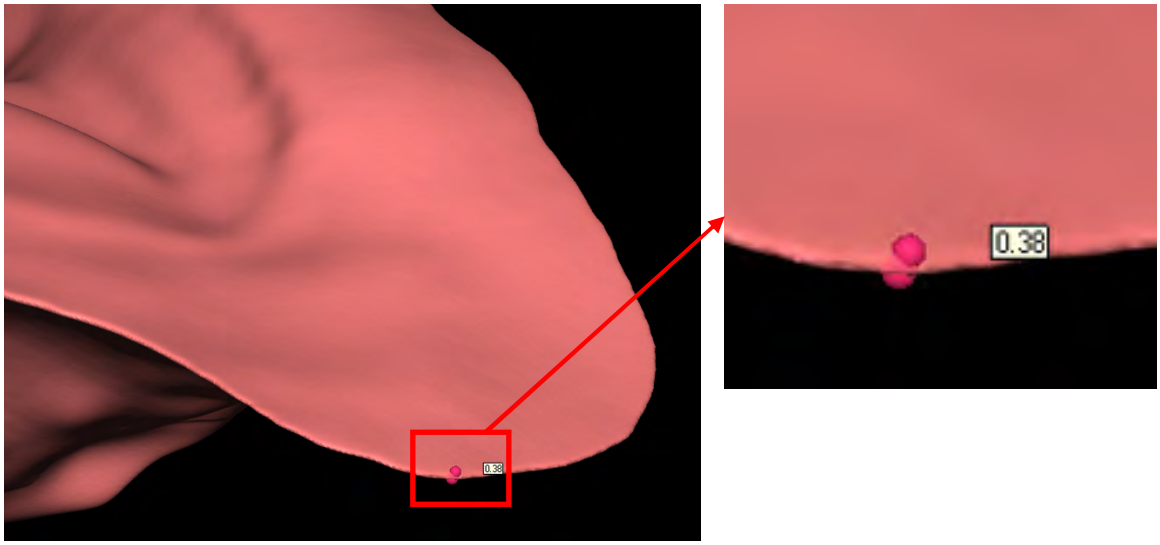


Figure 6a7. Measuring the edge thickness in FreeForm

The ThermoJet process produced a visually convincing pattern with sufficient resolution to describe fine detail and the thin sections that feathered out towards the fitting edges of the prosthesis. Extremely thin edges were however fragile and required careful removal of the support structure. This may limit the ability to produce edges as thin as those achieved by conventional methods.

In this case, the prosthetist estimated that the digital technique used saved approximately seven hours of production time typically associated with the stages from obtaining an impression and producing a wax pattern. This would effectively equal one less day of patient consultation and therefore offer a clinical advantage and potential economic benefit. Further studies would however be required to validate this.

6a.6 - Conclusions

This study demonstrated the viability of digital techniques in the production of an adhesive retained, orbital prosthesis. A clinically acceptable prosthesis was produced using CT data, CAD, RP fabrication combined with conventional finishing. The study has also highlighted limitations of the technique, including: the limited ability of CT data to capture fine details, the difficulty in achieving a thin margin to the digital pattern and the fragility of edges produced using ThermoJet printing. This meant that hand finishing was still required to ensure a convincing prosthesis was produced.

Further studies were required to:

- Explore the application of optical scanning technologies in the of capture facial topography including texture details
- Evaluate alternative methods of pattern production to achieve thin edges
- Explore the integration of implant retention mechanisms.
- Undertake measurement and quantification of the economic impacts.

6b – Experiment 1. Texture creation and capture

6b.1 - Introduction & objectives

Factors that contribute to the aesthetic success of prostheses include: colour match, contours and texture [Cheng *et al*, 2002]. The pilot study proved that CAD and RP technologies offer a suitable method for modifying and generating the overall prosthesis shape, but it did not consider the smaller details such as texturing that make a prosthesis more visually convincing. Given the importance of texture and wrinkling in achieving a natural looking, realistic result, it was considered in this thesis.

This experiment aimed to identify and assess suitable technologies that may be used to capture, create and produce fine textures and wrinkles. The objectives of this study were to:

- Identify suitable levels of skin texture.
- Identify suitable digital methods of capturing, creating and reproducing skin texture.
- Subjectively evaluate the technologies identified.
- Use the results to direct future research and identify methods of quantifying specifications against which technologies may be assessed.

6b.2 - Research design

Study type: Two experimental studies, not involving patients.

Data captured: Specifications of equipment and settings used.

Analysis techniques: Subjective assessment of the results by a trained and experienced prosthetist.

6b.3 – Methods

The creation of three-dimensional relief in a CAD environment and the capture of facial anatomy and texture using fringe projection, surface scanning. Patterns were produced using the suitable

rapid prototyping processes identified and these were subjectively assessed by a qualified and experienced prosthetist. The suitability of the technologies was commented upon, limitations discussed and future directions identified.

6b.4 - Definition of skin texture

Visible skin texture has been discussed in chapter 2 part 2.3.5. Using the assessment scale developed by Lemperle *et al* (2001) to assess and quantify deep facial wrinkles, the proposed margins for this study will range from >0.1mm to <0.81mm depth.

6b.5 Identification of suitable technologies

Specification requirements

A number of criteria were identified to aid in technology selection. For data capture this was summarised as: Accuracy, resolution, area of capture and speed of capture. For CAD tools this was summarised as: intuitive ability to manipulate anatomical forms, ability to apply texture relief and output suitable files for fabrication. For pattern production, this was surmised as: Resolution, production volume capabilities, production speed and material compatibility.

Based upon the rating scale developed by Lemperle *et al*, potential digital technologies must be capable of capturing, creating and reproducing wrinkle and texture details with a minimum depth of 0.1mm. This means that the actual positional accuracy of the surface data captured should be within a much higher tolerance, around +/- 0.02mm. The most important specification is however resolution or point density of the captured data, which should be sufficient to describe complex surfaces within the positional tolerance. The pilot study demonstrated that the CAD software should be capable of creating and manipulating complex anatomical forms and the RP process capable of producing patterns to the required resolution in a material compatible with current prosthetic methods

Capture of anatomical contours and skin textures

Past research has considered a number of topographic and tomographic capture methods: non-contact optical laser/structured white light scanning, CT and MR. Advantages and limitations of each of these techniques are discussed in chapter 3, part 2. Both CT and MR capture cross sections through the body in the form of pixel-based images. The resolution of these is relatively low (typical pixel size = 0.25-0.5mm and image size 512 x 512 pixels), so that if this data were to be used it would be necessary to add texture relief during the CAD stages. Non-contact, optical scanning techniques have been used to capture anatomical forms in previous research with varying degrees of success. Modern structured white light scanning technologies are capable of extremely high tolerances that meet or exceed the requirements. In addition, specialist three-dimensional texture scanners are available and are used by dermatologists and cosmetists to assess skin surfaces (for example, the Breuckmann DermaTOP). Table 6b1 provides a comparison between scanning technologies that have been used or are advertised for use in medicine. Whilst it is recognised that accuracy and resolution are also dependent on factors such as surface quality, the effects of noise and post capture processing of data, it is possible to identify potentially suitable technologies.

Digital photography, impression taking and pad printing may also be used to capture close up two-dimensional images of the skin, which can then be used to create three-dimensional relief using CAD software.

Scanner	**Accuracy (specified or measured)**	**Resolution (specified)**	**Area of capture in x-y-z (mm)**	**Speed (specified or measured)**
Steinbichler Comet 250	Manufacturer specification: Mean deviation (sigma) +/- 30µm Volumetric accuracy (z) +/- 100µm	x-y Point spacing 0.4mm	435x350x450	Tens of seconds
Inspeck Mega Capturor 2	Not defined	0.3mm point spacing in x-y, 0.4mm in z	400x320x500 (in small field of view)	0.7 seconds
Breuckmann Opto TOP-HE	Calibrated to 20µm in this study.	0.15mm point spacing in x-y with 250 FOV used in this study. This will alter with different	200x150x100 with 250 FOV used in this study. This may be altered.	<1 second

		FOV settings.		
Konica-Minolta Vivid 910	Manufacturer specification: X: +/- 220µm, Y: +/- 160µm, Z: +/- 100µm to the Z reference plane (TELE/FINE mode, Minolta's standard)	0.69mm point spacing with 14mm lens and subject at 1350mm distance.	445x333 in x-y with 14.5mm lens	Specified 0.3 seconds fast mode, 2.5 seconds fine mode
Cyberware, 3030 head & face colour 3d scanner	Not specified	Not specified	Enough to cover entire head to shoulders.	Typically 17 seconds

Table 6b1 – a comparison of a selection of scanners used in the capture of anatomical surfaces

6b.6 - Computer representation and manipulation of skin textures

Three-dimensional CAD packages have traditionally been developed for two main markets: engineering design and computer gaming/animation. Engineering design CAD has been developed to define exacting, but primarily geometric shapes and the modelling methods employed limits the ability to define anatomical forms, folds, sharp radii and textures. Textures are not normally required for these applications. Three-dimensional computer gaming and animation software (such as 3D Studio by Discreet) exhibits many of the same limitations as engineering CAD, but typically allows a greater freedom for freeform surface manipulation. However, textures are normally represented by wrapped two-dimensional images, creating an illusion of texture rather than true three-dimensional relief. This 'wrapped' texture cannot be physically reproduced using RP techniques.

Alternative methods of true three-dimensional texture creation have been explored. Jewellery design software such as ArtCAM (Delcam Plc.) incorporates tools to map three-dimensional textures around a CAD model. However, ArtCAM and other similar software do not represent an intuitive method for the manipulation of anatomical forms. More suitable CAD technologies such as ZBrush (Pixologic Inc.) and FreeForm (SensAble Technologies Inc.) may provide a more suitable solution. Table 6b2 highlights the features of potential software.

CAD Software	Intuitive ability to manipulate anatomical forms	Ability to apply texture relief	Ability to export suitable data for fabrication
FreeForm	Yes – with haptic feedback	Yes – multiple methods	Yes
ZBrush	Yes – without haptic feedback	Yes – multiple methods	Yes
ArtCAM	No	Yes – embossing	Yes
Rhino 3D	Yes – less intuitive as FreeForm or ZBrush	No.	Yes

Table 6b2. A comparison of sample CAD software.

6b.7 - RP Reproduction of skin textures

RP offers the most suitable solution to the production of a prosthesis pattern. Computer Numerically Controlled machining (CNC) has been used to create textures [Yean *et al*, 1998], but is not as well adapted to create fitting and undercut surfaces, has limited material choice and ability to create fine details over large areas. Table 6b3 compares a range of RP technologies capable of creating finely detailed, high-resolution textures. Of these, only the ThermoJet and Solidscape printing technologies are capable of producing parts in a material with a melt point and low enough residue to be compatible with current prosthetic construction techniques. The Solidscape process utilizes a single jetting head to deposit a wax material and another one to deposit a supporting material, which can be dissolved from the model. This produces very high-resolution parts but is unfeasibly slow for facial prosthetics work, especially if the prosthesis covers a large portion of the face. Solidscape's InduraCast wax-type material also has a higher softening and melt point that the TJ88 ThermoJet material. The ThermoJet process deposits a wax material through multiple inkjet-style printing heads and is therefore much faster. Support structures are built concurrently and manually removed when the part is completed and cooled. The material is also softer than that used by Solidscape, making it more appropriate for manipulating using conventional prosthesis sculpting techniques. Although no accuracy specifications are given for the ThermoJet, it is advertised as having a very high resolution and aimed at producing finely detailed parts. Suitability was also verified in the pilot study.

RP technology	**Resolution** (manufacturer specification)	**Production volume** (manufacturer specification)	**Speed** (relative)	**Material suitability**
3D-Systems, ThermoJet wax printing	300x400x600 dpi, approx. 40µm layer thickness	254x190x200mm	Fast	Suitable – wax with melt point of 85-95 Deg C. (for TJ88)
Solidscape T612	13µ - 76µm layer thickness	300x150x150mm	Very slow	Thermoplastic polymer with melt point 95° - 110° C.
Envisiontec, Perfactory	90µ – 148µ pixel size. 15µm – 150µm layer thickness	190x152x230mm – 120x96x230mm	Fast. Up to 25mm/hr on 0.1mm thick layers.	Unsuitable. Thermoset polymer
Objet Geometries, Eden 250	600x300x1600 dpi, 16µm layer thickness	250x250x200mm	Fast	Unsuitable. Thermoset polymer
3D-Systems, SLA Viper	0.25mm beam diameter (standard) or 0.075 (fine)	250x250x250mm standard, 125x125x250 fine.	Medium fast	Unsuitable. Epoxy thermoset resin

Table 6b3 – comparison of a range of high-resolution RP technologies

6b.8 - Suitable Technologies Identified

Referring to the criteria outlined in section 6b.5 and the review of potential technologies, the following technologies were selected for the studies:

- Breuckmann fringe projection scanning for its potential to capture anatomy with high accuracy, high resolution and high speed.
- FreeForm CAD for its ability to manipulate complex forms and apply texture detail.
- ThermoJet printing for its ability to produce parts with a resolution that should be capable of describing texture detail to the level identified in chapter 2 part 2.3.5 and in a wax material.

6b.9 - Case study hypotheses

The literature and technology review suggested that the selected technologies were capable of capturing, manipulating and reproducing textured prosthesis patterns. Three testable hypotheses were generated in order to clearly identify the capabilities and limitations of each process and link them to the target specification:

1. The scanning technology selected may be used to capture skin texture and wrinkle detail whilst also capturing sufficient anatomy to allow for digital prosthesis design.
2. The CAD techniques selected may be used to emboss skin texture like details to a scale identified by Lemperle *et al*.
3. The RP techniques selected may be used to produce textures to a visually convincing level.

6b.10 - Assessment methods

Prosthetists are primarily interested in achieving the visual effect of skin texture to ensure that a prosthesis is indistinguishable from the surrounding skin in casual observation. By definition, prostheses are one-off custom made appliances made to fit individual patients with the aesthetic outcome and accuracy subjectively assessed by the prosthetist and subsequently the wearer. Visual analysis of the results was therefore used test the hypotheses. Hypothesis 1 was tested by comparing dental stone models produced from conventional impression techniques with those from scan data and RP fabrication. Areas of the face that showed varying degrees of wrinkles were compared. Hypothesis 1 would be proved correct if the levels of detail visible on the scanned and RP fabricated models showed no or insignificant loss of detail. Hypotheses 2 would be proved correct if the chosen CAD software was capable of creating texture relief to the scales identified by Lemperle *et al*. Hypothesis 3 would be proved correct if the texture relief was produced to a visually convincing level without interference from the layer stepping effects commonly exhibited by RP fabrication.

Two studies were designed to test the hypotheses.

6b.11 - Case studies

Study 1 – using a two-dimensional texture image to generate three-dimensional relief on a CAD model.

Producing the texture image: A sample texture was manipulated to produce a high contrast, black and white image using Photoshop (Adobe Systems Inc.) software (Figure 6b4). Images may be obtained from a database, a digital macro-photograph or impression and pad print of skin.

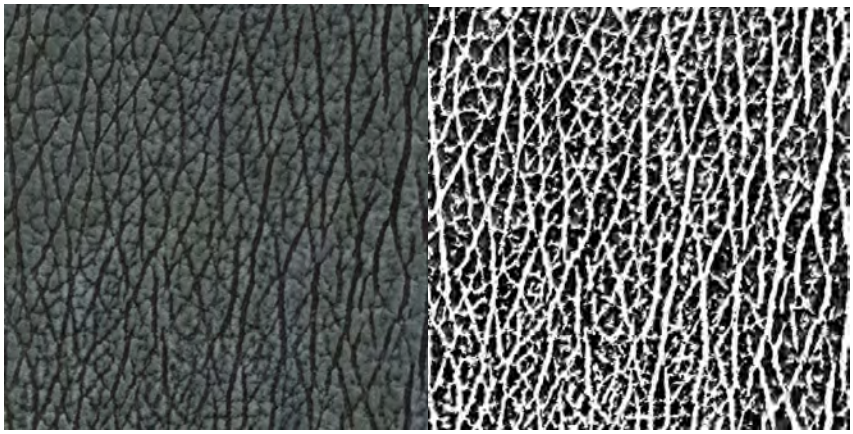


Figure 6b4. Left = the original image. Right = the modified, high contrast image used

Application of textures in CAD: In order to assess the effect of creating texture on a complex area of anatomy, a small section of data was taken from a CAD model derived from a CT scan of the head. The area selected displayed a variety of complex, compound surfaces that are shown if figure 6b5. This shape was also designed to test the visible effect of stair stepping in the RP produced patterns since this becomes more evident on curved surfaces. The selected area was imported into FreeForm with a fine, 0.1 mm edge definition. This was copied six times for each proposed texture depth and a comparison to leave un-textured.

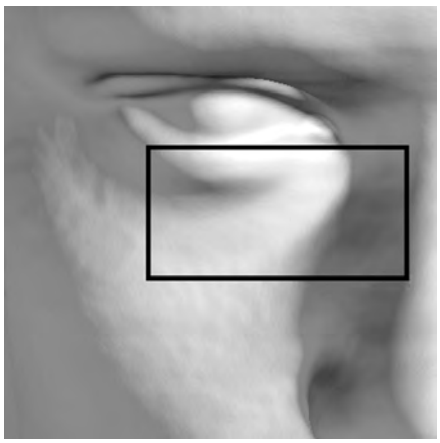


Figure 6b5. The area of face chosen to apply skin texture on

A rectangular box enclosing a surface area was drawn on to the piece surfaces and the 'emboss with wrapped image' tool used to overlay the sample textures in the box. The 'emboss' option was used to set varying texture depths of: 0.1, 0.15, 0.25, 0.35, 0.5 and 0.8mm. These depths corresponded to the wrinkle depth scale and associated measurements in various facial areas developed by Lemperle *et al*. The actual emboss depth is determined by the image grey scale value; black will emboss to the full depth, lighter greys will emboss to a proportionally lower depth.

The scale settings were also used to arbitrarily adjust the emboss density. The embossing may be previewed as either an image (figure 6b6), or relief (figure 6b7).

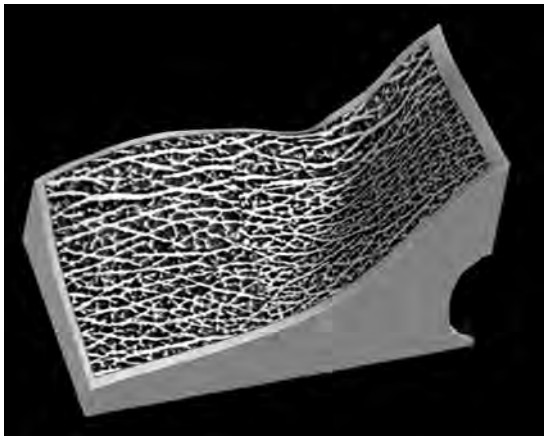


Figure 6b6. Wrapped image preview

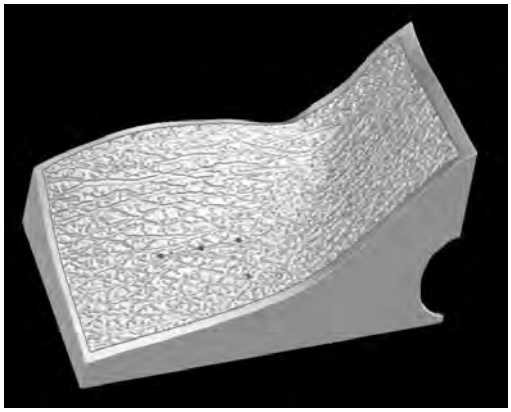


Figure 6b7. Texture preview

The 'ruler' function in FreeForm may be used to validate the depth of textures by measuring the distance from an original smooth copy of the part, to the grooves in the textured version (figure 6b8).

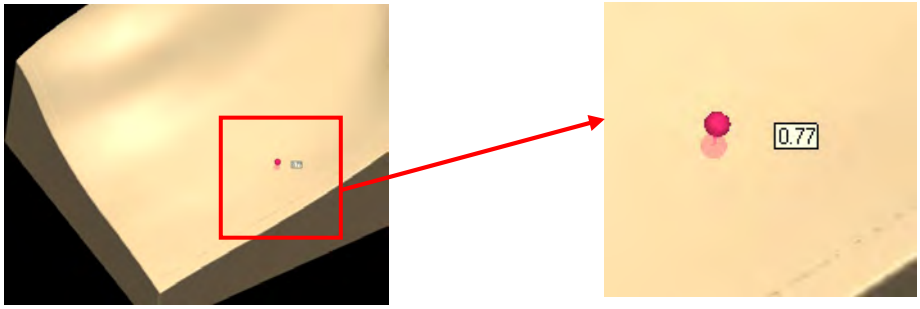


Figure 6b8. Verifying wrinkle depths using the ruler tool in FreeForm

RP manufacture: The blocks were manufactured using ThermoJet printing with the textured surfaces facing upwards. All six patterns were built in less than one and a half hours. The resulting parts can be seen in Figure 6b9.

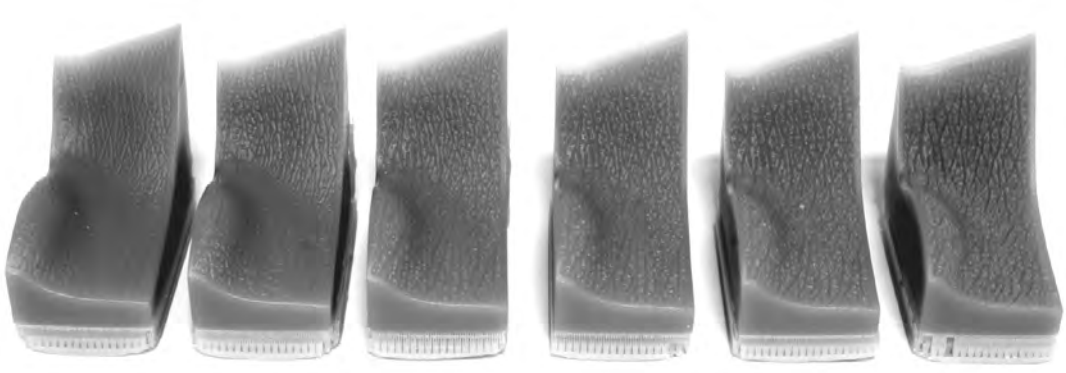


Figure 6b9. The RP produced patterns

Study 1 Results: Study 1 proved hypotheses 2 and 3 correct.

FreeForm was capable of embossing textures to the depths chosen. All of the texture depths were visible on the ThermoJet patterns. The stepping effect commonly exhibited by layer manufacture RP processes was not visible on the surface and did not interfere with the texture patterns. Textures would not however be well defined on down facing surfaces due to the dense support structure that when removed, left a rough finish. This may be a problem if the technique were used in the production of complex prosthetic forms where all surfaces are on show, such as hands.

Study 2 – using structured white light scanning to capture gross facial topography, wrinkles and textures.

Texture capture: A Breuckmann Opto TOP-HE scanner with a single lens was used to capture a portion of a subject's face.

The scanner was set up with a 250mm Field Of View (FOV) and focal distances of 845mm and 150mm. This set up was chosen because it was able to capture enough of the face to provide references when digitally designing a prosthesis, whilst still providing good close up detail. Other settings may be used in order to capture greater levels of detail within a smaller FOV. This would however limit the usefulness of the data for subsequent prosthesis design. Calibration accuracy was within 20μm and approximately 1 million data points were captured.

One scan was able to collect enough frontal face detail, but three were required in order to cover the facial features from ear to ear. Each scan took 0.8 seconds and required the subject to remain as still as possible in a relaxed pose. Once captured, the three sets of point cloud scan data were aligned to form one data set and then converted into an STL file using the proprietary Breuckmann and Raindrop, Geomagic Studio software. Optical scanners typically cannot capture surface detail through hair. Therefore, minor hole filling was undertaken on part of the stitched STL file in order

to create surfaces in areas the scanner was unable to capture, such as eyebrows and corners of the eye. The left side was left unmodified.

Impressions of the subject's right forehead and cheek were also made using a dental polyvinyl-siloxane impression material and converted to dental stone models.

CAD model and production: The surface STL files were imported into FreeForm using the 'thicken surface' setting to give a nominal thickness and make it a solid object. Figure 6b10 shows the areas captured by one scan and 6b11 shows the area captured by three, stitched scans. The figures also highlight areas that the scanner was unable to capture, such as the eyebrows, nostrils and eyeballs. Gap filling work on the subject's right side has been undertaken in figure 6b11.

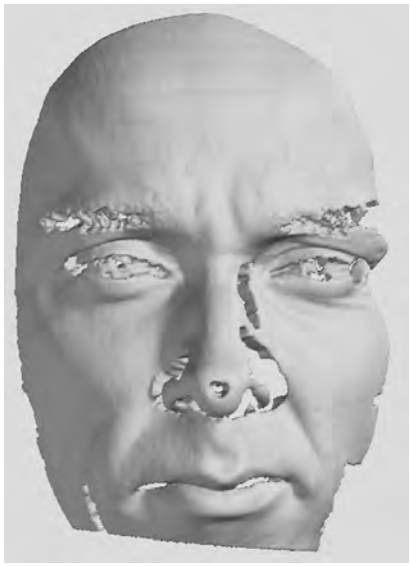


Figure 6b10. The result of a single scan imported into FreeForm.

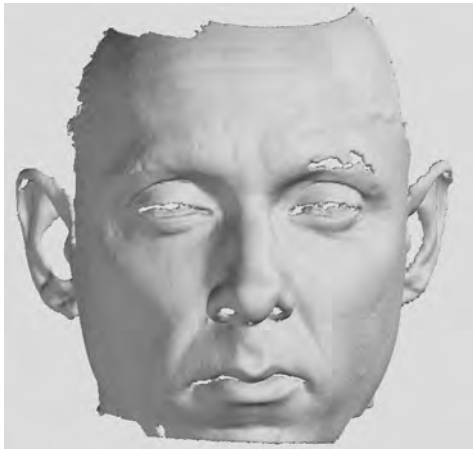


Figure 6b11. The result of three stitched sets of data, merged and with some holes filled on the subjects right side.

A section of the forehead and cheek corresponding to the areas from the polyvinyl-siloxane impressions were exported as STL files and produced using ThermoJet printing. Impressions were made of the ThermoJet models and these were converted to dental stone models for comparison.

Study 2 results: Study 2 proved hypothesis 1 incorrect. The casts produced from the scan data showed visible and significant reduction in texture detailing and only large winkle features remained (Figure 6b12). This indicates that although the ThermoJet process is capable of producing patterns with sufficient detail, the stages of scanning, data processing and CAD manipulation must be refined in order to faithfully reproduce finer skin textures.

Figure 6b12. Casts produced directly from impression (left) and from impressions of the computer data which were fabricated using ThermoJet (right)

6b.12 - Case study evaluation

The two techniques discussed may lend themselves to different prosthetic rehabilitation situations. Techniques applied in study 1 may be most suitable where a patient has already undergone a CT scan and three-dimensional CAD data are available, but texture detail must be added in order to achieve a realistic result. Techniques applied in study 2 are likely to be more suitable where CT scanning is not appropriate, no previous scan has been undertaken or the scan data that is available no longer provides an accurate representation of the facial contours.

The tools available in FreeForm were well adapted to creating texture relief from two-dimensional images. One possible limitation is large file size. In order to represent texture faithfully, large amounts of data are required. A high-resolution model setting that demands a lot of computer processing power must be used in the CAD and subsequent export to STL file stages. Whilst more modern, high specification computers may be able to handle the large file sizes, it may make the process unmanageably slow for others. Further research is necessary in order to optimise the file size versus quality settings.

The Breuckmann non-contact scanner used in this study was capable of capturing facial contours, but fine textures were not visible once the data had been fabricated. This may be due to a number of factors. Although scan times were in the order of 0.8 seconds and the positional accuracy within 20μm, slight facial movements during and between scans were likely to have distorted the detail captured. In addition, errors in the captured data are filtered in the subsequent software stages, which may further act to destroy fine details. Folds in the skin and undercut features, reflective surfaces and hair are also difficult for light based scanners to capture and require repair during the software stages, adding possible error. Addressing these limitations by adjusting the software and hardware parameters is likely to improve the capture of fine details. Simple methods such as preventing movement by supporting the subject's body may also improve the results.

The ThermoJet process was capable of producing all of the texture samples faithfully and did not exhibit the stair stepping effect that some other RP processes display. This ability combined with the suitable material properties demonstrated how the process may be integrated into digital prosthesis design and production techniques that are compatible with conventional hand crafting techniques.

6b.13 - Study limitations

This study indicated that CAD and RP processes may be used to generate visually convincing levels of texture detailing, but did not quantify the capabilities of each technology stage.

6b.14 - Case study findings

This study addressed the aims identified in the introduction. Levels of texture detailing that may be incorporated into digital prosthesis design were identified. Furthermore, suitable methods of applying and reproducing these levels of detail to a visually convincing level were evaluated. Further research is however required to address the limitations of texture capture using optical scanning methods. Research should concentrate on quantifying the specifications required to incorporate texture capture, manipulation and creation into digital prosthesis design and evaluate effectiveness in patient case studies. Methods such as profilometry could be applied to measure subject texture and quantify the capabilities of digital technologies post prosthesis production.

6c - Case study. Magnet retained auricular

6c.1 - Rationale

Previous studies conducted and in the literature have not explored the incorporation of implant retention mechanisms to digital prosthesis design. Given that implant retention is widely regarded as state of the art, this study explored a method of digitally designing an auricular prosthesis retained using a relatively new magnetic system. Evaluation was made in terms of quality, economics and clinical viability.

6c.2 - Introduction

This study aimed at identifying the degree to which non-contact scanning, Computer Aided Design (CAD) and Rapid Prototyping (RP) were capable of assisting the design and fabrication of magnetic retained auricular prostheses. Conclusions were also made on the development and specifications required to meet the maxillofacial profession's needs in terms or quality, economics, aesthetics and usability.

6c.3 - Methods

A 21-year-old male patient with total right pinnectomy following trauma was chosen for a single study. Maxi lipped O- ring magnets (Technovent Ltd, UK) were chosen as the preferred retention mechanism. An impression of the unaffected ear and the implanted defect site was made using conventional techniques, as described by McKinstry (1995) and adapted by Morriston Hospital. These were poured in dental stone and the magnets placed onto the replica Magnacaps (figure 6c1).

Figure 6c1. The defect area replica cast with magnets in situ

A Steinbichler Comet 250 structured white light scanner was used to digitise both of the replica models. This scanner captures approximately nine points per square millimetre and has a specified mean point accuracy of +/- 0.03 mm. The defect model was coated in a matt white powder to reduce the reflectivity of the magnets. Multiple overlapping scans were required to capture the entire surface area of each model and software (IMAlign, see glossary) was used to align and combine the data into a single point cloud representing the surface topography. Translation to the STL file format was undertaken using Spider software (Alias-Wavefront Inc. see glossary). Spider was also used to reduce the imperfections in the data, smooth the surface to more closely match that of the models and fill holes in the surface based upon the surrounding contours. The two sets of STL data were then imported into the FreeForm software package using the 'fill holes' option to make solid, closed volume models. The defect site model was imported using the 'buck' setting, which protects the data by preventing material being removed, but allows material to be added. The ear was imported as 'clay', which may be thought of as the wax used when sculpting prostheses conventionally. Undercuts beneath the magnets were filled by adding material in FreeForm (figure 6c2).

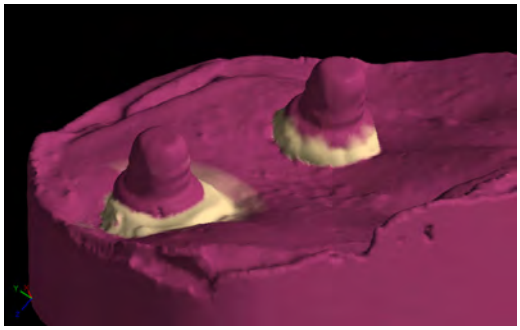


Figure 6c2. The digital defect cast in FreeForm. Areas beneath the magnets have been blocked out

The ear was then mirrored and subsequently positioned on the defect site using patient photographs as a guide to establish the correct protrusion and positioning. An addition operation was used to join the positioned ear to the defect site.

Modifications were made to the ear design to accommodate the magnets and alter the anterior margins. 'Smooth' and 'smudge' tools were used to blend the prosthesis edges into the surrounding anatomy. Once satisfied with the design, a subtraction operation was undertaken to leave just the prosthesis form with a fitting surface to the defect site (figure 6c3).

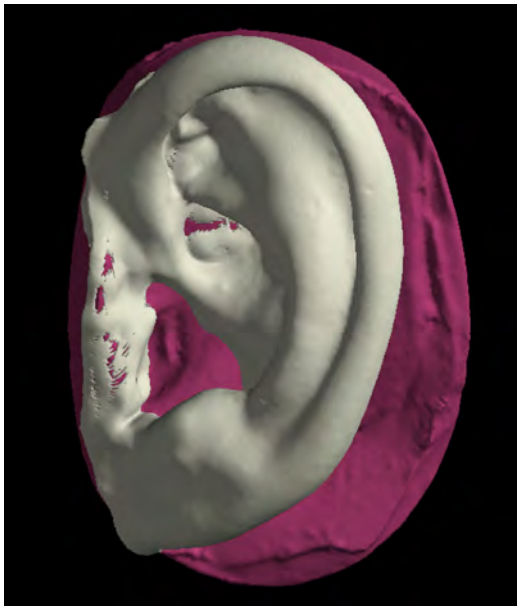


Figure 6c3. The completed digital prosthesis design on the defect model

A 'smooth' operation was undertaken on the design to remove jagged edges and the prosthesis was then exported as an STL file.

ThermoJet wax printing was chosen to produce the prosthesis pattern. Proprietary software was used to rotate the pattern so the fitting surface was down facing. The process took approximately two and a half hours to produce the single pattern.

The magnets were inserted into the prototype wax pattern, sealed into place and tried on to the patient (figure 6c4). The pattern fitted with a little adjustment leaving just the posterior fit and front edge to be added. Conventional techniques were then used to mould the pattern in dental stone and produce the final prosthesis in Cosmesil silicone elastomer. Figure 6c5 shows the completed prosthesis.

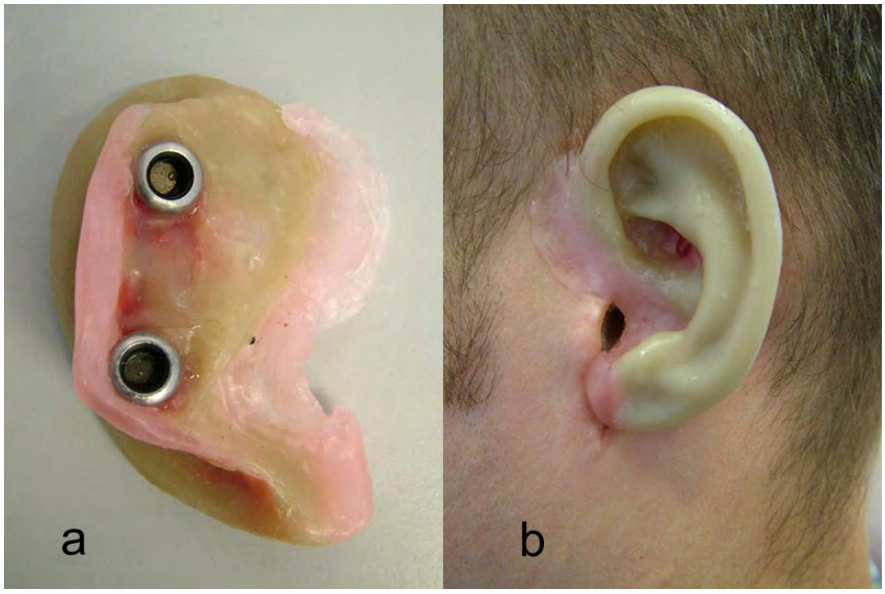


Figure 6c4. The adjusted wax pattern. a= magnets sealed in, b= modified edges on the anterior margin

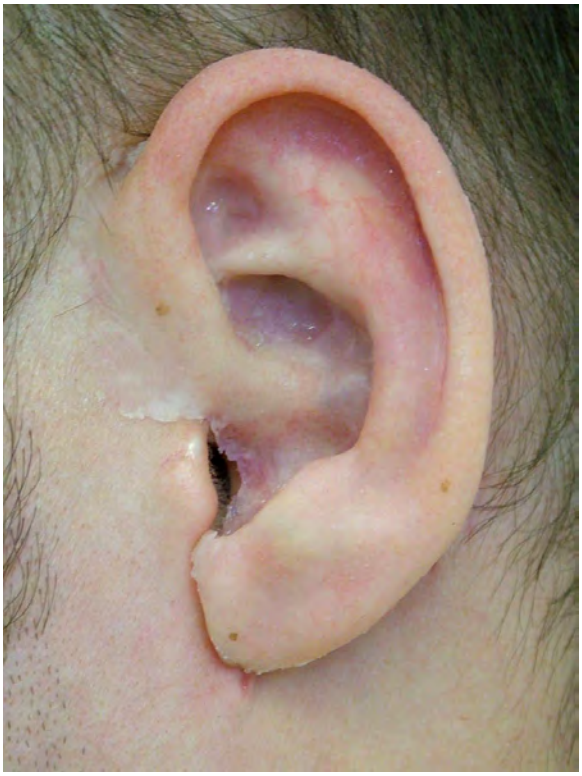


Figure 6c5 – The completed prosthesis

6c.4 - Evaluation

Quality: One of the primary advantages of this technique was the ability to match the prosthesis design to the patient's existing anatomy by mirroring. This undoubtedly provided an accurate prosthesis form. However locating the design was difficult due to the lack of surrounding anatomical landmarks such as the contra-lateral ear and eyes. Direct patient scanning typically provides more anatomical data, but the ability to capture small details may be compromised due to slight movement, areas hidden from line of sight, hairy and reflective surfaces often found around the face. Line of sight issues means that capturing behind the ear is typically extremely difficult for light based scanners. This study demonstrated that scanning a replica cast allowed an otherwise difficult area to be captured. However, holes were still visible where the scanner was unable to capture data. Some of these could be filled based on the surrounding contours during the software stages, but where holes were poorly filled, detail was lost. Lost detail was carved back in both the FreeForm software and into the wax pattern once physically produced. Ensuring that as much data is obtained in the early scanning stages and exploring alternative, more appropriate scanning technologies is likely to improve data quality.

Figure 6c6, a shows an image of the magnet and the detail of the magnets at the STL file stage in Spider. When compared, some loss of sharp edge and small feature detail is apparent. However, this level of detail is acceptable and demonstrated by the ability to locate the magnets into the wax pattern later in the process.

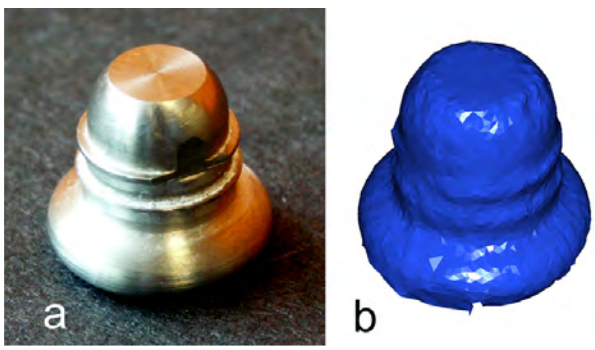


Figure 6c6 – The magnet (a) and scanned magnet at the STL file stage (b)

Quality aspects of this process may be improved in a number of ways:

- Application of a higher resolution scanning method. For example, Roland DG, LPX-1200.
- Blocking out undercuts such as beneath the magnets before scanning.
- Obtaining an impression that covers a larger area surrounding the defect to better enable accurate location.
- Directly scanning the patient and covering key anatomical features that would allow more accurate location of the prosthesis.

Economics: Economic issues may be broken down into time and cost, which although related are best considered separately in order to more clearly identify advantages and limitations of techniques.

Scanning and conversion to STL data took approximately three hours, all of which required an operator. Attributing a cost to this time depends on the situation, but as an indicator a commercial bureau is likely to charge around £150 (£50/hr). This represents a significant cost for prosthesis production and would therefore not be commercially viable for many cases. Alternative, more automated technologies that require less operator time are available and it may be foreseen that the cost of scanning could therefore be dramatically reduced. Another possible option would be to bring the scanning technology into the health care system. This would require an initial investment of at least £13,000 (Based on the UK retail price of a Roland LPX-1200).

Digital prosthesis design took approximately one hour, which is significantly faster than hand carving. An additional two and a half hours fabrication time was required to produce the pattern, only fifteen minutes of which required an operator.

In addition to the cost of scanners, suitable design software such as FreeForm requires an additional outlay of around £5,000 for a basic version to £20,000 for an upgraded version, plus yearly maintenance.

The ThermoJet machine used in this study is no longer manufactured but may be purchased used for around £15,000, with annual maintenance required. The wax pattern would retail for around £35, although economies of scale may reduce the price if many patterns were built at once.

The high costs associated with purchasing and running these technologies would prevent their introduction into many laboratories. However this study has shown that an accurate pattern may be produced in fewer operator hours and with reduced need for patient consultation. It is estimated that around one day hand-carving time was saved. However this was offset by the additional time required to scan, digitally design and fabricate the pattern using digital technologies.

Depending on the prosthetist's speed and the case complexity, hand carving a wax ear may take around four to six hours. A senior level prosthetists' salary calculates at approximately £16/hr, so the labour for hand sculpting an ear conventionally would cost approximately £64 - £96 (excluding overheads). The digital process described took three hours scanning and one hour to design, totalling £48 based on the same pay scale. This must be added to the ThermoJet pattern cost, so the total equals £83. These costs are only an indicator and further research is required to more accurately compare the economics of conventional versus digital techniques.

Clinical viability: The application of digital methods resulted in a more flexible working process, where the prosthetist was able to undertake design work without the need for the patient to be present. The 'O' ring magnet used is relatively new and although provides a high retentive force, the large diameter can be difficult to incorporate into the prosthesis. Working digitally enables the suitability of the magnets to be decided early on. It also improved the efficiency of the process at the design stage by removing the need to switch between fitting the pattern in clinic and carving in the lab. However functional limitations of the technologies may reduce their clinical viability. The

scanning and STL generation process applied in this study would not represent an intuitive and efficient solution for clinicians. A less labour intensive, simpler to use solution would be required. The FreeForm design software did represent an intuitive solution and is relatively simple to operate when compared to engineering CAD software. ThermoJet printing is a relatively simple process to operate, but it requires expensive maintenance, which may limit its appeal for hospital application.

6c.5 - Conclusions

This study has demonstrated that digital technologies provide a means to design and fabricate an auricular prosthesis pattern that incorporates features for magnetic retention. However, conventional finishing techniques were still required in order to produce an acceptable pattern with sufficiently thin edges.

Whilst the technologies utilised are capable of working to sufficient quality tolerances, limitations need to be addressed to make them economically and clinically viable. These include:

- Capturing sufficient anatomy to enable the digital prosthesis design to be more easily located.
- More intuitive and efficient methods of scanning that minimises operator time.
- Reduction in the purchase and maintenance prices of the technologies.

Digital technologies in extra-oral prosthesis design are at a stage where they may be clinically applied, although further research is required in order to make the process more efficient.

6d - Case study. Bar and clip retained, auricular prosthesis

6d.1 - Rationale

Bar and clip mechanisms are a commonly used method to retain prostheses since they provide increased retention over other mechanisms such as adhesives or magnets. The viability of producing bar structures, clip mechanisms and other retentive components using digital technologies has not yet been fully explored. Given the widespread application of bar and clip mechanisms in conventional prosthesis production, it was deemed important to evaluate the capabilities of digital technologies to design and fabricate such structures and incorporate them into digital prosthesis design.

6d.2 - Introduction

Bar and clip retention mechanisms are complex in design and construction due to their small size, high detail (described further in chapter 4 part 8.4), the need to consider the forces involved with their use and how they will be incorporated into the moulding techniques. Figure 6d1 shows the fitting surface of a bar structure and demonstrates the level of detail, especially in the cylinder components. Further details on retention mechanisms are outlined in chapter 2, part 5.4.

Figure 6d1. The fitting side of a bar structure.

6d.3 - Case study research design

Study objectives: This research aims to identify the degree to which current digital technologies are capable of assisting the design of an implant retained, auricular prosthesis.

Study design: A critical review of previous research and technologies was undertaken to identify potential challenges and suitable methods. A range of optical surface scanning, CT, CAD and RP technologies were then selected and evaluated through the design and fabricate of a bone-anchored auricular prosthesis including the retentive components.

Data capture and analysis techniques: Machine parameters recorded. Analysis by test fitting the components to the replica cast and testing for a rocker action in the bar or visible signs of misfits.

Validity control: Analysed by a trained prosthetist for clinical viability.

6d.4 - Identification of current digital technologies

A review of previous case studies, literature and current technologies highlights a range of techniques that may be suitable for this application:

- Non-contact surface scanning to digitise the skin topography. For example: structured white light, laser or photogrammetry.
- CAD software. For example: FreeForm, Magics or Rhinoceros.
- Rapid Prototyping to produce the components. For example: ThermoJet wax printing, Selective Laser Melting (SLM), Stereolithography, Perfactory, etc.

- CNC machining to produce bar components.

The use of each of these technologies has already been reported in the design and fabrication of patient specific devices.

6d.5 - Identification of potential challenges

Past research has identified limitations of current technologies and challenges that must be considered at each stage of the construction process, including:

Capturing the anatomy and abutment locations. Research has highlighted limitations of non-contact scanning techniques when capturing areas of hair, undercuts or where the subject moves. Insufficient data resolution and errors in the form of 'noise' may also limit the ability of scanning technologies to capture sharp edges, pointed geometry and small flat surfaces [Chen *et al*, 1997]. This makes it particularly challenging to accurately record facial topography and abutments. In engineering applications, technologies that combine touch probe scanning to identify key features and light/laser scanning to capture form (such as by Faro. See glossary) may be used, however these are less suitable when dealing with mobile patients.

Aligning and designing prosthesis components. Typical engineering CAD software handles geometric shapes. Alignment tools that enable components to be accurately positioned in relation to one another are a common feature in engineering CAD, but they are not suitable for aligning or representing anatomical forms and do not provide the physical tactile feedback that prosthetists are used to. CAD software such as FreeForm allows the manipulation of complex anatomical forms, provides tactile feedback but does not provide alignment tools and is less well adapted at representing geometric shapes. Therefore component alignment may require further software tools.

Producing the components in suitable materials. Material requirements for maxillofacial prostheses are varied. Currently no technology is capable of building the final prosthesis form

directly from CAD in a suitable colour matched material. Therefore, a pattern must be produced instead. The pilot and previous case studies have shown that producing the pattern in a material compatible with conventional sculpting techniques allows for adjustment during test fitting on the patient. Retentive components should be non-corrosive and un-reactive with each other, resist the effects of conventional processing such as mould heating, provide adequate wear resistance to repeated use, resist permanent distortion during everyday use and provide adequate retention for the prosthesis.

Technology specification. There is currently no specification that identifies the performance, economic and clinical requirements of digital technologies for facial prosthesis production. A conclusive, clearly defined specification is required in order to direct the development of these technologies to meet the needs of the prosthesis provider and healthcare system.

6d.6 - Materials and methods

Study 1 – direct patient scanning

An implant-retained auricular prosthesis case that required a bar and clip retention method was selected. A single-stage operation to place two Brånemark (Nobel Biocare, Göteborg, Sweden) 4mm implants and 3mm abutments had been undertaken and a healing period of six weeks allowed before commencing prosthetic construction.

Paired Konica-Minolta Vivid 900i laser surface scanners (Konica-Minolta, Milton Keynes, UK) with a 14 mm focal length lens were used to scan the patient. Surface data of the subject is represented as a cloud of points with a higher density resulting in more detailed information of the surface. The patient was seated 1.35 m from the lenses and an area of 445 mm x 333 mm was captured, resulting in a point density of one point per 0.69 mm^2. This technology was chosen due to relatively fast capture times and good accuracy identified in research by Kau *et al* (2004a&b). Research by Kau *et al* (2004a&b) has demonstrated that although the specified capture time is 0.6 seconds, the functional capture time per camera is around 2.5 seconds including a short pause between each scan, which meant that the patient had to remain still for approximately eight

seconds. The point-cloud data was aligned and converted to an STL file using Rapidform software and imported to the CAD package, FreeForm using the "thickness" option to make a solid model.

At this point, it was clear that the abutments were not defined with sufficient resolution to design the retentive components of the prosthesis (figure 6d2). The data was however sufficient to identify abutment locations, which allowed the overall prosthesis form to be designed. Techniques used in the pilot study and case study 6c were used to mirror the healthy ear from the obtained from the CT data to the prosthesis site, blend into the anatomy and subtract to leave an accurate fitting surface.

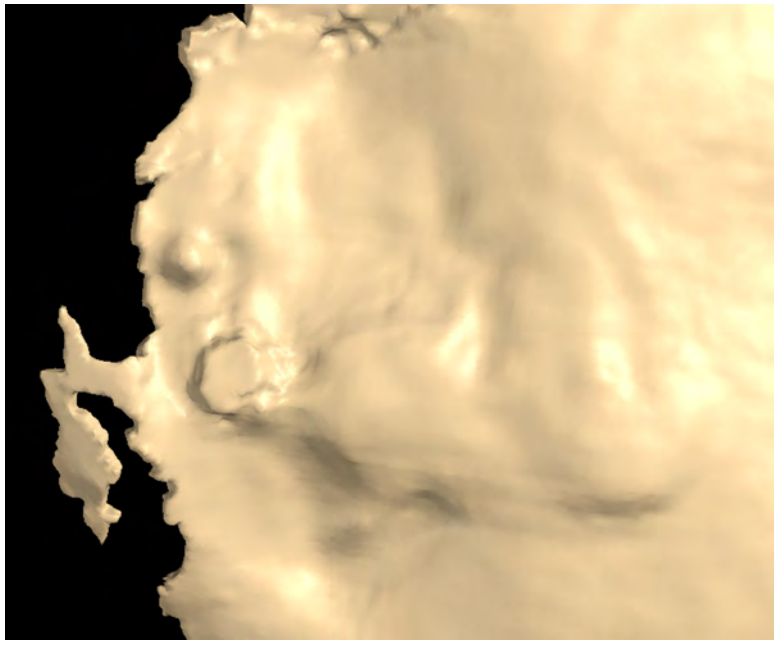


Figure 6d2. The abutments and surrounding tissue captured by the Konica-Minolta scanners

The prosthesis pattern design was produced directly in a wax material using ThermoJet printing. The wax pattern was adapted by hand to include the retentive components that were made using conventional methods. A silicone prosthesis was then fabricated from this pattern for the patient using conventional methods.

6d.7 - Study 1 results

Study 1 highlighted the limitations of non-contact scanning to capture anatomy and abutment details with sufficient resolution. An alternative method using a higher resolution scanner was required to capture abutment details.

6d.8 - Study 2 – cast replica scanning

An impression and dental stone replica was made using methods adapted from those described by McKinstry (1995). Implant replicas were used to record the abutment locations. A more accurate and higher-resolution, Steinbichler Comet 250 structured white light scanner was used to digitise the replica. A similar method has also been discussed by Sykes *et al* (2004). This scanner captures approximately nine points per mm^2 (three per mm in the x, y plane) and around 140,000 points per scan. The area captured is approximately 250 mm x 250 mm with a working range of approximately 180mm. Magnetic keepers (Technovent Ltd, UK) were screwed on to the abutments to provide a simple flat surface and the model was coated in a fine matt white powder to reduce reflectivity. Six overlapping scans were taken and the data aligned using Polyworks software. The point-cloud data was converted to the STL file format using Spider and the data imported into Magics. Alignment, sectioning and cut tools in Magics were used to remove each cap in turn to leave a perfectly flat surface representing the abutments. Figure 6d3 shows the abutment cap before removal with one triangle selected. The data was re-saved as an STL file and imported into FreeForm. The circular profile and flat surfaces of the abutments were much clearer, allowing the location of the centre screw holes to be identified (figure 6d4).

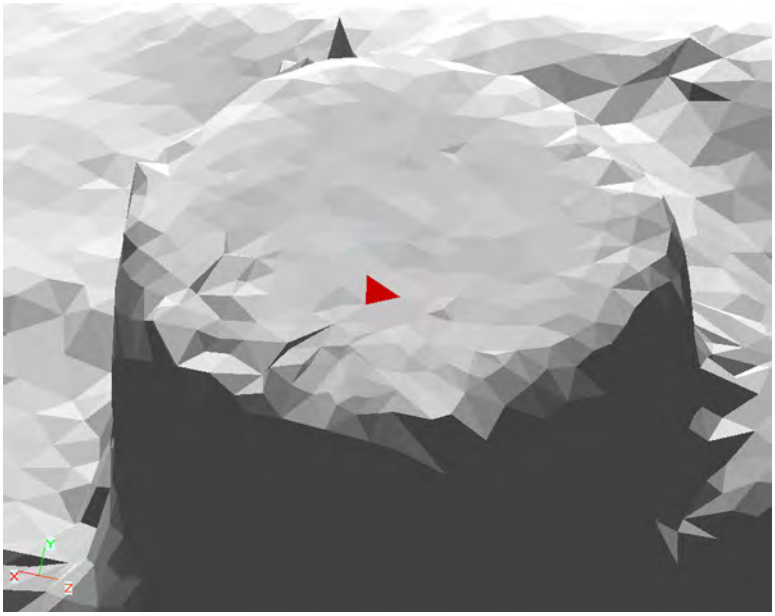


Figure 6d3. A triangle selected on the abutment cap surface (also illustrating the unevenness of the surface).

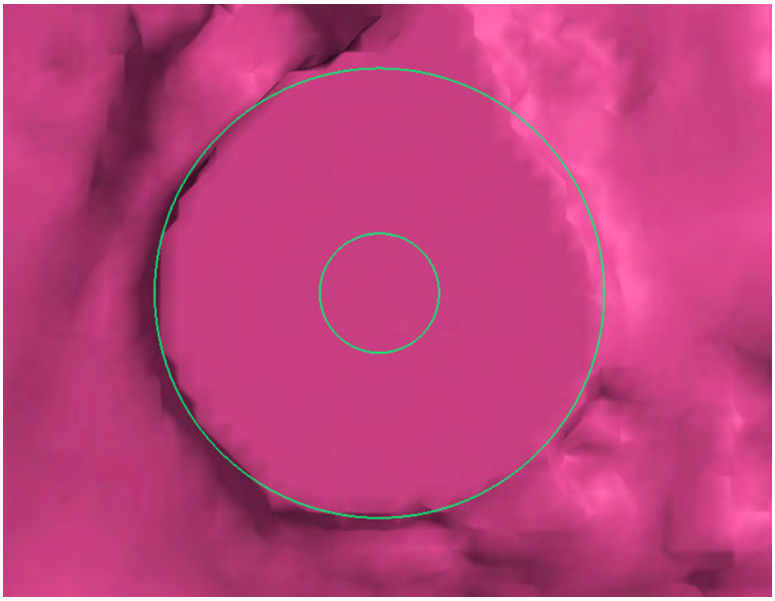


Figure 6d4. The centre of the abutments located in FreeForm.

Component design. The ear profile from the CT data was manually aligned to the digital cast based upon the estimated aesthetic requirements and possible substructure location. FreeForm was used to create digital versions of the screws used to attach frameworks to the abutments and cylinder components and a circular-section framework linking the two cylinders. 'Smoothing' tools were used to blend the cylinders into the frame, hemispherical dimples were created where cylinders located on the abutments and holes created for the screws. Figure 6d5 shows the design.

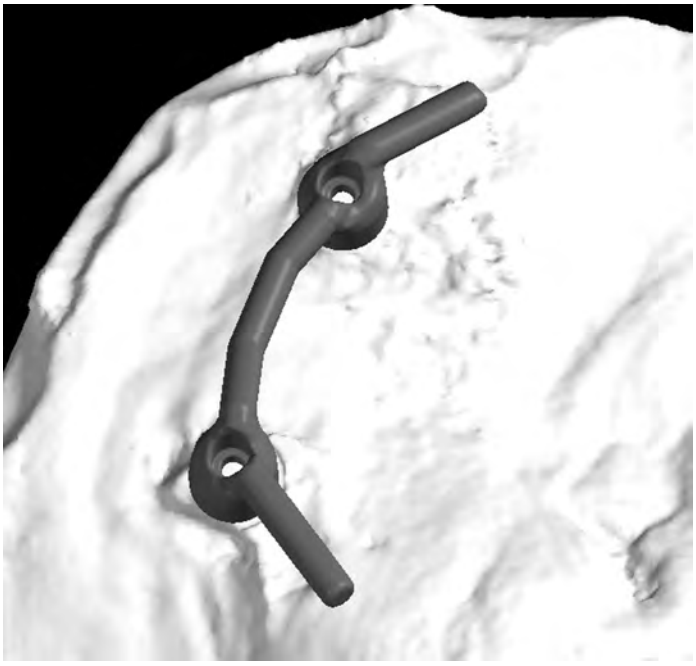


Figure 6d5. The completed bar design in FreeForm

A clip design was created, copied three times and located along the bar structure. A substructure shell that would be bonded to the silicone was required to secure the clips into the prosthesis body and to assist application. This had to provide enough clearance for the clips to spring open and closed, but provide firm anchorage for bonding to the silicone. A 1.5mm thick shell covering the clips and bar was created and joined to the top points of the clips, leaving space for them to open and close. The design is shown in figure 6d6.

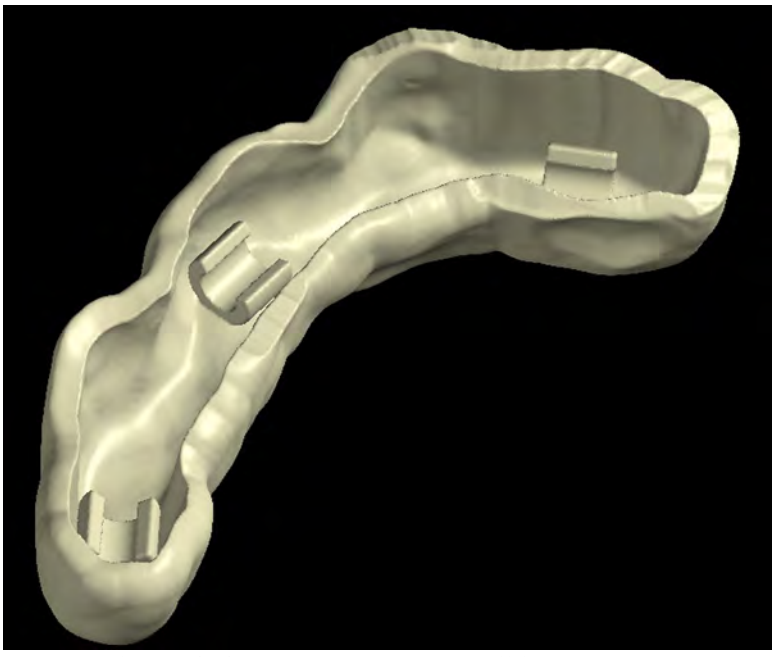


Figure 6d6. The substructure shell in FreeForm.

The prosthesis profile was modified slightly to accommodate the shell component and a Boolean subtraction operation used to create a fitting recess for the shell.

Figure 6d7 shows a computer generated image of the components in the FreeForm environment.

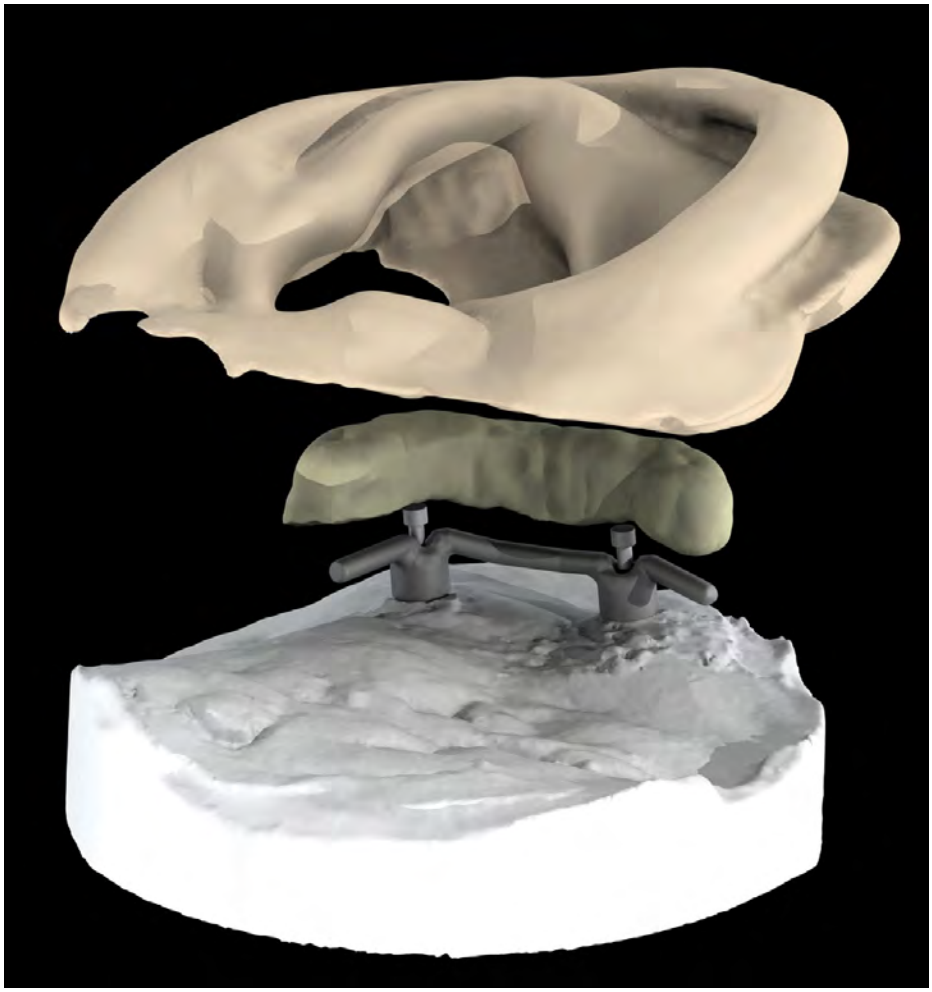


Figure 6d7. A computer generated image of the components in FreeForm.

Each of the components was then exported as high quality STL files ready for RP fabrication.

Fabrication. The bar component was built in 316L Stainless Steel using SLM, in 0.05 mm thick layers. Once completed, the support structures were removed using a high-speed cutting disk. The part then received grit blasting and polishing to achieve a visibly smooth surface.

The shell component was built using Stereolithography in 0.1 mm layers in DSM Somos, 10110 epoxy resin (Flexural modulus 1,720 MPa, hardness, 83 Shore D). ThermoJet wax printing was used to produce the prosthesis pattern. The physical components are shown in figure 6d8.

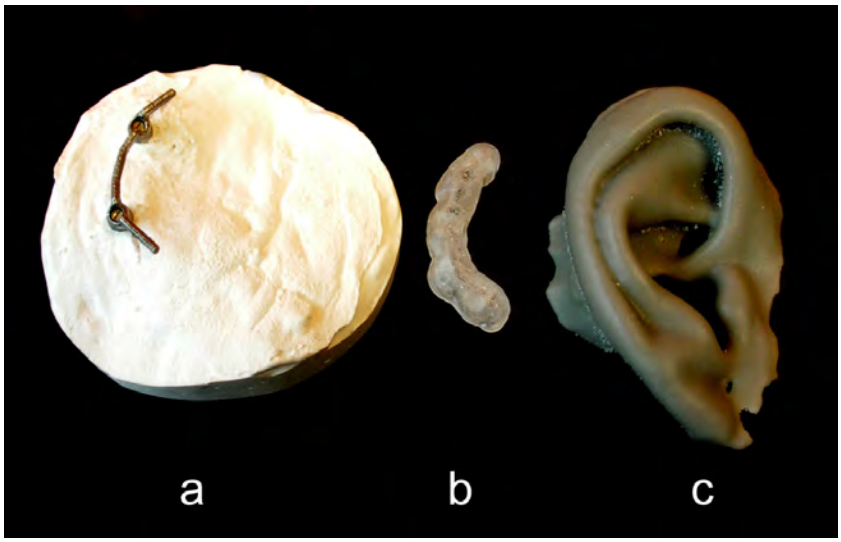


Figure 6d8. The individual components: left - SLM bar, middle – Stereolithography sub-structure, right – ThermoJet pattern

6d.9 - Study 2 results

Although the finished components were not used in a final prosthesis, it was possible to assess the performance of the components on the dental stone model. The bar did screw on to the abutment, but did not sit perfectly (figure 6d9).

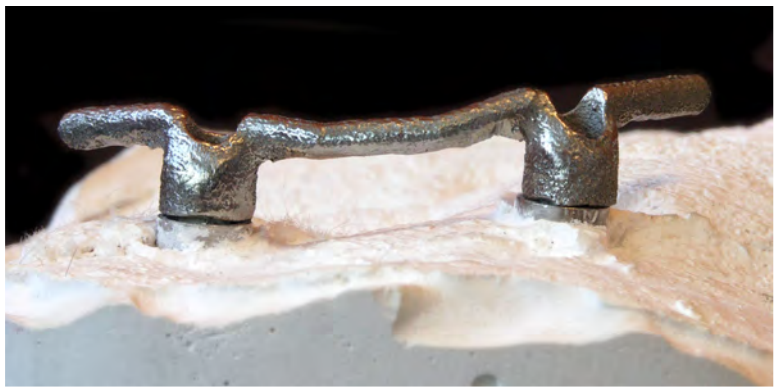


Figure 6d9. The bar fit before finishing.

The surface finish was relatively rough compared to conventionally produced gold bars, but this may be attributed the machine parameters, which may be improved with more experimentation. Grit blasting and polishing produced an acceptable result, but some pitting was noted. The shell and clip components did clip on to the bar, but repeated application caused wear that weakened the retention strength. This would be unacceptable for prosthesis retention. Fit between the ThermoJet pattern and shell structure was tight, but very small undercuts prevented the shell slotting straight into the recess without minor modifications. The relatively fragile nature of the ThermoJet wax compared to type 1 baseplate/modelling wax typically used for pattern carving would have prevented the edges from being made any thinner. Conventional sculpting techniques would be required to achieve the necessary edge thickness to blend into the surrounding skin.

6d.10 - Discussion

Whilst this study has demonstrated potential, it has also highlighted many limitations that would currently prevent the technologies identified from being clinically and commercially viable. These include:

- The difficulty of directly scanning patients with sufficient resolution to describe abutment details whilst also overcoming issues that cause poor data capture.
- Limitations in computer software that result in an inefficient process to align, manipulate and design components.
- The inability to produce components directly in materials with sufficient mechanical and aesthetic properties.
- The difficulty in predicting and accounting for the mechanical behaviour of components designed in CAD.

The difference in results between scanning the patient directly using the Minolta scanners and scanning the cast using the Steinbichler highlights the limitations of optical scanning technologies. Whilst the Minolta's offered sufficient speed to directly scan the patient, the resolution was insufficient to describe abutment details. The Steinbichler was capable of capturing the keeper surfaces, but noise in the data meant that flat surfaces were visibly uneven in the CAD software and

sharp edge details were generally rounded (figure 6d3). It may also be argued that directly scanning patients is a more efficient method that eliminates the need to take an impression.

The efficiency of the design and manipulation stages was compromised by the need to use multiple software packages. Component alignment was particularly difficult. From the research conducted to date it appears that an ideal solution that allows accurate component alignment and manipulation tools for prosthesis design does not yet exist. This is likely to become a more significant problem in larger facial prosthesis cases.

Conventional soldered gold bar and gold clip designs allows for adjustable retention strength according to patient requirements, but whilst the clips produced in this study did function (albeit for a limited period), the retention strength could not be predicted at the design stage, or adjusted post-production. The choice of clip and sub-structure material should also be refined in order to improve the durability and wear resistance. Alternative RP processes such as Perfactory (Envisiontec) that build in thinner layers and with a higher resolution may also offer a more suitable solution. Figure 6d10 shows a Perfactory-built version of the substructure compared to the SLA version. This was built using the high resolution focus. In this trial, the material was too soft for the thin shell structure design and broke when the clip was pulled away from the bar.

Figure 6d10. A Perfactory sub-structure (left) compared to the SLA (right) used in this case study. Note the improved definition of the Perfactory version.

Although the techniques for prosthesis retention are well established, very little research has been undertaken to identify the ranges of required retention strength for individual patient needs. Once this has been identified, a specification level against which digital methods may be assessed can be developed.

Galvanic corrosion between the Stainless Steel bar produced by SLM and the Titanium abutments should not be an issue (the anodic index are within 0.2 V), but if required SLM is able to produce components in a range of metals and alloys including commercially pure Titanium.

6d.11 - Conclusions

This and previous studies in this thesis have shown that whilst the technologies exist to enable full digital design and production of soft-tissue facial prostheses, they are often not ideally suited to the application. Development is required in the following areas:

- Scanning technologies that are capable of capturing patients directly with a speed <0.6 seconds to avoid noise caused by movement and with a resolution of at least nine points per mm^2 (preferably higher) to capture features with a diameter of 4mm accurately. Ideally, scanners should be capable of capturing abutment details without the need for coating in a matt finish or to remove detail using flat keepers.
- Software that provides alignment and design tools in an intuitive single solution for prosthetists.
- A specification for prosthetic material requirements and the development of RP materials and technologies that meet this specification.

6e – Experiment. Rapid prototyping of a bar structures

6e.1 – Rationale

The first study into the direct fabrication of bar structures demonstrated potential, but also identified shortcomings in quality, primarily due to limitations of the scan data and SLM build process. It was anticipated that alternative methods of capturing abutments that provided greater levels of detail would allow more accurate bar design. Improvements in the SLM process also suggested that bar structures could be produced with greater levels of detail and improved surface finish than had previously been possible.

This study followed on from the first and introduced an improved method of scanning small details and SLM production of finely detailed metal bar components.

6e.2 - Research design

Study type: pilot study using sample data without the original cast and single case study with the original cast to test fit a bar.

Data capture & analysis techniques: record of settings utilised. Visual analysis of the bar and test for fit on the original cast; test for rocker action and if the bar screws on to the abutments correctly. Visual assessment of the bar roughness and other quality aspects.

6e.3 - Pilot study methods

Scanning & data handling: A Roland Picza touch probe scanner was used to digitise a 27mm x 22mm area of replica cast with two abutments. A point spacing of 0.05mm in both x and y axis was used to achieve high levels of detail. Figure 6e1 shows the STL file produced from the data.

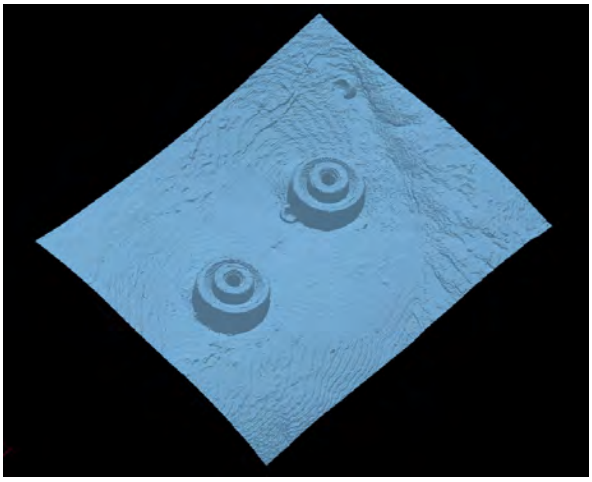


Figure 6e1. The STL data produced from touch probe scanning

The data were imported into FreeForm version 9 using the 'extrude to plane' setting and a 0.1mm level of clay detail. This produced a solid model volume. The protective 'buck' setting was used to prevent accidental modification to the original data and provide a virtual cast onto which the bar could be designed.

Design: A drawing plane was created and aligned to lay flat on the surface of one abutment. The abutment centre could clearly be identified and a circular profile the same diameter as the abutment was drawn on to the plane. This was then offset to create the cylinder diameter and extruded to create a solid piece of digital 'clay' on top of the abutment and towards the cast to create a small overlapping lip. The drawing plane was then moved to the top of the cylinder and the original circular profile offset to the inside to create a hole for the screw. An extrusion operation was used to create a screw recess and full length hole through the cylinder. The same operations were repeated for the second abutment.

A 2mm diameter, circular section bar joining the two cylinders was created using the 'add clay' tool. Minor smoothing operations were used to blend the joins and the buck cast was removed to leave just the bar design. Figure 6e2 shows the digital design on the cast.

The bar was exported as an STL file with no reduction in quality in order to maintain high detail levels.

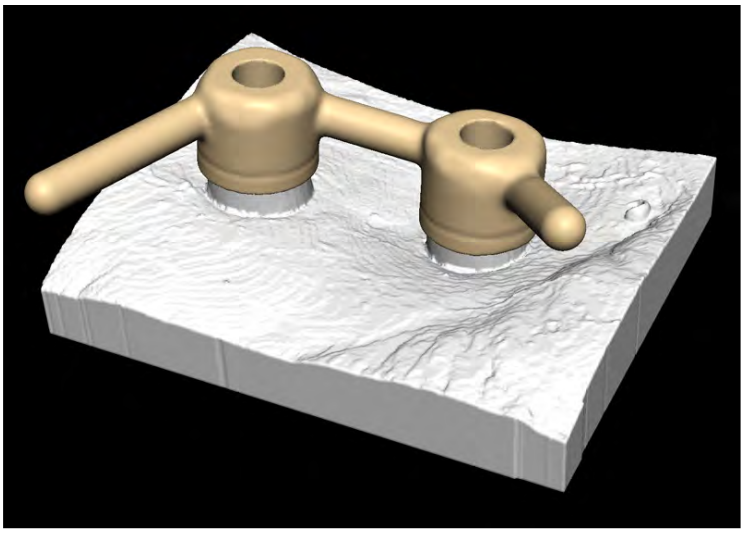


Figure 6e2. The completed bar in CAD

Fabrication: An SLM-100 machine designed specifically for the fabrication of small detailed components was used to fabricate the bar. The machine specification was:

Laser:	50 Watt Fibre Laser
Platform:	125 mm diameter
Max. build height:	70 mm
Layer Thickness:	30µm
Spot Size:	30 µm (less than half the size of the SLM 250 used in the previous study)
Material:	Cobalt Chrome F75

The bar was orientated to achieve the best surface finish on the critical features.

Figure 6e3 shows the bar with the support structure attached and figure 6e4 shows the underside of the CAD bar and the final bar after the supports were removed with pliers. Minor grinding was required to finish the down facing surfaces where the supports had attached. No further finishing was undertaken.

Figure 6e3. The SLM bar with support structure still attached.

Figure 6e4. The fitting surface of the bar in CAD (top) and SLM bar (bottom)

6e.4 - Pilot study results

The pilot study demonstrated that SLM could be used to fabricate a CAD bar structure with a visibly acceptable surface finish. A further case study was required to determine if sufficient tolerances could be achieved to fit a bar to abutments..

6e.5 - Case study methods

Scanning & data handling: the same scanner and settings used in the pilot study were replicated. An area of 65mm x 35m was scanned, which took approximately 40 hours.

Design and fabrication: the same methods as used in the pilot study were replicated for the design. Figures 6e5a, b and c show the completed bar design in FreeForm.

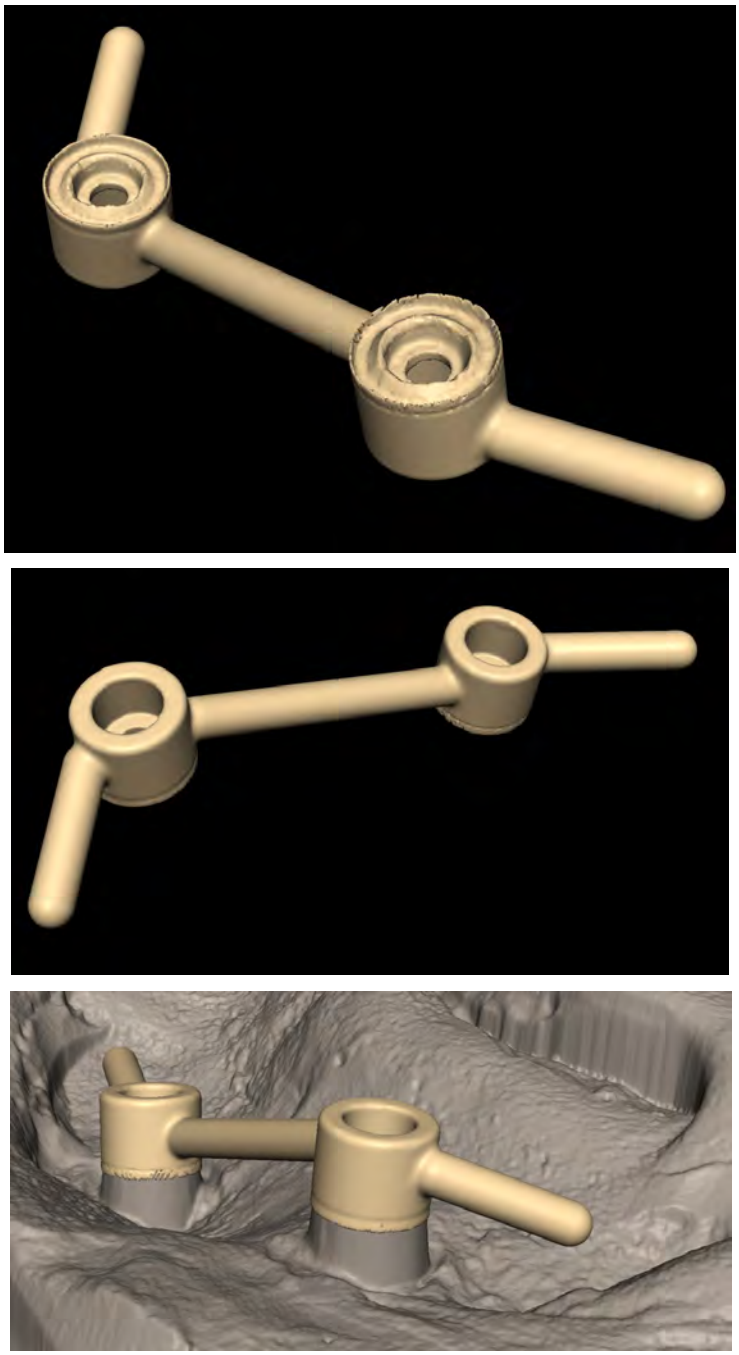


Figure 6e5a-c. The bar design in FreeForm.

The same specification SLM machine was used to fabricate the bars in 50µm layers. Two alternative orientations were compared to establish the effect on surface finish. Figure 6e6 shows the bars built using alternative orientations. Figure 6e7 shows the bar after hand finishing.

Figure 6e6. Comparison of the fitting surfaces with the bar built with the top surface facing down (top) and standing vertically (bottom).

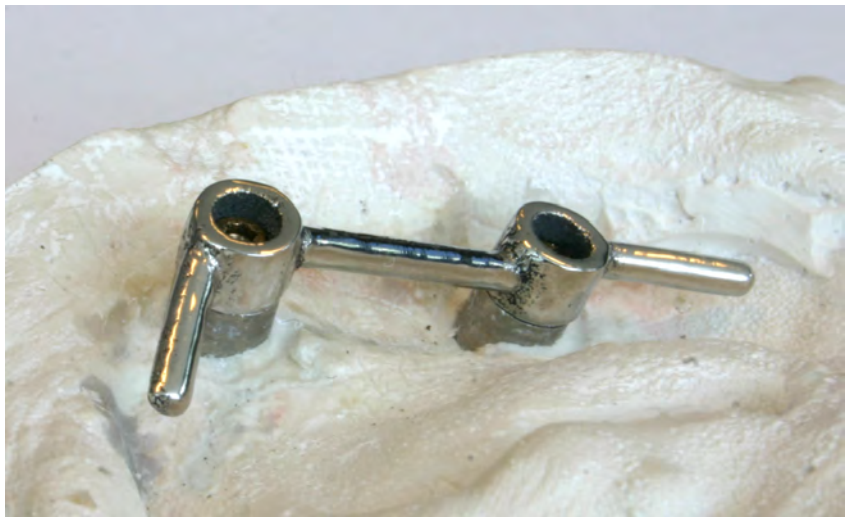


Figure 6e7. The bar after hand finishing.

6e.6 – Case study results

Finish: The pilot study and case study demonstrated that a visually acceptable bar could be fabricated using existing SLM technologies. In the case study, the vertically orientated bar gave a superior finish on the important fitting surfaces. In both the pilot and case studies, pitting was minimal and polishing the surface gave a mirrored finish that closely resembled that achievable using conventional methods. The junction between the cylinder features and bar were difficult to

polish. Smoothing these junctions would enable improve polishing. Figure 6e8 shows a comparison between a gold soldered bar and the SLM produced in this study.

Figure 6e8. A conventionally produced bar (top) and the SLM bar (bottom)

Fit: The case study bar fitted the cast and located on to the replica abutments. Although it was necessary to clean the holes by drilling to allow the screws to fit, it was possible to screw the bar down without excerpting force. This demonstrates that the processes of scanning, CAD design and RP fabrication are capable of producing a bar with sufficient tolerance. There were however gaps at the fitting surfaces (figure 6e9). Further research would be necessary to quantify fit.

Figure 6e9. SLM bar fit (before polishing)

6e.7 - Discussion

This study has demonstrated that a combination of touch probe scanning, CAD and RP fabrication is capable of producing a bar structure that shows potential clinical application. The reduced noise from touch probe scanning resulted in more clearly defined abutments with minimal loss of sharp edge detail. There are two limitations with contact scanning: the difficulty digitising undercuts and slow speeds. The difficulty in digitising undercuts may be overcome to some extent by using a fourth axis option, which is available for some machines. Slow speeds may limit capacity and the ability to undertake multiple cases in quick succession, but may not be an issue where a cast can be digitised overnight. An ideal solution would incorporate the speed of non-contact scanning, with the reduced noise and high resolution of touch probe. This would currently require combining the use of both scanner types and merging the data in a software package.

Importantly, the improved data resolution allowed for a more streamlined design and fabrication process where only one CAD package was relied upon. The improved resolution and low noise made it possible to locate the centre of the abutments more easily and allowed for a more detailed bar design. The ability to orientate a drawing plane to a flat surface in FreeForm also made cylinder design simpler. Further improvements in the design process could be made by the

development of a component library. Components could be pre-designed and imported then aligned as necessary.

Previous attempts to produce a bar structure in metal directly from CAD resulted in a badly pitted surface that would not be satisfactory for clinical application. The SLM machine used in this study overcame these problems and the surface finish was much closer to that currently produced using conventional methods. This technology has the ability to generate complex, detailed features with undercuts. This makes it more versatile than machining and has the potential to allow an entirely new mechanism of prosthesis retention to be designed.

6e.8 – Conclusions

Potential for clinical application is evident from this case study, however further work on the economic viability of SLM technology is required. SLM has found application in other medical areas, such as dental components and prostheses, custom surgical guides and devices, but remains a relatively expensive RP technology. It also requires further development and approval for use in the fabrication of devices that are in permanent contact with skin.

6f - Case study. Magnet retained, nasal prosthesis

6f.1 - Introduction

The purpose of this study was to apply the most effective technologies identified in previous studies and evaluate the quality and production times of digital and conventional prosthesis methods.

Previous studies have demonstrated that:

- CT scanning is suitable for capturing surface topography, but is only ethically viable where already available due to radiation exposure.
- Direct patient optical scanning can be suitable, but is limited to capturing anatomy with few undercuts, little hair and non-reflective surfaces. Patient movement also causes problems, especially when capturing small features.
- Non-contact scanning may be used to digitise cast models, but still encounters issues capturing undercuts and may not capture sufficient anatomy to allow prosthesis positioning.
- Non-contact light/laser based scanners may be used to capture magnets on a cast with sufficient accuracy for incorporation into digital prosthesis design.
- Blocking out undercuts before scanning may help to reduce holes in the data.
- More research is required to develop methods of bar/clip type design.
- FreeForm is well suited to overall prosthesis, but may struggle to define thin fitting edges.
- ThermoJet RP provides sufficient resolution on up facing surfaces to describe skin texture, but is fragile and may therefore not be suitable to build fitting edges. The wax material is most suitable for incorporation into conventional carving methods.

6f.2 - Hypotheses

1: Digital technologies may be used to produce a clinically acceptable nasal prosthesis pattern and sub-structure that may be moulded and coloured using conventional methods.

2: There will be no significantly noticeable difference between a nasal prosthesis produced using conventional methods and digital techniques in three key areas: quality of edge, positional accuracy and shape.

3: Digital design and RP fabrication methods will not increase the construction time for the clinician or patient.

6f.3 - Case study

Patient who had undergone a nasal resection and had implants placed for a magnet-retained prosthesis.

6f.4 - Study design

The hypotheses were tested using a combination of quantifiable and subjective assessments.

The patient was scheduled for a three day period of clinical consultation. During this period the prosthetist produced a prosthesis using conventional methods. Each stage of the construction process was observed, recorded and timed. Front, side and three quarter photographs were taken of the completed prosthesis.

The original cast created from the impression was then used as the basis for digital design. The digital process was also recorded and timed and the patient called to another appointment for fitting. The same photographs were taken of the completed digitally designed prosthesis.

In order to test hypothesis 2, a five point scale was used to rate each prosthesis in terms of: quality of edge, positional accuracy and overall shape. Volunteer staff and clinicians from the Maxillofacial Unit at Morriston Hospital were asked to rate each of the prostheses based upon the images provided of each prosthesis. All were blinded to the production methods used (none were involved with providing the prostheses) and the images were provided sequentially. The results were analysed using a paired, student t–test (p=0.05) to identify the significance between the results. This method was chosen because of its suitability when dealing with expected low volumes of data. A similar, ordinal rating questionnaire method has also been used in a previous study [Sykes *et al,* 2004] and demonstrated validity.

6f.5 - Conventional method

A slightly wider than normal impression was taken of the defect area. This was made into a plaster replica that formed the base on which a nose could be carved. A substructure that encapsulated the three magnets was constructed in a light cure acrylic material and trimmed as required. Wax was added to the substructure and moulded to form the edge margin for the main prosthesis body (figure 6f1). Clay was then used as a modelling material to build up the main body of the nose (figure 6f2). The shape was gradually refined and eventually trial fitted to the patient (figure 6f3).

Figure 6f1. The substructure with wax edges

Figure 6f2. Building up the pattern in clay

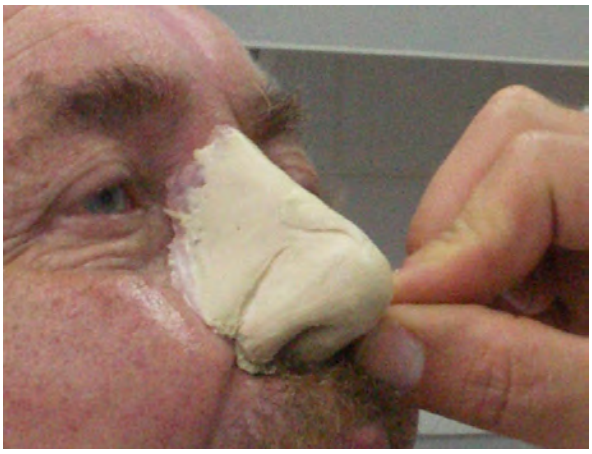


Figure 6f3. Adjusting the pattern on the patient's face

As is typical, the shape and margins required modification to blend more naturally into the face. Refinement was undertaken with the patient present for test fitting. The clay pattern was then stippled with a stiff brush to remove fingerprints and add a more skin-like texture before moulding.

A two-part, flask-less mould was created from the pattern. Plaster was poured into a paper former and the pattern, substructure assembly and abutment replicas were set in. The lower part of the mould was cleaned and keyed before the plaster fully set. Once set, the upper mould was poured. The mould was heated in hot water to soften the pattern, which was then removed and the mould cleaned.

The lower part of the mould was modified at the prosthesis margins to achieve extremely thin edges and conventional colour matching and final production undertaken. Figure 6f4 shows the completed prosthesis. Table 6f5 shows the breakdown of time taken to construct the prosthesis.

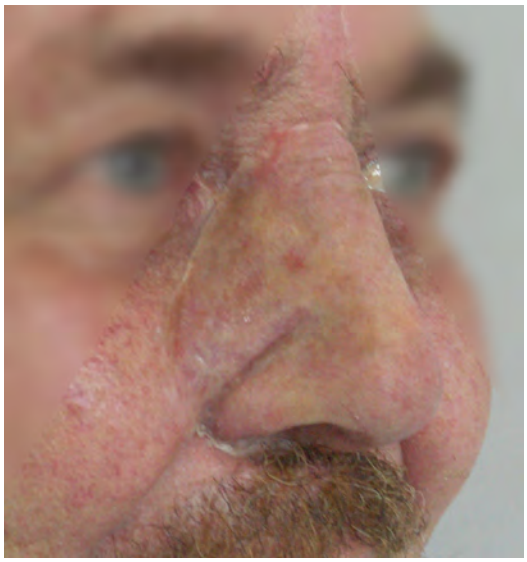


Figure 6f4. The completed prosthesis produced using conventional methods.

Stage	**Prosthetist time (minutes)**	**Patient time (minutes)**	**Setting / curing time (minutes)**
Initial consultation and impression taking	50	50	Incl.
Production of stone replica	50	0	15
Base-plate design	40	15	0
Pattern design	195	140	0
Mould production	95		40
Colour match	60	60	
Curing	0	0	75
Finishing	80	60	0
Total	9hrs, 30 mins.	5hrs, 25 mins.	2hrs, 10 mins.

Table 6f5. The time taken to construct the nasal prosthesis using conventional methods.

6f.6 - Digital design

Magnets were placed on the plaster replica of the defect, which was then coated in a fine white powder to reduce reflectivity. A Roland LPX-1200 laser scanner was used to digitise the cast. Two sets of four plane scans were undertaken in order to capture the entire cast from different

angles. The first four scans were set up with a point pitch of 0.3mm in the height and 0.2 in the width. The second set was set with 0.2mm in height and 0.3mm width. Noise and bad faces were removed from each data set, which were imported into PixForm (a version of Rapid Form for Roland scanners). The four point-cloud data sets produced from the first scan were merged and redundant points removed before a polygon mesh was created. This was repeated for the second set of four point-clouds. The two sets of data were aligned, merged and exported as an STL file using PixForm.

FreeForm V9 was chosen to undertake the pattern design. The STL fie outputted from the previous stage was imported as a protected 'buck' using the 'hole fill' option and an edge definition of 0.15mm. There was no pre-operative CT data of the patient's original nose available which meant that digital design had to be undertaken using a 'donor' nose from another dataset. This was imported as clay using the 'hole fill' option and with an edge definition matching the cast.

Manual alignment of the nose to the cast was undertaken first. Once positioned, the nose was modified to fit the anatomy better by tugging and deforming the digital clay whilst using the surrounding anatomy as a guide. The digital clay nose was joined to the buck cast and blended in at the edges. A texture pattern mimicking dimpled skin was embossed by using a wrapped two-dimensional image and given a depth of 0.2mm. This mimicked the use of brushes to create skin texture conventionally. The 'buck' cast was then removed to leave just the pattern.

Material was then removed from the inside of the pattern to reduce bulk.

A substructure was designed on the 'buck' cast by creating circular sections of clay to make a triangle that overlapped the three magnets. This was then modified to reduce bulk and the buck removed to leave just the substructure with locating features for the magnets. Further material was removed from the substructure to create clearance from the skin. With the substructure finalised, clay was added to the inside of the pattern to remove any undercuts. The substructure was then used to remove material from the pattern design, thereby creating a recess where it would bond in.

The digital pattern was then refined to 0.14mm edge definition, which also had a smoothing effect on the jagged edges. Any pieces of clay not attached to the main body were removed. Finally, the edges of the pattern were contoured in to the cast using the 'tug clay' tool. An STL file of the pattern was exported without file size reduction in order to maintain fine details. The file size was 51MB. The ruler tool in FreeForm was used to measure the thickness at five points around the edge. This varied from 0.26mm to around 0.5mm. Figure 6f6 shows the measurement tool on the front left of the nose.

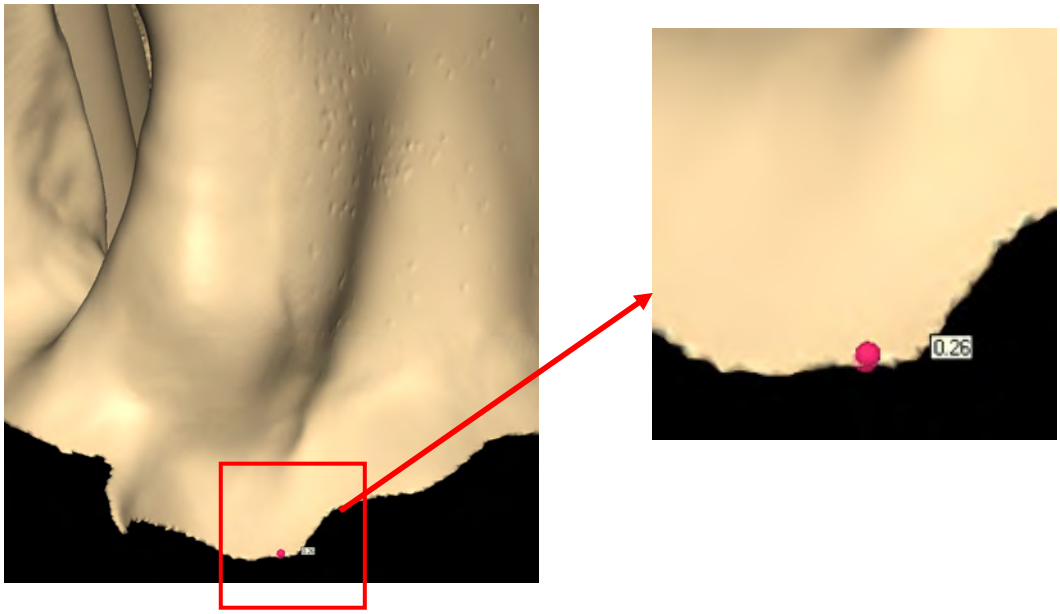


Figure 6f6. Measurement of the edge thickness in FreeForm.

ThermoJet printing was used to produce the pattern and Stereolithography to produce the substructure.

The substructure was test fitted to the patient's magnets and following verification of fit, was bonded using a light cure acrylic gel (figure 6f7).

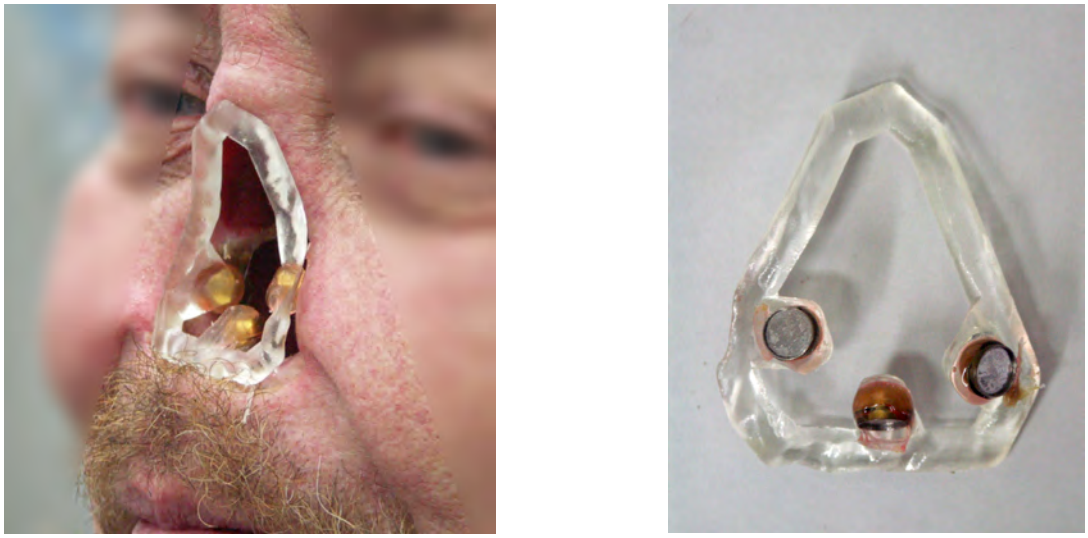


Figure 6f7. The substructure bonded to the magnets.

The substructure was then sealed into the wax pattern (figure 6f8).

Figure 6f8. The sub-structure bonded into the wax pattern.

When test fitted to the patient, a large margin around the left and right edges was apparent (figure 6f9). This was due to tissue shrinkage over the three months between taking the impression when the first prosthesis was supplied and the digital version being designed.

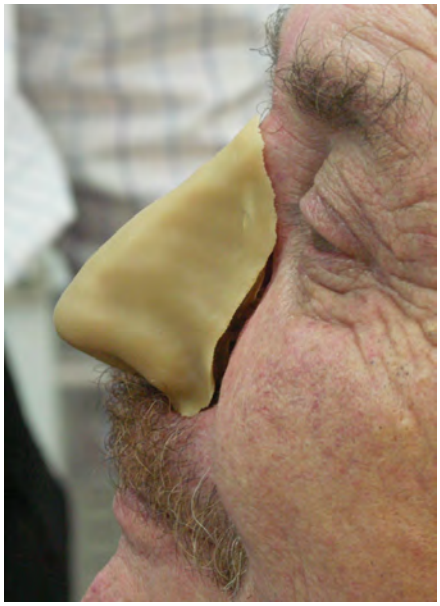


Figure 6f9. The pattern try-on demonstrating large gaps at the edges.

In order to establish a fair comparison between conventional and digital methods and provide the patient with an acceptable prosthesis, it was necessary to repeat the process using a new impression.

The process was repeated with a few minor alterations. The cast was modified to expose the magnets further (figure 6f10). This helped to make them easier to scan by improving the line of sight for the scanner.

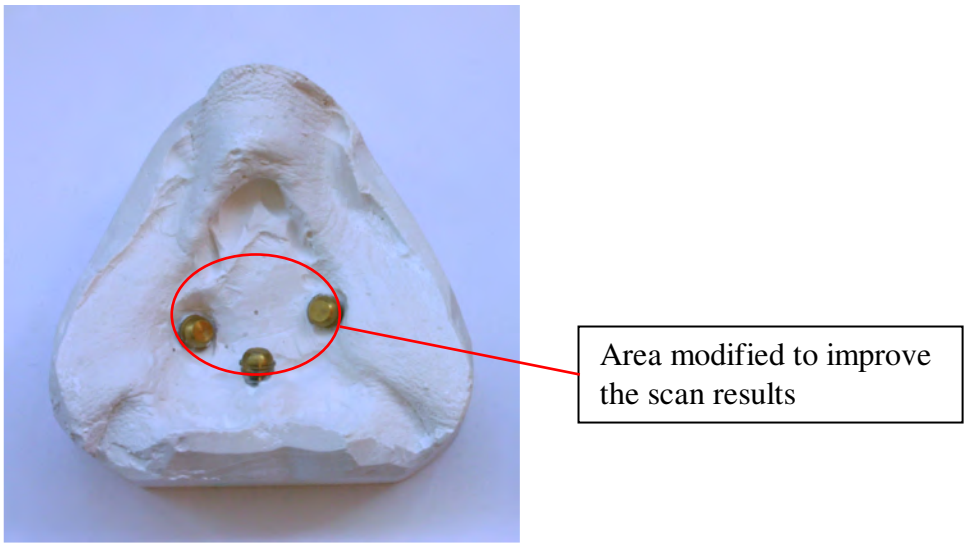
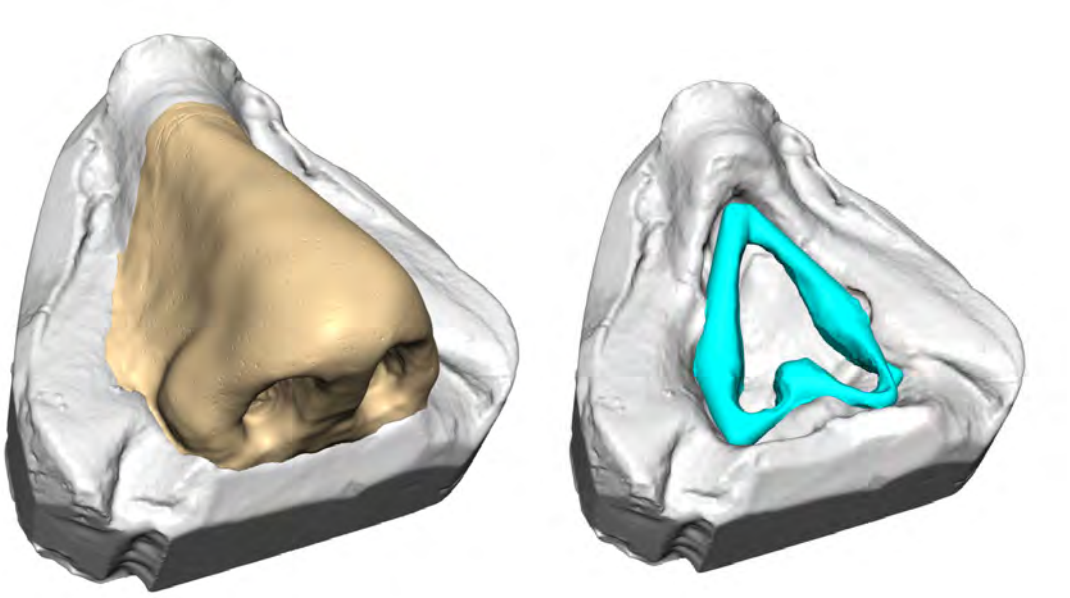


Figure 6f10. The cast generated from an impression of the defect site.

Two primary sets of plane scans were undertaken with a 0.3mm point pitch in the x and y axis. A third, local plane scan was also taken to improve the volume of data around the magnet areas. The data were exported into Pixform, aligned and merged to create a closed volume surface. An STL file was created and imported into FreeForm. The same techniques as previously described were used to design the prosthesis and sub-structure. Figure 6f11a shows the digital pattern and 6f11b shows the sub-structure. ThermoJet printing and Stereolithography were used to produce the pattern and substructure respectively.



Figures. 6f11a (left) and 6f11b (right). The completed digital pattern and sub-structure.

A mould was created directly from the ThermoJet pattern without the substructure in place. It was perceived that extra texturing was required to make the prosthesis more realistic. This was added with a scraper and tooth brush following selective heating of the pattern whilst on the lower section of the mould. The prosthesis edges were also melted to the lower mould to form thinner edges. Figure 6f12 shows the pattern sealed to the lower mould section.

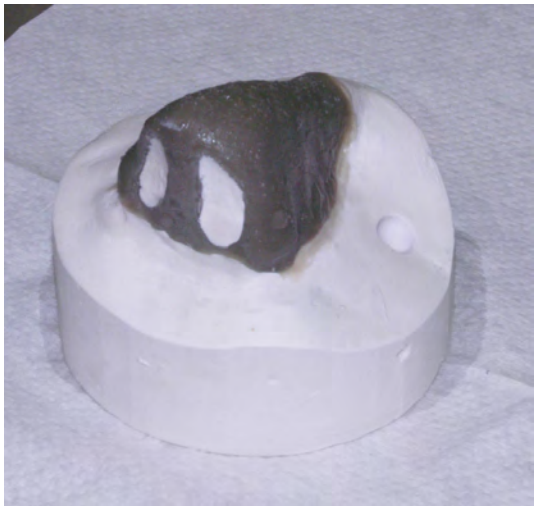


Figure 6f12. The pattern on the lower mould.

Once completed, the mould was also abraded at the prosthesis edges in order to create flash which creates thin feathered edges.

The following stages required the patient's presence. The sub-structure was bonded directly to magnets on the patient using light cure acrylic (figure 6f13).

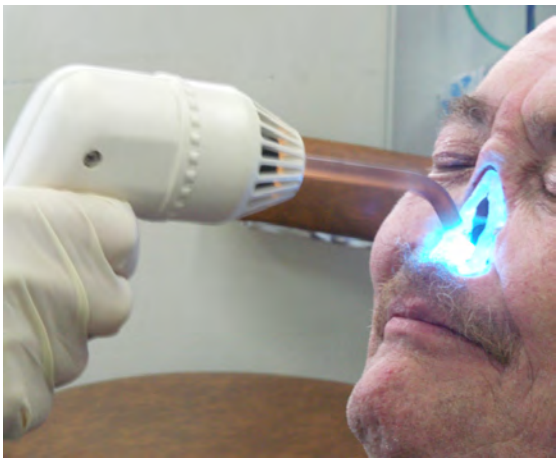
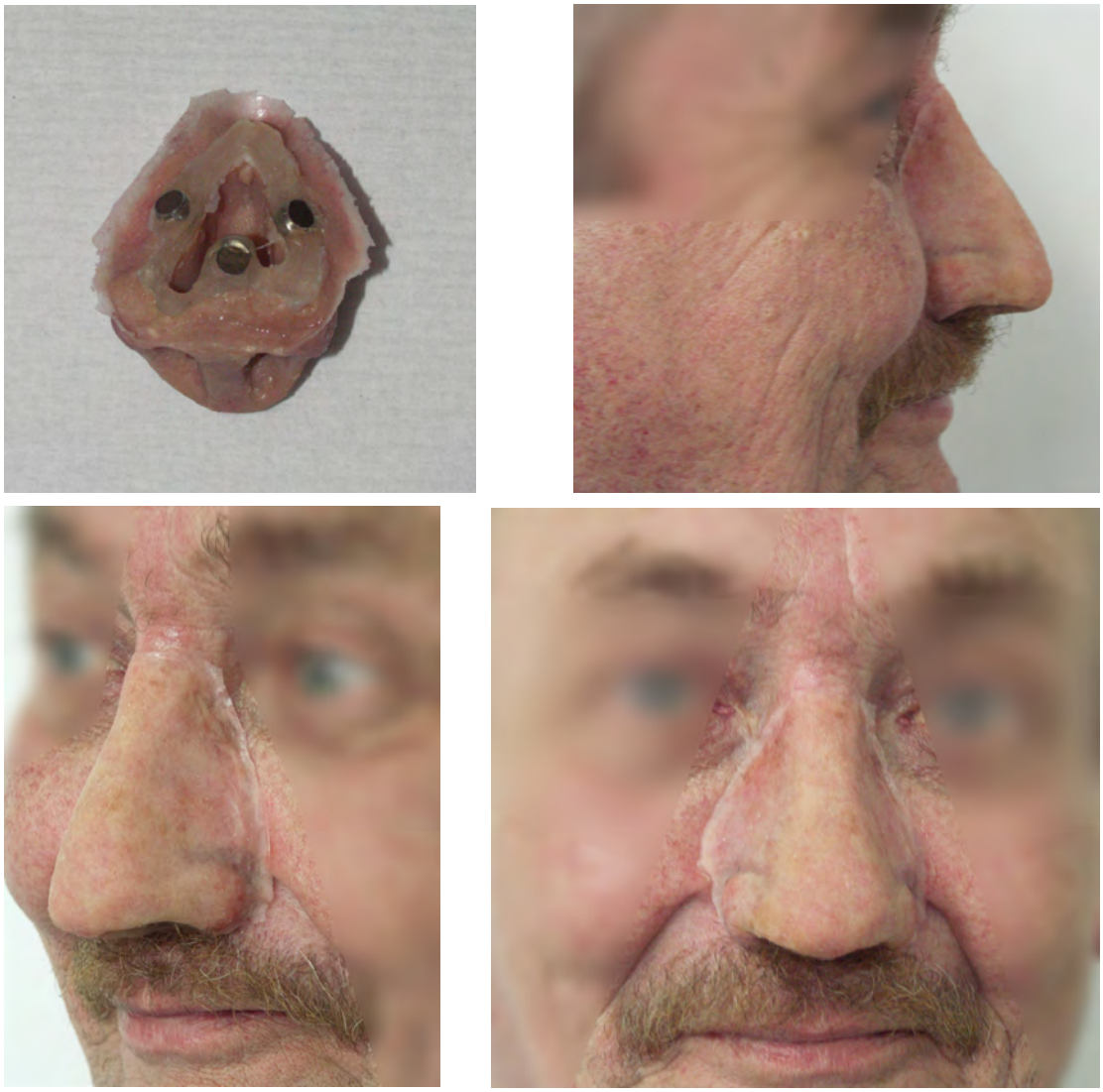


Figure 6f13. Bonding the sub-structure to the magnets

Colour matching was then undertaken using conventional methods and the sub-structure was bonded into the body the once the silicone had cured. Finishing touches using extrinsic colouring and trimming were undertaken with the patient present and the prosthesis was finally sealed. Figures 6f14a-6f14d show the final result.



Figures 6f14a-6f14d. The completed digitally designed prosthesis. Top left = the fitting surface showing the magnets and sub-structure. Top right = right view. Bottom left = ¾ view. Bottom right = front view.

Table 6f15 shows the construction time for the digital prosthesis.

Stage	**Prosthetist / operator time (minutes)**	**Patient time (minutes)**	**Setting / curing / fabrication time (minutes)**
Initial consultation and impression taking	50	50	Incl.
Production of stone replica	55	0	15
Scanning and conversion to STL	40	0	Approx. 120
Base-plate design	15	0	0
Pattern design	76	0	0
Pattern fabrication	15 (set up \ clean up)	0	Approx. 180

Sub-structure fabrication	20 (approx. to support, set up and clean)		Approx. 90
Mould production (assume same as conventional)	95	0	40
Colour match (assume same as conventional)	60	60	0
Curing (assume same as conventional)	0	0	75
Finishing (assume same as conventional)	80	60	0
Total	8 hours, 30 min	2 hours, 50 minutes	8 hours, 40 min.

Table 6f15. The time taken to construct the nasal prosthesis using digital methods.

6f7 – Quality assessment results

13 responses were obtained.

Feature ↓	Poor		Fair		Average		Good		Excellent	
	a	b	a	b	a	b	a	b	a	b
Quality of edge	3	5	1	5	3	2	5	1	1	0
Positional accuracy	0	1	0	1	3	4	5	4	5	3
Shape	0	1	2	1	2	6	3	3	6	2

Table 6f16. Responses to aspects of prosthesis quality. a = conventional, b = digital

6f8 - Discussion

Time: The application of digital technologies in this case gave a one hour reduction in the time spent by the prosthetist and reduced the patient time spent in clinic by two hours, thirty five minutes. Whilst these reductions in time do not appear hugely significant, the ability to go straight to colour matching effectively removes a much longer period where the patient must be either in clinic, or tentative (waiting). The tentative and in-clinic period may effectively be reduced to a single mornings work, given an early start.

Reduction in consultation and laboratory time was however offset by the additional stages of scanning and RP fabrication. Whilst this extra time does not require an operator, clinician or patient input, it does add to the overall delivery time. RP fabrication is typically an overnight process with an additional delay for postage if built by a service bureau. The forty minute period required to set up scans and process the data was represented by four block periods: three, five minute sessions to set the individual scans up and a final twenty minute period to process the data. This effectively meant that the operator had to attend to the scanner despite being able to carry on with other work. The same situation is reflected for the patient and prosthetist during periods between construction stages, such as material curing and boiling out of moulds.

The results support hypothesis 3.

Quality: Whilst case study 6c demonstrated that magnetic retention mechanisms may be incorporated to digital prosthesis design, this study was more challenging. This was primarily due to the difficulty obtaining sufficient data quality around the magnets where the surfaces were hidden from the line of sight. This resulted in loss of surfaces and poor definition (figure 6f17). There was however sufficient data to enable the sub-structure design and fit was acceptable when trailed on the patient.

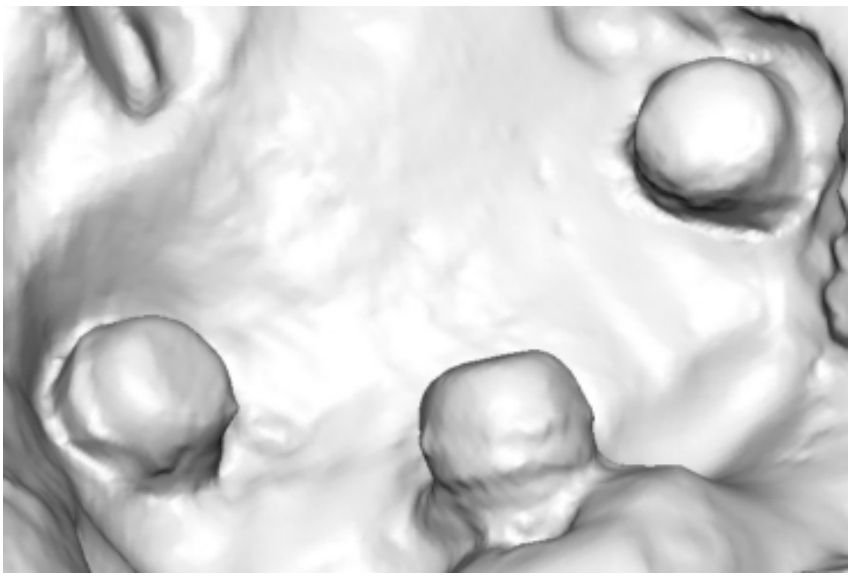


Figure 6f17. The magnets once imported into FreeForm.

In order to provide the patient with a clinically acceptable, aesthetically pleasing prosthesis, it was necessary to add texture to the RP produced pattern and thin the edges to the lower mould. It was not possible to measure edge gaps due to there only being visible gaps in close proximity to the patient's eye. Although minor adjustments were required, hypothesis 1 is accepted since a fitting prosthesis was provided.

The survey results provided mixed results for hypothesis 2.

In terms of edge quality, there was statistical significance in opinions between the two prostheses (P= 0.003695) in favour of the conventional prosthesis. The average score for the conventional prosthesis was 3 (st dev = 1.35). The average score for the digitally produced prosthesis was 1.8 (st dev = 0.93).

For positional accuracy, there was no statistical significance in opinions between the two prostheses (P=0.179533). The average score for the conventionally produced prosthesis was 4.1 (st dev = 0.76). The average score for the digitally produced prosthesis was 3.5 (st dev = 1.2).

For shape, there was no statistical significance in opinions between the two prostheses (P= 0.064649). The average score for the conventionally produced prosthesis was 4 (st dev = 1.15). The average score for the digitally produced prosthesis was 3.2 (st dev = 1.1).

These results demonstrate that the digitally produced prosthesis had a significantly worse edge quality, but that there was no statistical difference in positional accuracy or shape.

6f9 - Conclusions

This study has demonstrated that it is possible to design a clinically acceptable nasal prosthesis incorporating magnetic retention using digital technologies and RP fabrication techniques. There are however many limitations that would restrict the viability of digital techniques, the most prominent being limitations of non-contact scanning. Scanning was both time consuming and resulted in data with lost detail. Whilst it was still possible to use the data, it was not ideal.

6g - Review study. Comparison of scanning technologies

6g.1 - Introduction

Throughout the case studies, various methods of acquiring surface topographical data have been used. Methods have included:

- CT scanning
- Breuckmann Opto-Top-HE (white light, fringe projection)
- Konica Minolta Vivid 900 (laser)
- Steinbichler Comet 250 (white light, fringe projection)
- Roland LPX-1200 (laser)
- Roland Picza (touch probe)

In addition to the methods used in the case studies, data from other scanning technologies has been obtained for comparison. Data has been acquired from two photogrammetry techniques and a handheld, laser, portable scanner:

- 3DMD DSP400 (Photogrammetry)
- Dimensional Facial Surface Image Capture System (photogrammetry)
- Handyscan 3D (laser)

Each scanning technology has advantages and limitations in resolution, speed of capture and data processing capabilities. This affects the quality of data and suitability of the technology. It has already been established that an ideal scanning method will capture at a sufficient speed to avoid noise caused by subject movement, overcome the effects of noise caused by reflective surfaces, have sufficient resolution to capture skin texture and abutment details and provide an intuitive method of filling holes in the data. Limitations of each technology have been discussed and this section concludes the findings of further experiments in evaluating each technology.

6g.2 - Evaluation of capture speed

The fastest capture speeds are demonstrated by photogrammetry methods such as the 3DMD and Dimensional systems. The Dimensional, Di3D Facial Surface Image Capture System has a shutter speed of 1/20 second. Photogrammetry uses conventional digital camera technology and software algorithms to generate three-dimensional data from two-dimensional images. It does not rely upon a laser or light projection; therefore speeds are much closer to those used in conventional photography. This reduces the noise caused by subject movement during capture. The next fastest technologies used in the case studies are the Konica Minolta and Breuckmann scanners. These both have capture times of less than one second, but if a paired setup is used with the Konica Minoltas, the period during which the subject must stay still is in the order of 2.5 seconds. The Steinbichler is an older version of fringe projection scanning also used in the Breuckmann. It is much slower with capture speeds of tens of seconds. This makes capturing facial anatomy difficult since the subject is highly likely to move and distort the data. CT scanning as used in the first case study has been shown effective at capturing gross facial topography despite the slow capture speeds. This is because the subject is laying down with their head often supported. Large movements will distort the data, but small changes in facial expression cause less of a problem since the resolution is limited and accuracy therefore less critical. Both the Roland LPX-1200 and Roland Picza scanners are not capable of capturing facial anatomy directly and can only be used on capturing portions of stone replicas. Speed is therefore less important. In terms of clinical viability, speed is still however an issue. The LPX-1200 is laser based and therefore much faster than the touch probe Picza. Multiple models may be scanned in one day with the first, whereas far fewer may be with the latter. For example, scanning an ear impression and a defect site using the LPX-1200 will take approximately 3 hours, whereas the Pix-30 would take overnight or more with an equivalent resolution and would be unable to capture undercut features.

6g.3 - Evaluation of the effect of noise

Noise is manifested as points that do not follow the contours of the actual object surface. The effect is a "spiky" surface and the loss of detail. All laser and light based scanners, and to some degree, photogrammetry methods are affected by this problem, whereas touch probe is not. Filtering using software techniques can be used to eliminate noise in larger, less detailed areas, but definition will be lost particularly badly in areas of sharp edges and fine detail. Noise in CT scan data is limited to areas of metal objects such as braces, fillings or implants. Most facial prostheses are away from the mouth region which tends to cause the most problem.

6g.4 - Evaluation of resolution

Case studies have demonstrated the importance of acquiring sufficient resolution which will depend on the individual case needs. The necessary resolution depends on the level of detail required for subsequent prosthesis design (whether skin texture and intricate detailing is important and if it is necessary to capture retention components such as magnets or abutments). Whilst it is recognised that scanning an object multiple times will help to increase the number of points describing an object's surface, this also increases the effects of noise and makes many points redundant since they are often filtered in subsequent software stages. Starting with a high resolution scanner is therefore important when capturing small details.

Case studies 6b,c and d demonstrated that capturing texture detail such as wrinkles and features with sharp edges such as abutments and magnets represents a significant challenge for scanning technologies. Figures 6g1-6g10 show the results of various scanners at capturing abutment or magnet details.

Figure 6g1. Abutments captured by a Roland Picza touch probe scanner (0.05mm point spacing). The data has undergone a smoothing operation. This data represents the benchmark in quality and detail due to the high resolution and lack of noise.

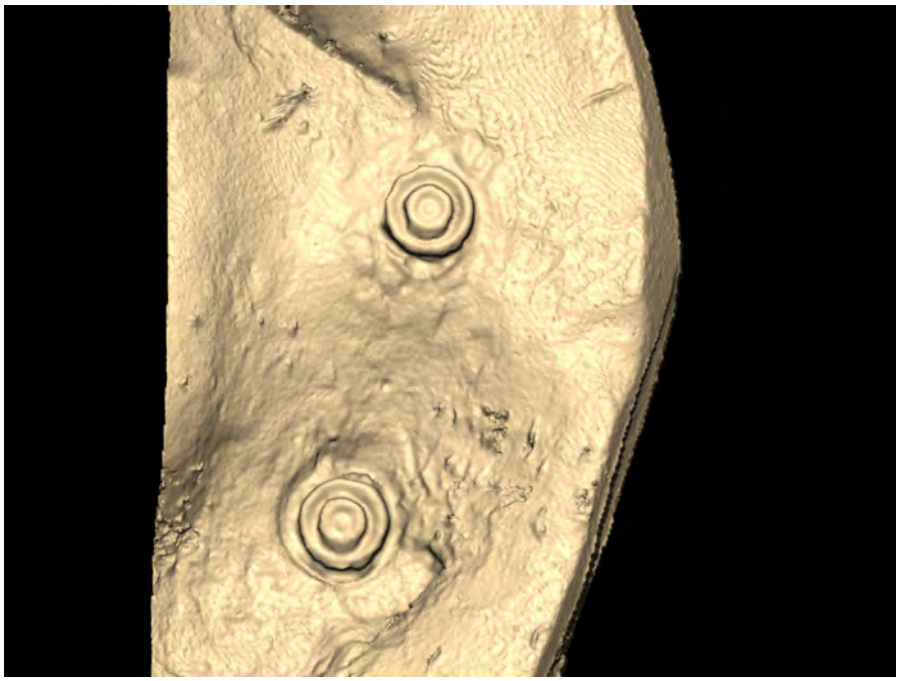


Figure 6g2. Abutments captured by a Roland LPX-1200 laser based scanner (0.1mm x-y point spacing). Although high resolution, the effects of noise have distorted the data around the abutments.

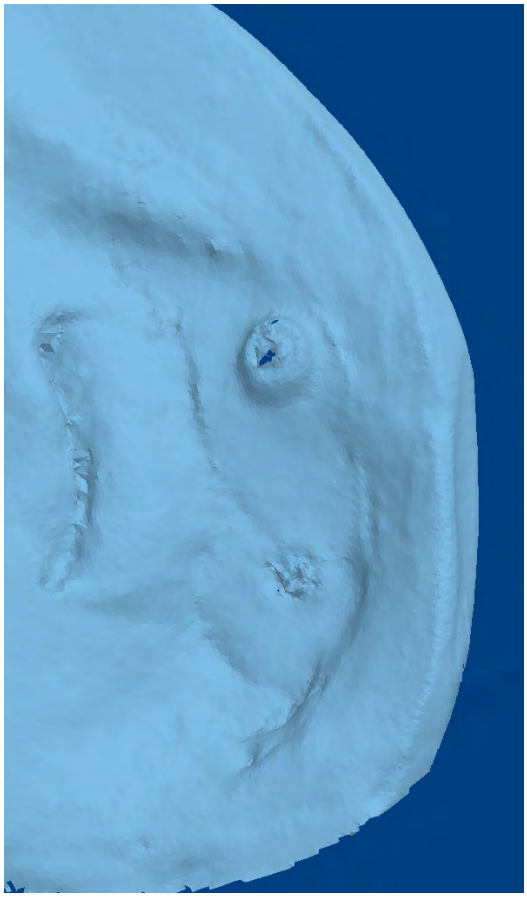


Figure 6g3. Abutments captured by a Steinbichler Comet 250 (approximately 0.4mm point spacing). The effects of noise coupled with a lower resolution have resulted in poor definition of the abutments.

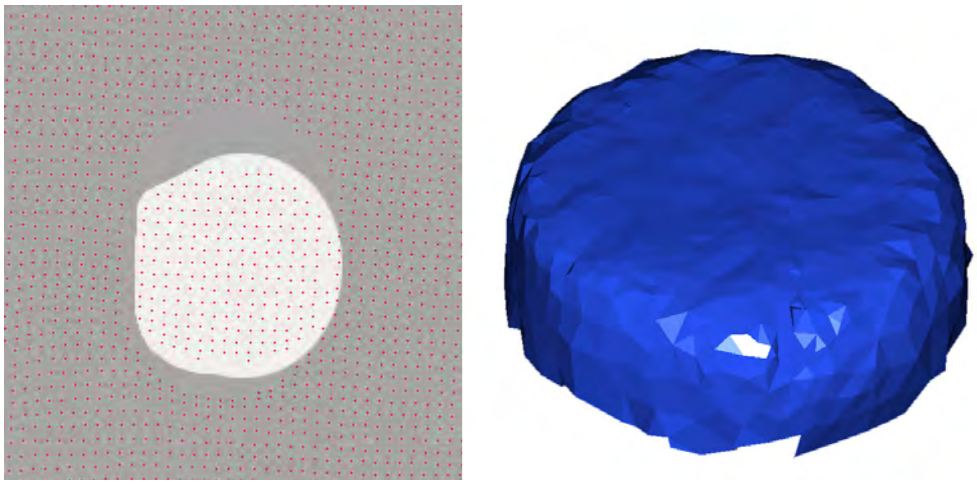


Figure 6g4. A magnetic keeper with a 4mm diameter scanned by the Steinbichler Comet 250. Left = the points from 1 scan viewed from above. Approximately 200 points represent the surface. Right = the keeper in the STL file format after multiple scans. Software stages select the best points from multiple sets of scan data and filter those that are far away from the perceived, true surface. Edges have become rounded and the surface lumpy.

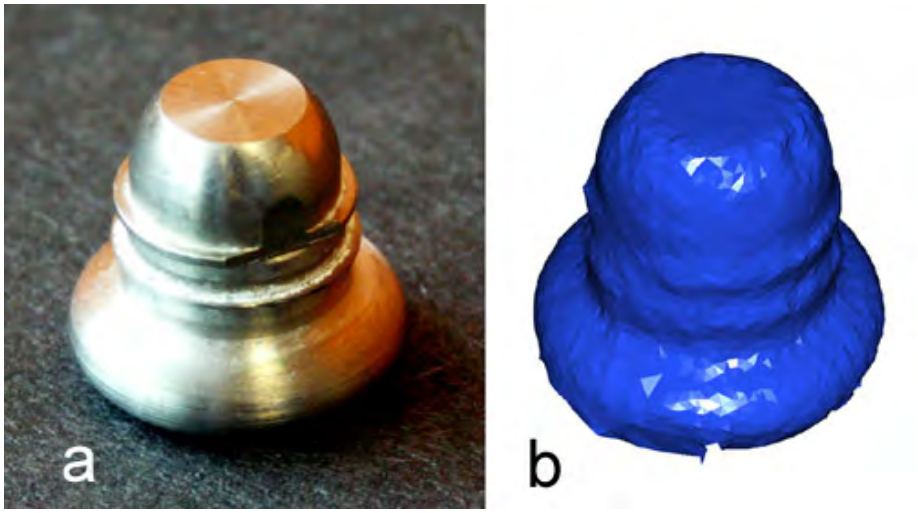


Figure 6g5. A Maxi lipped O-ring magnet from case study 6c captured by a Steinbichler Comet 250. a= the magnet captured. B= the STL file of the magnet. The sharp edge detail has been lost.

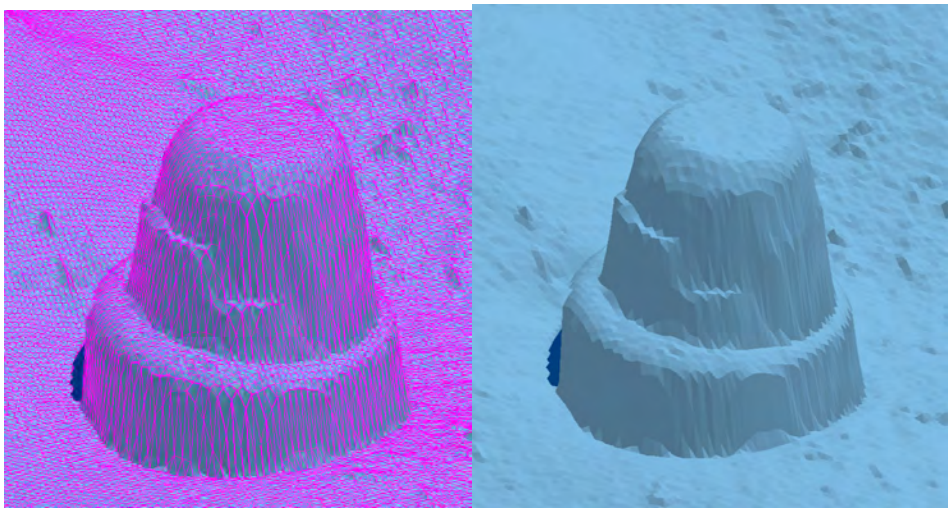


Figure 6g6. The same magnet as above scanned by Konica Minolta Vivid 900 scanners. This is the result of a single scan with a telephoto lens at 600mm, resulting in a point spacing of 0.17mm. Further scans from different angles and filtering of large, stretched triangles would help to improve the definition of side surfaces.


Figure 6g7. The results of a scan using a 3DMD DSP400. The resolution is much lower than the other scanning technologies noted and has resulted in larger triangles. Details around the eyes and nose have been lost.

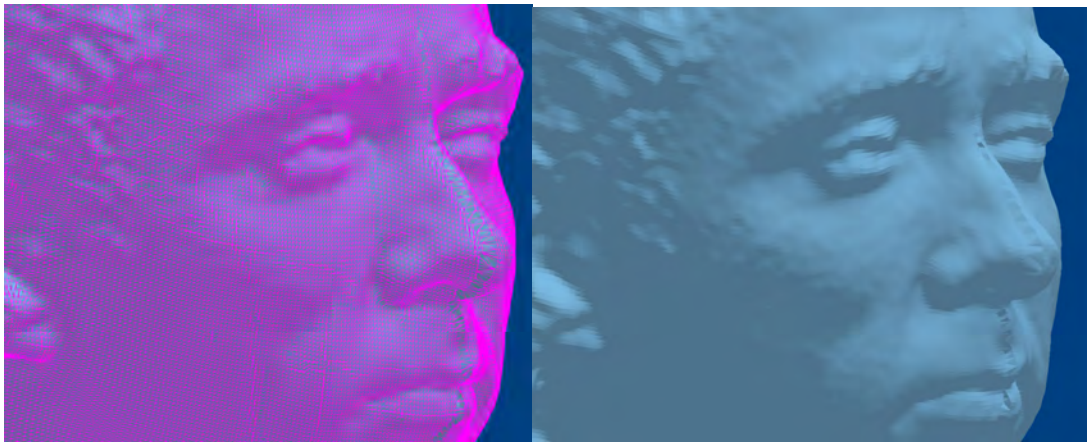


Figure 6g8. Scan results from a Dimensional Facial scanner. The data has been processed at half resolution, but the mesh is still significantly finer than the 3DMD data and provides better detail.

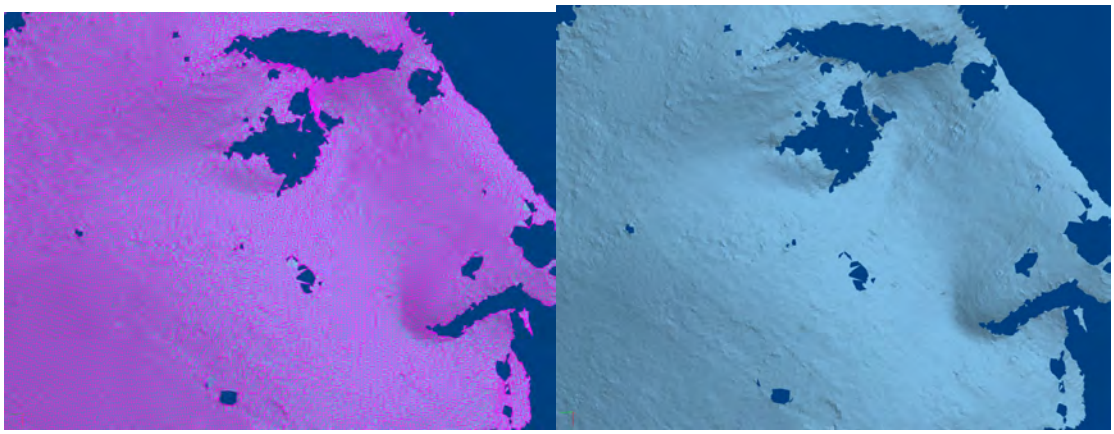


Figure 6g9. The results of a high resolution scan using the Handyscan 3D (no x-y point resolution specified). Left shows the surface with triangles highlighted. Right shows the surface only. Note the noise, but relatively high resolution compared with the photogrammetry methods. Subsequent hole filling and smoothing operations would be required to improve the data quality.

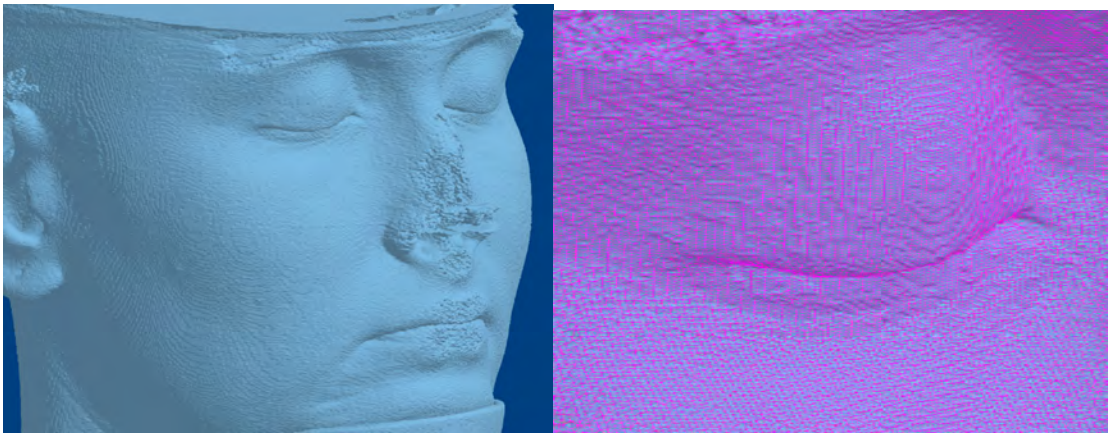


Figure 6g10. Three-dimensional reconstructions from sample i-CAT, cone beam CT scan data. The slice distance was 0.25mm, pixel size 0.25mm, resolution 640x640 pixels and FOV 16cm. The nose has not been fully covered by the FOV. The right image shows a close up around the right eye area and demonstrates the fine mesh created from a high quality STL reconstruction and the pixilation effect.

Where only the gross topography is required, many techniques are adequate, except those designed for scanning smaller objects. When finer detail is required, the number of options decreases.

Magnets may be captured with sufficient detail using scanners with a point spacing resolution of approximately 0.4mm upwards (as demonstrated by the Steinbichler), but capturing abutments is much more difficult. Only the touch probe Roland Picza was able to capture abutment details with sufficient quality of data to design a precisely fitting bar structure. This is due to a resolution twice as high as the nearest non-contact scanning method (0.05mm point spacing) and reduced noise over non-contact scanning methods.

Table 6g11 shows characteristics of various technologies capable of capturing surface topography.

Scanner \ performance	Capture speed	Overcome noise	Resolution	Ease of use	Notes
CT - conventional	Tens of seconds	Yes – except with metal	0.25-0.5mm pixels, 0.5mm> slice thickness	Established clinical technology	Only feasible where data already exists due to radiation. Can also capture undercuts
CT – cone beam	10-40 seconds	Yes – except with metal	0.2-0.4mm pixel size, 0.5mm> slice thickness	Established clinical technology	Lower radiation doses than conventional CT. Head specific. Can capture undercuts.
Steinbichler Comet 250	Approx. 10-15 seconds per image	No	Medium. Approx. 0.4mm point spacing	Requires specialist training	Old scanning technology, good accuracy, more engineering orientated
Breuckmann Opto-TopHE	0.8 seconds per image	No	High. Approx. 0.15mm point spacing	Requires specialist training	Can be configured with a multi scanner setup to capture more data in one scan. Dedicated head scanner available.
Konica Minolta Vivid 900	0.3-2.5 seconds depending on quality and number of scanners	No	Depends on settings. Medium to low. Max. res = 0.17mm point spacing	Requires specialist training	Various set ups available including multi scanner to capture more area in one scan.
3DMD DSP400	Approx. 1\20 second	Yes – automatic hole filling	Low.	Easy to use in a clinical environment	Old technology (2001), but easy to use.
Dimensional Facial	1/20 second (50ms)	Yes – automatic hole filling	High. 0.1mm x-y point spacing	Relatively easy to use	Updated, higher resolution photogrammetry

					technique
Roland LPX-1200	Slow (tens of minutes depending on resolution)	No	High. Up to 0.1mm point spacing	Requires training and practice to achieve good results	Can only capture small objects such as replica casts. Relatively automatic after a short set-up period. Data typically requires extra work after scanning.
Roland Pix-30	Extremely slow (hours depending on resolution)	Yes	Very high	Easy to use with little training	Can only capture small objects such as replica casts. Relatively automatic after a short set-up period. Not able to capture undercuts.
Handy Scan	Medium.	No	High	Requires training and practice to achieve good results	A handheld, highly portable scanner that does not require the subject to be still, but requires no facial movement during capture.

Table 6g11. Comparison of the characteristics of various, commercially available, non-contact and touch probe scanners.

6g.5 – Conclusions

The benchmark technologies identified are:

Speed:	Dimensional Facial photogrammetry
Resolution:	Roland Picza
Ease of use:	3DMD DSP400
Data quality:	Roland Picza
Capture area:	Steinbichler Comet 250, Konica-Minolta 900i, Dimensional Facial, 3DMD DSP400, Breuckmann facial or Opto-TopHE

Based upon the benchmark technologies identified, no one system is ideal. For capture of facial anatomy to replace impression taking, photogrammetry systems such as the Dimensional Facial provide the most suitable solution in terms of speed, resolution and ease of use. In practice however, there are limitations with capturing small features such as abutments, but this is common to all current scanning systems designed to capture larger areas of head. The Roland LPX-1200 is the most suitable scanner tested to capture replica casts of facial anatomy. It is capable of capturing relatively fine details such as magnets or magnetic keepers (although not abutments), is good at capturing recessed features and is provided with software which allows the alignment of multiple scans (Pixform Pro. See glossary).

6h – Analysis of the economic implications

6h.1 - Introduction

This section will discuss how the introduction of technology into the prosthesis construction process can impact the economics within a hospital department. The reasons for evaluating the economic impacts of technology are clear and are highlighted in chapter 4, part 6.1. Economic considerations in prosthesis production are complex due to a number of factors:

- Prostheses are unique, therefore no standard construction time exists.
- Production methods vary between prosthetist and units.
- Cost may be classified as direct, indirect and opportunity. These will vary dramatically between cases.
- Costs are "buried / hidden" in salaries and overheads.
- Technology costs are constantly changing and differ between manufacturers.
- Factors such as depreciation of equipment and maintenance should ideally also be considered. This will vary between hospital trusts and how the equipment is funded.
- A new piece of technology such as a surface scanner is likely to be used by many departments; therefore attributing a cost purely for prosthetics purposes is unrealistic.

6h.2 - Methods

A review of previous case studies and specific timed studies demonstrated the process differences and the associated economic impacts in terms of time and cost.

The introduction of digital techniques have a direct, indirect and opportunity impacts. Direct economic impacts include the cost of care during and after hospital stay. Indirect economic impacts include technology costs and overheads. Opportunity economic impacts represent factors such as lost earnings, travel time and the potential of treating increased patient numbers. This was

of particular interest since previous studies highlighted potential added value through reduction in production time.

6h.3 - Timed case studies

Through the development of the case studies, certain aspects of incorporating digital technologies became established to a point where it was feasible and fair to compare them with conventional methods. A number of ear casts had been scanned, mirrored and the patterns produced in wax using RP techniques. Since the first experimental cases, the methods became refined and more efficient with a reduction in time demonstrated. The first cases were undertaken using a more labour intensive scanning and file conversion method, but as new technologies became available, the amount of labour involved decreased. This is illustrated below. The RP build times were ignored, since in some cases, the ears were produced with other parts, which decreased the machine time per part. The approximate build time for a single ear using a ThermoJet was 3-4 hours.

Mirroring ear case 1:

Scanned using Steinbichler Comet 250, surface in Alias Spider, mirrored and extents reduced in FreeForm, built using ThermoJet.

Scan = 50 min. (all operator time)
Convert to STL = 28 min. (all operator time)
FreeForm operations = 7 min.
ThermoJet set up = 3 min.
Removal time = 10 min.

Operator time = 1hr, 38 min
Time the scanner was in use = 50 min

Mirroring ear case 2:

Using a Roland LPX-1200 scanner. Plane scans, 0.6mm x-y pitch. 4 planes @ 0^0, 40^0, 150^0, 270^0. Additional 2 plane scans with cast lying flat also required to capture behind the helix. Same pitch with scans at 40^0 and 310^0

Scan set-up time for both scans = 6 min. (operator time).

Scan time for both scans = 40 min (machine time)

Convert to STL (Pixform and Magics) = 17 min

FreeForm operations = 3 min

Mirroring ear case 3:

Scan set-up time for both scans (same settings as case 2) = 6 min. (operator time).

Scan time for both scans = 35 min (machine time)

Convert to STL (Pixform and Magics) = 13 min

FreeForm operations = 3 min

Average operator time (for cases 2&3) = 24 min

Average time the scanner was in use (for cases 2&3) = 38 min

Mirroring ear case 4:

Using a Roland LPX-1200 scanner with the same settings as case 3, but with an automatic hole filling option in Pixform.

Scan set-up time for both scans (0.6 point resolution) = 10 min. (operator time).

Scan time for both scans = 52 min (machine time)

Convert to STL (Pixform only) = 10 min

FreeForm operations = 3 min

Operator time = 23 min

Scanner time = 52 min

Hand modification of a ThermoJet pattern takes approximately 7 minutes.

Mirroring ear case 5

This study took the process a stage further by also timing the process of scanning the defect cast and digitally designing the prosthesis pattern to fit. This study used a Roland LPX-1200, FreeForm and ThermoJet methods. A base-plate incorporating magnets was designed and fabricated using light cure acrylic and the undercuts beneath it blocked out with wax. This was placed on the defect cast, coated in a matt white powder and scanned. This allowed the digital design to incorporate the magnets.

The same case was also undertaken by an experienced prosthetist using conventional methods of building up an ear from scratch. This allowed a direct comparison up to the stage where a pattern must be tried on the patient.

Ear scan:

Scan set-up time for both scans (0.6 point resolution) = 8 min. (operator time).

Scan time for both scans = 40 min (machine time)

Convert to STL (Pixform only) = 20 min

FreeForm touch up and mirror operations = 8 min

Operator time = 36 min

Scanner time = 40 min

Additional stages if designing the prosthesis:

Defect cast scan:

Scan set-up time for both scans (0.3 point resolution, plane scans from two directions) = 6 min

Scan time for both scans = 80 min

Convert to STL (Pixform) = 6 min

Touch up cast, export and re-import = 2 min

Position and design prosthesis pattern = 20 min

Export and prepare to build = 3 min

Additional operator time = 37 min

Additional scanning time = 80 min

Total digital time:

Total operator time to design a pattern = **73** min

Total scanning time requires = **120** min

Additional RP fabrication time = approx. 180 min

Conventional methods:

Shaping wax to base plate stage = **74** min

In addition to the times above, base plate design also took 12 min. This was required for both conventional and digital methods.

6h.4 - Discussion

The application of more automated scanning methods clearly reduced the operator time when scanning replica casts. Although the machine was still busy during the scan period, this made it possible for the operator to undertake other stages involved with prosthesis construction. It was

however still necessary for the operator to re-orientate the cast for a second scan in order to capture the areas not covered by the first.

Attributing exact costs to the process was difficult and case dependant for the reasons highlighted in the introduction. Case study 6c illustrated some basic figures. Assuming the same pay scale figures (£16/hr) and using the timings from case 6, the cost of producing a pattern was approximated. A total operator time of 73 min equates to approximately £20. Base plate design took 12 minutes, which equates to approximately £3. Assuming the cost of a ThermoJet produced ear = £35, the total direct cost of the digital process would be approximately £58. This excludes indirect costs such as equipment, maintenance and other overheads.

The same process undertaken using conventional hand carving methods were in this case very similar in the final case. Larger time differences between conventional and digital methods may be apparent if comparing a trainee or slower prosthetist. A senior prosthetist from the Queen Elizabeth Hospital in Birmingham suggested that a trainee will take approximately 2 hours to carve an ear pattern.

Whereas scanning, mirroring and producing a wax ear is relatively straight forward, the additional stages required to undertake full digital ear design brings the time and associated cost very close to conventional methods.

6h.5 - Identifying direct, indirect and opportunity costs of digital prosthesis production

Table 6h1 illustrates the stages, people and resources involved with prosthesis construction and links in the economic opportunities and additional indirect costs associated with the introduction of digital technologies. This is based on timed cases and the application of techniques pioneered in case studies and deemed clinically viable in the near future.

Conventional stage	People involved	Direct resource costs	Digital economic opportunity	Addition indirect costs of digital technology
Patient consultation	Patient Surgeon Prosthetist Nurse Receptionist	Clinic room Waiting room	No difference	No difference
Impression taking	Patient Prosthetist	Lab and clinic room	Reduced time if patient is scanned directly instead	Scanner hardware. Additional time if indirect scanning of a cast is required.
Create stone replicas	Prosthetist	Lab	Possible stage removal – reduced time	CAD software
Bar \ substructure design and fabrication	Prosthetist	Lab	Free up lab space	CAD software Additional RP fabrication time and cost
Hand carve pattern	Prosthetist Patient for final fitting of pattern	Lab and clinic room	Reduced design time. Removal of patient: - No travel time - Capacity to work / go to school - Removal of potential non-attendance - Free up clinic space	CAD software Additional RP fabrication time and cost
Flasking of pattern	Patient Prosthetist	Lab and clinic room	No difference	No difference
Boil out pattern & mould clean up	Prosthetist	Lab		
Colour matching	Prosthetist Patient	Clinic room		
Curing time	None	Lab		
Removal from mould, fitting and extrinsic colouring	Prosthetist Patient	Lab and clinic		

Table 6h1. Identification of direct, indirect and opportunity costs in the application of digital technologies

Table 6h1 illustrates that the application of digital technologies will require the additional indirect costs of: CAD software, scanning hardware, RP components (most likely from a bureau).

The case studies demonstrated that digital technologies reduce the design time, but only significantly in a few cases. Reducing the time spent by the prosthetist designing and constructing a prosthesis will reduce the direct costs. Reduction in design and construction time would also provide the opportunity to treat a greater number of patients and free up valuable resources such as clinic space. It would also reduce hospital stays, lost income and travel time for patients and possibly carers. Removing the need for patients to attend clinic also reduces the potential of "did not attends" (DNAs). These opportunities represent perhaps the greatest potential economic advantage of digital techniques. Design time and associated cost saved would however be offset by the extra time required to acquire digital data and the cost of new technologies. This is clearly highlighted in table 6h1.

6h.6 - When and how to implement digital technologies for the best economic results

In order to achieve the maximum economic benefits from the introduction of digital technologies, it is crucial to implement them as early in the process as possible and plan the case carefully to remove as many processes as possible. This means making use of whatever soft-tissue data is already available to avoid additional stages of impression taking and scanning. Where CT scanning is undertaken for pre-surgical planning, this provides an opportunity to acquire soft-tissue data to assist prosthesis production. This is an ideal solution when surface scanning is likely to be difficult or require additional stages. For example, ears are difficult to digitise with surface scanners due to undercuts and therefore requires an impression to be taken and the replica cast to be scanned. These are avoidable lengthy stages if CT data is available. Noses are difficult to position and shape and whilst easier than ears to surface scan, techniques exist using software such as Mimics (Materialise) to align pre and post surgical data, thereby matching as closely as possible a patient's original nose. Eyes are difficult to capture with light based surface scanners due to the

reflectivity and hair or eyebrows and lashes. Pilot study 6a demonstrated that CT scanning is suitable for capturing eyes. In cases where post surgical CT data is not available, the pre-surgical data may be used in conjunction with a surface scan.

In cases where surface scanning is required to capture post surgical topography, it would be most economical to take the scan in a multi-patient clinic or upon initial consultation to plan prosthesis construction. Where it is not possible to capture sufficient detail scanning the patient directly, scanning an impression is the only other option. Although only in the early stages of development and demonstrated by a limited number of case studies, digital technologies offer the potential to dramatically reduce or even remove the need to design the pattern in patient contact. Given sufficient planning and provided that the data was sufficient to undertake digital design, only one further consultation for colour matching and final production would be required.

6h.7 - Conclusions

Economic issues proved difficult to measure and quantify. Many of the benefits of digital technologies are represented by opportunities.

Referring back to chapter 4, part 6.2, four key areas for investigation that would help to identify if technologies were economically viable were identified: what the likely benefits of adopting technologies are, what the likely risks are, what likely patient outcomes are and what the likely departmental outcomes are. From the measured studies, it appears that the investment required in digital technologies will not yield sufficient time savings to make economic sense. Considering that a major unit such as Queen Elizabeth in Birmingham, Morriston in Swansea and Queen Victoria in East Grinstead fabricate approximately 10-20 new facial prostheses per year with other major units quoting similar figures, the return on investment would be poor. This means that the associated investment risk is high. Maximising the number of applications for a new technology within a hospital would help to spread the investment. For example, scanning technologies may be used to assist in burns splint fabrication and craniofacial surgery planning. CAD and CT data

preparation software may also be used to plan surgery, assist cranioplasty contouring, design implants, and drilling and cutting guides. As technologies become more integrated within a unit, their efficiencies and associated patient benefits are likely to improve.

In order to more accurately quantify the economic impact of digital technologies, a wider ranging, multi-unit study is required. This should measure the direct, indirect and opportunity costs of many cases undertaken conventionally and digitally using a standardised method of including factors such as overheads and staff costs. This would require the adoption of the most appropriate technologies and techniques identified by maxillofacial units, at significant costs.

Economic impacts are summarised below.

Patient: reduction in the need to attend clinic is likely to reduce the lost opportunity costs. If not in clinic, a patient may be able to work or go to school for example. There may also be reduced travel and accommodation costs. In some cases, this may also extend to a family member, carer or parents who would otherwise have to attend. Measuring the associated opportunity cost is highly case dependant, but worth considering in a nationwide economy context.

Prosthetist / health service: reducing the patient time in clinic is unlikely to dramatically reduce the direct cost implications of prosthesis delivery since the treatment being given is not resource intensive. However, the main potential economic advantage offered to the health service is reduction in construction time through the removal of lengthy processes and shifting pattern production to technology providers. This increases the opportunity to treat more patients and can assist in making the process more flexible for the prosthetist. Indirect costs are however likely to increase with the need to purchase and maintain new technologies such as scanners and CAD software. It may also be necessary to consider additional training. Even if no formal training is required, the learning curve associated with becoming competent with a new technology would take a prosthetist away from other aspects of work. A possible solution would be to fully integrate digital methods into formal degree and further education courses in maxillofacial prosthetics. One

potential problem with this is that there is no one standard set of technologies adopted; each technology is different in operation.

Ultimately, perhaps the only way digital technologies can save money within a maxillofacial unit is if they increase productivity; the same number of staff is capable of undertaking many more cases. This currently does not appear to be viable.

Chapter 7 – Discussion

This chapter discusses the findings of the case studies and identifies:

- Where specifications may be concluded
- Where further research and technological development is required

7.1 - Review of specification requirements

Quality aspects of prostheses were broadly defined in methodology sections 4.6.3 and 4.7 as: comfort, appearance, ease of use (application and removal). These subjective measures translated into more descriptive and potentially quantifiable factors:

- Fit. Marginal integrity of the prosthesis against the skin. Fit between components.
- Accuracy of the prosthesis and of the position in relation to anatomical landmarks.
- Resolution required to undertake different aspects of prosthesis design such as: folds, wrinkles and texture, and substructure component design.
- Mechanical, material and environmental performance of the prosthesis body and retention mechanisms.
- Colour and homogeneity. Detailing that provides a more lifelike look

Each of these factors was considered in turn.

7.1.1 - Fit

Prosthesis fit was defined in a number of ways: between the individual components and fit to the surrounding anatomy.

Evaluating marginal fit within a clinical setting typically relies on subjective assessment. Prosthesis margins should provide a seal against the surrounding skin and therefore no gap should be visible. It is also ideal if this seal remains in contact with the skin during facial expressions and

functions. Good marginal integrity is currently achieved by adding thin edges during the pattern making stage and contouring these towards the skin to apply pressure. This is carried out with the patient present for test fitting. Once the pattern is moulded, flash from the split line also helps to form fine edges which tend to blend into the skin. Measurements using a dial test indicator (figure 7.1) along the anterior margin of an auricular prosthesis ranged from 40µm - 130µm. Although there is no minimum edge thickness specified to achieve an accurate blend, practice has demonstrated that edges within this range will achieve a good result if combined with careful contouring.

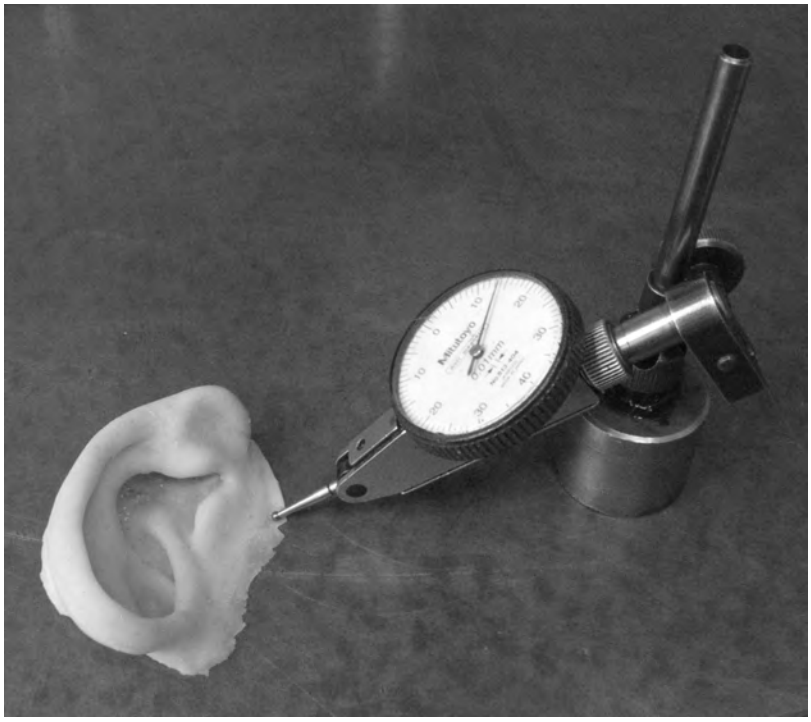


Figure 7.1. Use of a dial test indicator to measure margin thickness

Designing and producing patterns with edges this thin represented a challenge for digital technologies. In the case studies, FreeForm could not create edges sufficiently thin to blend into the surrounding skin. Ruler tools in FreeForm used in the pilot study and case study 6f verified that margins with a 0.26mm thickness could be achieved. It is recognised that it may be possible to achieve thinner edges by increasing the edge sharpness values of clay in FreeForm, or by using an alternative STL manipulation software package. This would require further investigation.

RP technologies for pattern fabrication must also be capable of building in layers less than100µm thick to create the fine edges. This also necessitates a suitably tough material and a method of support removal that will not damage the edges. Few RP technologies are capable of this, but some that are specified close include: Objet Eden machines (Objet Geometries), Perfactory (EnvisionTec GmbH), Solidscape machines (Solidscape Inc.) and ThermoJet printing. The only technologies that use a suitable material for boiling out of a dental stone mould are ThermoJet printing and Solidscape. The ThermoJet process is significantly faster than the Solidcape and the TJ88 wax material is more suitable for manipulation using conventional wax sculpting techniques since it has a lower softening and melt point (although it is still not ideal). This made it the RP process of choice in all of the case studies. Case study 6f demonstrated that it was still necessary for a prosthetist to adjust the edges of a ThermoJet pattern in a lab in order to achieve the necessary thin edges.

Fit between the abutments and the bar structure in a bar/clip arrangement is also critical. What constitutes a 'satisfactory' bar fit has been discussed [Kan *et al*, 1999], but no standard has been adopted. Brånemark (1983) suggested that a passive fit should exist on the 10µm level, whereas Jemt (1991) suggested that misfits smaller than 150µm were acceptable. A conclusive and commonly adopted method of evaluating fit also remains undecided and clinical methods typically rely on 'eyeballing' and testing for a rocker action in the frame. A frame should sit on two abutments without noticeable wobble when pressed and with no visible gaps.

Considering the effects of tolerance stacking, the stages of data capture, design and fabrication must ideally be capable of producing a framework that fits within the <100µm level. This represented a significant challenge for digital technologies, which typically quote tolerances around the +/- 100µm level. Experiment 6d demonstrated the difficulty in designing bar structures using data with insufficient resolution. Experiment 6e showed improved results due to improved data resolution and increased manufacture resolution and accuracy. However, it has not been possible to clinically trial a rapid prototyped bar yet and the fit has yet to be quantified. The accuracy and

tolerances of the SLM process used to fabricate the bars in these case studies also requires further investigation since there is currently little published literature.

7.1.2 Accuracy

Prosthesis accuracy is another highly subjective aspect that may be defined by two criteria: the accuracy of a prosthetic form in relation to the contra lateral side and the positional accuracy in relation to anatomical landmarks.

The positional accuracy of a prosthesis in relation to other anatomical features is often compromised or dictated by a patient's condition, surgical requirements and implant positioning. Prosthetists typically use rulers, callipers and protractors to assess the position of a prosthesis. It should also be noted that asymmetries could assist in creating a natural appearance in some cases. To this end, prosthetists strive to create a natural looking prosthesis, with a position and protrusion that looks natural and with size and detailing that complements the patients' face. Attributing a standard, quantifiable figure to the accuracy of prostheses is therefore impossible.

Given the highly subjective nature of prosthesis positioning, ideal digital technologies would provide methods of capturing sufficient anatomy to evaluate and measure the location in relation to other anatomical features and tools to adjust the position, protrusion and angle in an intuitive manner. Pilot study 6a, case studies 6c, 6d and 6f proved that FreeForm CAD was suitable for digitally positioning prostheses to an aesthetically acceptable degree.

7.1.3 Resolution and texture

Conventional impression techniques using syringable materials produce an extremely faithful reproduction of small features; they are not bound by describing details in points and suffer no loss in resolution. Constraints created by using digital technologies are therefore significant, as each of the case studies identified.

The case studies have demonstrated that with digital technologies, data resolution has a direct effect on how accurately and faithfully a physical object is described in a computer environment and subsequently reproduced. However, there are also many other factors that affect the quality of data obtained, especially from non-contact scanning.

The levels of data resolution necessary to describe a form will depend on the level of detail required in the final prosthesis. The pilot study demonstrated that relatively standard CT data (with slice distances of approximately 1mm or less) can provide sufficient resolution to allow a prosthesis form to be digitally designed, but is not suitable for capturing wrinkles, folds and other sharp edge details such as abutment. Many commercially available light based scanners also offer adequate resolution for capturing general facial forms. Case study 6d and previous published literature [Kau *et al*, 2004a&b] have demonstrated that resolutions of around 1 point per 0.69mm provides sufficient information to record overall facial profiles to design facial prostheses. A clinically acceptable auricular prosthesis was produced by Chandra *et al* (2005) from STL data describing an ear with 834,220 triangles from 458,566 points.

Experiment 6b demonstrated that when attempting to describe smaller features such as skin texture and wrinkle details, the data resolution required dramatically increases. The scale proposed in case study 2 suggests that in order to capture, describe and reproduce texture and wrinkle details, digital technologies must be capable of working to resolutions in the order of a point per 0.03mm in all axes to describe details with a cross section of 0.1mm. Accuracies must also be within the same

order. Whilst optical scanning methods may be used by dermatologists working on this scale, these are often limited to very small areas of skin, in the order of 30mm square. Scanners suitable for capturing larger areas to cover the face have a much lower point density and are therefore less suitable for capturing texture and wrinkle details. Scanners must also overcome the effects of noise, which are magnified with increased resolution. In addition to capturing texture details the subsequent stages of point filtering and surface generation must also maintain detail and provide a suitable model for importing into CAD software.

Case study 6d and review study 6g identified that many of the light based scanning methods evaluated that are suitable for direct patient capture are not suitable for capturing abutment details with sufficient resolution to allow bar design. Limited resolution, coupled with the effects of noise and the need to coat the object being scanned in a white, non-reflective powder produced poor definition of sharp edge details. Touch probe scanning provided a solution to capture small, sharp edge details, is limited to scanning replica casts due to the extremely slow speeds. A point resolution on 0.05mm provided adequate results to identify screw holes and definition of the abutment edges.

Significant development is required to improve the resolution and develop more suitable scanning hardware and software technologies that can capture the whole face in sufficient detail to allow all aspects of prosthesis design.

Suitable CAD software must also be capable of handling texture details to the levels described in chapter 2, part 2.3.5 and evaluated in experiment 6b. This makes many engineering CAD packages unsuitable. Experiment 6b demonstrated the viability of the voxel (see glossary) based modelling software, FreeForm as suitable for the addition and manipulation of textures. In addition to being capable of capturing, creating and handling texture details, digital technologies must also overcome the logistical issues of handling large amounts of data required to describe highly detailed models. The de-facto STL file format necessitates an extremely high number of triangles to describe small details accurately, which translates to extremely large file sizes. The use of large STL files can

slow all subsequent processes involved with manipulating the data and generating the files for producing the part. This may however be a diminishing problem as computer processing power inceases.

In order to transfer digital information of texture details on a prosthesis pattern to a physical model, suitable RP technologies must be chosen. This requires the ability to build in the 10µm level. Those RP technologies identified in the fit section have the potential to build in this level of detail and the capabilities of the ThermoJet process have been demonstrated in experiment 1.

7.1.4 Colour and homogeneity

Colour and homogeneity (aspects such as mimicking the skin tone and superficial capillaries) play a vital role in ensuring that a prosthesis is visually convincing. Colour represents a significant challenge for digital technologies

A full colour spectrum for computer displays is defined by 16.7 million tones. In order to incorporate colour into digital prosthesis design, it would be necessary to record colour during the scanning process over a sufficient area of face to design the prosthesis, maintain and create the colour when manipulating the design in CAD and then reproduce it in a suitable material. It is common for light, laser or photogrammetry scanning technology to capture a colour map of the subject, but the colour is not typically assigned to the three-dimensional geometry. At present, engineering CAD software or FreeForm CAD software is not suitable for assigning colours to the degree of complexity required. The STL file does have provision to assign a colour to each triangle and software such as ZEdit (Z-Corp, USA), designed for Z-Corp RP machines allow colour maps to be wrapped around an object. This may then be produced as a physical object. Although this process shows promise, the build materials are not suitable for prosthesis fabrication.

7.1.5 Mechanical and environmental performance

Mechanical and material performance: The performance of the prosthesis body and the retentive components should be considered.

Prostheses may be applied and removed around two times a day, which during a twelve-month period equates to 1,460 cycles of the retentive components. Studies have shown that the retentive qualities of clip mechanisms are reduced with repeated application and removal [Breeding *et al*, 1996]. Clip mechanism materials should therefore resist the effects of fatigue, abrasion and hardening/softening. 18k (75%) Gold is typically used for the clips and bar structures. Bar mechanisms should also be capable of withstanding the forces of application and removal. As an example, if 0.5kg of force is required to apply or remove a clip, which is attached 10mm from an abutment, the moment will be 49 N/mm. Given component size restrictions, this necessitates a relatively stiff, typically metal material. Pure gold has a stiffness of 78GPa. 1.8-2mmØ gold bar is typically used. Gold also allows the bar to bend in an impact rather than transfer the load to the abutments and does not cause an allergic response. Cast cobalt chrome or machined titanium bars may also be used, but are less common. Experiment 2 and published literature in similar applications have shown that Selective Laser Melting (SLM) has potential for the fabrication of bar components [Bibb *et al*, 2006] and that casting from Stereolithography patterns is also viable [Eggbeer *et al,* 2005]. It is not currently viable to design and fabricate clips using CAD and RP technologies.

The material requirements for the prosthesis body are outlined in chapter 2 part 6. Shore hardness values are typically around A20-A30, percentage elongation at break approximately 500%-650%, tear strength approximately 16kN/m and tensile strength approximately 4.8 N/mm^2 [Factor II Incorporated]. Whilst a new to the market material for the Objet printing process called Tango Plus provides a much softer (A27 Shore) and more flexible material, it has a much lower tear strength (3.4kN/m) than facial prosthetics silicones, it's physical properties will degrade on prolonged exposure to UV light and it cannot be coloured.

The properties of acrylic sub-structure materials are discussed in chapter 2, part 6.3. There are a number of Stereolithography resins which may be suitable for producing sub-structures with the required physical properties, however they are not suitable for the clips.

Environment: Prostheses typically have a lifespan of between six and twelve months depending on the environmental factors encountered. The prosthesis body will be subjected to UV light, temperatures experienced by the wearer, dirt, body fluids, other chemicals and mechanical forces associated with application and removal. In a silicone bodied prosthesis, this will typically cause colours to fade and edges wear, making the prosthesis more conspicuous. At present, RP processes are unable to produce a prosthesis form in suitable materials that will withstand the environmental conditions experienced by the wearer. Bar structures are subject to fewer natural elements, but must be inert in contact with the skin (not cause an allergic reaction), corrosion resistant in contact with sweat and possibly chlorinated water (in swimming pools). Study 2 and experiment 2 demonstrated the potential to fabricate bar structures using RP techniques in a stainless steel or cobalt chrome material. Both of these materials are commonly used in medical applications due to their relative inertness in contact with the skin and corrosion resistance. The SLM process used in these two studies is also capable of fabricating in titanium, which is commonly used for implants. This further demonstrates the potential of using RP to fabricate bar structures directly from CAD data. Sub-structure components will be subject to the same environmental conditions as bars. Epoxy or acrylate-based RP resins are classed as non-harmful once fully cured (fully polymerised) and are therefore also likely to be suitable for fabricating sub-structures.

Chapter 8 – Conclusions

This chapter concludes the findings of the thesis. Sections 8.1 to 8.3 conclude the current state of the art capabilities identified in this research for each prosthesis type from data capture, to component fabrication. Section 8.4 provides a summary list of necessary technologies required to undertake digital prosthesis production and shows a model of the prosthesis design and construction process using current state of the art techniques. Section 8.5 discusses future development requirements for digital technologies with the maxillofacial prosthetics profession and UK NHS, and presents a proposed model of the ideal scanning, design and manufacture process. Section 8.6 describes the necessary specification targets for technology developers wishing to meet the profession's needs. A summary of original contributions to the knowledge in this area are outlined in section 8.7 and section 8.8 gives concluding remarks.

8.1 - Data acquisition using non-contact scanning methods

Where available, use of CT data obtained pre or post-operatively should be used. This may remove the need to scan the anatomy using optical methods and assist in the design stage by providing a form based on the patients original anatomy.

Adhesive retained prostheses:

Where adhesive retention is used, the anatomy is simpler to capture since there are fewer undercuts caused by retentive components blocking the scanners line of sight. This will be especially apparent in orbital cases, where the recess of the orbit will hide the rear of the retentive components, which are often located around the orbital rims. This means it is also more likely to be able to scan the anatomy directly, without having to take an impression.

Nose: The area surrounding the nose does not include any undercuts that are likely to affect the ability to capture the anatomy. Where the nose is missing, a reflective mucosal layer is often

apparent. This is unlikely to capture well, but is unlikely to cause a problem in the subsequent design stages as long as the margins are captured in detail and without distortion.

Ear: It is particularly difficult to capture behind the helix and lobule (see figure 2.4 in chapter 2) due to the presence of hair and manoeuvrability of scanning equipment. This may make it necessary to take an impression and scan a replica cast of the remaining ear.

Orbit: A significant advantage of using non-contact scanning methods is that that the eyes can be captured whilst open. This allows details from the unaffected side to be mirrored to form the basis of the prosthesis design. The eye ball is unlikely to capture accurately due to its reflectivity and translucency. The data will require modification in the design stage.

Implant retained prostheses:

The fine detail and reflective surfaces of implant retention components makes them difficult to capture using optical based scanning technologies. When using magnets, a matt, light coloured, opaque coating is required (alternatively, replica magnets with a matt, light coloured, opaque finish could be used). For bar/clip retention mechanisms, it is necessary to design the bar, clips and sub-structure using conventional methods. This is primarily due to the limitations of optical-based scanning technology being unable to capture abutments accurately and the limitations in RP fabrication of clips. Conventional methods would necessitate taking a conventional impression and producing a replica cast. It would also be necessary to either coat or fabricate the sub-structure in a matt, light colour, opaque finish for subsequent scanning.

The best results are achieved by scanning a replica cast since the scanning angle can be more accurately controlled and angles that would be more difficult scanning the patient directly can be achieved, the object being scanned remains still, the matt white cast finish gives low noise, the implant mechanisms can be coated to improve the scan results and a narrower field of view can be concentrated on.

In magnetic retained cases it may be feasible to capture the magnets on the patients, negating the need to take an impression. Photogrammetry methods with capture speeds of 1/20th second or faster may be fast enough to overcome the effects of noise caused by subject movement. In cases such as ears and noses, the magnets are visible from many angles, making them easier to capture. In orbital cases, areas hidden by the magnets from a scanners line of sight would make it more difficult to scan the patient directly. When scanning the patient directly, it would be necessary to capture the entire profile of the magnets in one scan, or to take multiple scans and use scan data manipulation software (such as Raindrop Geomagic. See glossary) to align and merge the data sets.

Nose (magnet retained): Depending on the accessibility and angles required to scan the magnets, it may be necessary to take an impression and scan the replica cast, as undertaken in case study 6f. If the magnets are relatively exposed and sufficient angles are visible to capture their surface, it may be possible to scan the patient directly with the magnets in place, removing the need to take an impression.

Nose (bar and clip): It would be necessary to take an impression of the defect site and create a replica cast using conventional methods. Bar and sub-structure base plate design should be undertaken using conventional methods, positioned on the cast and the undercuts block out with wax or clay. A matt, light coloured, opaque coating should be applied and the cast with sub-structure unit in place scanned with a desktop scanner.

Ear (magnet retained): If the magnets are visible from sufficient angles, it may be possible to scan the defect site directly with magnets in place rather than take an impression. Scanning the patient directly will provide the opportunity to include facial features, such as the eyes and contra lateral ear that will assist in positioning the prosthesis during the design stage.

Ear (bar/clip retained): It would be necessary to take an impression of the defect site and unaffected ear in order to create a replica cast using conventional methods. Bar and sub-structure base plate design should be undertaken using conventional methods and a matt, light coloured, opaque coating should be applied. It may also be feasible to capture the sub-structure located on the patient, provided it can be captured from sufficient angles to avoid holes in the data. This would remove the need to take an impression and is likely to provide opportunity to include facial features, such as the eyes and contra lateral ear that will assist in positioning the prosthesis during the design stage.

Orbit: Orbital defects are likely to be more difficult to capture with implant retention mechanisms, due to the recess of the orbital cavity and difficulty in capturing the rear portion of the magnets/sub-structures hidden from a scanners line of sight. Although not evaluated in this thesis, it may be feasible to create a replica of the defect site using conventional methods and design a sub-structure, which incorporates the magnets/bar that is shaped to facilitate easy scanning. The patient could then be scanned with the sub-structure in place and their eye open, which would make the subsequent design stage easier.

8.2 – Pattern design

FreeForm has been demonstrated as the most appropriate tool for pattern and sub-structure design in all of the studies and in previously published literature. It represents the most appropriate way to manipulate anatomical forms and is also intuitive for prosthetists, therefore making it the most clinically viable option available. In addition, research into other applications has shown that FreeForm can be used in a maxillofacial lab in other ways including: cranioplasty contouring [Bibb *et al*, 2002], drilling and cutting guide design [Bibb, 2005] and dental appliance design [Eggbeer *et al*, 2005, Bibb *et al*, 2006].

8.3 – Fabrication

ThermoJet 3D printing has been shown to be suitable for producing prosthesis patterns. The wax material, although not an exact match to conventional baseplate / modelling wax, can be altered using conventional lab techniques. The ThermoJet process is fast, requires minimal clean up, is easy to use and produces patterns with sufficient detail to describe skin textures. Conventional production of the final prosthesis body in silicone still represents the only, clinically viable option.

Selective laser melting has demonstrated potential to produce bar structures, but further research is required to validate the dimensional accuracy, material compatibility and clinical viability.

Sub-structures and base plates may be fabricated using Stereolithography. Other RP processes such as Perfactory Digital Light Processing or Objet three-dimensional printing, ideally in a polymer material with a flexural modulus equal to, or greater than 1,720 MPa (value of Somos 10110, epoxy Stereolithography resin) also show potential.

8.4 – Illustration of the current state of the art using digital technologies

8.4.1 – Necessary technologies

A summary list of digital technologies required to undertake prosthesis design and construction is provided below.

- Non-contact surface scanner to capture the facial anatomy.
- Software to process scan data and output good quality STL data.
- Software to process CT data and convert to STL geometry from pre-surgical or post surgical scans.
- Haptic sculpting CAD software to design the prosthesis body and sub-structure.
- Wax printing RP technology to produce the prosthesis pattern.
- RP technology to produce stiff sub-structure components.

8.4.2 – State of the art models

Table 8.1 illustrates the design and fabrication process possible using current state of the art application of digital technologies in extra-oral, soft tissue prosthesis design, based on the trials undertaken in this thesis. This is based upon the use of magnetic retention mechanisms.

Table 8.2 illustrates the design and fabrication process possible using current state of the art application of digital technologies in extra-oral, soft tissue prosthesis design, based on the trials undertaken in this thesis. This is based upon the use of a bar/clip retention mechanism.

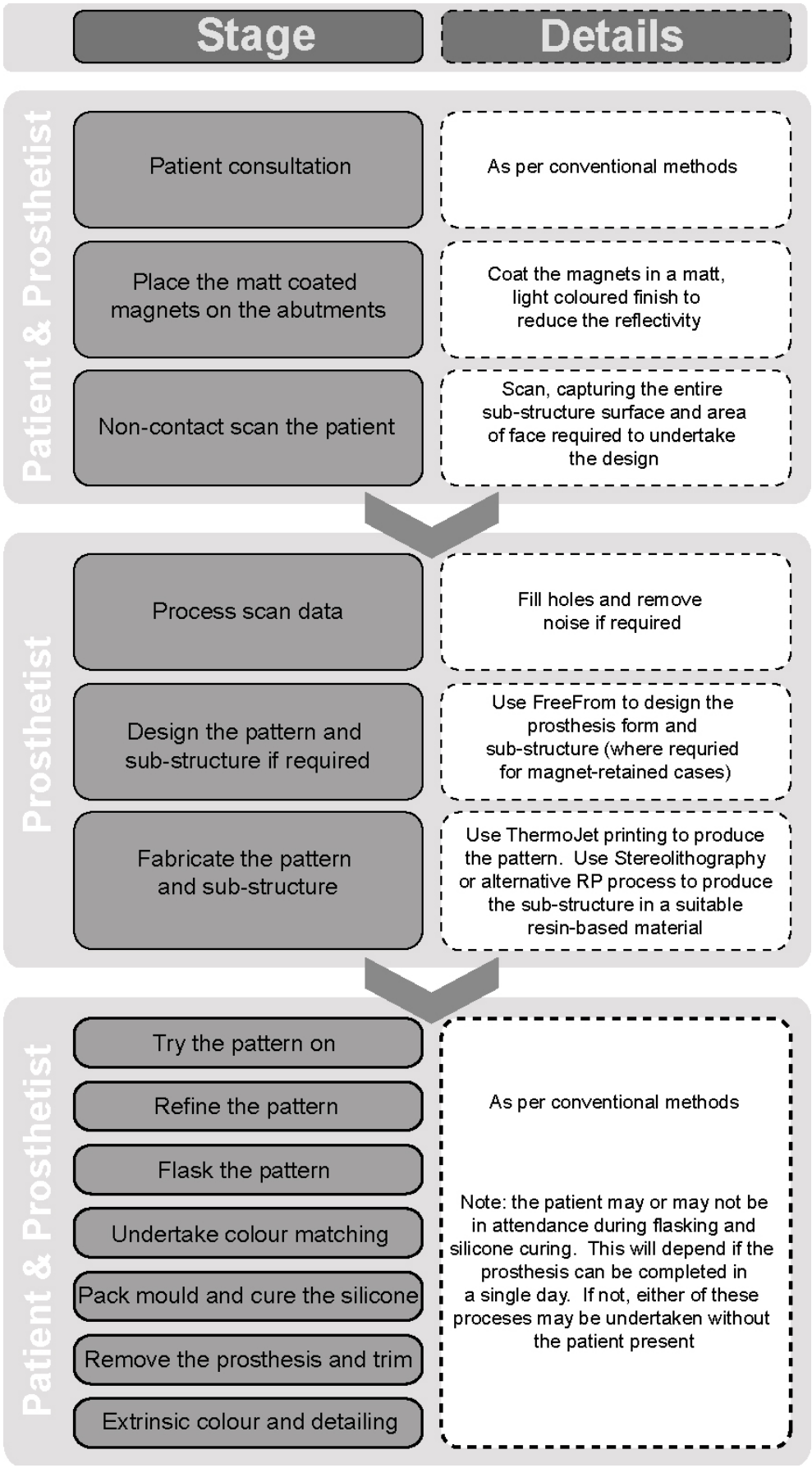


Table 8.1 – An illustration of the current state of the art in digital prosthesis design and fabrication, incorporating magnetic retention, based on research in this thesis.

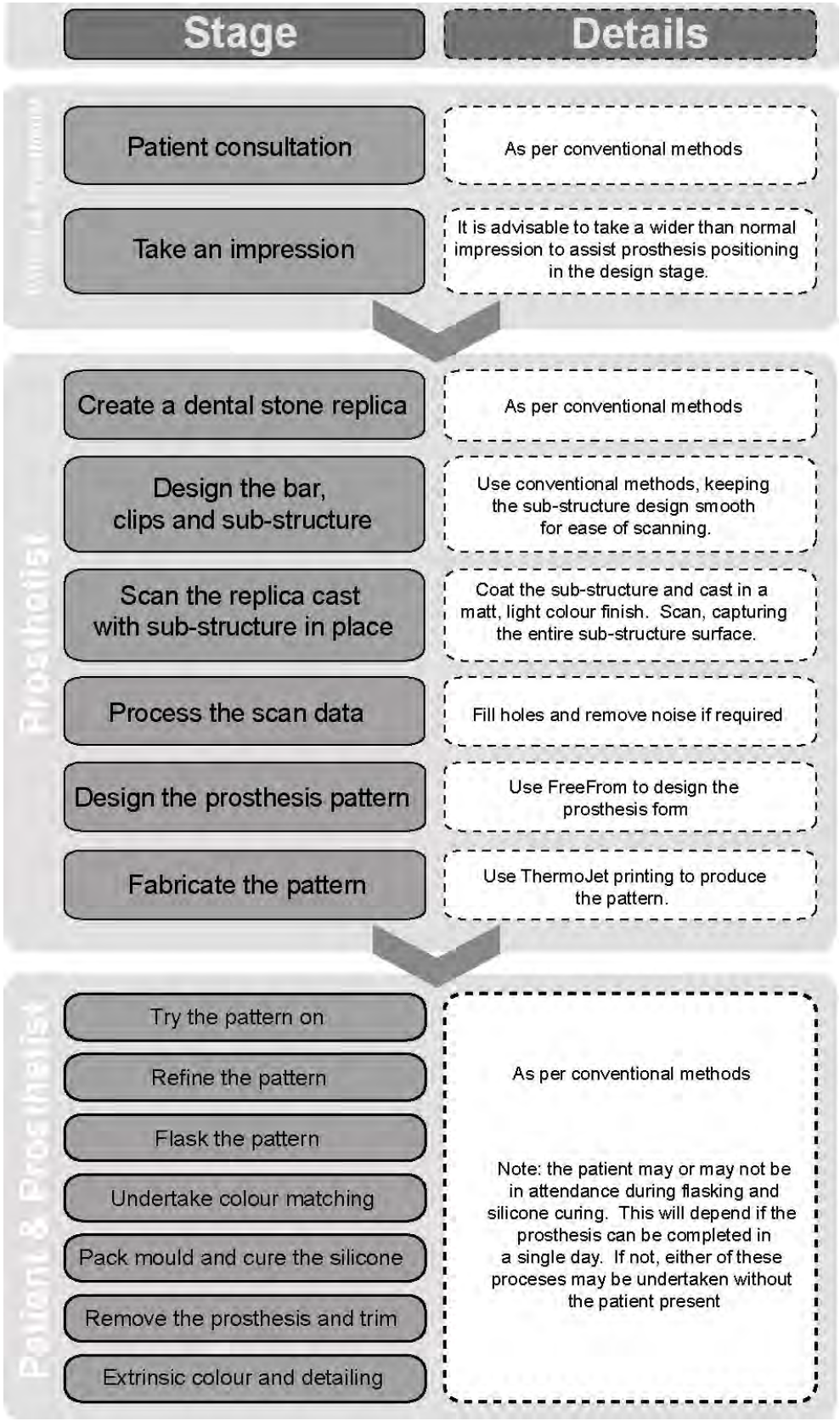


Table 8.2 - An illustration of the current state of the art in digital prosthesis design and fabrication, incorporating bar/clip retention, based on research in this thesis.

8.5 - Future development

8.5.1 – Discussion

As the case studies developed and techniques were refined, limitations of digital technologies became apparent. There are significant limitations with current data capture techniques, which hinders the design and production processes and results in the addition of stages. It may however be foreseen that these limitations are surmountable. As with all digital based technologies, performance is rapidly improving and they are becoming more affordable. Touch probe scanning demonstrates sufficient accuracy and resolution to capture small detailed features such as abutments, with the only limitations being slow speeds and inability to capture undercuts. Photogrammetry capture systems such as the Dimensional Facial are fast enough to avoid problems caused by patient movement and have an extremely high resolution, but suffer from the same problems as any light based, non-contact scanner, noise. This is the single biggest problem with non-contact scanning methods and therefore represents a priority challenge for technology developers. The presence of undercuts and areas hidden from the line of sight presents a major limitation. In cases such as implant retained orbital prostheses, directly scanning a patient would be difficult since the magnets or sub-structure could not be scanned from all angles. Undercut areas would also make it difficult to scan indirectly from an impression and cast replica.

Clearly, significant development of capture methods is required to address the limitations of capturing undercuts, noise and resolution. Possible solutions may be found in cone beam CT scanning, but this poses ethical questions due to radiation exposure. One other possible area for future consideration is CT scanning of replica casts. This method is commonly used to reverse engineer and inspect engineered components, especially in the aerospace and automotive sector [Reinhart *et al*, 2004].

Colour represents the most challenging specification for digital technologies to meet. Producing prostheses directly in a suitable, colour matched materials is currently not feasible. Within the

possible scope of existing technology, this would necessitate generating a three-dimensional colour map of the proposed prosthesis based upon data of the surrounding anatomy and taking into consideration the effects of metamerism and shadowing. Corrections for computer monitors would also be required in order to faithfully capture and display skin tones that would allow accurate prosthesis colour matching. Although photogrammetry methods are capable of capturing both three-dimensional surfaces and wrapped, full colour images, it would still be necessary to ensure that the colour calibration is maintained throughout the design process. Whilst other technologies such as spectrophotomers exist to provide accurate quantification and digital readout of colour, these typically work on an area too small for practical application and do not capture three-dimensional topography. If accurate colour and contour capture could be achieved, it must then be mapped on to the digital prosthesis pattern, ensuring the location of physical topography matches the colour associated with it. Ideally this process must also take into consideration the depth of colour and translucency of skin. In order to use this digital data, it must then be physically reproduced in colour and in a suitable material with the necessary physical properties and definition to match skin. Possible solutions may lay in computer graphics and gaming software capable of wrapping images around three-dimensional models. However, translating this into something that may be manufactured will require significant research and development and the generation of entirely new technologies.

CAD technologies are advanced to a point where it is possible to design all of the components to make a functional prosthesis. There are still however limitations that prevent any one software from providing an ideal solution. FreeForm is well suited to the shaping of prosthesis forms and other components, but would benefit from the ability to align components and shapes more accurately and intuitively. The ability to design and align geometrically constructed components (such as abutments and clips) designed in CAD and freeform geometry of anatomy derived from scan data would greatly benefit the suitability for prosthesis design.

Further research is also required to develop methods of producing intricate retention mechanisms in suitably wear resistant materials with sufficient mechanical properties to resist the forces applied

on a prosthesis. This may necessitate the development of new retention methods, more suited to CAD and RP fabrication and the associated limitations. Other, tougher Stereolithography resins, such as DMX-SL100 (DSM-Somos) or particle filled resins, such as Bluestone (3D-Systems inc.) or Nanoform 15120 (DSM-Somos), which are designed for endurance applications and cyclic loading may be suitable for producing a sub-structure that incorporates retentive clip-type features. The ability to hand-fabricate a sub-structure directly on the patient, without the need to take an impression would be a desirable step towards streamlining the scanning and design process.

The application of digital techniques could also offer less tangible benefits. These include the reduced dependence on model storage and cataloguing, which can take a significant amount of room in a hospital unit and be difficult to organise. This may also help to reduce the cost of re-makes by reducing the chances of models/moulds being lost or damaged and provide the means to fabricate as many prostheses as required many years into the future. Digital technologies are also more portable than conventional lab equipment. This could provide the opportunity to undertake much of the initial scanning work to be undertaken in a mobile environment, such as a patients' home, on a ward or at an alternative hospital location in a multi-person clinic. They also allow many of the design and construction stages to be undertaken independently of patient contact. This would help in a number of ways, including: improving patient access to state of the art techniques, reducing travel time and cost for patients, reducing the chances of non-attendances and make the profession more dynamic (a prosthetist would have to rely less upon appointments, providing a more flexible work schedule).

Table 8.3 illustrates a proposed ideal linear process model of digital prosthesis design and fabrication. Notably, this would:

- Remove the stages of impression taking and replace it with non-contact scanning methods.
- Allow the prosthesis to be digitally designed incorporating texturing and colour.
- Allow the retentive components to be designed using the same software CAD package as the prosthesis body.
- Utilise RP-style methods to fabricate the prosthesis components directly from the digital design data.
- Reduce the dependence on patient consultation by creating an entirely digital process from initial consultation and scanning, through to final fitting.

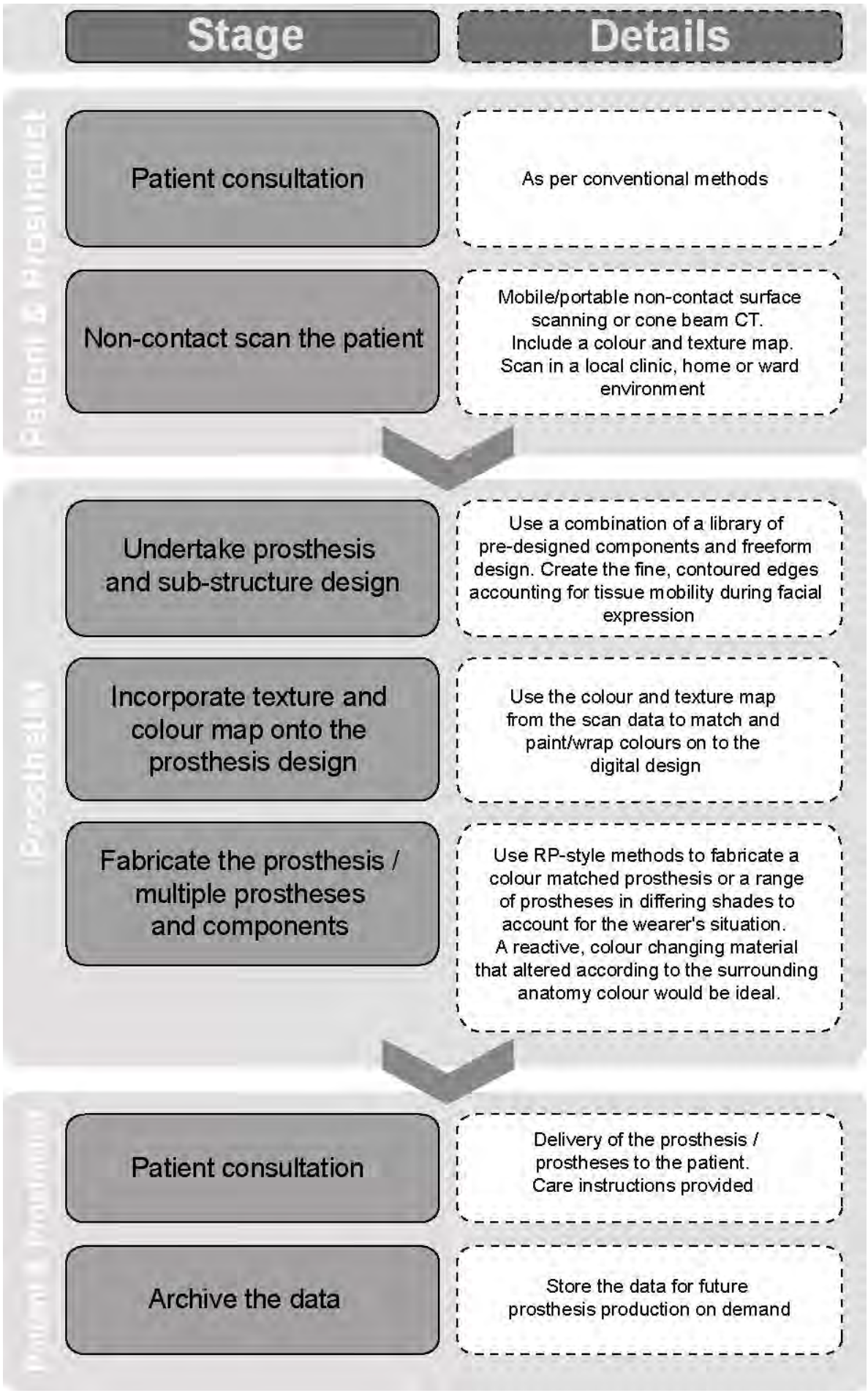


Table 8.3 – The proposed ideal linear process model of digital prosthesis design and fabrication.

8.6 - Target specification for technology developers

Table 8.4 concludes the specification criteria identified for each stage of the construction process and the individual components.

Construction stage / technology	Target value/ usability criteria
Topographical capture (non-contact surface scanning)	Resolution - 0.05mm point spacing or less for abutment capture Speed - 1/20 second or faster Capture area - 300mm x 300mm max capture area for a head Accuracy - +\- 0.02mm Other - Intuitive operation - Sufficient manoeuvrability to capture areas hidden from one angles line of sight. - Method of eliminating noise. - No harmful radiation
Colour capture (non-contact surface scanning)	Capable of capturing millions of colours wrapped around the three-dimensional geometry. Colours must also be accurately matched to a patient's skin.
CAD design software	- STL input. - Ability to fill holes in STL data based upon the surrounding contours. - Haptic feedback with intuitive software interface. - Voxel based modelling. - Ability to align separate components. - STL file output. - Capable of creating and wrapping colour map images around the prosthesis design.
Fabrication	**Bar structure** Material - Stiffness approximately equal to or greater than 18k (75% gold) gold (pure gold = 78 GPa). - Suitable to polish. - Bio-compatible. Resolution - Sufficient to build 1.3mm diameter holes with sharp detail. **Pattern** Wax material - Softening temperature in the order of 35-43 deg.C. - Melt point approximately 60-63 deg.C. (specification

		of Anutex wax by Kemdent) - 0% flow at 23 deg.C (room temperature) as specified by ISO standard 15854:2005. - In the order of 25-30% flow at 37 deg.C. (specification of Anutex wax by Kemdent).
	Resolution	- Equal to or better than a ThermoJet printer. 300x400x600 dpi (approx. 40µm layer thickness)
	Sub-structure / clips	
	Resolution	- Equal to or better than an Objet or Perfactory printer. Objet = 600x300x1600 dpi, Perfactory = 90µm minimum pixel size. 15µm minimum layer thickness.
	Material	- Wear / fatigue resistant (approximately 1460 cycles to represent 1 years use). Clips in the order of 150 Kg/mm^2 Vickers Hardness (that of gold 75%). - Able to bond to the prosthesis body. - Resist hot water to 90 deg.C during mould production (hot water is used to soften the wax pattern to release the mould cavities). - Hydrophobic (will not soften in the sustained presence of moisture / body fluids). Water sorption equal to or less than 0.6 mg/cm^2 (that of heat-processed acrylic).
	Other	- Ideally, clip strength should be adjustable.
	Prosthesis body	
	Colour	- Production process capable of creating millions of colours from digital colour matches of a patient's skin wrapped around a CAD model.
	Resolution	- Equal to or better than a ThermoJet printer. 300x400x600 dpi.
	Material	- A20-30 Shore, >500% at break, >16kN/m tear, 4.8N/mm^2 tensile.
	Environment	- Degradation resistant to UV light, dirt and body secretions.

Table 8.4. The specification criteria identified for each stage of the construction process and the individual components

8.7 – Thesis summary

As discussed in chapter 4.1, previous work in this area has been undertaken on an ad-hoc, single trial basis, concentrating on simple prosthesis form design using a range of engineering technologies. A common clinical and economic perspective on the effectiveness of digital technologies had not been established.

This research has identified the current state of the art in extra-oral, soft-tissue, maxillofacial prosthetics. Previous research into the application of digital technologies has been reviewed and the limitations that require further development identified. A series of case studies, experiments and trials have been undertaken in order to address these limitations and develop new techniques in the application of digital technologies to extra-oral, soft-tissue, maxillofacial prosthetics. The findings of these studies have been used to develop models of current best practice and ideal process models for the application of digital technologies. A target specification of standards has been proposed, towards which technology may be developed to meet the needs of the maxillofacial prosthetics profession.

Original contributions to knowledge are:

- The development of texture creation methods suitable for prosthesis design in a CAD environment.
- Incorporation of magnet retention mechanisms into a digital prosthesis design, including sub-structure components.
- Digital design and fabrication of bar structures using CAD and RP technologies.
- Fabrication of sub-structure components incorporating clip mechanisms.
- A more in-depth identification of the direct, indirect and opportunity costs represented by the introduction of digital technologies.
- A proposed target model for digital prosthesis design and construction.
- A target specification for technology developers.

Limitations of this thesis have also provided the foundation for future research to develop the techniques. It was not possible to evaluate all available technologies or develop specific methods of addressing limitations such as materials properties, colour or retention mechanisms.

Notwithstanding the limitations noted above, this thesis has achieved the aims stated in chapter 4 part 1.2.

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