# RAPID PROTOTYPING TECHNIQUES IN MEDICAL SECTOR

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***Abstract***

*Different applications of RP manufacturing technologies in the medical sector are discussed. In South Africa, in general the use of RP technology has been slow, but more specifically in the medical field, although the potential of RP has been widespread in other fields. The paper shows that this technology has a definite application in surgical planning, prosthesis development and bioengineering.*

## 1. INTRODUCTION

Rapid Prototyping is a group of manufacturing technologies that manufactures products on an additive or layered-basis, and thus far have been used to support Rapid Product Development (RPD) - a manufacturing methodology that accelerates the development of new products, from the initial design stage to mass production. RPD involves new technologies such as Computer Aided Manufacturing and Design Technologies (3D CAD/CAM), Rapid Prototyping and Rapid Tooling, combined with new management philosophies, to address the reduction of time to streamline the manufacturing process. RPD techniques not only allow companies to put new products into manufacture faster, they concurrently reduce associated development costs. Internationally, companies are finding these techniques to be extremely beneficial and it is adopted at an ever-increasing rate. According to Wohlers [12], revenue and unit sales growth percentages in the RP industry remain in the double digits.

RP has moved beyond its initial “fast concept manufacturing” phase, becoming used more and more as final or real manufacturing method, starting a Rapid Manufacturing (RM) culture, meaning that $1-n$ products can be manufactured directly from CAD, without spending any time or money on tooling development (where $n$ ultimately is a function of complexity of the design, the material and the required volume per time unit). Current processes offer a range of materials such as epoxy resin, nylon, aluminium/nylon compounds and brass infiltrated steel and tool steel matrices, acceptable as final engineering materials, dependent on the end-use. RM also redefines the traditional design principles, as virtually no design limitations are imposed by the manufacturing process followed. RM typically fits products of which the complexity is high, production rate is low (and spread over time) and are applied in high value-added environments, such as the medical product development and aerospace industries [12]. Models can be applied indirectly, where created geometries are used by surgeons to prepare for intricate surgery.

Medical product development starts with Physiological data, which is captured through a CT or MR scan and manipulated/translated to .STL data (the ***de facto*** standard for RP technologies), where new geometries can be added, using existing features as basis for design. The current research builds on earlier success achieved in using CT scans for the development of physical models through RP for operation planning as reported by Schenker et al. [7] and De Beer and Schenker [1; 2; 3]. Recent development on the isolation and modelling of medical data, as reported by Truscott et al [8], includes the use of data to prepare exact replicas of selected bone structures through various RP technologies. Through Laser Sintering technologies, bone reproductions can be grown locally in either Nylon or Polystyrene. Both materials will allow surgeons to practice procedures to be followed, and are excellent representations of real or dry bone. Furthermore, polystyrene reproductions can be used for investment casting of implants, using Titanium. Excellent results, both in reproducing accurate geometry, as well as in terms of surface finish, have been obtained in the casting of Stainless Steel and Aluminium reproductions, using CAD to create cavities for moulds using a Boolean operation, and the laser sintering of sand to grow sand moulds.

The latest results obtained proved the use of data obtained through CT scans to create mirrored images (in the case where some data was lost, e.g. in the case of an accident, or by deterioration of existing structures).

Through new triangular-based CAD modeling software, features can be added in .STL format (such as mechanical features, e.g. screws, plates, stems, hinges, etc), whilst having exact surfaces and or geometries that will match existing bone structures, resulting in perfect fits, less fatigue and longer functionality.

A new generation of single process, direct metal sintering technologies capable of sintering FDA approved materials such as Titanium, Chromium Cobalt and Stainless Steel is emerging. The CUT group is currently evaluating a number of these processes, such as the Selective Laser Melting (SLM) process, a process developed by F + S, Germany, through international collaboration. Promising results have been obtained, and Titanium models generated as patient-unique developments, will be available for evaluation by South African surgeons, working with the CUT group. Using a scaffolding/space frame structure, regenerative bone growing will be stimulated by the Titanium structures, opposed to the rejection that takes place with solid implants.

The research is in an early stage, but positive results have been obtained. Geometries produced, have been measured with 3D measuring and inspection equipment, and measurements fall within an acceptable range for medical use. The surface resolution and finish obtained through investment casting of Stainless Steel have been evaluated by the surgeons, and is found to be conducive for hydroxyappatite/collagen treatment. Most important, is the speed or lead-time for production. As from receiving the CT data by the surgeon, a visual representation can be ready within 24 – 48 hours for less complex cases, with a RP model available within another 24 hours after approval by the surgeon. The availability of the direct metal system will imply that a Titanium implant will be ready within the quoted time scales – proving Rapid Manufacturing for the medical industry. The direct production of these implants promises to be a huge improvement on conventional processes, such as CNC machining.

## 2. MANUFACTURING OF PROTOTYPES

All the RP techniques rely on a software interface which uses computer-aided design (CAD) data and convert it to a .STL type file format [10]. The manufacturing of parts by RP begins with the input of .STL files. The following techniques were used for the manufacturing of the 3D models:

### 2.1 Stereolithography (SL)

Stereolithography (SL) is a form of RP whereby a solid 3D object is built, layer by layer curing liquid photopolymer with a CNC-controlled laser beam. Like all RP processes, it needs a computer-generated design and .STL file, which is sliced according to the layer thickness of the RP system in use. The liquid-material will need support structures for overhangs.

RP technology bypasses the need for casting and fabricates the object (e.g. femur) directly from the CAD file – obtained through various methods of RE, (including CT scans) or generated on CAD. SLA parts are often used as masters to produce silicon moulds for vacuum casting or reaction injection moulding.

### 2.2 Selective Laser Sintering (SLS) and Laser Sintering (LS)

The DTM Sinterstation 2000 is capable of growing parts in various materials, such as Nylon Polyamide, sand or steel, but currently is used mainly for the growing steel prototypes. The EOS P380 is used for Nylon Polyamide, Prime Cast 100 (a patented Polystyrene) and Alumide. Both machines were used in the project.

Both processes (SLS and LS) use powder material, and similar to SL, parts are being built on a layered basis. Unlike SL that cures a liquid material, these technologies sinter powder-based materials on each consecutive layer. Complex geometries (internal and external) can be achieved, as the powder material needs no support structures. Internal, excess material can be removed afterwards using a vacuum cleaner, scriber or by simply shaking it out, dependent on the complexity of the part. In building metal parts with the SLS, a two step process is followed.

A so-called green part is obtained from the RP machine, as it only sinters the polymer binding of metal powder. The polymer is replaced in a second stage, using a special furnace in a nitrogen environment. The final parts are infiltrated with bronze, to give a 93% bronze infiltrated part.

The Magics RP© image of the femur was sent to both the SL and LS for fabrication.

## 2.3 Indirect prototyping

### *2.3.1 Sand casting*

An alternative route to generate a metal part is offered through indirect prototyping, using laser sintering. Through modelling the cavity opposed to the model (this can be done through a Boolean function after the model data were generated), the cavity is built/grown with LS in sand. The process mimics the normal sand-casting (sand and core boxes) process, and allows the casting of the required alloy or metal, directly into the grown sand cavity. The EOS S700 Laser Sintering machine was used to grow sand moulds for metal casting (Figure 1 and 2).

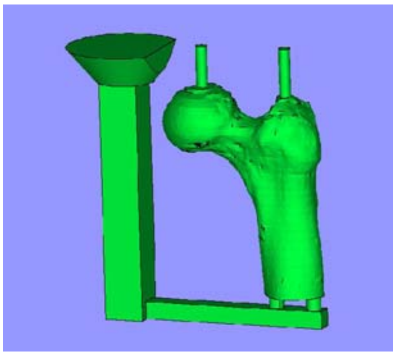

Fig 1 : Modelling of femur cavity data with Magics RP©

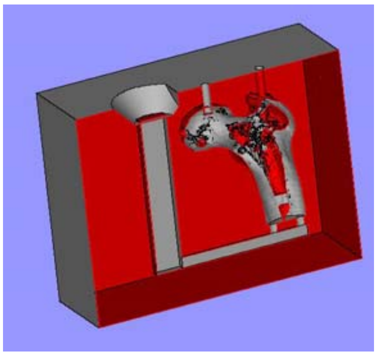

Fig 2 : Sand mould to be grown

### *2.3.2 Investment casting*

Traditionally, wax parts are used for the lost-wax-casting process, where the wax part is embedded in ceramic slurry. After burning out the wax pattern, the ceramic is cured and the required metal can be cast into the mould. Through the use of Prime Cast 100 a similar lost-pattern-investment casting process is possible, which offers a further indirect prototyping route, also used for fabrication of the femur.

### *2.3.3 Casting of the femur*

In this study, Aluminium and Stainless Steel replicas of a section of a human femur bone were produced to prove the process. Figure 3 depicts the implant design methodology followed:

| Conventional Process through CNC-machining | Process through indirect LS (Laser Sintering) | Process through LS (Laser Sintering) and investment-casting | Process through direct Sintering / Melting of Titanium |
|---|---|---|---|
| CT SCAN<br>MIMICS SOFTWARE<br>CAD DESIGN<br>CNC-CODING<br>CNC<br>MACHINING<br>IMPLANT | CT SCAN<br>MIMICS SOFTWARE<br>CAD DESIGN<br>RAPID PROTOTYPING<br>PROTOTYPE<br>MOULD<br>CASTING<br>IMPLANT | CT SCAN<br>MIMICS SOFTWARE<br>CAD DESIGN<br>RAPID PROTOTYPING<br>PROTOTYPE<br>CERAMIC ENCAPSULATION<br>CASTING<br>IMPLANT | CT SCAN<br>MIMICS SOFTWARE<br>CAD DESIGN<br>RAPID PROTOTYPING<br>IMPLANT |
| (a) | (b) | (c) | (d) |

Fig 3 : Implant design methodology

## 3. RESULTS

The CT data were successfully converted via the Mimics© programme into a solid 3D model. The actual human femur bone that was used can be seen in Figure 4.

Fig. 4 : Human femur bone

Figure 5 shows the 3D model grown in Prime Cast 100 on the EOS P380 SL RP machine. This model was used to cast Aluminium and produce a replica of the femur (Fig. 7).

Fig. 5 : Femur prototype in Prime Cast 100

The sand mould and aluminium casting made through direct casting into the sand mould/cavity is shown in Figures 6 and 7, respectively. The Stainless Steel casting generated through investment casting of parts grown in Fibre Prime Cast 100 is depicted in Figure 8.

Fig. 6 : Sand mould grown on EOS S700

Fig. 7: Aluminium casting made through direct casting into the sand mould cavity

Fig. 8: Stainless steel casting generated through investment casting of parts grown in Prime Cast 100

Using CopyCAD inspection software (Figure 9) the accuracy between the .STL file exported from the CT data and the Prime Cast 100 femur was compared. Results obtained are given in Table 1.

**Table 1: CopyCAD Error Analysis report between the .STL file and Prime Cast 100**

| | |
|---|---|
| Mean error | 0.2333 mm |
| Max error | 1.5513 mm at point 113200 |
| Standard deviation | 0.1820 mm |

In addition out of a total of 500 000 data points, 58% 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.

Furthermore, the accuracy between the Prime Cast 100 femur and the actual human femur bone was compared. Results obtained are given in Table 2.

**Table 2 : CopyCAD Error Analysis report between the human femur bone and Prime Cast 100**

| | |
|---|---|
| Mean error | 0.8324 mm |
| Max error | 4.3380 mm at point 105592 |
| Standard deviation | 0.3773 mm |

In addition out of a total of 500 000 data points, 50% of errors had a magnitude below 0.8324 mm, 91% of errors had a magnitude below 1.2097 errors and 97% of the errors had a magnitude below 1.5869 mm.

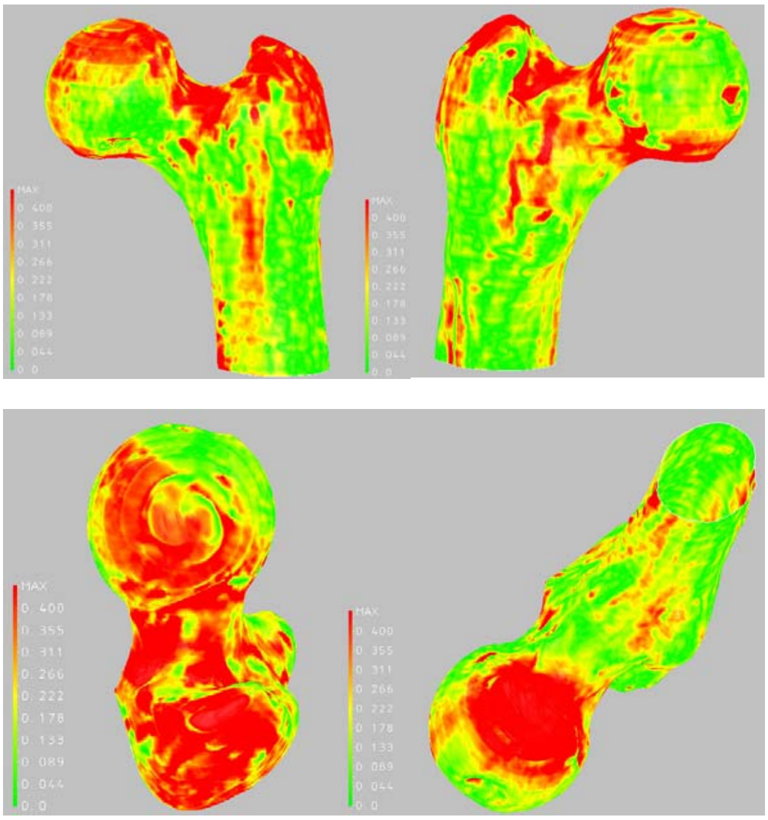


Fig 9 : Performed error analysis

## 4. DISCUSSION

RP has been used by industry for years to improve design and reduce product development time. It enables a 3D computer image to be accurately reproduced in a relatively short time as a physical model you can hold in your hand. Originally this process involved milling machines that carved the desired object from a solid block in either an automated or semi-automated process. Now the models are produced faster and less expensively by a machine that deposits a layer of wax, plastic or metal similar to the way in which an ink jet printer puts a layer of pigment on a page. The prototyping machine puts layer upon layer until it forms a solid structure [5]. RP processes may need a secondary clean-up or curing process.

For successful implantation/reconstructive surgery, sufficient bone structure is needed. Very often, due to osteoporosis or other causes, the bone structure of patients receiving such treatment, is in a developed state of deterioration. Data isolated from patient's pelvis [6] shown in Figure 10 clearly indicate deterioration of the bone structure.

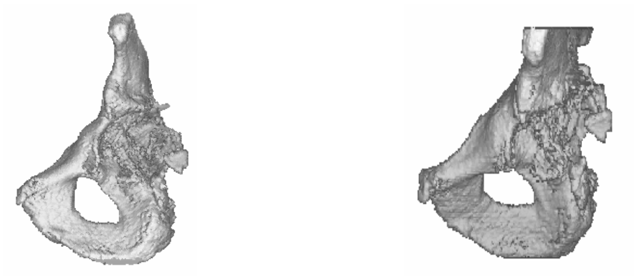

Fig 10 : 3D reconstruction of a pelvis [6]

From the femur parts grown, it is clear that exact matching areas can be developed (instead of relying on approximate areas/surfaces/volumes) which will not only ease the joint operations, but may impact positively on the force distribution, and may result in a longer service-life. It may also prevent further damage, which often occurs with implants of replacement structures.

A further advantage of having exact surface/volumetric data available is that operation jigs, which will allow the surgeon to drill exact locations, can be developed. Advantage of such jigs is the positive feed-back given to surgeons during operation. Over and above matching surfaces/volumes, internal CT-data/geometry can be used to add screws/pins/fixing devices to the replacement structures, incorporating internal data of the remaining structures. Vice versa, the opposite is possible with external geometry [9].

The CopyCAD inspection software shows a high degree of accuracy between the CT data of the original femur and the prototyped femur.

The ultimate would be to develop/use a material that replicates the strength, porosity and elasticity of real bone, which may lead to longer lasting implants. In the case of implants, stress-shielding inhibits the continuous growth of new cells that keep joints healthy and strong, which, in turn, causes implants to loosen over time and require corrective surgery [4]. The suggested methodology is depicted in Figure 3 (d).

Currently, four new technologies offer direct growing in Titanium, viz. Arcam, Selective Laser Melting (SLM) from Fockele and Scharze and commercialised by HEK/MCP, Concept by Hoffman, and the EOS Direct Metal system. Figures 11 and 12 show Titanium implants grown by the SLM, using the process chain depicted in Figure 3 (d). It is possible to obtain very fine structures (Figures 13) together with elasticity (Figure 14), which again opens up a further research field to substitute solid structures by space frames that can be designed such that it will closer resemble the modulus of elasticity of the bone structures to be replaced. Such a porous/lattice structure should also be conducive for regenerative bone growth, and may prolong the life cycle of the implant.

Fig 11 : Future products through direct prototyping

Fig 12: Titanium implants grown by SLM

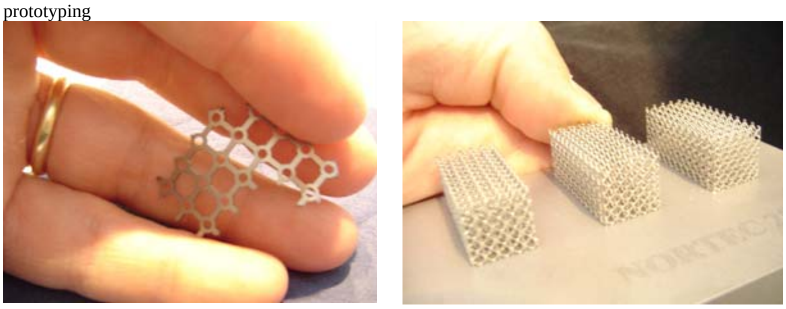

Fig 13: Fine structures obtainable

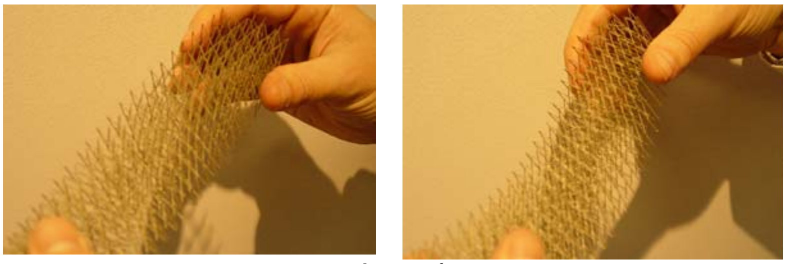

Fig 14: Elasticity of structures

Rapid Prototyping continues to develop, with constant innovation in both systems and materials. Judging the latest improvement in processes and materials, the use of RP offers infinite new possibilities and applications. Medical RP of a CT scan image data is a useful method for producing accurate anatomical models for simulation of the human body [11]. The advancement made in these enabling technologies poses a huge challenge to redefine conventional design paradigms and empirical structures or conventions used, and offer huge potential for further interdisciplinary research, involving Mechanical Engineering Design, Materials Science, Bio-Engineering and –Kinetics, to name but a few.

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