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Research Article

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A Comparative Analysis between Conventional Manufacturing and Additive Manufacturing of Ankle-Foot Orthosis

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Abstract
3D printing has been attracting attention in recent years due to its versatility in design optimization and reduced labour and production costs. It has been implemented in many major sectors such as automotive, aerospace, and healthcare. One of the most recent researches involving this technology is in the prosthetics and orthotics field. The aim of this paper is to review the recent researches on Ankle-Foot Orthosis (AFO) which uses 3D printing in its manufacturing and fabrication phase. This paper discusses the current 3D printing technologies used for AFO, the comparison between Conventional Manufacturing (CM) and Additive Manufacturing (AM) of AFO, as well as the mechanical properties of AFO prototypes built from 3D printing. Results from this review show that most current researches use Fused Deposition Modelling (FDM) or Selective Laser Sintering (SLS) for AFO manufacturing, and the materials used are mostly thermoplastics such as Nylon and Polyamide (PA). The results also show that the tensile strength and Young's Modulus of a 3D-printed AFO could reach as high as 43 MPa and 3.9 GPa, respectively. It can be concluded that 3D printing provides wider opportunities in the development of AFO due to its versatility in optimizing complex geometries, time and weight savings, as well as its cost-effectiveness.

Keywords: 3D print, Additive manufacturing, Ankle-Foot Orthosis, Conventional manufacturing, Fused deposition modelling, Selective laser sintering

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1 Introduction

In recent decades, more and more technologies have transitioned from analogue processes to digital processes. An example of this transition is the combination and integration of letters, phone, camera, map, and calculator into a single smartphone. Another example is the implementation of robotics in the industrial factories to replace manual labourers, which directly increases the production efficiency and decreases the production time. One technology which has caught a lot of attention recently is the use of Additive Manufacturing (AM) to replace the Conventional Manufacturing (CM) which requires highly skilled workers. Some of the most recent researches have been implemented in the development of Ankle-Foot Orthosis (AFO) [1].

AFO can be defined as a support brace or splint which encases the region from above of the ankle until the foot to treat foot and ankle disorders such as foot drop. Most of the AFO CM methods start with the creation of plaster casts to produce a positive mould which is then used as a reference to shape the AFO via either thermoforming polymer or carbon fibre sheets lay-up [1].

Current researchers tried to devise a new method that eliminates the use of plaster and could directly skip to the AFO production. Thus, 3D printing was introduced in the AFO manufacturing to reduce the production stages and the time taken for the AFO production. Figure 1 shows the two different methods of AFO manufacturing with their respective technologies.

Conventional Manufacturing of AFO usually uses thermoformed polymer sheets as they are cheap, lightweight, could be shaped easily, and aesthetically pleasing. Therefore, they have a high demand in the orthotics field. There are numerous research studies being conducted on Polymer-Matrix Composites (PMCs) to reduce the usage of polymer and strive for eco-friendly orthotics devices [2]. PMCs are highly attractive due to their high specific strength and stiffness, low-cost, and better crack propagation resistance which are usually used in the aerospace field [1], [3]–[6]. Researchers have also started implementing PMCs into Additive Manufacturing to increase the production speed and for better flexibility in the AFO design. Some of the PMCs that have been extensively researched are Glass [7], Kevlar [8], Bamboo [9]–[13], and Kenaf [9]–[11], [13].

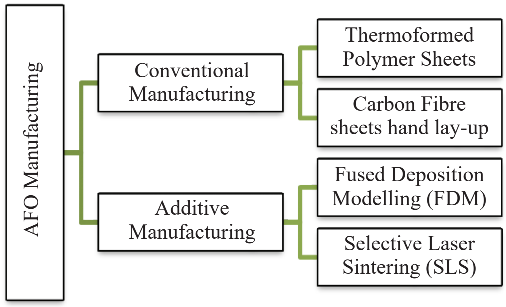

Figure 1: Manufacturing methods in AFO manufacturing.

The AFO manufacturing could show explicitly how different the production efficiency between CM and AM could be. AFO has been researched using both methods for several years, even though it is fairly new in the AM world.

An ideal AFO needs to be lightweight, form-fitting, durable, and cost-effective [1]. Both types of manufacturing methods are able to satisfy those specific conditions; however, AM shows more promising results compared to CM. For example, AM has the option to design and optimize an AFO design infinitely without wasting materials, whereas CM does not. Sometimes, a simple mistake made in the CM of AFO may render the device unusable and therefore, need to be discarded, resulting in material wastage [1]. In addition, the production speed in manufacturing an AFO must be able to cope with the high demand of AFO procurement. CM usually requires weeks for one complete functional AFO while AM may only require a few days [14]. The differences between CM and AM are further discussed in Section 3.

2 Current 3D Printing Technologies Used for Ankle-Foot Orthosis (AFO) Manufacture

3D printing has several types of technologies used in manufacturing an AFO. However, from recent researches, it was found that the fabrication and manufacture of AFO mostly used the Selective Laser Sintering (SLS) or Fused Deposition Modeling (FDM) technologies as shown in Table 1. Table 1 also shows that all of the materials used to manufacture AFO via 3D printing were made of thermoplastics such as Nylon, Polylactic Acid (PLA), Polyethylene Terephthalate Glycol (PETG), Polyurethane (PU), Polyamide (PA), and Acrylonitrile Butadiene Styrene (ABS).

Table 1: Recent researches on 3D printing

Year	Authors	Materials	Additive Manufacturing (AM) Technologies
2016	Walbran *et al*.[15]	1. Nylon	1. SLS
		2. PLA 3. PETG	2. FDM
2017	Cha *et al*.[16]	1. PU	1. FDM
2017	Deckers *et al*. [17]	1. PA	1. SLS
2018	Aydin and Kucuk [18]	1. ABS	1. FDM
2019	Vasiliauskaite *et al*. [19]	1. PA	1. SLS

SLS works by using a high-powered laser beam to sinter powdered polymer and bind the material together to create a solid structure according to a predefined 3D model [20]. The printing process starts with the roller scattering a thin layer of powder on top of a platform in the build chamber. The printer then preheats the powder to its melting point, so that the laser could easily raise the temperature of a specified region while tracing the predefined AFO model to solidify the selected part. After that, the platform lowers itself by each layer until the intended AFO part is completed. Once it is finished, the AFO is left in the printer until it gradually cools down. Finally, the printed AFO is moved to the cleaning station to separate the printed parts and the excess powder. Figure 2 shows the cross section of an SLS 3D printing machine during its operation.

Another type of 3D printing technology used in the manufacturing and fabrication of AFO is FDM. FDM works by melting a thermoplastic filament within an extruder and then forcing it out via the nozzle to print out the 3D model structure. Basically, this type of 3D printer involves a minimum of three stages which start with pre-processing, followed by production, and end with post-processing.

In the pre-processing stage, a CAD file (STL format) of the AFO 3D model is created first before proceeding with the production stage. In this stage, the type of material, printing orientation, and slice thickness are predefined in order to obtain the required AFO model. Then, the 3D printing software creates an output build file which then defines the precise motion control paths of the extrusion head. After every parameter is defined, the production phase begins. In this phase, the 3D printer automatically feeds the thermoplastic filament into the extrusion head. The

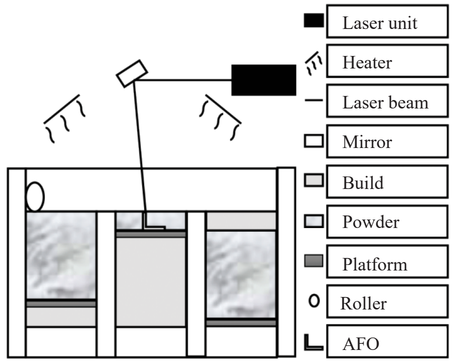

Figure 2: Cross-section of SLS 3D printer while printing AFO.

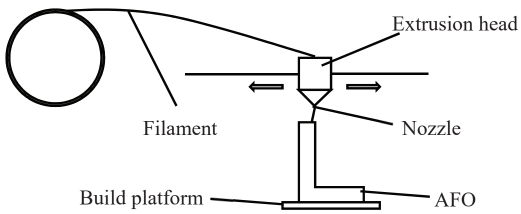

Figure 3: FDM printer.

extruder melts the filament and then forces it out through the nozzle. The extrusion head moves within predefined paths and deposits layers upon layers of the material to create a complete AFO. Finally, after the AFO has been printed completely, it is removed from the build chamber for post-processing. In this stage, the AFO is cleaned and separated from the support material. Figure 3 shows the cross-section of an FDM printer.

Although SLS and FDM are frequently used to manufacture and fabricate an AFO, both of these technologies work differently from each other. Table 2 summarises the comparison between SLS and FDM.

Table 2: Comparison between SLS and FDM [21]

Properties	SLS	FDM
Method	Laser fuses the polymer powder	Melts and extrudes the thermoplastic filament
Material support	Does not need support material/ structures	Needs support material/ structures depending on the 3D model
Types of material	Nylon; Engineering thermoplastics	ABS; PLA; Standard thermoplastics
Printing cost	Expensive	Cheap
Printing speed	48 mm/h	50–150 mm/h

3 Differences between Conventional Manufacturing (CM) and Additive Manufacturing (AM) of Ankle-Foot Orthosis (AFO)

AFO's CM involves several steps that start with a manual plaster casting [1]. The casting and rectification of the plaster cast must be in accordance with the Prosthetics and Orthotics (P&O) standard. The wet plaster cast is wrapped around the patient's limb and is removed after it hardens. The hardened plaster cast is then used to create a positive model. Once the model is obtained, a trim line is drawn on the mould following the P&O standards. After that, a thermoformed plastic sheet is shaped by wrapping it around the positive model by using the vacuum moulding method to get a form-fitting AFO. After the AFO cools down, it is cut or trimmed according to the outline that has been traced on the positive mould. The trimmed line is grinded and smoothen. Finally, add-ons such as Velcro or straps are added on the AFO to keep the limb in place while walking. These series of manufacturing stages shows that manufacturing a high quality AFO requires delicate hands-on skills from the worker and is highly time-consuming.

As for the AM technology, it was developed to solve some problems that arose from the CM method. The plaster cast is not necessary as the measurement of the patient's limb can be obtained directly from a 3D scanner [1]. In addition, with the help of CAD/CAM software, adjustments to the AFO are done easier compared to the CM method. Thus, it could also reduce the amount of wastes generated during the manufacture. In other words, the production of AFO using AM utilizes only the required materials unlike the CM method which produces waste during cutting or trimming. It is possible to make alterations on the design on every run and optimize it until a desired design is achieved using AM. This shows that AM leans more towards a design-driven process. In the AFO manufacturing, AM is used to create the lighter AFO parts with complex design that are harder to achieve using the CM method.

Once the desired AFO model has been designed through the CAD/CAM software, it is then ready to be printed via the 3D printer. Regardless of the type of 3D printing technology, the end product of AFO is printed layer upon a layer on the build platform until a complete AFO model has been printed. The process of AFO manufacturing is directly skipped into the production phase where each part of the AFO is directly manufactured from the 3D CAD file. It does not involve any lengthy process of positive mould creation and rectification, thus reducing the production time. Table 3 summarises the differences between AFO's CM and AM.

Table 3: Comparison between CM and AM

	CM	AM	Ref
Production time	4 weeks	2 days	[14], [22]
Production cost	Expensive	Cheap	[14], [23]–[26]
Required labour skills	• Physical dexterity • Detail-oriented • Physical stamina • Problem-solving skills • Problem-solving skills	• Operating 3D software designing skills	[16], [27]
Manufacturing steps	1. Cast creation 2. Cast rectification 3. Polymer moulding and shaping using vacuum moulding method 4. Trimming and edge cutting 5. Accessory add-ons	1. 3D scanning of ankle-foot 2. CAD/CAM AFO designing 3. 3D Model printing	[1], [28]

4 Characteristics and Mechanical Properties of Conventional Manufacturing (CM) and Additive Manufacturing (AM) of Ankle-Foot Orthosis (AFO)

To obtain the strength and stiffness for the AFO fabrication, most researchers use the ASTM D638 Type I Standard for testing. Table 4 shows the comparison of manufacturing using the CM method against the FDM of the AM method. The table shows that most of the tensile strength and Young's Modulus of the AM method are almost similar to those of the CM. This shows that manufacturing using the AM method will not compromise the original strength achieved by the CM method. Thus, this proves that using AM could be more beneficial compared to the CM method due to the close similarities in strength and stiffness as shown in Table 4, but with a simpler manufacturing method and required skills as well as reduced production time as shown in Table 3. It can also be noted that PLA has the greatest tensile strength among other thermoplastics and is also one of the cheapest materials available for 3D printing.

During printing, there is a chance for the printed object to be warped due to the changes in the surrounding temperature. Thus, it is important to consider this warping effect when selecting the materials for AFO. This also explains why there are very little researches conducted on 3D-printed polypropylene (PP) AFO. Unlike ABS and PLA which are famous in the AFO AM field, PP is rarely used due to its high warping rate.

ABS and PLA are amorphous polymers which have disorganized polymer chains causing each molecule to have a different range of temperatures at which it melts. This implies that ABS and PLA will shrink uniformly in the direction of the flow which results in less shrinkage or warping. However, PP has a semi-crystalline structure which is organized and tightly packed where certain areas could vary in shape and size and arranged between amorphous areas. Thus, this causes the structure to have a defined melting point, meaning the material will cool and solidify differently, affecting the shrinkage and warping during the printing process. This effect is highly undesirable for AFO manufacturing which requires precise measurement and safety.

5 Conclusions

This paper reviews and summarises the differences between the CM and AM methods for an Ankle-Foot Orthosis. It can be concluded that AM has a better opportunity in the AFO development, and it has the possibility of replacing CM due to its cost-effectiveness, simpler manufacturing method, fast production time, as well as tensile strength which is similar to the thermoformed polymer used in the CM method. However, in order to manufacture an AFO using the AM method, the user must have some skills in operating CAD/CAM designing software. Among all the materials that have been discussed, it was found

Table 4: Comparison between CM and AM properties and material characteristics

Ref	Types of Material	Tensile Strength (MPa)	Young's Modulus (GPa)	Fabrication Method	Material Cost (RM/kg)	Material Characteristics
[14], [29], [30]	ABS	25.390	1.325	FDM (AM)	57.75–111.37	• No warping during 3D printing • High impact resistant • Excellent chemical, stress, and creep resistance • Food grade thermoplastic • Excellent fire and heat resistant • Recyclable
[23], [31]–[33]	ABS	29.600	1.790	Thermoformed polymer (CM)	184.64–637.25	
[14], [29], [30], [34]–[36]	PLA	42.660	3.930	FDM (AM)	61.87– 111.37	• Minimal warping during 3D printing • Odourless when used in 3D printing • Eco-friendly (derived from corn starch or sugar cane) • Biodegradable
[14], [29], [30]	PP	20.040	1.508	FDM (AM)	251.68– 503.35	• High warping during 3D printing • Chemical resistant • Flexible • Lightweight • FDA approved
[23], [31], [32]	PP	20.000	1.000	Thermoformed polymer (CM)	40.40– 1757.00	
[14], [29], [30]	PETG	34.140	2.270	FDM (AM)	66.00 – 198.00	• No warping during 3D printing • Extremely durable and odourless • High impact resistant • Water, chemical, and fatigue resistant
[23], [31], [32]	PETG	50.000	1.900	Thermoformed polymer (CM)	178.58 – 3066.56	
[14], [29], [30]	Nylon	34.790	0.073	FDM (AM)	206.25– 319.87	• Low odour when used in 3D printing • Strong • Lightweight • Durable • Flexible • Mechanical stability and hardness • High fatigue resistance • FDA approved

that the PLA has the highest compatibility in the AFO manufacturing due to its eco-friendliness, low warping effect, and cost-effectiveness.

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