THE USE OF RAPID PROTOTYPING TECHNIQUES TO PREPARE PHYSICAL REPLICATES OF ORTHOPAEDIC IMPLANTS

Shabnam Rajaie [1], Gord Campbell [2], William Wells [2],
Ben Luan [2], Steve Kruithof [2], Robert Bourne [1], Cecil Rorabeck [1]
1 Dept of Orthopaedic Surgery, University of Western Ontario
2 Integrated Manufacturing Technologies Institute,
National Research Council Canada

INTRODUCTION

Rapid prototyping (RP) techniques are fabrication methods used to quickly manufacture the shape of a design in order to analyze, correct and improve products using three-dimensional computer aided design (3D-CAD) data [1] [2]. Stereolithography (SLA), which is considered the first rapid prototyping method, was introduced by 3D Systems of Valencia, CA, USA, in about 1986 [3]. Since then, rapid prototyping has become one of the most important design tools in different engineering disciplines. Although the primary reason for RP is to visualize and improve the design before committing to production, it can also be used to facilitate communication with others and correct mistakes early in the design process. In some cases RP samples can be used instead of test parts as well. This translates into cost and time savings that are crucial for projects with limited budgets and tight deadlines.

Although each RP method has its own strengths and limitations, all share the basic essentials. Stereolithography (STL) file format is the conventional file format, usually generated from a CAD model, which is ported into the RP machines. The STL file is converted into layered slices of the 3D volume. The physical volume of the model is built by generating the first layer, and then repeating the process for each succeeding layer. All of the thin layered slices are stacked until the volume of the model is generated

In this paper, the progress and use of the RP fabrication techniques in our project, as part of an ongoing challenge to implement and perform mechanical tests of the femoral stem of a hip prosthesis is presented. In addition, the highlights, advantages, as well as deficiencies of RP models for substituting real prototypes are examined.

Different RP techniques were employed to manufacture prototypes from different materials, to validate computer solid models, experimental methods, test apparatus, test set up and fixtures. In addition to this, the RP samples were used as trial specimens to practice on the test equipment. The main goal of RP in this stage of the project was to improve and correct possible mistakes before manufacturing and testing the femoral stem of a hip prosthesis from expensive titanium alloy (Ti-6Al-4V).

MATERIALS AND METHODS

The entire surface of a femoral stem for a total hip prosthesis was optically scanned using surface data captured from multiple angles. The data from all scanning angles was merged to produce a single 3D-mesh surface. The scanning hardware used was the Minolta Vivid 900 3D Laser Scanner. Controlled by the Minolta Polygon Editing Tool software, the Vivid 900 shines a low intensity laser on the part, measures the reflection, and outputs a grid of 3D data points that mimic the surface of the part that is currently facing the scanner. Multiple scans at different angles were necessary to provide surface data for the entire prosthetic. The result is a series of 3D mesh surfaces that must be joined together. The individual patches of surface data were loaded into the Innovmetric Polyworks software suite. The different data patches were first aligned, and then merged together as a single 3D model. The 3D model was saved in STL file format.

Although other commercial RP techniques have been developed, the SLA technique remains the most common RP technique in industry. SLA is a process in which the 3D-CAD model is mathematically divided into thin 2D cross sections. SLA prototypes are built from a liquid photopolymer that is selectively cured using an ultraviolet laser. A laser traces the path defined by each slice to change the liquid photopolymer into a solid. The part is formed by the build-up of the slices as layers (typically 100 microns thick). The result is a physical replica of the original part. Since this technique requires support structures for the part; the data files are edited for optimal SLA fabrication supports, using the Magics software. The STL data file is transferred to the SLA machine (3D systems). The parts were built on a model SLA 5000 using Accura SI10 resin as the liquid photopolymer. After removal from the SLA machine the parts are cleaned, post-cured and finished. At our facility we have the capability to coat the part with nickel which substantially improves the impact strength to avoid breaking the part if it is dropped and improves the appearance. The SLA part is shown in Figure 1.

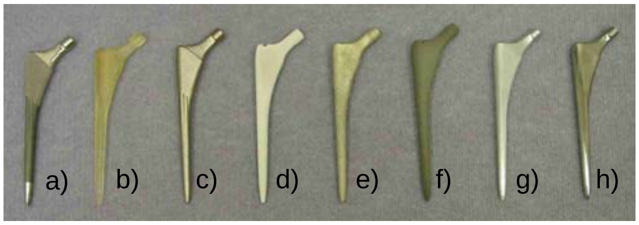

Figure 1: Rapid Prototyping manufacturing of hip implant. a) Original stem b) SLA prototype c) SLA prototype Nickel coated d) SLS prototype, glass-filled nylon e) SLS prototype Copper and Nickel coated f) SLS prototype, RapidSteel 2.0 g) Aluminum prototype h) Ti-6Al-4V prototype

The fabricated model using SLA confirmed the relative dimensions and shape of the original femoral stem. The volume of the RP was close to the volume of the original femoral stem. Although the RP model had indistinguishable edges in most of the sharp and delicate areas, it was an acceptable start to begin design of the stem. Later on, during the analysis of data on modeling a new design, it was observed that the computer model resulting from the optical image was twisted. The result of the optical imaging was a mesh surface that could not be modified in order to correct inaccuracies in the STL file resulting from the optical image, or to make any other improvements, it was decided to generate a new CAD model which would allow changes on the file.

To generate a CAD Solid Model, Unigraphics NX2 was chosen because, it includes a flexible hybrid modeler that gives users a choice of solid, surface, wireframe and feature-based parametric modeling as well as powerful photorealistic rendering, animation and rapid prototyping tools.

The STL file from the optical image was imported into Unigraphics. In order to obtain the outer surface of the stem three mutually perpendicular x, y, and z planes were positioned to intersect the optical image and define the borders of the stem in three dimensions. Also, different angular planes to the main axis of the stem were positioned to intersect the main body of the stem to identify the major cross sections. Consequently, specific cross sections, and boundaries at the critical planes were defined. With the use of these essentials facts, the basic volume of the femoral stem was created. By using the different features of the software all the major elements were created and merged together. Details were added to the main design later. All of the uncertain elements in STL file resulting from the optical imaging were corrected based on direct measurement of the critical planes.

The advantages of using the STL file resulting from the optical imaging was quick access to a moderately accurate volume, the ability to apply an indirect measurement technique, as well as having major frames for design of the new computer model. This technique is a novel idea to start new designs with irregular volumes to be consistent with old patterns. This proved to be an advantage for this project

Later, a second RP technique was selected to validate the computer modeling. Glass-filled nylon and RapidSteel 2.0.prototypes were fabricated with the use of Selective Laser Sintering (SLS). Again the CAD solid model was converted to STL format.

Selective Laser Sintering (SLS®, registered trademark by DTM™ of Austin, Texas, USA) is a process that was patented in 1989 by Carl Deckard, a University of Texas graduate student. As mentioned previously, the RP manufacturing process is based on creating multiple thin layers to form the final volume. The SLS® machine consists of two powder magazines on either side of the part bed. A leveling roller moves a thin layer of powder over the part bed from one magazine, crossing over the part bed to the other magazine. A laser is directed across the part bed by a scanning system and “selectively” sinters or melts the material based on the cross-sectional slice information from the 3D-CAD STL data file. The laser traces the layer. The part bed moves down by the thickness of one layer and the roller moves in the opposite direction to deposit a thin layer of powder. The process repeats until the part volume is complete. The powder in the part bed acts as a support for the part during fabrication and there is no additional support structure required. Another advantage of SLS prototypes compared to SLA is that they do not require post-cure and are ready to use after removal. The part was built on a DTM Sinterstation 2000 using glass-filled nylon powder. Although the material properties of the glass-filled nylon are better than the SLA liquid photopolymer, the parts were again coated with nickel to improve strength and appearance. The SLS part is shown in Figure 1.

After analysis and examination the SLS prototypes, some elements of the design were improved in the CAD model. After these corrections, at least two prototypes were manufactured. Different orientations for fabricating the stems were explored. The best position was laying the part on its side

Following verification of all the physical and computer model elements of the design, by analyzing SLS glass-filled-nylon prototypes; it was decided to fabricate prototypes from RapidSteel 2.0 using SLS, which has closer mechanical properties to the titanium alloy prototypes of the project. RapidSteel 2.0 is a stainless-steel-based powder mixed with binder. The SLS procedure results in a "green part". After the SLS procedure, the part undergoes two furnace cycles. The first is a sintering furnace cycle that burns off the binder and bonds the metal particles together through traditional sintering mechanics. The second is an infiltration furnace cycle that melts bronze to infiltrate the part through capillary action. These furnace cycles result in a fully-dense part that can be used as a prototype part in an assembly or to verify the mechanical integrity. Rapid Steel 2.0 powder was not used at the beginning because of the complexity of working with this powder. The SLS part using Rapid Steel 2.0 powder is shown in Figure 1.

Subsequent to manufacturing the prototypes and confirmation of the physical accuracy of prototypes, the design and manufacture of the apparatus for different mechanical tests were fabricated. Hip stem prototypes made from SLS-Rapid Steel 2.0 were embedded inside of the grouting agent, Polymethyl methacrylate (PMMA). Different cyclic loads were applied to the SLS- Rapid Steel 2.0 prototype to study the prototype behaviour using a MTS (858-Bionex, MN, USA) universal mechanical testing machine. , A machined hip stem prototype with the same geometry derived for the RP prototypes but made from Ti-4Al-4V was used to validate the loading procedure. To ensure a rigid mounting for specimens, the grouting agent was changed from PMMA to a eutectic composition of tin-bismuth alloy, Metspec 281 (MCP-metalspecialties, Fairfield, CT, USA). The same titanium alloy prototype was embedded in the new grouting material at an angle of 10±1° between the distal stem axis and the line of load application, and the angle between the distal stem axis and the line of load application was 9±1° according to ASTM F1612-95 [4] [5] [6]. The prototype was cyclic loaded in this torsion-bending configuration from -300 N to -3000N (compression), for a total of 10,000 cycles. The apparatus is shown in Figure 2.

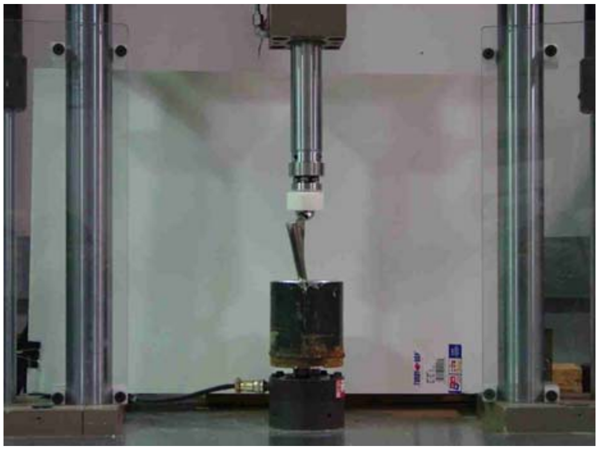

Figure 2: Apparatus, MTS 858-Bionex, MN, USA

RESULTS

During the cyclic loading the RapidSteel prototype made by SLS fractured at about 3000 cycles for a torsion-bending load. It was found that the PMMA grouting material failed at about 1000N, which is 1/3 of the maximum load. An alternate PMMA is being sourced since others have successfully used PMMA for a similar application.

Figure 3 and Figure 4 show the preliminary results after 10,000 cycles using the Ti-6Al-4V prototype.

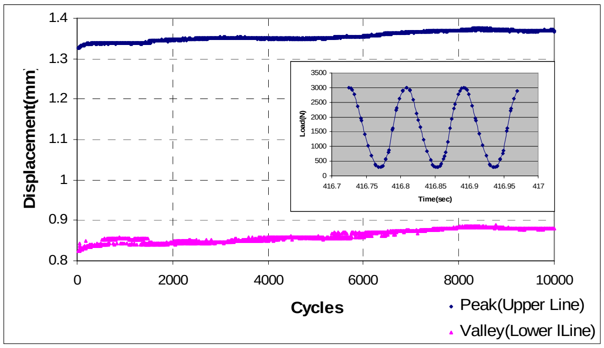

Figure 3: Specimen displacement during cyclic loading

The insert in Figure 3 shows the displacement that result from the cyclic loading. The minimum and maximum displacements of 0.85 mm and 1.35 mm. respectively increase only marginally (0.03 mm) during the 10,000 cycles. The difference between the maximum and minimum displacements remains constant at 0.495±0.015 mm during the 10,000 cycles. Figure 4 illustrates the displacement versus compression/release loading of the specimen at three cycles: beginning; middle; and end, of the experiment. At about 8,000 cycles the minor changes in displacement plateau at a constant. Figure 4 shows that the stem does not deform the same during compression and release of the loading. This hysteresis behaviour shifts slightly towards more displacement by the end of the 10,000 cycles.

Part of these small changes is likely related to changes in hydraulic system of MTS testing machine. This preliminary result helps us to understand the performance of the MTS as well.

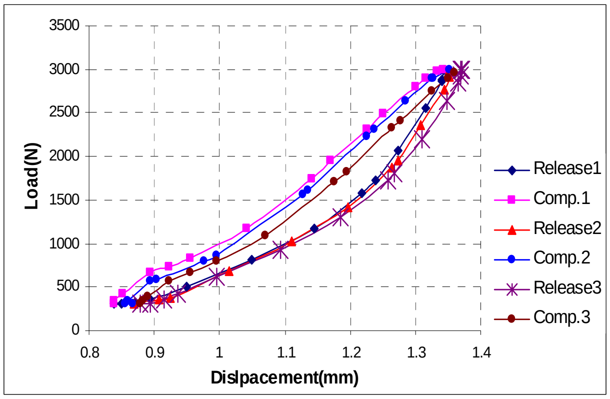

Figure 4: Compression/release behavior of Ti-6Al-4V Prototype for three different cycles at 1) the beginning 2) middle 3) end, of the 10,000 cycles

DISCUSSION

There are practical advantages to fabricating 3D-CAD solid models of orthopaedic prostheses and instruments, instead of 2D images or 3D visualization such as rendering images. Solid models by RP techniques provide the opportunity to touch and see the design, to correct and improve the geometry and flaws at the early stage of the project when it is not expensive to change. In some cases, the RP part can be the final part, but usually the RP material is not sufficiently strong or accurate. Although there are different commercial RP techniques, all of them share the same limitations, such as creating layers on the top of the previous layer. Therefore, the thickness of the layers determines the accuracy of the part, surface finish, and the time to build the part. Also, the process is limited to a few materials. In this project the feature of RP techniques were utilized in different ways. First, the SLA technique was applied to collect data from surface of the part. By importing the scanned data into a CAD/CAM package; access to preliminary information of surface data of the part was quickly available, and a solid model according to the imported data could be created. In a different stage of computer modeling we applied the SLS technique to validate and improve the design. Since the material for the real prototypes was expensive, the shape of the RP parts was used for validating the design of the experimental apparatus, test fixtures and test method.

However, the mechanical properties of the RP parts are weaker than the real prototypes, which resulted in the selection of an inappropriate grouting agent. When the prototype made from titanium alloy was tested; it was observed that the PMMA grouting agent, lacked sufficient strength to withstand the full load.

The use of RP technique and manufacturing RP parts had the benefits of saving money and time but their inferior strength must be considered when used as a substitute specimen for mechanical tests.

ACKNOWLEDGEMENTS

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