Design Methodology of a Personalised Wrist Orthosis for Fractures and Rehabilitation

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***Abstract*—The goal of this study is to develop an expeditious methodology for designing an orthosis which can be used both for wrist fracture immobilisation and later rehabilitation. This requires an orthosis that can (depending on the patient's needs) be flexible or fully stiff. It is possible to achieve this by making the orthosis out of a flexible material and by adding external plates for stiffness (which can be removed when the orthosis is used for rehabilitation purposes). Another reason why the orthosis should be made of a flexible material is to ensure that it can adapt to changes in swelling that may appear during the healing process. The design of the orthosis is expeditious in order to facilitate possible practical application of the methodology in clinics.**

I. Introduction

Currently distal radius fractures (DRF) are one of the most common fractures in clinical practices [1]. Additionally, these fractures have seen an increase in regions such as the United States and Scandinavia, which can make them a substantial burden on a country's healthcare system [1]. The DRF impedes functionality and prevents people in partaking in everyday tasks. The standard treatment technique is based on applying plaster casts, which have multiple drawbacks (weight, ventilation, hygiene, etc.).

Up to this point, numerous papers have been published on the topic of personalised hand, wrist and arm orthoses which were developed using 3D scanning, reverse engineering (RE) and additive manufacturing (AM) [2-18]. As these papers have clearly shown, 3D scanning, RE and AM are well suited for the development of personalized medical devices (and various other custom products), due to the freedom of design that they offer. Additionally, personalized orthoses have the potential to become widely available due to the fact that the cost of AM machines and optical 3D scanners has been dropping in response to more manufacturers joining the market and the rapid development of the technology.

Different research teams have had various approaches in creating a personalized orthosis. The most common approach is based on orthoses which are made entirely by 3D printing [2-11]. Naturally even hear there are divisions in the way different researchers have tackled the problem. Some have made orthosis that consist of two distinct halves which can be joint around the arm in order to fully immobilize it [2-9]. Others have made orthoses which consist of a single part which can be attached to the hand with bands (these models do not span the entire girth of the hand) [9-11]. Another interesting approach is the hybrid orthosis model which consists of two parts: an inner structure which is made with 3D printing (personalized to the user) and the outer cover made with injection molding [12]. This methodology has the added benefit of lower manufacturing time and cost [12]. The papers published up to this point focus on orthoses that offer full immobilization of the wrist joint and are meant to be used right after the fracture occurs. When the healing process has finished it is followed by a rehabilitation period in which the wrist joint is still vulnerable and thus in danger of injury. Furthermore, swelling is a factor that can follow wrist fractures and as it subsides, a non-flexible orthosis would allow for clearance between the internal surface of the orthosis and the external surface of the arm, there by defeating the purpose of the orthosis.

Therefore, we propose a design methodology for a personalised orthosis which can address both the healing and rehabilitation needs of a patient. This means that a single orthosis can be used both for fracture immobilization (with plates attached) and wrist joint protection during rehabilitation (without plates attached). This methodology is based on the use of two techniques (Fig. 1): 3D scanning and reverse engineering.

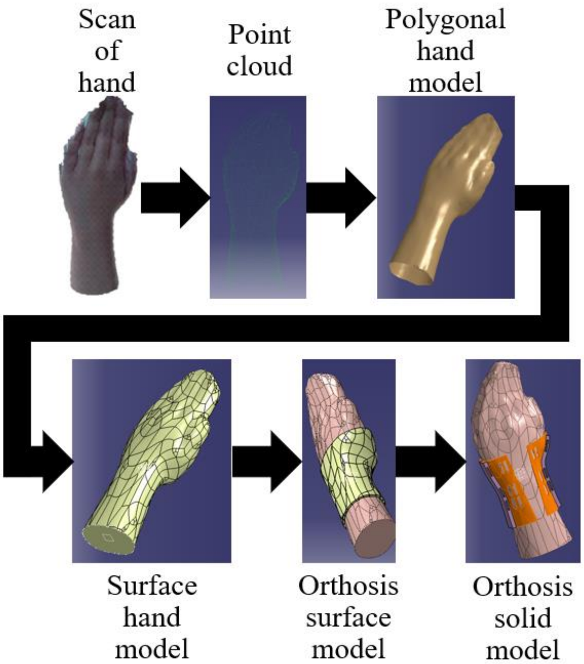

Figure 1. Design methodology of the orthosis

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Additionally, the orthosis is designed so the users can move their fingers freely for optimal functionality. Finally, it must be made so the patient can easily attach and remove it without additional assistance. The development process has been planned in such a way, that the time from data acquisition to a CAD (Computer-aided design) model of the orthosis does not last more than 4 hours.

Because we were developing this methodology without previous experience, we chose to make this attempt a trial run and thus we used the hand of a healthy subject for planning and testing the methodology. This was done to avoid prolonging someone's recovery, due to unforeseen circumstances during the design and production of the orthosis. The next study could look into the clinical application of the proposed methodology.

II. 3D Scanning

The first step was making a 3D scan of the hand, wrist and arm area. Multiple options were considered:

- CT scanner (as used in [7]),
- contact scanner and
- optical scanner.

In order to make the procedure as expeditious as possible and with the goal of using a scanner with the minimal price, an optical 3D Systems Sense RS scanner was chosen. During the scanning procedure the elbow was bent at an angle of 90^{o} (it was positioned horizontally), while the scanner was rotated around it in a full circle.

The CT scanner would offer a more precise scan but would needlessly irradiate the patient. Previously, while working on a project that developed a personalised dog leg prosthesis, we developed a methodology where a contact scanner (Roland MDX-15) is used to scan the residual part of a lost limb. This was done by creating an imprint of the body part with a dental die mixture, which was then used to make a plaster model of the residual part of the limb. This plaster model can then be used for the scanning procedure, but this would not be practical in context of time and cost (die mixture and plaster) when compared to an optical scanner.

During the scanning process we realized that it can be difficult for the subject to keep the hand in a straight position. This could further be made difficult because of pain caused by a wrist joint fracture. Also, some of the scans were unsuccessful (multiple tries were needed for a successful scan) due to the scanner losing tracking. This occurred because of relative (hand to scanner) changes in distance and because of the arm not staying in a completely straight position. This poses a question whether an additional system should be used for a more efficient scanning procedure.

Li and Tanaka presented a mounting system for a 3D System Sense scanner in their paper [13], which would be useful in this regard. They found that by using this system they could bring the scanning time down to 20s, where as it took us around 60-120s to complete one full scan [13]. Furthermore, a group of researchers from Italy, developed a specialised system called the hand-wrist-arm (HWA) scanner which uses multiple RGB-D sensors to acquire a scan in about 1.2s [14]. Further research should be carried out to compare the benefits and flaws of all three scanning techniques with special emphasis on: scanning time, precision, adaptability to different body parts and the overall prices of the scanner. By doing so an optimal system can be adopted or developed from the listed systems.

III. Reverse Engineering

After the scan (Fig. 2) has been completed it can be imported in to the Catia V5 software as a point cloud, where it can be further processed using the Digitized Shape Editor, Generative Shape Editor and Quick Surface Reconstruction modules.

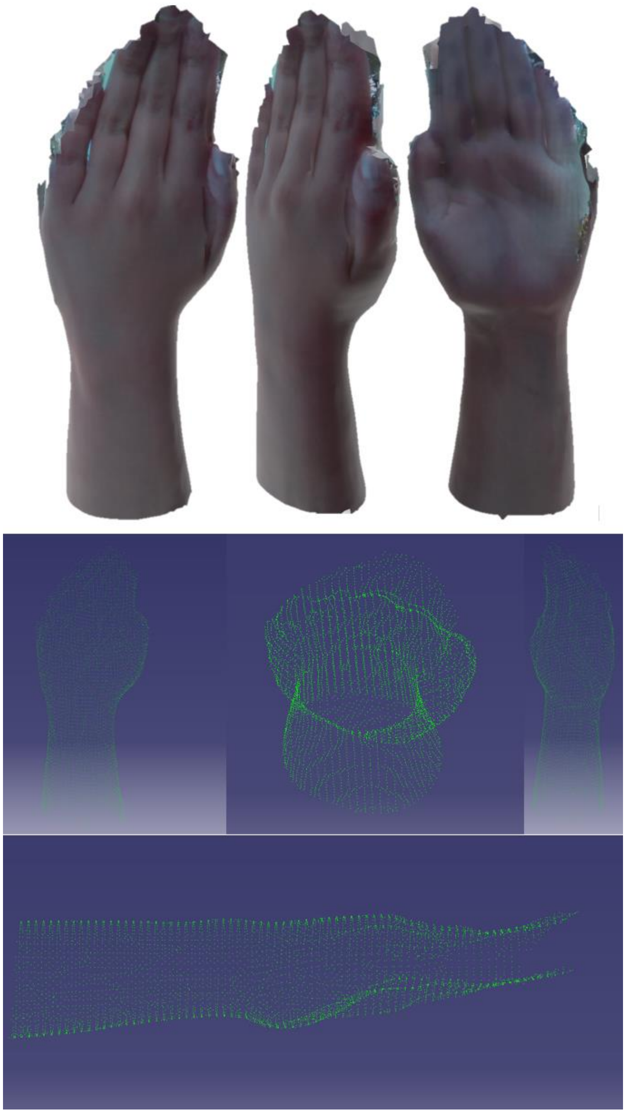

Figure 2. Scan of the hand, wrist and arm area

Firstly, the Remove tool (Brush mode) was used to remove the surplus points, after which a polygonal (mesh) model was created from the remaining points by using the Mesh Creation tool. Next the Fill holes tool was applied in order to close the holes in the created polygonal model, after which the Mesh Cleaner and Mesh Smoothing tools were used in order to make an even finer mesh (Fig. 3).

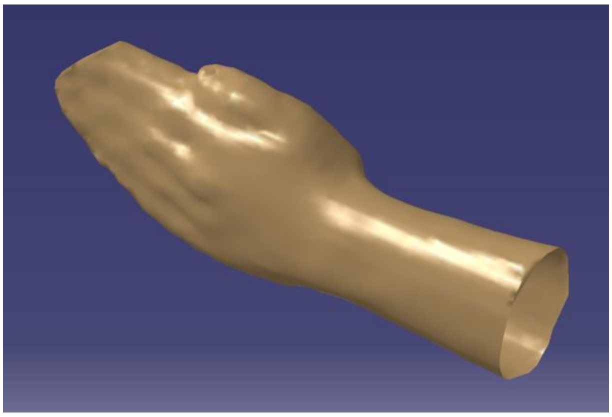

Figure 3. Polygonal model of the hand, wrist and arm area

Then the Automatic Surface tool (from the Quick Surface Reconstruction module) allowed for an expeditious creation of a surface model. The Split tool was then used (from the Generative Shape Design module) in order to make the open end of the surface model planar. Next the Boundary tool is used to make a curve that defines the edge at the open end of the surface model, which is then closed using the Fill and Join tools (Fig. 4).

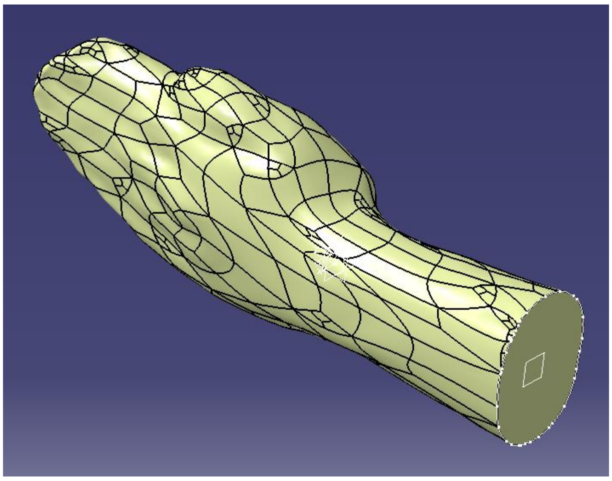

Figure 4. Surface model of the hand, wrist and arm area

Based on the surface model from Fig. 4 and using the Split tool the superior and inferior part of the surface model were removed in order to define the basic surface model of the orthosis (that has a length od 95mm). After this the Offset tool was used in order to create the external surface of the orthosis (the offset value is 2mm). The Boundary, Close and Join tools were then used to close the holes that are present in the offset surface, after which the same tools were used to define the edges of the internal and external surfaces of the orthosis (four curves) which were also closed producing a surface model of the orthosis (Fig. 5).

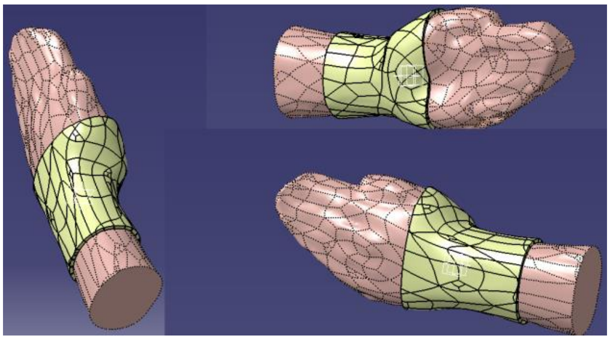

Figure 5. Surface model of the orthosis

The Close Surface tool was then used to create a solid model of the orthosis (Fig. 6).

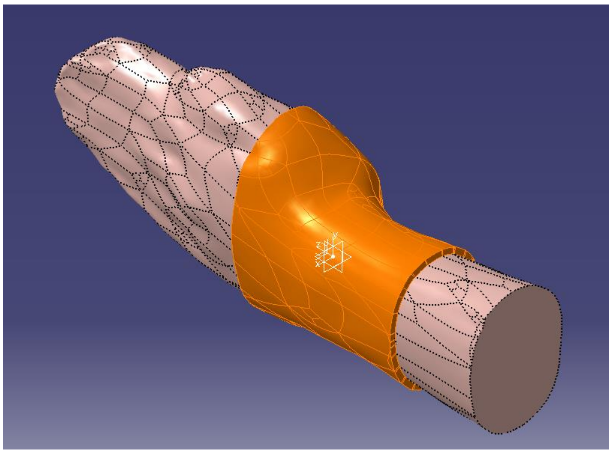

Figure 6. Solid model of the orthosis

Using the Sketch, Extrude and Remove tools, a portion of the top part of the orthosis was cut out and openings for Velcro strips where made (Fig. 7).

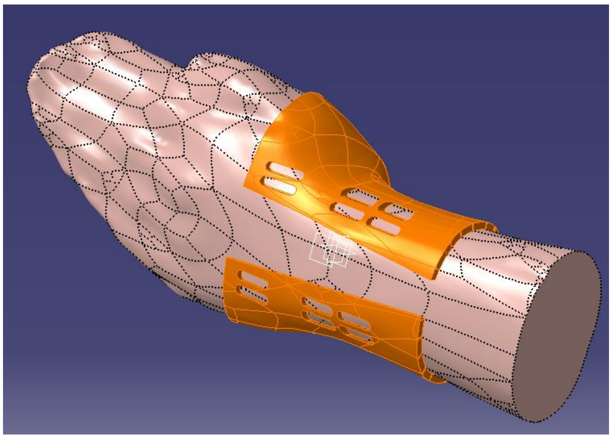

Figure 7. Orthosis model

The orthosis model from Fig. 7 when made out of flexible material and tightened to the hand using Velcro strips can be used to limit the angle of flexion for the wrist, which can be helpful to protect the joint during rehabilitation. But in order to achieve full immobilization (needed to heal a fracture), additional sturdy plates are added to stiffen the orthosis and prevent any movement in the wrist joint. This was done by using the Intersect tool in order to define the intersection contours of the orthosis and the frontal plane. The Sketch tool was then used to create external closed contours which follow the intersections of the orthosis. Finally, these sketches were extruded, after which holes for the Velcro strips were made (Fig 8.).

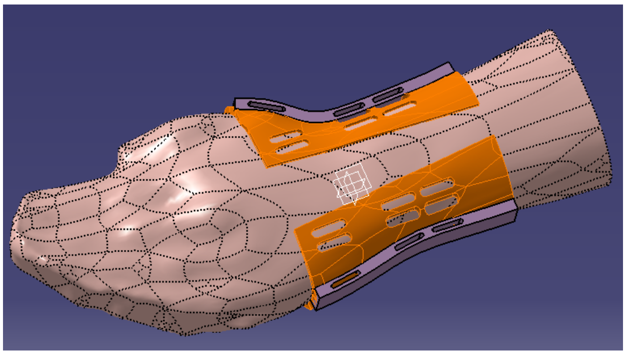

Figure 8. Orthosis and plates models

IV. CONCLUSION

This study showcases the methodology used in the design of a personalised orthosis which can be used both during the fracture healing process and rehabilitation. Additionally, due to its flexibility it can adapt to changes of hand geometry that follow a decrease in swelling. The orthosis would be produced out of plastic and rubber materials and because of this it would be water-resistant. Thus, it would not have the hygienic drawbacks present with traditional plaster casts.

The orthosis is designed so the users can move their fingers freely for optimal functionality. Furthermore, a patient can easily attach and remove the orthosis without additional assistance. The development process has been planned in such a way, that the time from data acquisition to a CAD (Computer-aided design) model of the orthosis does not last more than 4 hours. The short design time also indicates a great potential for using the presented methodology in clinical practice.

ACKNOWLEDGMENT

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