

# Design and additive manufacturing of a patient specific polymer thumb splint concept

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## Abstract

Traditionally, upper limb splints often fall short of being optimal with respect fit and patient expectations, resulting in a lack of use and no treatment of the underlying condition. In this study we address several current limitations and examine the feasibility of using 3D optical scanning, Computer Aided Design (CAD) and low cost 3D printing as a tool to create more ergonomic and efficacious splints for patients suffering from compromised musculature or trauma of the thumb. Optical scanning allows for a non-invasive and rapid means to reproduce the surface topology of a person's hand and this data was used as the template for the device design. We explore the use of CAD to create a more aesthetically pleasing and functional splint, enhancing both comfort and potential moisture release. Finally, we demonstrate that low cost polymer printing can allow for rapid design evaluation and production of a final, usable device.

Keywords: Splint, 3D Printing, CAD, Patient Specific, FFF, Polymer, Orthotic

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## 1 Introduction

The use of splint devices is the traditional benchmark treatment option for patients suffering from a large range of musculoskeletal conditions of the upper limb, both acute and chronic [1, 2]. Health professionals, such as Occupational Therapists, Physiotherapists and Orthotists with specialised training use several processes to manufacture custom made splints designed to meet the clinical requirement of a specific condition. Failure to produce a splint that meets these requirements, can impact recovery and can result in long standing deficits to the patient. Ultimately, reduced function of the upper limb may impact on the patient's ability to complete Activities of Daily Living (ADLs), maintain employment, pursue leisure activities and even their participation in the community.

The current clinical practice is to immobilise the target anatomy using a splint device. Immobilisation is typically achieved using plaster of Paris, which can be highly restrictive and uncomfortable for the patients. Splints can comprise either an "off the shelf" pre-made variant, or a custom device made from a thermoplastic material. The choice of which is implemented is typically

based on the judgement of the healthcare professional. Fabrication of a custom made upper limb splint can be a complex process by the necessity to tailor requirements to the individuals needs with respects to anatomical variances, aesthetic appearance and cost. From the practitioner's perspective, additional factors relating to cost, easy of manufacture and the suitability of available materials to achieve the desired end result play a part in the decision making process. Unfortunately, even with the provision of custom made splints, using the current techniques and materials the rate of non-adherence is relatively high, with comfort, splint appearance, influence on ADL's being cited as areas of concern [3]. As the devices are also handmade, there is the issue of variability in the device and its effectiveness between different clinics, which further confound this issue. Therefore the current accepted process for manufacturing upper limb custom made splints has the opportunity to be challenged, with new technology, design and processes implements to better meet the needs of the people who require these types of splints.

Additive Manufacturing (AM) is an emerging fabrication methodology which allows for the construction of products using a systematic 'additive' layer by layer build process and in complex configurations that would not be otherwise attainable using traditional manufacturing processes [4, 5]. Indeed AM allows for the relatively straight forward realisation of highly complex digitally generated models, with minimal user inputs to the manufacturing process, or intimate knowledge of the materials they are fabricated from. Such versatility in the build process is resulting in a disruption of traditional manufacturing paradigms, with impact in several major industries ranging across the automotive [5, 6] to the medical sectors [7-9]. With respect to the medical industry, AM's potency to disrupt existing practises stems for the ability to reproduce even the most complex of human forms in what has been described as patient specific devices, with practical examples being demonstrated for patient centric bone replacement implants [8], prosthetics [10] and rehabilitation/splint based devices [11-14]. The potential of this technology is enhanced further by the alignment of technologies to rapidly digitally reproduce the complexity of the human form, with demonstrations using both optical surface scanning [15, 16] and medical imaging [7, 10] data sets.

More recently, AM technologies have been utilised toward the development and production of custom splint devices [12, 15, 17-19]. Researchers are aiming to leverage the advantages found in non-contact data digitisation, advanced Computer Aided Design (CAD) and AM to realise more patient centric designs which overcome limitations of current devices and provide a less intrusive experience for the patient during the orthosis creation. With respect to current limitations of current splint devices, insights have revealed a range of factors relating to the non-adherence of wearing an orthoses [3, 18]. Factors include difficulties keeping splints clean/dry, poor aesthetical qualities, discomfort due to poorly fitting devices, compromised ability to perform routine tasks and odour related issues. It is believed that the versatility of CAD and AM can be applied to address these issues, realising more ergonomic and aesthetically appealing designs, tailored to the individual's unique needs and priorities.

In this study, we examine the use of high resolution optical surface scanning, CAD and AM to develop a new patient centric thumb splint device. We initially use optical scanning to rapidly capture a person's hand anatomy while they maintain the position for the final form of the thumb splint. We then convert the captured data into a three dimensional digital model, which is used as the template to form the splint device. We examine the ideal tolerances of the device alongside design features to ensure ease of fit, while still maintaining potential therapeutical effectiveness desired by a standard thumb orthosis. An open porous design is also examined to create an aesthetically appealing device, which more readily allows for the release of trapped moisture on the skins as compared to a tradition splint [12, 19-21]. Once a final design was derived, the model was manufactured using Fused Filament Fabrication (FFF) in ABS polymer to assess the final device and its potential for use in place of a

traditional thumb splint. Overall, we believe we have developed a robust methodology for thumb orthosis design and manufacture in a form which is more ergonomic, provides better fit and aesthetic qualities.

## 2 Existing Thumb Splint Fabrication

The short thumb spica splint is a commonly used splint that can be used across a number of musculoskeletal conditions including acute ligament repair, bone fracture and osteoarthritis of the thumb. This splint was specifically chosen to challenge the technology being studied as the desired immobilisation position the hand is one of the more challenging orientations to achieve in a respective device. The thumb position for the splint is vital to ensure the correct anatomical position is achieved, whilst also allowing functional use of the hand by maintaining freedom of the metacarpophalangeal joints of the fingers and interphalangeal joint of the thumb, whilst not restricting the natural action of the wrist. A low temperature thermoplastic (Aquaplast, OPC Health, Australia) is used to manufacture this splint, a material that is both strong and flexible enough to meet the requirements of this type of design, and the typical material used by the orthotist assisting in this study. An overview of the fabrication workflow can be seen in Figure 1.

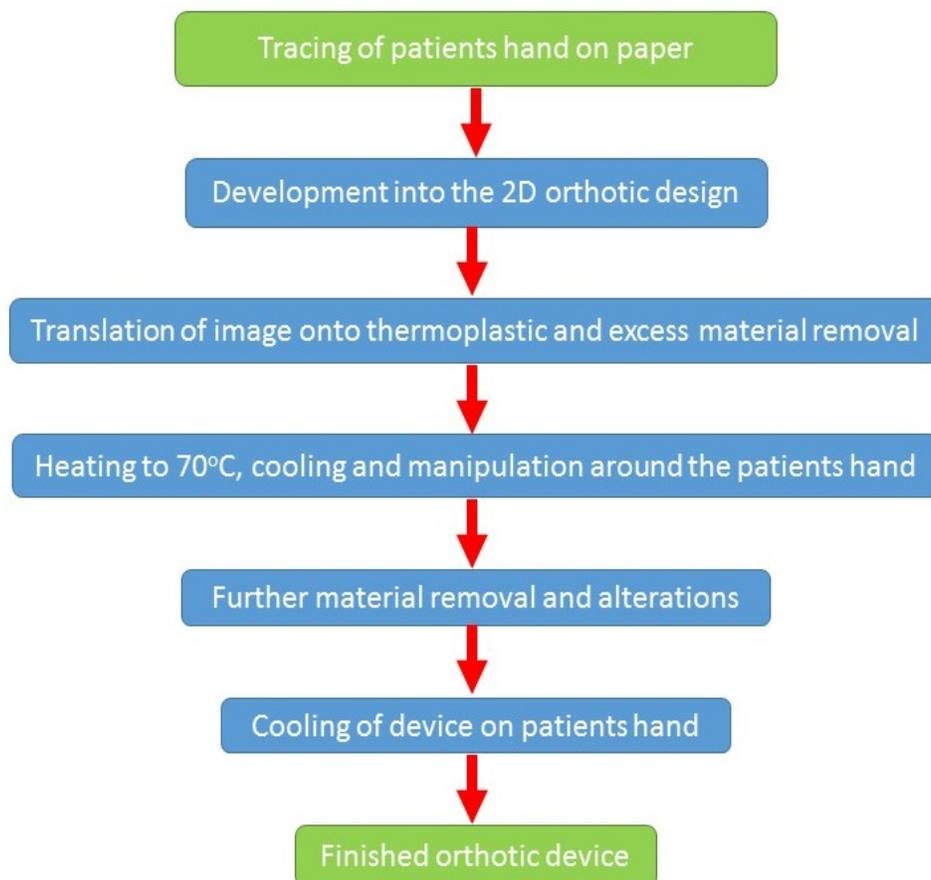


Figure 1: A diagram of the typical workflow performed by an occupational therapist to design and fabricate a thumb splint

In this study we asked a local orthotist to design a thumb splint for the volunteer in this study, which would act as a comparison for the device we will develop in this study. The technique described is a relatively typical example of how a thermoplastic thumb splint is created. The initial stage of the manufacturing process requires the health professional to create a template of the hand, this is commonly done by tracing an outline of the hand on paper/card and marking significant anatomical landmarks, such as the fingers, thumb, etc. A preliminary splint design is then traced over this template, and if the health professional is happy with the design, this is transferred onto the thermoplastic. The thermoplastic is cut to size and then heated in a hydroculator (heat bath) to the specified temperature of the thermoplastic, in this study this was approximately 70°C. The health professional then places the patient's upper limb into the required position ensuring that the thumb, fingers and wrist are in the correct orientation. This position is often held by the patient for several minutes while the health professional removes the thermoplastic from the water, lets it cool to a safe temperature and then places this directly onto the patient to mould the splint to the patients hand. This process relies on the skill and knowledge of the health professional to be able to mould the splint as required, in addition to the ability of the patient to maintain the desired position. Once the thermoplastic has cooled, it begins to harden and can be removed from the patient for any additional alterations. Alterations can include cutting away of excess material, addition of straps to secure the splint or any other modifications as required. If further alterations are required, the thermoplastic can be reheated but there is a risk it may lose its shape.

### **3 Methodology**

The primary elements of this study comprise the acquisition of a person data using optical scanning, construction of a 3D anatomical model of the hand, the development of the orthosis from this scan data, the manufacturing of the device and the final evaluation. A summary of a typical workflow can be seen in Figure 2.

#### **2.1 Optical Scanning**

Surface topography scans were obtained using a light reflectance scanning system (Spider, Artec, Luxembourg), which is minimally invasive and utilises visible light, meaning scans can be performed with no health risks to the person being scanned. The scanner has a scan resolution of approximately 50-100µm, which allows for both the major anatomical form and minor details such as creases in the skins surface to be resolved. In this study the scanner was set to a resolution of 500µm which was considered suitable for the level of detailed required to be captured. The scanner is designed to work alongside a propriety software package (Artec Studio 10, Artec, Luxembourg) which streamlines the data acquisition phase and allows for real-time visualisation of the capture process.

To capture a surface of an object, the scanner is activated and held as a constant distance of approximately 50cm from the object, before being translated around the object to build up a surface profile. Care must be taken to not translate the scanner too quickly (>10cm/s) or to move to far away from the optimal imaging distance or the scanner loses tracking of the object. A typical scan procedure can be completed within 3-5 minutes. The scanner software also allows for the data processing of the scanned surfaces to remove spurious data points, noise and unwanted scan data. The software is also capable of rudimentary smoothing and fixing processes to create an enclosed 3D model, but generally does so with some degree of data loss of finer details. Therefore, such operations were performed independently using CAD software to retain the model details.

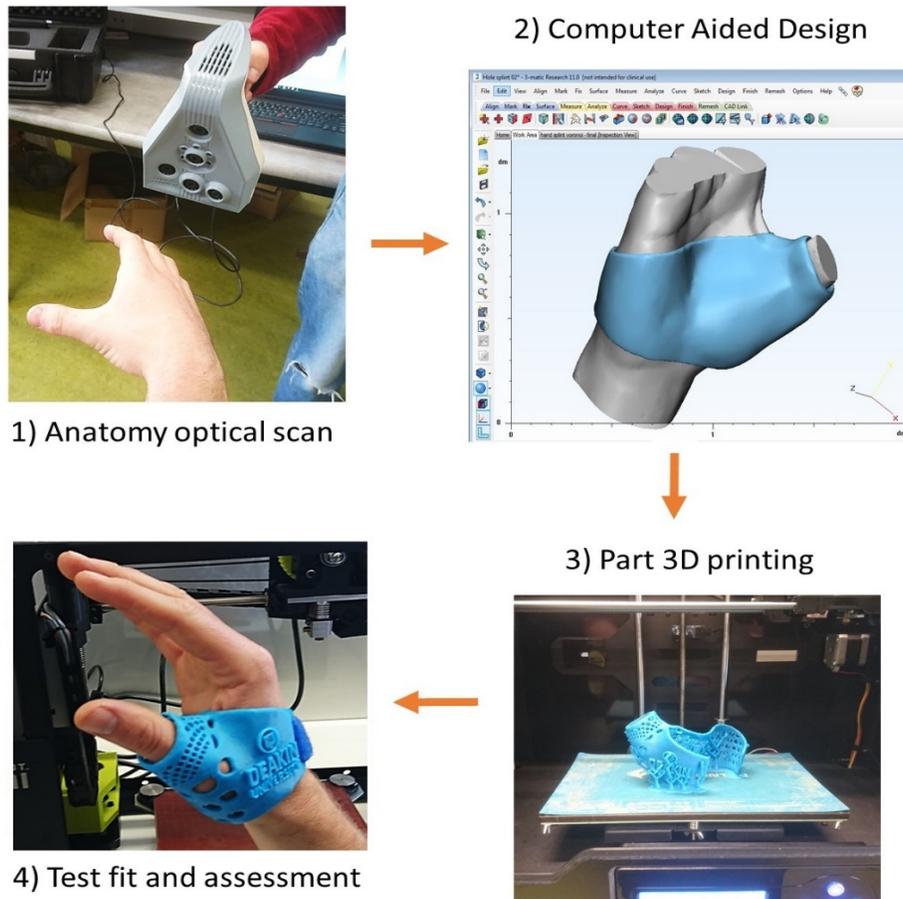


Figure 2: A diagram illustrating the workflow from data capture to final production of the thumb splint device.

## 2.2 Computer Aided Design

The scanner data was post processed using the CAD software 3-Matic STL 10.0 (Materialise, Belgium). Initially, the model was checked for digital errors before, some minor smoothing operations to improve the consistency of the data. Following this the model was remeshed to improve the consistency of the overall mesh, before the data was suitable for construction of the thumb splint. The splint is realised using an approach of applying multiple surface projections to create hand models that were 0.5mm and 3.5mm thicker than the original hand model. The hollow form of the model was created using Boolean operations, followed by selective trimming to create the basic form of the model. In this study we examined an approach comprising a single piece splint design, which can be strapped to the person using a single piece of Velcro. This matches the typical configuration of traditional thumb splint device.

Beyond formation of the general shape of the device, we examined a technique of projecting a two dimensional pattern on the surface of the model, before extruding a three dimensional shape into the segments of the pattern as we have described previously [12, 19]. This variant of design was realised using 3-Matic STL (v10, Materialise, Belgium).

## **2.3 Additive Manufacturing**

Once a device design had been finalised, the resulting models were 3D printed to create the final thumb splint model. Designs were manufactured using Fused Filament Fabrication (FFF) using a Flash Forge Creator Pro (Flashforge Corporation, Zhejiang, China) in standard ABS material, which provides adequate material stiffness to manufacture functional models. When printing a hotend temperature of 232°C, bed temperature of 105°C and layer resolution of 0.2mm were employed. When printing, parts were orientated upright in the z-direction (Figure 2-3) to ensure the parts were printed with minimal support material and achieved the best cosmetic finish with minimal surface roughness.

## **3 Results**

### **3.1 Patient specific data acquisition**

The primary intension of this study was to develop a methodology for streamlined data capture and model development and so scanning procedures were performed on a healthy individual who suffered no complications with respect to the thumb and its mobility. For therapeutic effectiveness, the correct orientation for immobilisation of the thumb is in a position which was described by the orthotist as the shape the hand would make 'holding a soft drink can'. A picture of the hand position can be seen in Figure 2-1, where the fingers are curved inwards in an arc shape, while the thumb holds a position parallel to the fingers, equally with an arc shape. The volunteer was asked to hold this position with their arm partially extended to allow for easy access of the scanner. Once in position the scanner was translated through various orientations, at a fixed distance, to construct the various surface profiles of the volunteer's hand. It was found that the majority of the hand could be easily resolved with a single translation of the scanner. However, additional adjustment of the scanner capture acquisition time and image saturation had to be suitably adjusted to ensure reflection based aberrations were reduced to produce a well-defined image for capture. It was also found that the inner contours of the hand proved to be more challenging to scan due to scan acquisition issues and the awkward positions that the scanner had to be rotated into to capture the lower portion of the hand. In this instance we believe scanning issues stemmed from interference of the reflected light due to natural shadows of the hand or reflectance of the light away from the scanner detectors. To compensate for these issues, several adjustments were made to the scanner to perform scan using the 'fast fusion' function, which disregarded skin pigmentation data, as only topological data was required.

Following optimal scanner set up, the data acquisition phase was not without its own challenges. Firstly, minor movements of the volunteer's hand resulted in alignment discrepancies during the post scan image processing. For the most part this was a minor issue as the scanner software was found to adequately compensate for this. Secondly, and perhaps more importantly, there was a certain degree of discomfort described by the volunteer in having to keep their hand and arm still for the duration of the scanning while we were optimising the best technique for data acquisition. Once our scanning techniques had been optimised, a typical scan could be performed within the space of 2-3 minutes. We therefore acknowledge that should this technique be implemented in real circumstances there will no doubt be a period of user training to refine optimal scanning technique by a practitioner. Comparing this to traditional methods of capturing a person's anatomical data using thermal polymer moulding, the examined technique is both non-invasive, quicker and potentially provides greater accuracy in reproduction. We hope to further qualify these

differences in further studies. Ultimately, despite both techniques suffering some limitations, we concluded that the scanning approach was the superior of the two techniques.

Figure 3a) illustrates segments of the scan data captured of the volunteer's hand, where it was found that the final model could be adequately constructed from three separate scan data segments. It was also found that due to complications with data acquisition, the final form could not be adequately resolved to the point where an enclosed 3D model could be constructed, and so final finishing of the surface data was performed manually using CAD software.

### 3.2 Orthosis Design

Initially the surface data of the volunteer was manipulated to completed regions that were unable to be captured during the scanning phase. This was achieved in the 3-Matic software using a manual triangulation bridging, where regions of the model mesh were manually reconstructed to complete the form of the model. Figure 3b) shows the compiled raw surface data which was output from the Artec software alongside the final, trimmed 3D model of the hand.

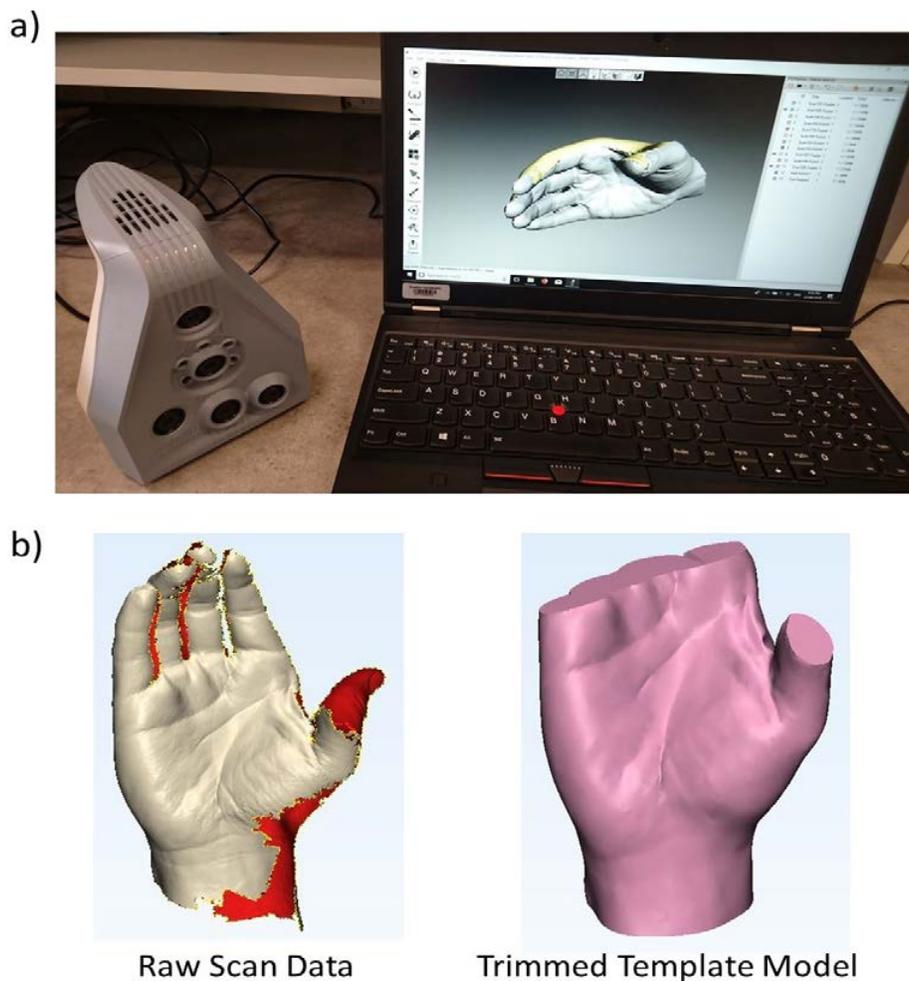


Figure 3: a) A picture of the scanner and image data processing equipment illustrating segments of the hand surface being stitched together and b) stages of the raw data from the scanner software to the final closed 3D model template data used for splint construction.

As a primary objective in this study was to create a more patient oriented splint, we use the model as the template to form the device. When manufacturing the splint, it is desirable to obtain a design which has adequate stiffness to resist the typical forces the patient may impose on the device to avoid breakages. Feasibly, the part could be deliberately made to larger thicknesses to increase the overall stiffness, thereby avoiding breakages. However, it is desirable to achieve a compromise such that the part is made as light and as thin as possible to increase the users comfort when wearing the device. From preliminary in house testing a thickness of 3mm was considered the ideal minimum thickness and so was used as the thickness tolerance for the final splint design. We hope to provide a more comprehensive evaluations of the stiffness characteristics resulting from varying part thicknesses in future studies.

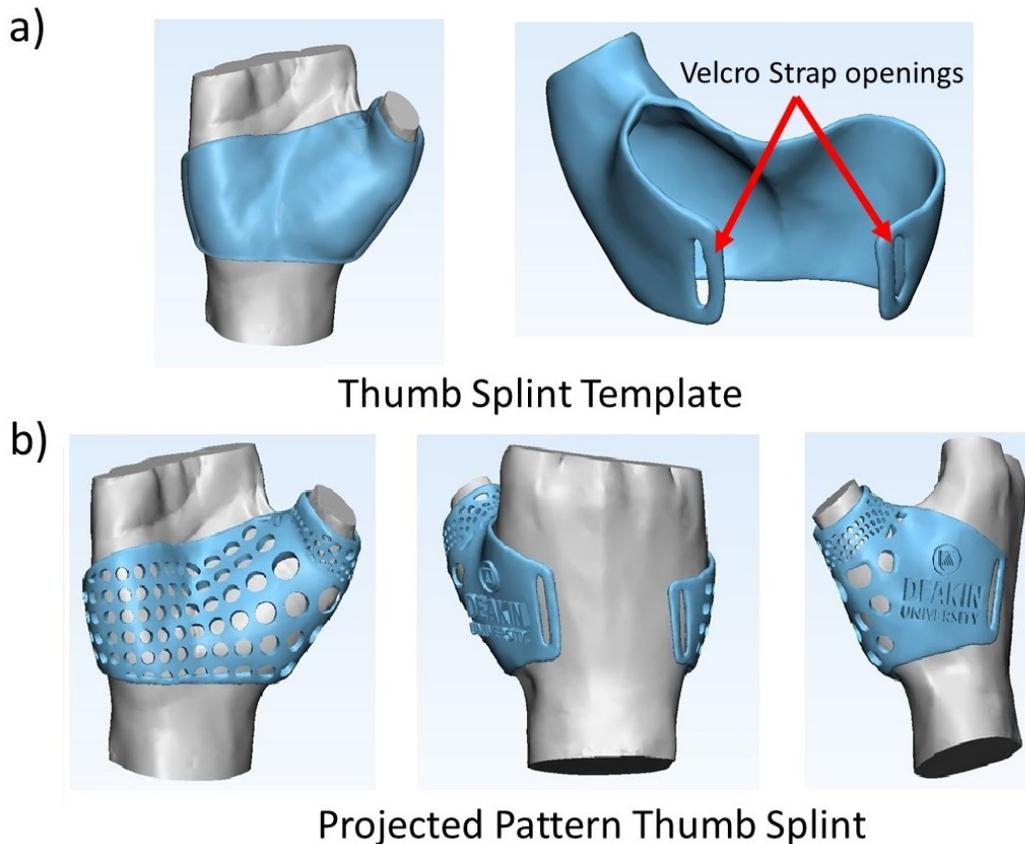


Figure 4: Various designs phases illustrating a) the thumb splint concept template and b) the final design of the projected pattern style splints.

The initial stages of forming the hand splint comprised the trimming down of the hand model to form a template of the how the splint will be located on the hand. To guide the trimming process, the distal palmar and interphalangeal creases of the hand were used, where a clearance of 10mm from the distal palmar and 5mm from the interphalangeal creases were used to ensure that the potential device would not restrict movement of the upper portion of the thumb, fingers and bending about the distal palmar. The lower portion of the splint was trimmed approximately 10mm above the crease of the wrist to ensure that when the splint was worn mobility was not compromised. From this template data, the surface of the models was extruded to 0.5mm and a second model to 3.5mm,

before a Boolean subtraction was performed to create a hollowed form of the splint. Then a region (65-70mm long and 25-35mm wide) relative to the back of the hand was trimmed and two recess holes created for the placement of a velcro strap. An image of the final template concept can be seen in Figure 4a). The digital template was now ready for application of the porous pattern and additional design stylisations.

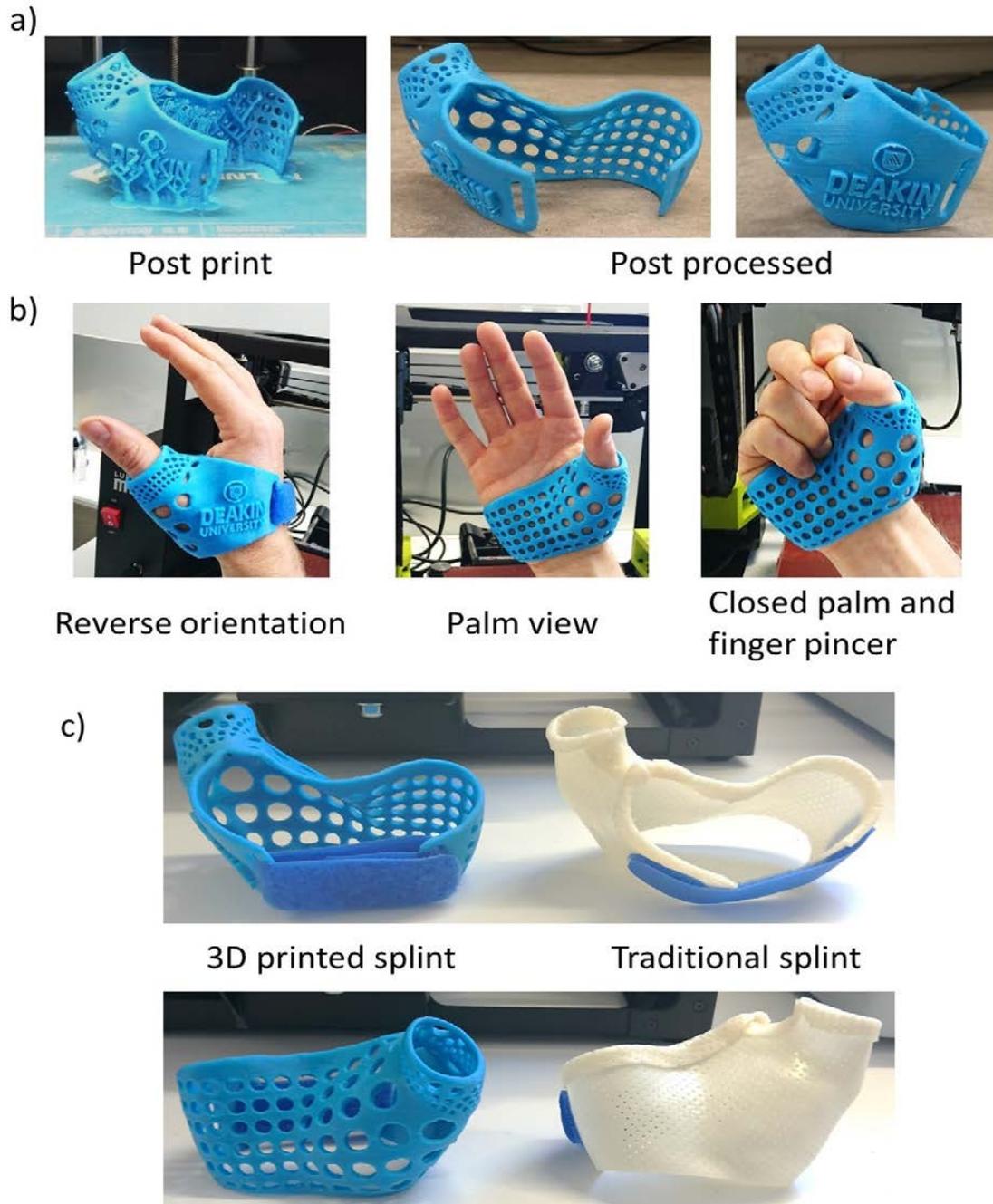


Figure 5: Images of the manufactured splint designs a) post print and post processed, b) being worn and used by the volunteer and c) compared to a traditionally designed splint.

To construct porous design, an approach using a 2D projected pattern was applied, similar to what has been described previously [12]. Firstly, the model is segmented to leave a border of 5mm around the edges of the model, alongside a patch around the back of the thumb. This border ensured that the porous pattern would not be applied around the edges of the model, which could result in stress concentration points, in addition to points which could potentially press into the wearer's skin. The region behind the thumb was to act as a platform onto which we would incorporate an example of a custom design feature to demonstrate the mass customisation potential of such splints. In this instance we incorporated the Deakin University logo onto the thumb model, as can be seen in figure 4b). For the remaining portion of the splint, a 2D pattern was projected onto the surface of the template and adjusted to give a complex, graded size to the pattern, further exemplifying the versatility of this approach. Once the projection was achieved a generic circle pattern was then extruded throughout this pattern resulting in the final design found in Figure 4b).

### 3.3 Manufacturing

The splint design was printed in ABS plastic using 100% infill to ensure the most robust part possible, and printed using a raft material to optimise print bed adhesion. As the part is to be worn, keeping the manufacturing surface roughness as low as possible was desirable to maximise comfort for the wearer. It was recognised that due to the complex form of the orthosis that support material would be required to ensure the integrity of the model during the build process. Despite this, initial tests were performed to examine if the design could be printed without the need for support material to both reduce the need for additional post process and to reduce additional material that could compromise the surface finish of the part, as the printer utilised the print material as the support material. All such printing attempts failed and so it was deemed necessary to use supports.

It was unknown what configuration of support material would be ideal and so two commonly used configurations were tested comprising 'rectangular' and 'tree like' branching types. Our settings for printing supports comprised overhang angles less than 40° and with a structure thickness of 3mm. Both configurations provided adequate support to reproduce the part in its entirety. Of the two structures, the tree like supports minimised the contact area with the part and were found to be the easiest to remove and so were considered the preferred choice of supports. It was found that in some instances, when the supports were removed there was residual material left behind on the model. To remedy this, a craft knife was used to scrape the bulk of the material off, followed by a light sanding using 120 grit sand paper, until a smooth finish was achieved. Following this methodology, a part was ready for use within 3-5 minutes following printing. Figure 5 illustrated the 3D printed part as it appeared from the printer, following post processing and in its final form containing the Velcro strap and placed upon the wearer's hand. As a comparison, we fabricated a thermoplastic splint using traditional methodologies, which can be seen next to the developed 3D printed splint in figure 5c). Superficially, the shapes of both matched one another, resulting in the hand of the wearer being orientated in approximately the same position. From a qualitative external inspection it can be seen that the 3D printed splint only uses the material necessary for production. By contrast the traditional splint contains sizable amounts of excess material folded over the outer surfaces around the opening for the thumb and the area in contact with the palm of the hand. Additional design benefits comparing the devices in this study are that the 3D printed design incorporates openings for the velcro strap, where by contrast the traditional splint required adhesive Velcro pads to incorporate the strap. Indeed the velcro fastening mechanism highlights additional limitations to the existing design. Firstly, the adhesive pads for the Velcro are often prone to losing adhesion when exposed to repeatedly to moisture, causing failure of the splint. Additionally, the velcro strap only has two small contact points

to maintain the tension of the device. By contrast the 3D printed splint, with the velcro strapping round the persons hand does not require any adhesive pads and can accommodate a much larger region of velcro hooks to keep the strap in place. Ultimately this leads to a much more firm fit which is less prone to failure. Further comparisons of the two designs can be found in table 1. It can be seen that both splints have identical weights but the new splint offers greater stiffness and a 3-12 factor increase in porosity, meaning a greater capacity for moisture release. In principal, the higher the porosity, the greater the capacity for a splint to release moisture, neglecting a materials moisture wicking capability. We hope in future work to develop concepts to investigate elements of moisture release in greater detail. It is worth noting that a negative to the 3D printing process is the fact that the splint took approximately eight to nine times longer to manufacture, which is still acceptable but less than desirable with respect to it potentially meaning an additional visitation by a potential patient. We believe that as printing technology develops, that the turnaround time for a part will begin to decrease and so this limitation may be overcome in the near future for FFF printing technology. Alternatively, new forms of printing could be employed, such as Continuous Liquid Interface Production (CLIP), which possess greater print resolution, with vastly improved speed of printing, potentially reducing production time by a factor of up to 50.

Design	Manufacturing time (hrs)	Weight (g)	Approximate Porosity (%)
Traditional Splint	1	30	2-8
Hole Patterned Splint	8-9	30	24

Table 1: Comparison of the various thumb splint manufacturing times and properties taking into account data capture, design, manufacturing and post processing times.

### 3.4 Qualitative Assessment

In a recent review conducted by Kelly et al 2015, various user based metrics were described relating to the adherence of wearing an upper body splint. Factors included difficulties in maintaining cleanliness and hygiene, aesthetics, comfort and ergonomics. However, such factors are arguably qualitative in nature and relate to the individual users experience and perception of the device. Therefore, performance metrics relating to such devices can only be qualitative in nature. In an attempt to assign metrics to assess such factors with respect to splints, research groups have taken an approach of user-centred experience questionnaires to either validate designs or provide suggestions for improvements [22]. In this study we apply a similar methodology to assess the effectiveness and ergonomics of the thumb splint. We asked the volunteer of the study to wear each device for a period of 2-3 minutes and perform tasks to bend the palm of the hand, attempt to move their thumb in a circular motion, bend their thumb, rotate the wrist and finally to perform a pincer action with the thumb and fingers, as can be seen in figure 5b). Once motions had been complete we asked the volunteer to rank each device on a scale of 1 to 10 (1 being low and 10 being high) for a series of user centred questions. These included:

- Q1) How do you rate the aesthetic qualities of the splint?
- Q2) Would you feel happy wearing this device in public?
- Q3) How comfortable is the device to wear?

Q4) How stiff would you say the device feels when worn?

Q5) How much mobility of your hand would you say you have remaining to perform everyday tasks?

Q6) How would you rate the device for ease of cleaning your hand and for release of moisture while being worn?

Following the questions we would obtain a score for each device with a maximum of 60. Based on these findings the highest scoring device would be considered optimal. Results for each question are found in Table 2, where it can be seen the 3D printed splint scored highest, and is therefore considered optimal in this study. It is noted that the results are highly subjective and only based on the single user analysis and so findings will no doubt vary between larger cohorts of users. We hope to develop these initial questions, suggested hand motion evaluations of the participant, wear time and user metrics, and to apply them to a larger cohort size in future studies. However, these very preliminary findings hint at the potential of AM devices to offer user evaluated improvements over traditional devices.

Design	Q1	Q2	Q3	Q4	Q5	Q5	Total Score
Traditional Splint	3	5	6	4	6	2	26
Projected Patterned Splint	7	9	8	8	8	6	46

Table 02: User based qualitative assessment of the various splints

#### 4 Conclusion

Findings from this study have proven the efficacy of using non-invasive optical scanning to readily derive patient specific anatomy. Following a brief period to refine our scanning techniques, the digitised data can easily be acquired using the Artec system, converted into a 3D hand model and be used as template from which to form a patient specific thumb splint concept. We have found there to be considerable scope for design freedom, and we demonstrate the efficacy of creating a design incorporating a generic, porous pattern. The design was evaluated by a trial user and stated to provide an excellent fit, while being both an aesthetically pleasing and ergonomic configuration to allow for ease of hand mobility. We note that the user evaluation is largely opinion based and so to more accurately affirm the efficacy of the splint a significantly larger cohort study (>25 people) must be performed, and done so over extended periods of user wear time. It is also noted that the turnaround time for fabrication of the new device is several hours longer than for the traditional device. We believe that this challenge will be addressed over time as printing technology develops. However, more importantly the improvements AM offers may lead to greater user adherences of such devices which ultimately would outweigh the negatives of longer fabrication time with regards to patient outcomes. We hope to better understand this facet in future studies and encourage other groups to explore the potential of AM for upper limb splints towards improved patient adherence.

#### Acknowledgements

This research was conducted by the Australian Research Council Industrial Transformation Training Centre in Additive Biomanufacturing (IC160100026). All resources for the study were

provided courtesy of the School of Engineering at Deakin University. Ethics approval for this project was granted by the Deakin University Ethics Committee (HEAG-H 55\_2018) following conformity to the requirements of the National Statement on Ethical Conduct in Human Research (2007).

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