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Digital design and fabrication of controlled porosity, personalized lower limb AFO splints

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Abstract: We present the preliminary phases of developing a custom lower limb splint concept which considers both design and mechanical elements of the final device. We present an approach to verify the flexural properties of the device through the systematic measurement of flexural stress of 3D printed samples and how this evolves based upon increased porosity. Our initial results demonstrate we can effectively predict the stiffness characteristics of a 3D printed splint concept and apply this to inform the design choices.

I. Introduction

Ankle Foot Orthosis (AFO) are a classification of externally worn medical devices which support the lower limbs of a person to treat an underlying physical impairment, from conditions such as compromised musculature, drop-foot, stroke and cerebral palsy [1]. Often users experience poor fit of an AFO, complaining of pain and discomfort, the aesthetics of a device and chaffing due to inadequate moisture release. This results in the user not wearing the AFO for the prescribed daily durations, thereby reducing the therapeutic usefulness. To improve user conformity, devices ideally need to be more ergonomic, incorporate great levels of airflow and have the flexibility to incorporate custom design aesthetics.

Traditionally, AFO devices are hand crafted using either plaster of Paris or thermoplastic materials using time consuming methods, which require several patient visitations. Digital scanning, Computer Aided Design (CAD) and Additive Manufacturing (AM) workflows are emerging as an advantageous alternative to traditional fabrication methods. This approach allows considerable potential for AFO production, as a patient's anatomy can be recorded precisely digitally using surface scanning and stored for future use [2]. Equally, design iterations are assessed virtually, reducing the potential number of patient visitations. Finally, the use of AM provides a considerable number of design freedoms to realise complex patient-specific device geometries, localised mechanical properties and unique aesthetic qualities matching patient preferences [3]. Indeed, such technologies have been demonstrated effectively for upper limb splints [2, 3], and more recently attention is moving to focus on applications for the lower limb [1].

We examine the use of digital design and fabrication toward the construction of functionally personalised AFO for drop foot. Ideally, devices need a balance of stiffness, flexibility and porosity while minimizing thickness to create a discrete AFO that can be worn easily within a person's existing footwear. Most studies to date focus on design elements, we now investigate how the flexural mechanical properties evolve based upon the introduction of open, porous design features. We conducted and compared standard 3-point flexural bend tests on various 3D printed samples with varying porosity against commercial splint thermoplastic material. We then assessed the feasibility of designing these porous features into a drop foot AFO concept based upon using a participant's anatomical data.

II. Material and methods

II.I Flexural tests

Flexural tests were conducted using 3-point bend tests as stipulated in ASTM standard D790 for flexural testing. This comprised five test repeats using rectangular test coupons with dimensions 3.2x12.7x127mm. All flexural tests were performed using an Instron 5960 Dual Column 50kN universal test system (MA, USA), set a with strain rate of 0.01 (mm/mm)/min.

II.II AFO Design and Manufacturing

Person specific data was obtained scanning a volunteers' foot placed at approximately 5 degrees of dorsiflexion, which mimics preloading. Scan data was obtained using an Artec Spider scanner and post processed using Artec Studio 10 software (Artec, Luxembourg), producing a template STL file for further design manipulation, as previously described [2]. AFO designs were creating using 3-Matic STL software (Materialise, Belgium) using the individual's scan data as a template to create the final concept. The AFO was 3D printed using a Creator Pro FFF system (Flashforge, China) in ABS polymer, using a 0.2mm layer thickness, print temperature of 235^{o}C, print bed temperature of 100^{o}C and print speed of 60mm/s. AFO bindings were realized using Velcro straps which were slotted into two recesses, designed into the AFO.

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III. Results and discussion

Several porous flexural samples were examined to determine the flexural stress strain relationship or configurations which could be incorporated into the AFO design. Figure 1a) illustrates the sample porosities examined for regularly spaced circular pores with a diameter of 7.5mm. Figure 1b) illustrates the measured flexural stress for increasing porosity of samples, alongside a measurement using standard 3.2mm AFO thermoplastic materials, for reference. It was found that the ABS material, even at the highest porosity examined (38%) was found to be approximately twice the flexural stiffness than standard thermoplastic material. This is a favorable result as increased porosity reduces mass and increases the moisture release capacity of a respective design. Additionally, initial results suggest we could use ABS material at porosities >38% and maintain an appropriate stiffness. We hope to investigate this further in future studies.

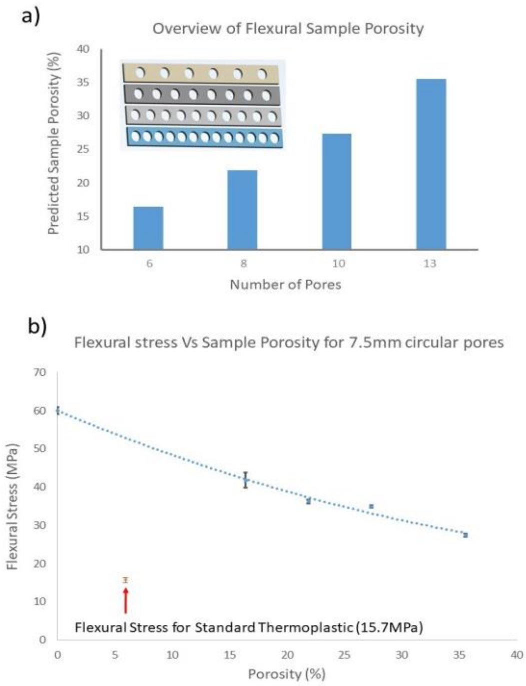

Figure 1: 3D Printed sample flexural data

Figure 2 illustrates a basic overview of the digital manufacturing process elements. The basic form of the AFO was created through various boolean subtraction, digital trimming and smoothing operations, before circular patterns were projected through the resulting model. Based upon the flexural data it was observed that with the maximum pore density examined (38% porosity), the stiffness of ABS still surpasses that of the thermoplastic material. We therefore utilized this density to create the final AFO CAD concept, which can be seen in figure 2. The resulting CAD model was then 3D printed and test fit on the study volunteer. Feedback from the volunteer was that the AFO fitted very well and felt comfortable to wear, even when worn within their current footwear. While much more work needs to be conducted, these preliminary results show the potential of our approach to create functionally personalised AFO.

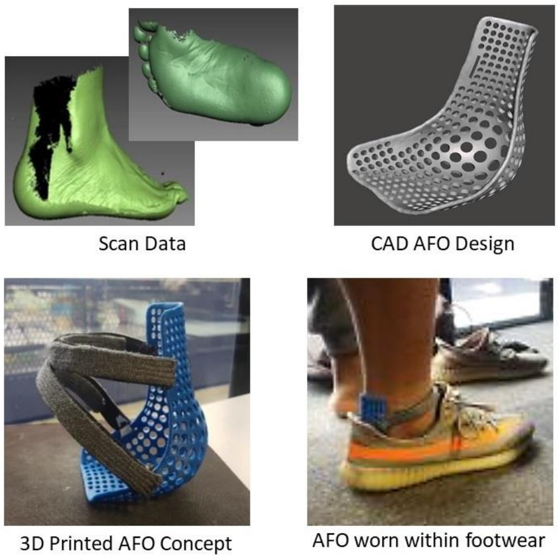

Figure 2: Various stages of AFO development

IV. Conclusions

We demonstrate a robust method of determining the ABS flexural stiffness for a given porosity. These results can be applied to inform the design of a lower limb AFO, which has been realized using digital manufacturing. Using this approach, we believe we could realise a generation of AFO, which has greater design and mechanical conformities for potential clinical use.

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Author's statement

Authors state no conflict of interest. The research related to human use complies with all the relevant national regulations, institutional policies and has been approved by the authors' institutional review board or equivalent committee.

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