Published by :
http://www.ijert.org

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 13 Issue 07, July-2024

Efficient Development of Kids' AFO (Ankle Foot Orthotics)

Dr. Amol Laxman Mangrulkar
Associate Professor, Department of Mechanical Engineering, MCT's Rajiv Gandhi Institute of Technology, Mumbai, India

Aishwary Amol Kakodkar, Rugved Raote,
Aakanksha Shirke, Vajresh Sawant
Students, Department of Mechanical Engineering, MCT's Rajiv Gandhi Institute of Technology, Mumbai, India

***Abstract*—Diseases related to musculoskeletal and neuromuscular cause injuries such as cerebral palsy, amyotrophic lateral sclerosis, and stroke lead to reduced patient's control over their limbs which further results in abnormal alignment of ankles and wrists. In the case of an ankle, this My lead to problems in walking with symptoms such as foot drop which is a health problem that leads to involuntary plantar flexion as well as trouble in front of the foot, because of weakness or nerve damage. Ankle foot orthoses (AFOs) or splints have been prescribed for several decades to help the patient with support and assistance during rehabilitation by limiting the ankle's range of motion. However, the current AFOs that are trending in the market require a long labour-intensive manufacturing process leading to unacceptable waiting periods for children and patients with varying conditions This research paper proposes a new approach to AFO manufacturing that utilizes digital and additive manufacturing technologies to adapt to the requirements and fit of an individual.**

***Keywords*- AFO; cerebral palsy; static structural analysis; mass reduction; topology optimization; 3D scanning; molding; layering; 3D printing; FDM printing; post-processing.**

I. INTRODUCTION

Patients with CP, ALS, stroke, and muscular dystrophy disease as well as cancer patients have a common symptom of foot drop. Ankle foot orthosis (AFO) can assist with stretching and support the ankle for daily activities. There are mainly two types of AFOs available commercially and are currently being used: standard off-the-shelf model with no patient customization and custom molded model created through a labor-intensive, time-consuming, and expensive process. The AFO production process is a long and labor-intensive process that cannot be accepted since children grow very quickly and few patients have varying conditions. The traditional orthosis technique lacks precision and depends on the fabricator's skill. Over-the-counter braces are basic and are available in multiple sizes. They are generally strapped with Velcro or slid on which helps them keep fixed in place. Injury projection is the most important purpose of these braces. [1].

This study also suggests a focus on the design and analysis of orthoses according to the patient's measurements. The newly discovered method for manufacturing orthosis involves additive manufacturing techniques and digital surface capture. This method simplifies the production of the AFOs and allows for the customization of mass [1].

II. GAP ANALYSIS

A. Problem Statement:

Due to these limited designs, traditional AFOs don't provide customized comfort and functionality. Also, manufacturing a custom-fit orthosis is a time-consuming and tiresome manual process accomplished only by professional orthotics. Creating a cast can take up as much as four hours of fabrication time per unit and the orthotics tool based on the cast itself will take days. Space will also be required when storing the cast and can only be kept for a few months and then a new cast has to be made.

B. Project Scope:

Upon doing the required research, we concluded that replacing the material used for manufacturing AFOs with PETG (Polyethylene Terephthalate) because of its high strength and elasticity & by optimizing the geometry; the weight, cost & manufacturing time of the Ankle Foot Orthotic Tools can be reduced.

C. Objectives

(1) To use reverse engineering software to design ankle foot orthoses and fabricate them by rapid prototyping method. (2) To fabricate a new method for 3D printing AFOs that both customizes the fit & form. (3) To analyze the AFO design and study its effectiveness. (4) To increase AFO strength and flexibility and reduce the manufacturing cost along the way.

III. METHODOLOGY FLOW

The following Table 1 explains the flow/sequence of the project.

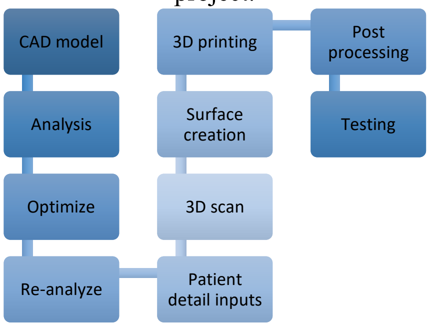


FIGURE 1- Flowchart of case study

IV. CURRENT TECHNOLOGIES

A. Biomedical Engineering

Biomedical Engineering is an important field that combines the study of biology with the concepts of engineering by applying engineering materials and principles to healthcare facilities. It focuses on the advances that improve human health and health care at all levels. It contributes to the research and development of revolutionary and life-saving concepts such as:

- Artificial organs
- Surgical robots
- Advanced prosthetics
- New pharmaceutical drugs
- Kidney dialysis

B. Additive Manufacturing

(AM) is another name for 3D printing or additive layer manufacturing. Here, the three-dimensional objects are created layer by layer using a computer-controlled process. There are no losses or material wastage in 3D printing. whereas, in traditional manufacturing methods, the material is removed at heated temperatures.

C. Fused Deposition Modelling Printing

The most widely used 3D Printing method is a process known as Fused Deposition Modelling (FDM) where the printers use a filament of thermoplastic material, which is heated till it reaches its melting point and then extruded layer by layer. Objects that are created with an FDM printer start as computer-aided design (CAD) files. Before an object can be printed, its CAD file must be converted to a format that a 3D printer can understand, which is usually STL format.

D. Reverse Engineering

Reverse engineering, which is also known as back engineering, is a process in which machines, aircraft, architectural structures, software, and other products are deconstructed to extract their design information. This process involves deconstructing individual components of larger products. It enables you to determine how a part was designed so that you can recreate it.

E. Topology Optimization

A mathematical operation called Topology Optimization improves the distribution of fabric within a predefined domain, by fulfilling given constraints previously established and minimizing a predefined cost function. Topology optimization has been used by engineers for several years, to attenuate the amount of used material and thus the strain energy of structures while maintaining their mechanical strength. In topology optimization, a few parts or structures are discarded and a brand-new layout is prepared. The structures of topology optimization have proven to be a valuable tool for the identification of concepts in the early phases of the designing process.

F. File formats

- The most used format for 3d printing is STL file format. The STL file stores information about 3D models. This format only describes the surface geometry of a 3d object without the representation of color, texture, or other characteristics of the file. (.STL) is the file extension of the STL file format.

- The STEP file is a file format for 3D models, and the letters in the name stand for "Standard for the Exchange of Product Data". The STEP format was created to improve the compatibility of files between different software programs so that designs could be more easily shared and modified. The file extension is ".STP".

- The OBJ file format is one of the most important file formats in 3D printing and 3D graphics applications. It is the preferred format for multi-color 3D printing and is preferably used for non-animated 3D models in graphics applications. The file extension corresponding to the OBJ file format is ".OBJ".

V. REVIEW OF LITERATURE

Modern scientists like Mammad & Hamid developed a method to manufacture AFO by 3D scanning using different technologies such as laser, white light, and X-ray scan. This system for scanning objects consists of several steps/prerequisites:
(1) The object is to be sprayed to obtain a matte surface before scanning. (2) Different fringe sizes are projected over the subject and their photos are taken from different views by two high-resolution cameras. The number of photos taken depends on the size and complexity of the object. (3) Later these photos are bought together and a point-cloud model is obtained. This model is converted into a 3D CAD model by determining surface numbers in the scanning software. Surface numbers can increase depending on the complexity of the object. (4) At the final step, the model is certified by using deviation analysis according to the predetermined tolerance value [1].
The SLS Nylon material had been used earlier and had significant structural issues. However, it is believed that these structural issues can be mitigated. As such, the SLS Nylon was tested with four separate samples by considering printer parameters. The tests were set to run until either the material fractured or 5% strain was reached. The results were that none of the SLS Nylon samples reached the fracture point as it is a highly elastic material. This is a required feature in a single-piece AFO as it allows the bending of the plastic. The strongest SLS Nylon sample was SLS No. 2 with a fracture stress of only 28 MPa. Due to this low fracture strength and the high cost of SLS printing, this method of manufacture was discounted [1].

Published by :
http://www.ijert.org

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 13 Issue 07, July-2024

VI. METHODOLOGY

New designs have been proposed both to provide comfort to the patient and to improve the efficiency of the available design. New designs lead to the development of new manufacturing methods. Moreover, different manufacturing methods have been improved due to the requirements of different designs and material types.

A. Traditional Method

Traditional AFOs are usually handmade by casting the patient's lower legs with Plaster of Paris (POP). Once set, this model is removed and stuffed with liquid plaster to create a model that is set. The set model is then modified through manual addition or removal of plaster, followed by forming a vacuum with thermoplastic over the set model with polypropylene. Removal of undesired or excess polypropylene and smoothing is done before patient fitting. This traditional approach provides limited design options labor-intensive and, is often costly and sometimes requires long wait times [6].

B. Calculations:

The S.I. unit system has been followed for the entire study.

The following are the calculations for 1st iteration:

Let the weight of the Kid 'W'= 60 Kgs. (1)

Let the acceleration due to gravity 'g'= 9.81m/s^2 (2)

Let the weight of the leg be 'WL' Kg

Let the mass of the leg be 'ML' Kg

The force exerted by the person on the ground 'F'= M*g N (3)

The Mass of the leg of the Kid, ML= WL/9.81 Kg (4)

According to scientific data, WL=W/7 Kg (5)

So from (5), WL = 60/7 = 8.54 Kgs (6)

So from (4), ML = 8.54/9.81= 0.87 Kgs (7)

Therefore F = ML * g = 0.87 * 9.81 = 8.54 N (8)

Note: 2nd iteration loadings are considered to be 'f'= F/3= 2.85 N & the magnitude of Kid's weight is assumed to multiply higher for safety limits reason.

C. New Methodology

The entire new methodology is segregated into three iterations, with steps 1 to 2 under the 1st iteration, steps 2 to 4 under the 2nd iteration & steps 3 to 9 under the 3rd iteration.

1) In the beginning a non-customized conventional (general) AFO available in the market was grabbed for the study. The CAD file was then converted to ".STL" file format and sent for analysis.

FIGURE 2- Readily market available AFO

2) The old AFO model was then imported into Ansys software for static structural analysis. The material was assigned as PETG, boundary conditions were set and the results were obtained. The first static structural analysis was conducted to obtain information about whether the market-available readymade AFO was strong enough for a further case study and durable to a child's rough and tough usage.

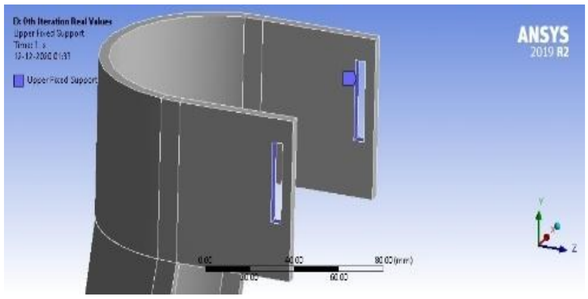


FIGURE 3- Fixed supports added at the cavity.

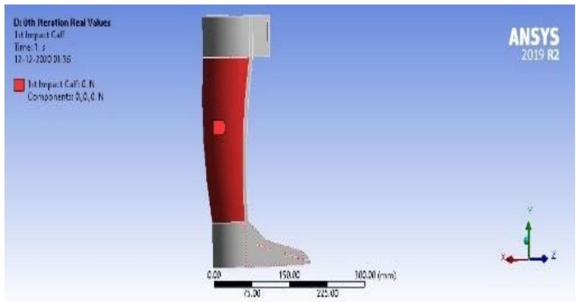


FIGURE 4- First impact on calf and heel section.

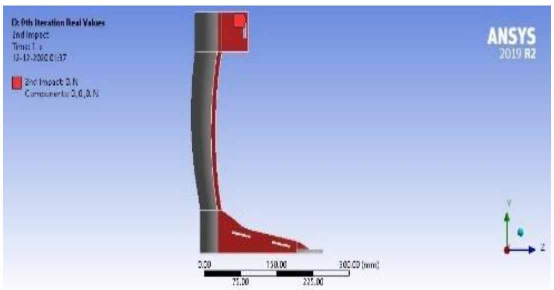


FIGURE 5- Second impact on the right side of the AFO.

Published by :
http://www.ijert.org

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 13 Issue 07, July-2024

3) When the AFO passed the static structural analysis test, it was forwarded into the topology optimization system. Initially, the mass reduction was set to 20% and analyzed. When the results were obtained to be of positive nature (i.e. optimization possible), the old AFO model was converted into ".STL" file format and was imported into Autodesk Fusion 360 software for a replica of actual mass reduction. For the same, rectangular slots and holes were made (cut–extruded) on the foot and calf section of the model respectively. This step provides replica /information about the final mass reduction to be done after 3D scanning as the 3D scanned model cannot be meshed for simulation in Ansys due to software limitations.

FIGURE 6- AFO model after topology mass optimization.

4) Then the old optimized model was again converted into ".STL" file format and was sent for static structural analysis in Ansys with the same previously defined conditions and parameters. Since this optimized old AFO is a simulated version of the new model, its analysis results will replicate that of the new one. When the results were obtained to be positive, the model was approved for final mass reduction.

5) Further, inputs from patients about their difficulties were obtained to create the required AFO model. The affected leg was scanned using a 3D scanner working on X-rays. The scanned data was then imported into Autodesk mesh mixer software.

6) The leg scan data was then layered with the help of selection tools in the form of a decided new design. Then the layering was projected on the old AFO to optimize it further.

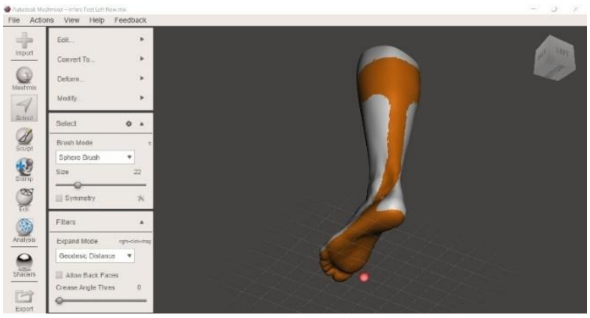


FIGURE 7- Layering AFO in mesh mixer

7) The new design is made such that it will have having smaller surface area than the old one. Hence after the projection, the unlayered portion of the old AFO was trimmed using sculpting tools, and the surface, and edges were made smoother. In this way, the new AFO model was prepared.

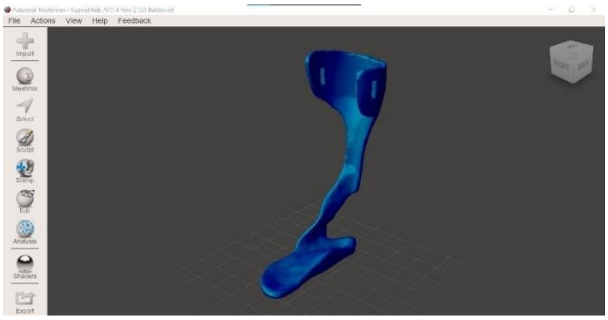


FIGURE 8- Extrusion of AFO in mesh mixer.

8) The model was then imported into Cura software from ".OBJ" format to ".STL" format. The required settings were made, the model was sliced, supports were generated and the model was sent for 3D printing.

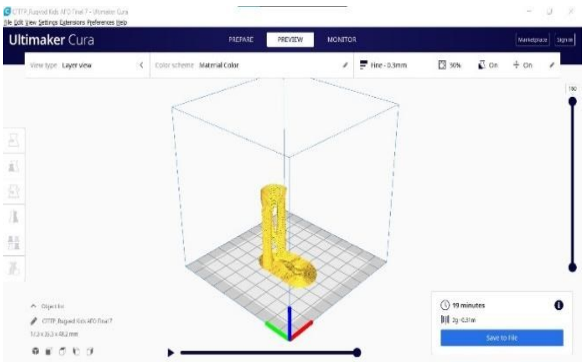


FIGURE 9- Imported AFO model in Cura

9) Finally, the 3D printed model was post-processed by removing the supports, cushioning with foam paper, and by attaching the Velcro straps.

FIGURE 10- Cushioning done on manufactured new AFO

Published by :
http://www.ijert.org

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 13 Issue 07, July-2024

VII. RESULTS

A. 1st iteration:

1) Static structural analysis result:

No considerable deformation was observed in the model. All the values were within permissible limits. Refer to Table (1), table (2), table (3), and Table (4).

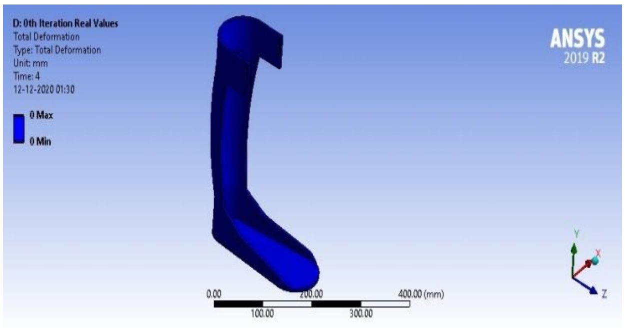


FIGURE 11- Nondeformed AFO model after stress analysis

2) Topology optimization results:

The analysis result shows that the model can be further optimized since the material from the knee and foot section was removed by the software indicating no stress/ very little stress concentration in that region.

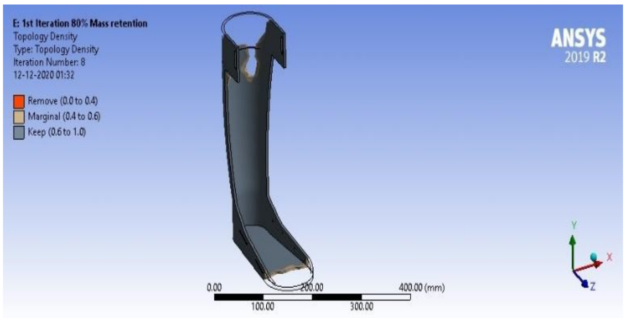


FIGURE 12- Analysis showing further optimization is possible

B. 2nd iteration:

1) Static structural analysis results:

The analysis proved that even after mass reduction in the final model, it will be safe to use the AFO or it will have no considerable deformation and the values will be under safe permissible limits.

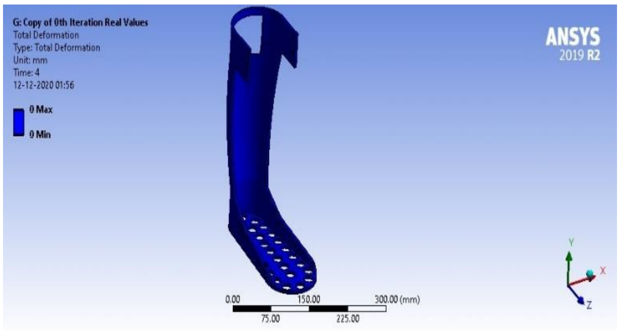


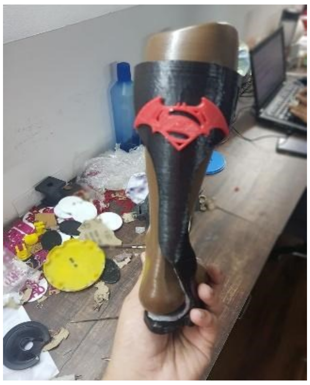
FIGURE 13- Final analysis of replica of new AFO showing no considerable deformation

C. 3rd Iteration:

1) FDM printing output:

The New AFO model has been printed as shown below in Figure (14)

(a)



(b)

FIGURE 14- Manufactured AFO after post-processing

TABLE 1- Maximum principal stress results

Sr. No.	Maximum Principal Stress		
	Time[s]	***1st iteration***	***2nd iteration***
1.	1	2.06×10^{-3}MPa	2.45×10^{-3}MPa
2.	2	4.44×10^{-3}MPa	4.69×10^{-3}MPa
3.	3	2.07×10^{-3}MPa	2.15×10^{-3}MPa
4.	4	0	0

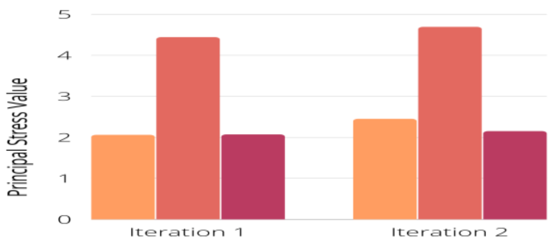


FIGURE 15- Maximum principal stress graph

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 13 Issue 07, July-2024

TABLE 2- Factory of safety results

Sr. No.	Factor of Safety (FOS)		
	Time[s]	*1st iteration*	*2nd iteration*
1.	1	15	15
2.	2	15	15
3.	3	15	15
4.	4	15	15

TABLE 3- Maximum principal elastic strain results

Sr. No.	Maximum Principal Elastic Strain		
	Time[s]	*1st iteration*	*2nd iteration*
1.	1	1.18×10^{-6}mm/mm	1.43×10^{-6}mm/mm
2.	2	2.43×10^{-6}mm/mm	2.63×10^{-6}mm/mm
3.	3	9.05×10^{-7}mm/mm	9.55×10^{-7}mm/mm
4.	4	0	0

VIII. FEASIBILITY

The advantages of additive manufacturing for Ankle-Foot Orthoses are compelling:

- Reduce the long delivery time: Typical delivery time is 2-4 weeks for traditional AFO. However, this study succeeded in scaling back the delivery time to 1 day through 3D printing. Refer to Table (4).

Table 4- Time in hours

Iteration no.	Old AFO	New AFO
1	25 Days	13
2	N.A.	9

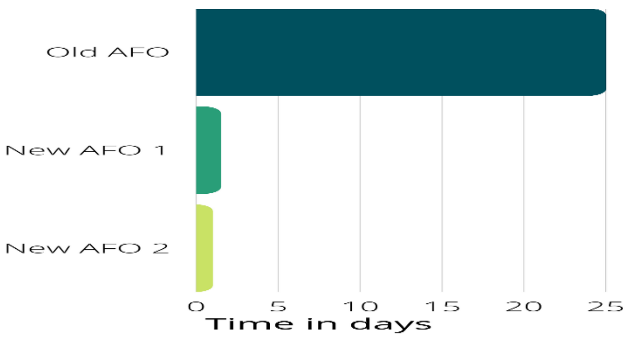


FIGURE 16: Manufacturing time comparison graph

- Enhance the extent of accuracy: Plaster shrinks after drying so plaster molds do not accurately duplicate the patient's ankle and foot shape without iterations or the skill of a licensed orthotist. This study efficiently utilized precise, 3-dimensional scanning to produce exact dimensions for immediate, exact AFO accuracy while utilizing design for additive manufacturing compensation techniques.

- Eliminate multiple visits: The traditional approach requires patients to be often taxed at health care centers and drives cost. This study enhanced the manufacturing process to produce single-visit patient care.

- Enhancement of the limited design freedom: Shapes of AFOs were limited by old manufacturing practices, which cannot fabricate orthoses that require more intricate, functional designs. This study proposes a methodology to manufacture custom-fit AFOs. Refer to Table (5) for information on the dimensions of both AFOs.

Table 5- Dimensional analysis of AFO

Prototype No.	Length[mm]	Breadth[mm]	Height[mm]
1	11.96	197.17	7.16
2	75.69	211.51	154.94

Note: The 1st prototype had been printed smaller than the final prototype just to get an estimation of the design.

- Material Selection: Both properties stiffness for structural functionality and softness for comfortable interfacing are available in the material used for this study. Refer to Table (6) to compare the material usage of the new AFO.

Table 6- Material Usages

Prototype No.	Material Used	Quantity Used [gm]	Cost/gm	Total Cost
1	PLA	108	Rs. 10	Rs. 1080
2	PETG	139	Rs. 25	Rs. 3475

- Use of Latest Technology: This study proposes collaborative usage of the latest generation 3D scanners & cloud technology-based CAD, CAM & CAE software for smooth transitioning between intermediate steps of manufacturing. Refer to Table (7) for gadget information.

Table 7- Tools & Equipment Used

Sr. No.	Technology	Product
1	3D scanner	Ein scan pro
2	CAD software	Dassault Solidworks, Autodesk Fusion 360 & Autodesk Meshmixer
3	CAE software	Ansys
4	CAM software	Ultimaker Cura

IX. CONCLUSION

In this paper, a methodology was successfully developed by which the time, material, cost, and labor required for manufacturing a patient's customized AFO was greatly reduced in contrast to traditional (molding) methods.

By using the principles of reverse engineering and topology optimization the new AFO was reduced in mass (Material usage) such that the AFO to skin contact stays minimum, allowing maximum air circulation.

By studying the human leg anatomy, the bio-medical tool (AFO) was molded using bio-mechanics to aid in the gait of the patient.

Then in the end by using the FDM (3D printing) method, the AFO was built with accuracy.

ACKNOWLEDGMENT

We would like to show our thanks & gratitude to our project guide Mr. Amol Mangrulkar of RGIT Mumbai & Mr. Amit Ghule, Mr. Dhruv Gandhi & team from SimpliForge Creations Pvt Ltd of Mumbai for their time, effort, and guidance for the accomplishment of this project.

FUTURE SCOPE

1) Efforts are underway the reduce the cost of manufacturing the AFO even further for serial orders.
2) With the help of engineering software, standard AFO templates can be finalized to reduce the modeling time.

REFERENCES

[1] M. Walbran, K. Turner & A.J. Mc Daid, "Customized 3D Printed Ankle Foot Orthotics with Adaptable Carbon Fiber Composite Spring Joint," Cogent Engineering, D.O.I. 10.1080/23311916.2016.1227022.
[2] Gabriele Baronio, Sami Harran, Alberto Signoroni, "A Critical Analysis of a Hand Orthosis Reverse Engineering and 3D Printing Process", Applied Bionics and Biomechanics, vol. 2016, Article ID 8347478, 7 pages, 2016.
[3] Amber Gatto, Stephen Sundarrao and Dr. Stephanie Carey, "Design & Development of a Wrist-Hand Orthosis for Individuals with a Spinal Cord Injury"
[4] Yu-an Jina, Jeff Plotta, Roland Chena, Jeffrey Wensmanc, Albert Shih, "A Review of the Traditional and Additive Manufacturing of Custom Orthoses and Prostheses", Conference: CIRP 25th Design Conference Innovative Product Creation, 2015.
[5] Octavian Ciobanu, Yavuz Soydan and Selman Hızal," Customized foot orthosis manufactured with 3D printers", Conference: IMS'2012 - The 8th International Symposium on Intelligent Manufacturing Systems, 2012.
[6] https://en.wikipedia.org/wiki/Plaster-of-Paris
[7] https://www.coursehero.com/file/68956176/REVERSE-ENGINEERINGpdf/