GMIT
GALWAY-MAYO INSTITUTE OF TECHNOLOGY
INSTITIUID TEICNEOLAÍOCHTA NA GAILLIMHE-HAIGH ED

"Integrated Design to Manufacturing Process of Customised Maxillofacial Prostheses"

Master of Science in Engineering

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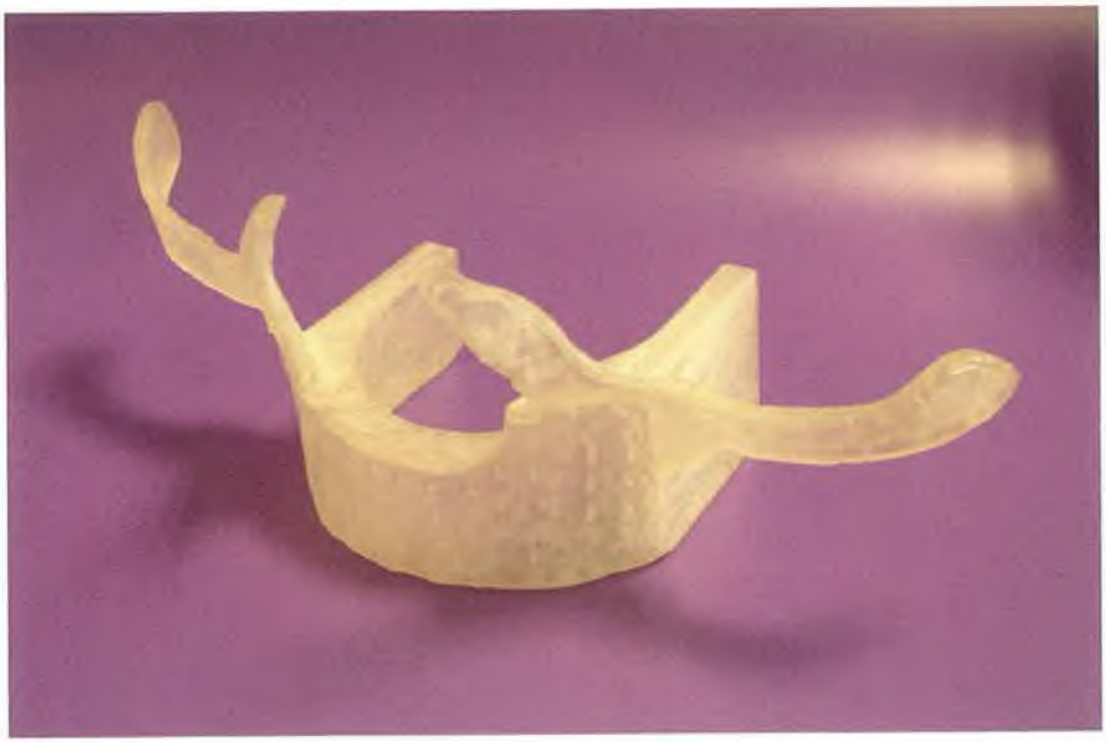

MAXILLOFACIAL PROSTHESIS

*To **my husband** and my parents who have*
supported me to stay these years in Ireland.
And to all the extraordinary people
I have met in this country.

Ireland, September 2004

ACKNOWLEDGMENT

In writing my thesis, I owe many thanks to many who helped me, in several different ways.

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Mr. Ninian Peckitt, BDS MB ChB LRCP MRCS (Eng) FRCS FFD RCS FDS RCS, Consultant Cosmetic Maxillofacial Surgeon, Director ComputerGen Implants Ltd, UK.

PUBLISHED WORK ASSOCIATED WITH THE THESIS

1. S.Lohfeld, D.Serban, D.Boyle, P.McHugh, N.Peckitt – "***Relieving Design and Manufacturing of Maxillofacial Prostheses***", Bioengineering in Ireland Conference, Ballyconnell, Co.Cavan, Ireland (January 25-26), 2003 (Oral PowerPoint Presentation)

2. S.Lohfeld, D.Serban, P.McHugh, D.Boyle, N.Peckitt – "***Digital Design of Maxillofacial Implants***", 4th National Conference on Rapid & Virtual Prototyping, and Applications, Buckinghamshire Chilterns University College, Bucks, UK (June 19-20), 2003 – Presentation Cancelled by Enterprise Ireland due to Confidentiality Agreement

3. D.Serban, D.Boyle, S.Lohfeld, P.McHugh, N.Peckitt – "***Design and Manufacturing of Customised Maxillofacial Prostheses***", CARS 2003 Computer Assisted Radiology and Surgery 17th International Congress and Exhibition, London, UK (June 25-28), 2003 (Poster Presentation)

SUMMARY

The results of the CORD feasibility study carried out at the beginning of the present research showed that little research has been done regarding the design and manufacturing processes of large customised titanium implants used for maxillofacial reconstruction. The large titanium implants, as a facsimile of the resected bone, used by the surgeon Mr. Ninian Peckitt, have used many techniques of Computer Assisted Surgery (CAS) to address "functional" surgical reconstruction.

This project was about taking the existing, successful implant further along the road of CAS and improving the design and manufacturing processes. The research study consisted in an integrated approach from design process and manufacture to dimensional quality assurance for the developed customised maxillofacial implant.

As the research has been completed successfully, a method has been devised to optimise the design process of a customised implant by using solid modelling techniques. Software used to do this was MIMICS from Materialise, Pro/ENGINEER from PTC and 3DataDesign from DeskArtes. The procedure initiated with the CT scans, which were converted and transferred to CAE software. The implant was designed virtually with respect to the patient anatomy and was thus accurate and patient specific. The result was an assembly of the CAD model representation of the patient anatomy and the implant, which fitted perfectly to the anatomical geometry. The implant was brought into Finite Element Analysis (FEA) environment, meshing of the component parts of the implant was investigated in HyperMesh from Altair Eng. and statically analysed for the stress distribution within ANSYS software when loaded with the average bite force identified in specialised publications.

The final tasks of the research included: titanium casting manufacturing process of the implant, dimensional/tolerance checking to verify the dimensional accuracy of the cast implant and performance testing to verify the reliability of the material used. Mechanical tests were performed to identify the properties of the materials and implants produced using the mentioned manufacturing process, for comparison with standard values of these materials. The dimensional checks of the actual maxillofacial implant assessed it as feasible engineering and suitable for insertion.

The study completed successfully and the carried out research wanted to prove the viability of an idea that by using CT scans, Finite Element Analysis, Computer Aided Analysis and Rapid Prototyping through an integrated approach, realistic modelling, simulation of the body structures and design of implants could be easily performed.

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CHAPTER 1

INTRODUCTION

1.1. Background for the Study

In recent years, computers were used increasingly as a supportive tool for the diagnosis, operation planning, and treatment in medicine and dentistry, as almost every medical specialty showed a tendency towards this type of less invasive procedures.

Therefore, there has been noticed a wide diffusion of ***Computer Assisted Surgery*** (CAS) techniques in clinical routine, to provide surgeons with new tools that can improve surgical accuracy and reliability, decrease surgical risks and achieve individualised planning to obtain shorter operating times and improved outcomes. The recently developed field of Computer Assisted Surgery embraces the use of Computed Tomography (CT) / Magnetic Resonance Imaging (MRI) scan conversion, rapid prototyping (RP), three-dimensional CAD, robotics, rapid manufacturing, reverse engineering and finite element analysis (FEA) to create and position customised implants for the purpose of improving the surgical procedures. Computer Assisted Surgery is applicable to almost every medical component part of the medical field, especially in orthopaedics (hip, shoulder, knee, arm, spine, hand), but its new application to maxillofacial reconstruction is still at the research stage.

Maxillofacial surgery is required to address defects, deformities or trauma in the jaws or facial bones. These can result from oral **cancer**, rare diseases, car accidents or other reasons. Computer assisted surgical (CAS) techniques permit high accuracy and facilitates the transfer of the surgical plan into the patient by creating customised implants that are positioned accurately using customised cutting and positioning jigs

across a wide range of clinical situations from treatment of facial deformity to facial pain. Computer assisted (CA) maxillofacial surgery has seen many advances when compared with other branches of computer assisted surgery and there are several types of benefits to be obtained. As compared to conventional maxillofacial surgery the CAS approach is less invasive, resulting in less trauma to the patient. This results in less intensive care unit time, the ability to treat elderly patients and results in less mortality. Patient care is also improved as there is earlier ambulation, quicker recovery time, less hospital time, better facial reconstructions and complications arise less frequently. Facial reconstruction can have profound psychological effects on patients and their families and thus this is a huge quality of life issue, and this can be done through patient-customised maxillofacial reconstruction.

An Enterprise Ireland funded CORD feasibility study carried out on this research topic has revealed that no one else is performing customised maxillofacial surgery using large titanium implants, except Mr. Ninian Peckitt[1], who is a collaborator to the present research. There is no patent on large customised implants used in maxillofacial surgery other that Mr.Peckitt's US patent ***(US Patent 6,254,639 Prosthetic Implants)***. The only European patent involving the use of rapid prototyping, CNC, customised tools and implants in maxillofacial surgery is Patent ***GB2138058 Three-dimensional modelling of maxillofacial implants,*** by Mr. Ninian Peckitt.

The large customised titanium implants, as a facsimile of the resected bone, used by Mr. Ninian Peckitt, have used many techniques of computer assisted surgery to address surgical reconstruction and evidence based results have indicated savings in time, cost, intensive care unit time, ambulation, morbidity and mortality. Furthermore, in some cases it is possible to perform the procedures on patients with compromised medical conditions or elderly people.

1.2. Objectives of the Project

The research study described in the present thesis is integrated part of a research project funded by Enterprise Ireland (Research Innovation Fund 2002) and was

[1] **Ninian Peckitt**, BDS MB ChB LRCP MRCS(Eng) FRCS FFD RCS FDS RCS, Consultant Cosmetic Maxillofacial Surgeon, Director ComputerGen Implants Ltd, UK

NUI,Galway and Mr. Ninian Peckitt, consultant cosmetic maxillofacial surgeon and patent holder of the existing, successful customised maxillofacial implant.

The overall objective of the project was to develop an integrated design to manufacture process for customised, prescription fit, maxillofacial implants. The project involved a synthesis of complementary technologies and it was multi-disciplinary in that it harnessed the expertise and experience of engineers, clinicians and professional business consultants.

The purpose of the present research was to further advance the technology used by Mr. Peckitt in order to create maxillofacial implants, which are more accurately designed and manufactured in a completely different way (Figure 1.1).

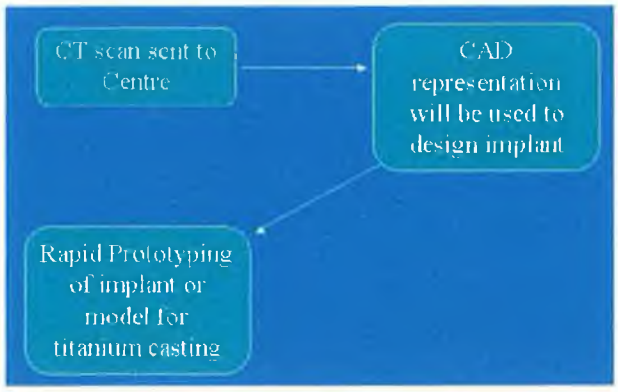


Figure 1.1 Proposed roadmap of the design and manufacture process of the implant

The **specific technical objectives** of the overall project were formulated as follows:

- To develop an efficient method of designing custom facial implants in and on three-dimensional CAD representations of human tissues.
- To create a prototype implant using titanium investment casting, which can be measured in order to prove its effectiveness.
- To create a high quality prototype using direct selective laser sintering (SLS) of Titanium powder.
- To develop a computer based finite element methodology for design and optimisation of the implant and an understanding of the stress and force interaction between the screws and hard tissue anchorage points.
- To design effective accelerated endurance tests of the implant.

- To design effective accelerated endurance tests of the implant.

The methodology in this project consisted of adopting two parallel tracks appointed to the collaborators in order to maximize the probability of a successful outcome. The project consisted of identifying the best design procedure using 3D CAD, in which there is already some experience. Once the most efficient design process was identified and perfected, the remainder of this project consisted of trying and testing two alternative manufacturing processes for direct and indirect manufacturing of high precision custom fit facial prostheses. The two alternative manufacturing paths were Titanium Investment casting and Selective Laser Sintering (Rapid Prototyping technique) of Titanium powder. In parallel with these activities FEA computer modelling of the prostheses was performed to optimise the prosthesis geometry and hard tissue fixation. Finally, the quality of the cast implant was assured by checking the dimensional accuracy and tolerances using a CMM machine. The last step was endurance testing of the implant.

The particular aims and objectives of the research study located in **Galway-Mayo Institute of Technology** were:

- Perform an intensive literature survey in the medical and engineering disciplines to consolidate the searches already identified during the feasibility study. The task also involved becoming trained in the sophisticated software packages required by the project, such as MIMICS and MAGICS RP for processing the CT/MRI scan images and producing CAD representations, Pro/ENGINEER and 3DATA EXPERT for the implant design.
- 3D geometrical solid model creation of the customised maxillofacial implant, the result being an assembly of the CAD model representation of the patient and the implant, which fitted perfectly to the anatomical geometry.
- Titanium Investment casting of the customised implant.
- Perform physical and mechanical tests (tensile tests, indentation hardness tests) to characterise the properties of the materials and implants produced using the manufacturing process, for comparison with standard values of the materials.
- Perform dimensional/tolerance checking of the cast implant using a Coordinate Measurement Machine (CMM) to check that the manufacturing tolerances have

not been exceeded and to ensure that an accurate representation of the implant has been manufactured.

1.3. Organisation of the Work

The work is organised into seven chapters and the following paragraphs provide a brief overview of each one of them.

Chapter 1 gives a general introduction of the research topic and the associated objectives of this study.

Chapter 2 supplies a comprehensive and critical literature review necessary to follow this work, with:

- an introduction to Computer-Assisted Surgery techniques which extend into all areas in the medical field ranging from orthopaedics to dental implantology and as far as the treatment of craniofacial malformations and advanced tumours within this anatomically complex region.
- an assessment of the maxillofacial surgery, in terms of oral cancer
- an assessment of the different materials used for biomedical applications, from which Titanium is identified as the most appropriate biomaterial
- a short description of the surgical principles of titanium implants osseointegration
- a description of the clinical and engineering specifications of maxillofacial implant
- a brief presentation of the "functional" and "non-functional" maxillofacial reconstructive procedures
- a justification of the present study

Chapter 3 is concerned with the virtual design of the customised maxillofacial prosthesis and the following points are developed:

- a presentation of the currently used implant design techniques
- CT scan data reconstruction and processing using MIMICS software
- a description of the two methods developed for designing the implant, one involving the use of Pro/ENGINEER and MAGICS RP software and another one making use of 3DATA EXPERT software from DeskArtes.

Chapter 4 describes the static stress analysis of the virtual designed prosthesis by presenting:

- the mechanics of loading the implant, from the view point of load distribution and fatigue failure
- preprocessing of the prosthesis as STL format using HyperMesh software
- processing the static stress analysis of the implant using ANSYS software, with a view to verify and to certify that the maximum stress achieved with the average bite force is well within the capabilities of the prosthesis.

Chapter 5 presents the different physical and mechanical tests performed to identify the properties of the cast implant including tension tests (performed on Titanium alloy test specimens) and indentation hardness tests (performed on cut pieces from the implant). The fractured surfaces of the Titanium test specimens following tension tests have been looked at using a Scanning Electron Microscope (SEM).

Chapter 6 focuses on the dimensional/tolerance checking of the prosthesis using the Coordinate Measuring Machine (CMM) to check that the manufacturing tolerances have not been exceeded, and analysing and discussing the errors occurred in measurements of the implant.

Chapter 7 consists of the most important statement of results obtained from the research carried out and their significance. Ideas generated by the work, limitations of the work, ways how it can be improved and recommendations for future study are also presented.

This research study consisted in an integrated approach from design process and manufacture to dimensional quality assurance for the developed customised maxillofacial implant.

The present research wanted to prove the viability of an idea that by using CT/MRI scans, Finite Element Analysis, Computer Aided Design and Rapid Prototyping through an integrated approach, realistic modelling and simulation of the body structures and the design of implants can be easily performed.

CHAPTER 2

CURRENT STATE OF KNOWLEDGE IN MAXILLOFACIAL SURGERY

2.1. Introduction to Problem: Computer Assisted Surgery – a review and an assessment of technology

The medical industry has seen great advancements in the quality of life offered to the patients. Many of these are related to various technologies such as imaging systems, laser scanning, robotics and rapid prototyping that are now affordable for implementation.

The recently developed field of **Computer-Assisted Surgery** embraces the use of different technologies such as [1]:

(i) Computed-Tomography (CT) / Magnetic Resonance Imaging (MRI) scan conversion,

(ii) Rapid Prototyping (RP),

(iii) Three-dimensional CAD,

(iv) Finite Element Analysis (FEA),

(v) Rapid Manufacturing,

(vi) Reverse Engineering and

(vii) Robotics, to create and position implants for the purpose of improving the surgical procedures.

Advances in the basic scientific research within the field of Computer Assisted Oral and Maxillofacial Surgery have enabled the surgeons to introduce features of this technique into routine clinical practice. The advantage of a computer assisted operation is especially apparent in cases where a comparison can be made during surgery of a patient model that has been previously stored in a computer with the actual patient situation *in vivo* for the support of the surgeon.

The industrial significance of each of the component features of CAS can be largely described, but in order to certify their medical applicability only some of their characteristics will be discussed.

Data acquisition and reconstruction from CT/MRI

In medical imaging, the two most common systems used in acquiring detailed anatomical information are Computed Tomography (CT) and Magnetic Resonance Imaging (MRI). Computed Tomography (Figure 2.1) is considered the greatest innovation in Radiology since the discovery of X-rays. The CT slice provides detailed cross-sectional information about internal structures of the head and face, skeletal and soft tissue, which cannot be obtained through routine radiographs [2].

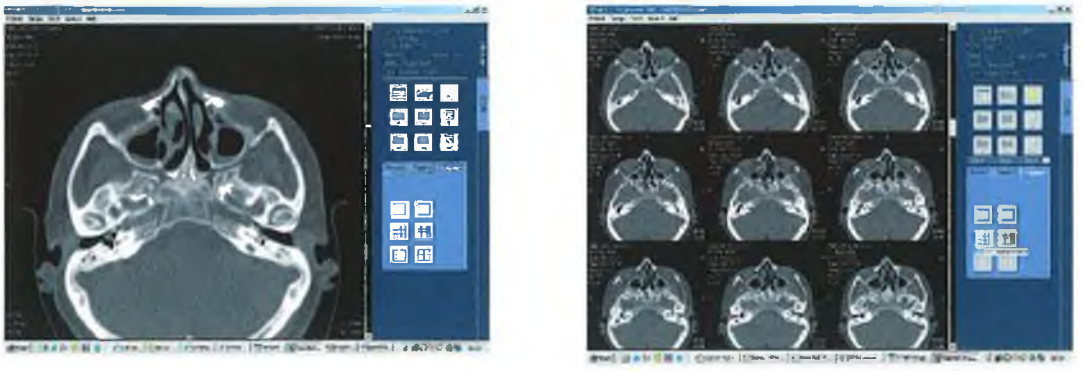


Figure 2.1 Computed Tomography

The CT image is reconstructed from the fraction of the X-rays passing through the body and intercepted by the detectors of the CT. Attenuation by the tissues is compared with attenuation by water on a numerical scale. The numbers on the scale are called densitometric numbers or Hounsfield units (H.U.) after the inventor of the CT.

On the other hand, MRI images are based on different tissue characteristics by varying the number and sequence of pulsed radio frequency fields in order to take advantage of magnetic relaxation properties of the tissues. For both procedures, the information from each plane can be put together to provide a volumetric image of the structure as well as the size and location of anatomical structures. The scanned model becomes a virtual volume that resides in the computer, representing the real volumes of the patient's bones.

When a series of CT images is reassembled to illustrate a 3D presentation of an anatomical structure, the medical practicioner and the prosthetic designer can use the information directly and the entire structure can be visualised. Some of these visualisation software packages include: ANALYZE Biomedical Image Processing package, SURGICAD Template from SurgiCAD Corporation and MIMICS form Materialise (Figure 2.2).

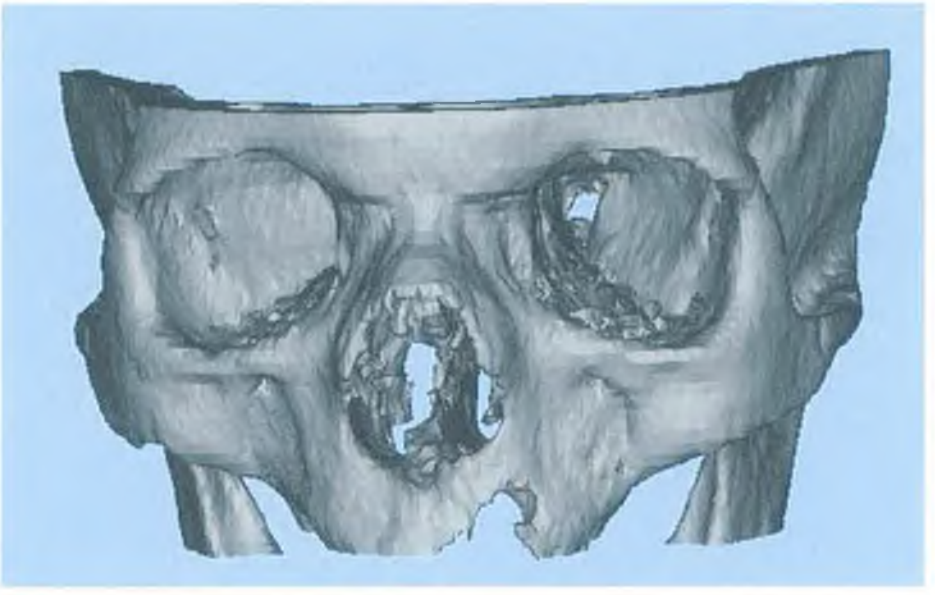


Figure 2.2 Three-dimensional skull representation (STL file)

These software packages take anatomical data from CT and MRI scans and create 3D computer models from the scanned anatomical structures. When segmentation and visualisation is completed the data can be translated into instructions for the manufacture of parts, often by Rapid Prototyping (RP) techniques. The standard interface from CAD to RP is the Standard Triangulation Language (STL), although other formats such as Initial Graphic Exchange Specification (IGES) or Virtual Reality Modelling Language (VRML) are also possible.

Meaning and application of RP techniques in medicine

Since a few years back, RP models are also being applied in the medical field. Various RP techniques are now available for biomodel fabrication, such as: stereolithgraphy (SLA), solid ground curing (SGC), fused deposition modelling (FDM), selective laser sintering (SLS), laminated object manufacturing (LOM), 3D printing.

Complex diseases in medicine often demand time-consuming surgery. Surgical planning tries to minimise the duration of surgery to reduce the risk of complications. A physical RP biomodel (Figure 2.3) derived from CT or MRI data *can be held and felt*, offering surgeons a direct intuitive understanding of complex anatomical details which cannot be obtained from imaging on the screen.

The opportunity *to hold the model in the hand* and view it from various angles in a natural fashion presents new avenues in diagnosis and treatment in medicine. The RP technique has a wide application across many surgical specialties: neurosurgery, orthopaedics, maxillofacial surgery, cranio-facial and skull-base surgery, plastic surgery, otorhinolaryngology and vascular surgery.

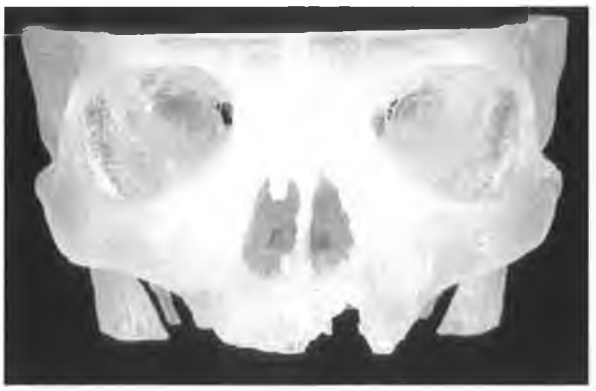


Figure 2.3 Stereolithographic biomodel

Three-dimensional Computer Aided Design (CAD)

When considering the reconstructive surgery, it should be kept in mind that the human body does not have sharp corners or edges and it necessary to select CAD software that facilitates irregular geometrical prosthetic modelling.

The CAD functionality makes it easy to construct metal implants to cover holes that will not close naturally and customised implants following the patient's anatomy.

The CAD functionality makes it easy to construct metal implants to cover holes that will not close naturally and customised implants following the patient's anatomy. The transfer of the simulation to the operation room can occur more easily if the simulation is done in a CAD environment.

Finite Element Analysis (FEA)

3D FEA has been widely used for the quantitative evaluation of the stresses induced in the implants by the applied loads. FEA packages can be utilised to perform the stress analysis of the designed implant with a view to understanding the stress distribution for the purpose of achieving a design of an implant that will have an optimised internal stress and be of a minimum weight.

Rapid Manufacturing – creation of 3D biomodels

For medicine, Rapid Manufacturing (RM) is a broad term including the use of rapid prototyping, rapid tooling, and the direct use of layer manufacturing technologies to produce final implants quickly, technology which has been developed to shorten the design and production cycle. The process utilizes the computer description of the implant shape directly, and allows integration of the Computer Aided Design (CAD) with the Computer Aided Manufacture (CAM) of the part. It therefore allows a manufacturing cycle with a seamless transition through the computer design, simulation, modelling, and fabrication procedures, which makes the technique fully applicable to the medical field.

Reverse Engineering

Reverse engineering enables the duplication of an existing part by capturing the component's physical dimensions, features, and material properties. It can be said that reverse engineering begins with the product and works through the design process in the opposite direction to arrive at a product definition statement.

In maxillofacial surgery, reverse engineering technique can be used as a mean of accurately specifying a computer model for subsequent finite element analysis, failure determination or for checking if the accuracy of the manufactured implant corresponds closely to the 3D CAD model.

Robotics

Surgery is a new and rapidly growing application field for robotics. In contrast with other applications, the robot cannot be considered as a stand-alone system but as part of a complex enviroment in the operating room.

Maxillofacial surgery requires highly skilled surgeons with an extensive knowledge about medicine and dentistry. In many cases in maxillofacial surgery, it is necessary to manipulate the skull bone, which involves handling various tools and performing accurate osteotomies. For a surgeon it is extremely difficult to achieve the desired accuracy of about 1 mm in bone and implant positioning by free hand. Not to mention the problems with achieving required orientation accuracy [3].

Currently, robotics in surgery is a research field with a big potential for new and challenging applications. A few products are available on the market such as AESOP and ZEUS (Computer-Motion), EndoAssist (Armstrong Healthcare), ROBODOC (ISS), CASPAR (Otto Maquet), MKM (Carl Zeiss) and the SurgiScope (ELEKTA/DeeMed).

In some countries, for example the German speaking countries (Germany, Austria, Switzerland) there has been rapid acceptance and development of CAS techniques within the surgical community. Either for reasons of natural and pragmatic conservatism or otherwise, the surgical community has not quickly accepted CAS techniques and progress is slow and in some countries somewhat stagnated. Reasons for this may be that many surgeons are satisfied with the results they currently achieve and have little incentive to change their procedures.

At some point CAS technologies will be brought to bear on surgical procedures and will be incorporated in the standard training of surgeons. This will not happen overnight, but when it does it will have far-reaching patient benefits.

Computer Assisted Surgery is applicable to almost every medical component part of the medical field, especially in orthopaedics (hip, shoulder, knee, arm, spine, hand), but its new application to maxillofacial reconstruction is still at the research stage.

2.2. Importance of Computer Assisted Maxillofacial Surgery

Since ancient times, humans have desired to replace diseased or injured tissue by transplanting healthy tissue from another source. The patron saints of medicine, Cosmo and Damian, who lived in the fourth century, were depicted by Renaissance painters as transplanting a healthy human limb to replace a diseased one. Jobi Meerkren has been credited with performing the first xenograft[1] in 1682 when he used a segment of a dog's skull to reconstruct a soldier's skull defect [4]. John Hunter was credited with the performance of the first autograft[2]. He transplanted the spur of a chicken to its head [5]. In 1881, MaCewen performed the first documented case of a human allograft[3] used to reconstruct a child's humerus [6].

Tessier introduced the concept of **craniofacial surgery** in 1967, and since then the principles and operative techniques of this unique surgical discipline have continued to evolve. Tessier's original work with craniofacial surgical techniques involved children and adults with congenital malformations including craniofacial dysostosis[4] and facial clefts [7]. Experience with the correction of craniofacial anomalies on children required the modification of the original principles. Subsequent modifications of Tessier's techniques now provide the oral and maxillofacial surgeon with improved access for tumour resection, management of post-traumatic deformities, and superior aesthetic outcomes in the correction of congenital anomalies. Further technical refinements continue to build upon the original principles of oral and maxillofacial surgery and expand the applications of these techniques for the corrections of facial deformities.

Maxillofacial surgery techniques deal with congenital and acquired defects/deformities, trauma, and complex reconstruction techniques as for example the resection of head and neck tumours (Figure 2.4). Oral and maxillofacial surgery encompasses orbital reconstruction, congenital/acquired deformity, cleft lip[5] and palate repair, tumour resection, reconstructive surgery, temporomandibular joint surgery, customised distraction osteogenesis[6], oral rehabilitation, diagnosis and treatment of facial

[1] See Appendix: "Glossary of medical terms"
[2] See Appendix: "Glossary of medical terms"
[3] See Appendix: "Glossary of medical terms"
[4] See Appendix: "Glossary of medical terms"
[5] See Appendix: "Glossary of medical terms"
[6] See Appendix: "Glossary of medical terms"

and nerve root pain, oral, oropharyngeal[7] and salivary gland cancer, facial skin tumours, orthognatic[8] surgery, aesthetic facial surgery [8]. Such surgery presents particular difficulties in achieving functional results with good aesthetics, which not only eliminates the presenting problem, but also ensures that the patient is left with a good level of ability to breath, speak, swallow and eat.

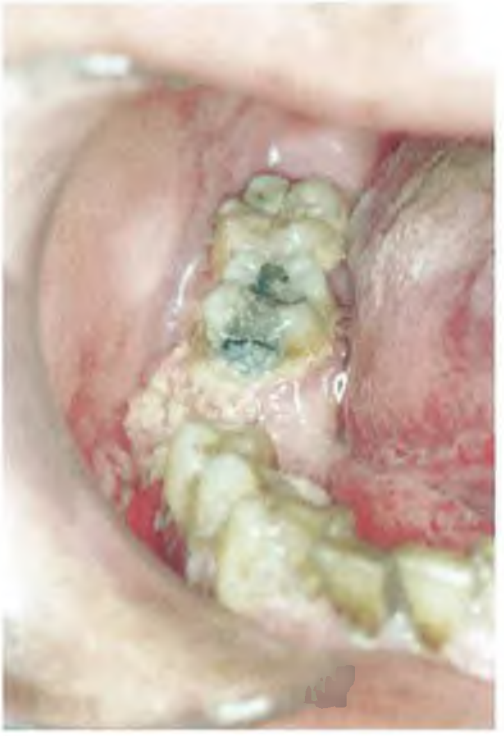


Figure 2.4 Maxillofacial surgery - tumour [9]

Computer assisted (CA) **maxillofacial surgery** has seen many advances when compared with other branches of CA surgery and there are several types of benefits to be obtained [9-12]:

1. An 81% theatre time reduction from 18 hours (for complex flap reconstruction of the maxilla) to 2.5 hours (for customised implant reconstruction of maxilla) has been documented. This has profound implications for resource management.
2. Computer Assisted Surgery techniques permit high accuracy and facilitate the transfer of the surgical plan into the patient using customised cutting and position jigs across a wide range of clinical situations from the treatment of facial deformity to facial pain.

[7] See Appendix: "Glossary of medical terms"
[8] See Appendix: "Glossary of medical terms"

3. Intensive care is not a requirement for patients undergoing procedures with reduced surgical trauma protocols.
4. Tracheostomy[9] is not a requirement for those patients treated with customised implants.
5. Elderly patients or patients with a medical history that would exclude them from long and complex surgery may be treated with Computer Assisted Surgery techniques (reduced surgical trauma).
6. Multiple resection/reconstruction surgical teams working in tandem are not required. This has profound implications for resource management.
7. Early ambulation (within 24hrs) and reduction in recovery time as a function of reduced surgical trauma.
8. Earlier discharge from hospital (within 7 days) as a function of reduced surgical trauma.
9. Reduction in morbidity and operative mortality as a function of reduced surgical trauma.
    - precision surgery is possible with reduction in operator error.
    - reduction in surgery time.
    - no second reconstructive surgical site is required.
10. There is no possibility of tumour recurrence within the implant.
11. There is no requirement for soft tissue healing over the implant on the oral and nasal mucosal surfaces.
12. A complete orofacial reconstruction including the teeth is possible as a single stage procedure. The patient returns to the ward wearing dentures that have been manufactured prior to surgery on the rapid prototyping model. This is of great psychological relevance for the patient and family, who also have to face the consequences of facial surgery.
13. The treatment of complications is simplified; the magnitude of complications and their consequences are less severe. Exposure of the osseous content of a free flap to the air results in infection and ultimate partial or complete loss of the flap;

[9] See Appendix: "Glossary of medical terms"

unintended exposure of titanium to the exterior through the skin may be treated with soft tissue coverage without loss of the implant.

2.3. Oral and maxillofacial cancer – an overview

Aspects of anatomy

Oral and maxillofacial surgery is required to address defects, deformities or trauma in the jaws, facial bones and the afferent soft tissues.

The term "**oral**" includes the lips and all intra-oral sites corresponding to the ICD-9[10] [13] codes 140 (lip), 141 (tongue), 143 (gum), 144 (floor of mouth) and 145 (other non-specific sites), but excludes sites 142 (major salivary glands), 146 (oropharynx), 148 (hypopharynx) and 149 (ill-defined oral/oropharynx) [14].

The term "**maxillofacial**" includes the anatomical regions of the face with the afferent bones, muscles and skin. The skeleton of the face is formed by 13 bones which are: 2 zygomatic bones (cheek bones), 1 maxilla, 2 nasal bones, 2 lacrimal bones, 1 vomer, 2 palatine bones, 2 inferior conchae, 1 mandible (Figures 2.5 and 2.6) [15].

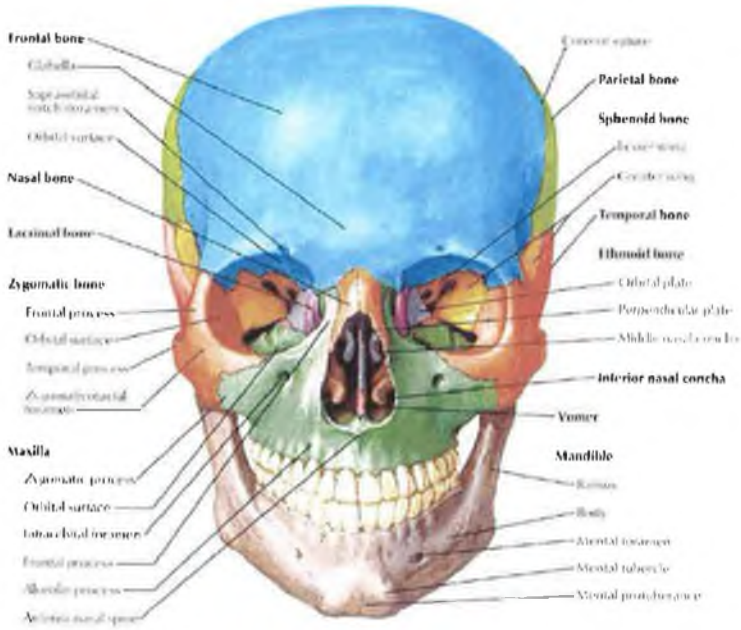


Figure 2.5 The bones of the face. Anterior view. [15]

[10] **ICD-9** (International Classification of Diseases, Ninth Revision) is designed to promote international comparability in the collection, processing, classification and presentation of mortality statistics.

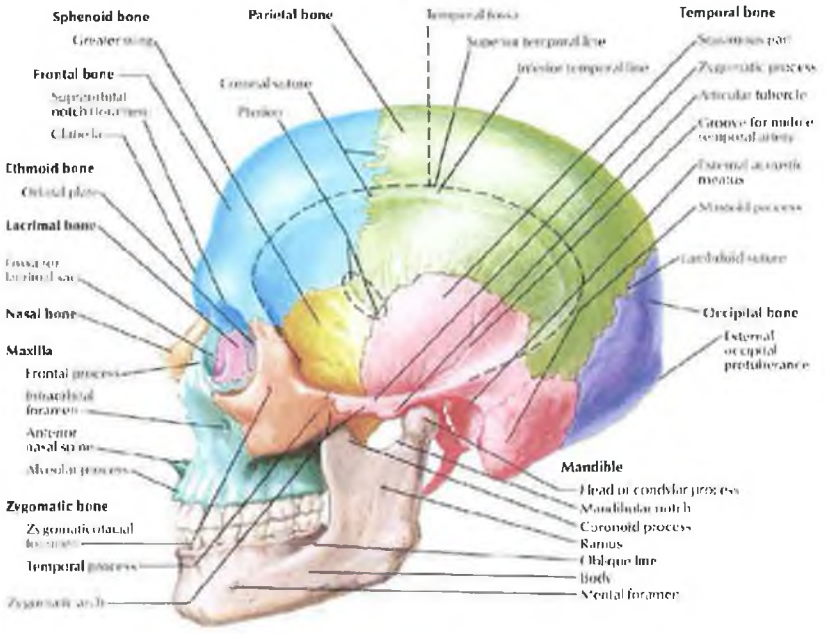


Figure 2.6 The bones of the face. Lateral view [15].

As **maxilla** (the upper jaw bone) is the anatomical part involved in the research and because of its functional and cosmetic importance, a short description of its anatomy is presented. Maxilla originates as two bones but their fusion takes place before birth. The maxilla forms the upper jaw, the anterior part of the roof of the mouth (the hard palate), the lateral walls of the nasal cavity and part of the floor of the orbital cavities. The alveolar process projects downwards and carries the upper teeth. On each side there is a large air sinus, the maxillary sinus, lined with ciliated mucous membrane and with openings into the nasal cavity (Figure 2.7) [15].

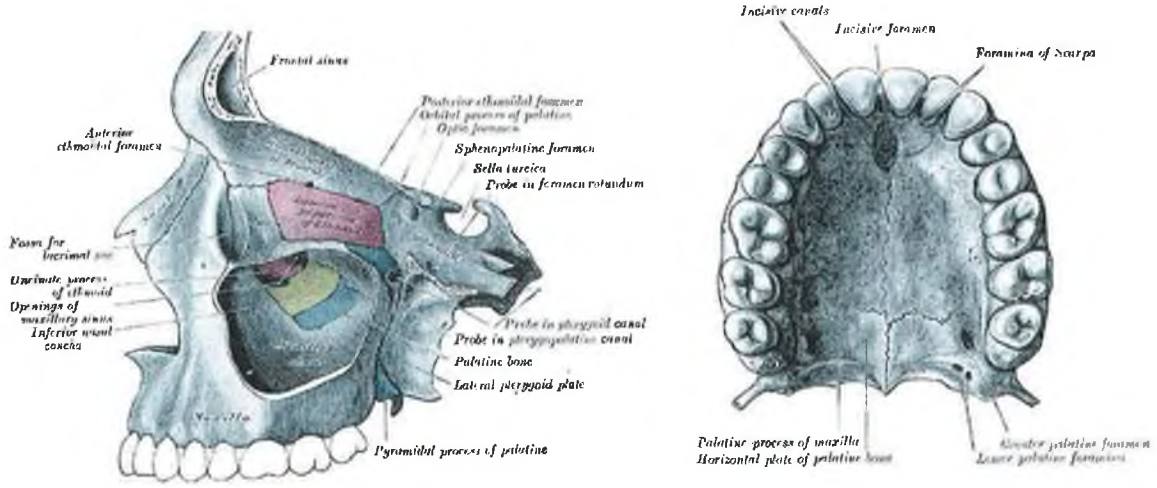


Figure 2.7 Maxilla (lateral and bottom views) [15]

Incidence/prevalence

Oral and maxillofacial cancer (known as "*head and neck cancer*" in different reference books) is the sixth most common cancer in the world and is largely preventable. It accounts for approximately 4% of all cancers and 2% of all cancer deaths worldwide [16]. Approximately 30,000 people in the US and 2000 persons in the UK develop oral cancer annually. Ninety-five percent of patients with oral cancer are over 40 years of age at diagnosis, and the mean age at diagnosis is 60 years. The incidence of oral cancer in young adults ranges between 0.4% and 3.6%. Between 10-30% of persons with primary oral cancer develop second primary tumours of the aerodigestive tract at a rate of 3.7% per year [17, 18].

The signs and symptoms of oral cancer include persistent mouth ulcers (frequently painless), warty lumps and nodules, white, red, speckled or pigmented lesions, recent onset of difficulty with speaking or swallowing and enlarged neck nodes. Although up to 90% of oral lesions can be easily visualised many changes may go unnoticed by both the patient and doctor. Approximately 6% of patients with oral cancer present with an enlarged cervical node as their only symptom [19].

The surgeon's goal is the complete removal of the primary tumour and of any involved regional lymph nodes, while preserving the integrity of uninvolved structures. Currently, distantly metastatic disease is incurable but it can be effectively palliated with chemotherapy[11] and radiation.

Aetiology/risk factors

Globally, tobacco consumption in its all various forms (smoking, chewing and snuff dipping) is the commonest aetiological factor for the development of oral cancer. In the Western world, cigarette smoking is responsible for the majority of all tobacco related oral cancer.

Alcohol is an independent risk factor for oral cancer and acts synergistically with tobacco in an additive or multiplicative fashion [20].

Approximately 15% of oral and oropharyngeal cancers can be attributed to dietary efficiencies and imbalances. Frequent consumption of fresh fruit and vegetable

[11] See Appendix: "Glossary of medical terms"

reduces the risk (0.5-0.7%) of developing oral and oropharyngeal cancer. Prolonged and heavy consumption of foods rich in nitrites and nitrosamines such as preserved meat or fish significantly increases the risk for the development of oral cancer [21].

There are some data implicating Herpes simplex viruses (HSV) and the Human papillomaviruses (HPV) in the aetiology of oral cancer, although if they do have an oncogenic role it is likely to be small [22].

Lower socio-economic status is linked as well with a higher incidence of oral cancer. First-degree relatives of persons with squamous cell carcinoma of the head and neck have significantly increase relative risk (3.79%) for developing head and neck cancer [18].

The prognosis in oral cancer

Approximately 12,000 people in the US and 900 in the UK die of oral cancer each year [23]. With a death to registration ratio of 0.45 it is a disease of high lethality, comparable to that of carcinoma of the cervix (0.48) and greater than that of malignant melanoma (0.38). Large tumours with evidence of metastatic spread and tumours thicker than 4 mm have a poorer prognosis than those that remain localised to the primary site or are less than 4 mm thick. As prognosis, 5-year survival rates are over 80% for the persons with early stage disease, over 40% for those with regional disease and less than 20% for patients with metastatic disease [24]. The status of the cervical nodes is the single most important prognostic indicator of survival for the patients with oral cancer. The development of nodal metastases halves the 5-year survival rate.

The prognostic factors in oral cancer – the TNM classification

Predictions for the clinical outcome for cancer are based on the **TNM** (tumour-nodes-metastases) **classification** (from UICC – International Union Against Cancer and AJCC – American Joint Cancer Committee), which brings together the relatively simple clinical factors of maximum diameter of the primary tumour, regional metastases (lymphoadenopathy[12]) and the clinically detectable presence of distant metastases.

Head and neck cancer involves the most complex area of anatomy in the body with complex pathologies and different treatment regimens. The accurate staging of

[12] See Appendix: "Glossary of medical terms"

cancer is essential to be able to compare different treatment regimens in terms of outcome.

The TNM classification remains the only universally accepted staging system (see Tables 2.1, 2.2, 2.3) [25].

Tis	Tumour in situ
T0	No primary tumour visible
T1	Tumour < 2 cm
T2	Tumour > 2 cm < 4 cm
T3	Tumour > 4 cm < 6 cm
T4	Tumour invades adjacent structures (invades mandible, maxilla, muscles of the tongue)

Table 2.1 TNM classification of tumour (T) size (after AJCC) [25]

NX	Nodes cannot be assessed
N0	No regional nodes involved
N1	Ipsilateral single node < 3 cm
N2a	Ipsilateral single node > 3-6 cm
N2b	Ipsilateral multiple nodes up to 6 cm
N2c	Bilateral or contralateral nodes up to 6 cm
N3	Nodes > 6 cm

Table 2.2 TNM classification of regional lymph nodes (N) size (after AJCC) [25]

MX	Distant metastases cannot be assessed
M1	No distant metastases
M2	Distant metastases

Table 2.3 TNM classification of distant metastases (M) size (after AJCC) [25]

The size of the **tumour** at the time of presentation is a useful predictor of outcome in oral cancer. In the oral cavity the commonest area for tumours to arise is the floor of the mouth and the tongue and these cancers often invade in the mandible. Similarly, almost all the tumours invading the maxillary alveolus are likely to have penetrated cortical bone, whatever their size.

The presence of lymph **node** metastases is well recognised as the most important and reliable prognostic factor in oral cancer. The 5-year probability of survival reduced from 86% to 44% in patients with metastases [26].

Unlike the common cancers that form distant **metastases** early (lung, breast, colon), head and neck primary tumours tend to recur in the primary site (local recurrence) or the neck (regional recurrence) prior to the clinical detection of the distant metastases. Only 10-20% of patients will present distant metastases as the first sign of recurrence, and the incidence of spread of disease below the clavicle ranges from 10 to 30% from clinical inspection, and increases to between 30 and 50% if a post-mortem is performed [27].

2.4. Materials for biomedical applications

The skeletal reconstructions after traumas, tumours and birth defects are often performed using the standard repair with **autografts** obtained from patient donor sites (Figure 2.8).

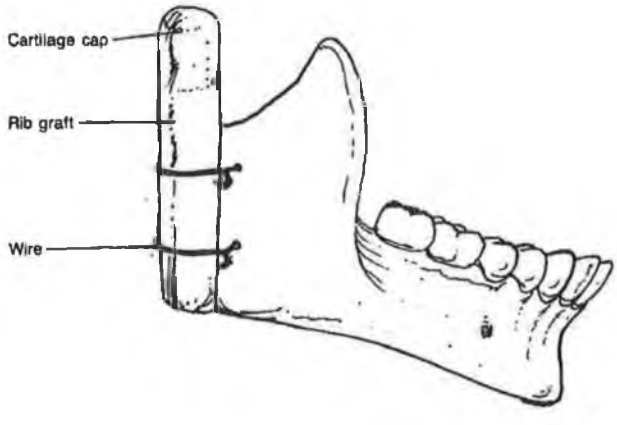


Figure 2.8 Bone-graft reconstructive surgery

Another common standard for bone reconstruction might be considered the **allografts** [9]. The modern era of allograft transplantation was inaugurated by Lexer in 1920 [6].

Allografts are removed aseptically from the human body or are secondarily sterilised with either ethylene oxide or gamma radiation. To remove immunogenecity[13], the bone is frozen or freeze-dried, demineralised or autoclaved. Ethylene oxide is an effective sterilant and the process does not destroy bone morphogenetic[14] properties as gamma radiation does. The advantage of demineralised bone is that it can be used in the form of paste, powder or blocks. Its mechanical strength is limited and its antigenicity[15] is reduced. Its advantage over the other allographic implants is its limited potential for resorption. Allografts can be used as primary reconstructive elements. As autogenous[16] bone is considered to be much more resistant to infection, allogeneic[17] bone has the great advantage of being plentiful. Allogeneic bone or freeze-dried bone can be used alone to bridge or reconstruct a portion of the jaws and it is also important to ensure that the soft tissue around the graft is sufficiently vascular [6].

Allograft bone obtained from tissue donors and synthetic bone cements are suitable for defect treatments. Allograft bone is difficult to form into a desired shape and introduces the possibility of pathogen transfer from the tissue donor to the patient. **Bone cements**, such as those based on poly methyl methacrylate (PMMA) can fill defects of variable size and shape.

Other materials such as **ceramics** or **metals** can be used for bone replacement. These materials have the potential to provide suitable alternatives to autograft and allograft bone while also providing the capability to be custom manufactured with respect to the patient anatomy and the application. Calcium phosphate-based ceramics are some of the materials used for implants due to their established history of safety and efficacy as biocompatible implantable materials [28].

The choice of **metal materials** for a particular implant application is considered by the surgeons to be a compromise to meet many different required properties such as

[13] See Appendix: "Glossary of medical terms"
[14] See Appendix: "Glossary of medical terms"
[15] See Appendix: "Glossary of medical terms"
[16] See Appendix: "Glossary of medical terms"
[17] See Appendix: "Glossary of medical terms"

mechanical strength, machinability, elasticity and chemical properties. There is, however, one aspect that is always of high importance: how the tissue at the implant site responds to the biochemical disturbance that a foreign material presents.

Titanium and Titanium alloys as biomaterials

The high strength, low weight, good corrosion resistance possessed by **Titanium and Titanium alloys** have led to a wide and diversified range of successful application which demand high levels of reliable performance in surgery and medicine as well as in aerospace, power generation, automotive, chemical plant, sports.

"*FIT AND FORGET*" is an essential requirement where equipment once installed, cannot be easily maintained or replaced. There is no more challenging use in this respect than implants in the human body.

Implantation represents a potential assault on the chemical, mechanical and physiological structure of the human body. There is nothing comparable with a metallic implant in a living tissue. Most metals in the body fluids and tissue are found in stable organic complexes. The corrosion of implanted metal by the body fluids results in the release of unwanted metallic ions, with huge interference in the processes of life. Corrosion resistance is not sufficient by itself to suppress the body's reaction to the toxic metals or allergenic elements (such as nickel), and even in small concentrations can initiate rejection reactions. From all the metals inserted into the human body, Titanium is considered to be completely inert and immune to corrosion by the body fluids and tissues (biological environment), and is wholly bio-compatible.

The regular and natural selection of Titanium for implantation is determined by a combination of most favourable characteristics including immunity to corrosion, bio-compatibility, strength, low modulus and density and osseointegration (i.e. the capacity for joining with bone and other tissue).

Another advantages presented by this metal can be considered the following:

- due to better pliability of Titanium in comparison to conventional steel and Cobalt-Chromium alloys, the Titanium plates can easily be fully adapted to the contour of the bone.

- in contrast with the steel implants, Titanium plates will rebound only minimally after bending, so the screw can be anchored tightly into the bone and resist loosening.
- in contrast to implants made from steel and Cobalt-Chromium alloys (which contain nickel), there have been no reports of allergic reactions to Titanium.
- the use of Titanium as an osteosynthesis[18] material produces artefact free images on CT and MRI scans.

In medicine, Titanium and its alloys are widely used for implant systems in cranio-maxillofacial surgery, hand surgery, middle ear surgery and orthopaedics, as well as in different areas like bone and joint replacement, dental implants, cardiovascular devices (pacemakers and defibrillators), external prostheses (artificial limbs) and surgical instruments (due to its outstanding resistance to repeated sterilisation without surface corrosion).

The most common grades used in medicine are **commercially pure Titanium** and the **Ti6Al4V alloy**, derived from aerospace applications, which once inserted into the human body remain essentially unchanged [29]. The human body is able to recognise these materials as foreign and tries to isolate them by encasing them in fibrous tissues. However, they do no illicit any adverse reactions and are well tolerated by the biological environment. The surface of Titanium is often modified by coating it with hydroxyapatite[19]. Plasma spraying is the only commercially accepted technique for depositing such coatings. The hydroxyapatite provides a bioactive surface (i.e. it participates in bone bonding), such that bone cements and other fixation devices are often not required.

Titanium and its alloys possess suitable mechanical properties for medical implantation, such as strength, bend strength and fatigue resistance to be used in orthopaedics and dental applications. Other specific properties that make it a desirable biomaterial are density and elastic modulus. In terms of density, it has a significantly lower density [29] than other metallic biomaterials, meaning that the implants will be lighter than similar items fabricated from stainless steel or Cobalt-Chrome alloys.

[18] See Appendix: "Glossary of medical terms"
[19] See Appendix: "Glossary of medical terms"

Having a lower elastic modulus compared with the other metals, Ti6Al4V tends to behave a little bit more like the bone itself, which makes it desirable from a biomechanical perspective. This property means that the bone hosting the biomaterial is less likely to atrophy[20] and resorb.

2.5. Surgical Aspects of Oseointegration

As osseointegration is one of the main advantages of Titanium as biomaterial it should be further explained. **Osseointegration** is defined as a direct structural and functional connection between the living bone and the surface of a load-carrying implant. A basic prerequisite for establishing tissue integration of a non-biological implant with minimal risk of local tissue reactions consists of an understanding of the response behaviour of the bone site, as well as the long-term tissue adaptation to functional demands.

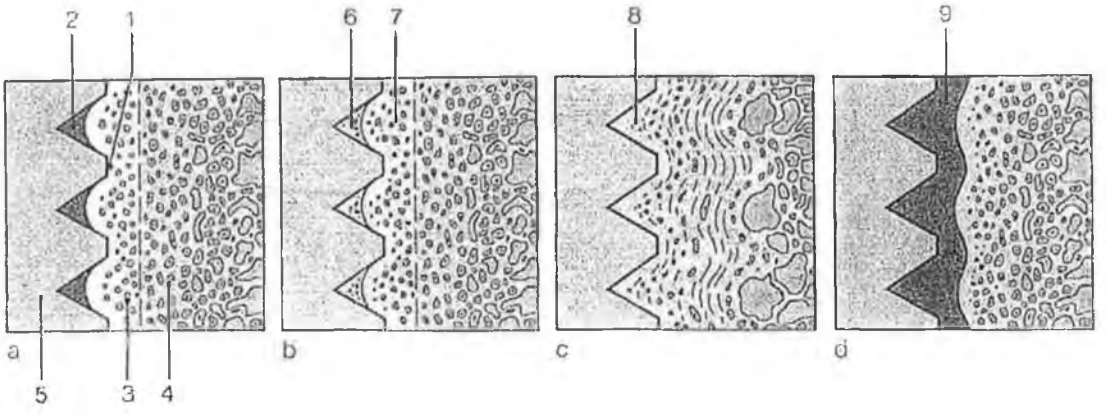


Figure 2.9 Biology of Osseointegration [30]

The diagrammatic representation of biology of osseointegration can be followed in Figure 2.9 [30], where:

1: contact between screw and bone (immobilisation)

2: hematoma in the closed cavity between the bone and screw

3: damaged bone after implantation

4: original undamaged bone

5: screw

6: callus formation (during the unloading period)

7: remineralisation of the bone

[20] See Appendix: "Glossary of medical terms"

8: border zone bone remodelled in response to the masticatory load applied
9: unsuccessful ossointegration, a kind of pseudoarthrosis initiated by excessive preparation trauma, infection, too early loading in the healing period .

Once lost, osseointegration cannot be reconstituted, due to the creation of a locus minoris resistentiae [30].

2.6. Clinical and Engineering Implant Specifications

Regarding the clinical and engineering specifications of the implant to be inserted, it is surgeon's responsibility to choose implants that will maximise the possibility of osseointegration and engineer's job to manufacture the required implant.

The following can be considered as important characteristics for a maxillofacial implant to be considered feasible for implantation from the engineering and clinical aspects:

Material

Titanium and its alloys are clinically the best documented materials to achieve osseointegration. Its surface is very stable to the body environment, which makes it fully biocompatible. No allergic reactions to this material are known.

Design

A screwed shape of the implant gives surface enlargement for interaction with the recipient bone tissue, enhances stabilisation and uniformly distributes the loads within the bone. In contrast to other designs, screw-shaped titanium implants have been shown to become totally osseointegrated. A design of the implant with round corner and edges will make it easier to insert and to fit in and around the bone.

Surface properties

The interfacial reactions of the bone tissue are greatly governed by the chemical and physical properties of the implant surface. The passivating titanium oxides and a certain degree of surface roughness [31] promote osseointegration.

Surface purity

The desired properties of the surface should not be changed by microbiological or metallic contamination during manufacturing, storing, sterilisation and surgery processes.

Fixture site positions

The most important principle is to achieve good stability of the implant, by locating accurately the attachment systems (screws) in good quality bone.

Load-bearing capacity

The whole effect of all considerations discussed above governs what dynamic load the fixtures, the implant and the bone tissues are able to bear. The long-term fixture survival rate is smaller for the maxillae than for mandible [32]. Such differences could require a greater fixture/bone interface in the maxillae for adequate load distribution.

Matching the implant to its bone site

Matching the implant to the prepared bone site should be performed with the aim of avoiding overtightening still creating an optimal fit, by assuring that the manufacturing dimensional tolerances have not been exceeded. Overtightening is likely to cause ischemia [33], but on the other hand, a very close fit is mandatory for osseointegration to occur. A very loosely attachment between the bone and the implant may lead to implant loss. Therefore, a compromise should be found between them.

Overall, the implant should be manufactured from a biocompatible metallic material, with a surface roughness acceptable to allow osseointegration, with well positioned bone attachment to prevent loosening and with a feasible design and optimal internal stress distribution to enhance stabilisation and resistance to shear forces.

2.7. "Functional" versus "Non-Functional" Maxillofacial Reconstructive Procedures

Surgical planning and execution of surgical procedures requires an in-depth knowledge of the anatomy and phsysiologic function of the surgical field. Knowledge of anatomy, physiology and cancer biology allows the surgeon to maximise the benefit and minimise the morbidity of the cancer surgery [34].

Traditionally, the reconstruction of the maxilla has involved mutilating procedures with compromised functional results. The Webber-Ferguson surgical approach (Figure 2.10) of the upper jaw involves dividing the upper lip in the midline, extending the incision lateral to the nose and below the eye, so that half of the face is opened like a book. One half of the maxilla can be resected using this approach. The

maxilla is reconstructed with an upper denture on which is placed an obturator to fill in the huge defect left by the resection.

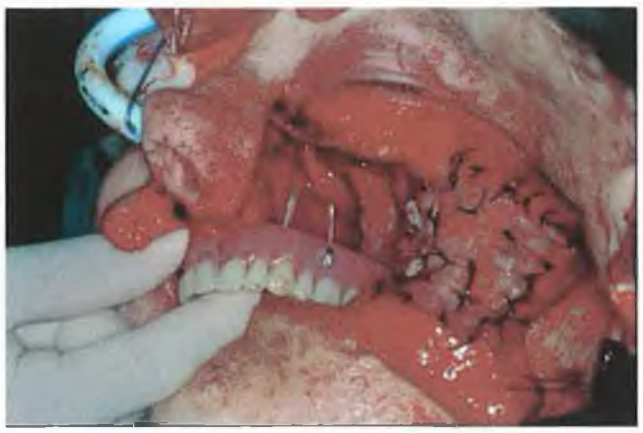


Figure 2.10 The Weber-Ferguson external surgical approach [35]

Recently, Tideman (Hong Kong) has described a complex osseous reconstruction of the maxilla. The new maxilla is made from a titanium mesh tray, which is filled by bone particles taken from the hip and ground into a paste (particulate cortico-cancellous bone graft - PCCB) [36]. The bone graft is covered by temporalis muscle, taken from the temple, which is harvested through an incision going over the top of the head (known as bicoronal flap). This muscle provides the environment for the ingrowth of blood vessels from the muscle into the graft, which survives and revascularises over a period of six weeks with minimal loss of bone. Titanium dental implants may be inserted into the bone graft for attachment of teeth or dentures. These implants fuse (osseointegrate[21]) with bone and may be brought through the tissues to the external environment without the development of infections, as described by Branemark. The success of implant oseointegration is dependent on healing by "primary intention" (i.e. no wound breakdown).

The surgical trauma involved in this type of surgical approach is extensive, involving surgery at three sites, in the mouth (primary surgical site), the hip (for collection of autograft bone) and the scalp (for collection of the flap cover).

[21] See Appendix: "Glossary of medical terms"

The conventional techniques, in which diseased or damaged bone is excised and replaced, have various drawbacks. Bone-grafts and osseofasciocutaneous[22] free flaps require to be harvested from a second surgical site. The free flap reconstructions are long complex procedures, which may take up to 12-13 hours to complete and involve multiple surgical teams trained in microsurgery techniques. Complications may occur in relation to these long operations, which include operative mortality, as a function of the degree of surgical trauma.

These "**non-functional**" multistaged reconstructive procedures are commonly carried out in the surgical treatment of malignancy. The complex volume and contour of the resected jaw may be difficult to replicate with these techniques. This is especially the case with complex surface contours present in the upper jaw (maxilla) and midface. The use of composite flaps leads to a secondary "**mutilation of reconstruction**". Surgical reconstruction with such flap techniques has an association with recurrent tumour within the substance of repair, which acts as a template for the seeding of residual or recurrent tumour, and such flaps may require removal at a second stage procedure [37].

The consultant oral and maxillofacial surgeon Ninian Peckitt has coined the notion of "**functional reconstruction**" which can be defined as the "*replication of the normal volume, contour and function of both hard and soft tissues to produce normal form and function of the face, mouth and jaws*" [9]. This functional reconstruction is impossible to achieve with living donor tissue, especially in those cases involving replication of complex osseous anatomy.

The use of computer generated implants permits greater accuracy of replication of normal anatomical contour. These implants – titanium anatomical facsimiles of the maxilla or mandible - are manufactured using Computer Assisted Design CAD/CAM and Computerised Numerised Control CNC engineering techniques to an individual prescription, and are inserted and fixed to the skeleton using evidence based surgery. Exposure of nasal and oral titanium surfaces without flap cover is possible, and this permits a single staged procedure, with preoperative manufacture of removable overdentures[23], which are secured to the implant by established precision attachment mechanisms.

[22] See Appendix: "Glossary of medical terms"
[23] See Appendix: "Glossary of medical terms"

Peckitt further devised a method of making a prosthetic implant by obtaining CT scans, using the scan data to create a three-dimensional model of the anatomy of interest, and using the three dimensional model to develop and fit to size a prosthetic implant for single-stage reconstruction of the maxilla, hemi-mandible and dentition without the use of composite flap cover after the removal of tumours. These custom-fit prostheses enable reconstructive surgery to be carried out much more rapidly, thus markedly reducing the surgical trauma, while reducing resource requirements and the cost of surgery.

The problem of maxillary reconstruction has been greatly simplified with the use of a customised titanium maxilla. The tumour resection was planned on the biomodel[24] (Figure 2.11) and a customised maxilla was made from titanium alloy.

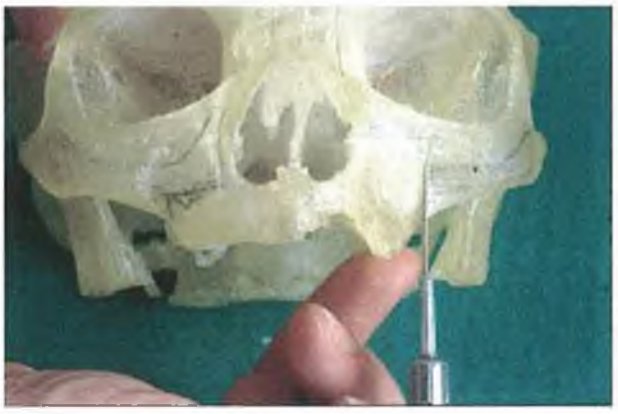


Figure 2.11 Marking the biomodel (surgical preplanning)

The titanium maxilla was designed to be an anatomical facsimile of the resected bone (Figure 2.11).

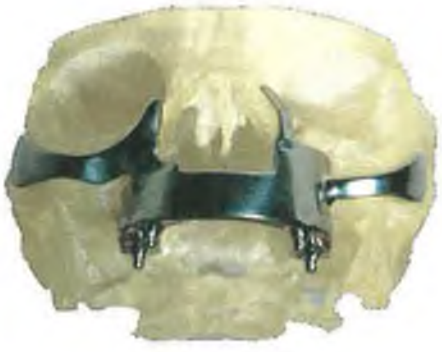


Figure 2.12 Customised maxillofacial implant designed on biomodel [35]

[24] **Biomodelling** is the generic term that has been coined to describe the ability to replicate the morphology of a biological structure in a solid substance through rapid prototyping techniques [38].

The use of customised implants and the reduced trauma of the reconstructive component of surgery is making the treatment of huge tumours possible with reduces risk for the patient as a function of reduced surgical trauma. As Peckitt advised, the concept of customised implant reconstruction must be compatible with conventional methods of reconstructive surgery so that salvage is possible as a second stage procedure in the event of implant failure.

2.8. Justification of the present study

The large titanium implants as a facsimile of the resected bone, used by Mr. Ninian Peckitt, have used many techniques of computer assisted surgery to address surgical reconstruction and evidence based results have indicated savings in time, cost, intensive care unit time, ambulation, morbidity and mortality. And also is possible to perform the procedures on patients with compromised medical conditions or elderly people.

These custom-fit prostheses enable reconstructive surgery to be carried out much more rapidly, thus markedly reducing the surgical trauma, while reducing resource requirements and the cost of surgery.

It is advocated that the biomodels and the customised implant techniques have converted a very difficult and potentially dangerous multistaged reconstruction into a simple single staged procedure, without the need for an osseous component to the reconstruction. This reconstruction is stable in the long term (8 years). No significant complications were encountered. It is likely that these principles of computer-assisted surgery will have applications not only in other aspects of head and neck surgery, but surgery in general.

CAS and particularly RP, in maxillofacial surgery through the customised implants designed by Mr N. Peckitt, show several benefits compared to conventional surgery. Of the seven different varieties of customised implants designed by Mr. N. Peckitt, one pertains to the reconstruction of the whole upper jaw (maxilla) which has been achieved with a spectacular outcome at 8 years, described by his peers as "the best result ever seen" (Brånemark Reunion Meeting, Dublin, 1997).

As it stands at present, computers and RP techniques enable us to derive a 3D model from CT/MRI scans of the skull. This model helps to get a better understanding and impression of which procedures have to be performed during the operation and facilitates the design of the prosthesis. However, the design is made in a traditional way by marking the model. CT or MRI scans are transferred to a biomodel of the region of interest by RP techniques. Subsequently, for the purpose of making the tools, the model has to be reverse engineered to transfer the design to a software environment. Depending on the design of the prosthesis, several parts are typically manufactured by pressing titanium plates into the correct shape, which need to be welded together. The final step is deburring and polishing in order to have smooth surfaces (Figure 2.13).

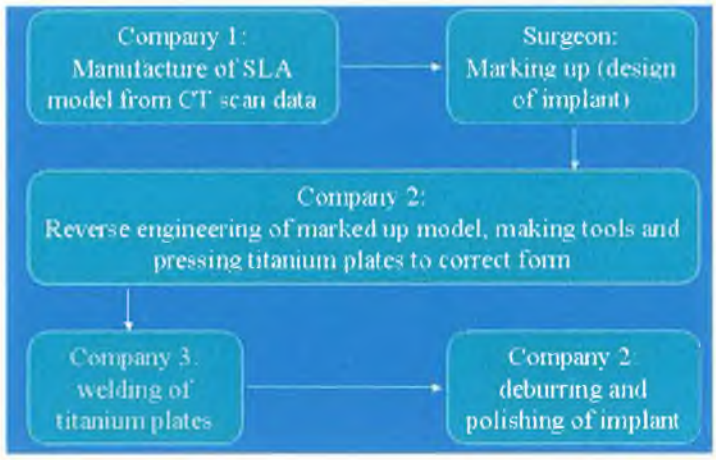


Figure 2.13 Roadmap of the Ninian Peckitt manufacturing implant's process

Currently, four different companies manufacture the implants used by Mr. Ninian Peckitt, as it can be seen in Figure 2.13.

The main purpose of this project is to develop a single-company integrated process (Figure 1.1) that, in comparison to the existing method, is more efficient, streamlined, accurate, cost effective and will constitute an integrated approach from design process and manufacture to dimensional quality assurance of the customised maxillofacial implant.

The work proposed by this research project is ***new and highly innovative*** and patents might result from the technology developed here, which is more efficient, streamlined, accurate and will produce an implant that is stronger, lighter and easier to position.

CHAPTER 3

DIGITAL DESIGN OF THE CUSTOMISED MAXILLOFACIAL PROSTHESIS

3.1. Currently used implant design and manufacturing techniques

Anatomical compatibility is a basic requirement for all implantable medical devices. The device has to fit into the anatomical space and to fulfil its function without interfering with the surrounding tissues. This is true for all orthopaedic implants, but it is critical especially for cranio and maxillofacial implants, which are stabilised against the host bone by means of mechanical attachment. In order to achieve the necessary mechanical stability immediately after the operation, the shape of the implant must be designed considering the local anatomy of the host/replaced bone.

The concept of custom-made manufacturing is very appealing in reconstructive maxillofacial surgery because each patient has a different anatomy and therefore, different requirements. In cranioplasty, this technique is suitable for the manufacture of prostheses for large cranial defects.

At present, well-established reconstructive techniques are available due to progress made in spiral Computer Tomography (CT), as well as to improvements in CAD/CAM. Various implant design techniques have been identified in the literature [39]. First generation implant design methods processed the 2D data of the CT sections according to their imaging information: images were transferred and then fabricated

section by section without any further geometric modelling (e.g. 2 ½ -axes-fabrication using CNC-technique or stereolithography using laser-technique). Based on these fabrication techniques, plastic models were produced for preoperative planning and modelling of prostheses by hand. These were after reproduced in biocompatible materials in another processing step (casting followed by moulding or milling). These manually modelled prostheses could not be standardised and reproduced [40].

But since the early 80's, 3D display of organs by CT scan has been possible and CAM of medical models based on CT data was performed using milling machines. The technology consisted first in creation of a virtual 3D defect reconstruction (in form of freeform surfaces) in case of unilateral defects by mirroring imaging from the contralateral side of the skull. Then the transfer of the data to a Rapid Prototyping machine was made in order to sinter a polycarbonate model for casting. In oral and maxillofacial surgery, this technique was first used by Brix and Lambrecht in 1987. An alterative route was the transfer of the 3D defect reconstruction to a CNC machine to manufacture the actual prosthesis by milling a Titanium block.

As found in the literature, these techniques for designing and manufacturing the customised implants were applicable for the reconstruction of skull defects in form of Titanium plates, where the accuracy of the bone shape is not of major importance (Figure 3.1.), and not for large and complex-shaped anatomical parts as the jaws.

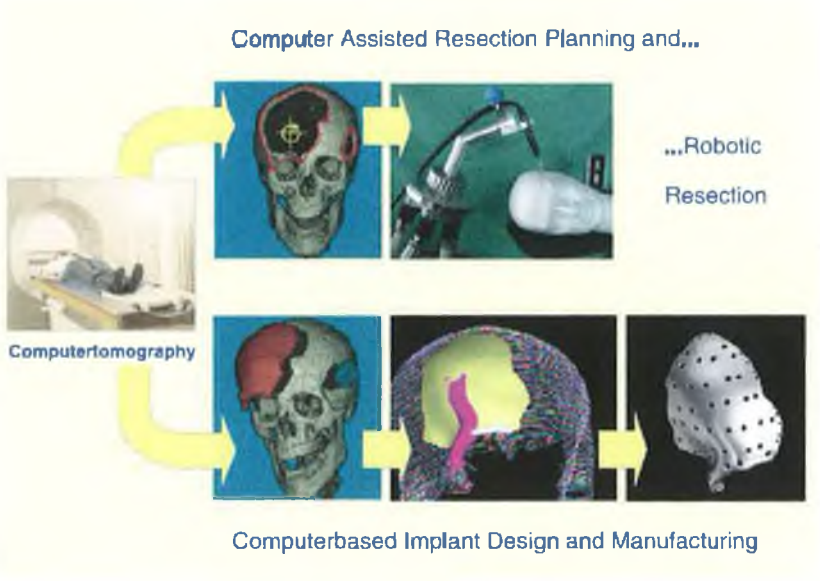


Figure 3.1 Currently used implant design technique [41]

The only patent which incorporates the use of rapid prototyping, CNC, customised tools and implants in maxillofacial surgery, applicable to the jaws, is Patent GB2138058 Three-dimensional modelling of maxillofacial implants, by Mr. Peckitt.

The present research study proposed the novel approach of 3D virtual design of large customised titanium implant for the full upper jaw (maxilla), contrasting to the designing method of Ninian Peckitt by marking up the RP model of the skull in order to obtain a prescription-fit implant.

3.2. CT scans data reconstruction and processing (MIMICS)

Currently, manufacturing of customized maxillofacial implants is quite laborious and involves more than one company (see Chapter 2, Figure 2.13), since up to now there are not known companies who can provide full service for manufacturing customised maxillofacial implants.

Interacting between physical and digital models can lead to errors and inaccuracies. Furthermore, the involvement of several companies not only raises this risk but also prolongs the production time of the implants, due to time elapsing during delivery. To save time and retain high precision, software can be used to replace the design steps that involve a physical model. Conventional software is capable of performing this task if it is used appropriately.

The present research programme was concerned with taking an existing, successful implant (Figure 3.2), further along the road of computer assisted surgery by considering that updating the design and manufacturing process, customised implants could benefit further with savings in unit manufacturing cost and time while achieving greater accuracy.

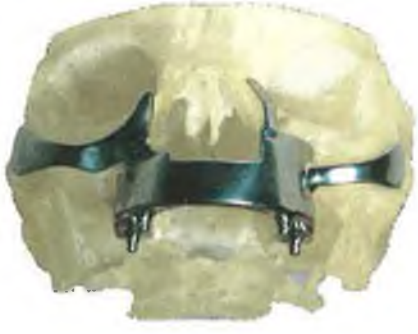


Figure 3.2 Customised maxillofacial implant designed on biomodel

With the purpose of finding the best way to design a precisely fitted prosthesis, several software packages have been evaluated in terms of their import functions, their capability to use imported 3D models as references, and their design capabilities. As a result of this work, an assessment of a number of design model generation methodologies was done to endorse the relevance for this application.

As the case report discussed in the research is the 81-year-old lady with squamous cell carcinoma of the mouth palate invading in the maxilla, the first step in designing a customised implant as a facsimile of the eroded bone was to use the CT scans of the skull for creating the 3D representation of the interest region. All the scans were acquired in axial mode. The images segmentation was performed using tools from the Materialise software packages and the PTC and DeskArtes CAD modelling software were used to design the maxilla implant.

MIMICS, from Materialise is a software suite that interactively reads CT/MRI data in the DICOM (Digital Imaging and Communication in Medicine) format, the international standard for interconnecting medical imaging devices on standard networks. The segmentation (with the use of the module *CT-convert*) and the editing tools available in MIMICS enabled the user to manipulate the data to select specific scanned regions as the bones of the face. Once an area of interest was separated, it could be visualised in three-dimensional and exported to CAD environment as STL (Standard Triangulated Language) file, to be visualised in 2D and 3D for design validation based on the anatomical geometry.

For the present research study, the skull CT images were available in DICOM format and they were read and reassembled in MIMICS software, in order to illustrate the 3D representation of the interest anatomic structure (Figure 3.3). The resulted 3D representation consisted of 170.268 triangles and was an exact representation of the anatomical shape of the skull.

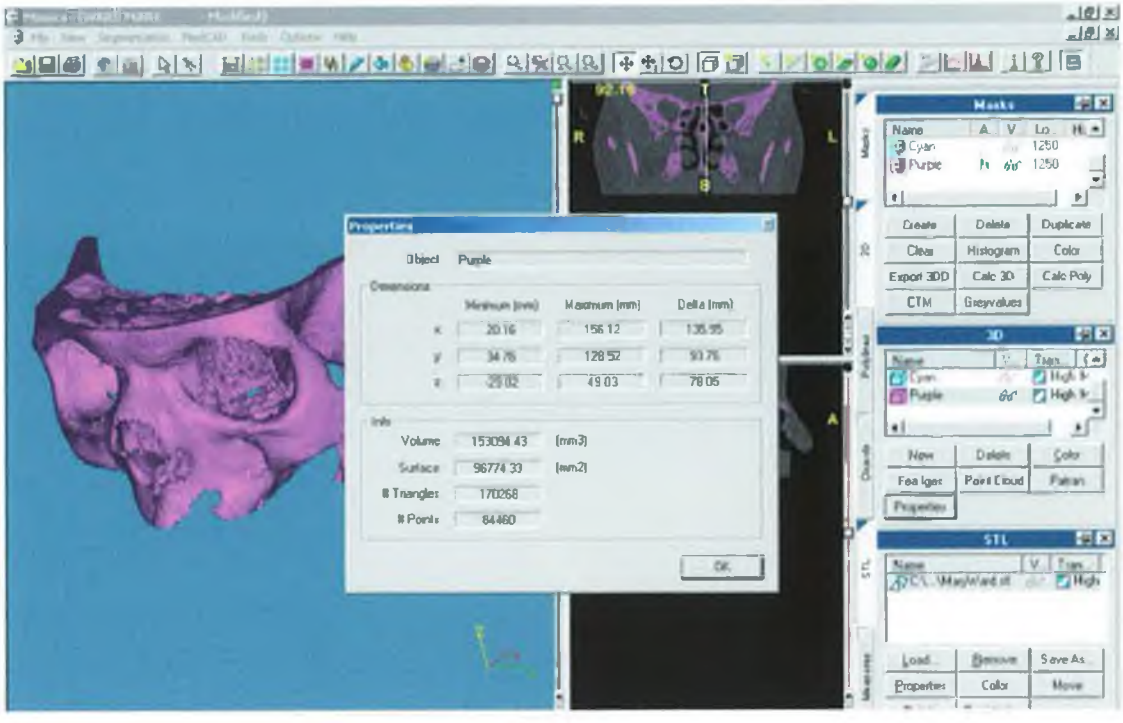


Figure 3.3 Three-dimensional model – MIMICS software

3.3. Studied possibilities of transferring the CT scans for virtual design of the prosthesis

Since the design capabilities of typical scan conversion software are limited, the 3D model needed to be exported to solid modelling software. Therefore, choosing an export format, which gives a good representation and allows further design was the initial task. Potential export formats were IGES (Image Graphics Exchange Specifications), STEP (Standard for the Exchange of Product Model Data), CLI (Common Layer Interface), VRML (Virtual Reality Modelling Language) or files for rapid prototyping – STL file, for instance.

The information to export could also be selected, and among the choices were:

(i) bone contours (polylines),

(ii) NURBS (Non-Uniform Rational B-Spline) curves and surfaces, calculated on the silhouette, and

(iii) 3D models (STL files).

Bone contours (Polylines)

Bone contours (Polylines) represent the basic geometric information on the bone topology, and are therefore highly geometrically accurate. The contours of the bone shown in each CT scan slice can be extracted as a polyline, which consists of a large number of lines segments. These polylines can be exported as an IGES file, a standard format that can be read by many applications.

Actually, IGES files contain information about surfaces and volumes. In the case of polylines, the line for each slice comes without a dimension in the scan direction (z axis), Figure 3.4. To close the gap between the lines resulting from scan-space the polylines can be used as a base to calculate a surface or a solid model in the CAE software. As a result of this, solid models can be readily created.

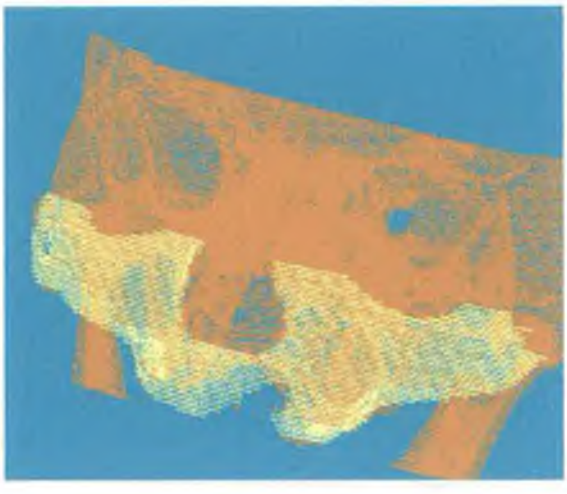


Figure 3.4 Bone contours from CT scan as polylines in IGES file

In some cases CAE software needs a watertight model to allow importation in terms of an IGES file. However, as a stack of lines represents the CT scan, there is no closed model available and IGES files cannot be used in these cases. Other packages allow the importation of lines, but a surface has to be put onto the lines in order to work with them. In Pro/ENGINEER, a surface calculated onto the lines went very rough because of the small lines forming the polyline were connected with another section in the next layer. The surface was closely tracing the sectioned polyline and therefore suddenly changing the direction of its normal (Figure 3.5). Such surfaces can be quite rough and the resulting representation is not accurate enough to use as a reference for prosthesis supports.

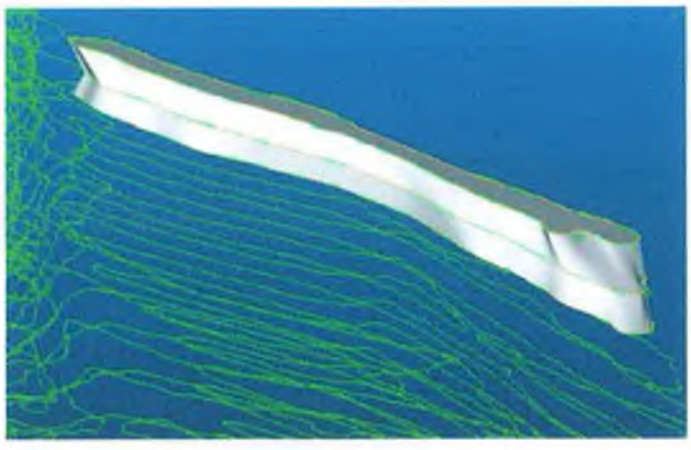


Figure 3.5 Surface calculated on polylines in Pro/ENGINEER

The polylines were imported in Pro/ENGINEER software for further processing in order to obtain a solid model which would have been used as reference for designing the implant. To be able to model the solid protrusion between the polylines, a spline curve was necessary to be created for each polyline, but it was proven that the computer-calculated spline curve was not following the bone contour (Figure 3.6). The protrusion creation process between the polylines for creating the reference surface of implant design was considered inefficient and inaccurate (the measured dimensional deviation from the actual bone contour was varying between 0.2-1 mm) and different export formats needed to be further investigated.

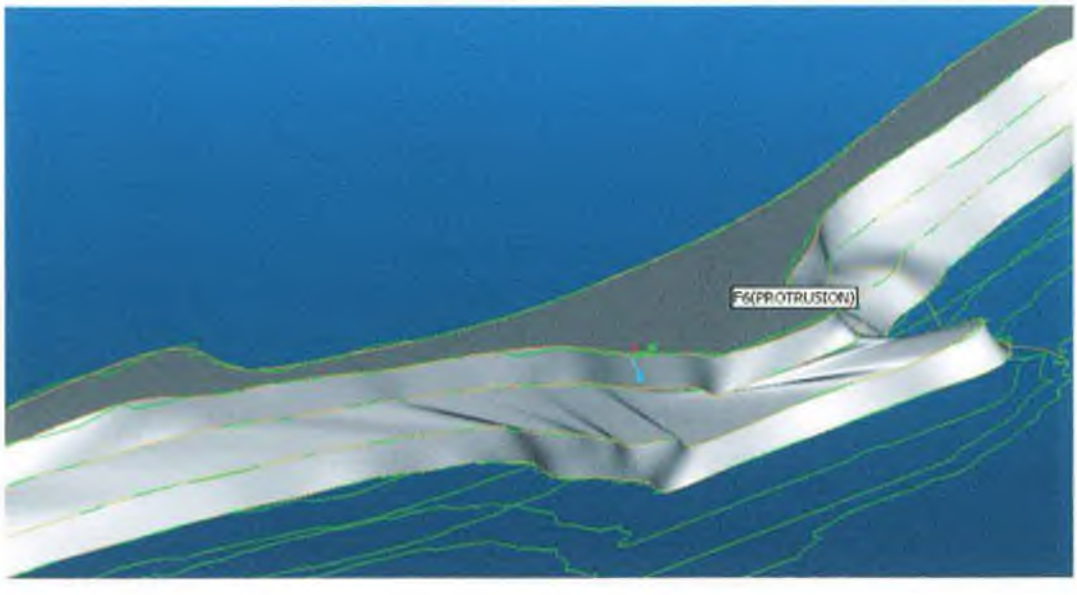


Figure 3.6 Protrusion on polylines (Pro/ENGINEER)

NURBS

NURBS curves and surfaces (Figure 3.7) can be generated in scan conversion software (MIMICS) or in CAE packages (such as Pro/ENGINEER). Calculated on the information given by the CT scans, they provide a smooth, good looking representation, but when compared with the actual bone contour it can be clearly shown that their accuracy strongly depends on the parameters given by the user for the calculation (e. g., number and position of control points, degree of polynomial etc.) and sometimes they turn out to be too wavy.

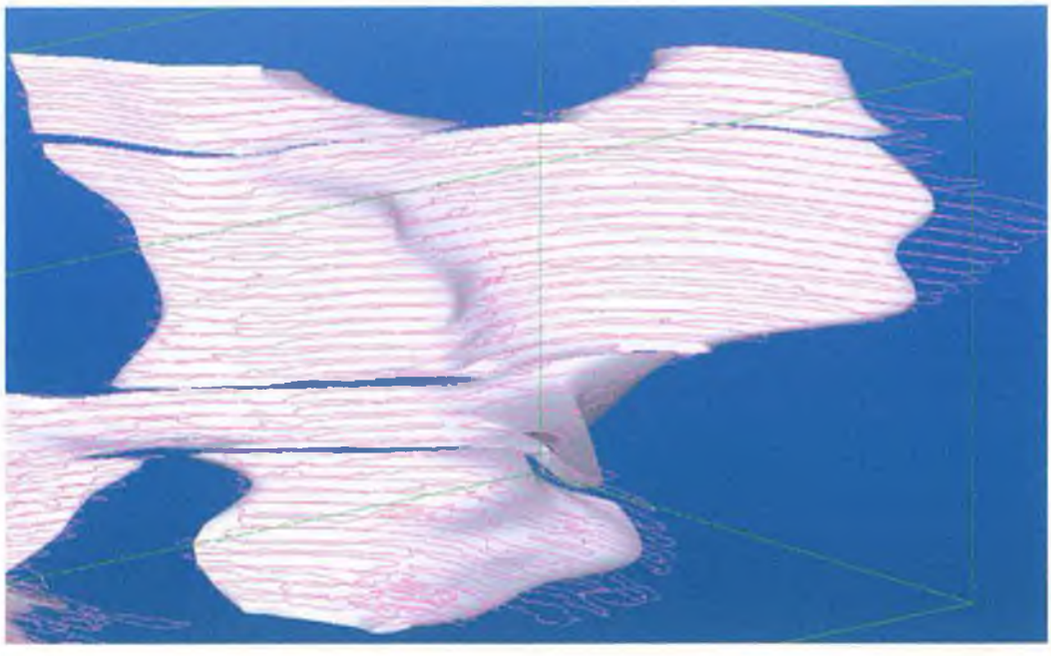


Figure 3.7 NURBS curves and surfaces based on bone contours

These surfaces were imported in Pro/ENGINEER for further design and their inaccuracy was proved. If the imported surface would have been used as reference for implant supports design, the regions with the deviation from the actual shape of the bone would have created gaps between the supports and the bone surface, which would have led in the end at implant loosening. To sustain this affirmation, the NURBS surfaces and the 3D skull representation were superimposed (Figure 3.8) and their inaccuracy could be easily seen and measured (maximum deviation of 0.6 mm).

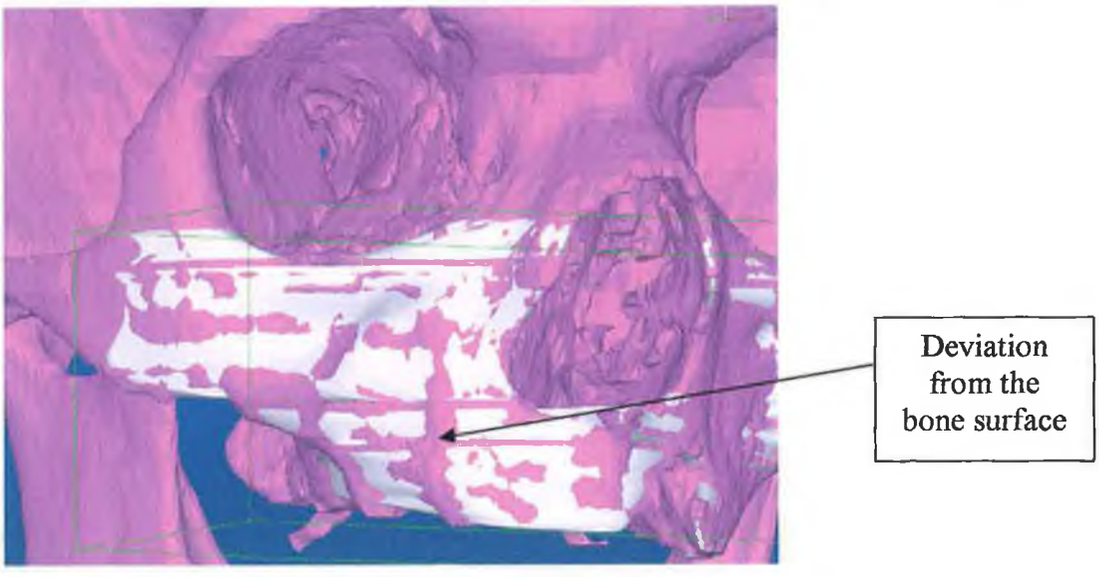


Figure 3.8 Superimpose of NURBS surface and 3D model

3D models (STL files)

The 3D representation shown in the scan conversion software MIMICS can be exported as a 3D model. There is a choice of several formats, some of which are used for direct manufacture on RP machines, such as *.STL (Standard Triangulation Language), *.SLC, *.SLL.

The STL file was conceived by 3D Systems for its SLA (stereolithography apparatus) machines and has become the standard input for almost all the RP systems. It consists of an unordered list of a mesh of connected triangular planar facets representing the outer skin of an object (Figure 3.9).

Figure 3.9 STL file (wire frame view)

As the STL file is a facet model derived from a precise geometry, it is considered to be an approximation of the particular geometry. The more triangles are used in the representation of the model, the more accurate is the approximation. The STL export format (Figure 3.10) has the advantage that it can be read by many solid modelling software allowing further design for a precise-fit, customised implant.

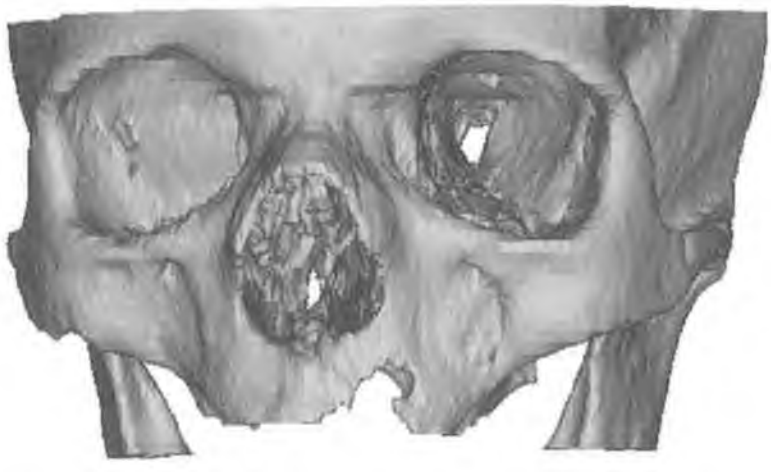


Figure 3.10 Three-dimensional model (STL file)

The contour of this model proved to be the same as the contour of the specific anatomic structure and therefore is its **most accurate representation**. Therefore, this constituted the MIMICS export format chosen for further design of the maxillofacial prosthesis.

3.4. First approach for design of the implant (Pro/ENGINEER and MAGICS RP)

Two methods were used for improving the design process of the prosthesis for maxilla. For the first method of designing the prosthesis, the CT scans converted to 3D models were successfully transferred to CAE software, using MIMICS software. A customised implant and its supports were designed on the virtual representation on the patient's anatomy.

For designing the main structure of implant, Pro/ENGINEER solid modelling software by PTC (Figure 3.11) has been examined.

Pro/ENGINEER is one of the solid modelling software that enables frequent virtual prototyping. It enables also the simulation and the design of a part to be performed simultaneously within a single development environment.

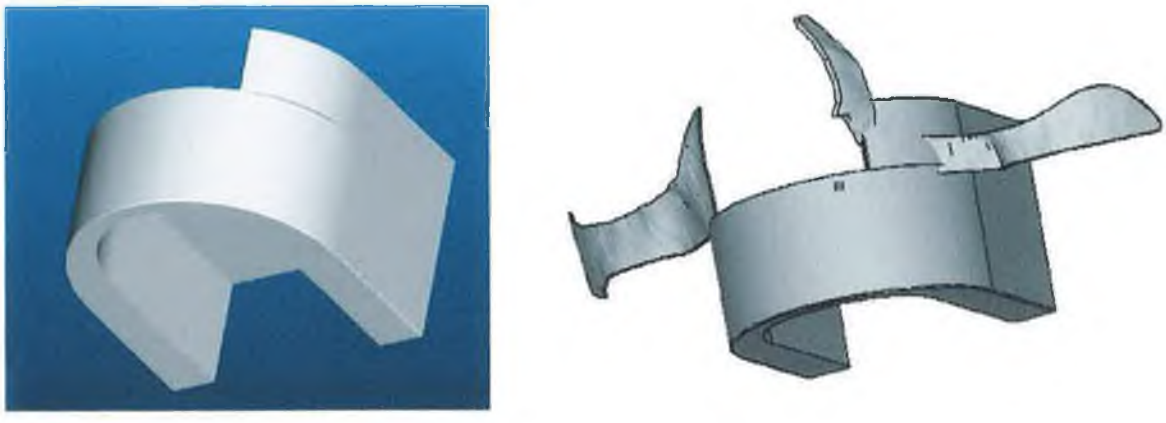


Figure 3.11 Body of implant technically designed in Pro/ENGINEER

The software has been evaluated on a basis of its abilities to import the 3D representations, to use them as reference to design on, and its design capabilities. Tests with this software package have shown that it is inconvenient or even impossible to import the STL files from MIMICS due to huge amount of data. In Pro/ENGINEER, the STL models can be viewed but not used as reference for further design, and they cannot be changed.

Though, considering the measurements of the bone structures in MIMICS, the body of prosthesis was designed independently in CAD environment (Pro/ENGINEER) using common technical techniques, and then exported as STL file to MAGICS RP software for further development (software used under evaluation licence).

MAGICS RP (Materialise, Belgium) is software for manipulation of STL files and among the offered functions one can find:

- Visualisation, measuring and manipulation of STL files,
- Fixing STL files, uniting shells, trimming surfaces,
- Cutting STL files, punching holes, extruding surfaces, hollowing, applying offset,
- Boolean operations, triangle reduction, smoothing, labelling,
- Colouring STL files.

With the tools provided by this software, the surface of the 3D model (STL representation) of the skull can be used to design the supports fitting exactly to the bone. The forces resulting from gravity will be transmitted to the skull by the prosthesis's supports, so their shape needs to be very accurate. Since the supports have a complex shape and they strengthen the idea of a customised implant, it seems to be the best way to design them using this software. The design of these wing-like plates specific for each patient was achieved in a fast and convenient way. These parts needed to be expanded where they will be connected to the prosthesis and after placing the imported prosthesis among the supports (Figure 3.12) and on the skull, the models of the supports and prosthesis could be merged to get one part using Boolean operations. It was compulsory that supports and prosthesis intersect to merge them to one single part.

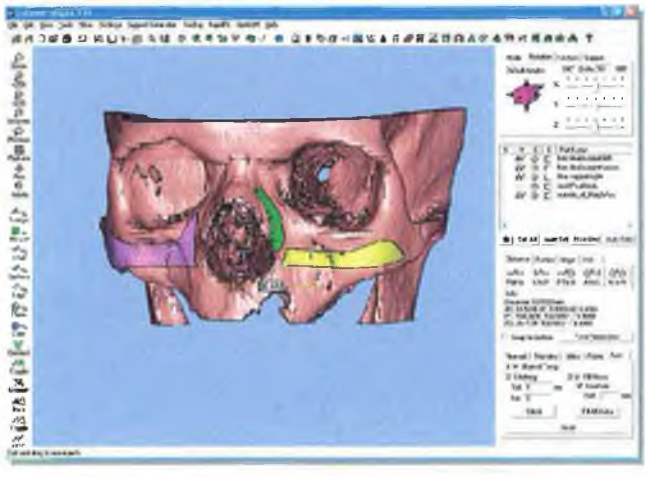


Figure 3.12 Supports of the implant designed in MAGICS RP

The whole virtual implant consists of one part, which can be cast or build by rapid manufacturing techniques (Figures 3.13).

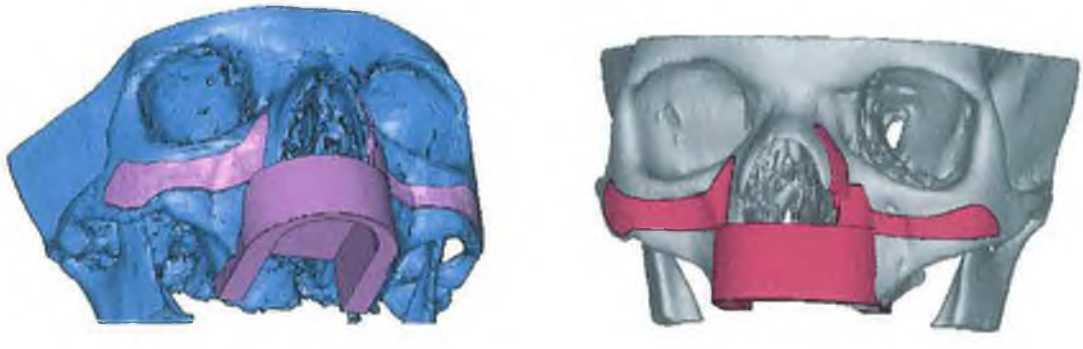


Figure 3.13 Full customised implant designed with respect to virtual model

3.5. Second approach for design of the implant (3DATA EXPERT – DeskArtes)

Biomechanical design work is closely related to sculptural work. The human body does not have sharp corners or edges, thus is necessary to select CAD software that is good enough to give the model the irregular shape.

To have a more accurate facsimile of the real bone structure, as a second approach of designing the prosthesis, the CT scans were edited in MIMICS. The defect bone was corrected by filling the hole and removing the tumour in the scans (Figure 3.14).

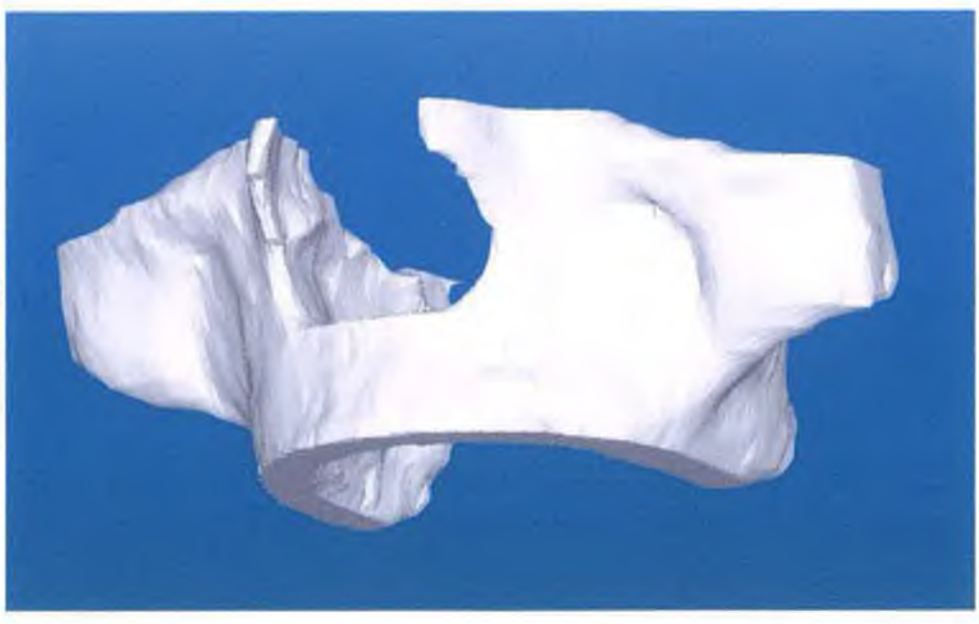


Figure 3.14 Repaired bone structure

The wide variety of modelling capabilities offered by the **3DATA EXPERT** from DeskArtes made it suitable for implant design (software used under evaluation licence). DeskArtes 3Data Expert is a tool for repair, conversion and manipulation of 3D CAD data. The base module includes positioning, transformation and repair of STL geometry, allowing also cutting parts with a curve and combining models, as well as shelling of STL models.

Segmented data of the skull was translated into STL file format in MIMICS and imported into the CAD environment. Including the STL file in DeskArtes environment also offered another advantage. It allows the file to be checked and repaired if the

conversion software had made any omissions. The STL file was checked for any defects using 3Data Expert and was found to be error free. The CAD environment also allows for both the surgeon and the designer to determine the critical dimensions and the mass properties from the CAD model.

One limitation of the procedure is the fact that there is a trade-off between the file size and the tolerances of the triangles. Taking a higher tolerance leads to a bigger file, slowing down the computer, while lower tolerance reduces the overall file size but leads to a simplified irregular model.

Considering the reference surface of the skull, the supports of the prosthesis were designed to maximise the overall attachment of the implant and to prevent loosening. Using the cut command, points were set onto the surface being automatically connected by a line which marked the section to be cut. The cut penetrated to whole part, but only the front surface was needed. Therefore, all other regions had to be removed by deleting the triangles. An offset of the kept surface created a plate with the demanded thickness. The operation was repeated to create the other supports. Their shape, length and position was arbitrary chosen by the researcher considering the thickness and structure of the bone for further screw attachment (Figure 3.15). In order to ensure the necessary stability, it is vital to position the implant into the host bone so to achieve the highest bone-implant contact area, and in particular with the denser bone tissue (cortical bone).

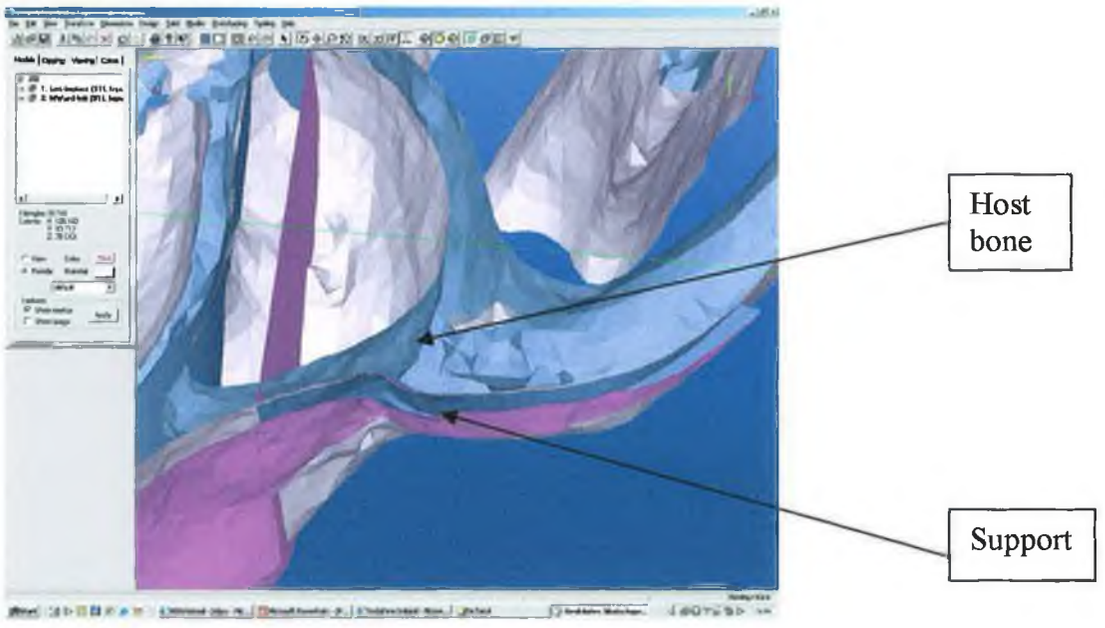


Figure 3.15 Bone-implant contact area for screw attachement

The main structure of the prosthesis was designed to the nearest/exact shape of the imported maxilla STL file just through cutting option, and combined with the supports afterwards using Boolean operations. The "naturally bone-shaped" prosthesis can be seen in Figures 3.16 and 3.17.

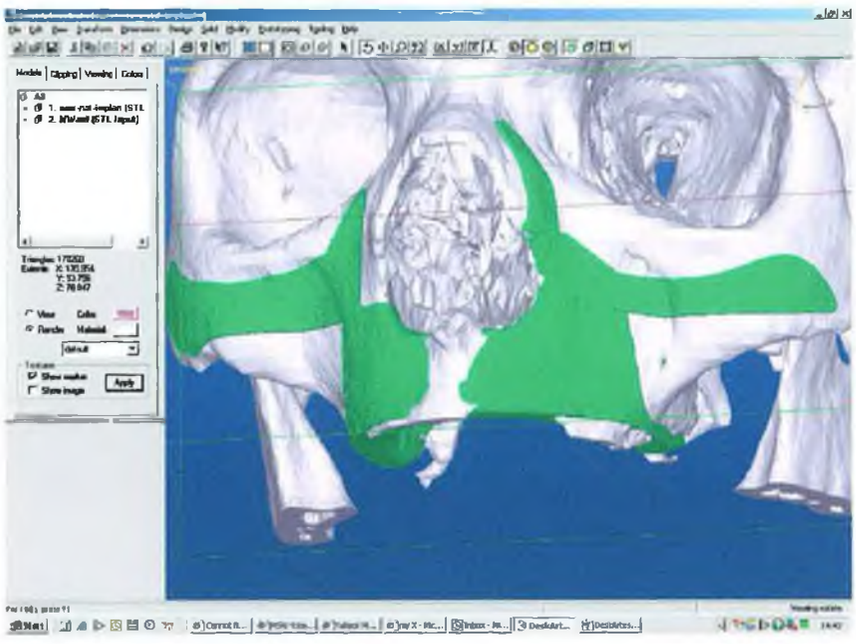


Figure 3.16 Virtual customised implant designed with respect to virtual model

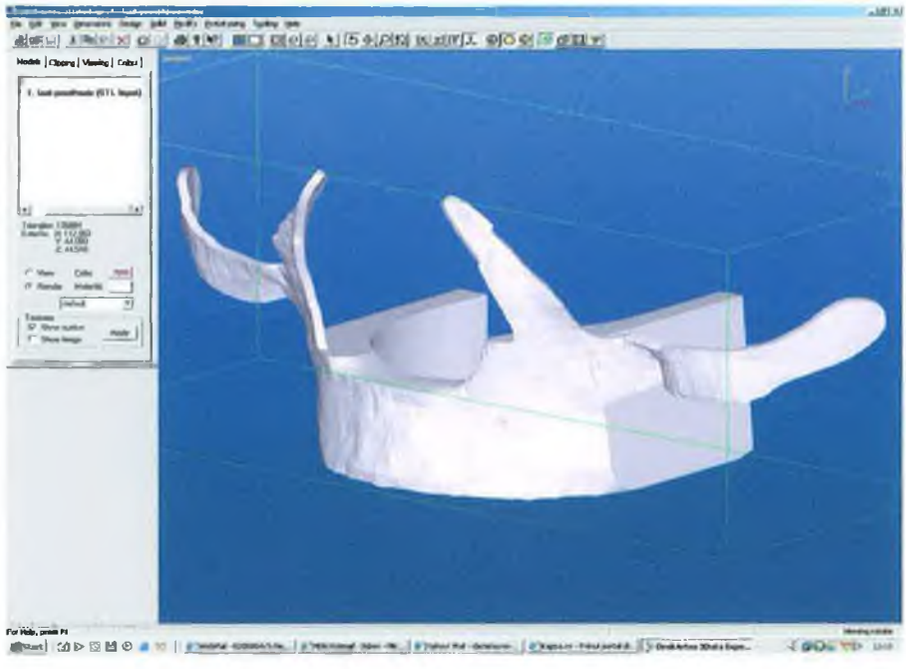


Figure 3.17 "Naturally bone-shaped" prosthesis

For viewing and handling purposes, samples of the implant and the corresponding skull have been rapid prototyped as two parts, both by researcher (through 3D Printing RP technique – Z Corporation,US) and collaborators from NCBES, NUIGalway (through SLS RP technique). Following the SLS process, the implant fitted perfectly to the skull model, no postprocessing being necessary, comparable to 3D Printing technique where the manufacturing tolerances have been exceeded and further processing of the implant (milling) was necessary to ensure the perfect fit between the skull and the prosthesis.

The usage of STL files brings as well the advantage that they can be easily transferred to the rapid prototyper, for the manufacturing process of the implant and be also imported to FEA software for stress analysis simulation.

Titanium Investment casting manufacturing process

The shape of the obtained maxillofacial implant was saved as STL file. In order to proceed with the research at GMIT, a Titanium Investment Casting company was contracted for further manufacture of the implant. The STL file was sent in digital format to the casting company, which created as well the mould for casting. The mould consisted in an SLA RP model as seen in Figure 3.18.

Figure 3.18 SLA RP model used as mould for casting

The titanium cast implant (Figure 3.19) was materialised with the required specifications (Ti6Al4V material, full volume for the body of the implant, as-cast

condition, + 1.5 mm manufacturing tolerances) and sent back to GMIT for further investigations (testing, measurements).

Figure 3.19 Titanium cast implant

3.6. Conclusions

Three methods for exporting the specific anatomic region for further customised implant virtual design were investigated and they can be summarised and compared as follows. The bone contour method has the advantage that one gets an accurate representation of the CT data, at least in the context of each slice. The main disadvantage is that in creating the surface between widely spaced scans, the resulting geometry can become excessively rough. NURBS surfaces and surfaces based on NURBS curves have the advantage that they can be created in scan conversion software or in CAE packages and are very smooth. However, geometrical accuracy can be poor. 3D model formats can be created in scan conversion software and have the advantage that represents the accurate geometry of the specific anatomic region, allowing further design of the customised implant.

Two approaches were considered in optimising the existing design process of the maxillofacial implant. The first consisted in technically designing the implant in Pro/ENGINEER and MAGICS RP, and the second conserving the actual shape of the bone when designing by making use of the capabilities of 3DATA EXPERT (DeskArtes) software.

By superimposing the technically and naturally bone-shape prostheses on the 3D representation of the skull, conserving the actual shape of the excised bone during the operation proved to be the best possible route for designing a customised, perfectly fit maxillofacial implant (Figure 3.20).

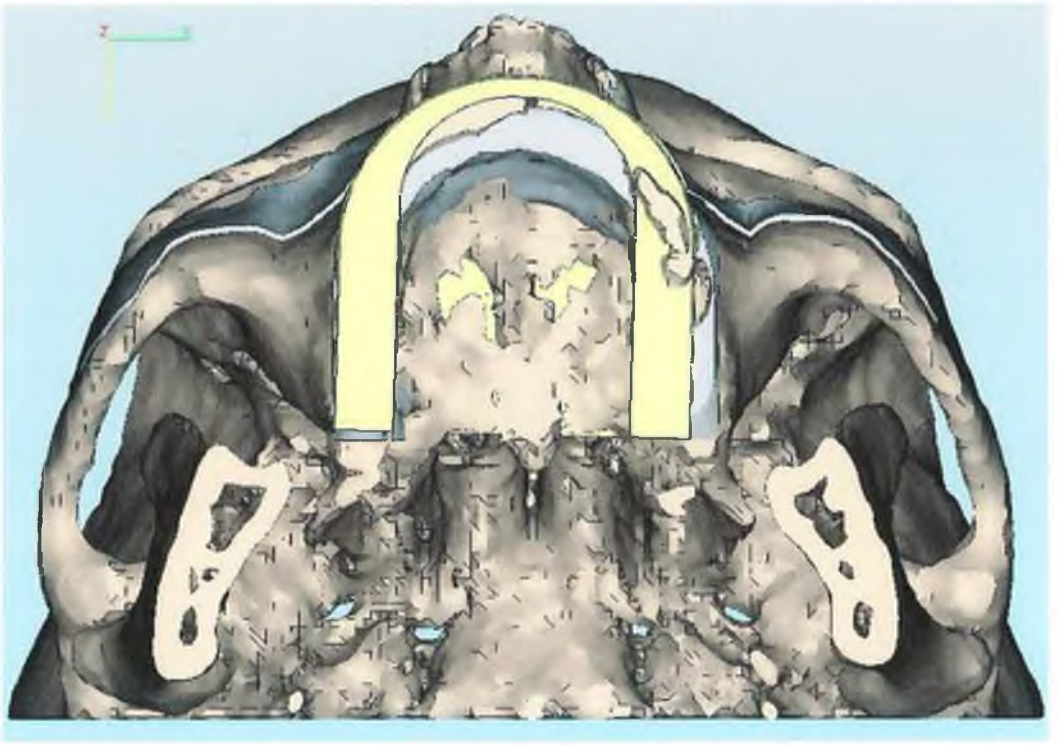


Figure 3.20 Superimpose of technical and bone-shaped prostheses

Some advantages of the bone-shaped, customised prosthesis over the technically designed one can be summarised, as follows:

- A better/perfect fit of the implant, not allowing the gaps to lead to implant loosening is ensured,
- There is an aesthetic implication (avoid the aspect of a huge, overdesigned implant),
- The same volume of the excised bone will be replaced by the implant.

By comparison with Ninian Peckitt's implant design approach, an optimised virtual implant design process was developed for customised maxillofacial implants in order to conserve the actual shape of the excised bone and to avoid the errors and inaccuracies occurred during the RP model based surgical preplanning and CNC-milling of the titanium implant.

As the implant design task constituted the centre of the overall objectives of the research study, it is considered that it was completed successfully. In other words, a **computer-based design method** has been developed for effective visualisation, communication and modification of the crucial aspects of the design between the surgeon and the engineers.

An important issue to be dealt with at this designing of the implant task, which is integral to the whole concept of the streamlined design to manufacture technology, was the incorporation of the surgical input with engineering know-how that resulted in the **most optimal design**. Though the surgeon still might have improvements for the design of the prosthesis, implementing these can be done quickly.

CHAPTER 4

FINITE ELEMENT ANALYSIS (FEA) OF THE MAXILLOFACIAL PROSTHESIS

4.1. Aspects of Biomechanical Considerations and Justification of Work

To be successful, all medical implants, whether oral, maxillofacial or orthopaedic, must withstand in vivo loads and deliver them to surrounding interfacial bone tissue in a safe manner.

The biomechanical considerations in the design and performance of prosthetic reconstruction with titanium implants consist of:

- knowledge about loading the implant in vivo,
- the nature of osseointegrated attachment system which transmits the stresses applied on the implant to the bone,
- understanding implant-bone interfacial stress transfer,
- appreciation upon implant or bone interface failure.

Each of these biomedical aspects will be commented upon for the purpose of justification of the finite element analysis carried out in the research.

The fact that maxillofacial implants can perform succesfully many years [9] indicates that such implants can transfer loads from the implant to the bone without

progressive failure or loosening. The magnitude of the bite forces in patients with osseointegrated implants have been shown to be comparable with the ones of the patients with natural dentition. Load-transfer at the bone-implant interface depends on [42]: type of loading, the material properties of the implant and prosthesis, the nature of the bone-implant interface, the quality and quantity of the surrounding bone, the implant geometry, length, diameter and shape and the implant surface structure. Even if extensive data is not available in the literature regarding the failure loads of the implant, the clinical experience indicates that failure loads are well above the usual bite forces [42].

For dentate human, the maximum bite force varies between individuals and different regions of the dental arch. The greatest maximum bitting force reported to date is 443 kg N [43]. It is considered that dentate patients have 5-6 times higher bite force than denture wearers [44].

The patients with implant-supported fixed prosthesis have a masticatory muscle function equal to or approaching to that of patients with natural teeth or with tooth-supported fixed dentures [45].

Haraldson and Carlsson [51] have measured **15.7 N** for gentle biting, **50.1 N** for biting when chewing and **144.4 N** for maximal biting for 19 patients. Carr and Laney [46] reported maximum bite forces between 4.5 and 25.3 N before and 10.2 – 57.5 N after 3 months of treatment with implant-supported prostheses and considered that the amount of increase was dependent on the duration of patient being edentulous. Mericske-Stern and Zarb [47] measured an average value of maximum occlusal force lower than 200 N for first premolars and molars and 300 N in second premolars. These data suggested that implants placed in the posterior region of the mouth are at greater risk of overloading (Figure 4.1).

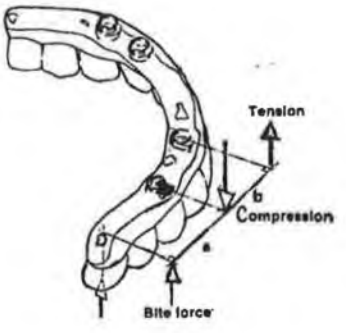


Figure 4.1 Forces on dental implants and interfacial stress transfer [48]

When a load is applied to an implant supported by osseointegrated attachments, two stages of load transsmision are important for the successful performance of the entire design. First is the consideration of the distribution of the load to the several osseointegrated screws supporting the prosthesis. Secondly, the load picked up by each screw must be transmitted safely to the bone without producing any fracture of the bone or loosening of the screw.

Of particular interest from the biomechanical factors is the endosseous interface, which develops within the bone of maxilla at the contact with the implant and attachment system. This interface is affected by several variables, including implant material, implantation procedures, bone quality and quantity at the implant site, healing potential of tissues at the implant site, and a number of biomechanical factors such as the forces on the implant, the details of stress transfer to tissues and biological reactions of interfacial tissues to the loading conditions.

The implant loads and forces can be distributed in various ways, depending on a number of factors [49]:

- The nature of mastication: frequency of chewing, strength of bitting, sequence of chewing cycle, mandibular movements, static versus dynamic bucal activities,
- The nature of prosthesis: full or partial dentures, tissue-supported or implant-supported prostheses, location of the prosthesis, angulation of the implant,
- The biomechanical properties of the structures and materials comprising the prosthesis, implants and bones: elastic modulus, stifness, nature of connection between implant and bone and deformability of the mandible or maxilla.

In all incidences of clinical loading of the implants, occlusal forces are first introduced to the prosthesis and then reach the bone-implant interface via the implant. Many researchers have focused on some of the steps of force transfer to gain understanding of the biomechanical effects of factors such as [50]: force directions, force magnitudes, prosthesis type, prosthesis material, mechanical properties of the bone-implant interface.

Considerations of the stress and strain distribution in an implant include the safe level of stresses and functionally satisfactory performance of the implant without failure in-service.

Since titanium implants are generally stronger than bone, any failure at the interface may be expected to be in the bone, or in the bone interface with titanium, rather than in the titanium implant. Taking into account the properties of titanium (Young's modulus of 114 GPa and yield strength in tension of 825 MPa) and of cancellous bone as maxilla (Young's modulus of 10^{10} N/m^2 and tensile failure stress of 5 x 10^7 N/m^2) it may be expected that when an implant is stressed, the titanium will be deformed much more less than the bone. This proves the significance of quality of the bone around the implant.

Implants are demonstrated to have less micromovement, increased initial stability and reduced stress concentrations in high density bone and a bone with low density is prevalent in the maxilla. Clinical healing time recommendations after maxillofacial surgery are a minimum of 3 months for dense bone, as in the mandible, and 6 months for cancellous type bone, as in the maxilla.

The original prosthesis created by Mr.N. Peckitt was loaded through the region of the base of the resected pterygoid plates and through these to the base of skull and also through the zygomatic flanges across the frontozygomatic suture and zygomatic arch to the calvarium and temporal bone. The implant was not loaded occlusally for 6 months postoperatively, after which a lower denture was constructed, rather than an implant-retained overdenture; this reduced the mechanical loading of the implant [28].

Current techniques employed to evaluate the biomechanical loads on implants comprises the use of mathematical calculations [51], photoelastic stress analysis [52], 2D or 3D finite element stress analysis [53, 54] and strain-gauge analysis (SGA) [55,56]. Since an almost actual representation of stress behaviours can be precisely provided, three-dimensional finite element stress analysis (3D FEA) has been introduced as a superior theoretical tool over 2D finite element stress analysis. It should be also emphasised that the FEA analysis is an approximation method for the representation of both deformation and three-dimensional distribution of stress in bodies that are exposed to any kind of stress.

The vertical loads from mastication induce axial forces and bending moment which result in stresses applied to the implant as well as in/to the bone. 3D FEA has been widely used for the quantitative evaluation of such stresses on the implant and its surrounding bone. Therefore, FEA was selected for use in this study to examine the effect of the type of loads on the stress distribution for the proposed geometry of the

maxillofacial implant developed in the present research. To gain insight in the biomechanics of maxillofacial implants, the purpose of this study was to determine the maximum level of stress induced in the implant when applying the maximum bite force with the values identified in the specialised publications.

4.2. Pre-processing of Prosthesis as STL format (HYPERMESH)

The STL files obtained from the conversion and 3D reconstruction of the CT scans present the advantage that can be imported to FEA software for simulation. Even though powerful software packages are available already, it was necessary to investigate for new pre-processor software that can handle and work with the STL files. The STL mesh of the parts was assessed as not suitable for direct calculations using FEA, since the elements are very irregular in size and shape (Figure 4.2).

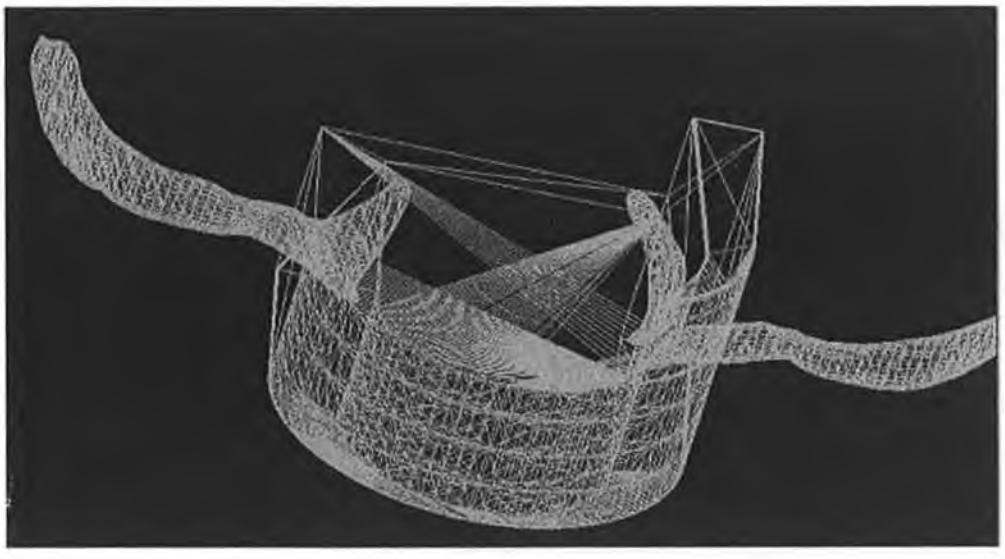


Figure 4.2 STL irregular mesh of the prosthesis

Re-meshing of the prosthesis components was a crucial task. **HYPERMESH** software from Altair Engineering, UK can import STL data and has many possibilities to create and manipulate the mesh.

HyperMesh software as part of HYPERWORKS package from Altair Engineering is a high-performance finite element pre-processor for major finite element solvers, allowing engineers to analyse design conditions in a highly interactive and visual environment. HyperMesh's user-interface supports the direct use of CAD geometry and

existing finite element models, providing robust interoperability and efficiency. HyperMesh simplifies the modelling process for complex and irregular geometry through high-speed, high-quality automeshing [57].

Due to the nature of the STL files of irregular shapes as the maxilla, the imported afferent files from solid modeller software DeskArtes needed a lot of handwork before a proper mesh could be produced. Much time and effort was expended to get a model being able to be meshed (Figure 4.3).

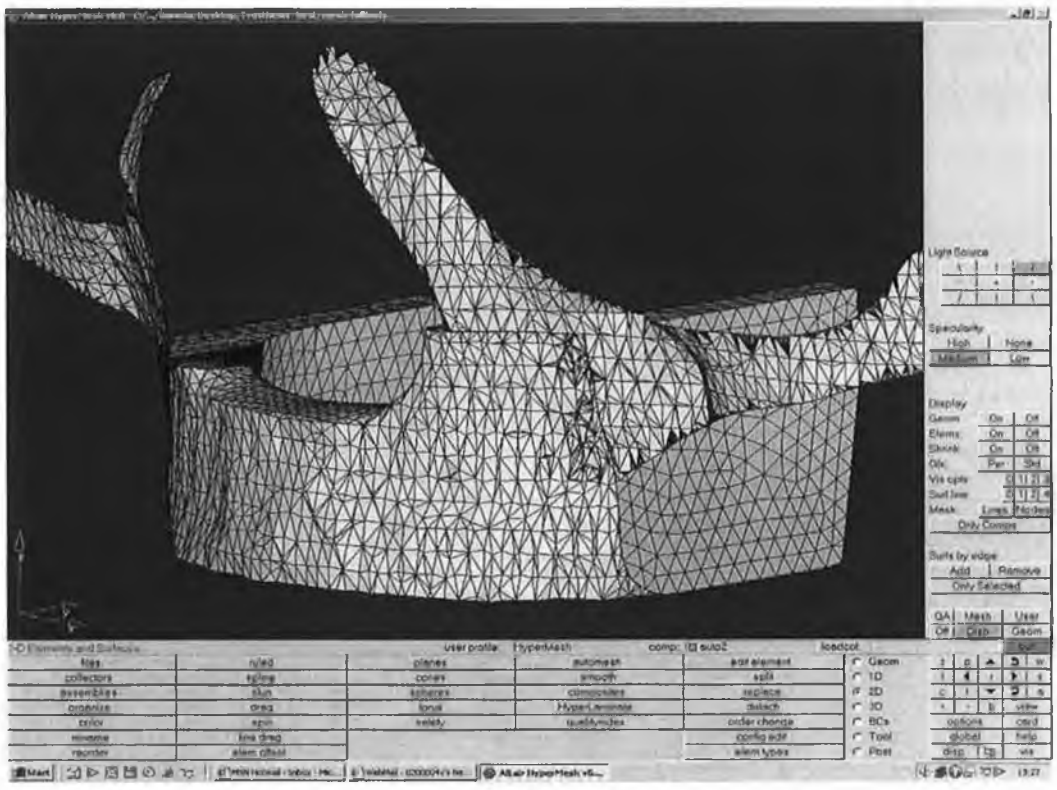
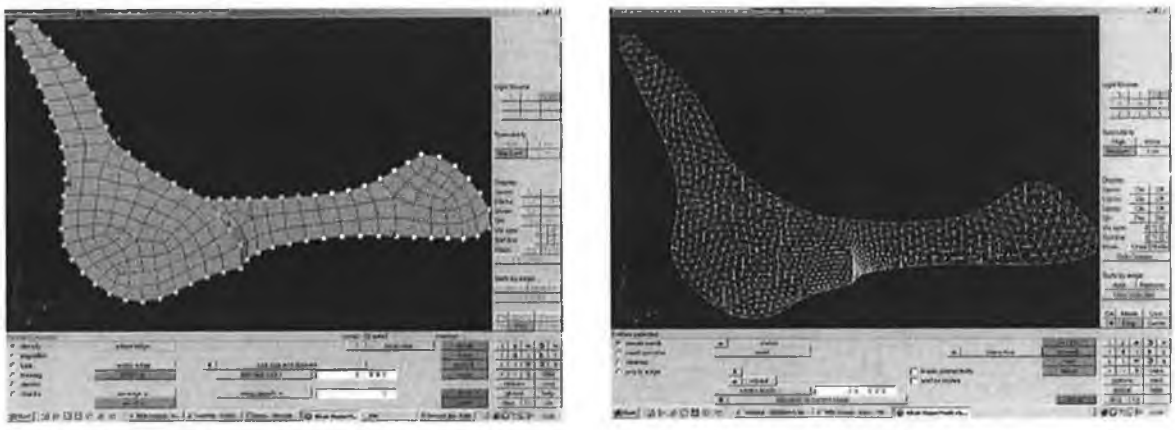


Figure 4.3 STL mesh partially worked on using HyperMesh

The wings like supports and the main structure of the prosthesis were meshed using shell elements. Needle shaped STL elements at the edges of these parts, resulting from the design route, had to be identified and removed by hand to achieve a suitable base for meshing. Figure 4.4 shows the supports after removal of STL artefacts and meshed using different mesh element types.



(a) (b)

Figure 4.4 Different mesh element types in HyperMesh (a) quads and (b) trias

The currently designed main structure of the prosthesis was better being meshed separately due to its irregular shape. The high numbers of STL elements and the complex shape of the "naturally shaped" implant required much time and effort in fine-tuning of the settings for the meshing procedure. Furthermore, reduction of the number of triangles representing the implant was necessary. The prosthesis was successfully meshed using shell elements, the model consisting in full, watertight volume with no free edges. The success in generating a mesh on the simplified model of the prosthesis (Figure 4.5) was a breakthrough in this task.

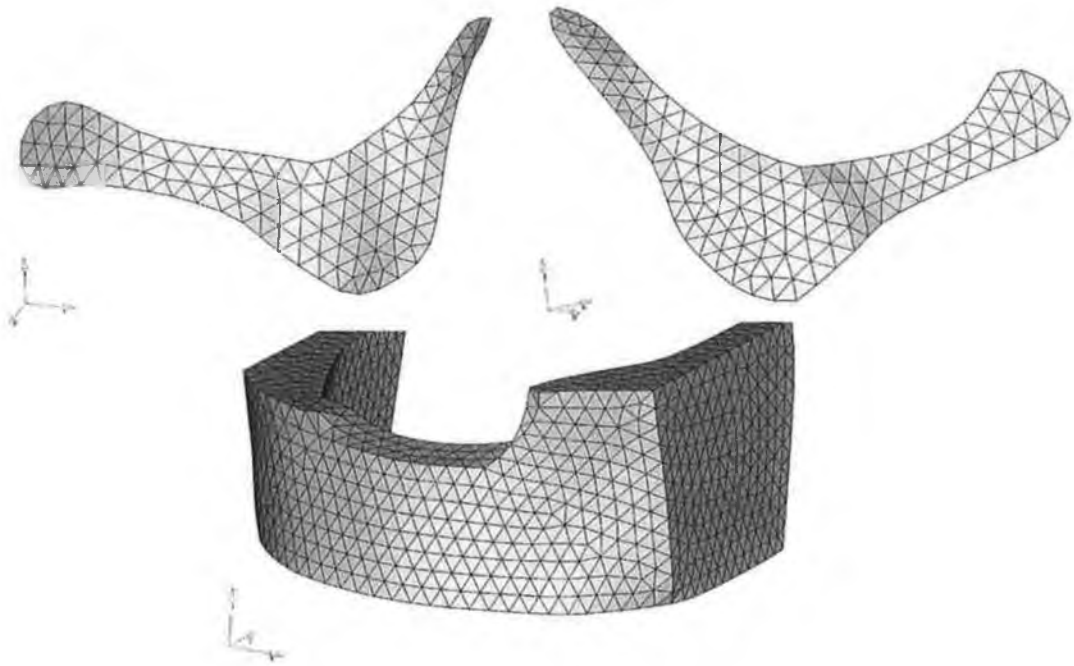


Figure 4.5 HyperMesh STL meshes of the component parts of prosthesis

4.3 Processing the Static Stress Analysis of Prosthesis (ANSYS)

The FEA software used to perform the stress distribution calculations for present research was **ANSYS version 7.0.** ANSYS FEA software designs, develops, markets and globally supports engineering simulation solutions used to predict how product designs will behave in manufacturing and real-world environments. ANSYS offeres associativity with different solid modeller softwares such as Inventor, Mechanical Desktop, SolidWorks, Por/ENGINEER, Unigraphics and can read input files from different other softwares exported as template files for ANSYS. The meshing option from ANSYS allows meshing using solid and shell elements, auto-mesh sweeping with tetrahedral or hexagonal elements, initial mesh sizing control, as well as manual mesh refinement [58].

The separate modelled and refined components of the prosthesis (supports and main structure) using HyperMesh software were saved using ANSYS template file export format. In order to be able to read all three files in a single one in ANSYS, a renumbering option was applied. The body of the implant consisted of 2774 elements and 1389 nodes, the left support – of 327 elements and 209 nodes and the right support – of 282 elements and 180 nodes, all numbered consecutively. The exported files from HyperMesh were imported and linked together successfully in ANSYS, as it can be seen in Figure 4.6.

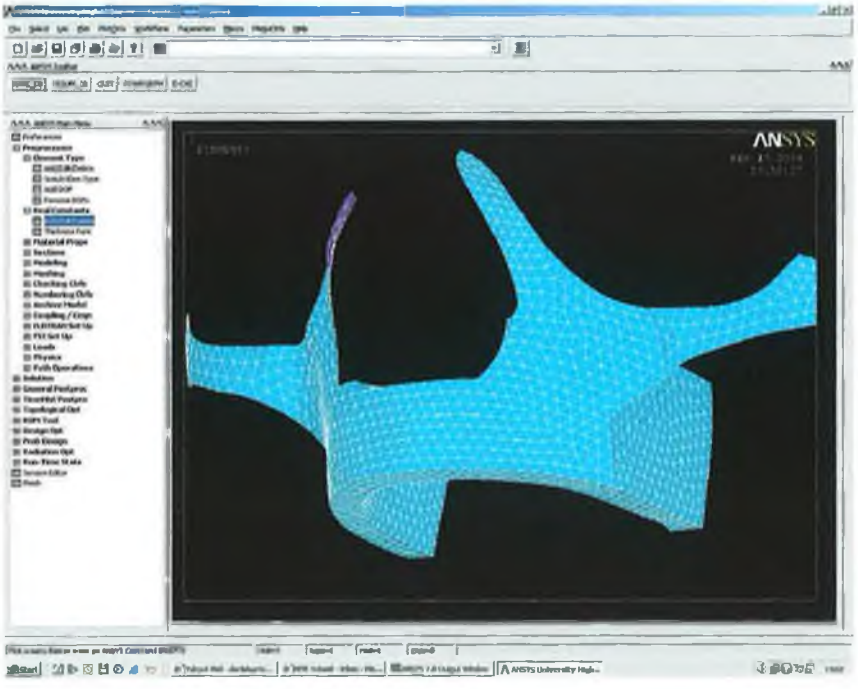


Figure 4.6 ANSYS imported model of prosthesis for stress analysis calculations

To perform the calculations in ANSYS software, the following were the input parameters for the stress analysis of the assembled model of the implant:

- Static analysis performed
- Meshing element type: SHELL63
- Real constants: Thickness of 1.4 mm
- Material properties of Ti6Al4V: Youngs's modulus – 114 GPa, Poisson ratio – 0.33
- Material type: Structural Linear Elastic Isotropic.

The full assembled prosthesis was remeshed in ANSYS using triangular elements with an edge size of 2 mm.

The average bite force determined from literature was 144 N and it was equally static distributed in the calculation model in 4 locations. Each of them consisted of 4 nodes. The 4 locations of force application were assumed to be the 4 locations of the abutments for overdenture attachment, as they constitute the means of transmitting the loads to the full implant. Overall, the 114 N total force was equally distributed on 16 nodes (nodes 106, 114, 115, 116, 139, 143, 144, 145, 229, 230, 231, 257, 275, 271, 283 and 285), on each of them with a magnitude of 9 N (Figure 4.7).

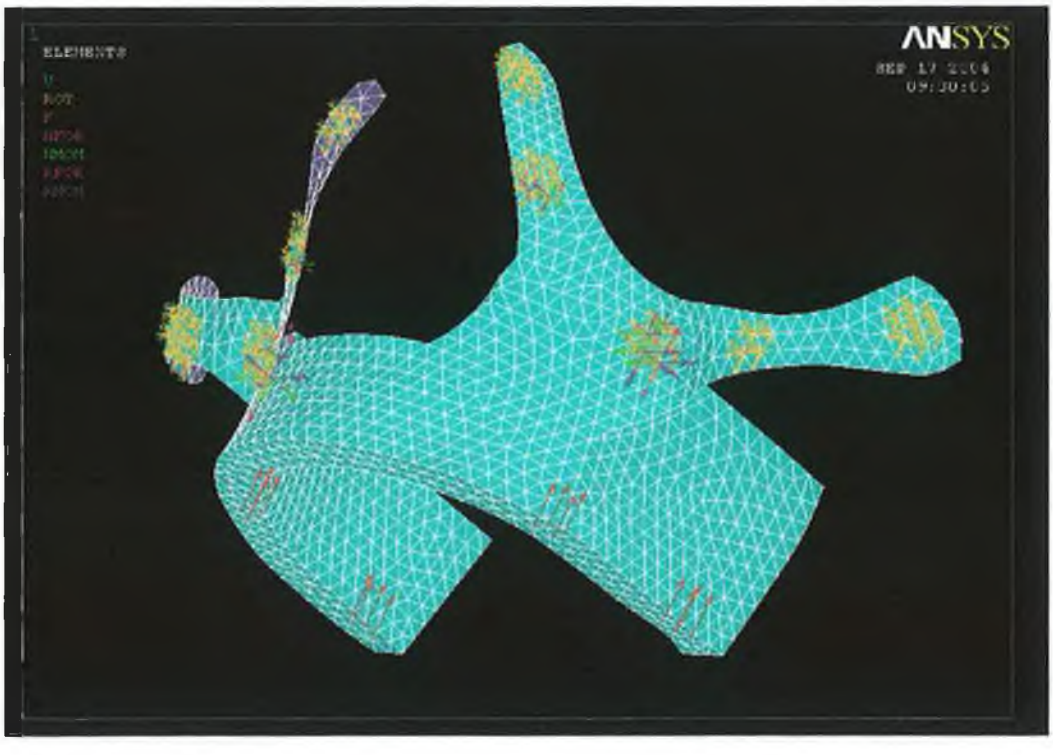


Figure 4.7 Loads and constrains for static stress analysis

In order to restrain the prosthesis for loads applications, presumed locations for screws attachment were arbitrarilly chosen by the researcher, considering the bone quality under the supports. As boundary condition, these locations constituted on fixed nodes (zero displacement, as all their DOF were constrained) (Figure 4.7).

The stability of a three-dimensional state of stress was evaluated according to the stress hypothesis by von Misses. Von Misses stresses are most accuratelly reported in FEA studies to summarise the overall stress state at a point. It is considered if the maximum stress for the structure is exceeded, the structure may fail in service. A colour scale with 9 stress values served to evaluate quantitatively the stress distribution in the prosthesis model (Figure 4.8).

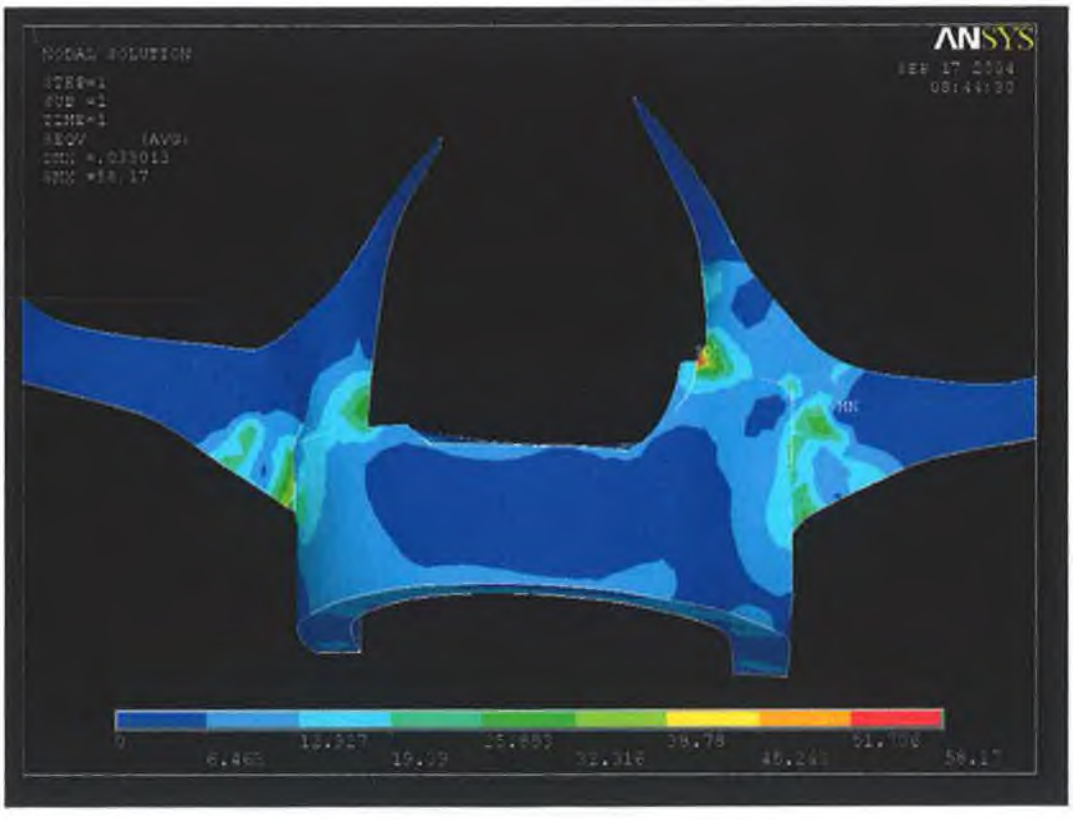


Figure 4.8 Von Misses stress distribution in the implant

Figure 4.8 shows a Von Misses stress pattern in the implant, if a loading simulating the 144 N bite force is applied in the supposed locations of the abutments. The results of the computer stress calculations can be followed in Figure 4.9, where a maximum stress level of 51.18 MPa was obtained for node 79, value comparable with the results of 177 to 233 MPa identified in specialised literature [49, 50, 60].

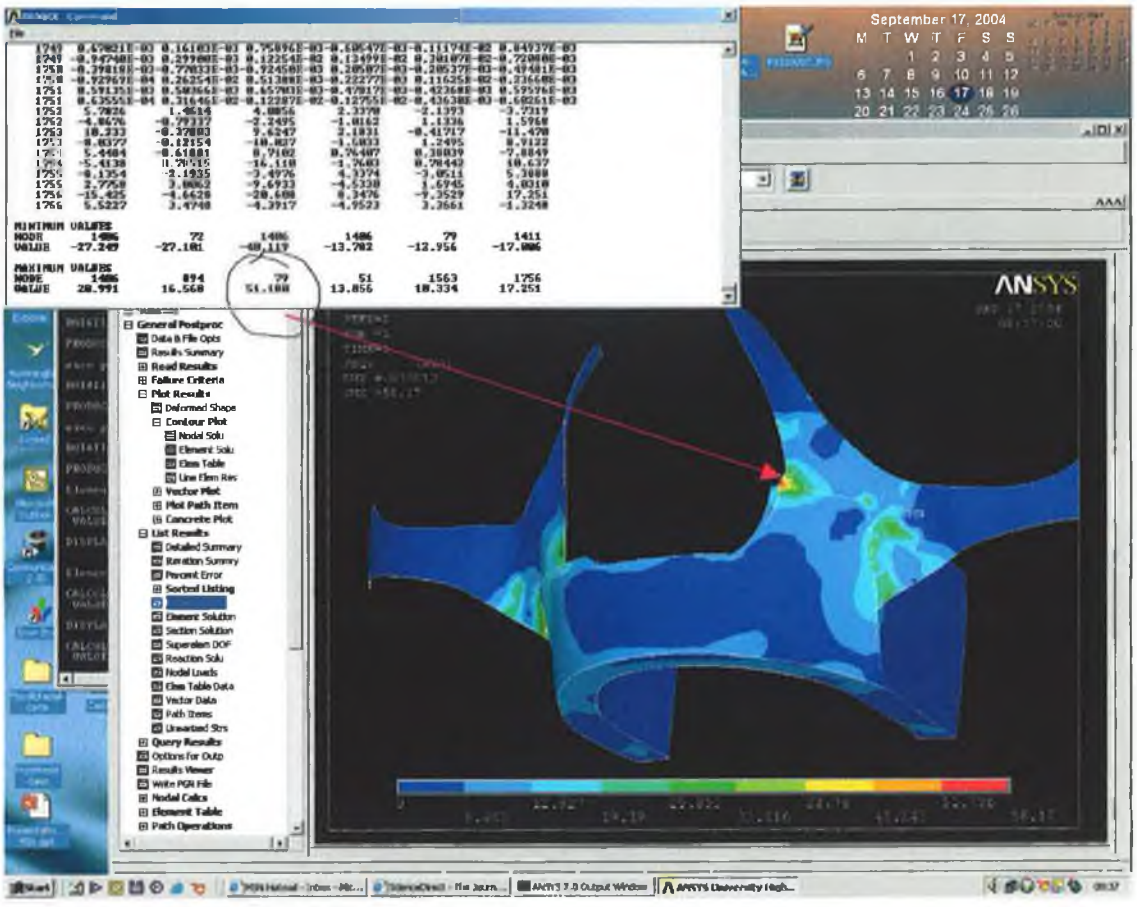


Figure 4.9 Results of the stress analysis of implant

When loading the implant with the identified maximum bite force, a maximum displacement of **0.033 mm** on the z-axis of the implant can be followed in Figure 4.10.

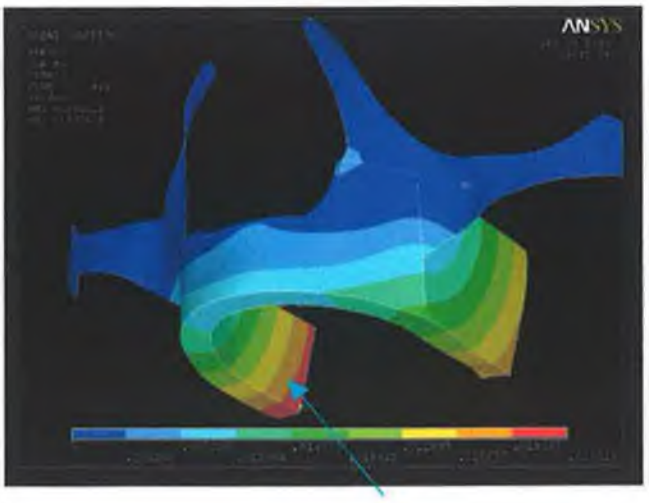


Figure 4.10 Maximum displacement

4.4 Discussion

The FEA model created for this study was a complex structure consisting of several assembled parts meshed with shell elements. The model used in this study implied several assumptions regarding the simulating structure. The structure of the model was assumed to be homogenous and isotropic and to possess linear elasticity. As only a static stress analysis was performed, the simulated stress distribution pattern may be different depending on the change of the input parameters of the model used in the experiment (e.g. mesh refinement, non-linear contact analysis to be performed). Thus, the inherent limitations of this study should be considered.

When applying FEA to medical implants, it is important to consider not only axial loads and horizontal forces (moment-causing loads) but also a combined load (oblique occlusal force), because the latter represents more realistic occlusal directions and, for a given force, will result in localised stress in cortical bone. In the current study, only vertical loads were considered (force applied on z-direction).

The design of the overdenture-implant contact surface of the model may influence also the stress distribution pattern. In the current study, the locations of the force application were specifically described as the presumed 4 locations of the abutments (attachment systems of the overdenture). However, the geometric form of the surface can produce a pattern of stress distribution that is specific for each of the modelled forms.

The type of loading may as well influence the stress patterns developed. The present study showed that the stresses induced in the implant following the maximum bite force application are well within the capabilities of the prosthesis.

Considering the limitations of this study, as only static stress analysis was performed, the results obtained are evaluated as being in agreement with the findings from the specialised literature [49, 50, 60].

The long term-success of any implant is determined in part by the ability of the material to withstand repetitive loading. Considering the fact that this study was the first effort at static modelling the stress distribution in the implant, a reasonably good agreement between experimental and referenced results was achieved. As this study consisted just in verification of the loading forces and distributed stresses, a model to simulate more accurately the real phenomenon could be developed. However, in order to

increase the confidence level in the accuracy of the present model it would be necessary to validate and optimise the key aspects of the model (e.g. mesh refinement) against more experiments at different conditions (fatigue elastic analysis). Once validated, such model has great potential for analysis different implant conditions and predicting performance.

A further non-linear contact analysis could be carried out in order to identify the distributed stresses in the implant attachment systems (screws, abutments), at the implant-bone interface and in the afferent bone structure. As this task is emphasis of collaborators from NUI,Galway, the results of the contact modelling will help achieving a design of the implant that will have an optimised internal stress distribution, will prevent the loosening and the loss of implant and will be of a minimum weight.

CHAPTER 5

PHYSICAL AND MECHANICAL TESTING OF THE PROSTHESIS

5.1. Introduction

As physical and mechanical testing was one of the objectives of the present research, mechanical tests were performed to identify the properties of the Ti6Al4V material and implant produced using titanium investment casting process, for comparison with the standard values of this material and for use as inputs for the finite element models.

Consulting the ASTM Standard B367-93 for Standard Specifications of Titanium alloy castings, the following were the main proposed test methods to be carried out for titanium castings:

- Tension testing of metallic materials
- Endurance testing: Fatigue characterisation
- Hardness of metallic materials
- Radiographic tests
- Chemical analysis checking

Due to the equipment available and the significance for the research of each proposed standard tests, it was decided to limit the work to the assessment of the tensile behaviour of the material in order to compare the results with those obtained from the literature.

The tensile test has been chosen here since it provides information concerning the strength (the yield strength, ultimate strength) and the ductility of the material under uniaxial tensile stresses. This information is useful for the comparison of materials, alloy development, quality control and design under certain circumstances. The Ti6Al4V material investigated was available for testing in form of test specimens (round cylinders with length of 8 cm and diameter of 10 mm) from the same pour as the cast implant.

Considering the assessment of the material used for casting as possessing a ductile behaviour, the fractured surfaces of the test specimens following tensile tests have been looked at using a Scanning Electron Microscope (SEM), in order to certify the ductile fracture character of the titanium alloy used.

The hardness of the material was also investigated for comparison with the literature, as the literature review showed that the hardness of different biomaterials changes after implantation in the living body [61]. The hardness of the material was assessed using indentation techniques, the tests being performed on cut samples from the cast implant.

Regarding the endurance testing of the material used for investment casting process, this constituted one of the tasks of the research collaborators from NUI,Galway and the test is under investigation at the present moment.

5.2. Tensile Behaviour

5.2.1. Experimentation

The tension tests were performed in accordance with the requirements of the Standard Test Methods E8 from the Annual Book of ASTM Standards 2000, volume 13.

The machine used in NCBES, NUIGalway was an INSTRON 8874 Servohydraulic Testing System (25 kN axial load). The bottom grip of the tester is fixed and the top one imposes a displacement of the specimen at a maximum distance of 80 mm. The resolution of the load indicated is of 0.5%.

The tensile tester is linked to a computer enabling the user to control the speed and the frequency of the measurements.

The rate of sample deformation is controlled by the speed imposed to the head of the tensile tester. Tests were conducted under Static loading (1mm/min), in Position control mode with a dynamical cycle (sample rate of 0.1 kHz), at a travel cycle of 60 mm (-50mm/+10mm).

The machine measured the force and the position of the head of the tensile tester. The data measured were stored in a test file readable by Microsoft Excel.

Test specimens were not available in standard shape and dimension for the tensile tests carried out. Hence, the specimens received with the cast implants (round cylinders with length of 8 cm and diameter of 10 mm) were machined using a lathe machine at a certain standard shape following the drawing from the Standard Test Methods E8 (Figure 5.1).

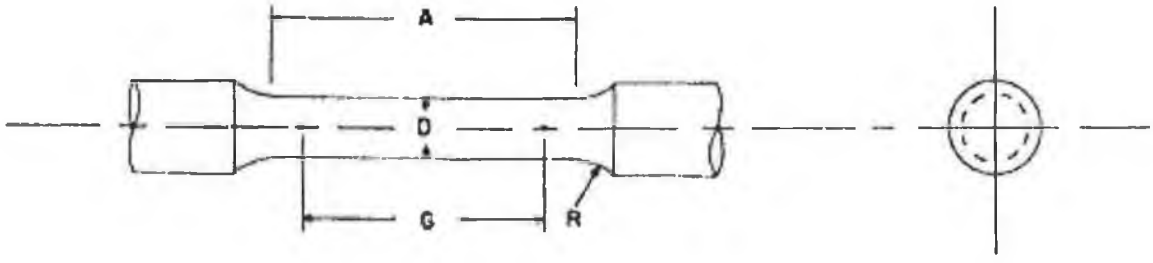


Figure 5.1 Round tension test specimen [62]

The dimensions of the 3 test specimens used for tensile testing can be followed in Table 5.1 and the specimens can be seen in Figure 5.2.

DIMENSIONS	TEST SAMPLE #1	TEST SAMPLE #2	TEST SAMPLE #3
G – gage length [mm]	34.45	34.67	35.01
D – diameter [mm]	3.73	3.78	3.93
R – radius of fillet [mm]	n/a	n/a	n/a
A – length of reduced section [mm]	36.23	36.26	36.34
L – total length of the sample [mm]	81.82	81.77	82.00

Table 5.1 Dimensions of the test specimens

The working of titanium test specimens raised particular difficulties. Normally the materials to be milled are specially alloyed for the fabrication so that optimum cutting capacities are obtained, which was not the case in medically specified titanium. With a hardness of 396 HV (Vickers) and an ultimate tensile strength of 895 MPa, titanium (Ti6Al4V) is a highly solid and tenacious material. Therefore, high cutting strengths were required to reduce the diameter of the test specimens to the standard requirements. With the resulting cutting strengths and temperatures and the surface of the test specimens was unevenly machined, leading to inaccuracies in the samples diameters. Therefore, it should be mentioned that the results of the tension tests of specimens machined to standardised dimensions may not totally represent the strength and ductility properties of the entire end product or its in-service behaviour in different environments, some of their properties might being affected by machining.

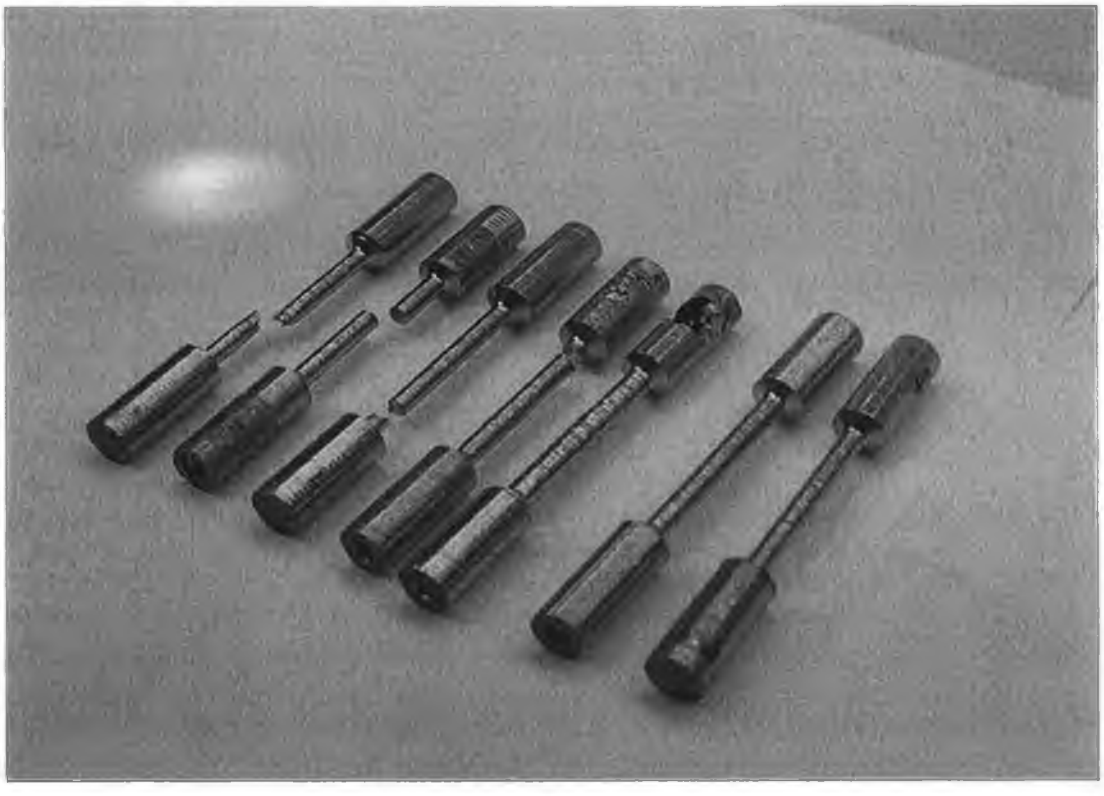


Figure 5.2 Titanium alloy test specimens used for tension tests

5.2.2. Data Processing

The tensile test was performed by subjecting the specimen to a uniaxial deformation at constant speed. A load cell (sensor) of the INSTRON machine was used to measure the stress that built up in the material as its length was increased by moving the crosshead. The change in the length (extension) of the sample as pulling proceeded was measured by the machine.

In order to compare the mechanical behaviour of the different specimens, some properties had to be looked at, such as: stresses, strains and strengths.

Engineering stress

Using the force F measurement by the load cell and the cross section A, the engineering stress was calculated using formula:

$$\sigma = \frac{F}{A} \qquad \text{(Formula 5.1)}$$

where: F: force [N]

A: cross section area [mm^2]

Engineering strain

Using the original length L_0 and the extension ΔL measured, the engineering strain ϵ was calculated.

$$\varepsilon = \frac{\Delta L}{L_0} \qquad \text{(Formula 5.2)}$$

where: ϵ: strain

ΔL: extension [mm]

L_0: original gage length [mm]

True stress and strain

$$\sigma_T = (1+\varepsilon)\sigma \qquad \text{(Formula 5.3)}$$

$$\varepsilon_T = \ln(1+\varepsilon) \qquad \text{(Formula 5.4)}$$

Hardening curve

If the stress (σ in MPa) is plotted as function of the strain (ϵ), both measured in the same direction, the curve obtained is referred to as hardening curve. The hardening curve in tension completely characterises the uniaxial behaviour and Figure 5.3 gives the examples of hardening curve for ductile and brittle materials.

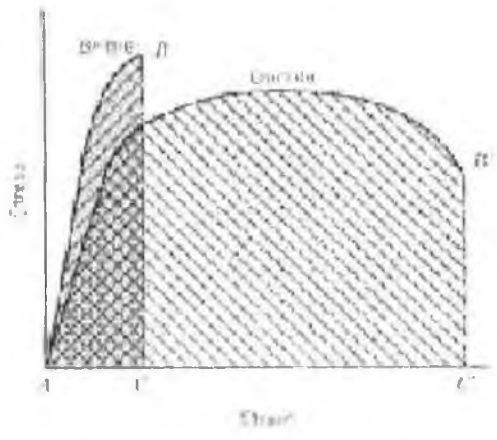


Figure 5.3 Schematic representation of ductile and brittle behaviour [63]

Yield stress

Detection of the yield stress presented an experimental problem since hardening curves did not show a well-defined yield point. The yield stress is therefore replaced by a value known as proof stress. The proof stress is the stress that corresponds to the occurrence of a specified amount of permanent strain. For quality control of materials, a conventional value of permanent strain equal to 0.2% is commonly used and was applied as well for the present results.

Ultimate tensile strength

The ultimate tensile strength is the maximum stress reached in the hardening curve.

The data obtained from this experiment were force F and elongation ΔL. The original gage length was known as L_0 and the original cross section area was A. In order to plot the hardening curve, the true strain and true stress had to be calculated.

Three samples were tested for tensile properties verification and according to the stipulated measurement frequency, different collections of points were materialised for each sample loaded to fracture:

- Sample 1: 1685 points
- Sample 2: 1867 points
- Sample 3: 2204 points.

The files containing the data measured were opened with Microsoft Excel. The first three columns were copied from the text file containing the data measured by the tensile tester. Engineering stress and strain were then calculated using the data and finally, true stress and strain were calculated using engineering stress and strain. The different calculations were done and the hardening curves were plotted.

Table 5.2 gives an example of values obtained for a specimen.

Diameter: 3.73 mm	Length: 34.45 mm				
Cross section area: 10.927 mm^2					
Test Specimen 1					
Time Sec	Position mm	Load N	Cycle	True stress	True strain
0	0	0.134575	1	0.207380363	0
0.01	0.0013	0.13513	1	0.258637866	3.77351E-05
0.02	0.0005	0.132307	1	-4.31663E-09	1.45137E-05
0.03	0.0007	0.135592	1	0.300703291	2.03191E-05
0.04	0.0006	0.136137	1	0.350543835	1.74164E-05
0.05	0.0005	0.13448	1	0.198865055	1.45137E-05
0.06	0.0005	0.134856	1	0.233275208	1.45137E-05
0.07	0.0012	0.133339	1	0.09469283	3.48325E-05
0.08	0.0005	0.133359	1	0.096275211	1.45137E-05
0.09	0.0012	0.133666	1	0.12461929	3.48325E-05
0.1	0.0017	0.136748	1	0.406860088	4.93457E-05
0.11	0.0018	0.138113	1	0.531820966	5.22483E-05
0.12	0.0018	0.147718	1	1.410868814	5.22483E-05
0.13	0.0043	0.208265	1	6.953502333	0.000124811
0.14	0.0099	0.306135	1	15.91575097	0.000287332
0.15	0.0158	0.405595	1	25.02680909	0.000458531
0.16	0.0208	0.499463	1	33.62771634	0.000603591
0.17	0.0257	0.587168	1	41.66653162	0.000745731
0.18	0.0308	0.667626	1	49.0441863	0.00089365
0.19	0.0357	0.748724	1	56.48225392	0.001035748
0.2	0.0403	0.821397	1	63.14985536	0.001169128
0.21	0.0452	0.886783	1	69.15220037	0.001311186
0.22	0.0481	0.937134	1	73.77333912	0.001395253
0.23	0.0516	0.978619	1	77.58423999	0.001496702

Table 5.2 Example of table obtained using experimental results

The hardening curves were plotted as true stress versus true strain (Figure 5.4) and their appearance certified the ductile character of Ti6Al4V alloy used [63].

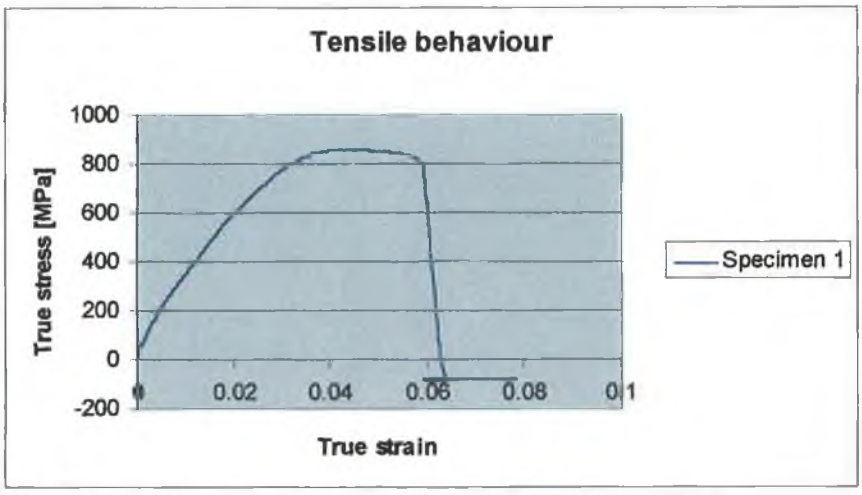


Figure 5.4 True stress versus true strain curve (hardening curve)

The same process was repeated for each specimen and all the curves were plotted in the same graph (Figure 5.5).

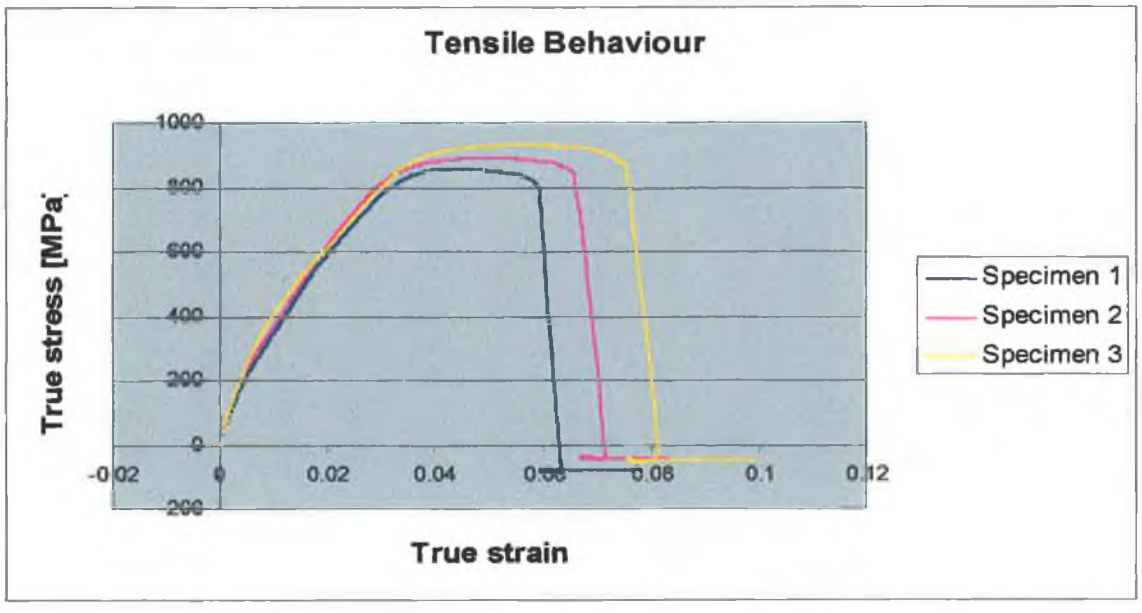


Figure 5.5 Curves obtained for 3 different specimens under tension

Due to the variation of the specimen diameters (Table 5.1), a variation of the strain was generated also.

The strain at breaking point varies between 0.065 and 0.085, which is less than 10% elongation in any case. Considering the accuracy of the test specimens and the accuracy of the equipment used, closer results could not be expected.

The aim of the study was to compare the hardening curves obtained for different specimens and to identify the mechanical behaviour of the material used for casting, in order to compare them with standard values, therefore the curves obtained were considered acceptable. Assessing the hardening curves, it could be as well certified the ductile behaviour of the material.

In order to compare the mechanical behaviour of the specimens, some properties had to be looked at. First, the yield stress needed to be examined since it is the critical point between the elastic and plastic behaviour. And secondly, the ultimate tensile strength at breaking point needed to be studied.

The hardening curves obtained for the tensile tests performed were presented in Figure 5.5. The following changes could be observed:

- The yield stress increased when the sample diameter increased
- The true strain at breaking point also increased with the increase of the sample diameter.

In order to closely examine the phenomenon, Table 5.3 presents the approximate yield stresses and ultimate tensile strengths at breaking points for the different samples, comparing them with the standard.

	SPECIMEN 1 (diam=3.73mm)	**SPECIMEN 2 (diam=3.78mm)**	**SPECIMEN 3 (diam=3.93mm)**	**STANDARD VALUE**
Yield stress [MPa]	807	816	824	**825**
Proof stress (+0.2%) [MPa]	808.6	817.6	825.6	**826.6**
Ultimate tensile strength [MPa]	857	889	929	**895**

Table 5.3 Yield and ultimate stress of specimens

Table 5.3 confirms the increase of the yield stress and the increase of the ultimate strength as the diameter of the specimen increases.

The obtained stresses variations from the standard values can be explained in accordance with the standard [62] and they were experimental errors due to: machined surface inconsistency, dimensional inaccuracy of the diameters and lack of fillets at the end of gauge length.

In order to calculate Young's modulus of the specimens, proportional limit was looked at first (Figure 5.6). Proportional limit represents the greatest stress which a material is capable of sustaining without any deviation from proportionality of stress to strain (Hooke's law) and Figure 5.6 shows the experimental proof stresses for the specimens tested.

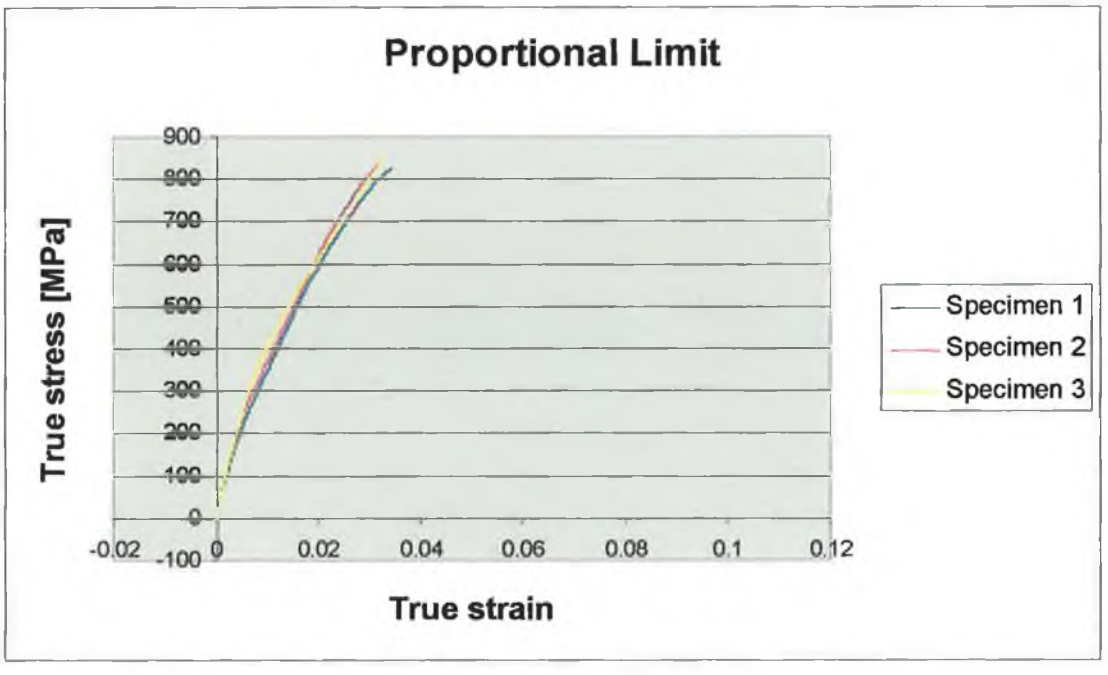


Figure 5.6 Proportional limit

Due to the variation of the stresses in the hardening curve, the experimental values of Young's modulus for the plotted limits of proportionality are considered not to be accurate.

The experimental value for Young's modulus was calculated using formula:

$$E = \frac{\sigma}{\varepsilon} \quad \text{(Formula 5.5)}$$

The values obtained for the different specimens were as follows:

- Specimen 1: 24.2 GPa
- Specimen 2: 25.9 GPa
- Specimen 3: 25.7 GPa.

However, as the experimental values are erroneous (due to lack of additional treatments of the material used, machining of the samples and variation of stresses in the hardening curves) and not representative for the material used, the certified standard value for Young's modulus of 114 GPa [64] will be adopted as it stands for the present research study.

5.2.3. Interpretation of Results

From the set of tensile tests carried out it can be concluded that:

- The graphical representation of the hardening curves (true stress plotted vs. true strain) certified the ductile behaviour of Ti6Al4V used.
- The yield stress increased when the sample diameter increased.
- The true strain at breaking point also increased with the increase of the sample diameters.
- The values of yield stress and ultimate tensile strength were comparable with the standard values, but their deviation was considered to be a consequence of the following errors: machined surface inconsistency, dimensional inaccuracy of the diameters and lack of fillets at the end of gauge length. Although only 3 test specimens were available for tensile testing in the present research, in order to better quantify the tensile behaviour of Ti6Al4V more specimens could be acquisitioned for further experimental tests.
- Considering its large variation from the standard value when calculating Young's modulus using tensile test, further experiments could be carried out for accurate determination.

5.3. Scanning Electron Microscope (SEM) Inspection of fractured surfaces

5.3.1. Experimentation

Considering the assessment of the material used for casting as possessing a ductile behaviour (Figure 5.5), the fractured surfaces of the test specimens following tensile tests have been looked at using a Scanning Electron Microscope (SEM), in order to certify the ductile fracture character of the Titanium alloy used.

For examining the fractured surfaces of test specimens used for tension tests a **HITACHI S-4700 Field Emission Scanning Electron Microscope (SEM)** was used in NCBES, NUIGalway. The S-4700 SEM is a high-resolution instrument, which can be used to image and analyse the microstructure of a wide variety of materials (metals, alloys, polymers, tissue).

The S-4700 microscope has been developed so that both the image display and SEM parameters are directly visualised on the computer monitor. The Image Manager software on the S-4700 provides flexible indexing, archiving, processing and printing of saved images. The microscope can provide very clear low magnification images for routine evaluation of material structure as well as high-resolution images.

Different pictures with different magnification rates were recorded for the fractured surfaces of the test specimens broken after the tensile tests (Figure 5.7) with various magnifications such as: 1000x and 3000x.

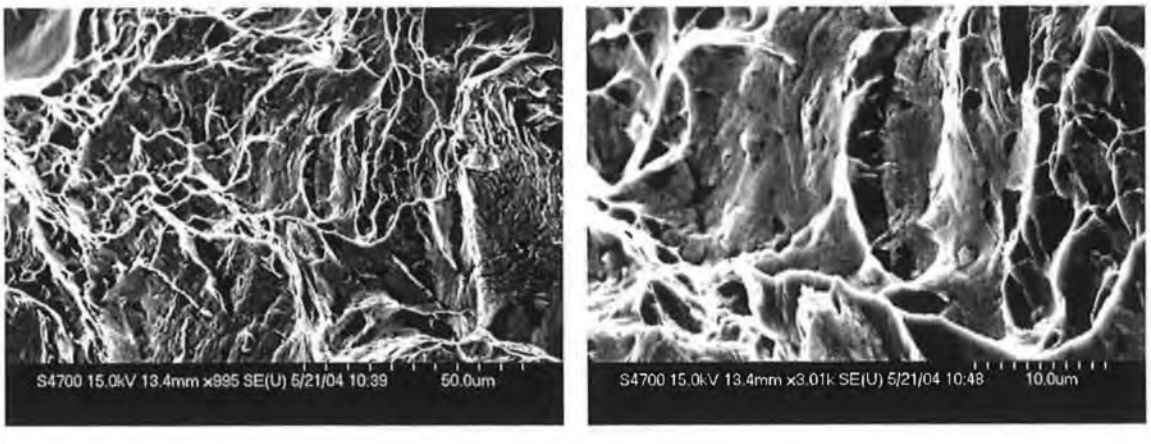


Figure 5.7 SEM images of fractured surfaces after tension tests

5.3.2. Interpretation of Images

For engineering materials there are only two possible modes of fracture, ductile and brittle. In general, the main difference between brittle and ductile fracture can be attributed to the amount of plastic deformation that the material undergoes before fracture occurs. Ductile materials demonstrate large amounts of plastic deformation while brittle materials show little or no plastic deformation before fracture. The crack initiation is essential to fracture. A crack that passes through the grains within the material is undergoing transgranular. However, a crack that propagates along the grain boundaries is termed an intergranular fracture and one that propagates within the grain boundaries is termed as intragranular fracture.

Comparing the obtained SEM aspects for the fracture of titanium alloy specimens in tension with the images from the specialised literature [65], it can be concluded that the material used for casting was undergoing an intragranular fracture.

5.4. Indentation hardness testing of the prosthesis

It has been revealed in the literature that the Vickers hardness changed (increased) on the specimen surfaces of implant materials Ti5Al2.5Fe, Ti6Al4V and SUS 316L after implanting into the paravertebral muscle of living rabbit for about 11 months [61].

As this research study was just an experiment and the implant produced was not going to be implanted to any patient, it was not possible to quantify the increase/decrease in the hardness of the implant surface. Still the experiment to determine the hardness of the surface of the actual implant was carried out in order to compare the results with the ones identified in the specialised standards.

It is considered that **hardness** of a material should be always determined on material representing each pour from the investment casting process. For the medical implants, hardness should be determined on a sample cast for that purpose, or on samples cut from the specific implant. The **indentations** should be made on a surface that is as-cast condition, which was not subsequently machined, in accordance with the requirements of the Standard Test Methods B367 from the Annual Book of ASTM Standards 2000, volume 13 [66]. Hardness values reported should be representative of

the base metal of the casting and not of any surface contamination due to mould-metal interactions [66].

For the purpose of the present research, the indentation tests to determine the hardness of the Titanium alloy used for the manufacture of the prosthesis were performed in NCBES, NUIGalway using a **CSM Nano-Hardness Indentation Tester**. Some of the features of the specific Indentation Tester are, as follows [67]:

- Unique surface referencing technique
- Hardness and Young's modulus determination for depth as low as 15nm
- Spherical, Vickers, Knoop, Berkovich and cube corner indent tips
- Dynamic mechanical analysis for visco-elastic properties
- Mapping option for up to 1000 indents
- Very high throughput and reproductibility
- Automated optical microscopic inspection

The CSM indentation testers are high precision instruments used for the determination of mechanical properties of thin films, coating and substrates. Properties such as hardness and elastic modulus can be determined on almost any type of material: soft, hard, brittle or ductile.

The operating principle of the instrument is as follows: an indenter tip, normal to the sample surface, is driven into the sample by applying an increasing load up to a set value. The load is then gradually decreased until partial or complete relaxation of the material.

The indentation test software includes a large set of features for setting up the indentation test and handling the data:

- Real time display of force against depth, with automatic calculation of the hardness and elastic modulus with Oliver & Pharr Method (Figure 5.8).
- Automatic measurement report generator
- Data export in ASCII format
- Creep measurement by holding a constant maximum load or depth over a set time
- Positioning of each indent with the microscope. Programming each indentation to a maximum depth or load. Precise relocation of each indent.

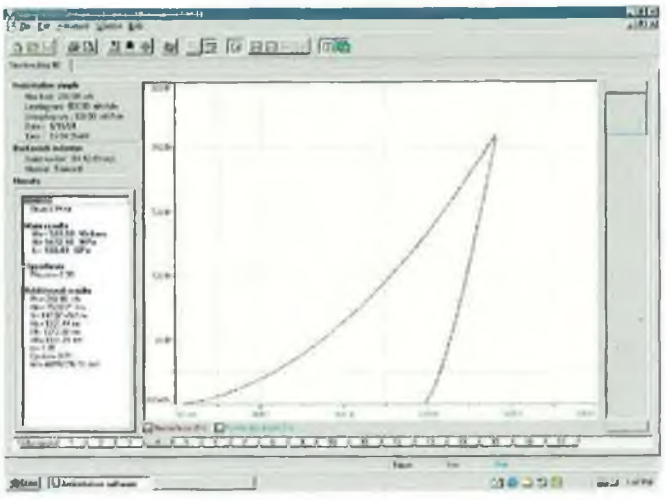


Figure 5.8 Indentation test software

- Easy video capture and measurement (Figure 5.9)

Figure 5.9 Picture of indented surface

The indentation hardness tests concerning this research were performed on two cut samples from the Titanium cast prosthesis, one sample from the main body of the prosthesis and one sample from the wing-like support. Samples **"as-cast" only** condition (as required by Standard B367 [66]) were embedded in resin, left to dry then grinded and slightly polished to reveal the surface to be indented (Figure 5.10).

Figure 5.10 Samples for the indentation tests

The parameters for the simple indentations performed on the two samples were set as follows:

- Maximum load: 250 mN
- Loading rate: 500 mN/min
- Unloading rate: 500 mN/min
- Indenter's type: Berkovich
- Depth of penetration: 15nm.

A matrix of 4x4 indentations was appointed to be performed for measuring the material properties and pictures of the indented surfaces can be seen in Figure 5.11.

Figure 5.11 Pictures of the indented surfaces from the cut samples of prosthesis

The results obtained from the indentation tests of the cut samples can be followed in Table 5.4 and in the plotted graphs from Figures 5.12 and 5.13. Figure 5.12 shows the variation in hardness of the material used (with no additional treatments, "as-cast" condition) versus standard value (determined for material "as-cast" only condition).

INDENTATION NO.	SAMPLE 1 (FROM THE SUPPORT OF PROSTHESIS)		SAMPLE 2 (FROM THE MAIN BODY OF PROSTHESIS)	
	Young's Modulus [GPa]	Hardness [Vickers]	Young's Modulus [GPa]	Hardness [Vickers]
1	125.85	522.60	140.60	479,01
2	122.93	517.29	137.21	395.39
3	124.33	524.12	148.00	493.43
4	133.61	522.00	131.81	380.20
5	137.64	552.73	160.56	534.16
6	131.38	561.45	158.35	458.81
7	129.59	552.02	143.00	408.63
8	135.07	592.66	150.07	500.40
9	135.36	541.23	159.86	501.28

10	126.44	531.39	158.70	479.59
11	124.87	507.15	154.22	486.99
12	126.70	527.95	146.54	435.93
13	132.05	565.13	160.54	484.64
14	127.13	545.79	153.11	481.83
15	128.96	579.40	155.66	482.10
16	129.86	568.32	144.94	412.35

Table 5.4 Results of the indentation tests

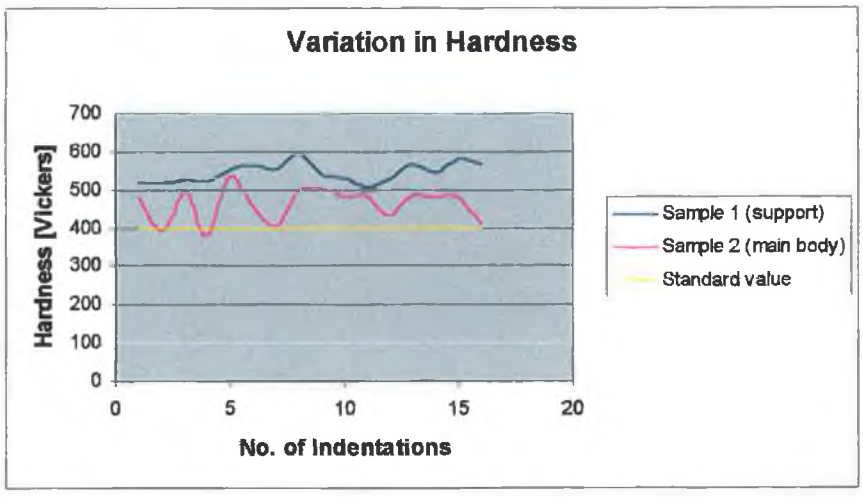


Figure 5.12 Variation in Hardness at Indentation test

As one of the capacities of Nano-Hardness Indentation Tester was the determination of the Young's modulus at the surface of the material, the results obtained using this technique were processed and compared with the standard value.

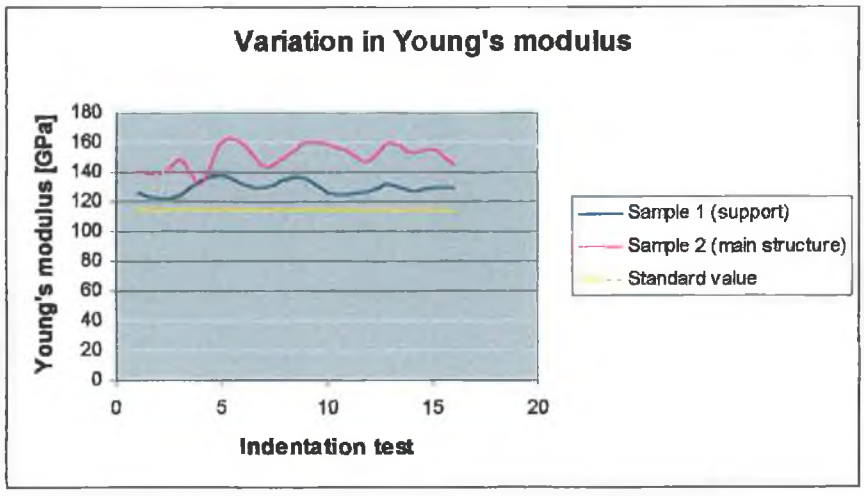


Figure 5.13 Variation in Young's modulus at Indentation test

The following conclusions can be drawn after performing the indentation hardness tests:

- Variations from standard value in hardness of Ti6Al4V material were noticed and it was confirmed to be a result of the casting process by the casting company, as the parts were produced and delivered as-cast condition only with no additional treatments.
- Variations in Young's modulus values from standard value of 114 GPa could be a consequence of their measurement at the surface of the material.

Phase transformations at the surface of material during casting process (burnout temperatures), intermediate crystallographic phases of Ti6Al4V formed between the surface layer and the substrate [68], and crystallographic relationships between them could also influence the variation of the material properties (e.g. hardness, Young's modulus). Their absolute quantification for this particular research study could not be achieved due to the funding limitations and lack of chemical analysis of material used for casting.

The testing aspect of the present research has high potential to facilitate further research for better quantifying the properties of the material used.

The indentation tests are probably more reliable the tensile tests for E modulus determination because they were not affected by the machining difficulties of the Titanium. It is known that using a nano-hardness indenter to obtain the modulus of elasticity for the entire cross-section of material is not a commonly used technique. Therefore, the certified standard value for Young's modulus of 114 GPa was adopted as it stands for the present research study.

5.5. Interpretation of the results

Considering the tests performed to characterise physically and mechanically the material used for casting and the dimensional properties of the implant, the following conclusions were drawn:

- The graphical representation of the hardening curves (true stress plotted vs. true strain) certified the ductile behaviour of Ti6Al4V used.

- The yield stress increased when the sample diameter increased and also the true strain at breaking point increased with the increase of the sample diameter.
- The values of yield stress and ultimate tensile strength were comparable with the standard values, but their deviation was considered to be a consequence of the following errors: machined surface inconsistency, dimensional inaccuracy of the diameters and lack of fillets at the end of gauge length.
- As the experimental values are erroneous (due to lack of additional treatments of the material used, machining of the samples and variation of stresses in the hardening curves) and not representative for the material used, the certified standard value for Young's modulus of 114 GPa [64] will be adopted as it stands for the present research study.
- Certifying that the Ti6Al4V material used for casting has a ductile behaviour, and comparing the experimental SEM aspects for the fracture of titanium alloy specimens in tension with the images from the specialised literature, it could be concluded that the material used for casting was undergoing an intragranular fracture.
- Performing the indentation tests, variations from standard value in hardness of Ti6Al4V material were noticed and it was certified to be a result of the casting process by the casting company. The possibly erroneous results obtained for the surface measured Young's modulus led to the decision that the certified standard value for Young's modulus of 114 GPa should be adopted as it stands for the present research study.
- Phase transformations at the surface of material during casting process (burnout temperatures), intermediate crystallographic phases of Ti6Al4V formed between the surface layer and the substrate [68], and crystallographic relationships between them could also influence the variation of the material properties, including hardness and Young's modulus.

The testing aspect of the present research has high potential to facilitate further research for better quantifying the properties of the material used.

CHAPTER 6

DIMENSIONAL/TOLERANCE CHECKING OF THE PROSTHESIS USING COORDINATE MEASURING MACHINE (CMM)

6.1. Introduction

Today, titanium investment casting process is used by various medical experts throughout the medical world as mean for manufacture of medical implants. Casting process versus milling the titanium implants offers the advantage of being able to form very thin tapered shapes. This may become even more important when constructing zygomatic bones or producing titanium spaceholders to promote guided tissues regeneration of skull defects [69]. While the clinical practice with medical implants has become more and more daily routine for those experts, quality assurance aspects, especially the dimensional accuracy of producing the models, have to be verified in order to meet the implant specifications and manufacturing tolerances.

In general, there will be errors of size in any cast or machined implant. This means that the actual dimension will be different from the nominal dimension. These errors should be within certain given limits by tolerances and determined by the dimensional measurement in order to guarantee the implant dimensional quality.

The custom-made cast titanium implant for maxillofacial reconstruction developed in this research needed to be measured and the dimensions of the implant to be compared to the dimensions of the computer-model, which were known from the design

stage. The result of the comparison yields data on the accuracy of casting process, assessing if the implant is valid for implantation from the engineering and clinical points of view.

The measurements of the manufactured implant were performed using a Coordinate Measuring Machine (CMM), which can efficiently and accurately monitor the dimensional quality of the manufactured implant, as it is an advanced, multi-purpose quality control system used to help inspection keep pace with product requirements.

6.2. Experimentation

6.2.1. Equipment used

The CMM machine used in NCBES, NUIGalway was a **MILLENNIUM CNC-CMM machine** from ELEY Metrology, UK and the TRUE MEASURE software allowed the measurements to be performed easily. Some of the features of the MILLENNIUM CMM machine used are as follows [67]:

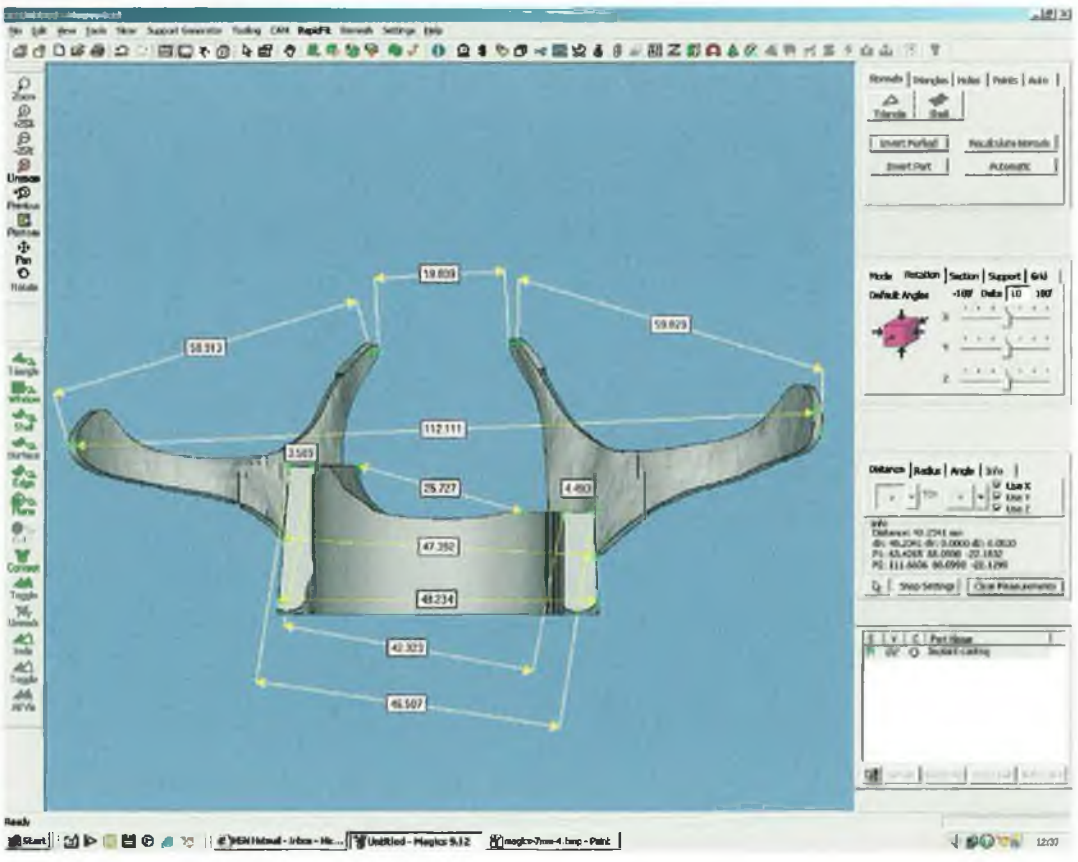
- Measuring range: 400 x 500 x 300 mm
- Resolution: 0.001 mm
- Reading system: Renishaw non-contact measuring scales
- Guidance method: air bearings on all axes
- Speed: 0.250 to 12 mm/s
- Table size: 900 x 900 mm – granite bed
- Operation: CNC control
- Probe system: full range of Renishaw probing system
- Communication with CAD systems: in form of IGES or VDA files.

6.2.2. Measurements and Results

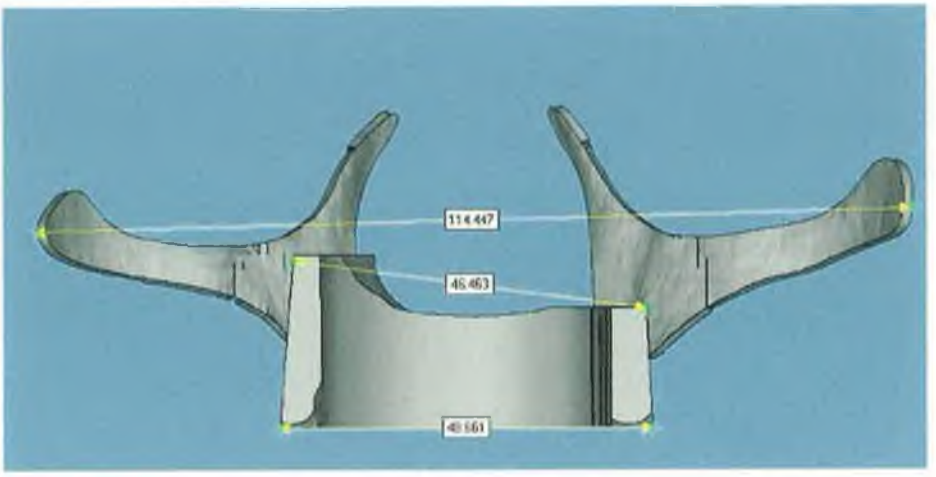
The dimensional/tolerance checking of the prosthesis usually involves the process of reverse engineering or the recovering of surfaces of the implant using the CMM machine to check that the manufacturing tolerances have not been exceeded.

A system, possibly using geometrical dimensioning and tolerance, was required to be formulated that will be efficient but at the same time severe enough, to ensure that accurate representation of the prosthesis has been manufactured. But due to the **irregular shape** of the implant, a programme could not be written to perform the automated measurement of the prosthesis' dimensions. Instead, a relative type of measurement, consisting in different **point to point** direct measurements was adopted to collect the key dimensions of the implant to examine the accuracy of the cast model. These dimensions were due to be compared and statistically quantified with the measurements collected from the 3D computer-model using a distance-measuring function of MAGICS RP software.

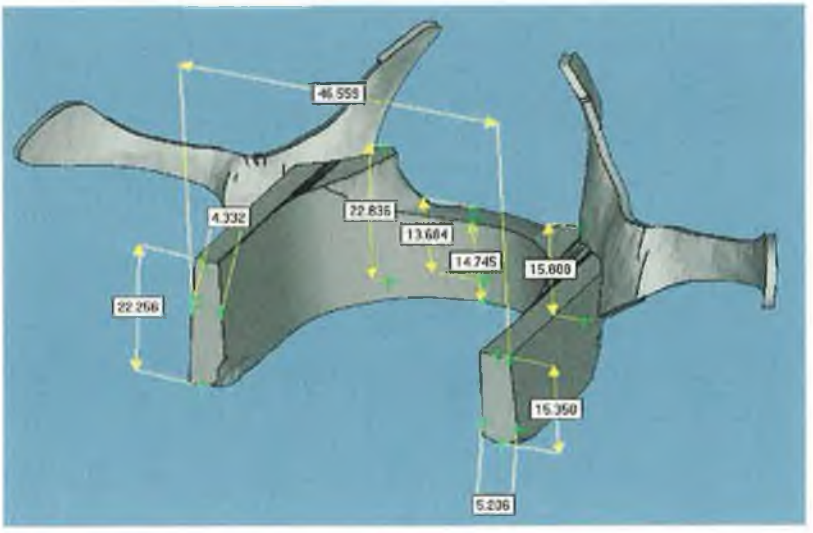
Since the objective locations of more of the landmarks used were pointed ambiguously (Figure 6.1 a, b, c), there is little room for subjective judgement that may cause measurement errors.



(a)



(b)



(c)

Figure 6.1 Prosthesis measurements using MAGICS RP software

For each key distance of the implant, 1 measurement was obtained and the values collected can be followed in Table 6.1.

	NAME OF THE DIMENSION	COMPUTER MODEL (MAGICS RP) [mm]	IMPLANT-CMM MEASUREMENT [mm]
1.	Total width between flanges (external points)	114.447	118.205
2.	Total height of the implant	42.511	43.345
3.	Width of implant (back view – bottom surface)	48.661	50.753
4.	Distance between external upper corners of implant (back view)	46.507	48.955

4.	Distance between external upper corners of implant (back view)	46.507	48.955
5.	Width of left support (front view)	58.913	61.338
6.	Width of right support (front view)	59.829	60.748
7.	Height of nasal left support	20.979	22.618
8.	Height of right nasal support	27.258	28.094
9.	Distance between nasal supports (distal ends – back view)	19.809	18.250

Table 6.1 Key measurements of implant

The mean and standard deviation of the absolute variations over all the measurements can be followed in Table 6.2. Percent variations are also provided in the table. For example, the percent variation between the computer-model and the implant was computed using the equation:

$$\% \text{ Variation} = \frac{\text{Measurement on implant} - \text{measurement on computer model}}{\text{Measurement on computer model}} \times 100 \qquad \text{(Formula 6.1)}$$

Measurement		Distance [MM]		Variation [MM]	% variation
		Computer model	Implant	Computer model-implant	Computer model-implant
1.	Total width between flanges (external points)	114.447	118.205	3.758	3.28
2.	Total height of the implant	42.511	43.345	0.834	1.96
3.	Width of implant (back view – bottom surface)	48.661	50.753	2.092	4.29
4.	Distance between external upper corners of implant (back view)	46.507	48.955	2.448	5.26
5.	Width of left support (front view)	58.913	61.338	2.425	4.11
6.	Width of right support (front view)	59.829	60.748	0.919	3.20
7.	Height of nasal left support	20.979	22.618	1.639	7.81
8.	Height of right nasal support	27.258	28.094	0.836	3.06
9.	Distance between nasal supports (distal ends – back view)	19.809	18.250	- 1.559	- 7.87
	MEAN OF ABSOLUTE DIFFERENCES			**1.83**	**4.53**
	STANDARD DEVIATION OF ABSOLUTE DIFFERENCES			**0.96**	**2.08**

Table 6.2 Measurements and errors in CMM measurements

The mean difference between the computer model and actual implant was **1.83 mm (4.53%)** with a standard deviation of 0.96 mm (2.08%). Figures 6.2 and 6.3 display the respective differences graphically.

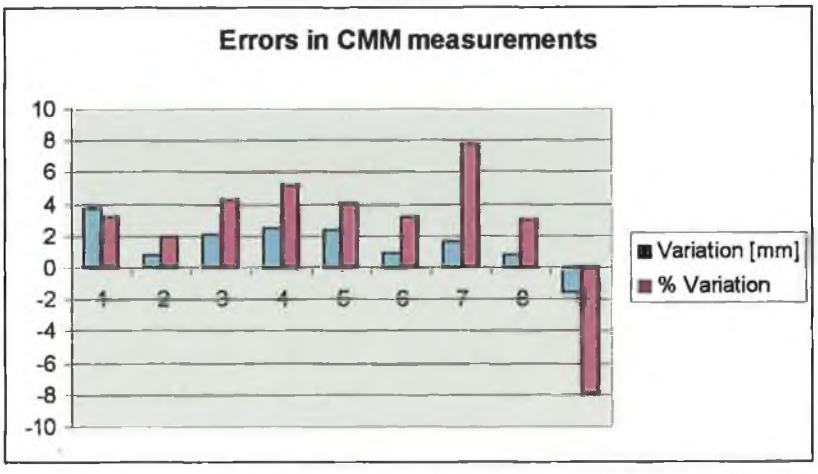


Figure 6.2 Errors in CMM measurements (computer model vs actual implant)

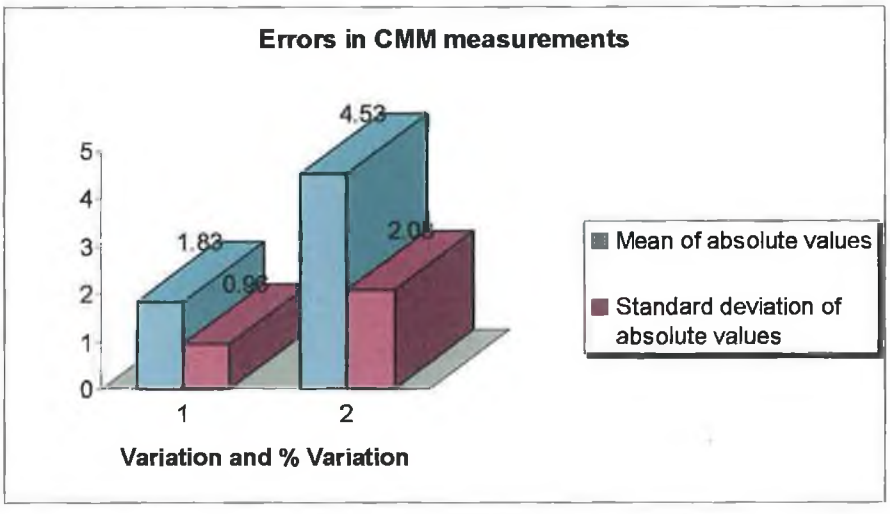


Figure 6.3 Errors in CMM measurements (mean and standard deviation values of absolute differences)

6.3. Analysis of Errors

First, the accuracy of milled models, a traditional method of producing 3D physical models, is considered for reference purposes. Lill et al. [70] generated CT data from a real skull, and produced a physical model by milling hardened polyurethane foam. The model deviated from the original measurement by **1.47 mm (2.19%)** on average. Kragskov et al. [71] conducted a similar study and the values obtained lead to a mean difference over all the cases of **1.98 mm (3.59%).**

In the present research study, with the input from the collaborator surgeon, the maximum deviation should not have been over **+1.5 mm** for each measurement. This was considered taking into account the bone tissue invaded by tumour which had to be removed. The following calculations representing the expected dimensions after casting process will be used for comparison with the actual obtained values of the measurements (Table 6.3).

	Measurement	Distance [MM]			variation [MM]	% variation
		Comp. model	Tol.	Implant	Computer model-implant	Computer model-implant
1.	Total width between flanges (external points)	114.447	+1.5	115.947	1.5	1.31
2.	Total height of the implant	42.511	+1.5	44.011	1.5	3.52
3.	Width of implant (back view – bottom surface)	48.661	+1.5	50.161	1.5	3.08
4.	Distance between external upper corners of implant (back view)	46.507	+1.5	48.007	1.5	3.22
5.	Width of left support (front view)	58.913	+1.5	60.413	1.5	0.84
6.	Width of right support (front view)	59.829	+1.5	61.329	1.5	2.50
7.	Height of nasal left support	20.979	+1.5	22.479	1.5	7.15
8.	Height of right nasal support	27.258	+1.5	28.758	1.5	5.50
9.	Distance between nasal supports (distal ends – back view)	19.809	+1.5	21.309	1.5	7.57
	MEAN OF ABSOLUTE DIFFERENCES				**1.5**	**3.85**
	STANDARD DEVIATION OF ABSOLUTE DIFFERENCES				**0**	**2.39**

Table 6.3 Expected maximum errors in CMM measurements

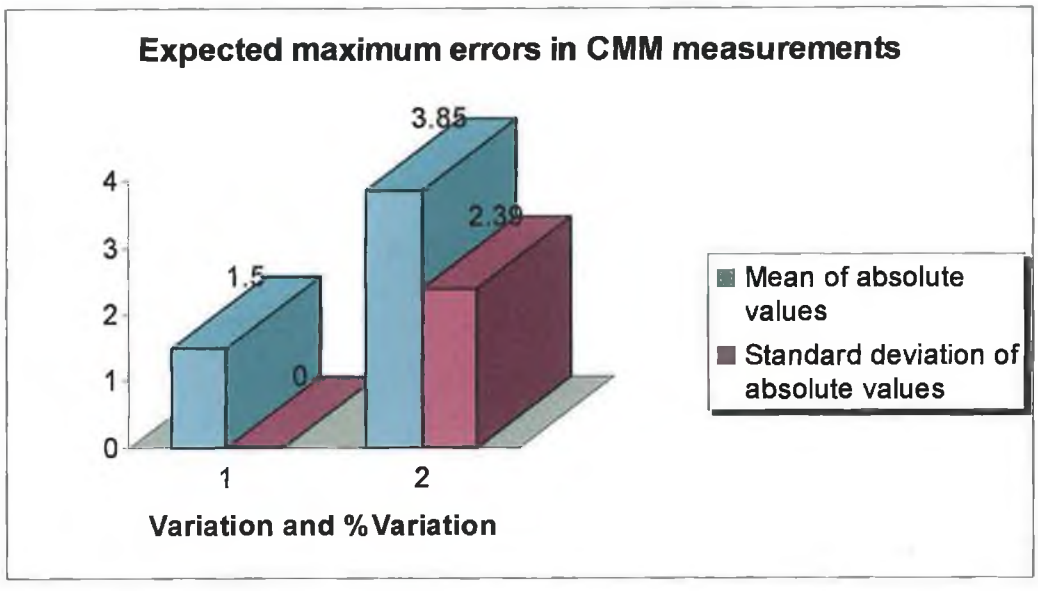


Figure 6.4 Expected errors in CMM measurements (mean and standard deviation values of absolute differences)

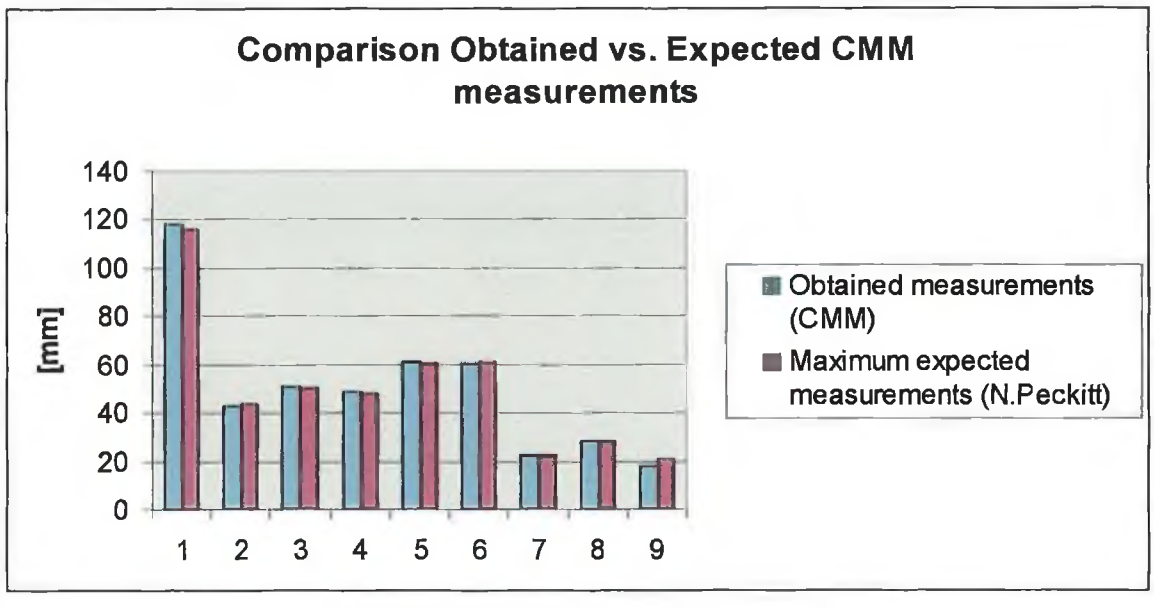


Figure 6.5 Comparison obtained vs. expected CMM measurements

Comparing and quantifying the experimental measurements with surgeon's proposed measurements, was assessed that their variation was of **1.09 mm** (0.93%).

Table 6.4 compare the results of previous measurements in the field of medical rapid prototyped and cast models with the results of the present research.

		Difference [MM]		% Difference	
		Mean	**Standard deviation**	**Mean**	**Standard deviation**
1.	**Results obtained in the present research**	**1.83**	**0.96**	**4.53**	**2.08**
2.	**Expected results (N. Peckitt)**	1.5	3.85	0	2.39
3.	**Lill et al.** [70]	1.47	0.94	2.19	1.37
4.	**Barker et al.** [72]	1.90	1.48	2.54	1.38
5.	**Krasgskov et al.** [71]	**1.98**	**1.2**	**3.59**	**2.67**

Table 6.4 Comparison with the results of other research

For the overall process, it was found that the structures of models are in most cases reproduced bigger than the original virtual 3D reconstruction, and this is caused by the errors occurred in the manufacturing process.

As dimensional checks were carried out on the cast implant, these showed that the stipulated tolerances have been exceeded. However, comparing the experimental results with those in the literature indicated that the maxillofacial implant was within the existing level of accuracy in this area. The actual maxillofacial implant was therefore assessed as feasible engineering and suitable for insertion.

In the design and manufacturing route identified by present research study, medical implants are produced by following the sequence: CT scanning, 3D model reconstruction, RP model fabrication, casting and measurement. A number of potential errors are present at each stage of this process, errors which are or are not controllable.

For the first stage of **CT scanning**, the following were the most encountered errors found in the literature [73]:

- Gantry tilt
- Section thickness
- Tube current and voltage
- Image reconstruction algorithm
- Patient movement

- Metal artefact.

For the conversion from CT image to a **3D reconstruction** of the interest anatomical structure, the following are the errors that may occur [72]:

- Threshold value
- Decimation ratio
- Interpolation algorithm
- Smoothing algorithm
- Triangle edge
- Closure error.

For the **creation of an RP model** from a 3D reconstruction through various RP techniques, sources of errors may be considered [72]:

- Creation and removal of supporting structure
- Laser diameter
- Laser path
- Thickness of layer
- Surface finishing

And the last source of errors may occur at the **casting process**, and they may be due to [73]:

- Water/powder accuracy – higher values reduce thermal and hygroscopic expansions, giving smaller castings
- Spatulation – increased spatulation increases expansion, giving larger castings
- Burnout temperatures – lower temperatures results in less thermal expansion and smaller castings
- Immersion time
- Water-added technique – decreased amount of water added to investment result in decreased hygroscopic expansion and smaller castings
- Water bath – temperatures below 37 ^{0}C lead to smaller castings.

The measured maxillofacial titanium implant was manufactured by a contracted Investment Casting company which first build the mould for casting through a very reliable RP technique, namely Stereolithography (SLA). Considering the specifications of used RP technique and based on the measurements performed by the casting company,

it was reached the decision that errors during the stage of RP model fabrication were within acceptable limits.

For this research study, it was concluded that the occurred errors were associated with the casting process and with the measurement errors. The resulted bigger model after manufacturing process was interpreted as "over-flow" by the casting company (exceeding the manufacturing tolerances), difficulties being encountered in casting such a complex and surface accurate shape of a small implant.

But the most important errors were the measurement errors, considered to be inevitable. These include human errors and the accuracy and resolution of measuring instruments. The later one can be easily excluded, as the accuracy of the CMM machine used was not questionable. In measuring medical 3D models, the major human errors usually involve locating landmarks. Making the exact location of the same landmarks as on the computer model is sometimes very difficult in 3D models, as Barker et al. pointed out [72].

Although the influence of model accuracy is a key issue in surgical planning and in actual reconstructive surgery, in the present research study it could not be quantified exactly how much each error source contributed to model accuracy, but a general concept of assessing and quantifying the errors was presented.

6.4. Conclusions

This study has produced numerous results and interesting conclusions can be drawn by comparing the findings with the results from the literature.

The experimental errors generated during the casting process and CMM measurement were investigated for the cast implant. The factors that caused dimensional errors were identified according to each production phase. The errors were mainly due to exceeding the manufacturing tolerances at casting process and difficulty in the exact replication of landmark locations. For comparison and statistical error quantification there were made measurement on the cast implant and on the computer model. The results showed that the absolute mean deviation between the computer model and the cast implant was **1.83 mm (0.96%),** which is smaller than values reported in previous studies.

For the overall process of casting, it was found that the structure of the implant was reproduced bigger than the original 3D virtual design. It was also found that there is a large variation between the computer model and implant dimensions when measuring with the CMM (see Table 6.1). This fact was a consequence of using a relative type measuring using CMM machine (point to point measurement) and not an absolute one (involving an accurate measurement reported to a fixed coordinate system) and was due to the difficulty of precisely identifying and locating the landmarks used for measuring.

The factors which were found to have the biggest impact on the accuracy are the casting process (by not respecting the manufacturing tolerance of +1.5 mm) and the measurement errors (human errors due to locating landmarks).

As dimensional checks were carried out on the cast implant, these showed that the stipulated tolerances have been exceeded. However, comparing the experimental results (mean of absolute values of 1.83 mm and a standard deviation of 0.96%) with those in the literature indicated that the present maxillofacial implant was within the existing level of accuracy in this area. The actual maxillofacial implant was therefore assessed as feasible engineering and suitable for insertion.

And as noted in work by Eufinger et al. [75], precise adaptation and accuracy is also not ideal as it makes the insertion of the prosthesis difficult.

However, it is proposed that the accuracy level of the measurement can be improved by precisely locating landmarks and by using an absolute type of CMM measurement involving a fixed coordinate system for all the measurements. This can be materialised by performing more experiments at different test conditions.

CHAPTER 7

DISCUSSIONS AND CONCLUSIONS

7.1. Main Findings and Limitations of the Work

This conclusions chapter consists of the most important findings revealed from the presented study, demonstrates their significance and summarises the contributions of this study to the research area. There are also presented ideas generated by the work, ways how it can be improved and recommendations for future investigations.

The present research study was concerned with taking an existing, successful implant (see Chapter 3, Figure 3.2), further along the road of computer assisted surgery by considering that updating the design and manufacturing process, customised implants could be more accurately designed. This should provide further benefits in savings in unit manufacturing cost and time.

This study covered these three main objectives:

- To develop a computer-based design method for 3D geometrical solid model creation of the customised maxillofacial implant,
- Perform physical and mechanical tests (tensile tests, indentation hardness tests) to characterise the properties of the materials and implants produced using the manufacturing process, for comparison with standard values of the materials.
- Perform dimensional/tolerance checking of the cast implant using a Coordinate Measurement Machine (CMM) to check that the manufacturing tolerances have

not been exceeded and to ensure that an accurate representation of the implant has been manufactured.

In addition to these objectives, extra research has been carried out dealing with the processing of static stress analysis for the implant using ANSYS software, to verify and to certify that the maximum stress achieved with the average bite force is well within the capabilities of the prosthesis.

The importance of **Computer Assisted Surgery technology** as a recently developed field embracing the use of Computed Tomography (CT) / Magnetic Resonance Imaging (MRI) scan conversion, rapid prototyping (RP), three-dimensional CAD, robotics, rapid manufacturing, reverse engineering and finite element analysis (FEA) is substantiated to apply it to maxillofacial surgery field. The extensive literature review carried out at the beginning of the research wanted to prove the importance of Computer Assisted Surgery as recently developed medical field, as well as the context of present research.

In medical practice, it was proved that by comparing conventional maxillofacial surgery with computer assisted surgery there are numerous advantages for its implementation and application. Some of its advantages are: theatre reduction time (for complex flap reconstruction of the maxilla); high accuracy and facilitate the transfer of the surgical plan into the patient using customised cutting and position jigs across a wide range of clinical situations from the treatment of facial deformity to facial pain; no possibility of tumour recurrence within the implant; less intensive care unit time, the ability to treat elderly patients and results in less morbidity and mortality. Patient care is also improved as there is earlier ambulation, quicker recovery time, less hospital time, better facial reconstructions and complications arise less frequently.

Results and discussions documented in Chapters 3. Digital design of the customised maxillofacial prosthesis, 4. Finite element analysis of maxillofacial prosthesis, 5. Physical and mechanical testing of prosthesis, 6. Dimensional/Tolerance checking of prosthesis using CMM machine revealed the following main findings and their limitations:

1. As the **implant design** task was the principal overall objective of the research study, it can be said it was completed in a successful manner. In other words, a computer-based design method has been developed to optimise the existing

design process of the customised maxillofacial prosthesis, allowing effective visualisation, communication and modification of the crucial aspects of the design between the surgeon and the engineers. By comparison with Ninian Peckitt's implant design approach, an optimised virtual implant design process was developed for customised maxillofacial implants in order to conserve the actual shape of the excised bone and to avoid the errors and inaccuracies occurred during the RP model based surgical preplanning and CNC-milling of the titanium implant. Therefore, it is believed that regarding the designing process of the implant, the work reported in this research study has been provided for the first time concerning the large titanium customised maxillofacial implants and it established one of the leading studies in this research area, as an integrated approach of design to manufacture process.

2. **Physical and mechanical tests** (tensile tests, indentation hardness tests) performed to identify the properties of Ti6Al4V material used for casting process showed that the material reasonably met the standard specifications. The slight variations of the yield stress, ultimate tensile strength and hardness experimental values from standard were interpreted as errors due to machining of the test specimens (machined surface inconsistency, dimensional inaccuracy of the diameters and lack of fillets at the end of gauge length) or due to the casting process. The erroneous results obtained for Young's modulus (due to inadequate measurement procedure) led to the conclusion that the certified standard value should be adopted as it stands for present research. The testing aspect of this research study highlights an area for future research and further work.

3. Quality assurance aspect of the cast implant, especially the **dimensional accuracy** of model was verified in order to check if the implant specifications and manufacturing tolerances have not been exceeded. As dimensional checks were carried out on the cast implant, these showed that the stipulated tolerances have been exceeded. Therefore, comparing the experimental results (mean of absolute values of 1.83 mm and a standard deviation of 0.96%) with those in the literature indicated that the present maxillofacial implant was within the existing level of accuracy in this area. The actual maxillofacial implant was therefore assessed as feasible engineering and suitable for insertion. However, it is

proposed that the accuracy level of the measurement could be improved by precisely locating landmarks and by using an absolute type of CMM measurement involving a fixed coordinate system for all the measurements. This can be materialised by performing more experiments at different test conditions.

4. As regarding the basic **stress analysis** performed in present research, the FEA model created for this study was a complex structure consisting of several assembled parts meshed with shell elements, assumed to be homogenous and isotropic and to possess linear elasticity. Considering the fact that this study was the first effort at static modelling the stress distribution in the implant, a reasonably good agreement between experimental and referenced results was achieved. As this study consisted just in verification of the loading forces and distributed stresses, a model to simulate more accurately the real phenomenon could be developed. However, in order to increase the confidence level in the accuracy of the present model it would be necessary to validate and optimise the key aspects of the model (e.g. mesh refinement) against more experiments at different conditions (fatigue non-linear contact analysis). Once validated, such model has great potential for analysis different implant conditions and predicting performance.

Based on presented and documented results from this research study it is believed that all three main objectives were fully satisfied.

This research study consisted in an integrated approach from design process and manufacture to dimensional quality assurance for the developed customised maxillofacial implant. The results achieved will support the purpose of the research to prove the viability of an idea that by using CT/MRI scans, Finite Element Analysis, Computer Aided Design and Rapid Prototyping through an integrated approach, realistic modelling and simulation of the body structures and the design of implants can be easily performed.

7.2. Contributions of the Research Study

The main purpose of this Enterprise Ireland funded research was to develop a process that in comparison to the existing method of designing and manufacturing maxillofacial implants proposed by Mr. Ninian Peckitt, is more efficient, streamlined,

accurate and will produce an implant that is stronger, lighter and easier to position surgically.

The research carried out as the subject of this thesis was integrated part of the larger study and by assessing the appointed and developed tasks is proven to be successful.

Regarding the accuracy of the customised maxillofacial prosthesis, the computer-based design method showed its superiority upon hand-marking the biomodel for further implant design and it was considered to be a breakthrough of the whole research. There were less errors induced in the design process as the process is completely computer based, originating from the CT scans, as opposed to the existing process where there is interchange between digital and physical models, with each step probably introducing extra errors into the process.

As regarding the mechanical testing of titanium alloy used, it could be mentioned that titanium and its alloys are biomedical materials with well established, proved and referenced properties, which do not need further investigations. This only needs to be rechecked if there is any doubt that the manufacturing process chosen may have affected the properties of the final produced implant.

One important aspect that was looked at in this research was the dimensional metrology of the implant. While the clinical practice with medical implants has become more and more daily routine for medical experts, quality assurance aspects, especially the dimensional accuracy of the models, has to be verified in order to meet the implant specifications and manufacturing tolerances. This assesses that the manufactured implant is feasible for insertion from engineering and clinical aspects.

If the collaborators' research proves to be successful as well, the whole process can be integrated in a stand-alone technology, from customised design and manufacture to quality assurance of maxillofacial implants, all provided by one single institution/company in collaboration with the surgeon.

Another important aspect to be considered it represents the costs involved in this procedure. For the research carried out in GMIT the costs could not be precisely quantified. The costs involved in the whole research and estimative expected costs for

implant design and manufacture will be established when the research is conclude, as well as the cost effectiveness of the proposed process.

Considering the Computer Assisted Surgery aspect some cost explanation could be given. Current operating theatres are not equipped for the sudden introduction of CAS techniques. Eventually theatres will need to be redesigned and be connected with computer networks and special side rooms incorporating specialist software and hardware. Though CAS results in much improved surgical outcomes it might not result in overall cost savings. This is because while each procedure would be less expensive than conventional ones, overall a lot of hardware, software and highly trained technicians would need to become involved with the surgical procedures. However, what would happen it that surgical procedures would be highly improved and, in particular, procedures that are difficult or impossible at the moment could be performed. At some point CAS technologies will be brought to bear on surgical procedures and will be incorporated in the standard training of surgeons. This will not happen overnight, but when it does it will have far-reaching patient benefits. It is important that development work of this type is done in such a way as to maximise its success. This means highly qualified engineers and surgeons should work closely and surgical procedures should be implemented in centres of excellence.

CAS maxillofacial surgery is one of the most important advances in medicine recently and further technical development will benefit many people in the future.

This type of research in the field of Computer-Assisted Surgery, is strategically relevant to the Irish economy, and has a ready market which has not been tapped yet. This research field, if continued to be investigated, would leap-frog Ireland into the very best of research that is being done anywhere in computer assisted surgery with immediate commercialisation thereafter.

7.3. Recommendations and Future Work

Knowledge and experience rose from executing this research study lead to suggest the following recommendations for improvement and future work:

1. Regarding the implant design process aspect, alternate designing routes may be investigated if prove their efficiency and superiority upon present approach. Since the research was carried out, design software MAGICS RP has extended its capabilities including an FEA module, which provides a link to FEA environment where volumetric mesh elements can be imported and linked to material properties. This future research should also review any new design software available.
2. A further non-linear elastic fatigue analysis could be carried out in order to identify the distributed stresses in the implant attachment systems (screws, abutments), at the implant-bone interface and in the afferent bone structure. As this task is emphasis of collaborators from NUIGalway, the results of the non-linear contact modelling will help achieving a design of the implant that will have an optimised internal stress distribution, will prevent the loosening and the loss of implant and will be of a minimum weight.
3. Alternative materials for casting may be useful to investigate for the scope of this research, such as Vanadium-free titanium alloys (Ti5Al2.5Fe and Ti6Al7Nb) as Ti6Al4V has been reported as toxic to the human body [76].
4. The testing aspect of this research has high potential to facilitate further research and development work for better quantifying the material used properties.
5. Optimal cooperation between the engineers and surgeons is proposed, taking into consideration the anatomical constraints and engineering feasibility when designing the implants.
6. The implant virtual designing approach was particularly concerned with the specific case study chosen, because of the patient/surgeon confidentiality. The principles demonstrated can however be extended to any similar surgical maxillofacial implant requirements (even if each customised implant will come with its own challenges they can be overpass due to collaboration design engineer-surgeon). CT scans of two more case studies (Figure 7.1) are available in DICOM format (for future work), but their public availability needs to be discussed with the surgeon.

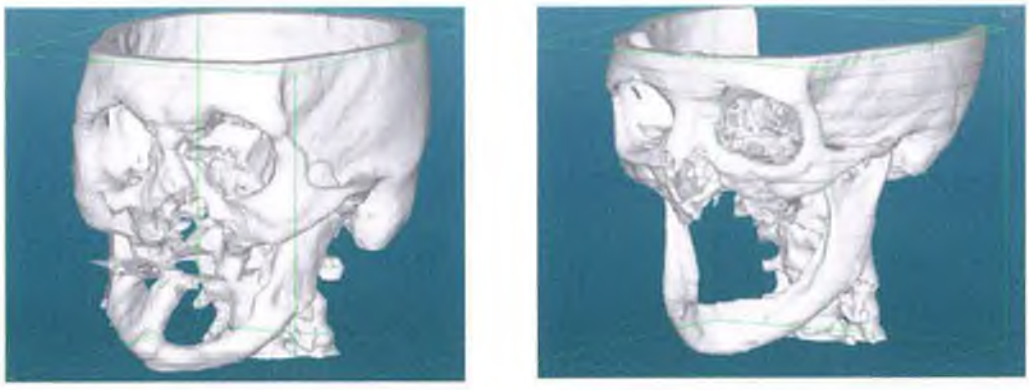


Figure 7.1 Available case studies for maxillofacial implant design

7. Clinical studies could be carried out and accurate monitor of the costs involved.
8. This research should be further extended to optimise the procedures from the present study, with potential commercialisation of the implant design to manufacturing process as an integrated approach.

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APPENDIX

GLOSSARY OF MEDICAL TERMS

No	Name	Definition
1.	**Xenograft**	A transplant composed of tissue from a different species than the recipient. Graft of a piece of tissue or organ from one individual to another of a different species
2.	**Autograft**	Tissue (such as skin, bone or muscle) taken from one part of a person's body and grafted to another part to replace damaged critical areas. For instance, surgeons may remove muscles from the back to replace damaged muscles in the lower leg or forearm.
3.	**Allograft**	A graft (transplant) of material from the body of one person (usually a dead person) to that of another person. The graft is harvested (taken) from the first person (the donor) and put into the second person (the recipient).
4.	**Dysostosis**	Defective bone formation
5.	**Cleft lip**	A birth defect in which the lip does not completely form. The degree of the cleft lip can vary greatly, from mild (notching of the lip) to severe (large opening from the lip up through the nose). Cleft lips may be caused by genetic or environmental factors.
6.	**Distraction osteogenesis**	A technique in which bone can be lengthened by de novo bone formation as part of the normal healing process that occurs between surgically osteotomized bone segments that undergo, controlled distraction. Compared to conventional approaches, the ability of the soft tissue envelope to accommodate the gradual expansion of the underlying skeletal framework that contributes to the stability of the reconstruction is unique to distraction.
7.	**Oropharynx**	Cavity formed by the pharynx at the back of the mouth

8.	**Orthognathic Surgery**	That branch of surgery concerned with the correction of developmental and acquired dentofacial deformity, particularly disproportion of the tooth-bearing segments of the jaws, and associated facial skeleton.
9.	**Tracheostomy**	A surgically created opening into the trachea (windpipe) to help someone breath who has an obstruction or swelling in the larynx (voice box) or upper throat or who have their larynx surgically removed.
10.	**ICD-9**	(International Classification of Diseases, Ninth Revision) is designed to promote international comparability in the collection, processing, classification and presentation of mortality statistics.
11.	**Chemotherapy**	A treatment for cancers that involves administering chemicals toxic to malignant cells
12.	**Lymphadenopathy**	Swelling or enlargement of the lymph nodes due to infection or cancer. The swollen nodes may be palpable or visible from outside the body.
13.	**Immunogenicity**	The property of being able to evoke an immune response within an organism. Immunogenicity depends partly upon the size of the substance in question and partly upon how unlike host molecules it is. Highly conserved proteins tend to have rather low immunogenicity or damaged teeth.
14.	**Morphogenetic**	Producing growth; producing form or shape
15.	**Antigen**	Any foreign substance, such as a virus, bacterium, or protein, that elicits an immune response by stimulating the production of antibodies. A substance that stimulates the production or mobilization of antibodies. An antigen can be a foreign protein, toxin, bacteria, or other substance.
16.	**Autogenous**	Originating within the body
17.	**Allogeneic**	A graft or tissue from someone other than the patient, usually a matched sibling (a brother or sister), but may be a matched unrelated volunteer donor.
18.	**Biological osteosynthesis**	The philosophy of treating comminuted fractures by bridging the fracture site without anatomic reconstruction of the fracture fragments. Correct length and anatomic alignment take precedence

		over fragment rebuilding during this approach to fracture repair.
19.	**Hydroxyapatite**	It is a calcium phosphate salt. Hydroxyapatite is the main mineral component of bone of bone and teeth, and is what gives them their rigidity.
20.	**Atrophy**	Decrease in size of an organ caused by disease/disuse.
21.	**Osseointegration**	Originally defined as a direct structural and functional connection between ordered living bone and the surface of a load-carrying implant. It is now said that an implant is regarded as osseointegrated when there is no progressive relative movement between the implant and the bone with which it has direct contact. In practice, this means that in osseointegration there is an anchorage mechanism whereby nonvital components can be reliably and predictably incorporated into living bone and that this anchorage can persist under all normal conditions of loading.
22.	**Ossoefascio-cutanoeus flap**	Technique of bone transfer, using a deep fascial blood supply to transfer bone together with a large area of skin. The viability of this flap and further confirmation by isotope scanning have established that the bone transfer is vascularised
23.	**Overdenture**	A type of denture that is secured by precision dental attachments. The attachments are placed in tooth roots or dental implants, which have been placed specifically for the overdenture attachment. Overdenture represents also a complete denture that is supported by both soft tissue and natural teeth that have been altered so as to permit the denture to fit over them. The altered teeth may have been fitted with short or long copings, locking devices, or connecting bars.

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Design and manufacturing of customised maxillofacial prostheses

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Customised implants created by Computer-Assisted Surgery (CAS) techniques and used in maxillofacial reconstruction indicate improved outcomes over conventional techniques.

"Non-functional" multistaged procedures are commonly carried out in the treatment of malignancy, often involving the harvesting of hard and soft tissue from a second surgical site. External approaches are associated with an increase in surgical trauma.

Large titanium implants, as a facsimile of the resected bone and designed on a biomodel, used by Mr. Ninian Peckitt, have used many techniques of CAS to address functional surgical reconstruction and evidence-based results have indicated savings in time, cost, intensive care unit time, ambulation, morbidity and mortality. Furthermore, in some cases it is possible to perform the procedures on patients with compromised medical conditions.

In this research an existing, successful implant has been taken further down along the road of CAS by improving the design and manufacturing process. A method has been devised by using solid modelling techniques to create a customised implant. The procedure initiates with a CT scan, which is converted and transferred to CAE software. The implant is designed virtually with respect to the patient anatomy and is thus accurate and patient specific. The implant can then be created by rapid manufacturing techniques.

The purpose of the present research is to further advance the technology used by Mr. Peckitt in order to create maxillofacial implants which are more accurately designed and manufactured in a completely different way. The result will be to create implants more accurately, faster and at less cost to the patient or health care provider.

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Design and Manufacturing of Customised Maxillofacial Prostheses

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Maxillofacial surgery can involve oral rehabilitation, implants, jaw resection and reconstruction of hard tissue as a result of cancer, other diseases or trauma. Large titanium implants, as a facsimile of the resected bone, used by Mr Ninian Peckitt, have used many techniques of **computer assisted surgery** to address surgical reconstruction and evidence based results have indicated savings in time, cost, intensive care unit time, ambulation, morbidity and mortality. Furthermore in some cases it is possible to perform the procedures on patients with compromised medical conditions or elderly people.

STANDARD "NON-FUNCTIONAL" APPROACH

Figure 1 Mutilation

Figure 2 Dehiscence

Figure 3 Loss of implant

Characterstics:

- External Approach
- Non Functional
- Mutilation
- Obturator
- **Surgery 12-18 hours**

"FUNCTIONAL" RECONSTRUCTIVE APPROACH

Figure 4 Biomodel

Figure 5 Presurgical Planning

Figure 6 Customised implant and overdenture

Figure 7 Roadmap of the process

Advantages:

- Atraumatic surgical technique
- No second donor surgical site required for successful reconstruction
- Reduction in morbidity
- No postoperative intensive care required

SURGERY 2.5 hours !

PROPOSED APPROACH

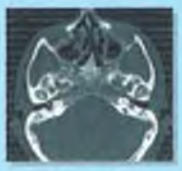


Figure 8 CT scan of the skull

Figure 9 Possibility of transferring CT scans - virtual 3D model

Figure 10 Implant designed with respect to virtual model

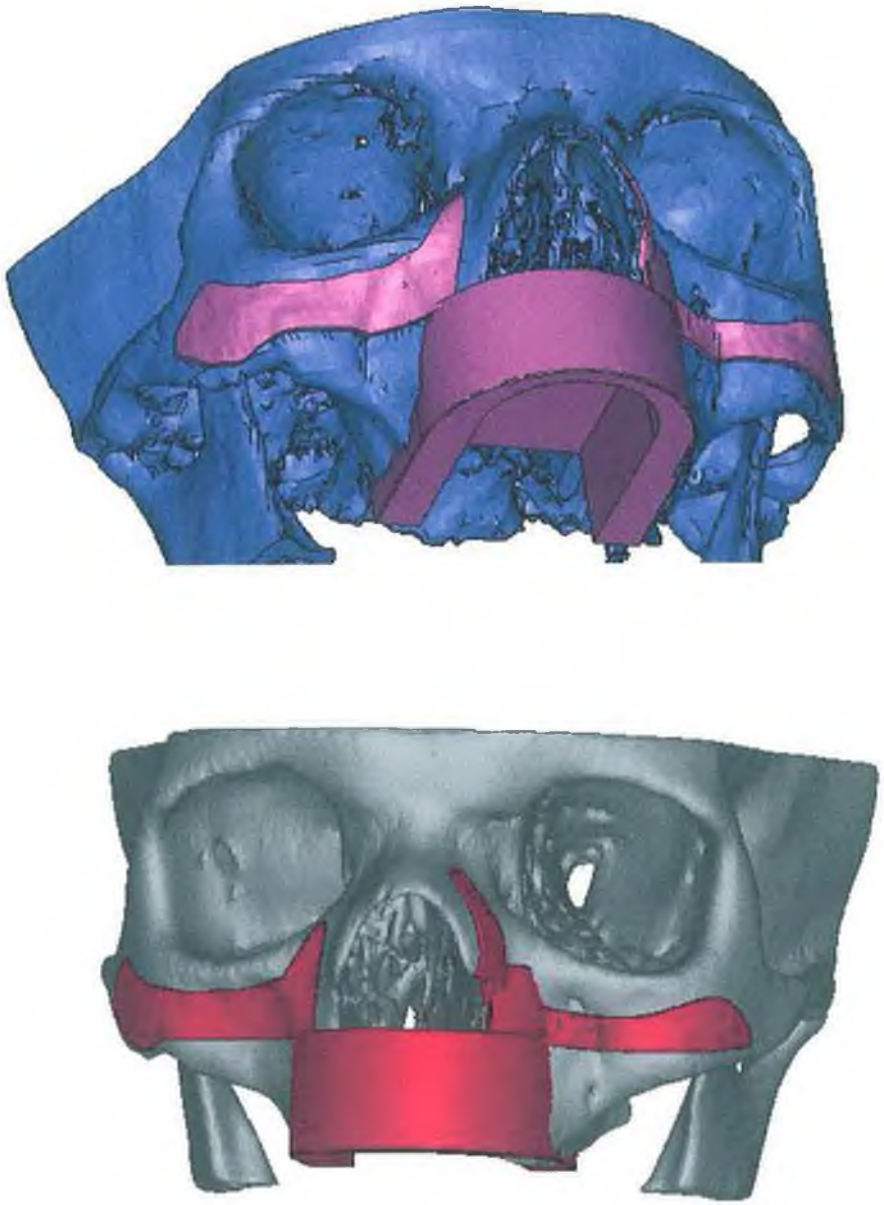
Figure 11 New proposed roadmap of the process

Additional Advantages:

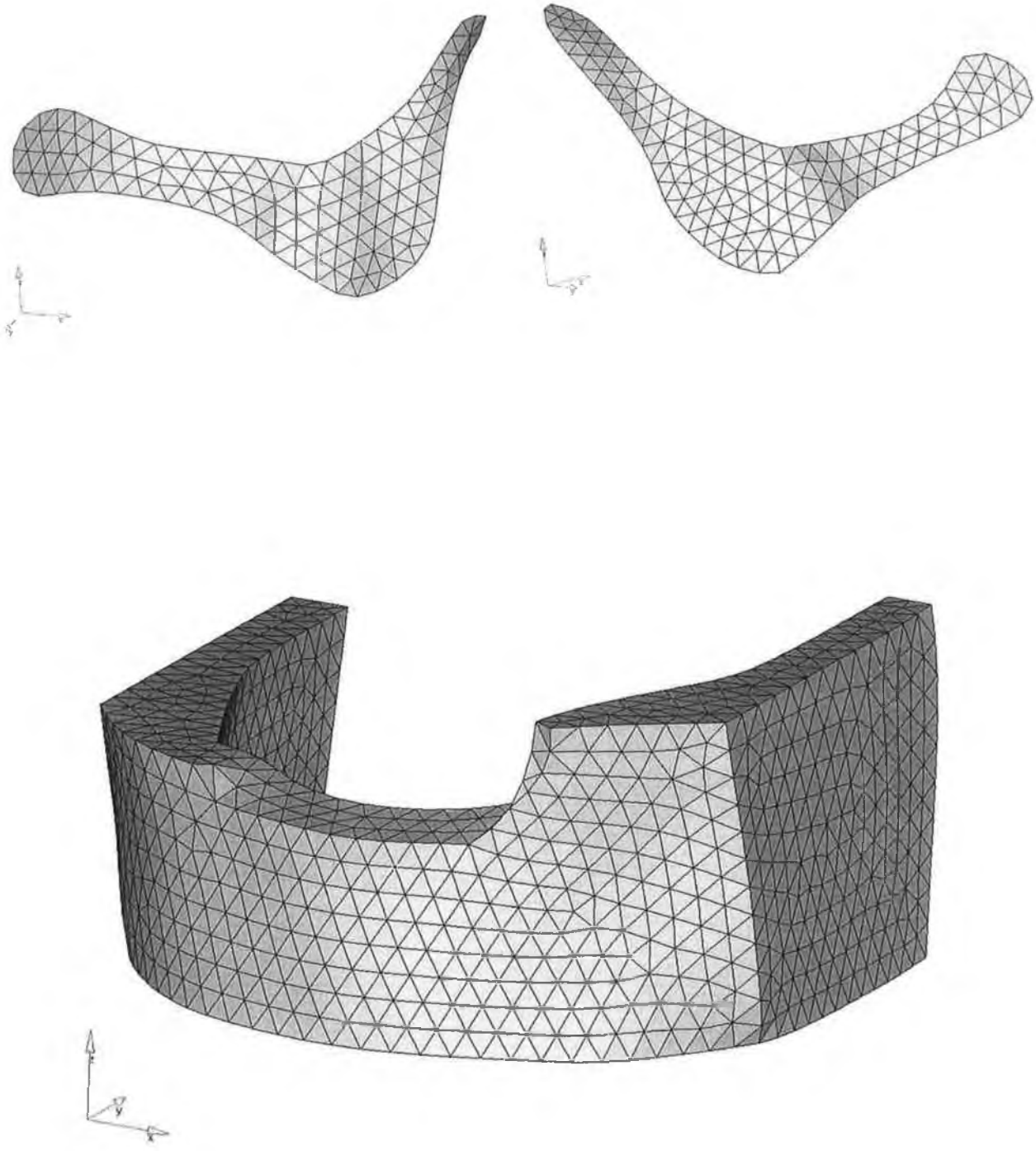
- Reduction in manufacturing time/cost
- High precision
- Digital model available for FEA

An existing, successful implant has been taken further down along the road of computer assisted surgery by improving the design and manufacturing process. A method has been devised by using solid modelling techniques to create a customised implant. The procedure initiates with a CT scan, which is converted and transferred to CAE software. The implant is designed virtually with respect to the patient anatomy and is thus accurate and specific to the patient (see Figure 10). The implant can then be created using techniques of rapid manufacturing.

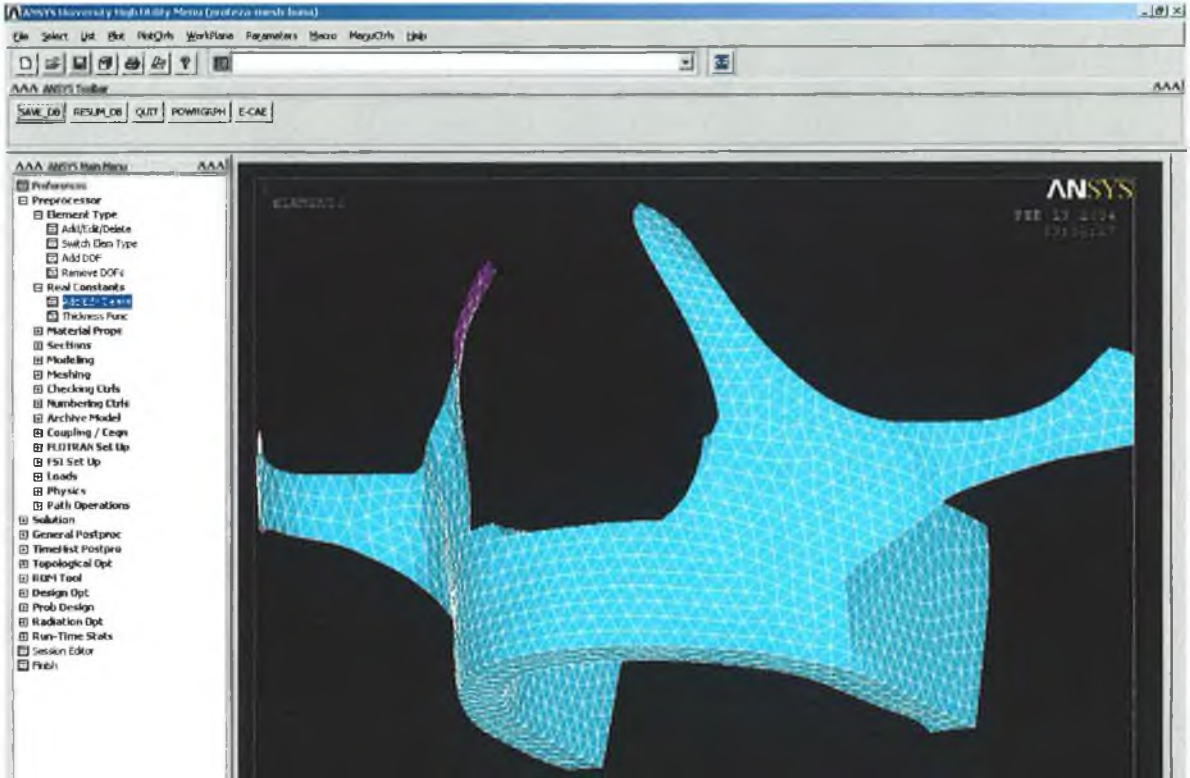
Acknowledgement: This research is funded by Enterprise Ireland as a part of Research Innovation Fund 2002.



Customised maxillofacial implant designed on biomodel



Meshes of components of the prosthesis (HyperMesh)


File Select List Plot PlotCtrls WorkPlane Parameters Macro MenuCtrls Help
SAVE_DB RESUM_DB QUIT POWRGRPH E-CAE
Preferences
Preprocessor
Element Type
Add/Edit/Delete
Switch Elem Type
Add DOF
Remove DOFs
Real Constants
Thickness Func
Material Props
Sections
Modeling
Meshing
Checking Ctrls
Numbering Ctrls
Archive Model
Coupling / Ceqn
FLOTRAN Set Up
FSI Set Up
Loads
Physics
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TimeHist Postpro
Topological Opt
ROM Tool
Design Opt
Prob Design
Radiation Opt
Run-Time Stats
Session Editor
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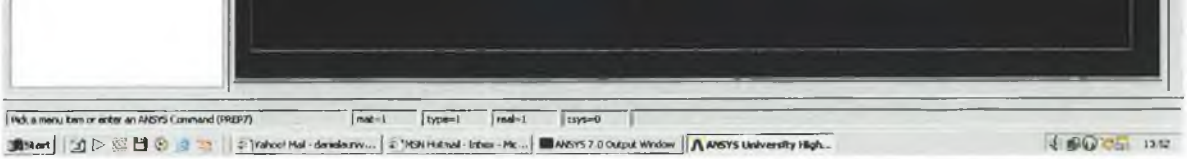
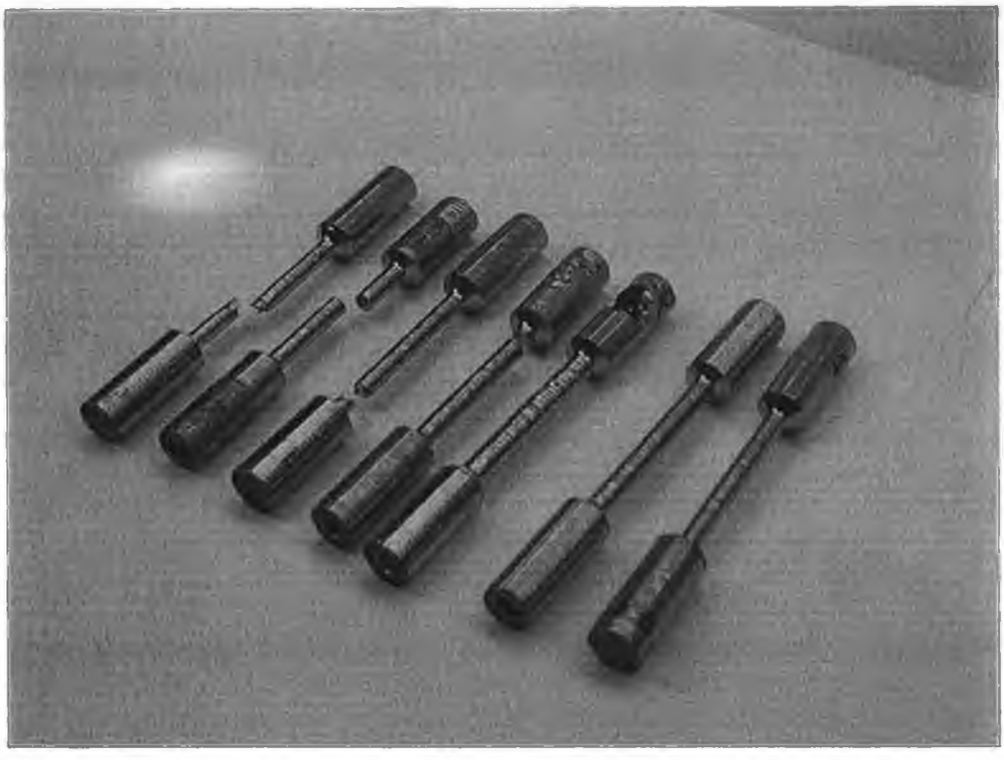
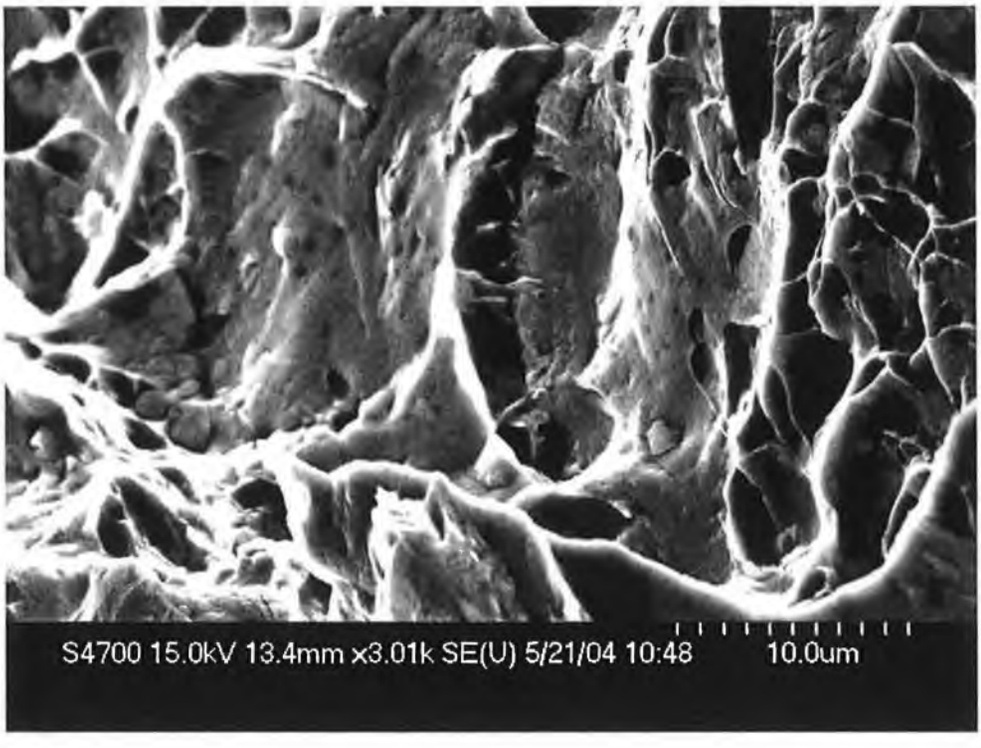
ANSYS



ANSYS mesh of the maxillofacial implant



Ti6Al4V test specimens for testing



SEM image of fractured surface