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ADDITIVE MANUFACTURING AND FINITE ELEMENT ANALYSIS OF CUSTOMIZED ANKLE FOOT ORTHOSIS

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Abstract:-
Additive manufacturing has a number of benefits, particularly when extensive customisation is required, as compared to traditional manufacturing techniques. In this paper, a process for developing a truly customized ankle-foot orthosis is developed. In this research, an ankle foot orthosis were developed for a 49 year old and 54 kg weight female patient has drop foot disorder due to neuromuscular diseases. With the help of 3D-scanning technique, patent's foot were scanned from toe to knee completely. This scanned data were collected in the form of point cloud data. This point cloud data were imported in SolidWorks software and developed a model of patient's foot. Customized ankle foot orthosis model were developed by offset of patient's foot model. The AFO is parametrically calculated and optimised to withstand the expected mechanical stresses. The device is again validated on the patient after being 3D manufactured on an FDM printer. The AFO and patient's foot have perfect geometrical alignment, which improves patient comfort and medical functionality. The mentioned technique is easily automatable, which further minimizes expenses and lead time of complete procedure.
Keywords: *Ankle Foot Orthosis, 3D-Scanning, 3D-Printing, Stress Analysis, FDM*

INTRODUCTION

Additive manufacturing in comparison to traditional production techniques, especially when extensive customisation is required, reveals significant benefits [1]. This is especially prominent in some medical specialties, including orthopaedics, where the effectiveness of a treatment is closely related to the anatomical geometry of each patient [2]. When the muscular/skeletal system alone is inadequate, an ankle-foot orthosis (AFO) is an external medical device that assists a patient in maintaining the proper ankle position by providing external mechanical support. Various types of AFOs are illustrated in Fig. 1 [3]. AFO are often produced by hand-casting plaster, moulding thermoplastic materials, and cutting those materials as a method of production. AFO required a great deal of work and sensitive expertise. In The entire production process must also re-performed if the AFO is destroyed or a patient's condition changes. Foot drop due to peroneal neuropathy is usually treated with an ankle-foot orthosis (AFO)[4].

Figure 1 Simple Ankle Foot Orthosis

Recent developments in digital scanning and AM technology have opened up new possibilities for creating cheap and highly customisable AFOs[5,6,7]. Researchers developed a method to successfully scan a human adult leg and create an AFO from this [8]. Using rapid prototyping methods they then constructed an AFO. This AFO had excellent ventilation and reasonable strength but minimal contouring to the patients leg. A process planning method for printing AFOs has been described [9] and gait analysis has shown 3D printed AFOs can have similar performance with thermoplastic AFOs of a similar design [10]
This case study is based on a 49-year-old female who had poor mobility after due to neuromuscular diseases; an AFO is used to treat foot drop disorder. Physical testing showed that the ankle's ability to dorsiflex had completely disappeared, and the patient walked with a steppage gait while using a single cane. She already owned a traditional AFO for foot drop, but she hardly ever used it because it was bulky and uncomfortable both indoors and outside. She accepted to take part in our research on customized ankle foot orthosis development. The treatment will be more comfortable and effective when more the orthosis's shape conforms to the patient's body. The method presented in this work uses 3D scanning and printing to create a fully customised ankle-foot orthosis for patient.
Methodology:
3D- Scanning of Patient's Foot: 3d Scanning-based foot scanning, the internal geometry must be created with the patient's foot's anatomical shape in mind as its primary consideration. As a result, it is necessary to collect the geometrical information for the area around the ankle. The patient's lower right leg was scanned with a 3D scanner to develop the AFO, which was manufactured using the 3D printing technology. Because the longitudinal, transverse, and metatarsal arches must be taken into account while creating the AFO, the patient was instructed to stand with their foot in a standing position in the sagittal and coronal planes prior to the scanning procedure. A 3D scanner was used for the scanning process in the standing position, and in the sitting position, using a 3D scanner, the scanning procedure was executed and shown figure 2. In the sitting posture, the scanning process was repeated for the lower leg's masked portions that were not visible in the standing position. The scanner can take up to 16 frames per second, and because the frames are automatically aligned in real-time, scanning is quick and simple. Scanned foot images shown in figure 3.

Figure 2 Step by Step Foot Scanning Procedure

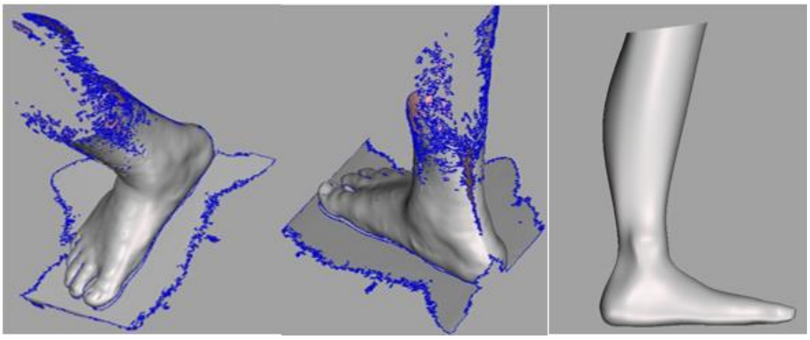

Figure 3 Foot Model Developed by Point Cloud Data

The three main components of the orthosis modelling are shaping, outer surface modelling, and inner surface modelling. In order to account for potential friction, a specific amount of space must be left between the inner surface and the foot. An Ankle-Foot Orthosis and patient's foot be spaced apart to compensate for geometrical inaccuracies and swelling. The inside surface is produced using the offset tool. Experience must be used to determine the offset's size because it is not a standard.In SolidWorks software, the boundary boss/base feature generates the outside surface (Fig. 4). Similar to the loft, but with a little more control over the resulting geometry, is this feature. Making a few section sketches that will be linked to produce the ideal surface is the first step in the process. Fewer sections are needed because, in contrast to the production of a foot-loft, there is no precise geometry that needs to be traced; this increases programme stability and efficiency at the cost of some of the control over the resulting geometry. The steps used to generate the outer surface are as follows: Along the foot, sixteen planes are drawn with equal spacing between them. The inner surface's intersection with each plane is produced using the Curve Wizard. The sketch-offset tool allows for the creation of a fresh profile on each plane from the associated intersection sketch. An essential variable that varies in respect to each segment is the entity of each offset. A new solid body is produced after the boundary boss or base is completed. Now, using the Boolean operator, the inner surface is subtracted from this, yielding a shell with variable thickness.

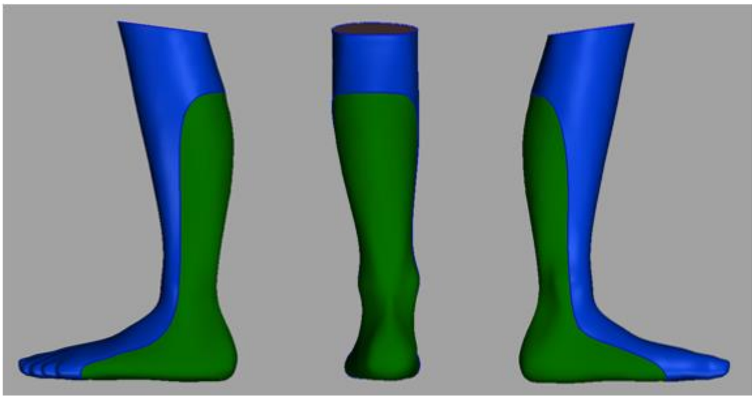

Figure 4 Solid Model of Ankle Foot Orthosis by Offset

In Figure 5, the mesh model was produced for FE analysis is each depicted. FE simulation using ANSYS® 11.0 was performed on this model. A model of an object constructed for a particular material is subjected to precise mechanical loads using the finite element method (FEM), and the results are analysed for details like stresses and strains, for example. The structural weaknesses of a part or object can be identified by analysing the areas where stresses are concentrated. Using this tool, it is feasible to optimise the ultimate outcome through a series of geometric changes without having to create expensive intermediary prototypes.

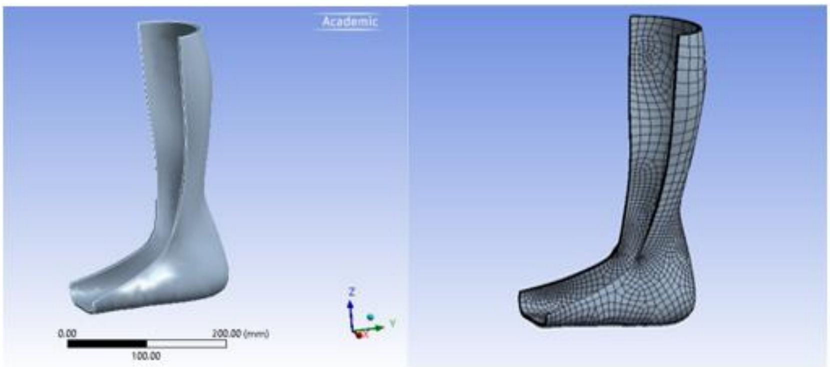

Figure 5 Models of Ankle Foot Orthosis

The polypropylene copolymer was assigned to the AFO model from the material library of Solidworks as the material type and was defined as linear, isotropic, and elastic (Table 1).Polypropylene is extensively used material for the fabrication of AFO. In the present analysis polypropylene AFO with 4mm thickness was analyzed for the developed stresses. Table 1 shows the mechanical properties of polypropylene. The parabolic tetrahedral solid element was used to better define free form surfaces in the mesh network. Mesh structure and boundary conditions of Model 1 are shown in Fig. 5.

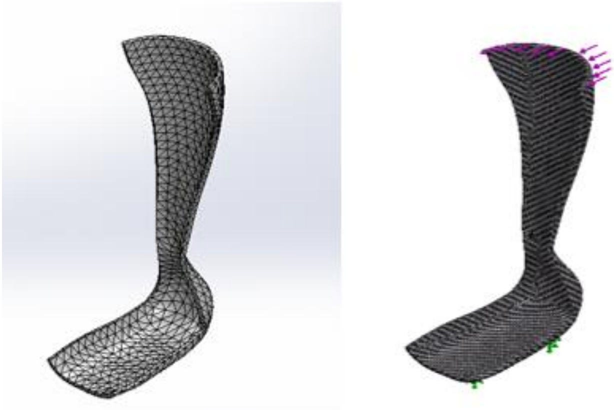

Figure 5 Mesh Models of Ankle Foot Orthosis

The model was fixed from its entire plantar surface. One external force of 250N was applied from axial, normally distributed at the calf element of AFO. Foot plate of the AFO was given the fixed constrains. For the FE models created for all other models, the boundary and loading conditions were considered to be the same as in Model 1.

Table 1: Mechanical Properties of the Polypropylene Materials (SolidWorks Material Library)

Tensile Strength	27.6 Mpa
Elongation	16%
Elastic Modulus	896 MPa
Mass Density	890 kg/m^3
Poisson's Ration	0.4103
Tearing Modulus	315.8 MPa

In order to develop a ankle foot orthosis, point clod data of patient foot were collected and imported in SolidWorks, to create the "STL" file for preparation of the customized Ankle foot orthosis for patient. A fused filament fabrication (FFF) type 3D printer was utilised to print the specified AFO. As the filament melt, the FFF process layers-by-layer accumulates the polypropylene. One of the thermoplastic filament used in this study are nontoxic, eco-friendly, and very flexible. The designed AFO was manufactured using this material, and then a post-printing method was used to take out the support structures and smooth down the surface using a pincer and sandpaper. The AFO orthosis was delivered and fitted to the patient following the post-printing procedure shown in figure 6.

Figure 6: 3D printed Ankle Foot Orthos is

Results:

Finite element analysis (FEA) was conducted for the constant load of 294 N applied to the foot portion of the AFO in order to understand how the AFO would behave in static conditions. Following the analysis, the maximum stress caused, the maximum deformation, and the safety factor were noted. The FEA findings for Von Mises stresses and Resultant displacements for the tested axial forces on the AFO are shown in Figures 7, 8, 9, 10.

The edges of the calf region were only subject to the highest stress. Table 2 summarises the analyses' findings for stress, displacement, and factor of safety for boundary conditions. The model is the closest to the geometry of the orthosis, and the results in this case permitted for significant stresses. For the most load-intensive situations, higher stresses are therefore seen to be localised on the lateral side of the orthosis, despite the fact that we saw the critical areas move away from the leg-ankle and ankle-foot lateral regions.

This is in accordance with the position of maximum stress seen and illustrated in Figure 3. As can be predicted, midstance, when the foot is fully on the ground, is when the stresses are at their lowest. An increase in the stress values during shock absorption of 26% and the heel rise of 118% in comparison to this value.

Table 2: FEA Results of Ankle Foot Orthosis

Force	Von Mises Stress	Factor of Safety	Displacement	Deflection
294 N	30.42 MPa	2.28	2.68 mm	0.92 θ
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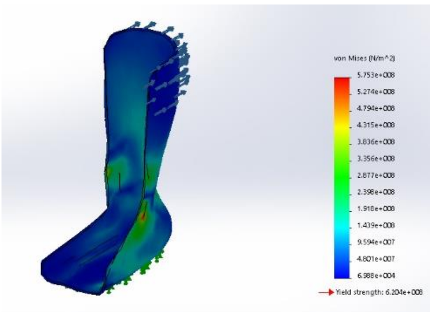


Figure 7 Von-Mises Stress

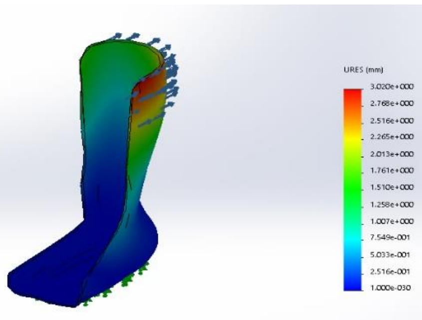
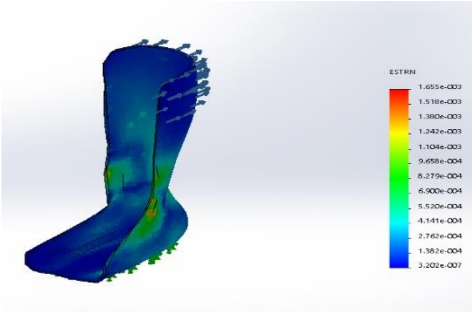


Figure 8 Resultant Displacement



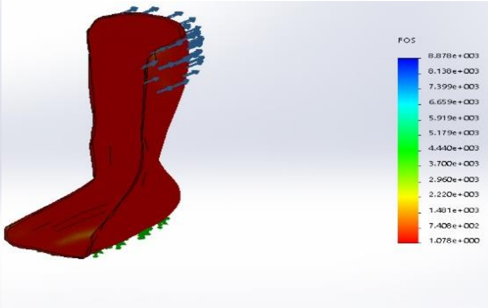


Figure 9 Equivalent Strain

Figure 10 Factor of Safety

Discussion:

In this study, AFO model simulations under static load circumstances with polypropylene were examined. The findings demonstrated that the polypropylene material AFO with a 4mm thickness had good static force resistance. This suggests that an individual weighing 54 kg would be well-suited for an AFO made of polypropylene. The suggested method has a lot of benefits. First, adaptability: This approach can be used in a variety of situations. It can be applied to different body parts in addition to being customised for every patient. Secondly, expenses and time. FDM printing is a very affordable production technique that enables the creation of fully working prototypes without the need for significant outlays of money.Future research can expand on this work by using more materials, increasing the static load, analysing the AFO dynamically, and investigating it experimentally.

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