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EFFICIENT DIGITAL MODELING AND FABRICATION WORKFLOW FOR INDIVIDUALIZED ANKLE EXOSKELETONS

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ABSTRACT

We introduce a new design method to tailor the physical structure of a powered ankle-foot orthosis to the wearer's leg morphology and improve fit. We present a digital modeling and fabrication workflow that combines scan-based design, parametric configurable modeling, and additive manufacturing (AM) to enable the efficient creation of personalized ankle-foot orthoses with minimal lead-time and explicit inputs. The workflow consists of an initial one-time generic modeling step to generate a parameterized design that can be rapidly configured to customizable shapes and sizes using a design table. This step is then followed by a wearer-specific personalization step that consists of performing a 3D scan of the wearer's leg, extracting key parameters of the wearer's leg morphology, generating a personalized design using the configurable parametric design, and digital fabrication of the individualized ankle-foot orthosis using additive manufacturing. The paper builds upon the design of the Stevens Ankle-Foot Electromechanical (SAFE) orthosis presented in prior work and introduces a new, individualized structural design (SAFE II orthosis) that is modeled and fabricated using the presented digital workflow. The workflow is demonstrated by designing a personalized ankle-foot orthosis for an individual based on 3D scan data and printing a personalized design to perform preliminary fit testing. Implications of the presented methodology for the design and fabrication of future personalized powered orthoses are discussed, along with avenues for future work.

Keywords: Additive Manufacturing, Scan-based Design, Rehabilitation Robotics, Active Orthoses, Personalized AFO

NOMENCLATURE

AM	Additive Manufacturing
AFO	Ankle Foot Orthosis
C1	Component 1 - Hard Exterior Calf Shell
C2	Component 2 - Hard Exterior Shoe Casing
C3	Component 3 - Soft Interior Calf Liner
D1 – D13	Parameters used in design table for C1
FDM	Fused Deposition Modeling
FEA	Finite Element Analysis
FFF	Fused Filament Fabrication

1. INTRODUCTION

Stroke and traumatic brain injury often result in long-term disabilities, including hemiparetic gait. Early, intense, and repetitive gait rehabilitation can facilitate recovery of walking function and improve quality of life [1,2]. However, cost-benefit considerations and availability of professional therapists often limit exercise dosage to suboptimal levels, preventing patients from achieving their full recovery potential [3].

Lower-extremity exoskeletons and powered orthoses have the potential to increase the frequency and intensity of treatments and enable highly repetitive practice, thereby improving gait rehabilitation outcomes [4]. These devices have been studied for nearly two decades in research laboratories around the world, but only recently have some of them been commercialized and cleared for use with brain injury populations [5]. Despite these advances, how to design powered orthoses and exoskeletons to best promote recovery of walking function is still an open research problem. In this regard, a key aspect of traditional exercise-based therapy, i.e., the importance of individualizing the interventions to the patient, has been largely overlooked by roboticists and designers.

The mechanical structure of most powered orthoses is often handmade by professional orthotists using plaster molding and thermoplastic vacuum forming, in a similar fashion to traditional passive orthoses. This process offers limited design options and involves significant labor. Trial-and-error readjustments are often required to improve comfort and fit, but these cannot completely prevent skin abrasions, bruises, pressure sores, and blisters from developing with orthotic use [6]. Frequent causes of skin injuries include excessive pressure points and relative motions between the limb and the orthosis due to poor fit. Because discomfort is the leading cause of low patient compliance with orthotic interventions [7], there is a compelling need for a new design methodology to enable the fabrication of patient-tailored (i.e., individualized) orthoses. This need is even more critical for powered orthoses and exoskeletons, which provide active assistance to the wearer, resulting in larger human-orthosis interaction forces [8]. Soft powered orthoses (exosuits) do naturally conform to the wearer's body. However, they do not provide the level of mediolateral ankle support that semi-rigid orthoses can afford. For this reason, semi-rigid ankle-foot orthosis (AFO) designs are more suited for patients with moderate to severe gait or balance impairments.

Herein, we introduce a new design method to tailor the physical structure of a powered ankle-foot orthosis to the wearer's leg morphology to provide a better fit and reduce discomfort. We present a digital modeling and fabrication workflow that combines scan-based design, parametric configurable modeling, and additive manufacturing to enable the efficient creation of personalized ankle-foot orthoses with minimal lead-time and explicit inputs. The workflow consists of an initial one-time generic modeling step to generate a parameterized design that can be rapidly configured to customizable shapes and sizes using a design table. This step is then followed by a wearer-specific personalization step that consists of 3D scanning of the wearer's legs, parameter extraction of the wearer's leg morphology, personalized design generation using the configurable parametric design, and digital fabrication of the individualized ankle-foot orthosis using additive manufacturing.

The paper builds upon the design of the Stevens Ankle-Foot Electromechanical (SAFE) orthosis presented in prior work [9,10] and introduces a new, individualized design (SAFE II orthosis) that is easier, faster, and more affordable to fabricate. The workflow is demonstrated and evaluated by designing and printing personalized ankle-foot orthoses for an individual based on 3D scan data and gathering feedback on fit and comfort.

The paper is organized as follows; in Section 2, the general design of the personalized ankle exoskeleton is presented by introducing the various components of the SAFE II orthosis. The workflow for personalizing the SAFE II orthosis to an individual leg morphology using 3D scanning and scan-based design is presented in Section 3. Section 4 presents the fabrication process and feedback from preliminary fit testing which is followed by a discussion of the presented workflow in Section 5 and the conclusion in Section 6.

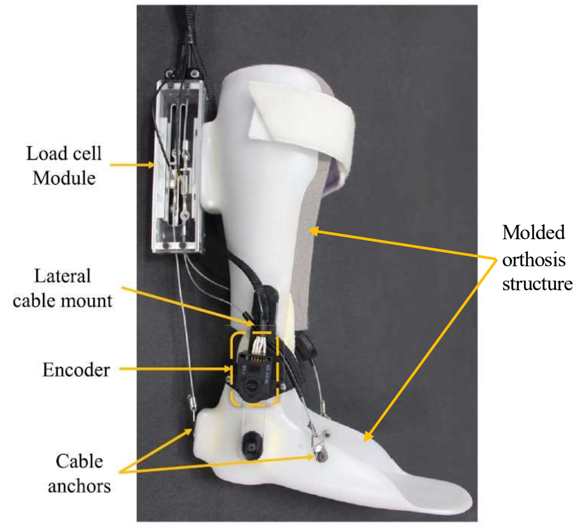

Figure 1*: The original Stevens Ankle-Foot Electromechanical (SAFE) orthosis presented in prior work [9,10]. Orthosis structure is handmade by professional orthotists using plaster molding, vacuum forming, and trial-and-error refinements for comfort and fit.*

2. SAFE II ORTHOSIS DESIGN

The SAFE II orthosis is designed to take advantage of parametric modeling and design tables to enable customization of the orthosis design to fit the leg morphology of an individual. It is designed to utilize the same sensors and cable-based actuation system for ankle plantar- and dorsiflexion as the original SAFE orthosis [9,10]. Changes were also made to the structural design of the orthosis to improve the wearer's comfort by replacing hard contact surfaces on the calf and the foot of the wearer with soft surfaces.

The generic design for the SAFE II orthosis is composed of three main components labeled as C1, C2, and C3 in Figure 2. C1 is a hard exterior calf shell used to mount the actuator box which houses the load cells and guide sheaths for the actuation cables. C2 is a hard exterior shoe casing that is rigidly bolted to the outsole of the shoe. The shoe casing was preferred to the shoe insert of conventional AFOs to improve the wearer's comfort. C3 is a soft interior calf liner that sits between C1 and the wearer's calf. This component was also added to improve comfort and allow for better fit during motion and muscle contractions. The generic shape of C3 (i.e., before individualization) is intentionally designed to intersect with C1 as well as the mesh of the scanned leg.

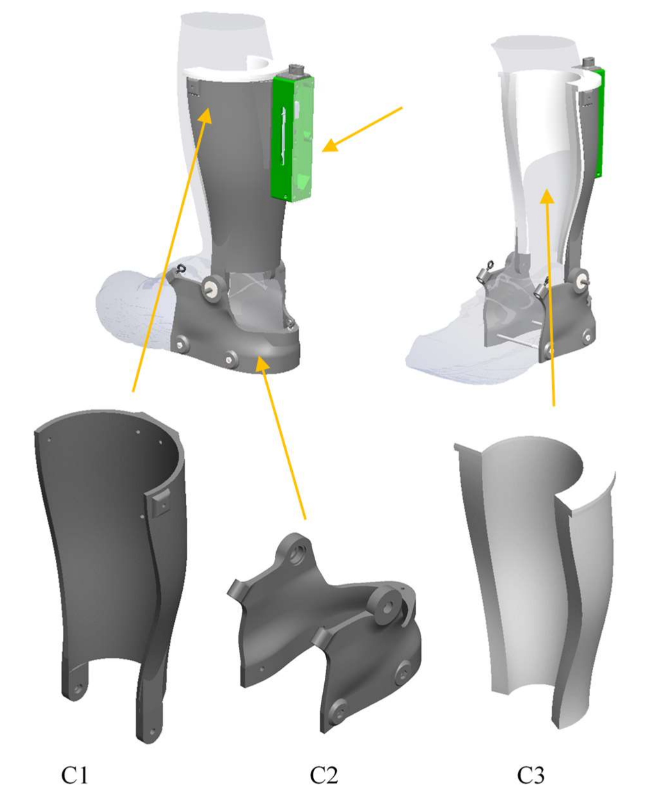

Figure 2*: Components of SAFE II orthosis generic design. C1- hard exterior calf shell, C2 – hard exterior shoe casing, C3 – Soft interior calf liner.*

2.1 Customizable Parametric Design

Following the generic design of the orthosis, critical dimensions are identified and added to a design table to enable quick adjustments to the structure of the orthosis. The main body of C1 is defined by a loft of three semi-circles that are created on three planes that are offset in the vertical direction. The critical dimensions that define the diameter, the location, the thickness of the semi-circles, and the distance between the sketch planes are parameterized and added to the design table (Figure 3 and Table 1). Other dimensions are related to the parameters in the design table using equations or are assigned a constant value if they are not expected to change when the parameters in the design table are adjusted. For example, the location and diameters of the mounting holes for the actuator box remain the same for different wearers and therefore they are defined as constants in the design table.

The ankle joint location is used as a common reference axis for C1 and C2. C2 is also parametrized similar to C1, however, since the same model shoe (New Balance 813) is used for all individuals, the overall shape remains the same for all individuals, with minor adjustments to length and width dimensions based on shoe size. The main parameter on C2 that varies from individual to individual is the location of the ankle joint, which is extracted from the scan data of the wearer's leg.

C3 is created by offsetting the loft that is used to create the main body of C1. The loft is offset by 15mm – 25mm inward and 1mm – 5mm outward from the inside face of C1. The top surface of C3 is also expanded outward by 5 mm and extruded in both directions by +/- 4mm to cover and overlap with the top surface of C1. By intersecting C1 with C3 and performing Boolean subtraction operations using the cavity tool in SolidWorks (Dassault Systèmes, Velizy-Villacoublay, France), overmolding-like features are added to C3. This enables the flexible polyurethane material that is used to fabricate C3 to wrap around C1 and create a tight fit.

Table 1*: Parameters used for design table of C1*

Parameter	Description
D1	Bottom to floor
D2	Top to floor
D3	Bottom semi-circle depth
D4	Bottom semi-circle diameter
D5	Bottom semi-circle thickness
D6	Top semi-circle diameter
D7	Top semi-circle depth
D8	Top semi-circle thickness
D9	Middle semi-circle diameter
D10	Middle semi-circle depth
D11	Middle semi-circle thickness
D12	Middle offset (lateral)
D13	Top offset (lateral)

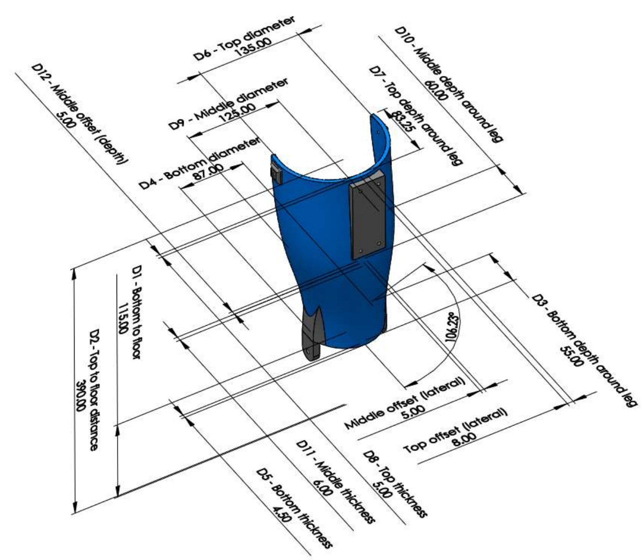

Figure 3: *Parameters used to customize the shape of C1*

2.2 FEA Aided Material Reduction

The Generic design shown in Figure 2 is further refined to remove unnecessary material and streamline the shape of the orthosis. FEA studies are performed using SolidWorks to identify the stresses in the parts under maximum loading conditions for walking derived from prior experimental results [9]. This resulted in a 500N load applied by the plantarflexion cable for the FEA study. The design insight tool is then used to identify minimally loaded material that could be removed without adversely affecting the strength of the parts. Figure 4 shows an example of the FEA analysis results for C1. Figure 5 shows the resulting shape-optimized design for C1, C2, and C3.

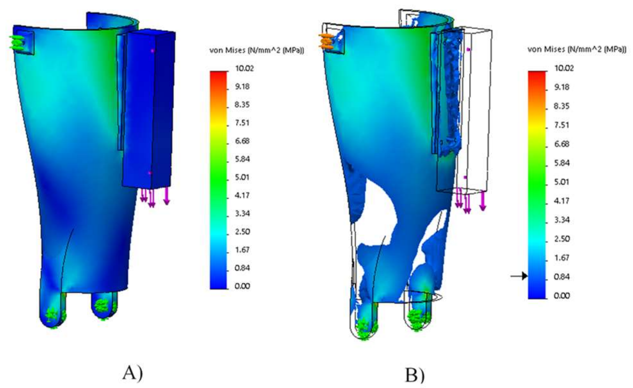

Figure 4*: A) FEA stress plot for C1 under expected loading conditions B) ISO clipped stress plot showing areas with stress greater than 1MPa.*

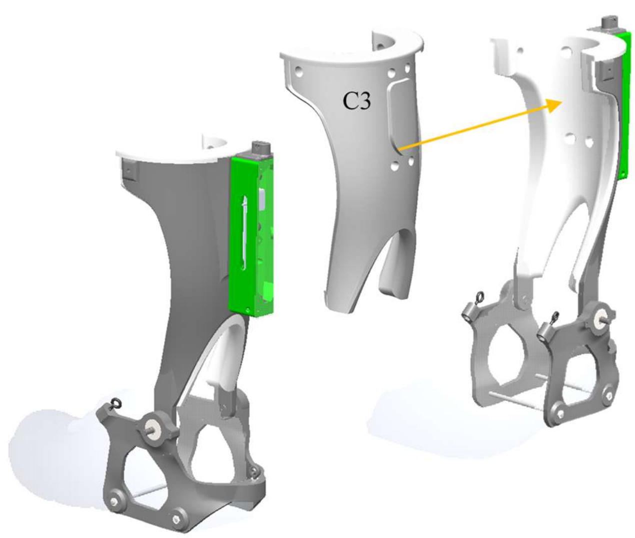

Figure 5*: Shape-optimized SAFE II orthosis design after FEA aided material reduction process. Boolean subtraction is performed on the outward surface of C3 to create overmolding-like features.*

3. SAFE II ORTHOSIS PERSONALIZATION

3.1 Scan Process

To personalize the SAFE II orthosis to the leg morphology of an individual, 3D scans of the individual's lower legs are taken along with the individual wearing the shoes. Adhesive spherical markers are placed at bony landmarks (medial and lateral malleoli, and femoral condyles) of the ankle and knee joints to aid in the identification of these key locations during the parameter extraction process.

During the scanning process, the individual is asked to stand on a platform with their feet shoulder-width apart and pointed forward. An Artec Eva hand-held structured light scanner (Artec 3D, Luxemburg) is used to generate a high-resolution scan of the legs and shoes of the individual starting from the base of the platform to approximately two inches above the knees. The entire scanning process takes approximately 2 minutes and is non-obtrusive to the individual.

After the scan is completed, the scanner's proprietary software (Artec Studio) is used to perform scan alignment, remove any extraneous scan noise/errors, and generate a watertight mesh file. The mesh file is then imported into Meshmixer (Autodesk, San Rafael, USA) where it is properly oriented to the desired coordinate frame using the scanning platform as a reference. The mesh density is then optimized to remove any redundant triangles, and the mesh is prepared for export to the SolidWorks CAD software for parameter extractions. Figure 6 shows example scans for three individuals after the scanning and clean-up process is complete.

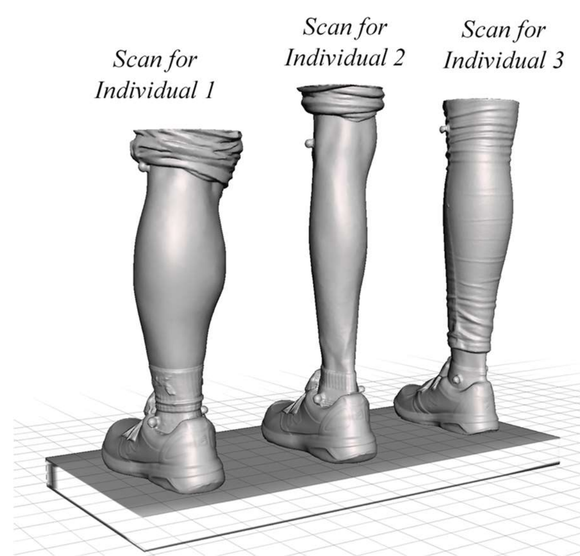

Figure 6*: Scans of left leg generated for three individuals. Small spherical markers were placed on the ankle and knee joints to aid in the accurate location of these joints during the design process*

In addition to being a non-obtrusive and accurate method of acquiring the leg morphology, the use of 3D scanning and digital mesh files has additional benefits which can be utilized during the design process. For example, individual 3 in figure 6 was wearing skin-tight Jeans which made it difficult to roll up above her knees. It was possible to still perform the scan with the jeans covering the legs and use digital smoothing and sculpting tools in Meshmixer to remove the creases from the Jeans and generate a close approximation of the individual's leg morphology that would be sufficient for the parameter extraction step (Figure 7).

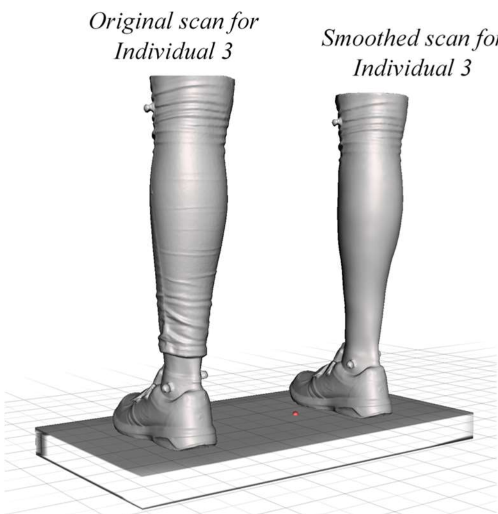

Figure 7: *Crease removal and smoothing for the scan of individual 3 to generate a close approximation of the leg without the jeans.*

3.2 Parameter Extraction and Personalization

To extract the parameters necessary to customize the SAFE II orthosis design to a specific individual, the mesh file for the leg scan of the individual is first imported into SolidWorks. Using the Mesh Modeling tools available in SolidWorks, the mesh surfaces for the spherical markers that were placed on the ankle and knee joints are selected and fitted to surface bodies. The centers of these spherical surface bodies are used to define the location for the ankle and knee joints.

The following procedure is followed to extract the parameters defined in Table 1 using the scan for individual 1 as an example. To extract parameter D1, a plane is created that is parallel to the ground plane and at a distance the is equal to the height of the tabs above the marker for the ankle joint. The distance of this plane from the ground specifies the dimension for D1. D2 is specified as the distance from the knee joint to the ground multiplied by 0.8. Three equally spaced horizontal planes are then created starting at D1 and ending at D2. These three planes represent the sketch planes for the main loft of C1.

The slicing tool in SolidWorks is used to slice the mesh files at these three plane locations and fit circles to the cross-sections of the profiles that are generated. The circles are then offset outwards by a distance between 10mm – 20mm to generate the diameter for the bottom, middle, and top semi-circles of the loft as shown in figure 8 (parameters D4, D9, and D6). The offset distance selected will set the gap distance between C1 and the user's leg and therefore the thickness of C3, the soft interior calf liner. A smaller offset will result in a stiffer liner and a larger offset with result in a softer and more compliant liner.

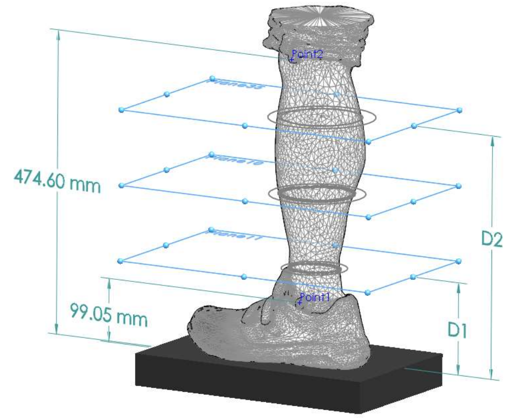

Figure 8: *Example of parameter extraction process for leg scan of individual 1 using mesh modeling tools in Solidworks.*

Whenever a new shoe size is used, similar parameter extraction steps are followed using the mesh modeling tools in SolidWorks to extract the new parameters for C2. While the parametric dimensions of C3 are primarily driven by C1, a secondary Boolean subtraction operation is performed on the interior face of C3 using a lofted solid body that is generated from the scan data (figure 9). This process ensures that the inner surface of the liner conforms to the wearer's calf morphology.

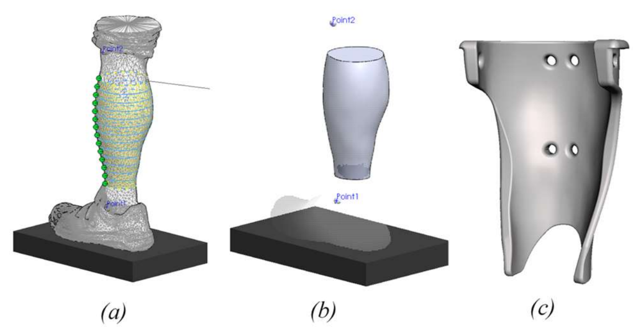

Figure 9: *(a) profile generation for loft using slicing tool, (b) generated lofted body, (c) C3 – calf interior liner after Boolean subtraction of interior surface with the lofted body.*

4. PERSONALIZED AFO FABRICATION

The SAFE II orthosis is designed to be fabricated using AM. To test the fit of the design for individual 1, all three components of the orthosis were fabricated using Fused Deposition Modeling (FDM) 3D printers (Figure 10). Components C1 and C2 were printed using Nylon X filament (Matterhackers, Lake Forest, US), a high-strength high-stiffness Nylon filament that is blended with 20% chopped Carbon Fibers. Both parts were printed with variable rectilinear infill densities ranging from 50% - 75%. Component C3 was printed using Varioshore TPU filament (ColorFabb, Belfeld, The Netherlands), a foaming thermoplastic Urethane filament that can produce parts that are lightweight and soft. C3 was printed with a gyroid infill density of 10%. The printed weights of C1, C2, and C3 were 220.8g, 120.9g, and 111.2g, respectively.

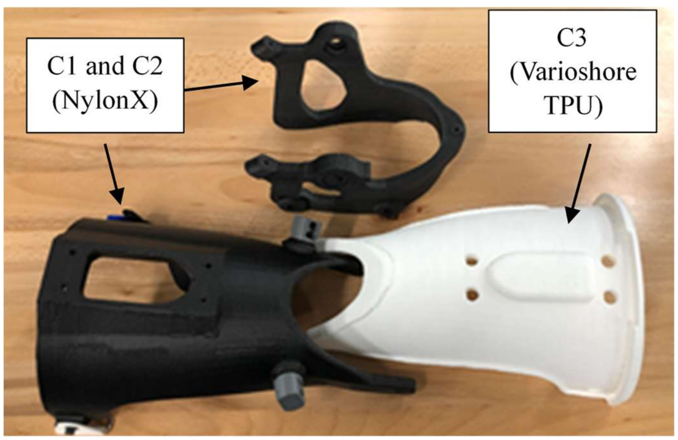

Figure 10*: Components C1,C2, and C3 of SAFE II orthosis fabricated using FDM AM for individual 1.*

C1 was securely bolted onto the shoe and C2 and C3 were secured to the wearer's lower leg using a Velcro strap (figure 11). The individual was asked to walk around in the orthosis and provide feedback on fit and comfort. The wearer was observed while walking back and forth. The feedback from the wearer stated that the SAFE II orthosis fit well and was comfortable to wear when walking forward. The wearer noted some constraint to the motion of his ankles when turning 180 degrees. This was expected as the AFO structure has a 1-degree-of-freedom design. The wearer likened the unpowered orthosis structure to the feeling of wearing a snow boot. Suggestions for improvement from the wearer included adding some compliance at the ankle joints to enable a greater range of motion when turning and adding a wider Velcro strap to component C1 to better distribute the pressure from the strap along the leg.

Figure 11*: 3D printed SAFE II Orthosis worn by individual 1*

5. DISCUSSION

This paper presents initial work on utilizing a fully digital workflow for designing and fabricating a personalized structure for a powered AFO. Using the presented methodology, it was possible to use 3D mesh data from a single leg scan to design and fabricate a tailored AFO structure for the wearer. The design was successfully fabricated using an FDM 3D printer and feedback from the wearer during testing confirmed the personalized fit and comfort of the fabricated AFO structure.

This digital design workflow presents many advantages and some challenges compared to conventional handmade orthoses. From the wearer's perspective, the digital workflow offers an unobtrusive and fast way of capturing the user's leg morphology as the 3D scanning process is non-contact and can be performed in a few minutes. From the designer's perspective, having an accurate 3D leg scan affords considerable design freedom for digitally extracting measurements and freeform geometries that can be used to create a tailored design. The adoption of a design table further simplifies and shortens this design process for new scans.

By utilizing a digital fabrication process like AM, the benefits of the digital workflow can be extended to the fabrication process as the designer can also define the build parameters. For example, parameters such as infill density and shell thickness can be adjusted in selected regions to improve function and performance or reduce weight. The cost of fabricating an AFO structure using an FDM 3D printer is relatively inexpensive (e.g., approximately $50 for individual 1) and requires minimal labor. This makes it easier to quickly fabricate new designs if one gets damaged or to accommodate growth-related anthropometric changes in children and adolescents.

Drawbacks of using AM to fabricate an AFO structure include limitations in material options and anisotropic material properties. While various material options are available for different AM technologies, the current selection of materials is relatively limited compared to the range of materials available when using forming or subtractive manufacturing techniques. For example, the TPU material used for C3 was only one of a few options for soft/elastic materials available for FDM 3D printers. The anisotropic material properties resulting from the layered manufacturing process of AM means that more thoughtful and creative designs need to be utilized to achieve the desired performance outcomes.

Liquid/powder-based AM technologies can be used to alleviate some of these drawbacks but may result in higher material and labor costs. The selection of AM materials has also been steadily increasing over the years and new composite material options, like the NylonX filament used for C1 and C2, provide significant improvements in material strength. As AM and 3D scanning technologies continue to improve and become more affordable, the use of a digital workflow for designing and fabricating wearable structures and devices, like the one presented in this work, may also contribute to making next-generation powered orthoses more comfortable and accessible.

6. CONCLUSION

A fully digital workflow was presented for the design and fabrication of a personalized ankle exoskeleton. A configurable parametric design was first developed. A 3D scan of an individual's leg was then used to extract parameters specific to the leg morphology and generate a personalized design. The design was then fabricated using AM and successfully fit tested.

The utilization of a digital design and fabrication workflow presents many opportunities for rapidly generating highly personalized orthoses. By utilizing a digital workflow most of the labor-intensive and error-prone steps of manual leg casting and plaster molding were eliminated. Most of the effort was instead directed towards developing a scan-based 3D model that can be fabricated using digital fabrication technologies like AM.

Ongoing work is focused on the use of machine learning techniques to further reduce the design effort and time required for generating a personalized AFO design. Topology optimization and lattice structure generation tools are also currently being explored to further optimize the shape and function of the orthoses and take full advantage of the unique capabilities that technologies like AM provide in their ability to fabricate complex shapes.

7. ACKNOWLEDGEMENTS

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