REVIEWED, Accepted August 16, 2012

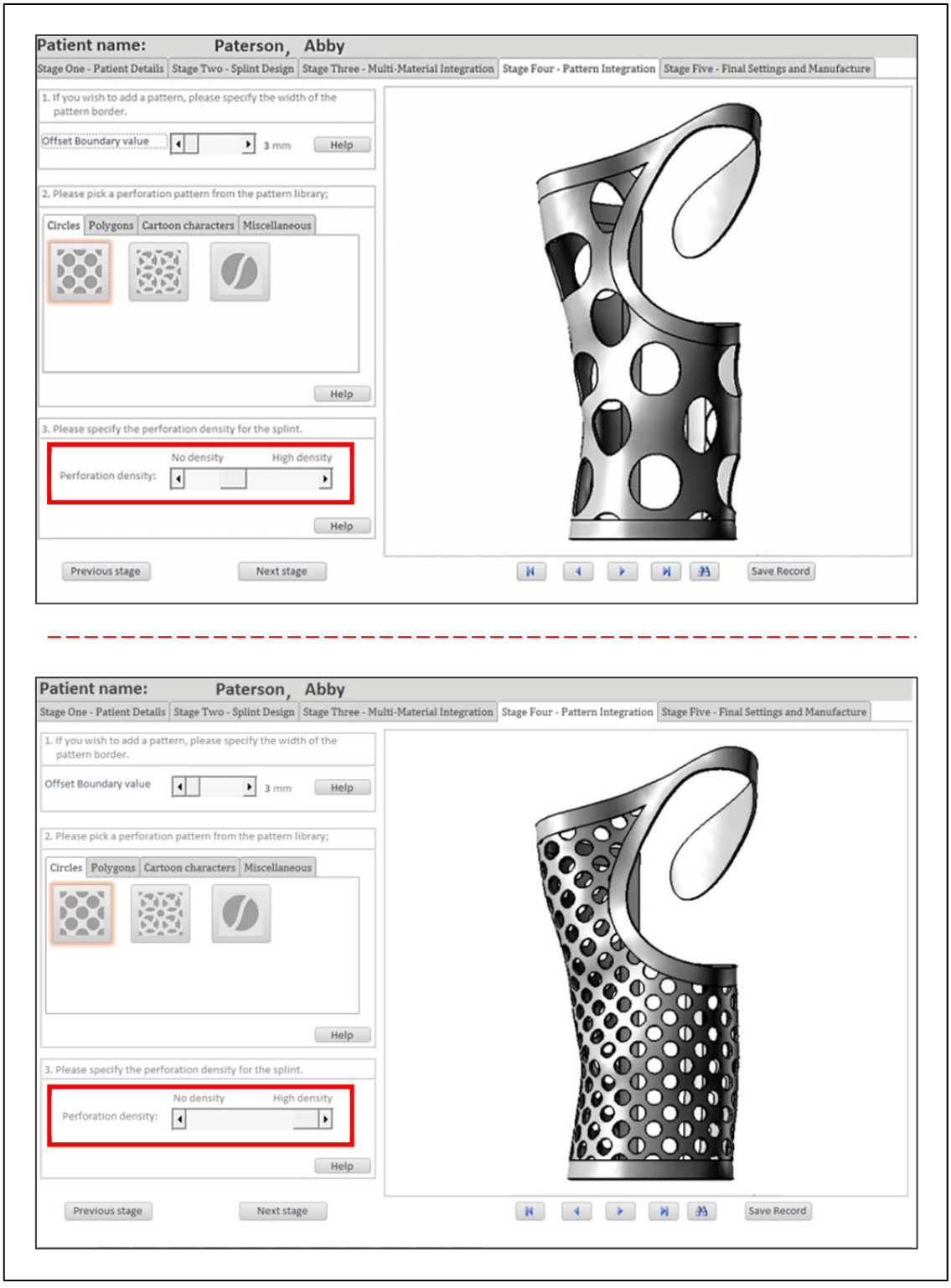

Figure 8: Prototype interface example, and resulting changes from altering pattern perforation density

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.

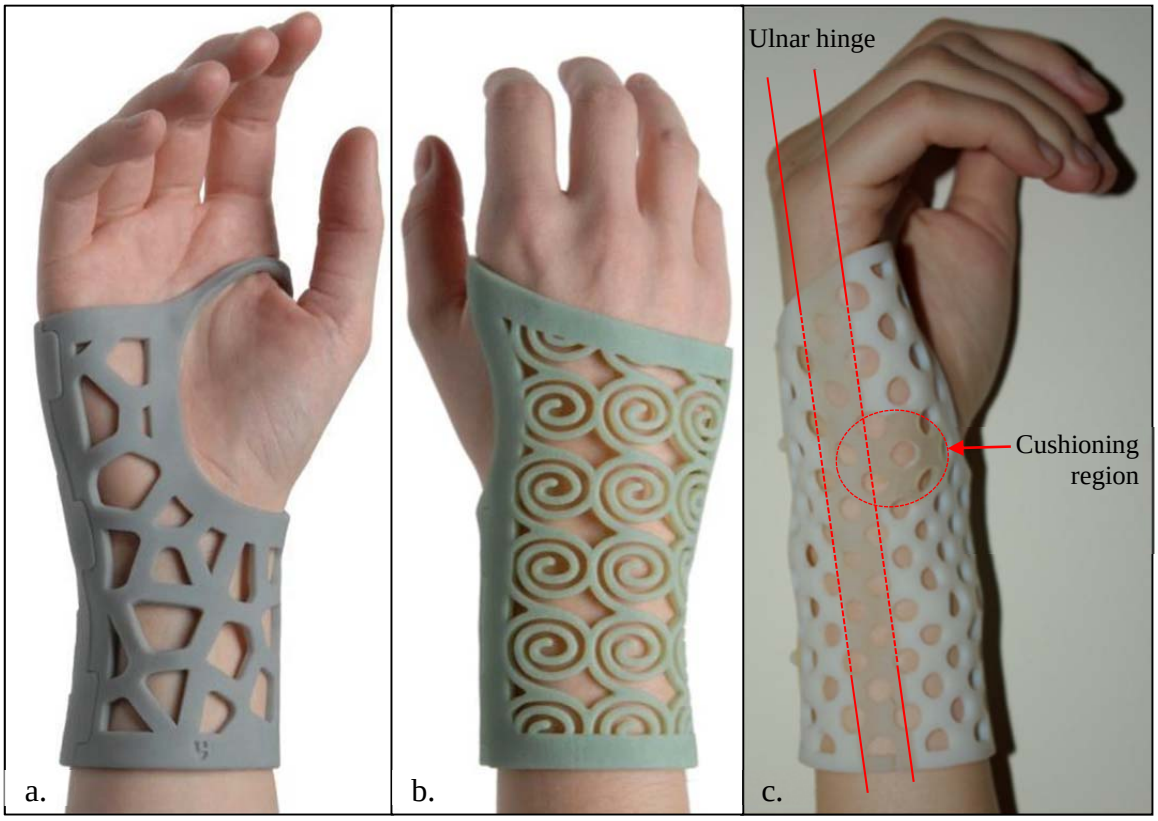

Figure 9: Proof-of-concept AM splints
a. Fabricated using 3D Systems SLA® 250 (3D-Systems Xtreme material). b. Fabricated using Objet Connex500™ (RGD5160-DM). c. Fabricated using Objet Connex500 ™, with multi-material regions (ulnar hinge: FLX9760-DM; cushioning region: FLX9740-DM; remainder of splint: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

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