

# **CUSTOMISED PATIENT IMPLANTS: FUTURE LIFELINE OF THE MEDICAL INDUSTRY**

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## **ABSTRACT**

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 the current additive processes, coupled with breakthroughs in new materials, which are expected to emerge over the next five to 10 years. These advanced materials will better satisfy the design requirements of many new products. The paper considers currently available technologies and discusses recent advancements in direct metal freeform fabrication and its potential of revolutionising the medical industry.

Keywords: Rapid Prototyping; Rapid Manufacturing; Medical Applications

## **1. INTRODUCTION**

Improvements of Layer Manufacturing processes have brought about the shift of Rapid Prototyping (RP) to firstly Rapid Tooling (RT) and secondly Rapid Manufacturing (RM) (Kruth et al., 2005). The industries who are considered to be the forerunners with RM technology are Aerospace, Medical and Formula 1 racing teams. Factors that have prompted these industries to use RM, apart from available budgets, are the need for low quantities (sometimes only a single custom piece/implant) of high value parts with complex geometry that is difficult to produce using conventional manufacturing methods (Park, 2006).

Many people suffer from some or other abnormality either caused by a genetic condition, birth defect, disease or injury, which could be extremely traumatic for the individual. The medical profession is increasingly more able to improve quality of life by rebuilding damaged areas through reconstructive surgery. Even so, the challenge for industry still lies in obtaining exactly the right fit with existing tissue and bone. The manufacturing industry has attempted to present different ways of producing high quality one-off prototypes of new products as quickly as possible and at a reasonable cost (Lenton, 2006). The medical industry was one of the very first industries to embrace the power of additive manufacturing processes which initially emerged in the form of RP and grew towards RM (D'Urso et al, 2000; Christensen & Humphries, 2006).

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) (Hieu et al., 2005). The latter scanning processes are very similar to the RP technology, in that software slices are combined to form a visual 3D model whereas RP uses the 3D model to produce a physical form by combining layers together. Although virtual models are helpful many medical applications

can benefit further having the physical models (Gibson, 2005). Scanning data are acquired using RE and CT/MRI of external as well as internal geometry of the anatomical structures (Hieu et al., 2005).

Driven by advances in scanning and manufacturing technologies more technological approaches to customisation have emerged in the medical field (Dalgamo et al., 2006). It is possible nowadays to fabricate complex 3D physical objects in a wide range of materials (from plastics to metals to biocompatible materials) and sizes (from big models to microstructures) (Hieu et al., 2005). The idea of customised implants has always been to restore the original anatomy as accurately as possible with a further objective that it be prefabricated to minimise surgery time and coinciding risks. Customised implants ranging from orthodontic treatment devices using Stereolithography to the use of anatomical replica models for surgical planning and medical device development have been prefabricated (D'Urso et al, 2000, Christensen & Humphries, 2006). Using customised Titanium implants could, in some cases, eliminate the need to perform reconstruction using bone harvested from a second site (Amethyst, 2005).

Although RP technology for preoperative planning models has been available for quite some time, the full adoption of the technologies have been slow and often only driven by the enthusiasm of the individual surgeon (Amethyst, 2005). It is envisaged that the uptake of the RM technology will also be slow as a result of high costs.

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. The development of custom jigs and fixtures is a laborious and highly expensive process and there is a need for processes to allow the cost and time efficient manufacture of such devices. Currently layered manufacturing processes are limited to the indirect manufacture of such devices, extending lead-time and increasing cost. There are now systems available that can manufacture the devices in biocompatible materials such as Titanium (Gibbons, 2005).

## **2. ACCURACY OF CT DATA**

The accuracy and quality of CT data is crucial for the manufacturing of customised implants. Thresholding of the data (in Mimics), as shown by Amethyst (2005), could have a significant influence on the size of the feature. Unfortunately the setting of the threshold limits remains rather subjective, using the general guidelines of Materialise. To verify the accuracy of the proposed process route (from original bone to CT data to .STL data to RP model produced in Nylon Polyamide), 3D measurements and analysis of the results obtained were performed on a cadaver femur bone (Truscott *et al.*, 2004, 2005). Using CopyCAD inspection software, the accuracy between the .STL file exported from the CT data and the RP model femur (made in Nylon

Polyamide material from EOS) was analysed. Measurements were made at 500 000 data point positions using a touch-probe scanner. Out of the 500 000 data points, 50% of errors had a magnitude below 0.2333 mm, 85% of errors had a magnitude below 0.4152 errors and 96% of the errors had a magnitude below 0.5972 mm.

### 3. CONVENTIONAL MANUFACTURING TECHNOLOGIES

South Africa mainly imports 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 (Chidrawi, 2003). CNC machining codes are generated from .STL data of the implant (Figure 1) and the implant can consequently be manufactured (Figure 2 and Figure 3).

The CNC milling machine can also be used to manufacture a mould from which the implant could be cast. It is difficult however 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 reliable (D'Urso et al., 2000).

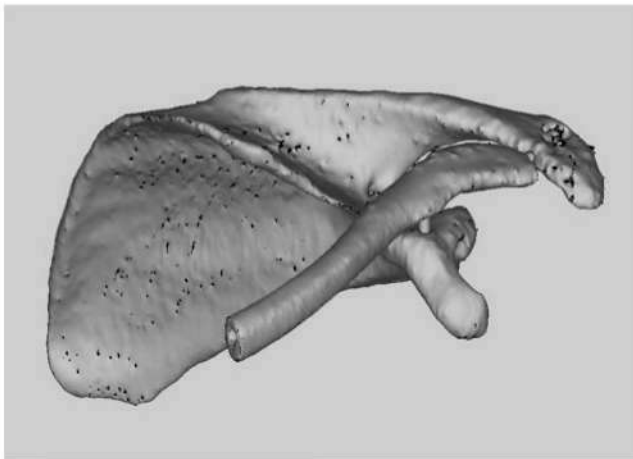


Figure 1: .STL image of a scapula



Figure 2: 5-Axis CNC machining of Titanium scapula (ISIQU)

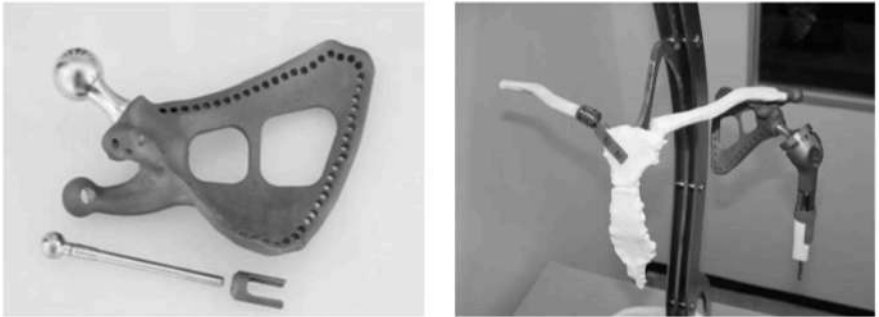


Figure 3: Machined Titanium implant (ISIQU) together with Nylon Polyamide prototypes (CUT)

**4. RP TECHNOLOGIES**

To date, stereolithography (SLA) has been the primary RP technology used for manufacturing preoperative planning models (Lenton, 2006). It is also the first ever commercially available RP system using resin (Gibson, 2005). It has some important advantages such as transparency, high resolution, accuracy and it can also be sterilised (Amethyst, 2005). Furthermore it must be noted that since the surrounding uncured resin is in liquid form, overhanging features need to be supported during the build process (Gibson, 2005). Although SLA has been the preferred technology, the CUT research team concentrated on working with Laser Sintering (LS) of nylon polyamide models (Figure 4), which 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. The models have not only been used for preoperative planning, but the .STL files (Figure 1) were used to generate CNC codes for machining the

parts with a 5-axis CNC machine in Titanium. The production of the planning models however still remains costly.



Figure 4: Laser sintered Nylon Polyamide prototype of scapula

Other techniques that exist to generate a physical prototype from computer generated data include Laminated Object Manufacturing (LOM) (Lenton, 2006; Objet, 2006), Fused Deposition Modelling (FDM), Droplet/Binder Systems and Direct Metal Systems (Gibson, 2005).

## 5. RAPID MANUFACTURING

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 (Lenton, 2006). According to Peckitt (2006) who is a cosmetic maxillofacial surgeon and the director of the National Centre Aesthetic Facial and Oral Surgery, small Titanium implants are not unusual in dental work, but using computers to manufacture large Titanium prostheses is considered to be a new concept.

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 (Dalgamo et al., 2006). 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 (Figure 4) 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 (Figure 2); the direct sintering of Titanium of an elbow implant with EOS Laser Sintering (LS) technology (Figure 5); the growing of a sand mould on the EOS S700 (Figure 6) for investment casting of stainless steel; and the growing of a nylon polyamide prototype on the EOS P380 which will be used for the casting of a

mould for silicon injection. In a case study performed the machining of a Titanium elbow implant with 5-axis machining took a lengthy 104 hrs (Truscott et al., 2007). Furthermore, the 5-axis CNC machine is unable to machine internal structures. However, using LS technology for the same data set the building time for the Titanium elbow implant was only 11,5 hours. In addition the intricate internal bone geometry could be sintered.



Figure 5: Laser sintered Titanium elbow implant (EOS)



Figure 6: Sand mould grown on EOS S700

The LS process is regarded currently as leading the way for RM applications, although SLA is still used more specifically for medical and dental applications (Park, 2006). The problem, however, is that SLA materials can only be used as a preoperative model and not as an implant. Amethyst (2005) suggests that a more effective route for the medical industry would be to use the CT

data to design and manufacture customised implants. Furthermore the manufacture of customised Titanium implants will in some cases eliminate the need to perform reconstructive surgery with bone harvested from a second site. Thereby possibly reducing morbidity and mortality and increasing the success of the operation (Amethyst, 2005). A further possibility to consider is the use of space frames in the manufacturing of implants, which will drastically reduce the weight of an implant.

Based on patient data, medical RP/RM ensures that custom-made designs meet both clinical and geometrical constraints (Hieu et al, 2005).

## **5.1 Challenges for RM**

Lenton (2006) 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. Peckitt (2006) believes that the usefulness of RP has been proved and that resistance to his work is motivated by a conservative medical profession that is more interested in maintaining established ways of working than exploring the possibilities afforded by new technologies (Lenton, 2006). 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 (Kruth et al., 2005).

## **6. CONCLUSIONS**

According to Park (2006) 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. Investigation of existing commercial solutions showed a number of emerging systems ready to build prototypes directly in Stainless Steel, Chromium Cobalt and some Titanium Alloys - all of which are applicable for medical use

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 to 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.

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