Development of an AFO with Dual-material using an FDM Printer

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Abstract. This paper presents a design and development of an Ankle Foot Orthosis (AFO) printed with a multi-extrusion Fused Deposition Modelling (FDM) printer. AFO is crucial in the healing of patients with ankle joint displacement. It helps to heal the foot easily. The model is designed to print with dual materials such as flex and polylactic acid (PLA). The critical problem in building a prototype is to obtain excellent bonding properties between the layers of different materials. The Flex material is softer than the PLA and both have different melting temperatures. Thus, successfully printing with an excellent adhesive is the key concern in multi-material applications. The paper also presents the simulation results of an AFO to justify the mechanical properties and required materials for sustainable development.

1. Introduction

An orthosis, also referred to as a hard brace, is an externally applied device to the body that assists to either stabilize, or immobilize, the movement of a body part varying on the desired goals. These goals can extend from the prevention of injuries and reducing pain, to controlling and correcting biomechanical misalignments and so assisting during rehabilitation. Orthoses operate based on systems that have forces acting in three dimensions. By monitoring where to apply these forces, we can ensure whether the design is fitted appropriately and strive for the desired outcome, and also determine where potential pressure issues might occur [1]. Orthoses vary in type depending on which part of the body they are designed to fit: e.g., upper limb orthoses (wrist orthosis, elbow orthosis, shoulder orthosis, finger orthosis), lower limb orthoses (knee-foot orthosis, ankle-foot orthosis, knee-ankle-foot orthosis), and neck and spinal orthoses.

Depending on the manufacturing process, orthoses can be categorized as prefabricated or custom-made. As the name implies, prefabricated orthoses are pre-manufactured based on certain standard foot sizes and they are suitable for mass production. Ordinarily, pre-made orthoses are prescribed for short-term applications and less complex cases. These orthoses do not consider a specific client in mind in the designing stage; however, they could be modified to meet a patient's specific needs in unorthodox cases in order to achieve the treatment goal. In contrast, custom-made orthoses are designed to address issues prefabricated orthoses cannot. These issues commonly arise due to diagnosis complexity or the anatomical shape of the individual [2]. Such devices are fabricated using a mold or cast of the patient's body part, characterized as the traditional manufacturing method.

A newer and innovative approach of producing orthoses endorses additive manufacturing methods together with various scanning technologies and computer-aided design (CAD) software. These have been widely applied in the healthcare industry for the last decades, and their use is currently growing exponentially. Additive manufacturing, commonly referred to as 3D printing, creates 3D solid objects from a digital file with successive layers of the material being laid down on top of one another. This technique allows for the manufacturing of objects with complex geometries, yet consuming less material than traditional methods [3]. Additive manufacturing applications can be found now be found...
in various industries – aeronautics, automotive industry, medicine, architecture, robotics, and, food and beverage – with this list being far from exhaustive.

This paper will describe the designing of a dual-material ankle-foot orthosis (AFO) and the use of a Fused Deposition Modelling (FDM) based 3D printer to print the product. AFO is a device worn on the lower leg by patients with different misalignments or improper biomechanical functionalities in the ankle, which is the most common cause of foot drop. The prevalent reasons that cause foot drop are cerebral palsy, stroke, spinal cord injury, hemiparesis (slight paralysis on one side of the body), and hemiplegia (total paralysis on one side of the body) [4]. For treatment purposes of such cases, AFOs provide stability/immobilization in joints, compensate for muscle weaknesses, and improve the gait.

2. Past work

The application of ankle-foot orthoses was described informatively in the book “Physical Medicine and Rehabilitation” by Braddon (Ch. 15). AFOs are mostly responsible for controlling the amount of dorsiflexion and plantar flexion. Patients might have ankle-joint problems with inversion and eversion. Supination at the subtalar joint, adduction at the tarsometatarsal joints, and plantar flexion at the ankle joint are considered inversion problems. Eversion problems, on the other hand, are pronation at the subtalar joint, abduction of the forefoot at the tarsometatarsal joints, and dorsiflexion at the ankle joint. Metal or plastic AFOs are commonly used to rehabilitate those problems as well as different foot drops [5].

Cha et al. [6] used thermoplastic polyurethane material in Fused Filament Fabrication (FFF) 3D printing technology to print an AFO (figure 1a) which was designed in an automated software program. A comparison of the clinical results after application with a conventional AFO made of propylene was made [6]. The study involved an elderly patient with foot drop and alternated between 3D-printed and conventional AFOs for two months. According to the results, the gait speed was higher with AFO worn (56.5 cm/sec) compared to without an AFO gait speed (42.2 cm/sec). Along with the gait speed, cadence and stride length were improved with the AFOs mentioned. Cha et al. [6] focused on the crack and damage of the 3D-printed AFO during the durability test within the scope of the research rather than stress-strain analysis and established no significant change between the before and after shapes. However, the 3D-printed AFO proved to be inferior to the conventional one by not preventing foot drop during the swing phase. Though both AFOs demonstrated similar functionality, importantly, the patient was more pleased with the printed one in terms of weight, comfort, adjustment, and ease of use, which were the aspects that were considered in the designing stage of the present work.

Evaluating clinical results of a customized Selective Laser Sintering (SLS) based AFO and traditionally fabricated AFO made of thermoplastic polypropylene, was the objective of the research conducted by Creylman et al. [7]. The clinical performances of the two AFOs applied on eight patients with unilateral foot drop were compared in terms of gait performance. The results concluded that the clinical performances of the SLS-based AFO were at least equivalent to that of the handcrafted AFO.

Figure 1. (a) FFF-based printed AFO [6]; (b) FDM-based AFO made of PLA tested on a patient’s leg.
Another 3D-printed AFO was designed as shown in the article “3D-printed ankle-foot orthosis: a design method” [8]. Here Dal Maso and Cosmi designed a fully customized 3D-printed ankle-foot orthosis (AFO) with reference to a case study regarding a 21-year-old woman with an injured ankle. The AFO was printed using an FDM printer with PLA as the primary material, which was not as resistant as expected, as mentioned by the authors. Unlike some other studies that used hinges and pins to adjust an AFO, this paper preferred a simple and effective closing mechanism that would be sufficient to do the required job (figure 1b). As the AFO was tested on the patient, there appeared an excellent geometrical correspondence between the inner surface of the AFO and the patient’s foot, and she was satisfied with the comfort it provided.

3. AFO design and development

Traditional AFOs in the healthcare industry goes through the casting and moulding processes. Material types include ABS, PE, PP, and different fibre reinforcements depending on the patients' condition. Traditional fabrication of AFO requires a lot of effort and time. In the case of 3D printing, AFO fabrication is under the control of a computer, which decreases the manual effort. The construction process of AFO given in this paper can be divided into several stages, including the data collection, material choosing stage, designing, and computational analyzing stage. Qualitative data was used in the material choosing part, where the experience of other scholars on material science was necessary to set the appropriate material type for the AFO. Quantitative data was used in giving boundary condition values in gait simulation. In the computational analysis part, the resultant data was derived by manipulating the variables.

The AFO model is designed in such a way that it meets the main criteria for work. The idea of the design comes from resolutdesign.com [13]. The design was developed by making some changes to make the design printable in the FDM 3D Printer. The leg model for this design is taken from the web library [11], and it should be noted that the design can be optimized depending on the leg model of the patient in the future, which means that the optimization is necessary because of differences in leg shapes of different people. The final model is designed using Autodesk MeshMixer software (figure 2), as it gives an STL format file right away after the designing stage which can then be sent to the printing stage. However, the STL format is not compatible for conducting FEM simulations in Ansys software. Therefore, SpaceClaim software was used to convert the STL format to produce a solid body with proper surfaces and edges necessary for assigning boundary conditions within the FEM simulation (figure 3).

![Figure 2](image_url)

**Figure 2.** (a) The leg model used in designing; (b) AFO developed in Autodesk Meshmixer worn in the leg model; (c) Final AFO design.
Figure 3. (a) The AFO model in STL format; (b) Converted solid body from STL using Ansys SpaceClaim software; (c) Modified final model in step format.

The decision regarding material was made based on existing analyses of thermoplastics and other materials. The material for the AFO must have good mechanical and structural properties. The fatigue strength, creep, and fracture toughness parameters of the material should be compatible. Redwood et al. [9] regarding 3D Printing give the thermoplastic material the most usable material for SLA and FDM printers. The experiment conducted by Daan et al. [10] shows that polyethylene material for AFO shows good stiffness results. Moreover, other sources from different scholars show the appliance and good material properties of thermoplastics such as PE, ABS, and polypropylene [6, 7, 14]. Finally, to select the proper material for the AFO, simulation was done for 3 different AFO with 3 different materials (PLA, ABS, PE) to compare equivalent stress, strain, and total deformation.

3.1 Printer specifications

The model was printed using a multi-extrusion printer developed at the laboratory. The printer can print multi-material objects synchronously without stopping the machine. The bed temperature was between 50 and 60 degrees, and the nozzle temperature was between 200 and 240 degrees. The printed layer height was 0.6 mm, and the printing speed was 22 mm/s.

Computational analysis was done using Ansys software. Three different gait cases were chosen to analyze the von-mises strain, von-mises stress, and total deformation behaviours. These are three prominent gait cases, which give critical and ultimate results for AFO's material properties. In the three cases, there are three different force effects for an AFO. For example, in the mid-stance position, the $F_{z}^{a}$ is taken as 490N, as it is the average approximate weight of a human for one leg. There is only vertical force affecting AFO, so $F_{y}^{b}$ and $F_{x}^{c}$ values are taken as zero.

Where $F_{z}^{a}$ refers to force in the z-direction, $F_{y}^{b}$ force in the y-direction, and $F_{x}^{c}$ force in the x-direction.

In the heel strike position where the leg is backward, $F_{y}$ is taken as 50N. And in toe-off position similarly -50N because it is forward. In the simulation part, the developed AFO was compared with the traditional AFO by giving the same material type and the same boundary conditions for three different cases. This was done to show the excellence of the developed AFO. Moreover, with the help of Ansys software, the AFO with three different materials (PLA, ABS, and PE) was analyzed to compare how the stress values differ for optimal materials. The same gait cases with the same boundary conditions were taken to ensure correct simulation, and get the most optimal material for an AFO.
Figures 5 and 6 show single material and dual material printed parts, including the assembled view of the AFO. The development of dual-material-based AFO is challenging, but a proper investigation of the material properties would solve this problem. In addition, various usable materials could be used to optimize the AFO’s performance. Finally, new composite materials would ease to help the printing process and give a wide-rang of material selections for the best performance.

Figure 4. Three different gait cases used in the simulation process [12].

Figure 5. Printed prototypes with (a) PLA and (b) flex material.

Figure 6. Assembly view of the dual-material AFO.
4. Results and discussion

This section illustrates FEM simulation results of equivalent stress and total deformation for the traditional and 3D printed AFOs assigning them three different materials. As was mentioned before, three cases of gait (heel strike, midstance, and toe-off) are considered for the comparison of the mentioned AFOs.

Table 1 shows equivalent stresses for the traditional and 3D printed AFO under three gait cycles with the same material (PLA). As was expected, traditional AFO shows slightly better failure resistance than the 3D-printed AFO. The maximum equivalent stress for the heel strike gait, for example, shows 10.05 MPa for the traditional AFO and 16.24 MPa for the 3D printed one. These results are quite reasonable as traditional AFO has about 3 times higher mass (278g) than the 3D printed AFO (93g). Even though maximum stresses show slightly higher values than the traditional AFO, they are not as critical as the tensile strength of the PLA is in the range of 50-60 MPa. The main focus of the 3D printed AFO was directed to the design and comfortability. The flexible and lightweight design of the 3D printed AFO compensates for its slightly low strength over the traditional method.

| Table 1. Equivalent stresses for Traditional and 3D printed AFO |
|---|---|---|
| **Heel Strike** | **Midstance** | **Toe-off** |
| **Traditio nal** | | |
| 10.05 MPa | 5.30 MPa | 4.01 MPa |
| **3D printed** | | |
| 15.07 MPa | 9.38 MPa | 6.24 MPa |

Table 2 depicts the simulation results for traditional AFO with PLA material. This single material was chosen to provide a general comparison between the two AFOs fabricated by different methods. Given that the main concern is to choose the best suitable material for the 3D printed AFO that is designed throughout this research, the emphasis was on comparing three different materials.
Table 2. FEM results for Traditional AFO (material: PLA)

|                     | Heel Strike | Midstance | Toe-off |
|---------------------|-------------|-----------|---------|
| Max. total deformation | 9.9 mm      | 3.72e-4 mm | 10.23 mm |
| Max. equivalent stress | 10.05 MPa  | 0.054 MPa | 11.12 MPa |

Table 3, Table 4, and Table 5 represent maximum deformation and maximum equivalent stress values for three different gait cycles for PLA, ABS, and polyethylene. Overall, the results for selected materials have slight differences. The PLA is more failure-resistant than the other two materials for the first gait cycle, while the polyethylene is more resistant to the third gait cycle. This depends on the material characteristics. For instance, PLA is stronger but not as flexible as two other materials as it has a higher flexural modulus. Therefore, it shows less failure resistance for the third gait cycle, where mainly bending occurred. Furthermore, ABS is a toxic material for 3D printing and non-biodegradable. In comparison, PLA is nontoxic plastic and biodegradable.

Table 3. FEM results for 3D printed AFO (material: PLA)

|                     | Heel Strike | Midstance | Toe-off |
|---------------------|-------------|-----------|---------|
| Max. total deformation | 4.51 mm      | 1.67e-4 mm | 4.97 mm |
| Max. equivalent stress | 16.24 MPa  | 0.19 MPa | 16.99 MPa |

Table 4. FEM results for 3D printed AFO (material: ABS)

|                     | Heel Strike | Midstance | Toe-off |
|---------------------|-------------|-----------|---------|
| Max. total deformation | 9.33 mm      | 3.56e-4 mm | 10.21 mm |
| Max. equivalent stress | 16.82 MPa  | 0.19 MPa | 16.55 MPa |

Table 5. FEM results for 3D printed AFO (material: polyethylene)

|                     | Heel Strike | Midstance | Toe-off |
|---------------------|-------------|-----------|---------|
| Max. total deformation | 13.46 mm      | 5.31e-4 mm | 14.64 mm |
| Max. equivalent stress | 17.6 MPa  | 0.19 MPa | 16.07 MPa |

Figure 7 shows the dual-material printed AFO. The bonding between the materials is robust and could have a longer life cycle. Further dimensional accuracy could be achieved with a digital 3D Scanner to customize the characteristics of any given foot.
5. Conclusions and future works

In conclusion, the AFO design with good static structural characteristics, which has less weight and volume than the traditional model, was successfully printed on an FDM printer with a PLA material. Although the traditional model showed slightly good results in the computational analysis part, the designed AFO has about 3 times less mass and volume than the traditional AFO while taking the same material and simulating the same boundary conditions in Ansys software. The research work concludes that PLA, ABS, and PE materials are good enough to be applied in constructing AFO design, showing stable von-mises stress, strain, and deformation ranges in the simulation part. Moreover, it was found that PLA has better failure resistivity than other considered materials for the first gait cycle and polyethylene for the third gait cycle. Eventually, PLA material was chosen to be printed in an FDM printer due to its nontoxicity and other material property behaviours.

In the future, it is necessary to make the 3D printed model for a compression test to compare with the simulation results.

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