PATIENT SPECIFIC DESIGN AND FEA BASED OPTIMIZATION OF ANKLE FOOT ORTHOSIS

A PROJECT REPORT

submitted by

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TKM21MECI08

to

the APJ Abdul Kalam Technological University
in partial fulfillment of the requirements for the award of the Degree

of

Master of Technology

In

Computer Integrated Manufacturing.

Department of Mechanical Engineering

TKM College of Engineering Kollam

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DECLARATION

I, Milan M, hereby declare that the project report "Patient specific design and FEA based optimization of ankle foot orthosis." submitted for partial fulfillment of the requirements for the award of degree of Master of Technology of the APJ Abdul Kalam Technological University, Kerala is a bonafide work done by me under supervision of Subhash N. N., Scientist/Engineer Department of Medical Device Engineering SCTIMST Govt of India, Prof. Fazial N S., Assistant Professor, Department of Mechanical Engineering, TKM College of Engineering, Kollam. This submission represents my ideas in my own words and where ideas or words of others have been included, I have adequately and accurately cited and referenced the original sources. I also declare that I have adhered to ethics of academic honesty and integrity and have not misrepresented or fabricated any data or idea or fact or source in my submission. I understand that any violation of the above will be a cause for disciplinary action by the institute and/or the University and can also evoke penal action from the sources which have thus not been properly cited or from whom proper permission has not been obtained. This report has not been previously formed the basis for the award of any degree, diploma or similar title of any other University.

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CERTIFICATE

This is to certify that the report entitled '**PATIENT SPECIFIC DESIGN AND FEA BASED OPTIMIZATION OF ANKLE FOOT ORTHOSIS**' submitted by '**MILAN M (TKM21MECI08)**' to the APJ Abdul Kalam Technological University in partial fulfillment of the requirements for the award of the Degree of Master of Technology in Computer Integrated Manufacturing, Mechanical Engineering is a bonafide record of the project work carried out by him under my guidance and supervision. This report in any form has not been submitted to any other University or Institute for any purpose.

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ABSTRACT

The digital workflow in orthotics and Prosthetics is the use of digital technology and tools to simplify and streamline the fabrication process of a prosthetics or an orthosis. There are a significant range of digital tools on the market and now, I am currently integrating them to create a digital workflow to design a angle foot orthotic device for foot drop.Foot drop,is a condition characterized by difficulty or inability to lift the front part of the foot, leading to dragging or scuffing of the foot while walking.The most common cause of foot drop is nerve damage,particularly to the peroneal nerve, which controls the muscles responsible for dorsiflexion. An Ankle Foot orthosis (AFO) is a medical device used to support and stabilize the ankle and foot. It is commonly prescribed for individuals who have difficulty with foot and ankle control due to conditions such as muscle weakness, paralysis, or neurological disorders. The primary function of an AFO is to provide support and alignment to the ankle and foot, helping to control and guide their movements during walking or other activities. This project focuses on the design of an AFO using digital workflow. Using the finite element method, computational and experimental assessments of the AFO structure were performed to determine the ideal force that could be applied in the event of the foot drop

Keyword: Ankle Foot Orthosis (AFO), Design of a Custom Ankle Foot Orthosis, Analysis of structure, FEM

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ABBREVIATIONS

AFO- Angle foot orthosis

P - Prosthetics

O - Orothotics

PP - Polyproplyene

PLA - Polylactic acid

PE - Polyethlyene

HDPE- High density polyethalyene

FEA- Finite Elemental Analysis

FEM- Finite Elemental Method

CIM- Computer Integrated Manufacturing

CAD- Computer Aided Design

CHAPTER 1

INTRODUCTION

Walking is the human's most important characteristic of locomotion. The brain, spinal cord, bones, muscles, peripheral nerves, and various joints all play a role in this voluntary and coordinated motion. However, due to gait disorders, many people around the world are unable to engage in the usual walking activity.These gait impairments are brought on by a variety of neurological conditions (including cerebral palsy, stroke, and spinal cord injury), muscular deficits (weakness in the plantar or dorsiflexion muscles), or traumas. The dorsiflexor and plantar flexor muscles, or both, are weak in people with neurological disorders or muscular inadequacies, which reduces their ability to walk.The inability to lift their foot through the ankle is a symptom of dorsiflexor muscle weakness. They extend their leg higher than usual while walking to prevent toe drag. Steppage gait is the term for this gait abnormality, which is characterised by foot drop. An ankle-foot orthosis (AFO) is a type of assistive device that can be used to correct for this gait impairment.By directing ankle dorsiflexion and plantarflexion, the AFO helps the individual's ankle and foot while they work to overcome the foot drop problem. Out of all the assistive devices, AFO is the one that is used the most frequently (approximately 26%). Based on their regulatory systems, these AFOs are divided into passive and active categories.Only mechanical components are used in passive AFOs to regulate the relative motion of the shank and foot components. Active AFOs have an actuator and onboard control system to regulate the AFOs' relative motions.

1.1 PATHOPHYSIOLOGY

In the context of Ankle-Foot Orthoses (AFOs), an understanding of the pathophysiology of the underlying condition being treated is crucial in guiding the design and use of the orthotic device. The pathophysiology of the condition helps determine the specific goals and objectives of AFO intervention.

1.1.1 Foot Drop

Foot drop is a condition characterized by the inability to lift the front part of the foot, leading to difficulty in walking and a high risk of tripping or falling. The pathophysiology of foot drop often involves weakness or paralysis of the muscles responsible for dorsiflexion (lifting the foot upwards). AFOs for foot drop aim to provide dorsiflexion assistance and help with foot clearance during the swing phase of the gait cycle.

1.1.2 Ankle Instability

Ankle instability can result from ligamentous laxity, muscle weakness, or previous injuries, leading to an increased risk of ankle sprains or instability during weight-bearing activities. The pathophysiology of ankle instability may involve compromised proprioception, altered muscle activation patterns, or mechanical instability. AFOs for ankle instability focus on providing external support and stabilization to the ankle joint, improving proprioception, and enhancing overall ankle control during movement.

1.1.3 Gait Abnormalities

Various gait abnormalities can result from different pathophysiological mechanisms, such as muscle weakness, spasticity, contractures, or abnormal joint mechanics. AFOs designed for specific gait abnormalities aim to address the underlying pathophysiology and improve gait mechanics. For example, in conditions like cerebral palsy, where spasticity and muscle imbalances are common, AFOs can help control excessive muscle tone, provide support, and facilitate more efficient gait patterns.

1.1.4 Post-Stroke Rehabilitation

AFOs are commonly used during post-stroke rehabilitation to help individuals regain mobility, improve walking patterns, and address foot drop or weakness on the affected side.

1.2 AFO

AFO stands for Ankle-Foot Orthosis. It is a medical device used to provide support, stability, and improved function to individuals with lower limb impairments. An AFO is typically worn externally and is designed to help address various conditions, such as foot drop, ankle instability, gait abnormalities, or post-surgical rehabilitation. It is constructed from materials like thermoplastics, carbon fiber composites, or metal components and is customized to fit the individual's leg and foot anatomy. AFOs work by providing mechanical support, controlling joint motion, and improving alignment to enhance mobility and walking ability. They are prescribed and fitted by healthcare professionals such as orthotists or rehabilitation specialists to meet the specific needs of each individual.

1.3 CLASSIFICATION OF AFO

AFO are divided into two categories based on its functionality and mode of operation, namely active and passive AFOs.The selection between active and passive AFOs depends on the individual's specific needs, underlying condition, functional goals, and the recommendations of healthcare professionals such as orthotists or rehabilitationspecialists. The appropriate type of AFO is determined through a comprehensive evaluation and assessment to ensure optimal fit, functionality, and user satisfaction.

1.3.1 Active AFOs

Active AFOs, also known as powered or motorized AFOs, incorporate mechanical or electrical components to actively assist or augment ankle and foot movements. These AFOs use motors, sensors, and control systems to provide dynamic support and assistive forces during gait. Active AFOs can be programmed to detect specific movement patterns or muscle activity and respond accordingly. They are designed to enhance the user's mobility, proprioception, and energy efficiency during walking.Examples of active AFOs include those that incorporate microprocessor-controlled systems, such as the WalkAide or Bioness systems. These devices use functional electrical stimulation (FES) to stimulate the affected muscles, causing the appropriate movement and assisting with foot clearance during the swing phase of gait. Active AFOs are often prescribed for individuals with foot drop or certain neurological conditions affecting muscle control.

1.3.2 Passive AFOs

Passive AFOs, also referred to as static or non-powered AFOs, do not incorporate any active mechanical or electrical components. They provide structural support, stability, and alignment without the use of additional energy sources or controls. Passive AFOs are typically made of rigid or semi-rigid materials, such as thermoplastics or carbon fiber composites, and are designed to control joint motion and prevent unwanted movements.

Passive AFOs are commonly used for conditions such as ankle instability, muscle weakness, gait abnormalities, or to provide postoperative support and immobilization. They work by maintaining a fixed ankle position, restricting excessive motion, and assisting with proper foot alignment during walking.Examples of passive AFOs include articulated AFOs with dorsiflexion stops or fixed plantarflexion stops, static carbon fiber AFOs, or posterior leaf spring AFOs. These devices provide varying degrees of support, range of motion control, and assistance based on the specific condition and functional requirements of the wearer.

1.4 TYPES OF AFO

Ankle-Foot Orthoses (AFOs) can be classified into different types based on their design features and intended function.The choice of AFO type depends on the individual's specific condition, functional requirements, and the recommendations of healthcare professionals, such as orthotists or rehabilitation specialists. A thorough evaluation and assessment are essential to determine the appropriate type of AFO that will best meet the individual's needs and goals.

1.4.1 Solid AFOs

Solid AFOs, also known as static AFOs, are rigid orthotic devices made of materials such as thermoplastics or carbon fiber composites. They provide stability, control joint motion, and offer structural support to the ankle and foot. Solid AFOs are commonly used for conditions like ankle instability, severe foot drop, or as postoperative immobilization devices.

1.4.2 Articulated AFOs

Articulated AFOs incorporate joints or hinges that allow controlled motion at the ankle joint. These joints can be dorsiflexion stops or adjustable range-of-motion hinges. Articulated AFOs provide support while allowing some degree of ankle motion, aiding individuals with conditions that require limited ankle range of motion or assistance with dorsiflexion during walking.

1.4.3 Posterior Leaf Spring AFOs

Posterior Leaf Spring AFOs utilize a leaf spring design to provide dynamic dorsiflexion assistance during the swing phase of the gait cycle. These AFOs consist of a curved, flexible spring along the posterior aspect of the leg, helping with foot clearance and reducing the risk of tripping. They are commonly prescribed for mild to moderate foot drop.

1.4.4 Carbon Fiber AFOs

Carbon Fiber AFOs are lightweight and strong orthotic devices made from carbon fiber composite materials. They offer an excellent strength-to-weight ratio, providing durability and comfort. Carbon Fiber AFOs are commonly used when optimal support and stability are required while minimizing the weight and bulkiness of the orthosis.

1.4.5 Ground Reaction AFOs

Ground Reaction AFOs, also known as floor reaction AFOs, utilize the principles of ground reaction forces to assist with gait. These AFOs typically have a rocker sole design and are used to control excessive ankle dorsiflexion or plantarflexion during the stance phase of walking.

1.4.6 Dynamic AFOs

Dynamic AFOs incorporate mechanical components, such as springs or cables, to provide dynamic assistance or resistance to ankle motion. These AFOs store and release energy during walking, aiding individuals with conditions like foot drop or gait abnormalities. Dynamic AFOs aim to provide a more natural and energy-efficient gait pattern.

1.4.7 Customized and Prefabricated AFOs

AFOs can also be classified as customized or prefabricated. Customized AFOs are individually designed and fabricated based on the specific measurements, anatomy, and functional requirements of the wearer. Prefabricated AFOs, on the other hand, are pre-made in standard sizes and designs, offering a more cost-effective and time-efficient option.

CHAPTER 2

LITERATURE REVIEW

Foot drop is a condition characterized by the inability to lift the front part of the foot, leading to difficulty in walking and a high risk of tripping or falling.Rogati GG, Caravaggi P, et.al (1) Patients with drop feet may be prescribed ankle-foot orthoses (AFO) to help them regain a somewhat normal gait pattern.The majority of patients with foot and ankle weakness can be effectively treated with standard off-the-shelf AFOs, but these devices have several drawbacks, particularly in terms of comfort. Custom AFOs are therefore increasingly used to treat drop-foot when conventional remedies are insufficient. Chisita CT, Durodolu OO et. al (2) Leveraging Digital Technology to Overcome Barriers in the Prosthetic and Orthotic Industry: Evaluation of its Applicability and Use During the COVID-19 Pandemic" discusses the use of digital technology in the prosthetic and orthotic industry. The paper highlights the challenges faced by the industry during the COVID-19 pandemic and how digital technology can help overcome these challenges. The paper also includes a web-based survey of working prosthetists, orthotists, and lower limb patients to assess the use of digital technology in prosthetics and orthotics. The survey was conducted between June and July 2020 and divided into three sections: lower limb amputees, prosthetist and orthotist (P&O) currently using digital technologies in their practice, and P&O not using any digital technology. The paper concludes that digital technology is transforming healthcare and can provide safer care during the pandemic. However, the technology must be implemented thoughtfully and designed to address issues that are barriers to current adoption.

Hassan F, Murtaza Q, Bhardwaj S et. al (3) The development of a custom ankle foot orthoses (AFO) using 3D scanning and finite element analysis to find the optimal force for droop foot patients. The study aims to simulate a better functional Custom ankle foot orthoses by measured force with deflection on the Custom AFOs.Computational and experimental analyses of AFO structure by finite element method to find out the optimal force that permits on the case study of droop foot. Cha YH, Lee KH, Ryu HJ, et. al (4) "The contribution of this paper is the description of the 3D printing technique and automated design software used to create an individualized ankle-foot orthosis (AFO) for a patient with foot drop caused by peroneal neuropathy. The paper also reports the clinical results of the 3D-printed AFO compared to a conventional AFO, which showed that the 3D-printed AFO exhibited similar functionality as the conventional AFO and considerably satisfied the patient in terms of the weight and ease of use. The paper suggests the possibility of using 3D printing techniques and automated design software to create individualized AFOs. Kubasad PR, Gawande VA, et. al (5) Presenting an optimized 3D model of a single piece passive Ankle Foot Orthosis (AFO) using Finite Element Analysis (FEA) technique. Conducting static analysis of AFO made of two different materials (Polypropylene and High-Density Polyethylene (HDPE)) with two different thicknesses (3mm and 4mm). Optimizing the design of AFO for shape and thickness based on the results obtained from the static analysis. Conducting dynamic analysis of the optimized AFO to know its behavior in walking condition. Comparing the results obtained from the static and dynamic analyses of the two different materials and thicknesses of AFO and concluding that the polypropylene AFO was better compared to that of HDPE AFO by generating less stress, deformation, and factor of safety.Proposing that the fabricated AFO can be tested for real-time walking conditions.

Hasibuzzaman M, Wahab AA,et. al (6) This paper provides a short review of the use of three-dimensional (3D) printing technology in developing orthosis for biomedical applications. The contributions of this paper are,discussing the findings on the use of 3D printing technology for developing orthosis that facilitate all regions of human bodies.Summarizing the available materials of orthosis and future directions of research and study in providing better healthcare services to patients and users.Providing new insights to researchers for developing an optimum orthosis for patients. Opitz M, Fröhlingsdorf P.et. al (8) The paper explores the underlying trends driving the adoption of digitalisation for customisation of prosthetics and orthotics (O&P). It shows that several trends in 3D image capture, 3D modelling, and 3D printing currently converge and thus fuel the rapid transformation of the O&P industry. The paper also reviews the impact of boundary conditions set by regulators as well as the reimbursement system. Towards the end of the paper, a digital scenario of the near future is outlined by following around an orthotist during her work. The paper finishes with a call-to-action targeting regulators, payors, prosthetists/orthotists, and patients to enable such a desirable future. Dr. Felix Capanni et. al (9) According to the World Health Organization (WHO), the number of elderly people aged 60 and up will increase by 22% by 2050, more than doubling from 12% in 2015. By 2050, low and middle-income countries would house 80% of the total geriatric population. Musculoskeletal injuries and other bone-related conditions are common among younger adults and the elderly. According to a WHO study, approximately 1.7 billion people worldwide have musculoskeletal conditions that cause disability. In addition, the increased R&D expenditure is expected to drive the global orthotic devices market in the coming years.

2.1 OBJECTIVES

The following are the objectives of this investigative experimental study:

1 To design customer specific angle foot orthosis using digital workflow.

2 Development of FEA methodology for analysis

3 FEA based design optimization

CHAPTER 3

METHODOLOGY

Prosthetic and orthotic services are typically provided face-to-face with a high amount of physical contact, so the pandemic presents unique challenges that can be challenging to overcome. Currently, the prosthetic and orthotic industry designs devices to restore, replace, correct, protect, or immobilize a body part through handcrafted artisan approaches. The digital workflow in orthotics and Prosthetics is the use of digital technology and tools to simplify and streamline the fabrication process of a prosthetics or an orthosis. There are a significant range of digital tools on the market and now i am currently integrating them to create a digital workflow to design a angle foot orthotic device for foot drop.Foot drop,is a condition characterized by difficulty or inability to lift the front part of the foot, leading to dragging or scuffing of the foot while walking.The most common cause of foot drop is nerve damage,particularly to the peroneal nerve, which controls the muscles responsible for dorsiflexion. An Ankle Foot Orthosis (AFO) is a medical device used to support and stabilize the ankle and foot. It is commonly prescribed for individuals who have difficulty with foot and ankle control due to conditions such as muscle weakness, paralysis, or neurological disorders.The primary function of an AFO is to provide support and alignment to the ankle and foot, helping to control and guide their movements during walking or other activities.This project focuses on the design of an AFO using digital workflow.

Foot drop, also known as drop foot, is a medical condition characterized by the inability to lift the front part of the foot. It causes difficulty in clearing the foot during walking, resulting in an abnormal gait pattern and an increased risk of tripping or falling.The primary cause of foot drop is weakness or paralysis of the muscles responsible for dorsiflexion, which is the upward movement of the foot towards the shin. These muscles, including the tibialis anterior, extensor hallucis longus, and extensor digitorum longus, are responsible for lifting the foot and keeping it in a neutral position during walking.Foot drop can result from various underlying conditions or factors, including:

- Nerve Damage: Damage to the nerves that control the muscles involved in foot dorsiflexion can lead to foot drop. This can occur due to conditions such as peripheral neuropathy, nerve compression (e.g., from herniated discs or entrapment syndromes), nerve injuries, or certain neurological disorders.
- Muscle Disorders: Conditions that affect the muscles themselves, such as muscular dystrophy, can cause muscle weakness or atrophy, leading to foot drop.
- Stroke or Brain Injury: Damage to the brain or spinal cord, such as from a stroke or traumatic brain injury, can result in foot drop due to the disruption of nerve signals or muscle control.
- Spinal Cord Disorders: Disorders affecting the spinal cord, such as spinal stenosis or herniated discs, can compress the nerves and lead to foot drop.

The symptoms of foot drop typically include difficulty in dorsiflexing the foot, resulting in a slapping or dragging motion while walking. Individuals with foot drop may compensate by lifting the leg higher than normal or swinging the leg outward to avoid tripping. This altered gait pattern can lead to fatigue, reduced mobility, and an increased risk of falls.Treatment for foot drop aims to address the underlying cause and improve gait mechanics. It may include:

- Physical Therapy: Strengthening exercises and stretching routines can help improve muscle strength, coordination, and range of motion.
- Assistive Devices: Ankle-Foot Orthoses (AFOs) are commonly used to provide support and assist with dorsiflexion during walking. AFOs help lift the foot and maintain proper alignment, improving foot clearance and reducing the risk of tripping.
- Electrical Stimulation: Functional electrical stimulation (FES) devices may be used to stimulate the affected muscles, causing them to contract and assist with foot dorsiflexion.
- Surgical Interventions: In some cases, surgical procedures such as tendon transfers or nerve decompression may be considered to improve muscle function and alleviate foot drop.

The prognosis for foot drop varies depending on the underlying cause, the extent of muscle weakness or nerve damage, and the effectiveness of treatment interventions. With appropriate management and intervention, many individuals with foot drop can experience improved mobility and quality of life. It is important to consult with healthcare professionals, such as neurologists, physiatrists, or orthopedic specialists, for an accurate diagnosis and appropriate treatment plan tailored to the individual's specific needs.

3.1 CONCEPT

Ankle-Foot Orthosis is known as AFO. For those with lower limb disabilities, it is a medical device that offers support, stability, and increased function. AFOs are normally worn externally and are intended to help with a number of disorders, including foot drop, ankle instability, aberrant gait patterns, and post-surgical rehabilitation. It is made specifically for each person's leg and foot anatomy from of components made of metal, thermoplastics, or carbon fibre composites. AFOs improve alignment, manage joint motion, and support the body mechanically to increase mobility and walking capacity. They are prescribed and fitted by medical professionals to fulfil each person's unique needs, such as orthotists or rehabilitation specialists.

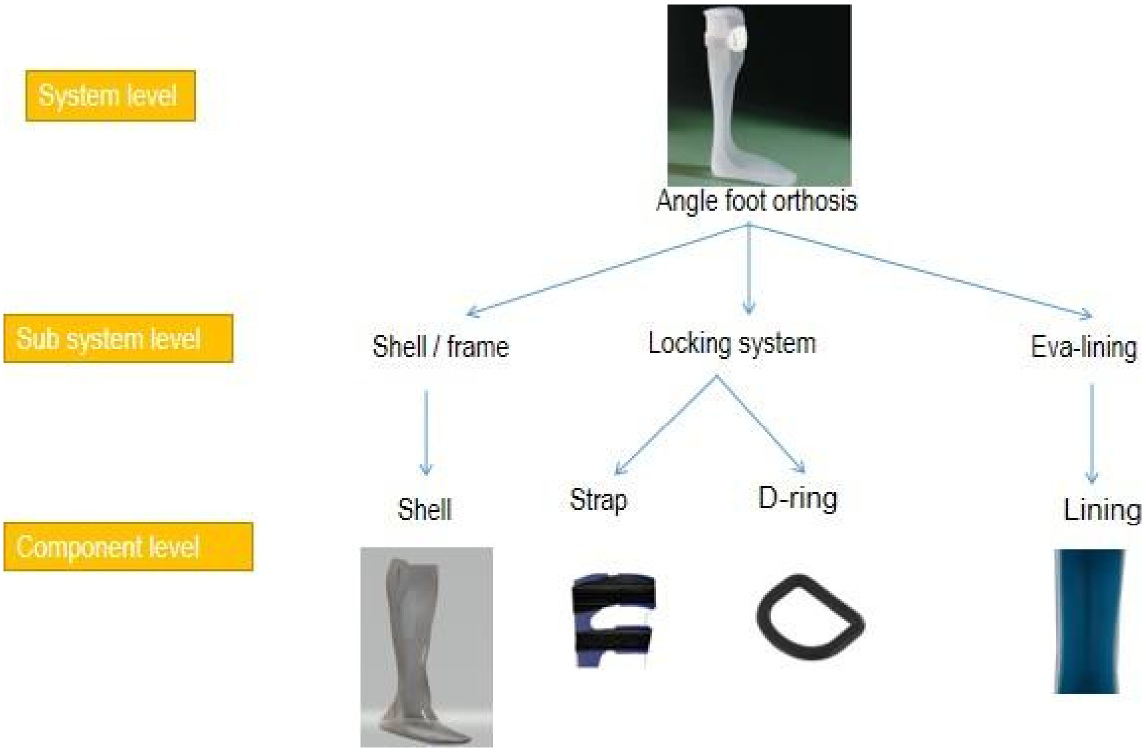

Fig 3.1 System level discretization

The AFO shell refers to the main component of an Ankle-Foot Orthosis (AFO) that covers and provides structural support to the lower leg and foot. It is the external, rigid portion of the AFO that helps maintain proper alignment, controls joint motion, and assists with improving gait mechanics.The AFO shell is typically made from materials such as thermoplastics or carbon fiber composites. These materials are chosen for their strength, durability, and ability to withstand forces and loads experienced during walking or other weight-bearing activities.The design and shape of the AFO shell can vary depending on the specific needs of the individual and the condition being addressed. The shell is custom-made or fabricated to match the contours of the lower leg and foot, providing a personalized fit and optimal support.The AFO shell covers the posterior and lateral aspects of the lower leg and extends to the foot, encapsulating the ankle joint. It is typically designed to allow for the necessary range of motion at the ankle, such as limited dorsiflexion or plantarflexion based on the specific requirements of the individual's condition.The AFO shell may incorporate additional features such as hinges, dorsiflexion stops, or adjustable straps to provide specific control or assistance based on the individual's functional needs. These components are strategically integrated into the shell design to optimize its performance and functionality.Proper alignment and fit of the AFO shell are essential for its effectiveness. Orthotists or healthcare professionals specializing in orthotics assess the individual's needs, take precise measurements, and use these measurements to design and fabricate the AFO shell to ensure a comfortable and functional fit.The AFO shell, along with other components such as straps, padding, and closures, forms a complete AFO device that helps address conditions such as foot drop, ankle instability, or gait abnormalities. The shell provides the necessary structural support and control to improve gait mechanics, enhance stability, and promote better mobility for individuals with lower limb impairments.

3.2 DESIGN AND DEVELOPMENTS

Digital workflow in the design of an AFO (Ankle-Foot Orthosis) involves utilizing computer-aided design (CAD) software and other digital tools to streamline the design process. It enables orthotists, engineers, and other healthcare professionals to efficiently design and customize AFOs for individual patients. The digital workflow begins with a comprehensive patient assessment, including a thorough evaluation of the patient's condition, gait analysis, range of motion measurements, and specific functional requirements. This information serves as the foundation for the subsequent design process.

3.2.1 3D Scanning

Digital workflow often incorporates 3D scanning or imaging techniques to capture the patient's limb shape and anatomy. This can involve using specialized scanners or taking digital photographs from multiple angles to create a 3D representation of the limb.

Fig 3.2 Scanner

The P&O respondents preferred the more cost-effective iPad with a structure scanner (Occipital) over high-end accurate scanners such as Vorum's Spectra scanner or Artec EVA scanner. P&O interviewees stated that the wireless iPad was easier and lighter to maneuver to capture the limb shape but can be limiting when capturing the posterior view due to the screen's position forcing an awkward posture of the person scanning.

Fig 3.3 Scanning of leg profile

- scanning using iPad and structural sensor (Techmed 3D app)
- approximately 2 to 3 minute for scanning
- 50 to 60 cm distance between leg and scanner

Fig 3.4 Scanned model

3.2.2 CAD Modeling

Using the acquired 3D data, CAD software is employed to create a virtual model of the AFO. The orthotist or designer can manipulate and modify the digital model to ensure proper alignment, fit, and functional requirements. CAD software allows for precise adjustments, such as modifying contours, adding reinforcements, or incorporating specific features like joints or strapping mechanisms.

For creating a CAD model for designing AFO, Mecuris design software is used.

Step 1: Install '3DSizeMe' on iPad.

Step 2: Change the bundle ID in the settings to "Mecuris".

Step 3: Create a Mecuris account and in the "IMED" settings log in with this account.

Step 4: Scan the model.

Step 5: Send the model to Mecuris cloud.

i. Model repair

Step 1: From the auxiliary model set reference points on the scanned model for 3Dcorrections.

Step 2: Pose correction for ankle joint and forefoot can be achieved.

Step 3: Save and upload the model for next step.

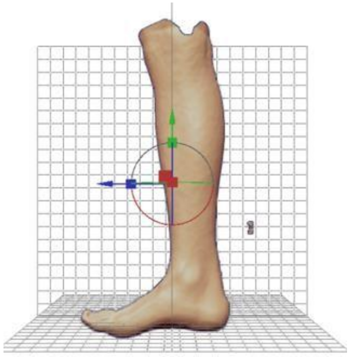

Fig 3.5 Repaired model

ii. Design Shell

Step 1: Define the wall thickness of the shell to be 3mm.

Step 2: Set contour points with reference to the earlier markings.

Step 3: Cut the model along the contour points.

Step 4: Make slotted holes for straps and pattern holes for ventilation.

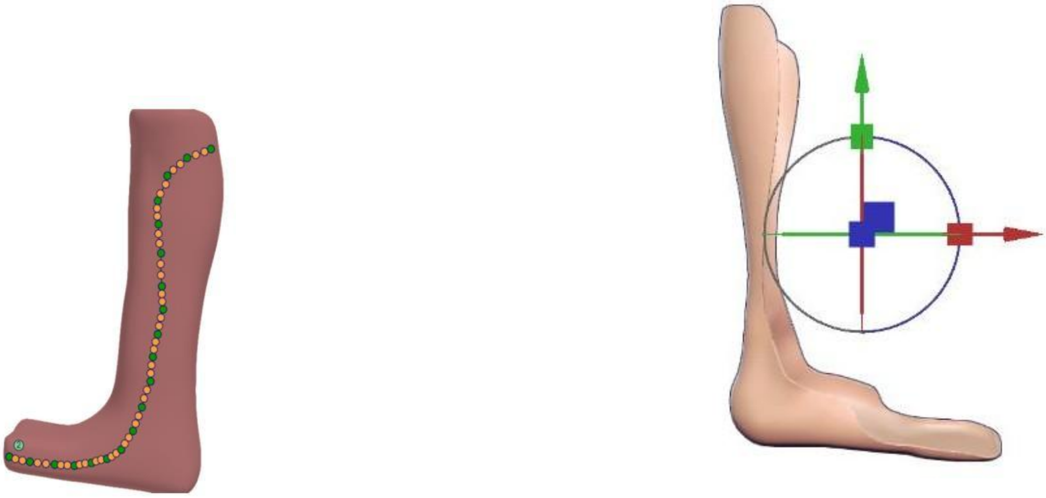

Fig 3.6 designed shell

This designed shell is downloaded as STL file format from mecuris design software .

Fig 3.7 Designed STL file

3.2.3 Pre-Processing

To convert an STL file into a STEP file,

Launch Creo: Open the Creo design software on your computer and ensure you have the appropriate license and access to the necessary tools for file conversion.

Create a New Part: Start a new part file in Creo by selecting the "New" option from the File menu or using the keyboard shortcut.

Import the STL File: In Creo, go to the File menu and select "Import." Choose the STL file you want to convert and click "Open" to import it into the software. The STL file will be displayed as a 3D model in the workspace.

Check the Import Settings: After importing the STL file, a dialog box may appear allowing you to adjust import settings. Verify that the units, accuracy, and other settings are appropriate for your needs. Click "OK" to proceed.

Save as a STEP File: Once you have created a solid model from the imported STL geometry, go to the File menu and select "Save As." Choose the STEP file format (.step or .stp) as the output format and specify the desired location and filename for the converted file. Click "Save" to complete the conversion process.

Verify and Validate: It is important to verify the converted STEP file to ensure that the geometry, dimensions, and other properties have been accurately transferred from the original STL file. Open the converted STEP file in Creo or another compatible software to review the model and perform any necessary validations or adjustments.

3.3 DESIGN OPTIMIZATION

Design optimization is conducted for a new design of Ankle-Foot Orthosis (AFO) to enhance its performance, functionality, and patient comfort. The primary objectives of design optimization for AFOs include:

Improve Functionality: Optimization helps to enhance the functionality of the AFO by optimizing its structural design, material selection, and component configuration. This can lead to better support, stability, and alignment, allowing individuals with conditions such as foot drop or ankle instability to have improved mobility and gait mechanics.

Enhance Patient Comfort: By optimizing the design, the AFO can be made more comfortable for the wearer. This involves minimizing pressure points, ensuring proper fit and alignment, and incorporating padding or cushioning materials to improve comfort during prolonged wear.

Optimize Weight and Size: Design optimization focuses on reducing the weight and bulkiness of the AFO while maintaining its structural integrity and performance. This not only enhances patient comfort but also improves ease of use, reduces fatigue, and allows for better integration with footwear.

Customization and Personalization: Optimization enables the customization and personalization of AFOs to meet the specific needs and anatomical requirements of individual patients. It allows for adjustments in design parameters, such as contouring the AFO to match the patient's leg and foot, adapting the strapping mechanism for a secure fit, or incorporating individualized features to address specific impairments.

Cost Efficiency: Optimization can lead to cost-effective designs by streamlining manufacturing processes, minimizing material waste, and reducing the need for additional components. This can make AFOs more accessible and affordable for individuals who require them.

Performance and Durability: Design optimization focuses on enhancing the AFO's performance and durability. By optimizing structural integrity, material selection, and component configuration, the AFO can withstand daily wear and tear, provide adequate support, and maintain its functionality over an extended period.

3.3.1 Finite Element Analysis (FEA)

Finite Element Analysis can be conducted within the digital workflow to assess the structural integrity and stress distribution of the AFO design. FEA software simulates the mechanical behavior of the AFO under various loading conditions, helping identify potential stress points, weak areas, or areas that require reinforcement.

3.3.2 Development of FEA methodology

Problem Definition: Clearly define the objective of the FEA analysis. Determine the specific aspects of the AFO that need to be investigated, such as stress distribution, deformation patterns, or the effect of different loading conditions.

iii. Geometry Creation

Create a digital representation of the AFO geometry using CAD software. This involves accurately modeling the shape, dimensions, and features of the AFO, including footplate, ankle joint, struts, and any additional components.

iv. Material Selection

Choose appropriate material properties for each component of the AFO. Consider the mechanical properties of the materials, such as modulus of elasticity, Poisson's ratio, and yield strength, which influence the AFO's behavior under load.

Table 3.1 Materials used

MATERIAL	ELASTIC MODULUS (GPa)	POISSION RATIO	DENSITY (g/cc)	TENSILE STRENGTH (MPa)
Polypropylene	1.1	0.43	0.9	30
polyethalene	1.2	0.418	0.95	25.7
polylactic acid	3.5	0.33	1.2	37

v. Mesh Generation

Divide the AFO geometry into smaller elements (mesh) to discretize the model for analysis. The mesh should have sufficient density and quality to accurately capture the behavior of the AFO. Consider factors such as element size, element type, and refinement in areas of interest, such as stress concentration regions or areas with complex geometry.

Table 3.2 Mesh

Nodes	**61343**
elements	221732
element used	solid 185

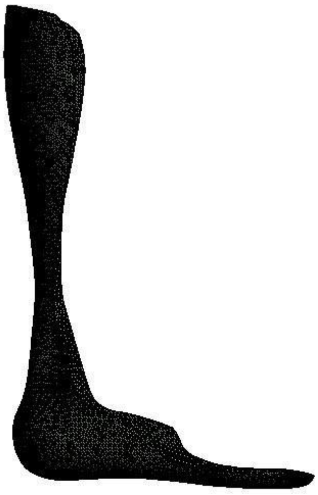

Fig 3.8 Mesh

vi. Boundary Conditions: Apply appropriate boundary conditions to simulate the real-world loading and support conditions. Fixation points, constraints, and applied loads should be defined based on the specific requirements of the analysis, such as the gait cycle or specific loading scenarios.

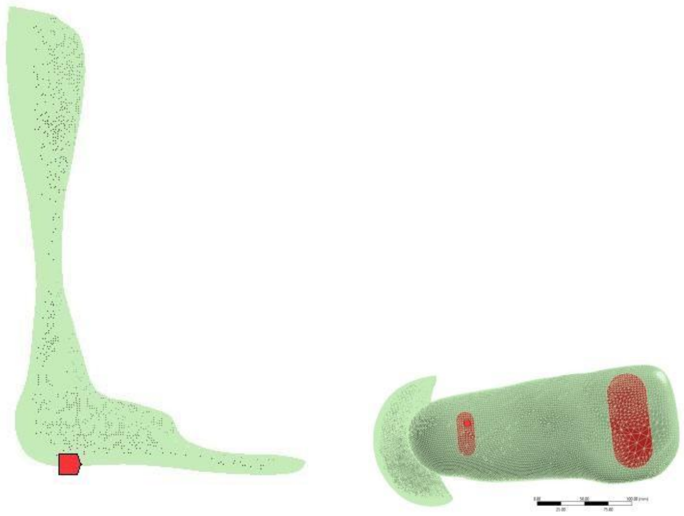

Fig 3.9 fixed support

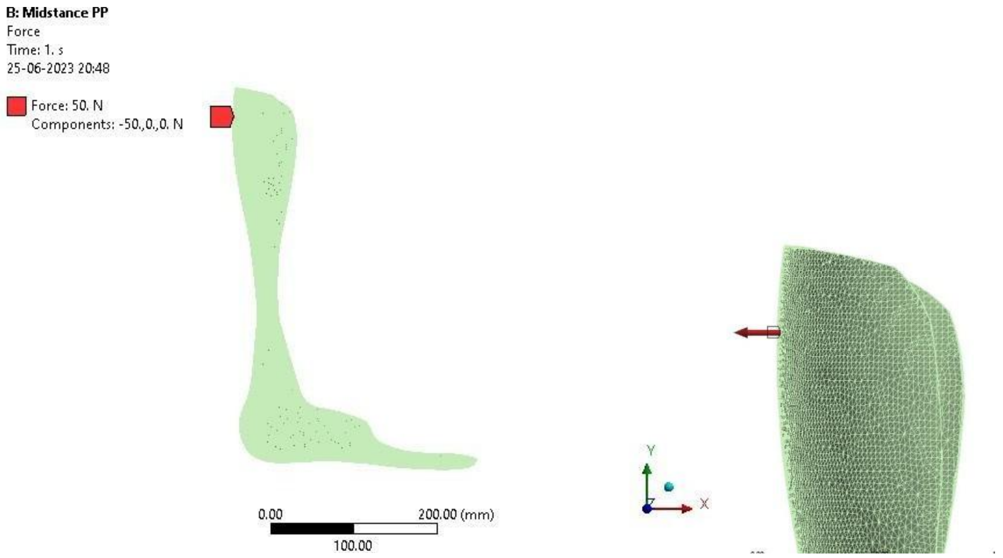

Fig 3.10 force applied and direction

CHAPTER 4

RESULTS

Design optimization can involve evaluating different material options and selecting the most suitable one based on mechanical properties, durability, cost, and other factors. The chosen material should exhibit the desired characteristics for the AFO's intended use and performance requirements.

The stress, strain and deformations results were analyzed from the FEA simulations and tabulated.

Table 4.1 Properties obtained

MATERIAL	DEFORMATION (Ux) (mm)	TOTAL DEFORMATION (mm)	EQUIVALENT STRESS (MPa)
Polypropylene	18.85	19.148	7.393
polyethalene	40.45	41.69	6.877
Polylactic acid	13.24	13.433	7.215

Analyzing stress distribution helps identify areas of high stress concentration in the AFO design. By optimizing the design, stress levels can be minimized, reducing the risk of material failure and improving the overall structural integrity of the AFO.

Evaluating the deformation behavior provides insights into how the AFO responds to applied loads. Optimizing the design aims to minimize excessive deformation, ensuring proper support and alignment while maintaining patient comfort.

Assessing displacement helps understand the magnitude and direction of movement in the AFO under loading conditions. By optimizing the design, displacement can be controlled to ensure appropriate foot clearance during the gait cycle and maintain proper joint alignment.

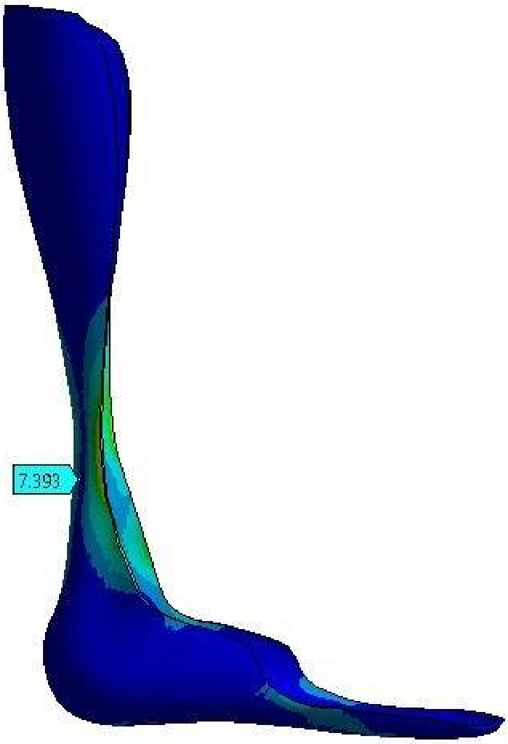

Fig 4.1 equivalent stress on polypropylene

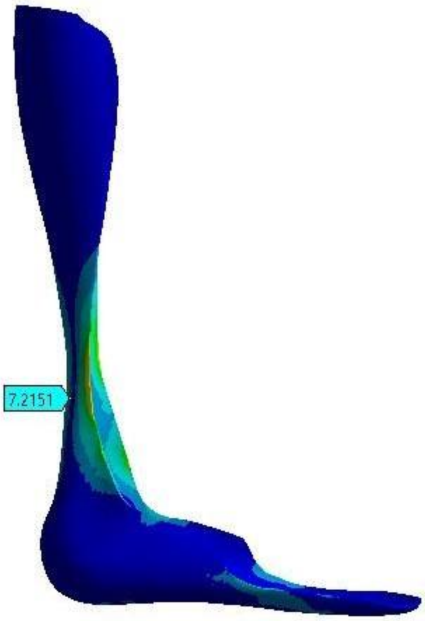

Fig 4.2 equivalent stress on Polylactic acid

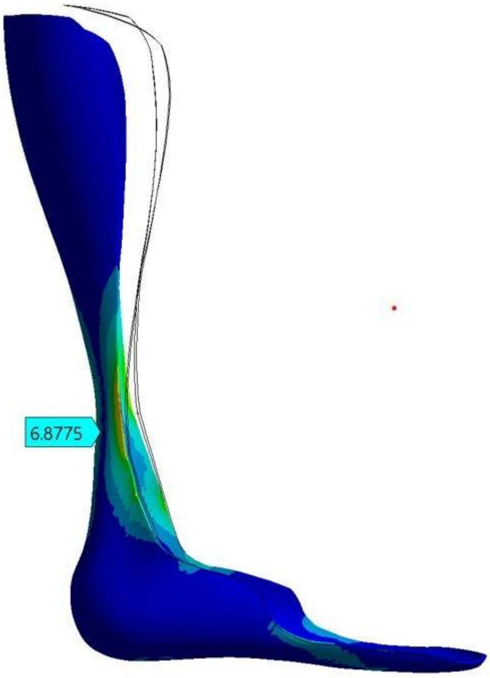

Fig 4.3 equivalent stress on polyethalene

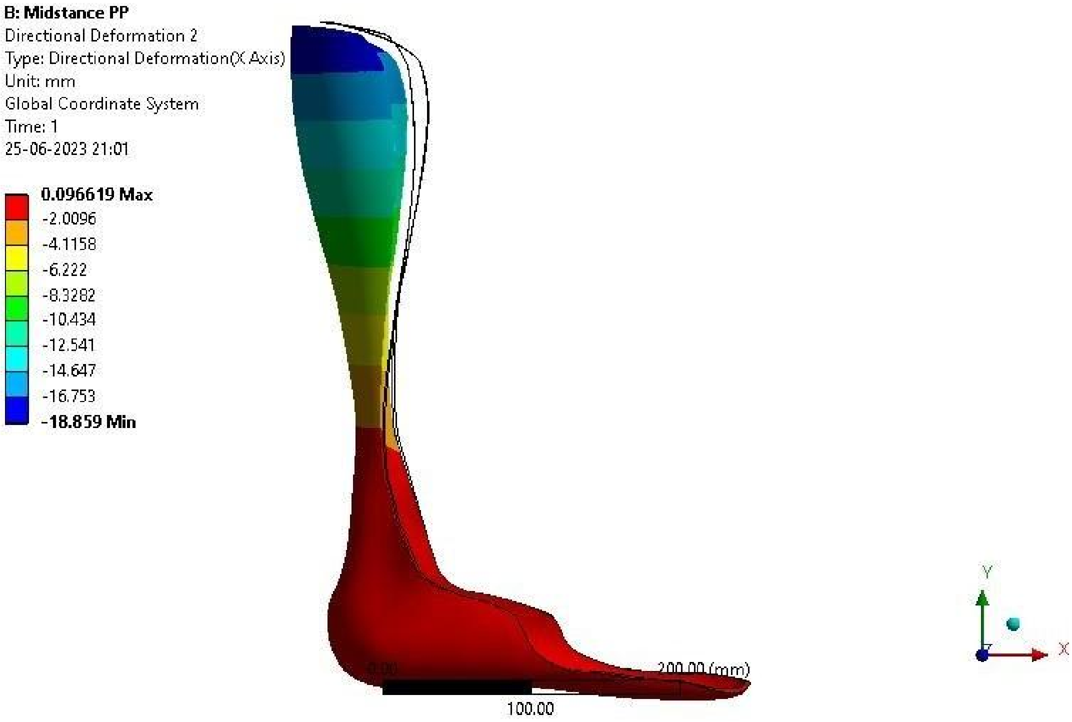

Fig 4.4 directional deformation of Polypropylene

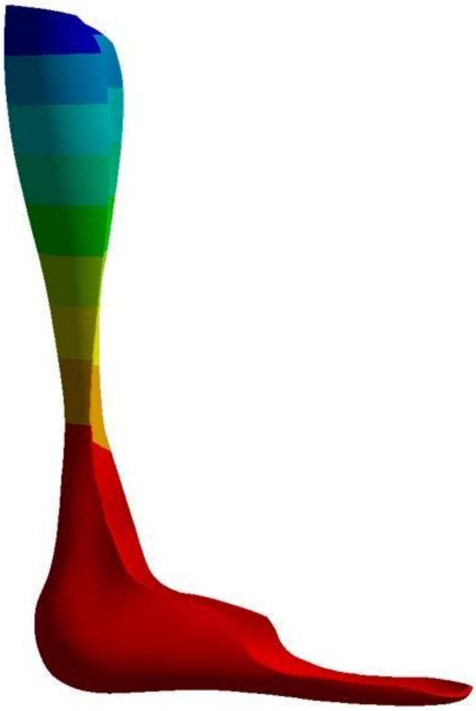

Fig 4.5 directional deformation of Polylactic acid

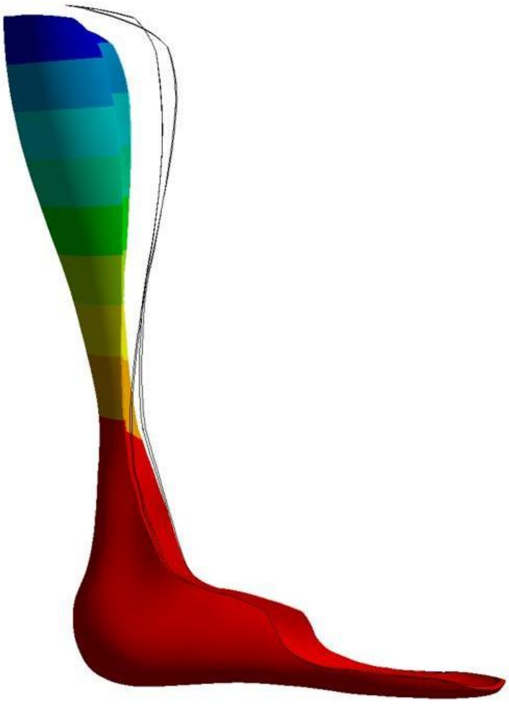

Fig 4.6 directional deformation of polyethalene

Optimizing the AFO design can help reduce its weight while maintaining structural integrity. A lighter AFO can improve patient comfort, reduce fatigue, and enhance overall mobility and function.

Polypropylene material is used for AFOs due to its favorable mechanical properties, such as high strength, flexibility, and low weight. It is relatively cost-effective and suitable for various manufacturing methods. PP offers good fatigue resistance and can be customized to achieve specific design objectives.

Strength: PP exhibits high strength, allowing it to withstand the forces and loads exerted during daily activities. This property ensures that the AFO maintains its structural integrity and provides effective support and stability to the wearer.

Flexibility: PP possesses a desirable balance of flexibility and rigidity. It can be engineered to provide the necessary flexibility to accommodate natural foot movement while offering sufficient resistance to control excessive motion or misalignment.

Low Weight: PP is lightweight, making it an excellent choice for AFOs. The reduced weight minimizes the burden on the wearer, enhancing comfort and reducing fatigue during extended periods of use.

Cost-effectiveness: PP is a cost-effective material compared to some other alternatives, This cost advantage makes it accessible and affordable for a wider range of patients.

Customization: PP can be easily customized to achieve specific design objectives. It can be modified through heating and molding techniques to contour the AFO precisely to the patient's leg and foot, ensuring an optimal fit and support.

Biocompatibility: PP is generally considered biocompatible, meaning it is well-tolerated by the human body. It is non-toxic and non-reactive, reducing the risk of allergic reactions or skin irritation when in contact with the skin.

CHAPTER 5

CONCLUSION

By leveraging digital tools, such as 3D scanning, CAD modeling, FEA and 3D printing, the design and production of patient-specific AFOs can be streamlined, cost-effective, and tailored to individual needs. This approach enhances the overall effectiveness of the AFO, improves patient satisfaction, and reduces lead times compared to traditional manual fabrication methods. By comparing three different materials, Polypropylene, polyethalene, polylactic acid with 3 mm wall thickness has designed and optimized. By the result comparision and material properties, polyethylene material shows favorable mechanical properties, such as high strength, flexibility, and low weight. FEA result shows PLA showing minimum deformation. Material optimisation at the calf and foot components of the AFO can increase the strength to weight ratio of the device.By adding more material and/or increasing thickness where there are excessive stresses, the strength can be increased.

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