Evaluation of a digitised splinting approach with multiple-material functionality using Additive Manufacturing technologies

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Abstract

The design and fabrication of custom-made wrist immobilisation splints can be a laborious process. In addition, patient adherence in terms of wear duration and frequency may be affected by a range of contributing factors including poor aesthetics, hygiene issues and fit. This paper suggests the use of additive manufacturing (AM) in a bid to resolve factors affecting adherence and improve the efficiency of design and manufacture. Particular attention is paid to the exploitation of multiple-material capabilities using Objet Connex technologies, with the intent to integrate completely novel and state-of-the-art characteristics within splints. However, in order to exploit the many benefits of AM for customised splint fabrication, appropriate Three Dimensional (3D) Computer Aided Design (CAD) methodologies must be considered for splint design. Furthermore, a specialised CAD approach must be developed for splinting practitioners to allow them to create such geometries. As a result, this paper describes the development of a customised 3D CAD methodology for splinting practitioners to design custom-made splints, in order to evaluate such novel features only available through AM fabrication.

Introduction

Rheumatoid arthritis (RA) is a chronic, systemic autoimmune disease, which typically affects joints within the hands, wrists, ankles and feet (Biese, 2007; Melvin, 1982). Symptoms can include inflamed synovia and tendon sheaths and destruction of cartilage and bone, resulting in pain and discomfort (Melvin, 1982). Borenstein *et al*. (1993) state that the approach to RA treatment is a multi-layered pyramid, consisting of 'education, physical and occupational therapy, rest and nonsteroidal anti-inflammatory drugs" (pp.545). Occupational therapy in particular addresses limitations that patients may encounter during everyday activities in an attempt to circumvent the limitations, and to improve wellbeing and quality of life. One method of intervention is splint prescription; the perceived benefits of which are multi-faceted (Melvin, 1982; Taylor *et al*., 2003; Jacobs, 2003; Colditz, 1996):

i. relieves pain through immobilisation and protection of affected joints.
ii. protects painful contractures from impacts, scarring and excessive movement.
iii. promotes movement of stiff joints through immobilisation of more mobile joints.
iv. encourages healing of fractures and contractures.
v. prevents or corrects deformities and contractures.
vi. rests affected joints.
vii. provides support.

Practitioners such as occupational therapists and physiotherapists may prescribe either custom-made or 'off-the-shelf' prefabricated splints. However, this paper will describe and discuss the design and fabrication methods of custom-made static wrist immobilisation (SWI) splints in particular (shown in Figure 1), since they are one of the most commonly prescribed splints amongst a range of conditions (Stern, 1991).

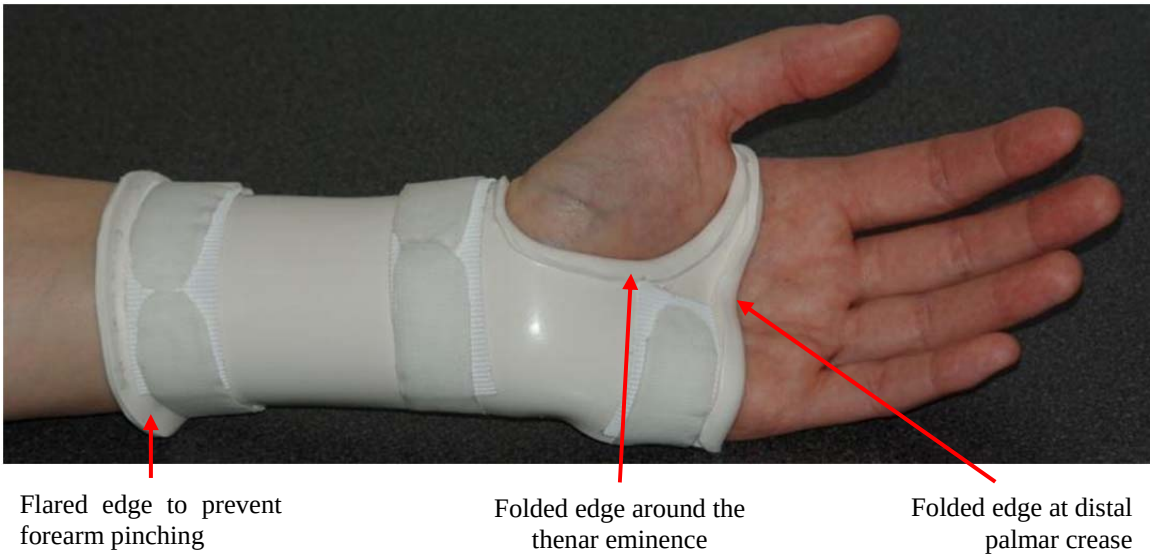

Figure 1: Traditionally manufactured static wrist immobilisation splint and common characteristics

Therapists must take into account the likelihood of their patients adhering to their splint wearing regimes. Unfortunately, Sandford *et al.* (2008) found that two-thirds of patients reported non-adherence, and advise therapists to be aware of and acknowledge low adherence levels. There are several reasons for poor patient adherence in terms of wear duration and frequency (Melvin, 1982; Taylor *et al*., 2003; Callinan and Mathiowetz, 1996; Sandford *et al*., 2008; Spoorenberg *et al*., 1994):

- The splint does not address the patient's condition.
- The patient has received insufficient information about their condition.
- The patient has not had sufficient information justifying the need for the splint.
- The splint is unattractive.
- The splint is difficult to don/doff.
- The splint is uncomfortable to wear.
- The splint is impractical in certain environments, or for certain tasks.
- The patient may not be interested or informed on the potential beneficial outcome of wearing their splint.

Hygiene issues may also contribute to low adherence; open-cell padding within splints can absorb moisture, such as perspiration, which can lead to odours and collection of bacteria (Coppard and Lynn, 2001). More generally and in terms of assistive devices, Louise-Bender Pape *et al.* (2002) reviewed literature linking perceived social stigma to the association of assistive devices, and can contribute to non-use of such devices. In addition, 78% of 27 participants reported immobilisation splints as unwieldy (Spoorenberg *et al*., 1994).

The splinting process

Figure 2 depicts the splint design and fabrication workflow, deduced from Lohman (2001) and Jacobs and Austin (2003). The therapist must choose the Low Temperature Thermoplastic (LTT) based on a variety of properties prior to splint forming, including contour conformability, thickness and colour. Colour selection by the patient may be encouraged in a bid to improve adherence (Coppard and Lynn, 2001). However, choice is often dictated by stock available in clinics or properties that are deemed more important by the therapist, such as thickness. In addition, therapists are advised to consider and apply

padding *before* forming the LTT, to avoid inducing pressure to prone areas (Taylor *et al*., 2003; Coppard and Lynn, 2001; Cooper, 2007). Padding types can vary from sheets and stockinettes to silicone gel discs or pads, which can be placed over bony prominences for cushioning (Coppard and Lynn, 2001). Other common SWI splint characteristics are proximal edge flaring to avoid forearm pinching, and folding of both the distal and thenar edges to provide a more comfortable edge against the skin whilst adding rigidity to the splint (Figure 1).

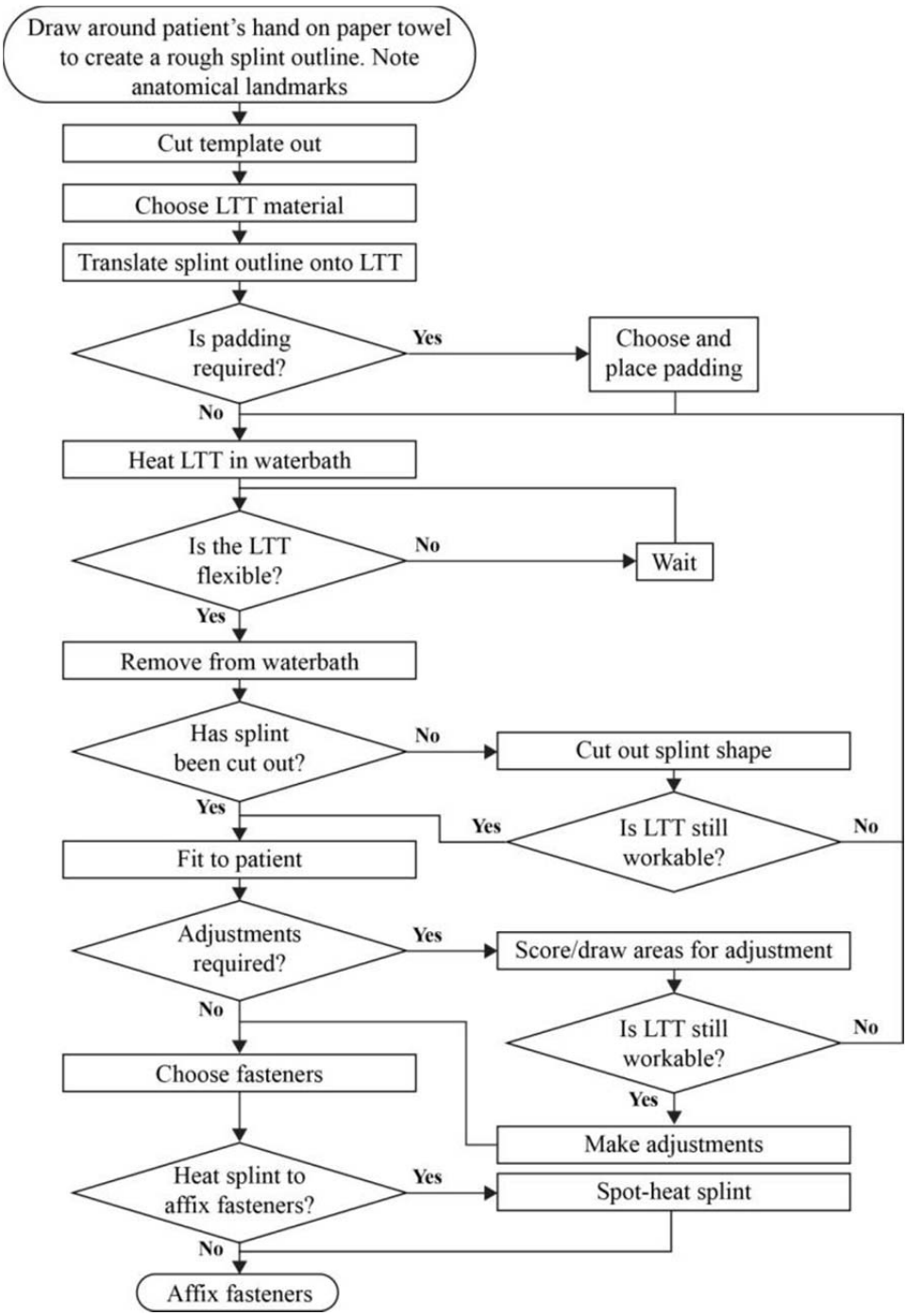

Figure 2: Traditional splint design and fabrication workflow
Deduced from Jacobs and Austin (2003) and Lohman (2001)

Although many of the characteristics described are integrated to address functional needs, results may appear unwieldy, voluminous and unsightly. For example, if cavities are integrated over bony prominences to relieve pressure, the appearance of the altered topology can be compromised. In addition, folded or rolled edges add volume to the palmar region, potentially affecting palmar grasp capacity. In terms of the fabrication process, there is little room for error; the farther the therapist progresses down the fabrication workflow, the more challenging adjustments may be to make. If additional or replacement splints are required the whole process must be repeated.

Additive Manufacturing for upper extremity splint fabrication

Several research studies have explored the use of Additive Manufacturing (AM) for upper extremity splint fabrication. Fraunhofer IPA fabricated a prototype SWI splint using an EOS P100 Laser Sintering (LS) system with Polyamide (PA2200) powder (Breuninger, 2012) (Figure 3); the benefits were improved aesthetics, bespoke fit and integral fasteners to exploit the AM capabilities of part consolidation. A hand immobilisation (HI) splint prototype developed by Materialise (fabricated using an EOS P730 LS machine with PA2200 powder) gave a reduction in weight (Pallari, 2011). Oxman (2011) fabricated *'Carpal Skin'* using Objet Connex500^{TM} technologies, by exploiting the system's capabilities to enable multiple-material builds (Objet Ltd., 2012b). The structures within the splint-like gloves were dictated by a predefined pain map to allow or restrict movement via a reaction-diffusion pattern (Oxman, 2011). Not only does the use of AM in the context of upper extremity splinting allow for exploitation of bespoke fit and function, but both prototypes by Oxman (2011) and Fraunhofer IPA also demonstrated improved aesthetics as a result of geometric complexity and freedom; synonymous characteristics which are only viable as a combination through AM.

Figure 3: Bespoke-fitting wrist splint fabricated using Selective Laser Sintering (EOS P100 system and Polyamide 12/PA2200 powder). Image Courtesy of Fraunhofer IPA, Stuttgart.

Sketches shown in Figure 4 by Bibb (2009) show the intent of AM for splint fabrication with lattice feature integration. The lattice structures were intended to look aesthetically pleasing whilst promoting airflow to the skin in a bid to reduce perspiration. An additional intent was to enable patients to personalise their splints by choosing their own perforation patterns in an attempt to improve patient adherence.

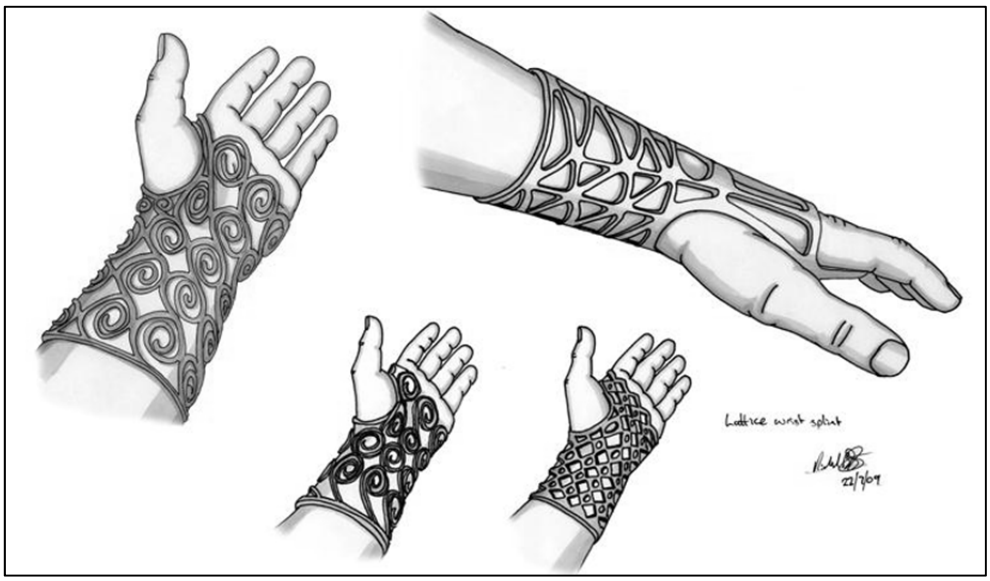

Figure 4: AM splint concepts

The investigators were also interested in exploring additional and novel approaches for multiple-material integration into splints, particularly the use of elastomeric regions for a variety of new design features as a result of Objet Connex capabilities. For example, radial and/or ulnar-based elastomer hinges could be integrated into the splint to allow for easier donning and doffing. In addition, specific elastomer regions could be placed over bony prominences (similar to gel discs and pads in traditional splinting). Both concepts could be achieved without affecting the overall topology of the splint. It was anticipated that regional patches could protect and cushion bony prominences, whilst providing dynamic pressure over areas prone to fluctuating oedema with an aim to prevent oedema pooling.

However, if such a design and manufacturing approach is to be realised for upper extremity splinting in a clinical domain, supporting software technologies need to be developed and tailored to suit the target user. Pallari *et al*. (2010), Rogers *et al*. (2000) and Knoppers and Hague (2006) support the need for product-specific Computer Aided Design (CAD) software for practitioners, to enable the intended users to adopt quickly and easily without dedicating time to learn. In addition, Smith (1991) justifies the need for customised software, as it gives the intended users the tools to achieve what they want and need whilst removing unnecessary functions.

Research Aim and objectives

A number of weaknesses in traditional splinting have been identified, as well as the strengths and feasibility of AM in splint fabrication. The need for customised Three-Dimensional (3D) CAD software to support the use of AM has also been noted. Therefore,

the aim of this paper is to evaluate the feasibility of new design features for upper extremity splinting only made viable through AM, as well as the digitisation of traditional splint characteristics. Objectives to achieve the aim are:

Objective 1. The replication of key splint features/characteristics in a virtual environment.

Objective 2. Exploration of new features only viable through AM, which could potentially address concerns regarding aesthetics, hygiene, comfort and form. Features include;
- 2.1. Aesthetically appealing and personalised lattice integration.
- 2.2. Multiple-material integration (using Objet Connex technologies) to;
  - 2.2.1. Imitate gel-discs/pads.
  - 2.2.2. Potentially replace the need to create bulbous features in splints.
  - 2.2.3. Provide dynamic pressure over areas susceptible to fluctuating oedema.
  - 2.2.4. Integration of flexible hinges for easier donning/doffing.

Objective 3. Evaluation into the feasibility of the digitised splinting approach via a specialised CAD software prototype;
- 3.1. Refine replicated characteristics into a virtual workflow.
- 3.2. Devise a representation of the digitised approach via a software prototype.
- 3.3. Evaluate the digitised approach, specifically new features as a result of AM.

It should be noted that the scope of this investigation is purely related to the data manipulation of acquired patient scan data within 3D CAD in order to support AM splint fabrication. The investigation does not address data acquisition methods suitable for clinical environments, although Paterson *et al.* (2010) review data acquisition methods to generate test data in support of this investigation. Similarly, the process does not investigate the use of Finite Element Analysis (FEA), although it can be assumed that this would be a crucial feature if the digitised approach were to be realised. It should also be noted that the digitised splinting approach is not intended to make the splinting profession obsolete, nor does it imply the redundancy of splinting practitioners. The intended proposition is to provide therapists with an additional toolset to capture their design intent quickly and easily, whilst addressing the needs and concerns of patients through improved aesthetics, fit and functionality.

A systematic approach was adopted to develop a sequence of functions to meet the objectives. Each objective will be addressed individually.

Methods

Objective 1 – replication of key splint features/characteristics in a virtual environment

The critical splint characteristics required for the specialised splinting workflow were tested iteratively in a range of 3D CAD software packages, including Geomagic Studio (2010) and McNeel Rhinoceros (2011), using an action research strategy. The approach was intended to test and refine different CAD tools and CAD strategies to capture and replicate the design intent of typical splint features, such as pressure relief cavities. An example of the iterative testing is described by Paterson *et al*. (2011).

Objective 2 - Explore new features only viable through AM

Objective 2.1 - Aesthetically appealing and personalised lattice integration

Similar to addressing Objective 1, an action research strategy was adopted to explore lattice applications to a previously defined splint surface. After iterative testing, it became apparent that an additional feature within the workflow was required to form a splint border (Figure 7, flow diagram item 3.1), which would encase the lattice structure. This would address inherent issues of sharp protrusions, which could otherwise cause lacerations if borders were not implemented into the proposed splints.

Objective 2.2 - Multiple-material integration/heterogeneous structures

As mentioned previously, the purpose of using Objet Connex technologies was to explore the viability of new features in the context of splinting, making the transition from homogeneous to heterogeneous splints. Objet Connex technologies can deposit materials in pre-defined combinations, which dictate regional material proportions to form so called *Digital Materials*™ (DM). For example, in order to create variations in shore hardness amongst the Objet flexible (FLX) FLX97-DM range, the primary material (TangoPlus) and secondary material (VeroWhitePlus) are interspersed by varying dual-jet distribution using Objet's PolyJet Matrix™ Technology. The material depositions are then cured using ultra-violet (UV) light (Objet, 2012; Objet Ltd., 2012c).

There were two main approaches to consider for multiple-material integration; Continuous Functional Grading (CFG) (Figure 5a) versus Stepped Functional Grading (SFG) (Figure 5b). CFG proposes a gradual transition of one or more properties across a defined volume, and has been of significant interest across a range of disciplines. However, the implementation of such a feature in terms of CAD modelling strategies, file export and AM systems is still under development (Erasenthiran and Beal, 2006). Knoppers and Hague (2006) and Siu and Tan (2002) highlight the difficulties in representing functionally graded geometries in Boundary Representation (B-rep) modelling, due to the geometries being defined by a series of surfaces to determine the topology of a closed volume. If functional grading were to be a viable feature in splints, an alternative or additional modelling strategy within the CAD methodology (e.g. voxel-based modelling) would need to be adopted. A consequential limitation, however, is the increased memory power, processing consumption and modelling complexity during the design phase (Oxman, 2011; Erasenthiran and Beal, 2006). This would add unnecessary complexity to the geometry and CAD strategies. In addition, current Objet Connex technologies only offer a finite number of pre-defined deposition variations, which limit the CFG approach. As a result, CFG was considered excessively complex and unnecessary for this particular application, and it was decided that SFG would be sufficient to deliver the finite variation that Objet Connex technologies offer.

The disadvantage of SFG is that it creates boundary lines between adjacent materials properties, which, depending on the differences in the adjacent properties could lead to stress concentrations at the boundary or abrupt changes in flexural modulus that could cause unwanted folds or creases at the boundary. The worst-case scenario can be imagined to be a choice of only two materials, for example very rigid and very flexible. In that circumstance, the abrupt change at the boundary is likely to present problems. This would be mitigated by the ability to specify a greater number of regions and a sufficiently high number of materials property choices. It can be assumed that, for a given application, a sufficiently high number of materials choices could satisfactorily approximate continuous variation.

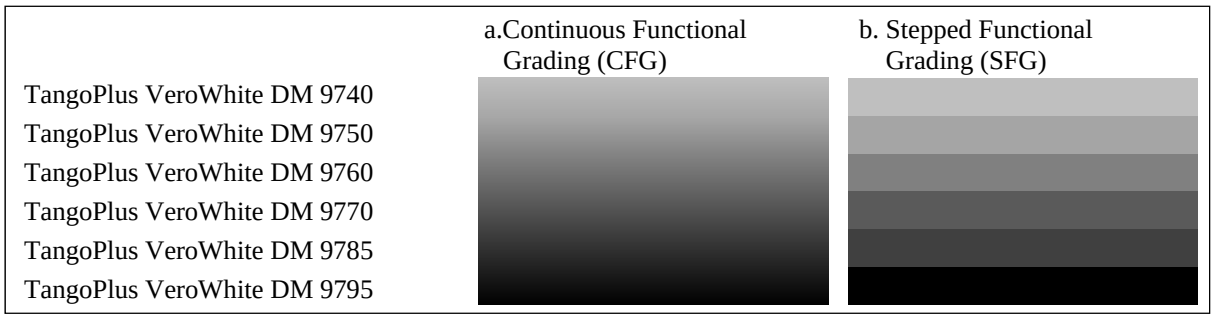

Figure 5: Functional Grading versus Specific Boundary Representation

Objective 2.2.1 - Imitate gel-discs/pads

This objective was to explore the possibility of using multi-material capability to reproduce the function of gel pads. In existing practice, the rigid shell of the splint is raised in local areas to provide space to insert soft pads. These are required to reduce pressure on bony prominences and improve comfort. The ability to define material properties within a localised region enables the body of the splint to be made soft in the required area. This eliminates the pads and reduces bulk of the splint.

Objective 2.2.2 - Potentially replace the need to create bulbous features in splint

This is essentially the same function as 2.2.1 except that in existing practice some areas of the splint may be raised to provide space for sensitive areas or bony prominences but without placing a gel disc/pad into the space.

Objective 2.2.3 - *Provide dynamic pressure over areas susceptible to fluctuating oedema*

This function is currently very difficult to accommodate with a single material rigid splint. The ability to alter the flexibility of the splint, possibly in specific regions would enable a conformal fit whilst allowing some degree of expansion that would accommodate temporary or fluctuating swelling. This would be a unique advantage of the AM approach over existing practice.

Objective 2.2.4 - *Integration of flexible hinges for easier donning/doffing*

With existing practice, the rigid splint has to incorporate large openings to allow donning and doffing. This leaves large regions unsupported. In addition, straps and fasteners have to be added into or onto the splint, which adds construction time, increases bulk and adds features that will be more susceptible to damage and wear. The ability to build in flexible joints or hinges enables a splint design with greater coverage and therefore increased support. The ability to build in hinges and fasteners reduces the bulk and the time required to add those features after forming the splint. This approach has many other potential advantages in the elimination of purchasing and stocking fasteners, straps, etc. In addition, it is frequently straps and fasteners such as Velcro that wear, fail or become unacceptably soiled in use earlier than the splint itself.

In terms of 3D CAD strategy testing to support the digitised splinting approach, the refined strategy for enabling multiple-material builds was to create a curve on the splint surface to act as a trim boundary prior to pattern application. After applying the pattern to the surface, the splint surface could then be trimmed (Figure 6a). Separate patches could then be thickened (Figure 6b,c), and exported as separate shells in a single STL file. Each shell can subsequently be assigned a digital material in the Objet preparation software. For example, in

Figure 6c there are three shells. The predominant grey shell could be a rigid material; the green shell could be an intermediate flexible material whilst the red shell could be very soft.

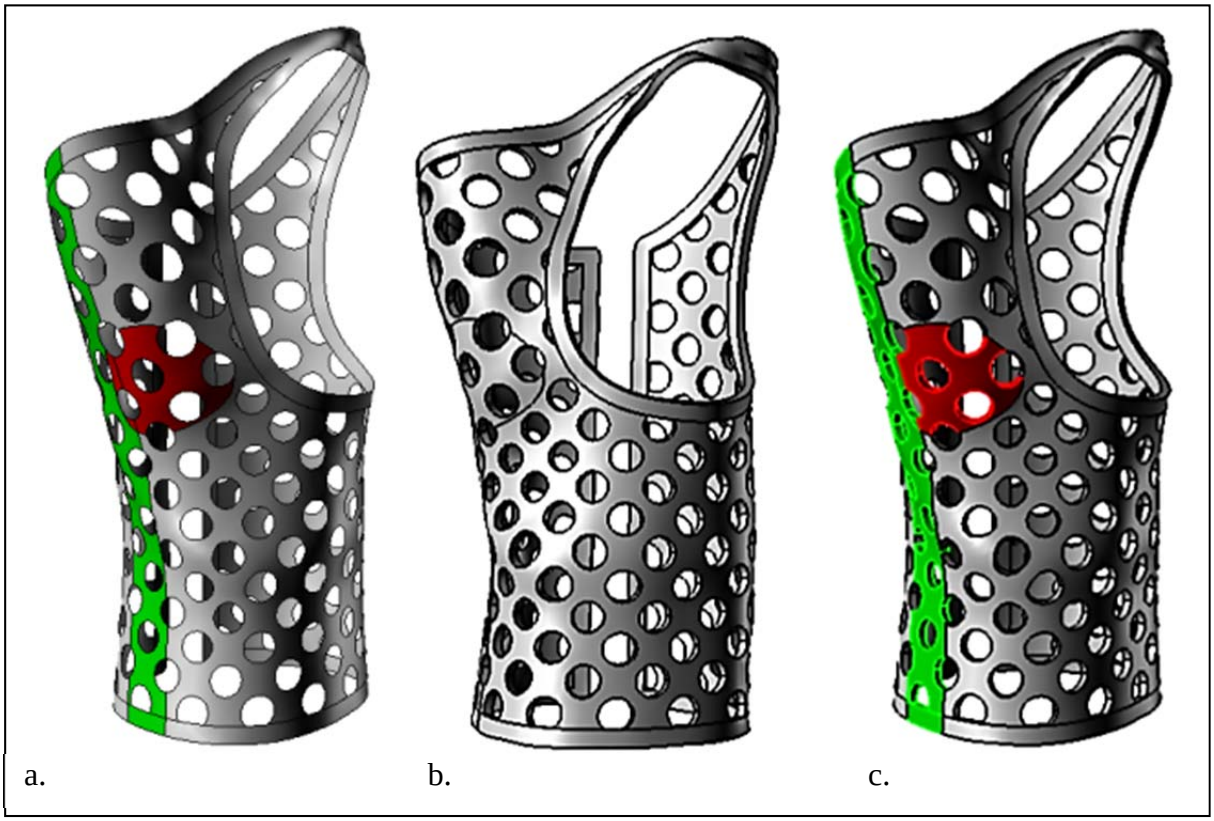

Figure 6: Example of SBR integration over a bony prominence (red- pisiform) and medial/ulnar hinge (green)
a. Three separate surfaces present b. thickened splint c. coloured regions of splints, depicting different materials

Objective 3 - Evaluation of approach via a specialised splinting CAD software prototype

The requirements established after CAD testing were refined into a specialised CAD software workflow (objective 3.1) (Figure 7). The order was determined by consideration of the traditional splinting workflow depicted in Figure 7, as well as constraining/best practice CAD approaches (e.g. detailed application to surfacing prior to thickening). An important feature to note in the digitised approach was the intent for traversal operation; the ability to move back and forth between different features independent of one another. This, fundamentally, was anticipated as an important step for splint fabrication when compared to traditional splint fabrication, where the further one progresses through design and fabrication, the more difficult and time consuming it may be to make adjustments.

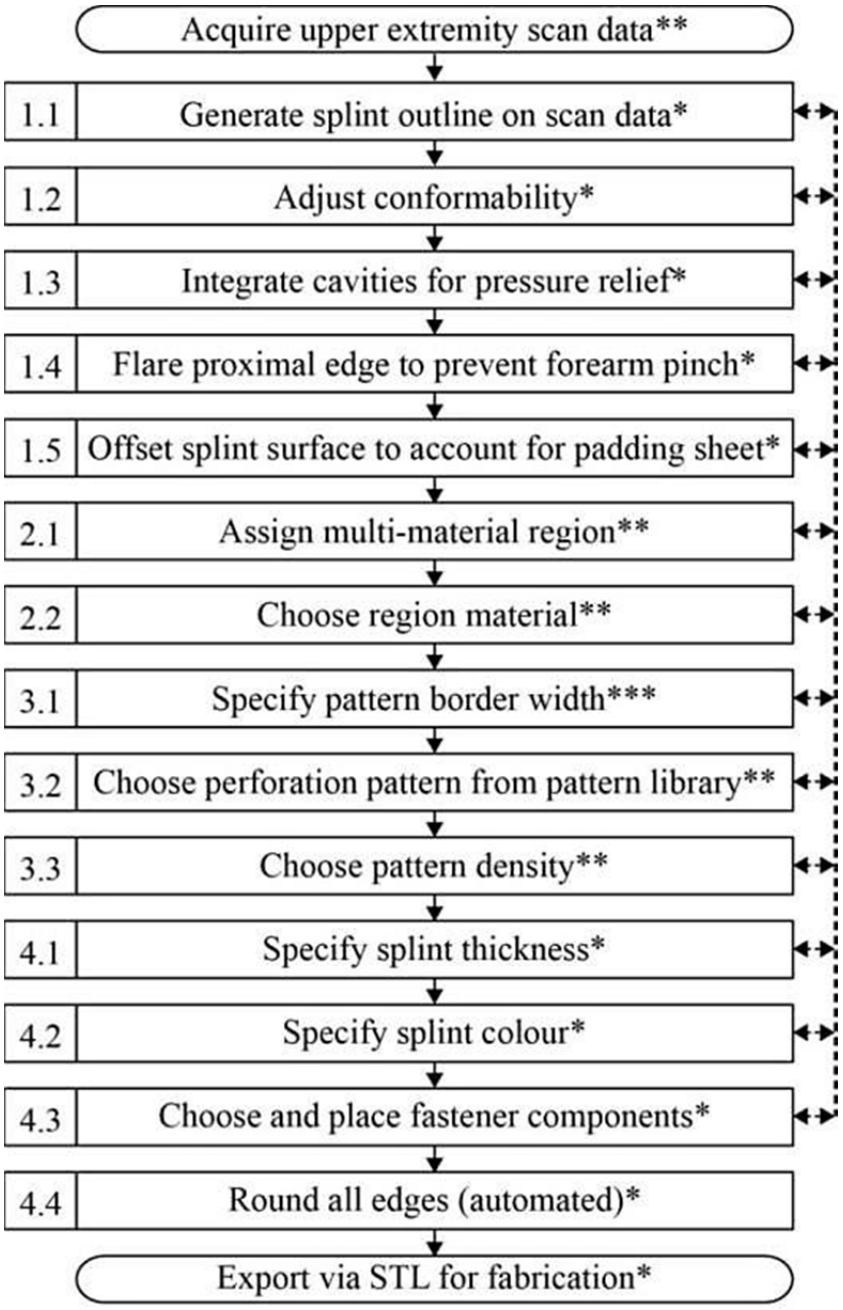

Figure 7: Refined digitisation workflow
*** = Existing feature/activity ** = New feature/activity ***= Necessary feature as a result of a new feature/activity**

Having established a refined workflow, a high-fidelity concept software prototype was developed within Microsoft® Access® (2010) using Microsoft® Visual Basic® for Applications (2010), which could be used to depict the workflow for final evaluation (objective 3.2). The prototype featured a viewport, and a series of slider controls and drop-down boxes to control features such as pattern density (Figure 8). When controls were adjusted, the image in the viewport would change to suit the recent adaptation to provide direct visual feedback to the user. The prototype also featured a pattern library and a separate fastener library, which allowed users to browse different perforation patterns and fasteners. The user would then be able to select the desired options from the libraries for automatic placement to the splint geometry in the viewport.

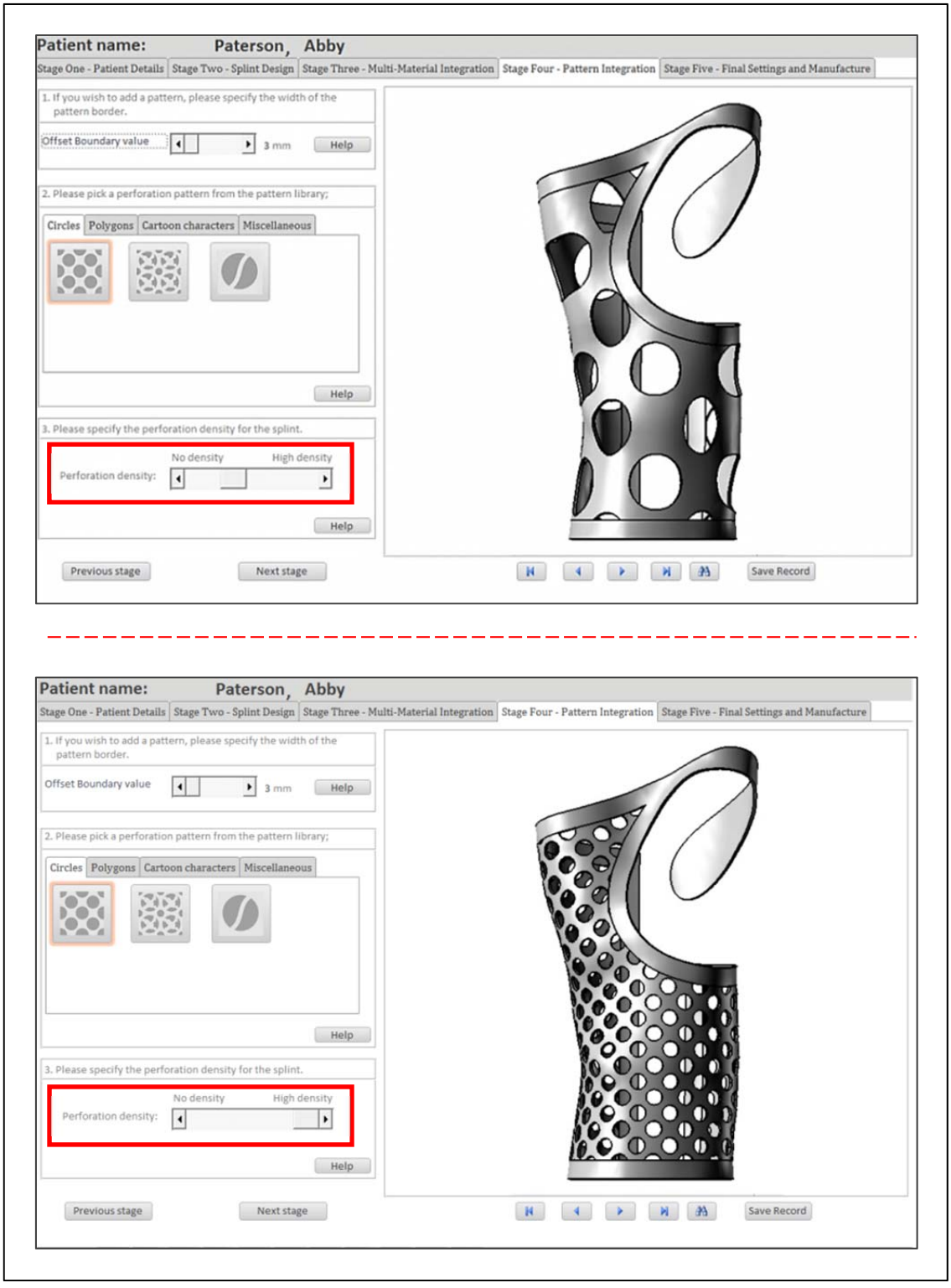

Figure 8: Prototype interface example, and resulting changes from altering pattern perforation density

Ten splinting practitioners within the UK were invited to participate in evaluation sessions (physiotherapist: n=2, occupational therapist: n=8). Eight participants had one-to-one sessions, whilst two participants joined in one session for their convenience. Each evaluation session comprised four activities; a briefing into the intent of AM for splint fabrication; a

demonstration of the prototype; user trials of the software prototype and a semi-structured interview. Qualitative data were captured regarding the digitised approach, together with specialist feedback regarding multiple-material integration into splints. Participants completed a demographic questionnaire to gather data including the number of years splinting experience. In addition, participants signed informed consent forms agreeing to the capture of audio and computer screen-capture recordings whilst testing the prototype. The recordings were used to identify trends in opinions and were transcribed into NVivo (2011), for coding and trend identification. In addition, proof-of-concept splints were manufactured using various AM processes to give physical, tactile representations of the intended output (Figure 9). The purpose was to show participants what could be achieved using AM, to ensure that the intent was conveyed effectively to participants in the context of upper extremity splinting.

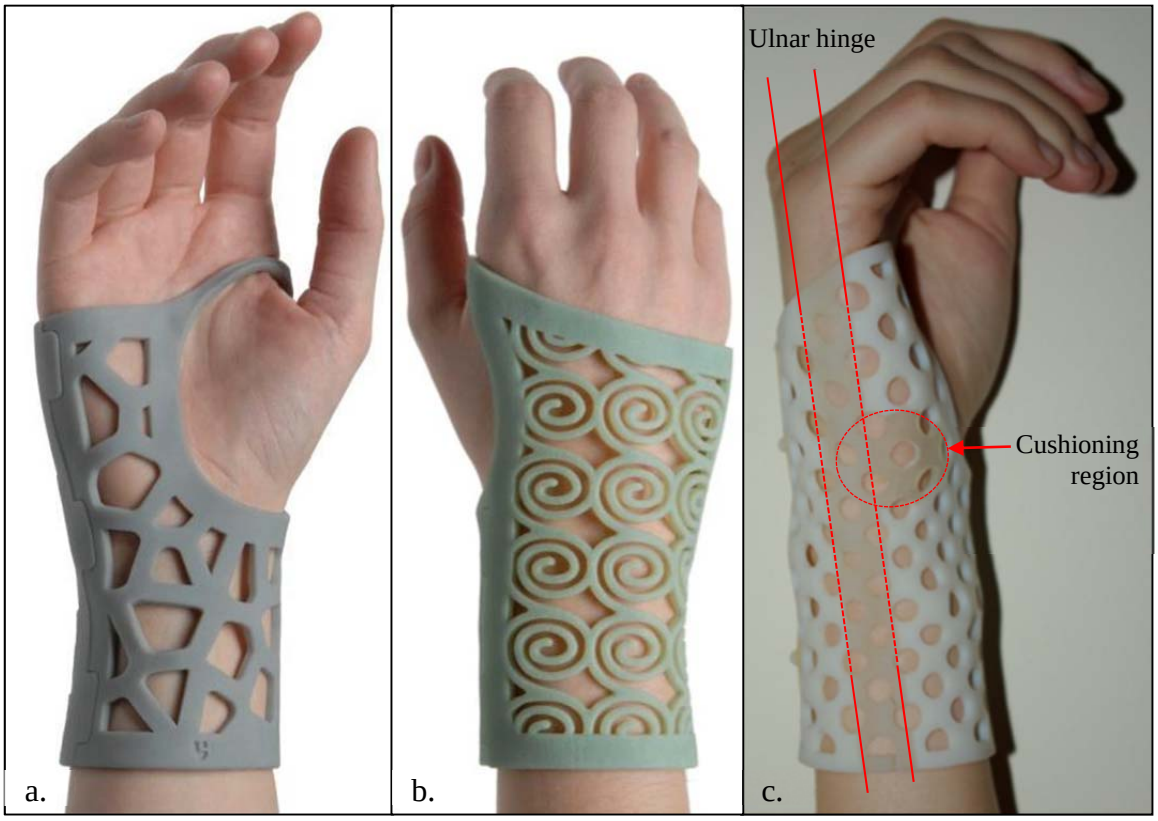

Figure 9: Proof-of-concept AM splints
a. Fabricated using 3D Systems SLA® 250 (3D-Systems Xtreme material). b. Fabricated using Objet Connex500™ (RGD5160-DM). c. Fabricated using Objet Connex500 ™, with multi-material regions (ulnar hinge: FLX9760-DM; cushioning region: FLX9740-DM; remainder of splint: VeroWhitePlus™ FullCure 835).

Results and discussion

A wide range of positive comments and suggestions were gathered during the evaluation sessions. The approach not only highlighted many exciting new avenues for exploration within splint design and fabrication, but it also expanded the window of opportunity for Objet Connex technologies. Participants mentioned that the integration of multiple materials within a single splint was a completely new and exciting toolbox for therapists, which could not be achieved using existing fabrication methods. Participants were interested in new applications as a result of multiple-material capabilities, such as protection and cushioning of bony

prominences without compromising the splint topography. Of the three participants who were asked, all three participants favoured 'mono-splints' with elastomer hinges (as shown in Figure 9c), to make donning and doffing easier for patients with restricted dexterity; two participants even suggested having two hinges, placed along the radial and ulnar aspects of the wrists to assist further. Three participants were interested in using elastomer materials to apply dynamic pressure over areas prone to fluctuating oedema. In extension to these applications, one participant suggested the use of elastomer materials in splints for treatment/management of burns and scars, and protection of post-surgical metalwork (i.e. alignment screws and brackets). Another participant suggested integration of elastomer borders on splint edges, which could aid in pressure distribution and provide a softer interface between the more rigid structure of the splint and the skin. Therapists also expressed their interests in allowing partial dynamic features to allow or restrict movement, similar to *Carpal Skin* by Oxman (2011).

Many participants suggested additional creative features to be integrated within the digitised workflow, such as multicolour integration; one participant asked whether photographs could be applied to splints. At present, colours are limited on the Objet Connex; 3D Systems offer the ZPrinter® 450 multicolour 3D printer (3D Systems Inc., 2012), but this would result in compromising multiple-material feature integration. However, Holmes (2012) speculates that Objet Connex Technologies will soon offer multicolour functionality in addition to multiple-material printing; Oxman (2012) prompted this speculation as a result of recent work, but the intent for market release is yet to be confirmed. Therapists were also keen on part consolidation with regards to fastener integration. Participants felt that the workflow depicted in the software prototype demonstrated the workflow used in traditional fabrication, with the exception of new features, and placement of colour and thickness controls. In response to traversal movement within the workflow; eight participants felt this was a useful feature, particularly since variables could be altered independently from one another; a desirable novelty when compared to traditional splinting.

The intent of edge filleting in the CAD workflow (Figure 7, flow chart item 4.4) was to relieve the need for rolling of splint edges, consequently reducing cumbersome structures presented in traditional splinting. Therapists were surprised at the strength and rigidity of the prototype splints without having folded or rolled edges within the palm. One participant was interested to know whether this would improve palmar grip capacity, since material volume was reduced. However, some participants felt they would still want the opportunity to produce the effect of rolled and folded edges within the splinting software.

Despite the abundance of positive responses, participants also raised concerns regarding data acquisition methods, structural integrity, fabrication time and cost of the approach. Two participants were concerned that oedematous, inflamed regions might protrude through the lattice structure, potentially causing discomfort for the patient. Another participant felt that patient adherence would not only be improved as a result of improved aesthetics, but the level of improved wear duration could potentially be detrimental; they were concerned that patients would be wearing their splints for longer durations than is necessary or recommended, potentially resulting in splint dependency. Cooper (2007) states that static splints should not be worn more than necessary as they contribute to stiffness, atrophy and joint disuse. Therefore, a more stringent wearing regime might be required to combat this concern if AM splints were to be eventually prescribed.

Future work

Although the investigation highlighted many new positive and exciting applications within AM splint fabrication, there is much to be done before the approach can be used as a clinically viable treatment method. To date, the software prototype described in this paper is purely a visual representation for evaluative purposes. Future development is required to create fully functional specialised splinting CAD software. New features must also be investigated for feasibility into workflow integration, such as edge-folding. The ability to re-use previously defined splint files to make replacement splints must also be an integral feature in the CAD approach, as this would allow therapists to fabricate duplicate splints without incurring additional design time. The opportunity to adjust previously defined splint files should also be explored, so therapists may alter one or many design variables where required. Alternative file format exports are also required to support depiction of complex organic geometry, whilst allowing for multiple-material and mono/multicolour capabilities; the development of STL 2.0 or Additive Manufacturing File Format (AMF) is promising, particularly for the composition of complex geometries and multiple-material builds in support of the Objet Connex capabilities (Hiller and Lipson, 2009). In terms of CAD process efficiency, Objet have developed CADMatrix^{TM}; a plugin for material assignment within selected CAD applications prior to automated STL creation (Objet Ltd., 2012a). If the proposed software prototype were to be developed, this approach could be applied within the custom software.

Cost was a concern expressed by the participants that demands further work. It is too early in the development of the CAD approach to predict costs realistically. However, the advantages of the CAD/AM approach for future cost reduction is based on two premises. Firstly, there is very little scope for cost reduction in existing practice. The materials costs incurred in current practice are minimal and by far the greater proportion of cost is attributed to time and salary costs for the professionals involved. There is little scope for cost reduction of the existing materials and significant cost reduction would only be possible by speeding up work or reducing salaries, neither of which is likely to be acceptable and any savings would be small and incremental. A shift to a CAD/AM approach would achieve cost savings by eliminating physical work (especially for remakes or replacements) and enabling a much faster design stage to be completed by the professionals. The separation of the manufacture from the design enables designs to be done at any time, potentially without the patient being physically present, whilst manufacture does not incur salary costs. Whilst AM machine and materials costs are currently high, it is reasonable to assume that these costs will reduce significantly over time as has already been demonstrated by other technologies. The potential advantages of a CAD/AM approach in the provision of custom-fitting medical devices have been recognised in other research, such as the provision of maxillofacial prosthetics (Bibb *et al*, 2010).

Further development of medical grade materials conforming to ISO 10993 category standards will also be necessary for this application, in preparation for clinical trials. In response to burns/scar treatment, further research into suitable materials would be required. The multiple-material splint shown in Figure 9c also suffered a significant amount of warping and deformation at room temperature; these issues will also need addressing.

Although not within the focus of this investigation, FEA should also be investigated to address concerns regarding structural integrity; both the way in which it may be applied to the splint geometry in 3D CAD, but also the way in which the user would interact with the

feature. The approach would need to be easy to use with the potential for automated alterations through analysis and regeneration of problem areas. Therapists expressed the interest into multiple-material splints to either permit or restrict movement, termed 'Synthetic Anisotropy' by Oxman (2011). Therefore, not only does research need to be performed into how to achieve such results in terms of 3D CAD modelling and specification of Objet Connex materials, but also the most efficient way to integrate such features within the specialised splinting CAD software.

In response to therapists' concerns into oedematous regions protruding through lattice structures, displacement mapping could be used on the outer splint surface to overcome such problems. This could be used instead of or in addition to material-to-perforation ratio alterations. Not only would this aim to resolve issues related to oedema, but it would also be a step forward in resolving concerns regarding structural integrity.

Acknowledgements

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