Solid Freeform Fabrication 2017: Proceedings of the 28th Annual International
Solid Freeform Fabrication Symposium – An Additive Manufacturing Conference
Reviewed Paper

Design Optimisation of a Thermoplastic Splint

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Key words: Patient Specific, Design, 3D printing, Orthosis, Optimisation

Abstract

Following partial hand amputation, a post-surgery orthosis is required to hold the remaining ligaments and appendages of the patient in a fixed position to aid recovery. This type of orthosis is traditionally handmade and fabricated using laborious and qualitative techniques, which would benefit from the enhancements offered by modern 3D technologies. This study investigated the use of optical laser scanning, Computer Aided Design (CAD) and Material Extrusion (ME) additive manufacturing to manufacture a polymeric splint for use in post-surgical hand amputation. To examine the efficacy of our techniques, we take an existing splint from a patient and use this as the template data for production. We found this approach to be a highly effective means of rapidly reproducing the major surface contours of the orthosis while allowing for the introduction of advanced design features for improved aesthetics, alongside reduced material consumption. Our demonstrated techniques resulted in a more lightweight and lower cost device, while the design and manufacturing elements afford greater flexibility for orthosis customisation. Ultimately, this approach provides an optimized and complete methodology for orthosis production.

Introduction

The use of orthotics devices post-surgery is an important part of the overall patient recovery process, particularly with respect to cases involving the upper limbs, such as hand/arm amputations (Carl R. Chudnofsky 2010) and shoulder joint replacements (Browner et al. 2014). The orthosis allows for vital load bearing support of the patient's residual appendages and whilst their remaining ligaments/musculature recover (Cross 2014). Traditionally, such orthotic devices are custom made, using thermoforming plastics, conforming to the natural anatomy of the patient, providing a configuration to stabilise the residual appendages in a desired orientation for directed recovery (MacDonald, Chinchalkar & Pipicelli 2016).

Modern 3D technologies are now allowing for unprecedented accuracy and flexibility for product development, with benefits to be seen in terms of 3D data acquisition (Treleaven & Wells 2007), how design iterations can be explored and developed and the final manufacturing of the prototype and functional devices (Bagaria 2015; Mohammed et al. 2016). Given the overwhelming potential of this technology as a transformative product development paradigm, we have seen adoption across multiple fields ranging from sports technology, prototyping of commercial products, and with a considerably large uptake for medical applications (Mohammed, Fitzpatrick & Gibson 2017; Mohammed et al. 2017). More recently, the use of such technology for orthotic development and production is a highly emerging area (de Jesus Faria 2017; Fitzpatrick et al. 2017; Kelly 2015; Lasane 2013; Paterson et al. 2015; Summit 2007), but also is a largely underexploited area of interest. We predict with the rise in the net global, and in particular aging, populations, such developments would become of growing interest and necessity in the coming decades.

In this study, we aim to develop a streamlined methodology for next generation orthotics production which leverages the advantages of emerging 3D technologies. As a case study, we examine an existing orthotic device made for a patient who has undergone a partial hand amputation, assess the merits and limitations both in terms of efficacy, ergonomics and aesthetics, and apply a combination of optical scanning, CAD and additive manufacturing to redevelop the part to address these limitations. We discovered optical scanning allows for rapid virtual reproduction of the orthosis (1-2minutes). The use of CAD can allow for the incorporation of intricate open structures alongside part thickness tolerance considerations; something not readily achievable using traditional fabrication techniques. Finally, additive manufacturing using ABS Material Extrusion (ME) printing readily reproduces the intricacies of the CAD design, producing a robust and superior final orthosis. We believe our findings would provide guidance to orthotists to streamline partial amputation orthotics and potentially provide a range of alternative orthotics for both the upper and lower limbs.

Original orthotic assessment

In the present case study, we examined an orthotic device made for a patient who had undergone a partial amputation of their hand (thumb and index finger). The devised splint was required post-surgery to help support and fix the mobility of the ligaments, nerves, and tendons to aid in the recovery process. Such devices are normally made using a thermoformable plastic, made of cured polyester resin, which has been the industry standard for several decades (fig 1). The plastic is available in a range of thicknesses (1.6-5.0mm), and can have small holes regularly spaced within the bulk of the material, with the intension of providing porosity for moisture release.

It is typically found however that such orthotic devices made from this material are generally quite uncomfortable for patients, due to both weight and excessive moisture build-up (even when using the perforated version), which causes issues such as chaffing. In worst-case scenarios, excessive moisture build-up and chaffing can result in ulceration (Gregory P. Guyton 2005). Additionally, the aesthetics of the device generally makes patients feel highly self-conscious of their condition, resulting in issues with respect to wider societal inclusion. We therefore identified that modifications could be made to the design to reduce the weight (in this case approximately 110g) to reduce strain on already compromised musculature, while introducing design elements, such as open structures, to both minimise moisture retention and improve the overall aesthetics.

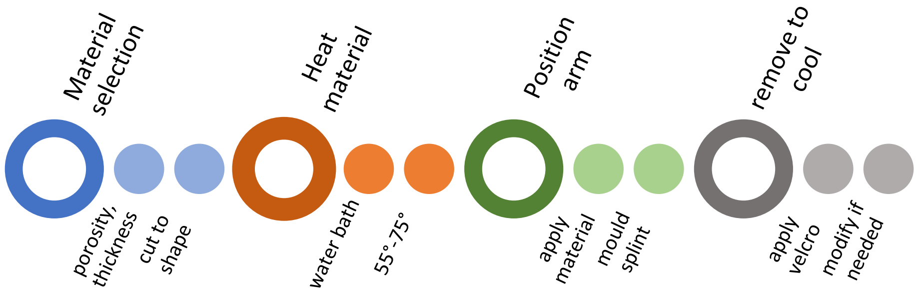


Fig 1. A diagram illustrating the typical phases of traditional upper limb orthotic production

Methodology

Optical Scanning and Digitisation

The current thermoplastic splint was virtualised using a Kreon Solano 3D laser scanner (Kreon, Belgium), attached to a 7-axis rotatable arm for ease of scanner translation. The scanner uses a red laser line, with a wavelength of 610-630nm (George et al. 2016), and a triangulation method of measurement. To perform a scan, the laser line is translated over the object at a fixed distance to build up the point cloud data profile for a respective surface. Once an exposed surface has been recorded, the orthosis was re-orientated to scan additional surfaces until the entire profile was obtained.

The scanner creates a point-cloud data file within its proprietary software, which requires post-processing to remove any outlying data points and any unwanted additional scan data from the surrounding environment. Once post-processing is complete the point-cloud forms the basis of the final 3D model. After cleaning, the dataset was solidified into an STL (Stereolithography) format. The STL model was measured virtually and compared to measurements taken from the physical model. The exported STL file was then taken into 3-Matic STL (Materialise, Belgium) for further error correction to ensure model integrity for 3D printing. Following this procedure, the virtual model was again checked for dimensional accuracy.

Orthotic Design

The exported model, once taken into 3-Matic STL, is in the same orientation as the scan was taken. Designs were developed using the original orthosis topography as the basis. At this stage, we use the data to introduce a parametric tile pattern (Figure 3.2) into the bulk of the digital structure. The pattern is scaled according strength and aesthetic requirements and it must be ensured that there is an effective boundary. To create this Surface map, a surface contour must be defined. This Surface is used to create a UV map (Policarpo et al. 2005). Using the UV mapping process, the chosen design can be applied to the surface in 3-Matic STL (Fitzpatrick et al. 2017). Using the applied map, the design can be subtracted from the blank model using the texture function, removing any unwanted sections. As the applied map is an image file, the borders of the pattern edges are jagged, this is due to the subtraction process as well as the tessellation of the model prior to this operation. This is fixed using the surface smooth function in the software.

Next the model is again checked for accuracy to ensure the design process has not moved any of the external faces which may affect comfort. Following this, FEA (Finite Element Analysis) is performed on the design to ensure mechanical integrity for the intended application. The variables that could change within the design are the splint thickness and the spar thickness. This could be an iterative process that would involve a dialog between the designer and the client. This is then verified for 3D printing and exported to the slicing software.

Manufacturing

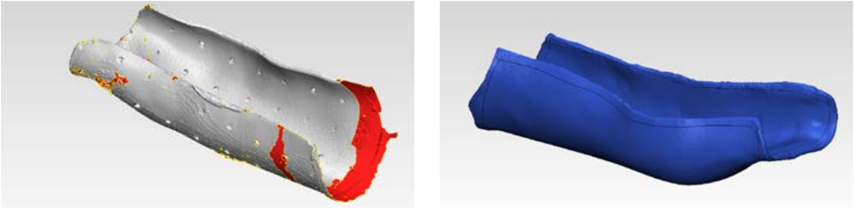
We opted for polymer-based ME as the preferred additive manufacturing method, which allowed for accurate reproduction of the developed design, whilst also being suitably low cost to serve as a method for mainstream orthosis production. The final design was printed using ABS plastic, due to its low cost and suitable mechanical and biocompatibility properties, and with the orthotic device orientated upright in the Z build direction. Initially, preliminary design iterations were printed using a Zortrax M200 ME printer (Zortrax, Poland). However, due to build volume constraints, the optimum orientation could not be reached, in addition to printed models being relatively weak. It did however allow a test fit model to be created at a much lower cost than the final splint. To overcome the mechanical and size constraints a Fortus 450M (Stratasys, USA) FDM printer was utilised to produce the final orthosis.

<u>Results</u>

Virtualisation

The time taken to 3D scan the splint accurately was around 45 minutes. This was because the scanning arm was unwieldy to use. A turn table would have made it easier, but it wouldn't have worked with the current scanner as it uses the arm to register its position rather than the surface topology. The aim was to get the splint scanned in one pass, rather than stitching multiple scans together. Although more time-consuming, this made the result more accurate (see fig 2).

The accuracy of the virtual model produced was +/- 0.1mm using a scanner resolution of around 16µm, measured within 3-Matic.



(a) (b)

Fig 2. The initial scan of the splint and the resultant cleaned model

The process of virtualisation was made easier as it was scanning an inanimate object. It would be made inherently more difficult if the scan was of a human subject as any movement would be shown in the scan.

Design process

The integration of end user input is an important aspect in customised designs, such as what we hope to achieve with the developed splint design. This is a trend that has been increasing within other fields of engineering (Collins 2016). However, this is a concept that has had a hesitant uptake in the medical devices industry (Money et al. 2011), but there are indications that this is beginning to change (de Jesus Faria 2017). Having control over the design of the treatment device has been shown to increase the quality of life (Fayers & Machin 2013).

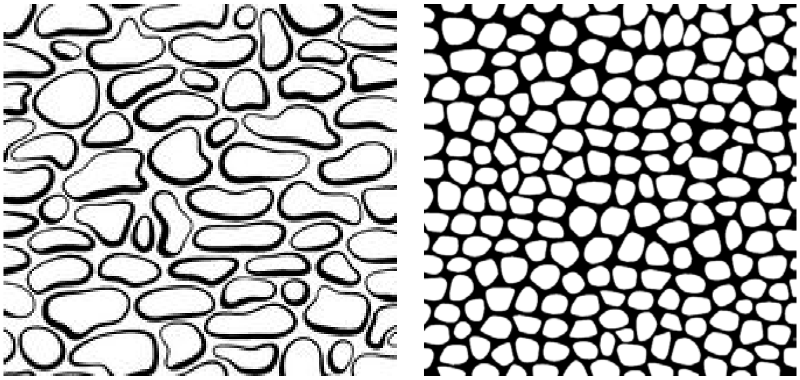

(a) (b)

Fig 3. Design variants chosen by the end user.

To examine facets of user based design, we selected two arbitrary, yet aesthetically pleasing designs (Fig 3) from the perspective of the researchers in this study, and assessed for viability for the splint. From preliminary design evaluations, the pattern in Fig 3(b) was chosen for the final design as it provided a greater strength throughout the splint. Additionally, this design was advantageous as manufacturing required less support material and could be achieved comparatively more quickly.

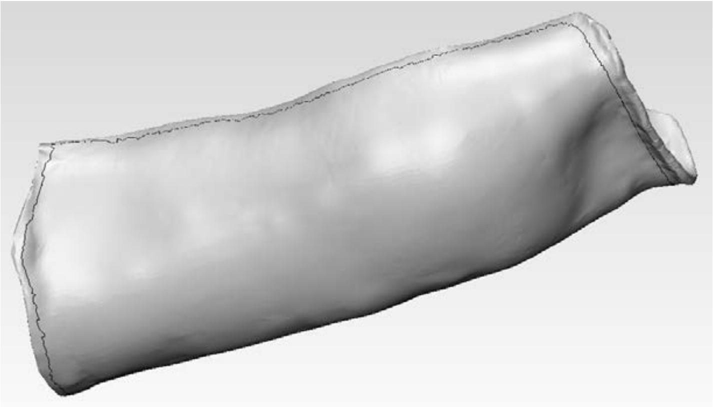


Fig 4. Surface contour defined for the virtual model.

The mapping process first requires the definition of the surface, leaving a border around the external contours of the virtual splint, shown in fig 4. The reasoning for this is to allow enough room for an adequate border around the splint to ensure its strength and stability.

The pattern is then applied to the UV map. This is then resized, positioned and rotated until it is in the correct orientation. Shown in fig 5, the UV map is shown alongside the wrapped model. This allows the accurate positioning of the pattern and to ensure the borders will have adequate support. The thinking behind the border was to minimise the sectioned holes, as they would be filled in the next step to increase the size of the splint border and to integrate the design seamlessly.

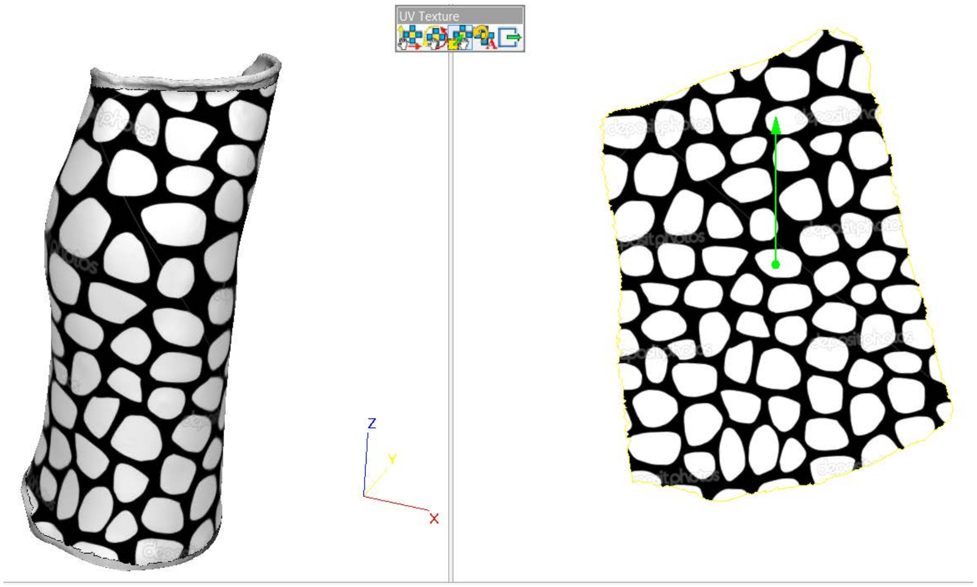
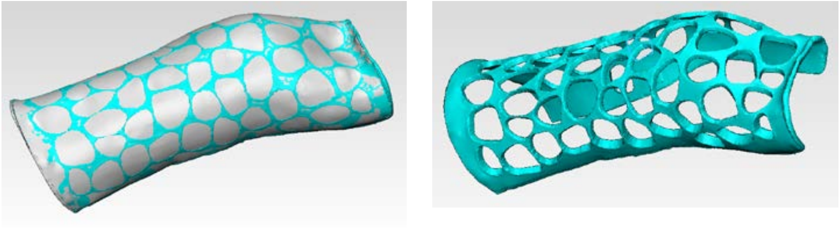


Fig 5. The wrapped model shown alongside the UV map.

Following the texture application, the model is modified using the 2D to 3D texture function in 3-Matic STL. The function gives the user the options of offsetting the surfaces positively or negatively in the direction normal to the surface. Using the external surface of the splint for the texture mapping, the white sections were offset through the splint, while the blue surfaces remained in a fixed position, as shown in Figure 6(a). At this stage, the model was error checked again, to ensure no digital anomalies (inverted normal, overlapping triangles, etc). The resulting splint model is shown in Figure 6(b).



(a) (b)

Fig 6. Splint overlayed with a textured model and the final model

The accuracy of the model following the design application stays the same as the scanned model. This is because borders and datum points were used to ensure any design variations wouldn’t affect the applicability of the model. Any changes that were made to the splint were completed on a duplication of the original scan. This was to assess the accuracy of the model through the design period.

This is completed in both 3-Matic STL as well as Magics (Materialise, Belgium), allowing for a smaller file size and the slicing software to quickly process the model.

Additive Manufacturing allows more complex designs to be manufactured. Using ME to print the model, the design needs to be as self-supporting as possible to minimise the material used in manufacture.

Following exporting the STL files, renders were done in Showcase (Autodesk, USA) for colour and design approval, shown in fig 7. Additive manufacturing allows the production of multiple pieces in a variety of colours, giving the end user the ability to pair the splint to their outfit for example.

(a) (b) (c)

Fig 7. Resultant models in colour variants

The current splint design was constrained by the aesthetic and ergonomic properties of the thermoplastic splint, however performed relatively satisfactory from a biomechanical stand point. For this reason, we aimed to retain these aspects such that the overall longitudinal rigidity, rotational stiffness and latitudinal compressive strength were equivalent in the developed splint. As the pattern in Fig 3(b) would result in a more open, porous structure in the bulk of the splint, we needed to ensure that all compressive or shear forces would be even distributed throughout the design. As our primary intension in this study was to demonstrate the design and product realisation facets of the splint, we hope to address this in future studies.

Manufacturing

The Splint took 23 hours to print, with 58g of ABS. The print was completed with the splint lying flat of the print bed. This was due to height restrictions in the Fortus. Because of the orientation, the splint required support. The weight of support used was 50g contributing to a slower build time.

The initial model printed on the Zortrax, and the final part, completed on the Fortus, (shown in fig 8.), acted very differently under load, with the Zortax model fracturing relatively early. This could have been due to the orientation that it was printed at. More work will be completed to characterise each of the designs and the mechanical properties that are affected by design changes.

Fig 8. Result after manufacture

Discussion and future work

Comparing the thermoplastic and 3D printed splints, some of the notable differences between these approaches are;

- The reduction in weight, with a possible 60% reduction
- The breathability of the AM splint should be considerably better in comparison to the thermoplastic, due to the open pore design.
- The comfort of the splint, due to the reduction in weight and sweat build up, should be considerably better with the AM splint.

Furthermore, indications are that the splint should chaff less as the design doesn't appear to move in relation to the body as much. The aesthetic appeal of the splint can be adjusted to suit the user, with even the possibility of having a number of variants to suit aesthetic requirements

Future work planned will take a more quantitative perspective, looking at the engineering properties of the design variants, material properties, stress, fracture load, etc. Being able to characterise the splint properties by varying the design constraints should provide a better quality of life for the end user, as well as make it easier to manufacture the splints. A variety of designs can be assessed, allowing the end user to have a wider range of patterns that can be easily designed and manufactured, while ensuring the correct care is provided.

The major problem to be solved is reducing the overall time to create the orthosis from start to finish. A more effective scanning method is being developed that will scan the upper limbs in real time. We are also working on optimising the design process to streamline the scan data manipulation whilst incorporating the aesthetic design components and maintaining mechanical integrity. Finally, we have chosen a Delta configuration ME system (Anzalone et al. 2015) which will allow the construction of larger orthoses to suit the upper limb with minimal supports. All of these approaches will considerably speed up the design and build process.

The materials that have been used in this study, will be assessed and compared in a future study. The study will look at the variation on materials with a standard design. These results will be compared to other materials that are used in current splinting practices.

Conclusion

Concluding this study, it was found that the current thermoplastic splint, whilst effective, it does not seem to be a perfect solution. The use of 3D printed splints can enable tailoring to suit the end-user's preferences, potentially increasing the quality of life during the treatment process. This can aid in the end-user's recovery as well as allowing the return to normality without the stresses of wearing something that they are not content with.

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