Rapid Prototyping of Human Surgical Hip Implants

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Abstract

The objective of this undergraduate research project is to demonstrate how rapid prototyping can aid the design process and the manufacture of human surgical hip implants. The optimum chord height tolerance (a measure of accuracy) was determined for a particular hip implant design. This optimum value was found to be 0.01 inches. Using this value, an STL file (industrial standard file) was created, which contained triangular facets that approximate the shape of the three-dimensional hip implant. This STL file was used to generate a pattern that was then analyzed for its accuracy of dimensions and surface finish properties. It was concluded that rapid prototyping techniques are valuable to the production of surgical hip implants.

Introduction

Most engineers use models, or prototypes, to test their designs. Rapid prototyping (RP) refers to a range of new technologies for making, in hours or even minutes, three-dimensional prototype parts. The systems and processes becoming available, and the materials being developed for use with these systems, show that RP now bids to become a standard procedure at the interface between design and manufacturing. Typical RP systems build solid patterns directly from computer design data, using liquid photopolymers (which cure upon exposure to ultraviolet light) or other materials, along with a computer-controlled laser and scanning system. Solid patterns are then used to make castings or to create replicas for numerically controlled machine tools, so as to build conceptual models for design evaluation. By reducing costs and development time, RP techniques have tremendously enhanced the design and manufacture of discrete parts. This introduction discusses the different RP techniques employed, the advantages of incorporating these techniques into the engineering process, and how RP can improve the design and construction of human surgical implants.

3-D Systems

The first company to venture into the RP market was 3-D Systems from Valencia, California. 3-D Systems holds the vast majority of the business in RP with 300-350 machines in use, while other competitors operate a handful of machines. Several different RP machines have been designed by 3-D Systems. The RP technique used by 3-D Systems is stereolithography, which is a photochemistry process. The solid-model data is sliced into two-dimensional cross sections, and then these cross sections control the laser-generated beam of ultraviolet radiation focused onto the surface of a bath of photo-sensitive resin. The light beam draws the shape of the slice onto the liquid resin, and the resin solidifies wherever the light strikes, resulting in a solid layer of the computer aided drafting (CAD) design. The process repeats, layer by layer, until the three-dimensional hard plastic object is completely built, from the bottom up.

The users of the stereolithography technology are currently obtaining more accurate parts compared to other RP technologies. However, steroelithography is not without its problems. The greatest criticism of the stereolithography process is the amount of experience and knowledge needed in order to obtain good parts. A number of decisions such as adding supports, interpreting material-chemistry interactions, and setting the laser parameters have to be made prior to running the machine. Other problems associated with this process include the use of hazardous material before and after production, part strength, and availability of using future materials, such as metals.

Patterns produced through stereolithography are not as strong as those produced by competing technologies. Also, even if a photopolymer with properties of engineering plastics such as ABS or nylon were developed, the stereolithography part would still be incapable of having the desired properties of the final part because the photochemistry process cannot simulate the high temperature and pressure of injection molding and other production processes.

Recent advances include a new resin called Exactomer which produces tough, resilient parts that are machinable. Using this new resin, patterns have been created with walls as thin as 0.0011 inches, slots with 0.015 inch width, and holes with 0.009 inch diameters. In addition, these parts have a good hardness for operations such as sanding and polishing, and they exhibit better impact strengths than previous parts. 3-D Systems technologies are currently being applied in industries ranging from automobile and aerospace to medical prosthetics and electronic components.

Cubital America

Cubital America utilizes the most complex and expensive of all current RP processes. The Cubital Solider machine uses a solid ground curing process which creates a physical solid model directly from a computerized three-dimensional CAD file. During the modeling process, a 3-D CAD description of an object of any shape generates a highly accurate physical model, layer by layer. The process begins with the conversion of a STL file, a standardized file generated from the CAD solid model, into an optical mask on a flat glass plate. An ultra-violet light is then used to activate a thin layer of resin on the unmasked portions of the image. The uncured resin is then removed and replaced with wax. After the wax is cooled, the part is milled to a precise height and the process is repeated until the part is complete. Each layer (0.006 inches) takes about 90 seconds to be created, and thus, approximately four hours are required for each vertical inch of the part. A slight variation of this process used at Cubital, known as light sculpting, is also used by the Light Sculpting Company that produces RP machines.

Some of the advantages of this process include the elimination of support structures, minimal shrinkage, no postcuring, and the capability of using any resin that reacts with ultra-violet light. Unlike the 3-D Systems machine, there is no need to fine-tune the equipment in order to obtain accurate parts. In addition, the large work envelope and the software are advantages which allow for the production of hundreds of parts in a single batch. Patterns have been created with slots as small as 0.015 inches, and walls as thin as 0.02 inches, and approximately 98% of all parts are produced correctly on the first try.

Disadvantages of this process include cleaning the wax from the parts and the constant monitoring of the process to ensure that parts are being produced accurately. The wax employed in this process is so sticky that full-time attention is required to remove the excess wax from the finished part. Also, the process must be checked and adjusted every twenty minutes to produce a good product. In an effort to reduce the problem of tremendous cost associated with the Cubital system, a new software feature has been developed. This software will allow users to save money building models in only a limited part of the available work envelope. The range of work volumes can be adjusted from anywhere between 56 to 5600 cubic inches. This software transforms the Cubital machine from a high quality, high volume production to a high quality, low volume machine when shorter runs are desired. Even with this new software, the Cubital system is by far the most expensive available.

DTM Corporation

DTM Corporation (DTM) uses a selective laser sintering process to sinter (weld) dry powders with a laser. The selective laser sintering process uses a CO_2 laser and scanning mirrors, process chamber, and a leveling drum that deposits a thin layer of powder (any material that softens and has decreased viscosity upon heating can be used). The laser scans and fuses the powder one layer at a time, and each layer is 0.0002 inches thick. The model is built from the bottom up at a speed of 0.5 to 1 inch per hour. Material not sintered remains to support the next layer of powder. This is an advantage over the stereolithography process, because supports do not need to be added to the part. Also, multiple small parts can be stacked three-dimensionally within the work volume. The DTM RP machine uses a variety of material including polycarbonate, investment-casting wax, nylon, ABS, polyester, PVC, polypropylene, and polyurethane.

The raster scanning enables the DTM system to make parts quickly. Scan speed is 30 to 40 inches per second, and most parts taking 2 to 6 months to complete by conventional methods, can by produced in only 6 to 8 hours. In addition to the quick production time, the DTM system has an advantage in the accuracy of the resulting pattern. The accuracy range varies from 0.002 to 0.01 inches over the 12 inch diameter and 15 inch deep working envelope. By sanding and coating the surfaces of the finished product a nice finish is added to the part.

The main problem with the selective laser sintering process is that powdered materials are conductive as well as absorptive, and some shrinkage occurs when the powder is fused. To ensure a good bonding between layers, the powder material is maintained at a high temperature which creates a danger of powder fire or explosion. Thus, it is necessary to maintain a nitrogen atmosphere in the chamber in order to prevent any fires or explosions. A final drawback of the selective laser sintering is the high cost of the RP machine.

Helisys

The laminated object manufacturing (LOM) process used by the Helisys company is the simplest of all the RP processes. The LOM process uses sheet materials that are pre-coated with heat-sensitive adhesives. The sheets are laminated one on top of the other in order to create a multilaminar structure. Once the layer is laminated a CO_2 laser cuts the outline of the specific cross-section based on the CAD data. Materials such as paper, plastics, composites, and ceramics can be used.

The Helisys method has several advantages. Because the process does not involve phase changes of material, LOM parts are not subject to shrinkages, warpage, internal stresses, and other deformations. A precise X-Y positioning table guides the laser beam, which results in production of accurate parts. Only the edges of the part are cut, reducing part production time as compared to other RP techniques. In addition, there is no need for supports during building, and the part can be reproduced by silicon molding or a casting process such as sand casting or investment casting. A final advantage of the Helisys system is that it is one of the least expensive RP processes.

While this system has several advantages, some disadvantages also exist. One of these disadvantages is that the parts come out of the machine inside a block of material that is equal to the work envelope, and this excess material has to be removed. The removal of excess material can be quite challenging when dealing with interior cavities and horizontal layers that have to be separated from unwanted material. Another disadvantage is that this process is not tailored to producing small intricate parts. The LOM process is much better suited to produce larger parts and heavier castings, where strength, stability, and accuracy are key parameters.

Recently, Helisys has installed and generated upgrades to its previous systems. These upgrades improve accuracy, speed, reliability, and safety and include a motor control system with closed-loop encoder feedback, an enhanced laser beam delivery system, a visible laser aligning system, and a high-precision lamination mechanism.

StrataSys

The RP system developed by StrataSys is based on a fused deposition modeling (FDM). In this process liquid thermoplastic material is extruded and deposited into ultra-thin layers from the lightweight FDM head one layer at a time. This builds the model upward off a fixtureless base. As the material cools, it solidifies and the model can be removed without further treatment or curing. The current choice of materials includes investment casing wax, machinable wax, and a nylon-like material. Parts produced with investment casting wax can be easily transformed into cast-metal parts, and if a conceptual part is desired, the nylon-link material provides good fit, form, and some part functioning.

The StrataSys system excels in speed, safety, accuracy, and in the variety of material available for model making. Parts are generated at a rate of 15 vertical inches per second. Other advantages of this process are the quick and easy material changeover, simplicity of the process (because no lasers are involved), and fast production rate. Material changeover is easy, and there are no messy liquids to be cleaned. Since this process requires no laser, it is simpler and also less expensive than laser-transformation processes. Also, because no excess material is generated and no post-curing is required, the production process is more rapid than other RP techniques. A final advantage of this system is that StrataSys offers one of the least expensive RP machines on the market today.

Disadvantages of this system are that the surface features and small intricate parts are difficult to produce accurately when compared to other RP techniques. Larger amounts of time are required to produce objects with higher surface quality and resolution. The accuracy of this process is a function of the traversing mechanism's ability to position the fused deposition modeling machine head. This accuracy is about 0.005 inches over the entire 12 inch cube work envelope. A major challenge is to control the flow of material and to get it to start and stop quickly in order to create detailed parts and good surface finishes. Also, delamination of parts has been a problem in the past because of the difficulty of bonding a new layer to the cold layer underneath. However, this problem has been reduced by the use of a new resin that is better suited for this process and can produce stronger parts.

Recent improvements by StrataSys have resulted in less processing time for increased finish quality. New software improvements have eliminated the surface imperfections associated with the start and stop points of the tool path. Additionally, the newer systems have a rollback feature on the material-feed system that prevents material oozing, providing a better surface finish.

Perception Systems

The RP process used in the Perception System machines consists of creating ceramic parts directly by spraying layers of ink using ink-jet technology known as ballistic particle manufacturing (BPM). The process involves using a computer-controlled, independently targeted jet of thermoplastic ink particles to construct parts. Particles are fired from an ink jet mechanism to a platform where they hit and solidify. The mechanism is positioned by a three-axis robot. A part is produced by printing multiple cross sections with cold welding or rapid solidification providing cohesion between particles. Tolerances are controlled by particle size and location. Shrinkage and warpage pose no problems, but this process does take large amount of time to complete.

Soligen

Closely related to the Perception System machine is the Soligen RP machine which creates ceramic molds by spraying layers of powder with a binder using ink-jet technology. This process is said to be the closest one can get to creating a functional metal part. A shell mold is obtained by building up, layer by layer, thin ceramic powder ejected by an ink-jet sprayer. This process allows for any geometry to be used since the mold is being removed destructively. Accuracy of this process is dependent on the positioning of the squirting nozzle. The drops of binder are about 0.002 inches in diameter and are deposited with a high resolution on the surface of the powder. This process results in no shrinkage, since there is no change in the state of the building process. A disadvantage of this machine is the large cost and time taken to finish a part.

Table 1 provides a summary of the different RP machines available in today's market.

Table 1: Comparison of RP Techniques

Company	**Process tradename**	**Material**	**Part size capability, in.**	**Equipment cost, $**	**Light source**
3-D Systems	Stereolithography	Photopolymer	10 x 10 x 10	185,000	Helium-cadmium laser
Cubital	Solider	Photopolymer	20 x 14 x 20	490,000	UV lamps
Light Sculpting	Light sculpting	Photopolymer	6 x 6 x 6	75,000	UV lamps
DTM	Selective laser sintering	Powders	12 x 15	15,000 per month to rent	CO_2 laser
Helisys	LOM	Sheet	11.5 x 11.5 x 17	75,000	CO_2 laser
StrataSys	FDM	Thermoplastic filament	12 x 12 x 12	178,000	None needed
Perception Systems	BPM	Thermoplastic ink	12 x 12 x 12	50,000 - 80,000	None needed
Soligen	Ceramic ink-jet molding	Ceramic	8 x 12 x 8	200,000 - 300,000	None needed

Future of RP Processes

The future of RP techniques will involve the development and implementation of devices that will create the actual part made of different metals directly from a three dimensional model CAD file. These new developments are the current topics of new research and development. The ability to make actual metal parts during a RP process will eliminate the need to create a pattern or mold from which the component can be developed.

The Importance of RP to Engineering

Without considering which RP technique is used to produce a prototype or pattern of a part, RP has improved the conventional manufacturing process for several reasons. Because the RP process is tailored to production of custom-made parts, this manufacturing process has unlimited capabilities for complex geometries and can be used for individual one-item manufacturing. A second advantage of RP is that the process allows for the part to be easily revised and retested. Since the part is generated from an industry standard solid model file, it is no problem to modify the file and complete another rapid prototype to create a new design. Also, the RP process requires less machinery and technical expertise than conventional manufacturing techniques. All these advantages contribute to making the RP process much faster and less expensive than conventional techniques. These reasons make RP an important component in the engineering design process.

The Importance of RP to Human Implants

Human surgical implants come in a variety of shapes and sizes, and they can even vary in geometry from individual to individual. Thus, since the RP process is tailored to individual custom-made parts, RP provides a useful tool in the design of human implants. In the past, the surgeon had to choose the correct size implant from a set of standard devices. If the implant is too small there will be relative motion between the implant and the bone resulting in a loose joint. An implant which is too large may cause a bone fracture or excessive pain due to improper fit. By using RP to design and manufacture implants, precise and exact implants can be constructed the first time, without guesswork. Hip joint replacements are a representative type of human implant that are frequently needed to replace damaged or infected hip joints. The present trend is to use stainless steel hip stems with plastic ball-in-socket joints. Often these metal and plastic replacement hips fail due to excessive wear on the tissue which creates infection and disease. Therefore, a titanium hip replacement with a zirconium ball-in-socket joint was selected for study in this research project. Its advantages include near-infinite life possibilities and the availablility of the RP process for production of the part. Finally, this information can be applied to prosthesis as well as implants.

Objective

The objective of this research is to demonstrate how rapid prototyping can aide the design process and the manufacture of human surgical implants. Also, an attempt was made to determine the optimum number of facets, or accuracy, during the rapid prototyping process required to produce an accurate model of a hip implant device. The approximated representation of a part by RP depends upon the accuracy of the CAD model, or STL file information. While in principle, the accuracy improves as the number of facets is increased, there is a practical limit to this number, depending upon the computer workstation and the RP machine. It is possible that a RP model could be so accurate that the model file is too large to handle efficiently, and the RP process will take too long. Thus, an accuracy level at which any further increase in file size and number of facets will be redundant due to the accuracy limits of the STL file generation procedure is believed to exist. It is therefore very important to investigate the influence of the number of facets on the accuracy of part, so that the former can be fixed at an acceptable value. Once the optimum level of accuracy is determined, the next objective is to investigate the actual level of accuracy by generating a RP model of the hip replacement. This pattern is generated using selective laser sintering at DTM. After the pattern is obtained, it is analyzed and compared to the original design drawings.

Methods

The first task involved the selection of a particular hip implant design to use in the research. Kemp Development Corporation provided a particular hip implant design in exchange for a casting and further research from the final hip implant developed later. A two-dimensional model of this particular hip implant device can be seen in Figure 1.

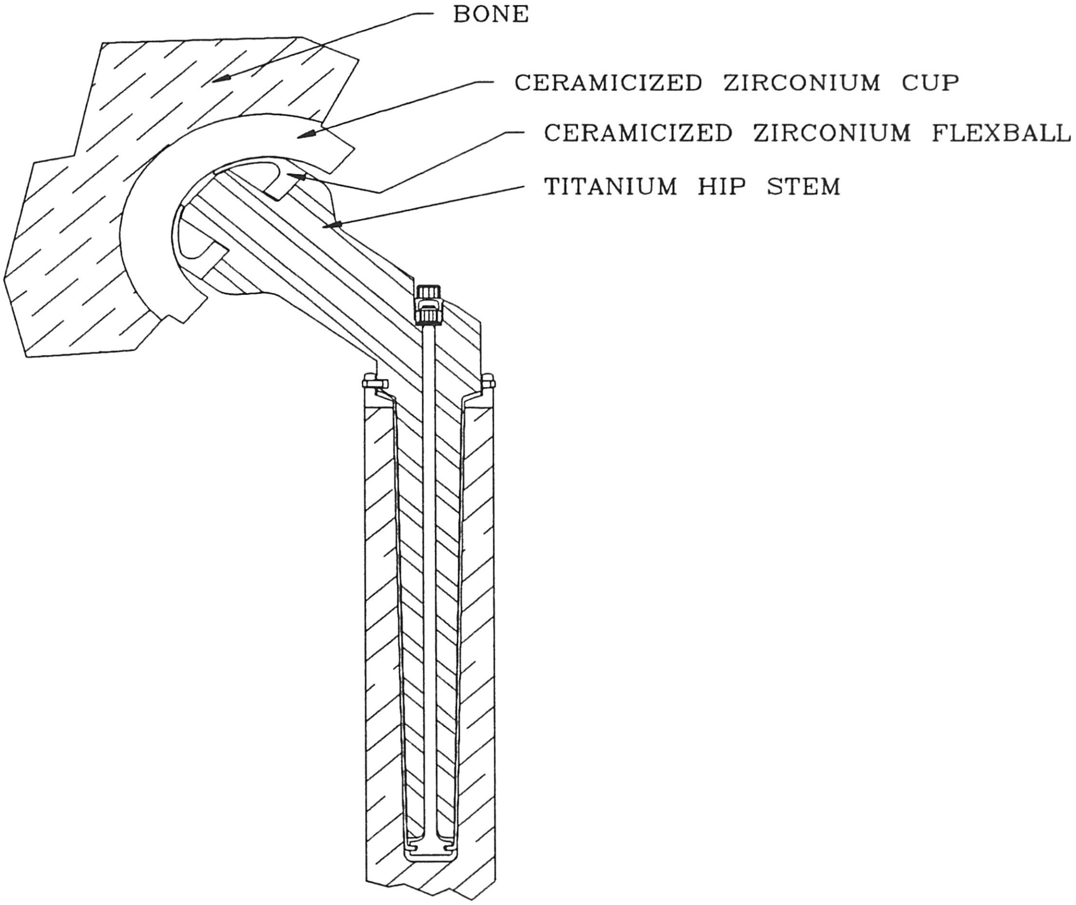


Figure 1: Two-Dimensional Hip Model

Once the two-dimensional model had been obtained, the next step in the research process involved generation of a 3-dimensional solid model. This CAD model was created using the Intergraph Workstations available at the Department of Mechanical Engineering at Texas A&M University. Using Intergraph/Electronic Modeling System software, the three different parts of the hip replacement were generated. A picture of the resulting model can be seen in Figure 2.

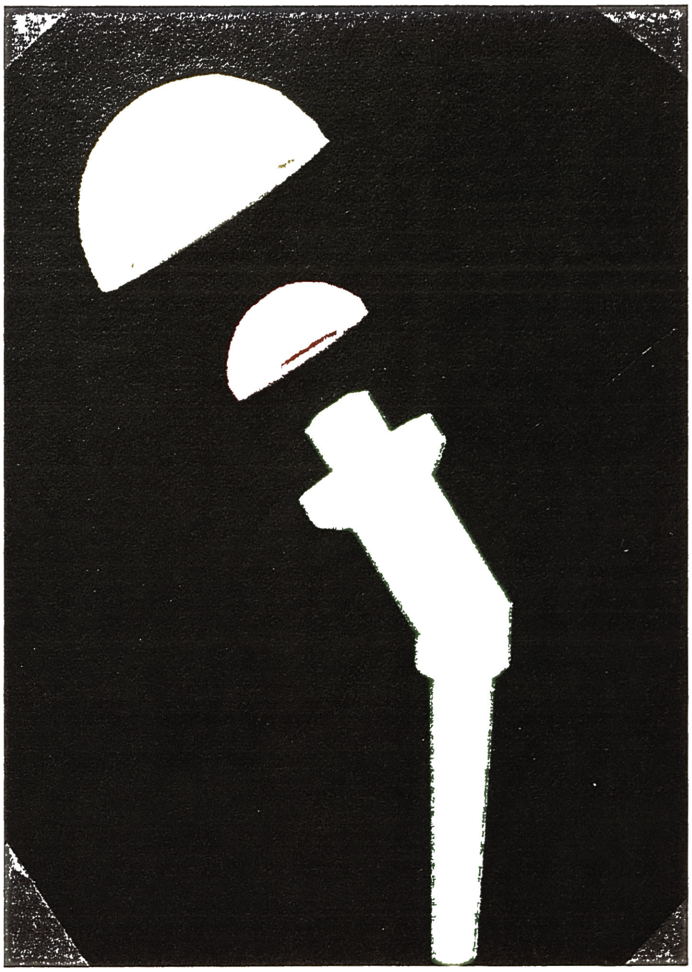


Figure 2: Three-Dimensional CAD Model

After the three-dimensional CAD model was obtained, the next procedure was to create several STL files. The STL files are industry standard files that contain the facet information that is used to approximate the geometry of the three-dimensional model. The surface of the model is represented by triangles of different sizes and orientations. The STL file records the vertices of each triangle along with a unit vector outward normal to the surface of each triangle. An example STL file of the hip implant model can be seen in Figure 3. This STL information is then read by the RP machine to create different cross sectional slices. These cross sectional slices are in turn used to drive the laser of the cutting tool used to generate the RP pattern.

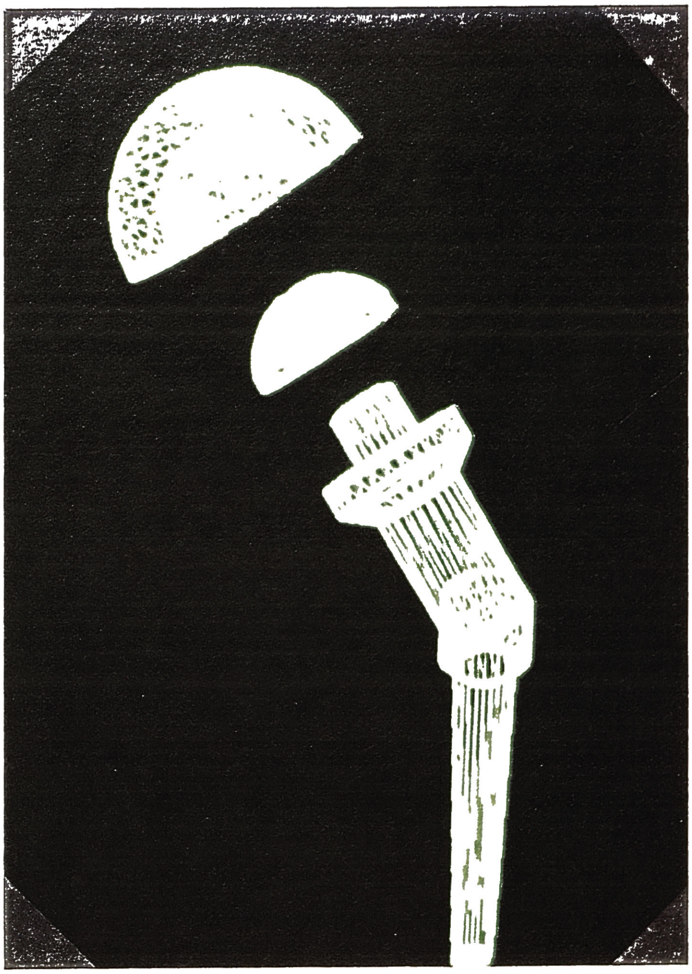


Figure 3: STL Representation of Hip Model

In order to determine the optimum accuracy for the hip implant model, several different STL files with different accuracies were generated. The accuracy was varied by changing the chord height tolerance (CHT). The CHT is the maximum length between any actual surface on the three-dimensional model and a surface of a triangular facet. The smaller the CHT value the more accurate the STL file will be. However, as the STL file increases in accuracy, the time required to generate the file also increases.

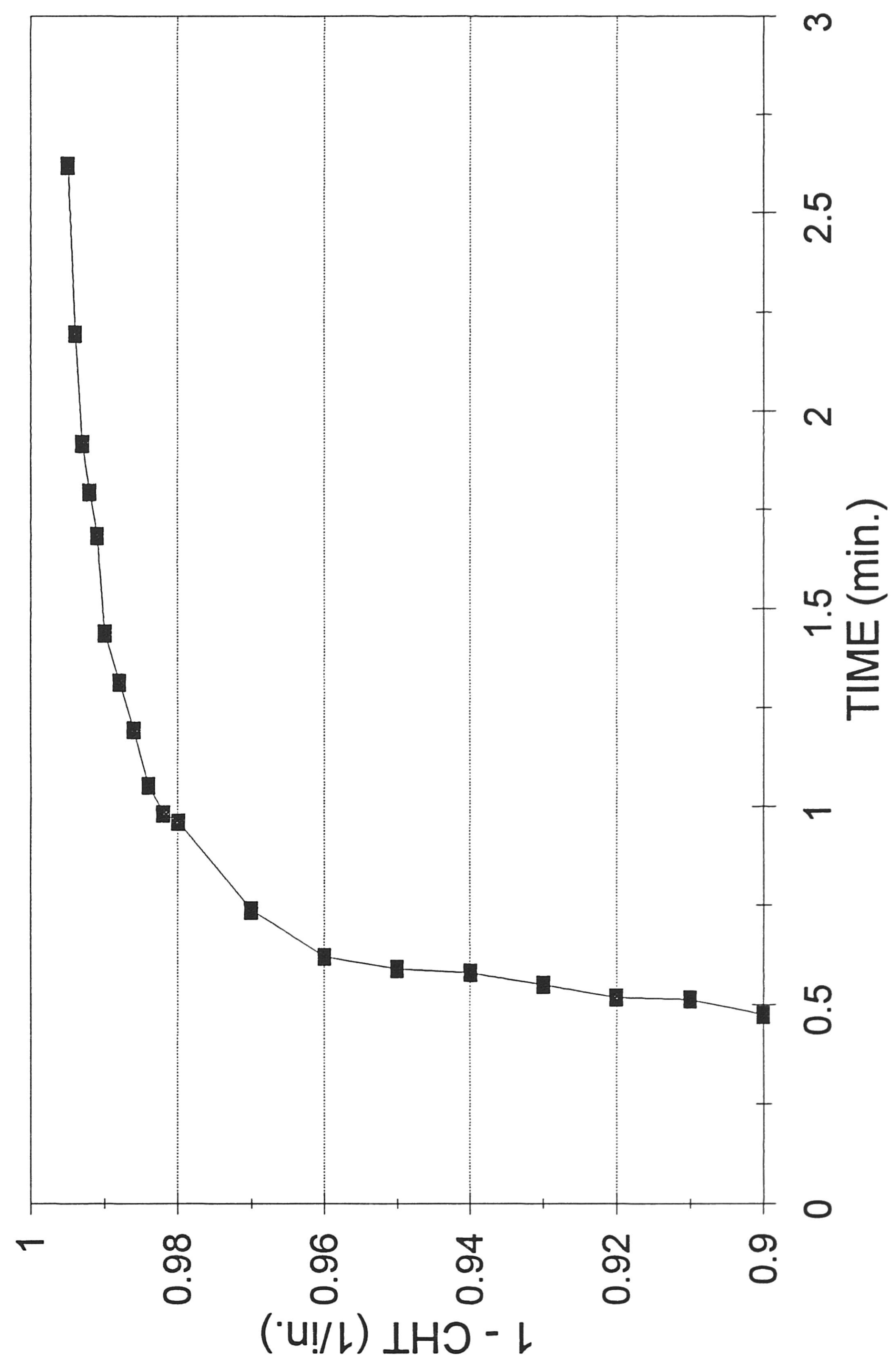
Once the optimum CHT tolerance value was determined, that particular STL file was sent to the DTM Corporation in Austin who produced a pattern using selective laser sintering. The accuracy of this pattern was then determined by measuring the different dimensions and comparing them to the original design specifications in the two-dimensional model. These processes will better determine the accuracies required for human hip replacements and demonstrate that an accurate hip implant can be generated using RP techniques.

Results

The results from the variation of accuracy with facet size and number of facets can be seen in Figure 4. The accuracy of the STL file model representation is measured by 1 minus the CHT value. As 1 - CHT increases, so does the accuracy. The facet size and number of facets are measured by the time required to generate the STL file. The CHT value was varied from 0.1 to 0.001 inches, and this resulted in a time variance of under 0.5 minutes to over 2 minutes. The results from this experiment indicate that a CHT value of 0.01 inches is the optimum value for the STL accuracy versus size of file trade-off. The STL with a CHT of 0.01 was a total of 700 KBytes in size.

Once the CHT value of 0.01 inches was determined as the optimum value, the corresponding STL file was sent to the DTM Corporation. At present the pattern is still in the generating process with DTM in Austin. Some unforeseeable delays were encountered due to sudden management changes within the DTM Corporation, and these delays have prevented completion of this portion of the project.

FIGURE 4: 1 - CHT VS. TIME



Summary and Conclusions

Several conclusions can be drawn from this experiment and research. RP as a manufacturing process is better than conventional techniques because it is faster, cheaper, easier to change design details, and RP is tailored to individual components, such as hip implants. A hip implant pattern can be accurately made using RP techniques. This pattern can then be used to make an investment casting. The final product being cast uses titanium for the stem and zirconium for the ball-in-socket surfaces. Finally, it can be concluded from this experiment that a CHT tolerance of approximately 0.01 inches is sufficient to produce the accuracy needed, while still maintaining a small manageable file size. This information is valuable for future hip plants designs so that accuracy, time, and computer space will not be wasted unnecessarily. Further, it is valuable to know that RP can be used to manufacture all-metal hip implant devices.

Future Study

Before any future study could be attempted, it is desired to complete the present study by receiving the pattern from DTM Corporation and comparing the dimensions to the original specifications of the two-dimensional drawing. Other future study of interest would be to actually cast the hip implant. Using this hip implant, fatigue tests and stress tests could conducted to determine valuable properties of the hip implant. Also, a metal casting would be informative to analyze the surface finish of the final product and compare it to conventional manufacturing techniques. Finally, further investigation into the effects and status of the metal on metal socket joint would be of interest. These investigations, however, would not be of a manufacturing nature.

Acknowledgments

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