DESIGN AND FABRICATION OF CRANIOPLASTY PROSTHESES: FIT EVALUATION BETWEEN PHANTOM-BASED HAPTIC ENVIRONMENT AND MATERIALISE 3-MATIC SOFTWARE

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ABSTRACT: Two different design methods for customized cranioplasty prostheses are presented in this paper. The first approach is designing the digital model of the cranial implants in a haptic environment, utilizing a combination of a PHANToM haptic device and a freeform software called Claytools. The other method makes use of a software solution provided by Materialise Inc. known as 3-matic. Next, the skull models and the designed implants are fabricated via stereolitography (SLA). Finally, the implants' fit over the skull models are evaluated to determine the most accurate method.

KEYWORDS: *SCranioplasty Prostheses, Haptic Environment, 3-Matic Software, Stereolitography.*

1.0 INTRODUCTION

Trauma, cranial tumors, infected craniotomy bone flap and external neurosurgical decompression can be the main causes for skull defects or deformity. Cranioplasty is the method of treatments of the skull defects such as mentioned above [1]. Cranioplasty involves surgery and cranial implants, which are required to protect the underlying brain and to correct skull's aesthetic due to major deformities.

One of the important aspects that is mainly focused in research is the design and fabrication of the cranial implants. In conventional method, implants were manufactured using clay and wax by the medical sculptors by hand. Nowadays, however, the use of CAD tools to regenerate or reconstruct the skull surface has been combined with the conventional clay technique. This combination has proven to be highly effective relative to the conventional method, but as it requires a huge amount of manual input, it still takes a long time to produce the implant [1]. In addition, the design stages cost is high, considering the labor and materials used [2]. Moreover, a tiny modification will require the entire model to be built again from the scratch. Human error due to the hand sculpturing processes also provides a room for improvement in terms of precision and accuracy of the implants design.

Several studies on design and fabrication of cranioplasty had been conducted for the past decades. As in [2], they compared two completely software based methods for the use of designing and fabricating the Ti implants. In one they employ STL file models to generate 3-dimensional skull models from CT scan data. The 3-D model is then used to mirror the portion of the skull which is intact. Boolean operations are then used to obtain the implant design. In another method, slice data from the IGES file formats was used and NURB based curve and surface fitting algorithms were carried out to generate an approximate implant design for the defect. Significant reduction in time was achieved by researching these two methods, not only individually, but also in conjunction with each other, in order to get an implant design. Costs on fabricating the implants with different materials are also briefly discussed.

Utilization of CAD/CAM to produce cranial implant is also discussed by [4]. The method is proven to overcome the soft tissue problem occurred on implants built using conventional method. However, the details on materials, methods, and cost are not discussed. There is also a method known as “The Leeds Method” [5], introduced by Leeds Dental Institute. Titanium plate is built for reconstruction of large craniofacial defects, by the means of using modeling wax to fill in and recontour to the correct shape of the skull, followed by producing flasked model and cutting the plate based on the guideline created. This method is proven to decrease titanium waste. Other works by [1] has investigated the use of haptic devices for the use of designing the implants. Such an approach allowed the designers to have an intuitive understanding of the structure of the implant while designing it.

This study will utilize the creation of the digital model for the cranial implants using two different methods. The first one uses CT data to create the model using haptic device, with the assist of software known as Claytool. The other method will utilize one of the modules in Mimics, software provided by Materialise Inc., called 3-Matic. This method will not require any external device.

Additive manufacturing (AM) processes have been used for fabricating biomedical implants such as stereolithography (SLA), selective laser sintering (SLS), 3D printing and fused deposition modeling (FDM). Among these processes, SLA is the most adaptable method with the highest accuracy and precision [3]. Its working principle is based on spatially controlled solidification of a liquid photo-polymerisable resin. Using a computer-controlled laser beam or a digital light projector with a computer-driven building stage, a solid, 3-dimensional object can be constructed in a layer-by-layer fashion. Thus, SLA has been chosen to fabricate the implants using biocompatible resin.

2.0 MATERIALS AND METHODS

The objective of this study is to design cranial implants using two different methods and directly fabricate the implants using SLA, and to compare the results between the different approaches. CT scan data from two real patients were obtained and used throughout this study.

2.1 Phantom-Based Haptic Approach

For this approach, CT images were obtained and MIMICS software was used to extract only the bony areas and reconstruct the 3D model of the skull. After converting the model into STL file, it was imported in to the Claytools modeling system, which was used in conjunction with the PHANToM Omni (as shown in Figure 1), a haptic device which provides force feedback to the operator.

Figure 1: Phantom Omni Basic device with 6 degree-of-freedom

The combination of Claytools software and the haptic device create a virtual reality environment which allows the user to interact with the computer base on tactile feedback. As depicted in Figure 1, using the device, user can perform the virtual sculpting of the implant through actions like deforming, cutting, smoothing, etc. When a satisfactory model of implant is achieved, the plate will be saved into STL file and then loaded into software called Magics.

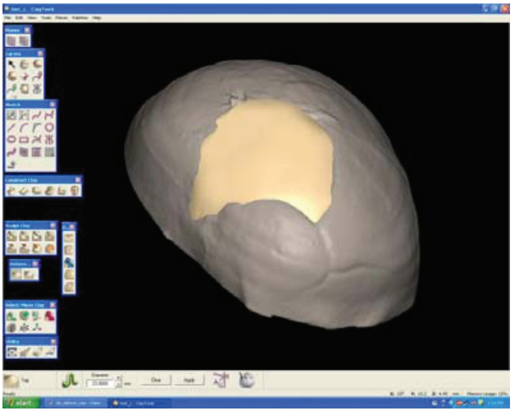

Figure 2: Implant designed in virtual scuplting environment

Magics was used to performed Boolean operation on the implant and the skull model. Boolean operations subtracted the skull from the combination, producing smooth edges around the plate and also produce a flat area around the edge to help the plate sit and fit nicely on the skull (Figure 3). Then, again, the booleaned plate was loaded into Claytools for finishing and trimming operations. These operations typically involving the removing of "satellites" around the plate and smoothing the surface of the plate. Finally, the plate was saved into STL file and ready to be loaded into an EBM machine.

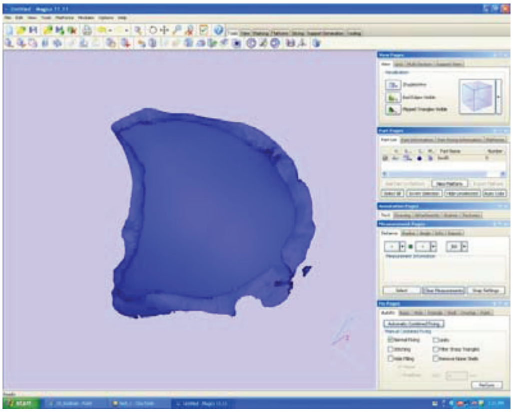

Figure 3: Boolean operation performed in Magics software

2.2 Designing With 3-Matic

Unlike Claytools, 3-Matic does not use any assists from a haptic device. 3-Matic is a module in Mimics that allow user to design complex implants. Using Mimics software, CT scan data of the patient's skull was processed. By varying the threshold values, the cranium and loose bone parts were calculated from the image data. To ensure that the inside surface of the implant did not interfere with the meninges; a Mimics segmentation of the same was also made.

To ensure the proper fitting of the implant, reliable design references need to be use, especially when designing an implant that covers a large defect. For this purpose, the meninges and the loose bone parts lying on the meninges could be used. The design of the implant obtain using 3-matic could be either convex, concave, or combination of both, depending on the type of defects and the complexity of the design. A pattern of holes could also be designed, through which the muscle could be attached during surgery. Finally, the design was saved into STL file and ready to be loaded into an EBM machine. Figure 4 shows a complete implant design in 3-Matic software.

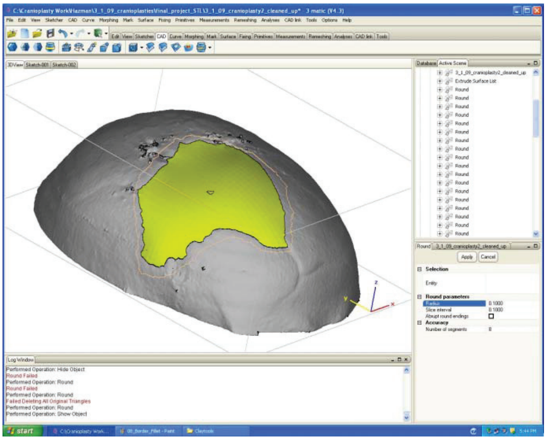

Figure 4: Complete implant design in 3-Matic

2.3 Build Preparation

The completed parts from Claytool and 3-matic were produced using stereolithography (SLA). However, before the parts can be loaded into the machine, the files need to be "prepared" first, known as the build preparation stage. 3D Lightyear software package was used for the SLA build preparation. First, the parts were arranged on the build platform in the manner such that they will not violate the build envelope of the machine (Figure 5). In addition, the z-height should be small enough to minimized overall build time. Then the STL files were fixed, to eliminate problems such as missing triangles, overlapping triangles, intersecting triangles, etc. which may cause errors to the built process or the part itself.

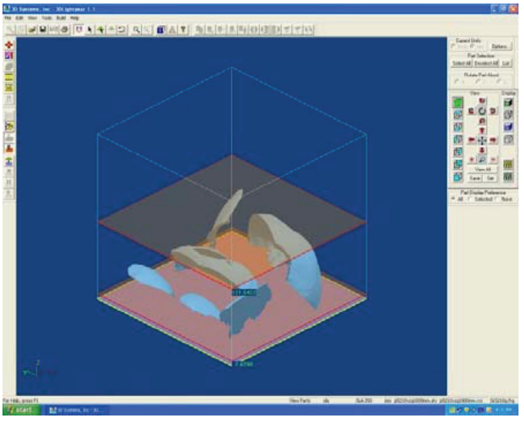

Figure 5: Parts arrangement on the build platform

After the STL files were fixed, support structure as generated for each part as shown in Figure 6. The function of this structure is to support overhanging parts during the build process. The final step before loading the files into the machine was performing slicing. This procedure sliced the file into layers (with pre-defined thickness) which allow the machine to read the contour layout of each slice.

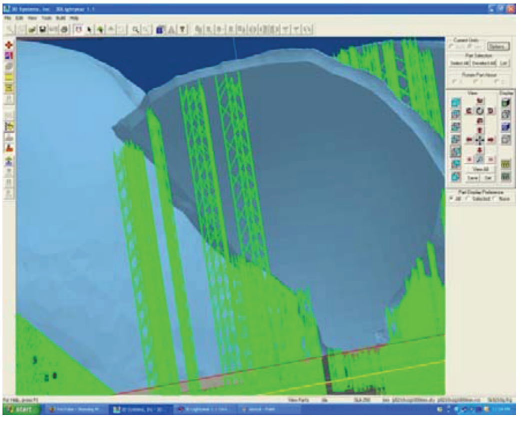

Figure 6: Generated support structure

2.4 Parts Cleaning and Completion

Completed parts are removed from the machine and cleaning process need to be done before the parts are ready for evaluations (Figure 7). The support structure was hand removed and the parts were cleaned chemically using tripropylene glycol monomethyl ether (TPM) to remove unreacted photosensitive resin. Finally, the parts were cured in the ultraviolet (UV) oven for several hours.

Figure 7: Completed SLA parts before the cleaning process

3.0 RESULTS

Figure 8 and Figure 9 below shows the final skull models and parts that were used for the evaluation purposes:

Figure 8: Models of defective skull (top: case 1, bottom: case 2)

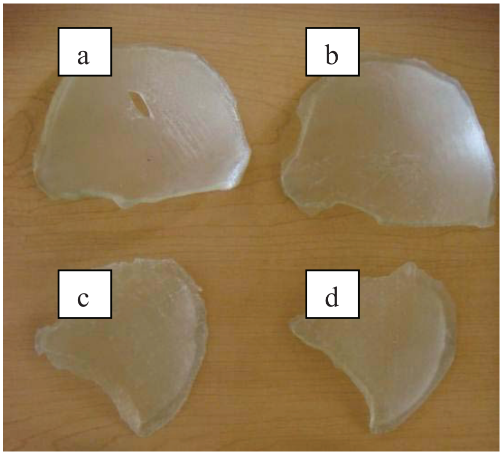

Figure 9: Models of cranioplasty prostheses (a) case 1 with Claytool (b) case 1 with 3-Matic (c) case 2 with 3-Matic (d) case 2 with Claytool

3.1 Qualitative Fit Evaluation

Fit evaluation had been done qualitatively between the prosthesis models and the correspondent skull. The factors evaluated consist of the rigidity of the plate on skull and the distance between the edges of the plate to the edge of the defect. Figure 10 to Figure 13 below show the comparison for both parts designed by these softwares.

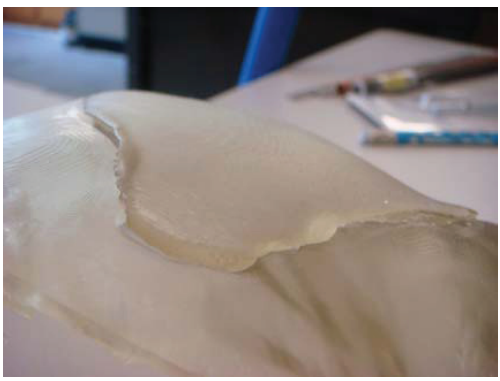

Figure 10: Fit between Claytool case 1 prosthesis & skull

Figure 11: Fit between 3-Matic case 1 prosthesis & skull

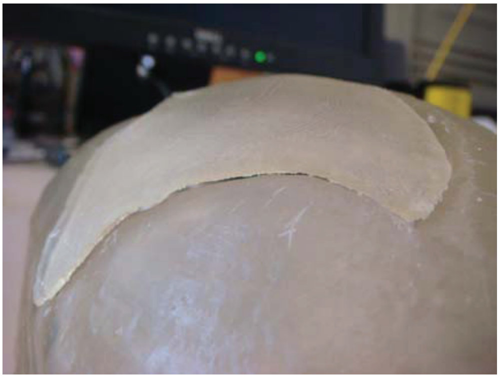

Figure 12: Fit between Claytool case 2 prosthesis & skull

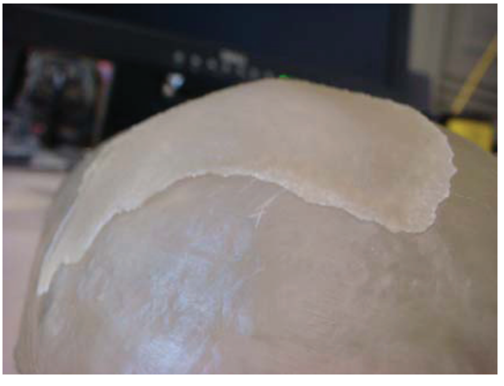

Figure 13: Fit between 3-Matic case 2 prosthesis & skull

4.0 CONCLUSION

Design and fabrication of cranioplasty prostheses using two different approaches has been explored in this paper using a PHANToM haptic device (with Claytool software) and a software solution provided by Materialise Inc. known as 3-matic. The results from the qualitative evaluation clearly indicate that the parts built with the 3-Matic software have better fit or accuracy towards their respective skull models. The learning curve for the 3-Matic software is also easier and it takes less time to design a part.

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