RAPID PROTOTYPING AND MANUFACTURING IN MEDICAL PRODUCT DEVELOPMENT

M. TRUSCOTT, G.J BOOYSEN AND D.J DE BEER

ABSTRACT

RP and recently RM have been key factors in the development of the manufacturing industry in assisting in the development of new products. Fortunately, the application of these technologies has been realised in the medical industry. Surgeons all over the world use physical models created from CT or MRI data using some sort of additive manufacturing. The fabrication of these models has exploded into a popular research area combining engineering, material and medical expertise. Long-term growth in the additive fabrication industry will come from designs that are difficult, time-consuming, costly, or impossible to produce using standard techniques. Growth will occur with advances in current additive processes which are coupled with breakthroughs in new materials. The applications of RP and RM are as diverse as the medical issues that arise. RM of custom design medical prostheses proves to be economically viable solution, not only because it is faster to produce but it gives the designer freedom of creation too. The paper discusses some interesting medical case studies.

Keywords: Rapid prototyping; Rapid manufacturing; medical application; case studies

1. INTRODUCTION

The Central University of Technology, Free State and more specifically the Centre for Rapid Prototyping and Manufacturing (CRPM) have been actively involved in the area of Rapid Prototyping and Manufacturing since 1995. It was then that the National Research Foundation (NRF) granted the CUT an opportunity to develop Research Niche Areas and the Integrated Product Development RNA was a direct outcome from this initiative. The CRPM mostly focused on industrial applications and acquired an SLA 250, a DTM Sinterstation, an EOS P380 plastic machine (industrial and medical applications), Dimension, EOS S700 sand machine (industrial applications), the Viper (jewellery applications), the DMLS (hybrid tooling), an EOS P385 (industrial and medical applications), Ti laser sintering machine by 2008 (industrial and medical applications) and SLA500 (investment casting). Although the first medical case study was done in 1998 the cranial 3D model was not grown in South Africa and it was only in 2004 that the CRPM became active in medical applications. Since 2004 the CRPM has had successful collaboration with various Orthopaedic and plastic surgeons in South Africa as well as England.

Improvements of Layer Manufacturing processes have brought about the shift of Rapid Prototyping (RP) to firstly Rapid Tooling (RT) and secondly Rapid Manufacturing (RM) [1] and the medical industry was one of the very first industries to embrace this opportunity.

Reverse engineering (RE) and medical image-based technology today enables construction of 3D models of anatomical structures of the human body based on anatomical information from scanning data such as computerised tomography (CT) and magnetic resonance imaging (MRI) [2]. Although virtual models are helpful many medical applications can benefit further having the physical models [3]. These physical 3D models can be manufactured in a wide range of materials (from plastics to metals to biocompatible materials) and sizes (from big models to microstructures) [2]. Furthermore advances in scanning and manufacturing technologies allowed more technological approaches to customisation in the medical field [4]. With customised implants the possibility arise that original anatomy can be restored as accurately as possible and that 3D models can be used for surgical planning thereby mimimising surgery time and related costs [5, 6].

Medical RP technology is considered to be a multi-disciplinary area, which involves human resources from the fields of RE, design and manufacturing, biomaterials and medicine. The medical industry represents one of the largest potential users of the RM technology, with applications in the manufacture of surgical tools, custom jigs and fixtures and internal and external implants and scaffolds [7].

South Africa mainly import implants from Europe or the USA. This however is very costly, especially for the patients who do not have a medical insurance. This prompted a South African Orthopedic Surgeon and Mechanical Engineer to start an orthopedic company (ISIQU) which manufactures implants in Titanium using conventional 5-axis CNC milling. These locally designed and manufactured implants are far more affordable than the imported components, making them more accessible to South African patients. In one particular instance the locally designed and manufactured prosthesis cost R40 000, whereas had it been imported the cost would have been R250 000 [8].

2. RP/RM TECHNOLOGIES

To date, stereolithography (SLA) has been the favoured RP technology used for manufacturing pre-operative planning models [9]. It has some important advantages such as transparency, high resolution, accuracy and it can also be sterilised [10]. Although SLA has been the preferred technology, the CUT research team concentrated on working with Laser Sintering (LS) of nylon polyamide for the manufacturing of 3D medical models.

These models have been used primarily as pre-operative models by orthopaedic surgeons. The models have been evaluated by the surgeon as well as a mechanical engineer for accuracy and have been proven to be accurate.

Considering the RP technologies the challenge arose to use the same methods to actually manufacture the prosthesis/implant that is custom-made to the patient's unique characteristics [9].

The advantage of RM technologies is that arbitrary geometries can be created without the need of extensive planning or data processing, allowing personalised geometries to be created quickly and with ease [4]. Different RP/RM technologies have been used by the CUT, ISIQU and EOS to develop customised implants. These include amongst others the laser sintering of a nylon polyamide prototype on the EOS P380 which was rescanned with a touch probe scanner in order to evaluate the accuracies between the .STL file and the generated CAD model; the generation of CNC codes for Titanium milling on a 5-axis CNC machine (Fig. 1) and the direct sintering of Titanium of an elbow implant with EOS Laser Sintering (LS) technology (Fig. 2). In a case study performed the machining of a Titanium elbow implant with 5-axis machining took a lengthy 104 hrs [11] opposed to the 11,5 hours when using LS technology. Furthermore, the 5-axis CNC machine is unable to machine internal structures, while the intricate internal bone geometry could be sintered.

Medically useful RP&M materials are mostly industrial materials that have been tested to internationally recognised standards. Only a few materials have been developed for Rapid Manufacturing of specific medical devices for example custom-fitting hearing aids. Despite the availability of medically acceptable RP&M materials, the choice is still limited [12].

Fig. 1.Titanium elbow machined on a 5-axis CNC machine together with Nylon Polyamide elbow prototype

Fig 2.Laser sintered Titanium elbow implant (EOS)

The LS and SLM processes are currently dictating the way for medical RM applications. Based on patient data, medical RP/RM ensures that custom-made designs meet both clinical and geometrical constraints [2].

As with all new ideas RM does not come without its challenges. Lenton (2006) [9] states that persuading the medical profession to take the step from using models as an aid to surgery to using them to produce implants has proved to be a significant challenge. A further challenge will be the development of implantable Titanium material or other materials with the suitable material and mechanical properties, process accuracies, surface quality, reliability, repeatability and making the process cost effective [1].

3. METHODOLOGY

The methodology used to design and manufacture the 3D model and/or the implant for the case studies are depicted in Fig 3.

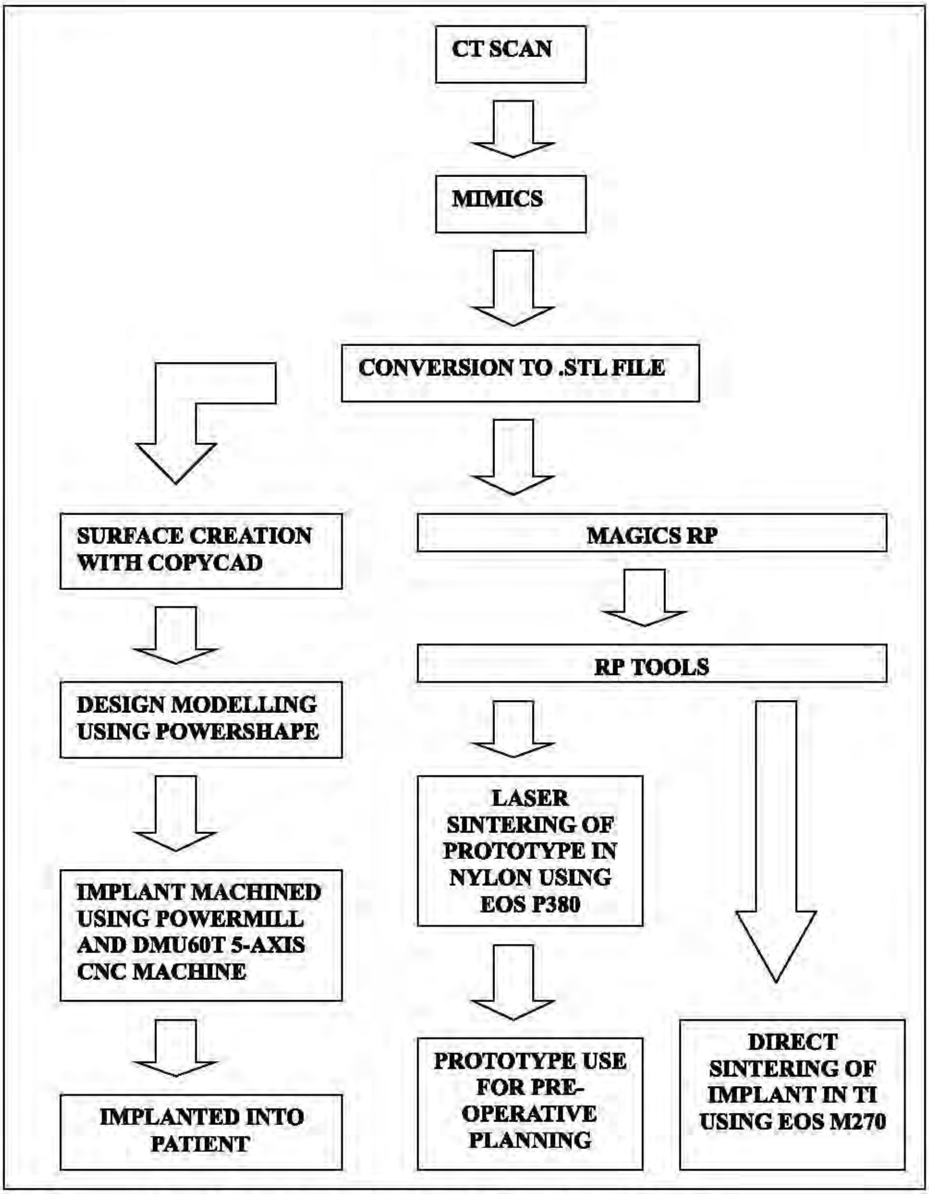

Fig 3. Processes followed for design and manufacture the 3D model and/or the implant

Computer Tomography (CT) is used as a starting platform, to enable the development of 3D CAD data for RP operations [11]. The CT scans are imported into MIMICS, a general-purpose segmentation program for gray value images, which performs segmentation by thresholding to identify bony structures or soft tissue. The region of interest can then be masked and calculated as a 3D model which can then be exported in the form of an RP machine ready .STL file or so-called slice files. These files, if required, can be manipulated further using Magics RP before the prototype or implant is manufactured using either an RP technology or 5-axis CNC machining.

4 CASE STUDIES

Five case studies will be reported on.

4.1 Pelvis and femur

Various case studies involving the pelvis and femur have been performed. In most instances these are extreme cases involving cancerous growths, polio as well as rectifying mistakes made during previous operations.

The 3D model in Nylon Polyamide was used for surgical planning and also for implant design as can be seen in the following sequence of photographs (Fig. 4).

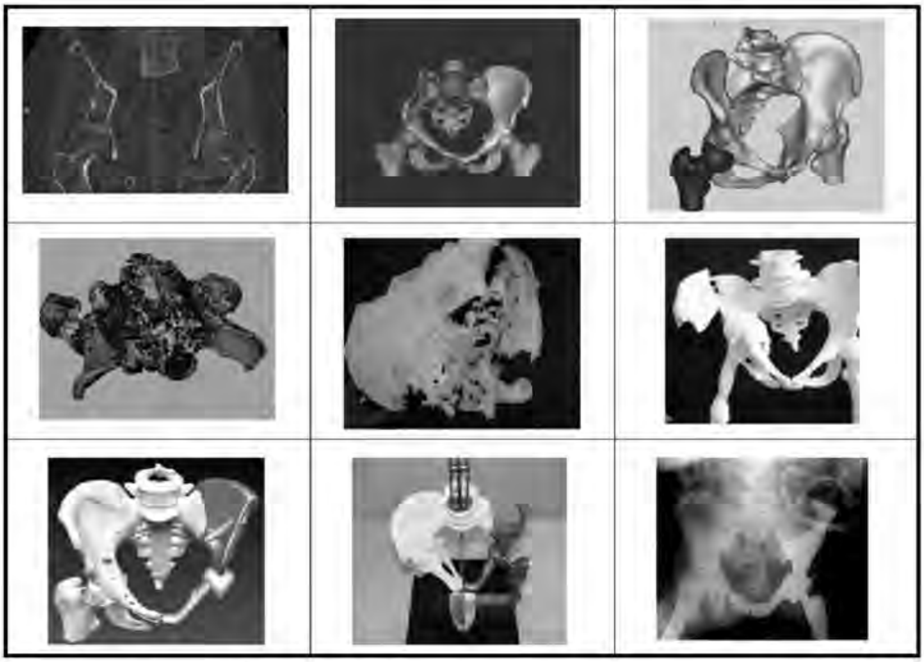

Fig. 4.Process for pelvis and femur implant design

The implant was manufactured in Titanium using a DMU60T 5-axis CNC milling machine and was done in collaboration with ISIQU.

4.2 Scapula

In this case study it was necessary to manufacture three implants after a wide resection removing the scapula, shoulder joint and proximal humerus of a patient was performed. The CT data of the right hand side scapula, shoulder joint and proximal humerus was mirrored and the .STL file and 3D model presented to the surgeons. The .STL file was then used to create a surface using COPYCAD and design modelling using PowerSHAPE was performed.

CNC Machining

CNC machining codes are generated from .STL data of the implant. and the implant can consequently be manufactured (Fig 5). The scapula implant was machined in Ti using PowerMill and the DMU60T 5-axis CNC milling machine. The custom-made Ti implant was successfully implanted into the patient with good cosmetic and functional result.

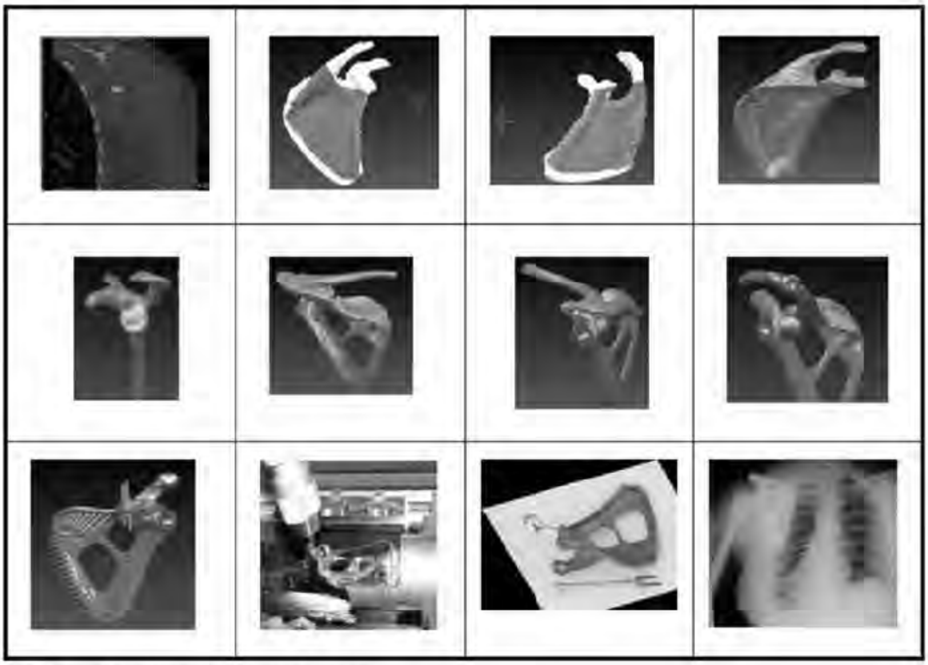

Fig 5.Scapula implant development process

It is, however, difficult and time consuming to manufacture complex geometries with CNC milling. Alternatively, anatomical models can be used as a template onto which Titanium can be shaped. The latter is however limited to the artistic ability of the technician and will therefore not be as reliable [5].

Direct Sintering

The direct laser sintering of the scapula in Ti was considered as an alternative to the 5-axis CNC machining (Fig. 6). The same data as for the patient above were used for this study. The .STL file was used to create extra support structures to anchor the part to the base. A right hand side scapula was sintered in Titanium using the EOS M270 XDTiLS RP machine. The additional supports had to be removed manually after the part was grown on the Titanium machine. The implant needs to cleaned and polished after the sintering process.

Fig 6.Direct Laser Sintering of the scapula in Ti

4.3 Clavicle and Sternum

This case study involved a patient with a benign lesion which was resected from the medial end of right clavicle and a sternoclavicular joint implant had to be inserted to maintain stability.The CT data of a left clavicle (mirrored) and sternum were translated into a. STL file and a 3D model grown in Nylon Polyamide. The sternoclavicular joint was designed using the .STL data and machined in Ti using the DMU60T 5-axis CNC milling machine (Fig 7).

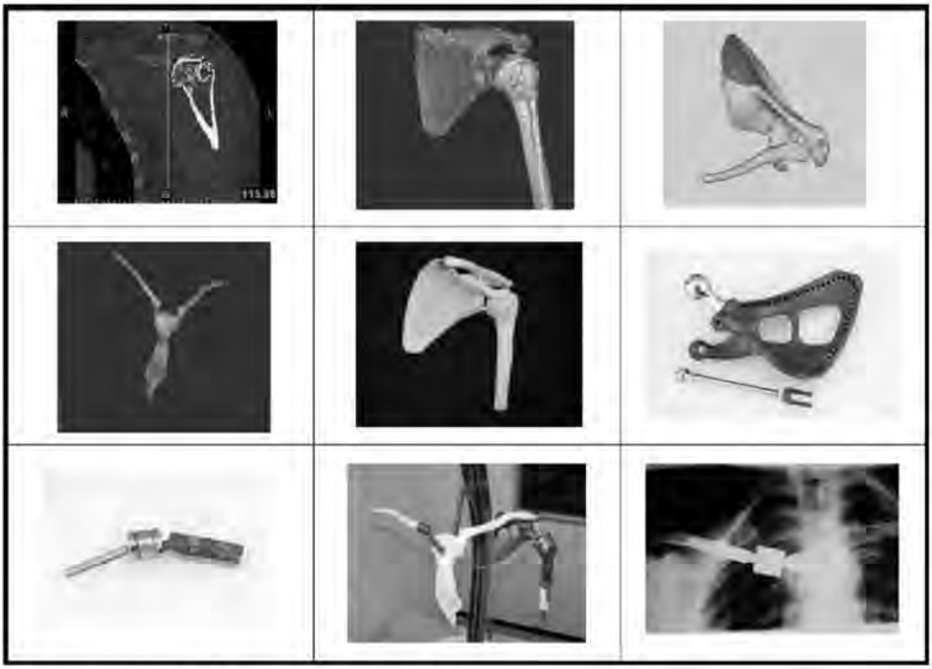

Fig. 7.Sternoclavicular joint machined on 5-Axis CNC milling machine

4.4 Pectoralis Major Muscle

Analyses of the pectoralis muscle data were performed and surgical planning for one of the studies performed to see the visual effect of such an operation. CT data of a female patient were used for the isolation of the soft tissue. The isolation of the data proved to be very difficult because only CT data and not MRI data were available. The representative volume of the pectoralis major muscle was obtained and mirrored using MIMICS, and a prototype built of the volume. Surgical simulation was performed on the case study involving the female pectoralis muscle using the simulation module of MIMICS. The prototype of the female patient was presented to the medical practitioner. A silicon mould was manufactured in Brazil and has consequently been implanted successfully into the patient (Fig. 8).

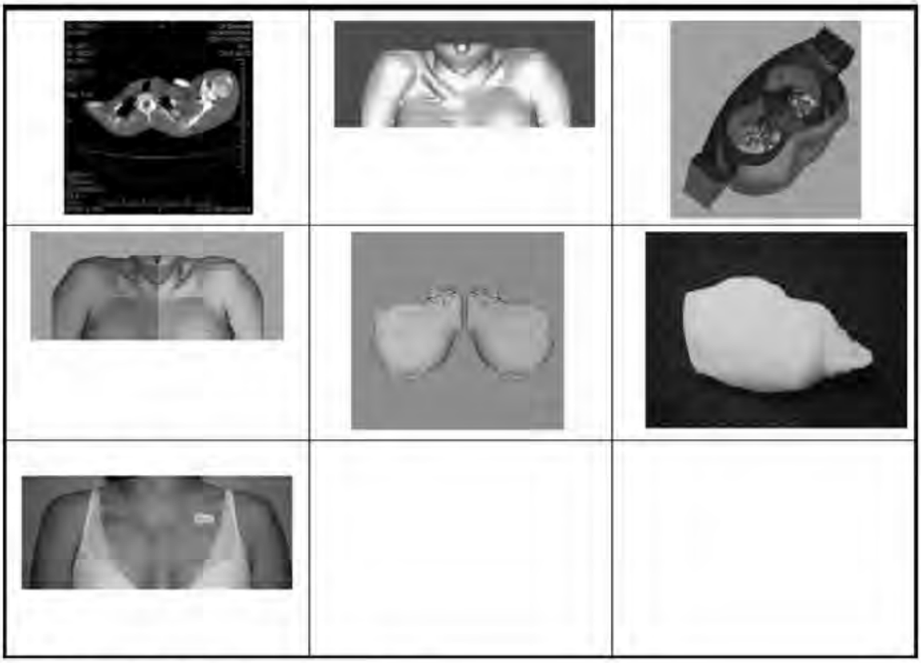

Fig. 8. Pectoralis implant development process

4.5 Eye Socket

The study has been conducted in collaboration with University of Wales, Cardiff and Morriston Hospital in the UK. The patient has part repaired facial cleft and cleft palate and needs a lip revision, augmentation of the anterior maxilla, a revision of the skin cleft scar which has to be opened to access the orbit on the right. The eye is non-seeing and about 1 cm lower than the left eye. The skin is tight over the area.

The .STL data from CT scans were used to generate the RP slice files and an implant was manufacture directly in Titanium using the EOS M270 XDTiLS RP machine. After sintering the implant was cleaned and polished and fitted to a SLA model of the patient's skull (Fig 9). This project has not been completed yet.

Fig 9.Titanium eye socket implant

5. CONCLUSIONS

According to Park 2006 [13] the future of RM appears to be bright and the potential that these technologies offer to manufacturing industry should not be underestimated. The vast majority of new applications yet to be achieved with RM have not been conceived.

Based on previous successes achieved, as well as the impact that the manufacturing of custom designed (or patient-specific) implants can have both socially and economically, the team has set its goals on direct production of metal implants using RM. During the production of an implant using conventional CNC milling a vast amount of material is wasted, which is not the case with direct Laser Sintering technologies.

Close collaboration with surgeons is essential to promote this technology to the utmost and also to know exactly what is required and expected by the surgeon. In order ensure successful preparation of patient data, the way in which CT scans are performed with regard to symmetry, gantry tilt, etc. plays a vital role.

6. REFERENCES

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