2007

THE PROCESS OF USING SUPERPLASTIC FORMING TO CREATE MEDICAL COMPONENTS

Daniel Lee Thomas
University of Kentucky, dlthom0@engr.uky.edu

Recommended Citation

Thomas, Daniel Lee, "THE PROCESS OF USING SUPERPLASTIC FORMING TO CREATE MEDICAL COMPONENTS" (2007). *University of Kentucky Master's Theses*. 489.
https://uknowledge.uky.edu/gradschool_theses/489

ABSTRACT OF THESIS

THE PROCESS OF USING SUPERPLASTIC FORMING TO CREATE MEDICAL COMPONENTS

In the present work superplastic forming (SPF) is used as part of a process to create medical implants out of titanium. SPF is a forming process which offers many advantages over conventional forming processes. It allows for greater complexity in shape as well as the ability to work with difficult to form metals such as titanium which is a key metal in the biomedical field. SPF has been used extensively in the aerospace and automobile industry, however in recent years it has been shown to be a viable means in creating medical implants.

The current process involves manipulating CT scans in order to create templates using rapid prototyping. These templates are then used to generate SPF molds out of investment material. Three different parts based on anatomical regions referenced from a model skull have been formed successfully. The parts formed are shown to be very accurate when compared against the skull model.

KEY WORDS: Superplastic Forming, Titanium, Manufacturing, Stereolithography, Rapid Prototyping.

Daniel Lee Thomas

12-10-07

THE PROCESS OF USING
SUPERPLASTIC FORMING
TO CREATE MEDICAL COMPONETNS

By

Daniel Lee Thomas

Dr. Marwan Khraisheh
Director of Thesis

Dr. Scott Stephens
Director of Graduate Studies

12-10-07

THESIS

Daniel Lee Thomas

The Graduate School

University of Kentucky

2007

THE PROCESS OF USING SUPERPLASTIC FORMING TO CREATE MEDICAL COMPONENTS

THESIS

A thesis submitted in partial fulfillment of
the requirements for the degree of Master of Science in the
College of Engineering
at the University of Kentucky

By

Daniel Lee Thomas

Lexington, Kentucky

Director: Dr. M.K. Khraisheh, ME Director of Undergraduate Studies

Lexington, Kentucky

2007

ACKNOWLEDGMENTS

The following thesis, while an individual work, benefited from the insights and direction of several people. First, my Thesis Chair, Dr. Marwan Khraisheh, who encouraged me to go into graduate school. In addition, Dr. Richard Curtis provided timely and instructive comments and evaluation at every stage of the thesis process, allowing me to complete this project on schedule. Next, I wish to thank the complete Thesis Committee: Dr. Marwan Khraisheh, Dr. Keith Rouch, Dr. Ibrahim Jawahir, and Dr. Richard Curtis. I would also like to thank Rajab Said and Simpleware. Without their knowledge and support the process would have stagnated.

In addition to the technical and instrumental assistance above, I received equally important assistance from family and friends. My wife, Megan Thomas, provided on-going support throughout the thesis process. My parents, Glenn and Jeana Thomas, instilled in me, from an early age, the desire and skills to obtain the Master's. My newly acquired parents, Don and Linda Kleine-Kracht, whom have supported my academic and career goals from the beginning. I'd also like to give a special thanks to Michael Cusick, without whom this thesis would have never been completed on time.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1: INTRODUCTION

1.1 Thesis Layout

The thesis is divided into five chapters. The first chapter, or introduction, details the problem being viewed as well as the motivation and goals behind the project. The second chapter is a literature review which provides the background and basis for the project. In the third chapter the setup and procedure for the process are discussed. The fourth chapter expounds upon the results, and the fifth chapter highlights future work which could be pursued as well as a conclusive statement.

1.2 Motivation

The concept of superplastic forming (SPF) in the medical community is relatively new. It has been shown to be a viable means to create denture bases and other oral implants (1; 2). However, it has yet to be successfully integrated and used on a larger scale. SPF opens up the possibilities of creating lower cost and more complex shapes than current cold forming processes, and its ability to form difficult to work with biocompatible metals such as titanium is invaluable. By applying the principles of manufacturing a procedure for the creation of customized maxillofacial and other medical implants using SPF will provide the medical community with more options, in some cases far superior, with respect to these implants.

In 2003 Fadi Abu-Farha, who is a part of Dr. Marwan Khraisheh's research group, wrote a paper titled "Superplastic Forming: Stretching the Limits of Fabricating Medical Devices and Implants"— (3). In this paper it is concluded that superplastic forming can be used effectively in the creation of medical implants and associated devices. However, this paper was a simulation only and actual parts were not created. The main reason parts haven't been created subsequently is the equipment requirements for such a process. Superplastic forming of metals such as titanium requires temperatures in the ranges of 800-900 Celsius; a press with this capability is not currently available at the University of Kentucky.

Fortunately in the years since publishing this paper Dr. Khraisheh has begun a collaborative effort with Dr. Richard Curtis of King's College in London, England. Dr. Curtis has been researching superplastic forming for medical and dental applications since 1996 some of his work can be seen in (1; 4). This association is the reason that the current thesis research can be done as Dr. Curtis has had an SPF press with capabilities to produce such parts since 1997. Discussions with Dr. Khraisheh at ISCAM 2003 in Oxford, UK led to the publication presented at the ASM International Conference on Medical Devices (3).

Through an NSF grant as well as the GAANN fellowship I have been able to work in collaboration with Dr. Curtis to continue the research begun at Lexington in 2003.

One of Dr. Curtis' goals has been to create custom maxillofacial prosthesis using a step by step process that can be seen in Figure 1.

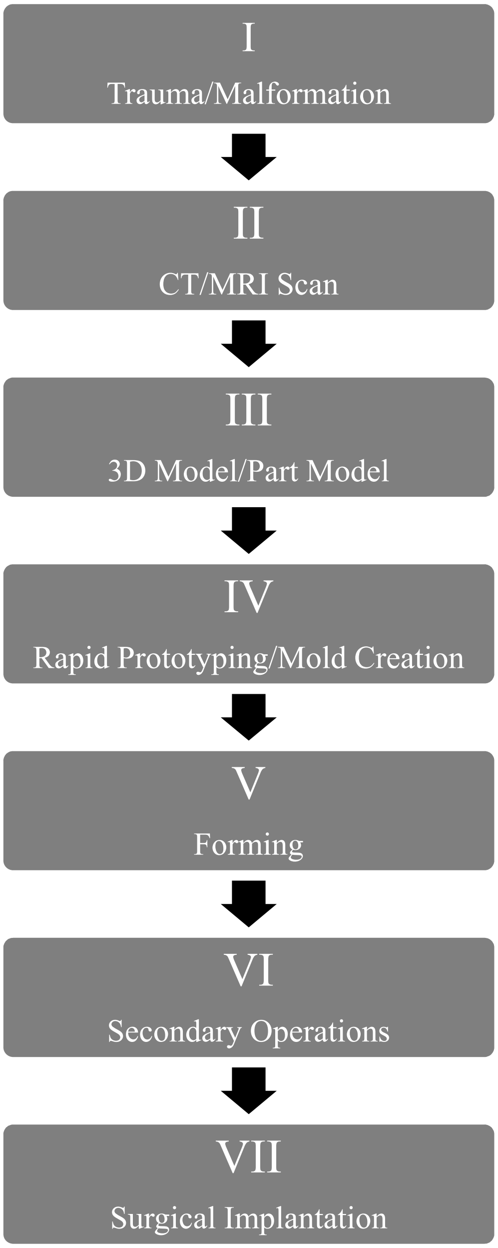


Figure 1: Ideal Part Creation Process for Custom Implants

I – Trauma/Malformation

The process begins with a patient having some sort of trauma or malformation that needs to be surgically corrected using a metallic implant. For instance a patient requiring a nose prosthesis.

II – CT Scan/MRI

Using current imaging technology a scan of the area of interest can be taken.

III – 3D Model/Part Model

From the imaging of the area of interest a part model can be created to a high degree of accuracy.

IV –Rapid Prototyping/Mold Creation

With rapid prototyping a replica of the part designed can be formed. With this part a mold can be created for the SPF process.

V – Forming

Next comes actually forming the part. This requires a high temperature press and the necessary equipment to create the mold from the rapid prototyped part.

VI – Secondary Operations

After forming of the part there may be need of secondary operations such as holes drilled for screw placement or cleaning of the part to meet ASTM standards.

VII – Surgical Implantation

The final step is to implant the part.

Each of the above steps in the process is at the present moment feasible in some way shape or form. However, the process has yet to be fully developed for production which is where the current research begins.

1.3 Objectives

The objective of the work is to create a process, which takes scanned patient data and creates custom prostheses. In this regard steps two through five from Figure 1 will be worked on in an effort to make this idea into a reality.

The emphasis is on the creation of viable components as well as highlighting the benefits of using SPF as compared to current practices for the creation of these prostheses. The main objective is to use SPF in a general process which can be used to create an implant from start to finish. The specific objectives can be defined as:

I. Investigate techniques in creating custom prostheses.
II. Design a process for creating implants using superplastic forming.
III. Create custom implants out of a biocompatible material.
IV. Verify the fit of created parts.

CHAPTER 2: BACKGROUND

Medical implants, specifically facial, have been created using a variety of techniques and materials throughout the past few decades. This chapter discusses some of these processes and materials as well as the chosen process, superplastic forming, and the chosen material, titanium.

2.1 Superplastic Forming

Superplastic forming is a near net shape process which typically uses high temperature and gas pressure to form particular materials onto a single step mold (5). It can create very detailed parts as well as form difficult to work with metals such as titanium, a common metal used in the medical industry.

Superplasticity is the ability of a material to experience extremely high elongations on the order of 200% or more. For a material to elicit superplastic behavior there are typical criteria, as seen from *Metal Forming Mechanics and Metallurgy Second Edition* (6), that must be satisfied including:

- An extremely fined grain size (a few micrometers or less), with generally uniform and equiaxed grain structure.
- High temperatures (usually on the order of half the melting temperature)
- Low strain rates (on order of 10^{-2}/sec or lower)

There are many advantages and disadvantages towards using superplastic forming over other forming processes. For medical applications the following are the most appropriate.

Advantages:

- The ability to form complex parts due to large deformations available with SPF.
- Low die cost which allows for cost-effective customization, an ideal quality for the custom prostheses idea.
- Reduces the amount of springback (7). Forming the implants during the operation using conventional techniques causes for imprecise angles as well as the potential for future problems after surgery.

Disadvantages:

- SPF is a slow forming process. Many times a slow forming process is defined as a disadvantage, however with custom prostheses time is less of an issue, therefore this is somewhat negated.
- Potential expensive pre-forming steps. Materials typically must be refined to allow superplastic behavior to occur. However, for Ti-6Al-4V the sheets available commercially exhibit fine grain structure suitable for SPF.

2.2 Superplastic forming applications and the medical field

Superplastic forming has found many applications in a variety of industries. In the automobile industry body panels have been made using an aluminum alloy (8). The Ford Motor Company has used SPF of aluminum closure panels for both the Ford GT and the Aston Martin Vanquish (9). This was done in an effort to reduce the weight of the cars. In a similar fashion the body panels for the Esperante luxury sport convertible from Panox are made superplasticly from aluminum (10).

Another major industry which has seen SPF use is aerospace. Boeing has seen significant cost savings due to the part number reduction associated with SPF in multiple aircraft. The Boeing 777 has a SPF wingtip housing (11) while the 737 has SPF parts in the form of blow-out doors, wing leading strakelets, and even exhaust vents (12). Superplastic forming has even seen use in both cookware and golf club applications (13).

However, the medical field while seemingly primed for it has yet to tap into the benefits of SPF. In the past few decades superplastic forming in the medical field has mainly been confined to the dental area.

Currently there is very little work being done in terms of superplastic forming with medical implants and devices. One of the most popular superplastic metals is a titanium alloy known as Ti-6Al-4V (13). This alloy has been used in the aforementioned aerospace industry to great extent. However, Ti-6Al-4V is also biocompatible (2) making its use in medical devices very straightforward and will be seen often in the following literature review.

Dr. Richard Curtis from King's College Medical and Dental Institute has been working with superplastic forming in the dental and maxillofacial aspects for many years as was noted in the motivation section of chapter one. The work done at the Dental Institute in London touches on many subjects of superplastic forming. Different dental devices have been formed (1), and two examples can be seen in Figure 2.

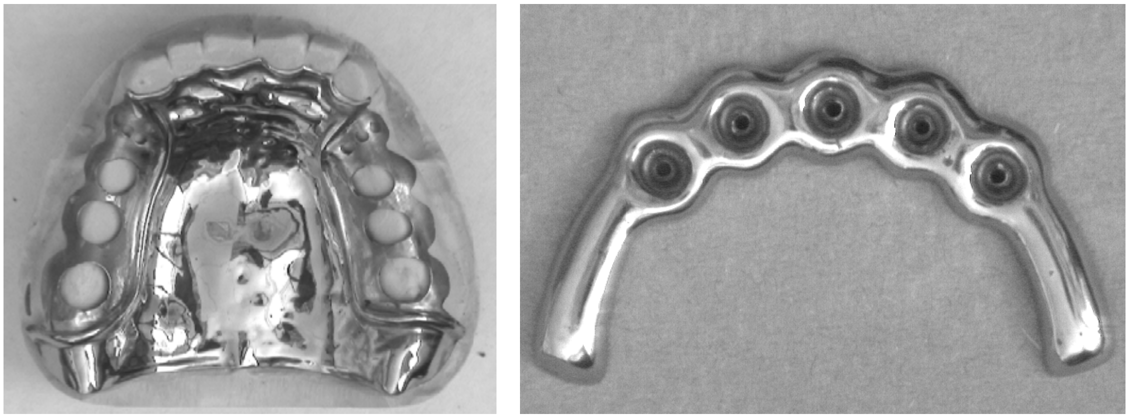


Figure 2: Superplasticly formed partial denture base (left) and dental implant superstructure (right) (1)

The work at King's also includes thorough research into the simulation of the SPF process (14) as well as looked at optimizing the forming of dental implants using finite element methods (15). Great effort has also been done in the testing of the investment material used as die material in their SPF forming process (16; 17; 18; 19). Unlike the aerospace industry which uses expensive dies multiple times, Curtis et al. (16) use dental investment material to create one-off molds. This is perfect for the application as each dental device is custom for the individual and does not need to be created multiple times.

Work along similar lines to the research done in London has been seen in a few other cases. Ito et al (20) formed denture bases, which were very accurate, out of the titanium alloy previously spoke of Ti-6Al-4V. In Japan titanium was superplasticly formed to create connectors for removable partial dentures (21). The same group also investigated the thickness and adaptation of Ti-6Al-4V denture frameworks (22).

Okada and Mitsuya (2) also looked at forming denture bases out of Ti-6Al-4V. Their work looked at the effect of grain size on the superplasticity of the alloy, as well as the overall merits of using SPF to create such devices. They noted the process of creating the dentures was largely simplified as compared to conventional casting and cold pressing.

Nonami et al. (23) began work on implanting hydroxyapatite granules into superplastic titanium. These granules held a better affinity for the living body, and it was hoped to use the titanium as a medium to hold the granules together.

2.3 Processes and materials used in facial reconstruction

The process for creating a given implant is highly dependent on the material chosen. Before a method could be fixed for the creation of implants using superplastic forming it was necessary to review how these type of implants have been made in the past to develop the most applicable and useful process. What follows is an overview of some of the previous works. Emphasis has been placed on highlighting the advantages and disadvantages of the various processes. In this way the advantageous features of the previous works can be incorporated into the current work while the disadvantages can be excluded if at all possible.

Schipper et al. (24) discuss individual prefabricated titanium implants versus titanium mesh in skull base reconstructive surgery. They used computer-assisted design and computer assisted manufacturing (CAD/CAM) to mill the implants out of solid blocks of titanium. It was noted that the CAD/CAM implants had superior stability over titanium mesh. The titanium meshes had to be shaped intraoperatively, while the prefabricated implants were ready beforehand saving in theatre time for surgery. The average implant thickness was around 2-3 mm. One advantage of the titanium mesh was its adaptability for smaller, having a surface area of 100 cm^2 or less, more complex surfaces such as the orbital floor. This titanium mesh is also discussed in (25). The CAD/CAM method was unable to reproduce small complex geometries like the orbital floor. Overall, the CAD/CAM method was technologically superior to the titanium mesh providing better stability and shock resistance. However, it was noted that this technique should only be employed in select cases due to the time and cost related disadvantages.

Berry et al. (26) discuss the early use of rapid prototyping in medical applications. It is noted that a rapid prototyping model could be useful as molds for fabrication of customized implants. This is said as opposed to traditional milling as it allows for complicated undercuts; something difficult to do with a normal milling machine. They also discuss the benefits of the STL format noting the fact that since each vertex's coordinates are listed for each face they are repeated three times making the format very robust. As an example of their work CT scans were taken and a 3D reconstruction was created using volume rendering, and ultimately manufactured using selective laser sintering. Their results show a difference of 1.0 ± 0.5 mm between the CT data and the model in all directions. They highlight the fact that the highest spatial resolution in the CT scans should be used in order to have the most accurate model. They argued that the manufacturing costs of the model are offset by the time-savings seen in surgery, and noted that the accuracy of the models was appropriate for orthopedic applications.

Joffe et al. (27) created cranioplasties using titanium. Indirect impressions were taken directly from the scalp of the patients' skull. From these impressions the titanium was pressure formed. It was concluded that titanium was an excellent material for use in cranioplasties, however the cranioplasties made in this method weren't very accurate.

D'Urso et al. (28) worked on creating custom cranioplasties using a combination of stereolithography and acrylic. Using CT data a master implant was generated and then produced using stereolithography. From this master an impression cavity mold was created and through a multi step process an acrylic implant was formed.

Wurm et al. (29) created cranioplasties using a carbon fiber reinforced polymer (CFRP). In the study 37 patients had cranioplasties implanted which were made of CFRP. The implants were created using a combination of stereolithography and wax modeling. Computed tomography (CT) data was taken and used to create a skull replicate from which a wax template was used to create the prosthesis and invested in dental stone. From this dental stone investment a CFRP implant was created by loosen mold. It was concluded that implants produced in this way were high in cost due to the time and materials used during the process, but it also highlighted the advantages of the shortened surgical times due to prefabrication. The goal for this study was to evaluate the value of the CFRP rather than focus on the process itself with which the current research is involved.

While selective laser sintering was used to create the custom parts as seen in (26) another method for creating custom implants is presented by Heissler (30). In this paper a method for creating custom-made cast titanium implants using CAD/CAM is shown. They state "Titanium is considered to be the most biocompatible alloplastic material. However, its material properties render it difficult to work with." In this process CT scans were converted to the VDAFS data standard, a format which can be read by multiple CAD/CAM programs. Using this data a virtual implant was created and exported to the STL format. Subsequently this STL representation was rapid prototyped as a polycarbonate model. The model experienced a few secondary operations and then it was turned into a casting mold from which the titanium implant was formed. The implant was then sandblasted and drilled to reduce weight. Ultimately using this process implants weighed from 48 to 72 grams and had thicknesses from 1.2 to 3.2 mm. A sample of the implants created can be seen below.

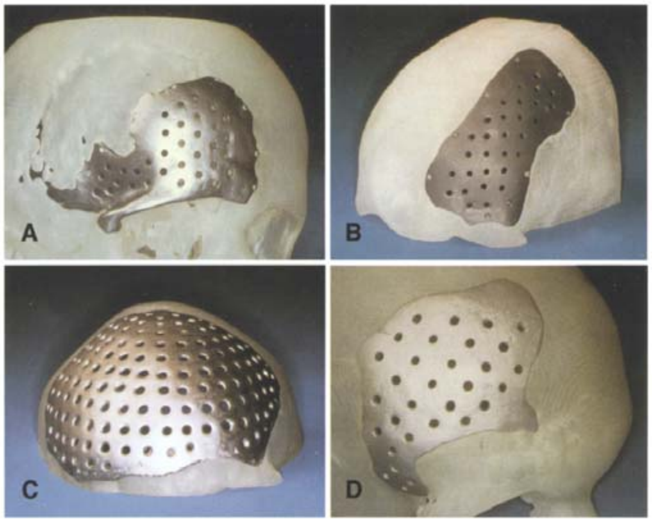


Figure 3: Cast titanium implant sample (30)

Conclusions of the paper included: operation time was shortened due to the prefabricated implant, casting versus milling offered the ability to have thinly tapered shapes, less waste material as compared to milling, and the prefabricated implants offered predictable and esthetically pleasing results.

Eufinger et al. (31) looked into prefabricated prostheses using the CAD/CAM method as well. In this case they manipulated CT data and sent it to an NC milling machine to fabricate the titanium plate. The part was designed on the computer by offsetting a surface a specified distance (the required part thickness) off the scanned bone. Careful work was done in determining the bone interface from the other tissue present in the scans. The prosthesis fabricated ended up being 1.5mm thick and weighed 64 grams. The CAD/CAM process was used in this instance as an alternative to the hand forming of titanium plates which was the other option at the time.

Eufinger et al. (32) also evaluated 169 cases of titanium cranioplasty implants which were created using a CAD/CAM technique. Each case was grouped according to size and position of the implant on the skull as seen in Figure 4.

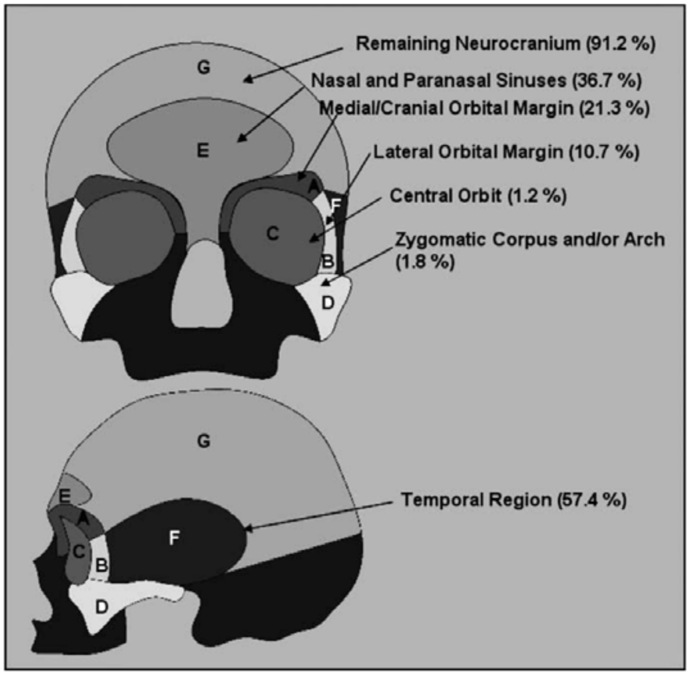


Figure 4: Standardized anatomical classification of the CAD/CAM implants (32)

It was concluded based on: primary fit, post operative complications, and cosmetic result that the titanium implants were of increased benefit in the temporal and neurocranial area as compared to the craniofacial area including the periorbital. This is due to the fact that the craniofacial implants are more difficult with regards to primary fit and cosmetic result.

Another instance of using rapid prototyping to create custom cranial titanium plats is shown by Winder et al. (33). First discussed is the older technique of taking a direct impression of a patients shaved head. Implants created using this technique created ill-fitting results 23% of the time, while 41% of them had poor aesthetic quality (34). The method discussed in (33) began with taking CT scans using a slice thickness in the range of 3 to 5 mm. It was later noted this slice thickness was the limiting factor in the model accuracy. This data was transferred to a rapid prototyping machine to have a full scale model built which took 18 hours. The defect was filled in using wax and used to create a dental stone mold from which the titanium part was formed. The advantage of using the rapid prototyping was shown to be an improved fit and cosmesis.

During the course of this work a paper was published by Lohfield et al. (35). The paper discusses the process of digitizing the design of an existing medical implant. They note that upon literature review an existing process for an optimized design and manufacture for custom prostheses is lacking. They use a variety of software programs in order to create a process which meets their goals. A pre-existing implant is considered and used for the process. MIMICS (a package in Materialise) is used to transform CT scans into a 3D model. It is noted that most scan software is limited, and that the 3D model must be exported to a solid modeling program. To export into solid modeling programs two different options were shown including Image Graphics Exchange Specifications (IGES) files and files for rapid prototyping like STL. They saw that exporting the 3D model in STL was the most suitable option due to its accurate representation of the actual bone surface. Using this as well as a pre-designed section from ProEngineer the whole part was created. A picture of this part and skull representation appears below:

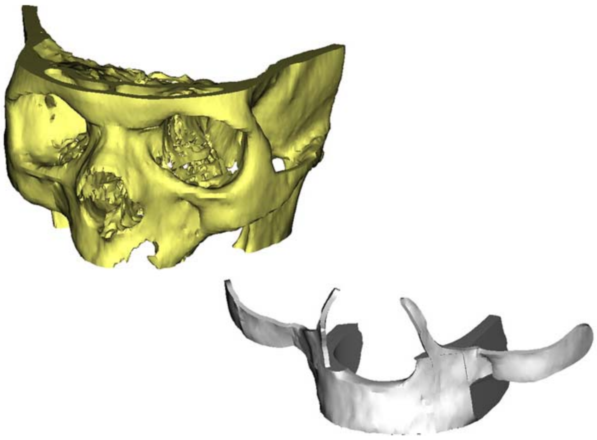


Figure 5: 3D model of the skull with bone defect, and prosthesis shaped as a replica of the original bone structure with removed defect (35)

2.4 Remarks

The literature review highlighted many things which are necessary to keep in mind while also providing a glimpse into how SPF can improve current processes.

Creating a process to use superplastic forming opens up many new doors when it comes to these custom prostheses. Recall in (24) the advantages and disadvantages of a milled prefabricated titanium implant versus the titanium mesh. The prefabricated CAD/CAM piece offered shorter surgery times and better stability, but couldn’t be used for the complex shapes made available with the titanium mesh. The difficulties of milling shapes were confirmed in (26), as was the time-savings in surgery of the prefabricated implants. Using superplastic forming these advantages can be married together. With a prefabricated superplastically formed part the surgery time savings and excellent stability will be preserved while also allowing the complex shape, like the orbital floor seen with the mesh, to be made. Proof of this can be seen later in this thesis.

There were many instances where entire models were rapid prototyped to create the custom implants (29; 30), while others used smaller sections in a more direct and efficient way (31). Clearly, for the current research the best way to proceed is to work with the data directly instead of rapid prototyping a full skull model, which is both time consuming and highly wasteful.

There were many things to learn from the literature review and which are applicable to incorporate into a new process. Below is a short summary of some of the important things learned and which should be kept in mind when working on the new process.

- Prefabricated implants produce better fit, aesthetics, and shorten surgical time.
- Current prefabrication costs are quite high, thus a new process needs to become cheaper if at all possible.
- Titanium is the choice biomaterial in these cases, although it is difficult to work with. Fortunately, this is rectified with the use of superplastic forming.
- Dental investment materials are useful in making custom molds for superplastic forming.
- STL files provide a robust and accurate reproduction of the 3D models in the cases using data from CT scans.
- Working with the CT data in STL format is fairly difficult and typically requires multiple programs. Therefore, a new process should strive to incorporate the least amount of software for efficiency and the least amount of data corruption.

In nearly all of the work reviewed titanium was the material of choice; however it is a difficult to work with thin metal. The previous work used many different techniques to work with titanium including milling, casting, laser sintering, and simple hand forming. As this is clearly the material of choice in these applications so too will it be used in the process designed for SPF. This not only gives it legitimacy in terms of using a biocompatible metal, but it will also be able to be compared to these former methods in the future. Luckily, titanium is very workable using SPF. While titanium has been chosen as the material to use in the current work it was clear that getting a better understanding of other metals used in the biomedical field would be beneficial. The next section provides a small look into some of the other metals and their uses in the industry as well as going into a little more depth about titanium.

2.5 Biomaterials

"A biomaterial is defined as any systemically, pharmacologically inert substance or combination of substances utilized for implantation within or incorporation with a living system to supplement or replace functions of living tissues or organs"- (36). Most importantly a biomaterial is biocompatible. An easily understood definition defines a biocompatible material as something that doesn't incite an unwanted response from the host, but promotes good tissue-implant integration (37).

Typical Metallic Biomaterials:

- CP (commercially pure) titanium
- Ti-6Al-4V alloys
- Cobalt-chromium alloys
- 316L stainless steel
- Ni-Ti alloys

Metals are used for two primary purposes (36). One is to serve as prostheses to replace a portion of the body such as joints and skull plates; the second is for fixation to stabilize broken bones.

Stainless Steels

Stainless steel is widely used in orthopedic applications, which are usually temporary implants needed for load bearing. Use of stainless steels is typically confined to these load bearing applications due to nickel toxicity to the human body (38). However, there are exceptions in places of high oxygen concentrations which keep oxide layers formed. One of which is a metal stent placed in arteries. Of all the metallic biomaterials stainless steel is one of the least corrosion resistant.

Cobalt-Chromium

Cobalt-chromium is superior to stainless steels in terms of corrosion resistance. Its excellent tribological properties of this alloy allow an artificial hip joint to be made totally of cobalt-chromium metal (39). Tribological properties are defined as coefficient of friction, wear rate, and lubrication in the presence of proteins.

Titanium

Titanium is very popular due to its biocompatibility. Also, Ti-6Al-4V is already a very popular SPF material (40; 41; 42; 43; 44). It has a very stable passive film formed at room temp due to rapid reaction with oxygen. Titanium is superior to stainless steel and Cobalt-Chromium in specific strength, corrosion resistance, and biocompatibility. However it is inferior in tribological properties. Lack of magnetic properties allows the use of MRI technology to monitor implants. “Contrary to implants made of stainless steel, those made of pure titanium reach their strength limit at a much lower rate of plastic elongation and may break. This means that the design of the original, as-sold implant should be as close as possible to the final shape on application.” – (45**).** As the preceding statement implies the forming of titanium needs to be as close to the final shape as possible which implies great things for the use of superplastic forming as it is a near-net shape process in and of itself.

Since most of the applications of metallic implants deal with a bone-metal interface shown below is a comparison of the modulus of elasticity as well as the ultimate tensile strength of different metals as compared to bone. In some cases it is actually a disadvantage to have an implanted metal much stronger then the bone it is interfacing with as it leads to loading complications and undesirable stress distributions. Therefore, having an implant material closer to the properties of bone itself is ideal, and as can be seen in Figure 6 titanium is one of the closer metals in terms of mechanical properties.

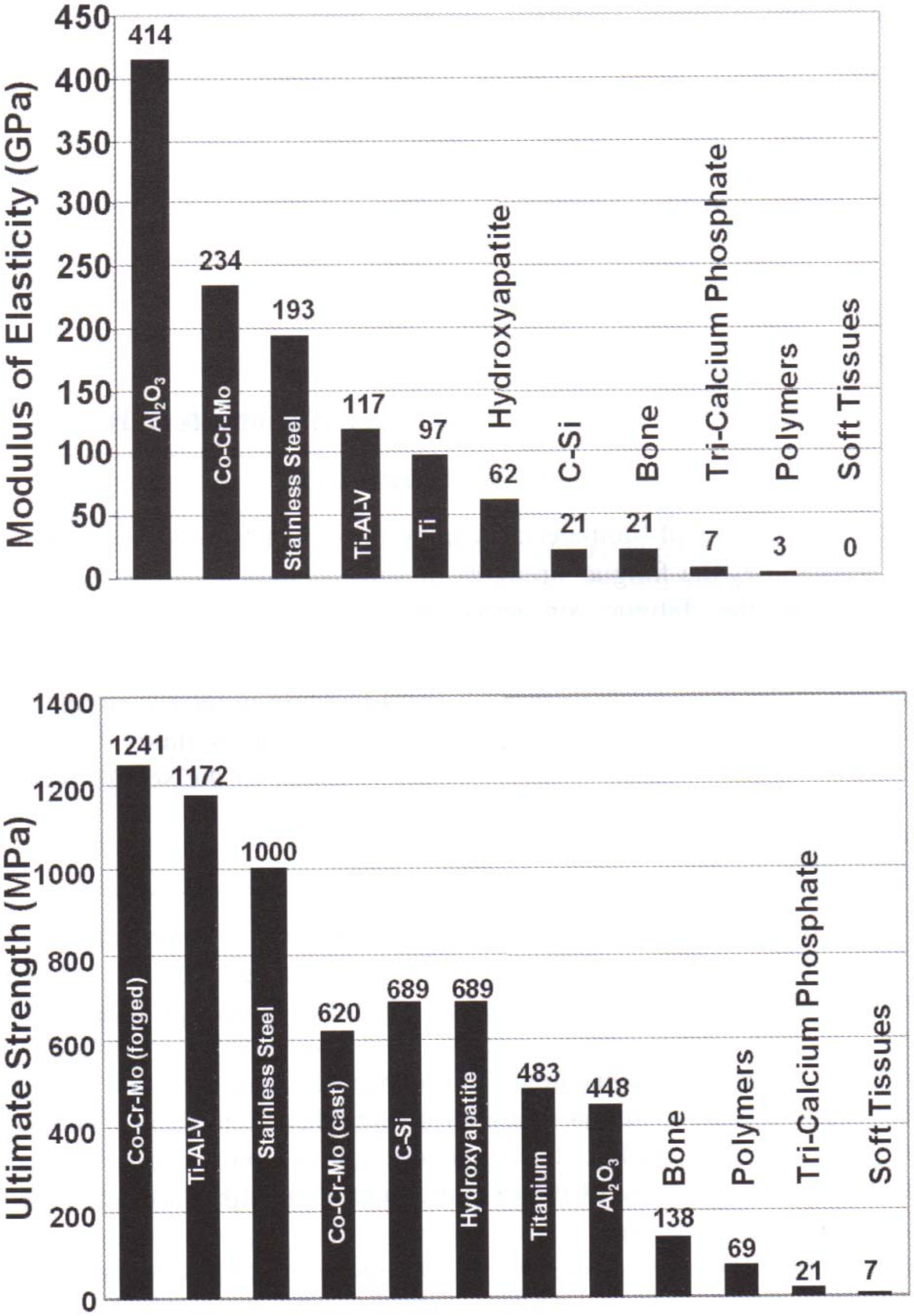


Figure 6: Modulus of Elasticity Comparison (Top); Ultimate Strength Comparison (Bottom) taken from (37).

CHAPTER 3: APPROACH

3.1 Foundation

Research began with an introduction into using the SPF press housed in Guy’s Hospital in London. In conjunction with a few of the other students; different parts were formed, and a working knowledge of the press was acquired. Seen below is just one example of the molds and subsequent parts formed.

Figure 7: Mold inside steel chamber (Left); and formed titanium part (Right)

Once the capabilities and limitations were understood with regards to the press the work began on extending the use of SPF. It was understood that SPF was capable of forming very complex parts using a variety of metals suitable for biomedical components such as Ti-6Al-4V, however the process for producing said parts was not defined. Therefore, research was undertaken to create a process which could produce medical implants beginning solely with patient data (CT Scans).

3.2 Data Manipulation

Dr. Curtis and his students had already refined the ceramic mold making process for use with their SPF press. Thus, it was mainly a matter of creating something from which to make a mold. In the dental aspect this is typically done using direct impressions from the mouth. However, in this case the goal was to use patient data which meant direct impressions were not worth considering. The only way to use patient data to create the molds was to rapid prototype the area of interest. For that reason, the conversion, and subsequent manipulation, of patient data into a usable form became the most vital aspect in the project.

There are many programs on the market today which can convert the stack of images provided from a CT scan into the stereolithography (STL) format, which is the most common format used by today's rapid prototyping equipment. The abundance of programs with these capabilities is likely due to the predominance of rapid prototyping in surgical planning (46).

As noted in (26) the STL file format is very robust. Its usage of many triangular facets provides accurate reproduction of a 3D model if the use of very large data sets is allowed (47). The STL file format is essentially a large list of triangles. Each facet is composed of the coordinates of the three vertices of the triangle as well as the coordinates of the normal oriented to the exterior of the solid (47). Shown below is an example of a 3D model and its associated STL representation.

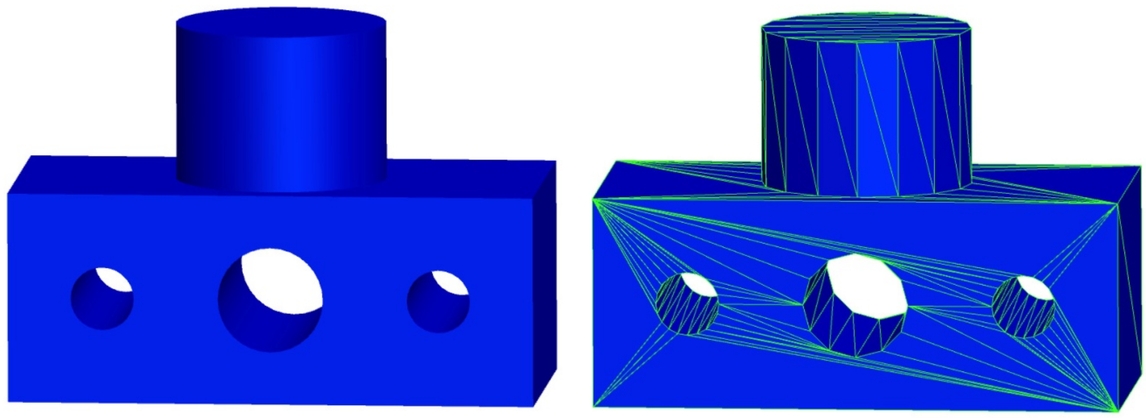


Figure 8: Solid 3D model (left), 3D model in STL format (right)

While the STL file format can accurately represent a 3D model, given a large enough data set, it is difficult to work with such a large data set in terms of direct manipulation. There are few programs which can conveniently modify this format, which makes developing a custom implant difficult in the virtual realm. Even in one of the most recent publications on the matter (35) it was necessary to export the 3D model produced in MIMICS (a product in Materialise) as an STL file to solid modeling software. It is worth noting that in this paper Lohfeld et al. state "Since the design capabilities of typical scan conversion software are limited, the 3D model *has* to be exported to solid modeling software." This is one of the flaws in the approach by Lohfeld, and as will be shown this is rectified in the current work by using a different approach and software package. The problem with exporting the STL file into a solid modeling program is you will inevitably lose or alter the data changing the surface and eventually the fit of any implant created using that data.

Fortuitously, Dr. Curtis had a contact in England with a company called Simpleware. Like many other programs their software has the ability to turn CT images into a 3D model in the STL format, however its approach allows for the manipulation of the data before the final STL file. This software and approach is discussed in the next section.

With the power to manipulate patient data into a workable form the next step was to create actual parts. The first decision made was to not use actual patient data and instead work with a model. In this way there are no issues with patient confidentiality as well as the ability to fit created parts onto the model to verify their accuracy. A picture of the model appears below. It was scanned like any other patient would be using a CT scanner and the resulting data was used for all subsequent work. The slice interval used was 1.25 mm.

Figure 9: Skull Model

3.3 Simpleware

Simpleware (48) is a combination of three different programs which are intertwined. The package includes ScanIP, ScanCAD, and ScanFE. This package was used for the data manipulation portion of the implant making process.

ScanIP takes a stack of images like those of CT scans and creates a 3D model which can be used in a variety of ways. An illustrative example of this idea with the scan from the model appears below:

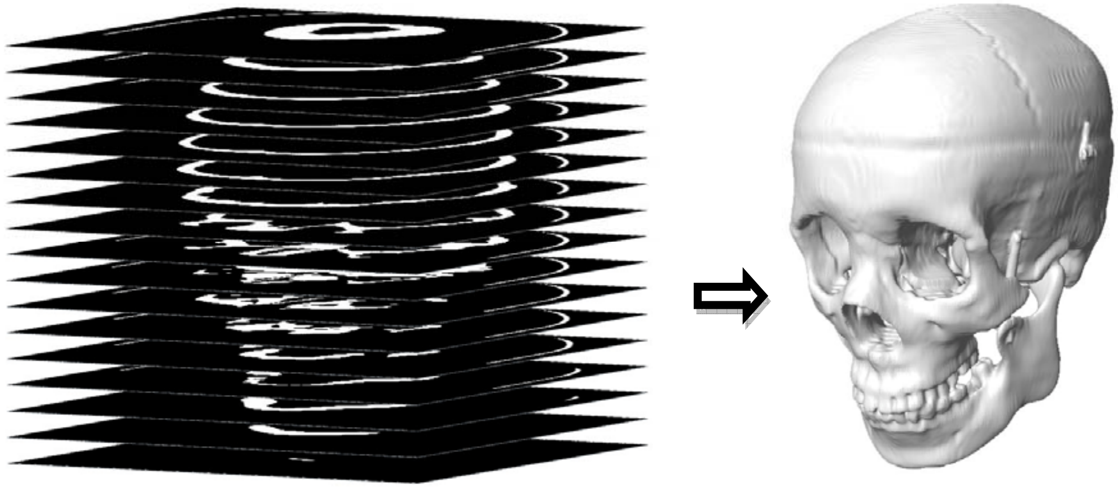
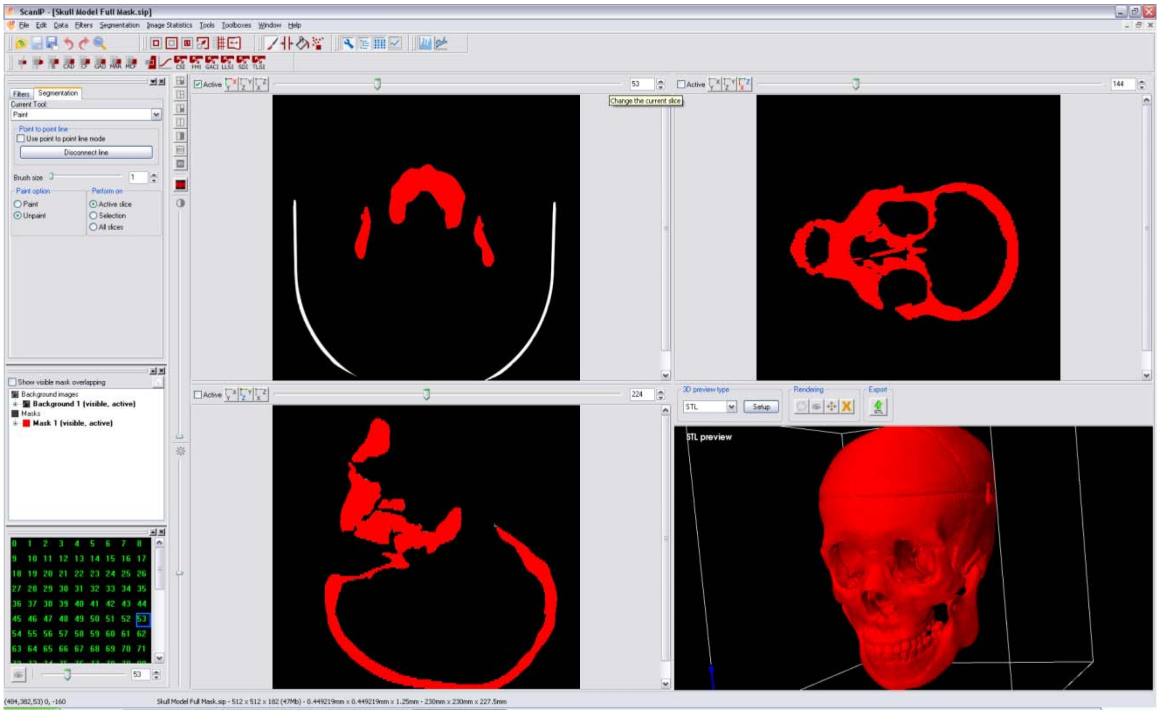


Figure 10: Representation of CT images (Left) and 3D model (Right)

This process is done using a masking scheme which is used to differentiate wanted areas such as bone from everything else such as the black background. A screenshot from ScanIP can be seen below. In this example the red color is the mask which is used to differentiate the bone from the background. The three two-dimensional windows represent specific layers of the image stack in the three coordinate directions x, y, and z. The bottom window on the right shows the 3D representation of the current masking scheme. For a closer look at this interface of Simpleware see Appendix A.



Current Tool: Paint

☐ Use point to point line mode

Brush size 1

○ Paint
● Unpaint

● Active slice
○ Selection
○ All slices

☑ Active 53

☐ Active 144

☐ Active 224

3D preview type: STL

☐ Show visible mask overlapping

Background images
Background 1 (visible, active)
Masks
Mask 1 (visible, active)

(484,382,53) 0, -160

Skull Model Full Mask.sip - 512 x 512 x 182 (47Mb) - 0.449219mm x 0.449219mm x 1.25mm - 230mm x 230mm x 227.5mm

Figure 11: ScanIP Example

ScanCAD allows for the positioning of outside objects in conjunction with the masks created in ScanIP. For instance if a hip was scanned into ScanIP and a hip joint replacement was modeled in 3D in a separate program; these two objects could be manipulated in the same space and placed together. ScanCAD also has the capabilities to convert a 3D model into a mask which can then be exported back into ScanIP and edited with the painting tools.

ScanIP masks can be converted into a variety of formats. One of which is the STL format used for rapid prototyping, and another is exporting it into ScanFE. Using ScanFE one can designate elements and surfaces and export the model to finite element software such as ABAQUS.

3.4 Procedure

Three different areas of interest were chosen to include: the orbital region which supports the eye, the roof of the mouth, and a section of the top of the skull. These regions were chosen in order to create three unique parts. Custom cranioplasties are something that has been done for many years as was talked about in (27) and (30) therefore this was an obvious choice for one of the trial implants. Also, the orbital region is a difficult region to obtain a good primary fit according to (32). The roof of the mouth was chosen as that has been done in the past by Dr. Curtis, which gives the ability for a direct comparison.

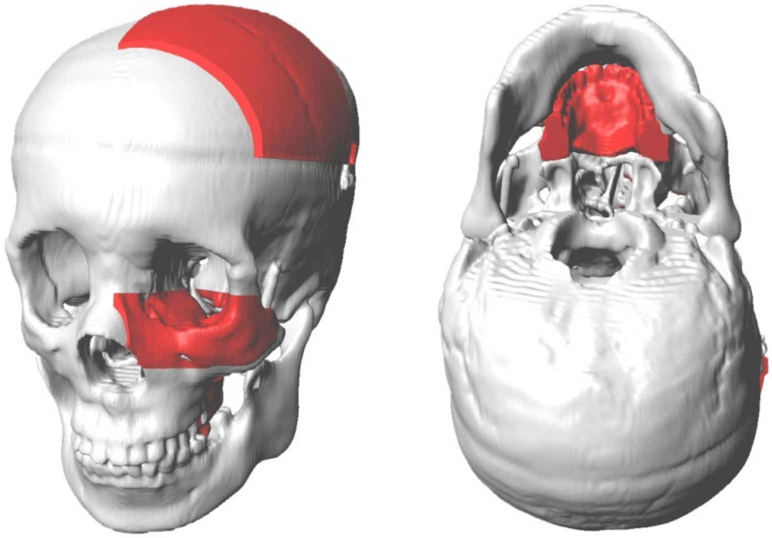
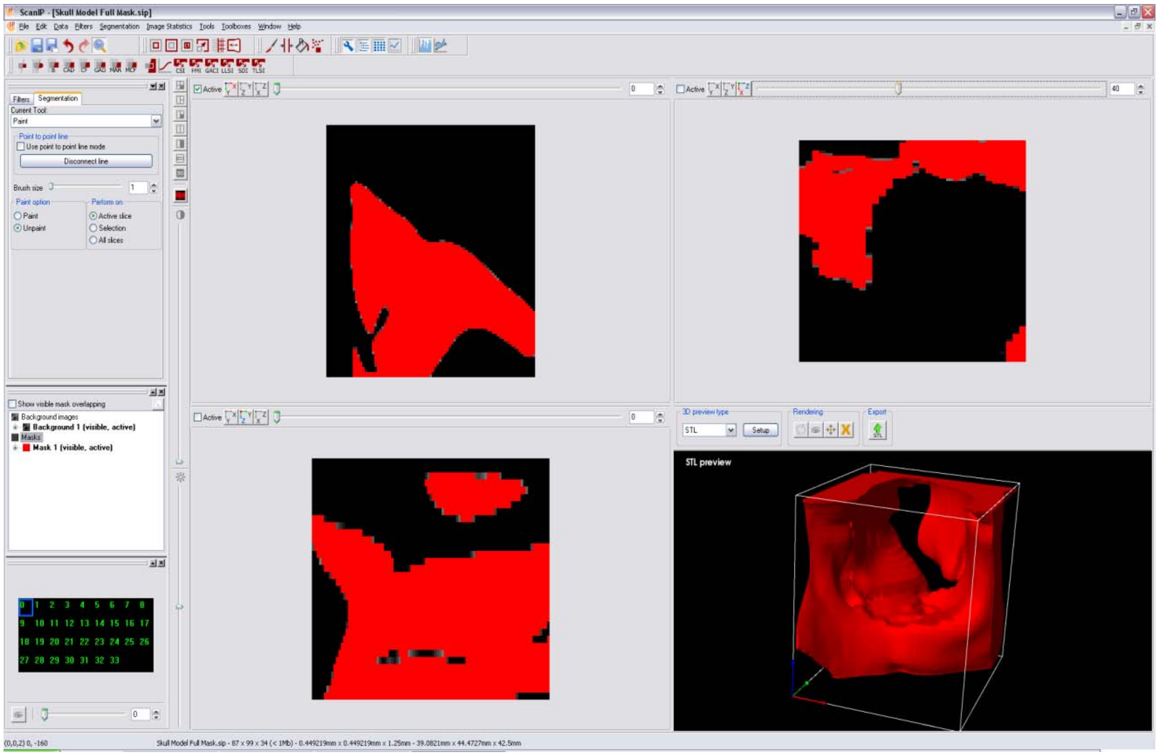


Figure 12: Areas of interest (highlighted in red)

To section off these areas of interest the 3D model constructed inside ScanIP has to be cropped down. This sectioning is done by manipulating the masks, instead of a full STL file like the approach used by (35), until the region of interest is the only area highlighted, using red in this case. From Figure 11: ScanIP ExampleFigure 11 which shows the entire skull highlighted, the window itself can be resized to look at a certain region, in this case the area around the eye. This cropped window, which shows the left orbital region, can be seen in Figure 13.


ScanIP - [Skull Model Full Mask.sip]

Current Tool: Paint

☐ Use point to point line mode

Brush size 1

Paint option: ○ Paint ● Unpaint

Perform on: ● Active slice ○ Selection ○ All slices

☐ Show visible mask overlapping

Background images

Background 1 (visible, active)

Masks

Mask 1 (visible, active)

3D preview type: STL

(0,0,2) 0, -160

Skull Model Full Mask.sip - 87 x 99 x 34 (< 1Mb) - 0.449219mm x 0.449219mm x 1.25mm - 39.0821mm x 44.4727mm x 42.5mm

Figure 13: ScanIP cropped region (eye)

The cropping seen in Figure 13 is only a part of the needed work to section off the region wanted. In this case the area of interest is the bottom region of the eye socket as well as the bony lip in the front. The implant wanted is a plate which would take the place of the bone in this region in cases of trauma or cancer when the bone must be removed. In order to refine the area other tools inside ScanIP must be used such as the un-painting tool which can be used to remove the red mask where it is not needed. Using these tools the region, seen in Figure 14: Orbital region of interestFigure 14 is cropped and exported to the ScanCAD program.

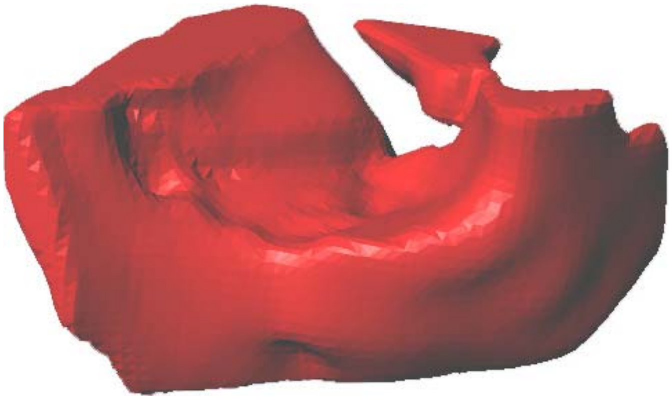


Figure 14: Orbital region of interest

In order to create the ceramic molds the regions of interest after rapid prototyped need to fit inside the steel ring for the SPF Press. To ensure the region fit, a template modeled using the inside dimensions of the steel chamber was created in ProEngineer and exported in STL format for use in ScanCAD.

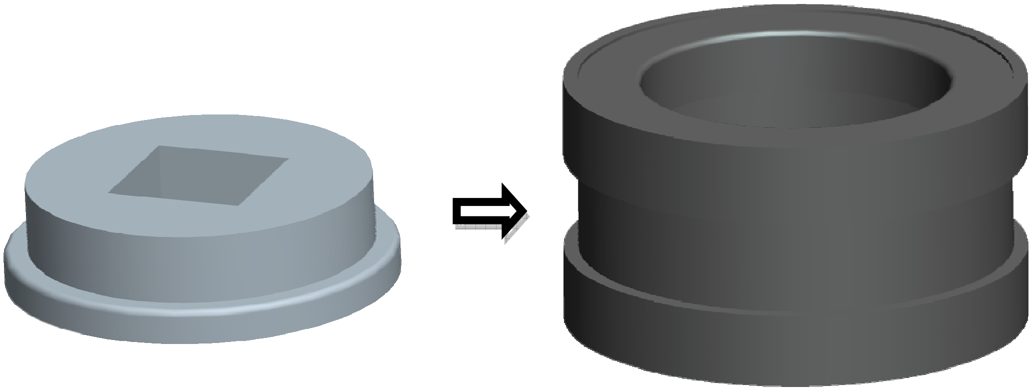
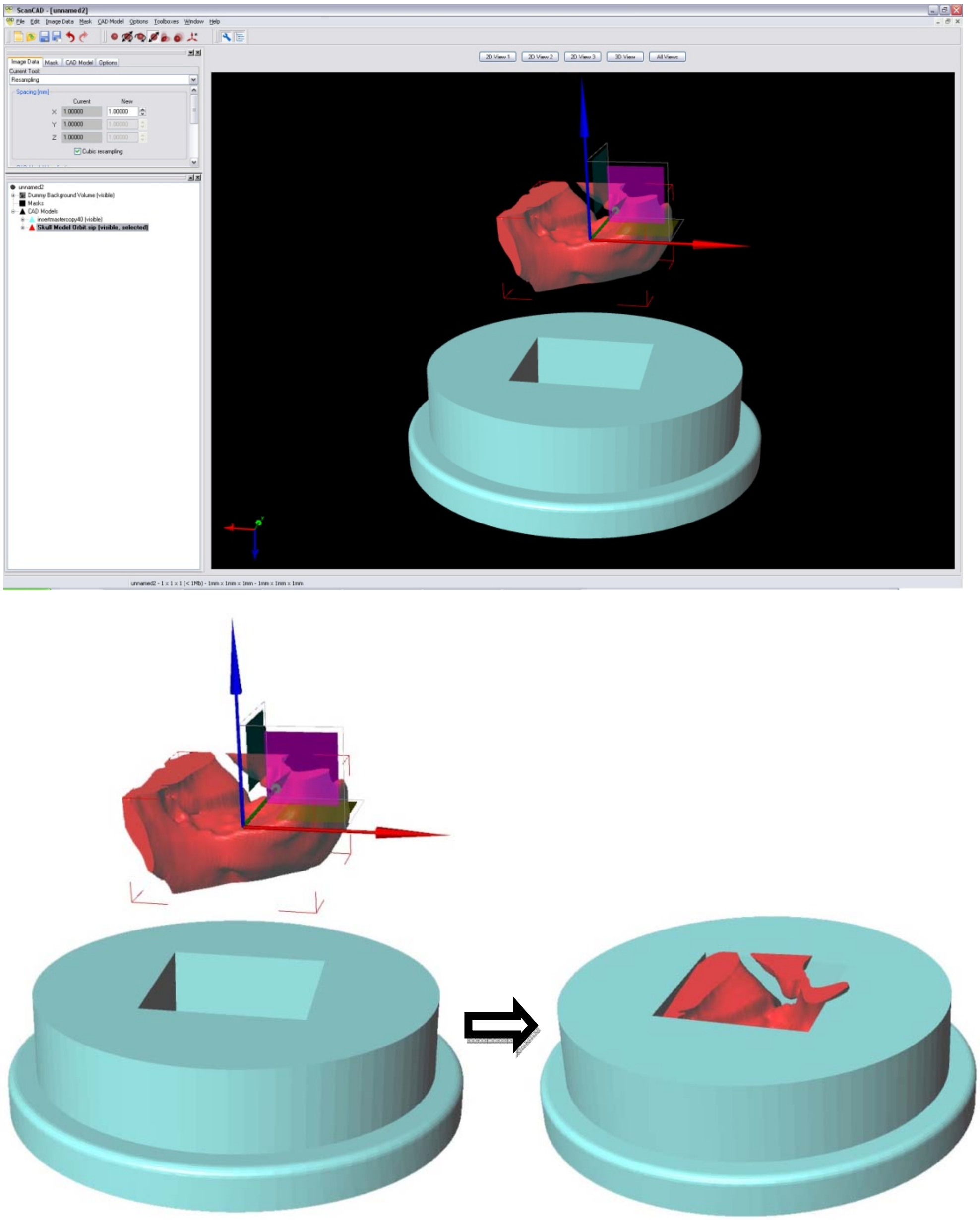


Figure 15: Template (left), and steel ring (right)

Using ScanCAD these areas of interest was merged into templates which fit the steel rings used in the SPF press. This is necessary to create precise molds. This mold process is shown later.



Current Tool: Resampling

Spacing [mm]

	Current	New
X	1.00000	1.00000
Y	1.00000	1.00000
Z	1.00000	1.00000

☑ Cubic resampling

- unnamed2
  - Dummy Background Volume (visible)
  - Masks
  - CAD Models
    - insertmastercopy40 (visible)
    - Skull Model Orbit.sip (visible, selected)

unnamed2 - 1 x 1 x 1 (< 1Mb) - 1mm x 1mm x 1mm - 1mm x 1mm x 1mm

Figure 16: Positioning the area of interest inside the template using ScanCAD

The next step was to fill in the gaps that existed between the template and the area of interest in order to create a smooth transition to aid in the superplastic forming process. To do this the merged area of interest and template shown in Figure 16 was converted into a mask and sent back into ScanIP. To see how the process was done in detail see

Appendix B. Often the process of filling gaps in impressions used to create molds for the SPF press is done by hand filling the region with wax. The Simpleware package allowed for this process to be completely contained in the computer so when the part is rapid prototyped it is immediately ready for the mold making process.

Once this is done the completed mold template can be exported in the STL format and rapid prototyped. The STL file representation for the orbital region and the completed rapid prototyped template can be seen below in Figure 17: STL version of template (Left); rapid prototyped template (Right)Figure 17.

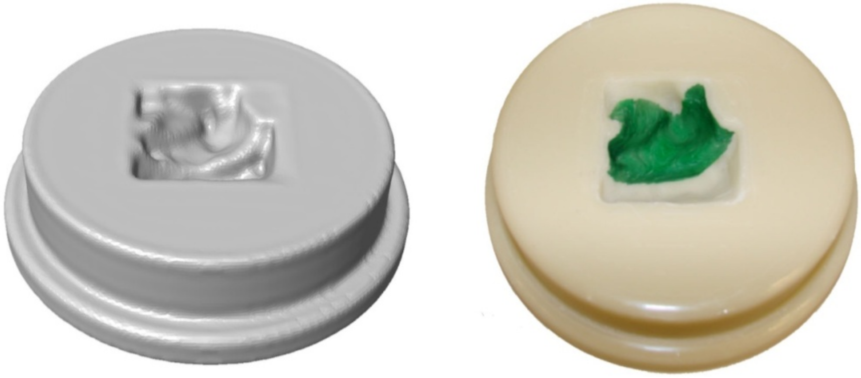


Figure 17: STL version of template (Left); rapid prototyped template (Right)

The process for selecting an area of interest and merging it into the blank template created in ProEngineer was the same for all three instances. A picture is featured below which shows all three finished templates after rapid prototyping. Notice that the area of interest has been highlighted in green with marker to differentiate it from the template and the transitional area. For a closer view of the individual templates see Appendix C.

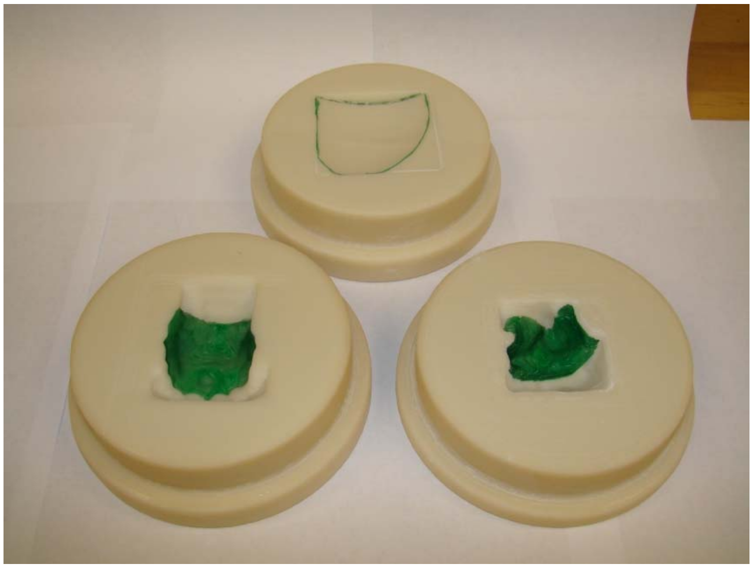


Figure 18: Finished rapid prototyped templates

With the template fabricated the mold can be completed and used to create the final part. Below is a representation of the materials used as well as a flow chart of the entire process beginning with the model template and ending with the formed part.

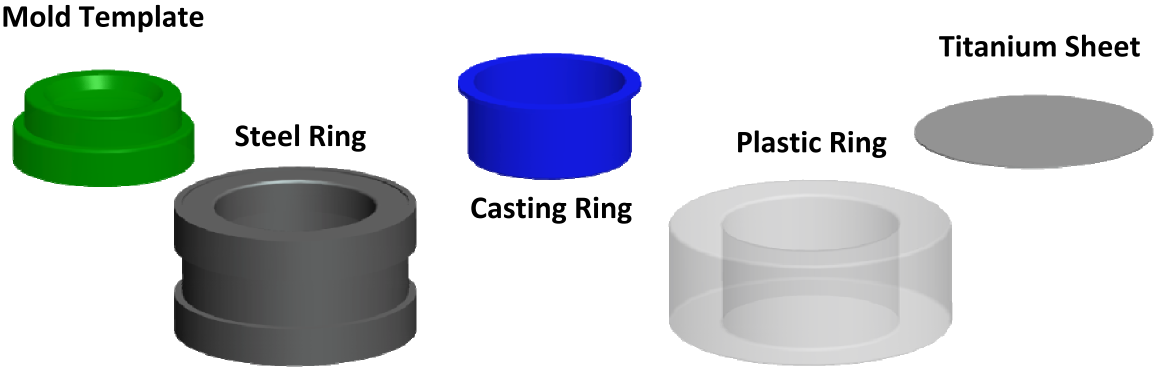


Figure 19: Mold making and SPF forming materials

Along with the above materials silicone and a material known as Croform WB, a high precision investment material is used to create the mold itself. Note the green mold template is representing the rapid prototyped STL file seen in Figure 17.

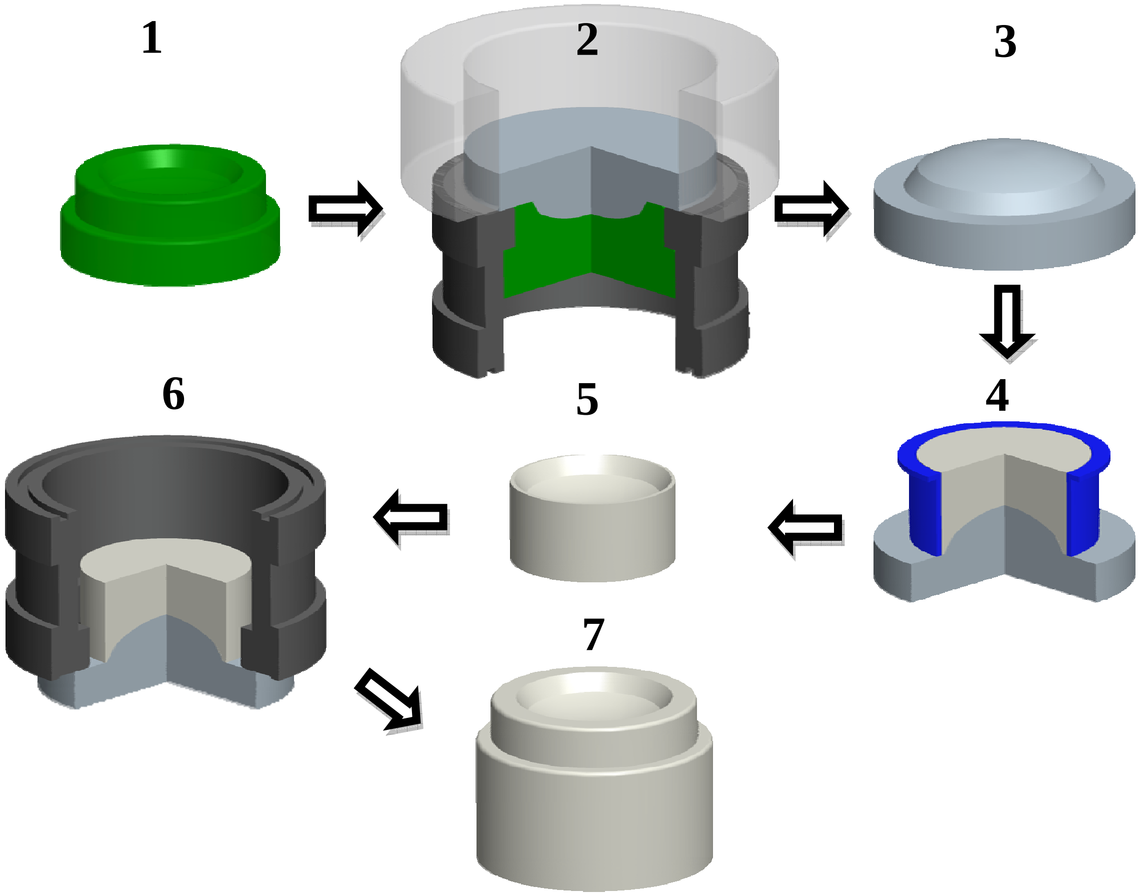


Figure 20: Mold making process

The mold making process is detailed in the above Figure 20. The first step is to pour a silicone copy of the mold template. This is done by placing the mold template **1** into the steel ring **2** and using a plastic ring to form an area the silicone can be poured into. The silicone impression **3** allows intricate details and undercuts to be formed into the mold without breaking. If the investment material was poured during this step and the template had any undercuts when the investment material was removed it would break in those areas. The silicone material is flexible and will bend enough to be removed from the template without damaging the copy. The next step is to pour the first part of the mold seen at **5**. Using a casting ring and the silicone impression **4** investment material is poured and set. The steel ring is then placed upside down **6** onto the silicone impression which is holding the first mold piece in place. This allows for the rest of the area to be filled with the investment material completing the mold. The silicone impression is used to keep the already set investment piece in place during the process of pouring the outer layer. The mold **7** is poured in a two step process because it stops crack propagation. If a crack were to form in the outer layer it will not propagate into the inner area due to the small line of separation between the two layers. It provides protection to the detailed area of the ceramic mold which is the most vital part. This concludes the mold making process. The next step is to form the part using the superplastic forming press. This breakdown is seen below in Figure 21.

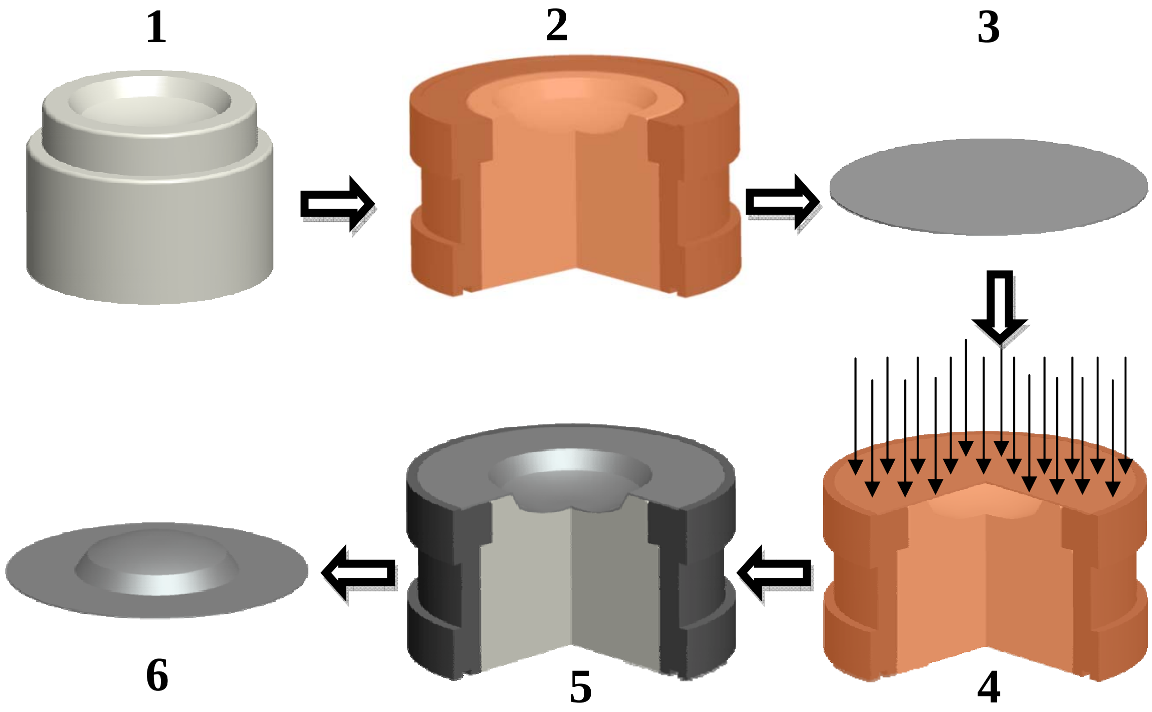


Figure 21: Forming process

Referencing Figure 21 once the mold **1** is set inside the steel ring it is placed in the SPF press to preheat **2**. Once forming temperature is reached the press is opened up temporarily and the metal sheet **3**, in the current work Ti-6Al-4V sheet, is placed and gas pressure is applied **4** once the press reaches the forming temperature. The gas pressure will slowly form the sheet into the ceramic mold **5** and once the press has cooled the part is finished **6**.

3.5 Equipment

Through the course of the research various pieces of equipment was used, however there were three main pieces which are cataloged in this section below.

The superplastic forming press used at Guy's Hospital is a computer controlled 20 ton press (Fielding and Platt International, UK). A picture of the inner chamber appears in Figure 22. The argon gas used to form the parts is controlled by an attached computer and can be easily set to apply pressure as needed according to the associated pressure profile.

Figure 22: Inside SPF Press (Guy's Hospital at King's College)

The mold templates were created at the University of Kentucky with a 3D Systems (SLA 3500) rapid prototype using a photo polymer resin DSM Somos® NanoTool™.

For accuracy measurements between the templates, skull model, and subsequent formed parts a Renishaw (49) cyclone contact scanner was used alongside with the Tracecut 24 software.

CHAPTER 4: RESULTS AND DISCUSSION

4.1 Skull Model and Template Comparisons

After the mold templates were completed and before the actual parts were formed the model skull and the templates were 3D scanned using a Renishaw cyclone surface scanner mentioned in the previous equipment section. Using 3DD ScanSurf and Cloud software the two corresponding surfaces, the template and the associate area from the skull model, were compared. The results for the denture and the orbital appear below; however the cranioplasty was unable to be compared. In the cranioplasty case the non-fit surface was used and with the gentle curvature of the selected area there were no outstanding features present that the software could align the surfaces against. It is worthy of note that of all the three parts accuracy is the least important in the cranioplasty case, while the fine details of the orbital and denture region require precise fit for a good implant. Thus, it is presumed if both the orbital and the denture have accurate fits then the cranioplasty would be around the same order of accuracy.

Using the cloud software for the surface comparison the two affiliated surfaces are broken down into smaller units designated as pixels. For each of the comparison cases the pixel sizes are noted in the tables linked to the histograms which show the number and distance of the deviations. The 3DD ScanSurf software outputs average distances along with their corresponding standard deviations. This is done for both the signed and unsigned differences. A simple example of how this comparison process is done can be seen in Figure 23 below.

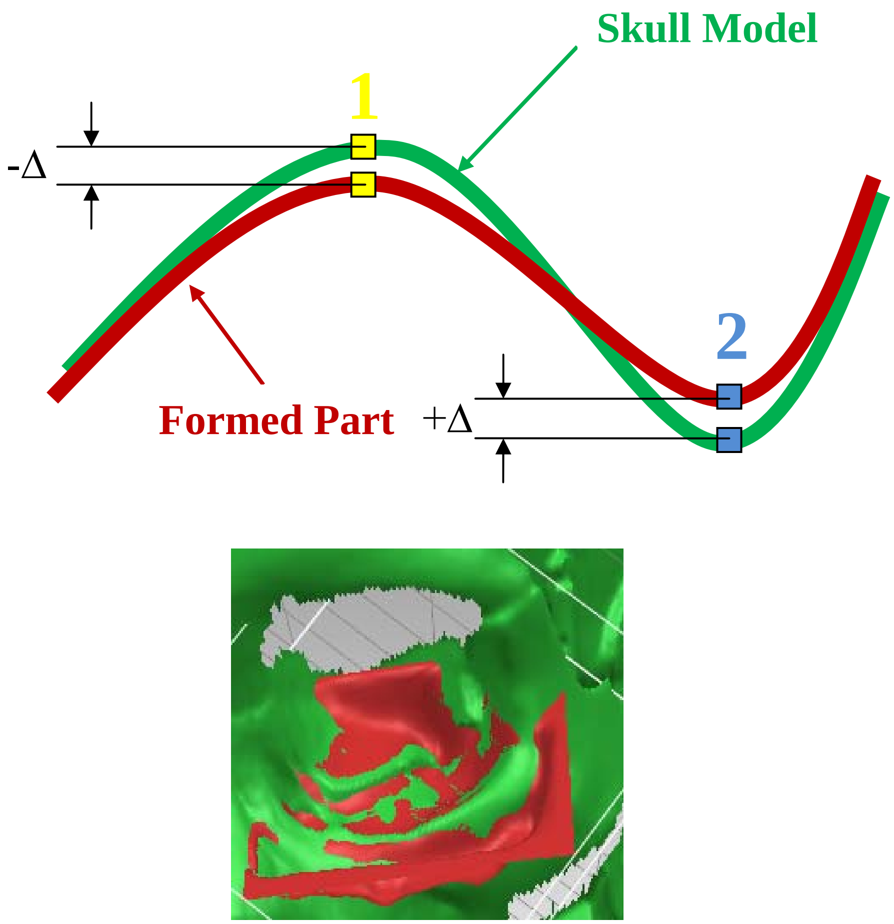
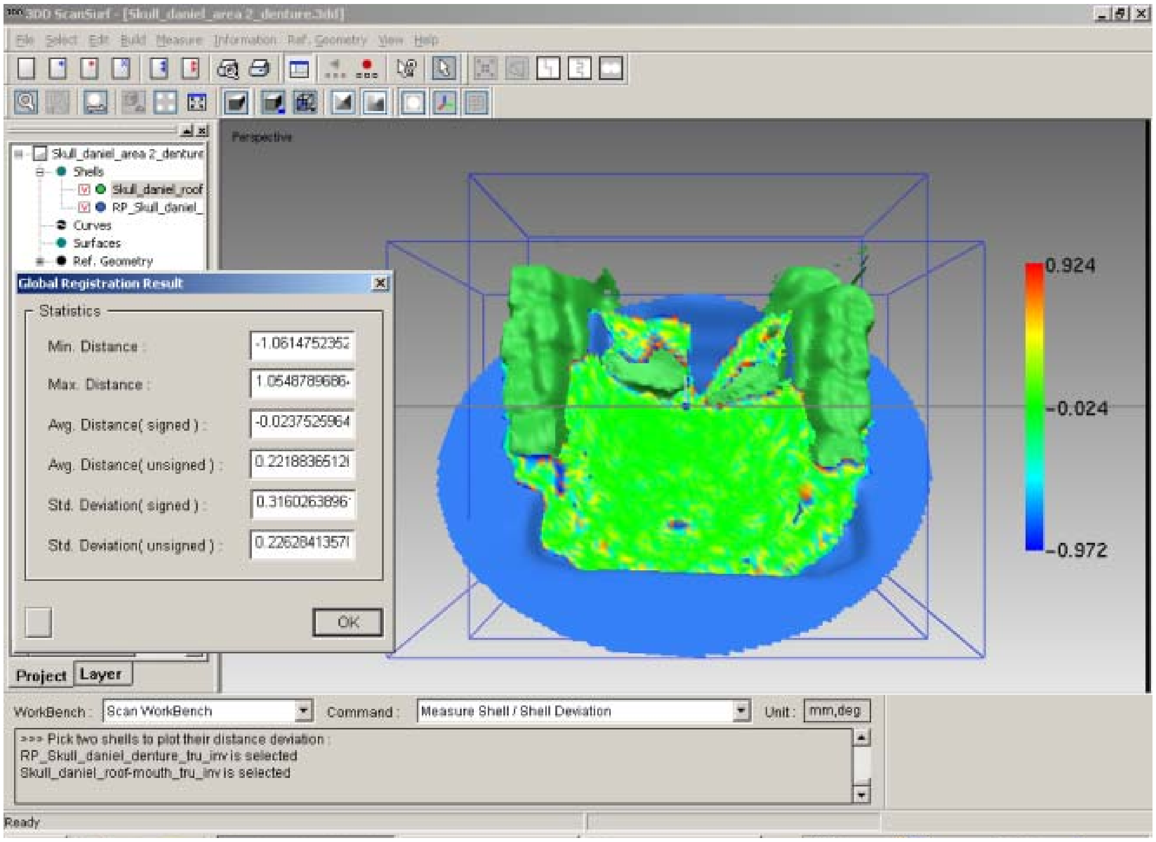


Figure 23: Surface Comparison Example

Using the 3DD ScanSurf software the comparison information is outputted in maximum and minimum distances, average distances (signed and unsigned), and standard deviations (signed and unsigned). Take for example the figure above where the skull model is represented in green and the formed part is represented in red. Corresponding points are compared in the software and assigned a difference value. For point one, seen in yellow, there is a negative difference while for point two, seen in blue, there is a positive difference. The skull model is used as the reference so if the surface compared is above the part as in point two then there is an associated positive difference. This is where the signed and unsigned differences come into play. The signed differences keep the associated positive or negative value with each point while the unsigned values are simply the absolute values of each difference.

The Cloud software compares the two surfaces in a similar manner; however it outputs the deviations into bins on a pixel by pixel basis. The results outputted from Cloud have been put into histograms such as the one seen in Figure 26. These histograms show the number of pixels in the bins on the y-axis along with the deviation associated for those bins on the x-axis. Obviously, to have an accurate part the fewer the pixels in the bins with large deviation values seen on the right-hand side the better.

Figure 24 below shows the interface of the 3DD ScanSurf software for the denture template versus the skull model.



Statistics

Min. Distance :	-1.061475235
Max. Distance :	1.0548789686
Avg. Distance(signed) :	-0.0237525964
Avg. Distance(unsigned) :	0.2218836512
Std. Deviation(signed) :	0.3160263896
Std. Deviation(unsigned) :	0.2262841357

WorkBench : Scan WorkBench

Command : Measure Shell / Shell Deviation

Unit : mm,deg

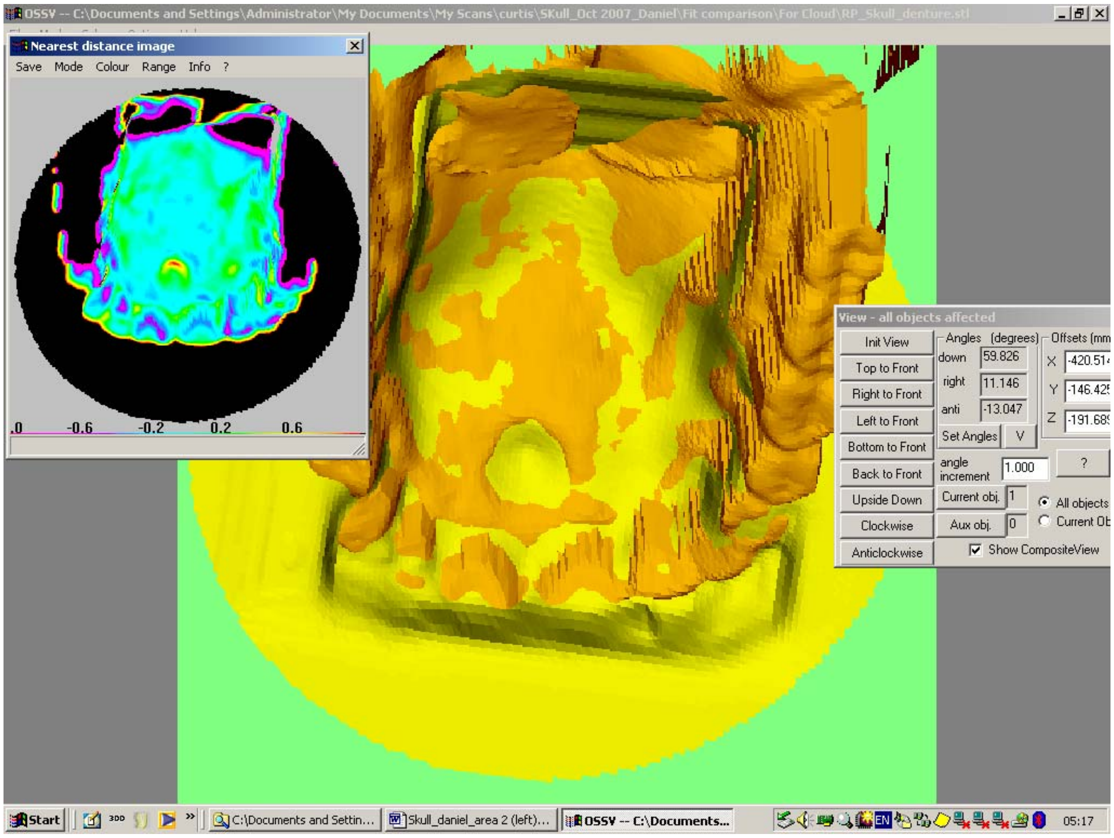
```
>>> Pick two shells to plot their distance deviation :
RP_Skull_daniel_denture_tru_inv is selected
Skull_daniel_roof-mouth_tru_inv is selected
```

Figure 24: 3DD ScanSurf for Denture Template Comparison

Table 1: Deviation Data from 3DD ScanSurf

Denture (Model vs. Template) Data	**(mm)**
Minimum Distance	-1.0615
Maximum Distance	1.05487
Average Distance (signed)	-0.0238
Average Distance (unsigned)	0.22188
Standard Deviation (signed)	0.31603
Standard Deviation (unsigned)	0.22628

Table 1 summarizes the results outputted from Figure 24 for the denture template compared to the skull model. Note it is broken into categories designated “signed” and “unsigned”. The signed data takes into account whether a point is above (positive) or below (negative), while the unsigned data deals solely in the distances themselves. As it is shown the maximum and minimum distances are on the order of one millimeter while the unsigned average distance is only 0.22188 mm. Another interpretation of the data outputted from Cloud for this case can be seen in the Figure 26 histogram. For convenience Table 2 shows information related to the histogram. In this case the surface was sectioned into pixels of 0.1276 mm in size. The most frequent differences shown are in the 0.0156 mm and 0.1406 mm bins, which clearly shows the template and the skull surfaces are very close.



Angles (degrees)
down 59.826
right 11.146
anti -13.047
Offsets (mm
X -420.51
Y -146.42
Z -191.68
angle increment 1.000
Current obj. 1
Aux obj. 0
● All objects
○ Current Ob
☑ Show CompositeView

Figure 25: Cloud for Denture Template Comparison

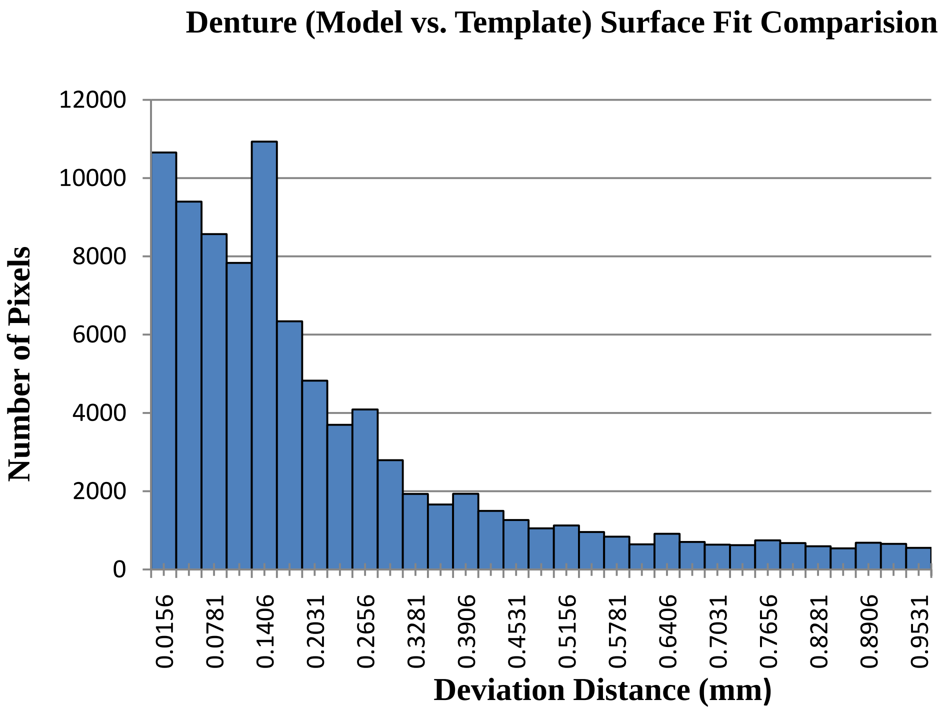
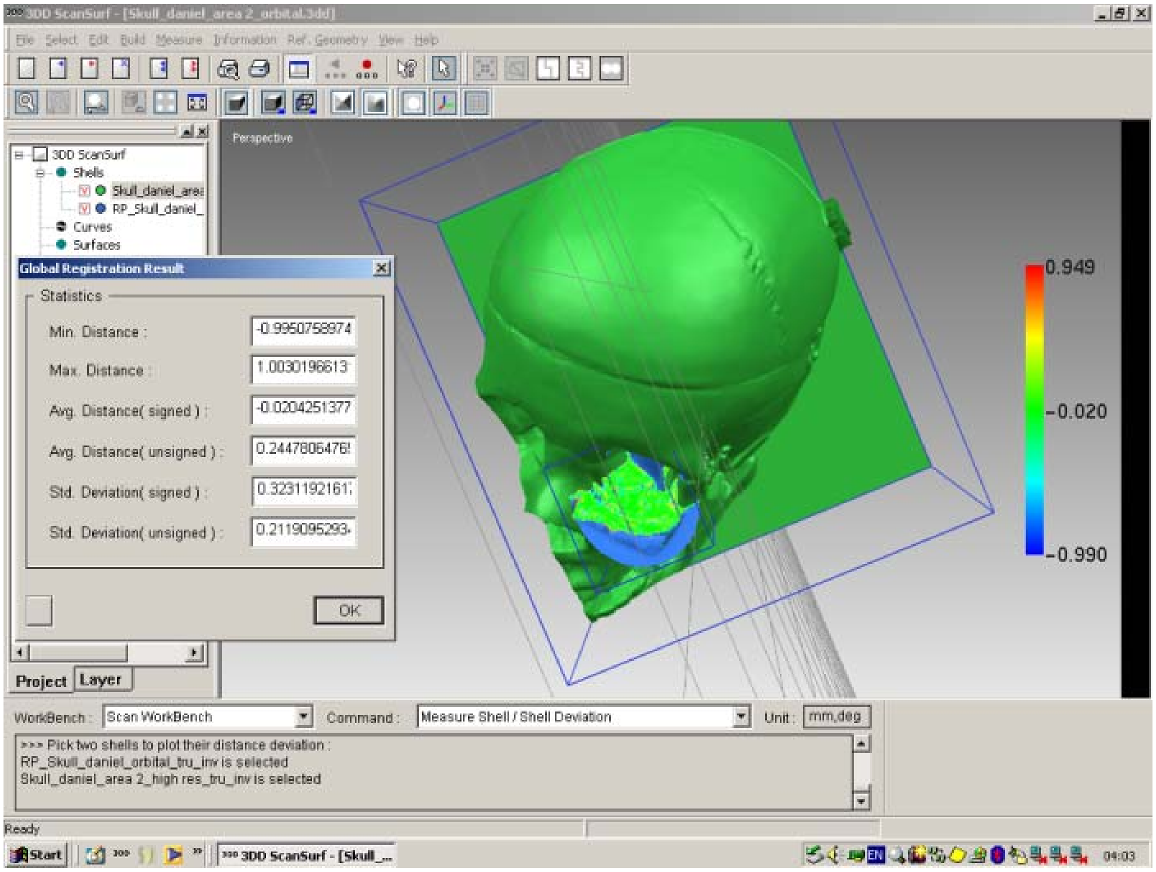


Figure 26: Denture (Model vs. Template) Histogram

Table 2: Deviation Data from Cloud

Denture (Model vs. Template) Histogram Data
range 0 to +0.968750 mm
bin width 0.031250 mm
pixel size 0.127596 mm
mean magnitude difference 0.223375 mm

Figure 27 shows the orbital case in 3DD ScanSurf while Table 3 summarizes the results outputted for the orbital template compared to the skull model. As it is shown the maximum and minimum distances are nearly identical to the denture case while the unsigned average distance is only 0.2448 mm.



Global Registration Result

Statistics

Min. Distance : -0.9950758974
Max. Distance : 1.0030196613
Avg. Distance(signed) : -0.0204251377
Avg. Distance(unsigned) : 0.2447806476!
Std. Deviation(signed) : 0.3231192161;
Std. Deviation(unsigned) : 0.2119095293-

WorkBench : Scan WorkBench
Command : Measure Shell / Shell Deviation
Unit : mm,deg

```
>>> Pick two shells to plot their distance deviation :
RP_Skull_daniel_orbital_tru_inv is selected
Skull_daniel_area 2_high res_tru_inv is selected
```

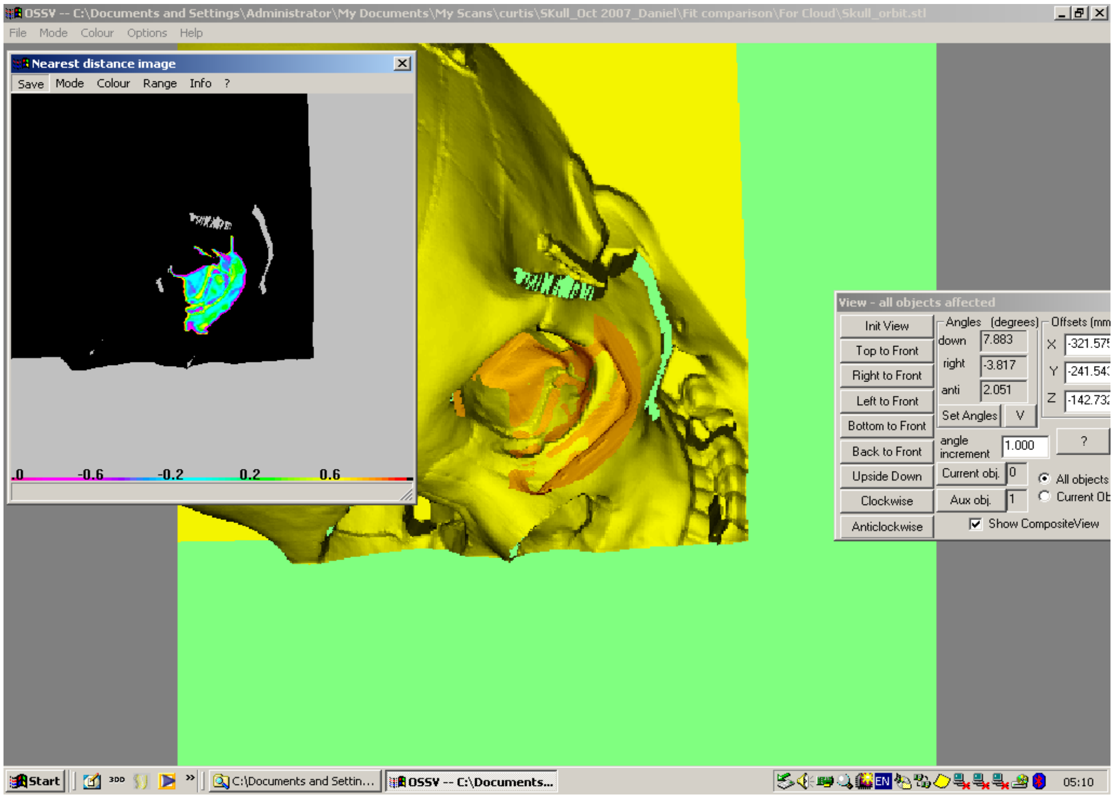
Ready

Figure 27: 3DD ScanSurf for Orbital Template Comparison

Table 3: Deviation Data from 3DD ScanSurf

Orbital (Model vs. Template) Data	(mm)
Minimum Distance	-0.9951
Maximum Distance	1.00302
Average Distance (signed)	-0.0204
Average Distance (unsigned)	0.24478
Standard Deviation (signed)	0.32312
Standard Deviation (unsigned)	0.21191

Again, another interpretation from Cloud of the data for orbital case can be seen in the Figure 29 histogram while Table 4 shows information related to the histogram. In this case the surface was sectioned into pixels of 0.358 mm in size. The most frequent differences shown are in the 0.0156 mm and 0.3906 mm bins. Like the denture case the template and the skull model are very close, certainly close enough when compared to the fact that many implants in the past have been hand formed.


OSSV -- C:\Documents and Settings\Administrator\My Documents\My Scans\curtis\SKull_Oct 2007_Daniel\Fit comparison\For Cloud\Skull_orbit.stl

down 7.883
right -3.817
anti 2.051
angle increment 1.000
Current obj. 0
Aux obj. 1
X -321.57
Y -241.54
Z -142.73
● All objects
○ Current Ob
☑ Show CompositeView

Figure 28: Cloud for Orbital Template Comparison

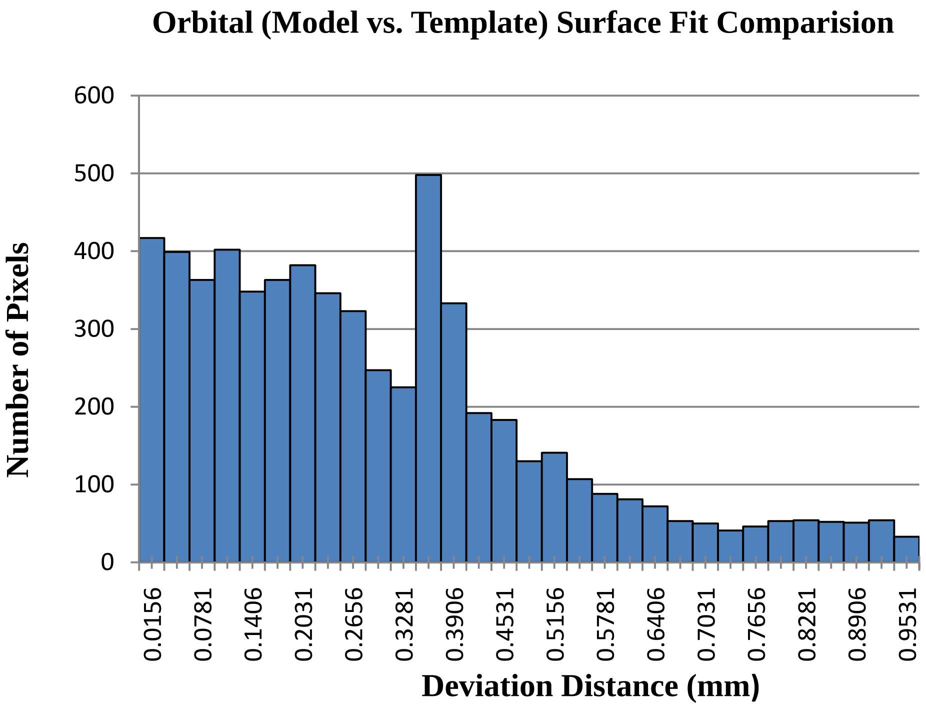


Figure 29: Orbital (Model vs. Template) Histogram

Table 4: Deviation Data from Cloud

Orbital (Model vs. Template) Histogram Data
range 0 to +0.968750 mm
bin width 0.031250 mm
pixel size 0.358000 mm
mean magnitude difference 0.295156 mm

Previously it was mentioned that the cranioplasty template and the skull model were note compared due to alignment issues. However, with the very similar results for the two more complicated parts the cranioplasty case is most likely either in the same range or even better due to the simpler shape.

4.2 Formed Parts

Thus far both the orbital and denture parts have been formed and scanned for accuracy, however as with the template the cranioplasty was formed but unable to be checked for accuracy using the scanning software. Seen below is the backside of the formed orbital part. All three parts were formed using 0.7 mm Ti-6Al-4V sheet at 900°C. The pictures shown are of the parts before final cutting which will remove the area of interest out of the transitional metal.

Figure 30: View of the orbital implant from below before final cutting

Figure 31: View of the denture from below before final cutting and cleaning

Figure 32: View of the cranioplasty before final cutting and cleaning

Each of the parts was formed using a pressure profile generated from the constitutive equations from Mosher and Dawson (50; 51). The pressure profile for each corresponding part can be seen below. As it is shown in these profiles the forming times for each part were roughly an hour or less.

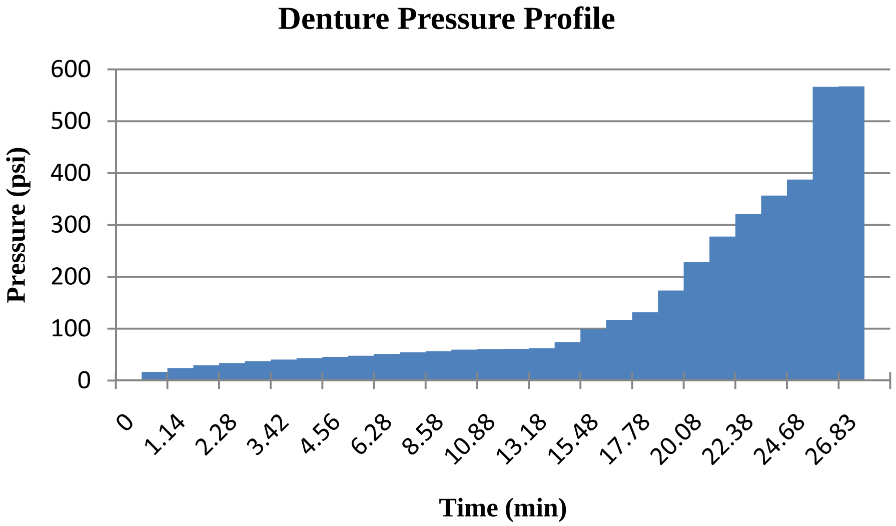


Figure 33: Denture Pressure Profile

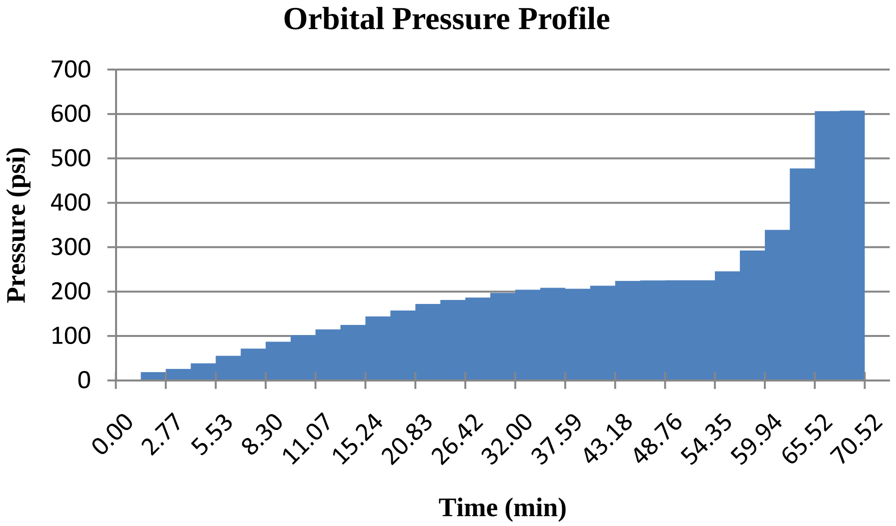


Figure 34: Orbital Pressure Profile

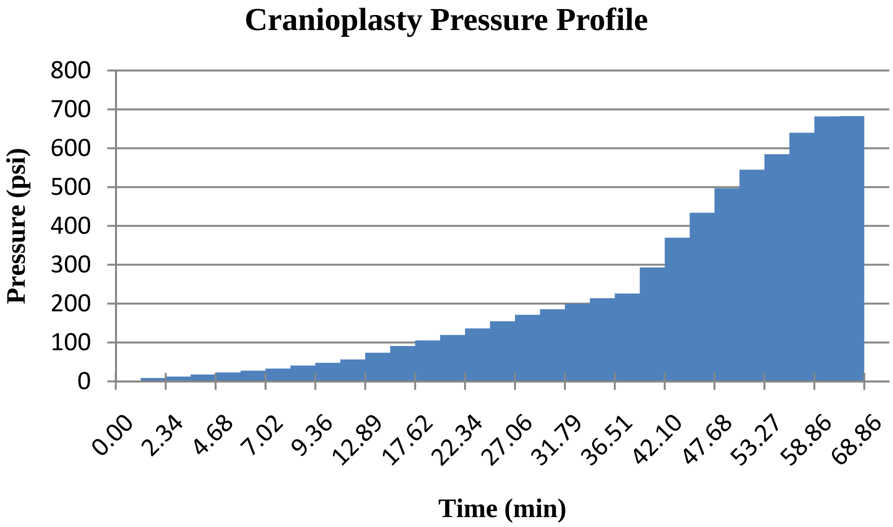
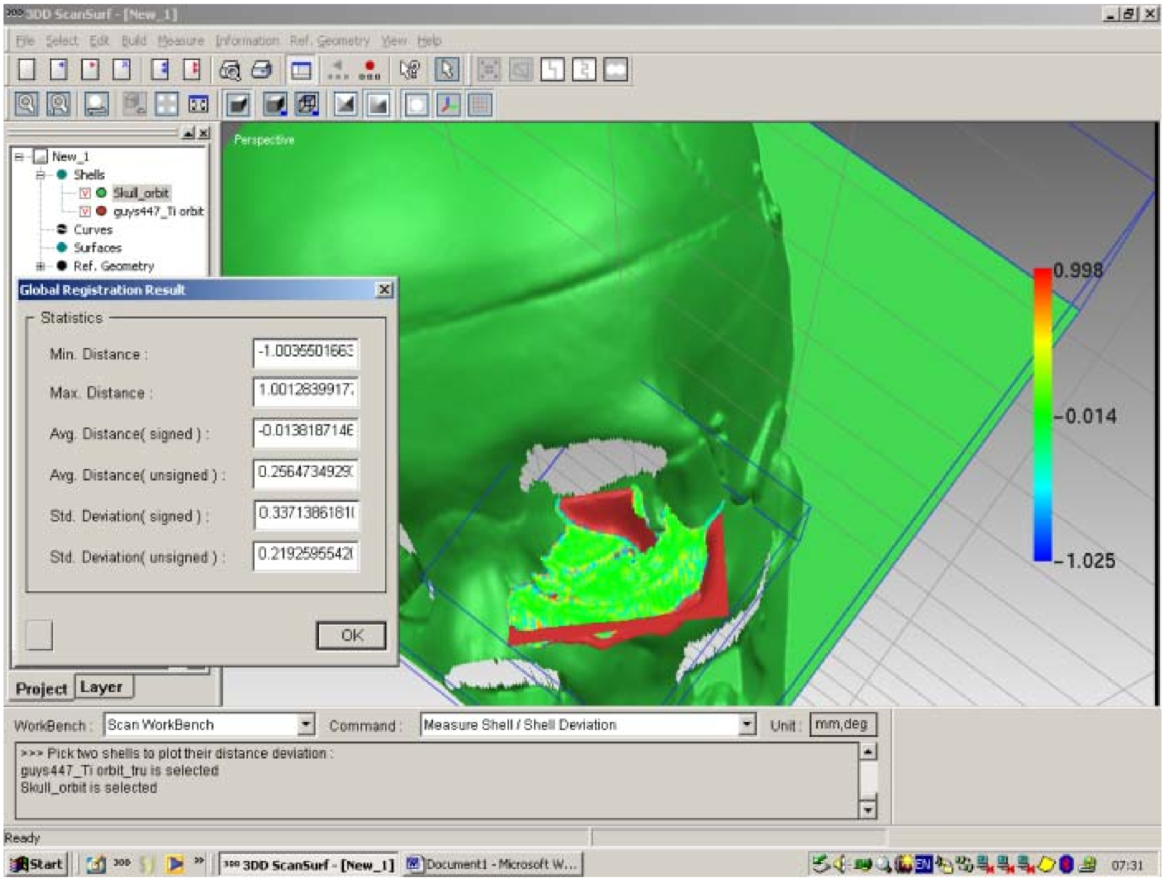


Figure 35: Cranioplasty Pressure Profile

4.3 Accuracy of the Formed Parts

Like the templates before it the orbital implant and the denture were scanned using the 3D contact scanner and compared to the associated area of the skull model. Figure 36 shows the 3DD ScanSurf comparison for the orbital part while Table 5 summarizes the results outputted from ScanSurf for the orbital template compared to the skull model. As it is shown the maximum and minimum distances are extremely close to the orbital template and skull model comparison case, with the unsigned average distance at only 0.25647 mm.



Global Registration Result

Statistics

Min. Distance : -1.0035501663

Max. Distance : 1.0012839917

Avg. Distance(signed) : -0.0138187146

Avg. Distance(unsigned) : 0.2564734929

Std. Deviation(signed) : 0.3371386181

Std. Deviation(unsigned) : 0.2192595542

WorkBench : Scan WorkBench

Command : Measure Shell / Shell Deviation

Unit : mm,deg

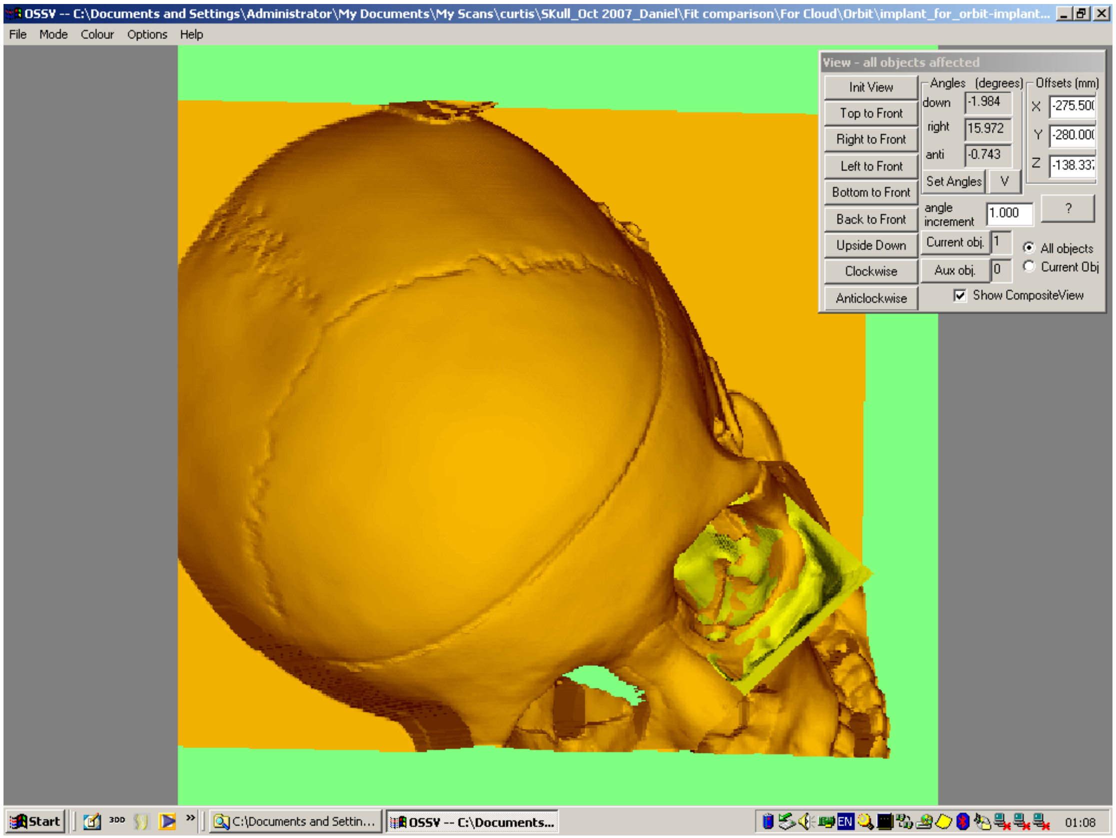
```
>>> Pick two shells to plot their distance deviation :
guys447_Ti orbit_tru is selected
Skull_orbit is selected
```

Figure 36: 3DD ScanSurf for Orbital Part Comparison

Table 5: Deviation Data from 3DD ScanSurf

Orbital (Model vs. Part) Data	(mm)
Minimum Distance	-1.0036
Maximum Distance	1.00128
Average Distance (signed)	-0.0138
Average Distance (unsigned)	0.25647
Standard Deviation (signed)	0.33714
Standard Deviation (unsigned)	0.21926

Again, another interpretation of the data from Cloud for this case can be seen in the Figure 38 histogram. Table 6 Table 4 shows information related to the histogram. In this case the surface was sectioned into pixels of 0.358 mm in size. The most frequent differences shown are in the 0.1422 mm and 0.3609 mm bins.



OSSV -- C:\Documents and Settings\Administrator\My Documents\My Scans\curtis\SKull_Oct 2007_Daniel\Fit comparison\For Cloud\Orbit\implant_for_orbit-implant...

View - all objects affected

Angles (degrees)
down -1.984
right 15.972
anti -0.743

Offsets (mm)
X -275.50(
Y -280.00(
Z -138.33;

angle increment 1.000
Current obj. 1
Aux obj. 0
● All objects
○ Current Obj
☑ Show CompositeView

Figure 37: Cloud for Orbital Part Comparison

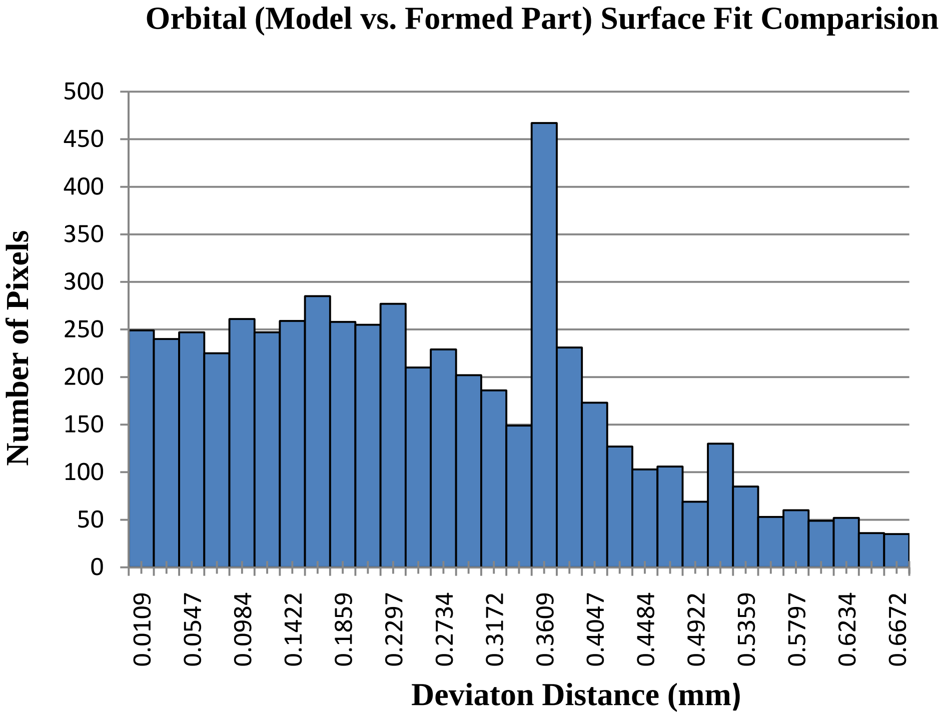
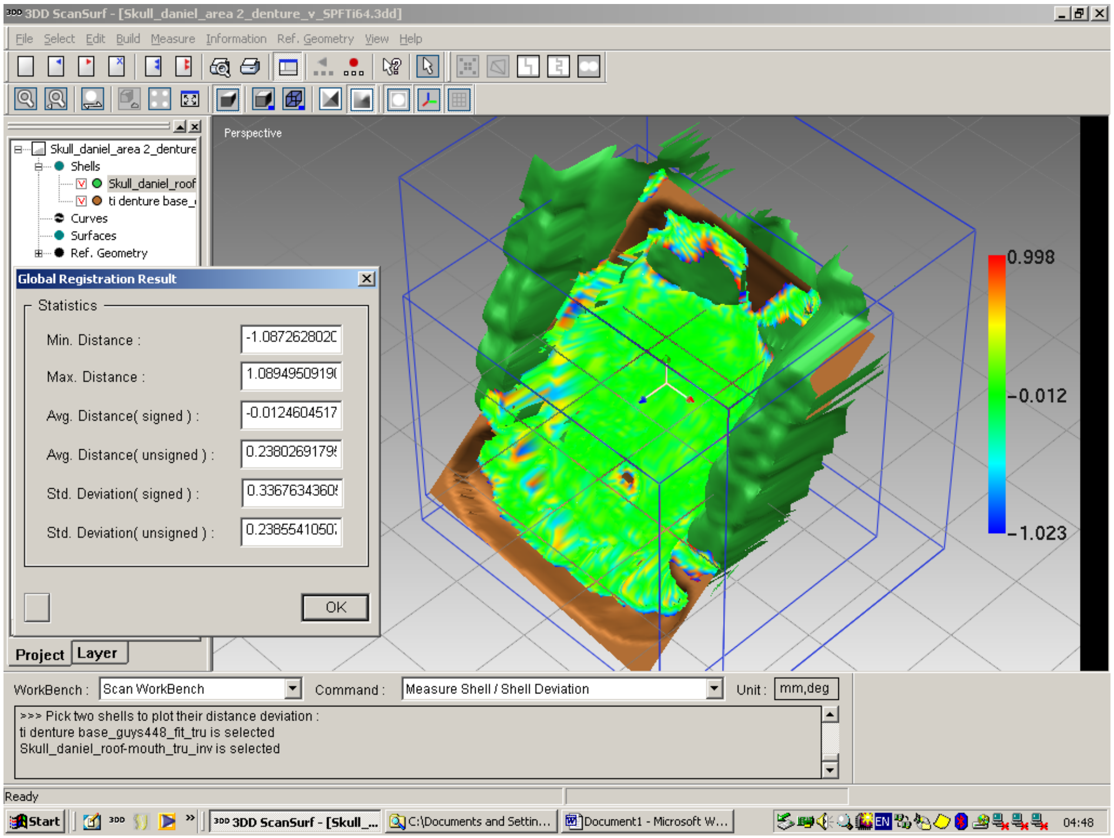


Figure 38: Orbital (Model vs. Formed Part) Histogram

Table 6: Deviation Data from Cloud

Orbital (Model vs. Part) Histogram Data
range 0 to +0.678125 mm
bin width 0.021875 mm
pixel size 0.358000 mm
mean magnitude difference 0.256690 mm

Figure 39 shows the 3DD ScanSurf comparison for the denture while Table 5 summarizes the results outputted from ScanSurf for the denture compared to the skull model. As it is shown the maximum and minimum distances are extremely close to the denture template and skull model comparison case, while the unsigned average distance is only 0.23803 mm.



Global Registration Result

Statistics

Min. Distance : -1.087262802

Max. Distance : 1.089495091

Avg. Distance(signed) : -0.0124604517

Avg. Distance(unsigned) : 0.238026917

Std. Deviation(signed) : 0.336763436

Std. Deviation(unsigned) : 0.238554105

WorkBench : Scan WorkBench

Command : Measure Shell / Shell Deviation

Unit : mm,deg

```
>>> Pick two shells to plot their distance deviation :
ti denture base_guys448_fit_tru is selected
Skull_daniel_roof-mouth_tru_inv is selected
```

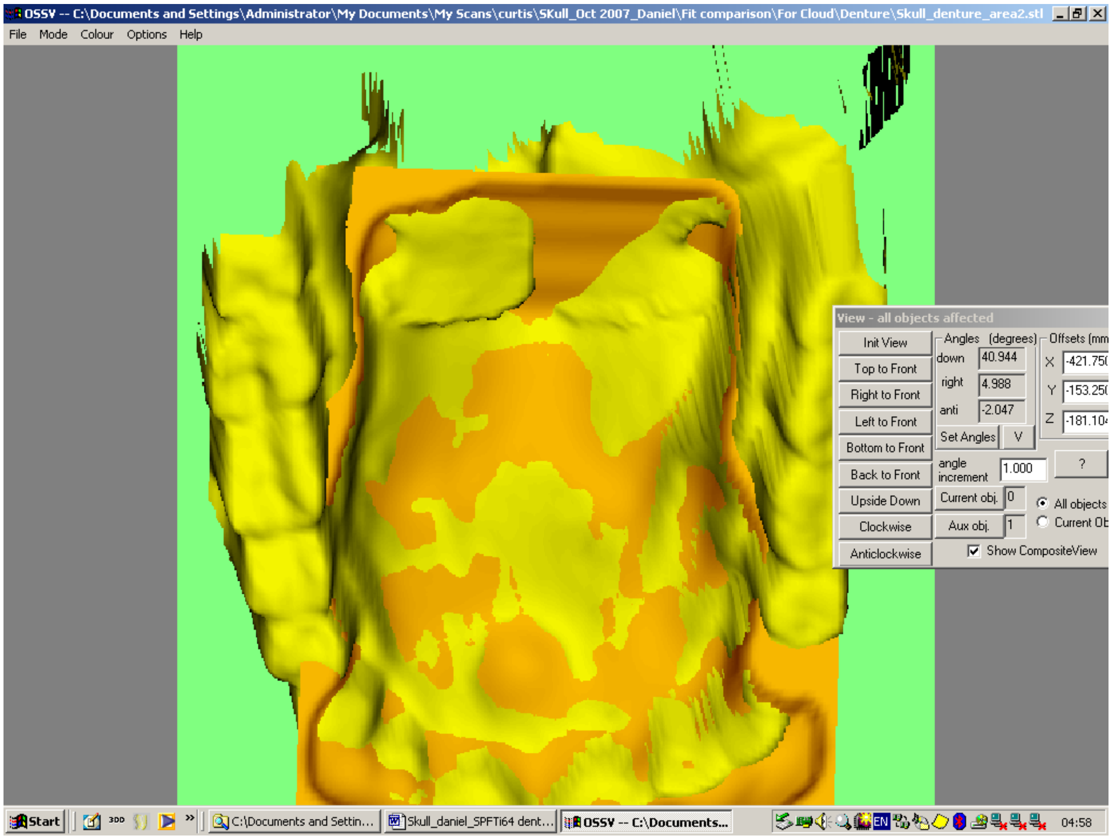
Ready

Figure 39: 3DD ScanSurf for Denture Part Comparison

Table 7: Deviation Data from 3DD ScanSurf

Denture (Model vs. Formed Part) Data	**(mm)**
Minimum Distance	-1.0873
Maximum Distance	1.08949
Average Distance (signed)	-0.0125
Average Distance (unsigned)	0.23803
Standard Deviation (signed)	0.33676
Standard Deviation (unsigned)	0.23855

Again, another interpretation of the data from Cloud for this case can be seen in the Figure 38 histogram. Table 6 Table 4 shows information related to the histogram while Figure 40 shows the visual representation. In this case the surface was sectioned into pixels of 0.358 mm in size. The most frequent differences shown are in the 0.0109 mm and 0.1203 mm bins.


OSSV -- C:\Documents and Settings\Administrator\My Documents\My Scans\curtis\SKull_Oct 2007_Daniel\Fit comparison\For Cloud\Denture\Skull_denture_area2.stl

View - all objects affected

Angles (degrees)
down 40.944
right 4.988
anti -2.047

Offsets (mm
X -421.75
Y -153.25
Z -181.10

angle increment 1.000
Current obj. 0
Aux obj. 1
● All objects
○ Current Ob
☑ Show CompositeView

Figure 40: Cloud for Denture Part Comparison

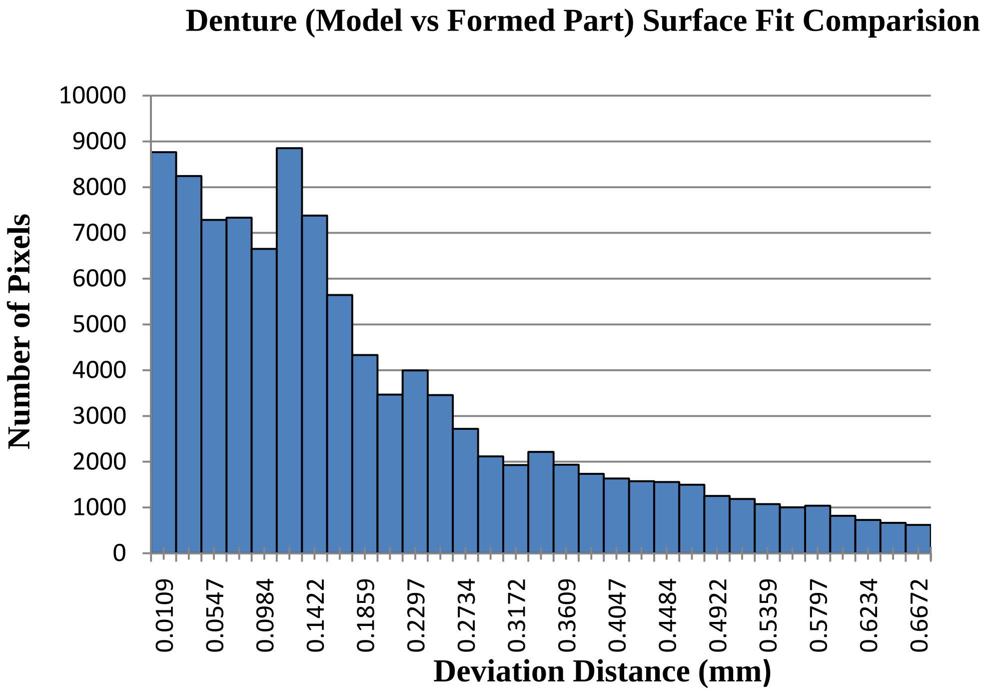


Figure 41: Denture (Model vs. Formed Part) Histogram

Table 8: Deviation Data from Cloud

Denture (Model vs. Formed Part) Histogram Data
range 0 to +0.678125 mm
bin width 0.021875 mm
pixel size 0.113000 mm
mean magnitude difference 0.193944 mm

Overall the accuracy of the formed parts was nearly identical to the differences seen between the templates and the skull model. This is a testament to the superplastic forming process and its ability to form to very precise shapes. There are a few things to keep in mind when looking at this data with regards to accuracy. When the templates were formed there was a very specific area of interest in mind that then had to be attached to a transitional area to fill in the gaps. This process was shown in the procedure section. The rapid prototyping process is a single color process; therefore it is difficult to differentiate the exact boundary between the area of interest and the transition region. An effort was made to hand draw the area of interest in marker, however this is imprecise at best. As this was the case some of the transition region shows up in the surface comparisons which contribute in the error of the two surfaces, because the transition region is made up and would not compare to anything seen on the skull model. Even with the transition surfaces interfering with the surface comparisons the differences were extremely slight on the order of less than a millimeter.

Another thing to keep in mind in terms of accuracy was the fact that the two parts compared are the first two parts ever to be formed using this particular process. In the end this has shown to be a great proof of concept, but with continued work and feedback now that actual parts have been made, the accuracy of the process could easily be pushed to a new level.

4.4 Real World Application

The current process was made using "healthy" data. In other words the CT scans were of a full model which showed no signs of trauma or malformation which is the purpose of creating prostheses in the first place. However, the process is still valid for actual cases. If a patient has a malformation there are many options to proceed. In on technique the healthy side is mirrored across the centerline, as shown in Figure 42, and the process becomes the same as before. This technique was used in (52).

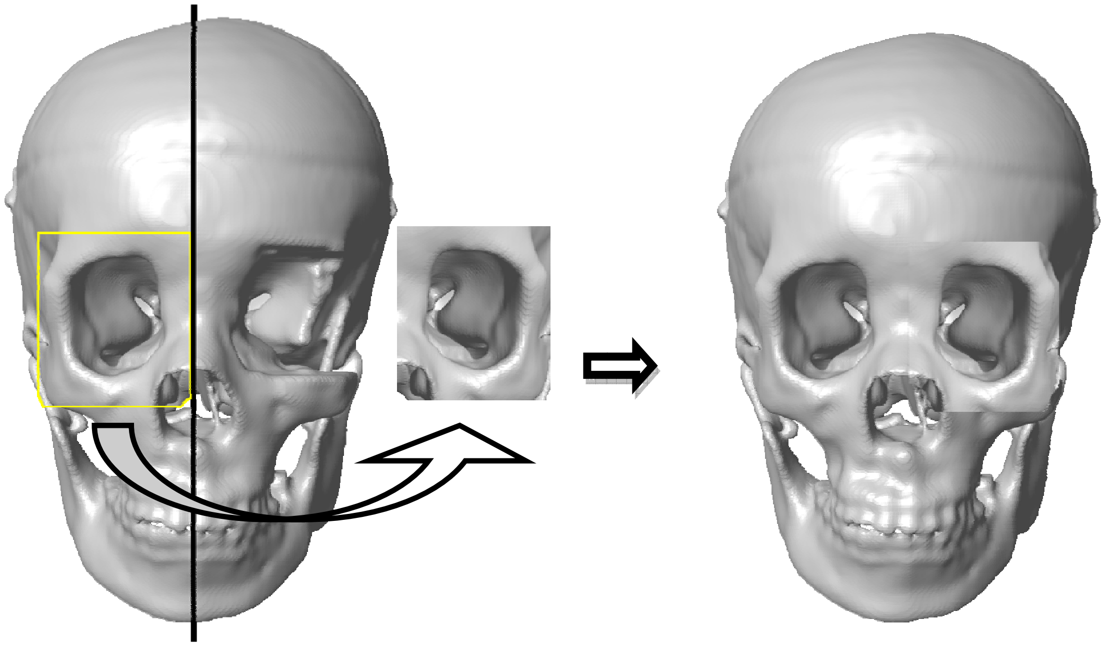


Figure 42: Healthy data (seen in the yellow box) is mirrored to fix a malformation

CHAPTER 5: CONCULSION

5.1 Completed Objectives

Recall from the introduction chapter the specific objectives for the research where:

I. Investigate techniques in creating custom prostheses.
II. Design a process for creating implants using superplastic forming.
III. Create custom implants out of a biocompatible material.
IV. Verify the fit of created parts.

Upon the culmination of the research each of these objectives has been completed. Varying techniques to create custom prostheses were investigated in the background section of chapter 2. These techniques ranged from casting titanium (30) to molding acrylic (28). Learning about these techniques was necessary, as was discussed in 2.4, in developing a process to create implants using superplastic forming.

The process developed was successful in superplastically forming proxy implants out of Ti-6Al-4V which as noted in (30) is one of the most biocompatible materials. This completes both objectives II and III.

Objective four involved verifying the fit of the creating parts. Creating an implant which doesn’t fit closely serves no purpose. However, as can be seen in 4.3 the accuracy of the formed parts was excellent.

5.2 Future Work

Currently the process from start to finish is laborious insofar as one has to create multiple molds to have an investment die which is used for fabrication of the implant. However, in the future a rapid prototyping machine could be outfitted in such a way that the medium it used would be able to handle the high temperatures of the SPF press. Thus, a die could be made in a single step instead of the multiple step process used in this thesis. This would dramatically decrease the time needed to create a custom implant as well as reduce the expense of the process.

Another step in refining the process is to optimize the orientation of the area of interest. In the current work the orientation was an educated guess when the area of interest was placed inside the template, recall Figure 16. In the future this could be optimized with regards to the superplastic forming process to both reduce thinning as well as decrease the forming time creating a better product.

Recall from Appendix B the gap filling process which merged the area of interest and the template created in ProEngineer. This was one of the most time consuming elements in the implant making process. It required going layer by layer and painting in a new mask which provided a transition for the metal to flow into the area of interest. In the future this process could potentially be done by developing an algorithm or feature insides Simpleware itself which filled in the gap automatically after selecting the two edges that needed to be merged. This could be married to the optimized orientation to create a total surface which was optimized for the superplastic forming process.

One of the more straightforward improvements which can be done is optimizing the superplastic forming process through finite element modeling. In the current work two of the three modules from Simpleware were used including ScanIP and ScanCAD. However, as discussed in the Simpleware section there is also a module known as ScanFE. Using this piece of the program one can easily output a surface which can be analyzed using finite element software such as ABAQUS.

Even without the above suggestions the accuracy could be improved with more cooperation with Simpleware and the use of their software. Anytime a person uses a brand new program for the first time the full potential of that program is never reached. With a more thorough understanding of the software as well as future updates the current process without any other improvements could become more accurate at the very least.

Other more important paths for this work to take are on the medical side of things. Essentially this process has become a proof of concept for potential real-world use; however before it can truly be used in surgery other factors must be taken into consideration. One of these is the path of insertion for the given implant. In this way the part can not only be designed to fit a given feature of the body, but also be married to a path for it to be fixated during surgery. This would allow for any potential interference issues to be worked out before the surgery took place. In this phase features could also be added to the implant, such as screw holes, to ensure proper fixation.

Another aspect on the medical side would be to focus on surface preparation for implantation. After the part is formed methods could be developed to create the optimal biocompatibility for an implant.

Clearly there are many areas in which this research can be taken. With a combination of the above suggestions this process could truly be used in the future to fabricate implants for real world applications.

5.3 Other Potential Applications

There are many potential applications beyond the individual custom implants of using superplastic forming with various medical devices and components. Illustrated below are some possible ideas:

Jarvick 2000

Figure 43: Jarvik Artificial Heart (53)

This is a heart assisting device. The pump is housed in a cylindrical titanium shell which could potentially be designed with SPF in mind which in the future might allow new functional features to be added.

NEDO Artificial Heart

Along the same line as above is the NEDO Artificial Heart (54). It also features a more intricate titanium shell with a pumping mechanism.

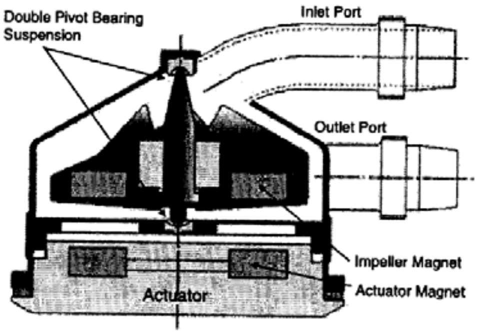


Figure 44: NEDO assist pump picture from (54)

Vascular Access Ports

A vascular access port is basically a drug delivery device which can supple a drug continuously to a given point in the body. These devices have cancer fighting applications. Seen below is an example of such a device.

Figure 45: Vascular Access Port Picture from (45)

Vertebrate Fixation/Fusion

As seen in the below x-ray a fraction in a vertebrate has been fixed using metal plating alongside a metal mesh and place with screws. In this case the metal plate can cause discomfort in swallowing. Therefore one could potentially form a plate which was thinner and conformed to the anatomy better allowing for more comfort. The strength and stiffness between the two cases would of course have to be tested.

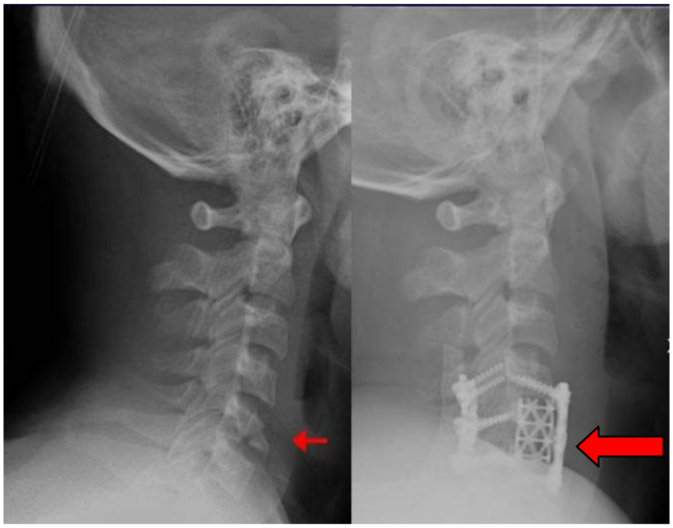


Figure 46: Vertebrate fixation example (55)

APPENDIX A

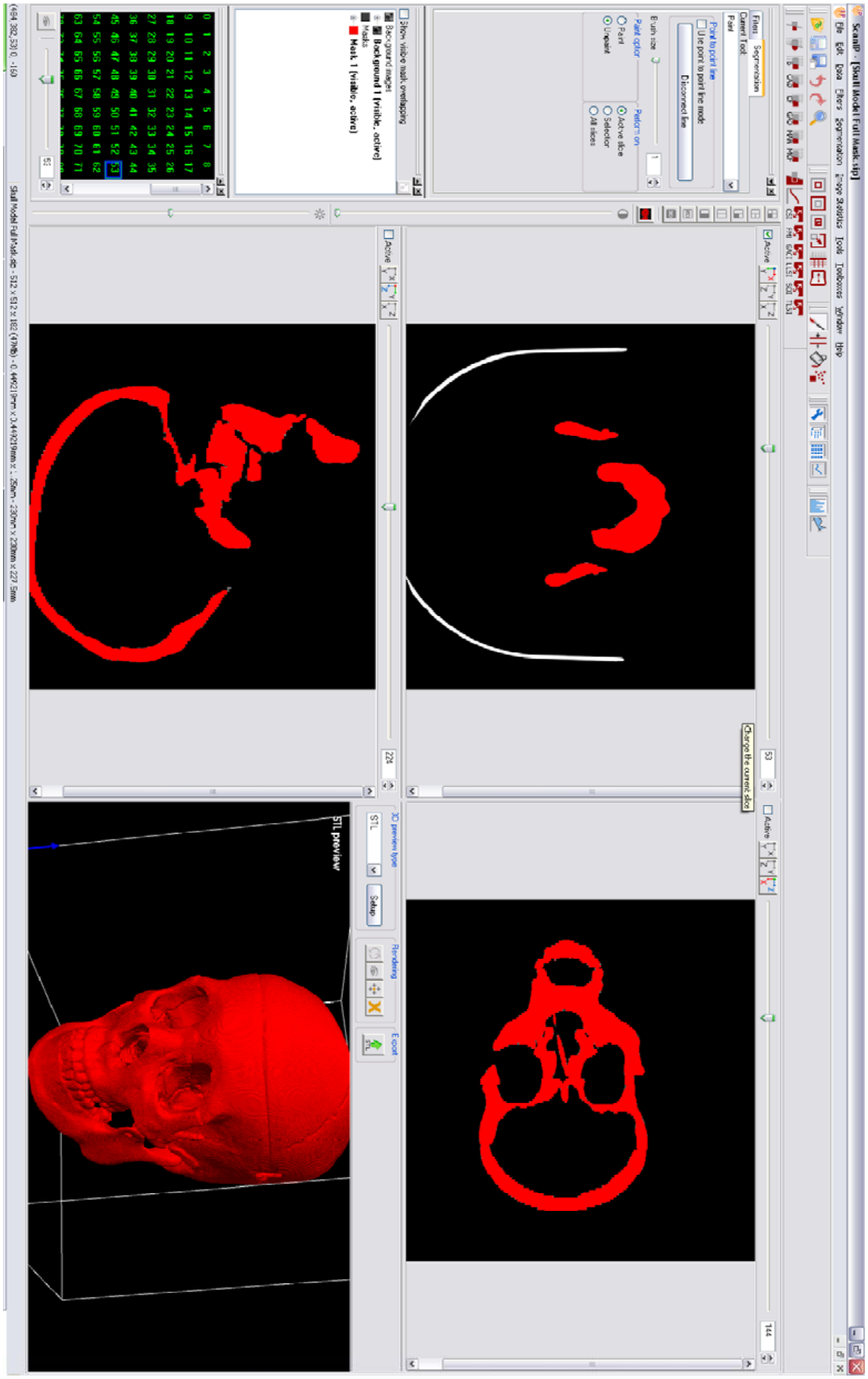
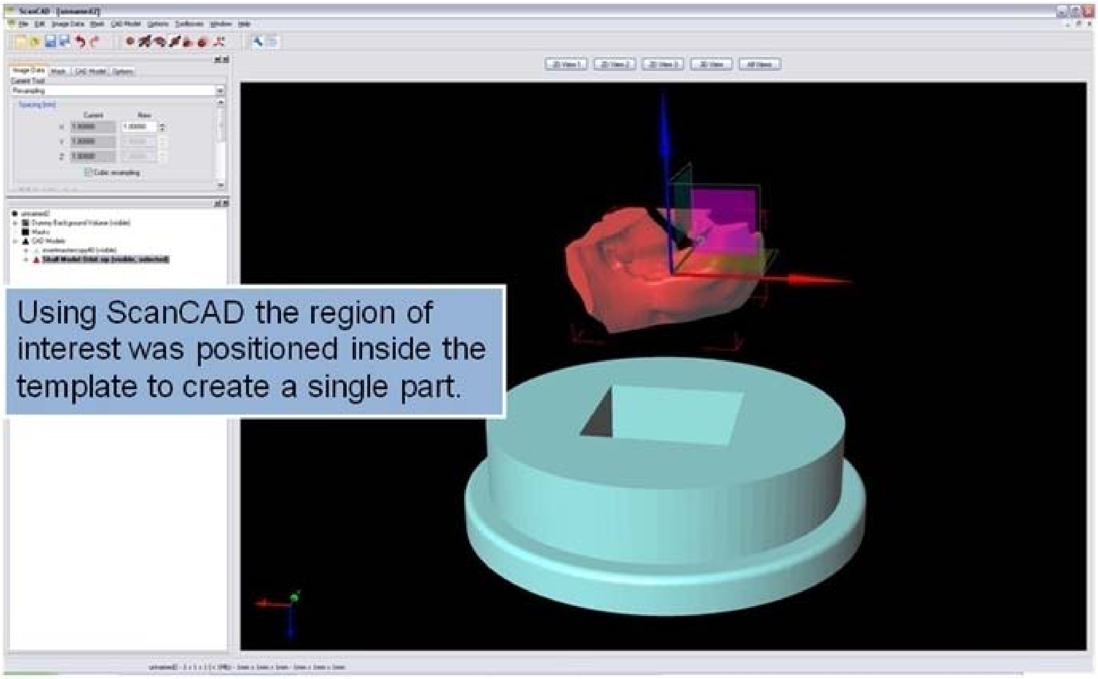
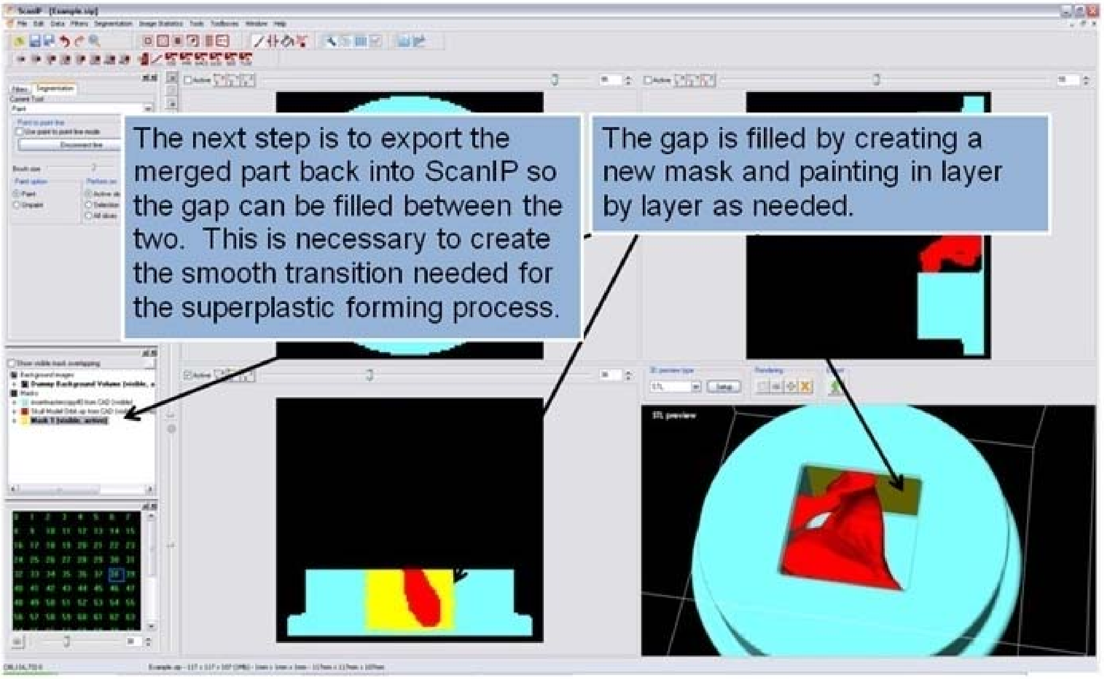


Figure 47: ScanIP Interface

APPENDIX B: GAP FILLING PROCESS

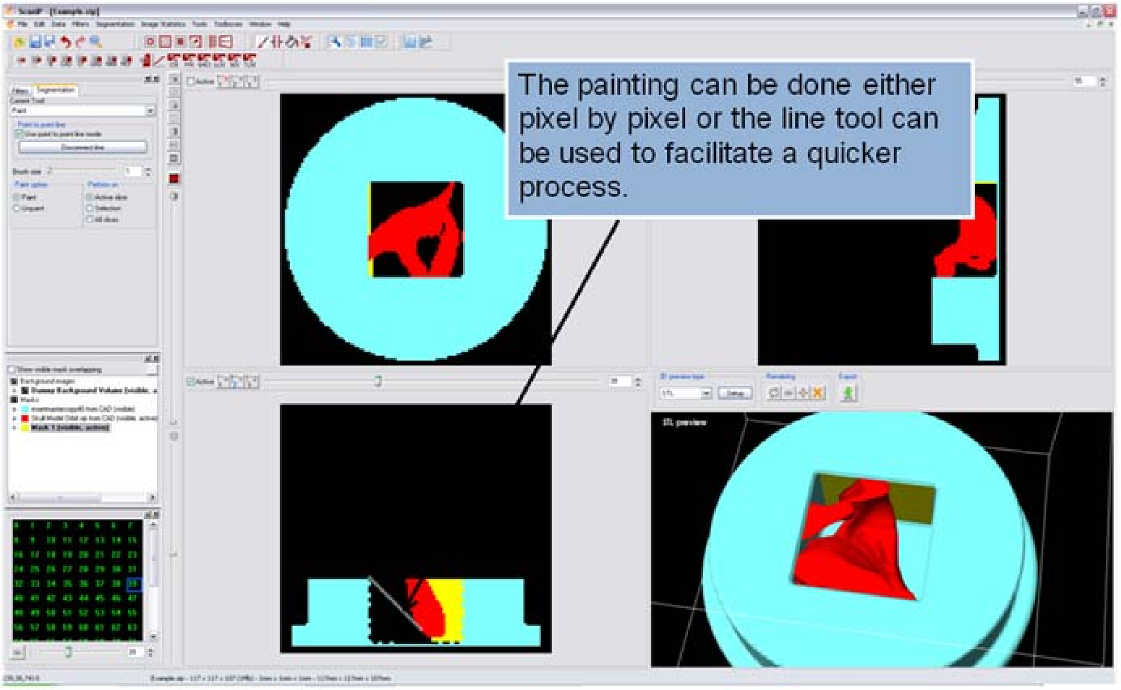


Using ScanCAD the region of interest was positioned inside the template to create a single part.

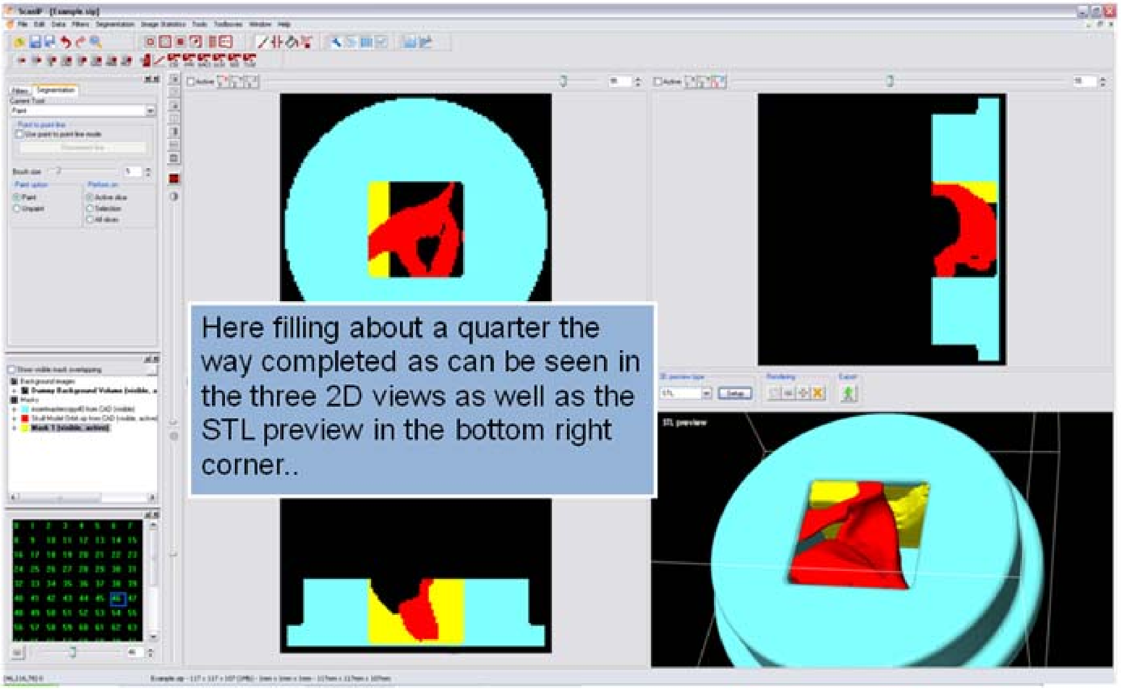


The next step is to export the merged part back into ScanIP so the gap can be filled between the two. This is necessary to create the smooth transition needed for the superplastic forming process.

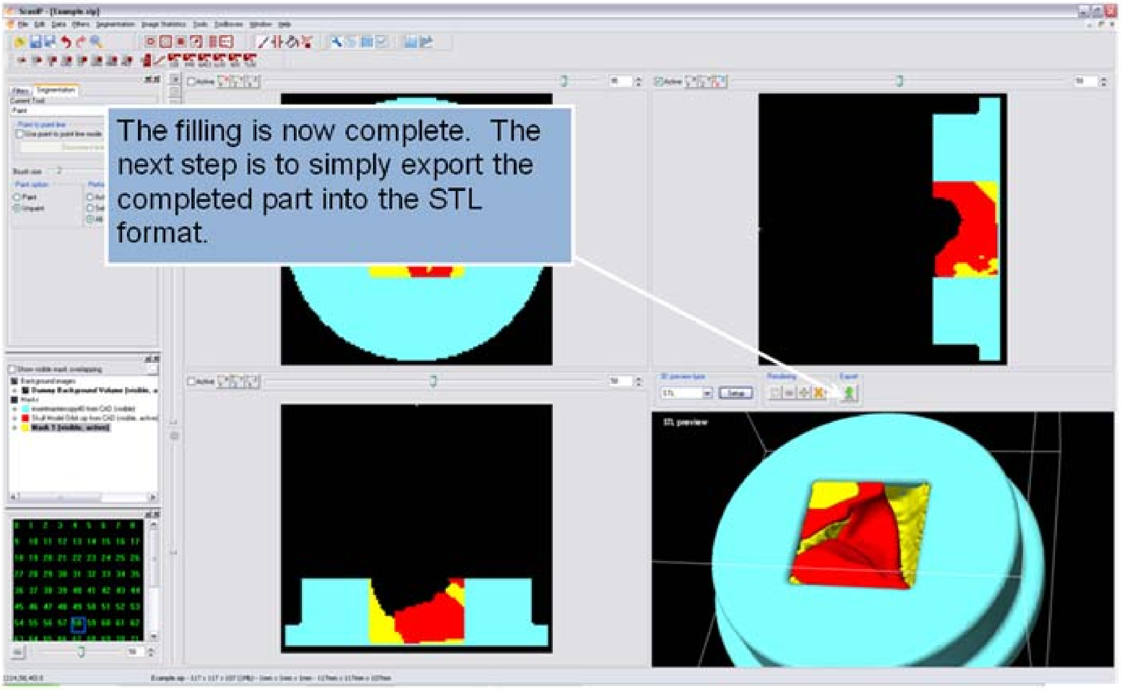
The gap is filled by creating a new mask and painting in layer by layer as needed.



The painting can be done either pixel by pixel or the line tool can be used to facilitate a quicker process.



Here filling about a quarter the way completed as can be seen in the three 2D views as well as the STL preview in the bottom right corner..



The filling is now complete. The next step is to simply export the completed part into the STL format.

APPENDIX C: TEMPLATES

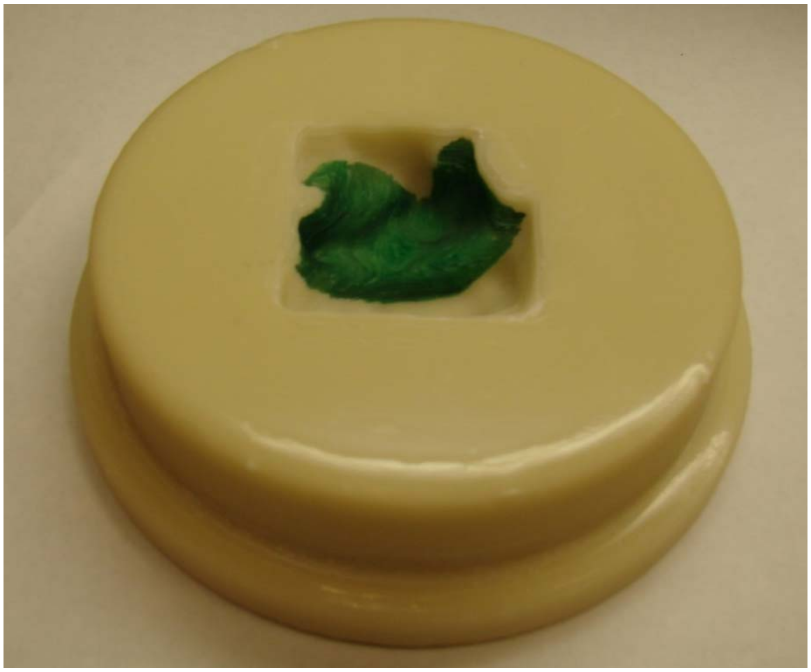


Figure 48: Orbital Template

Figure 49: Top of Skull Template

Figure 50: Roof of mouth template

REFERENCES

1. *Face On.* Curtis, R. 2005, Materials World, pp. 20-22.
2. *Superplastic Forming of Ti-6Al-4V Denture Base.* M. Okada, H. Mitsuya. November 1990, The Sumitomo Search, Vol. 43.
3. *Superplastic Forming: Stretching the Limits of Fabricating Medical Devices.* F. Abu-Farha, P. Deshmukh, M. Khraisheh, N. Thuramalla. Lexington : ASM International, 2003. Medical Device Materials - Proceedings of the Materials and Processes for Medical Devices Conference. pp. 368-373.
4. *Simulating superplastic forming.* J. Bonet, A. Gil, R. Wood, R. Said, R. Curtis. Computer methods in applied mechanics and engineering, March 18, 2006, Vol. 195, pp. 6580-6603.
5. *Microstructure-Based Modeling of Anisotropic Superplastic Deformation.* M. Khraisheh, F. Abu-Farha. 2003, Transactions of the North American Manufacturing Research Institute, Vol. 31, pp. 41-47.
6. W. Hosford, R. Caddell. *Metal Forming Mechanics and Metallurgy Second Edition.* s.l. : Prentice-Hall, 1993. 0-13-588526-4.
7. *Superplasticity and Its Application of Ultra-Fine Grained Ti-6Al-4V Alloy Obtained through Protium Treatment.* J. Nakahigashi, H. Yoshimura. 11, 2002, Materials Transactions, Vol. 43, pp. 2768-2772.
8. *Superplastic Forming of Aluminum Alloy Card Body Panels.* Z. Zeng, Y. Zhang, Y. Zhou, Q. Jin. Trans Tech Publications, 2005, Materials Science Forum, Vols. 475-479, pp. 3025-3028.
9. *Overview of Superplastic Forming Research at Ford Motor Company.* P. Friedman, S. Luckey, W. Copple, R. Allor, C. Miller, C. Young. ASM International, December 2004, Journal of Materials Engineering and Performance, Vol. 13, pp. 670-677.
10. *Superplastic Forming ofAutomotive Parts from Aluminum Sheet at Reduced Cycle Times.* J. Benedyk. June 2002, Light Metal Age, pp. 28-31.
11. *Commerical Airplane Applications fo Superplastically Formed AA5083 Alumnium Sheet.* L. Hefti. ASM International, 2006, Journal of Materials Engineering and Performance, Vol. 16, pp. 136-141.
12. *The Current State-of-the-Art and the Future in Airframe Manufacturing Using Superplastic Forming Technologies.* D. Sanders. Trans Tech Publications, 2001, Materials Science Forum, Vols. 357-359, pp. 17-22.
13. *Commerical applications of superplastic forming.* K. Osada. Elsevier, 1997, Journal of Materials Processing Technology, Vol. 68, pp. 241-245.
14. *Simulating superplastic forming.* J. Bonet, A. Gil, R. Wood, R. Said, R. Curtis. Elsevier, 2006, Computer methods in applied mechanics and engineering, Vol. 195, pp. 6580-6603.
15. *Optimisation of the superplastic forming of a dental implant for bone augmentation using finite element simulations.* D. Garriga-Majo, R. Paterson, R. Curtis, R. Said, R. Wood, J. Bonet. Elsevier, 2004, Dental Materials, Vol. 20, pp. 409-418.
16. *Stress-strain and thermal expansion characteristics of a phosphate-bonded investment mould material for dental superplastic forming.* R. Curtis. Elsevier, 1998, Journal of Dentistry, Vol. 26, pp. 251-258.
17. *Deformation of phosphate-bonded investment materials at elevated temperatures.* A. Juszczyk, D. Radford, R. Curtis. Elsevier, 2007, Dental Materials, Vol. 23, pp. 579-585.

18. *Measurement of the setting and thermal expansion of dental inversments used for superplastic forming of dental implant superstructures.* S. Soo, R. Palmer, R. Curtis. Elsevier, 2007, Dental Materials, Vol. 17, pp. 247-252.
19. *The longitudinal accuracy of fit of titanium implant superstructures superplastically formed on investment models.* S. Soo, D. Garriga-Mayo, R. Palmer, R. Curtis. Elsevier, 2004, Dental Materials, Vol. 20, pp. 269-276.
20. *Application of Superplastic Titanium Alloy for Denture Base.* M. Ito, O. Okuno, M. Ai, I. Miura. 1989, Kokubyo Gakkai Zasshi, pp. 429-434.
21. *A short-term clinical follow-up study of superplastic titanium alloy for major connectors of removable partial dentures.* N. Wakabayashi, M. Ai. June 1997, The Journal of Prosthetic Dentistry, Vol. 77, pp. 583-587.
22. *Thickness and accuracy of superplastic Ti-6Al-4V alloy denture frameworks* . N. Wakabayahsi, M. Ai. 1996, International Journal of Prosthodontics, pp. 520-526.
23. *Implanataion of hydroxyapatite granules into superplastic titanium alloy for biomaterials.* T. Nonami, A. Kamiya, K. Naganuma, T. Kameyana. Elsevier, 1998, Materials Science and Engineering, pp. 281-284.
24. *Individual prefabricated titanium implants and titanium mesh in skull base reconstructive surgery. A report of cases.* J. Schipper, G. Ridder, U. Spetzger, C. Teszler, M. Fradis, W. Maier. Springer-Verlag, 2004, Eur Arch Otorhinolaryngol, Vol. 261, pp. 282-290.
25. *Orbital floor reconstruction. Comparison of a new perforated 0.15mm thick PDS later with established titanium dynamic mesh.* A. Dacho, H. Steffen, CM. Ziegler, C. Conradt, A. Dietz. 2002, HNO, Vol. 50, pp. 21-28.
26. *Preliminary experience with medical applications of rapid prototyping by selective laser sintering.* E. Berry. January 1997, Medical Engineering Physics, Vol. 19, pp. 90-96.
27. *A retrospective study of 66 titanium cranioplasties.* J. Joffe, B Aghabeigi, E.Davies, M.Harris. 1993, British Journal of Oral & Maxillofacial Surgery, pp. 144-148.
28. *Custom cranioplasty using stereolithography and acrylic.* P. D'Urso, W. Earwaker, T. Barker, M. Redmond, R. Thompson, D. Effeney, F. Tomlinson. 2000, British Journal of Plastic Surgery, Vol. 53, pp. 200-204.
29. *Prospective Study on Cranioplasty with Individual Carbon Fiber Reinforced Polymere (CFRP) Implants Produced by Means of Stereolithography.* Wurm, Gabrielle, et al. 2004, Surgical Neurology, Vol. 62, pp. 510-521.
30. *Custom-made cast titanium implants produced with CAD/CAM for the reconstruction of cranium defects.* E. Heissler, F. Fischer, S. Bolouri, T. Lehmann, W. Mathar, A. Gebhardt, W. Lanksch, J. Bier. February 1998, International Journal of Oral and Maxillofacial Surgery, Vol. 1998, pp. 334-338.
31. *Prefabricated prostheses for the reconstruction of skull defects.* H. Eufinger, M. Wehmoller, A. Harders, L. Heuser. 1995, International Journal of Oral and Maxillofacial Surgery, Vol. 24, pp. 104-110.
32. *CAD/CAM titanium implants for cranioplasty--an evaluation of sucess and quality of life of 169 consecutive implants with regard to size and location.* H. Eufinger, C. Rasche, M. Wehmoller, K. Schmieder, M. Scholz, S. Weihe, P. Scherer. 2005, Internationl Congress Series, Vol. 1281, pp. 827-831.

33. *Medical rapid prototyping and 3D CT in the manufacture of custom made cranial titanium plates.* J. Winder, R. Cooke, J. Gray, T. Fannin, T. Fegan. 1, 1999, Journal of Medical Engineering and Technology , Vol. 23, pp. 26-28.
34. *Computer generated titanium cranioplasty: report of a new technique for repairing skull defects.* J. Joffe, P. McDermott, D. Linney. 1992, British Journal of Neurosurgery, pp. 343-350.
35. *Engineering Assisted Surgery: A route of digital design and manufacturing of customised maxillofacial implants.* b July 2007, Journal of Materials Processing Technology, Vol. 183, pp. 333-338.
36. S. Bhat. *Biomaterials Second Edition.* Harrow : Alpha Science International Ltd., 2002. 1-84265-207-9.
37. T Hin. *Engineering Materials for Biomedical Applications.* s.l. : World Scientific Publishing, 2004. 981-256-061-0.
38. G. Winters, M. Nutt. *Stainless Steels for Medical and Surgical Applications.* West Conshohoken : ASTM International, 2002. 0-8031-3459-2.
39. *Get Hip with Medical Metals.* Hunt, M. April 1991, Materials Engineering, pp. 27-30.
40. *Advanced superplastic forming and diffusion bonding of titanium alloy.* O. Kaibyshev, R. Safiullin, R. Lutfullin, O. Valiakhmetov, R. Galeyev, A. Dutta, T. Raghu, G. Saha. 3, 2006, Materials Science and Technology, Vol. 22, pp. 343-348.
41. *Analysis of the SPF of titanium alloy at lower temperatures.* E. Chumachenko, V. Portnoi, L. Paris, T. Billaudeau. Elsevier, 2005, Journal of Materials Processing Technology, Vol. 170, pp. 448-456.
42. *Applying Superplastic Forming Principles to Titanium Sheet Metal Forming Problems.* W. Swale, R. Broughton. Trans Tech Publishing, 2004, Material Science Forums, Vols. 447-448, pp. 239-246.
43. *Superplastic deformation in Ti alloy IMI 834 and alpha-2 titanium aluminide.* A. Wisbey, M. Kearns, P. Partridge. Elsevier, 1994, Materials Letters, Vol. 21, pp. 31-39.
44. *Biocompatibilty of materials and development to functionally graded implant for bio-medical applicaiton.* F. Watari, A. Yokoyama, M. Omori, T. Hirai, H. Kondo, M. Uo, T. Kawaski. Elsevier, 2004, Composites Science and Technology, Vol. 64, pp. 893-908.
45. D. Brunette, P. Tengvall, M. Textor, P. Thomsen. *Titanium in Medicine.* New York : Springer, 2001. 3-540-66936-1.
46. *Analysis of errors in medical rapid prototyping models.* J. Choi, J. H. Choi, N. Kim, Y. Kim, J.K. Lee, M.K. Kim, J.H. Lee, M.J. Kim. International Association of Oral and Maxillofacial Surgeons, 2002, International Journal of Oral and Maxillofacial Surgery, Vol. 31, pp. 23-32.
47. *Generation of a finite element MESH from stereolithography (STL) files.* **E**. Bechet, J.C. Cuilliere, F. Trochu. 2002, Computer-Aided Design, Vol. 34, pp. 1-17.
48. Simpleware. [Online] Simpleware Ltd. . www.simpleware.com.
49. Renishaw. [Online] http://www.renishaw.com.
50. *An orthotropic flow rule for superplastic Ti-6A1-4V.* D. Mosher, P. Dawson. Elsevier, 1994, Mechanics of Materials, Vol. 19, pp. 59-72.
51. *A state variable material model for superplastic titanium-6Al-4V.* D. Mosher, P. Dawson. 1992. TMS.
52. *Silicone rubber mould cast polyethylmethacrylate-hyroxyapatite plate used for reparing a large skull defect.* H. Rotaru, M. Baciut, H. Stan, S. Bran, H. Chezan, A. Iosif,

M. Tomescu, S. Kim, A. Rotaru, G. Bacuit. 2006, Journal of Cranio-Maxillofacial Sugery, Vol. 34, pp. 242-246.
53. Jarvik Heart, Inc. Jarvik Heart. [Online] 2004. www.jarvikheart.com.
54. *Development of the NEDO Implantable Ventricular Assist Device with Gyro Centrifugal Pump.* M. Yoshikawa, K. Nonaka, J. Linneweber, S. Kawahito, G. Ohtsuka, K. Nakata, T. Takano, S. Schulte-Eistrup, J. Glueck, H. Schima, E. Wolner, N. Yukihiko, Y. Nose. Internationl Society for Artificial Organs, 2000, Artificial Organs, Vol. 24, pp. 459-467.
55. Spine Universe. [Online] 2007. www.spineuniverse.com.

VITA

Daniel Lee Thomas was born on May 1st in 1984 in Henderson, Kentucky. He received a B.A. degree in Mechanical Engineering from the University of Kentucky in May 2006. He received an IREE grant from the National Science Foundation to pursue the current research. His Master's degree is funded through a GAANN fellowship.