A Review on the Development of Customized Ankle Foot Orthosis for Foot Drop using Additive Manufacturing Processes

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https://doi.org/10.26782/jmcms.2020.07.00058

Abstract

Ankle foot orthosis (AFO) device improves the walking ability by hold and directs the position and advancement of the lower limb, specifically ankle movement. The primary function of AFO is to correct the deformities of the damaged nerves and compensate for the weak & paralyzed muscles. Traditional AFOs are handcrafted using plaster moulds for generating patient’s geometry, by a thermoforming process. Hence, the fabrication of a customized AFO consumes more time and expense as well. In the current review paper, it is discussed thoroughly about the upcoming technology known as additive manufacturing and its potential application for the production of customized AFOs. This review aimed to present the different AFOs produced by the additive manufacturing processes along with gait performances and material properties compared to the traditionally manufactured AFOs.

Keywords: Additive Manufacturing, Ankle Foot Orthosis, Gait Performance, Material Properties, Thermoforming Process.

I. Introduction

Patients suffering from musculoskeletal and neurological disorders, including stroke (cerebrovascular accident), cerebral palsy, multiple sclerosis, and spinal injury, often lose control as well as strength in their lower limbs, which impair their gait ability[XII][XXVII]. Foot drop is a common gait impairment resulting from these pathologies, which consists of a significant weakness or paralysis of dorsiflexor muscles (e.g., tibialis anterior, see fig 1) of the ankle. It is characterized as the inability to lift the foot at the ankle from the ground during the swing phase in gait.

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As an effect, this can lead to inadequate gait compensations; increase the risk of falls, more significant energy consumption, and decreased endurance. Further, it also characterized by an abnormal plantar flexion, which leads to foot slap. As a result, patients drag their toes on the ground while walking. If this toe drag is not corrected, patients with foot drop can become incapable of balancing their weight. This gait cycle problem can become variable and depends mostly on the major causes of the foot drop.

![Fig 1: Anatomical description of ankle and foot][VI]

Ankle foot orthosis (AFO) is a medical device that can be used to treat patients with impaired lower limbs. AFOs could be a single piece of a plastic device designed to cover the dorsal segment of a leg or comprised of an articulated joint that improves walking speed and performance depending on the patient’s medical condition and functional requirements. In general, AFOs improve the walking ability by hold and direct the position and advancement of the ankle movement, compensates the weak & paralyzed muscles, correct the deformities of the damaged nerve and subtalar joints, eventually leading to comfortable and reduce metabolism rate during walking. Standard AFOs and custom fit AFOs are two standard types of AFOs. Fabrication of the custom fit AFOs usually made from Plaster of Paris (PoP) casting. Once cast set, a negative impression is made and loaded with the plaster slurry to make a positive plaster model. Then the positive model is tailored through either manual adding or removing of plaster, followed by encasing a thermoplastic sheet around the positive model through the thermoforming process. The final fabricated AFO device is wearied to the patient, observes the gait performance, and gets the patient feedback onto the fit and functionality. The following fig. 2 illustrates the traditional method for the manufacturing of custom AFO. However, manufacturing a custom fit orthosis by this traditional method...
method is a laborious, time-consuming process that depends on impression casting, which is reliant on highly skilled orthotic technicians.

Recent advancements in data capture techniques and additive manufacturing technology helped the manufacturing of cost-effective custom AFOs within less time. Figure 3. Shows the AM process in the manufacturing of AFO. The main steps of the AFO production using AM are a) Patient anatomical data is captured using a 3D scanner; b) captured data is then used to reconstruct in computer-aided 3D (three-dimensional) space and developed a customized AFO design and c) finally, the designed model is analyzed and prepared for AM machine[V]. Therefore, this method has the potential to reduce the manufacturing time and provides design freedom with geometric features, cost efficiencies compared to the traditional manufacturing method. Thus, AM technology represents an alternative method for manufacturing custom AFOs.
A broad range of research has already been carried out with the use of AM technology in the field of custom-fit AFOs, and the developments of methods for manufacturing AFOs highlighted as well. This review work aims to investigate the development of customized AFOs manufacturing using AM and to evaluate its biomechanical gait analysis, material properties, and compare their performance with traditional methods. The 3D scanning technologies in AFO modelling was also referred to in this work.

II. 3D Scanning Technologies for AFOs Modelling

3D scanning is a process by which size, shape, texture, or often color; data is retrieved across a physical entity for the creation of a digital 3D model[II]. In the orthoses manufacturing field, it is being used to capture the surface structure of the human body accurately, along with reducing the measuring errors and processing time compared to the traditional method[II].

Many 3D scanning technologies are used to capture the subject anatomy during the pre-process for custom orthoses design. Laser scanning is one method for collecting the necessary anatomical data for creating the digital 3D model by a projected single laser point or laser line from a hand-held device. The laser beam is first generated to fall on the object surface, and the reflected light from the 3D scanned surface is measured using a charged-couple device as well as a point cloud is formed with a triangulation technique[V]. Another type of 3D scanner is based on Stereoscopic photogrammetry. 3D photogrammetric scanners are using images that are captured from various viewpoints to replicate the object, and the images collected...
are reproduced into a 3D digital model using computational geometry algorithms
[XXIII].

3D scans provide many benefits for orthoses than traditional methods like plaster castings, foam impressions, and manual measurement. Firstly, 3D scanners allow quick scanning of many patients in a precise, clean, and easy way[III][IV]. Secondly, 3D scans eliminate storage space or data transfer problems so that the scanned body part could be stored and then used later if needed. After this, the scans data might be used with computer-assisted design software to manipulate it into the desired 3D model. Then finite element analysis (FEA) software allows using this digital 3D model to analyze the mechanical properties and functional performance of the orthoses [XXIV][XXXIII].

Most of the studies used the 3D scanning technology to manufacture of AFOs for acquiring the complex ankle-foot anatomical data. S.Milusheva et al. achieved an appropriate AFO design with the help of AM technology. The main distinction to the traditional method is that proposed AFO is produced with the optimized design based on laser scanning by manipulating computer-assisted manufacturing methods. The designed AFO is tested by FEA to assess the breaking resistance using frequency and temperature loads[XIV]. Dal Maso et al. produced the AFO using photogrammetry technique, highlighted that geometrical features between AFO and the patient foot were good and achieved significant comfort with the AM process[I]. The studies have shown that when combined with AM technology, 3D scanning is an efficient method for obtaining anatomical data on human body parts, it might be useful in the designing and fabrication of orthoses process.

III. Additive Manufacturing Technologies for AFO

According to the ASTM (American Society for Testing and Materials) technical committee, Additive manufacturing (AM) is a fabrication approach in which materials are joined layer upon layer, which builds any shape of 3D objects from digital source[III]. AM, also commonly known as 3D printing, offers many advantages compared to conventional manufacturing technologies, mainly where customization on large scales required[I]. This technology enables the manufacture of products of virtually any structure without any need for tooling, minimizing requirements for assembly and steps in a process. Besides, complex products can be manufactured without considerable cost increases [XVIII]. Moreover, AM technology reduces material wastage and develops fully customized products [XXVIII]. In the AM process, a 3D digital component model is typically designed in CAD or the data achieved through 3D scanning and converted to STL (standard tessellation language) file format, which is the standard file format for AM machines.[XXXI].

There are many systems for classifying AM processes; for example, that introduced by the ASTM F42 committee classifies AM processes into the seven
areas[III]. Guo et al., according to the starting material used, AM processes are divided into four types such as liquid, filament/paste, powder, and solid sheet[XXI]. The AM processes with the different states of material are illustrated in Table 1. However, among all methods, the liquid-based process such as stereolithography (SLA), powder-based process selective laser sintering (SLS), and filament/paste process fused deposition modeling (FDM) were used in the manufacturing of custom orthosis products.

Table 1. The AM processes with starting material [XXI]

| State of starting material | AM Process                                      |
|----------------------------|--------------------------------------------------|
| Liquid base                | Stereolithography (SLA)                         |
|                            | Multi-Jet Modeling (MJM)                        |
|                            | Rapid Freeze Prototyping (RFP)                  |
| Powder base                | Selective Laser Sintering (SLS)                 |
|                            | Electron Beam Melting (EBM)                     |
|                            | Three-Dimensional Printing (3DP)                |
| Filament/paste             | Fused Deposition Modeling (FDM)                 |
|                            | Freeze-form Extrusion Fabrication (FEF)         |
| Solid sheet                | Laminated Object Manufacturing (LOM)            |

**Fused Deposition Modeling (FDM)**

FDM is the most commonly used in AM processes due to its reliability, ease of use, short cycle time, minimal wastage, and wide range of material availability. In this process(fig. 4(a)), the thermoplastic polymer is melted into a liquid phase in a heated head and injected selectively by turning that head in X and Y directions to generate 3D parts from the CAD model in a layer by layer.[XXII]. The materials widely used for the FDM are poly-lactic acid (PLA), Acrylonitrile butadiene styrene (ABS) Polycarbonate (PC), Polyamide (PA), and PC-ABS blend[XXII]. The FDM process has the benefit of using low-cost materials, although its drawback is high manufacturing time.
Aydin et al. used FEA and compared the mechanical properties of the AFO model using default mechanical properties and experimentally measured mechanical properties. Aydin et al. used the FDM method to fabricate the test specimens and tested mechanical properties with various infill densities. The results showed that material displacements of the AFO model were more significant when mechanical properties have been obtained through test specimens compared with mechanical properties offered from FEA software. The study demonstrated that real mechanical properties of 3D-printed test specimens need to be used instead of the default material properties. Cha et al. clinically assessed the performance of the FDM polyurethane AFO (fig. 5(a)) to conventional PP-AFO in the gait analysis. The results of the study showed an improvement in gait speed after using both conventional AFO and FDM AFO compared to it without an AFO. Further, this study performed a mechanical stress test to confirm FDM AFO's durability. Cha et al. confirmed that there was no crack or damage, and the shape and stiffness of the AFO were not changed during the durability test. The authors concluded that FDM AFO had shown similar performance to conventional AFO and significantly satisfied the patient about weight, ease of use, and comfort due to the flexibility of the FDM AFO material.

In another study, Walbran proposed a novel three-segmented custom AFO (fig. 5(b)) typically consists of a calf and foot sections joined with a central beam of carbon-fibre spring, where the calf and foot sections made with PLA material by the FDM process. The study emphasized that this three-segmented AFO device offers optimal orientation in terms of material use, printing time, and strength during FDM manufacturing while ensuring that currently available AFO (one-piece) did not have significant strength in all directions. Chen et al. developed two FDM-AFOs using PC-ABS and ULTEM polymers and compared those performances to traditionally manufactured PP-AFO. A FEM model has been developed to calculate both static and dynamic loading in the gait cycle. The result indicated that the FDM
produced AFOs had lower strain during the gait than traditionally manufactured AFO\[XXVI\]. Schrank et al. measured the dimensional accuracy of FDM made AFO through the 3D FaroArm scanner, and it compared to the corresponding CAD model of the AFO. The results indicate that the dimensional accuracy of the AFO was excellent with the AM process. In addition to evaluating the dimensional accuracy, Scharank et al. measured bending stiffness and observed that the FDM-AFO presents high stiffness. Fabricated AFOs, including different stiffness ranges, as shown in fig.5(c) [VII].

**Stereolithography (SLA)**

SLA is the process defined by the conversion of photosensitive resin to a solid-state when selective exposure of resin to a UV laser (Fig. 4(b)). Every layer of the part is generated by moving a laser light on its surface by steering it in X & Y directions through galvanometric mirrors. The solidified layers are then lowered into the resin tank so that a new layer of resin is being spread on them to cover the previously polymerized contour of the part, which enables the new layer to be fabricated [X]. The typical materials, UV curable resin/photo-curable polymers are being used in the SLA process. Compared to other polymer-based processes, these materials are comparatively expensive. Therefore, the use of the SLA process for orthoses manufacturing is limited.

An example of using this technology in the manufacture of custom orthoses, Mavroidis et al. have adopted 3D laser scanning and SLA process to generate customized AFOs with two different materials for a healthy subject. Accura 40 resin was the first material to produce a rigid AFO (fig. 5(d)), whereas Somos 9120 was used to make flexible AFO production. The performance of SLS AFOs has been compared with a standard PP-AFO in the gait analysis. Biomechanical findings from the gait analysis demonstrated that both rigid AFO and flexible AFOs were performed similarly to PP- AFO. Thus, Mavroidis et al. concluded that the AFO manufactured with the SLA process could provide excellent comfort and fit to the subject's anatomy compared with standard AFO[V].

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Selective Laser Sintering (SLS)

SLS is an AM process that generates 3D solid parts by fusing powdered material selectively with a high-power laser beam (fig.4(c)). The laser beams are used for scanning, and combining powders in predetermined sizes and shapes of layers material corresponds to the various cross-sections of the CAD models. When the first layer is scanned, a new layer of loose powder is spread on it, and the process continues from bottom to top until the 3D object is finished[XXIX]. SLS can generate components from a wide range of powders, such as metal powders, nylon, nylon composites, and polycarbonate[XXIX].

Milusheva and colleagues constructed a 3D model of the ankle-foot complex and used SLS technology to produce the AFO prototype. The designed AFO had two major components, such as foot and calf, connected with various types of exchangeable elastic elements. The study indicates that the exchangeable elastic elements could allow the precise fitting and provide effective rehabilitation to the foot drop patients[XXX]. Faustini et al. determined the energy dissipation and storage characteristics of three polyamide materials: Nylon 11, Nylon 12, and glass-filled Nylon 12. The manufactured SLS AFOs were compared to carbon fibre AFO (CF-AFO), commonly used for traditional AFO production. The results of the study confirmed that Nylon 11 material had the least mechanical damping properties among
the three SLS material tested. However, mechanical damping in Nylon 11 (fig. 5 (e)) was still significantly higher than in CF-AFO. It can be only material among three materials tested to withstand large deformations during destructive testing[XVII].

Harper et al. conducted a clinical study to evaluate the gait performance between the AFO with CF strut, and SLS manufactured strut with Nylon 11 material. The study included ten individuals with unilateral lower-limb disabilities. Harper et al. from gait analysis found that minor differences in gait performance did occur between CF-AFO and SLS- AFO during waking. Thus, the study suggested that Nylon 11 is a useful material for customized AFOs[XX]. In contrast, Telfer et al. developed an AFO with adjustable stiffness in the sagittal plane (fig. 5(f)). Telfer et al. manufactured AFO with the Nylon 12 using the SLS process and evaluated it in a gait analysis on a healthy subject. The study results demonstrated that ankle kinematics had been changed significantly by adjusting the stiffness of AFO in the sagittal plane. Therefore, the study suggested that AM could produce custom AFOs in the future with high functionalities than current AFO[XXXII]. In another study, Scharrank and Stanhope investigated the dimensional accuracy along with the custom fit of SLS produced AFO for two healthy individuals, for the study purposed four half-scale AFO, as well as two full-scale AFOs, were fabricated. The results showed that dimensional discrepancies between SLS-AFO and its CAD models were less than 2mm and also that SLS build orientation & position did not affect the dimensional accuracy significantly. Two full-scale AFOs developed for two healthy individuals did give a better fit to the subjective visual inspection[VIII].

Creylman et al. evaluated the performance of customized SLS-AFO (fig. 5 (g)) and compared with the traditionally manufactured PP-AFO on eight individuals with unilateral foot drop during gait analysis. The results found no considerable difference between the performances of SLS-AFO and PP-AFO. However, the study concluded that SLS-AFO presents at least equivalent performances to the traditionally manufactured AFOs[XXXIV]. Similarly, Deckers et al. compared the SLS based AFO (fig. 5 (h)) performance with the traditionally manufactured AFO. This research highlighted the significance of mechanical characterization tests, including strength, fatigue, and impact resistance on both the material samples and the final AFO model [XII]. In contrast, Banga et al. found that SLS produced AFO design(fig.5(i)) in daily use could minimize excessive heating and sweating associated problems[XXV].

IV. Conclusion

The rapid development of AM technologies enables the cost-effective manufacture of custom AFOs than traditionally manufactured ones. Integrating AM technology and individual anatomical data with 3D scanning technology allows for major improvements in the manufacturing process of AFOs as patient anatomy is captured quicker, production time is reduced, and patient comfort is allowed. The
observations presented in this study specifically demonstrate the benefits of AM for AFOs manufacturing. Some of important observations through this study are:

I. Fabricated AFOs with AM process provides similar gait performances when compared to the traditionally manufactured AFOs in the gait analysis.

II. The dimensional accuracy between the AM developed AFO, and the corresponding CAD model is good. Moreover, it enables the testing of different materials for optimized material selection to manufacturing.

III. The most used AM technologies for manufacturing the orthosis devices are FDM, SLA and SLS were explored. Despite its low material cost, FDM is the most affordable then the use of materials is limited.

Further, research is needed to explore the AM-produced AFOs for patients after stroke and to identify the most suitable printing technique and materials for improving gait performance. On the other hand, more investigation should also be required to assess the long-term usage and functioning of AFO in daily life-activities.

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