Customized design and additive manufacturing of kids' ankle foot orthosis

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Abstract

Purpose – The purpose of this study is improvement of human gait by customized design of ankle foot orthosis (AFO). An has been the most frequently used orthosis in children with cerebral palsy. AFOs are designed to boost existing features or to avoid depression or traumatize muscle contractures. The advantages of AFO's utilized for advancement in human walk attributes for the improvement in foot deformities patients or youngsters with spastic loss of motion. In this research on the customized design of AFO's to improve gait, there are limitations during walking of foot drop patients. In children with foot drops, specific AFOs were explicitly altered to improve parity and strength which are beneficial to walking positions.

Design/methodology/approach – This study proposes the customized design of AFOs using computerized and additive manufacturing for producing advances to alter the design and increase comfort for foot drop patients. Structuring the proposed design fabricated by using additive manufacturing and restricted material, the investigation was finalized at the Design Analysis Software (ANSYS). The system that performs best under investigation can additionally be printed using additive manufacturing.

Findings – The results show that the customized design of AFOs meets the patient's requirements and could also be an alternative solution to the existing AFO design. The biomechanical consequences and mechanical properties of additive manufactured AFOs have been comparable to historically synthetic AFOs. While developing the novel AFO designs, the use of 3D printing has many benefits, including stiffness and weight optimization, to improve biomechanical function and comfort. To defeat the issues of foot drop patients, a customized AFO is used to improve the human gait cycle with new material and having better mechanical properties.

Originality/value – This research work focuses on the biomechanical impacts and mechanical properties of customized 3D-printed AFOs and compares them to traditionally made AFOs. Customized AFO design using 3D printing has numerous potential advantages, including new material with lightweight advancement, to improve biomechanical function and comfort. Normally, new applications mean an incremental collection of learning approximately the behavior of such gadgets and blending the new design, composite speculation and delivered substance production. The test results aim to overcome the new AFO structure issues and display the limited components and stress examination. The outcome of the research is the improved gait cycle of foot drop patients.

Keywords Finite element analysis, Additive manufacturing, Ankle foot orthoses (AFO), Human gait

Paper type Research paper

1. Introduction

Human foot motion has a significant role in human movements, for example, it helps in standing, walking, running and jumping. The multifaceted nature of the foot causes walking difficulties and understanding and breaking down the system of movement, particularly with methods for capability (Aniwaa, 2016). By and large, the human foot comprises three areas: forefoot, midfoot and hindfoot. Human foot structures are produced using phalanges, metatarsals, bone, calcaneus in addition to many other parts and are bolstered by muscles and ligaments. The biomechanics of each ankle component has a significant job in the structure of the movement and adjustment framework during walking (Bahler, 1986).

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Ankle-foot orthosis (AFO) is a prop or gadget ordinarily used for lower body movement and to address the dangers of lower body movement and lower leg point (foot drop) (Apeagyei, 2010). By using an AFO, the client may improve the walking design execution and the inappropriate control movement of the gadget. In addition, using AFO will improve foot portability or can be used as restoration gadgets (Arbace *et al.*, 2013).

This study was performed to analyze the finite element analysis (FEA) aftereffects of an added substance to the fabricated AFO model under two diverse worth sets, specifically default material-based mechanical properties and estimated mechanical properties. To decide the genuine mechanical properties of the added substance produced by AFOs, 3D printed test examples with various infill densities were arranged and tried by the suggested guidelines. Mechanical test outcomes were then stacked in the CAD programming and FEA was performed. This investigation represented that the default mechanical properties of existing materials in CAD programming produce deceptive reenactment results for AMOs, i.e. that genuine mechanical properties ought to be used to get increasingly precise outcomes (Levent and Kucuk, 2018). The lower leg joint lead has a prompt torsional spring without a hysteresis. With a target to test the suitability of the AFO, a clinical step investigation of foot drop patients was done and a modified 3D conveyed lower leg foot orthosis was mounted to give better stride cycle execution. The impact of this examination showed that foot drop patients with 3D appropriated lower leg foot orthosis was evaluated through clinical gait appraisal (Banga *et al.*, 2020). The performance of the method was validated via numerical analyses and experiments, the results of which confirmed the excellent stiffness properties and adaptability to the AM constraints of the designed absorbability (Jiaqi *et al.*, 2019).

An AFO can be classified into three types: inactive, semi-active and completely dynamic. A latent AFO is used to fix or articulate the foot joints. A semi-dynamic AFO is used to regulate damping at the joints and a completely dynamic AFO is used to create torque for propulsive help and movement control (Smalley, 2014). An AFO can be used to help disabled children, for instance, those with cerebral paralysis (CP). CP is a gathering of disorders that affects motor skills and has tangible effects on capabilities. Because of the mental debilitation at the onset, children with CP have the nondynamic issue of stance development which leads to the low dimension of wellness and physical movement (Arnold, 1999).

Patients with hemiplegia CP (half-body incapacitated) tend to walk where the toes on the influenced foot strikes the ground first rather than the standard impact point strike. This is because of the inordinate plantarflexion and frail dorsiflexion amid swing stage (in stride cycle), otherwise called "foot drop". Foot drop is a condition wherein the foot is not viably clearing the ground because of feeble or missing dorsiflexors, causing stride design steppage-type (Banga *et al.*, 2014). An AFO can be used to keep away from foot drop conditions by attaching it to the child's leg or through recovery by fortifying the related muscles (Chu and Reddy, 1995). An AFO uses various kinds of actuators to control the development (Kada *et al.*, 2016). This paper demonstrates that 3D printing-assisted FEAs can be used to predict the performance of a lumbar cage design with varying manufacturing parameters and potentially reduce product design and development time (Elena *et al.*, 2019).

An AFO is a mechanical gadget used by drop foot patients with paretic lower leg dorsiflexor muscles, to help and improve the working of the foot and lower leg joint (Romkes *et al.*, 2006). Although the point of an AFO is to forestall the forefoot drop influence by limited the lower leg development, it additionally improves the lower leg capacity to help body weight, enhance progression and verify push-off capacity for the walking position (Shorter *et al.*, 2013). AFOs are regularly used for foot drop brought about by enduring neuropathy (Wingstrand *et al.*, 2014). Traditional materials/polymers used in manufacturing AFOs comprise of manual mortar throwing, embellishment of thermoplastic materials and cutting them into an AFO, which needs sensitive capacity and to withstand high exertion (Morteza *et al.*, 2014). In addition, the entire procedure of assembling must be repeated if the AFO is destroyed or a patient's condition changes (Kao and Ferris, 2009). The 3D printing system has been generally used in remedial fields and their utilization is rising daily (Rosenbaum *et al.*, 2007). 3D printers can create effectively modifiable products with no fixed moldings following specifications and the 3D printing procedure makes it feasible for doctors and specialists to create essentially custom-fitted items for them by a 3D geometric examination of the patient's foot (Uning *et al.*, 2008). 3D printing is not just used in restorative fields; however, it has been demonstrated in other applications and has recently been used in many preliminary trials to produce AFOs (Chin *et al.*, 2009). An orthosis made with 3D printing systems has focal points in less sensitive aptitudes and exertions to produce simple multiplication over traditional orthosis made with thermoplastic material. In addition, because the structured 3D displaying record is saved, assembling an AFO can be effectively repeated (Choi *et al.*, 2006).

The FEA is used to reduce pressure dissemination design at the surface. Because of a past research, numerous models of feet and AFOs have been created that have many design faults, such as straightforward geometry of movement properties and direct limit conditions without the wilting impact of rubbing (Banga *et al.*, 2017). The aftereffects of this examination may influence the limited component investigation because of the genuine circumstance of the nonlinearity approach. Numerous investigations have been completed using weight sensors but nonattendance of a better technique for the exploration, the heat exchange system and the pressure examination inside the AFO has not been very well managed. To overcome this constraint the FEA has been altered for better demonstration (Park *et al.*, 2011) and has assisted in testing to anticipate load dissemination and stress examination – a plan of orthosis trialed by the examination of the pressure and assembling the orthosis using the 3D printing strategy. In this research, the assembling procedure of AFO into two separate newly designed parts is done and assembled as a combined product for patients.

2. Methodology

2.1 Anthropometric measurement of the foot

With ethical permission (no. PGI/IEC/2019/001235) the first step of this study was to conduct the anthropometric measurements of the foot. The measurements were conducted by taking sample measurements the children's feet. Ten children (five male and five female) aged five were selected as trial subjects. There were in total 18 areas of the lower limbs that were selected, as shown in Table 1.

Table 1 Anthropometric measurement area

Sr. no.	Size
1.	Tibia length
2.	Calf girth
3.	Knee girth
4.	Ankle girth
5.	Foot length
6.	Ball of foot length
7.	Outside ball of foot length
8.	Foot breath diagonal
9.	Foot breath horizontal
10.	Heel breadth
11.	Ball girth
12.	Instep girth
13.	Short heel girth
14.	Sphyrion height
15.	Sphyrion fibular height
16.	Navicular height
17.	Toe height
18.	Instep height

Figure 1 shows the anthropometric measurements at the calf girth and navicular height area and standard professional anthropometer tools (Rosscraft) were used during the process. The measurements were conducted to have a reference size (mean size) of the children's feet.

The methodology for customized design AFO flowchart of approach is shown in Figure 2.

To create an FE model, the first geometrics of a patient's foot is obtained using a 3D scanning technique with a 3D human body scanner. The 3D scanned foot model is used to obtain a solid AFO model (Figure 3). Although some models were based on a model and simplified geometry, an accurate description with a proper shape obtained from the 3D scanning of the patient's foot and a model of a solid AFO was based on the geometry generated. The geometry of the model was modified at the joint to increase its flexibility and the material changed from polypropylene to carbon fiber to increase strength. To join a misshapen section two proper components were structured using design software (SolidWorks), in particular adjustable and hinged features (Figure 3). After the segmentation of these mechanisms in the software the foot AFO model was incorporated into FEA software (ANSYS) for meshing, to obtain biomechanical functionality and observe the deformation of an AFO.

In the next steps the mechanism that bears greater stress force with lesser deformation while comparing the two under-static and dynamic analysis is selected for 3D printing for further testing of the FE model on patients. Numerous prototyping procedures have been applied in clinical sciences and this investigation has helped when choosing 3-D printing as the wellspring for manufacturing chosen model.

The solid AFO model was obtained for modification at the joint using two mechanisms: adjustable and hinged. These mechanisms were designed using SolidWorks. The adjustable mechanism has sliding hubs on both parts on opposite sides and a sliding pin inserted to join the parts. This mechanism is more flexible than the solid AFO and can easily be removed by patients by just using removing the pin between them.

Figure 1 Anthropometric measurement of ankle

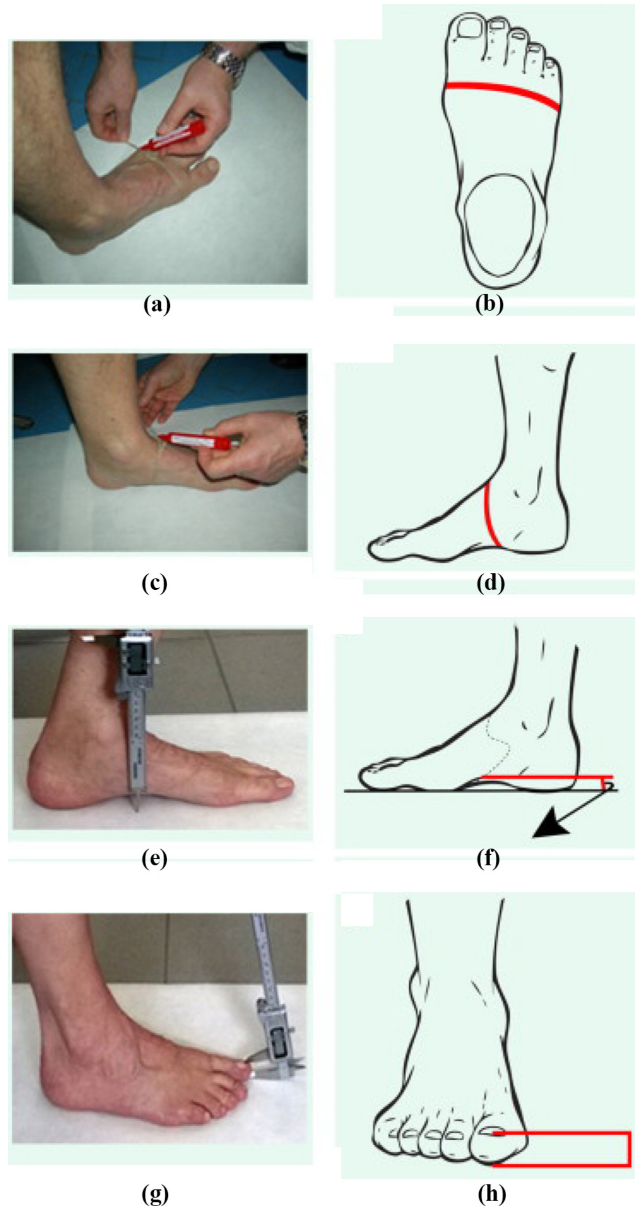
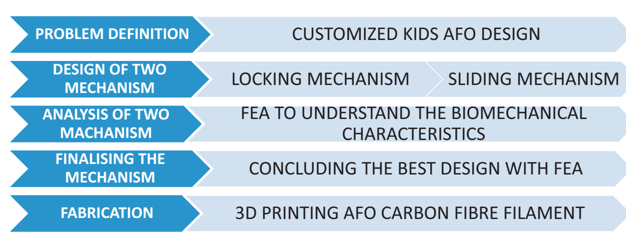


Figure 2 Methodology for customized design AFO



The hinged mechanism has four holes in two parts: two on the opposite sides of the leg and two on the opposite sides of the foot. Two C-shaped hinges are designed and join the foot with leg parts of the model. This hinge is assembled using rivets. This

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mechanism is secure and, because of the use of rivets, can bear more stress which was tested during the FE analysis of this model.

2.2 Design of the mechanism

The original AFO model was rigid, with less flexibility, less stress endurance capacity and was difficult to wear during motion. The area near the talus and the sub-talus joint extruded to form the leg and foot parts and are connected by a joining mechanism and enables the foot to move in motion with the leg along the joint. To impersonate the movement of a bone joint and to move the foot with the leg, systems imitating the joint were planned based on structure programming (Figures 3 and 4) to empower the movement of the foot while it is attached to the AFO. The sliding pin in the adjustable mechanism increases flexibility during gait and has more stress–strain endurance. The hinged mechanism, on the other hand, can bear more strength and be easily tested on children weighing between 15 and 20 kg (the average weight range for a 4-year-old).

In summary, these mechanism results validate the existing designs, were more flexible and the material used, i.e. carbon fiber, can bear more stress during walking and improve the disabilities in patients.

Figure 5 illustrates the optimized design of AFOs which was created using SolidWorks. The updated joint allows movement for 20 degrees in the front and 10 degrees to the back. This hypothesis checked the stride cycle which clarified the development of the foot movement along with the leg while walking and it showed that while walking the foot and the leg move toward one another at 20 degrees though are far from one another and climb to 10 degrees (Figure 5). The components of the AFO include the foot, the leg and the joint assembly. These components have been carefully designed with the software per the anthropometric data of children to get them fitted properly for the assembly while walking.

Figure 3 (a) and (b) CAD model of existing design of AFO

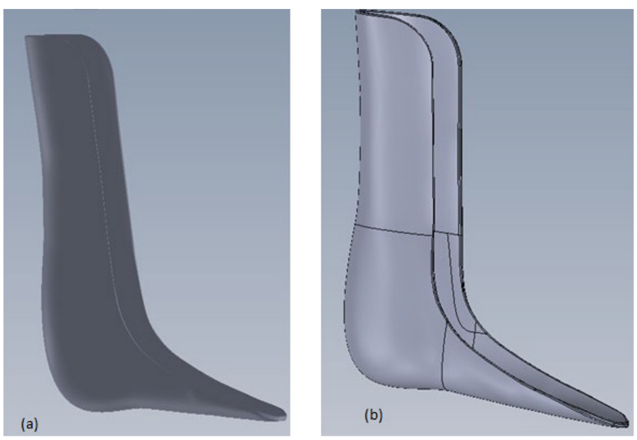
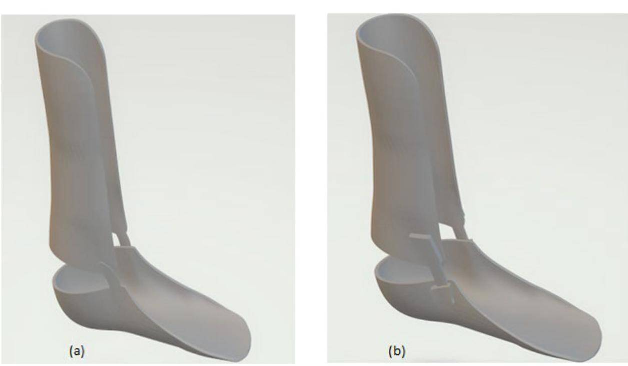


Figure 4 (a) Adjustable and (b) hinged mechanism made using design software



2.3 Finite element analysis of proposed mechanisms

For FEA, the load applied to the model obtained by assuming children's body weight ranges from 15 to 20 kg. Based on the study, the upper boundary of the ankle portion was assumed to be fixed in all planes (Figure 6) and force was applied on the leg portion. The height of the upper boundary was assumed to be one-third of the height of the normal leg above the ankle joint for children. In addition, there is no slippage between the bones and soft tissues of the foot and the flat portion of the AFO model. The STL file of scanning software was converted into an IGES file so that FEA could be performed in the design file. The FEA was performed by shifting the SolidWorks file to ANSYS software and the mechanical properties of the carbon fiber were taken into consideration.

2.3.1 Material properties

The existing solid AFO was made of polypropylene (PP) and assumed to be isotropic, uniform or linear. Isotropic material such as polypropylene is strong but heavier and this disadvantage is crucial in an AFO because children need an

Figure 5 Customized design of AFO

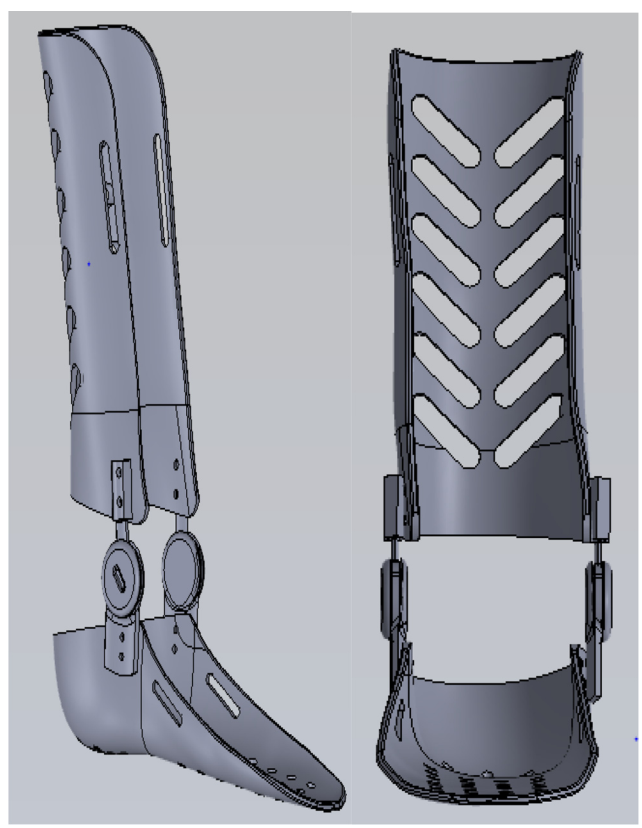
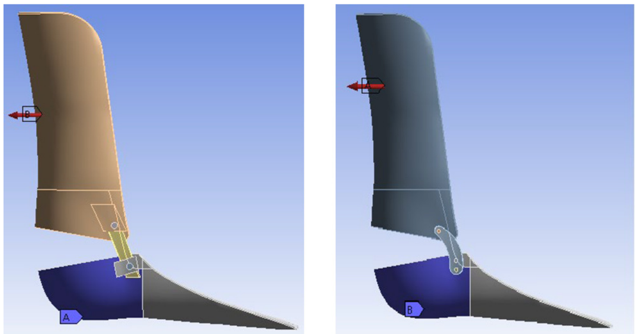


Figure 6 Fixed support on the foot on the two mechanisms



orthotic device that is lightweight to help them walk. An experiment has been conducted, stating that the carbon fiber substantially improves tensile and flexural strength and has less variations on observed impact energy than polypropylene. The mechanical properties of carbon fiber considered were by incorporating Young's modulus, Poisson's ratio, Bulk modulus, Shear modulus and density (Banga *et al.*, 2018) as illustrated in Table 2.

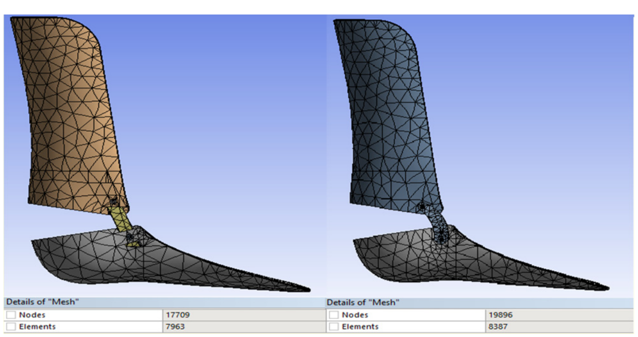
2.3.2 Model meshing

This method is used for automatic mesh generation where the structure's geometrical boundaries are defined using SolidWorks. A coarse mesh is appropriate because the deflection needs to be assessed during a small deformation. Owing to the double-curved surface of AFOs, a triangular-shaped element is generated in critical regions to incorporate material nonlinearity into the model. As this component underpins fine disfigurements, correctly matching them is significant during the examination. With regards to these variables there are 8,387 components with 19,896 hubs in the pivoted system and 7,963 components with 17,709 hubs in the flexible instrument (Figure 7) in which the component of forces

Table 2 Properties of carbon fiber and polypropylene

Material	Tensile strength (MPa)	Tensile modulus (GPa)	Density (G/cm3)	Diameter (μm)
Carbon fibre	4,900	230	1.8	6.687
Polypropylene	18.35	1.47	0.9	–

Figure 7 Meshing details of the two mechanisms



applied are integrated into the software to give the final deformation values for the two proposed designs concerning time in the range of weights is considered.

2.3.3 Loading conditions

The weight of a young child is on average between 15 and 20 kg and the gravitational acceleration to be 9.8 ms^2 force applied on an AFO is calculated (using the formula F = mg, where *m* is the weight of the child and *g* is the gravitational acceleration) for different weights. The force is considered on the leg of the AFO while keeping the foot stationary as shown in Figure 7.

2.3.4 Static and dynamic analysis of the ankle-foot orthosis model

The loading conditions of the AFO have been subjected to static analysis. These loads vary timewise in a cyclic manner which makes dynamic analysis necessary to find a better mechanism solution. The loads may vary owing to nonlinearity in material properties, change in geometry and contact conditions between the foot and the AFO. In the static analysis the foot and leg remained in fixed positions while applying force to the leg and the effect of deformation in the joint of the two mechanisms were obtained (Tables 3 and 4). The first analysis performed with a 10-degree dorsiflexion rotation about the ankle joint axis. Considering this, dynamic analysis was performed in which the foot was fixed, the leg moved about 10 degrees and force was applied on the leg and its effects were seen on the joint. Both mechanisms were analyzed and compared using these two studies to calculate the deformation with stress-bearing capacity (Figure 8).

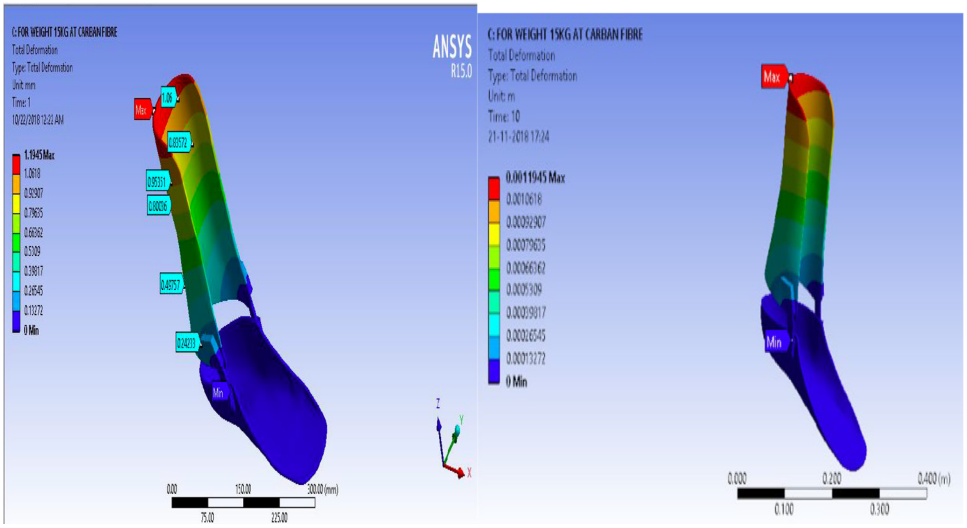
Table 3 Deformation analysis of hinged mechanism

	Carbon fiber testing on different weight (hinged)					
Time (s)	15 kg	16 kg	17 kg	18 kg	19 kg	20 kg
0.1	0	0	0	0	0	0
0.2	0.243	0.259	0.275	0.291	0.307	0.324
0.3	0.486	0.518	0.551	0.583	0.615	0.648
0.4	0.729	0.777	0.862	0.875	0.923	0.972
0.5	0.972	1.037	1.102	1.166	1.231	1.296
0.6	1.215	1.296	1.377	1.458	1.539	1.62
0.7	1.458	1.555	1.653	1.75	1.847	1.944
0.8	1.701	1.815	1.928	2.042	2.155	2.268
0.9	1.944	2.077	2.204	2.333	2.463	2.593
1	2.1878	2.337	2.479	2.625	2.771	2.917

Table 4 Deformation analysis of adjustable mechanism

	Carbon fiber testing on different weight (adjustable)					
Time (s)	15 kg	16 kg	17 kg	18 kg	19 kg	20 kg
0.1	0	0	0	0	0	0
0.2	0.132	0.141	0.15	0.159	0.168	0.178
0.3	0.265	0.283	0.3	0.318	0.336	0.357
0.4	0.368	0.424	0.451	0.477	0.504	0.536
0.5	0.53	0.566	0.601	0.637	0.672	0.715
0.6	0.663	0.707	0.752	0.796	0.84	0.893
0.7	0.793	0.864	0.902	0.955	1	1.072
0.8	0.929	0.991	1.05	1.115	1.176	1.251
0.9	1.061	1.132	1.203	1.274	1.344	1.43
1	1.194	1.274	1.353	1.433	1.513	1.608

Figure 8 Deformation in sliding and adjustable mechanisms at the joint



The stress-bearing capacity, at a maximum weight of 20 kg, of the adjustable mechanism, came to 140.67 Nm^{-2} and the hinged mechanism came to 365.02 Nm^{-2} (Figure 7). This can be explained by the inverse relation of stress and area. As stress is defined as force per unit area, the value of the area of the joining mechanism of the adjustable mechanism is more than that of the hinged mechanism which makes it less valuable in terms of the stress analysis. The value of the deformed material in different AFO designs which could be helpful in identifying the optimal design for foot drop patients (Figure 9).

3. Fabrication of customized ankle-foot orthosis design

The customized AFO design was fabricated using the additive manufacturing technique which incorporated the fused deposition modeling as the operating mechanism for products.

3.1 Additive manufacturing of customized design of ankle-foot orthosis

It took the 3D printer 14 h in total to print the AFO. The pictorial representation of the AFO while being 3D printed is shown in Figure 10. A 3D printer 0.4 mm in diameter of was used for the AFO fabrication while the positioning resolution was on the *X*/*Y*-axis with a layer of 0.78125 micron and repeatability up to 5 microns.

After the fabrication was completed the parts were ground using a grinding wheel to remove any excess material created by the printer during printing and were shaped into various curved surfaces of the AFO. The final parts of the AFO after assembly are shown in Figure 10(a) and 10(b).

The previously mentioned AFO has been 3D printed using polypropylene and is ready for assembly. This AFO will be used for curing the deformity of foot drop patients.

3.2 Assembled 3D ankle-foot orthosis

The final AFO is shown in Figure 11. This 3D printed AFO has been made for foot drop patients and gives a rotation of 10-20 degrees in the forward and backward motion of the leg while moving. The elevated view of the AFO is shown in Figure 12 which clearly illustrates the grooves meant for aeration and material optimization and the Velcro for attaching the AFO to

Figure 9 Stress analysis of the two customized designs

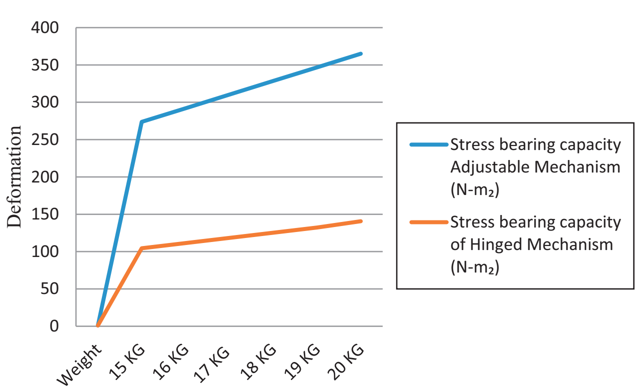


Figure 10 Fabrication of an AFO by a 3D printer

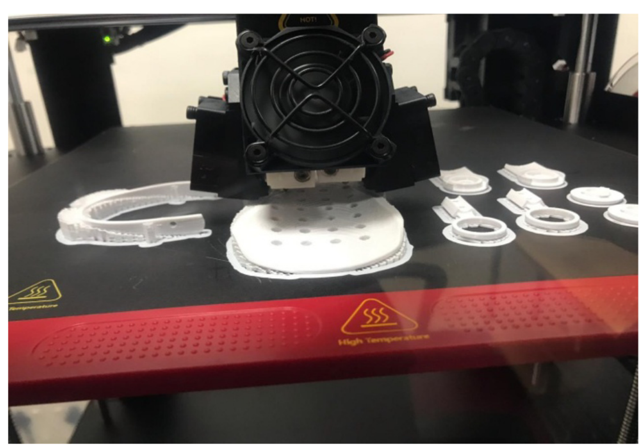


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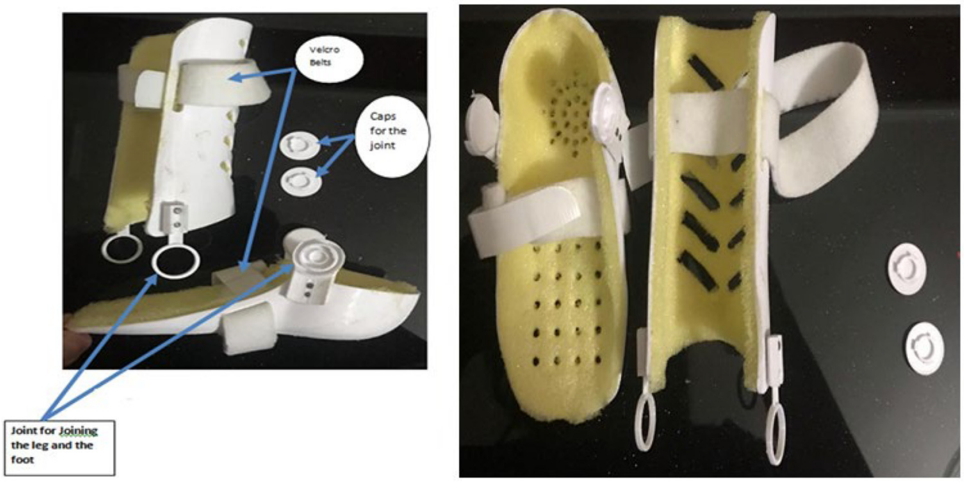
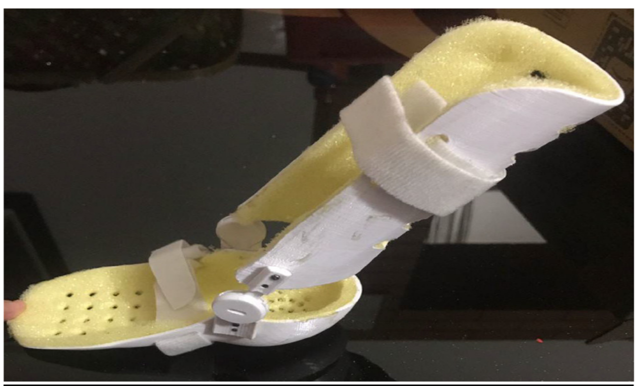
Figure 11 (a) Assembly of 3D printed AFO (b) The top view of the 3D printed parts of AFO



(a) **(b)**

Figure 12 Assembled 3D printed AFO



the foot and leg of the patients. The foam has been provided for cushioning purposes.

3.3 3D ankle-foot orthosis trials on the foot drop patient

The 3D printed AFO has been tested on foot drop patients (Figure 13), and it seemed the gait cycle was improved by using the customized design but more testing was conducted in the laboratory to create a more accurate design.

4. Results and conclusions

A customized AFO orthotic device can help improve foot deformity in children and help improve quality of life. In static analysis the foot and leg were considered fixed; hence, while applying force to the leg, the effect of deformation in the joint of the two mechanisms could be obtained (Tables 3 and 4). The first analysis was performed with a 10-degree dorsiflexion rotation about the ankle joint axis. Taking this into consideration, dynamic analysis was also performed in which the foot was considered fixed and the leg moved about 10 degree when force was applied to it. Both mechanisms were analyzed and compared using these

Figure 13 The Front view of 3D Printed AFO

two studies to calculate the deformation with stress-bearing capacity (Figure 8). The stress-bearing capacity, at a maximum weight of 20 kg, of the adjustable mechanism was 140.67 Nm^{-2} and the hinged mechanism was 365.02 Nm^{-2} (Figure 7). During deformation testing the hinged mechanism had better stress analysis compared to the adjustable design which is shown in Figure 9. Customized adjustable AFO designs will undergo further

Figure 14 Printed AFO being tested on a patient

testing on foot drop patients to improve the human gait. The improved lower leg point minute utilization of an AFO shows that an AFO improves dorsiflexion in foot drop patients. After it is created this model will be additionally tested by studying the walking patterns of drop foot patients for additional research. Further clinical trials of AFOs are taking place. Based on the results from these studies, and feedback from patients, further adjustments will be made to the automation process.

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