A review of wrist splint designs for Additive Manufacture

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1 ABSTRACT

Currently, patients with wrist ailments may be prescribed wrist splints to aid in their treatment regime. The traditional fabrication process of custom-made splints is skill dependent, time-consuming and the splints themselves pose numerous problems with regards to patient compliance. To overcome this, the use of Additive Manufacture has been proposed in recent years and there has been an increase in public awareness and exploration. Many of these developments have been as a result of the Maker-movement, the Internet-of-Things and development of more accessible technologies and infrastructures to enable production of AM builds; hobbyists, industry and academia are exploring the use of AM for splints, all with strengths and weaknesses. This paper highlights and describes specific examples of AM wrist splints currently available in the public domain and summarises strengths, weaknesses, opportunities and threats for the future implementation into the healthcare sector.

2 INTRODUCTION: BACKGROUND OF SPLINTING

Wrist splints are prescribed for a number of reasons; patients suffering from wrist fractures or longer-term conditions such as osteo/rheumatoid arthritis may benefit from splints, in addition to patients who require post-surgical interventions to assist in their rehabilitation. The aim of splints can vary significantly, from stabilising the affected joints and providing protection, to promoting movement in a controlled manner through restricting movement of other, more mobile joints. Alternatively, they may be used to prevent or correct deformity.

The traditional splinting process is time consuming, skill dependent and does not always guarantee a satisfactory splint. Furthermore, patient adherence (compliance) is often a problem, sparking the need to improve the process and subsequently the outcome [1,2].

Most splints are fabricated using Low Temperature Thermoplastic (LTT). LTT's are used as the low temperature at which it becomes pliable allows the clinician to shape the plastic directly onto the patient's extremity. The clinician places the patient's hand in a neutral position on a sheet of paper and then draws around the patient's hand, wrist and forearm and marks any anatomical landmarks that may be important to the clinician during the splinting process. This creates the overall shape of the splint and a custom pattern for the patient. The thermoplastic is then heated in a water bath and the pattern is cut out. The clinician moulds the thermoplastic to the patient's forearm and or wrist. The clinician has a very limited time in which to make adjustments to the splint. Smaller sections of the splint can be reheated for local reshaping. Overall, this process is extremely linear; if the clinician needs to make any

major changes to the design usually the simplest and most efficient method is to start the whole process again. The LTT technique was first introduced in the 1960s and has not changed since [3].

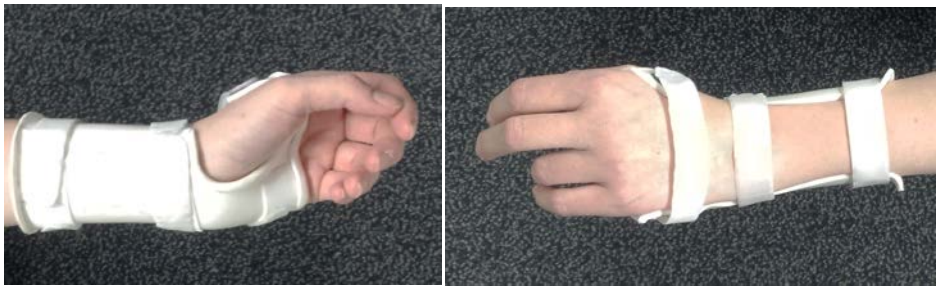

Figure 1: Traditional, custom-made wrist immobilisation splints

There are certain features that clinicians integrate into splints, such as rolled edges (for smoother interaction against the skin, leading to reduced skin irritation), flared proximal edges (to prevent pinching of the forearm) and cavities over bony prominence or areas likely to swell.

The main aim of using Additive Manufacturing (AM) to produce splints is to get higher levels of compliance amongst patients who are required to wear a wrist splint. To achieve this, the reasons for non-adherence must be addressed. Non-adherence can often be due to a number of varied reasons [1,4–7];

- Difficulties keeping splints clean and dry
- Induced perspiration, subsequently leading to odour issues
- Poor aesthetics
- Weight implications
- Discomfort – poorly fitted splints can cause pressure points and friction
- Limited function and compromised performance during everyday tasks
- Fasteners which may be difficult to fix, adjust, remove and replace
- Difficulty putting on and taking off the splint

The above problems can be solved by utilising current AM technologies. Splints can be made that are easier to clean. Splints can be made that have a pattern cut out leading to a greater aesthetic value and a lighter and more breathable splint. Using a scan of the patient's hand, a splint can be fabricated that fits perfectly. There are many ways that AM can be used to improve the quality of life for someone who needs to wear a splint and there are many examples of how this has been implemented. Once an AM splint is designed any number of splints can be made on demand.

3 AIM AND OBJECTIVES

The aim of this paper is to review the current state of the art in AM alternatives to the traditional splinting process as many of the problems associated with traditional splints can be

solved by utilising current AM technologies. It is hoped through the use of AM splints compliance can be significantly improved.

The first objective of this work is to identify ways in which AM can create an immobilisation splint that can lead to greater compliance. The second objective will be to collate and review all the instances where AM has been used to produce immobilising splints. Lastly the need for a workflow to create AM splints will be discussed and the need for design rules to ensure this workflow will create a splint that is at least equivalent to traditional splints. It is hoped that this review will help collectively steer the area of digitised splinting closer to realisation.

4 CURRENT EXAMPLES OF ADDITIVE MANUFACTURED WRIST SPLINTS

In the recent times there has been a plethora of AM splints in the mainstream and trade media. Most of these designs tend to be physical prototypes with limited or no clinical input or validation. There also tends to be no recognition of how important clinical input is to the splinting process. Most processes look to reduce clinical input of splinting practitioner and in some cases make the clinical practitioner redundant. Furthermore, the examples do not consider the level of CAD training and work required to design a splint relative to the clinician's abilities and requirements.

The splints described have a wide range of creators, from patients who experienced some form of traditional wrist immobilisation such as Kelly [8], Bush [9] and Evill[10], to start-up companies such as Amphibian Skin [11], to research-led design [12,13]. All have their strengths and weaknesses and it is hoped by reviewing these that a clear plan of how to make digitised splinting a reality will be revealed.

4.1 Fused Deposition Modelling

Fused Deposition Modelling (FDM) is one of the most accessible and one of the cheapest types of AM. It is also one of the easiest processes to maintain and operate.

Bush [9], Zdravprint [14], piuLab [15] and WASP [16] all used FDM to produce their immobilisation splints. These four splint designs begin to address some of the main issues associated with traditional splinting, but still share some of the same problems as they are produced by printing a one-sided splint in a flat form, then heating and moulding the splint to the patient as in the traditional process. Amphibian Skin [11] (Figure 2) utilises the design freedoms of AM and is produced using scan data of the patient's arm and wrist. Amphibian Skin is one of the first commercially available splints on the market. The splint consists of a lattice style circumferential structure and although there is no customisation of the pattern available yet, patients are able to choose from an array of colours.

Open-Bionics and Abby Taylor [17] from the University of Bristol investigated the use of PLA material and Ninjaflex flexible filament for FDM to create a low-cost splint. This circumferential splint design utilises multi-material capabilities to create a hinge within the Voronoi pattern. This kind of utilisation of multi-material capabilities opens up possibilities of integrating several features into the splint previously impossible when using FDM. HealX [18] is a unique splinting system in which two single sided splints are created and each part

glued to the patient to ensure full immobilisation. This method is hoped to reduce compression of swelling associated with some bone fractures and some musculoskeletal injuries. Palousek et al [13] (Figure 4) also explored using FDM to reverse engineer the traditional splint and an adaptation of the traditional splinting process suited for AM. This is one of the only FDM splints that does not exploit the design freedom enabled by AM to produce a more aesthetically pleasing, lightweight splint.

Osteoid [19] (Figure 3) is one of the only FDM splints that has a feature not previous inbuilt in traditional splinting practices. Osteoid is a circumferential splint with ventilation perforations that uses a low intensity pulsed ultrasound (LIPUS) bone stimulator system to reduce healing time of non-union fractures. Exovite [20] (Figure 5) also proposes a unique feature that reduces healing time by integrating an electro stimulator system, although it is unclear what AM process is used to create the Exovite splint. At this time neither has been clinically proven but it is claimed that the splint and electro stimulator system is soon to be clinically tested.

Figure 2: Amphibian Skin. Image courtesy of Dianna Hall, Amphibian Skin

Figure 3: Osteoid. Image courtesy of Deniz Karaşahin

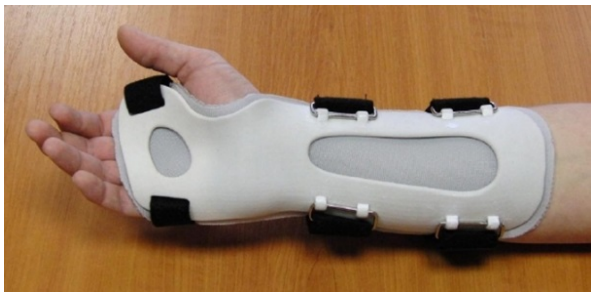

Figure 4: FDM splint. Image courtesy of David Paloušek

Figure 5: Exovite. Image courtesy of Juan Monzón, Exovite

Figure 6 shows an ulnar deviation splint made with FDM; the only splint that the authors are aware of that has been clinically evaluated. The intention of the splint was to treat the deformation of digits which can shift and angle towards the ulnar side of the forearm. The splint was made of seven articulated parts which could be modified in their position relative to an arc-shaped metal wire to depict the natural curvature across the hand. Results to date have been positive with patient treatment, although further research is required to expand the clinical trials.

Figure 6a. Ulnar Deviation of the digits. Figure 6b: Ulnar Deviation prevention splint. Images courtesy of Valeria Meirelles

4.2 Selective Laser Sintering

Selective Laser Sintering (SLS) is a process where a layer of polymer powder is laid down and a laser fuses the powder. The build plate drops and a new layer of powder is spread across the previous layer and the process repeated. Due to the unsintered powder acting as support, SLS designs do not need supports. Four of the splints reviewed exploit the advantage of SLS.

Cortex by Evill (Figure 7) [10] was one of the first splints to appear in the general media. It is a circumferential immobilisation splint. This lattice design is used to treat bone fractures and has support localised around the fracture site. Evill also hoped by changing fracture treatment to this digitised approach the amount of medical waste produced from current fracture treatment could be drastically reduced. Splint+ [21] is also used to treat bone fractures. Students Solakian, Nguyen, and Buell developed a prototype designed to reduce the amount of supplies transported to areas requiring disaster relief. Like the Evill design, Splint+ has varying density with support localised to the fracture site. #Cast [22] is based on the tradition of friends and family of the patient writing messages on the patient's cast. Using a smartphone application, the patients can choose which messages of support submitted by friends and family are applied to the splint. These messages are then used in place of lattice type struts seen on many of the other splints. Although this process leads to a denser perforation pattern, the level of co-design is one not previously seen in digitised splinting.

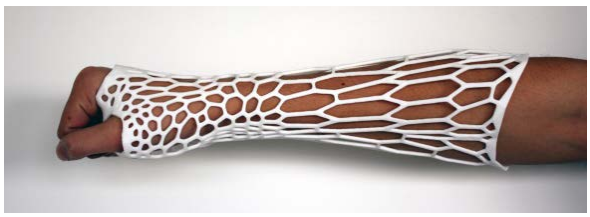

Figure 7: Cortex. Image courtesy of Jake Evill

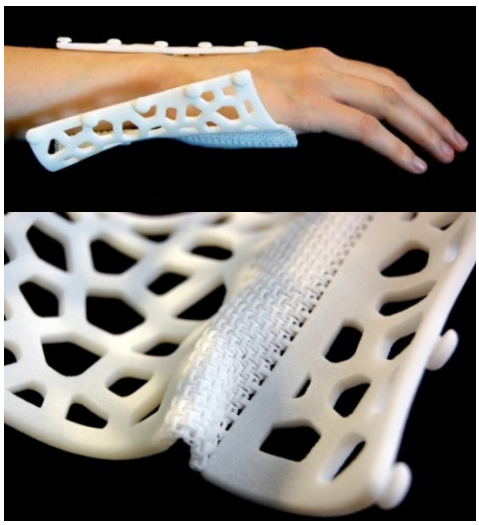

Figure 8: SLS textile hinge

All of the reviewed SLS splints are (theoretically) either permanently attached to the patient's forearm during the course of treatment (for example 6 weeks for fracture healing) or have no clear methods of donning and doffing. Work by Paterson et al. [23] (Figure 8) demonstrated how through the use of an AM textile hinge, all of the benefits of using SLS can be attained without incurring difficulties with donning and doffing; a particularly important yet overlooked aspect when considering chronic patients who encounter significant discomfort when placing or removing splints. Whilst this may not be a necessary function for fracture treatment, it is vital for individuals with longer term degenerative conditions such as rheumatoid arthritis.

4.3 Material Jetting

Material Jetting is similar to two-dimensional ink jet printing. Material is jetted onto a build plate where it solidifies. The build plate then drops and the next layer is jetted. This process has high accuracy and allows for multiple material parts to be produced. This multi-material approach was first proposed by Paterson et al. [24] and allows for an in-built soft hinge to ease donning and doffing and integrated padding, although there are huge benefits from using multi-material jetting systems such as the Objet Connex, the poor long-term material properties are still limited to prototyping. However, as technologies progress more opportunities will become available. For example the Connex3 system can now offer multi-colour, multi-material builds; a prototype developed by the authors is shown in Figure 10, with the intention of further improving patient preference and customisation in colour options.

Figure 9: Multimaterial splint

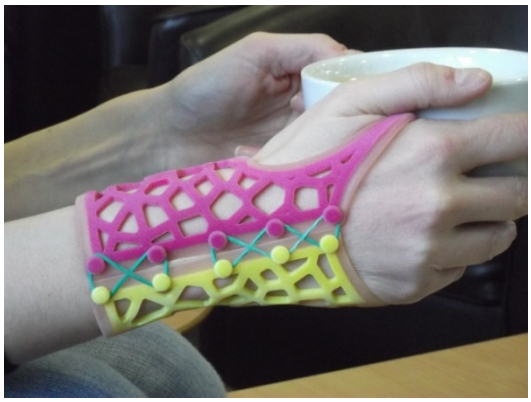

Figure 10: Multi-material, Multicolor splint by Paterson Image courtesy of Bibb, January 2015

5 IMPROVEMENTS POSSIBLE WITH AM TECHNOLOGIES

5.1 Comfortable splints

Anatomical data capture is vital to produce a custom fitting splint. By using anatomical data capture, be it magnetic resonance imaging (MRI), computed tomography (CT) or a 3D laser scanning, a splint can be created that, in theory, should be intrinsically more comfortable than other methods of splint manufacture. Although the design freedom that comes with AM can easily be exploited to produce a custom-fitting splint, not all processes exploit this. Splints from Bush [9], Zdravprint [14], piuLab [15] and WASP [16], are printed flat, and then like the traditional splinting method, they are heated and moulded to the patient. This can not only

lead to an ill-fitting splint but also requires the clinician to either choose a splint from a range of sizes already printed or requires the patient have an initial session with the clinician where anatomical data is collected to create the 2D splint and then the patient must come back to the clinic for a second fitting when the splint has been printed. There is also a risk that individuals with no clinical knowledge or expertise would build and form these devices to themselves with little/no understanding of the impact they may have on their health, and may cause more harm than good.

5.2 Clean and well ventilated splint

The design freedom used to create a comfortable, well-fitting splint also allows the alleviation of induced perspiration, which can cause odour and skin irritation. The vast majority of splints produced using AM are designed with an open pattern or ventilation holes that allow the skin to breath. This can be seen in some AM splints that have been widely circulated in the media, such as the Evill's Cortex [10] and the Osteoid [19]. Most AM splints also allow the patient to continue all daily activities without fear of soiling the splint as the splints are waterproof, washable and do not contain absorbent materials.

6 ADDITIONAL FEATURES POSSIBLE WITH AM TECHNOLOGIES

6.1 Fasteners and Donning and Doffing

There are many additional features that can be added to a splint produced using AM that are not possible using traditional methods. Some designs include unique fasteners. Osteoid features a secure locking mechanisms [19] and work by Paterson [12] includes a unique fastening system that incorporates rubber bands, as can be seen in Figure 10. This work by Paterson was also the first of its kind to integrate multi material technologies. In this research three main features were identified that can be reproduced using multi-material 3D printing such as Objet Connex multi-material technology. During the traditional splinting process, bulbous features are created to allow gel discs or padding to be placed over sensitive areas or bony prominences. Through the use of multi-material technologies this cushioning can be created reducing the overall bulk of the splint. The use of soft materials can also be used to replace rolled edges. In traditional splinting the clinician often rolls the edges of the splint for smoother interaction against the skin. Again this feature can be recreated thus reducing the overall bulk of the splint and allowing for a more comfortable splint that allows more dexterity. The last feature immediately addresses the need for a splint that is easier to don and doff. By integrating a flexible hinge into the design, the splint is not only easier to don and doff but the necessity for the Velcro straps typically used is negated.

6.2 Features unavailable using the traditional approach

Both Osteoid [19] and Exovite [20] also have additional features that could not be incorporated into traditional splints. Exovite boasts electro-stimulators that can be controlled using an application on a smart phone, while Osteoid incorporates an ultrasound system also controlled by a smart phone application. Both systems aim to reduce healing time in a way not easily achieved using traditional methods.

7 BETTER AESTHETICS AND CO-DESIGN

Currently, patients have very little input in the design of their splint. In some clinics there may be a choice of different coloured LTT or Velcro straps. This is often not enough personalisation for the patients, with many choosing to personalise their own splints at home. Although many AM splints seem aesthetically better than traditional splints, the perception of what is aesthetically pleasing varies from patient to patient and little has been done to address this. A concept first proposed by Paterson et al [25] aims to integrate patient choice into the splint production workflow. It is hoped that this co-design will allow patients to feel more involved in the process leading to greater acceptance and compliance. Bush [9] has likened this process to that of spectacles. Spectacles were once seen as a stigmatising medical device and now are seen as a fashion item. It is hoped that by allowing patients to co-design their splint, the same change in social perception will happen with splinting.

8 CLINICIAN INPUT

Although AM technologies can fabricate a splint, there is a need for a specialised CAD system to allow clinicians to design splints for AM. Furthermore, the intent to keep practising clinicians at the forefront of splint prescriptions is of utmost importance. Most of the designs discussed tend to be physical prototypes with limited or no clinical input or validation. There also appears to be very limited recognition of how important clinical input is to the splinting process. Most processes look to reduce clinical input from the splinting practitioner and in some cases may even make the practitioner redundant. Furthermore, the examples often overlook the CAD work involved to design a splint relative to the clinician's requirements. Paterson [12] proposed a digitised splinting approach, specifically through development of a 3D CAD software strategy to allow clinicians to capture their design intent without compromising creativity.

This research describes the feasibility of capturing clinicians' design intent in a 3D CAD virtual environment, whilst capturing clinicians' opinions of the approach with suggestions for future research and development. Results concluded that clinicians were excited by the proposed transition in AM splinting, but that significant development is required elsewhere to establish a supporting infrastructure in order to make the approach a viable option in future upper extremity splinting.

9 DISCUSSION AND FUTURE WORK

By giving the power of design to patients it will lead to greater compliance but leaves the clinician unable to account for all the new variables within the design process and therefore unable to guarantee a structurally sound splint. The patient ideally would have some input into the design of the splint; this is a strategy developed to increase patient adherence. Clinicians are quite keen for this to be brought into the splinting process but are worried that there would be a compromise in rigidity if patients were enabled to input their own designs[25]. It is here that the relationship between the structural integrity and the pattern will need to be controlled by design rules. These design rules will allow the clinician peace of mind, knowing that the splint they prescribe and design with the patient is effective and safe.

Some aspects are transferable to different AM systems which can offer benefits overall; for example, multi-material splints by Paterson *et al.* [25] demonstrated multi-material splints but proved expensive to build, with the materials susceptible to tearing; however, with low-cost approaches such as that by Open-Bionics [17] demonstrate lower-cost solutions with improved material properties. Unfortunately, low-cost extrusion systems pose weaknesses of their own such as poor reliability and high failure rates, so further research and exploration should be spent to resolve these issues.

Proposed future work will include creating design rules that feed into an interactive design tool that allows for the AM production of safe and effective splints. These design rules will allow the clinician to focus solely on the design and allow the patient to become more involved in the design process. The clinician will have the freedom to design the features they need in a manner that allows for their expertise to be utilised in the planning of the splint. These design rules would include factors such as wall thickness, pattern strength, material, and AM process selection. Through this future work it is hoped that an interactive design tool will be created that allows the clinician to design the splint in a dynamic manner and removes the clinician from the manufacturing stage of the process.

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