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Giving Patients What They Want: Proposing Additive Manufacture as a Method to Design and Fabricate Wrist Splints

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ABSTRACT
Patients with Rheumatoid Arthritis may be prescribed wrist splints as part of their treatment regime however; compliance is known to be a problem. Whilst the literature provides an insight into some of the determinants behind compliance, it does not provide comprehensive knowledge of the reasons why patients wear and do not wear wrist splints. Recently, additive manufacturing has been proposed to create wrist splints. However, before developments in AM are made further, it needs to be understood why patients do not comply and what it is about the splint itself which makes patients not want to wear them. The aim of this paper is to use generative design research methods to understand these motivators, highlight the negative features of traditional splints, and explore participants’ dreams for a future splint. This data is then used to discuss how AM can be used in the splinting process.

KEYWORDS: Additive manufacture; Design; Orthotic; Wrist splint; Rheumatoid Arthritis; Compliance; Generative techniques

1 INTRODUCTION
In 2002, it was estimated that in the UK there were more than 400,000 adults with Rheumatoid Arthritis (RA) with up to 20,000 new cases each year [1], [2]. Symptoms of RA can cause reduced mobility, reduced range of motion, pain, fatigue, and discomfort in the hands, wrists, ankles or feet [3], [4]. There are many other conditions that require the same splinting treatment as Rheumatoid Arthritis, such as Osteoarthritis or Carpal Tunnel Syndrome. In clinical practice, many therapists and physicians have observed poor compliance with splint wear [5]. Splint compliance for rheumatoid arthritis patients has been recorded between 17-82% [5], [7]–[11]. Hicks [6] claims this is because rheumatic diseases tend to have a chronic course, and treatment (both medical and rehabilitative) is administered over a long period. This classic approach to the treatment of RA, described as a multi-layered pyramid of ‘education, physical and occupational therapy, rest, and nonsteroidal anti-inflammatory drugs’ [12], has been much unchanged over time.

It has been well documented that are many problems with wrist splints that cause patients to be non-adherent. These include;

- Induced perspiration, consequently leading to odour issues [13], [14]
- Difficulties keeping splints dry and clean [13], [15], [16]
- Limited Function and compromised performance during everyday tasks [16]
- Poor aesthetics [9], [14], [15]
- Fasteners which can be difficult to fix, adjust, remove, and replace [14]
- Discomfort caused by poorly fitted splints can lead to pressure points and friction [13], [15], [16]
- Difficulty donning and doffing the splint [16]
However, many of the statements listed above have been generated from studies focused only on investigating compliance in terms of wear duration, whilst others come from text books and articles with little clinical evidence to support them. Whilst these have provided an insight into some of the negative aspects of splinting, it does not provide a comprehensive understanding of the drivers for patients to wear and not wear wrist splints, along with the extent to which they affect adherence. This understanding of patients is needed to come up with genuine strategies to improve compliance.

2 RESEARCH AIM AND OBJECTIVES
The aim of this paper is to understand why patients do not comply with wearing traditional wrist splints and investigate how additive manufacturing technologies can be utilised to overcome these problems. This will provide evidence for the use of AM technologies in splinting and guidelines to direct the development of the AM splinting process.

Objective 1- Identify the motivations behind why participants choose to not wear wrist splints, the problems they experience when wearing splints and their desires for a future splint.
Objective 2- Review AM technologies and discuss how AM as a fabrication method for splinting could overcome patients’ problems with traditional splints and improve compliance.

This study is designed to understand the motivations behind why participants choose to wear and not wear wrist splints and, investigate participants’ ideal characteristics for a future splint. This data can then be used to see where AM technologies can be utilised to find solution to some of these problems.

3 APPROACH
‘Design research methods’ have been used in this research, a collection of research methods which has not yet been used in this research area. Design research methods are used to inform and inspire the design and development process [18]. Generative design research in particular, gives people a language with which they can imagine and express their ideas and dreams for future experience [18]. This approach allows the researchers to gain rich insights by learning about participants’ behaviour in a realistic context and encouraging them to tell stories about their experience. It provides an empathic understanding of the motivations behind why patients do and do not wear their wrist splints along with their dreams for a future splint to inspire the development process.

4 METHOD
To address the first objective, it was necessary to understand participants’ behaviours in terms of splint wear. Context mapping was selected as a design research tool for this study. This is a technique used for mapping the contexts of people’s interaction with products [19]. The technique is used in this study to visually map participants’ splint wear behaviour over a period of time and within the different contexts of their daily lives. Participants created maps in the form of a timeline, which were then used to encourage participants to tell stories about their experiences of wearing splints throughout a normal day. This is the basic principle behind generative techniques where researchers let people make “designerly” artefacts and then tell a story about what they have made [19]. Using this technique also allows participants to imagine and express their own ideas about how they want to live, work and play in the future [19].
calling up their memories of the past they are more able to elicit their dreams of the future [19]. Participants are given tools to think to the future, to specify their needs and wants for a new splint design.

A picture card task was also carried out to explore the effect of social situations on splint wear. Participants were asked to group scenario cards by whether they would ‘wear’ or ‘not wear’ their splint and by whether they would be ‘happy’ or ‘unhappy’. Participants were then asked to select 3 cards from each group where they could tell a story about an experience they had. Semi-structured interview was used to determine why they behaved the way they did, how they felt and what it was about their splint which made them behave this way.

5 STUDY PROCEDURE
Participants who had taken part in a previous study were contacted to take part. Seven female participants were recruited between the ages of 28 and 62 years. Participants had been diagnosed with Rheumatoid Arthritis for at least 2 years with one participant being diagnosed since birth and, all had been prescribed a wrist splint for at least 2 years. Loughborough University’s Ethic procedures were followed throughout the study. Participants were asked to read a participant information sheet, given the opportunity to ask questions and then sign the consent form. The study was carried out in participants’ homes and the researcher was accompanied by a chaperone.

A timeline of a recent work day was carried out first (weekday for retired or unemployed participants) and then a weekend day. In both timelines, participants were asked to think about the most recent appropriate day to help them recall their activities and behaviours accurately. The picture card task was carried out last, as it was considered a more interactive task which would help to keep the participants engaged.

6 RESULTS AND DISCUSSION
Thematic analysis was used to interpret the results of the study using NVivo. This method is used to identify, analyse and report patterns (themes) within data [20].

The data was initially coded into two groups; motivators to wear splints and motivators to remove splints. It was then further coded into the following groups; negative aspects about wearing splints, positive aspects about wearing splints, negative aspects about not wearing splints, positive aspects about not wearing splints and future splint. The themes within these groups revealed themselves and were not guided by the literature or the researchers’ prior assumptions. In this paper, the negative aspects of splints which lead to patient unhappiness and
non-compliance are discussed, along with participants’ dreams for a future splint. Primary themes are listed within tables 1-3, along with how many participants mentioned the theme and how many references from the data there are to support each theme.

6.1 Negative aspects about wearing splints

<table>
<thead>
<tr>
<th>Themes</th>
<th>Participants</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practical issues with splint</td>
<td>7</td>
<td>149</td>
</tr>
<tr>
<td>Negative social reactions</td>
<td>7</td>
<td>92</td>
</tr>
<tr>
<td>Negative feelings</td>
<td>7</td>
<td>64</td>
</tr>
<tr>
<td>Appearance</td>
<td>6</td>
<td>55</td>
</tr>
<tr>
<td>Tasks harder, doesn’t do enough</td>
<td>7</td>
<td>27</td>
</tr>
<tr>
<td>Rather not wear</td>
<td>4</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 1: Negative aspects about wearing splints

The biggest negative aspect about wearing splints was ‘practical issues with splints’. This theme includes practical elements that are wrong with the splint itself or physical issues the splint causes. The main subthemes include the splint getting dirty, being unhygienic, too restricting, getting in the way and being too bulky. Others include making the pain worse and Velcro sticking and pulling clothing.

‘Negative social reactions’ was the second most prominent theme and refers to unwanted and undesirable attention or responses from outsiders. Interestingly, almost 90% of the ‘negative feelings’ experienced by participants were directly related to the ‘negative social reactions’ participants experienced. This suggests that participants’ moods are affected by the negative social experiences they have when wearing their splints. ‘Appearance’ is a theme which was referenced from nearly all the participants. In this theme, appearance refers to the undesirable visual aesthetic of a splint. All but one participant commented that their splint was unattractive in some way and this could be regarding the way it looks, the colour, the bulkiness of it, the wear and tear caused to it and the medical like appearance to name a few. It was found however that the problem was not always down to an unattractive appearance but was sometimes was down to the blatant visibility of the splint which participants didn’t like.

‘Tasks harder, doesn’t do enough’ is another theme and this encompasses things from when wearing a splint makes a task more difficult to when the splint doesn’t do enough and therefore participants cannot perform or must find another way.

6.2 Motivators to not wear splints

<table>
<thead>
<tr>
<th>Themes</th>
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<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practical issues with the splint</td>
<td>7</td>
<td>140</td>
</tr>
<tr>
<td>Don't need to wear</td>
<td>7</td>
<td>101</td>
</tr>
<tr>
<td>Negative social reactions</td>
<td>7</td>
<td>44</td>
</tr>
<tr>
<td>Doesn't help achieve task</td>
<td>7</td>
<td>24</td>
</tr>
<tr>
<td>Appearance</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td>Alternative way to do things</td>
<td>6</td>
<td>26</td>
</tr>
<tr>
<td>Break from wearing</td>
<td>5</td>
<td>34</td>
</tr>
<tr>
<td>Negative feelings</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Don't have splint on them, laziness</td>
<td>4</td>
<td>9</td>
</tr>
</tbody>
</table>
The most prevalent motivator for participants to not wear splints was ‘practical issues with splint’. This theme has been broken down into subthemes. All participants agreed they would remove their splint if it were to get ‘wet’. This is because the splint is not waterproof and therefore if it got wet it would stay damp. This could lead to bad odours or making the skin uncomfortable and, the splint would end up needing to be washed and dried which is inconvenient when most participants have only one. The data shows that participants will almost always choose to take their splint off because of this reason than deal with the consequences of a wet splint. Another issue linked to getting wet is the splint getting ‘dirty’ or being ‘unhygienic’ as tasks such as washing hands after the toilet, prepping food or cleaning bathrooms all have problems with cleanliness. ‘Restricting’ and ‘in the way, bulky’ are two subthemes which are also seen in the negative aspects about wearing splints. Here the data shows us that for nearly all the participants the experience is negative enough for them to remove their splint. Other notable practical subthemes are ‘inconvenient to don/doff’, ‘makes pain worse’ and ‘Velcro’.

Another theme supported by all participants was ‘negative social reactions’. With the most prominent subtheme being people ask questions or comment, the data tells us that just over 70% of participants consider this type of response from others a reason to not wear their splint. Another common subtheme is draws attention, and of the 6 participants who were affected by this negative interaction, half of them found it reason to take their splint off at some point. Other notable subthemes were look incapable and meeting someone new. Following on, ‘appearance’ was also a theme supported by all participants. All but one participant stated that at some time the way their splint looked was reason enough to not wear it. Some of the reasons that contributed to this were the scruffy appearance due to wear and tear, the splint not matching their outfit and not looking nice or attractive.

The final theme ‘do not want to wear’ is where participants were blatant in that they simply do not want to wear their splint without giving a specific reason.

### 6.3 Dreams for a future splint

<table>
<thead>
<tr>
<th>Themes</th>
<th>Participants</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Discreet, blend in</td>
<td>7</td>
<td>19</td>
</tr>
<tr>
<td>Lees restricting, more flexibility</td>
<td>6</td>
<td>16</td>
</tr>
<tr>
<td>Colour range</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>More attractive</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Match outfit</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Wipe clean, washable</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Waterproof, wear whilst wet</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Better sizes, shaped to me</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Less bulky, thinner</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Less medical</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 3: Dreams for a future splint

After discussing motivations to wear and not wear splints, participants were asked what they would like from a future splint. It is worth noting that most participants were unaware of the
research focus of AM and the splinting possibilities. Their responses were encouraged to be ‘blue sky’ rather than driven by AM.

Whilst just over half of participants said they would want the splint to be more attractive, the more prominent factor in relation to visual appearance was that they wanted it to be discreet. Participants often referred to wanting to ‘blend in’ or ‘disguise’ their splint rather than standing out, and suggestions for this was to have a splint that matched their clothes or one that could roll away up their arm, so it could be quickly hidden. Colour was also mentioned as a factor that could be improved. Participants said they would like to choose a colour that would match their clothes, was more appropriate for work or match their skin tone better. Participants didn’t mention wanting bright or patterned colours.

Almost all participants expressed the need to have a splint which is less restricting. Rigidity was mentioned repeatedly throughout the study as participants said some tasks were just too difficult to perform with a splint on as they felt too restricted. Participant examples taken from the timeline task are using a computer and performing tasks at work, along with household tasks such as ironing, getting dressed and going food shopping.

Having a waterproof or wipe clean splint was discussed by more than half the participants. This is relevant to the data as getting wet or dirty was the biggest practical reason for participants to remove their splint at times when they need it. Participants discussed wanting a splint that was easily wipe clean or one that they could wear as a ‘skin’ and wash their hands with the splint on.

Over 40% of participants mentioned wanting a splint that was bespoke and made to fit them, despite splint size not being mentioned throughout the study. Other desires were for the splint to be less bulky as participants often found they got in the way.

6.4 AM technologies and how they could improve patient experience and compliance

Examples of previous attempts to use AM to create a wrist splint can be seen in a review of wrist splints design for manufacture using AM conducted by Kelly et al. [21] As discussed in this previous work, there has been very little work looking at how AM can benefit patients. Most of the problems discussed above can be directly addressed by incorporating AM technologies into the splinting process.

With the use of AM technologies comes a design freedom unparalleled in other manufacturing techniques. This combined the use of anatomical data capture such as 3D laser scanning allows for the creation of a splint that fits the topography of the patients’ hand, wrist and forearm precisely. As it stands there is currently no commercial system that could capture the topography of the patients’ hand, wrist and forearm in a manner that would allow a clinician to easily manipulate the data. Although there are systems currently being developed such as the 3D Handscanner being developed in TU Delft [22].

This design freedom can also be utilised to create a splint that is less bulky and easier to don or doff. Two prevalent examples include work by Paterson et al.[23] and the Osteoid splint designed by Karasaahir [24]. Both have unique fastening systems and the splint designs seen in [23] also incorporates AM textile hinges. Work by Oxman [25], [26] have shown how functionally grading can be used to create splint can constrain lateral bending while still supporting the wrist. This work has be followed up by a patent application [27]. A less bulky splint could also easily be created, but as of yet there is no evidence that any research has been
carried out investigating this. Any attempt to create a less bulky splint would immediately lead to an increase in dexterity.

The traditional splinting process allows for very little patient involvement, further to that if a patient is prescribed an over the counter splint, the patient may get no choice in the appearance of their splint. It is hoped that by using AM to create splints, which the patient can be brought into the design process and co-design the splint with the clinician. This idea was first proposed by Paterson [28]. It is hoped that by integrating the patients’ opinions into the process, the level of compliance will rise. Currently many of the AM technologies allow for some colour personalisation. ActivArmor [29], formally AmphibianSkin advertises a range of colours in ABS. A splint designed by Paterson uses the Connex3 system to create a multi-coloured splint [21]. Other examples of multi-coloured splints include a splint designed at Morriston Hospital, Cardiff [30] and another Open Bionics and Abby Taylor [31].

Most AM splints tend to be circumferential with a perforated pattern cut out. This design intent creates a splint that will naturally allow for better skin ventilation. By creating a splint with a perforated pattern, there will be better skin ventilation, and therefore less perspiration and associated odour and irritation. One of the biggest concerns of patients is getting their splint wet. As mentioned this is such a concern that nearly all patients in this study remove their splint in cases where their splint may get wet. This fear of getting their splint comes for the fact their splints are fabricated using fabric. This could cause skin irritations and general discomfort if the splint is worn wet or if the patient chooses not to wear their splint, they forego the benefits or wearing the splint and become uncompliant. A combination of material properties and geometry of an AM splint means that the water will not be retained in the splint, meaning it is possible for the patient to wear their splint while doing tasks with water. This will also lead to a less “scruffy” appearance most patients associate with their splint. It is also hoped that by allowing the patient to design their own splint, they will inherently see the process in a more positive manner. Kate Bush [32] has likened the evolution of wrist splints to that of glasses. These were once seen as a medical device but are now worn as a fashion item.

Using AM to create splints will allow patients to design a more discreet splint, including one that is more transparent or a closer match to the patients’ skin tone. It is postulated that the reason patients want a more discreet splint is due to the negative social stigma that comes with wearing a wrist splint. It is hoped that by changing the way in which a patient views their splint, from a medical device, to a piece of art they created, that the public will follow suit. Probing questions will no longer be negative, but questions about the new technology, the design and how much input the patient had.

7 Future Work
This study exposed many determinants for patients to wear and not wear wrist splints along with participant desires for a future splint. Proposed future work will investigate using AM to fabricate personalised splints giving the patient choice and involvement in the process. Participants will digitally personalise the appearance of a splint to allow the researcher to understand the aesthetic choices they make and how this affects their acceptance of a splint. It is also important to note that although it is currently possible to design and manufacture a more aesthetically pleasing, personalised splint, there is little research to back the safety of AM splints. Proposed future work will investigate the implicit safeness of a splint created using AM and how design rules could allow for the creation of safe splints.

REFERENCES


[22] “TU Delft: 3D Handscanner.”


