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Author(s)	Serban, D.;Boyle, D.;O'Donnell, G.;Lohfeld, Stefan;McHugh, Peter E.;Peckitt, Ninian
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Engineering Assisted Surgery™: A route for digital design and manufacturing of customised maxillofacial implants

S. LOHFELD, P. McHUGH, D. SERBAN*, D. BOYLE*, G. O'DONNELL*, and N. PECKITT**

National Centre for Biomedical Engineering Science (NCBES) and Department of Mechanical and Biomedical Engineering, National University of Ireland, Galway, Ireland

* Department of Mechanical/Industrial Engineering, Galway-Mayo Institute of Technology (GMIT), Galway, Ireland

** ComputerGen Implants Ltd., St Chad's House, Hooton Pagnell, Doncaster, UK

Corresponding author:

Dr. Stefan Lohfeld

National Centre for Biomedical Engineering Science (NCBES)

National University of Ireland, Galway

Galway

Ireland

Phone: +353-91-492963

E-mail: stefan.lohfeld@nuigalway.ie

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Abstract

Rapid Prototyping (RP) and more recently Rapid Manufacturing (RM) as a part of Engineering Assisted Surgery™ enables manufacturing of customised implants and prostheses prior to surgical procedures. Beginning with CT or MRI scans, implants can be customised - designed for a named patient and optimised for shape and mechanical requirements using digital data only, disregarding all physical models except for the final implant. In this paper a route to digitise the design of an existing implant is described, consisting of transfer of CT data, design of the prostheses, FE analysis, rapid manufacturing from titanium, and quality control.

Keywords

Engineering Assisted Surgery™, Customised Implants, Finite Element Analysis, Rapid Manufacturing

1. INTRODUCTION

Engineering Assisted Surgery™ (EAS™) is a new field of research now accepted internationally by Healthcare institutions as defined by Peckitt (www.maxfac.com) as the “*application of engineering and manufacturing technology in the delivery of healthcare*”. EAS™ processes include CT and potentially MRI scan conversion, Rapid Prototyping (RP), 3D CAD, Robotics, Rapid Manufacturing (RM), Reverse Engineering (RE), and Finite Element Analysis (FEA), aimed at the improvement of surgical procedures. In medical applications, the use of EAS™ has led to improvement in services offered to patients by improvements in such areas as 3D visualisation of a specific anatomy, surgical planning, implant designs, and prostheses production [1, 2]. Most frequently, stereolithographic models are used to plan surgical interventions and to communicate them to the patient, as described elsewhere [3, 4].

CAD/CAM has already been used to design implants by mirroring healthy bone structures. In some cases, craniofacial titanium implants have been manufactured using RP techniques to produce a polycarbonate model for casting [5, 6].

EAS™ and particularly RP and more recently RM in maxillofacial surgery show several benefits compared to conventional surgery. Reconstruction of hard tissue can be necessary after treatment of oral cancer, other diseases or trauma. The planning of the operation in 3D and the design of an implant using an RP-manufactured model of the skull offers a precision not previously available in surgery. Independent corroboration (Phidias Study [7]) confirms more accurate diagnosis, facilitation of treatment planning and delivery of the surgical task, with the most appropriate surgical team. Peckitt has demonstrated huge savings of theatre time: a thirteen hour “traditional” maxillary resection and reconstruction may be carried out in 2.5 hours using EAS™ – a 500% efficiency improvement in the use of theatre time. Intensive care utilisation (as a function of surgical trauma in major cases) is often not required in EAS™ procedures, as the degree of surgical trauma is significantly reduced. This not only benefits the patient, in terms of enhancement of rehabilitation but promotes the appropriate use of resources. Additionally, decreased morbidity and mortality after treatment with large exposed customised implants made of titanium instead of free flaps raise the treated person’s life quality and lower the costs per patient significantly [8].

EAS™ techniques have become so refined now by Peckitt that the management of cases are now possible under local anaesthesia within the primary care setting - i.e. under local anaesthesia - avoiding admission to hospital [8].

The manufacturing of customised maxillofacial implants is a laborious multi-step process involving the generation of physical models of the patient's skull (or physical biomodels, as defined in Lohfeld et al. [9]) to aid in prosthesis design.

Currently EAS™ and RP techniques permit the manufacture of accurate 3D anatomical models from CT scans. These models are invaluable in diagnosis and treatment planning. However, the prosthesis is traditionally designed by marking up a physical replica of the bone (physical biomodel). CT scans are used to generate a biomodel of the region of interest by stereolithography or other RP techniques. Subsequently, the model is reverse engineered to transfer the design of the prosthesis to a software environment. The complexity of the anatomical region and prosthetic design have important influences on the choice of the optimum manufacturing process for the given part or parts; at the time EAS™ was conceived, reverse engineering of the prosthesis could involve the welding of several component parts to re-create the complex anatomy. The prosthesis is finished with deburring and polishing processes in order to generate smooth surfaces.

Interaction between physical and digital models can lead to inaccuracies and errors. Furthermore, where the process of prosthesis manufacture involves different specialists in different locations, the risk of inaccuracy and error is increased. In addition, the production time for implants is prolonged. To save time and retain high precision, software should 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.

Many EAS™ related publications discuss the use of biomodels generated using rapid prototyping for diagnostics, operation planning [10] and preparation of implants [11, 12], even in a virtual environment [2, 5, 13-15]. Some studies have been performed using digital design and RP techniques for direct manufacturing of an implant model [6]; but not with respect to material suitable for implantation.

A literature review confirms the absence of a complete route for an optimised design and manufacturing process for customised prostheses with an acceptable quality assurance system. The present paper will demonstrate how customised prostheses can be generated and assessed for quality and accuracy using a standardised, lean planning and manufacturing process.

2. OBJECTIVES

A method for designing large maxillofacial implants in a virtual environment is presented, without the use of physical biomodels. In addition, direct manufacturing of the final implant using rapid manufacturing is explored.

In this study, customised implants are designed in a virtual environment to eliminate frequent interchanging between physical and virtual models. In addition, a computational analysis of the implant has been devised to verify its mechanical stability, and a quality assurance system is proposed. Such a comprehensive route has not been published before, and will result in cost and time effective development of prostheses with highest accuracy, functionality, and reliability with the leanest profile possible.

To illustrate the process an existing successful large maxillofacial implant, shown in Figure 1, is considered. As extensively reported in [16], this implant was designed and manufactured using EAS™ technology, an anatomical biomodel, with reverse engineered welded component parts of the implant. Being implanted for nearly ten years now without any complications, it has a proven record of surgical success.

(Figure 1)

Several software packages have been evaluated for optimal implant design in terms of their import functions, their capability to use imported 3D models as references, and their design capabilities. Therefore, the present paper also reports on an assessment of a number of design model generation methodologies that are relevant to this application.

3. PROCEDURES

3.1 Model Data Transfer

Using MIMICS scan conversion software (Materialise, Belgium), CT scans can be viewed and transformed into a 3D model. For this study, a segment of maxillofacial bone was selected, the geometry of which was available in CT scan format. Since the design capabilities of typical scan conversion software are limited, the 3D model of the bone segment has to be exported to solid modelling software. Therefore, the initial task would be to choose an export format which gives a good representation and allows further design. Potential export formats include IGES (Image Graphics Exchange Specifications) or files for rapid prototyping. Which geometrical information to export can also be selected, and amongst the choices are (1) the bone contours, (2) NURBS (Non-Uniform Rational B-Spline) curves and surfaces, calculated on the silhouette, and (3) 3D models.

Bone contours

Bone contours 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 line segments. These polylines are exportable as an IGES file, a standard format which can be read by many applications.

In actuality, IGES files contain information about surfaces. In the case of polylines, the line for each slice comes without a dimension in the scan direction (z axis), Figure 2. To close the gap between the lines resulting from the scan spacing, the polylines can be used as a basis to calculate a surface or a solid model in CAE software. As a result of this, solid models can be readily created.

(Figure 2)

In some cases CAE software needs a “watertight” model to allow importation in terms of an IGES file. However, as the CT scan is represented by a stack of lines, there is no closed model available and IGES files can’t 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. Such surfaces can be quite rough and the resulting representation would not be accurate enough to use as a reference for prosthesis supports.

NURBS curves and surfaces

NURBS curves and surfaces, Figure 3, can be generated in scan conversion software or in CAE packages. Calculated on the information given by the CT scans, they provide a smooth 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. the number and position of control points, degree of polynomial, etc.) and sometimes they turn out to be too wavy.

(Figure 3)

3D models

The 3D representation shown in the scan conversion software 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, *.SLC, *.SLL, etc.

The contour of these models (left hand side in Figure 4) is the same as the contour of the 3D visualization and therefore seems to be the most accurate representation. However, even if CAE software is able to import these files for viewing they often cannot be used as a reference for design. The huge amount of data needed to represent the model within the CAE software can sometimes slow down a computer to a level on which further work is not practical.

As discussed above for the bone contour exportation, the solid model format can be exported as an IGES file. Using this method, a stack of polylines will again result, although the lines are more numerous and closer together. This presents the potential for greater ease in surface creation between the lines and for more accurate representation of actual bone geometry. Again, the import functions of the CAE software regarding this file format must be taken into account.

(Figure 4)

Due to its high accuracy in representing the actual bone surface, the 3D model exported as STL model data proved to be the most suitable for this kind of application. STL manipulation software, such as 3Data Expert from DeskArtes, enables one to extract marked regions from the bone model. The functions available were used to design the flanges of the prosthesis. To ensure perfect fitting of the flanges to the bone, the actual bone contour was copied and extruded to the desired thickness, as shown in Figure 5. Contrary to the approach using idealised freeform surfaces that has appeared in the literature for covering defects [17, 18], this particular STL based step that ensures an exact fit with the bone, for the flanges, has not been reported before; this represents a significant novelty and gives the overall methodology considerable flexibility for use in different situations. The main body of the prosthesis, i.e. the section that will replace the resected bone, can be designed using any one of a number of conventional CAD software packages. In this case the software package Pro/ENGINEER (PTC, USA) was used. Finally, the flanges and the main body were united in one model, see Figure 6.

(Figure 5)

(Figure 6)

As an alternative to an engineered design of the prosthesis, the actual bone shape can be re-produced. Tools available in the software MIMICS allow the manipulation of the CT scans and subsequently of the 3D models generated from the CT scans. This allows the designer to “repair” at least smaller defects prior to the 3D modelling step. The advantage of this procedure is that if replicas of bone contours are used for the prosthesis, the patient’s appearance will not be altered. This is an important psychological benefit for the patient. Depicted in Figure 7 is a prosthesis shaped as a replica of the original bone structure, as shown in Figure 5, with the defect removed. Additionally, for this model it was decided to include the hard palate in the denture and not in the prosthesis. This allows easy inspection of the nasal cavities.

(Figure 7)

3.2 Finite Element Analysis (FEA)

A traditionally-designed prosthesis is likely to have an exaggerated level of mechanical stability and could potentially use excessive amounts of material. However, this means the patient's natural tissues will have to bear higher loads than is physically necessary. By linking in FEA to the design process, it is possible to generate a leaner and more lightweight design of the prosthesis. Several formats of CAD model data can be read by FEA software, and the STL format is no exception. The STL data of the model shown in Figure 7 were transferred to the pre-processor HyperMesh from Altair. The STL model mesh consists of triangles, however, these usually have a very bad quality for FE analysis, and remeshing the model is advisable. Needle shaped triangles may have to be removed before remeshing, as they are obstacles to a continuous mesh seed. This task was very laborious but necessary to get a good mesh. Recently, a remesh module available for the CT scan conversion software MIMICS has been released which facilitates the remeshing. It changes the shape of the triangle in the STL model and provides a better mesh quality to satisfy the demands of FEA. However, improvement of the mesh is still required. Using the pre-processor a mesh suitable for FEA was generated and forces and constraints were applied to the model. A force of 150 N represented the maximum biting forces. This value was taken from the literature [19].

In the current case, several calculations with different boundary conditions were performed using the model. ABAQUS was the FEA solver used for these calculations. In one case a solid prosthesis body from titanium alloy (Young’s modulus: 110 GPa, Poisson’s ratio: 0.327) was modelled, using 10-node tetrahedral elements (Number of elements: 19168). In a second case the mechanical performance of a shelled body was investigated, using 4846 10-node tetrahedral elements for the flanges of the prosthesis as beforehand, and 5365 shell elements for the prosthesis’ body. The prosthesis was constrained by four screws on each side and at four node on top of the prosthesis where it is pressed against the upper jaw, while the load was applied on one node at the bottom of the prosthesis. The FE tool is very flexible and allows quick checking of the effects of changing wall thickness for a shelled body. As a result

of these calculations it was observed that for titanium alloy a wall thickness of 0.5 mm for the main body of the prosthesis is sufficient to withstand the observed chewing forces. The maximum von-Mises-stresses were 400 MPa, see Figure 8. Compared to the solid material this reduces the weight of the prosthesis pictured in Figure 7 by 57 %. The overall weight for the shelled prosthesis was lowered to approximately 25 g. This is in good accordance with the weight of the bone portion that has to be resected for this implant, which was calculated to be 31 g.

If a choice of materials is available, the material properties of the FE model can easily be changed and the mechanical performance of the implant based on the material can be examined.

(Figure 8)

As an extension to the route presented here FE aided design could be introduced. An FE model of the skull, or at least of the affected regions, will allow one to determine the loading of the bone through the implant and the most suitable positions for screws to fix the prosthesis. The results of this analysis then can be incorporated into the design of the entire prosthesis.

3.3 Manufacturing

Rapid Prototyping, also referred to as solid freeform fabrication (SFF), allows the manufacture of the complex shapes that are found in the facial region and therefore is the preferred manufacturing process. Several techniques of SFF exist, that allow working with varying materials, even metals. For the specific case of interest here, the prosthesis shown in Figure 9 was manufactured by Fraunhofer Institut für Lasertechnik, Aachen, Germany, using Selective Laser Melting, which is a SFF technique capable of processing titanium and other metallic powders with 20-40 μm particle size directly. In a similar way to the Selective Laser Sintering Process, selected areas of a metallic powder bed are melted by a laser in an inert gas atmosphere, and no binder is needed. The material solidifies and a new layer of powder is added and the laser acts again. This way, a solid part is created layer by layer in a bed of loose powder. Working with this process and titanium or titanium alloy powder directly has several advantages: the steps of making a model and a mould for investment casting is omitted, geometries unsuitable for casting are possible and hollow parts can be produced. To take advantage of a hollow part an outlet for trapped powder must be included. Abutments for attachment of a denture as can be seen in Figure 1 have not been included in the digital designs of the prosthesis. However, they can easily be added in an additional production step. The sites for these parts can be used for powder removal. The holes are then closed when attaching the abutments.

(Figure 9)

A hollow prosthesis not only benefits from being more lightweight, but can also be produced faster as the production time of SFF processes strongly depends on the area to be scanned with the laser in each layer.

Due to the nature of this powder based process the surface of the model is rough. If a smooth surface is required grinding and polishing is inevitable. Alternatively, the prosthesis can be coated with hydroxyapatite, if desired. The rough substrate then will enhance adhesion of the coating.

3.4 Quality control

Quality control is an important part of the route presented. As the prosthesis is manufactured prior to the operation, precision in fitting and mechanical reliability have to be ensured. Further need for modification during the implantation is not expected by the surgeon and may not be feasible. In addition to a dimensional check of the custom-made prosthesis, the FE analysis confirms that the design provides mechanical reliability, given that the material properties are as assumed. However, at least occasional verification of the properties by mechanical testing of samples contributes to a high quality standard.

For the dimensional check, an automated, standardised measuring system using a coordinate measuring machine (CMM) appeared impracticable, as each customised implant has a different shape. However, from the point of view of dimensions the RP process proved to be very reliable. To verify that the prosthesis is dimensionally accurate, it is proposed here that a model with simple geometric shapes is included in every build when manufacturing the prosthesis, e.g. as shown in Figure 10. As the number of prostheses manufactured increases the designer/manufacturer will be able to generate and update a sufficient set of geometrical shapes to be included in the accuracy check model. This model can be measured automatically using a standardised program for the CMM. Measurements performed on the prosthesis itself is limited to gauge the dimensions of highest importance.

(Figure 10)

In order to examine the structural integrity of the sintered titanium produced using the SFF process, standard test specimens, e.g. for tension tests, were built simultaneously with the prosthesis. This enabled investigation of the mechanical and physical properties of the material for comparison with wrought titanium/titanium alloy and for inclusion in the model data for FE analysis. The tensile strength for TiAl6V4 specimens was determined to be approximately 1300 MPa. While the achieved elongation at break for these specimens was around 5 %, it can be increased to values greater than 12 % by annealing of the parts after production. The parts are approximately 100 % dense and the grain size is typically around 100 μm . More details about microstructure and chemical composition of parts manufactured by Selective Laser melting can be found in [20]. Altogether, this is a robust system to ensure the mechanical integrity of each prosthesis and goes beyond the current quality assurance system. Using titanium for the original prosthesis in Figure 1, its mechanical capabilities are much higher than the needs and mechanical failure is unlikely. Only the welds were checked using X-ray. However, welds as critical sites do not occur in the solid freeform fabricated prosthesis, though if the prosthesis required thin walls and/or different materials the mechanical reliability would need to be checked. Hence, to ensure in future that the material processed via SFF compares to bulk material or, if this is not the case, at the very least to validate the values used in the FE analysis, mechanical tests could be performed on a test specimen built with each prosthesis. The data gained from these tests can be entered into the FE analysis for a conclusive prosthesis check before delivery.

4. CONCLUSION

The presented route constitutes a robust method to design and manufacture large customised maxillo-facial prostheses with a lean profile. The method incorporates novel use of the flexible STL data format to aid geometric design. The integration of FE analysis and quality control provides a high quality standard using relatively simple methods. Starting with a quick transmission of CT scan data, e.g. via the Internet, and providing that all tools and machines are available locally, a prosthesis is likely to be designed and manufactured in only one week. The discussion of the design with the surgeon, before the prosthesis is manufactured, could also be easily accommodated over the Internet. The lean design achievable using the route presented here enables one to make large, but lightweight, prostheses and, given the clinical success of the prosthesis used to illustrate the developments, the overall process can make a significant contribution to improving the life quality of the patient. The cost and time effective design and manufacturing route benefits both patient and insurance companies.

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Figure 1: Cantilevered Maxillary Implant[®] designed using a stereolithography biomodel.
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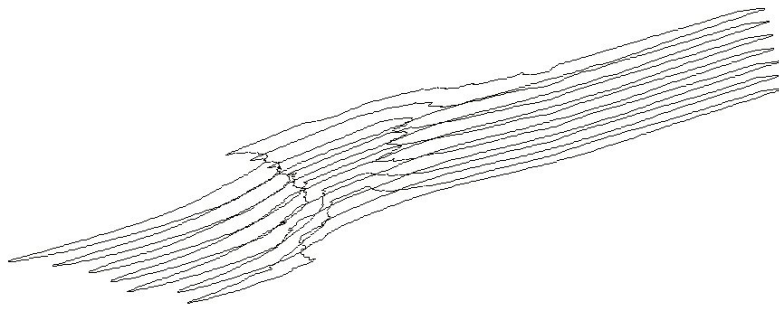


Figure 2: Bone contours from CT scans as polylines in IGES file

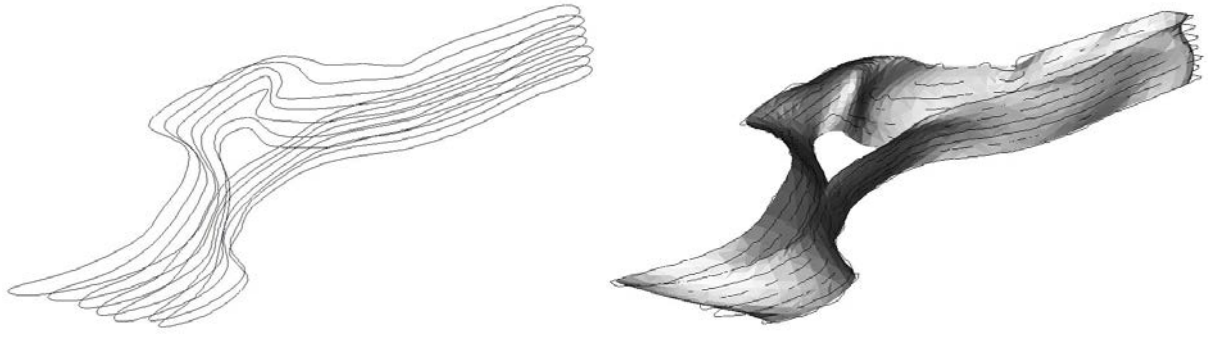


Figure 3: NURBS curves (left) and NURBS surface (right) based on bone contours

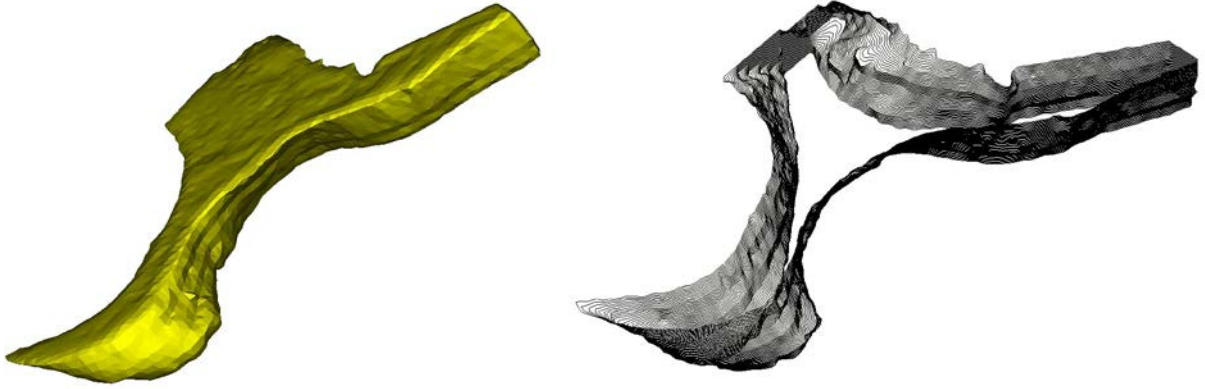


Figure 4: 3D model represented by solid (left) or polylines (right)

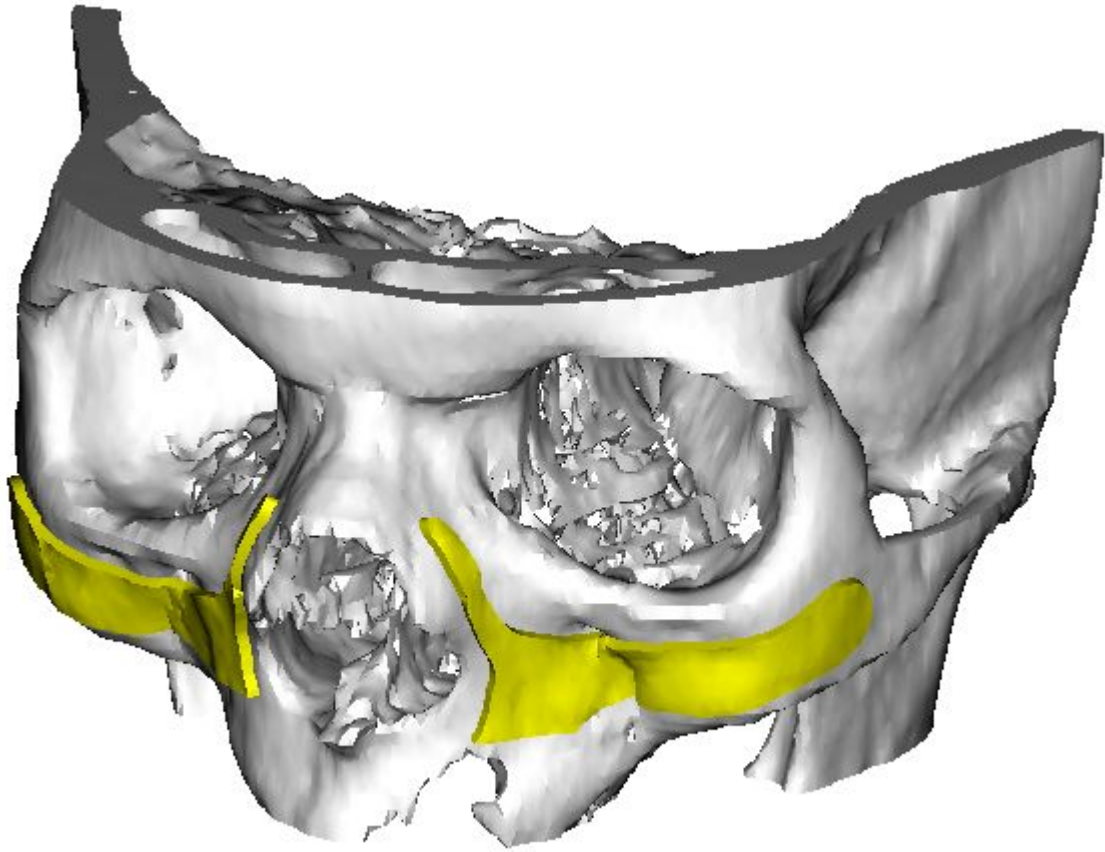


Figure 5: Extruded areas of bone to design the flanges.
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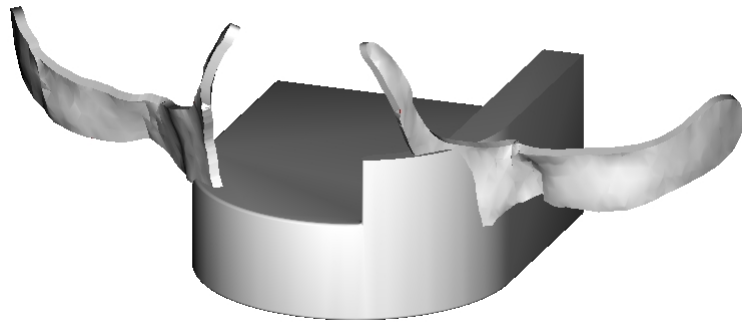


Figure 6: CAD designed main body of the prosthesis joined with bone-shaped flanges.
Implant design based on the Cantilevered Maxillary Implant[®], ComputerGen Implants Ltd.,
www.maxfac.com

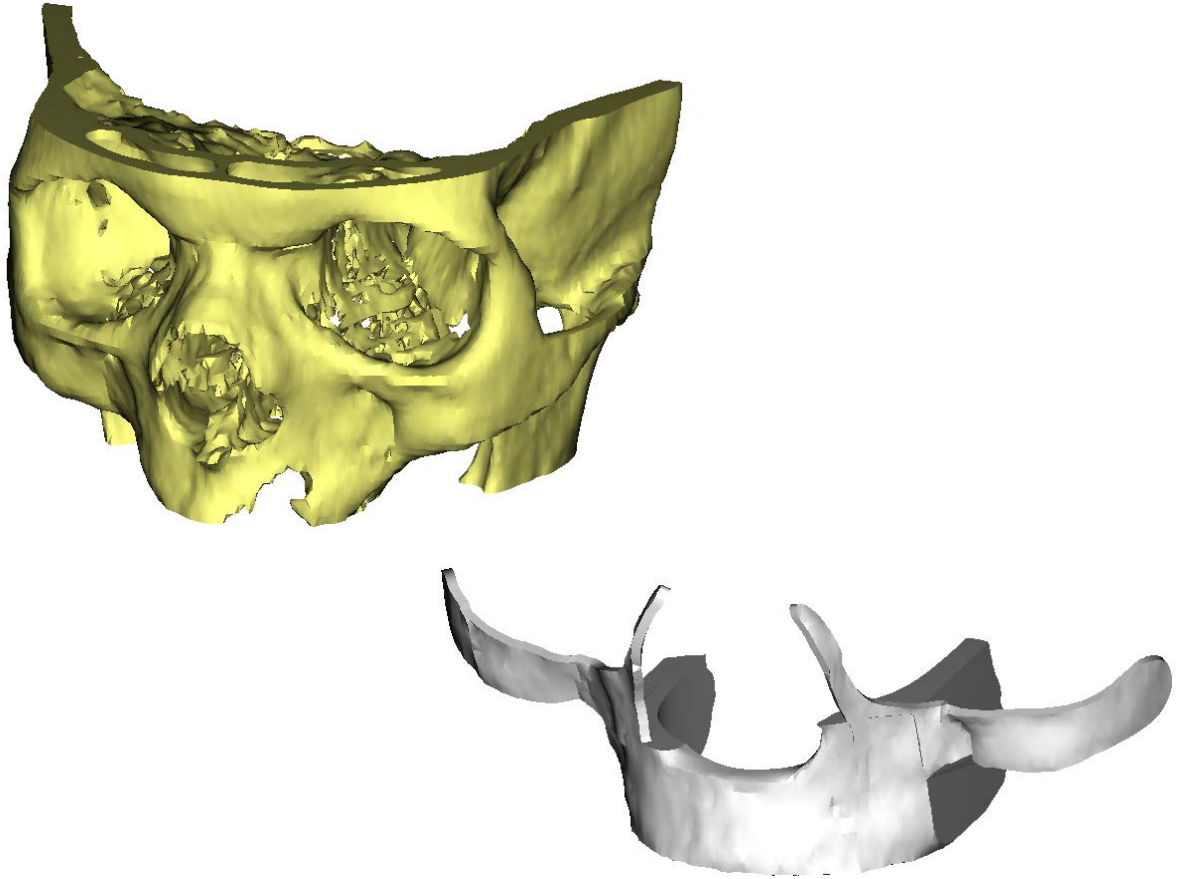


Figure 7: 3D model of the skull with bone defect in maxilla, and prosthesis shaped as a replica of the original bone structure with removed defect

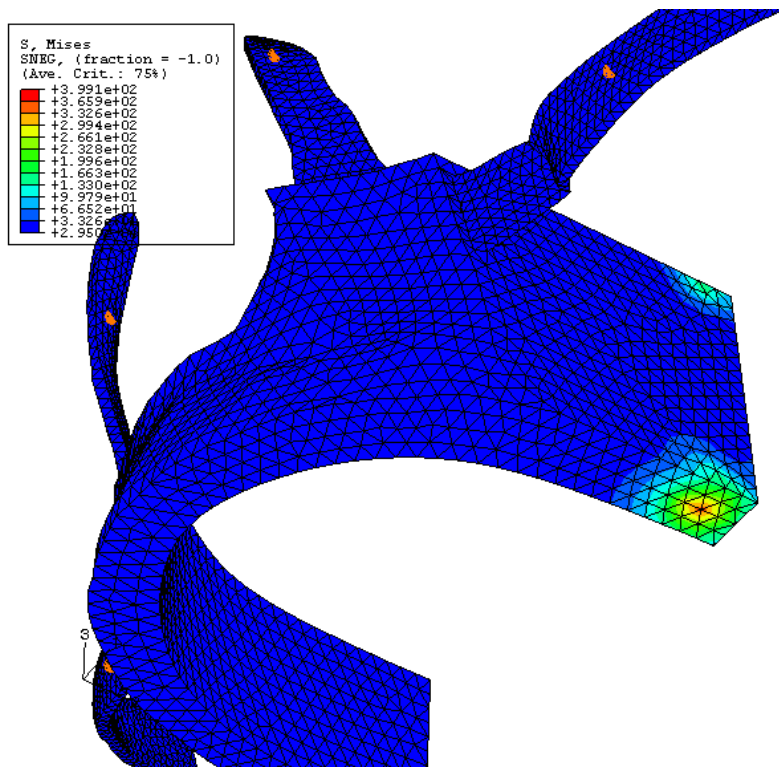


Figure 8: Stresses in shelled body prosthesis (Ti6Al4V)



Figure 9: prosthesis model manufactured by solid freeform fabrication of titanium

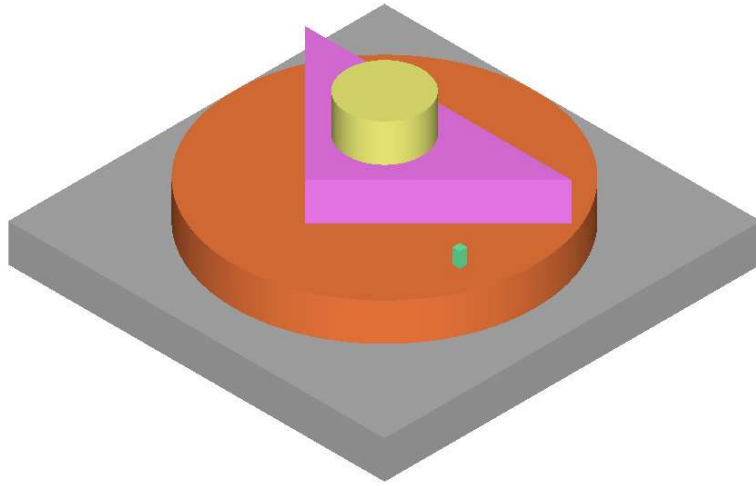


Figure 10: Sample model for dimension accuracy check

Summary

Engineering Assisted Surgery™ links traditional engineering methods and tools, e.g. Rapid Prototyping, 3D CAD, Robotics and Finite Element Analysis, and medical applications with the aim to improve surgical procedures. Computers and Rapid Prototyping are used to derive 3D models from CT and potentially MRI scans and to design prostheses prior to surgery. The report describes a route to design a maxillofacial prosthesis without interchanging between virtual and physical models.

A review of CT scan data transfer methods and 3D model manufacture is undertaken. The options for efficient customised implant manufacture are discussed with reference to rapid prototyping and the advantages of rapid manufacture. Finite element analysis was included in the design route to optimise the model regarding its mechanical properties and to achieve lean and lightweight profile. At the end of the design process a solid freeform fabrication process provided a solution for the manufacture of a complex shaped titanium prosthesis. The measurement of irregular shapes in RP models is difficult and expensive, and automated measurement was not an option. Quality control therefore was implemented by manufacturing standard measurement models with each customised implant to check the accuracy of the manufacturing process using a program controlled coordinate measuring machine. Furthermore, standard test specimens were included in the manufacturing step to perform mechanical tests which ensured that the manufacturing process produced reliable parts.