Developing a Patient-Specific Maxillary Implant Using Additive Manufacturing and Design

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Abstract
Maxillectomy is the surgical removal or resection of the maxilla or upper jaw bone. A total or partial maxillectomy can be performed depending on how far the tumour has spread. This paper will discuss a patient diagnosed with an aggressive tumour in half of the top jaw who had to undergo an operation to remove the hemi-maxilla and orbital floor. Due to the extent and complexity of the defect, it was decided to manufacture an anatomical model of the hard tissues for planning a possible laser-sintered titanium implant using Additive Manufacturing (AM). The CRPM had only two weeks to design and manufacture the titanium implant, due to the severity of the tumour. The anatomical model was sent to the surgeon to cut the nylon model where the bone resection was planned. Furthermore, the prosthodontist made a wax model of the planned titanium frame that was reverse- engineered and used as reference geometry in the design software.Materialise® design suite was used to design the patient-specific maxilla and cutting jig. The EOS M280 Direct Metal Laser Sintering (DMLS) system was instrumental in achieving the direct manufacturing of the bio-compatible titanium implant. The EOS P385 system was used to manufacture the pre-operation planning model as well as the cutting jig.The process chain followed to complete this case study will be discussed showing how this intervention improved the quality of life of a SA patient. Furthermore, the proposed paper and presentation will discuss the post-operation review of the patient showing the impact AM had in accelerating patient-specific implant manufacturing. The authors seek to claim a progressed level of maturity in the proposed manufacturing value chain. The claim is based on the successful completion of the analysis and synthesis of the problem , the validated proof-of-concept of the manufacturing process and the in-vivo implementation of the final product.

Keywords
Additive Manufacturing, patient-specific, titanium

1 INTRODUCTION

Amelobastomas are rare, benign tumours of odontogenic origin. They are slow-growing, locally invasive, and commonly affect the posterior maxilla and mandible. These tumours were first described by Cusack in 1827 [1]. They are the most common odontogenic tumours in Africa, and the second most common odontogenic tumours in the United States [2-5]. The global incidence of these has been estimated to be 0.5 cases per million people per year, with their peak incidence occurring between 30-60 years of age [6]. They most often present as a painless swelling of the jaw [7], with up to 35% identified incidentally on radiographs [8]. Pain can be present if there is bleeding following fine needle aspiration [9]. Paraesthesia, tooth resorption, and tooth displacement are uncommon findings with these tumours [10]. These tumours have a predilection for occurring in the posterior regions of the jaws, with the mandible accounting for up to 80% of all cases [11].

Maxillectomy or maxillary resection is defined as surgical removal of a part, or all of the maxilla [13]. The maxilla's central location in the facial skeleton unifies the orbits, zygomatic maxillary complex, nose, and stomatognathic complex into a functional and aesthetic unit [14]. The maxilla provides the structural support connecting the skull base to the occlusal plane, resists the forces of mastication, anchors the maxillary dentition, provides a separation between the oral and nasal cavities, forms the floor of the orbit supporting the globe, and supports the facial musculature. The bony and soft tissues constituting the midface are supported by the maxilla and provide much of the facial contour and profile giving each person a unique appearance [15–17].

Reconstruction of maxillectomy defects remains a considerable challenge because the 3-dimensional architecture of the midface serves both functional and aesthetic roles. Based on these considerations, the final goals for midface reconstruction should ideally be [18]:

(1) to give support to the orbital content, thus minimizing changes in globe position, orbital volume, eyelid functions and treat the exenterated orbit cosmetically;

(2) to maintain a patent nasal airway and oronasal separation creating sufficient platform for mastication, speech quality, and potential dental rehabilitation; and

(3) to restore an adequate and symmetric facial contour with the other side of the face.

Additive manufacturing (AM), or better known as 3D printing (3DP), describes a number of processes where a product is fabricated through a layer-wise construction method. The Direct Metal Laser Sintering (DMLS) AM process at the Centre for Rapid Prototyping and Manufacturing (CRPM) can offer a unique solution for the manufacturing of custom-designed maxillofacial implants, using Ti64 (Ti6Al4V).

Vandenbroucke & Kruth (2007) continue to state that because of technical improvements of layer manufacturing (LM) processes and the possibility to process different metals (and compounds), Rapid Prototyping (RP) has moved beyond its initial applications into rapid manufacturing (RM). They also point out that the progress made could benefit medical and dental applications beyond polymer applications for visual (anatomical) models or single-use surgical guides, to also support the manufacturing of functional implants or prostheses.

This paper presents factual evidence that the process chain based on customized manufacturing has evolved to a level of maturity which can be replicated with confidence.

2 CASE PRESENTATION

2.1 Clinical report

A 54-year old female patient was referred to the surgical team for a resection of a tumour in her left maxilla. Clinical and radiographic findings revealed that the tumour filled the entire left maxillary sinus, and measured 60x50x40mm in size.

2.2 CT conversion

Due to the extent and complexity of the defect, it was decided to fabricate an anatomical model of the hard tissues for planning a possible fabrication of a Ti6Al4V laser-sintered frame for the patient. Computer Tomography (CT) was used as a starting platform and the Digital Imaging and Communications in Medicine (DICOM) files from the scanner were converted to Standard Triangulation Language (STL) format (Figure 1) using Mimics™ dedicated software from Materialise®. The software allows altering the greyscale values from the DICOM images to differentiate between soft tissue and bone.

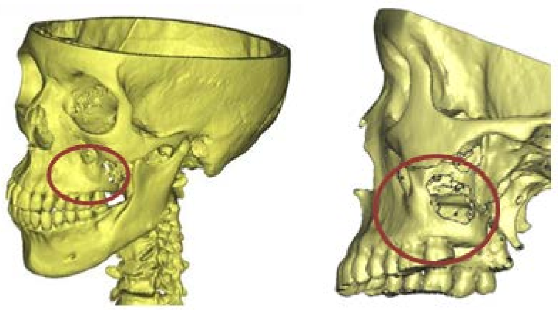

Figure 1 - CT conversion to STL format

2.3 AM of pre-operative model

The region of interest was then masked and calculated as a 3D model, which was exported as a STL file, sliced using RP Tools, and sent to the AM machine to manufacture the planning model. The CRPM did the CT segmentation of the skull and produced the 3D model in an EOS P385 Laser Sintering machine in PA 2200 polyamide material at 150 µm layer thickness (Figure 2).

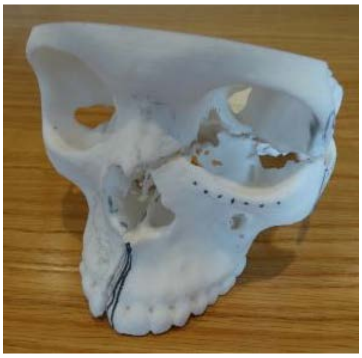

Figure 2 - Skull replica manufactured using Additive Manufacturing in PA 2200 polyamide material

The treatment plan involved a complete resection of the tumour with simultaneous reconstruction using a custom-made titanium framework to replace the resected bone. The nylon model was sent to the surgical team to be cut where the bone resection was planned (Figure 3)

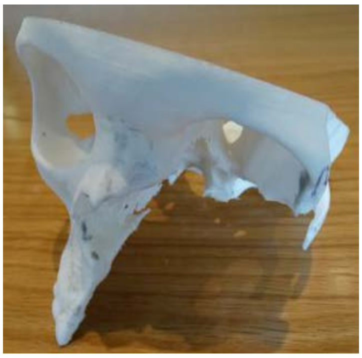

Figure 3 - Nylon model cut where the bone resection was planned

2.4 Reverse engineering and design of titanium implant

The CRPM had only two weeks to design and manufacture the Ti6Al4V implant, due to the severity of the tumour. Furthermore, the prosthodontist made a wax model of the planned titanium frame (Figure 4).

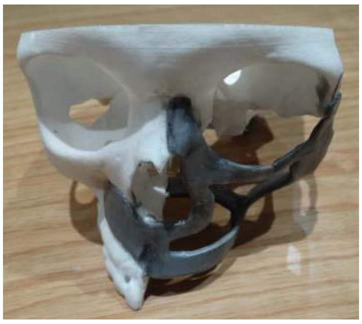

Figure 4 - Wax model of the planned titanium frame

The wax model and skull were reverse-engineered using a Minolta 3D camera and Geomagic® software (Figure 5). The reverse-engineered geometry was used to identify the boundaries and fixation areas of the planned implant.

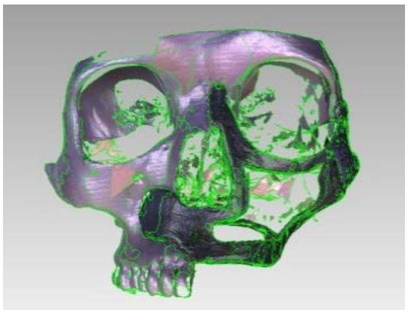

Figure 5 - Reverse engineering data in Geomagic® software

The 3D data were imported into 3-MATIC® (from Materialise) in order to design the implant (Figure 6).

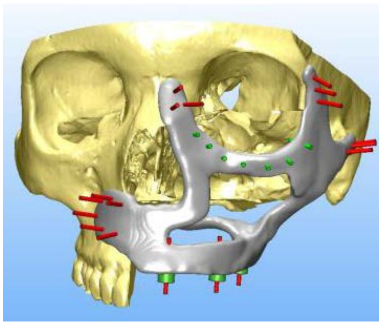

Figure 6 - Implant design done on 3-MATIC®

3 AM OF BIO-COMPATIBLE TITANIUM IMPLANT

3.1 DMLS

The implant design was exported as an STL file, which was converted to a slice file and transferred to an EOS M280 DMLS machine. The implant was manufactured from a biocompatible Ti6Al4V (ELI) powder of sub-40 µm particle size (Figure 7).

Figure 7 - DMLS implant in Ti6Al4V

The DMLS implant was removed from the titanium substrate. The support structures were removed and the implant was manually polished. The implant's fitment was checked on the pre-operative model (Figure 8).

Figure 8 - Checking the implant's fitment on the pre-operative model

A cutting guide (Figure 9) was designed and manufactured in nylon on the EOS P385 machine. The surgeons used this guide to remove the affected bone at the correct angles.

Figure 9 - AM nylon cutting guide

The DMLS titanium prosthesis was successfully implanted during a nine-hour operation (Figure 10). The patient was transferred to the Intensive Care

Unit and a week later to a general ward. The post-operative review was good and many valuable lessons were learned from this case study.

Figure 10 - DMLS Ti6Al4V prosthesis in position

The swelling, as shown in Figure 11, was due to the soft tissue harvested from the patient's forearm and transplanted into the oral cavity. This soft tissue was implanted to create a separation between the oral and nasal cavities.

Figure 11 - Post-operative review one month after the operation

3.1.1 Timeline for design and AM of maxilla

The CRPM only had fourteen days from receiving the patient data to the operation due to the severity of the tumour. The process steps are shown below:

- CT translation, pre-operative model – 2 days
- Surgical planning & wax mock-up – 1 day
- Reverse engineering – 3 hours
- Final design – 3 days
  - Design time – 19 hours (implant and surgical guide)
  - The remainder of the 3 days was for consultation and approval
- Manufacturing – 2 days (including support removal and stress relieving)
  - DMLS – 18 hours
- Polishing – 2 days
- Micro CT scanning – 1 day
- Heat treatment – 1 day
- Cleaning and packaging – 2 days
- Operation – 9 hours

Compared to:

Conventional manufacturing – 5 weeks

or

Additive manufacturing overseas at a cost of $17000 - 4 weeks

3.2 Challenges encountered with DMLS implant manufacturing

Figure 12 shows a summary of a proposed workflow which must be adhered to for certification of the DMLS process

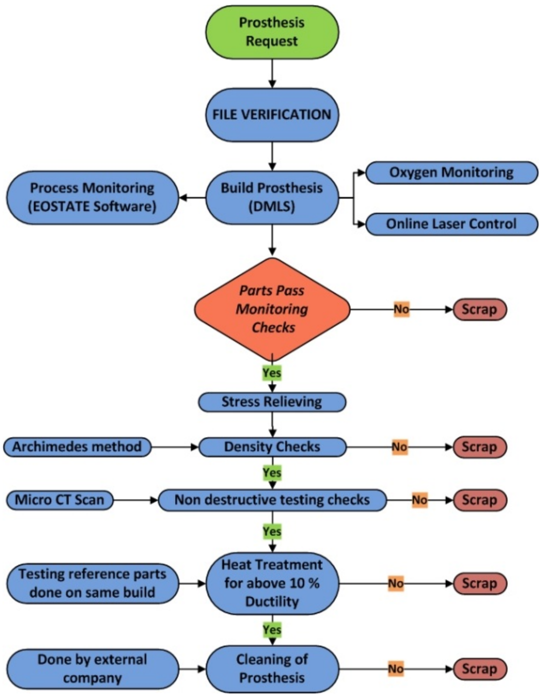

Figure 12 - The proposed AM of titanium implants workflow (author's own creation)

The DMLS process uses a cold bed platform which induces high residual stress in the manufactured part. The parts need to be stress-relieved at 650°C in an argon atmosphere while still fixed on the titanium substrate. Initial research showed that between 76 to 81% of the residual stress can be removed with this stress-relieving cycle [12]. In this study, the researchers used recrystallizing, duplex and beta-annealing processes to further remove the residual stress to levels up to 97%. As-grown the parts are still too brittle for medical use and need to be heat-treated at 1000°C to increase the elongation to above 10%, as required for medical implants. Further in-depth research needs to be conducted to fully quantify residual stresses, as well as optimise stress-relieving and heat-treatment cycles. In the current practice, the part integrity is tested by scanning all the implants using X-ray micro- computer tomography (microCT). For this, a commercial system from the Central Analytical Facilities at Stellenbosch University (SU), a General Electric Phoenix V|Tome|X L240, is used. X-ray settings are 180 kV and 160 µA, using a directional X-ray source. This is done to detect any microscopic voids and cracks that could cause implant failure due to fatigue. The surface fit function allows for a good 3D visualization, as shown in Figure 13.

Figure 13 - Post-operative review one month after the operation

The part showed no voids, but loose powder was seen inside the blind hole (Figure 14).

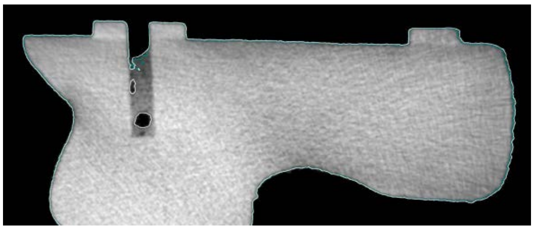

Figure 14 - Powder trapped inside blind hole

Furthermore, test pieces for destructive testing (Figure 15) are manufactured on the same platform as the implants and are tested in an as-grown and heat-treated state. Results are shown in Table 1.

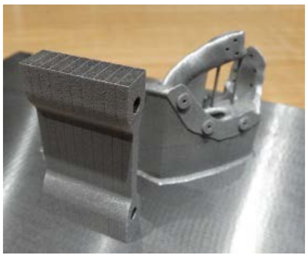

Figure 15 - Test pieces for destructive mechanical testing

Description		UTS (MPa)	Elongation (%)
As grown	Mean of 3 specimens	1155	4.12
After heat treatment	Mean of 3 specimens	850.30	11.88

Table 1 - Tensile test results

4 CONCLUSIONS

It was possible to successfully complete this extremely difficult case study in only two weeks. Considering the timeframes given by the surgeons, it would have been difficult to manufacture the implant using conventional manufacturing techniques. The wax mock-up made of the cutting guide on the pre-operative model by the prosthodontist saved around 10 hours in design time. The part integrity proved to be good as the microCT scan showed no voids or cracks inside the implant. The microCT scan was done at 85µm slices.The heat treatment increased the ductility from 4% (as grown) to above 10%, which is required for implants.

This case study shows that AM can be successfully used in the manufacturing of patient-specific implants. Similarly previous cases by the same team have developed the process chain into a value chain of progressed maturity level. Process parameters are now known and parameter boundaries are set to ensure confidence in quality consistancy. 100% inspection of part integrity by microCT is retained to build out the knowledge database and confidence.

Adequate confidence has now been demonstrated that the value chain can be further optimized and predictive models on cost and time applied. Several unpublished design for manufacturing safeguards are still employed, that may become unnecessary as DMLS technology continuously improves. The presented value chain can therefore be agrued progressively matured by the complexity of the case study.

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7 BIOGRAPHY

Gerrie Booysen is the director of the Centre for Rapid Prototyping and Manufacturing (CRPM) at Central University of Technology, Free State (CUT) in Bloemfontein, South Africa. The primary focus is on AM of patient-specific implants and devices, which led to the first SA 3D-printed hemi-mandibular implant in 2014.

André van der Merwe holds a B-Eng Mechanical (1986), a M-Eng Industrial Engineering (1989) and a PhD Engineering (2006). At Stellenbosch University he focusses on Resource Efficient Production Engineering in Digital Manufacturing. After 18 years in industry as engineering manager, his 10 year academic career produced 12 conferences papers (co)authored, 7 Journal publications, 3 PhD graduates, 8 M.Eng graduates and reviewed as many publications and conferences.

Deon de Beer is currently serving as Chief Director: Technology Transfer and Innovation (Institutional Office at NWU), since 2014. Prior to this he served in similar positions at VUT and CUT, and in parallel has been promoted to full professor in 2005. He also retained his professorship when moving to VUT – both as a consequence of his C1 NRF rating (which he received while at CUT, and successfully applied for again at VUT). Deon played an instrumental in the South African Additive Manufacturing (AM) development.

Cules van den Heever is appointed as a Clinical Advisor to the NRF Chair as well as Extraordinary Professor at the Centre for Rapid Prototyping and Manufacturing, Department of Mechanical Engineering and Mechatronics at the Central University of Technology. His fields of interest and expertise include maxillofacial prosthodontics, osseointegrated implant therapy, and additive manufacturing in South Africa, in 2014.

Johan Els started his career in 2007 as a Research Assistant at the Centre for Rapid Prototyping and Manufacturing (CRPM) at the Central University of Technology (CUT) and was appointed in his current position at the CRPM as Project Engineer in 2008. He has to date been involved in 34 medical cases, six of which he was instrumental in the design and manufacturing of custom DMLS titanium implants, including the first hemi-mandibular DMLS prosthesis implanted