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DESIGN INSIGHT

Development of a bespoke 3D-printed spinal brace for lumbar support

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SUMMARY
Low back pain (LBP) is a significant contributor to disabilities in the UK. Many factors cause LBP, including poor posture, obesity, and spinal fractures, all resulting in spiralling healthcare costs. If spinal fractures are not properly braced, they can lead to weakened vertebrae in the spine and larger risks that can reoccur. There are many problems with flexible, semi-rigid and rigid braces currently available on the market. We present the user-centred design approach undertaken by a multidisciplinary design team consisting of product designers, design engineers, technical specialists, and healthcare professionals to develop a bespoke 3D-printed spinal brace using a digital design workflow.

Key Words
3D printing; 3D-printed lattices; Lumbar support; Spinal fractures; User-centred design

INTRODUCTION

Low back pain (LBP) is a common musculoskeletal problem and a burden to the global population. The prevalent numbers of people with LBP in 1990 was 377.5 million, increasing to 577.0 million in 2017[1], and these numbers continue to increase. It is estimated that 15 per cent to 20 per cent of adults a year will have back pain, but 50 per cent to 80 per cent of people experience at least one episode of back pain during their lifetime.[2] The costs associated with LBP are significant and continue to increase both directly and indirectly.[3]

Numerous treatment options exist for LBP, including staying active; back exercises/stretches; use of pain killers; application of hot/cold packs; specialist treatments, including manual therapy, psychological support, etc.; nerve treatments; and in a worst-case scenario surgery.[4] In some cases, a spinal brace is prescribed to help reduce LBP muscle tension, to help improve posture or weight distribution in the spine, provide a healthy healing environment for spinal structures, or even increase functionality during daily activities. Spinal braces are available in various shapes, sizes, and types and are used for both nonsurgical and post-surgical scenarios. They can range from the flexible back brace type to rigid and semi-rigid orthoses. Spinal braces are often used post-surgery for spinal fractures, lumbar support braces and for rehabilitation after surgery. Published research has suggested that the use of lumbosacral orthoses can result in improved disability index and pain scores when participants use a rigid spinal brace when compared with a flexible brace.[5]

The production of a rigid or semi-rigid lumbosacral orthoses is a time-consuming manual process, and the results can be uncomfortable to wear and expensive to produce. However, use of modern digital fabrication equipment and software such as 3D scanning, reverse-engineering CAD programs, additive manufacturing, etc., could enhance the design and fabrication of bespoke rigid braces or semi-rigid spinal braces.

SUMMARY

In response to the numerous issues identified with existing spinal braces, we sought to develop a bespoke 3D-printed spinal brace using a patient-focused digital design workflow. With the project team adopting a user-centred design approach during the research and design phase, the team completed a full assessment of the current state-of-the-art by reviewing literature and products available on the market. We undertook an examination of existing products through product teardowns, as well as ethnographic and empathic research observations using existing braces (Figure 1). We also explored a variety of possible 3D-printing techniques to enhance product strength using lattices such as triply periodic minimal surface (TPMS), conformal, and honeycomb structures.

Figure 1: Ethnographic and empathic research assessing different back braces currently available on the market*

** The individual modelling in Figure 1 granted the authors permission to use his images.*

The team employed recognised research and design activities, including literature reviews, interviews with medical professionals and patients (Tables 1–3), ergonomic and anthropometric research, product design specification definition, concept generation, design detailing, and 3D-printed structure testing. Our multidisciplinary project team used a digital design workflow (Figure 2) to demonstrate how patient assessment and product development can result in the final bespoke solution (Figure 3).

Figure 2: Anticipated workflow to produce a bespoke Lattibrace for a patient

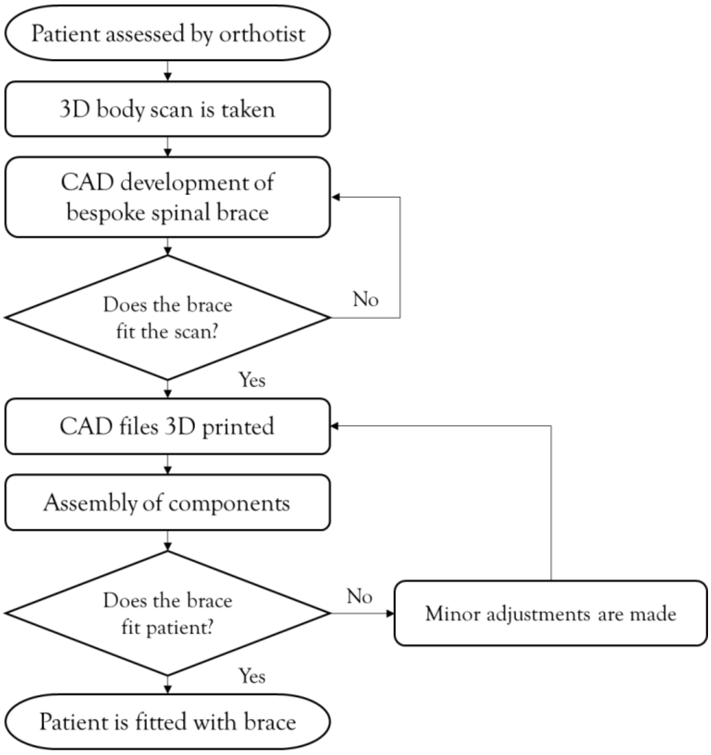

Figure 3: Lattibrace–a bespoke spinal brace for lumbar support

** The individual modelling in Figure 3 granted the authors permission to use his images.*

A critical aspect to our approach were the insights collected from five semi-structured interviews conducted with two physiotherapists, two spinal surgeons, and a patient (current user of a spinal brace). From the interviews we identified numerous themes, which yielded insights and reflections that enhanced our design progress (Table 1–3). The designed bespoke spinal brace for lumbar support (Lattibrace) consisted of the following features:

- 3D-printed anterior and posterior spinal supports using a conformal lattice structure, which provides enhanced structural integrity and suitable airflow to patient anatomy.
- These anterior and posterior spinal supports are lined with padding secured to the brace using an epoxy adhesive.
- Velcro is attached to the relevant cavities on the brace using an epoxy adhesive.
- The straps (with Velcro attached via stitching) are secured to the front of the brace, using binder screws providing support from both sides of the brace, the straps slot around the torso and through the back piece before attaching to the Velcro on the brace.

Table 1: Summary of key quotes from interviews with physiotherapists

Key Theme	Key Quote	Reflections
Competitors	*"They tend to use an LSO off the shelf, which is a carbon flex material. That has got a bit of give on it though, but that is the standard one off the shelf that they use".*	It was interesting to hear that physiotherapist's mostly used off-the-shelf braces, typically the carbon flex ones. This was mostly down to the fact that it was easily obtainable, and it was the most effective option available to them to achieve the desired outcome.
Usability	*"All the patients that we use it for tend to be a little bit older or a little bit more frail, so the biggest disadvantage to it is the patients putting it on and off themselves and then needing family support in order to put on appropriately".*	The general demographic that uses braces was the older generation. The physiotherapist suggested that if you use one big Velcro strap to secure the brace together, it would potentially be easier for the individual who is slightly weaker to secure the brace themselves.
Anatomy	*"The evidence out there already is quite minimal, and it tends to be more clinical evidence. I think it also tends to be the levels that have the surgery on, so to have their lower thoracic, so like T12 and L1/L2, they will tend to brace for there as opposed to an L3/L4 just based on the anatomy".*	It was critical to understand how the anatomy of the spine impacts whether a patient is a candidate for a brace or not. To be effective, any designed brace will need to support the precise point of injury.
Mobility	*"Patients are more likely to want to move and bend. Depending on if it's a fixated one, or one that is a little bit more flexible, it means you can't move and do normal activities".*	Although the physiotherapist deals with clients further down the treatment pathway, mobility considerations will be critical for patient recovery and therefore accessibility considerations must be factored into any new solution.
Heat	*"Soft tissue massage or some manual therapies to reduce the pain. It could be heat; heat is a really good one".*	Heat is deemed an effective method of relieving pain; it relaxes muscles, which subsequently reduces the tension that is causing the back pain.
Product Lifespan	*"Making something fixated you have to bear in mind you wouldn't want something like that for a long time because it is restricting someone's normal movement".*	Typical longevity of a brace is very short, which suggests that any design must consider the recyclability and end-life considerations after final use.

Table 2: Summary of key quotes from interviews with spinal surgeons

Key Theme	Key Quote	Reflections
Sustainability	*"For me instead of having something off the shelf that's made of non-recycled material, having something that was actually recyclable so it could be the same cost or around that price range, but is recyclable then used again, then that will add huge value".*	An interesting point was made that most back braces cannot be recycled or repurposed after their short period of use. This means that back braces in their current form are incredibly unsustainable. Moving forward the brace should be designed in order to be easily recyclable considering suitable recyclable materials.
Lead Time	*"Point out that in the NHS, so if the private sector is this like the model of perfection that the minimum turnaround is a week, but in the real world in the NHS it might be you know 3–4 weeks wherever else".*	Looking at both perspectives of the public and private healthcare sectors it was noted that custom braces take no longer than a week to be made. This was not the case for the NHS, as it would typically avoid custom braces where possible as the lead time was extensive.
Challenges with 3D Printing	*"Can you make it rigid enough to produce the function we want to produce—that is, control the spine in 6 dimensions. So that's the first challenge, structural. Second would be cosmetic, is it acceptable to the patient, is it acceptable to people around them, and is it acceptable to the doctors prescribing it".* *"Thirdly, it's going to be sustainability and making sure that it's made of a material that is actually recyclable. Fourth is going to be cost. Then fifth is speed of delivery and the technology required to take the mould if you like and turn that into your 3D brace".*	It was helpful to hear the perspectives from spinal surgeons on the use of 3D printing and possible challenges that could be encountered during the manufacturing stage. The five key points made are to be factored into the project product design specification and the design and manufacture of the final prototype.
Existing Technology	*"They'll either take a 3D scan of the patients or they take a cast of the patients dependent on what is needed and then make a custom brace for the patients".*	This insight supports the advancement and acceptance of 3D printing in the medical field in addition to the use of 3D scanning. 3D scanners will allow a bespoke solution to be made quickly through accurate body scans, which can be converted into CAD measurements and morphology of a patient.

Manufacturing Time	*"I think the advantage you have is perhaps that the core plastics work is done very quickly".*	It was interesting to hear from a medical professional perspective that the main advantage to 3D printing is that the main core plastic part production is perceived to be a relatively quickly process, which then allows for more time to be spent on making sure the padding attached to the bespoke device is sufficient.

Table 3: Summary of key quotes from an interview with a patient and back brace user

Key Theme	Key Quote	Reflections
Competition	*"The NHS can only use a product given to them through the company because they have sponsors that lend them the products before you have to pay".*	The participant explained that the NHS can only use certain brands of braces that they get from sponsors or approved suppliers. This helped with further research on existing braces where an assessment of their strengths and weaknesses can be completed.
Padding	*"There was a lot of padding that wasn't thick enough. It must be tight on you, but the edges dug into my waist where the plastic parts were".*	After learning about the patient experience from wearing a back brace, it was made abundantly clear that comfort was a significant factor due to the fact the user is wearing it for many hours of the day.
Rehabilitation	*"I had to take it off and not wear it if it wasn't pain related, so I'll just take it off and if I started to hurt, I'll put it on again".*	Towards the end of the rehabilitation period the participant was asked to take the brace off to help stimulate muscle growth. This suggested that the fastening aspects of the brace would need to be easily accessible to allow for adjustment or removal numerous times.

LESSONS LEARNED

The production of Lattibrace has enabled the project team to produce a solution that is lighter and structurally enhanced and provides increased comfort and airflow to the patient. Significantly, the use of digital design tools such as 3D scanning, reverse-engineering CAD software, and 3D printing, can reduce the need for uncomfortable and time-consuming procedures such as the production of custom orthotic castings, whereby subsequent models are used to produce a patient's brace. By using a digital design workflow, we can potentially reduce the number of stakeholders in the manufacturing process, but also reduce the number of appointments a patient will need to attend. While there may be significant initial setup costs associated with the use of equipment associated with a digital design workflow such as 3D scanning/3D printing, over a sustained period there is potential to make significant savings.

Traditional solutions result in a more time-consuming process involving consultancy fees, casting and workshop costs, and follow-up appointments required for the manufacture and testing of a traditional brace.

Feedback provided by a spinal consultant on Lattibrace was overall very positive. The spinal consultant noted that "the brace has clean lines and the ability for it to breathe, which will be welcomed by users" and "the new securing mechanisms and load characteristics are impressive; the latter should mean the brace is robust in everyday use for people with spinal problems".

In conclusion, we cannot overstate the importance of using a multidisciplinary research and design process and an interdisciplinary design team. The combination of product designers/design engineers working alongside technical specialists in 3D scanning/3D printing, allowed the project team to produce an enhanced solution. The valuable input from healthcare professionals and stakeholders was imperative to allow this bespoke spinal brace to be produced. The value and importance of patient feedback is imperative when working in multidisciplinary design teams consisting of product designers, design engineers, technical specialists, and healthcare professionals.

This study has demonstrated the use of a patient-focused digital design workflow that uses 3D scanning of patient anatomy to produce a 3D CAD model based on the patient's anatomy, enabling a 3D-printed solution specific to the patient to be produced. This workflow has proven successful in the production of a successful and desirable solution. This use of a digital design workflow could potentially allow for patient-specific spinal braces to be produced in the future, which in turn could result in a more efficient workflow with the potential to increase patient throughput and reduce costs. We therefore strongly recommend and advocate for the use of multidisciplinary design teams and the use of digital design tools such as 3D scanning/3D printing in the development of future bespoke spinal braces.

DESIGN INSIGHT

This article touches on two very current and important approaches in human-centred design. First, the multidisciplinary design team (designers, engineers, and doctors) employed empathic research to understand the user's interaction and points of view about a product (brace) that is worn on their body. Empathic research allows people to see from perspectives different than their own, gain deeper understandings of their users, and use divergent thinking to find and identify problems. The team explored how the user dons the brace and sought to understand not only the physical but also the emotional impact of the user's experience. Rather than focusing solely on the end-user, they also incorporated insights from multiple expert-users including physiotherapists, spinal surgeons, as well as the patient. This puts all the users' needs at the heart of the product. This type of research can lead to more intuitive outcomes in all types of product development, but especially in the case of this medically necessary brace.

Second, while various users may have similar physical needs for a back brace (eg, due to a specific type of surgery or injury), the requirements for individual customisation prevent it from being a truly mass-produced product (where a one-size or multiple-size approach is unlikely to fit even most). This led the team to the idea of a "bespoke", product built for a specific user (eg, a suit made from scratch to fit one individual). At its inception, 3D printing was a means to demonstrate a concept built in CAD that was designed to be mass-produced. However, continued advancements in this technology as well as the number of materials available have revolutionised the way that we can prototype and produce goods. As shown in this example, rather than modifying mass-produced component parts to fit a user, digital files (that might be somewhat componentised) are scaled and customised to match a specific user's need, and the physical 3D-printed part becomes a cost-effective bespoke product that is truly designed and built directly for a unique user. As a practicing industrial designer and ID educator, I am excited to see this implementation of human-centred design.

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CONFLICTS OF INTEREST

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ETHICS COMMITTEE APPROVAL

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