

# **The Development Of Innovative Patient-Specific Surgical Guides**

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# Declaration

## Declaration

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

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## Statement 1

This thesis is the result of my own investigations, except where otherwise stated. A bibliography is appended.

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# Abstract

Over the last three years this PhD research has focussed on the area of Maxillofacial Additive Manufactured Surgical Guides. A mix of qualitative and quantitative research has been undertaken to develop new knowledge about how guides are used, the cleanliness and surface roughness characteristics of the materials and the accuracy of procedures.

The PhD thesis will cover the research results from the above topics, summarising and highlighting specific advantages & limitations from the planning, designing, fabrication and use of maxillofacial surgical guides. The discussion will highlight how the work has challenged some common assumptions; conclude the clinical implications of this and the need for further research.

**Keywords:** *Maxillofacial, Surgical Guides, Surgery, Additive Manufacturing.*

# Acknowledgements

To my supervisory team Dr Dominic Eggbeer, Dr Huw Millward and Professor Robert Williams, I would like say thank you for putting up with me for three years, guiding me towards the correct pathway and being my towers of strength on this journey.

Massive thank you to all at the Maxillofacial Unit in Morriston Hospital as without their support the clinical qualitative research of this PhD would not have been possible. A special thanks to Peter Evans, Mr Adrian Sugar and Mr Simon Hodder; who offered consistent support, guidance and access to their clinical cases throughout the three years of this research study.

Many thanks to Renishaw Plc. for allowing access to use their testing machines and supplying AM samples. Thanks to Fraser Walker at Southern General Hospital Glasgow, Kevin Page at South Mead Hospital Bristol, Professor Richard Bibb and Professor Russ Harris at Loughborough University for fabricating the test material samples. Special thanks to Professor Rose Cooper for her guidance, support and use of her 3M Clean Trace System.

I would like to show my appreciation to my colleagues at PDR, especially to the Surgical & Prosthetic Design team for absorbing me into the team, for the endless puns, laughter and support. I have many memories to take from this three year PhD with both Dominic Eggbeer and Sean Peel at the forefront of most; Inverness, Beijing, London and the unforgettable karaoke night. Thank you for being both my colleagues and friends on this journey.

To my friends that have kept my feet firmly on the ground; namely my best friend Sarah Thomas for the daily texts of support and always being there no matter what. Thanks to Kelly, Heather G, Emily P, Elena, Heather T, Catherine, Delyth, Eleri and Lowri – Good friends are hard to find, harder to leave, and impossible to forget.

To my family thank you for putting up with me through my academic years; the stress and tears. I would like to dedicate this PhD to my parents, May and Eamonn O'Malley, without doubt the two people I look up to the most; thank you for everything you do. Thank you to my niece Aimee and nephews Sam, Osian and Declan for always without fail making me smile.

Finally, gigantic thanks to Chris Mosley for standing by my side every step of the way xxx

In loving memory of Granny Lawrence, Granny O'Malley, Auntie May and Uncle Jack.

# Biography & Publications

I joined the Surgical & Prosthetic Design research team at PDR in December 2012 to pursue a Research Innovation Award PhD on the development of innovative patient specific surgical guides. My research focused on both qualitative and quantitative methods, examples of which include clinical observations of maxillofacial surgery, additive manufacturing materials and the analysis of accuracy for digitally planned cases. I also worked one day a week for ABMU's Maxillofacial Unit at Morriston Hospital on the Innovate UK ADEPT project.

I attained a Master of Science in Advanced Product Design in 2011 and a 1<sup>st</sup> class BA (Hons) in Product Design in 2010 from University of Wales Institute Cardiff.

I have worked for two medical companies based in the Institute of Life Science at Swansea University: Seren Technology Ltd. (developers of ideas into pioneering solutions for the healthcare and beauty industries) and Haemair Ltd. (developers of a patented prosthetic lung and respiratory aid) as a Design, Test and Research Engineer.

## Conference Presentations:

O'Malley, F\*. Summary of key findings and results of PhD research undertaken on Maxillofacial Additive Manufactured (AM) Surgical Guides. 27th Scientific Congress of The Institute Of Maxillofacial Prosthetists and Technologists. 10<sup>th</sup>-11<sup>th</sup> September, 2015. London, UK. \*presented

O'Malley F\*. Research to Inform Optimal Maxillofacial Surgical Guide Design & Manufacture. 5<sup>th</sup> Advanced Digital Technologies in Head and Neck Reconstruction Conference. Sept. 6-8<sup>th</sup>, 2014. Beijing, China. Link to the programme. <http://www.adt-conference.com/conferenceprogramschedule.html> \*presented

O'Malley F\*. Research to inform the improved accuracy of zygomatic implants placed using computer design & additive manufactured surgical guides. ADT UK Workshop. July 24<sup>th</sup>, 2014. Loughborough, UK. \*presented

O'Malley, F\*. Efficacy of Computer-Aided Planning and Patient-Specific Surgical Guides in Complex Facial Osteotomies. 26th Scientific Congress of The Institute Of Maxillofacial Prosthetists and Technologists. 4<sup>th</sup>-6<sup>th</sup> September, 2013. Inverness, UK. \*presented

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# Glossary of Terms & Abbreviations

3D Systems	Company that provides consumer and industrial 3D printing and manufacturing solutions
ABMU	Abertawe Bro Morgannwg University health board
ADEPT	Additive-Manufacture for Design-Led Efficient Patient Treatment – a 3 year Innovate UK project
ADT	Advanced Digital Technologies in head and neck reconstruction
AM	Additive Manufacturing
ATP	Adenosine TriPhosphate
BAHA	Bone Anchored Hearing Aid
CAD	Computer Aided Design
CARTIS	Centre of Applied Reconstructive Technologies In Surgery
CAM	Computer Aided Manufacturing
CMM	Coordinate Measurement Machine
Coronal	A plane – also known as the frontal plane
CRB	Criminal Records Bureau
CT	Computer Tomography scanning. A medical scanning method that produces sliced, pixel computer images.
DRM	Design Research Methodology book
EPSRC	Engineering & Physical Sciences Research Council
Haptic	The sensation of touch
HSDU	Hospital Sterilisation & Disinfectant Unit
IMPT	The Institute of Maxillofacial Prosthetists & Technologists
LM	Laser Melting. An AM process that builds in metal.
Malignant	Cancerous tumours or cells
Materialise	A software developer and supplier of Additive Manufacturing services based in Belgium
Maxillofacial (surgery)	Surgical speciality concerned with the diagnosis and treatment of diseases affecting the mouth, jaws, face and neck.
MDD	Medical Device Directive
MMR	Mixed Method Research
MPT	

	Maxillofacial Prosthetist and Technologist
MRI	Magnetic Resonance Imaging.
	Medical scanning technology.
NHS	National Health Service
Objet	Objet Geometries RP system that manufactures in a photopolymer.
Osseo integration	A fixed, bone anchored retention method for attaching external or oral prostheses.
Osteotomy	Surgical operation where a bone is cut
Osteoplastic	Surgery on or based on the replacement of bone
PDR	The National Centre for Product Design & Development Research, Cardiff Metropolitan University
Pinnectomy	Surgical removal of an ear
Rhinectomy	Surgical removal of a nose.
RLU	Relative Light Units
RP	Rapid Prototyping
Sagittal	A plane – vertical which passes from anterior to posterior
SLA	Stereo lithography Apparatus
SLM	Selective Laser Melting. An AM process that builds in metal.
SLS	Selective Laser Sintering
SOP	Standard Operating Procedure
SPD	Surgical & Prosthetic Design
SPSS	Statistical Package for the Social Sciences
STL	STereoLithography file format. Defines 3D volumes in faceted triangles.

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# Chapter 1: Introduction

This chapter sets the context for the thesis by exploring the motivation for the research, its justification, the central research aim and the research objectives. Following this, the chapter sets out the thesis structure by introducing the remaining chapters through a thesis overview.

## **1.1 Motivation for the Research**

This PhD researches the application of the latest additive manufacturing (AM) technology with patient-specific medical device expertise and evaluates the resulting surgical guides in a challenging clinical environment.

The research uses the methodology to quantify surgical guide characteristics. It hopes to provide an impact basis on surgery in terms of the accuracy of surgical intervention, the reproducibility of AM parts used in clinical procedures and the suitability of selected AM materials to use in the maxillofacial area. These measurable healthcare benefits are captured throughout the duration of the research, and disseminated through the appropriate NHS networks, conferences and publications.

The research into surgical guides will also be employed to inform the development of permanent AM implants. Surgical guides are temporary implants that are removed towards the end of a surgical intervention. This research work on biocompatible metals, aseptic fabrication/assembly and sterilisation techniques can be directly translated into permanent (+ 30 days) implants. Some of these types of implants are currently machined rather than fabricated through AM technologies.

This PhD will be the first formal research project established between PDR and Renishaw. It is hoped that this will be the forerunner of additional research projects undertaken between PDR and Cardiff Met. At the UK level, Renishaw (and its partners) have been involved in a number of successful EPSRC research projects,

and the research from this project will act as data gathering for longer-term research council funding.

In addition to research publications and follow-on research funding, this research project will help to refine PDR's clinical services and therefore potentially generate greater commercial income. The direct impact will be twofold: (1) improving PDR's manufacturing environment; and (2) implementing new quality standards.

Surgical guides for implantation require clinically-appropriate fabrication and assembly environments. PDR's workshop areas will be updated to reflect the need for these new clean clinical procedures, and this will be made visible to other clients in order to attract new business. Furthermore, the fabrication and delivery of surgical guides requires higher levels of risk management because they interact directly with patients, and the quality of the clinical intervention is highly dependent on their function.

## **1.2 Justification for the Research**

The research was part of a PhD Scholarship, Research Innovation Award (RIA) from Cardiff Metropolitan University; the research would employ the latest AM techniques and generate new knowledge that could help to inform new surgical guide designs and explore the implications of using new technology.

The PhD has drawn on both quantitative and qualitative data gathering and analysis, and used experimental design to evaluate both new components and new procedures. The 36 months of research produced publications, including peer-reviewed journal papers and conference presentations.

## **1.3 Aims of the Research**

### **Aim**

To develop new knowledge and techniques that will help improve clinical procedures through the application of innovative patient-specific surgical cutting, drilling and repositioning guides.

### **Objectives**

1. To establish a strong understanding of the emerging regulations, ethical requirements and user needs surrounding the development of bespoke surgical products.
2. Review the academic literature and clinical/commercial application of surgical guides.
3. Investigate the application of AM techniques and product development methods for the fabrication, measurement and analysis of surgical guides.
4. To employ an appropriate research methodology to critically evaluate research testing and results.
5. To produce recommendations in the implementation of new surgical guide design and production methods.
6. To test, analyse and validate the effectiveness of the new features through empirical testing within the laboratory and qualitative evaluation within the operating theatre.
7. To discuss the extent to which the techniques have been successful and to analyse the impact of findings in the context of wider surgical procedures and patient outcomes.
8. To recommend further avenues for technical exploration and clinical application, and identify opportunities for further collaboration and funding.

## 1.4 Structure of the Thesis

This thesis is divided into 11 chapters. An explanation on what each chapter will entail will be shown in the following sections along with figure 1 which illustrates the structure.

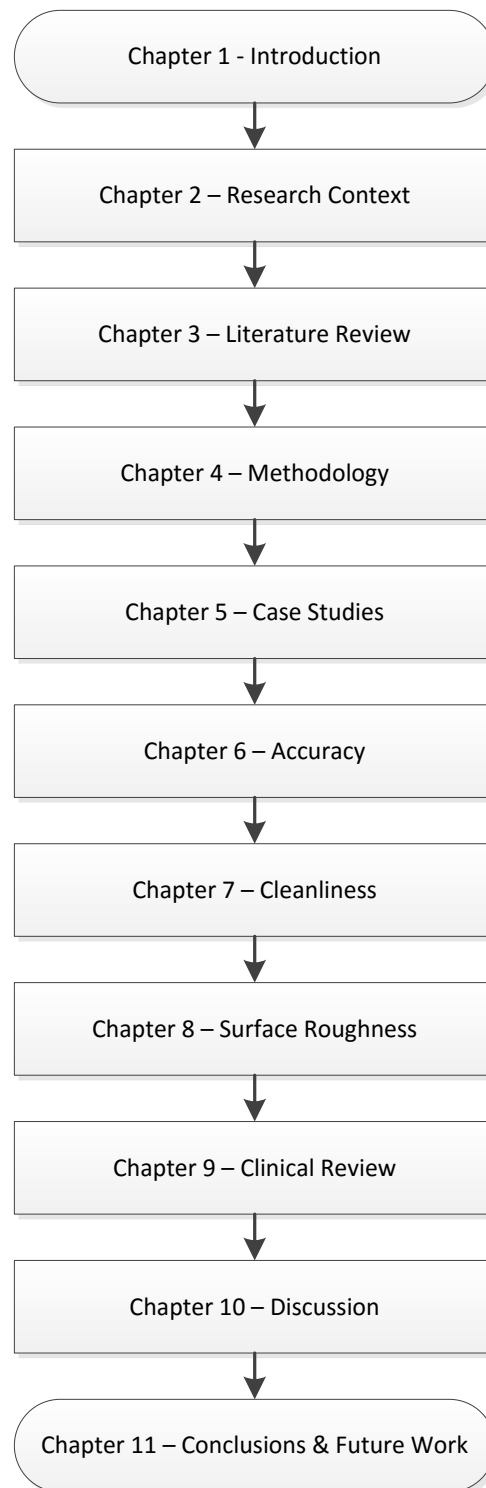


Figure 1 – Structure of the Thesis and Chapter Layout

## Chapter 1 – Introduction

This chapter sets the context for the thesis by exploring the motivation for the research, its justification, the central research aim and the research questions. Following this, the chapter sets out the thesis structure by introducing the remaining chapters through a thesis overview.

## Chapter 2 – Research Context

Chapter 2 sets the context of the research by introducing the different companies/ research partners and their motivations for supporting the study. The key sources of information for this chapter are the partner's literature (internal and external) including websites, brochures, reports and presentations.

## Chapter 3 – Literature Review

This chapter reviews the literature to build the foundations for the remainder of the research. Due to the interdisciplinary nature of medical and design, the literature for any thesis relating to these fields will require insights from many different disciplines. The research gained developed into the research questions and the study structure of the thesis.

## Chapter 4 – Methodology

This chapter sets out the research approach, design, methods and data gathering activities deployed to conduct this study. It also explains the rationale for the study selection as supported by the description of the companies/partners in chapter 2. This chapter will describe how the research questions stated in chapter 3 will be answered.

## Chapter 5 – Case Studies

This chapter presents the qualitative data generated by observing a series of maxillofacial case studies from the start of planning to final surgical output. Twenty case studies were selected and followed to gather a clinical understanding on the application of AM surgical guides to each. The clinical research recorded the needs perceived by medical specialists as involved in the specification, design and application of surgical guides.

## Chapter 6 – Accuracy

This chapter shows a series of maxillofacial cases to generate qualitative data on the needs perceived by medical specialists involved in the specification, design and application of surgical guides. The qualitative data generated by observing surgical, clinical and design perceptions was analysed to inform the design of experimental studies that would enable development of optimal approaches that utilised computer-aided and AM processes.

## Chapter 7 – Cleanliness

This chapter focuses on the surface cleanliness of AM materials used in medical applications. Adenosine TriPhosphate (ATP) bioluminescence technology is a rapid, user-friendly method of quantifying surface cleanliness and was used to gather data on levels of contamination on AM materials at three different process stages: post build, post cleaning and post sterilisation. The surface cleanliness of eleven AM materials, three metals and eight polymers, was tested. ATP bioluminescence provided the sensitivity to evaluate different material surface characteristics, and specifically the impact of surface finishing techniques on overall cleanliness.

## Chapter 8 – Surface Roughness

This chapter focuses on the surface roughness of Maxillofacial AM surgical guides of the two common materials that they are fabricated in, Stereo lithography (SLA) ClearVue / Visijet Clear and Laser Melted (LM) Cobalt Chrome. The surface roughness of these materials results in different surface friction coefficient when used on the bone. Surgical guides are used in clinical procedures in order to be as accurate and precise as possible therefore locating correctly on the bone is critical.

## Chapter 9 – Clinical Feedback

This chapter comprises of clinical feedback of the research gathered in the core chapters of the thesis. Two documents were compiled with information and results on: 1. Accuracy (Chapter 6) and 2. Cleanliness & surface roughness (Chapter 7 and 8).

## Chapter 10 – Discussion

This chapter is divided into four sections; discussion of core chapters, applications of the research, methodology and research methods: limitations.

## Chapter 11 – Conclusions & Future Work

The final chapter will highlight the conclusions, summary of response to research questions, recommendations for future work and the publication plan.

## Chapter 2: Research Context

The purpose of this chapter is to set the context of the research by introducing the different companies, research partners and their motivations for supporting the study. The key sources of information for this chapter are the partners' literature (internal and external) including websites, brochures, reports and presentations. The candidate was embedded in a number of the institutions which helped gain a deeper organisational understanding to the research and potential bias. The ease of access to research data due to the well connected organisations helped form the study design.

### **2.1 Who – Company Overview**

PDR is a design consultancy, applied research centre and wholly-owned subsidiary of Cardiff Metropolitan University (formerly UWIC). It is a trading name of Cardiff Met., and trades under company registration number: 2656744, UWIC Company Ltd. They have a unique approach, blending leading, high quality research activity alongside award winning, proven and highly experienced consultancy practice. For over two decades this perspective and the culture, knowledge and capabilities that have built around it have generated world class results and outcomes for the companies and organisations they work with.

Located within Cardiff Metropolitan University, PDR is organised across eight groups, each a leading exponent in its field with an extensive history and back catalogue of projects, innovations and knowledge. Each group is a source of expertise and practice in its field (PDR, 2015).

The eight groups at PDR:

User Centred Design

New Product Development

Service Design



Surgical & Prosthetic Design

Prototype & Manufacture

Eco Design

Design Management

Design & Innovation Policy

## **2.2 When – Company History**

### **2.2.1 Surgical & Prosthetic Design (SPD) at PDR**

Since 1998 one of the eight groups at PDR, Surgical & Prosthetic Design (SPD), has delivered thousands of custom surgical plans, 3D printed models, guides and implants to the NHS. They improve the predictability, accuracy, safety and speed of procedures.

Ongoing research and development collaborations with surgeons, prosthetists and technologists have delivered unique insights into the real-world constraints of the lab and theatre – making the devices practical, effective and reliable. SPD's team of design engineers are routinely embedded in hospital departments to learn first-hand about the unique challenges posed by trauma, deformity and disease (PDR, 2015).

#### **2.2.2 CARTIS**

The Centre for Applied Reconstructive Technologies in Surgery (CARTIS) is a unique partnership that aims to make Wales a world-leader in the research, development and application of advanced technologies in surgery and prosthetics. The group have received numerous awards and accolades over the years; media recognition, numerous publications, presentations all over the world and most recently the Queen's Anniversary Prize for Higher and Further Education.

The partnership combines the medical and technical expertise of Abertawe Bro Morgannwg University (ABMU) Health Board's Maxillofacial Unit at Morriston Hospital and PDR at Cardiff Metropolitan University. The CARTIS partnership also extends to include other National and International collaborations.

Through collaborative research and clinical application, the centre continues to pioneer the effective application of advanced design and manufacturing technologies in reconstructive surgery and prosthetic rehabilitation. CARTIS is also involved with disseminating and developing international best practice through the ADT Foundation and Conference Programme.

CARTIS research has consistently produced quality publications in a range of high impact journals, at conferences worldwide and in other reference material. Research outputs demonstrate high impact through transference of new techniques into clinical application that improve patient care and healthcare economics, relevance to industry and implications to wider medical specialties.

CARTIS is also heavily involved with other research, academic and knowledge exchange activities. This includes post-doctoral research, technical and medical advisory boards, organising international conferences, external examining, running training courses and seminars and reviewing publications (CARTIS, 2015).

PDR have produced four PhD theses in which the CARTIS collaboration has played a crucial role. CARTIS is currently involved with a further three PhD projects in the areas of:

Optimisation of patient-specific implant design and production,

User-centred design method development for bespoke medical devices,

Optimising surgical guide design and fabrication (this PhD).

### **2.2.3 ABMU Morriston Maxillofacial Unit**

A support partner for the PhD is the Maxillofacial Unit at Morriston Hospital, Swansea. The Maxillofacial Unit is an essential part of the services at Morriston Hospital, providing Oral and Maxillofacial, Orthodontic and Restorative services on a local and regional basis. The service is led by 7 Maxillofacial Surgeons, 3 Orthodontic and 3 Restorative Consultants and their teams all supported by a 19-

strong state of the art, Maxillofacial Laboratory. The unit has a world renowned reputation for its work in implantology, craniofacial surgery and 3D planning and regularly delivers advanced training courses for postgraduate students in all three disciplines. The role of the Maxillofacial Unit is to provide the controlled clinical setting, in which the novel surgical guides can be robustly evaluated.

Mr Adrian Sugar (Consultant Cleft & Maxillofacial Surgeon) and Peter Evans (Maxillofacial Unit Manager & Reconstructive Scientist) represent the clinical arm of CARTIS, and their role was to provide on-going clinical expertise and co-ordinate the delivery and evaluation of surgical trials as part of this PhD research study.

The CARTIS and ABMU collaboration helped the team at Surgical and Prosthetic Design to obtain honorary contracts within the hospital. This allows the same access as a NHS maxillofacial staff member would have into the various offices, laboratories and operating theatres. This helped with the PhD research with regards to clinical access and observations on current best practise.

#### **2.2.4 Renishaw Plc.**

Renishaw is a global company and was established in 1973. The company has always made a significant commitment to R&D and partnered research projects. This has enabled Renishaw to undertake innovative product development and diversify into new areas, such as machine tool automation, co-ordinate measurement, AM and medical applications.

The majority of Renishaw's R&D activities are carried out at their headquarters, located at Wotton-under-Edge, South Gloucestershire. The company location is less than an hour from Cardiff Met, and there have already been a number of informal projects in collaboration with Renishaw, notably in the area of CAD/CAM dental frameworks. This PhD study aims to build on this early work between Renishaw and Cardiff Met, and apply the latest knowledge and technology to patient-specific surgical guides. The involvement of this international company will allow access to

key people and in-house technology. Renishaw have allowed access to two important areas of in-house technology: AM and Co-ordinate Measurement.

AM.

In April 2011, Renishaw acquired ownership of the layer-based metal fabrication technology Selective Laser Melting (SLM). This technology has the potential to produce precision metal parts for challenging high-tech environments, such as aerospace and medical devices. PDR evaluated the SLM technology some years ago, but Renishaw now has the ability to reveal the potential of this new technology. Importantly, Renishaw has the appropriate team of individuals in place to ensure that this type of technology can progress and deliver accurate, high quality final parts. This technology has previously employed medical-grade Cobalt Chrome for the fabrication of dental frameworks. The next step is to evaluate AM techniques for the more demanding application of surgical guides.

Co-ordinate Measurement.

Renishaw produce the world's leading range of touch-trigger and scanning measurement systems for Co-ordinate Measuring Machines (CMM). These CMMs provide fast, accurate acquisition of component dimensions and surface data. By providing access to a range of CMM technology, Renishaw will enable accurate and consistent measurement of the various surgical guides/parts that plan to be fabricated. Detailed component geometry and surface roughness measurements will provide a rich data set for quantitative evaluation. Previous PDR-based PhD projects have needed to source CMM technology through Cardiff University, which has not been an ideal scenario due to access and time issues.

Furthermore, the PhD presents the beginnings of a strategic collaboration with Renishaw Plc., a global company and world leader in AM, measurement and medical applications.

## 2.3 Where – Organisational Framework

This PhD is a combination of both clinical and industrial expertise. It has developed an interesting mix of outlooks on the future capabilities of AM within healthcare and perception views on what they expect clinically compared to what can be achieved (figure 2).

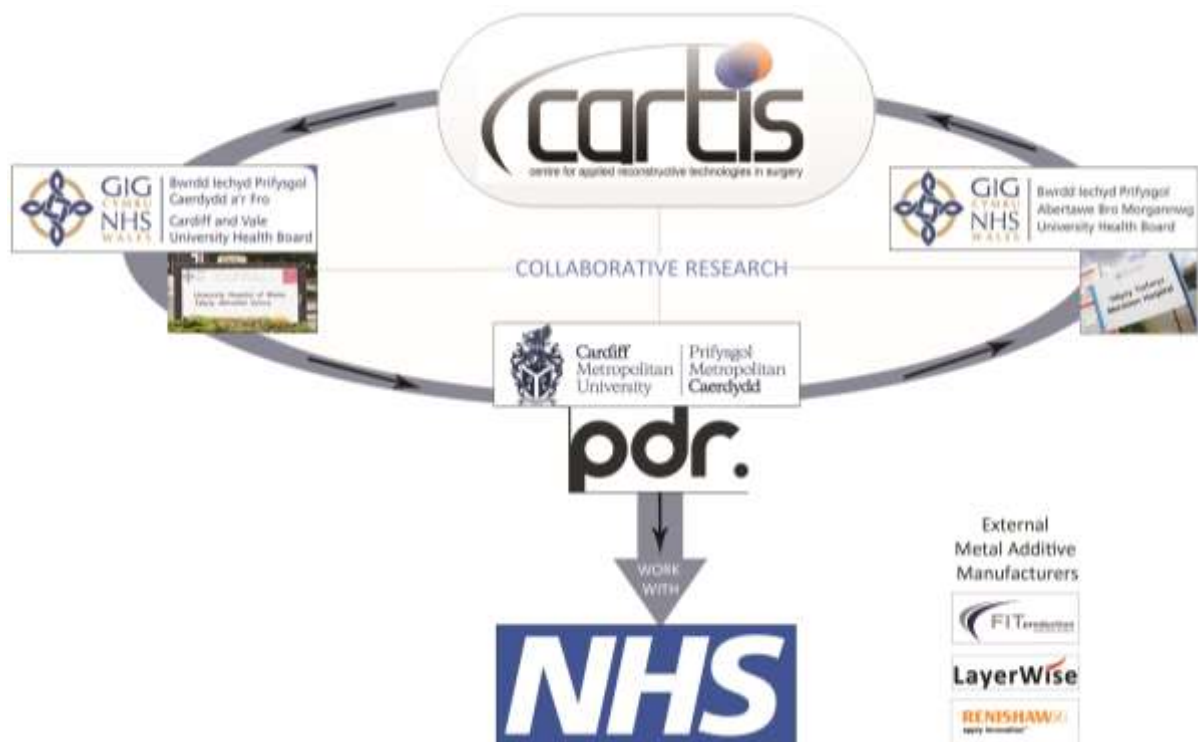


Figure 2 – CARTIS Group and working collaborations

All the resources of this PhD are within an 88 miles range along the M4 from the South West of Wales to Gloucester.

## 2.4 What – Case Types and Portfolio of Products

Cranio-Maxillofacial surgeries have five different case types:

**Trauma** – Fast turnaround (hours) to preserve life and (to a lesser degree) function e.g. decompressive craniectomies & poly-trauma. Some cases allow approximately a week to plan e.g. orbital floor/wall reconstruction.

**Facial Deformity & Prosthetics** – Long-term planning to correct facial features. Multiple procedures usually required over months or years.

**Disease Control** – Timescale for planning dependant on rate of disease progression.

**Elective Correction** – Longer period available to plan procedures e.g. to improve aesthetics post-trauma.

**Cranioplasty Reconstruction** – Longer period available to plan procedures.

Plans, models and guides for the case types explained can be delivered within days, with some implants designed, fabricated and delivered inside of a week.

The Surgical and Prosthetic Design team at PDR currently offer the following services which are applicable to the research:

**Medical Models** - Custom physical reproductions of anatomy from CT, Cone Beam Computed Tomography (CBCT), MRI, photogrammetry or surface scan data. They are used to rehearse surgeries, to communicate procedures to patients, as in-theatre visual references or as jigs to assist the shaping of off-the-shelf implants. PDR use CE-marked scan-data processing software validated for clinical use. Models are fabricated using AM.

**Custom Surgical Guides** - Metal or polymer AM devices which translate digital surgical plans precisely and predictably into the operating theatre. They can operate in parallel with PDR's custom implants service. They are designed to sit securely onto consistent anatomical landmarks and to guide saw cutting vectors, drilling angles, drilling locations and bone repositioning. Typical applications include: controlling osteotomy cuts and bone repositioning, tumour excision and resection, implant placement for prosthesis retention and accurate fibula flap harvesting (amongst other possible grafts) for facial reconstruction.

## **2.5 Why – AM Development**

Although surgical guides are commercially available through a small number of companies, there are significant limitations relating to the materials used and the design/production process. There is significant scope to improve surgical outcomes and create a more efficient service based on optimising the entire supply chain involved with data capture, guide design, guide fabrication and delivery.

PDR have previously worked closely with surgical and technical maxillofacial specialists at Morriston Hospital in Swansea to pioneer new guide design and production methods. However, further collaboration with equipment developers and engineers from commercial partner (Renishaw Plc.) was required to develop and optimise appropriate methods prior to clinical and commercial application.

Due to the vast expertise available with the numerous partners, both clinical and industrial, three key themes have been highlighted in order to focus the PhD which emerged from early pilot studies:

1. Patient-specific Surgical Guides
2. AM Materials: Polymer and Metal
3. Characteristics: Accuracy, Roughness and Cleanliness

Each of the above themes would provide research start points for the literature review in chapter 3. The literature review will help to highlight appropriate research questions which are then discussed in chapter 4 methodology in order to choose suitable research methods to begin the testing phase of the PhD.

## Chapter 3: Literature Review

This chapter reviews the literature to build the foundations for the remainder of the research. Due to the interdisciplinary nature of medicine and design, the literature for any thesis relating to these fields will require insights from many different disciplines. The insight gained would help the evolution of research questions and the beginning of the study structure of this thesis.

### 3.1 Key Themes

The literature review focussed on three key themes;

1. Patient-specific Surgical Guides
2. AM Material: Polymer and Metal
3. Characteristics: Accuracy, Roughness and Cleanliness

Understandings of these themes were required in order for the areas to be combined and for research to populate the gap within the literature; this PhD aimed to capitalise on this.

### 3.2 What is a patient-specific surgical guide?

Surgical guides are typically used in head and neck, orthopaedic, spinal and neurological surgery. Each guide is unique to each procedure and must fit a precise area of anatomy on an individual patient. They are used to drill, cut and reposition bone of the patient's anatomy (figure 3).

Medical imaging techniques, such as Computer Tomography (CT) are typically used to acquire 3D computer models of anatomical structures. The specialist software used by PDR and Morriston Maxillofacial unit is Materialise Mimics® which imports DICOM scan data in order to threshold and extract the anatomy of interest that the surgeon would like to work on. Geomagic® Freeform® is then used together with a haptic arm device to manipulate anatomical structures, undertake virtual surgical operations and design custom-fitting devices, such that the surgical guide interfaces accurately with the desired anatomy.





Figure 3 – Varieties of surgical guides. Top image shows a surgical guide used for drilling implant pathways, Middle images shows a cutting guide used to cut bone in specific digitally designed places.

The lower images show a repositioning guide which placed the loose bone back into their correct digitally planned location.

Each surgical guide is designed depending on the chosen AM material. Different geometries, material thicknesses and incision lines are discussed between the surgeon and design engineer. AM materials have specific AM processes that are undertaken on each part. Each part fabricated follows a specific AM standard operating procedure (S.O.P.) which is generated by each manufacturing company, please refer to appendix IV for illustrative S.O.P. AM processes/procedures involve different implications for example build orientation, where the supports will be placed and whether the part will require any post finishing i.e. electro polishing for metal AM parts.

Build supports are required for the first layers of the build, the unsupported layers of the part and to successfully build parts. For metal parts build supports also act as heat distribution to '*reduce warping caused by thermal stresses during the build.*' (Wohlers, 2014). Build supports do affect part fabrication as without them the build will encounter issues causing ruined unusable parts.

Build supports are not the only factor that need to be considered when fabricating parts, the build orientation and location on the build bed also needs to be addressed. The build orientation of a part determines the angle of the supports and the top surface of the orientation produces the best surface finish.

When the build supports are removed, especially in metal parts, post finishing is required. Polymer supports are quicker to remove and post process than metal parts. Metal post finishing entails burring away supports and polishing the surface of the part to the specification from the surgeon.

Once designed, guides can be fabricated in polymer or metal AM materials, sterilised and used in theatre (Figure 4). Any surgical guide fabricated should adhere to following characteristics: to be accurate, robust, rigid and able to withstand sterilisation (Bibb *et al.*, 2010).

The guides can be used on the skin in order to mark with surgical ink the drill points or incision lines, or used on the bone to drill through the guide a pathway for implant placement (Ciocca *et al.*, 2010).

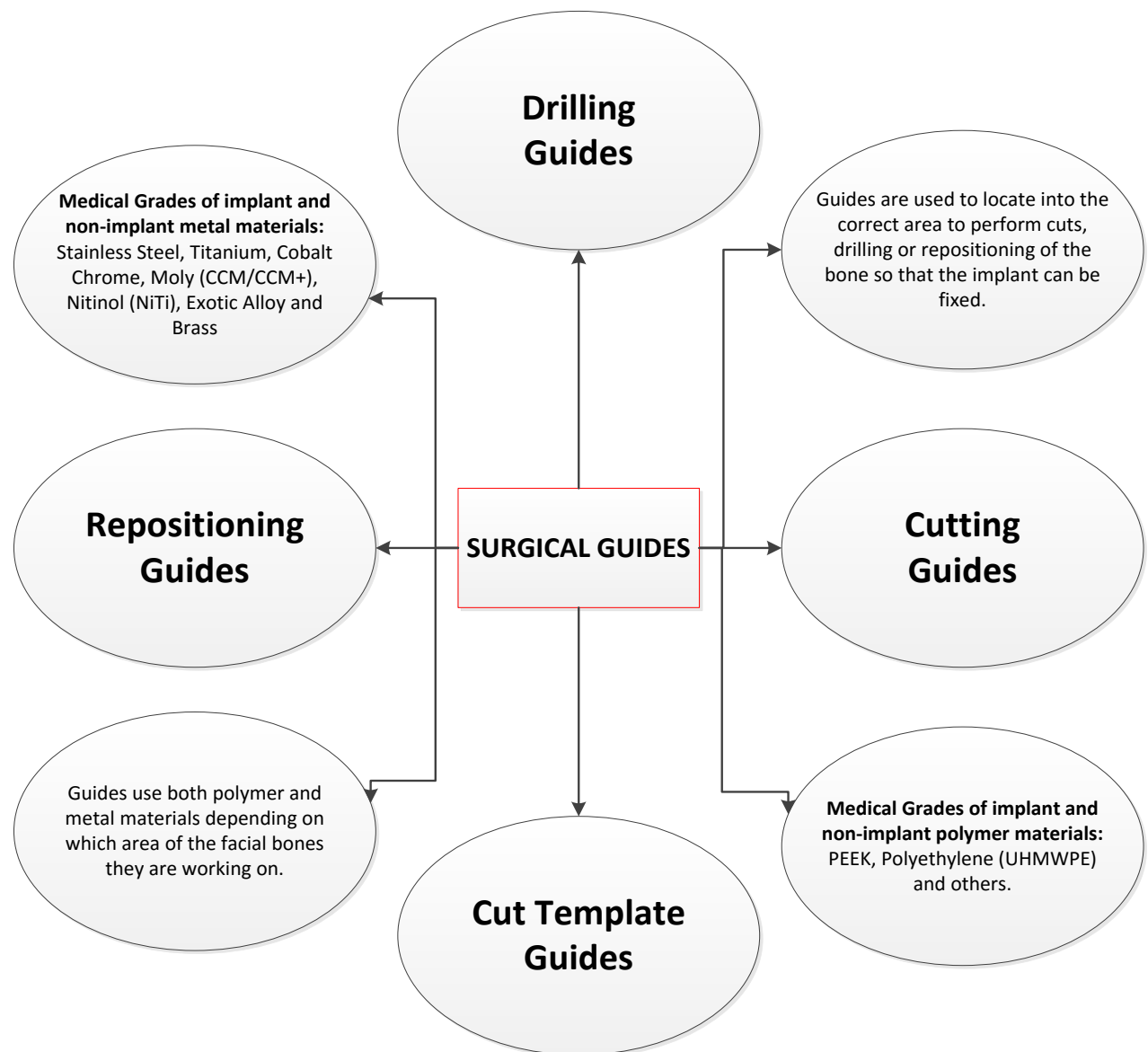


Figure 4 – Diagram of different surgical guides, their uses and materials

Surgical guides are used in other medical sectors and have commercial companies that provide them. For the dental industry, Nobel Biocare provide the Nobel Guide which helps 'predictable implant placement' and 'increases patient satisfaction' (Nobel Biocare, 2016). Medical companies like Materialise offer 'patient-specific' surgical guide services to anatomical areas such as shoulder, arm and hand, hip, knee and leg (Materialise, 2016). Another company that produces patient specific products is Zimmer®, they state that their patient specific instruments can 'streamline total knee replacement surgery' (Zimmer, 2016).

Although surgical guides are commercially available through a small number of companies, there are significant limitations relating to the materials used and the design/production process. There is significant scope to improve surgical outcomes and create a more efficient service based on optimising the entire supply chain involved with data capture, guide design, guide fabrication and delivery.

### **3.3 AM links to Maxillofacial Surgery**

Maxillofacial surgery is a speciality concerned with the diagnosis and treatment of diseases affecting the jaws, face and neck. Maxillofacial surgery was chosen as the focus area of surgical guides due to the working relationships and clinical access identified in chapter 2. Maxillofacial surgery is performed on facial bones as shown in figure 5; the specific surgical terminology that is highlighted in this thesis is described in table 1.

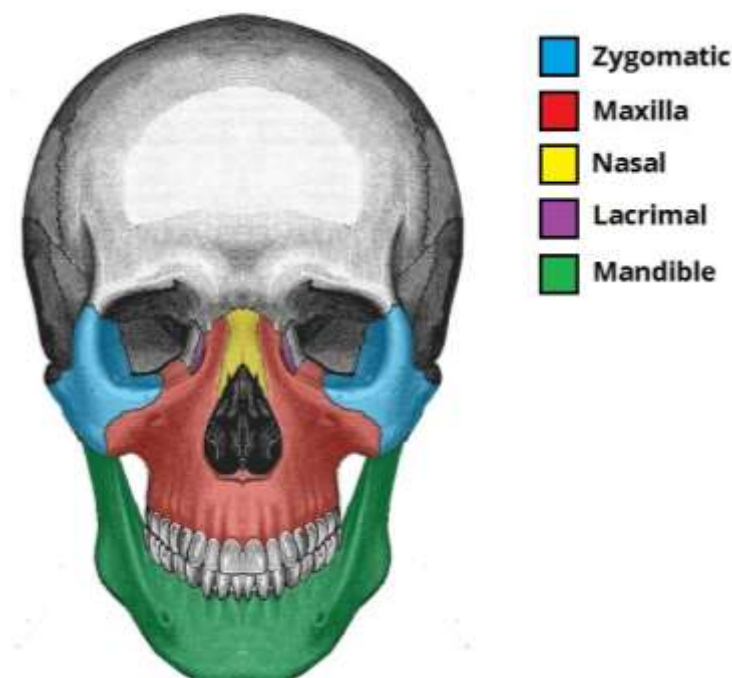


Figure 5 – Frontal view of the facial bones. Blue highlights the zygomatic bone, red highlights the maxilla bone, yellow highlights the nasal bone, purple highlights the lacrimal bone , green highlights the mandible and the grey highlights the cranium.

<b>Surgery Terminology</b>	
Reconstructive Surgery	Performed on abnormal structures of the body caused by birth defect, trauma, infection, tumour or disease. Performed to improve function but may also improve appearance or aesthetics.
Osteotomy	The surgical cutting of a bone for re-alignment
Tumour Removal	Surgical removal of an abnormal growth
Implant Surgery	Surgical placement of an implant into bone
Orthognathic Surgery	To correct conditions or problems of the jaw and face that cannot be easily treated with braces
Neck Dissection	Surgical procedure for control of neck lymph nodes metastasis
Rhinectomy	Surgical removal of all or part of the nose
Pinnectomy	Surgical removal of all or part of the ear
Maxillectomy	Surgical removal of all or part of the maxilla

Table 1 – Surgical terminology specific to the research and case studies conducted in this thesis.

The channel 5 Making Faces TV series in 2012 gave an insight into the day to day happenings of a busy Maxillofacial Unit at Queen Elizabeth Hospital in Birmingham. The following quote from Worrollo (2012) highlights the importance of the area and the patient perspective:

*“Losing a part of your face is the most difficult thing to come to terms with; as you could probably image. Obviously it’s such a dramatic catastrophic thing to happen that you have to then re-evaluate and honestly re-look at how you’re going to manage for the rest of your life; taking into account what’s happened to you. The real big thing is being rejected. That’s what a lot of patients are frightened of is being rejected or people being repulsed by how they are. That’s a really big thing. So for us to turn up and fix everything is a big call and that’s what we have to bear in mind.”*

The programme emphasised the use of both traditional/conventional (long-established maxillofacial laboratory techniques using materials such as light cure resins, wax and clay) and AM techniques used at the hospital. The use of medical models and surgical guides shown in this programme highlighted the use of AM in the maxillofacial area.

Surgical guides are made using two methods; one is the traditional/conventional method used within maxillofacial units. When using conventional techniques the outcome is often unpredictable and relies on the skill and experience of the surgeon (Frisardi *et al.*, 2011; Bullock *et al.*, 2013; Cassetta *et al.*, 2011; Feng *et al.*, 2011; Parthasarathy & Parthiban, 2008; Theinpont *et al.*, 2013).

Secondly, the guides can be fabricated by AM methods in a layer-by-layer formation (Duran, 2008). Commonly used AM methods include SLA polymer fabrication and LM metal fabrication.

AM has many different processes but only some can be appropriately used in medical applications (see table 2).

<b>ASTM approved system of AM process categorisation</b>	<b>Wohlers, 2014 Classification</b>	<b>AM Process Example</b>
Material extrusion	<i>'AM process in which material is selectively dispensed through a nozzle or orifice'</i>	FDM (Fused Deposition System)
Material jetting	<i>'AM process in which droplets of build material are selectively deposited.'</i>	Projet
Binder jetting	<i>'AM process in which a liquid bonding agent is selectively deposited to join powder materials.'</i>	Z Corp
Sheet lamination	<i>'AM process in which sheets of material are bonded to form an object.'</i>	LOM (Laminated Object Manufacturing) and UAM (Ultrasonic Additive Manufacture)
Vat photo polymerisation	<i>'AM process in which liquid photopolymer in a vat is selectively cured by light-activated polymerization.'</i>	SLA (Stereolithography)
Powder bed fusion	<i>'AM process in which thermal energy selectively fuses regions of a powder bed.'</i>	SLS (Select Laser Sintering), SLM (Select Laser Melting), LM (Laser Melting) & EBM (Electron Beam Melting)
Directed energy deposition	<i>'AM process in which focused thermal energy is used to fuse materials by melting as the material is being deposited.'</i>	LENS (Laser Engineered Net Shaping) & DMD (Direct Metal Deposition).

Table 2 – ASTM approved system of AM process categorisation (Wohlers, 2014)

Commonly used AM method SLA can be fabricated in a number of polymer resins with ISO 10993 and USP Class VI certification. SLA is defined by Stratasys (2016) as a process which 'rapidly builds components using a precise UV laser to cure and solidify thin layers of a photo-reactive resin.'

Another polymer AM process that produces medical surgical guides is Selective Laser Sintering (SLS). The process produces parts in medical grade nylon and these guides are used in knee surgery (Krisnan *et al.*, 2012). 3D Systems (2015) describes how the process uses '*high power CO2 lasers (carbon dioxide lasers) to fuse plastic, metal or ceramic powder particles together, layer by layer, to form a solid model.*'

The other AM method mentioned earlier for use in surgical guide is LM metal fabrication. These machines can fabricate parts in titanium, cobalt chrome, nickel alloys, aluminium alloys and stainless steel metals. Renishaw (2015) described the process as '*digitally driven, direct from sliced 3D CAD data. For each slice of CAD data a thin even layer of fine metal powder is deposited across the build plate, then the selected areas of the powder are precisely melted by the laser. This process is repeated building up, layer by layer, until the build is complete.*'

Members of the CARTIS team published the first recorded application paper on the use of SLM technology in manufacturing surgical guides (Bibb *et al.*, 2010).

The cross over from traditional methods to digital planning and AM fabrication is particularly focussed on complex surgical interventions and medical models. AM medical models are used with maxillofacial units and surgery as visual models to help assess the patient's anatomy, and are also used as a patient reference to fabricate conventional surgical guides and implant plates (figure 6).





Figure 6 – Medical models, the left image shows an off-the-shelf mandible plate being bent to the patient AM medical model and the right image shows a conventional surgical guide being made using light cure resin on the patients AM medical model.

Accuracy studies have shown that the transition from the traditional/conventional plaster models (used in dentistry and for maxillofacial prostheses) to AM medical models resulted in good alignment therefore this helped gain more justification and acceptance to the maxillofacial area (Keating *et al.*, 2008).

Surgical guides and implants were primarily used in the dental industry (Frisardi *et al.*, 2011; Kruth *et al.*, 2005; Vandenbroucke & Kruth, 2007; Eysers & Dotchev., 2010) and then were introduced to the maxillofacial area. The guides help with reducing operating time, gaining better accuracy and achieving an improved aesthetical result for the patient (Bibb *et al.*, 2003; Nam *et al.*, 2012; Kermer *et al.*, 1998; Adolphi *et al.*, 2013; Salmi *et al.*, 2012; Rouse, 2009; Giannatis & Dedoussis, 2009; Dandekeri *et al.*, 2013; Campbell *et al.*, 2011; Al Mardini ., 2009; Dérand *et al.*, 2012; Duron, 2008; Asher *et al.*, 1999; Bellanova *et al.*, 2013; Sarment *et al.*, 2003).

The technology push within the maxillofacial area has helped to increase the efficiency of procedures and help develop the procedures to cope with the problems they encounter (Acebal-Bianco, 2000). Maxillofacial units in the UK have adopted these AM techniques into their everyday procedures. Some units have even purchased their own 3D printer instead of outsourcing it to an AM bureau (Aleid *et al.*, 2010).

Surgical navigation is a system that allows surgeons to track their surgical instruments in relation to surgical markers on the patient's anatomy. It is an alternative route to the use of surgical guides but papers have explained that it is an



expensive technique and requires an experienced surgical team. Papers have shown that, compared to surgical guide post operatively, results are very similar (Herlin *et al.*, 2010; Olszewski, 2011).

Evidence of improved facial aesthetics for the patient helps to bring back their confidence and acceptance (Erickson *et al.*, 1999; Hatamleh *et al.*, 2010; MHRA, 2006; Dos Santos *et al.*, 2010). Chandra *et al.* (2005) explains:

*“As a person’s face is the presentation of that person to the world, the emotional trauma caused by disfigurement to what is conceived as a normal face can be enormous.”*

In a study among the maxillofacial profession they felt that they were not only doing their day to day job but also acting as a counsellor, friend and advice bureau for each and every patient that came into their lab (Watson *et al.*, 2006; Goiato *et al.*, 2009).

The uses of AM in maxillofacial does not only benefit the patient with decreased operation time and stress (Bill *et al.*, 1995), it benefits maxillofacial prosthetists and the consultant surgeon. Swaelens & Kruth (1993) explained that surgeons prefer ‘*tangible*’ models rather than interpreting scans on screen. Within the maxillofacial area AM models, guides and implants offer lots of advantages.

AM techniques advance when there is a particularly complex patient case. Off-the-shelf implants usually cover the normal scope of patient requirements but when reconstructing extremely damaged anatomy, customised implants, guides or devices are fabricated (Bell *et al.*, 2007). A key advantage of AM technology is that any fragment of bone within a human skeleton can be fabricated and used in an operating theatre without additional shaping (Popov *et al.*, 2004; Bullock *et al.*, 2013)

When using the conventional way surgeons are not able to visualise the whole dataset (physical AM medical model and 3D virtual digital plan) and communicate this to other members of the clinical team. Yet, when in an operating theatre the whole team needs to know what the surgery is going to involve so they all have the same picture (Xia *et al.*, 2010; Federspil, 2009; Berström, 1997; Tuomi *et al.*, 2014). The uses of AM medical models and virtual digital plan imagery help the clinical team to fully understand the procedure prior to the operation start. The teams' appreciation of the surgeon's problems can lead to helpful suggestions which produce better techniques and final results (Brasier, 1954).

Miscommunication within clinical teams can cause post-treatment complications associated with the rehabilitation of patients (Lemon *et al.*, 2005; Gulati *et al.*, 2011). AM surgical guides can be digitally planned pre-operatively with the clinical team, this helps to reduce the unpredictability of traditional freehand methods (Dérand & Hirsh, 2009; Giordano *et al.*, 2012; Ciocca *et al.*, 2010).

The relationship between the surgeon and their clinical team is of primary importance, but secondly, the inclusion of AM technology design engineers; the combination of all these professions become vital to the success of the patient result and hence forms a multidisciplinary team (Rohner *et al.*, 2013). Fantini *et al.* (2013), Ciocca *et al.* (2009) & Kontio *et al.* (2012) all explain in their research that communication between design engineers and surgeons '*paved the way for efficient exploitation of available tools and technologies*'. This helps to combine the medical clinical expertise with manufacturing and design engineering expertise. Explanation for each patient case and the involvement of surgical guides and implants needs to be considered for the multidisciplinary team with clear imagery and visuals to await further surgeon instruction.

Cassetta *et al.* (2011) explain that although *in vitro* and *ex vitro* studies in research papers are good, there is nothing like experiencing clinical studies and the factors/variables that need to be taken into account in that scenario, for example movement of the guide, restriction of access, incision lines. Anchieta *et al.* (2011) explains that:

*“During surgery it is practically impossible to accurately establish the asymmetrical relations because only one side is exposed.”*

Incision lines and ensuring best possible scar formation is crucial for surgeons (Adam *et al.*, 2012) on their patients, therefore any reduction in size of surgical guide so it can be placed into the incision area with ease is a big advantage.

### **3.4 AM Materials & Motivations of use**

Within the CARTIS previous case study database, surgical guides were fabricated in polymer, metal or a mix of the two materials. The combination mix usually comprises of an SLA polymer guide with titanium or stainless steel tube reinforcements or inserts into drill guides.

It is important that design engineers have a good understanding of the AM materials they have available to use for the fabrication of the end product, surgical guide or implant in order to make the correct decision for that area of anatomy (Hague *et al.*, 2004; Hague *et al.*, 2006; Gibson *et al.*, 2004; Kruth *et al.*, 2005). However, research into guidance on where certain material should be used on the anatomy with appropriate justification was not apparent.

Surgical guides can be used on soft tissues, bone anchored, mucosa (membrane lining over the bone) or tooth supported surfaces (Ramasamy *et al.*, 2013; Flügge *et al.*, 2013; Ozan *et al.*, 2009) These surfaces all offer different mechanical properties and surface characteristics. .

Both polymer and metal AM materials used for surgical guides and implants consisted of a mix of advantages and disadvantages. The use of metal AM materials for surgical guides allows them to be fabricated smaller and thinner whilst still retaining rigidity. The smaller the guide, the smaller the incision that needs to be made, which makes the surgeons access and visibility significantly improved (Bibb *et al.*, 2010).

Bibb *et al.* also explains in their (2009) paper that stiffness is required when handling and placing the implant or guide and good wear resistance is key when tools are used against it (drills and saws). Primarily focussed on AM metal surgical guides this

paper shows no statistical evidence that metal is a better material to use but is portrayed as the more superior material option.

Wohlers (2008) stated that materials suitable for metal implants were titanium (Ti), titanium alloys (TiAl) and cobalt chrome (CoCr). Titanium is the main choice for many medical implant suppliers due to its characteristics that complement medical standards (Vandenbroucke & Kruth, 2007).

Biocompatibility, osseointegration (structural and functional connection between living bone and the surface of an implant), strength and corrosion resistant make titanium a suitable choice for implants. (Laoui *et al.*, 2004; Balazic *et al.*, 2009; Salmi *et al.*, 2012; Brunette, 2001). Simple design features advantages built into guides and implants like low mass or using a mesh pattern reduces sensitivity to hot and cold temperatures (Salmi *et al.*, 2012). Another issue highlighted and explained by Gumierio *et al.* (2009) and Schoen *et al.* (2001) is a general concern among the surgical team that metal implants *'within the irradiated field may, because of scattering, cause an overdose in the adjacent tissue over the course of radiation therapy.'*

When researching AM polymer use in surgical guides the Bibb *et al.* (2009) paper deemed SLA polymer guides as fragile and needed the requirement of metal reinforcements to prevent damage from drilling. It goes on to state that the metal inserts address the physical deficiencies of the SLA guides. The paper also suggests that SLA guides were limited to one material, limited to primitive shapes and lacked sophistication. Within this paper it was argued whether the use of a secondary process of incorporating metal reinforcements into polymer guides can be eliminated by using metal guides saving both cost and time (Bibb *et al.*, 2010). Cassetta *et al.* (2011) paper also highlighted another problem that had been encountered with the use of SLA polymer surgical guides; they explained about the issues of detachment of metal tubes, guides cracking and/or breaking.

However, Anchietta *et al.* (2011) highlighted that the translucency of the SLA polymer acts as an important attribute for the evaluation of drill direction and depth.

Park *et al.* (2009) stated that guides can be categorised based on the material used and the amount of surgical restriction but a guideline for this was not present in the literature reviewed.

The literature gathered in this area has highlighted an area of fundamental research that is required. AM polymer, metal materials and a combination of materials need to be addressed further to see whether the patient-specific guides are also material specific. A focus is needed on which materials would suit best to specific anatomical areas depending on design, restriction and incision lines.

### **3.5 Characteristics of AM**

#### **3.5.1 Accuracy**

The shape of an implant or guide needs to contour and locate into specific landmarks of the anatomy identified by the surgeon. Length, diameter, thickness and tolerance are all aspects that can be varied in the design of a surgical guide and so can affect the accuracy of the part and its use (Ma *et al.*, 1997; Cassetta *et al.*, 2013; Koop *et al.*, 2012).

69% of maxillofacial prosthetists and technologists believe that the use of digital technologies is helping to gain better accuracy, planning, reproducibility of procedures and time saving (Hatamleh *et al.*, 2010).

The uses of guides have been established in areas where high accuracy is a concern, such as restorative dentistry, cranio-maxillofacial surgery and spine surgery (Duron, 2008). Xiaojun *et al.* (2009) paper describes the use of drill guides and how it affects location, angle and depth of insertion of an implant, all of which are important in relation to accuracy.

When using freehand methods (procedure completed manually by the surgeon without aid of surgical guide), one of the many variables that can occur is '*slight movements*' of the hand whilst drilling; this can result in deviations from planned to placed or fixed position of the implant which defines the accuracy of the entire procedure (Kühl *et al.*, 2012; Melchels *et al.*, 2010; Koop *et al.*, 2012; Casetta *et al.*, 2012).

When drilling an implant pathway through a surgical guide it is important to minimise the surgical trauma to the bone. Federspil (2009) paper state that the important points to follow are:

*“The use of a new and sharp drill/cutting burr, low drill speed (1500-2000 Rpm) and extensive cooling through flushing with ringer’s solution.”*

The inaccuracies or deviations from the planned to fixed position can be a sum of different variables or sources of error that can occur at different stages of the process from the start (CT scanning) to the end (final placement of implant) (Casetta *et al.*, 2011).

Bibb & Winders stated in (2009) that anything above a one millimetre of movement in the fabrication process may make an AM medical model ‘*unusable*’. Therefore designing guides and implants digitally on a virtual model can be performed with greater accuracy than on an AM medical model (Leiggener *et al.*, 2009). The way a medical model, surgical guide or implant is fabricated is highly important. The build orientation can change the parts accuracy, time and support placement (Cheng *et al.*, 1995).

Many issues can occur as an effect of inaccurate implant placement including long-term use of the implant, implant osseointegration success and the aesthetic outcome of the prosthesis (Ozan *et al.*, 2009). In an accuracy study from (2005) on the use of surgical guides for implant placement the authors Di Giacomo *et al.* explains that:

*“The technique requires improvement to provide a better stability of the guide during surgery, in cases of unilateral bone-supported and non-tooth supported guides.”*

The paper highlighted technique improvements which was sparse in this literature review. Many of the papers reviewed provided the positive results without highlighting any negatives, improvement requirements or clinical cases that went wrong. The lack of publications in clinical issues, patient feedback and improving performance of surgical guides highlights the need for research to identify and develop new solutions. It seems fundamental for the development of research in the area of surgical guides that both positive and negative findings are reported.

Therefore any negatives or improvement requirements relevant to the PhD were included in the core research studies of the thesis.

Casetta *et al.* (2012) summed up that:

*“Limited studies in the literature consider potential errors that could arise from the inherent limitations of stereolithographic surgical guides (the intrinsic error). Despite the lack of data in the literature, it remains important to examine the mechanical factors that may influence the accurate placement of an implant when a stereolithographic surgical guide is used, in order to fabricate a surgical guide that limits the deviation of the drills being used.”*

Within the maxillofacial area there are a high number of variables, through reducing these errors at each stage of design and production, the accuracy of a procedure could be improved.

### 3.5.2 Surface Roughness

AM parts can be orientated and fabricated in such a way that it can reduce the supports necessary (i.e. the supports required for the AM process) and avoid the bone fitting surface (Bibb *et al.*, 2010; Bibb & Sisias, 2002; Lan *et al.*, 1997). The step formation and support placement that becomes apparent on AM parts from the layer-by-layer technique could become a fundamental research study into how it could be used as a positive characteristic on the bone-bound surface of the surgical guide.

However, the surface finish of a part has been addressed as a ‘*critical feature*’ (Ippolito *et al.*, 1995) and it has been highlighted that if the layers in the AM fabrication are thinner that it produces a smoother surface and is deemed more appealing (Anchieta *et al.*, 2011; Lan *et al.*, 1997). Surface roughness classification as defined by Federspil *et al.* (2009) is highlighted in figure 7.

smooth	0.0–0.4 $\mu\text{m}$
minimally rough	0.5–1.0 $\mu\text{m}$
moderately rough	1.0–2.0 $\mu\text{m}$
rough	>2.0 $\mu\text{m}$

Figure 7 – Surface Roughness Classification from Federspil *et al.* 2009.

Surface roughness of an LM metal part depends on many factors: '*material, powder particle size, layer thickness, laser and scan parameters, scan strategy and surface post treatment*' and in addition the top surface can differ significantly from the bottom surface (Vandenbroucke & Kruth, 2007; Kruth *et al.*, 2005; Campbell *et al.*, 2002)

The build orientation of a part with circular or cylindrical shapes should be built upright so that the circular section can be '*faithfully reproduced*' (Bibb *et al.*, 2015). This is important with regards to drill surgical guides as the drill cylinder needs to be precise in order to gain the planned implant drill pathway.

Cheng *et al.* (1995) explain that post processing is required if:

*"Staircase effects appear along inclined surfaces. These are difficult to remove and have to be polished off the surface during post processing. The appearance of the stair step becomes worse when the inclination is more gentle. When the slicing thickness is thinner, the staircase is smaller and the surface will be smoother."*

Larsson *et al.* (1997) explains: to choose appropriate material and surface characteristics it is best to use '*systematic variation*' either by selecting the material based on its characteristics or by modifying the surface of a single material. Larsson also enlightens that electro polishing (smoothes and streamlines the surface of a metal part) of a surface did not significantly lower the bone growth around the implant. However, electro polishing provided a beneficial effect as it eliminated surface contaminates (Puipe, 2003).

Richards (2007) stated that the higher the surface roughness the better the bony integration or osseo-integration for implants. It goes on to say that this can act as either an advantage or a disadvantage depending of the patient specific case. In some cases, screws or implants need to be removed due to a secondary reconstruction surgery. For example, this usually happens with complex trauma cases, if the implant osseo integrates over months or years they become difficult to remove. This would also be disadvantageous if an infection occurred in the area and the implant had to be removed. The closing sentence to Richards (2007) paper states:



*“There is no ‘One Surface’ for all applications and surfaces even on one implant interacting with different tissues need to be considered as separate entities.”*

For traditional techniques used in maxillofacial and dental labs they polish most of the items they fabricate (Del Curto *et al.*, 2005). Research justification of why polishing is required to the material surface is sparse and therefore questions does the polishing act as a positive or negative addition, and how do different AM materials compare. Surgeons perceive metal to grip better or have a high friction coefficient onto the bone as mucosa, soft tissue and bodily fluids usually cause the surgical guides to slip if fabricated in polymer.

Wexell *et al.* (2013) states:

*“The interaction between proteins, cells and implant surfaces may be influenced not only by the chemical properties of a surface but also the surface roughness which in turn may influence the wettability (hydrophilicity) which plays an important role. Therefore optimization of both surface chemical and topographical properties need to be considered when new materials are designed.”*

Nuño *et al.* (2006) stated that when testing a polished and matt stainless steel surface in wet conditions that there was no statistical difference found but the effect of wetting the surface of polished steel did increase the coefficient of friction. However, with the matt steel it was not clear that the wetting of the surface changed the coefficient of friction.

As stated throughout the literature review the combined areas of surface roughness, friction and material characteristics are detrimental to the performance of the surgical guide intra-operatively.

### **3.5.3 Cleanliness**

Although surgical guides are in direct patient contact for minutes in relation to a multiple hour surgery, it is important to take into account the biocompatibility, cleanliness and sterility of the material used.

Popov *et al.* (2004) identified that:

*“Design and synthesis of advanced materials for hard tissue engineering and replacement is one of the main objectives in biomaterial research worldwide.”*

The effects of sterilisation on fabricated surgical guides may cause characteristic changes of the material or distortion which cause inaccuracies when used in the operating theatre. However, sterility is one of the main requirements for any custom guide or implant used on a patient, Rouse *et al.* (2009) explains that:

*“The requirement for sterility is absolute, but without the ability to re-sterilise a custom implant if something should contaminate it, we can find ourselves in the operating room with the patient ready for the implant, but unable to continue with the surgery. This puts the surgeon in an impossible position and endangers the patient unnecessarily.”*

Bibb *et al.* (2009) stated that when they sterilised LM metal guides compared to SLA polymer guides that the cost and time was reduced. Although they stated that the exact details of the sterilising was difficult to measure. Each of the case studies witnessed in the chapter 5 of this thesis, regardless whether it was a polymer or metal AM surgical guide, went through the exact same Standard Operating Procedure (SOP) protocol at the Hospital Sterilisation and Disinfectant Unit (HSDU) department in the hospitals, the sterilisation of a surgical guide prior to use is important.

The contamination of a guide or implant for a patient is something that needs to be avoided. When critically reviewing the literature there is confusion to whether different materials, surface finishes or roughness affect the adhesion of bacteria to the surface.

Kasemo & Lausmaa (1988) explain that:

*“It is appropriate to spend a short time on concepts and nomenclature: A clean surface means different things to different contexts. A surface that looks perfectly clean to the eye may still be extremely dirty (contaminated) in a chemical sense, since it may be covered by hundreds of molecular layers of foreign, contaminating species, invisible to the naked eye.”*

The above statement is a concern especially when dealing with so many varieties of materials and finishes. The surface finishing techniques for traditional or conventional parts fabricated in dental or maxillofacial laboratories are also judgements made by the '*naked eye*' (Taylor *et al.*, 1998).

Yoda *et al.* (2014) suggests that the minimum level of surface roughness affecting bacterial adhesion is dependent on what biomaterial is being used. Taylor *et al.* (1998) paper also agreed that the surface roughness influences the amount of microbial adhesion.

Polishing of a surface has been stated as a favourable surface finish due to its aesthetic appearance and the surface being less likely to be contaminated with bacteria (Richards *et al.*, 2007; Taylor *et al.*, 1998). Del Curto *et al.* (2005) paper specified that when they treated the surface of a titanium dental implant it seemed suitable in order to resolve the bacterial plaque adhesion to the surface of the material which had caused implant to fail in the past. However, in Taylor *et al.* (1998) paper, materials that had undergone post-processing electro-brightening enhanced the retention of microbes and bacteria on the surface. The polishing media used on the material can become embedded creating a contaminated surface.

The cleanliness of guides and implants used intra-operatively could be questioned if post-op results report implant failure due to infection. Kasemo & Lausmma (1988) explained that:

*"Even minor changes in the preparation procedure should be suspected to influence the biological properties of the implant."*

ATP has been used in both the food and healthcare industries to provide 'practical, real time and quantitative evaluation capabilities' to contamination levels and confirm the cleanliness of a surface (Fushimi *et al.*, 2013; Sherlock *et al.*, 2009; Ali *et al.*, 2012; Griffiths *et al.*, 2000; Luo *et al.*, 2009; Griffiths *et al.*, 2003; Cherry *et al.*, 2015; Alfa *et al.*, 2015; Aycicek *et al.*, 2006; Boyce *et al.*, 2009; Park *et al.*, 2014; Amodio *et al.*, 2014; Fernando *et al.*, 2014).

Griffiths *et al.* (2000) explain that there is a large difference between '*visibly clean*' and '*microbiologically or chemically clean*' as stated earlier therefore the use of ATP

in this situation is used to give an accurate cleanliness reading. Ali *et al.* (2012) state that with an increase in surface roughness you would expect to see an increase in the retention of bacteria and micro-organisms influencing the clean ability of the material surface.

Also, Rosales-Leal *et al.* (2010) paper states that:

*“Surface properties control the amount and quality of cells adhered on the implant and consequently, the tissue growth.”*

It seems that it is really important for the surgeon to state from the start the specific behaviour of how the guide or implant needs to react to the patient and its surrounding tissues as this affects both cell adhesion, bony integration and the location onto the bone. This specification of what the guide or implant needs to be can help to define the material choice and surface roughness.

It seems that surgical guides require a list of specifications before use; however, appropriate fundamental research is needed to indicate how AM materials used in the maxillofacial area are to perform. The literature review has identified four categories: clinical issues, accuracy, surface roughness and cleanliness, for further research. The research required will provide new knowledge to the area and whether surgical guides need to be material specific as well as patient-specific.

### **3.6 Identifying areas of concern, problems & opportunities**

The future of facial prosthetics workshop report by experts in the field Eggbeer *et al.* (2012) highlighted four priority items that need to be focussed on in the maxillofacial area: patient needs, healthcare trends, training requirements and budget considerations. The report also highlighted that standards and best practise for both traditional and digital techniques are required. Oncology cases are increasing and a push towards evidence-based practise is becoming increasingly important.

Perceptions and the lack of research evidence in opinions of AM in maxillofacial representatives have become apparent. The workshop report highlighted above explains that:

*“Linked to this is the disparate nature of research undertaken to date, which has resulted in a lack of consensus on whether newly attempted techniques are appropriate and whether they can be successfully measured.”*

Casetta *et al.* (2012) paper also highlights that because of the rapid development in AM technology and techniques that it has led to:

*“Unrealistic clinical expectations for the efficacy and ease of use of this technology, while the risk of deviation (transfer error from the software planning stage to the surgical field) remains substantial.”*

The expectations, perceptions and opinions towards AM technology have to be justified by further research into new techniques, materials and clinical procedures. This PhD thesis will address some of the issues, problems and unjustified perceptions.

### **3.7 Research Questions**

The relationship between early observations within clinical research and this literature review in identifying the gaps in knowledge and informing the research questions can be extracted into four core elements:

1. Clinical Issues
2. Accuracy
3. Surface Roughness
4. Sterilisation/Cleanliness

The core elements have highlighted appropriate research areas:

- Whether different AM materials suit different areas of the patient's anatomy depending on design, surgical restriction and incision lines. Derived from early clinical research.

- Polymer and metal; whether used individually or in combination, do they have to be tailored to be surgeon as well as patient-specific? Derived from early clinical research.
- Whether incremental design and material changes help gain better accuracy? Derived from literature review.
- The difference between polymer and metal AM materials when used on the bone with regards to friction co-efficient and surface roughness. Derived from clinical research and literature review.
- The difference between polymer and metal AM materials and their cleanliness characteristics. Derived from clinical research and literature review.
- How AM materials act in the four core elements and whether the research changes opinions on which material is best suited? Derived from early clinical research and literature review.

The research questions were divided into three; question one exploring clinical research due to the lack of reporting clinical issues, surgical guide procedure performance and highlighting clinical problems with the designs within the literature available. Question two to explore what evaluation metrics can be used to help quantify the performance with regards to accuracy, cleanliness and surface roughness of surgical guides, and question three to answer the overarching question on whether AM is good practice in maxillofacial surgical guides.

1. What are the clinical issues associated with surgical guides?
2. What evaluation metrics can be developed and employed to quantify the performance of innovative surgical guides?
3. Can AM be used to solve clinical problems associated with surgical guides?

### **3.8 Summary**

Patient safety is the primary consideration when implementing any new medical intervention, therefore quantifying the cleanliness; accuracy and surface roughness of AM materials were the main focuses of the PhD research. The core elements identified were highlighted due to the current lack of research evidence and aimed to improve on common wisdom on the areas.

## Chapter 4: Methodology

This chapter sets out the research approach, design, methods and data gathering activities deployed to conduct this study. It also explains the rationale for the study selection as supported by the description of the companies/partners in chapter 2. This chapter will describe how the research questions stated in chapter 3 will be answered.

### 4.1 Research Approach

#### 4.1.1 Literature Review Approach

The literature review focussed on three key themes;

1. Patient-specific Surgical Guides
2. AM Materials: Polymer and Metal
3. Characteristics: Accuracy, Roughness and Cleanliness

Understanding of these themes was required to outline the research needed to populate the gap within the literature. In order to gather the appropriate publications for the literature review, stages were followed in order to obtain and source accordingly.

Stage 1 – List the fields of interest within the three key themes identified above.

Stage 2 – Source key textbooks and identify the experts in the field.

Stage 3 – Select appropriate search engines and research databases (Google Scholar, Scopus, Pubmed, ScienceDirect, Emerald).

Stage 4 – Set up a search query within the engines and research databases.

Example of search: *(Maxillofacial OR Surgical OR Guides OR Patient-specific OR Drilling OR Cutting OR Repositioning) AND (Accuracy OR Cleanliness OR Surface-roughness OR AM-Polymer OR AM-Metal) AND ("Rapid Prototyping" OR "RP" OR "AM" OR "CAD/CAM" OR "Rapid Prototyped" OR "Additive Manufacture" OR "Computer Aided Design" OR "Computer Aided Manufacture")*



Stage 5 – Collect relevant research articles and journals, obtain citation and import into Endnote reference organisation software linking the papers to digital PDF's or digital scanned copies.

Stage 6 – Set up email alerts in Google Scholar and Science Direct for newly published articles using the search queries. This safeguarded an up-to-date, continuous literature review throughout the PhD.

#### **4.1.2 Initial observation review**

During the first few months of the PhD the researcher was embedded in both PDR and Morriston Maxillofacial unit to gain initial understanding, observe staff and learn the different procedures. The researcher was in PDR 3-4 days of the week and in Morriston 1-2 days.

The researcher adopted both ethnographic and inductive techniques in order to determine early qualitative 'fact finding' research. Ethnographic techniques involve flexible discovery of what people do, the reasons they give for doing it and make meaning of their worlds (Jonker & Pennink, 2010; Bryman & Bell, 2015).

LeCompte & Schensul (1999) explains '*scientific ethnographic research is conducted in field settings where the researcher enters as an "invited guest" to learn what is going on.*' This worked well for this PhD especially in the clinical setting. LeCompte & Schensul (1999) also explained that '*the basic tools of ethnography use the researcher's eyes and ears as the primary modes for data collection.*' These primary modes alongside the research tools discussed later in this chapter combined and produced rich qualitative data. Ethnographic research suited this early initial review as it was an embedded in-depth study of the staff members involved in the design, production and use of surgical guides.

The inductive research worked well alongside ethnographic techniques. Dorrington (2011) describes inductive theory as '*the outcome of research, i.e. the process of induction involves drawing generalisable inferences out of observations.*' The approach started with initial observations and theories were formulated towards the

end of the research and as a result of the observations. The researcher followed Glaser & Strauss (1967) inductive approach where any recordings were transcribed and combined with the logbook notes. This generated common themes and topics when comparing the different observed case studies.

The theories from the initial observation review coincided with the literature review to help gain both industrial, clinical and publication knowledge, understand the issues and develop the research questions.

#### **4.1.3 Research Questions**

The research questions were divided into three:

1. What are the clinical issues associated with surgical guides?
2. What evaluation metrics can be developed and employed to quantify the performance of innovative surgical guides?
3. Can AM be used to solve clinical problems associated with surgical guides?

#### **4.1.4 Research Aims and Objectives**

The research aim of this PhD is to develop new knowledge and techniques that will help improve clinical procedures through the application of innovative patient-specific surgical cutting, drilling and repositioning guides. Research objectives (shown in section 1.3) were planned based on the guiding research questions, aim and the gaps identified in the knowledge.

The research was structured to address the objectives appropriately:

1. Who, what, where, when and why understanding

Reviewing academic literature, clinical/commercial applications & fabrication methods. Engaging with CARTIS members, identifying areas of concern, problems, opportunities, mapping relationships & surgical developments.

2. Assessment of tools and methodology

Identify what methodology would be appropriate to answer the questions generated in point 1 and evaluate suitable technologies, techniques & pilot studies.

3. Qualitative & quantitative testing

Mixed Method Research (MMR) identified in point 2 was used to test, analyse and validate research through empirical testing and qualitative evaluation.

4. Combine, Correlate and Conclude

Combine quantitative with qualitative results and analyse the impact of findings. Conclude the studies outcomes and recommend avenues for exploration for further collaboration and funding opportunities.

The design of the research methodology includes the processes of observation, classification, measurement and communication. To understand the interdisciplinary needs within the area of patient-specific surgical guides a number of qualitative and quantitative studies were required to observe and classify appropriate design features and fabrication processes. The AM samples would need to be evaluated quantitatively by measuring the physical characteristics; this would fulfil an identified gap in the research.

## 4.2 Methodological choices - Research Design

### 4.2.1 Selection of Research Strategy

#### Quantitative and Qualitative Research

Quantitative and qualitative research is described simply by Shields & Twycross (2003) as: *“Quantitative research usually contains numbers, proportions and statistics.”* And *“qualitative research usually has no measurements or statistics but uses words, descriptions and quotes to explore meaning.”*

Quantitative methods include polls, questionnaires, formal interviews, surveys or by manipulating statistical data using computational techniques. The method uses measurable data to formulate facts and uncover patterns in research.

Creswell (2013) demonstrates that specific methods of quantitative research *“exist in both survey and experimental research that relate to identifying a sample and population, specifying the type of design, collecting and analysing data, presenting the results, making an interpretation, and writing the research in a manner consistent with a survey or experimental study.”*

Qualitative methods vary using unstructured and semi-structured techniques. Methods include focus groups, informal interviews, participation and observations. Sample sizes are small but selected samples are chosen for quality rather than quantity. The research is used to uncover trends in thoughts and opinions, and helps to develop ideas and eliminate problems.

Guests, Namey & Mitchell (2012) explains the advantages of using qualitative *“is the ability to probe into responses or observations as needed and obtain more detailed descriptions and explanations of experiences, behaviours, and beliefs.”*

An example of the difference between quantitative and qualitative research is closed/structured interviews and open/semi-structured interviews.

Closed/structured interview are known as formal interviews. Questions are set before it begins and are followed in a specific order. These interviews take a short amount of time, allow easy repeatability and reliability. Limitations include no further questions can be asked; they are based on closed ended questions and can lack detail.

Open/semi-structured interview are more of a guided conversation or informal. These qualitative interviews are more flexible as questions can be adapted and changed depending on the respondent's answers and timeframe. They allow the respondent to talk in some depth, choosing their own words which results in perceptions and opinions. Limitations of this method are it can be time consuming and the interviewer needs to have the ability to create rapport and knowing when to probe.

To critically analyse the two research strategies the researcher looked at the limitations and advantages of quantitative vs. qualitative. The limitations of qualitative research are: fewer people studied, less easy to generalise, difficult to make systematic comparisons and it is dependent on the skills of the researcher. The advantages of qualitative are: it provides depth and detail, creates openness, simulates people's individual experiences and attempts to avoid pre-judgements. This is why qualitative research strategy was chosen to complete the clinical side of the research and it also fits well to the researcher's strengths and skills.

The limitations of quantitative research are: it can create narrow superficial datasets, the results are limited to numerical and statistical descriptions, the research is carried out in artificial environments with levels of control, answers may not reflect how people really feel just the closest match and development of standard questions can lead to structural bias or false representations. The advantages of quantitative are: it is a broader study, allows greater objectivity and accuracy of results, it is a standard means of research and personal bias can be avoided. This strategy lends itself well to the measurements, geometries and material research needed where statistical analysis is required.

In order to answer the research questions most appropriately each chapter and experimental study needed prioritising to which research strategy (qualitative and quantitative) suited best. Qualitative research describes a research strategy, with quantitative research describing another research strategy. Researchers often choose to follow one research strategy or another. This PhD required the use of both strategies in order to answer the research questions.

The access to clinical and industrial partners splits the research methods into two categories. 'A research method' is simply a technique for collecting data' (Bryman & Bell, 2011). E.g. interviewing, carrying out a survey, or a more lab-based method such as surface roughness testing. The clinical research i.e. observations and informal interviews goes into the qualitative category and the industrial research i.e. measurements and statistical data goes into the quantitative category.

Healthcare and scientific researchers have historically used quantitative methods for their studies in order to identify trends and frequencies. However, a deeper detailed understanding is now required in the health related research giving emphasis on the meaning, experiences and views of the participants (Al-Busandi, 2008).

### **Mixed Method Research**

The development of AM technologies is growing rapidly, but to properly evaluate the application of these technologies in the field of maxillofacial surgical guides, the design requirements must be understood and testing methods must be developed to evaluate part performance. A mixed methods approach was chosen. A mixed methods research approach involved the use of quantitative and qualitative methods.

MMR is defined by Tashakkori & Teddlie (2008) as: *"a type of research design in which qualitative and quantitative approaches are used in types of questions, research methods, data collection and analysis procedures, and/or inferences"*.

Johnson & Onwuegbuzie (2004) and Östlund *et al.* (2011) agree that MMR is not adopted in order to replace either approach but to exploit their combined strengths and to minimise their weakness individually.

MMR is formally defined by Johnson & Onwuegbuzie (2003) as *“research where the researcher mixes or combines quantitative and qualitative research techniques, method approaches, concepts or language into a single study.”* Östlund *et al.* (2011) highlighted that MMR is used within healthcare research and is therefore appropriate for this PhD.

Silver (2014) displays in his What the Fox Knows Manifesto a chart which *“posits a distinction between quantitative versus qualitative approaches on the one hand and rigorous versus anecdotal approaches on the other.”* This chart is shown in figure 8 and shows the differences between the two research areas. The MMR approach is identified in Silver (2014) chart for clinical qualitative research (anecdotal and *ad hoc*) and quantitative research testing (rigorous and empirical).

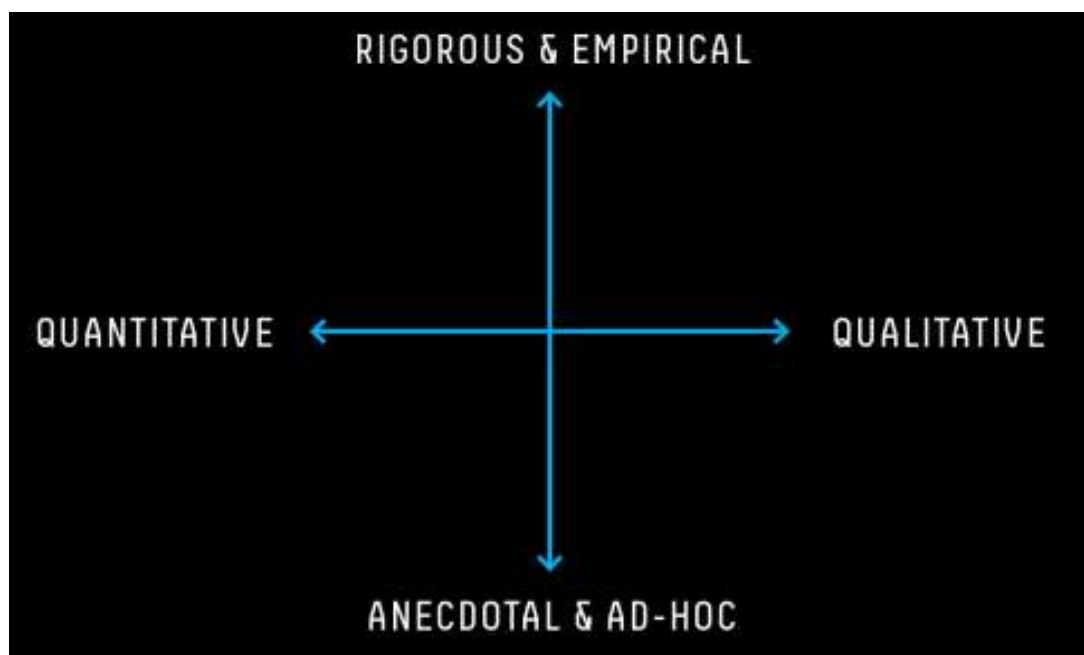


Figure 8 - What the fox knows – Quantitative and qualitative chart

Figure 9 is extracted from the Guest, Namey & Mitchell (2012) book; it shows a useful diagram that explains the appropriate balance needed in research projects.

They explain that the three elements of time, resources and scope need to be planned.

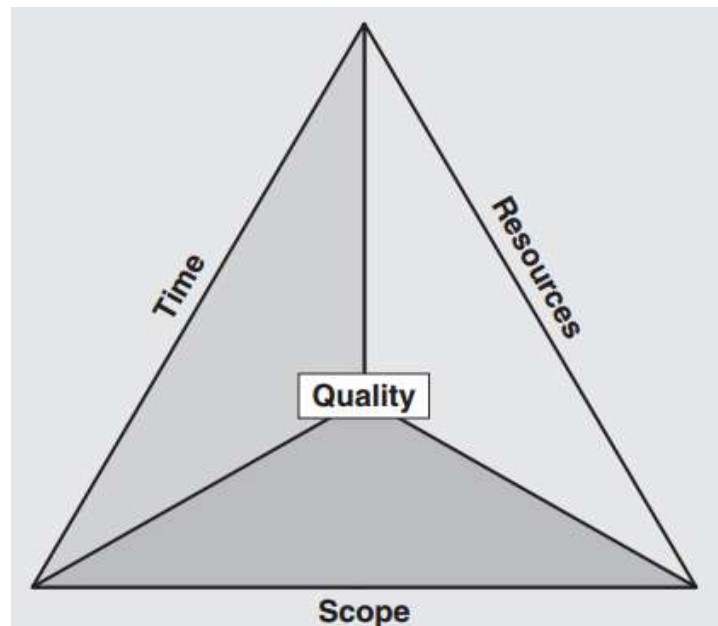


Figure 9 – Balancing Research Scope, Time, and Resources

Figure 10 extracted from the same book explained the structure of the MMR approach and the use of both qualitative and quantitative research; the funnel approach starts broad and gets more specific as the topic develops. The structure of this PhD is explained further in section 4.2.

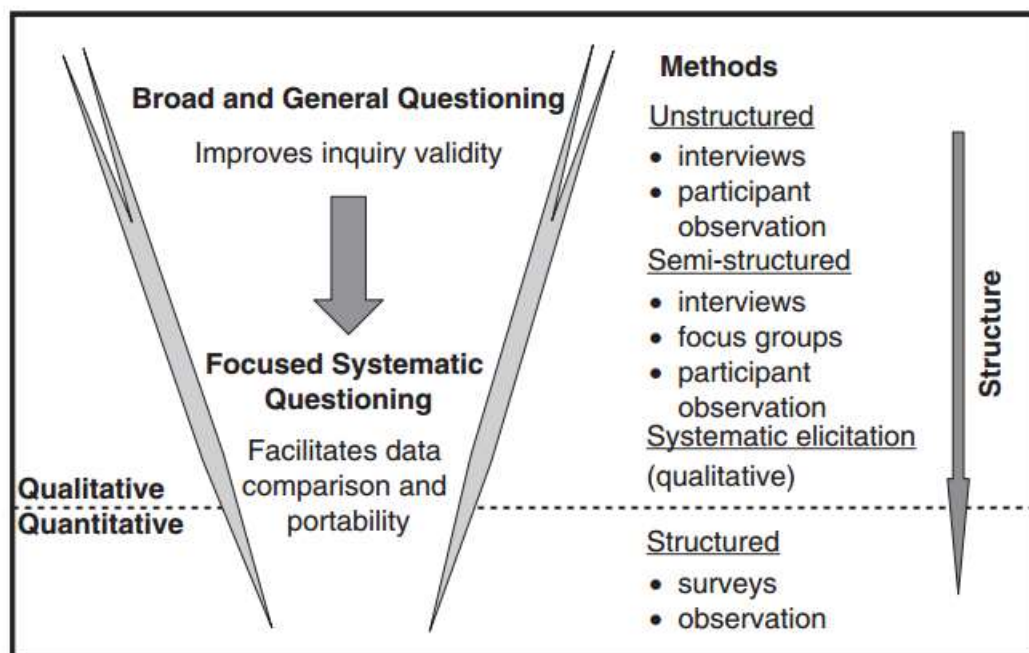


Figure 10 – The Research Process and Degree of Structure



Another structure that came from the Silver (2014) manifesto was a four stage process in which the stages are: collection of data or evidence, organisation, explanation and generalisation. Silver explains that predictions in sciences are poor, however, are made better by repetition or iterations therefore any studies designed for this PhD would have a pilot and core study in order to gain detailed repeatable results.

### **Validity in Mixed Research**

The validity of evaluating MMR can be difficult and can either be quantitative biased or qualitative biased.

However, the MMR approach strengthens today's research practice in order to fully understand '*interdisciplinary, complex and dynamic*' areas and counterbalance the weakness of '*mono-method*' studies (Creswell & Plano Clark, 2011; Teddlie & Tashakkori, 2009; Onwuegbuzie & Leech, 2004; Johnson & Onwuegbuzie, 2004).

This PhD realises the importance of having the MMR; the qualitative research from the clinical exposure available through Morriston Hospital and how this will become a factor throughout; firstly gathering case studies/observations at the beginning through to the clinical feedback towards the end of the study. It will highlight key themes and problems in the clinical part that can then be tested and answered with the quantitative research using the access to the companies/partners test machinery involved in this PhD. Therefore the mix of both methods (quantitative and qualitative) validates the research throughout.

## **4.3 Methodological choices - Research Methods**

### **4.3.1 Research Design Model**

'A research design provides the framework for the collection and analysis of data' (Bryman & Bell, 2011). It reflects the decision the researcher makes about the priority of key parts of the PhD research. The research consists of four phases in order to answer the research questions identified and explore the interdisciplinary areas. The phases were extracted from the DRM, a design research methodology book by Blessing & Chakrabarti (2009) and modified specifically for the research in this PhD.

#### **4.3.1.1 Phase 1 (P1) – Research Classification (Review Based)**

In chapter 2 the research context identifies key themes and early observations. In chapter 3 the literature review highlights what has been previously achieved in the field. Both chapter 2 and 3 help identify gaps in the research, define research avenues and evolve research questions.

#### **4.3.1.2 Phase 2 (P2) – Descriptive Study (I)**

In phase 2; the aim was to answer the research questions through the methodology and research studies. This involved visits to the clinical and industrial partners in order to collate what tools were available for the research studies. With mixed methods studies planned specific tools were chosen to gather the research data.

#### **4.3.1.3 Phase 3 (P3) – Prescriptive Study (Qualitative & Quantitative)**

Phase 3 spans over chapters 5, 6, 7 and 8 with both quantitative and qualitative research and results. This phase takes the research studies and tooling identified in phase 2 and conducts the research. Chapter 5 consists of qualitative research into a number of case studies, chapter 6 consists of quantitative research into nasal guide accuracy, chapter 7 consists of quantitative research into cleanliness and chapter 8 consists of quantitative research into Surface Roughness.

#### **4.3.1.4 Phase 4 (P4) – Descriptive Study (II)**

Phase 4 evaluated the research gathered in the phase 3. Qualitative semi-structured interviews were used in chapter 9 to review the results of the research with the clinical professionals.

The phases provide a model for the overall research design of the PhD shown in figure 11. The figure shows how the research design model fits in to the PhD chapters. Figure 12 shows the chronological project plan for each of the three years of study with focus in year 1 on regulations, ethics, user needs, literature review, product realisation options, coherent research methods, research map and recommendations. Year 2 and 3 focussing on the core chapters; design, manufacture, measure, detailed testing, funding, clinical feedback, impact, future work and findings.

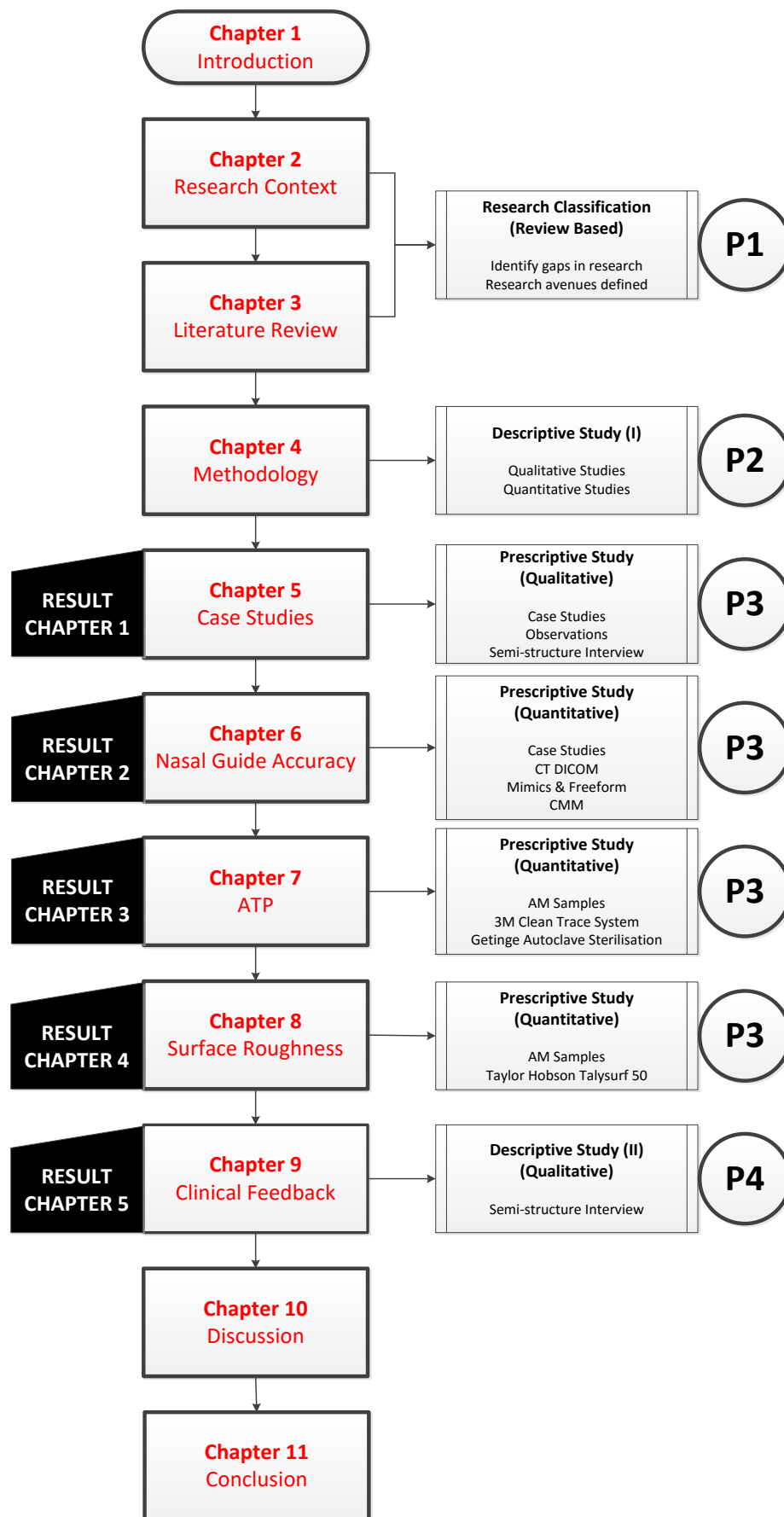


Figure 11 – Research Design Model

Ffion O'Malley PhD Activity 2012-2015												
Researcher Handbook 2012	Months											
	1	2	3	4	5	6	7	8	9	10	11	12
	Dec-12	Jan-13	Feb-13	Mar-13	Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13
Enrolment	x	x										
Research Methods Training	x	x	x	x								
Literature Review	x	x	x	x	x	x	x	x	x	x	x	x
Problem Identification	x	x										
Research Methodology Design			x	x								
Submission for Registration					x	x						
Selection of Research Methods			x	x	x	x						
Identification of Data Sources						x	x					
Equipment Purchasing					x	x	x					
Methods of Calibration						x	x	x	x	x	x	x
Data Collection												
Data Analysis												
Validation												
Writing						x			x			x
Editing												
Final Document												
Soft Binding												
RDC Reports					x							
Sponsor Reports												x
<b>PhD Submissions/Meetings</b>												
Supervisory FORMAL meeting	x			x			x		x		x	
Supervisory INFORMAL meeting	x	x	x	x	x	x	x	x	x	x	x	x
Research Training Review Form		x										
Research Degree Proposal					x							
Annual Monitoring Report										x		
Research Induction Workshop			x									
Effective Researcher Workshop					x							
Skills Week				x								
<b>Research Plan from PhD Application Form</b>												
<b>YEAR 1</b>												
<a href="#">Regulations, Ethics &amp; User Needs (Phase 1)</a>	x	x	x	x	x	x						
<a href="#">Clinical Literature Review (Phase 2)</a>	x	x	x	x	x	x	x	x	x			
<a href="#">Product Realisation Options (Phase 3)</a>			x	x	x	x	x	x	x	x	x	x
<a href="#">Coherent Research Methods (Phase 4)</a>						x	x	x	x	x		
<a href="#">Research Map &amp; Recommendations (Phase 5)</a>							x	x	x	x	x	x
<b>YEAR 2 &amp; 3</b>												
<a href="#">Design, Manufacture &amp; Measure (Phase 6)</a>												
<a href="#">Detailed Testing &amp; Clinical Validation (Phase 7)</a>												
<a href="#">Clinical Feedback &amp; Impact (Phase 8)</a>												
<a href="#">Future Work &amp; Funding (Phase 9)</a>												

Researcher Handbook 2012	Months											
	13	14	15	16	17	18	19	20	21	22	23	24
	Dec-13	Jan-14	Feb-14	Mar-14	Apr-14	May-14	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14
Enrolment												
Research Methods Training												
Literature Review	x	x	x	x	x	x	x	x	x	x	x	x
Problem Identification												
Research Methodology Design												
Submission for Registration												
Selection of Research Methods												
Identification of Data Sources												
Equipment Purchasing												
Methods of Calibration	x											
Data Collection		x	x	x	x	x	x	x	x	x	x	
Data Analysis						x	x	x	x	x	x	x
Validation												x
Writing			x			x			x			x
Editing												
Final Document												
Soft Binding												
RDC Reports	x											
Sponsor Reports												x
<b>PhD Submissions/Meetings</b>												
Supervisory FORMAL meeting	x			x			x			x		
Supervisory INFORMAL meeting	x	x	x	x	x	x	x	x	x	x	x	x
Research Training Review Form												
Research Degree Proposal												
Annual Monitoring Report										x		
Research Induction Workshop												
Effective Researcher Workshop												
Skills Week												
<b>Research Plan from PhD Application Form</b>												
<b>YEAR 1</b>												
Regulations, Ethics & User Needs (Phase 1)												
Clinical Literature Review (Phase 2)												
Product Realisation Options (Phase 3)												
Coherent Research Methods (Phase 4)												
Research Map & Recommendations (Phase 5)												
<b>YEAR 2 &amp; 3</b>												
Design, Manufacture & Measure (Phase 6)	x	x	x	x	x	x	x	x	x	x	x	x
Detailed Testing & Clinical Validation (Phase 7)				x	x	x	x	x	x	x	x	x
Clinical Feedback & Impact (Phase 8)												
Future Work & Funding (Phase 9)												



Figure 12 – Year 1, 2 & 3 project plan in chronological order

## 4.3.2 Data Collection Methods

### 4.3.2.1 Qualitative Tools

#### 4.3.2.1.1 Companies and Partner Visits

The companies and partners this PhD has been given access to have been important in the research and development of the study. The first year of the PhD primarily involved observing digital planning at PDR and Morriston Hospital, the fabrication of AM surgical parts at PDR and Renishaw, the process of the surgical part including sterilisation, the use of the parts in the operating theatre and the post-operative care of the patient. Recordings were made along with notes in various logbooks, photographs and a database of the digital plans of cases observed. Figure 13 highlights the CARTIS group and the external companies that they work with.

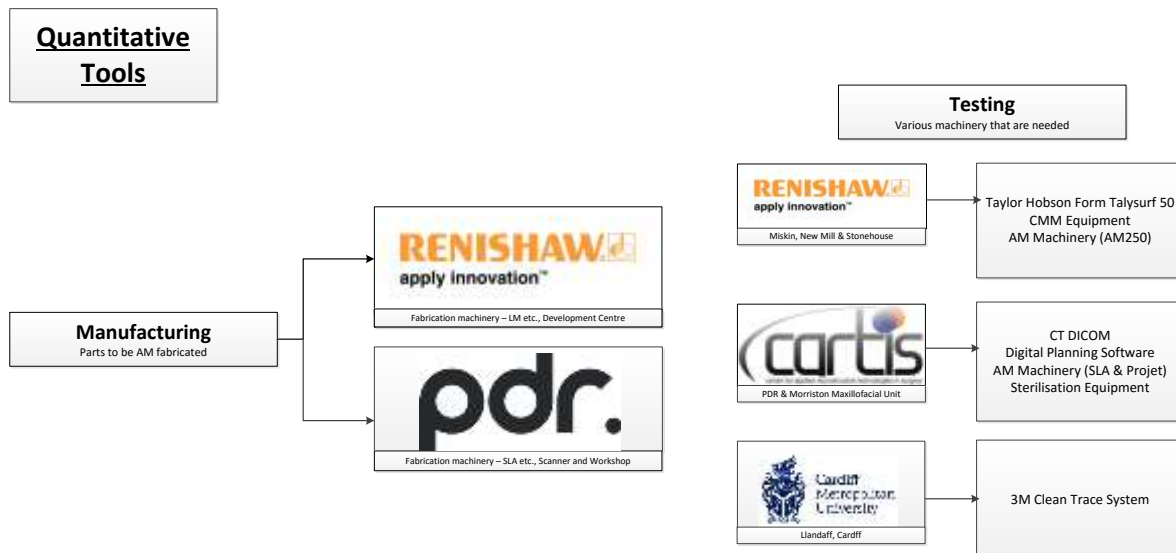


Figure 13 – Quantitative Tools

#### 4.3.2.1.2 Desk Research

The desk research conducted was primarily the literature review but also included background research of the companies, machinery used and research methods.

#### 4.3.2.1.3 Semi-Structured Interviews

Semi-structured interviews are open, allowing new ideas to be brought up during the interview as a result of what the interviewee says. The interviewer in a semi-structured interview generally has a framework of themes to be explored.

Four key themes were explored to ensure consistency of each interview:

Key theme 1 - The creation of a checklist that was followed for each interview e.g. for the case studies each stage of the process was a checklist – receiving patient scan data, digital design of surgical guide, fabrication of surgical guide and surgical use of guide.

Key theme 2 - The outlined expectations of interview candidates was already fulfilled due to the access to PDR and NHS staff.

Key theme 3 - The categorising of the specifics of each case study e.g. operation type, surgical procedure, performing surgeon, surgical guides required, chosen materials, geometries, AM fabrication technique and how the guides performed in surgery.

Key theme 4 - The interviews were recorded using phone, laptop or dictaphone and extensive notes made in logbooks. Transcripts were typed of the interviews for analysis and review. A case study data sheet was generated for each case from the recordings and notes taken in logbooks throughout the process.

Due to the busy nature NHS departments and difficulties in gaining one-to-one access to surgeons there was a need to interview in an 'ad hoc' fashion. These were carried out using 'what', 'how' and 'why' style questions (Saunders *et al.*, 2009), a flexible working approach (Bryman & Bell, 2015) and open ended interviewing techniques (Silverman, 2006). When it was convenient to gain access these techniques provided the opportunity to conduct semi-structured interviews whilst digital planning or within the operating theatre. Dorrington (2011) explained that '*the use of a semi-structured approach offers the opportunity to triangulate the data from a range of cross-field participants in order to support reliability and validity.*'

The time of the clinical team is precious therefore being embedded in the hospital resolved the pressure of booking in meetings. This is the reason why open ended interviewing techniques and convenience sampling were chosen as the most appropriate.

#### **4.3.2.1.4 Case Studies**

Yin (2003) describes case studies as '*a study that investigates a contemporary phenomenon in depths and in its real-world context*'. A 'case' is '*the main subject of study in a case study – usually a concrete entity (e.g. a person, organization, community, program, process)*'. For this PhD thesis the cases are the patients.



The access to the maxillofacial unit allowed observations of cases through the whole patient journey from presenting disorder to post-operative care. The key areas of the case studies to this PhD was the presenting complaint, digital planning meetings with the team, design of the surgical guides and implants, fabrication of the AM parts, sterilisation of the parts, surgical use in the operating theatre and post-operative analysis of the fixed position of the implants.

Yin (2003) also describes case studies as an '*empirical inquiry*' that questions the '*why*' and '*how*', this was important to this PhD as it provided hidden rich data that would not be found without these qualitative strategies and the access to the clinicians.

As stated in section 4.3.2.1.3, four key themes were explored through semi-structured interviews and observations (qualitative research) in order to gather the appropriate information from each case study. Once the specific data was gathered a case study data sheet was generated from the notes and the transcribed recordings.

#### **4.3.2.2 Quantitative Tools**

Figure 11 highlights the location of the quantitative tools and the resources associated with each.

##### **4.3.2.2.1 AM Samples**

AM represented a spectrum of potentially suitable materials for guide production, the materials were chosen and sourced from appropriate suppliers. Material samples were sourced from four different sources; PDR which have SLA and Projet, Renishaw Plc. which have the ability to LM in metal, Loughborough University which have Objet and Select Laser Sintering (SLS) and Southern General Hospital, Glasgow which have an Objet AM machine.

#### 4.3.2.2.2 3M Clean-Trace System (Luminometer and Swabs)

ATP bioluminescence technology is a rapid, user-friendly method of quantifying surface cleanliness that has been employed to evaluate contamination of a wide range of instruments and surfaces (Fushimi *et al.*, 2013; Sherlock *et al.*, 2009; Ali *et al.*, 2012; Griffiths *et al.*, 2000; Luo *et al.*, 2009; Griffiths *et al.*, 2003; Cherry *et al.*, 2015; Alfa *et al.*, 2015; Aycicek *et al.*, 2006; Boyce *et al.*, 2009; Park *et al.*, 2014; Amodio *et al.*, 2014; Fernando *et al.*, 2014).

The ATP bioluminescence test employed for this PhD was the 3M Clean-Trace system ([www.3M.com/3M/en\\_US/company-us/all-3m-products/?N=5002385+8711017+8711099+8711106+3294857497&rt=r3](http://www.3M.com/3M/en_US/company-us/all-3m-products/?N=5002385+8711017+8711099+8711106+3294857497&rt=r3)). This testing system was sourced from Cardiff Metropolitan University School of Health Sciences. The procedure starts by taking the test swab and applying it to the surfaces to be evaluated. The swab is gently rotated as it is swept across the test area. The swab is then immediately placed in a cylindrical vial, which brings it into contact with the enzyme solution (luciferin-luciferase) and the enzyme reacts with any ATP residue on the swab. The cylindrical vial is then placed in a hand-held 3M luminometer, and the light generated from the bioluminescence reaction is captured, and the measurement is expressed in Relative Light Units (RLUs). The greater the level of ATP present on the swab, the higher the RLU reading produced. The test can be performed in less than 30 seconds, providing a real-time indication of the cleanliness of the surface tested. The swab and enzyme solution are disposed of after each test reading.

#### 4.3.2.2.3 Getinge Autoclave Sterilisation

Getinge autoclave (<http://www.getinge.com/healthcare/products/sterilization/steam-sterilizers/getinge-hs69-series/>) was chosen as it complies with medical standards and is representative of the most common method of sterilisation used in hospitals around the world. The temperature of the Getinge autoclave cycle reaches 134°C. The source of this autoclave is based within the Hospital Sterilisation and Decontamination Unit (HSDU) department in Morriston Hospital.

#### **4.3.2.2.4 CT DICOM**

The patient case studies in this PhD were selected from Morriston Hospital and the CT machine they use at the hospital for the Maxillofacial Unit is a Toshiba One Aquilion (<http://www.toshiba-medical.eu/eu/product-solutions/computed-tomography/aquilion-one/>). The settings of slice thickness for each patient case differ depending on what the consultant and radiographer choose.

#### **4.3.2.2.5 Mimics Software**

Mimics (<http://biomedical.materialise.com/mimics>) is medical image processing software, it can be used for the thresholding and segmentation of 3D medical images from CT, CBCT or MRI DICOM data. This results in a highly accurate 3D model of the patient's anatomy with sagittal, coronal and axial views. This software is used in PDR and Morriston Hospital.

#### **4.3.2.2.6 Freeform Software**

Freeform (<http://www.geomagic.com/en/products/freeform/overview/>) is a design platform that can create complex, sculptural and production ready 3D models or parts and prepare them for AM fabrication. This software is used in PDR and Morriston Hospital.

#### **4.3.2.2.7 Coordinate Measurement Machine (CMM)**

The source of the CMM is Renishaw Plc. The CMM access provided is to the PH20 5-axis touch trigger system (<http://www.renishaw.com/en/ph20-5-axis-touch-trigger-system--12487>). The equipment was used to analyse the build accuracy of AM materials. The PH20 was chosen as the most appropriate CMM to use for its precision measurement capabilities.

#### **4.3.2.2.8 Taylor Hobson Form Talysurf 50**

The source of the Taylor Hobson Form Talysurf 50 (<http://www.taylor-hobson.com/products/14/107.html>) equipment is Renishaw plc. The equipment was used to analyse the surface roughness or Ra values of the different materials. The data length of the Taylor Hobson Form Talysurf 50 machine was set at 10mm, run length set at 0.3mm and speed set at 0.5mm/s.

### 4.3.3 Data Analysis

#### 4.3.3.1 Microsoft Excel

Excel was used to document and analysis the quantitative data gathered from the research. Statistics in the software will be used to create graphs to portray the results appropriately.

#### 4.3.3.2 SPSS

SPSS was also used to document and analysis the quantitative data gathered from the research. The program can compare results highlighted in Microsoft Excel to judge if they need further statistical analysis or whether Microsoft Excel is appropriate for the specific studies.

#### 4.3.3.3 Sample size

Sample size differs across the core results chapters. In chapter 5 the sample size depended on access to the operations that took place during the qualitative research phase in year 1 and 2. Focus was given only to maxillofacial surgeries that were using AM surgical guides to reduce the number of variables; there are only a handful of these specialist surgeons in the UK. Operations mostly took place at Morriston Hospital with only a couple at University of Wales Hospital, Cardiff. In chapter 6, 7 and 8 the sample size was dependant on the quantitative studies. As explained in the choice of research methods the qualitative clinical research provided rich, focussed data, which although it did not generalised across a population the small sample sizes were '*purposive sampling*'. Dorrington (2011) refers to '*purposive sampling*' as '*the interactive process carried out by a researcher when directing their data generation, analysis, theory and sampling activities.*' This sampling method compliments the PhD study due to the researcher's clinical access, qualitative strategy and sample size.

## **4.4 Perception and Bias**

### **4.4.1 Clinical and Industrial Perception**

The opinions and perceptions of the different partners provide clinical and industrial insight into the research. The PhD crosses over both clinical and industrial expertise in which each partner specialises in great depth.

### **4.4.2 Research Bias**

At key stages throughout the study the research has involved playing an active and integrated role specifically at PDR and Morriston Hospital. However, the research has been conducted in a professional and diligent manner, where logbooks have been maintained. Sampling bias may occur because the research clinical access was dealing with clinicians who commission AM surgical guides.

## **4.5 Research Novelty, Validity and Reliability**

Given the context of access to leading technology and clinicians, this research evaluates AM technologies and provides qualitative and quantitative guidance on which would be most appropriate for patient-specific surgical guides. The surgical & clinical approach (qualitative research) would inform the development of technical specifications for surgical guides.

## **4.6 Ethics**

The PhD study involves NHS staff at various stages of the research through semi-structured interviews, observations and digital planning. By having an honorary contract granted with the ABMU health board this made sure all checks (D&B (originally CRB) and bloods) had been completed so that access could be gained within the hospital (please refer to appendix III for honorary contract agreement request form and NHS ABMU identification card).

When conducting the research within ABMU the hospital's data protection and confidentiality policy (please refer to appendix III for sections 3.1 and 3.2 of the policy) had to be adhered to under the honorary contract granted. As an additional protocol to each case study included in this thesis each patient was asked to fill out the department of medical illustration form for consent of photographs to be used for medical publication, health records, research and training database. All of the patient's forms (except case study B section 5.2.2) were signed, collected and stored in the patient hospital folder but a blank copy is shown in appendices III. This is why no operation imagery was present for case study B.

The ethical implications were considered and ethical approval was sought from Cardiff Metropolitan University Ethics Committee (please refer to appendix III for ethics form). The studies are concerned with collecting opinions and information about the design process only, meaning the data collected was non-personal, non-confidential and non-sensitive. Therefore the research has no ethical implications regarding confidentiality or impact on working practices for the participants. The School Ethics Committee granted ethical approval and further ethical reviews were not required.

## **4.7 Risk Assessment**

### **4.7.1 Risk: Resources**

Steps to reduce the risk: Risks associated were getting access to the relevant people and machinery at the time of need due to schedule, workload or limited access. To avoid this affecting the timescale of the PhD other resources were identified so that resources were not totally dependent on one place or person.

### **4.7.2 Risk: Limited access to case study data**

Steps to reduce the risk: Clinical secure location in Surgical & Prosthetic Design at PDR. They have been collaborating with the Maxillofacial Unit at Morriston Hospital, Swansea and other hospitals for over 10 years and have wide access to patient cohort.

#### **4.7.3 Risk: Experimental design solution affecting a person clinically**

Steps to reduce risk: All potential design solutions/outputs deemed suitable for clinical use were subject to design verification and sign off by the prescribing clinician in accordance with the standard procedures of PDR's Surgical & Prosthetic Design team.

#### **4.8 Summary**

This chapter has highlighted the structure, resources and specific areas required to complete this PhD to an appropriate, rigorous and suitable standard. External resources were an important part to the research for both the quantitative and qualitative elements; specific staff members and test machines have been highlighted in each place for when the studies commence so no delays occurred. The mixed method research was key to this interdisciplinary study to gain high quality clinical research with data driven statistical results. The validity of this research method crossing over the healthcare and engineering sectors seems to be most suited.

# Chapter 5: Case Studies

## 5.1 Clinical Research

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This chapter will demonstrate the qualitative data generated by observing a series of maxillofacial case studies from the start of planning to final surgical output. Twenty case studies as shown in figure 14 and 15 were selected and followed to gather a clinical understanding on the application of AM surgical guides to each. The clinical research recorded the needs perceived by medical specialists involved with the specification, design and application of surgical guides. The procedure type, location of operation and surgeon/registrar that performed the surgery is shown in table 3.













No.	Area	Background	Operation	Surgical Guides / Implants	Materials	Dimensions	Comments
1		Cancer	Rhinectomy	Left and right AM surgical guides Left and right Branemark implants	SLA Clear jacket with stainless steel tube inserts	To fit a Branemark 2.9mm pilot drill, Left and right drill cylinder length 5mm	Surgical Guide - SLA Clear with stainless steel tube inserts Nasal and neck dissection completed. Branemark zygomatic implants placed into bone after SLA guides were used to drill the implants pathway.
2		Cancer	Rhinectomy	Left and right AM surgical guides Left and right Branemark implants	SLA Clear jacket with stainless steel tube inserts	To fit a Branemark 2.9mm pilot drill, Left and right drill cylinder length 8.5mm	Surgical Guide - SLA Clear with stainless steel tube inserts Nasal and neck dissection completed. Branemark zygomatic implants placed into bone after SLA guides were used to drill the implants pathway.
3		Cancer	Rhinectomy	Left and right AM surgical guides Left and right Branemark implants	SLA Clear jacket with stainless steel tube inserts	To fit a Branemark 2.9mm pilot drill, Left = 10mm and right = 8mm drill cylinder length	Surgical Guide - SLA Clear with stainless steel tube inserts Nasal and neck dissection completed. Branemark zygomatic implants placed into bone after SLA guides were used to drill the implants pathway.
4		Cancer	Rhinectomy	Left and right AM surgical guides Left and right Branemark implants	SLA Clear jacket with stainless steel tube inserts	To fit a Branemark 2.9mm pilot drill, Left and right drill cylinder length 8mm	Surgical Guide - SLA Clear with stainless steel tube inserts Nasal and neck dissection completed. Branemark zygomatic implants placed into bone after SLA guides were used to drill the implants pathway.
5		Cancer	Rhinectomy	Left and right AM surgical guides Left and right Branemark implants	SLA Clear jacket with stainless steel tube inserts	To fit a Branemark 2.9mm pilot drill, Left and right drill cylinder length 10mm	Surgical Guide - SLA Clear with stainless steel tube inserts Nasal and neck dissection completed. Branemark zygomatic implants placed into bone after SLA guides were used to drill the implants pathway.
6		Cancer	Rhinectomy	Left and right AM surgical guides Left and right Branemark implants	SLA Clear jacket with stainless steel tube inserts (* test AM cobalt chrome version)	To fit a Branemark 2.9mm pilot drill, Left = 8mm and right = 9mm drill cylinder length	Surgical Guide - SLA Clear with stainless steel tube inserts Test Guide - AM cobalt chrome with left = 6.5mm and right = 7.5mm drill cylinder length. Nasal and neck dissection completed. Metal surgical guide tried onto the nasal bone but the tolerance and material choice was too tight and offered no flexibility on the bone. Branemark zygomatic implants placed into bone after SLA guides were used to drill the implants pathway.
7		Cancer	Ear Implant Surgery	Right AM surgical drill guide Cochlear implants top and bottom	SLA Clear	2.0mm thick	SLA Clear surgical guide was mobile on the bone due to the mucosa and blood on the mastoid area. Once located the guide was held in place by the surgeon and the drill holes were marked with surgical dye in order to drill in the correct planned location.
8		Burn Defect	Ear Implant Surgery	Left AM surgical drill guide Cochlear implants top and bottom	SLA Clear (* test AM cobalt chrome version)	SLA Clear 3.0mm thick Cobalt Chrome 0.5mm thick	Surgical Guide - SLA Clear & Test Guide - AM cobalt chrome SLA guide used as a reference on the medical model of the patient. The AM cobalt chrome guide was used on the bone, it located and gripped to the contact area well with the mucosa and blood on the surface not an issue. The guide was used to mark the area and drill in the correct planned location.
9		Burn Defect	Ear Implant Surgery	Right AM surgical drill guide Cochlear implants top and bottom	AM Cobalt Chrome	Cobalt Chrome 0.5mm thick	The AM cobalt chrome guide was used on the bone, it located and gripped to the contact area well. The material offered good friction on the bony area with the mucosa and blood on the surface not an issue. The guide was used to mark the area and drill in the correct planned location. (Video available of the guide being used).
10		Burn Defect	Ear Implant Surgery	Left and right AM surgical skin guide Cochlear implants top and bottom	SLA Clear skin guide and AM cobalt chrome drill guide	SLA Clear L & R 1.0mm thick Cobalt Chrome L & R 0.5mm thick	The SLA Clear surgical guide used on the skin of the patient in order to mark the outline of the incision to locate the small area correctly and reduce scarring due to the patient being very young. Once the incision area was marked the patient was opened up and the AM cobalt chrome guide was placed into the mastoid area. The guide was held in place by the surgeon and the drill holes were marked with surgical dye in order to drill in the correct planned location.

Figure 14 – Case studies 1 to 10 demonstrating the different operations observed with details on the area, background, operation, surgical guide/implant, materials, dimensions and comments of the case.











No.	Area	Background	Operation	Surgical Guides / Implants	Materials	Dimensions	Comments
11		Trauma	Zygomatic Osteotomy	Cutting and repositioning guide Zygomatic and orbital floor implant	Both guides: AM cobalt chrome Both implants: AM Titanium 64	Thickness: CG = 2.5mm RG = 2.5mm ZI = 0.7mm OFI = 0.5mm	Successful operation.  Use of all guides and implants in the operating theatre. Metal guides offered the rigidity needed to reposition and hold the osteotomised bone in the correct place.
12		Trauma	Zygomatic Osteotomy	Repositioning guide Zygomatic, orbital rim and two orbital floor implants	Guide: Trad DensSupply light cure resin All implants: AM Titanium 64	Thickness: ORI = 1.2mm ZI = 1.3mm OFI1 = 0.4mm OFI2 = 0.4mm	Conventional and digitally designed implants made for the surgery. A mix of the both types were used due to the surgeon dropping the AM zygomatic implant on the floor. Zygomatic implant did not have enough surface area on the bone, the orbital floor was tricky to get into the correct location and digitally designed surgical guides would have been brilliant.
13		Birth Defect	Mandible Distraction Osteogenesis	Cutting guide Fusion of a Synthes mandible Distractor	SLA Clear for guide Titanium Alloy for distractor	Guide: 1.5mm thick Distractor available in 20mm and 30mm lengths	Distractor placed onto mandible in order to help the bone growth in new planned position for the patient.
14		Cancer	Mandibular Fibula Flap	Mandible and fibula cutting guides. Synthes pre-bent plate on reconstructed medical model	SLA Clear for guide Synthes titanium plate for implant	Guides: 1.8mm and 2.0mm thick	Removal of cancerous area in the mandible by using a cutting guide in order to gain the correct cut angle and location of the bone. Another cutting guide was used on the fibula to gain new bone for the vacant mandible area. The Synthes implant is fixed onto the new bone and blood supply connected.
15		Cancer	Tumour Ext. & Reconstruction	Cranio and two orbital floor implants.	All implants: AM Titanium 64	Thickness: CI = 0.6mm OFI1 = 0.5mm OFI2 = 0.5mm	Removal of cancerous area in the cranio. Cut template surgical guide needed for cranio surgery. Cranio implant successfully placed in the defect area and the top of the orbital implant plates. The first implant was not used due to swelling and access to the area. Suggested changes included a gap needed between two orbital plates and cut template guide needed for removal of cancerous area.
16		Blocked Sinus	Osteoplastic Frontal Sinus Exploration	Sinus cut template guide. Synthes fixation plates.	SLA Clear for guide Synthes titanium plate for implant	Guide: 2.0mm thick Synthes plates: 0.8mm thick	Cut template guide used on the frontal bone to mark out where the extents of the sinus were and where to cut into the skull to drain the sinus area. The Synthes plates were used to fixate the cut bone back into its original place in the anatomy.
17		Hemifacial Hypo Atrophy	Bone Reduction	Reduction template guide	SLA Clear for guide	Guide: 2.0mm thick	Reduction template guide was used to get the bony effected side of the patients anatomy reduced down to the normal side of the face using tools and burrs in the medical tool kit available in the operating theatre.
18		Cancer	Maxillectomy	Maxilla framework template	AM Titanium 64 for implant	1.3mm thick	Successful removal of cancerous maxilla. Fibula flap cut in three pieces to fit into the maxilla framework template. Once the bone has been fixated onto the maxilla framework, the blood supply to those bone were connected.
19		Trauma	Fracture Reduction	Medical model and Synthes plates	SLA Clear for medical model Synthes titanium plate for implant	Synthes plates: 0.4mm to 0.8mm thick	Motorcycle accident trauma victim first surgery was performed quickly after accident due to the vast amounts of bone fragments loose in the frontal region of face. The reconstructed medical model was used as an anatomy guide to the loose fragments in order to piece the bones together to gain a better anatomy structure using various Synthes plates.
20		Trauma	Alloplastic Reconstruction	Two part custom made orbital floor implants	Commercially pure titanium	0.25mm thick	Reconstruction of the patients orbital floor using plates that were custom made in the maxillofacial lab by the clinical team. The two part plate was formed using a reconstructed medical model and used three divots to connect the two plates together in the orbit area.

Figure 15 – Case studies 11 to 20 demonstrating the different operations observed with details on the area, background, operation, surgical guide/implant, materials, dimensions and comments of the case.

Type	Location	Surgeon 1	Surgeon 2	Surgeon 3	Surgeon 4	Surgeon 5	Registrar 1	Registrar 2
Rhinectomy	MORI	4					2	
Implant s (Ear)	MORI		4					
Osteotomy	MORI		1					1
Distraction	MORI		1					
Tumour removal	UHW			1				
Reconstruction	UHW			1		1		
Sinus Exploration	MORI				1			
Maxillectomy	MORI	1						
Fibula Flap	MORI					1		
Trauma	MORI					1		

Table 3 – Type of surgical procedure conducted in the twenty case studies specifying the location of the hospital and the variety of surgeons that conducted each case.

The two highest volume areas that use surgical guides at Morriston hospital are for auricular and nasal prostheses as shown highly populating the case study tables. Depending on whether the surgical guide is used for cancer, trauma or birth defect cases they are sometimes required urgently. The AM polymer option is used for speed, the AM metal option does not have as quick of a turnaround but both materials can be used as shown in the case study tables.

Key features of a surgical guide are accuracy, location of fixation and visible markings on the surface. Another area that will be shown in this chapter is surgical guides in the future may need to become both patient and surgeon specific.

Seven of the twenty case studies were selected to explain in detail the observations, opinions and perceptions witnessed through the qualitative clinical research (Figure 16). The seven cases will highlight the patient and surgeon specific detail and specific method behind each. All SLA guides were fabricated at PDR and LM guides and implants were designed at PDR but fabricated at Renishaw.



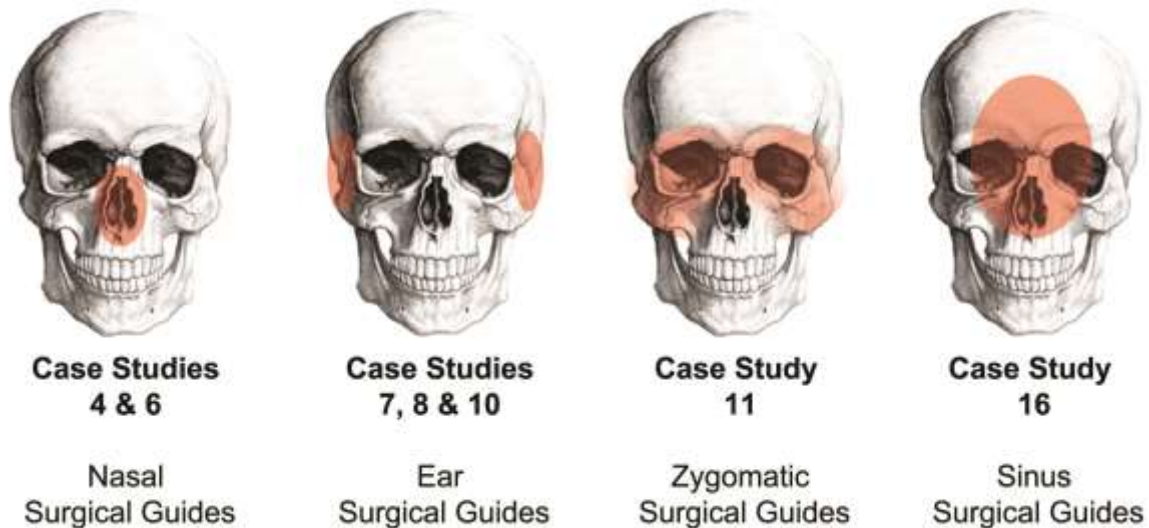


Figure 16 – The detailed case studies and areas that are going to be focussed on looking at the use of the surgical guides and the observations witnessed at the surgery.

## 5.2 Clinical Case Studies - Observations, Opinions & Perceptions

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### 5.2.1 Case Study A (4)

#### **Background & Surgical Guide Design**

Case Study A (4) was booked in for a rhinectomy operation which involved the surgical removal of the nose due to malignant cancer of the area. This operation usually includes a neck dissection of the lymph glands. Cancer surgery cases usually gain priority over trauma or reconstructive cases.

Common pathway for a cancer victim is:

1. Removal of tumour from specific area
2. Whilst in operation the implants are fixated into the bone
3. Radiotherapy or Chemotherapy treatment is then started after healing from operation

The implants have more of a chance for survival due to the bone density and blood flow prior to the start of the treatment. Usual timings from placing implants for the prosthesis to fitting the final prosthesis take six weeks. The nasal surgical guides designed and used at Morriston Hospital are an SLA Clear guide that locates onto the nasal bone. The drill part of the guide had a cylinder which was angled to the planned digital location of the best bone pathway for the Brånemark (the most scientifically documented implant system) zygomatic implants. For this case, stainless steel tube inserts were used and placed into the inner diameter of the drill cylinder in order to improve strength when drilling the area. Drilling guides use stainless steel tube inserts to stop plastic bits wearing away from the guide and getting into the blood stream. Two guides were used, one to place the left zygomatic implant and a separate one to place the right (Figure 17).

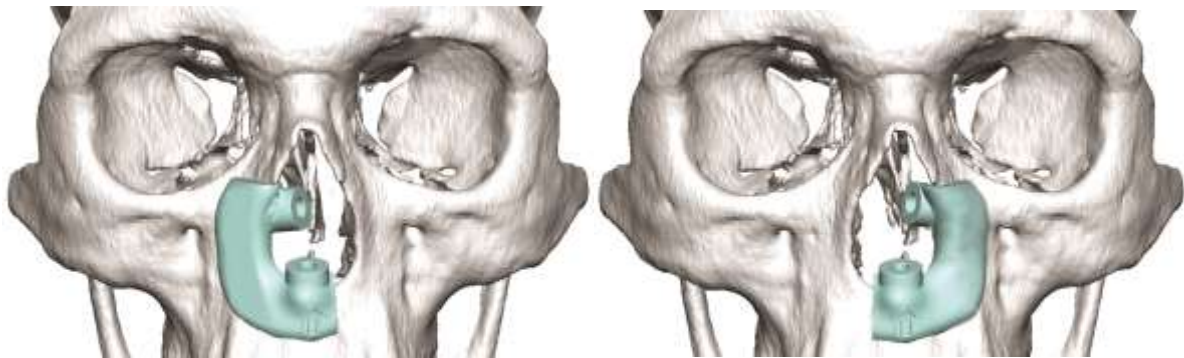


Figure 17 – Case study A (4) shows the imagery of the left and right nasal surgical guides that was digitally planned and designed for this patient's surgery. Both guides were SLA Clear with stainless steel tube inserts in each of the drill cylinders.

## Operation Images



Figure 18 – Neck dissection and nasal removal of Case Study A.

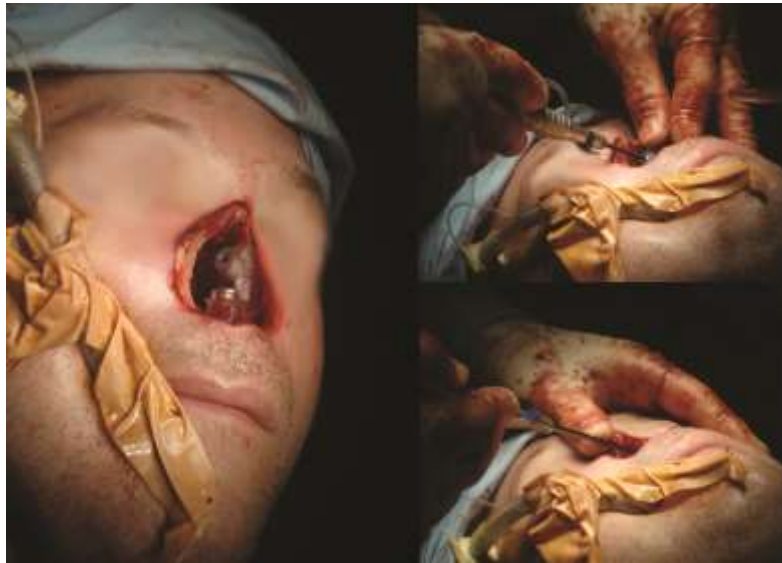


Figure 19 – Use of left hand side nasal surgical guide for the Brånemark pilot drill to drill the planned pathway of the digitally designed guide.

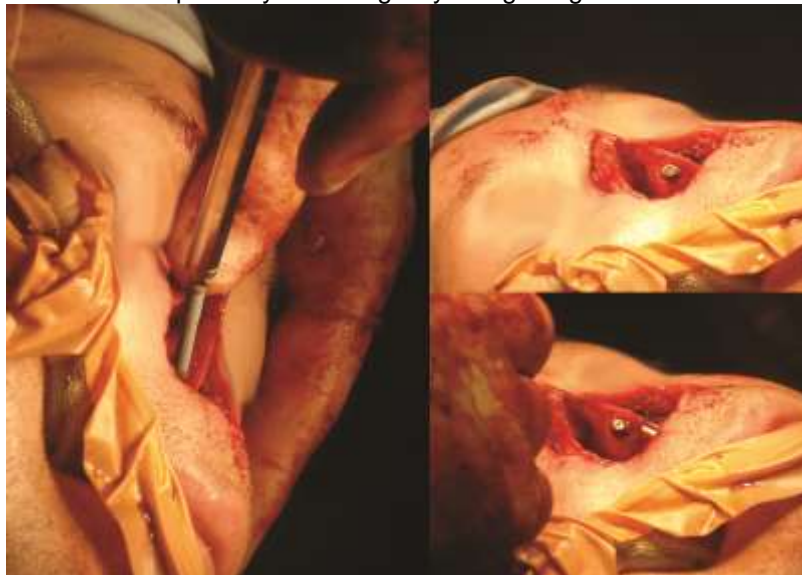


Figure 20 – Fixation of the left hand side zygomatic Brånemark implants into the bone.



Figure 21 – Use of right hand side nasal surgical guide for the Brånemark pilot drill to drill the planned pathway of the digitally designed guide. Fixation of right hand side zygomatic Brånemark implant into the bone.

### **Observations & Surgical Notes**

Notes and quotes gathered from the planning and surgical stages of this case study:

“Digital planning gives an inexperienced surgeon the skills an experienced surgeon has.”

“Before it was guess work, but with digital planning the surgeon knows how much of an area they have either side to fixate on good bone.”

“There’s no point surgical planning the positioning of implants if there is no surgical guide to assure the accuracy of location fit.”

“The metal inserts in the SLA guides can bind on the drill if the tolerance is too tight, this causes heat distortion and the insert becomes removed from the drill cylinder onto the drill. This is dangerous as the metal insert could easily fall into the patients airways.”

This case associated that surgical guides help to reduce the problems with surgeon experience levels, exchanging guesswork into planning and with the accuracy of the implant placement. Although the surgical guides are a positive tool to have in theatre the problems of the inserts coming away from the drill cylinder is a concern.

Therefore standardised lengths, tolerances and fixed diameters are needed.



### **5.2.2. Case Study B (6)**

#### **Background & Surgical Guide Design**

Case Study B (6) was booked in for a Rhinectomy operation which involves the surgical removal of the nose due to malignant cancer of the area. This operation includes a neck dissection of the lymph glands. As explained in case study A (4) the same pathway, timings and degree of difference was applied to this case study.

Current drill guides have large movement in the drill cylinder due to having no fixed tolerance. If the tolerance is too large then the drill pathway will become loose and inaccurate to the digital plan. If the tolerance is too small the insert will bind onto the drill and will create the problem identified in case study A (4). Tolerance is an important aspect for the drill surgical guide because if it is drilled on a wrong angle/direction or area it can result in damage to brain, orbit or sinus.

For this case two examples of nasal surgical guides were planned, one example being the SLA Clear guide with the stainless steel tube inserts and the second being a laser melting (LM) additive manufactured Cobalt Chrome guide. This nasal surgical guide case was fabricated using Cobalt Chrome. The clinical team deemed the AM metal as a better material to use, they preferred the material as it can be designed thinner due to the higher material strength and resistance to distortions during autoclave sterilisation.

Both types of surgical guide needed to locate onto the nasal bone with the drill part of the guide angled to the planned digital location of the best bone pathway for the Brånemark zygomatic implants. The best bone quality and aesthetics of implant location is important. The patient had four guides in total, two for the left hand side and two for the right hand side, a mix of metal and polymer (Figure 22).



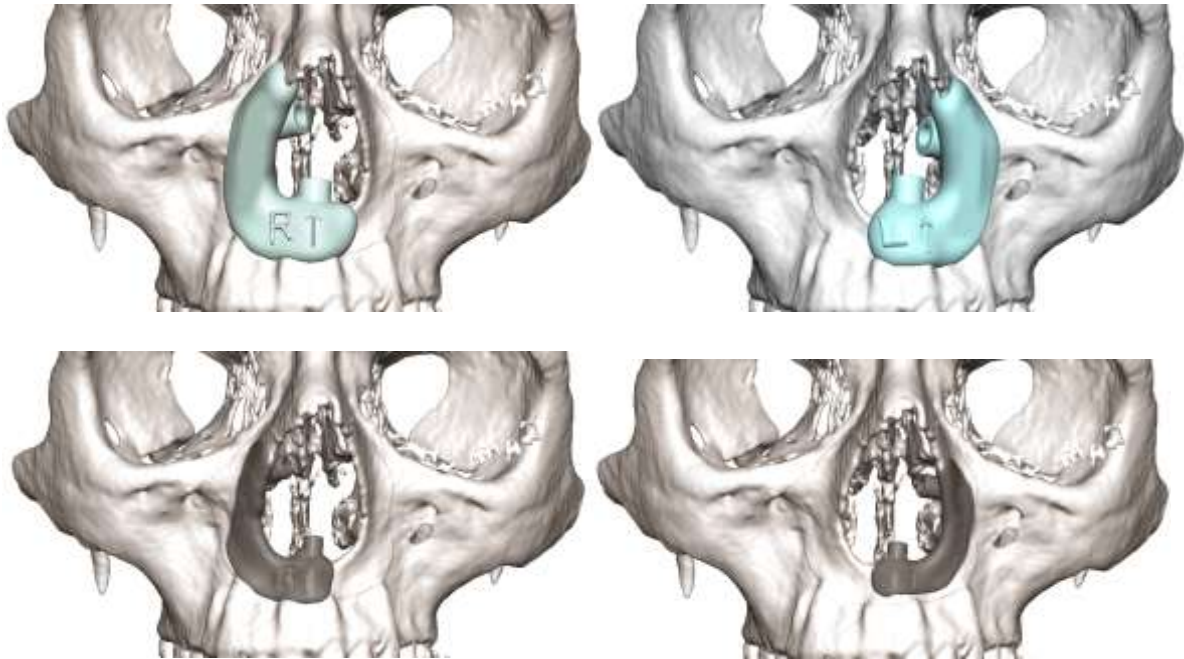


Figure 22 – Case study B (6) shows the imagery of the left and right nasal surgical guides. Both guides were fabricated in SLA Clear with stainless steel tube inserts in each of the drill cylinders and AM Cobalt Chrome. The left hand polymer guide was 30mm in width and 44mm in length.

## Operation Images



Figure 23 – Both metal and polymer nasal surgical guide's sterilised and ready waiting on the operating trolley for use in the surgery.

## Observations & Surgical Notes

Notes & quotes gathered from the planning and surgical stages of this case study:

“Be wary of the hoop curve at the top of the nasal bone. This can affect the angulation of the drill and may need to be trimmed back to compensate this.”

“It would be easier to drill through a longer length shaft on the nasal guide as it would have less room to angulate.”

“Extensions are needed for the pilot drill on the drill guide.”

“For implant placement, the drilling guides need to have a guide plus an extension to allow more precision. Extension fitting could be a snap fit or screw in feature that would allow the pilot drill to go in first, the longer extension of the shaft will gain better accuracy. Once the extension is removed from the guide the implant drill hole remaining will be there ready for the second drill to be used.”

“Longer shaft needed on all guides.”

Tolerances need to be smaller and tighter than the SLA guides used.

The Cobalt Chrome surgical guide was tried on the nasal bone, but was not used. The reason for the metal guide not to be used was because it was too rigid on the bone and offered no flexibility. This case study is evaluated in greater depth in chapter seven where analysis on accuracy and nasal surgical guides takes place.



### **5.2.3. Case Study C (7)**

#### **Background & Surgical Guide Design**

Case Study C (7) was booked in for a Pinnectomy operation which involved the surgical removal of the patient's right ear due to cancer of the area. This operation also includes fixation of a Cochlear Baha® implant. As explained in case study A (4) and B (6) the same pathway and timings applied to this case study. This operation is common in males in their seventies.

The two Cochlear Vistafix® ear implants were digitally placed where the thickest part of the planned prosthetic ear would sit so that the implants could be covered.

When positioning ear implants the bone area chosen has to be correct, the implants need to go into the bone 3-4mm. The mastoid area where the ear implants are located usually has a honeycomb like structure with several air pockets inside the thickness of the bone.

Osseo-integration is important in this case as the implants need to support the prosthetic ear. The cortex layer of the skull is thin, so it is vital to avoid the air pockets as this will cause the implant to fall out of the planned area of bone.

Each SLA ear drill guide designed at Morriston are 2-3mm thick and are usually 0.1mm offset from the bone. The ear surgical guide needs to locate onto a curved bone area with minimal anatomical landmarks to be located into.

The positional tolerance of error of ear surgical guides should be fine in this case as it is only entering the bone 4mm. The guide will be primarily used to mark the bone with the correct point of where the implants need to be located. Most surgeons use the guide to make a pilot hole, it is then removed from the area and the drilling continues in the pilot hole until 4mm. Some surgeons mark the bone location point

with the guide, it is then removed from the area and it then drilled on the mark but this is usually the case for an experienced Surgeon (Figure 24).

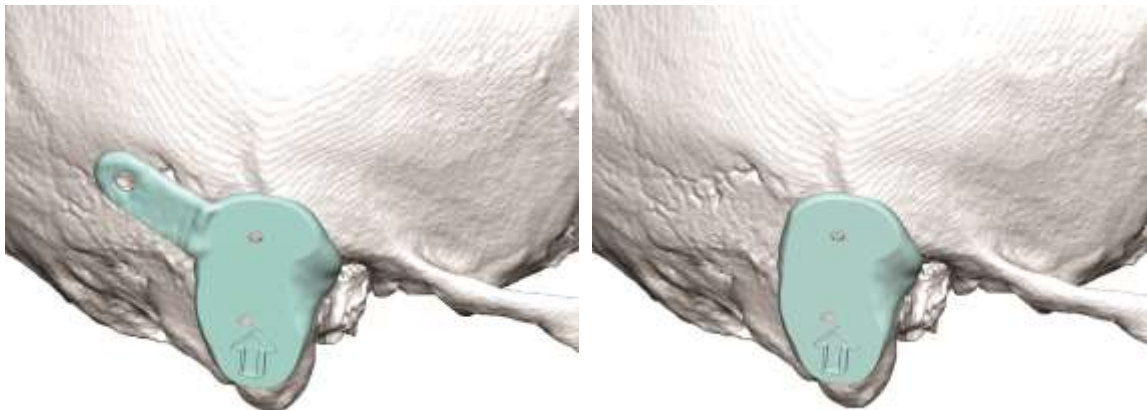


Figure 24 – Both types of ear drill surgical guides were fabricated in SLA Clear, the guide on the left hand side has an extended tab designed to mark the drill point of where the Cochlear Baha® implant needed to be placed in relation to the Cochlear Vistafix® ear implants. The guide on the right hand side is used if the Baha® implant does not need to be fixated in the surgery.

## Operation Images

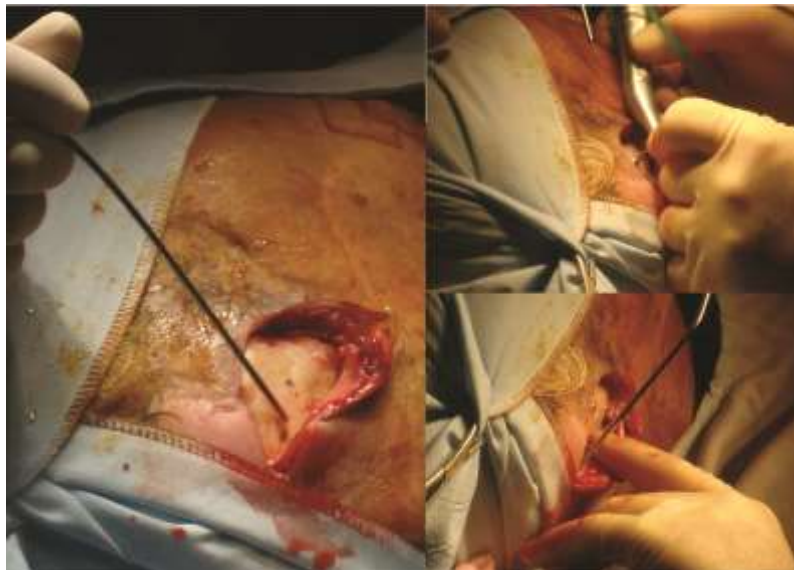


Figure 25 – Ear is removed due to cancer. Area of mastoid bone exposed and guide is used to mark the drill points of the two Vistafix® ear implants and the Baha® implant.



Figure 26 – The implant marks are drilled to the correct diameter of the implant, once complete all the ear implants are fixated into the planned bony positions.

## **Observations & Surgical Notes**

Notes & quotes gathered from the planning and surgical stages of this case study:

“Before it was guess work but with digital planning they know how much of an area they have either side to fix onto good bone.”

SLA guides and anatomical reference models were heat sterilised using the hospital’s autoclave.

The SLA Clear surgical guide was mobile on the bone due to the mucosa and blood on the surface of the mastoid area. This made the guide harder to locate in the correct area as the smooth surface area offered no friction onto the bony area.

Ear surgical guides were used to mark the drill points on the bone with surgical ink.



#### **5.2.4. Case Study D (9)**

### **Background & Surgical Guide Design**

Case Study D (9) was booked in for an ear implant operation which involves the fixation of Cochlear Vistafix® ear implants. Ear implant operations are usually due to birth defects or cancer of the ear, this case study was a birth defect. At Morriston there are more male ear patient cases than female as female patient usually cover the area with their hair. As explained in the previous case study the same timings apply. The ear implants are fixed 4mm into the mastoid bone and are 3.75mm diameter.

The thickness depends on what material is used. Metal is preferred by clinicians as it can be designed thinner than the polymer and is perceived as more accurate. For this case study the right hand side ear needed a Cobalt Chrome ear surgical guide to place the implant into the correct digitally planned position (Figure 27).

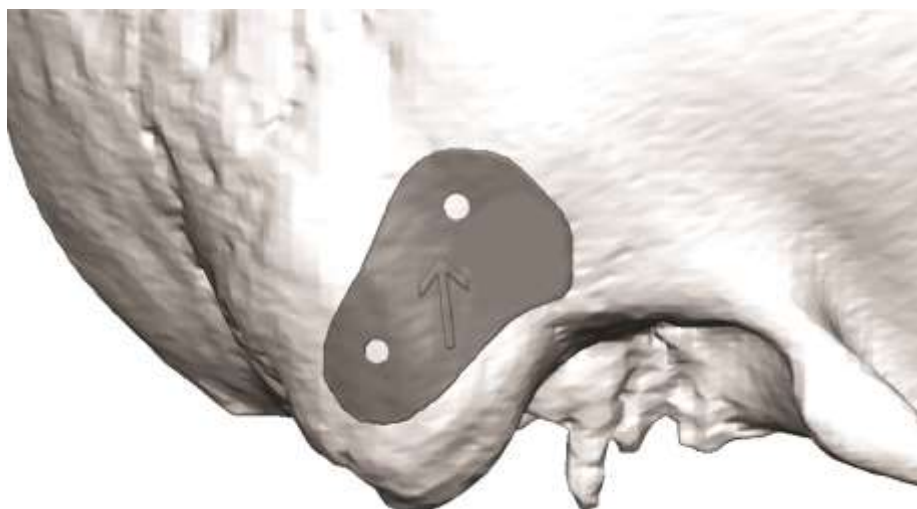


Figure 27 –Ear drill surgical guide for case study D (9) was fabricated in AM Cobalt Chrome. The guide was digitally designed to mark the drill point for where was best for the Cochlear Vistafix® implants to be placed in relation to the patient's ear on the left hand side in order to gain symmetry.



## Operation Images



Figure 28 – Removal of ear lobes and testing that the guide fixated securely into its planned position.



Figure 29 – Ear surgical guide used on the bony mastoid area to mark the digitally planned points where the drilling needs to take place. Once drilled to the correct diameter of the implant they are fixated into the bone.

## Observations & Surgical Notes

Notes & quotes gathered from the planning and surgical stages of this case study.

When surgeon moved the guide on the bone: “You see if I try to move it (up and down) you can see that the metal guide goes nowhere. If I try to move it (left to right) and I am really putting high force onto it and again that is going nowhere.”

“I just think it is spot on.”

Quotations from videos from the operation – Use of the metal guide.

“Wonderful. Bingo.”

Laser Melted (LM) is preferred as it has a thinner layer thickness and it is easier to get into position. The metal guides have a higher surface roughness so they have better grip on the bone, whereas the SLA guides slip around in surgery as the friction coefficient is not evident on the smooth surface.

The surgeons do not drill through the guide they place it on the bone, mark the holes on the bone, remove the guide and then drill the marked bone.



#### **5.2.5. Case Study E (10)**

### **Background & Surgical Guide Design**

Case Study E (10) was booked in for a bilateral ear implant operation which involved the fixation of Cochlear Vistafix® ear implants. Ear implant operations are usually due to birth defects or cancer of the ear, this case study was a birth defect.

This patient required both skin and bone anchored surgical guides. This was due to the young age of the patient and with the hope of reduced scarring when using both types of guides. The patient was born with only ear lobes on each side, therefore the Cochlear Vistafix® implants needed to be placed in the correct position so that prosthetic ears could be made.

For its flexibility properties the material chosen for the skin-anchored surgical guides was SLA clear. The skin guides were digitally designed to indicate where the incision needed to be and highlight the outline of where the bone surgical guides would be



positioned. The bone guides material choice was Cobalt Chrome and located onto the mastoid area. The bone guides were designed to mark the correct area of where the ear implants should be placed (Figure 30).

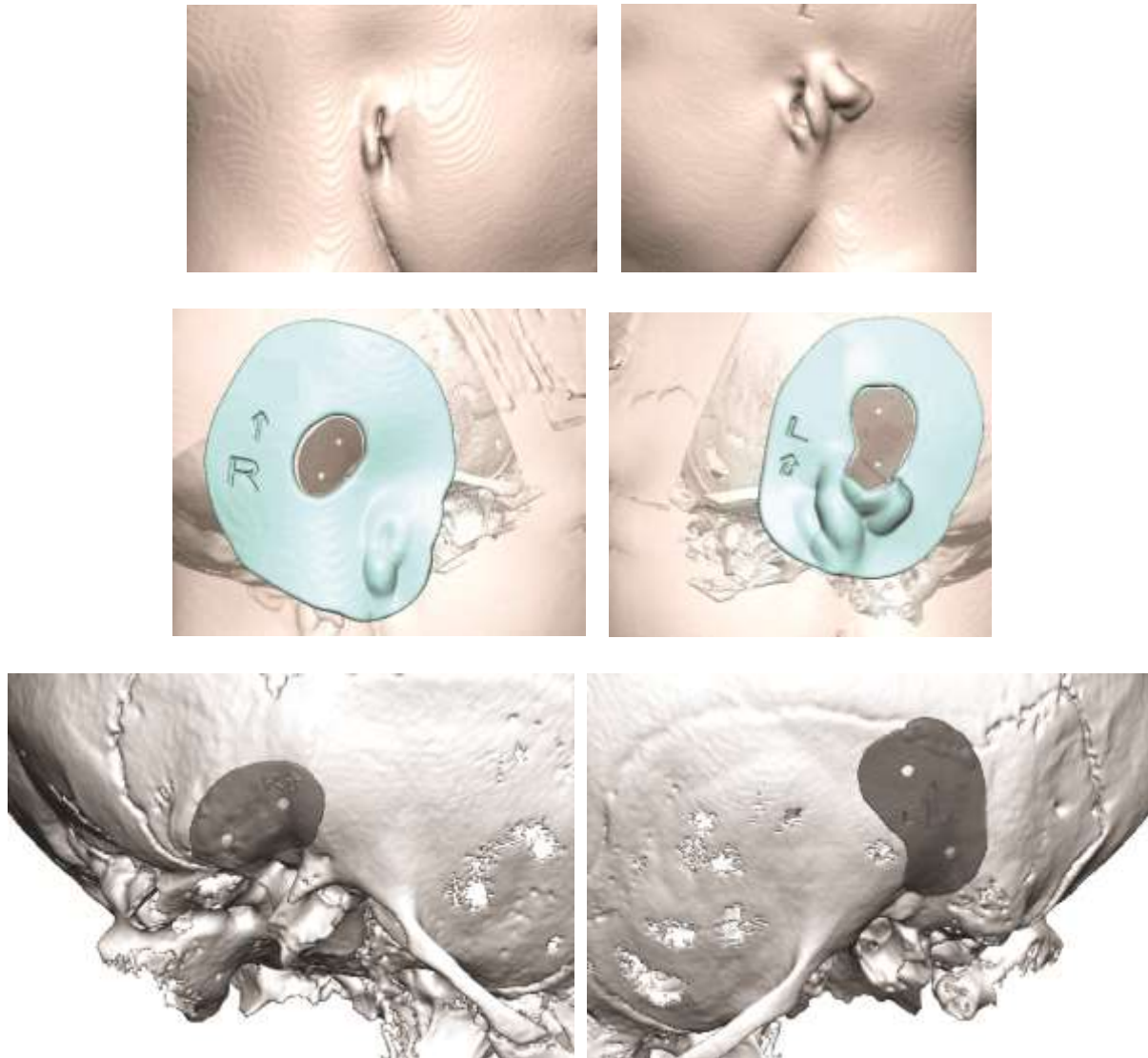


Figure 30 – This case study patient required both skin and bone anchored surgical guides. The patient was born with ear lobes (shown in the top left and right images). Skin guides (shown in the middle left and right images) fabricated in SLA Clear. The bone guides (shown on the bottom left and right images) fabricated in AM Cobalt Chrome.

## Operation Images



Figure 31 – Left and right ear skin surgical guides used to mark out the extents of the inner ear bone surgical guide. Each guide was used and marked the patient's skin with surgical ink.



Figure 32 – On both the left and right side of the patient the surgical ink was used to mark the extents of the inner ear bone guide as well as the incision line in order to gain precise and correct access to the area of bone. The incision line was opened up and peeled back so that the bone area was prepared ready for the bone surgical guide.



Figure 33 – The AM cobalt chrome bone surgical guides were used on both the left and right side to help mark the drill points for the planned implants. The drill points are marked with surgical ink, once complete the guides are removed and the drilling takes place so that the implants can then be fixated in their planned position.

## **Observations & Surgical Notes**

Notes & quotes gathered from the planning and surgical stages of this case study:

The SLA skin guides worked well as they flexed to the movement of the skin but located securely onto the bilateral lobe area. The clear appearance of the guides helped to show where the incision line was in relation to the lobe anatomical landmark.

Metal locates and sits to the bone better.

“Metal is 100% needed as plastic guides will slip into the wrong location due to mucosa and blood on the bone surface area. The bone needs the mucosa scrapped away in order for the guide to have the chance of locating the area correctly.”

The combination of the two materials for the skin and bone anchored guides worked well for this case.



#### **5.2.6. Case Study F (11)**

### **Background & Surgical Guide Design**

Case Study F (11) was booked in for a Zygomatic Osteotomy operation which involves osteotomisation of the zygomatic bone with fixation of zygomatic and orbital floor implants. This case was a trauma victim and it was the second operation for the patient on the area.

Trauma victims usually have immediate surgery to build and structure the basic contours of facial appearance, then months or years later have additional surgery to reconstruct the area to regain facial symmetry and improve appearance. Trauma fracture from immediate surgery can set in the incorrect place; therefore the bones need to be reset and the orbital floor raised so the globe of the eye sits in the correct position.

Metal is the preferred material choice for surgical guides for this surgeon, but polymer materials are also used in some cases. There is a need for surgical guides and jigs to make accurate cuts. The surgeon explained that metal guides tend to be thinner and easier to get into position. The guide needs to almost cut all the way through.

The surgeon explains that the guides and implants need to have more location points but believed too many may impede on the path of insertion. The position of the screw holes on the zygomatic piece are critical and may have to be on a diagonal so that two screws can be fixated in the area of bone.

Due to the high complexity of this case, the surgical guide and implant design was broken up into 3 stages. Figures 20 to 22 explain the step by step stages which involve a Cobalt Chrome cutting guide, Cobalt Chrome repositioning guide, a

Titanium (Ti-6AL-4V) zygomatic implant and a Titanium (Ti-6AL-4V) orbital floor (Figure 34, 35 & 36).

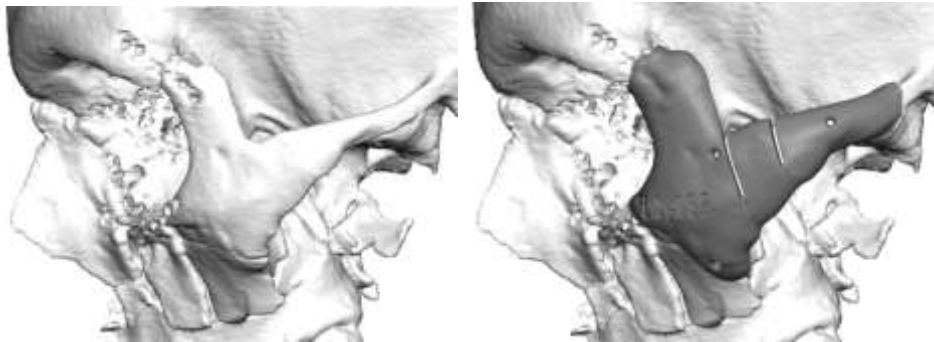


Figure 34 – Stage 1 shows the original anatomy on the left hand side. On the right hand side is the cutting surgical guide which was fabricated in AM cobalt chrome. The cutting guide was 70mm in width and 60mm in length.

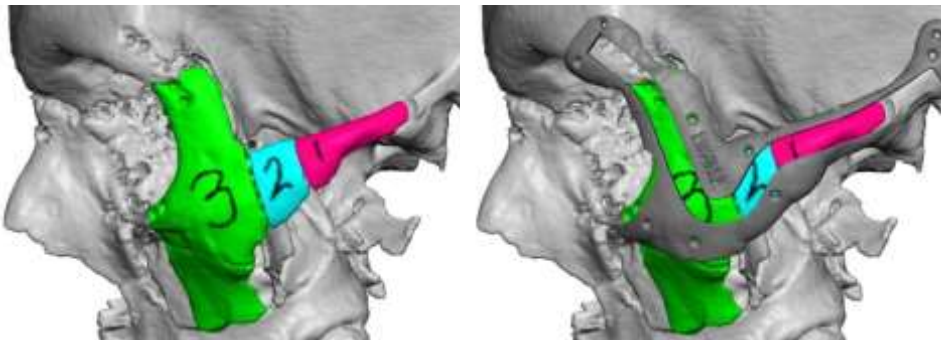


Figure 35 – Stage 2 shows on the left hand side the three fragments of bone that were cut using the AM cutting guide in stage 1. The three fragments of bone were loose and the repositioning guide shown on the right hand side was fixated onto the three pieces of bone and was held into position by the three stationary parts of the anatomy where the repositioning guide extended onto. The guide repositioned the bones into the correct planned position and was 86mm in width and 60mm in length.

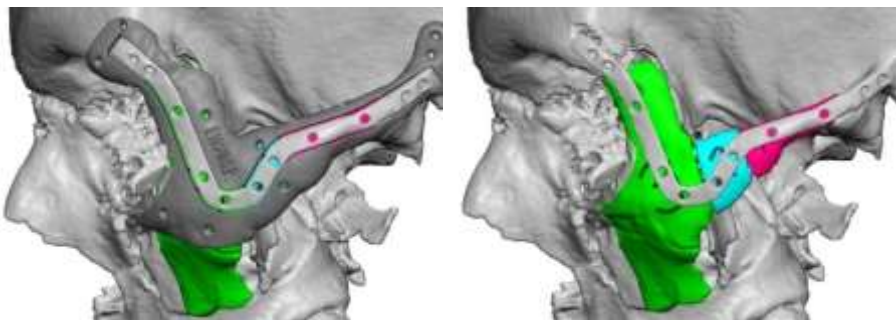


Figure 36 – Stage 3 shows on the left hand side that once the bones are in the correct position the zygomatic implant can be placed within the repositioning guides centre groove and is fixated onto the bone using various screws. The right hand side shows both the zygomatic and orbital floor implants in position.



## **Operation Images**

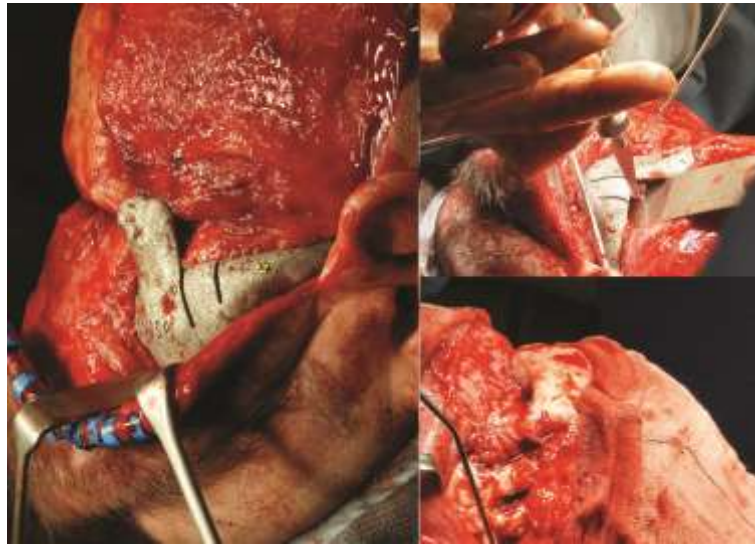


Figure 37 – Once the area had been opened up the cutting guide was fixated onto the bony area. The guide was used to cut the bone into three fragments as demonstrated on the top right of the figure.

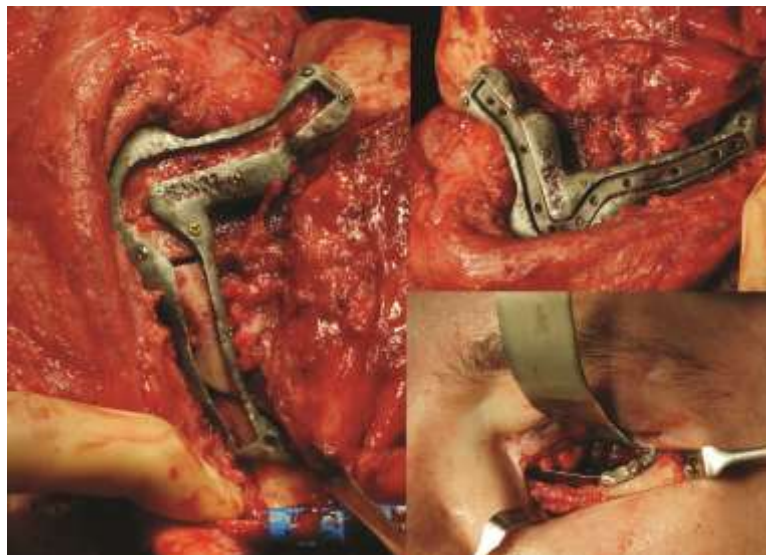


Figure 38 – The three fragments of bone were placed into the repositioning guide in order to place the bones in the new planned position. Once in that position both zygomatic and orbital floor implants were placed and fixated onto the bone area.

## **Observations & Surgical Notes**

Notes & quotes gathered from the planning and surgical stages of this case study:

A lot of meetings were needed with the clinical and PDR team to plan before surgery due to it being the first fully AM metal digitally designed surgical guides and implants.

“Without medical models, this kind of surgery would have never happened; it would be the surgeon’s choice on whether one or more operations would be worthwhile but it would be usually just one.”

“Having the model in theatre makes the surgeon’s life easier.”

“If you do not fix or locate the zygomatic bone at the beginning of the trauma it is very difficult to make right at a later stage.”

“When explaining to another surgeon in the theatre the approach you would do to the patient you must explain it to them as if you are sitting in their seat and sometimes it can be a mirror image of where you’re sitting opposite them so your mind needs to gain its perspective.”

“Measurement is critical.”

Surgeon explains that although the virtual computer model is 3D software it only generates a “2D image of a 3D model”. The printed models are easier and better to work from as you have a better idea on scale.

“If you only have one screw on a loose bone area the piece will rotate so it always needs at least two screws on each area. Three screws would be better but sometimes we do not get that luxury.”

Always have various holes so that the surgeon can choose in the surgery where to drill as long as implant and guide ones do not overlap.

Surgeon is not a fan of polymer guides as he thinks that they can bend and break, he prefers metal.

The larger surface area of the surgical guide can take further downwards force when cutting or drilling.

“It was a great idea to make the orbital floor locate into the guide.”

Zygomatic implant all in one piece is a worry because if it got infected or the patient becomes sensitive to that material the implant would at a later surgery need to be taken off the bone to rectify.

“Have surgical guides always and have plan B plates that can be bent into shape.”



#### **5.2.7. Case Study G (16)**

##### **Background & Surgical Guide Design**

Case Study G (16) was booked in for an Osteoplastic Frontal Sinus Exploration operation which involved relieving a blocked sinus by cutting into the frontal area of the skull and draining the sinus. This was the first surgical guide for this type of surgery at Morriston hospital.

A cut template surgical guide was digitally designed for the surgery to locate onto the frontal bone to mark out where the extents of the sinus were and where best to cut into the skull in order to drain the sinus area. The guide was fabricated in SLA Clear and covered a large area (Figure 39).



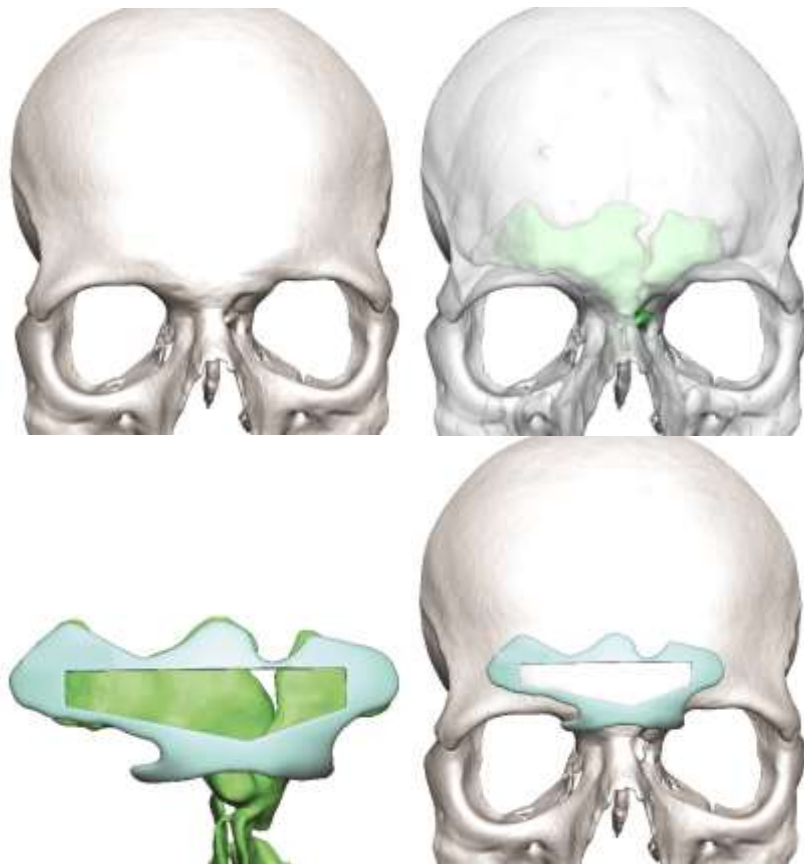


Figure 39 – Due to the patient having a blocked sinus it was important in this case to highlight the sinus area using Mimics software. Once highlighted the sinus cut surgical guide was designed to overlay onto the bone the extents of the sinus area and where would be the best place to cut the bone in order to gain access to the problem area.

## Operation Images

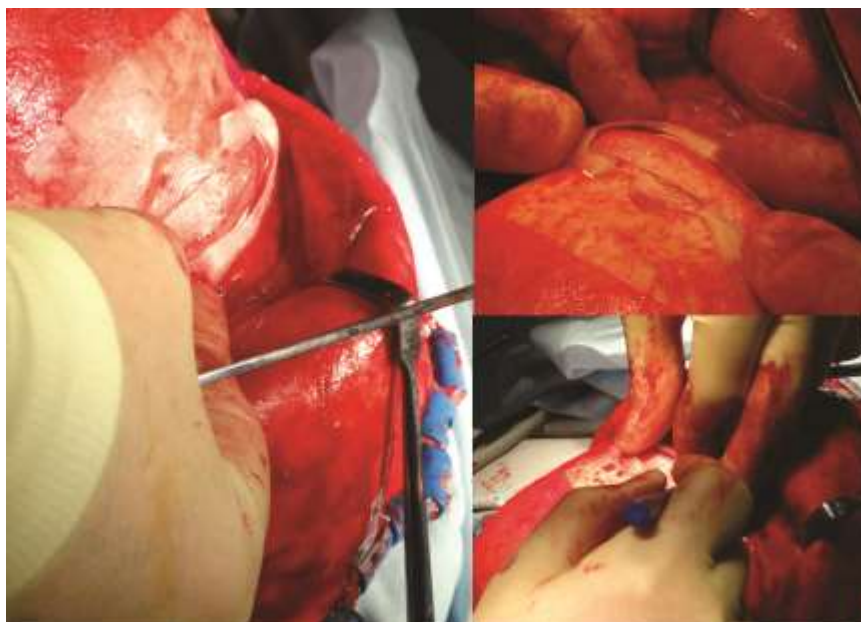


Figure 40 – Once the area had been opened up the sinus cut guide was placed onto the bony area. Once in position surgical ink was used to mark the cut area onto the bone.

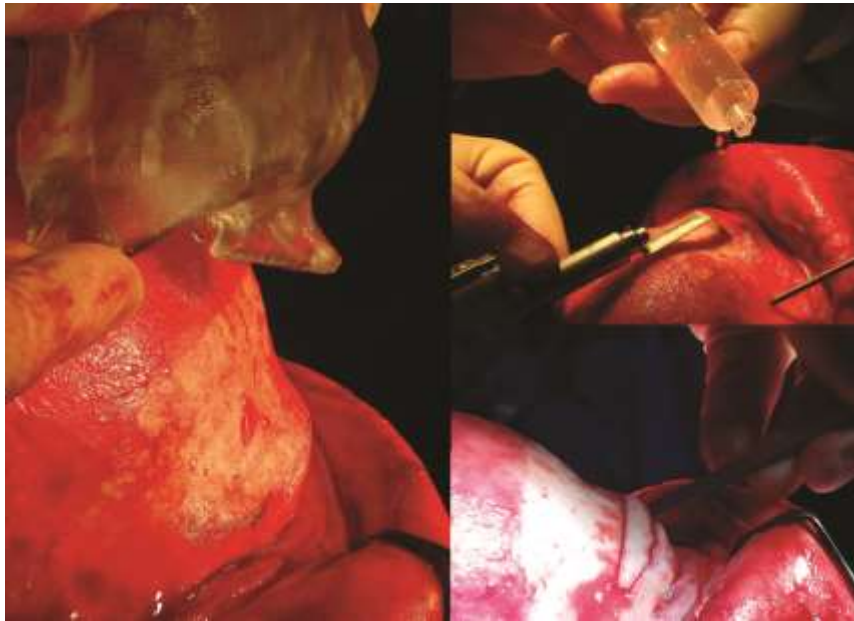


Figure 41 – Once the surgical ink has marked the cut area the drill is used to cut the fragment of bone and remove it from the area. The cuts have to be completed carefully as the bone will need to be placed back into position once the draining of the sinus has taken place.



Figure 42 – The cut fragment of bone is removed from the area and the exploration of the sinus area begins. Endoscopic cameras were used to analysis the sinus which were placed down the cut open area. Once the sinus had been cleared the loose fragment of bone was placed into its original anatomy position and fixated using Synthes plates.

## **Observations & Surgical Notes**

Notes & quotes gathered from the planning and surgical stages of this case study:

Guide was placed onto the frontal bone, the extents and inner cut template was marked with surgical ink.

The blocked nasal airways were cleared using an endoscope, cutting implements and suction device. Widening of the nasal cavities up through the nose and down through the skull cut.

The bigger surface area of the surgical guide made it easier to handle.

“As long as the pre-cut edge is in the correct place and the bone that needs to be removed is in one piece it should fit back into the area nicely.”

“The surgical guide makes our cuts precise and provides easy access into the sinus and nasal cavity.”

## **5.3 Summary**

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Main areas for investigation that have been highlighted in the qualitative case study research are:

1. Materials and Fabrication (Combination, Metal and Polymer)
2. Accuracy (Tolerance, Diameter and Length)
3. Friction and Surface Roughness
4. Patient and Surgeon Specific
5. Perspective View
6. Surface Area
7. Bone, Osseo-Integration and Sterilisation

### **1. Materials and Fabrication (Combination, Metal and Polymer)**

Metal is preferred by the surgeons observed as they perceive it more capable of being fabricated in thinner material layer and therefore more accurate.

Those observed and suggested that they perceived polymer as being too fragile or prone to distortion.

Although the surgeons showed a preference for metal guides, in some instances combination of materials suited better. In case study B the reason for the metal nasal guide not to be used was because it was too rigid on the bone and offered no flexibility although the combination nasal guides metal inserts bind on the drill.

In case study E the SLA skin guides worked well as they flexed to the movement of the skin but located well onto the bilateral lobe area. The clear appearance of the guides helped to show where the incision line was in relation to the lobe anatomical landmark. The metal guides bonded and sat better on the bone. Metal is “100% needed” as plastic guides will slip into the wrong location due to mucosa and blood on the bone surface area. The bone needs the mucosa scraped away in order for the guide to have the chance of locating the area correctly. The combination of the two materials for the skin and bone anchored guides worked well for this case.

Although metal guides are preferred by the surgeons in this sample the polymer guides are perceived as a quicker method of fabrication if an urgent case (cancer or trauma victim) comes along. In case study A the surgeon states that there is no point surgically planning if there is no surgical guide to be fabricated.

## **2. Accuracy (Tolerance, Diameter and Length)**

With all the digitally planned case studies explained in this section it is clear to see that measurement is critical.

Although the nasal surgical guides (case studies A & B) are a positive tool to have in theatre the problems of the inserts coming away from the drill cylinder is a concern therefore standardised lengths, tolerances and fixed diameters is needed. Drill guide tolerances are important because if the drill pathway is placed in the wrong direction damage may occur in the surrounding areas. It

is easier to drill through longer length shafts on the nasal guides, developments are needed in this area with extensions of the guide.

Rotation of loose or cut bone is critical and screw location is key to this. Lots of screw and drill holes are needed but none should overlap when using the different guides and implants.

### **3. Friction and Surface Roughness**

In order to gain correct location and accuracy, the guides need to have a specific grip or friction onto the bone as well as using anatomical landmarks. It has been perceived that this is something to do with the materials surface roughness on the bone bound side of the surgical guide.

In the case studies, the different material options seemed to work better in specific areas of the anatomy. In case study C it was explained that the SLA clear surgical guide was mobile on the bone due to the mucosa and blood on the surface of the mastoid area. This made the guide harder to locate in the correct area as the smooth surface area offered no friction onto the bony area.

Whereas in case study D the metal guides have more surface roughness so they have better grip on the bone whereas the SLA guides slip around in surgery as the grip element is not there on the smooth surface. The surgeon was happy with the metal guide's friction coefficient on the bone area.

### **4. Surgeon Specific**

In the case studies and the observational work within the clinical team, the digital planning cases can be adapted for patient and surgeon specific designs. Patient-specific means the design of the guide/implant on the anatomy of the patient and their need for the procedure. Surgeon specific means the design of the guide/implant to suit the working style and experience of the surgeon.

Case study A demonstrates that surgical guides help with diminishing the problems with surgeon experience levels, exchanging guesswork into planning and with the accuracy of the implant placement. Digital planning gives the inexperienced surgeon the skills an experienced surgeon has.

## **5. Perspective View**

Observations, perceptions and perspectives were evident throughout the case study examples. In case study F, the perspectives of different sitting position of the surgeons in the operating theatre needs to be thought about and discussed during guide design and pre surgery planning. Virtual planning is a 2D image of a 3D model therefore printed models and prototypes give a better idea of scale.

## **6. Surface Area**

When applying pressure or downwards force to an anatomical area whether it be drilling, cutting or repositioning, it does help if the guide makes the task functional and as easy as possible. In case study F, the bigger the surface area of the guide the more increased downwards forces could be applied when cutting the area. Also in case study G, the large surface area of the cutting guide provided cuts for easy access.

## **7. Bone, Osseo-Integration and Sterilisation**

In case study C, the bone placement is highly important due to the mastoid cells of the mastoid bone and Osseo-integration is important in this area. The SLA guides material ability to withstand the autoclave process were also deemed as important.



## Chapter 6: Accuracy Results

### 6.1 Case Studies Background

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A series of maxillofacial cases were followed to generate qualitative data on the needs perceived by medical specialists involved with the specification, design and application of surgical guides. The qualitative data generated by observing surgical, clinical and design perceptions was analysed to inform the design of experimental studies that enabled development of optimal approaches that utilised AM processes.

Due to the high number of Rhinectomy cases seen in the clinical case-study research part of this PhD, the nasal surgical guide was chosen as an area to focus on to evaluate how the guides performed with regards to accuracy. The process of a Rhinectomy case starts with the patient having a CT scan with 0.5mm slices. The scan is then sent over to the Maxillofacial clinical team and a 3-dimensional reconstruction is completed using two software packages, *Simplant (Dentsply, US)* and *Mimics (Materialise, Leuven NV)*. This allows the implant position to be accurately planned, ensuring that the zygomatic bone is fully engaged with, and the infra orbital nerve / foramen avoided.

At this planning stage it is essential to offset the implants, one being placed 3-4mm higher than the other to allow better access when inserting the implants. This helps to ensure easier access for patients to clean the site. *Freeform (3D Systems, US)* is then used to design surgical guides to facilitate the offset position of the implants and guide correct trajectory to engage the zygomatic bone.

Surgical guides are fabricated in *ClearVue* or *Visijet Clear, Accura® 3D resin* using SLA printing or in cobalt chrome using LM. The standard surgical guide used is a *Visijet Clear* jacket that locates onto the nasal bone in a J shape, either hooking over the bridge or along the base of the nasal bone. The surgical guides drill cylinder position is dependent on the trajectory pathway that the implant needs to be placed. Within the *Visijet Clear* cylinder a stainless steel tube is set into position using light-

cure resin in order to make the area more rigid for the drilling to take place. Limited access for surgical equipment in the area around the nasal bone means that two separate components or surgical guides are required to place the left and right implants. Manufacturing and delivery time is approximately two to three days, and the guides are heat sterilised in the HSDU department of the hospital prior to delivery to theatre.

Intra operatively, wherever possible, the nasal bones are maintained to provide a firm tissue base for the prosthesis and allow the patients nasal bridge to support spectacles. The inferior turbinates shown in figure 43 are removed and a minimum of 1cm of the anterior nasal septum which reduces crusting, improves air flow for breathing and provides better access for cleaning. It is important to advance the skin over the nasal margins at the time of surgery as this will reduce the tissue mobility under the final nasal prosthesis.

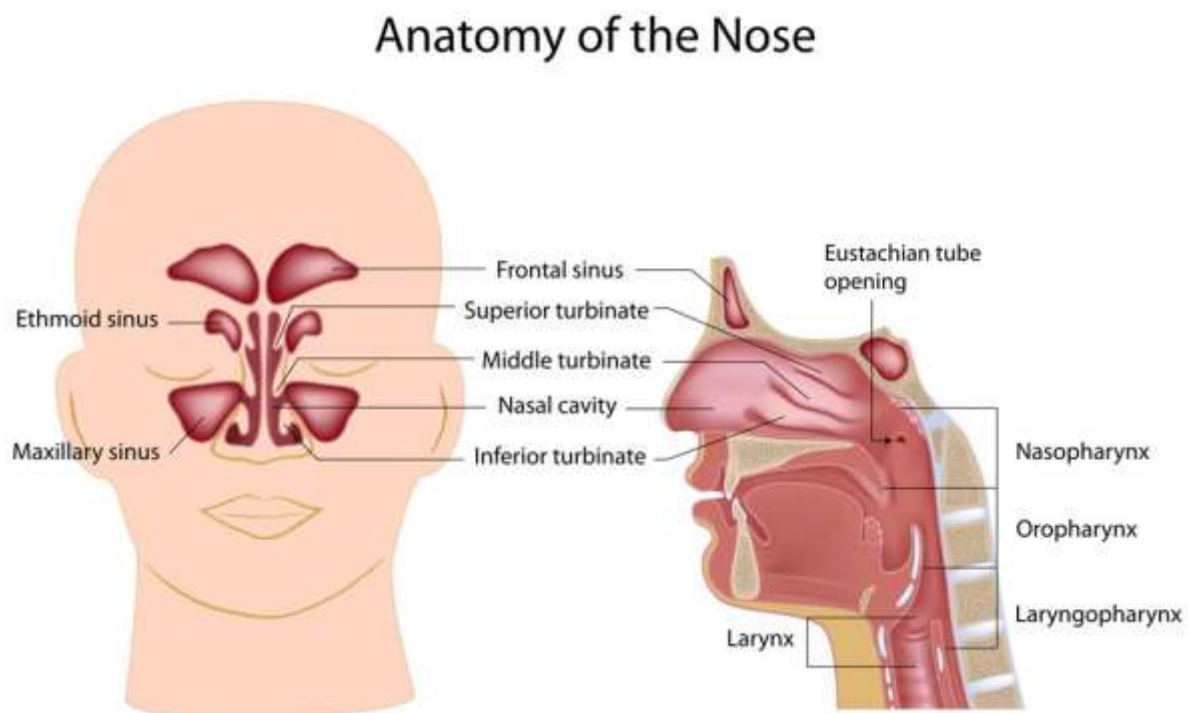


Figure 43 – The anatomy of the nose highlighting the nasal cavity and inferior turbinates described in the text.

In Morriston hospital the zygoma *Brånemark system*® provided by *Nobel Biocare* (Goteborg, Sweden) is used for all rhinectomy operations. These implants have a



*TiUnite* or machined surface with a diameter of 4.4mm and length ranging from 30mm to 52.5mm. Figure 44 illustrates intra operatively a 2.9mm rose head drill used to create the entry point in the maxillary bone and zygoma using the surgical guide. This is followed by a pilot hole of 2.9mm drilled to full zygomatic implant length. The diameter of this drill hole is then increased to 3.5mm using a twist drill and the zygomatic implant is then inserted. The head of the implant is angled at 45° to the patient's coronal plane. Healing abutments are placed to prevent overgrowth of the soft tissue during the healing phase and dressings are changed weekly for four to six weeks.

Prosthetic construction is completed six to eight weeks post-operatively or after radiotherapy treatment is complete; this is the point when full implant loading can occur. CT data and patient photographs prior to the disease are used to construct a clay or wax prototype of the nose before moulding in dental stone. From this a silicone elastomer nasal prosthesis is constructed with appropriate colour matching. The prosthesis is magnetically retained using closed-field *Maxi Magna* abutments (*Technovent, UK*); the magnet residing in the prosthesis and the keeper component screwing into the threaded implant head. The patient is provided with two nasal prostheses which take about 36 hours to produce.

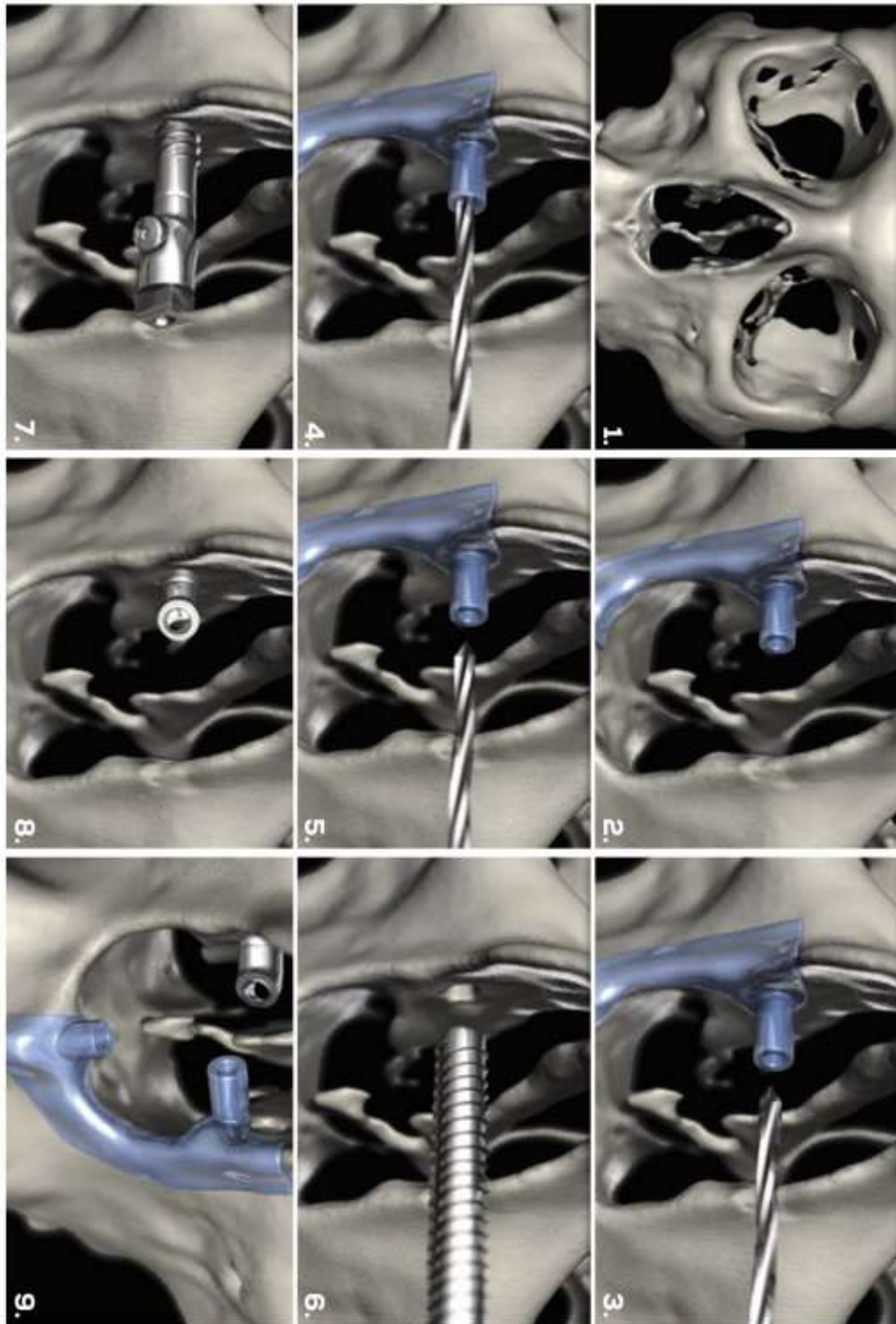


Figure 44 – Process illustrations 1 to 9 show the use of nasal surgical guides in rhinectomy operations. 1. The patient's skull at the start of the operation, 2. Right nasal surgical guide is placed onto the bone, 3. The 2.9mm pilot drill is used through the right guide, 4. The trajectory pathway for the right hand side is drilled, 5. The pilot drill and nasal guide is then removed from the area, 6. After the larger 3.5mm drill is used to increase the pathway the Brånemark nasal zygomatic implant is inserted into the drill hole, 7. The implant is placed all the way into the drill pathway, 8. The implant head is angled at 45° to the patient's coronal plane, 9. Process 1 to 8 is repeated for the left hand side guide and implant.

Six rhinectomy cases were analysed to review and compare the accuracy of the planned pre-operative position to the fixed post-operative position. These six cases were chosen as they were the cases that had a post-operative CT scan and were the case studies that had been reported on in chapter 5. Each of the guides from the cases was patient specific and although they went through the same design process, each one had a different geometrical or material difference.

The results and analysis of the six patient cases presented along with the qualitative data gathered from clinical research highlighted key themes and issues that needed to be addressed in the design of the nasal guides currently used.

## **6.2 Accuracy of Nasal Surgical Guides**

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### **6.2.1 Method**

The method of the study consisted of four stages:

- Stage one - Gathering the six sets of CT data for both pre-operative (the implants in their planned position) and post-operative (the implants in their fixed position).
- Stage two – Collation of the datasets into Mimics software and alignment of the scans together using the STL registration tool in the software or manually using the tools provided. Once overlapped, recordings were taken of the centre point of the nasal Brånemark implant at its entry position into the bone and the centre point at its end position giving X, Y, Z co-ordinates for each.
- Stage three – The gathered X, Y, Z co-ordinates were placed into the dot product equation to calculate the angle between the planned and fixed position. The results were developed into new design features and digitally designed to proceed with further testing to help gain better accuracy.
- Stage four – The designs were a combination development of gained clinical knowledge and the results data from this chapter. Once all testing was completed the new developmental features were placed into one of the cases used in this study and tested with surgeons and their clinical teams.

Stages one to three will be shown in more detail in the remainder of this section (6.2), stage four will correlate the results of the section and incorporate them into new design developments that will be shown in section 6.3.

### 6.2.2 Visual Results

To demonstrate the visual results of the study, three dimensional reconstructions of the patients' pre- and post-operative scans were created using the Mimics software. To highlight the post-operative implant fixed pathway, the coronal (cross sectional plane front to back), axial (cross sectional plane head to toe) and sagittal (cross sectional plane left to right) views were used. Figure 45 shows the entry point of the implant on the patient's left hand side and the end point of the implant on the right hand side in their coronal and sagittal views in the bone.

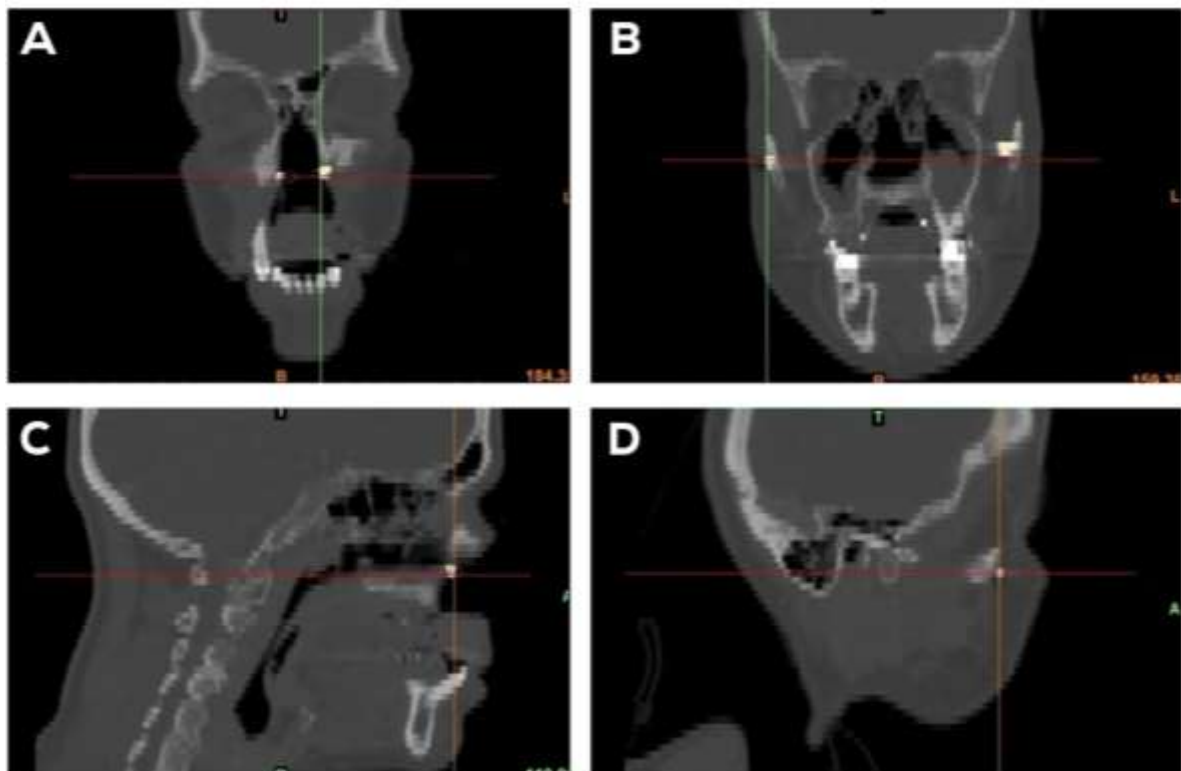


Figure 45 – Coronal and Sagittal views taken from the study. A - The coronal view of the bone entry position of the implants in their post-operative position (fixed), B - The coronal view of the bone end position of the implants in their post-operative position (fixed), C - The sagittal view of the bone entry position of the left implant in their post-operative position (fixed) and D - The sagittal view of the bone end position of the left implant in their post-operative position (fixed).

A visual example of how the CT scans and implants were analysed is shown in figure 46. The pre-operative CT scan had the implants planned by the surgeon and clinical team in the pathway with the best angle and bone to support the implant and prosthesis. Once the implant was placed and planned digitally, the surgical guide was designed and fabricated based on the trajectory pathway.

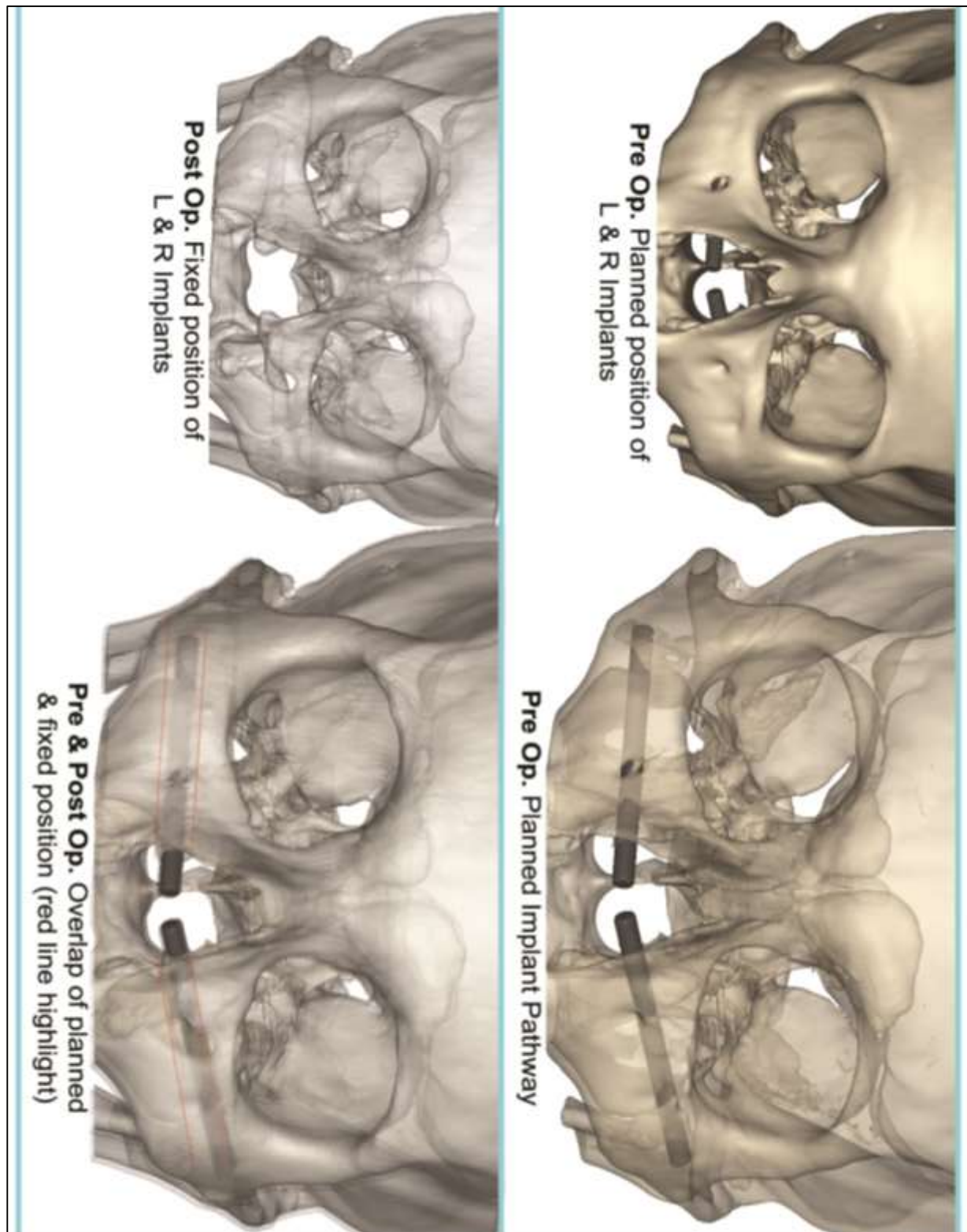


Figure 46 – A case example of the CT scan data both pre- and post-operatively. Pre-operative and planned implant pathway demonstrated by the three top images. Post-operative and fixed implant position demonstrated by the three bottom images.



The planning, design and fabrication process was repeated for the 6 patients. CT scans of the implants in their fixed position were completed post-operatively. Figure 47 shows an example of their pre and post-operative overlaps. Visually the patient's right implant seems to be closer to the planned position than the left implant; it appears the left implant has its end point projected upwards towards the orbital rim.

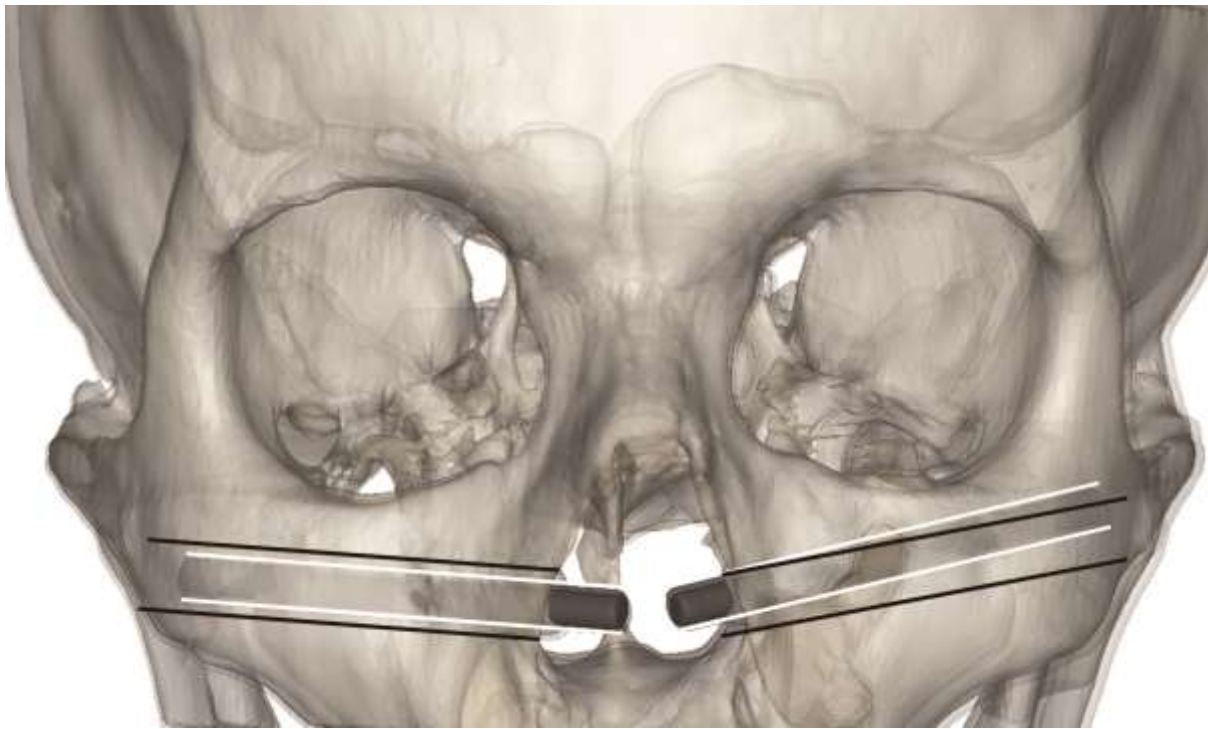


Figure 47 – A case example of the pre and post-operative CT scans demonstrating the planned implant highlighted in a solid black colour with white outline and the post-operative fixed implant pathway highlighted with black lines.

On inspection, the study demonstrated a visual difference in angle and projection but there was no quantitative value on the measurement. To gather quantitative values for the study, the centre point of the entry and exit point of both planned (pre-op) and fixed (post-op) for each patient were recorded using their X, Y, Z co-ordinates.

### 6.2.3 X, Y, Z Co-ordinates and Vector Results

To demonstrate how the X, Y, Z coordinates were measured, figure 48 shows the two points on the implant that were of interest in both pre-operative and post-operative views.

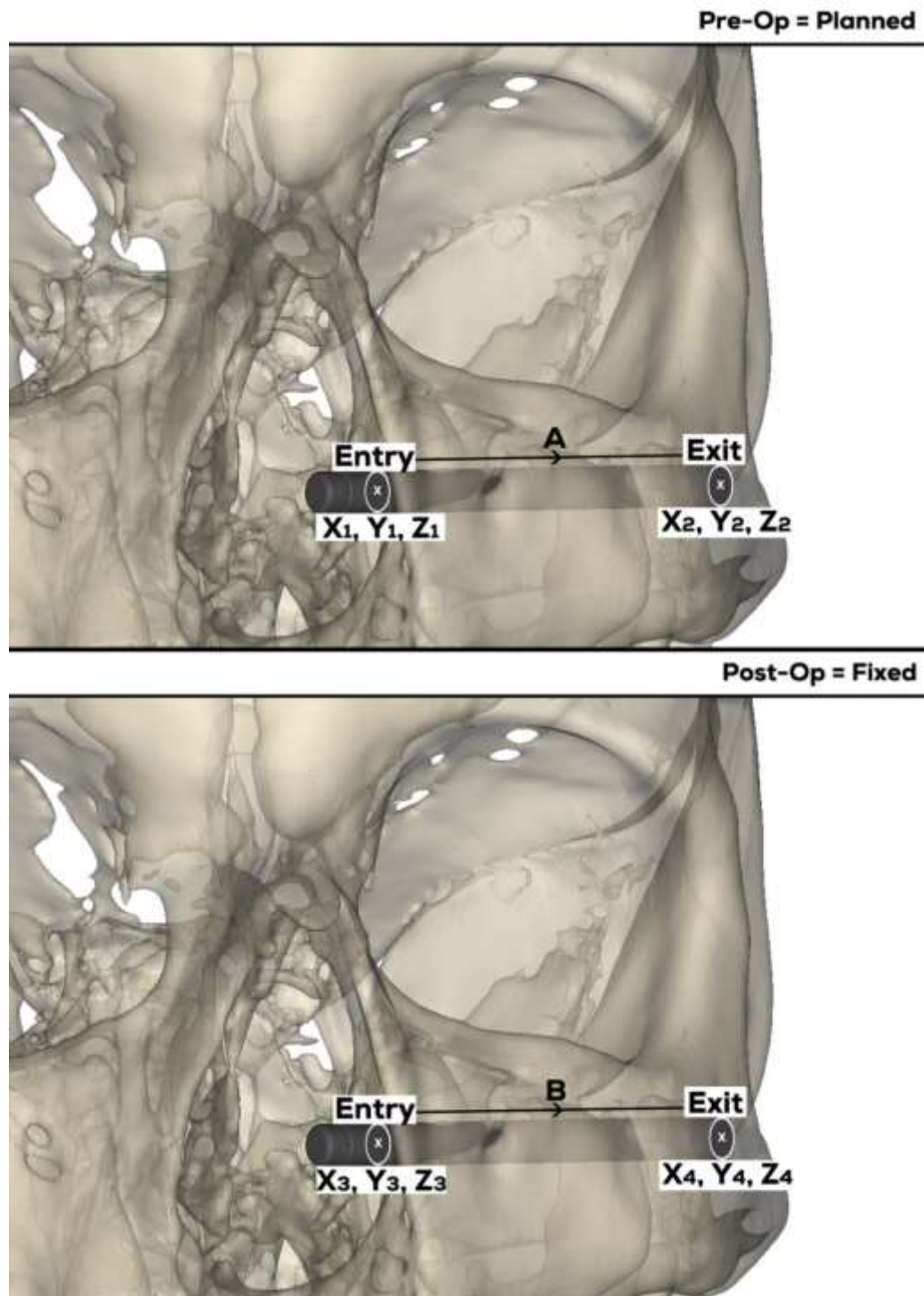


Figure 48 – A case example showing the two centre points, entry and exit, X, Y, Z coordinates recorded for both the pre-operative planned implants and post-operative fixed implants.



The figure shows the coordinates for the pre-operative entry point ( $X_1, Y_1, Z_1$ ), the pre-operative exit point ( $X_2, Y_2, Z_2$ ), the post-operative entry point ( $X_3, Y_3, Z_3$ ) and the post-operative exit point ( $X_4, Y_4, Z_4$ ). These recordings were completed for the six cases for left and right implant in their planned (pre-op) and fixed (post-op) positions.

The six sets of X, Y, Z data were collected and the degree of difference was calculated using the dot product equation:

$$\cos \theta = \frac{A \cdot B}{|A||B|}$$

$$\cos \theta = \frac{(X_1 \times X_2) + (Y_1 \times Y_2) + (Z_1 \times Z_2)}{\sqrt{(X_1^2 + Y_1^2 + Z_1^2)} \times \sqrt{(X_2^2 + Y_2^2 + Z_2^2)}}$$

$\theta$  = Angle between vectors A and B

The dot product equation was used to calculate the angle between vectors A and B; from planned to fixed implant position for all six cases and twelve implants. Figure 49 shows the degree of difference for the six sets of patient data for left and right implants in their planned and fixed positions.

The entry co-ordinates for both pre-operative and post-operative of all patients were more accurate than the exit co-ordinates. Patient 5 had the largest degree of difference in both left ( $14.00^\circ$ ) and right ( $11.74^\circ$ ) implants. For the right implants, patient 2 had the lowest degree of difference at  $6.00^\circ$ . For the left implants, patient 1 had the least degree of difference at  $7.53^\circ$ . Across all results the reading was  $\text{mean} \pm \text{SD} = 9.37 \pm 2.5^\circ$ . Patient 6's left implant was chosen as the benchmark guide as it was observed during the planning, design and surgical stages and complementary qualitative data was captured. Patient 6's left implant also had one of the closest combined degree values to the mean reading making it the most appropriate benchmark against which newly developed approaches could be evaluated.

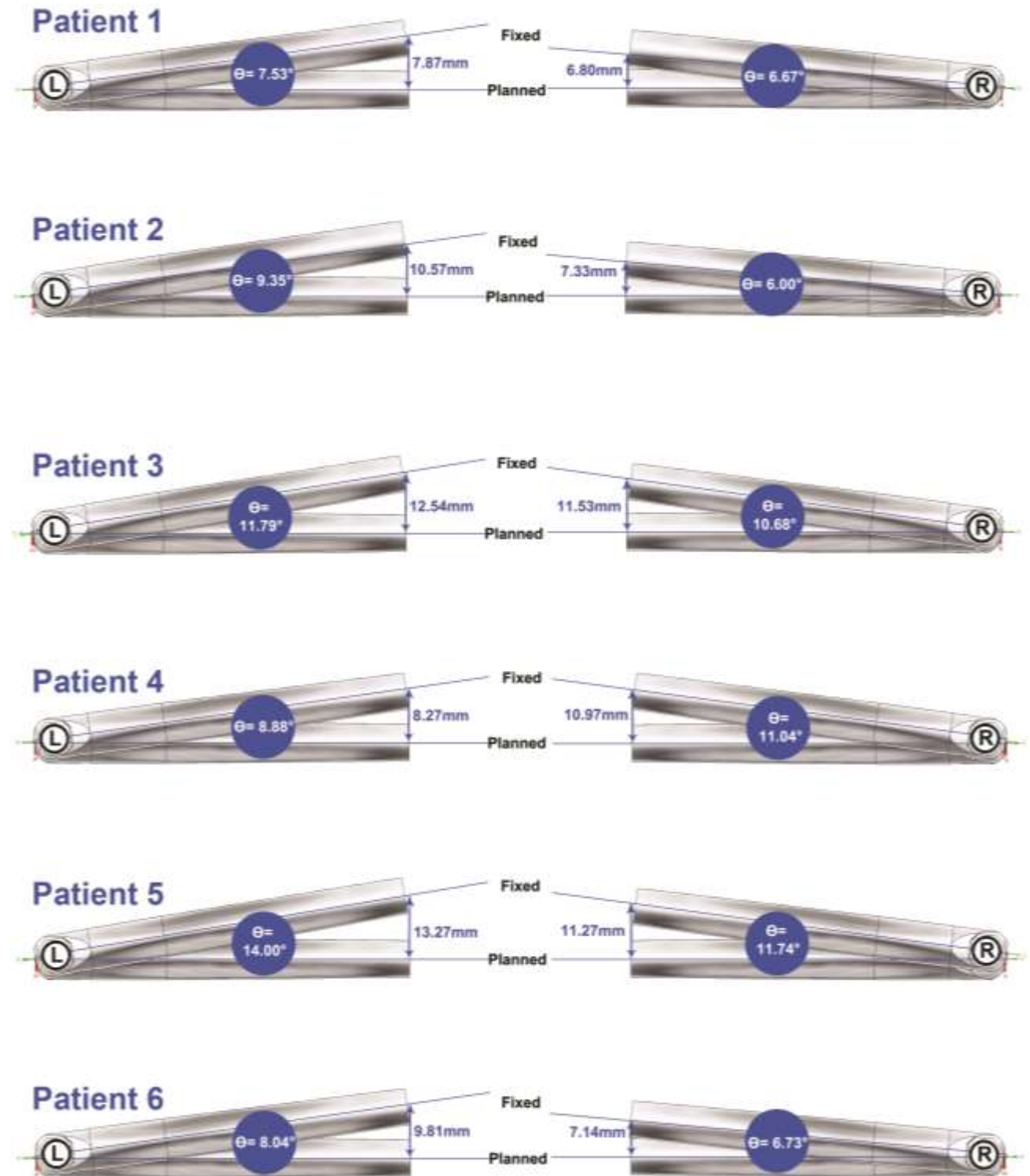


Figure 49 – The degree of difference results for the six Rhinectomy patient cases of the left and right zygomatic implants. The blue disc displaying the degree of difference and the millimetre difference demonstrated at the end of the implants showing the difference between the planned and fixed position.

Patient 6's left implant with a reading of  $8.04^{\circ}$  was used as the benchmark surgical guide to explore in more detail and to develop further in order to help reduce the angle pre- to post-operatively. 45mm zygomatic Brånemark implants were placed using a Morriston Hospital-designed Visijet Clear polymer jacket with a stainless steel tube inserts as shown in figure 50.

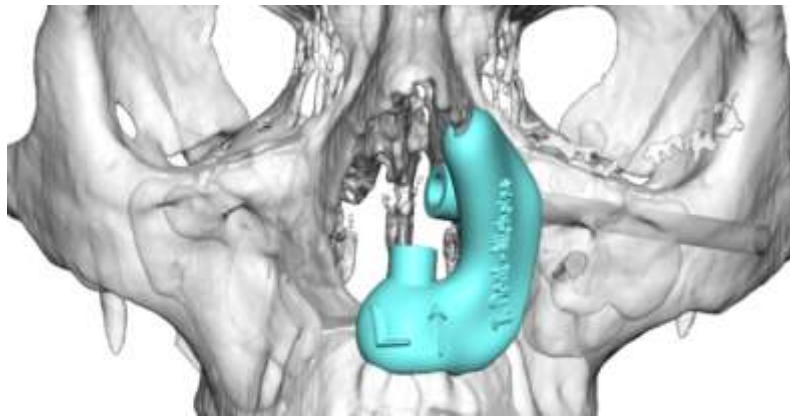


Figure 50 – CAD image of the benchmark surgical guide design. Left hand side guide, jacket made from Visijet Clear resin with stainless steel tube inserts in the drill cylinders.

For this patient case, an alternative AM cobalt chrome guide shown in figure 51 was fabricated; the guide was not used due to the AM metal rigidity on the bone which offered no flexibility. The flexibility is important especially in nasal surgical guides; the patient is CT scanned at least two weeks prior to surgery, and depending how developed or active the cancer is the more of the nasal area or bone that may need to be removed. This is only known when the surgeon and team expose the area of the patient in theatre. Therefore polymer guides offer flexibility if extra bone needs to be removed. Polymer guides can be trimmed if needed, whereas the metal guides cannot be adjusted.



Figure 51 – AM cobalt chrome surgical guide which was trialed on the bone, but was not used on the benchmark guide patient. The guide was deemed too rigid around the nasal bone.

#### **6.2.4 Observations, Problems Highlighted and Developments Needed**

The clinical research has identified specific problems within the nasal surgical guide process from design to end use. These problems will be reviewed in this section and used to inform the development of experimental studies in section 6.3.

On review of the six cases of nasal surgical guides used, there was no consistency or standard specification used over the diameter, length and tolerance of the drill cylinders. Most of the nasal surgical guides were a Visijet Clear jacket with a stainless steel tube insert in the drill cylinder (figure 52). The stainless steel tubing is a stock extrusion profile bought off-the-shelf from a supplier, cut to a length depending on the maxillofacial technician's judgment. Once cut it is placed into the polymer component using a light-cure resin to fix it in place.

Problems identified in chapters 3 and 5 have occurred when using the nasal surgical guides clinically:

1. Tight tolerances between the metal tube and the drill can cause the drill to bind.
2. The friction caused by binding of the drill on the tube caused the tube to work loose from the polymer component during the surgical procedure. The guide without the tube is unusable, problem of a loose piece of tube in the area and if not removed has the potential of falling into the patients' airway causing unnecessary complications. An example of stainless steel tube insert in a polymer guide is shown in figure 52.

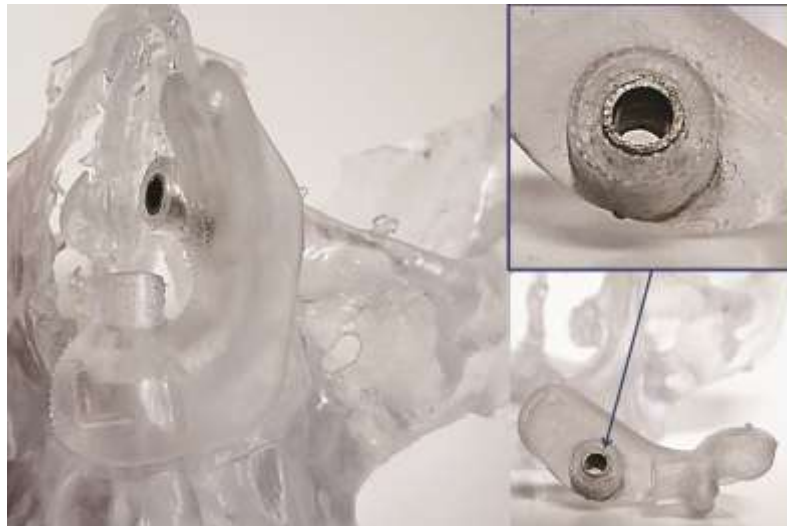


Figure 52 – Benchmark surgical guide with close up imagery of the stainless steel tube insert. Binding and overheating of the metal drill on the metal tube insert can cause the insert to work loose and become detached during use.

The study results in section 6.2.3 demonstrate the variability of technical performance based on the choice of manufacturing process. It challenges conventional wisdom identified in chapters 3 and 5 on the suitability of the clinically favoured metal AM process.

As stated earlier in the explanation of the benchmark case, two types of guides were AM fabricated in metal and polymer. The metal cobalt chrome was deemed too rigid on the bone and was not used. The polymer guide allowed greater flexibility on the bone. The metal inserts in the nasal surgical guides offered rigidity and geometric accuracy to the pilot drill whilst drilling the implant vector.

## **6.3 Developmental Design Changes**

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### **6.3.1 Materials and Methods**

The two AM materials that were used for nasal surgical guides were visijet clear and cobalt chrome. Both materials and AM processes require an appropriate build orientation and supports depending on the geometry and function of the part.

AM can produce many geometries but the ability to obtain a perfect AM circle is difficult and highly dependent on the part build orientation (Thomas, 2009). Post finishing is required for each hole, reaming occurs to ensure they are accurately round to their design intent diameter before surgical use.

Due to the lack of consistency and standard specification for nasal surgical guides, tolerances were looked at in more detail. A range of tolerances were chosen to test in both polymer and metal material in order to judge which one would be appropriate to use and to be specified as a standard when using a 2.9mm pilot drill for drilling implant pathways.

The length of the drill cylinder was also considered, it is assumed that the longer length reduces the amount of angulation at the end point of the zygomatic implant. The length of the drill cylinder is dependent on each patient's anatomy; for example, the gap between the bridge of the nose and the length of zygomatic implant that has been chosen to be used for the patient.

Another factor that influences further developments are the surgical instruments used. When analysing the pilot drill in more detail, shown in figure 53, the total length of the double start drill to complete a 360° pitch was longer than any of the drill cylinders analysed in the previous study. This minimum length of support on the drill cylinder to help prevent angulation of the pilot drill is 11mm. This along with incorporating the length of the drill and implant are important factors in the developmental changes of the nasal surgical guide.



Figure 53 – The total length of the double start drill to complete a 360° pitch is 11mm, the measurement should influence the drill cylinder length and act as the minimum measurement in order to avoid inaccuracy due to the sway of the drill if the drill cylinder is designed less than 11mm.

### **6.3.2 Experimental Design Development**

Due to the non-consistent specification of the surgical guides analysed in the previous study, a range of hole diameter tolerances from 0.0 to 0.5mm were tested. AM Materials Visijet Clear and Cobalt Chrome were used to fabricate test bars shown in figure 54 with different sized holes 2.90mm, 2.95mm, 3.00mm, 3.10mm, 3.20mm, 3.30mm and 3.40mm in order to work out which amount of tolerance would be best for a 2.9mm pilot drill. The length of the test bars remained the same length (7mm) as the benchmark guide drill cylinder to keep the pilot study consistent and comparable.





Figure 54 – Tolerance test bars fabricated using AM Cobalt Chrome and Visijet Clear. The tolerances on the circular diameter are 0, 0.05, 0.1, 0.2, 0.3, 0.4 and 0.5mm in each. For best results of the circles geometries the test bars were built up facing.

The test bars were fabricated to test the accuracy of the two different AM process, the materials and the tolerances in comparison to the CAD design original test bar.

Incorporating an equilateral triangle into the testing helps to resolve the binding effect of the circular counterparts. An equilateral triangle can fit a circle in the middle of it and will touch, hold it rigid and support it at more than one point. A cylindrical insert can only support the drill at one point. The fundamental development of the triangle geometry can be placed into the drill cylinder design of the guide. The triangle can be built into the SLA Visijet Clear guide or as an AM Cobalt Chrome metal insert inside a SLA Visijet Clear guide.

The tolerances shown in the test bars in figure 54 can also be calculated into the triangle geometry to allow the pilot drill to be placed through it with ease and improved accuracy. The equation shown in figure 55 shows that no matter what drill diameter used in a drill surgical guide the triangle geometry can be adapted to support the drill.



The reason for the development of a triangle geometry insert into the nasal surgical guide is that the geometry is easier to AM compared to a circle in both SLA and LM. The triangle is a rigid structure that will securely hold and support the drill at more than one point and the triangle also allows the cooling water for the drill to channel down three parts (WC1, WC2 and WC3) that surround the drill all the way to the bone, which is shown in figure 52. This not only acts as a coolant surrounding the drill but also overcomes the problem of the off-the-shelf stainless steel tube insert from coming away from the guide when binding and overheating occur. Another trait of using a triangle is that the insert/sleeve cannot rotate when compared to using a circular tube insert in a cylindrical sleeve it can rotate.

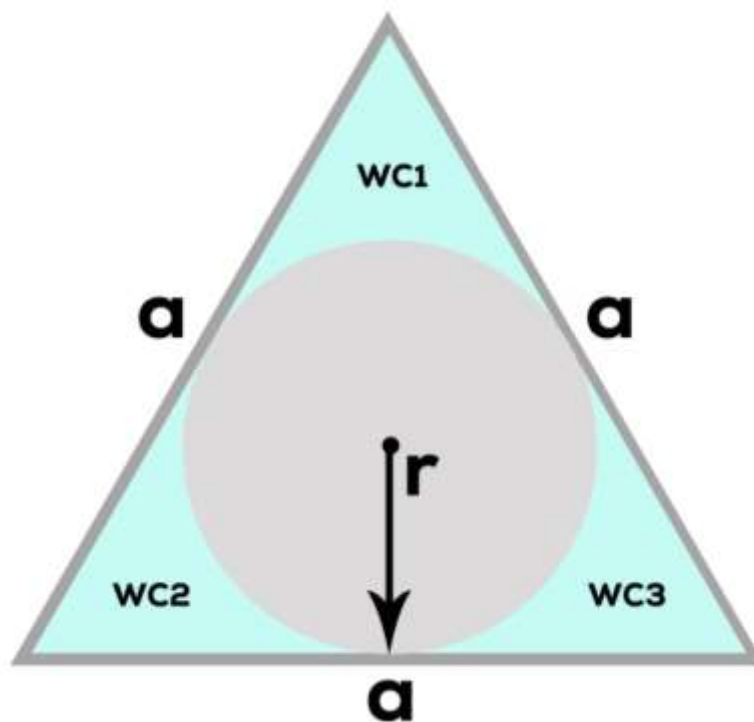


Figure 55 – The equilateral triangle figure demonstrates the equation for working out the tolerance and lengths of the triangle edges  $r = \frac{1}{6}\sqrt{3}a$ . The figure also indicates where the water channels (WC1, WC2 & WC3) are located. The water channels surround the drill, acts as a coolant and removes any debris from the drill area.

In order to test the triangle development, test bars were fabricated in the same way as the circular versions with the same range of tolerance shown in figure 56. This allowed both geometry and tolerance to be tested in the accuracy study.

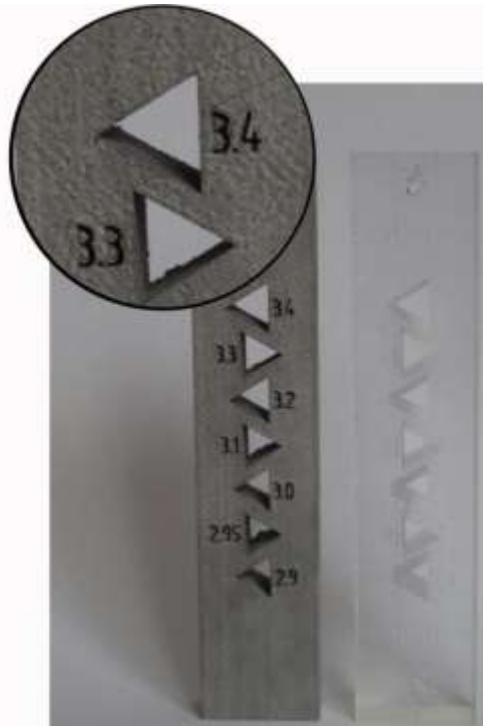


Figure 56 – Tolerance test bars fabricated in AM Cobalt Chrome and Visijet Clear. The tolerances on the triangle inner circular diameter are 0, 0.05, 0.1, 0.2, 0.3, 0.4 and 0.5mm in each. For the best result of the triangle geometries the test bars were built up facing.

Once the test bars were built and supports removed, testing commenced at Renishaw. The test bars were clamped into a vice at the base of a CMM to keep the bar steady when using the touch probe to measure the accuracy of the build.

The CMM shown in figure 57 was calibrated and set so it could identify the four corners of the test bar and the top surface before measuring each of the different tolerance holes.



Figure 57 – Renishaw Plc. CMM was used to calculate the angulation and build error of each test bar. The CMM gathered three readings at -1mm, three readings at -4mm and three readings at -7mm.

### **6.3.3 Test Bar Study**

The test bars used in this study were fabricated in two materials; Visijet Clear using SLA technique on 3D Systems Projet 6000 machine and the other fabricated in Cobalt Chrome using LM technique on a Renishaw AM250 machine.

In order to test the build accuracy of each machine and material, two of each type of geometry was fabricated in the two materials mentioned above. The build beds of each AM machine used were 250mm x 250mm x 250mm. One of the bars was built in the centre of the machines build platform and the other bar was built in the corner of the bed in order to judge the accuracy of the build at different points on the bed. Both the circle and triangle test bar holes were CMM measured from top surface to bottom at three points: -1mm, -4mm and -7mm. The midpoints' of triangle side lengths were estimated by eye for each of the test bars and professionally set up by a technician in Renishaw Plc. The results in figures 58 and 59 for the two materials show that it does not make a difference where the part is placed on the build bed as the build accuracy is consistently within an incremental range of the perfect build correlation ( $R^2=1.00$ ;  $R$ = linear fit correlation coefficient).

The design intent (x axis) compared to the actual reading (y axis) for perfect build is demonstrated by the diagonal line in each graph. The closer the blue diamonds are to the diagonal line the higher the level of accuracy for the AM builds. The graph results in figures 58 and 59 highlights a mean average of  $R^2 = 0.992$  compared to a perfect build correlation of  $R^2 = 1.00$ . The results demonstrate that AM can offer high levels of build accuracy which can improve accuracy of procedures and it is not dependent on where it is built on the bed.

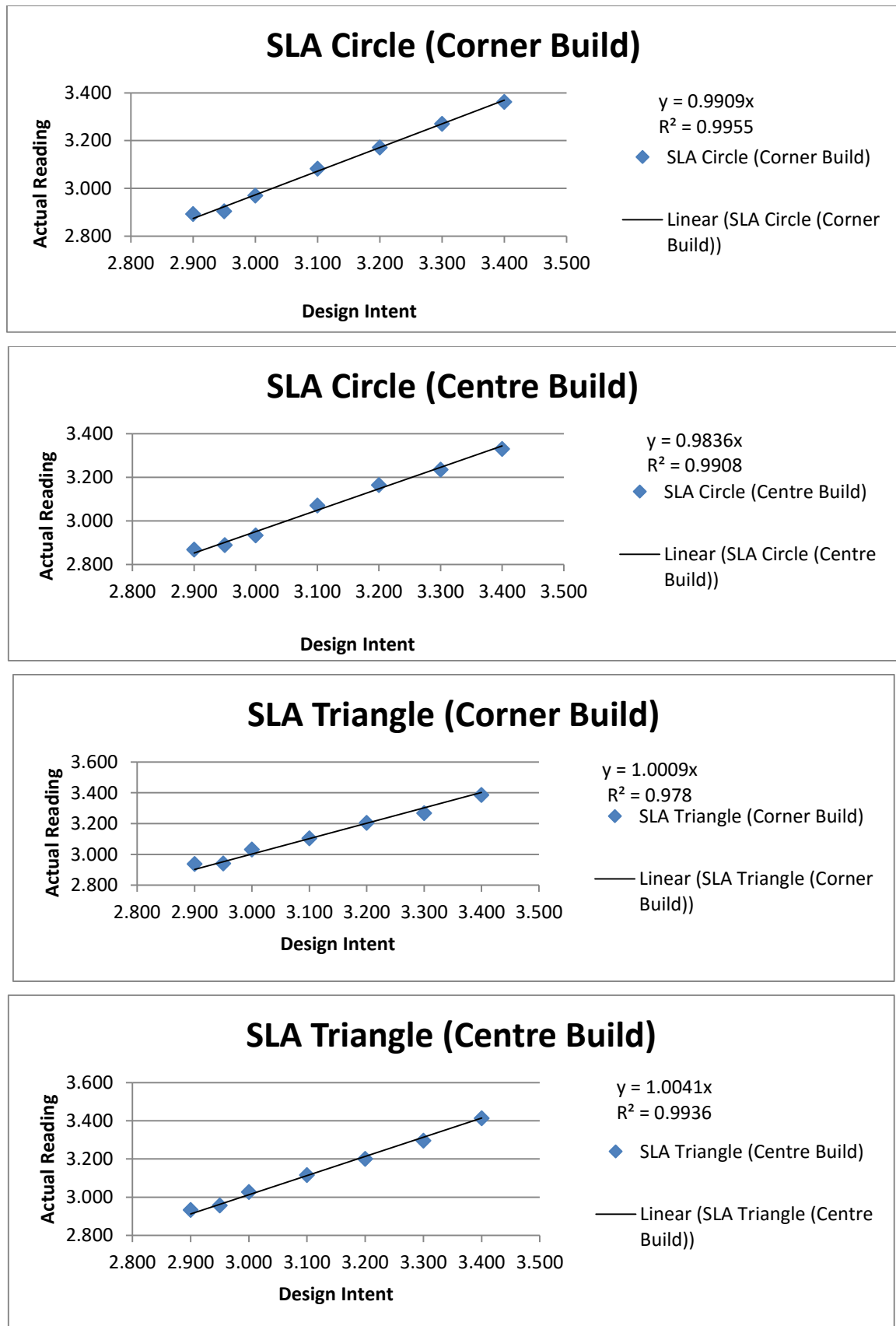


Figure 58 – Accuracy of the build of SLA parts; circles and triangles were built in two different bed positions. One was built in the centre and one in the corner of the bed this test was to see if the accuracy changes depending on build bed position.

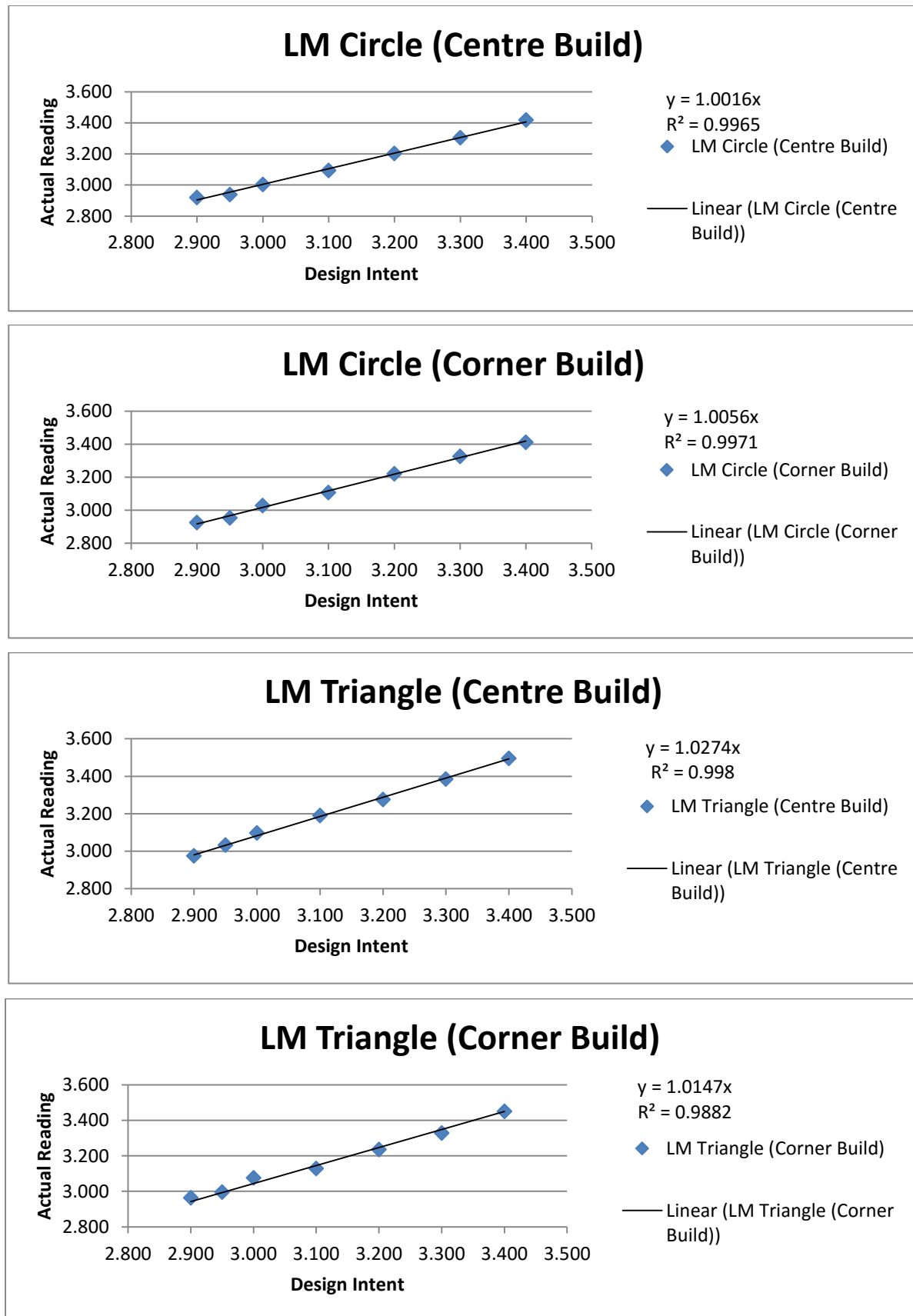


Figure 59 – Accuracy of the build of LM parts; circles and triangles were built in two different bed positions. One was built in the centre and one in the corner of the bed this test was to see if the accuracy changes depending on build bed position.

Figure 60 highlights the measurements attained by the CMM readings in order to calculate the total angle error.

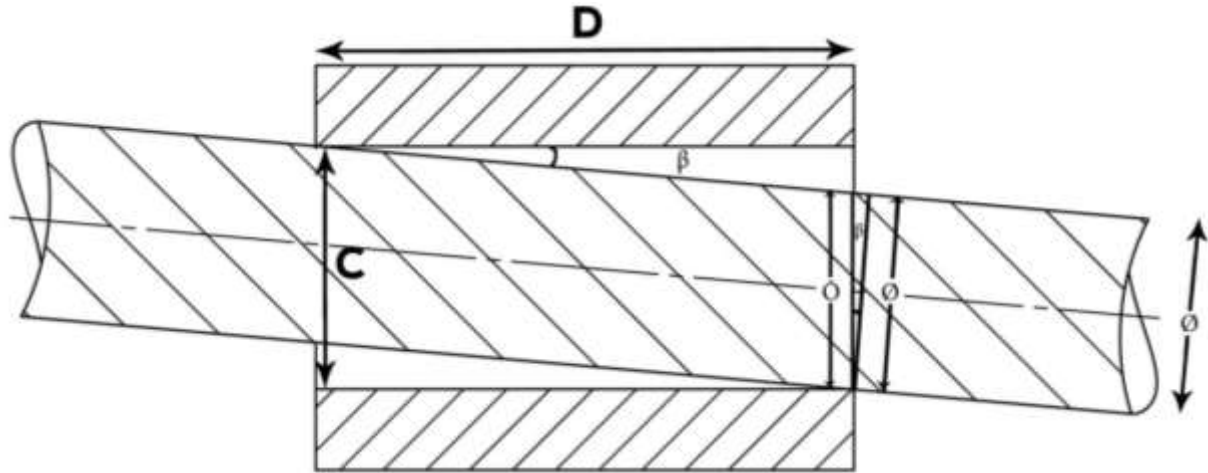


Figure 60 – Diagram to demonstrate the inaccuracy and total angle error of each of the test bar tolerance holes.

The equation below and summary of symbols displays how each test bar holes were measured and calculated to find total angle error.

$$\tan \beta = \frac{C - \frac{\phi}{\cos \beta}}{D}$$

$$\tan \beta = \frac{C - \phi}{D} \quad \text{As } \cos \beta \approx 1$$

$$\cos(5^\circ) = 0.996$$

Therefore

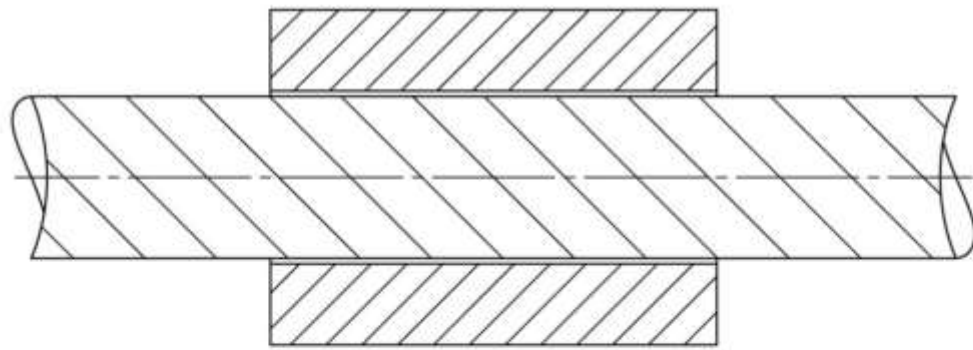
$$\cos(\beta) \approx 1.0 \text{ for small angles}$$

Annular Angle Error =  $\beta$   
 Diameter of Drill Cylinder Hole =  $C$   
 Diameter of Pilot Drill =  $\phi$   
 Length of Cylinder =  $D$

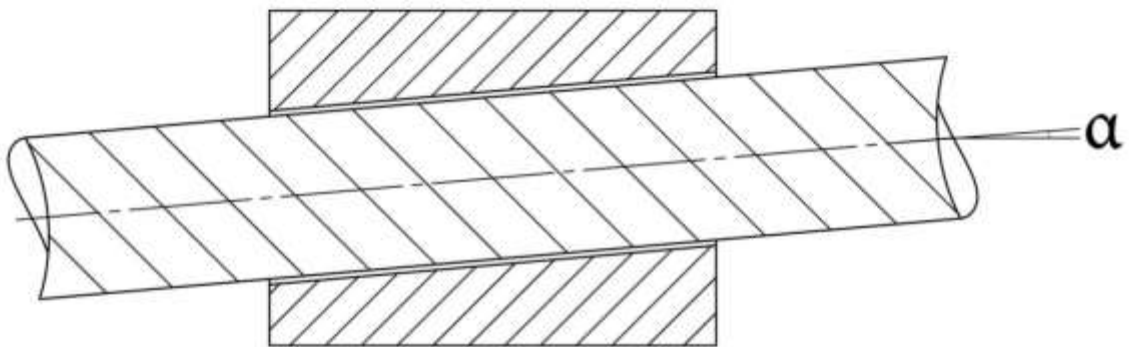
Build Angle Error =  $\alpha$

$$\text{Total Angle Error (Worst Case)} = \delta = \beta + \alpha$$

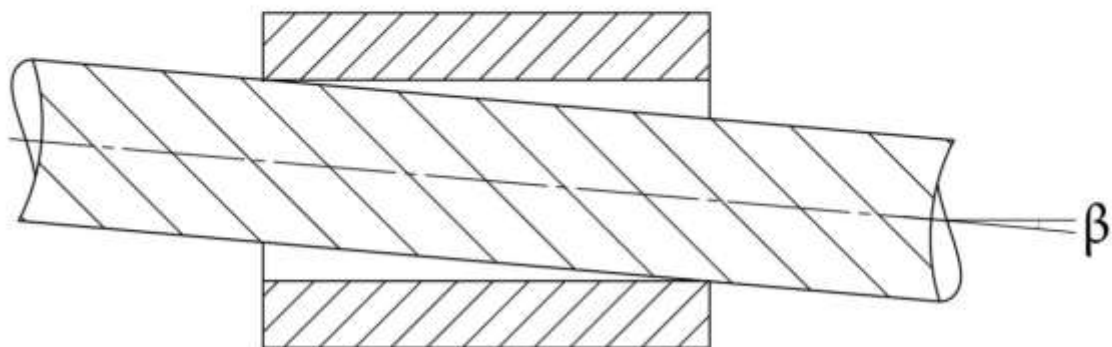
Figure 61 shows the two error readings gathered from the CMM data; Build angle and annular angle error. The readings were in two forms; X, Y, Z coordinates of the projection angle of the cylinder or triangle geometry and the error of the build compared to a 90° angle.



**DESIGN INTENT**



**BUILD ANGLE ERROR**



**ANNULAR ANGLE ERROR**

Figure 61 – Two measurements that were taken from the CMM to be used to compare against the Design Intent; build angle error ( $\alpha$ ) and Annular Angle Error ( $\beta$ ). The design intent of the part consists of perfect alignment from both the build and annular angles.

### 6.3.4 Test Bar Study Results

The results generated from the CMM test bar study were used to analyse the build accuracy of the test bars and if surgical guides were built using these geometries and tolerances what would be the projected vector that you could achieve if you had to drill a pathway for a zygomatic nasal implant.

To calculate the projected vectors the benchmark case study 45mm Brånemark implant length was used to show what would be the degree of difference when using the tolerances from the test bars in section 6.3.3.

The calculations for the total angle error were completed for the circular and triangle test bars in both materials; the results are shown in figure 62 and figure 63.

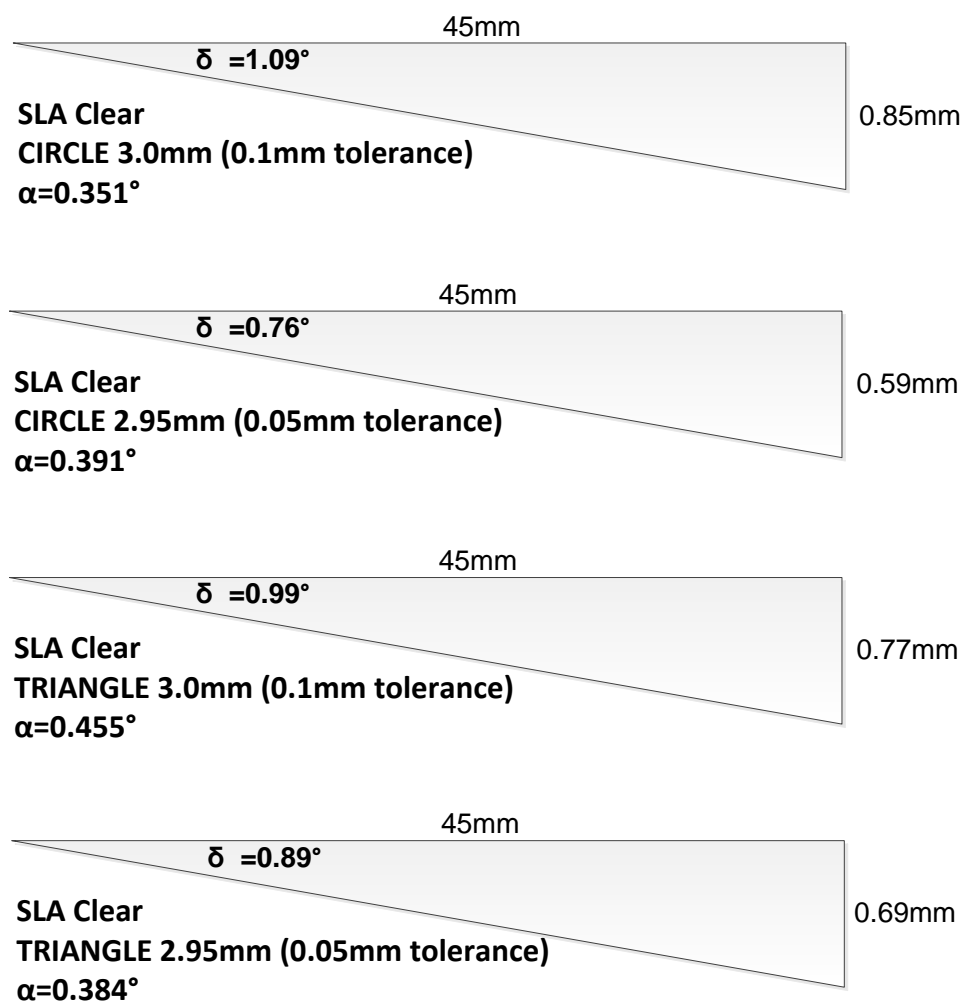


Figure 62 – Angulation error readings of the 7mm depth of the test bars were projected over a 45mm implant length in order to gain what would be the total angle error if the surgical guide drill cylinder was AM in SLA Clear.



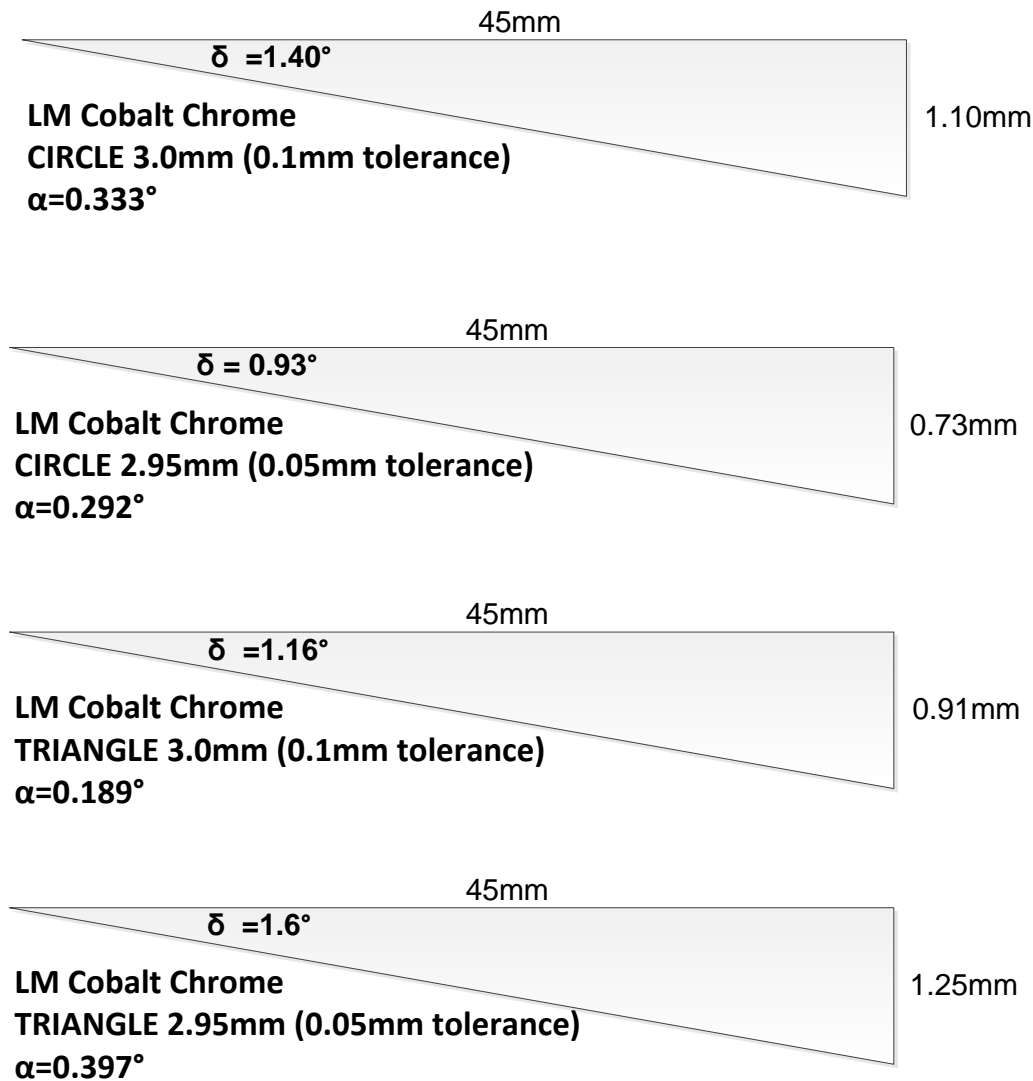


Figure 63 – Angulation error readings of the 7mm depth of the test bars were then projected over a 45mm implant length in order to gain what would be the total angle error if the surgical guide drill cylinder was AM in LM Cobalt Chrome.

After analysing the results, test bars with 0.05mm and 0.1mm tolerances had the lowest total angle error (worst case) in the projected vectors in both AM metal and polymer materials. The results for 0.05mm and 0.1mm tolerance ranged from  $0.76^\circ$  to  $1.60^\circ$  with a mean reading of  $1.10^\circ$ .

The result shows that all are within the region of one degree of difference from the planned position (design intent) to the fixed position (actual reading); this is with the same characteristics used on the benchmark guide of a 45mm Brånemark implant with a 7mm length on the drill cylinder calculated with the total angle error on each build.

When comparing this  $1.10^\circ$  result to the benchmark surgical guide degree of difference angle of  $8.04^\circ$  there is a  $6.94^\circ$  difference between them. These tolerance results can be incorporated into a new developed surgical guide and, in theory, be more accurate than the benchmark guide currently used and improved accuracy results between the pre- and post-operative scans of the future.

An improvement in angular accuracy of  $6.94^\circ$  would not be fully achievable based on other variables that occur. For example, whether the surgeon is left or right handed varies the position of the drill, the surgeon's experience of using surgical guides and whether the surgeon is in a standing or sitting position in the operation.

To ensure the quantitative results of the test bar study were correct, a physical examination with the 2.9mm diameter pilot drill was performed as shown in figure 64. Both 0.05mm and 0.1mm tolerances in both SLA Visijet Clear and LM Cobalt Chrome gave enough clearance without the drill being physically unstable, and it also counteracted the binding problems explained earlier.

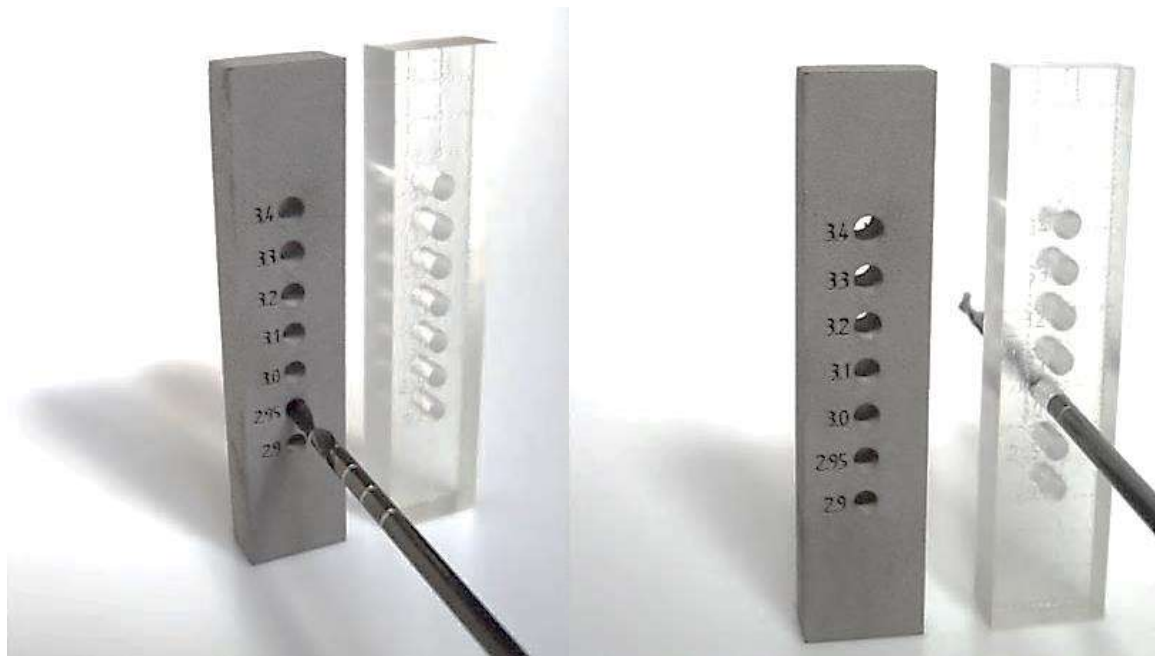


Figure 64 – Tolerance test bars physical testing with the Brånemark 2.9mm pilot drill to judge which diameter is best to use in the both AM material options.

In figure 65, the upper graph shows the angular error with regards to the six surgical case results generated in section 6.2.3 highlighted with a blue solid line; the estimated build error of the surgical guides used in the cases with a red dashed line and the estimated bone interface error highlighted with a green dashed line. The mean of section 6.2.3 results in  $9.37 \pm 2.5^\circ$  highlights that there must be other variables that make the error difference larger; the estimated mean of the build annular error is  $3.46 \pm 1.0^\circ$  and the estimated error mean of the bone interface error is  $5.91 \pm 1.5^\circ$  lower degrees then the surgical cases.

The lower graph shows the probability density function of angular error with regards to the 2.95mm triangle test bar results highlighted with a red solid line; the estimated total error associated with guide with a blue dashed line and the estimated bone interface error highlighted with a green dashed line. The mean result of the SLA and LM 2.95mm triangle test bar is  $1.17 \pm 0.6^\circ$  highlights the best-case error that a guide could get after the build error. There are other variables that increase the error; the estimated total error associated with guide is  $7.08 \pm 2.1^\circ$  and the estimated error mean of the bone interface error is  $5.91 \pm 1.5^\circ$ .

The research has looked at improving the accuracy at the interface of the drill and guide. The interface between the guide and the bone has not been measured i.e. same in upper and lower graphs in figure 65. The annular error and build error for the 2.95 triangle surgical guide is reliant on AM fabrication accuracy. These graphs and results were brought forward into the development of a new surgical guide in sections 6.3.5 and 6.3.6.

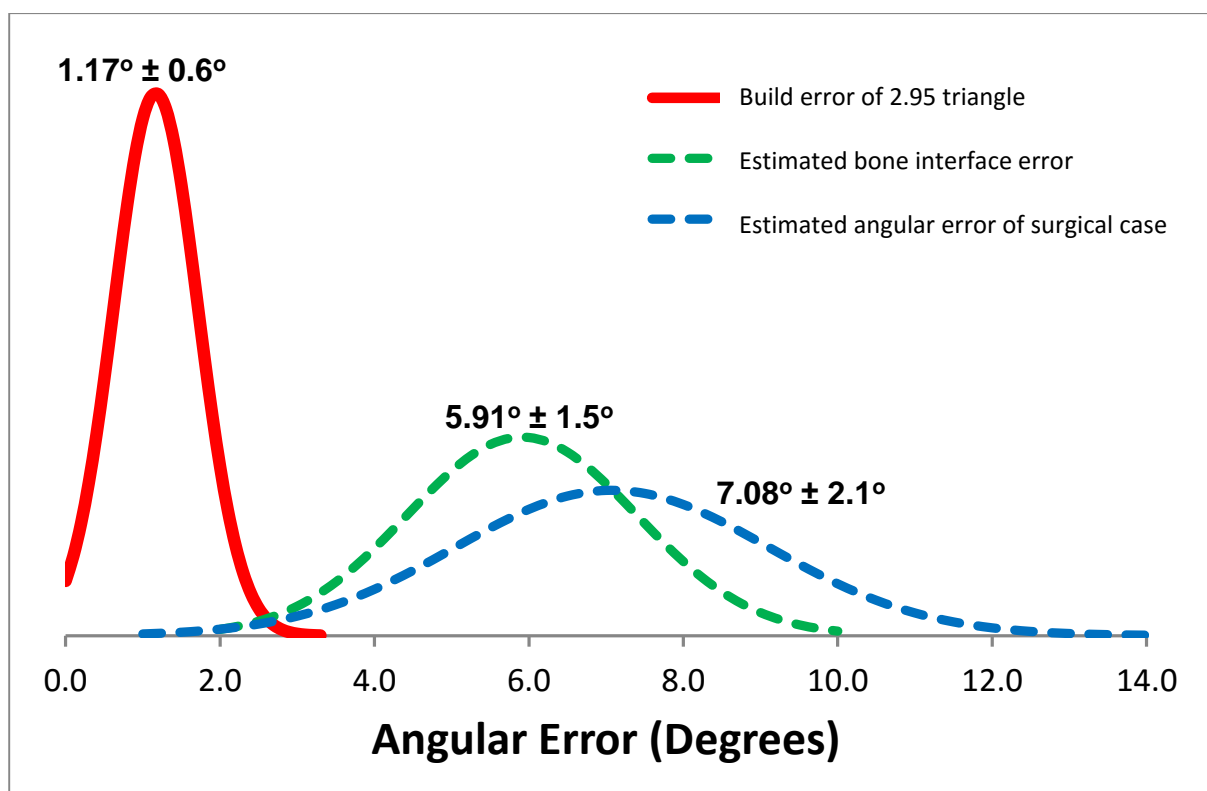
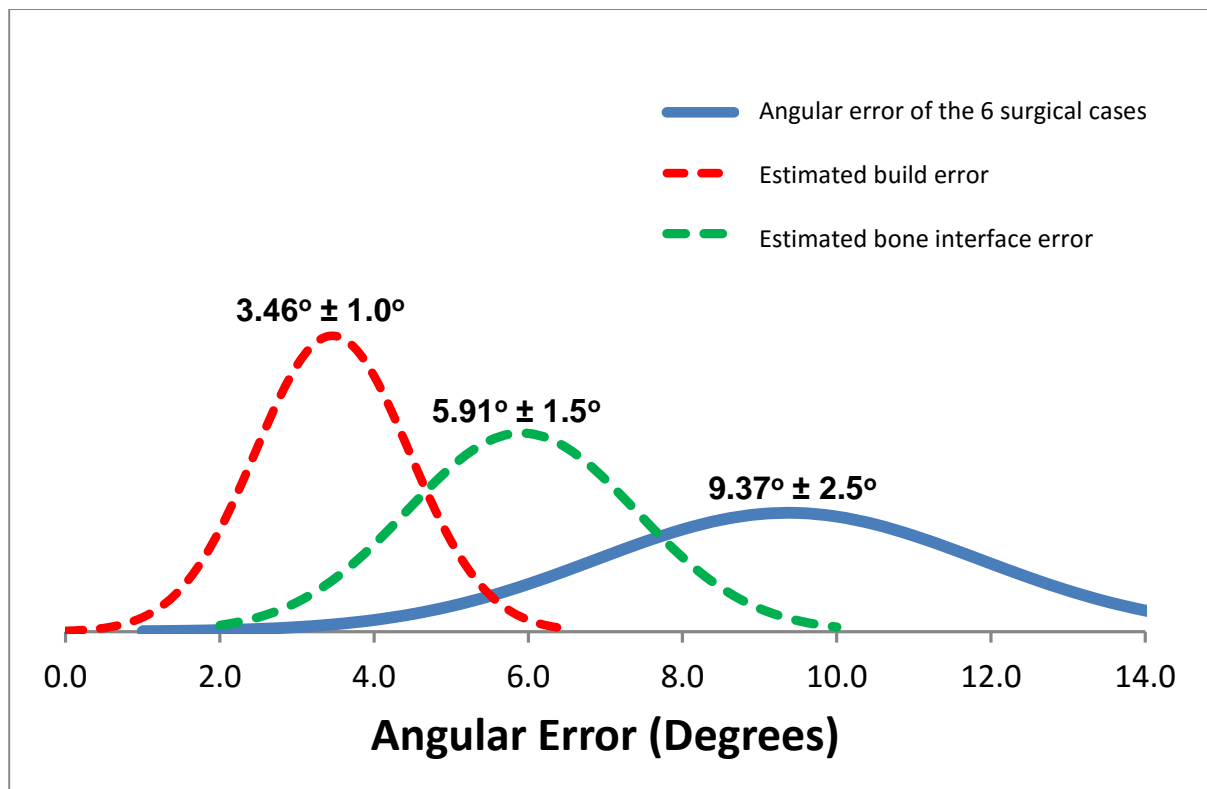


Figure 65 – Angular Error; the figure demonstrates two graphs (upper and lower). The upper graph displays three measurements; the red dashed line represents the estimated build error, the green dashed line represents the estimated bone interface error and the solid blue line represents the angular error of the six surgical cases. The lower graph also displays three measurements; the solid red line represents the angular error of the 2.95 triangle.

### **6.3.5 Developed Surgical Guide Study**

With the promising results demonstrated in the test bar study the findings were then developed on into the core study for this chapter. The tolerance values of 0.05mm and 0.1mm along with the AM material choices of Visijet Clear and Cobalt Chrome were incorporated into the design development of the nasal surgical guides. The developed designs united the incremental changes of the new tolerance information and geometries.

From the previous research and results in this chapter it was decided that a series of nasal surgical guides would be fabricated using the AM techniques tested. The same benchmark patient was used to create new guides using the CT scan data in both Mimics and Freeform software. The jacket of the guides remained as the Visijet Clear material with variations in the drill cylinder. The drill cylinders were either the drill insert geometry built into the Visijet Clear jacket or an AM Cobalt Chrome insert that would be placed into the drill cylinder of the Visijet Clear jacket.

The developed surgical guides mimicked the benchmark guide with incremental changes to judge how much of a difference in regards to projected vectors did they make. Figure 66 shows the benchmark guide on the left hand side and the newly developed guide on the right with geometrical, material and tolerance changes.



Figure 66 – Benchmark (left) and one of the developed guide (right) example, Benchmark guide is a SLA Clear jacket with a stainless steel insert and the developed guide is 2.95mm triangle cobalt chrome AM insert in a SLA Clear jacket.

Six nasal surgical guides were developed shown in figure 67 with key changes to each:

1. 2.95mm Triangle (0.05mm tolerance) in Visijet Clear
2. 3.0mm Triangle (0.1mm tolerance) in Visijet Clear
3. 2.95mm Triangle (0.05mm tolerance) Cobalt Chrome insert with no clearance allowance in a Visijet Clear Jacket
4. 2.95mm Triangle (0.05mm tolerance) Cobalt Chrome insert with 0.15mm clearance allowance in a Visijet Clear Jacket
5. 3.0mm Triangle (0.1mm tolerance) Cobalt Chrome insert with no clearance allowance in a Visijet Clear Jacket
6. 3.0mm Triangle (0.1mm tolerance) Cobalt Chrome insert with 0.15mm clearance allowance in a Visijet Clear Jacket



Figure 67 – The six developed nasal surgical guides with different iterations and tolerances on the triangle geometry.

The clearance allowance was designed into the guides as when fabricating the benchmark guide the stainless steel insert was placed and set into the guide using a light cure resin. The 'no clearance' allowance guide (three and five) inserts fit exactly into the hole with no need for resin, whereas the 0.15mm clearance allowance left enough of a gap for the light cure resin to flow around the insert.

In order to remain consistent with the testing of the developed guides, the same CMM was used for this study. The study looked at how the benchmark and developed guides fitted on the bone; how a 2.9mm diameter fitted into the drill cylinder and what was the projected vector results of each design. In order to fixate the surgical guides onto the nasal bone and for it to be kept in a stationary fixed position for the CMM testing to commence, a datum block was designed using Mimics and Freeform software and fabricated in Visijet Clear.

The datum block, as shown in figure 68, was a rectangular block with the left side of the patient's skull (from the mid-point of the orbit to the top of the maxilla). The left side of the anatomy is the area that the surgical guides had been designed on; the partial skull highlights the nasal and zygomatic bone.

The datum block was placed in the correct X,Y,Z position to how the implant pathway would be drilled in the operating theatre. The datum block comprised of an extended base that clamped into the vice at the base of the CMM securely. The benchmark guide, cobalt chrome guide that was trial fitted on the benchmark patient and six newly developed guides were placed onto the datum block at the same location point.

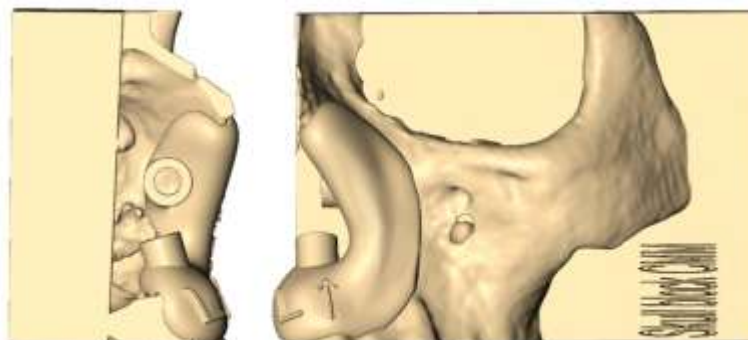


Figure 68 – The datum block for the CMM testing. The datum block allowed the benchmark guide and each of the developed nasal surgical guides to be fixated onto the nasal bone so that the CMM measurement of the drill cylinder angulation could take place.



To mimic a 2.9mm diameter pilot drill a 2.9mm diameter pin gauge of 51mm length was used and placed into the drill cylinder of the guide. The CMM shown in figure 69 was calibrated and set so it could identify the four corners and the top surface of the datum block before measuring the angulation and projected vector of the pin gauge that was placed within the drill cylinder of each of the different nasal surgical guides.



Figure 69 – Renishaw Plc. CMM was used to calculate the angulation error of each of the benchmark and developed surgical guides using the datum block as constant stationary object clamped into the vice. The CMM gathered six readings at -5.5mm, six readings at -10mm and six readings at -14mm.

Points were taken from the pin gauge to demonstrate the angle of projection of it from each guide. Six points were measured at each of the three lengths 5.5mm, 10mm and 14mm from the top of the pin gauge. The surgical guides when fabricated to their design intent should hold the pin gauge vertically at 90°.

### 6.3.6 Developed Surgical Guide Study Results

The results generated from the CMM core study were the angulation error derived from the X, Y, Z axis of the pin gauge at 5.5mm, 10mm and 14mm lengths from the top of the pin gauge.

Table 4 highlights the angulation error results from the guides; Benchmark guide 2 provided the lowest error with a reading of 0.927°. This guide was the LM cobalt chrome guide trailed on the benchmark patient. This guide was deemed unfit for use and the material was too rigid on the nasal bone offering no flexibility to the area. However, in this CMM result it was the most accurate compared to the benchmark and developed guides at the drill cylinder; this result was expected.

Guide Name	Guide Information	Angulation Error Degrees
Benchmark 1	SLA CV with SS inserts	5.821
Benchmark 2	LM Cobalt Chrome	0.927
Development 1	SLA 2.95mm Triangle	3.960
Development 2	SLA 3.0mm Triangle	4.161
Development 3	SLA with LM CoCh Triangle Inserts 2.95mm (no clearance)	8.842
Development 4	SLA with LM CoCh Triangle Inserts 2.95mm (0.15 clearance)	5.653
Development 5	SLA with LM CoCh Triangle Inserts 3.0mm (no clearance)	5.639
Development 6	SLA with LM CoCh Triangle Inserts 2.95mm (0.15 clearance)	8.900

Table 4 – Angulation Error CMM results for the benchmark and developed surgical guides. Benchmark 2 provided the best angulation error result but could not be used in the operation due to the metal being too rigid on the bone.

Four of the six developed surgical guides had angular errors less than the angulation error of the benchmark guide of  $5.82^{\circ}$ . The readings ranged from  $3.96^{\circ}$  to  $8.90^{\circ}$ .

The incremental changes to the developed guides have proved that in theory they would help improve with the accuracy and placement of nasal zygomatic implants. After demonstrating the decrease in angle in the test bar and developed guide studies of this chapter, the Maxillofacial Clinical Team at Morriston Hospital agreed to trial the new designs in the next Rhinectomy patient.

## **6.4 Applications of the research**

The process of the six surgical cases tested in 6.2.3 was repeated for operation 1 shown in section 6.4.1. This provides a full cycle of research from the clinical case studies, testing and analysing the area, developing new ideas and then clinically testing the ideas to show if they have helped improve the accuracy of drilling the implant pathway.

### **6.4.1 Operation 1 – Nasal Zygomatic Surgical Guides with Triangle Inserts**



#### **Background & Surgical Guide Design**

In June 2015 one of the surgeons involved in the nasal review in the clinical feedback chapter explained that a zygomatic implant case had come through. This case was similar to case study A and B shown in chapter 5 but the patient had already received a partial rhinectomy in an earlier operation.

Usual timings from placing implants for the prosthesis to fitting the final prosthesis take six weeks. The nasal surgical guides were designed by the author incorporating all the findings from the PhD into the final design.

The guides were designed in SLA Clear material in a J shape that located around the base of the nasal bone as previous nasal surgical guides have been made. The main difference was the use of the triangle inserts that had a tolerance of 0.05mm on the diameter of the 2.9mm diameter pilot drill. The inserts were designed to snap fit into the SLA clear J guide in the drill cylinder part. The length of the drill part was increased in length to 15mm in order to make sure it was above the 11mm length of the pitch of the pilot drill whilst also making sure that there was enough space in the area to allow this increase to happen. The triangle inserts were made in AM cobalt chrome with no polishing required.

This was repeated for both sides (left and right) of the patient on the trajectory drill pathway that was identified by the surgeon. The drill part of the guide where the triangle inserts were inserted was angled to the planned digital location of the best bone pathway for the Brånemark zygomatic implants. Two guides were used, one to place the left zygomatic implant and a separate one to place the right (Figure 70).

### **Design & Operation Images**

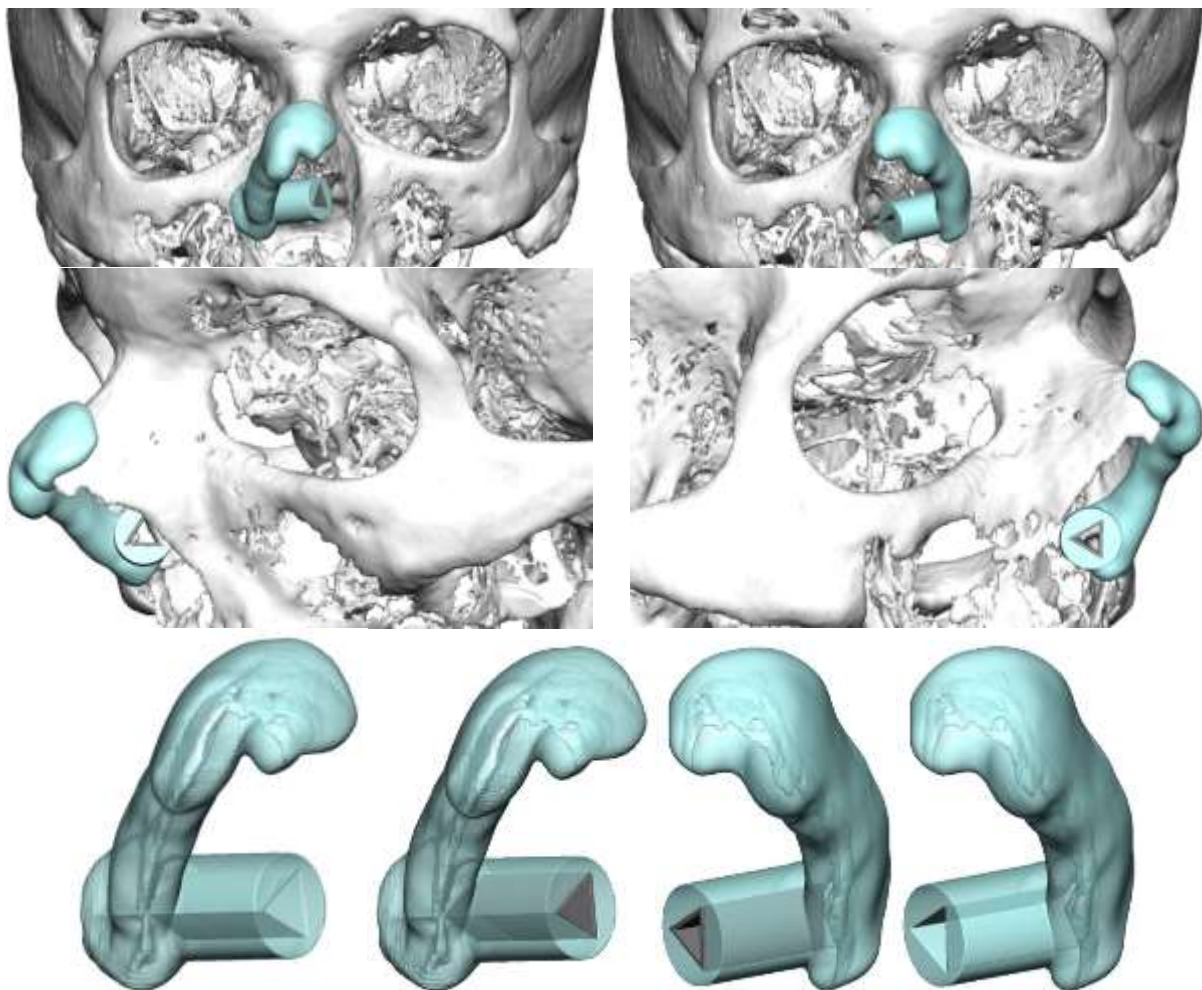


Figure 70 – The newly developed design of the surgical guides are shown in the imagery both the left and right guides that was digitally planned and designed for this patient's surgery. Both guides were SLA Clear with triangular inserts in each of the drill cylinders.



Figure 71 – Use of left hand side nasal surgical guide for the Brånemark pilot drill to drill the planned pathway of the digitally designed guide. Fixation of left hand side zygomatic Brånemark implant into the bone.



Figure 72 – Use of right hand side nasal surgical guide for the Brånemark pilot drill to drill the planned pathway of the digitally designed guide. Both zygomatic Brånemark implants located into the bone.

### **Observations & Surgical Notes**

The operation started at 11.25am and ended at 12.00pm, therefore 35 minutes in total. The operation consisted of placement of left and right nasal zygomatic implants and intra oral implants.

Fixation of left nasal guide @ 11.34am (figure 85)

Drill through left nasal guide @ 11.36am

Fixation of right nasal guide @ 11.38am (figure 86)

Drill through right nasal guide @ 11.40am

Review with surgeon after use of the newly developed nasal surgical guides:

“No wobble, straight through and easy to use.”

“Left guide worked well.”

“Right guide did not have enough location onto the bone.”

The surgeon was happy how the drilling went.

Fixation of right implant @ 11.47am (figure 72)

Fixation of left implant @ 11.50am (figure 71)

Review after fixation of nasal zygomatic implants:

“Well that worked very well.”

“I am concerned with the right implant as the patient’s bone was very thin on that side due to his age.”

“No binding occurred on the drill due to the change in tolerance and geometry and I like the triangle.”

“Post-operative CT scan will be completed for accuracy analysis.”

“The guides will be sterilised and sent back to the lab.”



## Results

The post-operative CT scan of the patient became available a couple of months after the operation took place. The DICOM data was sent to be analysed against the pre-operative CT and digital plan for the placement of the nasal zygomatic implants. The same process used in Chapter 6 in section 6.2.3 was used for operation 1 to calculate the degree of difference of the implants from pre-operative (planned) to post-operative (fixed) position.

The left surgical guide and implant was focussed on to compare against the benchmark surgical guide used in Chapter 6. The benchmark guide had a degree of difference of  $8.04^\circ$ ; the degree of difference of the developed surgical guide used in operation 1 was  $6.3^\circ$  as shown in figure 73.

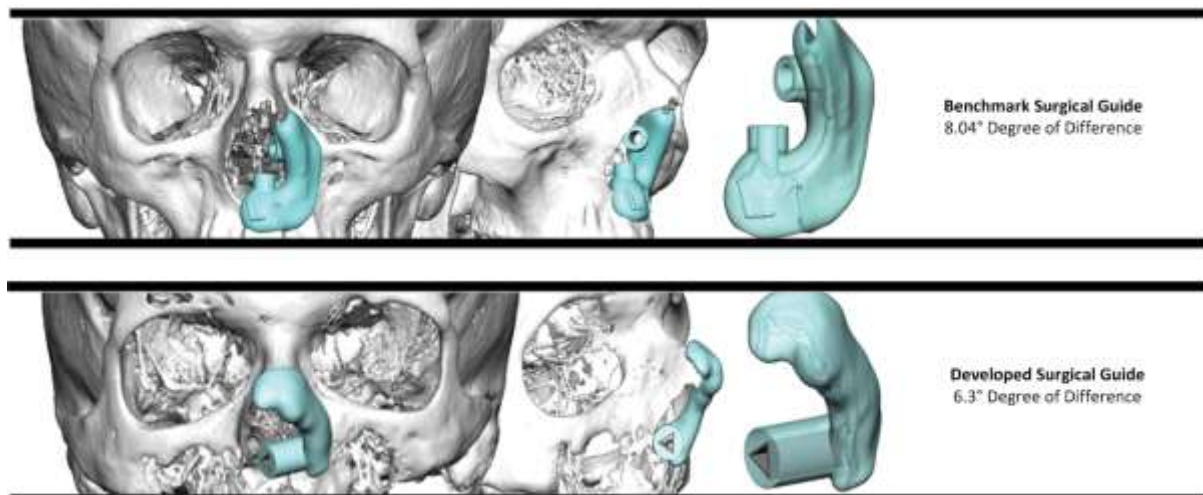


Figure 73 – Benchmark surgical guide ( $8.04^\circ$ ) versus Operation 1 developed surgical guide ( $6.3^\circ$ ) degree of differences.

Earlier in this chapter (figure 65), the graph showed the estimated annular error of the developed guides if all the incremental changes from the chapter were placed into the guide. The graph estimated that an annular error of  $7.08^\circ \pm 2.1^\circ$  would be the prediction for any of the future guides used.

Figure 74 shows where the developed surgical guide from operation 1 appears on the estimated line, the result shows that the guide achieved less than the mean reading estimate predicted earlier in the chapter. This shows that the developed surgical guide produced was more accurate than the six cases reviewed in chapter 6 and exceeded the prediction of the estimated annular error of future developed guides.

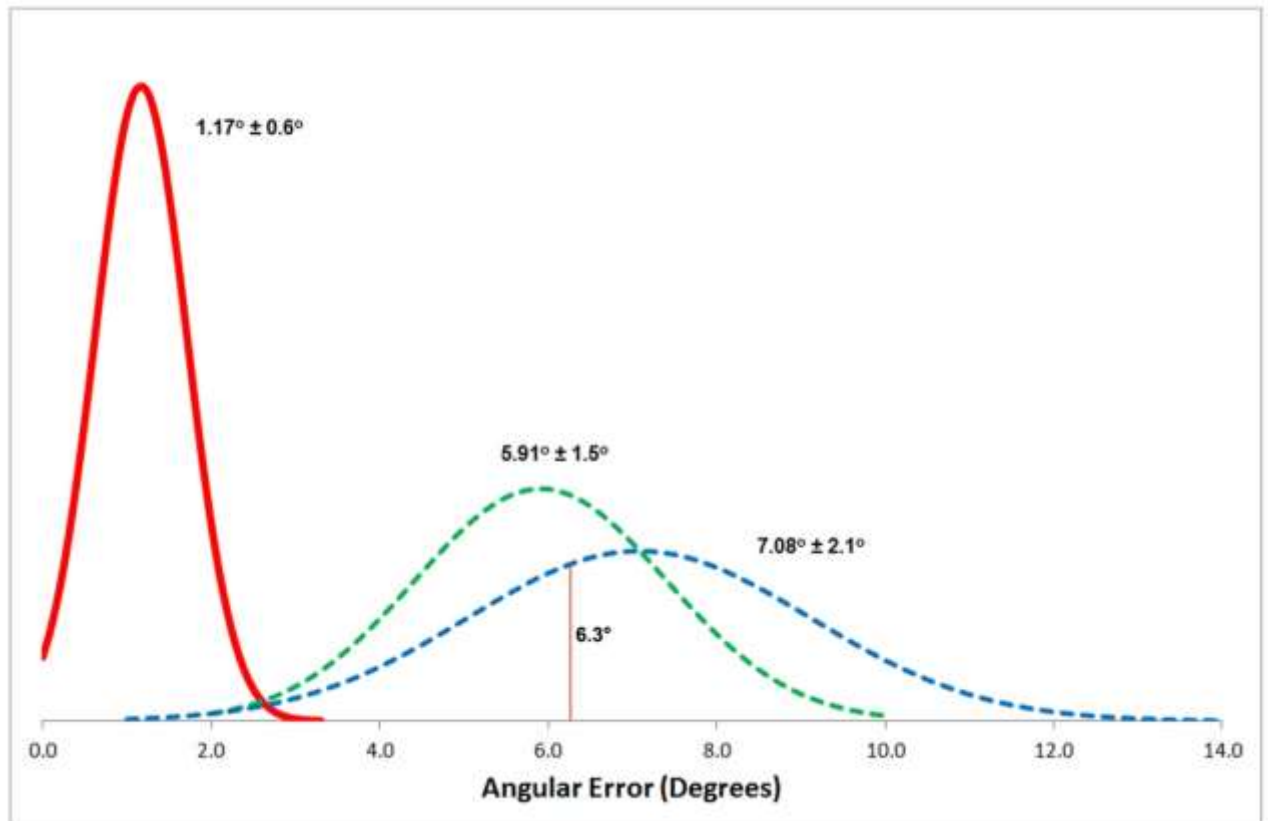


Figure 74 – Angular Error Graph; The graph displays four measurements; 1. The red solid line represents the angular error of the 2.95 triangle, 2. The green dashed line represents the estimated bone interface error, 3. The dashed blue line represents the estimated angular error results of developed surgical guide cases and 4. The orange line onto the dashed blue line demonstrates where operation 1 developed surgical guide ( $6.3^{\circ}$ ) degree of differences lies in relation to the estimated angular error results.

## **6.4.2 Operation 2 – Fibula flap & mandible surgical guides with TRIFLO Keys**

### **Accuracy Chapter Development - TRIFLO**

As highlighted in section 6.4.1, an operation has already incorporated the findings and developments from this chapter into surgical guides. The surgical guides worked very well and the surgeon was pleased with the result. The use of the triangle received high commendation by the surgical team. Quotes from the operations include “No wobble, straight through & easy to use”, “Well, that worked very well” and “No binding occurred on the drill due to the change in tolerance & geometry and I like the triangle.”

Following the application of the triangle in section 6.4.1 the researcher began to evolve the concept. The development of the TRIFLO key was the result of the positive accuracy result from the triangle insert used in the previous operation. Instead of the triangle being a one use insert that is placed and fixed into the drill cylinder of a SLA surgical guide; the TRIFLO key can be placed into numerous drill guides and used multiple times as a surgical set that can incorporate different drill diameters and lengths. The TRIFLO key is an insert for any drill surgical guide; it has a triangle centre as developed from chapter 6 of this PhD thesis. The outer diameter can fit into any AM surgical guide and can be repeatedly used for each drill hole in the guide. The handle allows the insert to be held in place with one hand as the surgeon drills with the other hand. The triangle centre of the insert can be designed for any sized drill used for maxillofacial purposes with the inclusion of the 0.05mm tolerance tested in chapter 6. The researcher hopes to commercialise the TRIFLO keys which are currently being designed into a system for all drills used in surgery and in the future could be sold as a kit to various NHS hospitals (Figure 75).

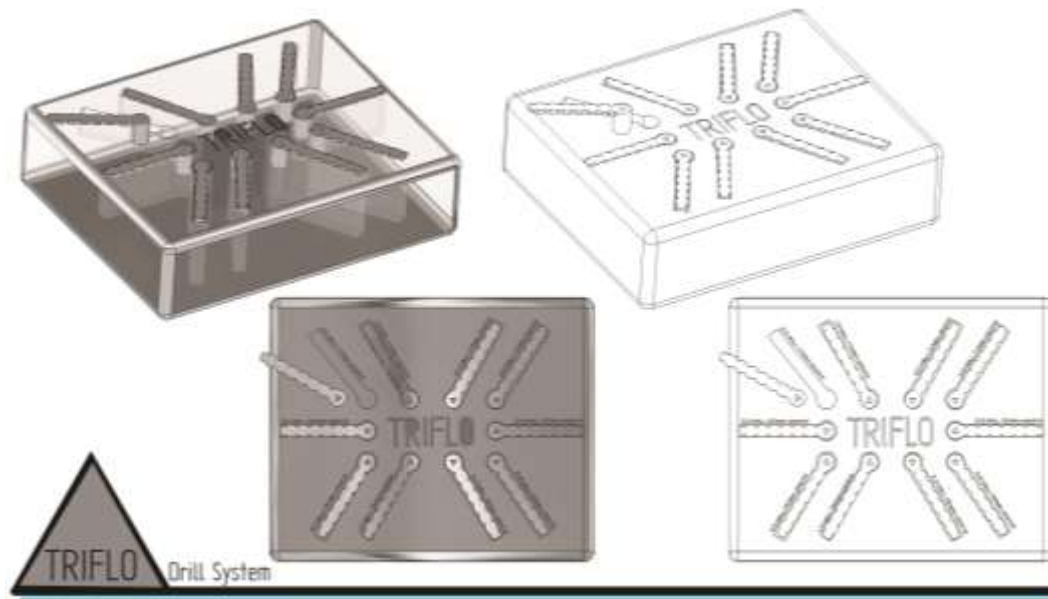


Figure 75 – The TRIFLO key system for use in conjunction with surgical guides for drilling within surgery.

## **Background & Surgical Guide Design**

In September 2015 a fibula flap case came through for a mandibular cancer patient. These complex cases are common in both PDR and Morriston; they require both cutting and drilling guides and are used on the fibula and mandible.

A PDR design engineer designed the surgical guides and implants in accordance to the surgeon's instructions. The surgeon required a combination mandible cutting & drilling guides and a combination fibula cutting & drilling guides with an AM titanium mandible plate implant (Figure 76).

The PDR design engineer asked the author if the triangle inserts could be incorporated into the drilling part of the cutting guide. In a development on from the first operation a set of TRIFLO keys were designed which allowed the PDR design engineer to proceed with his guide and implant designs for the case whilst the author designed the TRIFLO key inserts.

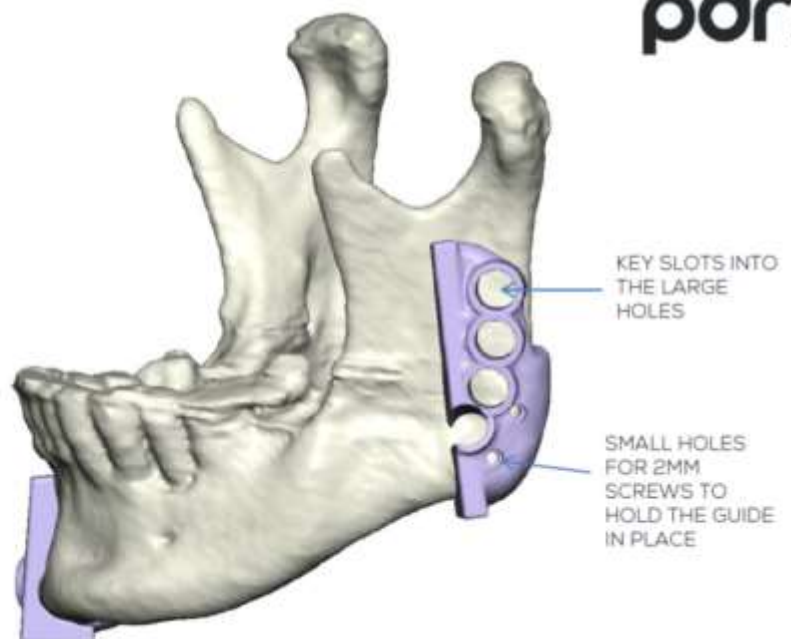
The PDR design engineer made a 7mm diameter space for each key to be placed into in order to drill with the TRIFLO key a pilot hole of 1.5mm diameter for the pilot drill they use in mandibular cases.

The author used the triangular theory and produced a TRIFLO key that could be placed into the 7mm diameter space for repeated use throughout the different guides. The TRIFLO key had a 0.05mm tolerance for the 1.5mm pilot drill and was placed in the centre of the 7mm diameter circle so that the planned axis of the drill pathway lined up correctly. The length of the TRIFLO key was 8mm and they were fabricated in AM titanium. Each TRIFLO key had a handle of 30mm length in order for the thumb and first two fingers of the hand to hold the key in place.

## Design & Operation Images

### PROPOSED MAND. GUIDES

- FOR USE WITH 1.5mm PILOT DRILL FOR 2mm SCREWS
- USED IN CONJUNCTION WITH A CUSTOM, TRIANGLE KEY
- MATERIAL = SLA EPOXY-BASED RESIN READY TO AUTOCLAVE & TITANIUM KEY



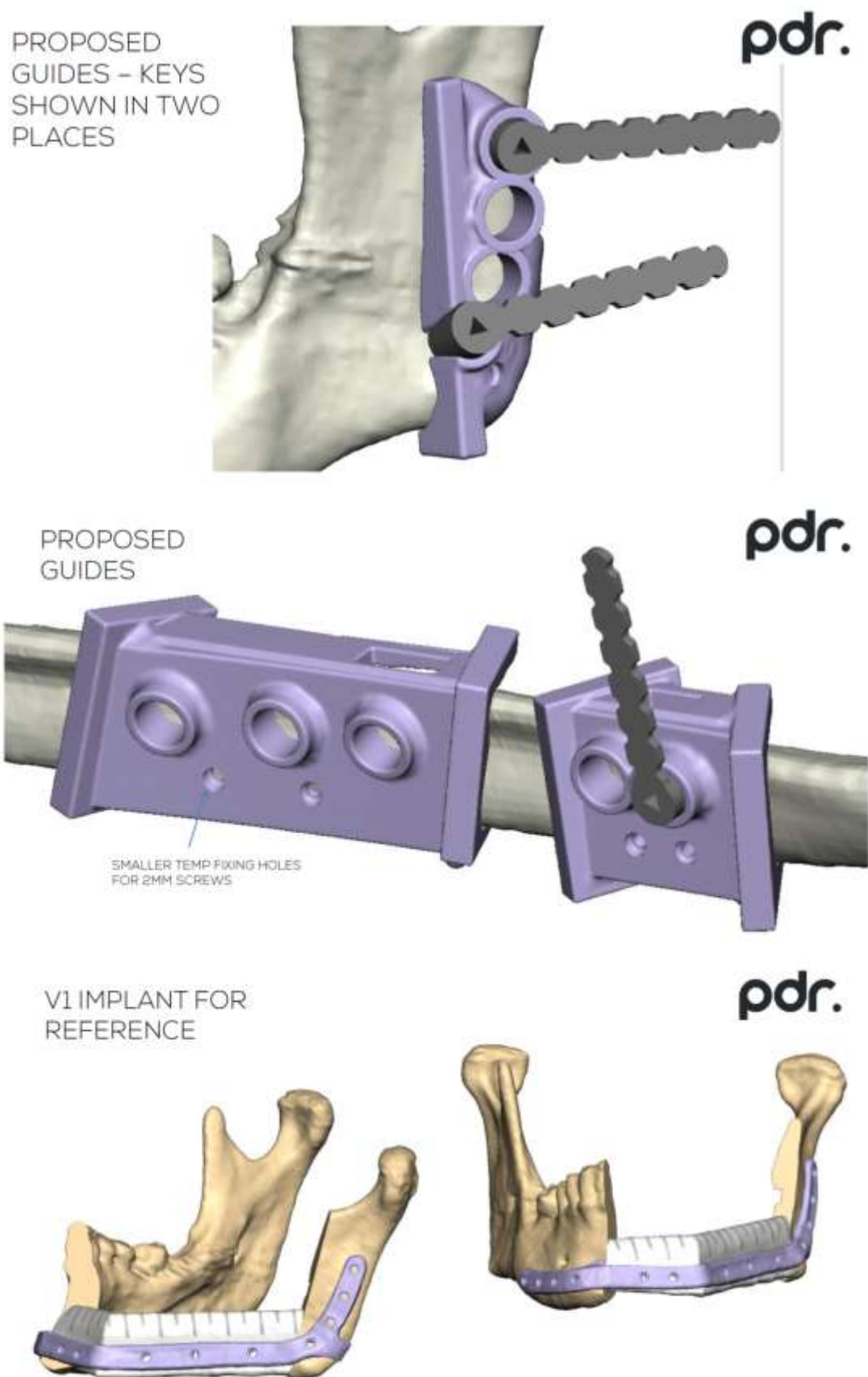


Figure 76 – The newly developed design of the TRIFLO keys incorporated into the mandible and fibula cutting & drilling guides system and plate.



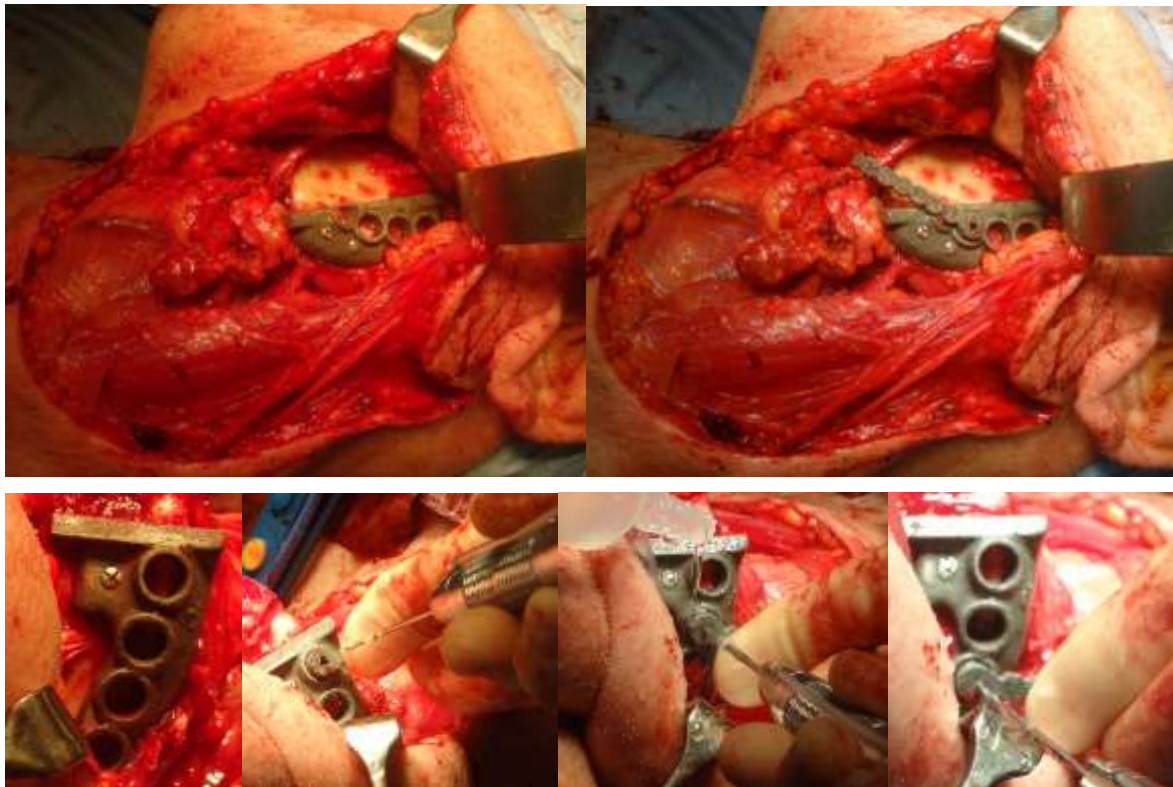


Figure 77 – Use of TRIFLO keys used on the mandible part of the operation.

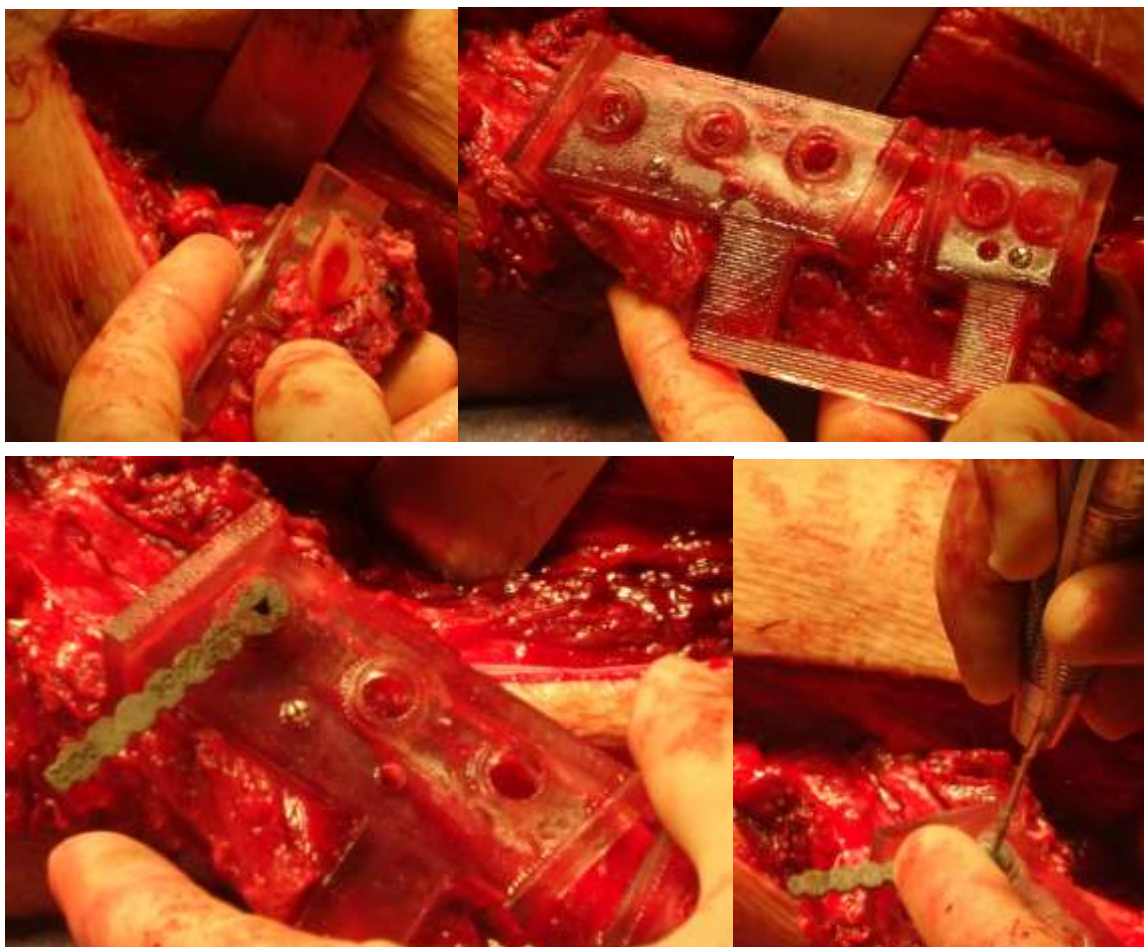


Figure 78 – Use of TRIFLO keys used on the fibula part of the operation.



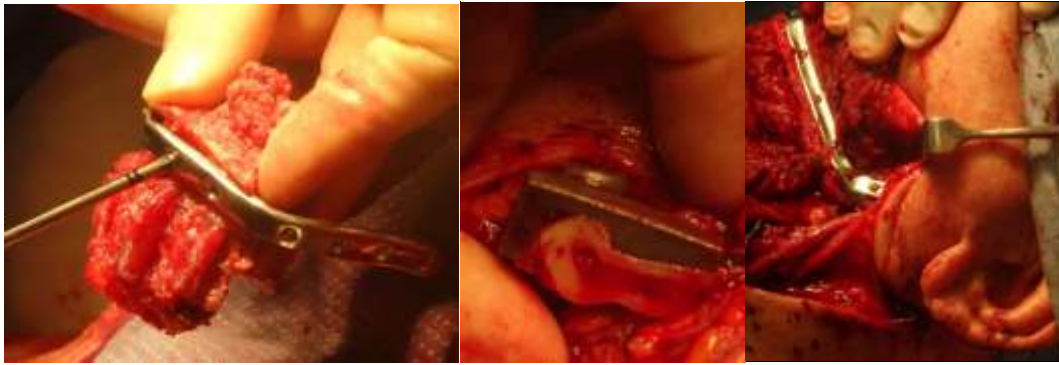


Figure 79 – Fixation of the plate and fibula flap onto the mandible part of the operation.

### **Observations & Surgical Notes**

The operation started at 10.30am and ended at 6.00pm, the operation consisted of neck dissection, exposure of fibula, partial removal of the mandible, use of the cutting and drilling guides on both mandible and fibula, fixation of plate on fibula, fixation of fibula and plate onto mandible area, connect the blood supply of the fibula to the area and close up both exposed areas.

Review with surgeon after use of the newly developed TRIFLO key incorporated to surgical guides:

“Mandible cutting guides worked well and the drilling with the key insert.” (Figure 77)

“The mandible cutting guides located onto the bone lovely and the metal cutting guides were easy to cut against.”

“Liked the inserts and fixating triangles; it felt secure and precise.” (Figure 78)

“I take the muscle with the fibula bone as it provides a better blood flow and feeds the bone better. The muscle protection over the bone and plate in the mandible helps when the patient goes through radiotherapy.” (Figure 79)

“I would like to try the inserts in a longer length next time.”

The surgeon asked to write this case up for publication with both the author and PDR design engineer to be involved in the technical note part of the paper.

## **6.5 Summary**

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The results from this chapter identified six nasal surgical guide cases and calculated their pre to post-operative accuracy, tested developmental test bar and surgical guide studies in an attempt to gain better accuracy in the placement of nasal zygomatic implants.

There were four main results to take from this chapter:

### **X,Y,Z Co-ordinates & Vector Results**

Six sets of patient data analysed from pre- and post-operative CT scans. Patient 5 demonstrated the largest angles with left implant (14°) and right implant (11.74°). Mean reading for all data  $\text{Mean} \pm \text{SD} = 9.37 \pm 2.5^\circ$ . Patient 6 left implant was chosen as the benchmark reading 8.04°. AM Cobalt Chrome guide trialled on the benchmark patient but was not used due to the part being too rigid on the bone, not enough flexibility and harder to adjust.

### **Clinical & Literature Review Issues**

There was no consistency or standard specification for surgical guides. Problems encountered with stainless steel inserts with them binding on the drill, overheating and removal of the insert from the guide. AM build of a perfect circle is difficult and dependant on build orientation. Extension in length was discussed and the 360° pitch length of the pilot drill is 11mm therefore it should act as a minimal length of the drill cylinder of the guide. PhD triangle development; supports the drill at more than one point, allows water channels to cool drill and remove debris, cannot rotate and overcomes clinical problems.

### **Test Bars**

It did not make a difference where on the build bed the AM part was fabricated it can offer high levels of build accuracy at every position. Total angle error from circular and triangular test bars with 0.05 and 0.1mm tolerances have a mean reading of 1.10° over a 45mm implant length.

The benchmark guide degree of difference was  $8.04^{\circ}$  compared to  $1.10^{\circ}$  total angle error from the test bar that is a decrease of  $6.94^{\circ}$ . Total error associated with the guides as an estimate (taking into account all the results, bone interface error and the 2.95mm triangle result) was  $7.08 \pm 2.1^{\circ}$ .

### **Developed Guides**

Six developed guides designed, fabricated and located onto a datum block in a CMM for quantitative readings. AM Cobalt Chrome guide that was trialled on the benchmark patient achieved the lowest angulation error but was deemed unusable. Four out of the six developed guides attained readings less than the benchmark guide.

In theory the tolerance and length used in the studies provided evidence that if incorporated into the future guide designs will help decrease inaccuracies. The material results challenge the conventional wisdom on the suitability of polymer and metal AM materials.

### **Applications of the research**

The adoption of the developed guide has been used on a rhinectomy patient shown in section 6.4.1. Pre and post-operative comparisons in relation to the benchmark guide were completed and showed a positive accuracy result when compared to the estimated data shown in the lower graph of figure 65.

The two case examples shown in section 6.4 provided evidence that the triangle and evolution of the TRIFLO key concept was well received by the operating surgeons.

# Chapter 7: Cleanliness Results

## 7.1 ATP & Surface Cleanliness

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### 7.1.1 Introduction

A classification of medical applications of AM by Tuomi *et al.* (2014) divides these applications into five areas: (1) medical models; (2) external aids; (3) surgical guides; (4) surgical implants and (5) bio manufacturing. The range of applications covers the relatively simple task of providing insight to the surgeon/patient (medical models) through to biologically-active tissue implants (bio manufacturing). Common standards that developers cite are USP 23 Class VI and / or specific parts ISO 10993, but relatively little is published on how these materials were tested and even less on the implications for devices such as bespoke surgical guides.

The area of surgical guides covers patient-specific custom-designed drilling, cutting and repositioning devices, and this area provides an ideal fit with AM technology. Typical guides used in maxillofacial and orthopaedic applications are hand-held (small build volumes), incorporate patient-specific features that engage appropriate internal anatomical structures and can be easily cleaned and sterilised (Bibb *et al.*, 2009 & Salmi *et al.*, 2012). Surgical guides have been fabricated by AM in a range of polymers and metals (Bibb *et al.*, 2009 & Salmi *et al.*, 2012). Recent research within the field of maxillofacial surgery (O'Malley, 2014) has evaluated the use of AM surgical guides by a range of surgeons. The results show that surgical teams are keen to engage with AM technology but they have a number of pre-conceived perceptions as to the types of materials that are appropriate. It may be that material choice (specifically metal versus polymer) is strongly influenced by experience of previous conventional manufacturing processes, and there is little quantitative data to guide the clinical team for new AM applications.

Three areas have emerged that need more empirical evidence to guide surgical decisions in the use of AM materials for surgical guides: geometrical accuracy,

surface roughness and cleanliness/sterility. Patient safety is the primary consideration when implementing any new medical intervention, therefore quantifying the cleanliness/sterility of AM materials is the main focus of this research chapter.

AM technology and material vendors are continuing to develop a wide range of materials that have the potential for medical applications. For invasive surgical devices and implants, there are a series of ISO 10993 standards for the biological evaluation of medical devices that are in permanent (or prolonged) contact with the patient. In these cases criteria on biocompatibility and toxicity take precedent over other material issues. For medical devices that are single-use, disposable items that have limited contact with biological tissue (as in the case of surgical guides) there is a wider choice of potential materials. A typical surgical guide will arrive at the operating theatre within a sterile package from the hospital's HSDU department, and labelled for a specific patient. The whole medical intervention could last hours but the AM material may only be in contact with the patient for a matter of minutes. In this scenario there are no clear guidelines or specifications to help define cleanliness and sterility.

It is the responsibility of the device manufacturer to ensure that it is fit for purpose and complies with the guidance set out in the Medical Device Directive (MDD). Cleaning and/or sterilising becomes an increasingly important part of the production process as the risk to the individual using the device or the patient receiving the treatment increases. When choosing an AM process for fabricating end-use medical devices, the ability to rigorously clean and/or sterilise parts should be at the forefront of consideration.

The whole AM process, in terms of build orientation, cellular elements, removal of support structures and post-processing, provides a number of opportunities to introduce potential contamination into a medical device that could provide a hazard for the end user. Many AM manufacturing processes have fully-prescribed methods for post processing, but there are significant opportunities to detrimentally impact part cleanliness, especially when dealing with complex anatomical-based structures

that include small voids that are difficult to fully access with fluids and cleaning implements. Techniques that enable contamination levels to be quantified during the various clinical delivery stages (post-build, post-cleaning and post-sterilisation) of AM medical parts is therefore highly desirable. Despite the wide range of medical applications where AM technologies are used, there is a limited range of academic literature describing how parts should be cleaned and sterilised.

ATP bioluminescence technology is a rapid, user-friendly method of quantifying surface cleanliness that has been employed to evaluate contamination of a wide range of instruments and surfaces. Recent studies have used ATP to assess invasive medical devices (Fernando *et al.* 2014), hospital surfaces (Amodio & Dino, 2014) and environmental hygiene monitoring (Park *et al.*, 2014). The bioluminescence test utilises the light-producing reaction between ATP, luciferin and luciferase to measure the amount of ATP present on a surface. ATP is the basic source of energy for all animal and microbial cells; its presence on a surface provides an estimate of all viable and non-viable organic residues, including microbiological contamination. The use of ATP bioluminescence tests is growing within healthcare, pharmaceuticals and food science industries. The ATP technology has two key advantages over traditional microbiological testing. Firstly, the technique provides results within minutes (as opposed to days) and effectively gives a real-time evaluation of surface cleanliness. Secondly, the test apparatus is highly portable and does not need specialist training or dedicated controlled facilities. ATP testing is therefore a very practical technique that can be adopted by non-specialists. The source of ATP can be anything that the sample comes into contact with, for example the way it is handled or where the sample was stored. The ATP method cannot identify the exact source of the contamination.

In the context of medical applications, a measure of residual organic matter is an indicator of surface cleanliness, but also quantifies the potential for surface reservoirs to harbour bacteria, fungi and viruses. Therefore ATP bioluminescence may be employed to give a dual estimate of: (1) the cleanliness of a surface at a fixed point in time; (2) the likelihood that a surface is susceptible to microbiological contamination over a longer period of time.

To date, the use of ATP bioluminescence to measure the cleanliness of AM materials intended for medical use has not been reported. The aim of this research is to demonstrate that ATP bioluminescence testing is an appropriate technique for quantifying the cleanliness of a range of polymeric and metallic AM samples. It is hoped that the results can be used to highlight which AM materials (and associated surface modifications) have the greatest potential to be used in single-use, disposable medical applications, specifically materials that maintain levels of surface cleanliness that are appropriate for patient-specific surgical guides.

### **7.1.2 Materials and Methods**

The aim of this chapter is to evaluate the ATP bioluminescence test in terms of its application to a range of representative AM materials to quantify their surface cleanliness. In this context, material properties are of more concern than geometrical features. The test sample geometry was therefore kept relatively simple, and is shown in Figure 80. The two 25x25mm square areas were the surfaces of interest for cleanliness/sterility testing, and the majority of samples were fabricated with the (x, y) plane as the up-facing surface. The surface area of the samples needed to be a minimum of 10x10mm to order gain an accurate reading.

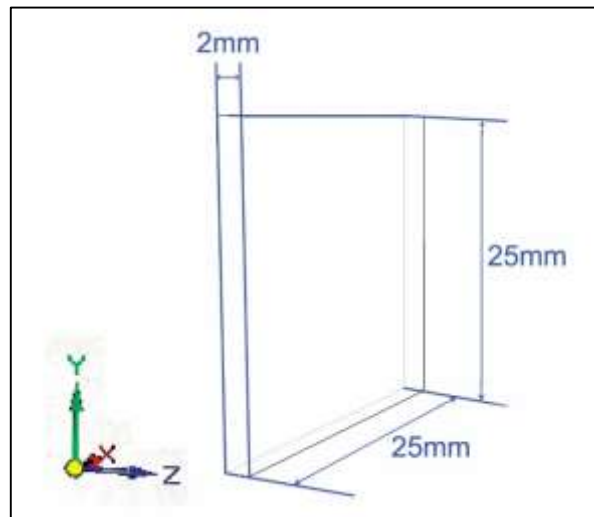


Figure 80 – Dimensions of the material samples – 25mm x 25mm x 2mm



Eleven AM materials were chosen to provide a representative sample of polymers and metals that have been employed in a range of medical applications. Details of the AM materials used in this research study are provided in Table 5. Each material category had 12 test samples manufactured. The three metals were all manufactured using LM technology (*Renishaw Plc., UK*), with one of the cobalt chrome set of samples having additional electro-polishing finishing. The eight polymer categories can be divided into: three SLA (*3D-Systems, USA*) resins; three polyjet (*Objet, Statasys Ltd., Israel*) materials; and two Selective Laser Sintering (*SLS, EOS GmbH, Germany*) materials.

<b>I.D Code</b>	<b>Material</b>	<b>Metal or Polymer</b>	<b>Build Layer Thickness</b>	<b>Build Orientation</b>	<b>Comments</b>	<b>Machine Manufacture</b>
SLA CV	Accura Clearvue	Polymer	0.15mm	(x,y) up-facing	SLA 250 machine Material can be Sterilised	3D Systems
SLA G	Accura Xtreme	Polymer	0.15mm	(x,y) up-facing	SLA 250 machine Material cannot be Sterilised	3D Systems
Projet	Acrylate	Polymer	0.032mm	(x,y) up-facing	Projet EX200 machine Material cannot be Sterilised	3D Systems
SLS N GF	Glass Filled Nylon	Polymer	0.15mm	(x,z) up-facing	SLS machine Material cannot be Sterilised	EOS
SLS N NGF	Nylon	Polymer	0.15mm	(x,z) up-facing	SLS machine Material cannot be Sterilised	EOS
Objet VW	Vero White	Polymer	0.016mm	(x,z) up-facing	Objet machine Material cannot be Sterilised	Stratasys Objet
Objet TP	Tango Plus	Polymer	0.016mm	(x,z) up-facing	Objet machine Material cannot be Sterilised	Stratasys Objet
Objet VB	Vero Blue	Polymer	0.016mm	(x,y) up-facing	Objet machine Material cannot be Sterilised	Stratasys Objet
LM CC EP	Cobalt Chrome F75 Electro polished	Metal	0.06mm	(x,z) up-facing	AM250 machine Material can be Sterilised	Renishaw Plc.
LM CC NEP	Cobalt Chrome F75	Metal	0.06mm	(x,z) up-facing	AM250 machine Material can be Sterilised	Renishaw Plc.
LM T NEP	Titanium Ti-6AL-4V (Grade 5)	Metal	0.06mm	(x,y) up-facing	AM250 machine Material can be Sterilised	Renishaw Plc.

Table 5 – Information table on the material samples including type of material, metal or polymer, build layer thickness, build orientation, comments and machine manufacture.

The ATP bioluminescence test employed in this study was the 3M Clean-Trace system ([www.3M.com/3M/en\\_US/company-us/all-3m-products/?N=5002385+8711017+8711099+8711106+3294857497&rt=r3](http://www.3M.com/3M/en_US/company-us/all-3m-products/?N=5002385+8711017+8711099+8711106+3294857497&rt=r3)). The procedure starts by taking the test swab and applying it to the surfaces to be evaluated. The swab is gently rotated as it is swept across the test area. The swab is then immediately placed in a cylindrical vial, which brings it into contact with the enzyme solution (luciferin-luciferase) and the enzyme reacts with any ATP residue on the swab. The cylindrical vial is then placed in a hand-held 3M luminometer, and the light generated from the bioluminescence reaction is captured, and the measurement is expressed in Relative Light Units (RLUs). The greater the level of ATP present on the swab, the higher the RLU reading produced. The test can be performed in less than 30s, providing a real-time indication of the cleanliness of the surface tested. The swab and enzyme solution are disposed of after each test reading.

The 3M instrument manufacturer recommends a pass/fail threshold of 250 RLUs to indicate part cleanliness (Boyce *et al.*, 2009). In addition, a literature review by Amodio and Dino (2014) covering the period 1990-2012, has shown that the  $\leq 250$  RLUs threshold is the most widely used benchmark for indicating clinical surface cleanliness. A recent Danish standard DS 2451 – 10 has been monitoring hospital cleanliness with standardised ATP measurements using a hygiene 5 level, the cleanest of the levels, which is set at 250 RLU's (Andersen, 2014).

The ATP Bioluminescence testing was chosen as the most appropriate testing method due to it being well established in the health science sector but also due to the rapid results the test provides. Other tests i.e. contact plates and surface swabs as shown in Cherry *et al.* (2015) paper take 48 hours to give a result, but ATP is almost instant. Recent ATP publications have populated the medical and healthcare sectors with Russotto *et al.*'s (2016) paper on the bacterial contamination study of a intensive care unit, Alvarez *et al.*'s (2016) study of ATP use within a healthcare setting and Rutala *et al.*'s (2016) on the monitoring of surface cleanliness. The use of ATP technology in this area is growing therefore this study and the adoption of its use for medical AM parts is a suitable choice.

### **7.1.3 Pilot Study**

A pilot study was undertaken to test three stages of production at PDR, cleaning and sterilisation to evaluate which procedures gave AM parts with ATP readings in the region of the pass/fail threshold (250 RLUs). An overview of each stage is given below:

- Stage 1: Post Build. The AM parts were removed from the build platforms, support structures were removed, and the parts finished for standard delivery to a medical customer. In this scenario the parts were packaged and sealed for delivery, but all post-production handling was in a non-clean/non-sterile environment.
- Stage 2: Post Cleaning. The sealed post-production AM parts were taken through a series of cleaning steps; the standard operating procedure for this is given in figure 81. The key additional processing step was soaking each test sample in 250ml of Isopropanol for 60 minutes. This was achieved by placing four or five test samples in a one-litre beaker, and rotating the sample after 30 minutes to ensure an even contact time on both the main 25x25mm surfaces. After 60 minutes, the samples were removed individually, dried and packaged.
- Stage 3: Post Sterilisation. Post-production parts were dispatched directly to a clinical partner (Morrison Hospital, UK), and individual samples were placed in labelled autoclave bags and sterilised on the standard 134°C autoclave cycle specified by BS EN ISO 17665-1:2006 standard on the sterilisation of health care products: moist heat. This sterilisation process was chosen as it is standard across all UK NHS in Hospital Sterilisation and Decontamination Unit (HSDU) departments.

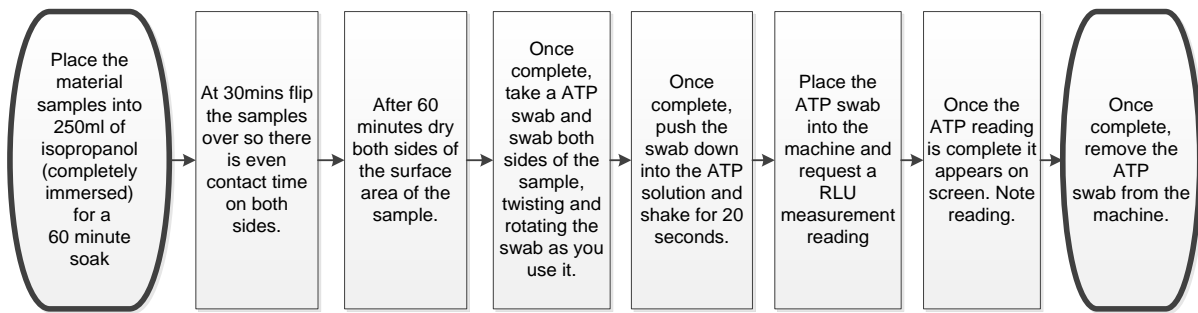


Figure 81 – Standard Operating Procedure (SOP) for cleaning of medical AM parts – Step by step guide to the cycle of what each material sample went through before the ATP swab acquired a reading from the materials surface.

The three different stages produced a wide range of RLU readings; the data for each set of samples was compiled into a series of spread sheets for analysis. Each set of sample readings were characterised in terms of mean and standard deviation values. Statistical analysis of the data employed the t-test for hypothesis testing, and highlighting differences between discreet sample sets (assuming pseudo-normal distributions). The t-test was the most appropriate statistical test because the data was on an interval/metric scale and has an approximate distribution (McCrum-Gardner, 2008)

#### 7.1.4 Pilot Study Results

The preliminary investigation into the feasibility of using ATP measurements to evaluate the cleanliness of AM materials took a small sample size of representative polymers and metals through the three stages of cleaning/sterilisation. Two samples of SLA Clear (Accura ClearVue, 3D-systems) SLA Grey (Accura Xtreme, 3D-Systems), LM Cobalt Chrome (F75) and LM Titanium (Ti-6AL-4V) were tested post-build, post-cleaning and post-sterilisation. The  $n=2 \times 4$  RLU readings at the three stages were pooled to give overall mean values, and the results are shown in figure 82. There was an order of magnitude difference in RLU values between the three stages; post-build readings were in the order of thousands, post-cleaning were in the order of hundreds and post-sterilisation were in the order of tens. There were no outliers from the small sample size, and the polymers and metals gave a similar range of values at each cleaning stage.

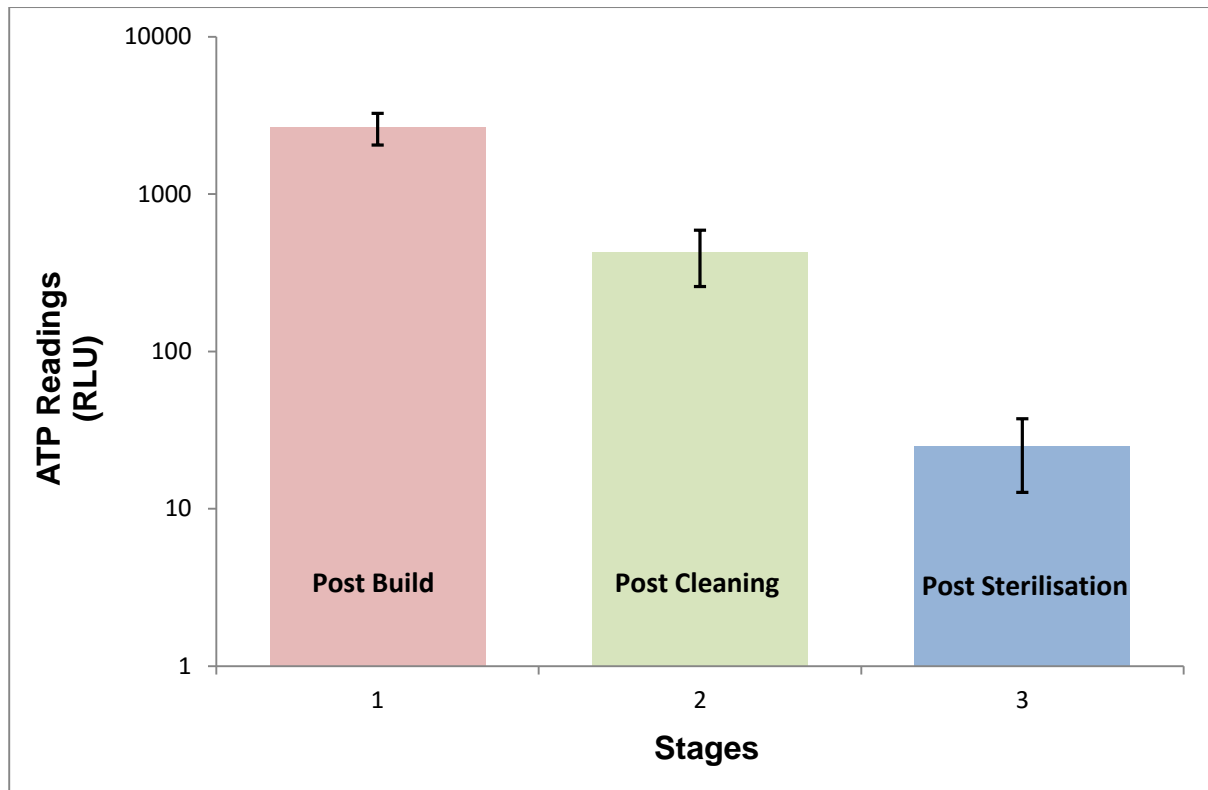


Figure 82 – Pilot study results. Log graph of the ATP results of the three stages tested. Stage 1: Post Build, Stage 2: Post Cleaning and Stage 3: Post Sterilisation.

The pilot study results show that the cleaning protocol established for stage 2 gave ATP readings in the region of the threshold value of 250 RLUs. 250 RLUs or below is the value of cleanliness that needs to be reported for every area of the patient care environment. The value is there to as a threshold to the ATP testing to achieve more complete monitoring, cleaning assurance and sterilisation assurance. The post-build samples were well in excess of the threshold value (mean±SD=2651±606 RLUs). The autoclave sterilisation gave results well below the threshold value (25±12 RLUs), as would be expected. The data from the post-cleaning samples (424±165 RLUs) are of most interest because they span the threshold region. The pilot data indicated that it may be possible to process and clean AM materials for clinical use in the absence of sterilisation.

### 7.1.5 Core Study

The full set of AM samples from Table 5 were taken through the cleaning protocol (stage 2), and this data set gives the core sets of results for this research study.

The aim of the initial analysis of the ATP results was to evaluate whether each AM material could be labelled as 'clean' relative to the 250 RLU threshold value following a relative simple cleaning process. The full data set from the eleven materials gave a wide range of RLU readings (from thousands to tens), and the results have been divided into three groupings to aid analysis: (a) Objet materials; (b) remaining polymers; and (c) metallic materials.

### 7.1.6 Core Study Results

The three Objet materials are shown in Figure 83. The highest readings were for the Objet Tango Plus (6325±1429 RLUs) this data is comparable to the post-build values obtained during the pilot study. The lowest readings were for the Objet Vero Blue (861±606 RLUs), whilst the Objet Vero White gave an intermediary range (1805±278 RLUs). Given the low sample size (n=12), a t-test statistic was employed to compare the data relative to the threshold value (McCrum-Gardner, 2007). Based on a one-tailed test at the 99% significance level, all three Objet material samples gave mean values significantly higher than 250 RLUs.

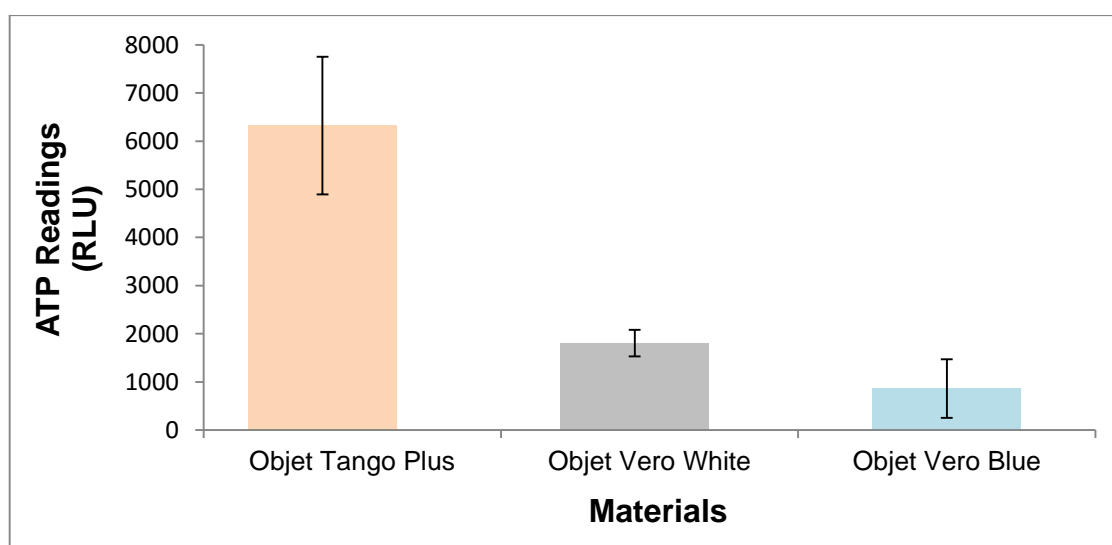


Figure 83 – Objet material results. ATP testing at Stage 2: Post Cleaning for the three Objet samples.



The remaining five polymeric material results are shown in Figure 84. In contrast to the Objet readings, all five samples gave a mean value significantly lower than the 250 RLU threshold value (t-test 99% level:  $p < 0.01$ ). This indicates that the Projet, SLA and SLS materials used in this study can be cleaned for clinical use. Across this grouping there are a range of readings. The highest values are given by SLA Clear at  $181 \pm 59$  RLUs, whilst the lowest readings were given by the glass-filled SLS Nylon at  $41 \pm 8$  RLUs.

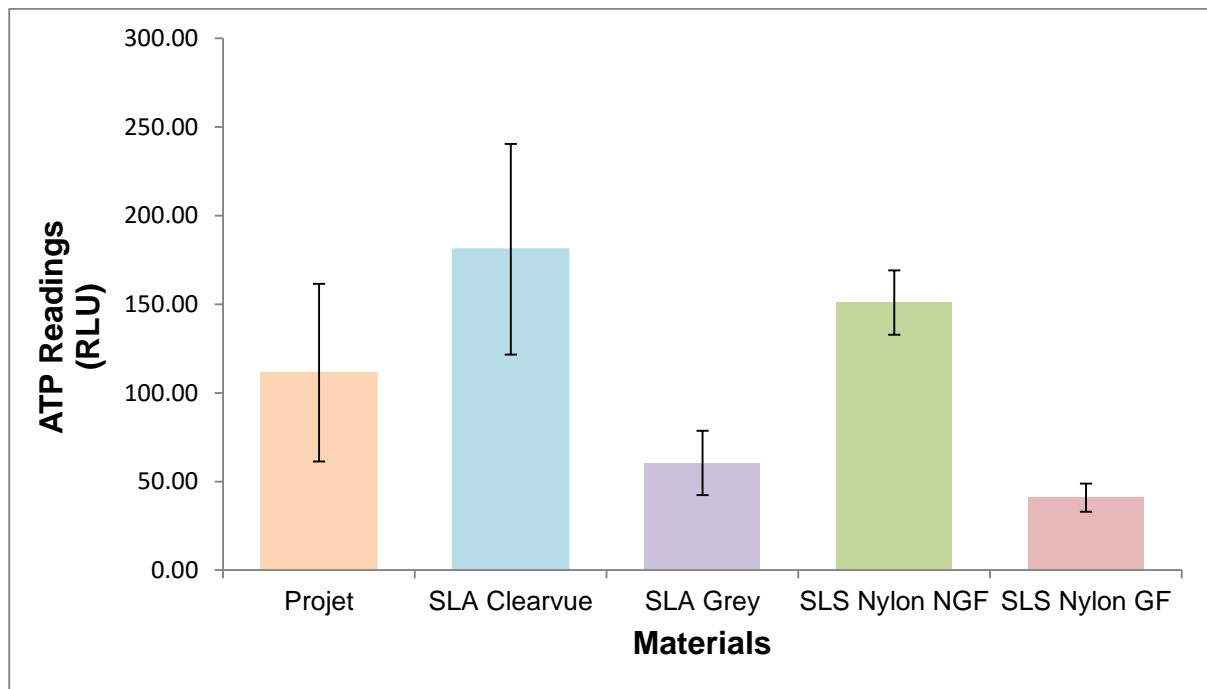


Figure 84 – AM polymer material results. ATP testing at Stage 2: Post Cleaning. NGF is Non Glass Filled and GF is Glass Filled.

The final grouping of three metallic materials is given in Figure 85. In this set of readings, the main difference is between the Cobalt Chrome and the Titanium. The two cobalt chrome samples give mean values significantly below 250 RLUs (t-test 99% level:  $p < 0.01$ ), whilst the titanium sample is not significantly different ( $p > 0.05$ ).

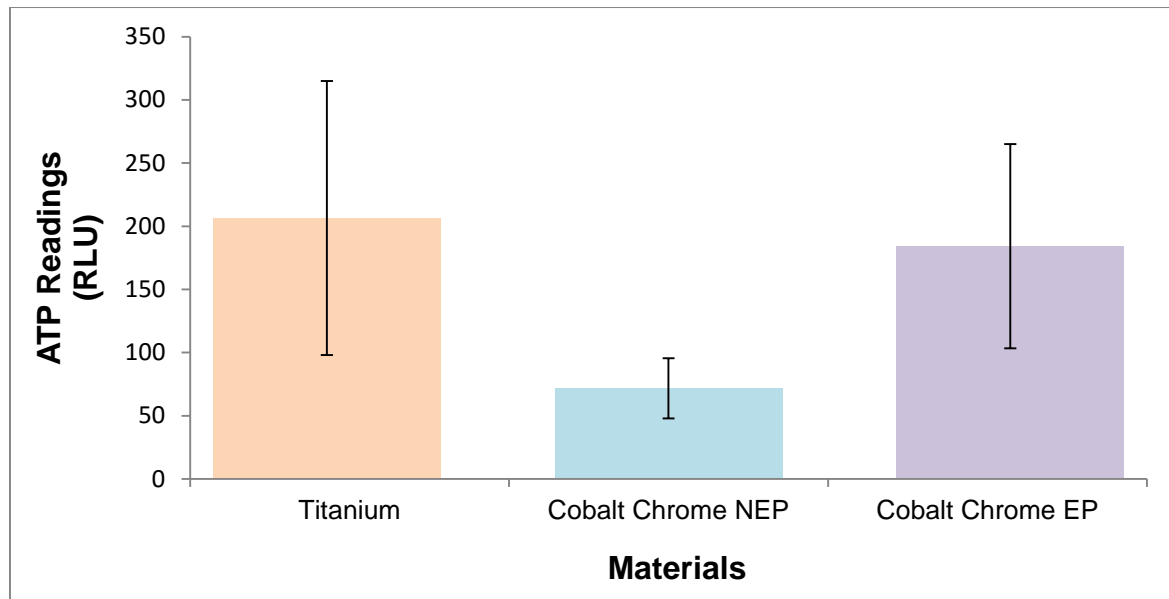


Figure 85 – AM metal material results. ATP testing at Stage 2: Post Cleaning. NEP is Non Electro Polished and EP is Electro Polished.

In summary, across the eleven AM materials tested there are two key findings from the post-cleaning analysis: (a) the three Objet materials are significantly above the 250 RLU threshold; and (b) the Projet, SLA, SLS and Cobalt Chrome materials are significantly below the 250 RLU threshold.

For inter-sample analysis, the maximum number of pair-wise comparisons was 55. This was used as the Bonferroni correction factor for further t-test statistical analysis across the sample sets (McCrum-Gardner, 2007). The assumption is that the ATP values can be modelled as a t distribution, and comparisons across two different materials use the t-test, which in turn gives a p value as an indicator of statistical significance. If you perform multiple comparisons (i.e. compare all materials with one another) then there is a danger of showing statistical significance purely by chance. The Bonferroni correction factor (applied to the t tests) raises the threshold for significance and hence lowers the risk of false findings. The full set of material sample data is shown on the Bonferroni T Test chart in figure 86. It was assumed that a conservative correction factor would militate against inflated false positives for multiple comparisons ( $p < 0.01/55$  or  $p < 0.0002$  now required for 99% significance level).

Key											
No Sig. Dif.											
= No Significant Difference											
P<0.0002											
= 99% Significant Difference											
Samples	Objet Tango Plus	Objet Vero White	Objet Vero Blue	Projet	SLA Clear Vue	SLA Grey	SLS Nylon NGF	SLS Nylon GF	LM Cobalt Chrome EP	LM Cobalt Chrome NEP	LM Titanium
Objet Tango Plus											
Objet Vero White	P<0.0002										
Objet Vero Blue	P<0.0002	P<0.0002									
Projet	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.								
SLA Clear Vue	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.							
SLA Grey	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	P<0.0002						
SLS Nylon NGF	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.					
SLS Nylon GF	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	P<0.0002				
LM Cobalt Chrome EP	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.			
LM Cobalt Chrome NEP	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	LM Cobalt Chrome EP		
LM Titanium	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	No Sig. Dif.	P<0.0002	LM Cobalt Chrome NEP	
									No Sig. Dif.	No Sig. Dif.	LM Titanium

Figure 86 – Bonferroni T Test Chart shows the significant difference values of each of the AM samples when compared to the other AM samples. The chart shows two levels of significant difference, 1. No significant difference and 2. 99% significant difference.

Within the Objet grouping, the Vero Blue samples gave a mean RLU value significantly lower than both the Tango Plus and Vero White samples ( $p < 0.0002$ ). It is worth noting that the Objet Vero Blue samples were sourced direct from a UK NHS hospital (Southern General, Glasgow), and it is their material of choice for anatomical medical models – these models are not used for direct patient contact.

For the polymers shown in Figure 84, the notable pair-wise comparisons are between the two SLA materials and the two SLS materials. There is a significant difference between the SLA Clear and the SLA Grey ( $p < 0.0002$ ). In this context, the Accura ClearVue resin tends to be employed more in medical applications than the Accura Xtreme Grey resin since it has undergone prerequisite testing to USP Class 23/6. There is also a significant difference between the non-glass-filled SLS Nylon and the glass-filled SLS Nylon ( $p < 0.0002$ ). These samples were sourced from different suppliers so more data is required in order to draw a firm conclusion as to the reason for this difference.

The interesting result from the metallic materials in Figure 85 is the fact that the electro-polished Cobalt Chrome samples gave a mean RLU value that was significantly higher than the non-electro-polished Cobalt Chrome samples ( $p < 0.0002$ ). Electro polishing is employed (particularly in the dental industry) to inhibit contaminants adhering to the surface. However, the ATP results indicate that the non-electro polished surface is cleaner. The greatest variability was exhibited by the Titanium samples ( $207 \pm 108$  RLUs), and the mean value for the Titanium was not significantly different to the two Cobalt Chrome samples.

### **7.1.7 Comparison Study**

To establish what level of polishing current cranioplasty plates possess, samples were requested from a leading Reconstructive Scientist and Maxillofacial Laboratory Services Manager in the UK to give a RLU reading comparison for traditional/conventional fabrication methods.

Five samples were tested in total:

1. The titanium sheet as supplied to the lab.
2. The titanium sheet polished using a medium lisko wheel.
3. The titanium sheet polished using a black rubber wheel.
4. The titanium sheet shot blasted using fine glass beads.
5. The titanium sheet polished using pumice and tiger brilliant polishing paste.

The above samples followed the exact standard cleaning operating procedure that was used in the core study in section 7.1.5.

### 7.1.8 Comparison Study Results

In figure 87 all the metal AM samples and the five conventional titanium samples are shown. The lowest of the metal readings is the Cobalt Chrome Non-Electro Polished samples and the lowest of the conventional titanium samples was the Titanium as supplied to the lab. Any additional polishing of the surface of the metal material samples caused a rise in the RLU reading and hence indicates that when you polish a surface that surplus debris may gather on the surface.

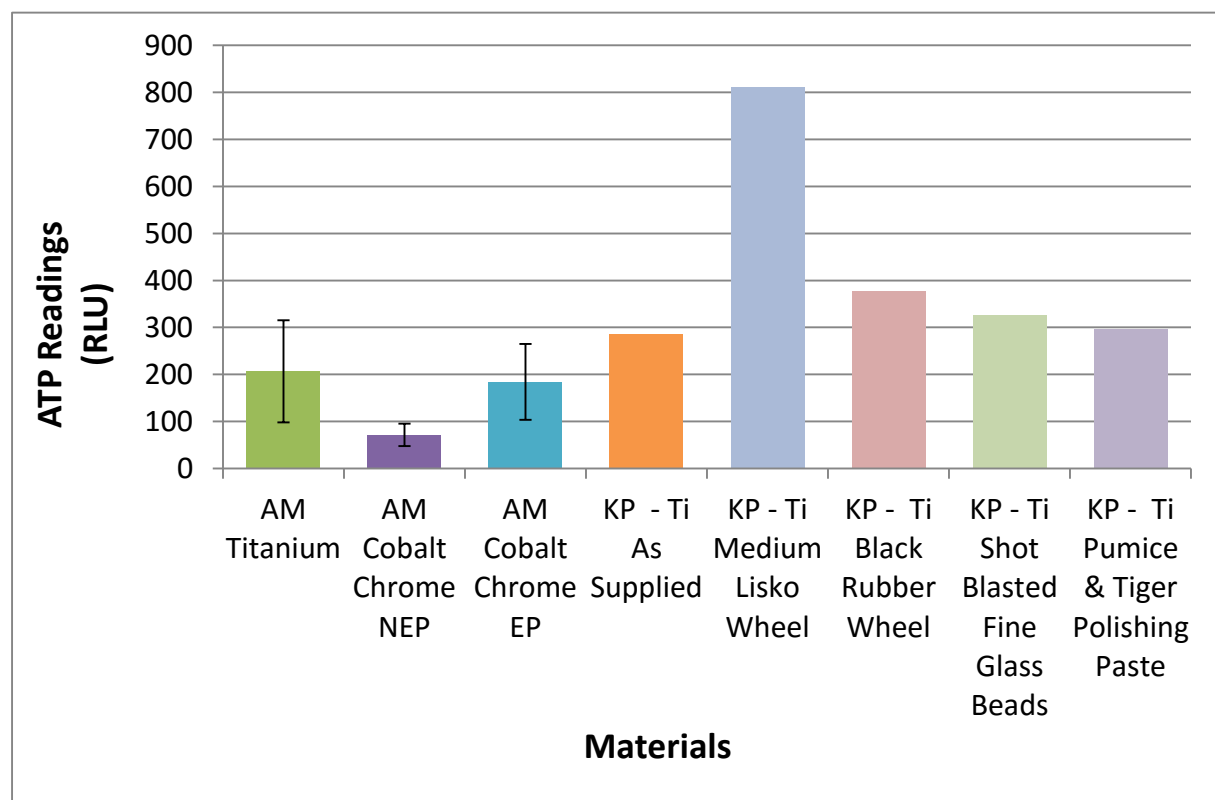


Figure 87 – AM metal samples and the Conventional Titanium sheet samples each finished with various polishing methods.

## **7.2 Summary**

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Cleanliness RLU readings of both polymer and metal materials demonstrated interesting results. Firstly from the pilot study, the different stages: post build, post cleaning and post-sterilisation showed an order of magnitude difference in RLU values thousands, hundreds and tens.

The core study results also flagged interesting results showing that the Objet materials gave extremely high (pilot study post build range) RLU's, the remaining polymers were within the pass/fail threshold range, and that when you compare electro polished to non-electro polished samples the non-electro polished were deemed cleaner.

This also became apparent in the comparison study where AM metals were compared to traditional/conventionally fabricated samples. The non-electro polished cobalt chrome and the conventional titanium sheet as supplied to the lab offered lower RLU readings than all the other polished AM and lab polished conventional samples.



## Chapter 8: Surface Roughness Results

### 8.1 Surface Roughness

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#### 8.1.1 Introduction

The Maxillofacial AM Surgical Guides that were observed in chapter 5 have two common materials that they were fabricated in, SLA ClearVue / Visijet Clear and LM Cobalt Chrome. These guides are patient-specific physical devices used to turn computer-aided planning of drilling, cutting or repositioning bone procedures into clinical reality. When used in surgery, speculations on the surface roughness of AM materials have been discussed and whether they result in varying friction coefficient on the bone. Surgical guides need to make these procedures as accurate and precise as possible for the clinical team therefore locating correctly on the bone is critical.

#### 8.1.2 Materials & Method

Taylor Hobson Form Talysurf 50 equipment shown in figure 88 was used to analyse the surface roughness or Ra values of the different material options. Ra is calculated as the Roughness Average (Ra) of a surfaces measured microscopic peaks and valleys. The stylus of the Talysurf 50 travels over a 10mm distance of the surface of the material as highlighted in figure 89.

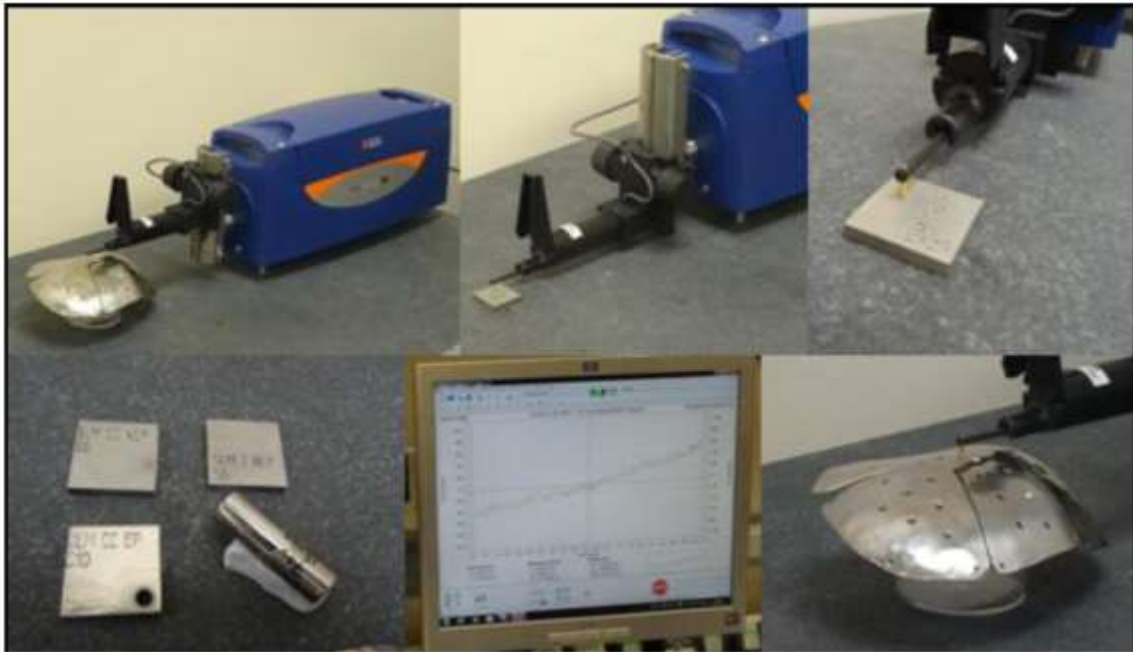


Figure 88 – Taylor Hobson Talysurf surface roughness testing.

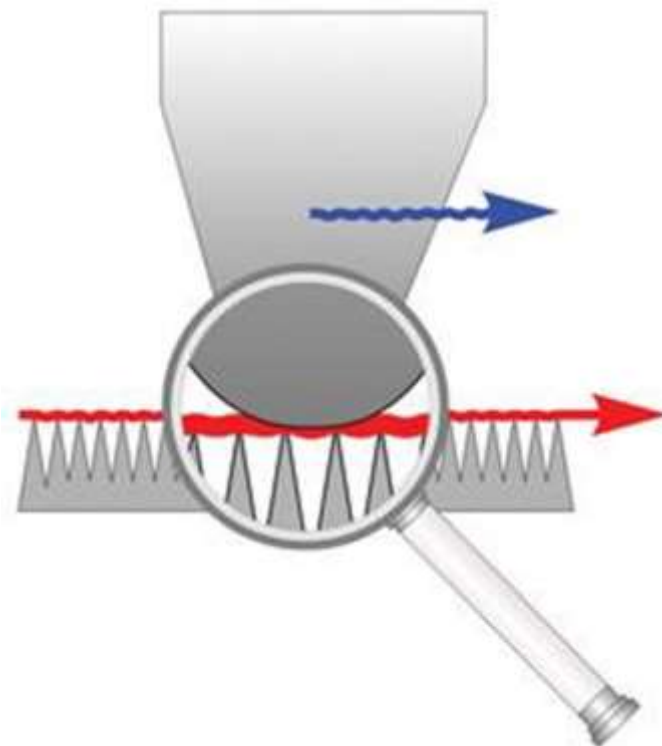


Figure 89 – Surface roughness stylus measuring the microscopic peaks over a 10mm length of a materials surface.

A pilot study took place in order to analysis and compare Ra values of currently used both AM and conventionally made implants and surgical guides. A core study also took place looking in more detail at the Ra values of AM materials.

### 8.1.3 Pilot Study

The pilot study consisted of a surface roughness review of the existing conventional and AM maxillofacial guides, implants and materials used. A single sample (n=1) of each material part was taken to give the background figures for the range of surface roughness readings currently used in the medical field.

### 8.1.4 Pilot Study Results

The results shown in Table 6 provided a range of surface roughness measurements that are currently used for implants, guides and plates. The results generated from the surface roughness testing helped to set a surface roughness range for implants and surgical guides. The surface roughness range taken from the pilot study results were from 0.04µm to 4.48µm.

<b>Material Samples</b>	<b>Ra Reading µm (n=1)</b>
Conventional Custom Made Titanium Cranioplasty Plate	<b>0.04</b>
AM LM Titanium (non-polished) sample	<b>2.29</b>
AM LM Cobalt Chrome (non-polished) sample	<b>2.40</b>
AM LM Cobalt Chrome (electro polished) sample	<b>0.10</b>
Optimum Polished Conventional Custom Made Titanium Plate	<b>0.04</b>
DePuy Synthes Mandibular Plate	<b>0.12</b>
Layerwise AM Plate (non-polished) minimum range	<b>1.05</b>
Layerwise AM Plate (non-polished) maximum range	<b>4.48</b>
AM SLA Clear Ear Surgical Guide	<b>2.62</b>
AM SLA Clear Jacket with metal inserts Nasal Surgical Guide	<b>3.39</b>
AM LM Cobalt Chrome Ear Surgical Guide	<b>2.09</b>
AM LM Cobalt Chrome Nasal Surgical Guide	<b>2.05</b>

Table 6 – Pilot Study Results (n=1) Ra Readings of all the AM and conventionally fabricated surgical guides, implants and parts.

The AM ear and nasal surgical guide examples were also tested on the Talysurf machine but due to the high curve geometry of the nasal guides the surface roughness Ra readings became irregular. A fixed geometry of the material samples was used in the core study of this chapter in order to gather consistent Ra data for each of the materials.

### **8.1.5 Core Study**

A core study also took place and looked at the Ra values in more detail of the materials samples. Six AM materials were chosen in an attempt to understand the surface roughness and whether there were any differences between the sample groupings. Some of the material samples were built by third party suppliers this resulted in the samples being built in different orientations (Figure 90) which were a limitation of outsourcing and to the testing. For the core study, n=6 samples of each material were tested.

The materials chosen were:

1. LM Cobalt Chrome electro polished on one side (grouping a)
  - a. Build orientation (x,z) up facing
2. LM Cobalt Chrome non electro polished (grouping a)
  - a. Build orientation (x,z) up facing
3. SLA Accura Xtreme Grey (grouping b)
  - a. Build orientation (x,y) up facing
4. SLA Accura ClearVue Clear (grouping b)
  - a. Build orientation (x,y) up facing
5. Objet Vero White (grouping c)
  - a. Build orientation (x,z) up facing
6. Objet Vero Blue (grouping c)
  - a. Build orientation (x,y) up facing

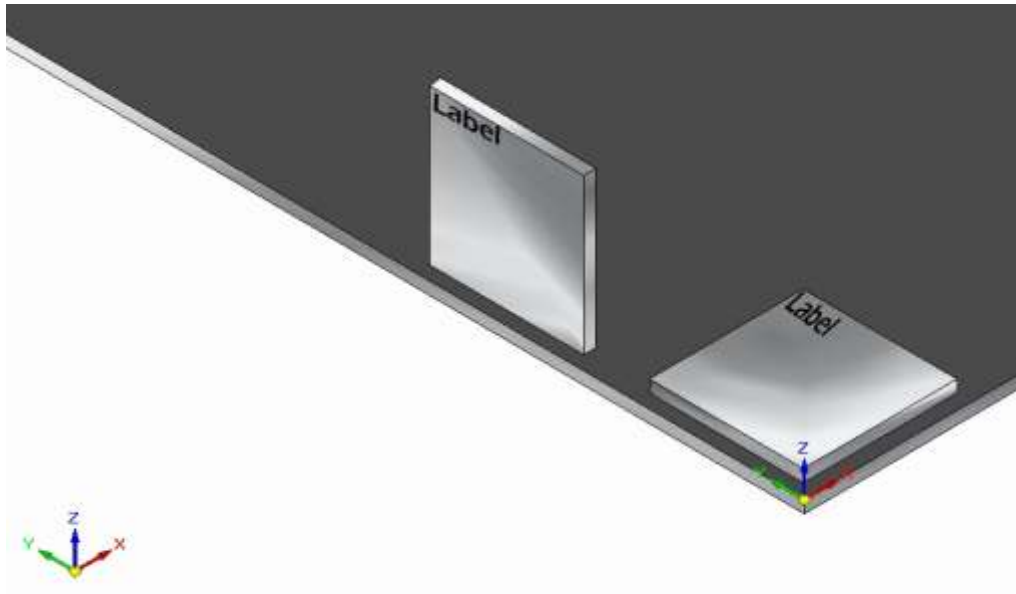


Figure 90 – The two build styles of the material samples tested. The left hand side example demonstrates the (x,y) up facing orientation and the right hand side example demonstrated the (x,y) up facing orientation as placed on the build bed plate.

The dimensions of the samples were 25x25mm square and had a material label on the upper left hand side surface. The core study entailed analysing the surfaces of each sample with four readings; upper labelled surface left to right (R1), upper labelled surface top to base (R2), lower unlabelled surface left to right (R3) and lower unlabelled surface top to base (R4) as shown in figure 91.

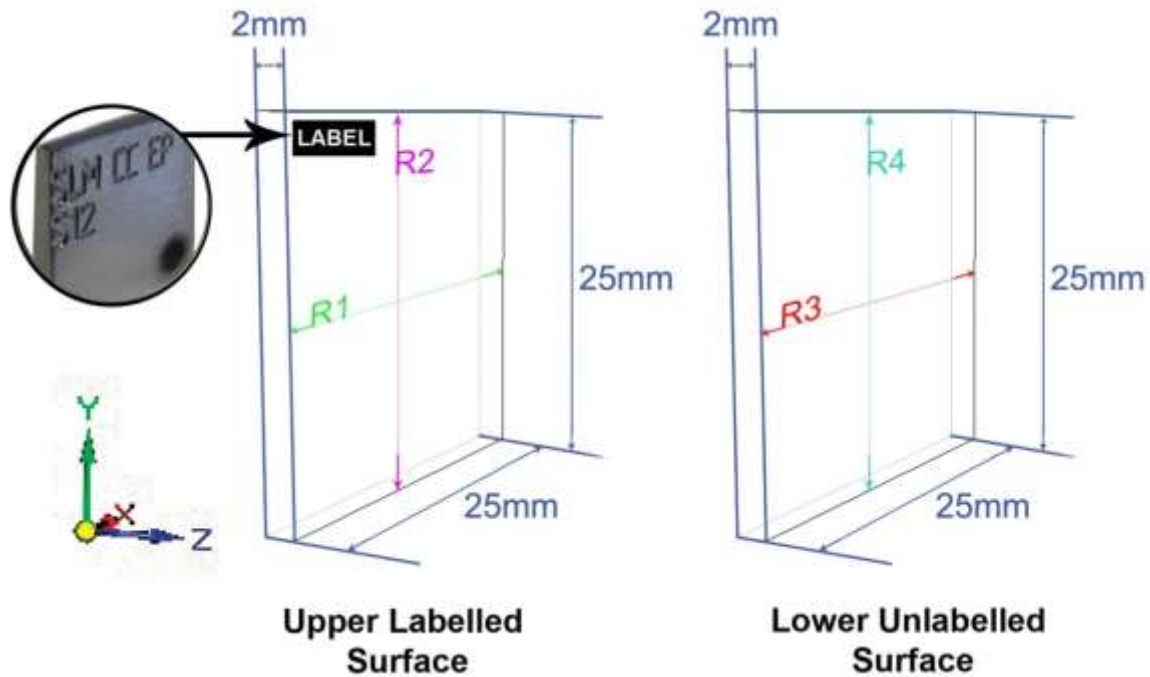


Figure 91 – Core Study material sample dimensions and four Ra readings; upper labelled surface left to right (R1), upper labelled surface top to base (R2), lower unlabelled surface left to right (R3) and lower unlabelled surface top to base (R4).

The data length of the Taylor Hobson Form Talysurf 50 machine was set at 10mm, run length set at 0.3mm and speed set at 0.5mm/s.

### 8.1.6 Core Study Results

The upper labelled surface Ra readings R1 (n=6) and R2 (n=6) for each material sample were combined so n=12; the mean and standard deviation for the readings were calculated for each material and grouping. The lower unlabelled surface Ra readings R3 and R4 were also combined so n=12; the mean and standard deviation were calculated.

The AM metal material results shown in figure 92 established there was minimal difference on the non-polished surfaces. The only noticeable difference in grouping a) was the Cobalt Chrome electro polished surface demonstrated a smoother and low Ra reading.

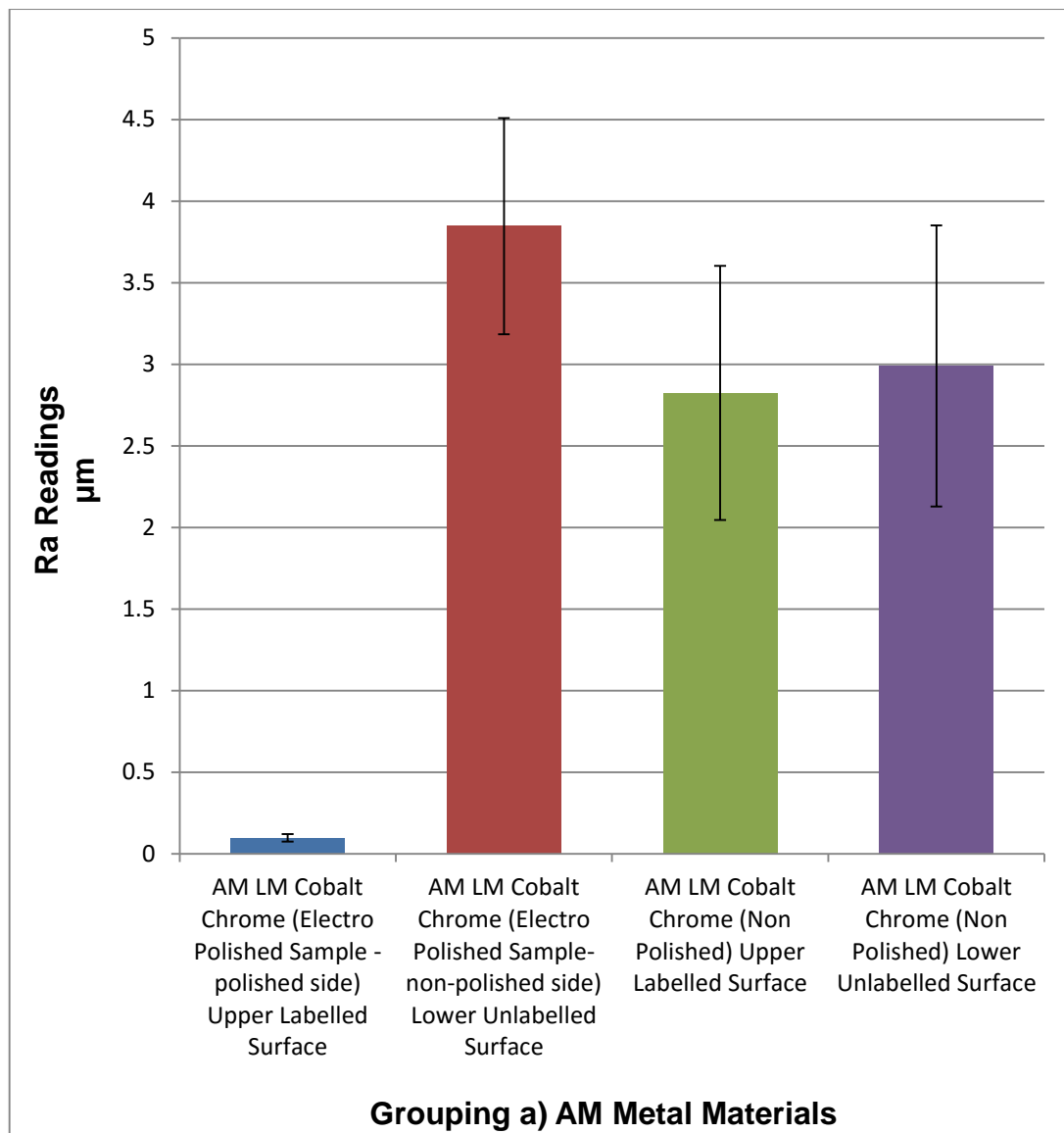


Figure 92 – Core Study Results – Ra readings of the AM metal materials grouping a) both upper labelled and lower unlabelled surface.

Cobalt chrome electro polished upper labelled surface generated a low mean Ra reading of  $0.097 \pm 0.023 \mu\text{m}$ . The lower unlabelled surface generated a higher mean Ra value of  $3.847 \pm 0.662 \mu\text{m}$ .

Cobalt chrome non electro polished upper labelled and lower unlabelled surfaces were consistent with the upper mean Ra reading of  $2.824 \pm 0.779 \mu\text{m}$  and a lower mean Ra value of  $2.989 \pm 0.862 \mu\text{m}$ .



The results of grouping b) shown in figure 93 demonstrates that SLA grey appears consistent in the mean Ra reading for upper labelled  $2.315 \pm 2.055 \mu\text{m}$  and lower unlabelled  $2.522 \pm 2.373 \mu\text{m}$  surfaces.

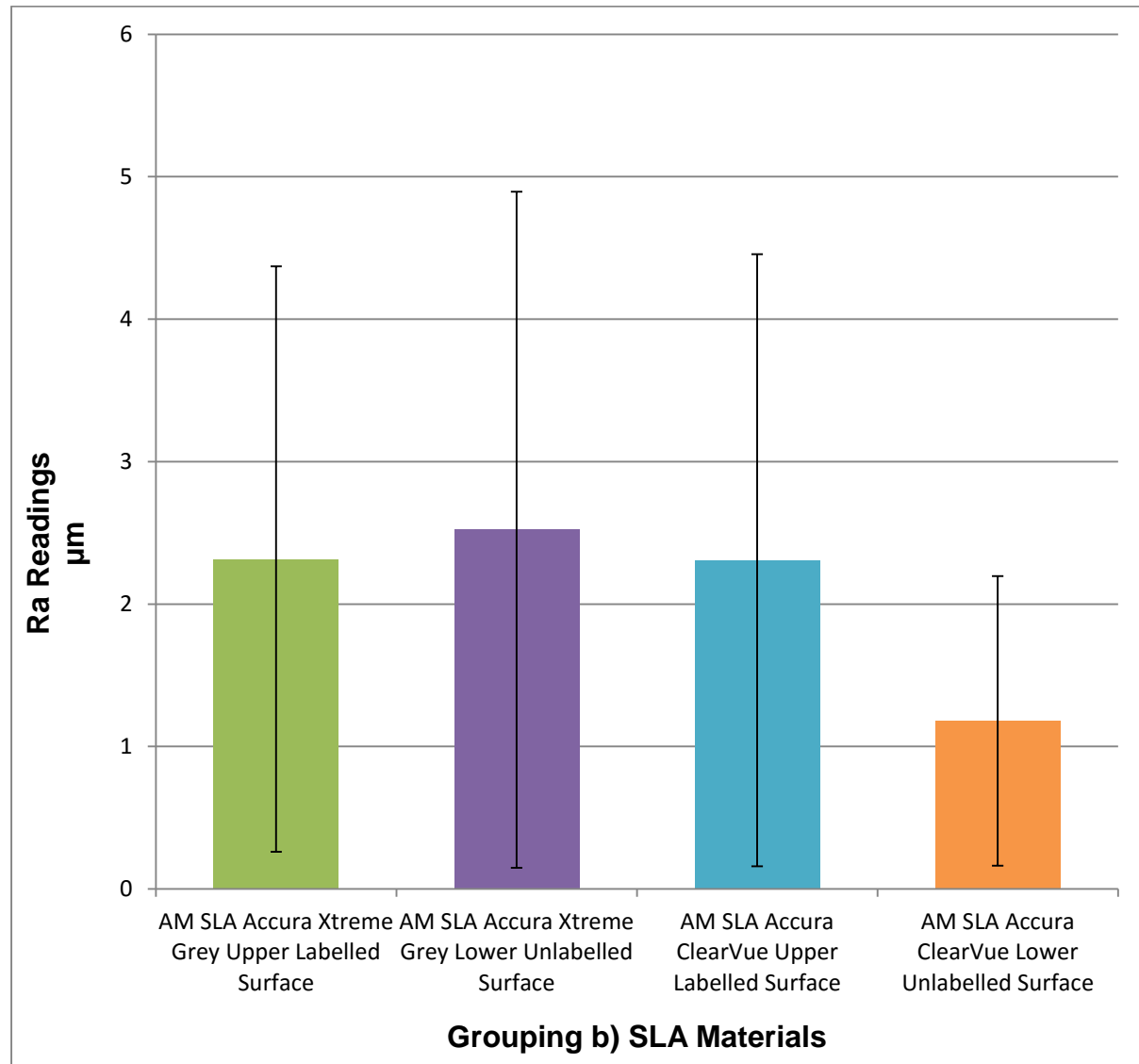


Figure 93 – Core Study Results – Ra readings of the AM SLA Materials grouping b) both upper labelled and lower unlabelled surface.

However, when you compare both the R1 reading of  $0.393 \pm 0.140 \mu\text{m}$  and R3 reading of  $0.435 \pm 0.097 \mu\text{m}$  to the R2 reading  $4.238 \pm 0.633 \mu\text{m}$  and R4 reading of  $4.608 \pm 1.388 \mu\text{m}$  the build and step formation is evident. The step formation and therefore higher Ra readings of R2 and R4 are shown in table 7. This means the

build orientation of the SLA Grey is important and changes the surface roughness of the part fabricated.

<b>R1 Upper Labelled Surface Left to Right</b>	<b>R2 Upper Labelled Surface Top to Base</b>	<b>R3 Lower Unlabelled Surface Left to Right</b>	<b>R4 Lower Unlabelled Surface Top to Base</b>
0.311	3.751	0.404	5.713
0.289	4.474	0.580	3.579
0.343	5.407	0.530	5.145
0.563	4.134	0.484	2.839
0.579	3.880	0.333	3.908
0.271	3.783	0.361	6.466

Table 7 – Ra readings for grouping b) material SLA Grey; when comparing R1 and R3 to R2 and R4 it shows the step formation difference.

SLA clear presented similar results to the SLA grey parts but with a slight increase difference between the upper labelled reading  $2.308 \pm 2.149 \mu\text{m}$  and the lower unlabelled reading  $1.180 \pm 1.017 \mu\text{m}$ . The step formation was also evident for this material with comparing the R1 reading of  $0.294 \pm 0.054 \mu\text{m}$  and R3 reading of  $0.268 \pm 0.078 \mu\text{m}$  to the R2 reading of  $4.322 \pm 0.649 \mu\text{m}$  and R4 reading of  $2.091 \pm 0.526 \mu\text{m}$  shown in table 8.

<b>R1 Upper Labelled Surface Left to Right</b>	<b>R2 Upper Labelled Surface Top to Base</b>	<b>R3 Lower Unlabelled Surface Left to Right</b>	<b>R4 Lower Unlabelled Surface Top to Base</b>
0.278	5.172	0.272	2.005
0.363	4.278	0.187	2.217
0.269	3.848	0.232	2.236
0.359	4.807	0.254	1.199
0.259	4.457	0.248	2.061
0.233	3.370	0.418	2.829

Table 8 – Ra readings for grouping b) material SLA Clear; when comparing R1 and R3 to R2 and R4 it shows the step formation difference.

The results in grouping c) shown in figure 94 demonstrates that Objet Vero White showed a consistent Ra surface roughness for upper labelled reading of  $0.187 \pm 0.175 \mu\text{m}$  and lower unlabelled reading of  $1.033 \pm 0.587 \mu\text{m}$  shown in figure 94.

Objet Vero Blue also showed consistent Ra surface roughness for upper labelled reading  $0.470 \pm 0.259 \mu\text{m}$  and lower unlabelled reading of  $0.672 \pm 0.330 \mu\text{m}$ . There was no step formation was present or visible from the results of this grouping.

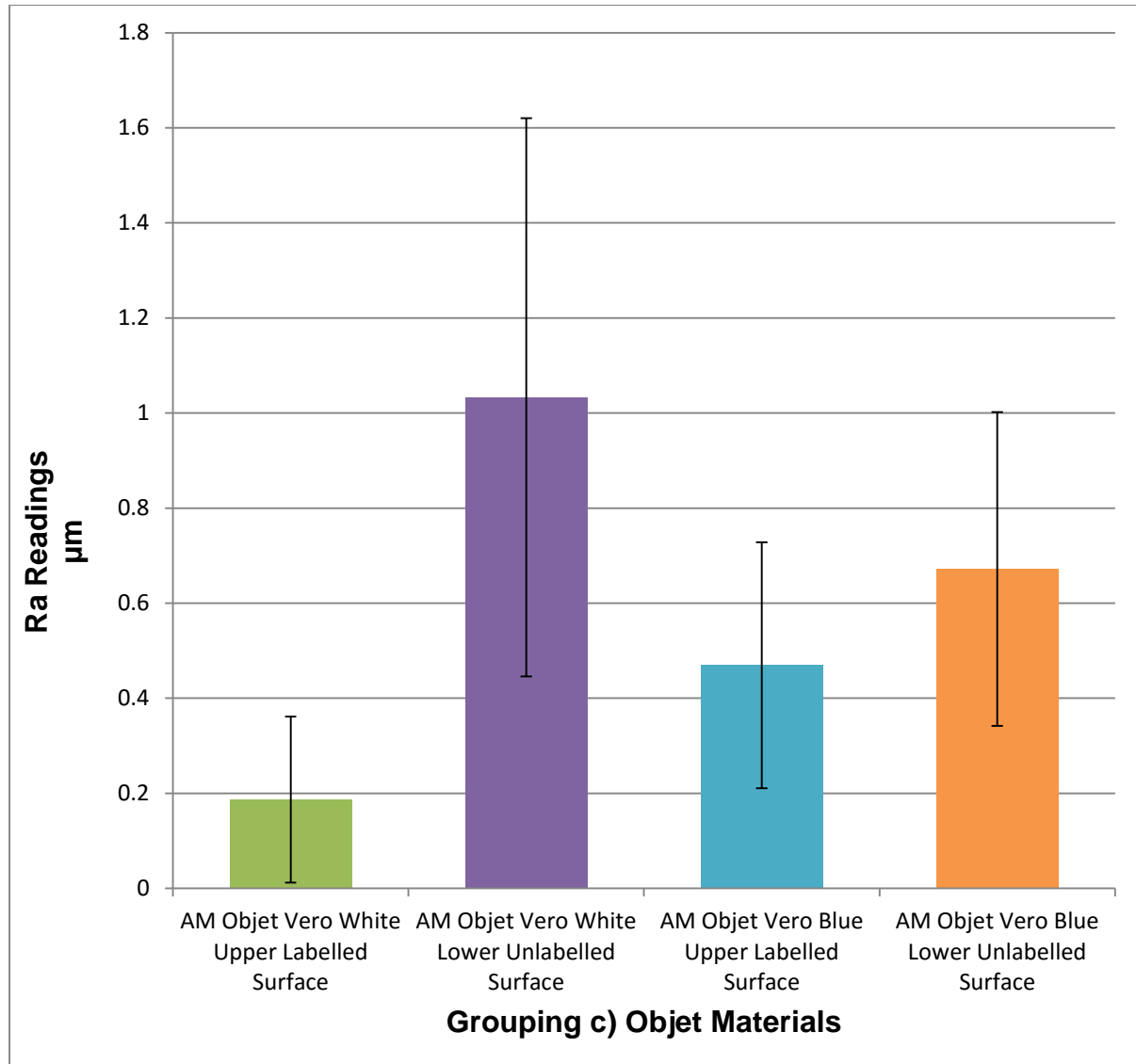


Figure 94 – Core Study Results – Ra readings of the AM Objet Materials grouping c) both upper labelled and lower unlabelled surface.

The results showed that dependent on the build orientation both grouping b) materials (built x,y up facing) demonstrated the step formation that occurs due to the layer by layer technique on R2 and R4 surfaces. Grouping a) kept consistent Ra readings on all surfaces regardless of the build orientation except for the the lower Ra reading present on the electro polished side of the cobalt chrome sample.

## **8.2 Summary**

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There were three main result areas from this chapter:

1. Pilot Study Results

Currently used implants, guides and plates produced a result range for surface roughness of 0.04 to 4.48 $\mu\text{m}$ .

2. Core Study Results

6 materials were tested in three different groups; grouping a) Laser melted Cobalt Chrome non-electro polished and electro polished samples, grouping b) SLA Accura Xtreme Grey and Accura ClearVue samples and grouping c) Objet Vero White and Vero Blue samples.

Grouping a): Only noticeable difference in surface roughness was the electro polished surface which demonstrated a smoother low Ra reading of 0.097 $\pm$ 0.023 $\mu\text{m}$ . The non-electro polished sample surface readings ranged from 2.82 to 3.84 $\mu\text{m}$ .

Grouping b): Both SLA Accura Xtreme Grey and Accura ClearVue both presented a step formation when comparing the R1 and R3 readings against the R2 and R4 readings. For the Grey samples the R1 and R3 readings ranged from 0.393 to 0.435 $\mu\text{m}$  compared to the R2 and R4 readings range of 4.238 to 4.608 $\mu\text{m}$ . For the Clear samples the R1 and R3 readings ranged from 0.268 to 0.294 $\mu\text{m}$  compared to the R2 and R4 readings range of 2.091 to 4.322 $\mu\text{m}$ . Both material samples in grouping b) were built in the same orientation (x,y up facing ) which explains the R1 and R3 reading being lower than the R2 and R4 readings.

Grouping c): There was no step formation visible in the Objet sample readings. Vero White upper surface was 0.187 $\pm$ 0.175 $\mu\text{m}$  and lower surface 1.033 $\pm$ 0.587 $\mu\text{m}$ . Vero Blue upper surface was 0.470 $\pm$ 0.259 $\mu\text{m}$  and lower surface 0.672 $\pm$ 0.330 $\mu\text{m}$ .

### 3. Comparison

When comparing the core study results to the pilot study all the core study readings were within the surface roughness range of currently used implants, guides and plates 0.04 to 4.48 $\mu$ m.

When comparing the core study results to Federspil *et al.*'s, (2009) surface roughness table shown in the literature review chapter it seems that the readings are a mix of smooth or rough on the tables scale. In grouping a) the electro polished surface is declared smooth whereas the non-electro polished surface is rough. In grouping b) for both of the SLA materials the R1 and R3 readings are declared smooth whereas the R2 and R4 readings are rough. In grouping c) the Vero White is declared smooth whereas the Vero Blue differs in both upper and lower surfaces with the upper declared as smooth and the lower as minimally rough.

It was evident in grouping b) that when using SLA the build orientation is important for surgical guides. The bone anchored side of an SLA guide may benefit from the step formation and could act as a friction characteristic to locate and grip onto the bone. It was also evident that electro polishing of the cobalt chrome samples in grouping a) made the surface smoother and reduced the Ra reading.

The reasoning behind measuring surface roughness from the material samples was to establish a correlation between chapter 7 ATP results and this chapter. The reasoning behind measuring up, down and side surfaces was to investigate whether the up facing surface was smoother depending on build orientation and position of build supports; this was evident in the SLA parts as explained in grouping b). It was difficult to show any correlation and although this chapter is informative it does not show any further insights to the area.

## Chapter 9: Clinical Feedback Results

### 9.1 Clinical Results Review

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To review the research gathered in the core chapters of the thesis, two documents were compiled with information and results on:

- Surgical Guided Nasal Implant Accuracy & Nasal Surgical Guide Development (Figure 95 – Full document available in the appendices)
- AM Materials – ATP Surface Cleanliness Testing & Surface Roughness (Figure 96– Full document available in the appendices)

The documents were shown to surgeons, registrars and lab managers in order to gain a perspective at all experience levels. The clinical staffs asked to review the research were involved in almost all of the case studies identified in the earlier chapter 5 and therefore familiar with digital planning and the use of AM surgical guides.

#### 9.1.1 Surgical Guided Nasal Implant Accuracy & Nasal Surgical Guide Development

A review document was shown to four clinical staff from various experience levels (Consultant to Registrar). Each of the reviewers was recorded and notes taken on their perceptions, opinions and responses to the research work undertaken in the document. There was a discussion throughout the document and at the end of the document once all had been reviewed.

The opinions were then categorised into the main topic areas that became evident in each of their responses, most of which correlated to the same topic areas that were highlighted in chapter 5 of the thesis.





Figure 95 – Surgical Guided Nasal Implant Accuracy & Nasal Surgical Guide Development document pages 1 to 9. This document highlighted the research, development and results of this chapter. Full A4 document example available in appendices.



## **Nasal Review 1 - Consultant Maxillofacial Oncology Surgeon at ABMU.**

Interview and discussion of the PDF results took place in the Research Room, Maxillofacial Unit, Morriston Hospital.

The analysis results from this review was categorised into five main areas:

1. History (method, papers and conferences)
2. Materials and Fabrication (combination, metal and polymers)
3. Accuracy (tolerance, diameter and length)
4. Valid Points
5. Rhinectomy Operations

### **History (method, papers and conferences)**

“Historically we went for round as we could buy round tubes and we could cut it as we made them by hand but now obviously we have the computer designs instead.”

“All guides from Materialise use round holes, it is deemed as historical.”

“I was challenged in one meeting about why we do our own guides and the circular thing and I was asked are we infringing any patents from Materialise by designing the guides and then using a circular drill hole. But historically we could prove we were doing it before Materialise was. But if we used this system you have a completely different system. We have been doing these guides for 12-14 years and we didn't patent it.”

“There was, remember Pools and Dedonc paper from Canada where they were analysing the accuracy of 1mm of the tip of the implant and we never really challenged that. Yes they were using drill guides but if it is not placed exactly then if we get Brainlab in we can also use that to guide us. Brainlab (surgical navigation software) will be in and running by the first of April 2016.”

### **Materials and Fabrication (combination, metal and polymers)**

“The cobalt chrome guide had hardly any tolerance on the tubes it was not just the bone fit it was also the drill fit, it was very tight.”

### **Accuracy (tolerance, diameter and length)**

“So the tolerances of these guides are 0.05 and 0.1 and it has 3 point of contact which will allow you to have less binding.”

“Yes I can see the theory behind it and I did not know you could get triangular cobalt chrome inserts. Plus if they are AM inserts that is the accuracy that we didn't have with the bought in stainless steel tubes. We have never had the ability to produce something that accurate before.”

“The trouble was with the circular ones is that they were always rough inside so even if we produced them with the tolerance with the finishing of drilling and burring (reaming) through them to make them smooth you lose the accuracy of the tolerance of the inner diameter of the tubes.”

“I will let you know if any Rhinectomy cases come in. I think we should try it as you are right because in my own mind I was thinking do we need to lengthen the cylinders to gain more accuracy by 5 or 10mm. I never realised about the 360 degree twist rotation of the drill; that is interesting. ”

### **Valid Points**

“You will not get water to the tip of the drill at all, the tip of the drill is far beyond it will go into the shank and to the top of the drill but as soon as it goes through the mucosa bone it is not going to penetrate. So the temperature control is more on your force, speed and your timing so that the heat can be dissipated as you do not want a lot of pressure and a lot of speed that will give you friction and heat. You need low pressure and low speed to get heat dissipation. Water cooling is more for the debris.”

“It is actually a good insight into what we actually do, I mean a lot of this is historic and we have actually progressed it *ad hoc* and now we are at a stage that we are changing quite dramatically. I mean the three point contact of the triangle offers less binding.”

### **Rhinectomy Operations**

“I do not know of any patients coming through in this present time, you usually wait for months and nothing happens and then a bus load will turn up.”

## **Nasal Review 2 - Consultant Cleft and Maxillofacial Surgeon at ABMU**

Interview and discussion of the PDF results took place in the Research Room, Maxillofacial Unit, Morriston Hospital.

The analysis results from this review can be categorised into four main areas:

1. Materials and Fabrication (combination, metal and polymers)
2. Accuracy (tolerance, diameter and length)
3. Valid Points
4. Triangle Developments

### **Materials and Fabrication (combination, metal and polymers)**

"I have always preferred the metal surgical guides."

### **Accuracy (tolerance, diameter and length)**

"The problem is if you want a longer tube I think it is a good idea because it offers control on the direction, but the only thing is that there is not a lot of space to extend the tube. It's challenging."

Explain the CMM of Guides. "One of the things that I have criticised when using the zygomatic implants is that most of the time we only tend to use one of the guides and that only gives the pilot drill hole. Shouldn't we have a guide for each drill size and are you doing that? I think that should be done, a set of surgical guides for the 3 or 4 different drill sizes."

### **Valid Points**

Review at the end. "Well I think that it is very interesting. I think by the way one of the differences that you have got an equilateral triangle and a circle should fit in there but what you are testing here is a 3D equilateral triangle which is just a little bit different so first of all it needs to be consistent down the middle. It is very interesting. Have you had a 2.9mm diameter Brånemark pilot drill down this?" Yes was the answer. "Well that is fascinating I would not have thought of that. That is a good idea and it could be a revolutionary idea but you have to test it first but you better tell the people you are speaking to to keep it quiet because it might be patentable. If you show it or if you publish it then you cannot patent it but the only problem is that it is

expensive to patent something. Well done I think that this is clever, it is logical and you just have to test it now.”

“I think that it is fascinating and good stuff. It is fascinating when you come up with something original but I have emphasised that we have to keep it under wraps because if that works out ok that is patentable.”

### **Triangle Developments**

Equilateral triangle page. “If you put an insert in would you have the same problem as the stainless steel tube inserts where they dislodge?” Explanation of the water channel idea. “Ah yes interesting.”

### **Nasal Review 3 - Registrar Maxillofacial Surgeon at ABMU**

Interview and discussion of the PDF results took place in the Research Room, Maxillofacial Unit, Morriston Hospital.

The analysis results from this review can be categorised into six main areas:

1. History (method, papers and conferences)
2. Materials and Fabrication (combination, metal and polymers)
3. Accuracy (tolerance, diameter and length)
4. Valid Points
5. Rhinectomy Operations
6. Future Studies

### **History (method, papers and conferences)**

“I have done about 7 of these cases with the consultant surgeon so we must be due another lot of cases soon. We have in Morriston completed 28 cases in this way and have fixed 56 zygomatic implants. The consultant surgeon is the only one in South Wales that does Rhinectomies and zygomatic implants.”

“It would be interesting to test the benchmark guide versus free hand. Because the most recent Maxillofacial Registrar Conference in Birmingham in October there was a heavy prosthetic feel to the conference and one or two of the local consultants from Birmingham were using zygomatic implants not always for noses but for

supporting upper arch prosthesis and doing them freehand. The explanation that was given was a finger on one side and a finger on the other and just drill but we know that we do that in the profession and did here before the guides.”

“In the zygomatic paper that we have just submitted it has not been mentioned anything about this that we are thinking of changing the guide design and it has not been alluded to the results of the final positioning of the 6 patients that were reviewed earlier last year. Because despite all of this as far as we are aware we have only seen out of 56 implants only one drop out but then how much bone support do you need to support a nose, not a lot. Even the length of the implant, even if it is not in the bone, the length alone should support it. Obviously you need more bone support the more load you are placing on the implants like the T-bar for example.”

### **Materials and Fabrication (combination, metal and polymers)**

“There is no flexibility in the Cobalt Chrome guide at all.”

### **Accuracy (tolerance, diameter and length)**

“The problem is with drilling the holes are that you have the guide at one end on the nasal bones but you still have the variation of the movement of the drill going across the maxillary sinus and the variation and wobble on that. Lengthening the cylinder could be the best option.”

“We obviously have the surgical guides in two parts so that we can get the drill in on one side. I know the maxillofacial team initially made it all in one part and we couldn't do it. There is always enough space to get the drill in, so although you cannot lengthen that across the sinus, if you had that cylinder section lengthen and coming out in the drill direction would that decrease it at the end point of the implant in the zygomatic bone.”

“So can you have a stent that sticks onto the end that connects into the cylinder on the surgical guide, an extendable piece that clips into the end that offers more support to the drill that should in theory bring you degrees of difference down as well. I have always thought when doing this operation when we go across the sinus we always wonder where it is going to end up. The edge of the nasal bone can always

be trimmed back if needed in order to get a longer cylinder support in position. We can always advance the mucosa over and the prosthesis is going to sit over here so if you lose a little of the nasal bone in order to fully engage the zygomatic bone then the implant will sit well.”

“I think it is good but I think the only thing that could be a positive is to extend the cylinder out this way (towards the drill) whether it is a separate thing that joins on or an extension piece.”

“The only thing I would question would the drill bits be long enough? The longest zygomatic implant is 52.5mm.”

### **Valid Points**

“So the closest you have got so far with using the normal surgical guide method is on average 8 degrees of difference between its planned and fixed position. And the highest of these cases being a difference of 14 degrees so from that there are probably zygomatic implants that are not even in the zygomatic bone.”

“I’ve got to admit I think it is brilliant and if we can ensure every time that we can get into the zygomatic bone then that is great. Because I suppose part of the problem is then they have the extended Rhinectomy and if their zygomatic implants are not sitting in the correct position then when they apply a load like the T-bar mechanism that combine the denture into the load and if there is nothing supporting it in the zygomatic bone then the implant may drop out.”

“The only reason we advance the skin over the nasal bone is to give the lab a better finish so it is easier for them to get a very fine margin on their prosthesis.”

“The drill we use is on the lowest number of resolutions so we cannot get any lower on that.”

### **Rhinectomy Operations**

“It would be really interesting to be part of the operation where the plan B guide will be used and to see how it gets on.”

## **Future Studies**

Questioned a further study on the after quality of care of the patient with regards to the (complications) they have after treatment and whether this is caused by the results generated by the degrees of difference and the possible perforation of the sinus/glands/nerves.

## **Nasal Review 4 - Reconstructive Scientist & Maxillofacial Laboratory Services Manager at Morriston Hospital.**

Interview and discussion of the PDF results took place in the Research Room, Maxillofacial Unit, Morriston Hospital.

The analysis results from this review can be categorised into three main areas:

1. Accuracy (tolerance, diameter and length)
2. Valid Points
3. Future Studies

### **Valid Points & Accuracy (tolerance, diameter and length)**

“Yes, I think that it is a big step forward, I think the irrigation and the idea that you will be able to get water down the channel of the drill and cooling that drill is good. It is touching at three points so I think that will offer less resistance when drilling and I think it should improve the accuracy but I think that there is some work that needs to be done as far as the length is concerned. There is also the possibility of being able to rapid prototype these so that they could slot into each other so you could have a longer length to be used first to gain an accurate pathway and then a shorter one for the larger drill to make the pathway ready for the implant. I think that would be good and there is no reason why there couldn't be a two part one that clicks together as you can rapid prototype anything so I think yes that idea is ideal really.”

### **Valid Points & Future Studies**

“I think when you had the idea in a previous conversation of drilling into models would be a good idea because patients are always very different and there are no



standards so if you were to test with different surgeons then really a test model would be best as it will be the same anatomy that will be used. It offers that degree of controllability that one surgical case would not offer. I think a soft tissue model over a medical model is a great way of testing.”

### **Valid Points**

“Very good research and very exciting for the future.”



## **ATP Review 1 - Consultant Cleft and Maxillofacial Surgeon at ABMU**

Interview and discussion of the PDF results took place in the Research Room, Maxillofacial Unit, Morriston Hospital.

The analysis results from this review can be categorised into four main areas:

1. History (method, papers and conferences)
2. Materials and Fabrication (combination, metal and polymers)
3. Polishing
4. Future Studies

### **History (method, papers and conferences)**

"I think when it comes to cranioplasties and orbits and especially so in the orbit my view has always been the under surface doesn't need to be polished but the upper surface does need to be polished so that soft tissues can move smoothly on it and for the under surface you more or less want the opposite effect you want bone to grow on it and Osseo-integrate. But where you have muscles moving for example the eye muscles it is very important you want it to be freely moving on that surface so that has been the rational."

"This applies mostly just to orbits as there are tissues which are moving, in a cranioplasty its somewhat different there are some muscles there but on the other hand you do not really want them to adhere to the cranioplasty because if you ever have to go in and operate you would want it to separate from them I would say."

### **Materials and Fabrication (combination, metal and polymers)**

Looking at the Metal Graph "The Cobalt Chrome non electro-polished is cleaner then electro-polished sample, how interesting"

### **Polishing**

Question raised is the polishing affecting the surface of the material "To be honest I thought it would be the other way around."

- Looking at the conventionally made samples included. "So it looks like polishing contaminates the surface."

## **Future Studies**

Review at the end of chapter PDF. "You would expect after it has been polished that the Ra value will come down and it is doing that but the findings in terms of cleanliness are quite unusual and interesting. The question is if there is a relationship between the two. It is coincidence or is it a relationship, the rougher it is the less clean or more clean I suppose we better not guess and it is better to wait and see."

## **ATP Review 2 - Reconstructive Scientist & Maxillofacial Laboratory Services Manager at Southmead Hospital.**

Interview and discussion of the PDF results took place in the Laboratory, Maxillofacial Unit, Southmead Hospital.

The analysis results from this review can be categorised into six main areas:

1. History (method, papers and conferences)
2. Materials and Fabrication (combination, metal and polymers)
3. Polishing
4. Osseo Integration
5. Valid Points
6. Future Studies

## **History (method, papers and conferences)**

"All the way through the process when I make a cranioplasty at the different stages I always clean it with one of these Azowipes. Azowipes are hard surface disinfectants wipes and at every stage that is something I always do. Between rubber wheeling the surface, polishing, before it goes back into the mould I wipe, I do things in a very particular way. I do not know if that is the norm but it is just something that I have just got into a habit of doing. When you mark them up with a marker pen to trim the edge back I would use a wipe after that stage and from day one I have always cleaned

them off. It gets cleaned with these wipes four or maybe half a dozen times. It consists of isopropanol solution which is within the wipe. My process is not written down really with regards to a standard operating procedure it's just the way I have been doing these plates for 15 years maybe even longer than that. It is something that I have always done."

"We buy the titanium in big sheets and then we cut it down and that is commercially pure titanium and that is how it is supplied originally from Japan I think."

"The only time a cranioplasty would be taken away is if the wound was to get infected. What really maddens me is when the plate is thrown away when they take the plate off and then you have to start again to make a new one when there was nothing wrong with the plate itself it was the wound that was infected. A cranioplasty is two weeks' worth of work and all you needed to do is to get the plate back re-polish and sterilise it ready for it to be inserted again unless the bony defect has changed with the infection getting into the parameter of the defect."

"I would be good if we could understand exactly what processes are involved to produce that titanium supplied sheet. I get it from a company called Argany Technology, Birmingham and I think they get it from the Coby Mill, Japan. 0.5mm thick titanium for cranioplasties and 0.25mm thick titanium for orbital floors."

### **Materials and Fabrication (combination, metal and polymers)**

"I find these results rather interesting. I am not surprised with the lisko wheel result, a lisko wheel is like a scourer so what you do is that you place it into a mandrel and whizz it around and you end up with a surface. It is a very rough process."

"When they make the titanium sheet it is milled, they stretch it between rollers. That process must do something to the surface and the properties of the material."

"Basically what I did was I sat down with those samples I sent you and thought what surface finishing processes I use for Cranioplasties. The reason I used sand blasting was that I sand blast the Dura side of the cranioplasty plate, the reason why I do that is as it has gone from a flat titanium sheet to a curved plate the material properties are under a lot of stress therefore by sandblasting you a putting force into it to relive some of the pressure stresses."

“The only thing I can think of is what I said to you earlier, I wondered if the titanium samples that I sent you were milled. We have a technique called burnishing which smooths a surface; I reckon that could be that if it is milled from a block like the old steel mills. I wonder if it has been milled by heavy rollers.”

## **Polishing**

“Another thing I am always conscious of is the pumice pot; this is where I feel bacteria may fester. The cranioplasty needs to be polished as it is rough but if a denture is being used on the face pumice wheel as the plate then cross infection may occur. Every time I polish using the pumice after I have finished I empty and clean the pumice pot until the next cranioplasty.”

“The reason I polish the outside is when you start to bend the titanium sheet to form the cranioplasty it shows up with surface imperfections almost like ripples in the material.”

“Getting back to the polishing because that is important, I mean you have been to theatre and you have seen the blood and gore that goes on. If you have a plate with a polished surface it is easier to clean all the blood and debris of it. I think if it is not cleaned and is left in there and it can stick to the surface that is where you would have infection risks so by polishing the surface to a high specification probably more than the polished samples I sent you, you need almost a mirror finish it is easier to clean and they quiet often make sure that they clean all the debris off before they close it back off. That is why I polish them and that is why my colleague polishes them because it is easier when they are in theatre. Also you are less likely if there is no debris on there that you could theoretically get adhesions onto the surface.”

## **Osseo Integration**

“When you look at titanium implants like the Brånemark implants they are the principles that they use with regards to surface finish so the implant can Osseo integrate into the bone. If you are using a similar material for the cranioplasty plate you could with that material get some Osseo integration.”

## **Valid Point**

“The research results are interesting actually.”

## **Future Studies**

“Those results are just from one sample and from the same titanium batch. The only titanium one that would have been different is if it was anodised but we do not do that here. I could never see the point of anodising but some people years ago thought that if the plate was anodised in gold colour that if the patients skin was thin on the plate that the gold colour would blend in better than the silver titanium. That is what I was told but I have never looked into it but do wonder if anodising it would have an effect on the cleanliness of the material.”

“It would be interesting to look at surface roughness and how when bending these sheets or plates to see what happens to the surface.”

“It would be interesting to do a combined study with our new operative theatres as they have a new circulatory system. The theatres here supposedly have a state of the art for re-circulating the air and taking all the bugs out.”

“What we could do is we could arrange for an operation to be in theatre and we could provide you with a trolley on the side of the patient so that it would not interfere with the operating tools or table so you can proceed with the testing and swabbing.”

“We have cases here that sometimes go on for 12 hours so time intervals would not be a problem. Comparing Morriston to our new state of the art theatre. You could write to us and if willing we can get you an honorary contract here as well.”

“The only other hospital ours could compare with is the new hospital they are building in Glasgow.”



### **ATP Review 3 - Reconstructive Scientist & Maxillofacial Laboratory Services Manager at ABMU.**

Interview and discussion of the PDF results took place in the Research Room, Maxillofacial Unit, Morriston Hospital.

#### **Future Studies**

“Have you considered the antibacterial properties of metal? Because that may have a bearing on it as metal does have some natural antibiotic properties. Just being a metal should have reduced the RLU's but maybe it is certain metals that do this better than others.”

“Did you do anything to look at sterilisation and how it affects the polymers or metals with regards to distortion as that would be an interesting extra bit of research on this data.”

## **9.2 Summary**

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### **9.2.1 New Observations, Opinions and Perceptions**

#### **Nasal Review:**

The participants in the nasal review were all agreed that the drill cylinder would need to be lengthened in order to gain better accuracy, offering more control on pathway placement and the use of extendable pieces however, there were concerns about the space available in the area.

The triangular inserts were commented on with regards to the three points of contact, the water cooling channels and their ability to cool the drill and remove debris. The three points of contact also offers less resistance or binding on the drill. They were happy to trial this developed idea and deemed it as clever, logical and to have the potential to be a 'revolutionary' idea.

### **ATP & Surface Roughness Review:**

The participants in the ATP and surface roughness review explained when deciding whether to polish the surface of an implant or guide it is dependent on the area of fixation and whether they would like it to osseointegrate, or to have movement on the bone; this varies the surface finish decision. This seems to be the case for both aesthetic and physical attributes; one participant explained that the visibility of plates under a thin section of skin can be a problem as well as the sensitivity to temperature change in metal materials although this point is only relevant for implants not surgical guides.

It was a surprise result for the participants that polishing a materials surface contaminates the area. The use of pumice in the polishing of these plates was flagged as a potential contamination method within maxillofacial labs.

One participant questioned whether the metal materials were considered to have antibacterial properties hence the low ATP results and contemplated whether this could be looked at in a future study.

It was interesting to learn that throughout the process of conventionally making orbital floors and cranioplasties that Azowipes are used to clean the surface area of the material. Azowipes are isopropanol wipes therefore the standard operating cleaning procedure used in the ATP chapter of the material samples soaking in the isopropanol solution is not only appropriate for AM materials but also used in maxillofacial labs for conventionally made implants and guides.

### **9.2.2 Comparison of Old with New Attitudes**

#### **Nasal Review:**

The participants portrayed new attitudes when comparing to old attitudes expressed during the case study chapter 5 and they were contradictory.

In the case study chapter it was well noted that metal was the material of choice by the surgeons, but when they reviewed the nasal review document they complained that the cobalt chrome nasal surgical guide offered no flexibility and tolerances were too tight. They did agree that the cobalt chrome triangular inserts could rectify the dislodging problem of the stainless steel tubes used currently.

### **ATP & Surface Roughness Review:**

The participants in the ATP and surface roughness review found the comparison between polished and non-polished cobalt chrome very interesting and thought that the results shown would have been the opposite way around. The results contradict their perceptions and illustrate the lack of an evidence base surrounding common practise in U.K. labs.

The reasoning behind polishing, one participant explained was for both aesthetic and functional purposes; aesthetically to remove any surface imperfections of the parts and functionally in order to wipe away any debris or dry blood when using the part in the operating theatre.

## **9.2.3 Changes and Adaptations Needed**

### **Nasal Review:**

The participants in the nasal review liked that the triangular inserts would not require any additional finishing, such as reaming, in order to create a circular hole. They agreed with the length of the drill cylinder should exceed the 11mm length pitch of the drill; they classed this as an important change and wondered why this had not been flagged before.

They hinted at the possibility of having a series of drill cylinders for each diameter of drill used that would fix into the surgical guide and considered whether a comparison study between freehand, currently used and developed surgical guides should occur as a future study.

### **ATP & Surface Roughness Review:**

The participants in the ATP and surface roughness review explained that a future study on the different AM materials could be conducted. The study would involve ATP testing the AM materials during different time intervals in an operation to compare how the materials react to the operating surroundings and air circulation. Also another future study was proposed on the sterilisation of the materials and the effects it has on the parts.

### **9.2.4 Key Findings**

The surgeons regard the AM triangular inserts as more accurate explaining that the AM capability for inserts was not used before in nasal surgical guides.

The rhinectomy cases discussed with the application of the triangle inserts are shown in section 6.4 in chapter 6. Both operations took place after the clinical review of the PDF's.

The surgeons discussed how this research is a good insight into maxillofacial surgery. The difference between how they previously have progressed adhoc compared to quantitatively analysing new concepts was regarded by the review participants that it 'will change the future dramatically and for the better.'

There is still preference occurring towards metal surgical guides but the results did interest the surgeons.

In nasal review 2 a set of surgical guides was proposed for 3 to 4 different drill sizes. The TRIFLO concept shown in section 6.4.2 has fulfilled this proposal.

The consultant oncology surgeon has completed 28 cases of rhinectomy and nasal implants using the original nasal surgical guide way and is the only surgeon in south Wales that performs this surgery.

Explanation was given that if the nasal implants are not placed in the zygomatic bone it can affect the support of a load e.g. T-bar mechanism for a denture. If the newly developed guides can ensure everytime that it hits the target zygomatic bone that would be beneficial.

All reviewers were intrigued that cobalt chrome non-electro polished is cleaner then the electro polished sample. They did not expect that the polished and electro polished samples would give a higher RLU reading then non polished.

One reviewer explained that they were not surprised that the lisko wheel polishing technique was a high RLU as it is a very rough process.

There were two reasons or opinions given on why implants should be polished. One that it is easier to wipe the surface of the implant in surgery when blood is on it before implantation preventing infection risks and two that orbital floor implants should always have the top surface polished as the soft tissue of the eye is mobile and needs to glide on the surface of the implant.

Many future studies were identified in the reviews of this chapter and they will be discussed further in chapter 11.

# Chapter 10: Discussion

## 10.1 Introduction

This Discussion chapter is broken into three distinct parts:

### **1. Discussion of Core Chapters (Section 10.2).**

- a. Case Study Chapter (10.2.1)
- b. Accuracy Chapter (10.2.2)
- c. Cleanliness Chapter (10.2.3)
- d. Surface Roughness Chapter (10.2.4)
- e. Clinical Feedback Chapter (10.2.5)

### **2. Methodology (Section 10.3)**

### **3. Research Methods: Limitations (Section 10.4)**

- a. Testing Facilities(10.4.1)
- b. Access to Appropriate Case Studies (10.4.2)
- c. Measuring Accuracy (10.4.3)
- d. Measuring Cleanliness (10.4.4)
- e. Measuring Surface Roughness (10.4.5)
- f. Unbiased (10.4.6)

## 10.2 Discussion of Core Chapters

### 10.2.1 Case Study Chapter

The findings from the qualitative research generated from this chapter showed that there were seven main areas that kept being discussed during the planning, operation or review of each case. The seven areas included:

1. Materials & Fabrication (Combination, Metal & Polymer)
2. Accuracy (Tolerance, Diameter & Length)
3. Friction & Surface Roughness
4. Patient & Surgeon Specific
5. Perspective
6. Surface Area
7. Bone, Osseo Integration & Sterilisation

In materials & fabrication, it was clear that AM metal was the favoured material as this was highlighted in several of the cases shown. They believed that because it can be fabricated thinner that it can be placed into an incision easier and is deemed more accurate. This favoured metal material was also highlighted in Bibb *et al.*'s 2009 explaining that SLA surgical guides were fragile. The metal guide however did not work well in case study B it was explained as being too rigid on the bone and did not offer enough flexibility. This was an interesting finding as in the literature review and from the surgeons' perspectives on metal guides, they were always placed as a positive tool superior to the polymer guides. The nasal guides from case study A and B needed a degree of flexibility in the material due to the curvature of the nasal bone.

The polymer guides in each case worked well in reflection of their design intent but the surgeons see them as fragile and worry about the polymer distorting in the autoclave whilst being sterilised. All of the surgical guides in the case study chapters went through the same ABMU HSDU autoclave cycle and all except for case study B metal nasal guide worked and performed the procedure as they were designed to do.



Issues that were highlighted with surgical guide materials:

- Polymer Guides – problems in the past over polymer particles that were removed from the guide after cutting or drilling. Concern if they are left in the human body would the resin be safe or cause infection.
- Metal Guides - no metal particles were removed from the guide after cutting or drilling.
- SLA Guides - you can cut or adapt in a lab prior to surgery if last minute changes are needed but metal guides cannot be changed once fabricated.

The case study chapter explained that surgical guides or extensions on ends should be kept to a minimum. This is to keep the guides as compact and space efficient as possible making sure the location and strength parameters are intact. This is highly important as the smaller the incision hole during surgery the better as it prevents further tissue damage and cuts healing time. Bibb *et al.*'s 2009 paper also agreed that a smaller/thinner guide can increase the surgeon's visibility and access to the area is '*significantly improved*'.

In accuracy, the use of stainless steel tubing in case study A and B worked fine for the patients but in the surgeon review they explained, as was highlighted in the literature review (Cassetta *et al.*, 2011), that the use of the tubing or inserts can be problematic. The explanation that the metal inserts can bind to the drill if tolerances are incorrect which causes heat distortion and then removal of the insert; these inserts could easily fall into a patient's airways which is a worry to surgeons. The standardisation of length, tolerances and fixed diameters were discussed, the surgeons explained that a longer length of the drill cylinder should in theory allow better precision of implant placement. However it was highlighted that awareness of the space within the anatomy is important as they do not want to remove bone unnecessarily.

When discussing friction and surface roughness it became evident that dependant on whether it was skin bound or a bone bound guide the different materials performed in different ways. In case study C the polymer guide was explained to be slipping on the bone surface making it hard to locate it correctly in the right place. In contrast, in case study D which used a metal guide on the bone, the surgeon

explained that this was exactly what he wanted that once located into position the metal guide did not move in any direction. However, the use of both materials became evident in case study E; where the skin bound guides were polymer and the bone bound guides were metal. The flexibility that the polymer offered complemented the movement of the skin whereas the specific location needed for the metal guide was located correctly due to the friction coefficient on the bone. Bibb *et al.*'s 2009 paper explained that the mobility of soft tissue leads to inaccuracies but with the combined mix of polymer and metal guides in case study E it complemented the operation type.

Patient and surgeon specific, each surgeon observed had their own technique and routine of how they would complete the procedures and their material preferences. However, the researcher does agree with Cassetta *et al.*'s 2012 paper that the rapid development of AM has led to '*unrealistic clinical expectations*' on the efficacy and ease of use of the technology. A surgeon specific guide would be designed with said surgeon to suit the working style and experience they possess. Another area that became apparent in this chapter due to three case study examples (C, D & E) was that it is not only patient and surgeon specific surgical guides that are needed but also material and area specific on a case by case format.

Whilst observing the surgical guide cases the amount of variables were high, such as, whether the surgeon was sitting or standing, right or left handed and their personal experience should all be taken into account when designing the surgeon and patient-specific surgical guide.

AM metal surgical guides are highlighted as the surgeon preferred material choice due to thinner and rigid quality characteristics which they felt helped to gain better accuracy.

Even though polymer surgical guides performed to their planned job, the surgeons have negative perception on them deeming them as fragile, that they distort and that polymer particles and fragments are removed from them when drilling and cutting. Bibb *et al.*'s 2009 paper echoes this perception throughout. However, polymer guides can be adapted if needed in surgery whereas the metal guides are harder to

adapt. Polymer guides also offer an increase in flexibility when compared to metal guides which suit certain anatomy area types.

The mix of polymer guides with stainless steel tube inserts was highlighted as problematic due to the inserts binding of the drill, heat causing distortion and removal of tube which cause worry for the surgeon due to the loose part in the patient's airways.

The different materials perform better in different surface scenarios. Case study E showing the correct use of materials for different surfaces; the polymer material on the skin bound guide and the metal material used on the bone bound guide.

The surgical guide needs to have many attribute specifics; it needs to be patient-specific so it is designed on the patients CT scan so it fits the anatomy correctly in surgery; surgeon specific so it can be designed with the said surgeon to suit their working style and experience they personally possess; material specific depending on the area the procedure will take place and what surface the material will be used on.

Each of these will be case by case specific but the author feels that all the above specifics need to be thought of in the design of the procedures surgical guides and implants. Richards *et al.*, 2007 paper agrees that there is not '*one surface*' for all applications and the anatomical area where the part will be used needs to be considered at all times. Park *et al.*, 2009 paper also stated that guides should be categories on the '*materials used and the amount of surgical restriction.*'

To demonstrate this visually, the author has derived a material and area specific skull in both bone and soft tissue to highlight which area from the combined PhD research is best for the material choice of the surgical guide (Figure 97).

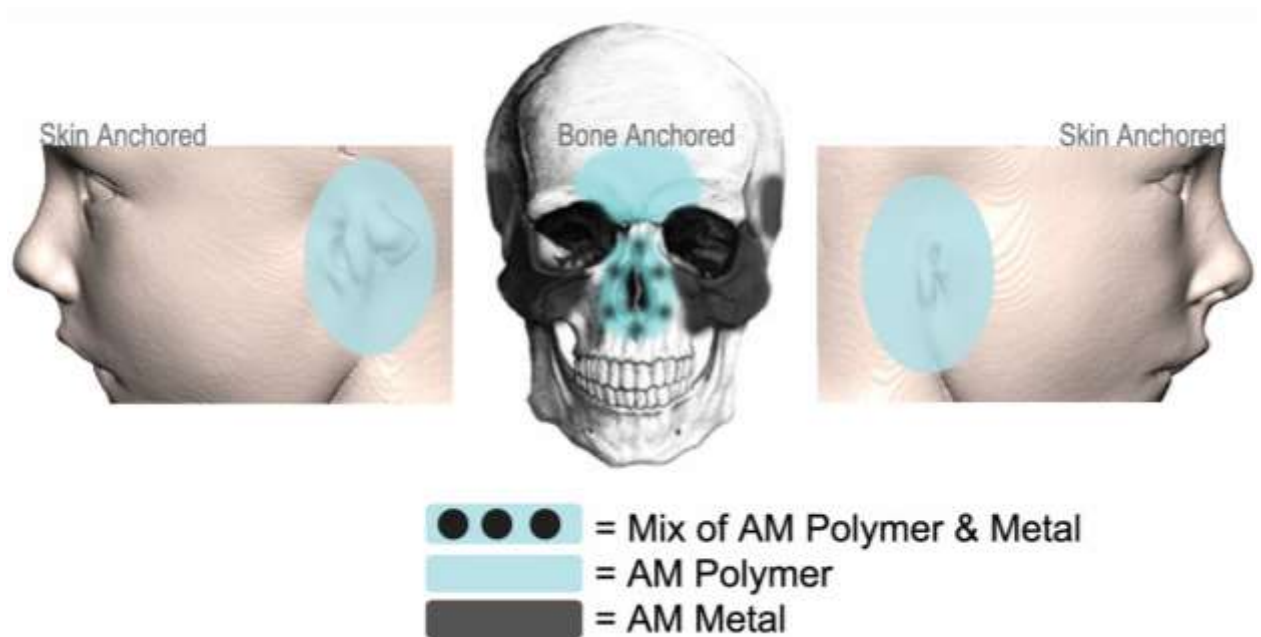


Figure 97 – Material and Area Specific Skull image which highlights the best suited areas for the different AM materials. The blue with grey dots symbolises the mix of AM polymer and metal materials: an example of this would be the developed nasal guides shown in chapter 6. The blue symbolises AM polymer for the areas that require flexibility on the surface anatomy or where the transparency of the polymer is effective. The grey symbolises AM metal where the rigidity and strength of the metal suits the cutting and repositioning of the bone.

### 10.2.2 Accuracy Chapter

The results from this chapter have shown that incremental changes to the surgical guide has helped to gain better accuracy in the placement of a zygomatic implant. This research adds and follows on from the work shown in Park *et al.*, 2009 paper.

The data generated from the six surgical cases gave the mean degree of difference reading between pre- and post-operative of  $9.37^{\circ} \pm 2.5^{\circ}$ . The benchmark guide was chosen which has a degree of difference reading of  $8.04^{\circ}$ .

The benchmark guide chosen was the same as case study B in chapter 5. This case study was the one that also had a metal nasal surgical guide fabricated in cobalt chrome but it could not be used due to its rigidity on the nasal bone. Within this chapter it was explained that flexibility is important in nasal surgical guides. The patient is usually scanned at least two weeks prior to surgery and depending how

developed or active the cancer is the more of the nasal area or bone needs to be removed. This is only known when the area is exposed during surgery. Polymer guides offer the flexibility needed if the bone needs to be removed also polymer guides can be trimmed whereas metal guides are harder to adjust.

Out of the six surgical cases there was no consistency or standard specification used over the diameter, length and tolerance of any drill surgical guide. This research will add to the limited studies in the literature that consider potential errors from SLA surgical guides (Cassetta *et al.*, 2012; Giacomo *et al.*, 2005).

Again as highlighted in the literature review and case study chapter the binding of the metal inserts on the drill, the overheating of the area which results in the removal of the insert were discussed as a problem area that needed addressing in the development.

Another point that had previously come up in the literature review was the building of a perfect circle in AM. The requirement of post finishing to ream out the holes of impracticable material to get back to the design intent diameter was highlighted as an error area.

The length of the drill cylinder has come up in both literature review (Cassetta *et al.*, 2012; Park *et al.*, 2009) and case study chapter; all with the theory that if the length was increased it would help improve accuracy. When reviewing the pilot drill in the development stages the author noticed that for the drill to complete a pitch the length is 11mm. The six nasal surgical guides explored in this chapter drill cylinders length ranged up to 10mm; therefore the use of the pilot drill would have compensated for an additional wobble or inaccuracy variable in which the drill cylinder did not exceed over the 11mm length of the drill pitch. This increased length was therefore built into the trial rhinectomy operation discussed in section 6.4.1.

The introduction of the triangle was explored in this chapter. The reasoning behind the triangle being included in the development was to address some of the issues found in both the literature review and the case study chapters. The triangle resolves the binding effect of the metal inserts on the drill, easier to AM build the geometric triangle rather than the a circle, the shape has three natural water channels that help

to cool the drill and prevent overheating and it supports the drill securely at more than one point.

The tolerances that produced the best results were 0.05 and 0.1mm. They produced a total error angle of  $1.10^\circ$  compared to the  $8.04^\circ$  degree of difference angle produced by the benchmark guide from the start of the chapter. That gives a  $6.94^\circ$  difference between them. Although there are many other variables that can occur with the incremental difference in tolerance, it will help gain better accuracy of implant placement.

Developed surgical guides were fabricated and tested on the CMM. The developed 2.95mm triangle guide was used to generate an angular error graph in comparison to the six guides that were reviewed at the start of the chapter. The developed guide graph produced lower build annular error readings and estimated less total error than the six surgical guides reviewed at the start.

These incremental changes were then discussed with Morriston Hospital and they were willing to trial the triangle and tolerance developed guide on the next Rhinectomy case they had.

The adoption of the developed guide was used on a rhinectomy patient shown in section 6.4.1. Pre and post-operative comparisons in relation to the benchmark guide were completed and showed a positive accuracy result when compared to the estimated data shown in the lower graph of figure 62.

The two case examples shown in section 6.4 provided evidence that the triangle and involvement of the TRIFLO key concept was well received by the operating surgeons.

### 10.2.3 Cleanliness Chapter

The results in this chapter have shown that the ATP methodology is a practical technique for providing real-time measurements of surface cleanliness across a range of AM materials. The use of AM materials for medical applications with direct patient contact is growing, therefore tests to verify cleanliness and sterility at various stages of the AM process are of significant importance. This research will help form future studies of surface contamination and Wexell *et al.*'s 2013 paper stated it as being '*one of the several important factors influencing the biological response.*' This study is the first to report the application of the ATP technique to a range of AM sample materials. The work has been undertaken within the context of an AM/RP research centre, specialist biomedical/clinical facilities were not required. The results show that it is feasible to use ATP as a screening technique to highlight AM materials that may be more suited to medical devices and the clinical environment.

The data from the initial pilot study has shown that ATP testing can identify and highlight the differences between three nominal delivery stages: post-build, post-cleaning and post-sterilisation. Across the various materials, there was an order of magnitude change in RLU measurements associated with each of these stages. There is the potential to establish benchmark RLU values for each key phase of AM in order to provide the process validation required for any medical product.

The key <250 RLU threshold reported in this chapter is the nominal cut-off for surface cleanliness within a hospital, however, operating theatres had lower ATP results than the threshold (Griffiths *et al.*, 2000). A relatively simple cleaning protocol was used to generate ATP readings in the region of this threshold value. The main finding was that the Objet materials could not be cleaned or disinfected – all three Objet AM materials were significantly above the threshold value. In contrast, the majority of the remaining polymers and metallic AM materials were significantly below the 250 RLU threshold value (post cleaning). It would appear that the Objet polyjet process adheres more surface contaminants when compared to the other AM processes. More research is required in order to identify the cause of Objet's higher RLU readings.



For the AM materials below the 250 RLU threshold an interesting feature was the influence of surface finishing. Metallic medical parts are electro-polished for aesthetic and functional purposes; however, the results from this study question whether this is beneficial. The electro-polished Cobalt Chrome samples had significantly higher RLU readings compared to the non-electro-polished samples. Contaminants from the finishing process may have been impregnated into the electro-polished surface. The comparison study of the AM materials to the traditional or conventional examples showed that the lowest of the metal readings was the AM cobalt chrome non-electro-polished samples and the lowest of the conventional samples was the titanium as supplied to the maxillofacial lab. Any additional polishing to either of the samples caused a rise in RLU reading, however, Richards *et al.*'s 2007 paper questioned whether polishing metal surfaces could be advantageous to lowering bacterial adhesion and infection risks. Taylor *et al.*, 1998 and Yoda *et al.*'s paper also explained that results show that a small increase in surface roughness from smooth has a '*significant effect on microbial adhesion to that surface.*' This research would require future studies to gain further evidence.

This research has used a single ATP reading (post-cleaning) in order to evaluate the suitability of various AM materials for medical applications. More research is required in order to show how a fixed time-point ATP reading correlates to the likelihood that a surface is susceptible to microbial contamination over a longer period of time.

The three Objet materials produced consistent elevated RLU readings (post cleaning), and this indicates that they may not be appropriate for patient-contact medical devices. Following the cleaning protocol, a number of the polymeric and metallic samples were significantly below the 250 RLU threshold value, and this shows that a number of standard AM materials have the potential for a wide range of medical applications.

#### 10.2.4 Surface Roughness Chapter

The surface characteristics of a selection of the AM materials used in the cleanliness chapter were further investigated through surface roughness measurements in this chapter.

Build orientation naturally has an impact on surface roughness as expressed in the literature review (Bibb *et al.*, 2015, Bibb *et al.*, 2010; Thomas, 2009; Bibb & Sisias, 2002; Lan *et al.*, 1997) and in the case study chapter. The electro-polished Cobalt Chrome gave  $Ra=0.10\mu m$ , in comparison to  $Ra=2.82\mu m$  for the non-electro-polished samples. This latter reading was comparable to the SLA Clear ( $Ra=2.32\mu m$ ) and SLA Grey ( $Ra=2.31\mu m$ ) measurements. The Objet materials gave values of  $Ra=0.19\mu m$  for Vero White and  $Ra=0.47\mu m$  for Vero Blue. These surface roughness readings are in line with expectations, but they do not highlight surface discrepancies that could account for differences in RLU readings.

It was evident in grouping b) that when using SLA the build orientation is important for surgical guides. The bone anchored side of an SLA guide may benefit from the step formation and could act as a friction characteristic to locate and grip onto the bone. It was also evident that electro polishing of the cobalt chrome samples in grouping a) made the surface smoother and reduced the Ra reading. Both materials in grouping c) demonstrated a low Ra reading.

This surface roughness result in this chapter could change the design of future bone anchored guides and implants with the bone bound side of the part to have the step formation present in order to locate and grip to the bone easier. This was one of the key themes and issues surrounding the case study chapter and the reasoning behind surgeon's enthusiasm for AM metal guides. If the polymer guides can use this step formation roughness as a positive friction characteristic for bone bound guides this would help change attitudes and perceptions that the surgeons have of slippery non grip polymer guides. Bibb *et al.*'s 2009 paper disagrees explaining that '*the fitting surface of the surgical guide would not be affected or damaged by the supports or their subsequent removal*'. Nuño *et al.*'s 2006 paper also explains that rough surfaces do have a stronger bond on the bone and if the surface of the part

debonds it may result in damage to the area. Therefore further studies are required in this area.

The friction coefficient and surface roughness for AM materials could be a future study for the SLA grouping. The study could be how to use the step formation as a positive material characteristic for the bone friction element of SLA surgical guides.

Future studies would include correlation between RLU readings and the Ra readings; is there a common factor occurring in these areas. In the ATP chapter the RLU readings indicated that the polishing of metal gave the surface a high RLU, non-polishing the AM materials or using the titanium material as supplied to the lab for conventional parts produced a lower RLU reading therefore parts are believed cleaner.

When comparing the materials between ATP and surface roughness it seems to be the case that the smoother or more polished it is the more prone to dirt or debris fixating on the surface.

The raw material parts with no polishing or intervention gave the RLU results as a cleaner reading. The Ra values of these parts were within the range of current implants, guides and plates as an acceptable surface roughness for a medical part. However, when comparing the results to the surface roughness classification table from the Federspil *et al.* (2009) paper, in grouping a) the electro polished surface is declared smooth whereas the non-electro polished surface is rough. In grouping b) for both of the SLA materials the R1 and R3 readings are declared smooth whereas the R2 and R4 readings are rough. In grouping c) the Vero White is declared smooth whereas the Vero Blue differs in both upper and lower surfaces with the upper declared as smooth and the lower as minimally rough.

Even with both RLU and Ra evidence from the cleanliness and surface roughness chapters the author questions whether the low RLU reading gathered from a rough material surface could be explained by the fact that the swab does not reach fully into the crevices or step formation left on a rough surface. Does the ATP swab not

pick up all the debris that is on the rough surface, or at least not as much as it does on a smooth surface?

Electro polishing of the AM metal materials did make the surface smoother but when you correlate this to the RLU readings it seems that the smoother or more polished the surface, the more prone dirt or debris is to fixating on the area. Puipe 2003 paper disagrees explaining that a '*beneficial effect of the electro polishing is the elimination of surface contaminates.*' Richards *et al.*, 2007 paper also explained that there is more to surface polishing than '*simple macro changes for friction of surface roughness*'. The conflict of opinions in this area highlights the need for further research.

Another point that the author would like to highlight, was the RLU reading lower on the non-polished metal materials because the ATP swab did not fully reach into the crevices or step formation left on the surface.

### **10.2.5 Clinical Feedback Chapter**

The qualitative methods used in this chapter were data collection interviews which were carried out objectively. The rigour between the methods used in chapter 5 and chapter 9 were similar but did differ due to chapter 5 being more involved with the case study from start to finish (observing, making notes, recording data and photographs) whereas in chapter 9 it was going through the PDF with the individual and recording their thoughts and opinions on the results.

The rigorous research entailed research tools such as semi-structured interview, observations, logbook note taking and recordings (as discussed in chapter 4). Before each case study or clinical review took place the hypothesis set common questions/data required for chapter 5 and PDF result findings for chapter 9. This set hypothesis helped to objectively focus all the interviews and reviews.

For chapter 5 the questions and data was collected via recordings, photographs and note taking/observations. Each recording of the semi-structured interviews were

transcribed and a file was created which combined the photos, notes and transcribed data. Once all case studies were in their file format the data collected was compared and analysed. When comparing the answers from the participants common themes and results occurred.

For chapter 9 the PDF result findings were given to each participants and each page was reviewed consecutively. The data was collected via recordings and note taking/observations. Each recording of the reviews was transcribed and a file created which combines the notes and transcribed data. Once all the reviews were in file format the data collected was compared and analysed. When comparing the answers from the participants common themes and results were discovered.

The results from this chapter contradicted opinions previously stated in both the case study and literature review (Bibb *et al.*, 2010). AM metal guides and implants have been highlighted as the better material option throughout this PhD by different papers and surgeon experience. However, with the accuracy and cleanliness results the opinions although still in favour of the metal AM materials have altered what they perceived as the best.

In the accuracy review, two of the four participants complained about cobalt chrome surgical guides, the same guide that has been explained in case study B. They said that the metal guide offered no tolerance on the drill cylinders therefore not only offered no flexibility to the fit on the nasal bone but also did not work on the drill cylinders.

All participants were agreed that the triangular insert idea was a worthwhile development. The participants explained that they were not aware of the ability to produce something as accurate before and that it was novel and logical. The positives being that it would not require any post finishing by reaming the holes to get back to the original diameter, water channels to cool and remove debris from the area and supporting it at the three points. They all agreed that the lengthening of the drill cylinder would be beneficial to the accuracy of the implant placement.

They felt like with the development and use of the new guides can ensure that the implants are in the correct pathway of bone. They deemed this important as these implants are load bearing through the nasal prosthesis or a combination T bar of the

nasal prosthesis and denture plate, it reassures them that if the implants are in the correct planned position that the bone can take the weight of the load.

It was stated that many of the procedures they do are historic and they have progressed them over the years in an '*ad hoc*' way but now at this stage that quantitative results are being conducted, they can see ways that it can improve and change quite dramatically for the benefit of the clinical team and patient.

In the cleanliness and surface roughness review, all were interested that the polished metal materials whether AM or conventional had a higher RLU reading than the non-polished samples.

One participant stated that with regards to orbital floor implants the top surface should be polished and the bottom surface non-polished as the polished top surface allows the movement of the orbital globe and surrounding soft tissues as expressed in Richards *et al.*'s 2007 paper. Another reason stated for polishing was that when in the operating theatre that the excess blood can be wiped away easier from a polished surface rather than a non-polished surface, however, the author feels that further studies need to be done in this area and regard the statement as an unfounded perception.

This cleanliness review has highlighted hidden statements and opinions on procedures that are not justified in the current research. The author presented a key summary presentation on all topics within this PhD at the IMPT congress in London in September 2015. Again the cleanliness chapter caused the audience to fully engage with many questions on this topic only, asking about tests on further AM material and traditional polishing methods so they could gauge where their procedures and materials fit in relation to the work completed in the chapter. Therefore the author thinks that the cleanliness chapter has opened up new research studies, outputs and publications in this area.

### **10.3 Methodology**

In order to fulfil and answer the research questions posed at the start of the thesis many areas were explored.

The research conducted was a balance of clinical observation and qualitative investigation from the engagement with and access to NHS surgeons and their clinical staff; alongside experimental studies and quantitative investigation from testing and statistical analysis of key technical aspects within the PhD topic.

The use of a mixed method approach, explained in chapter 4, was suited to the qualitative and quantitative results that needed to be collected. The PhD focussed on qualitative methods in chapters 5 and 9 using semi-structured interview techniques, observation notes, photography and review documents for each case study visited. For the quantitative methods used in chapters 6, 7 and 8, the use of facilities outside of the work base of PDR featured heavily.

The PhD study focused on the application of AM into maxillofacial surgical guides and the development of its use through qualitative and quantitative review. The results from the research will be used to inform further studies (section 11.3), in an array of different areas (medical, engineering & scientific).

The combination of clinical research, quantitative trials and measurements, provided strength to this PhD study and allowed a diverse approach to answering the initial research questions.

As identified in the literature review, many research studies have focused on either the technology or the clinical outcome by subjective assessment, with a lack of publications on clinical issues, patient feedback and improving performance on surgical guides. This mixed method research approach focused on bridging clinical knowledge and technical measurement in the topic of AM Maxillofacial Surgical Guides.



## **10.4 Research Methods: Limitations**

### **10.4.1 Testing Facilities**

As expressed in section 10.3 the use of facilities outside of the work base of PDR featured heavily during the testing part of the research. Renishaw Plc., in Charfield, Gloucestershire was visited for the use of the CMM and Talysurf equipment. The Charfield site was situated 1hr away from PDR therefore prior arrangements were required to see if the machines were, first of all, available for use and secondly, to book an allocated time on the equipment. This was key in the organisation and planning elements of the PhD.

The use of the 3M CleanTrace system from Cardiff Metropolitan University School of Health Science was convenient as the equipment was based at the university at all times. However, orders were made with 3M to acquire the CleanTrace swabs; these were kept refrigerated at all times at PDR.

The use of the testing facilities needed to be carefully planned throughout this PhD; the author had to take into account availability of machines, the working hours of facility staff, travel to and from PDR work base and working around other people.

### **10.4.2 Access to Appropriate Case Studies**

Due to the links through collaborative research group CARTIS and the NHS honorary contract, the author had access to a large variety of different patient cases both in the digital planning and surgical operation stages. However, the author had to be ready to adapt and adjust timings around new case studies when they were presented at the hospital. The work base was situated 1hr away from the hospital therefore as in section 10.4.1, as much planning as possible was key to ensure full qualitative research was captured for each case study.

When conducting observations or semi-structured interviews with surgeons and clinical staff the author had to adhere to strict timings that suited the NHS staff. Access and time with consultant surgeons is precious therefore the author feels that the contact gained has benefited the qualitative research.

#### 10.4.3 Measuring Accuracy

In chapter 6 various tools and software were used in measuring accuracy of both patients CT scan data and AM parts. In each of the measuring outcomes there was room for error to occur.

In the pre and post-operative comparison for the six nasal zygomatic implant patients there was several occasions where error could have occurred; pre-operative CT scan, importing of DICOM data into Mimics, post-operative CT scan, overlaying the pre and post-operative scans in Mimics and location of centre point of the entry and exit X,Y,Z co-ordinates of the planned and fixed implants.

For the AM parts that were measured for accuracy (test bars and developed guides), again there was several occasions where error could have occurred; exporting STL file from CAD software, AM building of the parts, removal of supports from the part and any post build finishing of the part.

Another aspect of measuring accuracy was the use of the CMM at Renishaw Plc. Each time the CMM was used for testing it was set up appropriately by a Renishaw professional to ensure reliability of measurements.

In this chapter a number of different sample sizes were used; n=6 patients used for pre and post-operative analyses each with two implants (left and right), n=8 AM test bars fabricated each with 7 different tolerance holes and n=6 developed surgical guides.

#### 10.4.4 Measuring Cleanliness

In chapter 7 eleven AM materials were tested for cleanliness. Three of the eleven were fabricated at work base PDR and the remaining eight materials samples were outsourced to other suppliers.

Each of the suppliers and materials recorded the build orientation and the AM machine the samples were fabricated on so that the measuring of the cleanliness testing could take place and be analysed correctly. However, relying on outsource suppliers to fabricate and send the samples back took longer than anticipated. This affected the timings of the PhD testing and the author had to work around delivery of the sample parts.

Another aspect that needed to be checked thoroughly was the surroundings of the testing site. As the chapter research was measuring cleanliness a strict SOP was followed each time testing commenced and became a rigorous routine for each of the AM material samples.

In this chapter a number of different sample sizes were used; n=11 different AM materials were used as samples and n=12 of each AM material chosen.

#### 10.4.5 Measuring Surface Roughness

In chapter 8 there were six AM materials tested for surface roughness. Two of the six were fabricated at work base PDR and the remaining four materials samples were outsourced to other suppliers.

Each of the suppliers recorded the build orientation of the materials and the AM machine the samples were fabricated on so that the measuring of the surface roughness testing could take place and be analysed correctly. However, relying on outsource suppliers to fabricate and send the samples back took longer than anticipated. This affected the timings of the PhD testing and the author had to work around delivery of the sample parts.

Another aspect of measuring accuracy was the use of the Taylor Hobson Talysurf machine at Renishaw Plc. Each time the machine was used for testing it was set up appropriately by a Renishaw professional to ensure reliability of measurements.

In this chapter a number of different sample sizes were used; n=12 different implants, guides and plates used in the pilot study, n=6 AM material chosen to test for surface roughness and n=12 AM samples of each material.

#### 10.4.6 Unbiased

Throughout the PhD the author attempted wherever possible to remain unbiased toward clinical opinion and the results generated from the core chapters.

Schulz (1995) explained that some researchers may find it difficult to remain unbiased or hold a '*dispassionate stance*' if they know a better way of completing the task or have experience in the area, however, this would be detrimental to the study and would sway results into the researcher's bias view.

To avoid the above happening '*methodologic barriers*' (as shown in methodology chapter 4) were put in place to avert any distortion of results and prevent bias.

Schulz (1995) also stated that these '*methodologic barriers*' require '*assiduous and excruciating attention to design, implementation and reporting*'.

With chapter 4 explaining the '*methodologic barriers*' in place it highlights and concurs with Suresh (2011) thoughts that '*A good experiment or trial minimizes the variability of the evaluation and provides unbiased evaluation of the invention by avoiding confounding from other factors, which are known and unknown.*'

The researcher negated any bias towards agreeing with opinions and design/material choices, however, being immersed in the clinical environment where working relationships were forming it was difficult.

During qualitative data collection in chapter 5 the researcher observed each case study. The observations were carried out objectively which required note taking, photography and recording of data therefore involvement or researcher bias towards design/materials choices was negated. It was negated as each of the audio recordings was transcribed and combined with the note taking for cross referencing and analysis (Rowley, 2002). In chapter 6, 7 and 8 the majority of the research data collected was quantitative with the software/machine, each machine was calibrated appropriately before use, and therefore bias was not a problem. Maintaining this unbiased attitude was particularly difficult in the clinical feedback chapter 9 when the author was conducting the semi-structured interviews with the clinical staff; when they would ask a question about the research or the results the author had to make sure no biased answers or viewpoints were proposed nor discussed.

# Chapter 11: Conclusions & Future Work

The final chapter will highlight the conclusions, summary of response to research questions, recommendations for future work and the publication plan.

## 11.1 Conclusions

The PhD thesis has been able to provide contributions to knowledge in the fields of Maxillofacial Surgery, Patient-Specific Surgical Guides and AM Materials. The individual chapter conclusions are listed in this section.

### 11.1.1 Case Study Chapter

This chapter concluded that the surgical guide being patient-specific is not enough. The research demonstrates that the surgical guide needs to be:

- Patient-Specific
- Surgeon Specific
- Material Specific
- Area Specific

To explain in further detail; the surgical guide needs to be patient-specific so it is designed on the patients scan data so it fits the anatomy correctly in surgery. It should be surgeon specific so that the guide can be designed for the operating surgeon to suit their working style and experience level. It needs to be material specific depending on the anatomical area the procedure will take place on and, depending on the area chosen, what surface the material will be best suited to it (figure 97). Each of these will be case by case specific, but the author feels that all the above specifics need to be thought of in the design of the surgical guides and implant procedures. This finding is an original contribution to knowledge as it has not been reported in the literature to date. This contribution will help design engineers and surgeons to work better as a team with these specific topics as a starting point when designing new guides and implants.

### 11.1.2 Accuracy Chapter

Incremental changes were key to the success of this chapter. The changes occurred in tolerance, material and length of the surgical guides. The changes and developments were as a result of the six nasal zygomatic implant cases that were reviewed at the start of the chapter. The six cases did not demonstrate any consistency or standard guidelines for the design of the surgical guides.

Problems that were addressed in the chapter included the problematic metal inserts, AM build issues with circles, build orientation/accuracy, length of drill cylinder and tolerances of the drill area. The developmental use of triangles within the drill surgical guide has eliminated problems and issues due to the design; resolving the binding effect, easier to AM build, three water channels providing cooling and removal of debris and the drill held securely at more than one point.

The tolerances of 0.05mm and 0.1mm provided a total angle error result of  $1.10^\circ$  compared to the benchmark guide degree of difference angle of  $8.04^\circ$ ; this gave a decrease of  $6.94^\circ$ . Although there are many variables that can occur both in the design, fabrication and use of the surgical guide; with incremental differences introduced in future design it will help gain increased accuracy of implant placement. Operation 1 shown in the discussion chapter 10 was one clinical case example where the incremental changes were placed into the design of a surgical guide, producing a lower degree of difference and was therefore more accurate. The findings from this chapter if embedded into the design of future surgical guides and implant will help to gain better accuracy; which is of value to both surgeon and patient.

### 11.1.3 Cleanliness Chapter

The cleanliness chapter demonstrated that ATP bioluminescence is an appropriate and practical test method for measuring the surface cleanliness of AM materials intended for medical applications. The experimental technique is a user-friendly, quick method for quantifying cleanliness levels during the various stages of AM production, preparation and clinical delivery. The screening technique is ideal for the growing use of AM materials within the medical application area.

The ATP test method appears to have the sensitivity to evaluate different material surface characteristics, specifically the impact of surface finishing techniques on overall cleanliness.

In conclusion, this chapter has opened up numerous research publications that could be completed within this multidisciplinary area of AM materials, cleanliness and medical products.

#### 11.1.4 Surface Roughness Chapter

Chapter 8 showed that the build orientation naturally has an impact on the surface roughness of AM materials. The results are in line with expectations; however, they do not highlight any surface discrepancies that could account for the differences in RLU readings from Chapter 7. From the set of surface roughness results it is not possible to state a definitive conclusion from this chapter.

As stated in the conclusion of the cleanliness chapter (section 11.1.3), the author feels that this is only the start of many publications within this multidisciplinary area. Many further questions have been extracted from chapter 7 and 8 which will be highlighted in the recommendation for further work section 11.3.

#### 11.1.5 Clinical Feedback Chapter

In order to gather clinical feedback on the PhD research, the core result chapters were reported back to various surgeons and clinical staff. AM metal was the preferred choice of the surgeons but with the research findings it did alter their previous perceptions of surgical guides.

They deemed the triangle development as novel and logical and thought that the development of the guides ensured correct drill pathways for the implants which is important for both patient and clinical team. This finding is a contribution to knowledge which has not been reported to date and is of value to design engineer, surgeon and most importantly the patient.



Historically, they explained that the guide designs progressed on an *ad hoc* basis but explained that with quantitative data and results they could now change their procedures, guides and implants quite dramatically and for the better.

All participants in the chapter were interested to see that the electro-polished sample produced a higher RLU compared to the non-polished metal materials. In conclusion there are many more studies that can be derived from this PhD research.

## **11.2 Summary of Response to Research Questions**

### **What are the clinical issues associated with surgical guides?**

The clinical issues associated with surgical guides were analysed in more detail in chapter 5. The author observed and recorded twenty case studies that occurred with the use of surgical guides during the three years of the PhD scholarship. During the qualitative research of this chapter various issues, problems and perceptions were highlighted. As discussed in chapter 10 it became apparent that surgical guides should not only be patient-specific but also surgeon specific, material specific and area specific.

In the qualitative research it was highlighted that surgeons are particular about their working style and that this is dependent on their experience. They have perceptions on AM materials without research justification and are precious on each of their surgical process techniques.

It also highlighted that certain AM materials were best suited to different working areas of the facial anatomy. This was analysed further and figure 97 demonstrates where the materials should be used.

Issues highlighted in chapters 3, 5 and 6 were the problems associated with surgical guide inserts, drill cylinder lengths and tolerances. The studies which took place in chapter 6 tried to address some of the issues with experiments in tolerance, materials and design developments. The results from the study were then placed into a surgical guide design for patient case operation 1 in chapter 10 and achieved better accuracy with positive feedback from the surgeon and surgical team.

## **What evaluation metrics can be developed and employed to quantify the performance of innovative surgical guides?**

Four evaluation metrics were used in the PhD study in order to gather quantitative data on surgical guides. Two of the metrics were used in Chapter 6; firstly with the combined use of Mimics, X,Y,Z Co-ordinates and Dot Product equation to analyse the performance pre to post-operatively of implant position achieved by the use of nasal surgical guides. These recordings can be documented within the NHS so that the surgeons and clinical team can review and compare the accuracy performance of implant placement on a series of patient cases. The results could be used as a quality review of patient outcomes and could be shared with the patient during their outpatient clinic appointments.

Secondly, the CMM was used to test the AM builds of a part in relation to the original design intent. The employed use of CMM as a quality control for AM surgical guide prior to delivery could be completed. The CMM quality control for both guides and implants could ensure that: 1. The AM build bed is functioning and fabricating correctly in all bed positions and; 2. The built AM part is accurate to the uploaded STL file or design intent dimensions.

In chapter 7 the third evaluation metric used was the 3M® CleanTrace System. ATP demonstrated rapid measures of cleanliness which could be adopted and employed for testing surgical guides as a quality control for cleanliness prior to use to prevent infections from occurring. The CleanTrace system is simple to use and would not require costly training courses for NHS staff to include it in their daily routine.

In chapter 8 the final evaluation metric was used, which was the Taylor Hobson Talysurf. The machine generates surface roughness measurements or Ra values for different materials. Again this could be adopted as a form of quality control for AM surgical guides and implants to ensure that they are within the correct surface roughness range. If further studies could be completed on how to use the step formation as a positive characteristic for SLA polymers for bone bound surfaces of guides to act as a friction coefficient on the bone surface that could be a beneficial Ra measurement to influence the design of future surgical guides.

The addition of these four evaluation metrics to the process of both AM Surgical Guides and Implants would help ensure that the quality of accuracy, cleanliness and surface roughness is achieved for each part.

### **Can AM be used to solve clinical problems associated with surgical guides?**

There is a basis that AM can solve certain clinical problems with surgical guides. Everything that has been tested, analysed and discussed in this PhD study indicates that AM is an appropriate route for guides. This is harnessed on the accuracy associated with AM for the benefit of surgical guides. The AM materials tested also specified positive cleanliness and surface roughness characteristics.

The multidisciplinary contribution to knowledge gained in this PhD has helped to identify which areas to include incremental changes; if these changes are utilised correctly, it will demonstrate that AM can be used to solve clinical problems associated with surgical guides.

### 11.3 Recommendations for Future Work

Despite the overall success of the PhD research, there are several studies and new research avenues that would make further contributions to knowledge within this multidisciplinary field.

The accuracy chapter highlighted further clinical research that could be completed to show whether the post-operative implant position and any of the larger degrees of difference from pre to post operatively caused any problems to the patient and whether they required any revision surgery at a later date. A limitation of this future work would require the researcher to be embedded within the hospital with an honorary contract in order to access the patient files and perform the research thoroughly.

A research study that would add to the accuracy chapter would be to compare implant placement results of free hand drilling, current surgical guide drilling and developed surgical guide drilling. This study would analyse which is the best process to use and would need to be a large study with various participants at all stages of their surgical career to test experience levels. A limitation of this research would be the length of time it would take the researcher to gather the appropriate cases and scan data.

A qualitative research study would be useful to help understand the reasoning behind the '*ad hoc*' perceptions of polishing an implant or guide; questioning participants on whether is it for aesthetical purposes, functional purposes or for wiping blood away from the materials surface when used in the operating theatre.

Extracted from the cleanliness chapter, research would be required into ATP testing of further AM materials and traditional or conventional methods to compare where they are in relation to the other materials tested in chapter 7. An online database of all the ATP results would help summarise the materials more suited to each use.

The cleanliness chapter establishes further research in order to identify the cause of why the Objet materials had higher RLU readings then the other AM polymers. A

focus could be given to the microscopic surface characteristics of the material and the reaction of the ATP swab on the surface.

Also from the same chapter, research to demonstrate how a series of fixed point ATP time readings could correlate to the likelihood that a surface is susceptible to microbial contamination over a longer period of time. The studies within this area could look at how different AM materials react to the operating room environment with the starting state as just removed from its sterilised packaging. Each swab would be taken at different time intervals in order to see whether a rise in RLU reading happened to the material the longer it was exposed to the operating room environment.

Another study from the cleanliness chapter would be research to explain whether the ATP swab can extract all the debris on a rough surface and to question whether the swab can reach into the materials crevices or step formation. This study would also explain whether the ATP swab picks up as much debris on a rough surface as it does on a smoother material surface. A limitation to this research would be seeking expertise from other university departments and would require a joint funded project in order to get the specific data.

A combined research study of the cleanliness and surface roughness chapters is to demonstrate whether there is an association between RLU and Ra readings. This could question whether there is a common factor occurring, what the polishing of a metal material does to the surface, how it affects its cleanliness, what the non-polishing of a metal material does to the surface and how it affects its cleanliness

The surface roughness chapter extracted further research into what friction coefficient and surface roughness is required for AM material SLA polymer. A study within this area could look at how the step formation in SLA polymer guides be used and act as a positive material characteristic for the friction coefficient on the bone.

## 11.4 Publication Plan

The following article has been published:

- O'Malley, F L., Millward, H., Eggbeer, D., Williams, R., Cooper, R. (2015). *The use of Adenosine Triphosphate bioluminescence for assessing the cleanliness of additive-manufacturing materials used in medical applications.* Additive Manufacturing Journal.  
(Accepted 14/12/2015 – Copy of manuscript in appendices).

Plans for a further two submissions to be written:

- Author list; O'Malley, F L., Hodder, S., Eggbeer, D., Millward, H., Evans, P. The paper will be based on the research completed in chapter six with the title of '*A retrospective review of nasal surgical guides cases, the developments of the surgical guides and the developed guides clinical results*'. The journal of choice for submission once written is the International or British Journal of Oral and Maxillofacial Surgery.
- Author list; O'Malley, F L., Eggbeer, D., Millward, H. The paper will be based on the findings throughout the PhD chapters with the title of '*The specifics of additive manufactured maxillofacial surgical guides – patient, surgeon, material and area specific.*' The journal of choice for submission once written is the Additive Manufacturing Journal.

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# Appendices

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**Appendix I:** Manuscript of journal publication (accepted in Additive Manufacturing Journal 14/12/2015)

**Title:**

**The use of Adenosine Triphosphate bioluminescence for assessing the cleanliness of additive-manufacturing materials used in medical applications.**

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## Abstract

Additive Manufacturing (AM) is widely gaining popularity as an alternative manufacturing technique for complex and customized parts. AM materials are used for various medical applications in both metal and polymer options. Adenosine Triphosphate (ATP) bioluminescence technology is a rapid, user-friendly method of quantifying surface cleanliness and was used in this study to gather quantitative data on levels of contamination on AM materials at three different stage processes: post build, post cleaning and post sterilization. The surface cleanliness of eleven AM materials, three metals and eight polymers, was tested. ATP bioluminescence provided the sensitivity to evaluate different material surface characteristics, and specifically the impact of surface finishing techniques on overall cleanliness.

## Keywords

- Additive Manufacturing;
- Medical Applications;
- Adenosine Triphosphate Bioluminescence;
- Surface Cleanliness;
- Metals vs. Polymers

## 1. Introduction

There is a clear synergy between the benefits of additive manufacturing (AM) technology and the requirements of patient-specific medical devices. AM parts are best suited to high-value applications that require rapid fabrication of complex geometry. Some of the most challenging medical applications demand bespoke anatomical features to be accurately replicated and delivered in a compressed timescale to meet the needs of trauma surgery. As the field of AM continues to expand then the list of AM-based medical devices is equally likely to grow.

A classification of medical applications of AM by Tuomi *et al.* [1] divides these applications into five areas: (1) medical models; (2) external aids; (3) surgical guides; (4) surgical implants and (5) biomanufacturing. The range of applications covers the relatively simple task of providing insight to the surgeon/patient (medical models) through to biologically-active tissue implants (biomanufacturing). The area of surgical guides covers patient-specific custom-designed drilling, cutting and repositioning devices, and this area provides an ideal fit with AM technology. Typical guides used in maxillofacial and orthopaedic applications are

hand-held (small build volumes), incorporate patient-specific features that engage appropriate internal anatomical structures and can be easily cleaned and sterilised [2, 3].

Surgical guides have been fabricated by AM in a range of polymers and metals [2, 3]. Recent research within the field of maxillofacial surgery [4] has evaluated the use of AM surgical guides by a range of surgeons. The results show that surgical teams are keen to engage with AM technology but they have a number of pre-conceived perceptions as to the types of materials that are appropriate. It may be that material choice (specifically metal versus polymer) is strongly influenced by experience of previous conventional manufacturing processes, and there is little quantitative data to guide the clinical team for new AM applications. Three areas have emerged that need more empirical evidence to guide surgical decisions in the use of AM materials for surgical guides: geometrical accuracy, surface roughness and cleanliness/sterility. Patient safety is the primary consideration when implementing any new medical intervention, therefore quantifying the cleanliness/sterility of AM materials is the main focus of this research paper.

AM technology and material vendors are continuing to develop a wide range of materials that have the potential for medical applications. For invasive surgical devices and implants, there are a series of ISO 10993 standards for the biological evaluation of medical devices that are in permanent (or prolonged) contact with the patient. In these cases criteria on biocompatibility and toxicity take precedent over other material issues. For medical devices that are single-use, disposable items that have limited contact with biological tissue (as in the case of surgical guides) there is a wider choice of potential materials. A typical surgical guide will arrive at the operating theatre within a sterile package, and labelled for a specific patient. The whole medical intervention could last hours but the AM material may only be in contact with the patient for a matter of minutes. In this scenario there are no clear guidelines or specifications to help define cleanliness and sterility.

The whole AM process, in terms of build orientation, cellular elements, removal of support structures and post-processing, provides a number of opportunities to introduce potential contamination into a medical device that could provide a hazard for the end user. Many AM manufacturing processes have fully-prescribed methods for post processing, but there are significant opportunities to detrimentally impact part cleanliness, especially when dealing with complex anatomical-based structures that include small voids that are difficult to fully access with fluids and cleaning implements. Techniques that enable contamination levels to be quantified during the various clinical delivery stages (post-build, post-cleaning and post-sterilisation) of AM medical parts is therefore highly desirable.

Adenosine triphosphate (ATP) bioluminescence technology is a rapid, user-friendly method of quantifying surface cleanliness that has been employed to evaluate contamination of a wide range of instruments and surfaces. Recent studies have used ATP to assess invasive medical devices [5], hospital surfaces [6] and environmental hygiene monitoring [7]. The bioluminescence test utilises the light-producing reaction between ATP, luciferin and luciferase to measure the amount of ATP present on a surface. ATP is the basic source of energy for all animal and microbial cells; its presence on a surface provides an estimate of all viable and non-viable organic residues, including microbiological contamination. The use of ATP bioluminescence tests is growing within healthcare, pharmaceuticals and food science industries. The ATP technology has two key advantages over traditional microbiological testing. Firstly, the technique provides results within minutes (as opposed to days) and effectively gives a real-time evaluation of surface cleanliness. Secondly, the test apparatus is highly portable and does not need specialist training or dedicated controlled facilities. ATP testing is therefore a very practical technique that can be adopted by non-



specialists. The source of ATP can be anything that the sample comes into contact with, for example the way it is handled or where the sample was stored. The ATP method cannot identify the exact source of the contamination.

In the context of medical applications, a measure of residual organic matter is an indicator of surface cleanliness, but also quantifies the potential for surface reservoirs to harbour bacteria, fungi and viruses. Therefore ATP bioluminescence may be employed to give a dual estimate of: (1) the cleanliness of a surface at a fixed point in time; (2) the likelihood that a surface is susceptible to microbiological contamination over a longer period of time.

To date, the use of ATP bioluminescence to measure the cleanliness of AM materials intended for medical use has not been reported. The aim of this paper is to demonstrate that ATP bioluminescence testing is an appropriate technique for quantifying the cleanliness of a range of polymeric and metallic AM samples. It is hoped that the results can be used to highlight which AM materials (and associated surface modifications) have the greatest potential to be used in single-use, disposable medical applications, specifically materials that maintain levels of surface cleanliness that are appropriate for patient-specific surgical guides.

## **2. Materials and Methods**

The aim of this study was to evaluate the ATP bioluminescence test in terms of its application to a range of representative AM materials to quantify their surface cleanliness. In this context, material properties are of more concern than geometrical features. The test sample geometry was therefore kept relatively simple, and is shown in Figure 1. The two 25x25mm square areas were the surfaces of interest for cleanliness/sterility testing, and the majority of samples were fabricated with the (x, y) plane as the up-facing surface. The surface area of the samples needed to be a minimum of 10x10mm to order gain a good enough reading,

Eleven AM materials were chosen to provide a representative sample of polymers and metals that have been employed in a range of medical applications. Details of the AM materials used in this research study are provided in Table 1. Each material category had 12 test samples manufactured. The three metals were all manufactured using Laser Melting (LM) technology, with one of the cobalt chrome set of samples having additional electro-polishing finishing. The eight polymer categories can be divided into: three Stereolithography (SLA, 3D-Systems, USA) resins; three polyjet (Objet, Statasys Ltd., Israel) materials; and two Selective Laser Sintering (SLS, EOS GmbH, Germany) materials.

The ATP bioluminescence test employed in this study was the 3M Clean-Trace system ([www.3M.com/infectionprevention](http://www.3M.com/infectionprevention)). The procedure starts by taking the test swab and applying it to the surfaces to be evaluated. The swab is gently rotated as it is swept across the test area. The swab is then immediately placed in a cylindrical vial, which brings it into contact with the enzyme solution (luciferin-luciferase) and the enzyme reacts with any ATP residue on the swab. The cylindrical vial is then placed in a hand-held 3M luminometer, and the light generated from the bioluminescence reaction is captured, and the measurement is expressed in Relative Light Units (RLUs). The greater the level of ATP present on the swab, the higher the RLU reading produced. The test can be performed in less than 30s, providing a real-time indication of the cleanliness of the surface tested. The swab and enzyme solution are disposed of after each test reading.

The 3M instrument manufacturers recommend a pass/fail threshold of 250 RLUs to indicate part cleanliness [8]. In addition, a literature review by Amodio and Dino [6], covering the



period 1990-2012, has shown that the <250 RLU's threshold is the most widely used benchmark for indicating clinical surface cleanliness. In addition a recent Danish standard DS 2451 – 10 has been monitoring hospital cleanliness with standardised ATP measurements using a hygiene 5 level, the cleanest of the levels, which is set at 250 RLU's [9].

Here a pilot study was undertaken to test three stages of production, cleaning and sterilization to evaluate which procedures gave AM parts with ATP readings in the region of the pass/fail threshold (250 RLU's). An overview of each stage is given below:

- Stage 1: Post Build. The AM parts were removed from the build platforms, support structures were removed, and the parts finished for standard delivery to a medical customer. In this scenario the parts were packaged and sealed for delivery, but all post-production handling was in a non-clean/non-sterile environment.
- Stage 2: Post Cleaning. The sealed post-production AM parts were taken through a series of cleaning steps; the standard operating procedure for this is given in figure 2. The key element was soaking each test sample in 250ml of Isopropanol for 60 minutes. This was achieved by placing four or five test samples in a one-litre beaker, and rotating the sample after 30 minutes to ensure an even contact time on both the main 25x25mm surfaces. After 60 minutes, the samples were removed individually, dried and packaged.
- Stage 3: Post Sterilization. Post-production parts were dispatched directly to a clinical partner (Morrison Hospital, UK), and individual samples were placed in labelled autoclave bags and sterilised on the standard 134°C autoclave cycle specified by BS EN ISO 17665-1:2006 standard on the sterilisation of health care products: moist heat. This sterilisation process was chosen as it is standard across all UK NHS hospitals in Hospital Sterilisation and Decontamination Unit (HSDU) departments.

The three different stages produced a wide range of RLU readings; the data for each set of samples was compiled into a series of spread-sheets for analysis. Each set of sample readings were characterised in terms of mean and standard deviation values. Statistical analysis of the data employed the t-test for hypothesis testing, and highlighting differences between discrete sample sets (assuming pseudo-normal distributions).

In addition to the ATP testing, the surface properties of the AM materials were further analysed using the Talysurf surface roughness apparatus (Renishaw Plc, UK) in order to measure the arithmetic average roughness (Ra) of selected surfaces.

### **3. Results**

#### **3.1 Pilot Study Results**

The preliminary investigation into the feasibility of using ATP measurements to evaluate the cleanliness of AM materials took a small sample size of representative polymers and metals through the three stages of cleaning/sterilization. Two samples of SLA Clear (Accura ClearVue, 3D-systems) SLA Grey (Accura Xtreme, 3D-Systems), LM Cobalt Chrome (F75) and LM Titanium (6/4 alloy) were tested post-build, post-cleaning and post-sterilisation. The n=2x4 RLU readings at the three stages were pooled to give overall mean values, and the results are shown in Figure 3. There was an order of magnitude difference in RLU values

between the three stages; post-build readings were order thousands, post-cleaning were order hundreds and post-sterilisation were order tens. There were no outliers from the small samples size, and the polymers and metals gave a similar range of values at each cleaning stage.

The pilot study results show that the cleaning protocol established for stage 2 gave ATP readings in the region of the threshold value of 250 RLU. The post-build samples were well in excess of the threshold value (mean $\pm$ SD=2651 $\pm$ 606 RLU). The autoclave sterilization gave results well below the threshold value (25 $\pm$ 12 RLU), as would be expected. The data from the post-cleaning samples (424 $\pm$ 165 RLU) are of most interest because they span the threshold region. The pilot data indicates that it may be possible to process and clean AM materials for clinical use in the absence of sterilization. The full set of AM samples from Table 1 were taken through the cleaning protocol (stage 2), and this data set gives the core sets of results for this research study.

### **3.2 Cleanliness Threshold Value**

The aim of the initial analysis of the ATP results was to evaluate whether each AM material could be labelled as 'clean' relative to the 250 RLU threshold value following a relative simple cleaning process. The full data set from the eleven materials gave a wide range of RLU readings (from thousands to tens), and the results have been divided into three groupings to aid analysis: (a) Objet materials; (b) remaining polymers; and (c) metallic materials.

The three Objet materials are shown in Figure 4. The highest readings were for the Objet Tango Plus (6325 $\pm$ 1429 RLU) – this data is comparable to the post-build values obtained during the pilot study. The lowest readings were for the Objet Vero Blue (861 $\pm$ 606 RLU), whilst the Objet Vero White gave an intermediary range (1805 $\pm$ 278 RLU). Given the low sample size (n=12), a t-test statistic was employed to compare the data relative to the threshold value. Based on a one-tailed test at the 99% significance level, all three Objet material samples gave mean values significantly higher than 250 RLU.

The remaining five polymeric material results are shown in Figure 5. In contrast to the Objet readings, all five samples gave a mean value significantly lower than the 250 RLU threshold value (t-test 99% level:  $p < 0.01$ ). This indicates that the Projet, SLA and SLS materials used in this study can be cleaned for clinical use. Across this grouping there are a range of readings. The highest values are given by SLA Clear at 181 $\pm$ 59 RLU, whilst the lowest readings were given by the glass-filled SLS Nylon at 41 $\pm$ 8 RLU.

The final grouping of three metallic materials is given in Figure 6. In this set of readings, the main difference is between the Cobalt Chrome and the Titanium. The two cobalt chrome samples give mean values significantly below 250 RLU (t-test 99% level:  $p < 0.01$ ), whilst the titanium sample is not significantly different ( $p > 0.05$ ).

In summary, across the eleven AM materials tested there are two key findings from the post-cleaning analysis: (a) the three Objet materials are significantly above the 250 RLU threshold; and (b) the Projet, SLA, SLS and Cobalt Chrome materials are significantly below the 250 RLU threshold.

### **3.3 Inter-Sample Comparisons**

For inter-sample analysis, the maximum number of pair-wise comparisons was 55. This was used as the Bonferroni correction factor for further t-test statistical analysis across the sample sets. It was assumed that a conservative correction factor would militate against inflated false positives for multiple comparisons ( $p < 0.01/55$  now required for 99% significance level).

Within the Objet grouping, the Vero Blue samples gave a mean RLU value significantly lower than both the Tango Plus and Vero White samples ( $p < 0.0005$ ). It is worth noting that the Objet Vero Blue samples were sourced direct from a UK NHS hospital (Southern General, Glasgow), and it is their material of choice for anatomical medical models – these models are not used for direct patient contact. For the polymers shown in Figure 5, the notable pair-wise comparisons are between the two SLA materials and the two SLS materials. There is a significant difference between the SLA Clear and the SLA Grey ( $p < 0.0005$ ). In this context, the Accura ClearVue resin tends to be employed in medical applications then the Accura Xtreme Grey resin since it has undergone prerequisite testing to USP Class 23/6. There is also a significant difference between the non-glass-filled SLS Nylon and the glass-filled SLS Nylon ( $p < 0.0005$ ). These samples were sourced from different suppliers so more data is required in order to draw a firm conclusion as to the reason for this difference.

The interesting result from the metallic materials in Figure 6 is the fact that the electro-polished Cobalt Chrome samples gave a mean RLU value that was significantly higher than the non-electro-polished Cobalt Chrome samples ( $p < 0.0005$ ). Electro polishing is employed (particularly in the dental industry) to inhibit contaminants adhering to the surface. However, the ATP results indicate that the non-electro polished surface is 'cleaner'. The greatest variability was exhibited by the Titanium samples ( $207 \pm 108$  RLUs), and the mean value for the Titanium was not significantly different to the two Cobalt Chrome samples.

## **4. Discussion**

The results have shown that the ATP methodology is a practical technique for providing real-time measurements of surface cleanliness across a range of AM materials. The use of AM materials for medical applications with direct patient contact is growing, therefore tests to verify cleanliness and sterility at various stages of the AM process are of significant importance. This study is the first to report the application of the ATP technique to a range of AM sample materials. The work has been undertaken within the context of an AM/RP research centre, specialist biomedical/clinical facilities were not required. The results show that it is feasible to use ATP as a screening technique to highlight AM materials that may be more suited to medical devices and the clinical environment.

The data from the initial pilot study has shown that ATP testing can identify and highlight the differences between three nominal delivery stages: post-build, post-cleaning and post-sterilisation. Across the various materials, there was an order of magnitude change in RLU measurements associated with each of these stages. There is the potential to establish benchmark RLU values for each key phase of AM in order to provide the process validation required for any medical product.

The key  $<250$  RLU threshold reported in this paper is the nominal cut-off for surface cleanliness. A relatively simple cleaning protocol was used to generate ATP readings in the region of this threshold value. The main finding was that the Objet materials could not be cleaned or disinfected – all three Objet AM materials were significantly above the threshold

value. In contrast, the majority of the remaining polymers and metallic AM materials were significantly below the 250 RLU threshold value (post cleaning). It would appear that the Objet polyjet process adheres more surface contaminants when compared to the other AM processes. More research is required in order to identify the cause of Objet's higher RLU readings.

For the AM materials below the 250 RLU threshold an interesting feature was the influence of surface finishing. Metallic medical parts are electro-polished for aesthetic and functional purposes; however, the results from this study question whether this is beneficial. The electro-polished Cobalt Chrome samples had significantly higher RLU readings compared to the non-electro-polished samples. Contaminants from the finishing process may have been impregnated into the electro-polished surface.

The surface characteristics of a selection of the AM materials were further investigated through surface roughness measurements. Build orientation naturally has an impact on surface roughness, therefore only the top build surface measurements are given as representative values. The electro-polished Cobalt Chrome gave  $R_a=0.10\mu\text{m}$ , in comparison to  $R_a=2.82\mu\text{m}$  for the non-electro-polished samples. This latter reading was comparable to the SLA Clear ( $R_a=2.32\mu\text{m}$ ) and SLA Grey ( $R_a=2.31\mu\text{m}$ ) measurements. The Objet materials gave values of  $R_a=0.19\mu\text{m}$  for Vero White and  $R_a=0.47\mu\text{m}$  for Vero Blue. These surface roughness readings are in line with expectations, but they do not highlight surface discrepancies that could account for differences in RLU readings.

This research has used a single ATP reading (post cleaning) in order to evaluate the suitability of various AM materials for medical applications. More research is required in order to show how a fixed time-point ATP reading correlates to the likelihood that a surface is susceptible to microbial contamination over a longer period of time.

## **5. Conclusions**

ATP bioluminescence is an appropriate test method for measuring the surface cleanliness of AM materials intended for medical applications. The experimental technique is a user-friendly, quick method for quantifying cleanliness levels during the various stages of AM production, preparation and clinical delivery.

The three Objet materials produced consistent elevated RLU readings (post cleaning), and this indicates that they may not be appropriate for patient-contact medical devices. Following the cleaning protocol, a number of the polymeric and metallic samples were significantly below the 250 RLU threshold value, and this shows that a number of standard AM materials have the potential for a wide range of medical applications.

The ATP test method appears to have the sensitivity to evaluate different material surface characteristics, specifically the impact of surface finishing techniques on overall cleanliness.

## Figures and Table

Figure 1

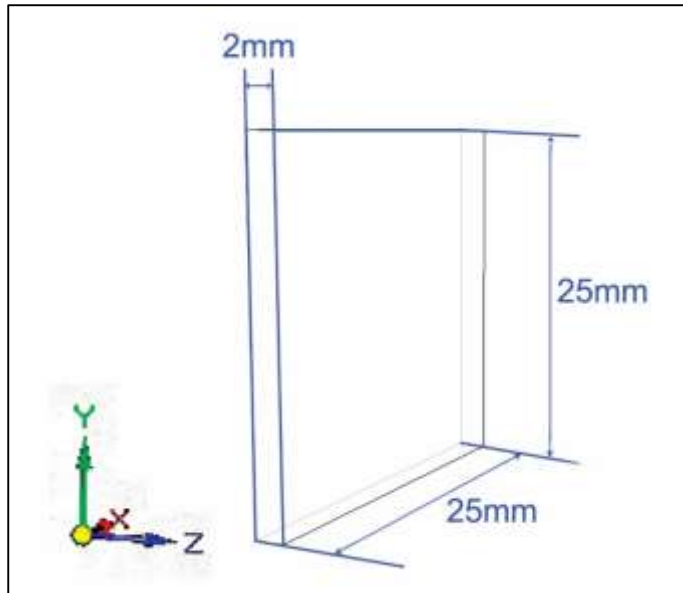


Figure 1 – Dimensions of the material samples – 25mm x 25mm x 2mm

Figure 2

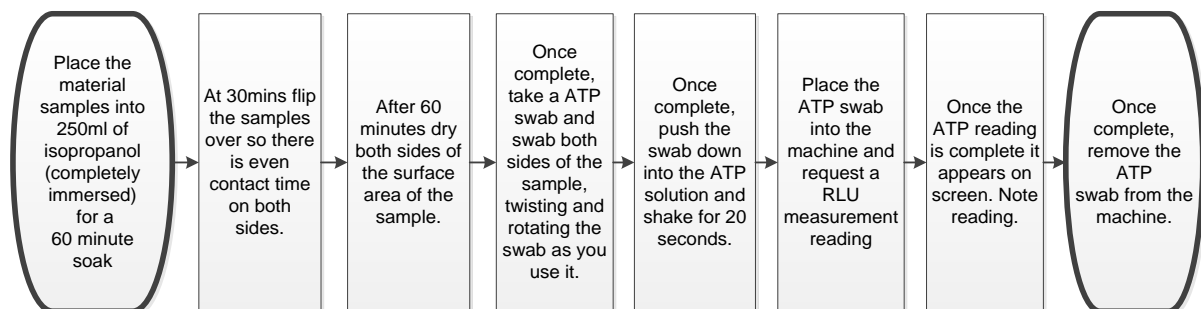
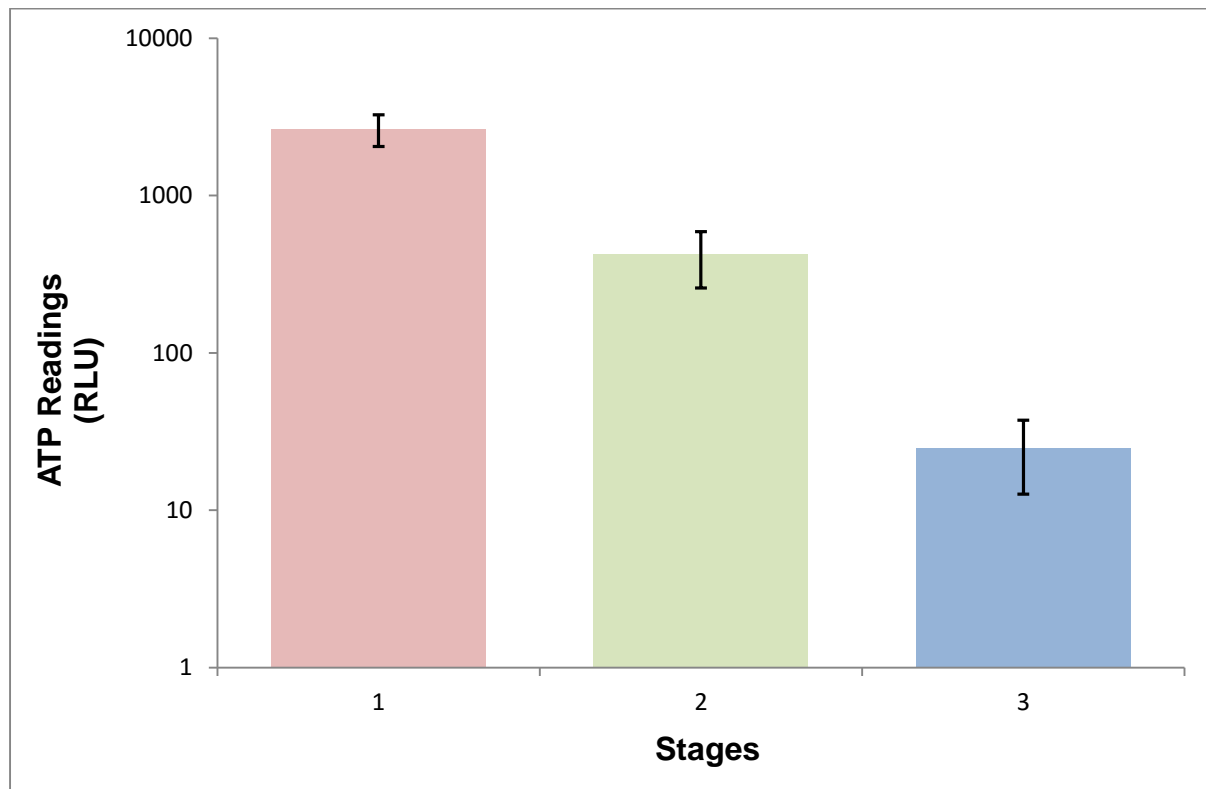


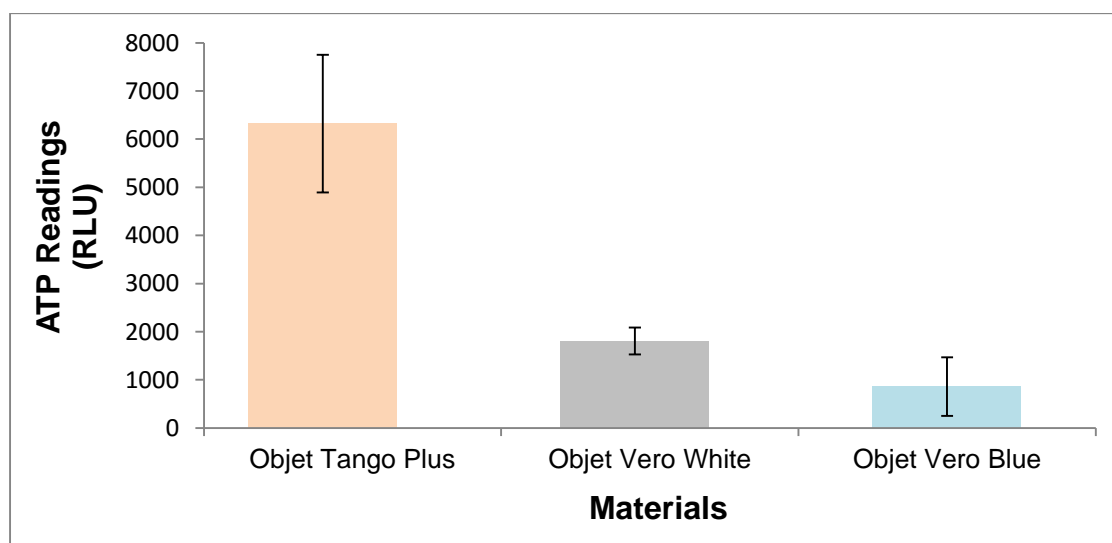
Figure 2 – Standard Operating Procedure (SOP) for cleaning of medical AM parts – Step by step guide to the cycle of what each material sample went through before the ATP swab took a reading from the materials surface.

**Figure 3**



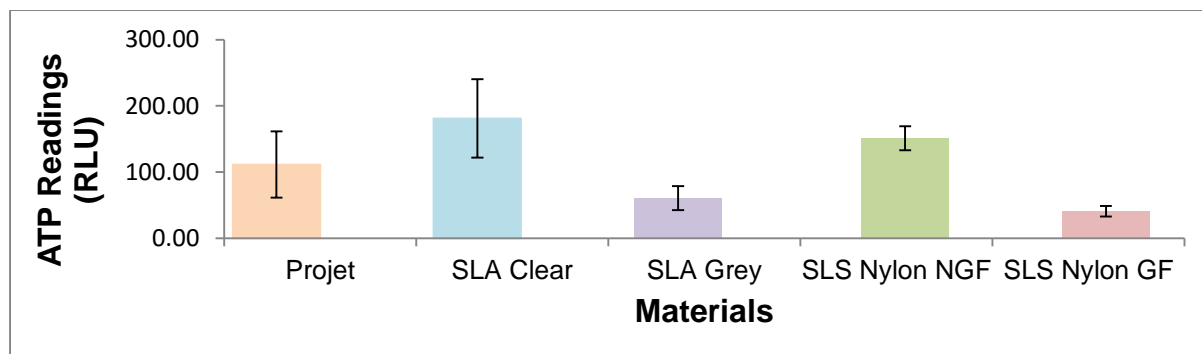
**Figure 3** – Pilot study results. Log graph of the ATP results of the three stages tested. Stage 1: Post Build, Stage 2: Post Cleaning and Stage 3: Post Sterilisation.

**Figure 4**



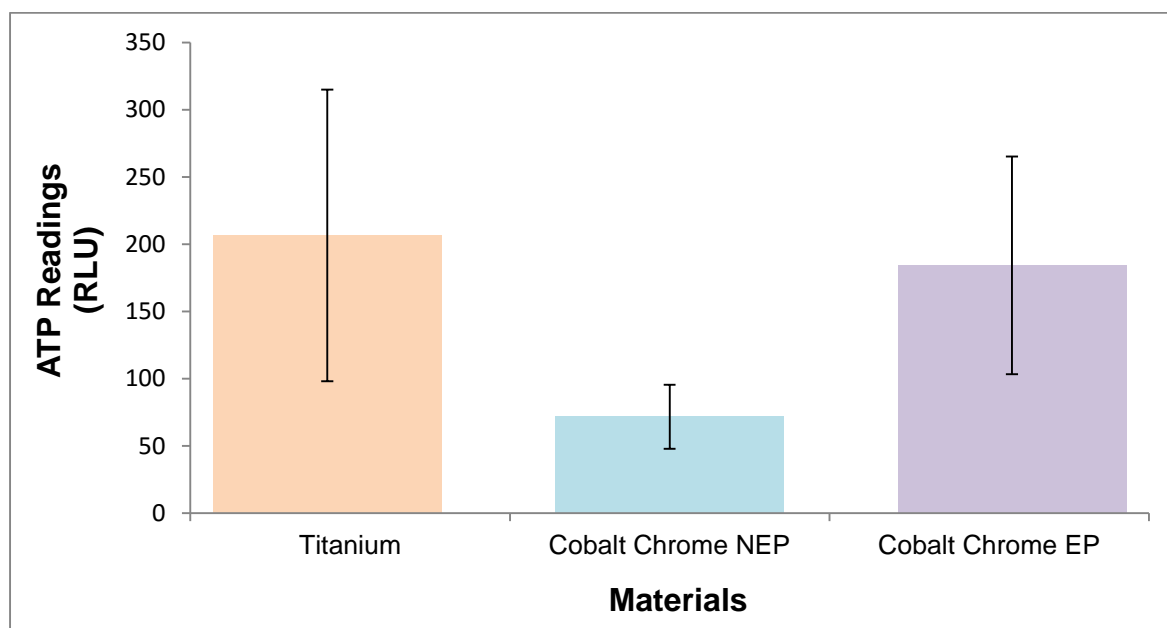
**Figure 4** – Objet material results. ATP testing at Stage 2: Post Cleaning for the three Objet samples.

**Figure 5**



**Figure 5** – Remaining AM polymer material results. ATP testing at Stage 2: Post Cleaning.

**Figure 6**



**Figure 6** – AM metal material results. ATP testing at Stage 2: Post Cleaning.



**Table 1**

<b>I.D Code</b>	<b>Material</b>	<b>Metal or Polymer</b>	<b>Build Layer Thickness</b>	<b>Build Orientation</b>	<b>Comments</b>	<b>Machine Manufacture</b>
SLA CV	Accura Clearvue	Polymer	0.15mm	(x,y) up-facing	SLA 250 machine Can be Sterilised	3D Systems
SLA G	Accura Xtreme	Polymer	0.15mm	(x,y) up-facing	SLA 250 machine Cannot be Sterilised	3D Systems
Projet	Acrylate	Polymer	0.032mm	(x,y) up-facing	Projet EX200 machine Cannot be Sterilised	3D Systems
SLS N GF	Glass Filled Nylon	Polymer	0.15mm	(x,z) up-facing	SLS machine Cannot be Sterilised	EOS
SLS N NGF	Nylon	Polymer	0.15mm	(x,z) up-facing	SLS machine Cannot be Sterilised	EOS
Objet VW	Vero White	Polymer	0.016mm	(x,z) up-facing	Objet machine Cannot be Sterilised	Stratasys Objet
Objet TP	Tango Plus	Polymer	0.016mm	(x,z) up-facing	Objet machine Cannot be Sterilised	Stratasys Objet
Objet VB	Vero Blue	Polymer	0.016mm	(x,y) up-facing	Objet machine Cannot be Sterilised	Stratasys Objet
LM CC EP	Cobalt Chrome F75 Electro polished	Metal	0.06mm	(x,z) up-facing	AM250 machine Can be Sterilised	Renishaw Plc.
LM CC NEP	Cobalt Chrome F75	Metal	0.06mm	(x,z) up-facing	AM250 machine Can be Sterilised	Renishaw Plc.
LM T NEP	Titanium Alloy Ti64	Metal	0.06mm	(x,y) up-facing	AM250 machine Can be Sterilised	Renishaw Plc.

**Table 1** – Information table on the material samples including type of material, metal or polymer, build layer thickness, build orientation, comments and machine manufacture.

## References

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- [4] F. O'Malley, Research to inform the improved accuracy of zygomatic implants placed using computer design and additive manufactured surgical guides. Presentation at ADT 5<sup>th</sup> Triennial Congress, 6<sup>th</sup>-8<sup>th</sup> September, 2014, Beijing, China.
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- [9] D. Andersen, Monitoring Hospital Cleanliness with Standardised ATP Measurements, Presentation at Healthcare Infection Society (HIS) Conference, 17<sup>th</sup> November, 2014, Lyon, France.

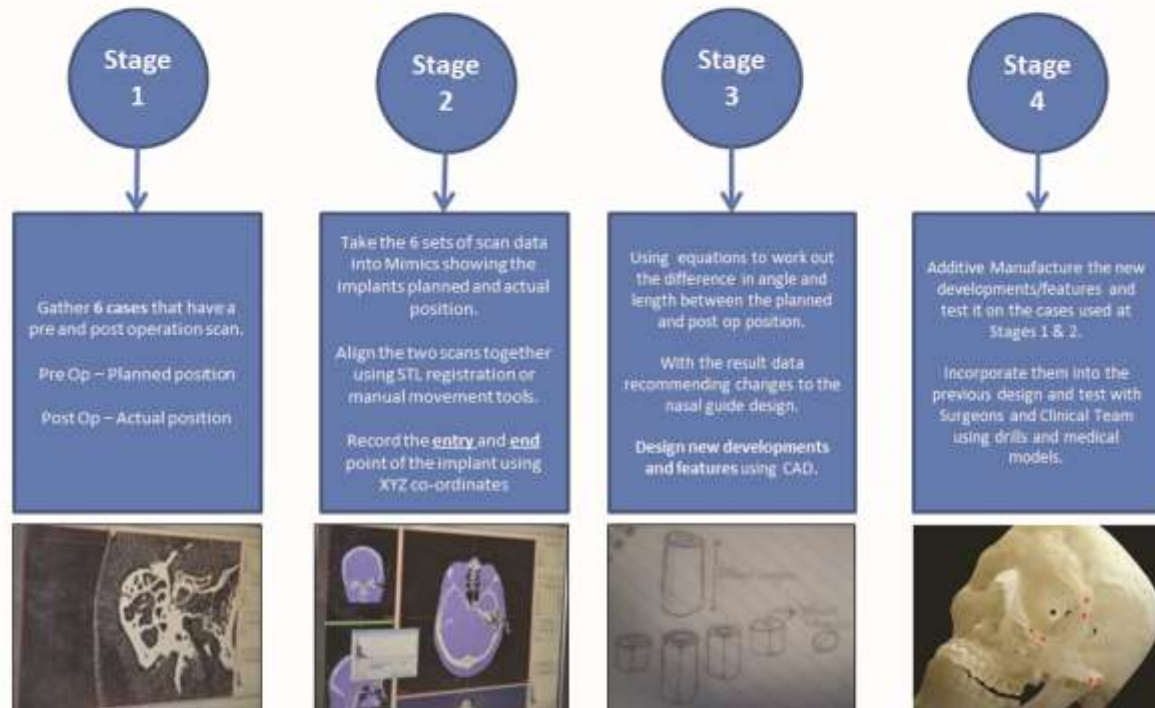
## Appendix II: Clinical Review PDF's

### Accuracy PDF



## Surgical Guided Nasal Implant Accuracy and Nasal Surgical Guide Development

This research is on the accuracy of zygomatic implant placement in the nasal region. Stage 1 & 2 was a combined research study between PDR and ABMU health board on the use of nasal drilling surgical guides. The results and analysis of the 6 patient cases presented along with the PhD qualitative data gathered from clinical research highlighted issues and questions that needed to be addressed in the design of the guides currently used.



The study has 4 main stages:

**Stage 1** – to gather the 6 patient case CT Data for both pre-operative (the implants in their planned position) and post-operative (the implants in their fixed position)

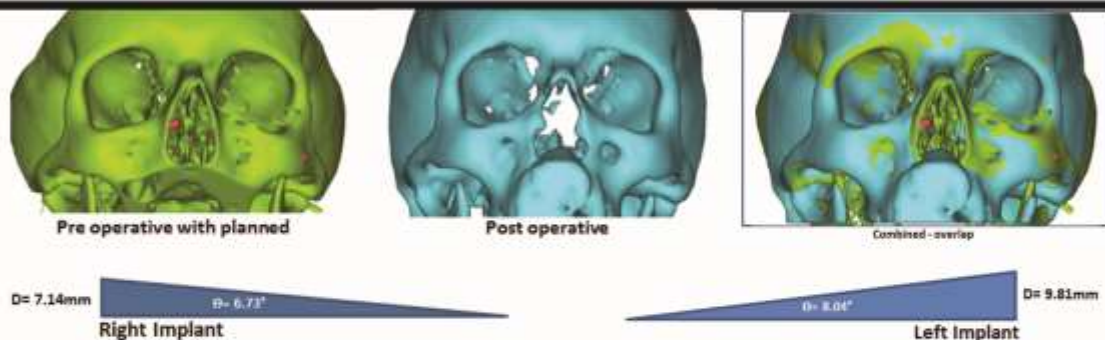
**Stage 2** – Bringing the sets of data in Mimics and aligning the scans together. Once overlapping to record the centre point of the implant at it's entry position and the centre point at it's end position using X, Y, Z co-ordinates.

**Stage 3** – With the gathered data the X, Y, Z co-ordinates are then converted to generate a degree of angle to show the differences between the planned and fixed position. These results were then taken into account and new design developments/features were explored and CAD'ed up to proceed with further testing to help gain better accuracy.

**Stage 4** – The CAD'ed parts were additive manufactured and the designs were a combination of gained clinical knowledge and the results data from this study. Once all the testing of this section was completed the new developmental features were then placed into one of the cases used in this study for further analysis.

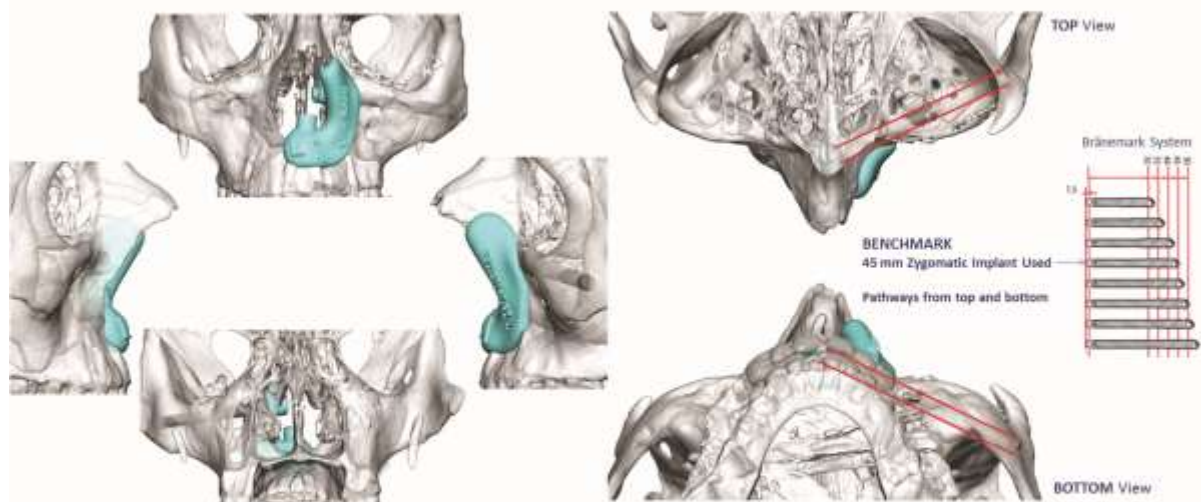


## Surgical Guided Nasal Implant Accuracy and Nasal Surgical Guide Development



Shown above is a patient example from the nasal implant study, The degree and length of difference was calculated using the X, Y, Z co-ordinates of the entry and end point of both left and right nasal surgical guide. In basic terms, the narrower the triangle the better the result with regards to accuracy. The larger the triangle indicates the larger the difference in both angle and length between planned and fixed position.

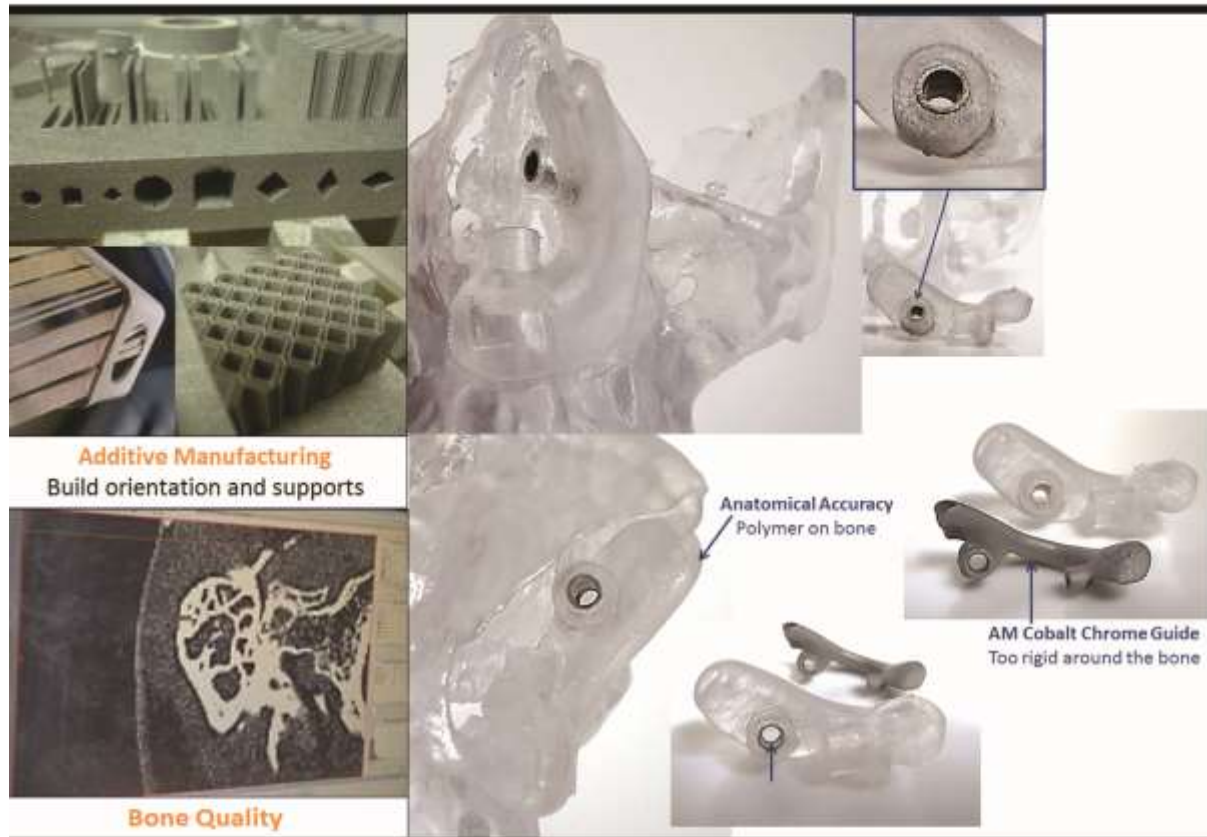
The average reading of the 6 patient results was taken and the above left implant was chosen as the benchmark guide. As well as being the average reading this patient was chosen due to PhD observations allowed me to witness the process of planning, design and surgery pathway. The above patient was taken forward as a Benchmark value to beat with regards to gaining better accuracy in the use of AM surgical guides with the degree of difference to beat is 8.04 degrees.



The benchmark nasal surgical guide was designed as a drill guide to the planned pathway position of the nasal implant that was placed digitally by Surgeon and Clinical Team.

The nasal implant used on the left side of this patient was a 45mm length Branemark zygomatic implant.

## Surgical Guided Nasal Implant Accuracy and Nasal Surgical Guide Development



There are problems with inaccuracies with the current nasal surgical guides for example: no consistent or fixed diameter, tolerance or length of the drill cylinder. Another issue is the numerous influences and variables for example material, build orientation/support, rigidity, flexibility, post processing of current SLA Clearvue guides, bone quality of the implant pathway, over heating of the stainless steel tubing insert of the guide etc.

All the variables and inaccuracies mentioned above can be reduced in simple incremental developments to the nasal surgical guides in order to gain better accuracy of the nasal implant.

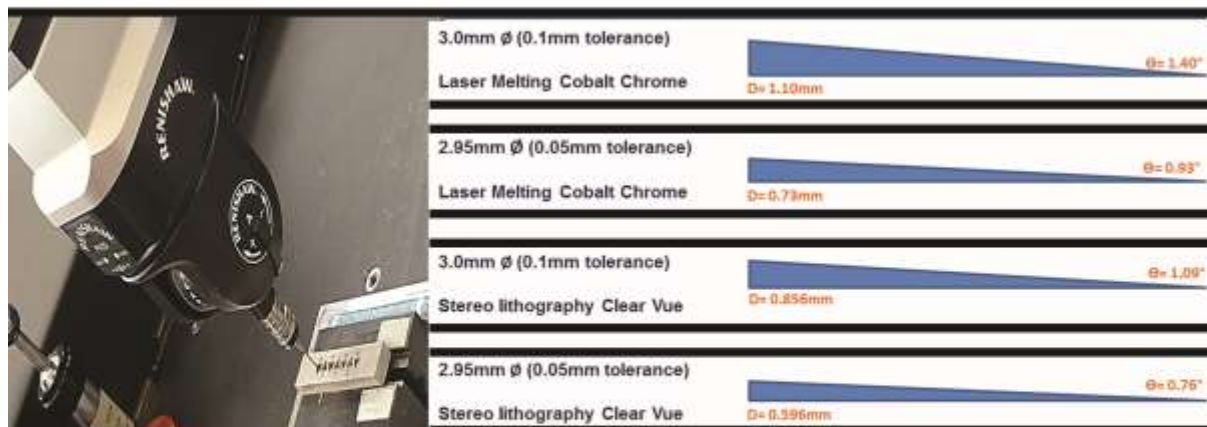


AM test bars were manufactured in two materials used for surgical guides currently Cobalt Chrome and SLA Clearvue. The test bars had numerous tolerances from 2.9mm to 3.4mm to see which would be best for a 2.9mm Branemark pilot drill to go through.

The test bars were placed on a CMM machine in order to gain co-ordinate measurements to how accurate the AM parts can be built and depending on the tolerance which would suit the guide best.



## Surgical Guided Nasal Implant Accuracy and Nasal Surgical Guide Development



If the tolerance is set (diameter 3.0 or 2.95mm, 0.1mm or a 0.05mm tolerance) and used in AM processes in either Cobalt Chrome or SLA Clearvue the degree of difference for the test bars using the same theory as the patient guides is approx. 1 degree instead of the benchmark guide which was 8.04 degrees

The above results can be developed into a surgical guide in theory and it should be more accurate than the benchmark guide. If this theory was to be placed into a newly developed design of the nasal guide this will be a substantial difference between the pre and post op. scans for the future.

In my opinion the decrease difference of 7 degrees may not be fully achievable based on other variables that need to be considered for example whether the surgeon is left or right handed (this differs the position of the drill), the surgeon experience and whether the surgeon's standing/sitting position in the operation.

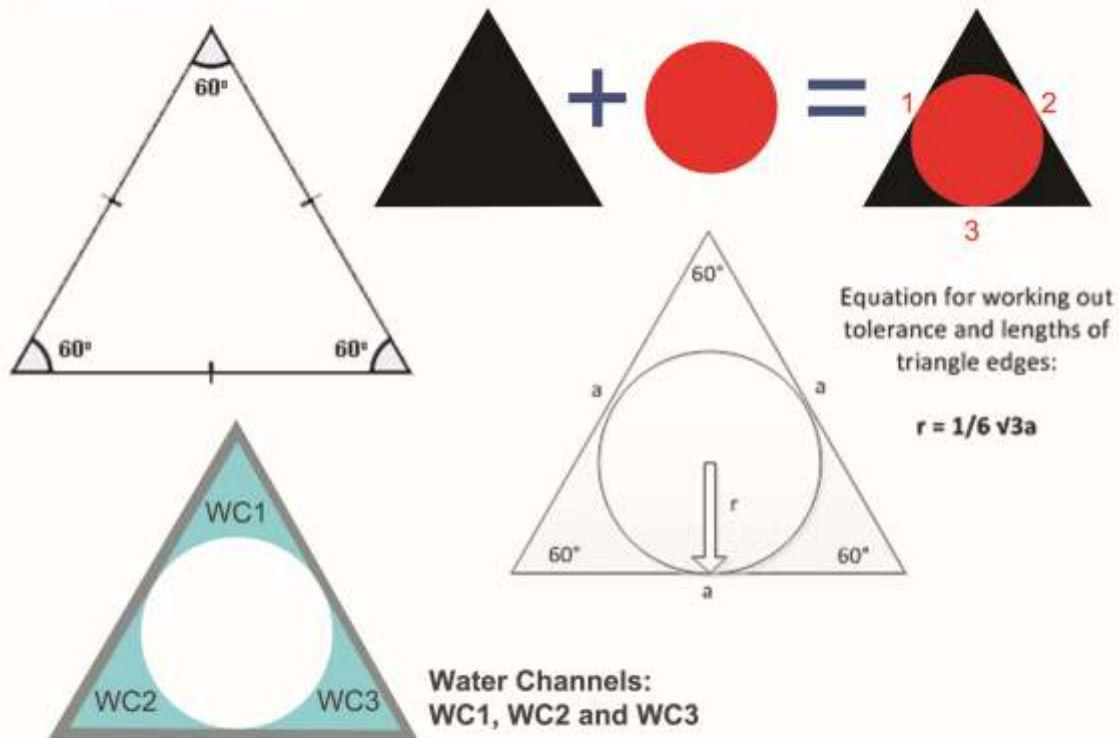




## Surgical Guided Nasal Implant Accuracy and Nasal Surgical Guide Development

Another theory that has come from this research is incorporating the equilateral triangle. An equilateral triangle is a triangle with all three sides of equal length and all the angles within the triangle are 60 degrees.

If you take an equilateral triangle a perfect circle will fit in the middle of it and will touch and support it at three points.



The triangle theory can be placed into the drill cylinder design of the guide. The triangle can be either built in to the SLA Clearvue guide or as Cobalt Chrome metal inserts inside the SLA Clearvue guide. With the tolerances from the previous page (0.05 and 0.1mm) incorporated into the triangle geometry to allow the pilot drill to be placed through it with ease and improved accuracy.

The reasons for the developments of a triangle insert nasal surgical guide are:

- The triangle geometry is easier to AM compared to a circle in both SLA and SLM.
- The triangle is a rigid structure that will securely hold and support the drill at three points.
- The triangle also allows the water from the drill to channel down three parts that surrounds the drill all the way to the bone. This will not only cool the surround of the drill but will also stop the problem of the stainless steel circular insert from coming away from the guide.

## Surgical Guided Nasal Implant Accuracy and Nasal Surgical Guide Development

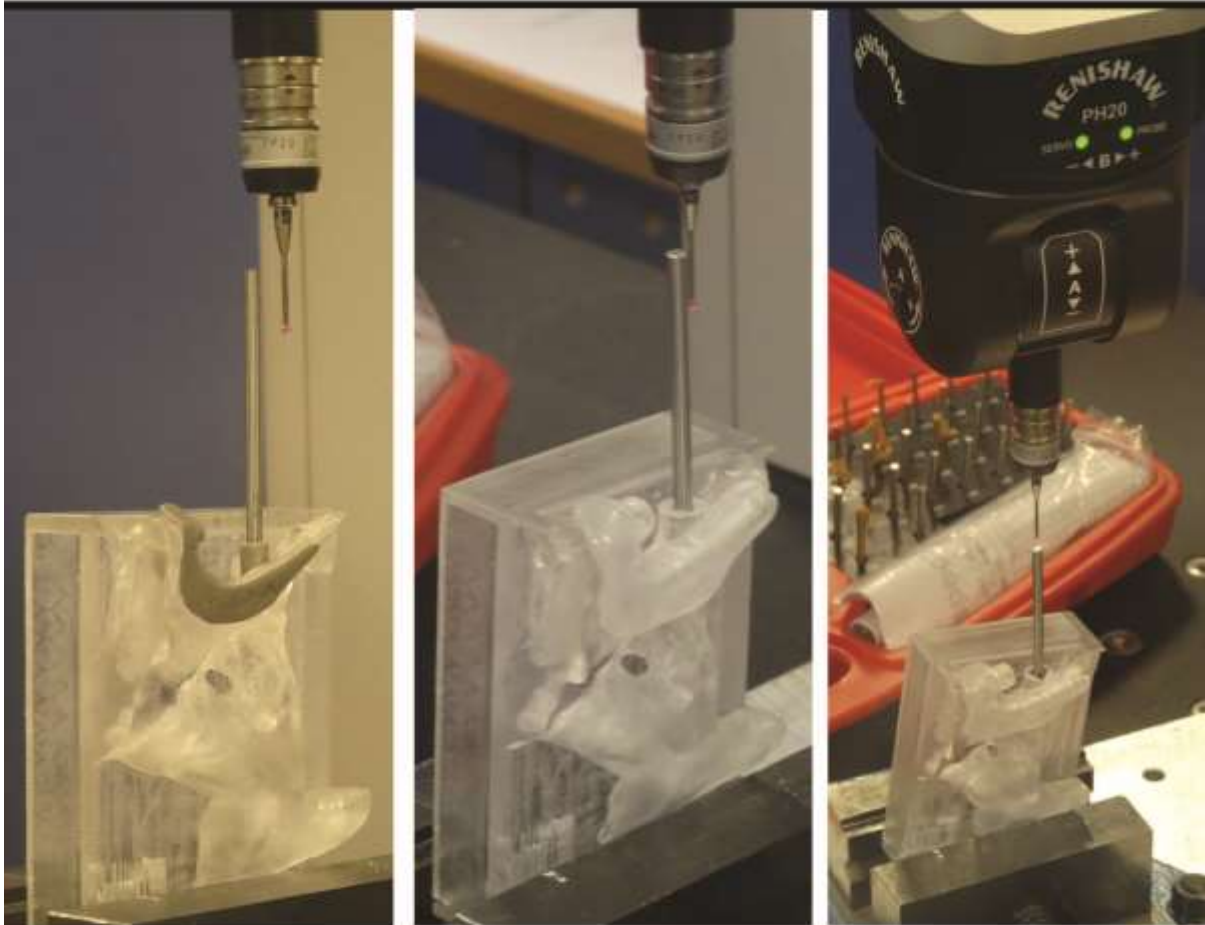


Taking all the results, theory, influences, variables and inaccuracies into account the benchmark guide (shown on the left) with degree of difference of 8.04 will be developed into a new nasal surgical guide that will improve the accuracy of the placement of the nasal implants.

With the results from the test bars of 0.05 and 1mm tolerance on the diameter of the 2.9mm Branemark pilot drill plus the equilateral triangle theory a series of newly developed nasal guides have been AM'ed.



## Surgical Guided Nasal Implant Accuracy and Nasal Surgical Guide Development



The benchmark surgical guide and the trial cobalt chrome guide that was used in the patients surgery was included in the next CMM testing shown above.

6 newly developed guides were also included in the CMM testing. A 2.9mm diameter pin gauge which represented the 2.9mm pilot drill was used to place into the drill cylinder of the surgical guide. The guide was placed on the skull block into its planned position.

The CMM recorded the angulation of the pin gauge in relation to the gauge being placed into the surgical guide drill cylinder.

The Cobalt Chrome surgical guide performed the best with regard to minimal error of angulation but in the operating theatre it was deemed too rigid to fixate correctly on the bone.

In comparison to the benchmark surgical guide used on this patient developments 1, 2, 4 & 5 had less angulation error then the benchmark guides angulation error.

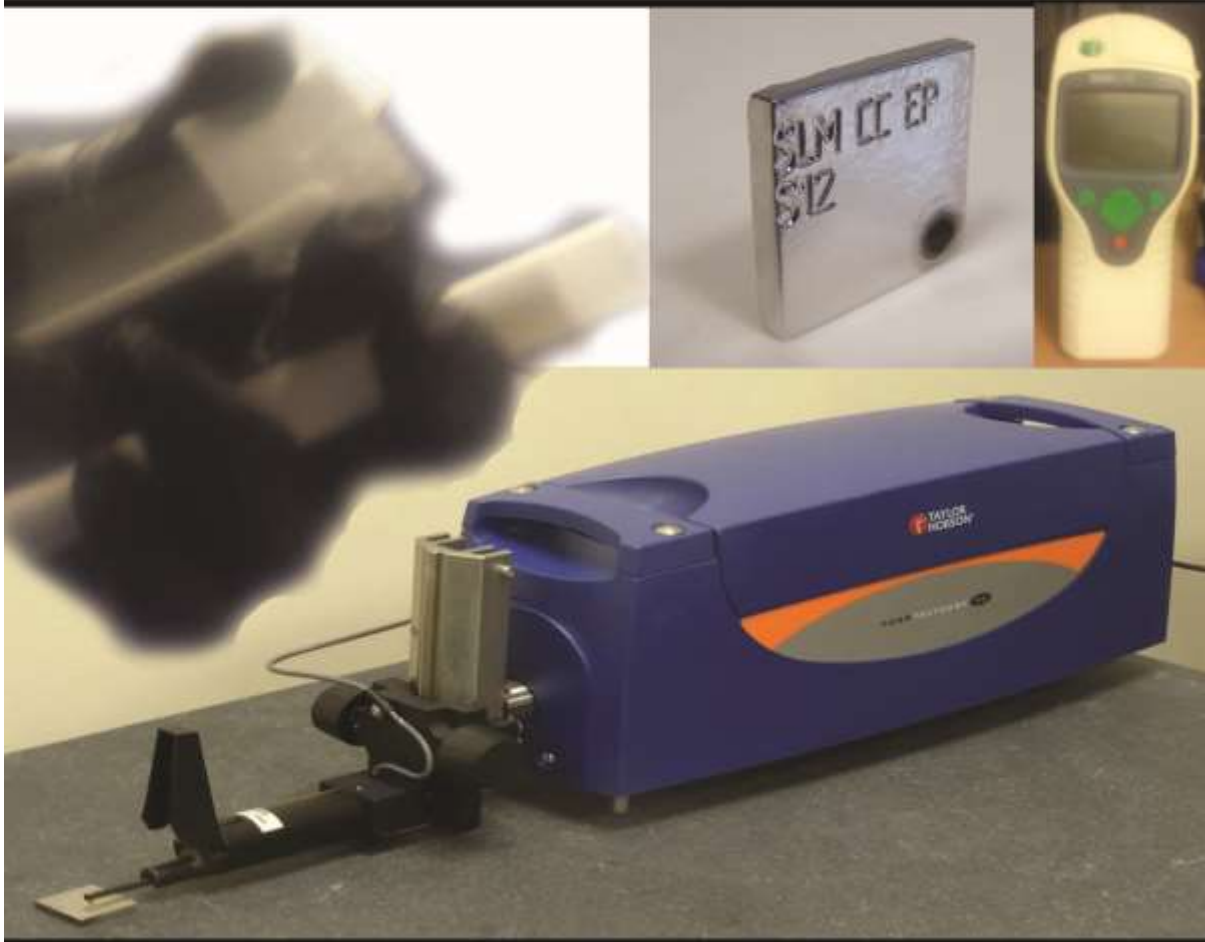
All developments incorporated the triangle and tolerance theory stated earlier in this PDF.





## Cleanliness PDF

### AM Materials - ATP Surface Cleanliness Testing & Surface Roughness



Cardiff  
Metropolitan  
University

Prifysgol  
Metropolitan  
Caerdydd



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CYMRU  
NHS  
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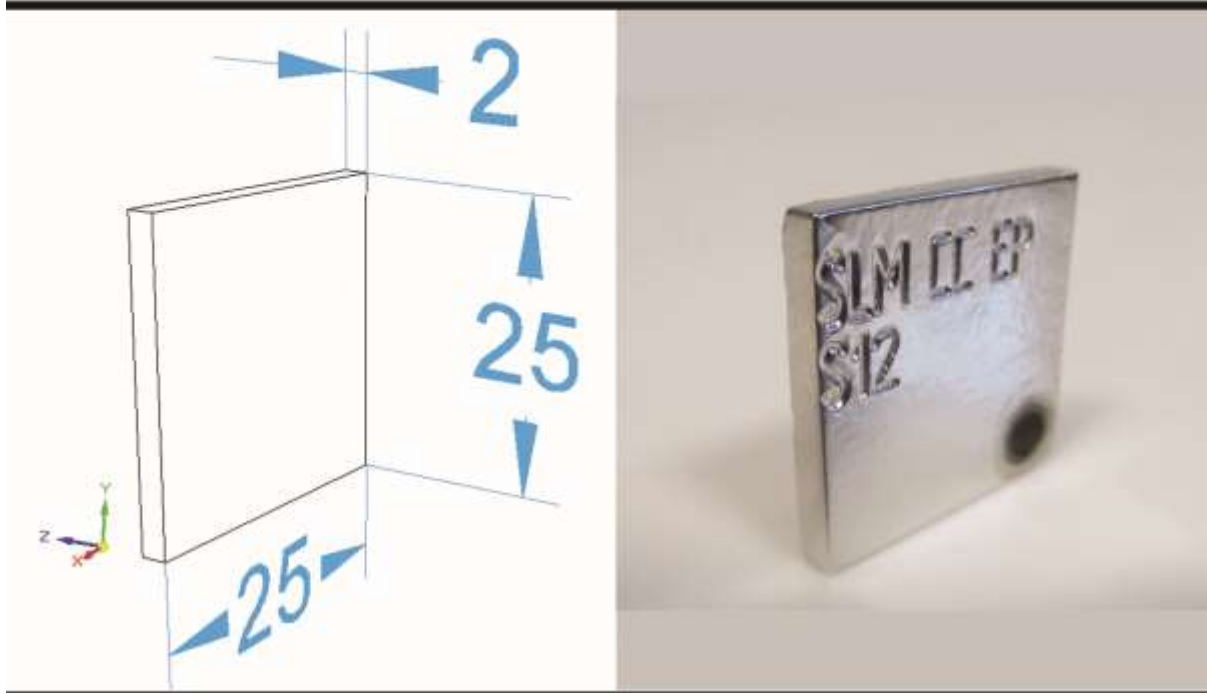
Bwrdd Iechyd Prifysgol  
Abertawe Bro Morgannwg  
University Health Board

pdr

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FOR PRODUCT DESIGN +  
DEVELOPMENT RESEARCH



## AM Materials - ATP Surface Cleanliness Testing & Surface Roughness



11 Additive Manufactured Materials tested:

- SLA Clearvue (Polymer)
- SLA Grey Extreme (Polymer)
- Projet Arcylate (Polymer)
- Objet VeroBlue (Polymer)
- Objet VeroWhite (Polymer)
- Objet TangoPlus (Polymer)
- SLS Glass Filled Nylon (Polymer)
- SLS Non Glass Filled Nylon (Polymer)
- SLM Cobalt Chrome Electropolished (Metal)
- SLM Cobalt Chrome Non Electropolished (Metal)
- SLM Titanium Non Electropolished (Metal)



## AM Materials - ATP Surface Cleanliness Testing & Surface Roughness

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The aim of this research is to evaluate the ATP bioluminescence test in terms of its application to a range of representative AM materials to quantify their surface cleanliness. In this context, material properties are of more concern than geometrical features.

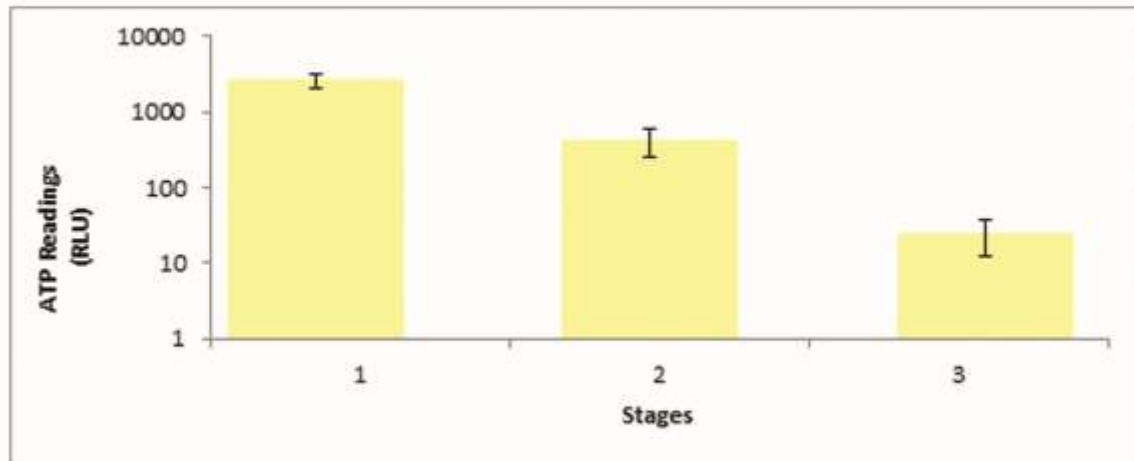
This research study undertook a pilot study to test three stages of production, cleaning and sterilization to evaluate which procedures gave AM parts with ATP readings in the region of the pass/fail threshold (250 RLUs).

An overview of each stage is given below:

- Stage 1: Post Build. The AM parts were removed from the build platforms, support structures were removed, and the parts finished for standard delivery to the lab or surgical scrub team. In this scenario the parts were packaged and sealed for delivery, but all post-production handling was in a non-sterile environment.
- Stage 2: Post Cleaning. The sealed post-production AM parts were taken through a series of cleaning steps; the standard operating procedure.  
The key element was soaking each test sample in 250ml of Isopropanol for 60 minutes. This was achieved by placing four or five test samples in a one-litre beaker, and rotating the sample after 30 minutes to ensure an even contact time on both the main 25x25mm surfaces. After 60 minutes, the samples were removed individually, dried and packaged.
- Stage 3: Post Sterilisation. Post-production parts were dispatched directly to a clinical partner (Morrison Hospital, UK), and individual samples were placed in labelled autoclave bags and sterilised on the standard 134 degree celsius autoclave cycle.



## AM Materials - ATP Surface Cleanliness Testing & Surface Roughness

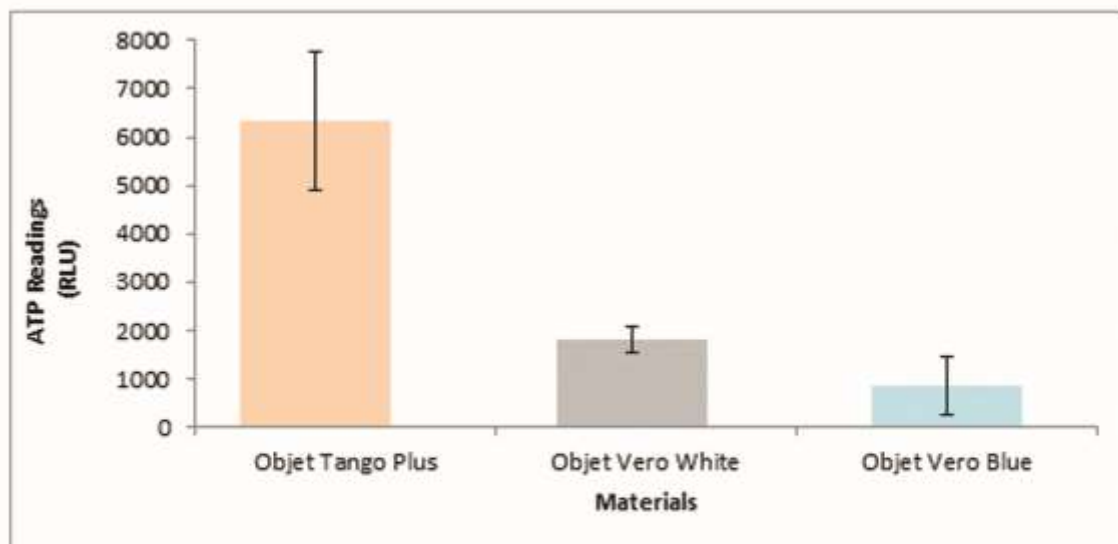


Stage 1: Post Build

Stage 2: Post Cleaning

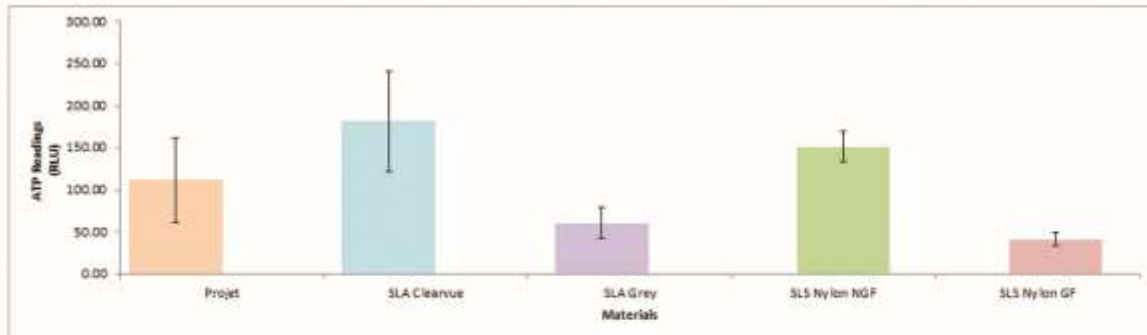
Stage 3: Post Sterilisation

Stage 2: Post Cleaning recorded results in the region of the 250 RLU pass/fail threshold therefore this stage was looked at in more detail to try and see what are the differences between the 11 AM materials and how the material samples properties reacted.

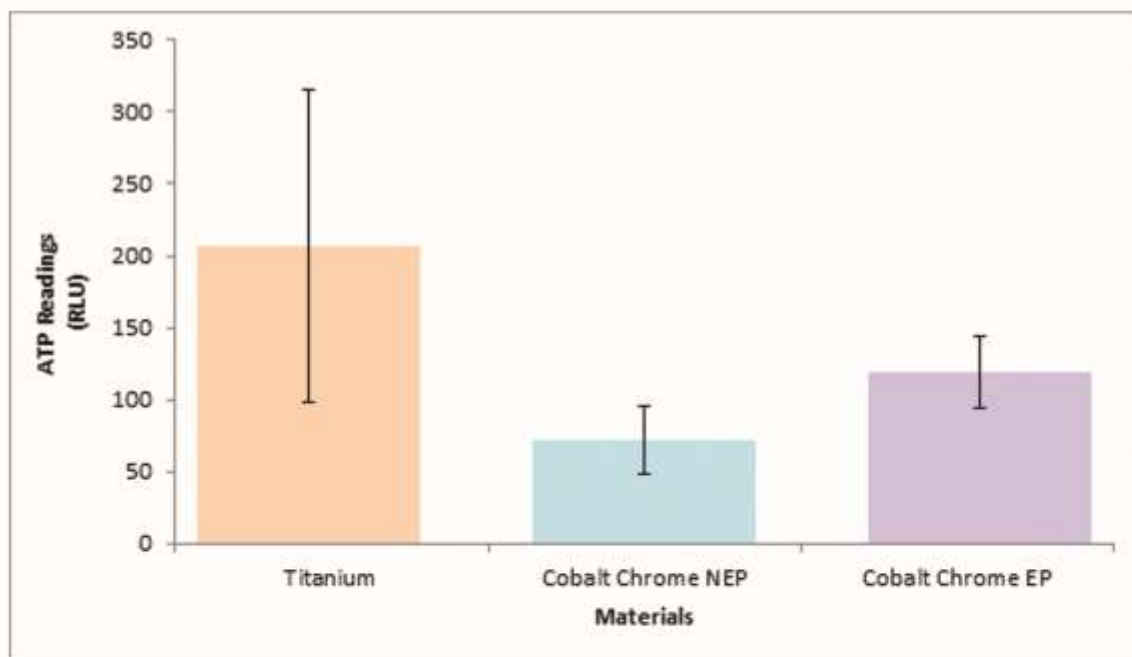


All of the Objet polymer material samples recorded RLU readings in the 1000's with TangoPlus material having the highest RLU and the dirtiest surface cleanliness. The three Objet materials readings were in the same range as the Stage 1: Post Build recordings.

## AM Materials - ATP Surface Cleanliness Testing & Surface Roughness

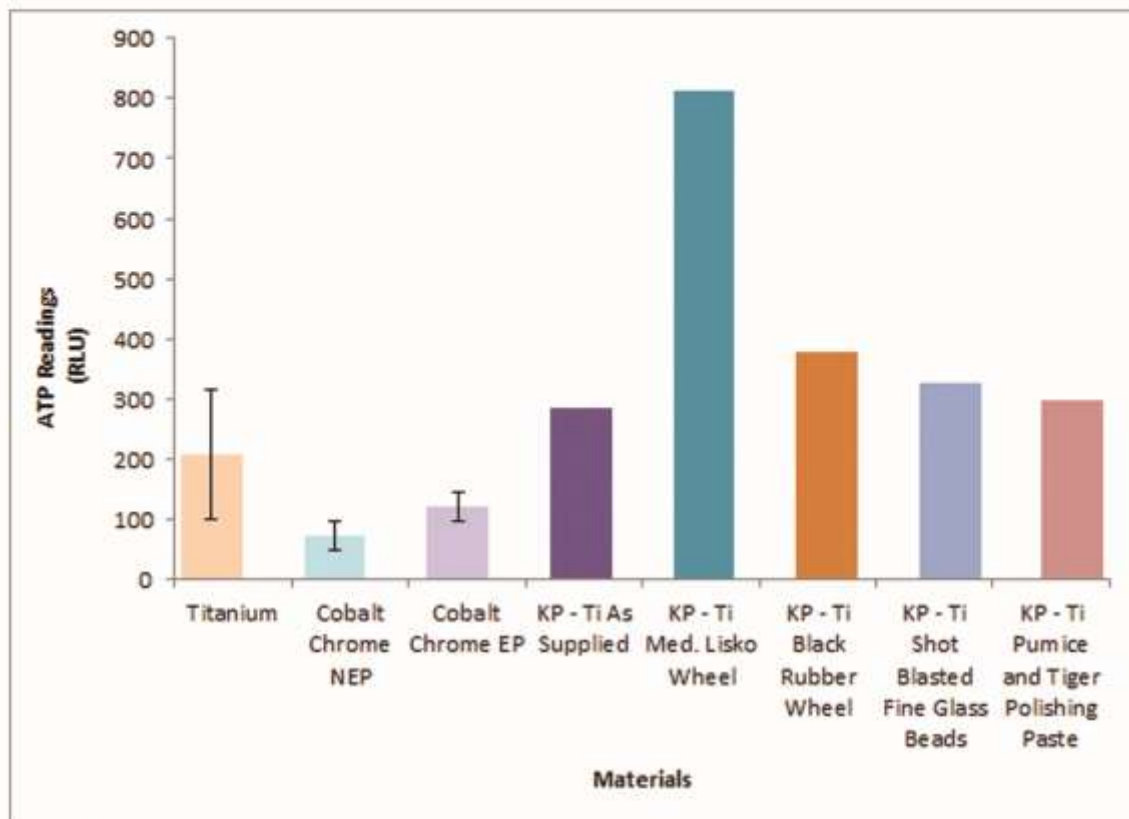


All remaining polymer materials came below the 250 RLU pass/fail threshold at the Stage 2: Post Cleaning. SLA Clearvue being the only polymer of the 5 shown above that can be sterilised and used by the scrub team of the operating theatre.



The metal materials samples also did well and all came under the 250 RLU pass/fail threshold at the Stage 2: Post Cleaning. The Cobalt Chrome samples performed better than the Titanium material samples but there was a significant difference between the Non Electropolished (NEP) Samples and the Electropolished (EP) Samples with the NEP samples surface cleanliness coming out cleaner and with less debris on the surface than the shiny EP samples.

## AM Materials - ATP Surface Cleanliness Testing & Surface Roughness



To establish to what standard current cranioplasty plates are polished to samples were requested from Kevin Page MBE to give a reading for traditional/conventional methods. 5 samples were sent in total: 1. The titanium sheet as supplied to the lab, 2. The titanium polished using a medium lisko wheel, 3. The titanium polished using a black rubber wheel, 4. The titanium shot blasted using fine glass beads and 5. The titanium polished using pumice and tiger brilliant polishing paste.

As you can see from the graph above the lowest of the metal readings is the Cobalt Chrome Non Electropolished samples and the lowest of the Kevin Page samples was the Titanium as supplied to the lab. Any additional polishing of the surface of the metal material samples caused a rise in RLU reading and hence shows that when you polish a surface that extra debris will gather on the surface.

To see if there was a comparison between ATP Surface Cleanliness and Surface Roughness the surface properties of the AM materials were further analysed using the Taylor Hobson® Form Talysurf 50 surface roughness measurement apparatus.

## AM Materials - ATP Surface Cleanliness Testing & Surface Roughness

Examples of previously recorded surface roughness RA values are as follows:

A polished Ti cranioplasty plate or orbit has a RA value of 0.04 $\mu$ m. A Synthes mandibular plate has a RA value of 0.12 $\mu$ m,

As you can see from the results below all the polymer material samples surface roughness RA values differed depending on build orientation of the sample piece which caused a step layer formation which resulted in a higher RA value in certain directions or sides of the geometry.

As for the metal material samples it did not make a difference of which build orientation the samples were built but there was a noticeable difference in the Cobalt Chrome Electropolished samples in which only one side of the sample was polished and demonstrated a noticeable difference on the smoother top electropolished surface.

Ra values	Top L2R	Top U2D	Bottom L2R	Bottom U2D
CC EP	0.0953 0.0806 0.0763 0.1178 0.0777 0.1160	0.1277 0.0888 0.0686 0.1407 0.0891 0.0889	3.0817 3.6312 5.2903 4.1850 3.7913 3.1121	4.3050 4.6850 3.5652 3.3839 3.7744 3.3571
mean		0.0971		3.8469
SD		0.0229		0.6622
CC NEP	2.7685 3.9561 2.3689 3.0705 2.4784 3.3343	2.9378 3.7613 1.2374 3.1123 1.7735 2.8912	2.8641 3.9574 2.6709 3.0889 3.7858 3.2368	2.4618 4.6952 1.5478 2.8502 2.9349 1.9763
mean		2.8240		2.9892
SD		0.7789		0.8617
SLA Gray	0.3107 0.2892 0.3425 0.5631 0.5792 0.2712	3.7507 4.4736 5.4072 4.1338 3.8800 3.7633	0.4036 0.5799 0.5300 0.4038 0.3327 0.3607	5.7134 5.5795 5.1455 2.8391 3.9076 6.4660
mean		2.3154		2.5218
SD		2.0553		2.3730
SLA Clearvue	0.2780 0.3631 0.2691 0.3590 0.2594 0.2327	5.1725 4.2773 3.8479 4.8072 4.4568 3.3589	0.2719 0.1872 0.2317 0.2539 0.2478 0.4175	2.0051 2.2166 2.2363 1.1991 2.0615 2.8293
mean		2.3077		1.1798
SD		2.1492		1.0174
Objet VV	0.4342 0.1475 0.2091 0.4899 0.4668 0.1337	0.0302 0.0393 0.0674 0.0790 0.0629 0.0733	0.8272 0.9007 0.9839 1.6666 0.9815 2.3053	1.5832 0.2547 0.5167 1.2727 0.4327 0.9747
mean		0.1869		1.0333
SD		0.1747		0.5873
Objet VB	0.6604 0.2554 0.5801 0.8055 0.5232 0.2835	0.0848 0.3729 0.1086 0.9035 0.5913 0.4653	0.4222 0.8025 0.4654 0.8187 1.1213 1.4226	0.4701 0.6291 0.3144 0.4844 0.7289 0.4038
mean		0.4696		0.6720
SD		0.2588		0.3300



## Appendix III: Ethics Documentation

### Cardiff Metropolitan University Ethics

#### CARDIFF METROPOLITAN UNIVERSITY APPLICATION FOR ETHICS APPROVAL

When undertaking a research or enterprise project, Cardiff Met staff and students are obliged to complete this form in order that the ethics implications of that project may be considered.

If the project requires ethics approval from an external agency such as the NHS or MoD, you will not need to seek additional ethics approval from Cardiff Met. You should however complete Part One of this form and attach a copy of your NHS application in order that your School is aware of the project.

The document *Guidelines for obtaining ethics approval* will help you complete this form. It is available from the [Cardiff Met website](#).

Once you have completed the form, sign the declaration and forward to your School Research Ethics Committee.

**PLEASE NOTE:**

**Participant recruitment or data collection must not commence until ethics approval has been obtained.**

**PART ONE**

Name of applicant:	Ffion O'Malley
Supervisor (if student project):	Dr Dominic Eggbeer
School:	PDR, Cardiff Met.
Student number (if applicable):	
Programme enrolled on (if applicable):	RIA PhD
Project Title:	The Development of Innovative Patient-Specific Surgical Guides
Expected Start Date:	03/12/2012
Approximate Duration:	3 years
Funding Body (if applicable):	RIA Doctoral Scholarship, Cardiff Met.
Other researcher(s) working on the project:	N/A
Will the study involve NHS patients or staff?	Yes
Will the study involve taking samples of human origin from participants?	No

**In no more than 150 words, give a non-technical summary of the project**

The PhD concerns the optimisation of design and manufacturing methods in the production of patient-specific surgical guides.

The first phase of the PhD is a series of case studies to audit current methods and processes of planning and producing different patient-specific surgical guides produced within Morriston

## CARDIFF METROPOLITAN UNIVERSITY APPLICATION FOR ETHICS APPROVAL

Hospital and various appropriate UK hospitals that MAG has commercial links with.

### Methods:

- Observation, Ethnography, Process-mapping and shadowing of NHS staff (Technicians & Surgeons) at Morriston Hospital during the specification, planning, design and fabrication of the surgical guides.
- No direct interaction with patients or specifying of treatments.
- Recording of NHS staff actions and comments via notes, photographs and audio for later review (subject to gaining informed consent from all NHS professionals).

Does your project fall entirely within one of the following categories:	
Paper based, involving only documents in the public domain	No
Laboratory based, not involving human participants or human tissue samples	No
Practice based not involving human participants (eg curatorial, practice audit)	Yes
Compulsory projects in professional practice (eg Initial Teacher Education)	No
If you have answered YES to any of these questions, no further information regarding your project is required.	
If you have answered NO to all of these questions, you must complete Part 2 of this form	

DECLARATION:	
I confirm that this project conforms with the Cardiff Met Research Governance Framework	
Signature of the applicant:	Date:
FOR STUDENT PROJECTS ONLY	
Name of supervisor:	Date:
Signature of supervisor:	

Research Ethics Committee use only	
Decision reached:	<div style="text-align: right;"> Project approved <input type="checkbox"/> </div> <div style="text-align: right;"> Project approved in principle <input type="checkbox"/> </div> <div style="text-align: right;"> Decision deferred <input type="checkbox"/> </div> <div style="text-align: right;"> Project not approved <input type="checkbox"/> </div> <div style="text-align: right;"> Project rejected <input type="checkbox"/> </div>

**CARDIFF METROPOLITAN UNIVERSITY  
APPLICATION FOR ETHICS APPROVAL**

Project reference number: Click here to enter text.	
Name: Click here to enter text.	Date: Click here to enter a date.
Signature:	
Details of any conditions upon which approval is dependant: Click here to enter text.	



## ABMU Data Protection and Confidentiality Policy (sections 3.1 and 3.2)

For full policy document:

<http://www.wales.nhs.uk/sites3/documents/950/ABMU%20Data%20Protection%20and%20Confidentiality%20Policy.pdf>

2.6 The HB is held accountable through clinical governance procedures, for continuously improving confidentiality and security procedures governing access to and storage of personal information. The Healthcare Governance Committee, in conjunction with the Health Records Committee, oversees the development of this policy and reports to the Board on matters relating to patient confidentiality.

### 3 Definitions

The use of the terms Personal data or Patient Identifiable information relate to the information from which a living individual can be identified.

#### 3.1 Patient / Staff Identifiable information

Key identifiable patient information includes the patient's name, address, full postcode, date of birth, NHS number and local patient identifiable codes as well as photographs, videos, audio tapes or other images of patients.

Key identifiable personal information includes the member of staff's name, address, full postcode, date of birth, NI number and staff number as well as photographs, etc.

#### 3.2 Anonymised information

This is information which does not identify an individual directly, and which cannot reasonably be used to determine identity. Anonymisation requires the removal of all key identifiable information referred to in 3.1 and any other detail or combination of details that might support identification.

Once information is effectively anonymised it is no longer confidential and may be used with relatively few constraints. However, it should be remembered that in some circumstances a patient / person might be identified directly or indirectly from other information. For example, rare diseases, drug treatments or statistical analyses, which have very small numbers of patients, within a small population, may allow individuals to be identified. Particular care must be taken in these circumstances to limit access and circulation of the information to minimise the likelihood of the patient being identified inadvertently.

### 4 Compliance

**Confidentiality is an obligation for all staff**

Breach of confidence, inappropriate use of health records, inappropriate disclosure of identifiable information or abuse of computer systems may lead to disciplinary measures being taken (see Information Security Policy for further information). It may also bring into question professional registration and could result in legal proceedings.

### 5 Additional responsibilities

#### 5.1 Caldicott Guardian

The Medical Director is the Caldicott Guardian for the Health Board, they are responsible for ensuring that patient confidentiality procedures are maintained, particularly with regard to ensuring that when patient identifiable information is shared, the six Caldicott Principles are adhered to (Appendix 3). The Caldicott Guardian function is devolved to the Information Governance Manager with regard to day-to-day operational matters. The Caldicott Guardian's approval must be obtained before any patient identifiable information is disclosed to a third party "in the public interest". (See section 10).

**The Caldicott Guardian also takes responsibility (through the Information Governance Manager) for the confidentiality of staff personal data**

# Honorary Contract Agreement Request Form

## Honorary Agreement Request Form

Please complete and return to the central.recruitment@wales.nhs.uk along with the following:

Applicant's CV  
Letter/Reference of support from Employer/University  
Occupational Health Questionnaire (Part A completed)

Section A (To be completed by Authorising Manager)	
Applicant's name & title:	Pete O'Malley MSc
Address:	[REDACTED]
Daytime Contact No:	[REDACTED]
e-mail address:	Pete.O'Malley@wales.nhs.uk
Current Employer/University:	PCR, Cardiff Metropolitan University
Current Job Title/University Course:	PhD and Research Technician
Has the Current Employer/University provided a letter of recommendation for the Honorary Contract?	YES
Professional Body:	MAST
Professional Register or number:	
Section B (To be completed by Authorising Manager)	
Reason Applicant has requested an Honorary Agreement:	Research
Job Title for Honorary Agreement:	Senior Research Engineer
Host Department:	Statistical Unit
Base:	Wrexham Hospital
Brief summary of duties to be covered under the Honorary Agreement:	Research and development into various reconstructive treatments
Where will the research be carried out?	
Will the Applicant come into contact with patients/children/vulnerable adults during the Honorary Agreement?	No direct contact but will observe treatments
Supervisor/ Director of Applicant (Name & Job Title):	Peter Evans, Maxillofacial Laboratory Services Manager
Agreement Start Date:	2013
Agreement Expiry Date:	2016

Does this role involve an element of Research? ☒ Research Passport applied for, CRB checked and completing this honorary agreement.  
If 'Yes' please contact the Research and Development Department to discuss whether a Research Passport would be more appropriate than an Honorary Agreement?

Authorising Manager:	Peter Evans
Job Title:	Maxillofacial Laboratory Services Manager
Signature:	
Date:	
Section C (To be completed by the Workforce team)	
Occupational Health Check sent:	
Occupational Health Clearance Form received:	
Letter of support from Employer/University received:	
References Received (Letter of support not received):	
References received:	
Identity & Permission to work study is UK verified:	
Agreement issued by:	
Date:	

NHS ABMU Identification Card – Honorary Contract



Blank copy of Medical Illustration Patient NHS Form

<b>Department of Medical Illustration</b> <b>Swansea NHS Trust</b>			
Please Print Clearly. Please note all requests must be authorised by a clinician in charge of the patient			
Photographer	Date		
No of Views	ID No		
Consultant	Department		
Requested By (please sign)	Bleep No		
Family name	Date of Birth		
Forename	Sex (M/F)		
Unit Number	Post Code		
<b>Site and Views</b> Primary Clinical Diagnosis / Procedure			
<b>Database Keywords</b>			
<b>Requirements</b> <input type="checkbox"/> Slides <input type="checkbox"/> Prints <input type="checkbox"/> For <input type="checkbox"/> Publication <input type="checkbox"/> Notes <input type="checkbox"/> Teaching			
I understand that these images and their copyright belong to Swansea NHS Trust, but that they will not be used for any purposes other than that indicated without my consent.			
I understand that due to the ease of copying and transmission, once my images are released to the teaching database, they are effectively in the public domain, and there is no successful way for Swansea NHS Trust to control how my images may be used outside of its environs.			
<b>Consent given</b>			
<b>Medical Publication</b> <input type="checkbox"/> Consent withdrawn		<b>Health Records</b> <input type="checkbox"/> Consent withdrawn	
<b>Research and Teaching Database</b> <input type="checkbox"/> Consent withdrawn		<b>Timeline</b> <input type="checkbox"/> Pre-treatment (never had treatment) <input type="checkbox"/> Pre-treatment (Pre/treatment more treatment planned) <input type="checkbox"/> Intra-treatment <input type="checkbox"/> Post-treatment	
<input type="checkbox"/> Provisional <input type="checkbox"/> Confirmed			

Scanned by CamScanner

#### **Appendix IV: Illustrative S.O.P. of PDR's SLA**

STL file of completed signed off part (model or guide) is uploaded onto Materialise Magics software.



Supports are generated from the software onto the part in order to allow it to be fully supported so that a complete full build can be made.



The supports and part are brought into Build Assembly software to position on the build bed of the machine.



The position is then sliced into the specific layer thickness of the machine and the build file is saved.



The build file is uploaded onto the SLA machine and the build begins.



Once the SLA build is complete, the parts with supports intact are removed from the SLA build bed and soaked in fresh Isopropanol to that the supports become soft for removal.



The supports are carefully removed from the SLA part and the part is cleaned thoroughly to remove any surface resin or debris.



Once the part is cleaned it is placed in the post curer for approx. 10 minutes.



Once removed from the curer the part is visually checked and then sealed into clear bags ready for dispatch.