Regional Centre of Excellence in Biomedical Engineering and E-Health (CEBE)

Master's Degree Program in Biomedical Engineering

PERFORMANCE EVALUATION AND ANALYSIS OF DIFFERENT MATERIALS USED FOR ORTHOTIC DEVICES TO SUPPORT AN INJURED LEG

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2024

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A dissertation submitted in partial fulfilment of the requirements for the award of degree of Master of Science in Biomedical Engineering in the school of Engineering in College of Sciences and Technology of University of Rwanda.

2024

DECLARATION

This dissertation is my original work and has not been submitted for the academic award of either a degree or diploma in any other University, college or higher learning institution.

05/10/2024

MUNYANEZA Augustin

This dissertation has been submitted for examination with our approval as the university supervisors.

07/10/2024

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DEDICATION

This work is dedicated to my lovely and precious wife, Mrs. Xaverine UWANYIRIGIRA; my Children: GANZA MUNYANEZA Ian Dierick, IGANZE Niella Gladys and IGABE MUNYANEZA Alan Derrick and my family members for being there for me all through my studies. May the Almighty God bless you so much!

ACKNOWLEDGEMENTS

I would like first and foremost to thank the Almighty God for giving me this life, wisdom and ability to do this dissertation. I’m also thankful to my supervisors, Prof. Venant KAYIBANDA and Prof. David TUMUSIIME for their tangible supervision effort and mentorship that made this dissertation more fruitful. My thanks also go to Prof. Celestin TWIZERE and Dr. Gerard RUSHINGABIGWI for their kind guidance and advice during the entire period of my postgraduate studies. I thank the College of Sciences and Technology (CST) and the Center of Excellence in Biomedical Engineering and E-Health (CEBE) for supporting me financially during my studies. Last but not least, my thanks go to all my classmates for their awesome collaboration during the journey of my studies.

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LIST OF ABBREVIATIONS

ABS	Acrylonitrile Butadiene Styrene
AFO	Ankle Foot Orthosis
CAD	Computer-Aided Design
CFRP	Carbon Fiber Reinforced Polymer
DF	Dorsiflexion
DOF	Degree of Freedom
FEA	Finite Element Analysis
FEM	Finite Element Method
GRF	Ground Reaction Force
MPC	Multi-Point Constraint
PA	Polyvinyl Alcohol
PC	Polycarbonate
PE	Polyethene
PLA	Poly Lactic Acid
PP	Polypropylene
PVC	Polyvinyl Chloride
RBC	Rwanda Biomedical Center
USA	United States of America

ABSTRACT

Injuries occurring worldwide, including in Rwanda, are often the result of incidents in various workplace sectors, with transportation being the leading cause. These injuries frequently lead to prolonged suffering during medical treatment due to the lack of appropriate medical support devices. This study aims to develop and evaluate the performance of a realistic three-dimensional Finite Element (FE) model of a foot-ankle orthotic device made from various materials. The foot-ankle model was designed and analyzed using SolidWorks, and the obtained results were validated using ABAQUS software. The validation process incorporated a realistic patient model, assuming a standard person weighing 70 kg and measuring 176 cm in height. Three different materials, Polypropylene (PP), Carbon Fiber Reinforced Polymer (CFRP) and Poly Lactic Acid (PLA) were evaluated to determine the most suitable material for the orthotic device. The FE model was subjected to rigorous mesh reliability verification in each software. Von Mises stress and deformation displacement of the foot-ankle orthotic device were studied separately for each material. The simulation results indicate that CFRP demonstrates superior resistance to external forces under typical patient usage conditions, followed by PP. CFRP also exhibited the least deflection, measuring 7.603 mm in ABAQUS and 8.579 mm in SolidWorks. The corresponding Von Mises stresses of 1.981e+01 MPa in ABAQUS and 1.796e+01 MPa in SolidWorks. The contact area during the analysis was found to be 483.55 mm^2 for the normal foot-ankle orthotic device. PLA showed the least resistance under the same conditions, as also indicated by previous experiences. Thus, CFRP emerges as the preferred material for foot-ankle orthotic device design due to its superior stability under contact pressure and lower von Mises stress compared to other materials. However, it is important to note that no formal analytical validation has been conducted for the preclinical analysis of the foot-ankle orthotic device in line with 3D simulation. The AFOs (Ankle-Foot Orthoses) designed and evaluated in this study are recommended for future implementation and use.

Keywords: Carbon Fiber Reinforced Polymer, Orthotics, Poly Lactic Acid, Polypropylene, displacement, stress

CHAPTER 1. INTRODUCTION

1.1 Background

Human activities worldwide, including those in Rwanda, such as transportation, workplace, and sports accidents, as well as various natural diseases, often lead to different individuals experiencing significant hardships. Orthotic devices have been used for many years to assist in the recovery and rehabilitation of individuals with leg injuries from several human activities' incidents. Particularly, Ankle-Foot Orthoses (AFOs) are designed to improve the gait function of ambulatory children with neurological conditions [1]. According to Caneiro orthotic devices can be used to treat a wide range of conditions of human being, including sports injuries, arthritis, and post-surgical recovery [2]. Ankle-foot orthose types are used to control the motion of the ankle and subtalar joint, compensate for muscle weakness and drop foot, and correct deformities in the ankle and subtalar joints due to injuries, stroke, and congenital anomalies and spina bifida [3]. These devices are designed to provide support and stability to the injured limb, thereby reducing pain and improving mobility. The use of orthotic devices can also help correct any underlying biomechanical issues that may be contributing to the injury, which can help to prevent future problems. It covers the ankle and foot and extends above the ankle to control the giant and angular motion of the leg. Therefore, analysing different types of AFOs is crucial to enhance their applications both within the country and globally.

Various types of Ankle-Foot Orthoses (AFOs) are utilized in biomedical and clinical settings for medical purposes. During dynamic conditions occurring during human movements such as walking, standing, and swaying, these AFOs are subjected to repeated and excessive external loads from various directions [3]. Therefore, ensuring the optimal use of AFOs requires engineering studies to understand the devices' behavior before introducing advanced biomedical devices to hospitals for their daily application. The external force loading often results in high levels of stress concentration and plastic deformation, particularly around the ankle area of solid AFOs. Consequently, traditional AFOs may fail to adequately support the required movement, thus limiting the device's effectiveness for patients. To ensure the effectiveness of AFO biomedical devices, it is crucial to evaluate both deformation and stress analysis, considering the applied forces on the top part of the device and the ground reaction when a patient steps. Therefore, comparing and identifying preferred materials for the fabrication and usage of AFOs is essential in biomedical engineering applications. This process aims to reduce device deformation, restore mobility, alleviate pain, provide protection and immobility, and ultimately, enhance patients' quality of life [4], [5]. Thus, the analysis of a particular type of AFO using most used materials in the fabrication of the device can be play a big role in the biomedical sector. While prefabricated AFOs are cost-effective, they may offer less conformity to a patient's specific needs compared to custom-made AFOs. Custom-made AFOs, while potentially offering greater comfort, are often produced under less-than-optimal manufacturing conditions [5].

The Finite Element Method (FEM) is a widely used technique to estimate the mechanical behaviors of the materials of solid AFOs geometry structures in biomedical engineering applications, particularly to reduce deformation, the magnitude of peak stress and homogenous stress and strain distribution [1], [6]. In Biomedical, the FEM has also been increasingly applied to analyse the human ankle, bones for the development of both computing capabilities and imaging techniques [6]. The plastics such as Polypropylene (PP), Carbon Fiber Reinforced Polymer (CFRP) and Poly Lactic Acid (PLA), Acrylonitrile Butadiene Styrene (ABS) and Nylon 12 are more preferred in AFO applications due its lightweight, more cosmetic, and more supportive in compensating for ankle weakness. The plastic deformation of the ankle is lateral and media parts are the main effect of the device stabilization [1]. SolidWorks software is usually used to form the geometrical boundary surfaces of all model components and then the solid model can be analysed using other different software [6]. The predicted pressures and von Misses stress distributions for a normal foot were consistent and primarily focused on in FEM models given in the literature which would lead to insufficiency in maintaining the stability of the AFO [1, 6].

Knowledge of the stress distribution of the foot-ankle complex is a very important point in biomedical for remedial of the human injuries. The simulation of the device was mostly used to the cost and difficulties of direct investigations of stress distribution, deformation, wear and locating the contact pressure. The static vertical loading conditions were considered in the analysis with simplification on the geometry and materials properties in modelling and the analysis of the normal foot ankle [6]. The little improvement in the design and development of the foot ankle in terms of material as well as the design geometries at the knee and leg femur has been done. This may be due to the device structure, loading and boundary conditions [7].

The FE analysis evolves on the most effective computational techniques for solving biomedical problems. With FEM, it is easy to model complex model with irregular geometry, and complex materials properties and easily simulates the complicated boundary and loading conditions. Therefore, a foot ankle in FEM model can help to predict the load transfer mechanism, and loading situation and understand the biomedical justification of the human injury behind different cases of the treatments. FEM can serve the data for improving and optimizing of a new foot ankle as in the real life of the device usage.

1.2 Materials of AFO

The AFOs are usually fabricated from metal, leather and some plastics such as Polypropylene (PP), Polyethene (PE), CFRP, Acrylic and Nylon. The Solid plastics AFOs are preferred for their light, more cosmetic, flexible and more supportive in compensation for ankle weakness [1], [8].

1.3 Mechanical behaviors of AFOs

The stress concentration occurs in the ankle region and can be increased when the region is trimmed out [1, 6]. Mainly, the displacement and Von Mises stress under the loading conditions experienced by a human during walking should be taken into consideration.

1.4 Effect of materials on AFOs

The ideal orthotic materials must be light, stiff and strong to the application needs, and can be made in plastics metal and polymer-based composites, leather or a hybrid of the materials alloys [5]. For instance, Acrylonitrile Butadiene Styrene (ABS) was with 38.4 MPa that corresponding to unit consistency to the size of the models in mm [4, 5, 9], Poly-Lactic Acid is 9.78 MPa [5, 10, 11], Nylon 12 AFO is 2.91 MPA [4, 12] while Polypropylene copolymer (PP) is 27.6 MPA [5].

1.5 Problem Statement

Several hospitals in Rwanda are currently importing ankle devices at high costs, which are regulated by Rwanda Biomedical Center (RBC). Despite the increasing need for ankle devices among patients in Rwanda, the idea of recycling old, used ankle devices to save money has not been explored. The biomedical center faces challenges because the imported devices do not meet the required quality standards, and there have been no studies conducted on ankle-foot orthosis (AFO) devices in the country. In various Rwandan university, referral, and district hospitals, there are numerous complaints from AFO users regarding poor fit, discomfort, pain, appearance, design, materials, and footwear. The shapes of AFO devices are relatively simple, aligning with the Rwandan government's goal of producing these devices locally, as part of the "Made in Rwanda" initiative aimed at reducing reliance on imported medical equipment. Recently, researchers have utilized Finite Element Analysis (FEA) modelling to optimize orthotic design. This approach enables the estimation of stress distribution, material deformation trends, and necessary dimensions for improved AFO performance. Analysing the expected new AFO devices using materials available in Rwandan biomedical centers, starting with used AFO devices made from different materials, could significantly enhance medical services in Rwanda. FEA of Computer-Aided Design (CAD) models can predict stress and strain under conditions mimicking real-world use, thus determining essential functional aspects of AFOs, such as bending stress, bending stiffness, von Mises stress distribution, and deformation data, utilizing fully parameterized CAD models [13].

1.6 Aim and scope of the study

The aim of this study was to compare the von Mises stress and deformation displacement of the ankle-foot complex under normal vertical load conditions, considering a standard adult weight of 70 kg and height of 176 cm.

1.7 Objectives

1.7.1 Main objective

The main objective of this study is Performance Evaluation of Orthotic Devices for determining its mechanical strength to supporting an Injured Leg. The designed device FE model of foot and ankle orthotics using various materials was considered for the case of injury impact.

1.7.2 Specific objectives

The specific objectives of the study were:

1. To develop a 3-D FE model of a foot-ankle orthotic of the human.
2. To simulate an FE model of the foot-ankle orthotic device to analyze the stress, deflection and via simulation under medical usage constraints.
3. Investigate the effect of ankle materials and loads transfer on the stress, deflection and via simulation under medical usage constraints.
4. To conduct a comparative analysis of the stress and strain to the AFOs devices to select the preferred material for foot-ankle for biomedical patients' usage.

1.8 Organization of the Thesis

This thesis is written into five chapters. The present chapter is the **Introduction** which explains the problem this research aimed at solving and gives objectives through which the solution of the problem was to be achieved. The second chapter is the **Literature review** which highlights the existing literature about the research problem. It summarizes the research that has been done about designs and modelling of medical orthotic devices, the findings and gaps that need to be addressed. The third chapter is the **Methodology** that explains the research design, approach, and methods used in the current study. It details the procedures for model development and analysis, providing a clear rationale for the chosen methods. The fourth chapter is **Results and Discussion** that presents the findings of the study and interprets them in relation to the research gaps and objectives. The results are presented clearly using tables and figures and then discussed in depth, considering their implications for theory, practice, and future research. The fifth chapter is **Conclusion and Recommendations,** this summarizes the main findings of the study and their implications. Recommendations for future research or action are provided, based on the insights gained from the study.

CHAPTER 2. LITERATURE REVIEW

2.1 Design Concepts of AFOs

In the 20th century, the advancement of technology and the fabrication of AFOs require more innovative and advanced considerations [4]. The incorporation of manufacturing technology is crucial for the fabrication process of these advanced devices. The use of 3D modelling and analysis software such as SolidWorks, ANSYS, and ABAQUS is particularly significant in modern biomedical engineering applications.

2.1 Types of AFO

AFOs are designed to support the ankle and foot region and are used in conditions such as foot drop, cerebral palsy, and ankle instability. Another type of orthotic device is the knee brace. One commonly used orthotic device is the ankle-foot orthosis (AFO). Knee braces are used in various leg injuries, including ligament tears, osteoarthritis, and patellofemoral pain syndrome [14]. The non-articulated passive AFOs are used to control the ankle movement, but they are constructed in one piece without the incorporation of a joint mechanism [3].

2.2 AFO Modelling

2.2.1 Materials properties of AFO

Ankle-foot orthoses (AFOs) in plastic materials that are externally useful as a supportive medical device for the lower leg, ankle and foot of the human body [3].

The AFOs are usually fabricated from metal, leather and some plastics such as polypropylene (PP), polyethene (PE), acrylic and nylon. The solid plastics AFOs are preferred for their light, more cosmetic, flexible and more supportive in compensation for the ankle weakness [1]. The ankle function should allow motion of the shank and foot segments from materials with sufficient stiffness to withstand the motion of the limb. To improve the stiffness of the AFOs, the simulation considers its mechanical structure behavior in engineering such as modulus of elasticity, geometry of shape and the force system. Young’s modulus is a numerical ratio of the stress (force to strain (deformation) that describes the relative stiffness of materials. The thermoplastic has a very low modulus, which exhibits lower resistance to force and deformation than the AFOs metal made however, they are cheaper.

To enhance a significantly higher modulus, some materials were selected for the AFOs application in biomedical such as carbon composite laminate for its superior strength compared to weight ratio (0.23e+06 psi), Acrylonitrile Butadiene Styrene (ABS) with 38.4 MPa [9, 10]. The geometry shape of the AFOs is half cylindrical shell with different modifications. The material stiffness and the structure stiffness provided by the cylindrical shell were required to effectively use a three-force system, to minimize the plantarflexion (PF) and the dorsiflexion (DF). To maximize the moment of arm length of reaction forces during standing and walking based on transfer points of the ankle joints [15].

Previously, the AFO were usually made in pure leather and wood. By industrialization revolution, the AFO technology was evaluated to various techniques and materials, therefore, the thermoformable polymer sheet and carbon fiber sheet materials are being used for the fabrication of the devices. The most selected materials are such carbon fiber, ABS, and polypropylene and Polylactic acid (PLA). ABS is more ductile and flexible than PLA. The nylon is more flexible and durable than the ABS to PLA, with high stiffness and high chemical resistance. The carbon fiber reinforced polymer (CFRP) composite is the material of reinforced carbon fiber and polymer in a matrix type [8]. The CFRP is lightweight, and high strength as for metals with higher corrosion resistance. It is 1500-1600 kg/m^3, tensile strength of 550-1100 MPa [16].

Acrylonitrile butadiene styrene (ABS) as a polymer with toughness and strength, and polylactic acid (PLA) as a biodegradable thermoplastic are the most used materials of rapid AFO prototype [17]. The AFO used in the Finite Element (FE) analysis, employing the aforementioned materials, was obtained from a young male adult subject with a popliteal height of 27.4 cm, knee height of 33 cm, foot breadth of 11 cm, and a body weight of 65 kg. [16].

2.2.2 AFO models

An ankle-foot orthosis (AFO) is a medical device that is worn externally and supports the foot, ankle and lower leg of the injured human to treat lower limb problems such as unsteadiness, foot drop, and bony foot abnormalities [13]. They are mostly recommended to both children and adults with neurological injuries, cerebrovascular accidents, Charcot-Marie-Tooth diseases, and multiple sclerosis to improve their walking capabilities [13]. The AFOs usage is to minimise the trips and falls due to foot drops, reduce the chronic pain and fatigue caused by joint deformities, and reduce the fatigue caused by controlling the ground reaction force during the stand and walking phase of the gait.

In the biomedical field, the characteristics of Ankle-Foot Orthoses (AFOs) include plantar pressure, stress on metatarsals, midfoot bones, calcaneus, cartilage, and tensile force on the plantar fascia and ligaments [18]. Kinematic and kinetic assumptions for AFO device forces during walking conditions of injured individuals were observed. Subsequently, a 3D model of the AFOs was developed and modeled using SolidWorks software. Sensitivity analyses were conducted to investigate the biomedical effects of materials on foot-ankle stiffness. The developed Finite Element (FE) model enables the evaluation of different structural and material parameters of foot structures and design parameters of foot contact wear [19].

Therefore, the development of a 3-D FE model of the foot ankle complex with the inclusion of all working loading and boundary conditions and proper material property distribution can be performed [7]. The investigation involved evaluating the effect of material, loads transfer and stress distribution on the foot-ankle complex [7].

Ankle fractures are relatively common injuries with an incidence of 10% among all fractures. Most of the fractures are posterior malleolus (10-44%) and posterolateral-oblique (67%) ankle fractures. The FEA technology is a modern computational method based on structural mechanics analyses. The FEA results would be possible closer to the real biomedical ontology to analyse their effectiveness, stiffness, and mechanical strength considering the materials [20]. Furthermore, the highly analysed models will allow the fabrication of the foot ankle to be improved without investing time and resources in trials.

2.2.3 AFO geometry

The common AFOs for different designs for various clinical conditions are the Solid ankle-foot (SAFO), Dynamic ankle-foot orthosis (DAFO), Hinged ankle-foot orthosis (HAFO), Ground (floor) reaction ankle-foot orthosis (GRAFO), Posterior leaf spring ankle-foot orthosis (PLS AFO). The GRAFO was focused on in the current study.

2.2.4 AFO simulation consideration under materials

Initially, the AFO models are created by CAD software which is then converted into importable files such as STL, Step, GIS and another compatible file. Most researchers used ANSYS in investigating and analysing the FEA of the AFOs, however, the ABAQUS has recently been used in addition to SolidWorks. The motivation for using ABAQUS is to provide a details dynamic evaluation of the orthotics to save cost of experimental tests. The human working force and weight obtained during the experimental test can be applied in simulation for example 3N, 5N and 490 N (negative) in the x, y and z-direction, respectively. This force can be applied in the central points of the AFO devices with the assumptions that be selected during the analysis. The fixed regions and where the forces are applied are the constraints of the AFOs during FE simulation. The fixed regions are assumed to be fully in contact with the ground when in gait and walking conditions. In FE analysis, the assigning materials and optimum meshing are essential and they are critical things that need attention to get the right simulation results. The average size of the AFO is 315 and 51 mm for height and width, respectively [8].

2.3 Materials Parameters used in the evaluation of the AFOs

There are some material hypotheses to this study. First, the mechanical properties of the AFO materials were assumed linear isotropic, elastic and failure strain, which would not precisely represent the mechanical behavior of the PP, PLA and CFRP materials. Second, the FE genetic analysis was performed under static conditions in which the deformation displacement and von Mises stress of the AFO materials would be observed. To simulate the job process, the boundary conditions and loading and step input and output experienced during walking and giant were defined which would be the same for all materials. The meshing optimization was also performed as the shape of the AFO is complex, and where it is necessary, some repetition of the section has been performed before assigning material to the AFO section [4].

In the early 20th century, the AFOS was largely made of metal, leather and fabric for over 80 years to significant breakthroughs in patients. The materials used in manufacturing the AFOs fall into three categories of requirements: accommodative, shock-absorbing and loading to assure comfort, support and protection, and aesthetic improvements. The materials with a higher strength-to-weight ratio, higher elasticity, lighter, and more flexibility are suitable AFO.

The selection of materials for an AFO has often been based on the availability, cost, clinic purpose and the patient’s technology. However, due to some essential properties and conditions that must be fulfilled during the AFOs fabrications, the AFO design analysis based on simulation could consider the strength, stiffness, durability, density, corrosion resistance of materials and the patient’s weight and activity of the patients [4]. Therefore, knowledge of the mechanical properties of the AFOs design and production is very important.

The AFOs technology of today utilises composite or hybrid materials that are thermoplastics and thermosetting polymer, metals, leather, fabrics, and foamed plastics. The most materials used in manufacturing of the AFOs are briefly described as follows.

1. Leather

The leather is made from animal skins and the tanning process makes the skin stronger and flexible.

2. Textile Fibers and Fabrics

Fabrics made of natural and synthetic polymers have been developed for prosthetic and orthotic applications. However, there are few applications of natural fibers. The natural fibers used in orthotics include jute, flax, hemp, sisal etc. The advantages of natural materials are their availability at affordable cost they are lightweight and their capacity to maintain strength, resilience, stiffens, malleability and then durability. The main disadvantages are distortion and deformation. In this study a comparison of the AFOs made in polypropylene (PP), PLA and CFRP. The polylactide composite has a stiffness with 22 GPa flexural modulus and 286 MPa strength.

The synthetic polymeric-based fabrics used in AFOs include polyester and polyamide (nylon and aramid.

3. Plastics

Modern AFOs have been fabricated based on the use of plastic-moulded orthoses to replace the metal orthoses that were commonly in place. The plastic AFOs are lightweight, have aesthetic appeal, affordability, cosmetic (because they can fit into a user’s shoe), and interchangeability with shoes with an ability to provide better foot support. The other properties of plastics are their poor conductivity of heat and electricity, inflammability and corrosion resistance. The plastics AFOs are harm-free in any physical or chemical way.

- Thermoplastics

The most common polymer used in clinical is PP for its low density, recyclability, thermal stability and strong chemical resistance. The PP is more rigid, durable and resilient than PE which makes it to be used in the correction of the AFOs. The thermoplastic material can repeatedly reheat and mold enabling the freedom to make change alterations to AFOs during fitting. When the structure strength is highly needed in the continuous shell of the AFOs, the thermoplastic polymer is preferred. Most thermoplastics include polyethene (PE), PP, polycarbonate (PC), acrylonitrile, butadiene styrene (ABS), acrylics, polyvinyl acetate, polyvinyl chloride (PVC) and polyvinyl alcohol (PA). ABS is a strong and rigid materials and it is widely printable for AFOs due to its smooth surface properties, ease of processing, low cost and dimensional stability.

- Thermosetting

Thermoset polymers are placed can be placed as positive models and chemically cured to solidify to the desired shape. It is a strong, long-lasting, physical linkage that are not heat reversible once it is formed. They are polyester resin, silicones, polyurethanes and epoxy that are used in AFOs fabrications. The most thermoset polymers most used are polyester and epoxy.

- Polymer-based composite

Polymer-based composites consist of polymer matrix and fiber reinforcement. It withstands the axial loads and bending and it has higher stiffness, hardness and wear resistance. It has a tensile strength of 0.24-170 MPa, stiffness of 15-150 GPa, more comfortable to wear. The most thermoset composite are polyesters, vinyl esters epoxies, bismaleimides, cyanate esters, polyimides, and phenolics.

4. Metal

Metal AFO designs are either integrated foot plates or attached to the shoe achieved through a U-shape with solid stirrup. It is a customer-made orthosis for a specific patient's need. The metal ankle area is ideal for adult patients. A steel dorsiflexion spring assists motion of the ankle mobility and stability [4].

2.3.1 Mechanical properties of Ankle and foot orthotics materials

The PLA is the most common cheap and biocompatible thermoplastic. The PLA and PLA-C materials are most used and available at low cost to manufacturing AFOs due to their mechanical strength [13]. The ABAQUS is most used to analyse the deflection and fracture of AFOs based FE model [13]. The most of the simulation hypotheses for AFOs considered stress distribution, von Mises stress, contact pressure and deformation [22]. The polypropylene copolymer materials were chosen from simulation software libraries and defined as linear, isotropic, and elastic materials. The Mechanical properties of some used materials for AFOS in the Finite Element Analysis for the PP, PLA and CFPR are as shown in [1, 8, 16, 23, 24].

The maximum stress generated at the lower shank of AFOs is 39.058 and 50.21 MPa for PLA and PLA-C respectively [13].

The simulation was adopted in this study as it is difficult to represent the stress and deformation in experimental tests by localizing the more suffered areas of the AFOs. Therefore, this study focused on representing the curves of the von Mises stress and displacement from simulation analysis in ABAQUS and SolidWorks of the AFO 3D model [13]. The contact interaction between the foot materials and the surface leads to the wear of the human AFOs. The encapsulated and orthotic materials were most used to define a hyperplastic of the AFOs. The Ground reaction and muscle forces were applied at the corresponding point of the device. The FE model can be used to conduct the manufacturing the human AFOs [24].

The developed FE model can be used in biomedical applications to investigate the foot behaviour of different designs of good foot ankle orthotics to allow efficient parametric evaluations for outcomes of the shape modifications in terms of the design orthotic/footwear design. From the parametrical FE model analysis, it is found to be a more important design factor in defining the plantar pressure and the stiffness of the orthotic materials in terms of thickness [24]. The peak metatarsal stress in jogging reached 34.36 MPa. The peak stress lay in the tarsal navicuralar bone reached 31.86 Mpa. The. The peak stress on the joint surfaced and reached 46.32 MPa. The tensile force reached the maximum value of 147.0 N [18].

2.4 Software for Analysis AFOs

The mechanical behavior of an AFO design exposed to various was analysed using FEA, 3 digitalized 3D AFO models were usually analysed in CAD softwares such as Solidworks corporation, concord, MA, USA; ABAQUS. In this softwares, the models were arranged in 3D coordinate directions (x, y and z) [3]. The Mesh size of the AFO is determined around 4 mm of solid type referring to the traditional AFO. The most used mesh is the parabolic tetrahedral elements type [25].

2.4.1 Three-Dimension CAD model and simulation

The AFOs have free-form geometry, however, it is difficult to draw a 3D AFO model with CAD software. Therefore, the 3D CAD software, SolidWorks can be used to model the simple solid biometric devices for analysis in computational simulation software, such as ABAQUS [3]. The simulation is better validated by the experiment procedure to measure displacements; however, it is expensive due to the higher cost of the text. Therefore, the simulation is preferred to save time and destruction of sample tests. The maximum applied force to the AFOs in experiments in the previous research was 34 N perpendicular to the axis that will be used in the current simulation [3]. The maximum measured and theoretical displacements were around 18.65mm and 18.73 mm to the anteroposterior axis, respectively [3].

CHAPTER 3. RESEARCH METHODOLOGY

The study evaluated the stress and strain experienced by the AFO device under local utilization conditions, considering different existing materials. Polypropylene (PP), Poly Lactic Acid (PLA), and Carbon Fiber Reinforced Polymer (CFRP) materials were selected to determine the preferred material for the fabrication of the AFO using 3D printing (advanced manufacturing) techniques. The main objective of this study was to compare the von Mises stress and contact pressure distributions of the ankle-foot complex under normal vertical loads. To achieve this, the main dimensions and materials were defined based on literature review and information gathered from hospitals in Rwanda. The device was designed to the correct dimensions using SolidWorks and analyzed through Finite Element Method (FEM) simulation within the same software. Subsequently, the 3D CAD model was imported into ABAQUS to validate the obtained results of the device. The design process incorporated realistic patient data, including a weight of 70 kg and a height of 176 cm. Detailed AFO analysis was conducted as outlined in the below sub-sections.

3.1 Materials

The model was constructed in SolidWorks, with the foot and ankle combined into a single homogenous part. The simulation analysis utilized Polylactic Acid (PLA)-based Ankle-Foot Orthoses (AFOs), as well as Carbon Fiber Reinforced Polymer (CFRP) and Polypropylene (PP) materials, as indicated in Table 3.1 [8]. In order to accurately predict the real-life performance of the AFOs, the neck size of the lower section was taken into consideration during the design phase. Additionally, an ABAQUS-based Finite Element Analysis (FEA) simulation was conducted to provide a more detailed analysis of the materials' impact on the mechanical behavior of the AFOs [13].

Table 3. 1. Properties of Polylactic acid material (PLA), of Polypropylene material (PP) and Carbon Fiber Reinforced Polymer material (CFRP)

Property	PLA	PP	CFRP
Elastic Modulus (N/mm^2)	3300	2400	7000
Poisson's Ratio (N/A)	0.349	0.43	0.1
Shear Modulus (N/mm^2)	318.9	318.9	5000

Mass Density (kg/m^3)	1250	900	1600
Tensile Strength (N/mm^2)	57.8	30	600
Compressive Strength (N/mm^2)			540
Yield Strength (N/mm^2)			
Thermal Expansion Coefficient (/K)			
Thermal Conductivity (W/(m·K))	0.2256	0.2256	0.2256
Specific Heat (J/(kg·K))	1386	1386	1386
Material Damping Ratio (N/A)	3300		

3.2 Methods

The data collected from real patients were used in the 3D modelling of the AFO. Initially, a SolidWorks geometric model with a thickness of 4 mm was created. This geometric model was then imported into ABAQUS, where tetrahedral finite element (FE) meshes were applied. The meshing process and distribution of material properties for the AFOs (refer to Table 3.1) were carried out. Subsequently, the FE model was prepared for analysis. The material properties for the foot-ankle orthotic in this study were selected based on literature review. The FE model of the right foot of the realistic patient, with a height of 174 cm and weight of 70 kg, positioned in the vertical foot stance, was used to construct the AFO. As a result, Stress and strain values were obtained from the FE 3D geometric model of the ankle-foot orthosis (AFO) design.

3.2.1 Design and Modelling

The AFOs, defined in the literature with a uniform layer of varying thicknesses (3, 6, 9, and 12 mm), were utilized as reference. In this study, however, a thickness of 4 mm was chosen. Additionally, material stiffness was adjusted to simulate the behaviors of ankle-foot orthosis materials. The FE model of the human foot and ankle in the horizontal position was constructed, along with the vertical ankle, as illustrated in Fig. 3.1. The boundary surface of the AFO was defined using CAD software, specifically SolidWorks Model 2018, and subsequently imported into ABAQUS 2020.

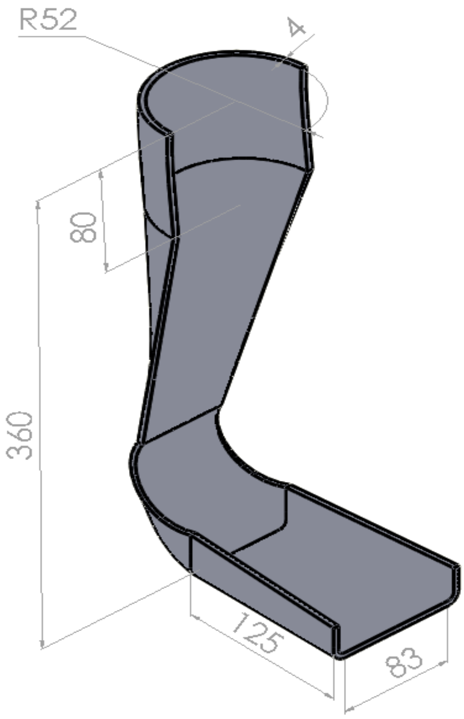


Figure 3.1. Geometric design of Foot Ankle Orthotic (Solidworks model)

The 3D model of the foot ankle was modelled in SolidWorks and exported to ABAQUS software. After the design was modelled in SolidWorks, the design was imported into the FE simulation process in ABAQUS. The simulation started by applying several forces indicating the conditions of foot drop in the patient incident case. This simulation was conducted based on the Ground Reaction Force (GRF). The design process was performed based on the specific conditions of the foot drop case. This condition requires and AFO with full support called Posteriort Leaf Spring AFO, a type of AFO for patient who need dorsiflexion assistance. The geometry was developed based on the average dimensions of feet in Rwanda, such as foot length, width and calf height, calf curvature, lateral ankle curvature, medial ankle curvature, and medial plantar arch. The model was saved into STL format in Solidworks and imported in ABAQUS. The imported geometry in ABAQUS is as shown in Fig. 3.2

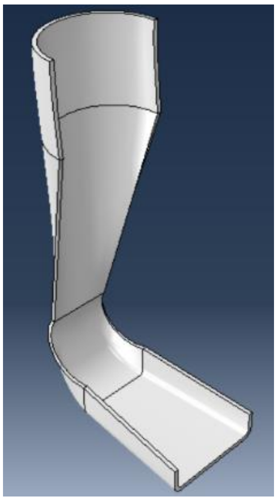
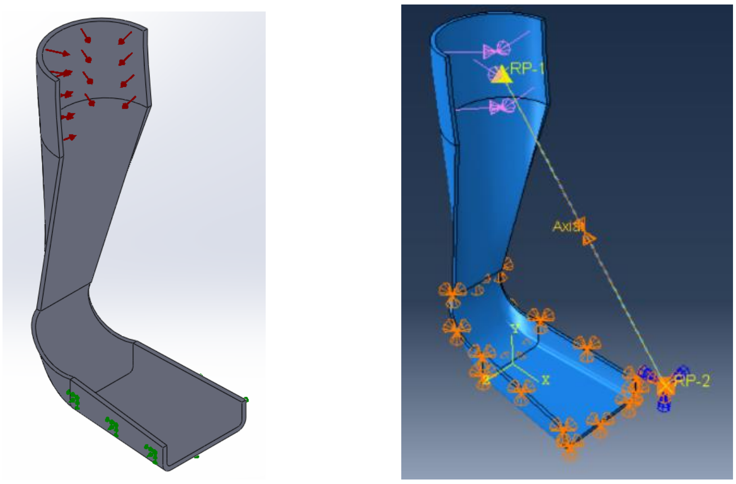


Figure 3. 2. Imported Simplified Foot Ankle orthotic (AFO) device (ABAQUS model)

3.2.2 Assign materials and Meshing

The AFOs were meshed with the linear tetrahedral element (C3D4). The focus of this study in the GRF is on the initial contact, mid-stance, and terminal stance phase. The loading conditions and meshing were applied [27]. Material analysis for AFO is available in ABAQUS, which can be applied for analysis of different materials used at the AFO. The behavior of the AFO model is implemented into ABAQUS Explicit using a complaint layout provided by ABAQUS. The Poisson's ratio for the Young's modulus, shear moduli, Poissons's ratios and strength of the materials used are given in Tables 3.1 for PP, PLA and CFRP. The vertical threshold is set at 10 N in normal vertically. The boundary and loading conditions were set for FE analysis. The axial load of 490 N was used. The thickness of the AFO is 4 mm, the optimal mesh size of 2 mm was chosen and a total of 273,123 elements were finally generated. While a hard contact between the planar surface and the ground was defined with a friction coefficient of 0.6. After the boundary and loading conditions were applied, a standard static solver was adopted and an FE simulation of the foot-ankle orthotic was performed. The model validation in this study adopted the same boundary conditions of balanced standing reported by Zhang, 2022, constrained the proximal cross-sectional surface of the AFO in 6 DOF, set at 10 N and then the plantar surface). This study adopted a pressure of 0.18 MPa, which was closer to the experimental value of 0.17 MPa in the review [18].

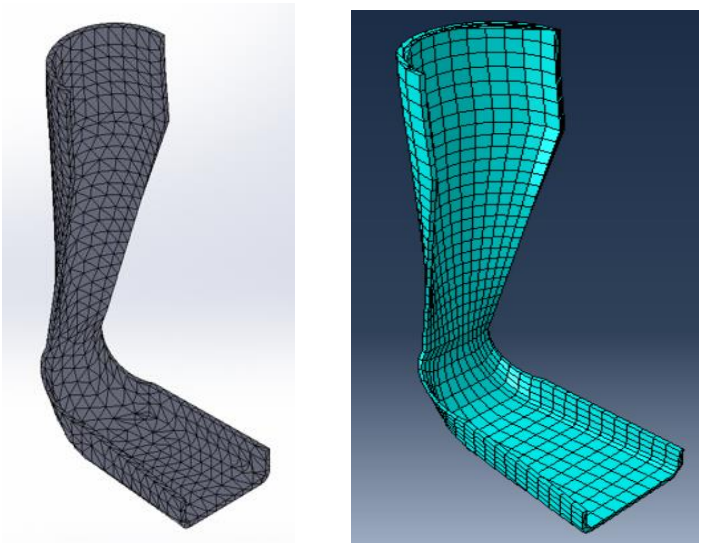


✓ (a) (b)

Figure 3. 3. Boundary conditions and load for the Foot Ankle orthotic device in: (a) Solidworks and (b) ABAQUS

3.2.3 Mesh and model simulation

The maximum contact stress of the AFOs was related to the displacement correlation [28]. The model from the SolidWorks structure model can be imported into ABAQUS for creating the tetrahedral FE meshes. A negligible peak contact pressure was observed from a size of 5 to 4.5 mm and further to 4.0 mm of 0.065 MPa [29].



(a) (b)

Figure 3.4. Optimization of the Foot Ankle orthotic device (AFO) meshes for the Foot Ankle orthotic device in: (a) Solidworks and (b) ABAQUS

FE analysis of Composite Ankle Orthosis with Hashin Damage model. Model analysis and failure criteria were suitable for simulating the solid geometry composite using a 3D solid of

AFO employed to simulate the failure mechanism of AFO of the Hashin Damage model. He was healthy without any knee and foot injuries in the past 1 year. All the above is the general information. After being fully informed of the study of the AFO, the experimental procedure was started by jogging training with RFS at the speed of 3 m/s for about 5 min. The external force was a vertical load of 490 N to indicate the patient's weight of 50 kg. The external force position was based on the foot's contact position with the gait floor. The AFO design was proposed for simulation. Polypropylene copolymer was used for the simulation with properties: tensile strength of 27.7 MPa, elastic modulus of 896 MPa, density of 890 kg/m^3, and Poisson's ratio of 0.413. This material is most used for the analysis of the AFO. The simulation results give information about the von Mises stresses, deformation and strain of the 3D model in each step of the stance phase [27].

- Slice increment: 0.9 mm
- Number of slices: 238

A meshing tetrahedral with 0.5 to 1 mm was considered based on mesh convergence. Linear elastic, homogenous and isotropic materials properties were also considered for AFO modelling, where Young's modulus and Poisson's ratio of 896 MPa and 0.415 were considered, respectively [7].

Table 3. 2. AFO Mesh information used

Mesh Type	SolidWorks	ABAQUS
Mesher Used:	Standard mesh	Tetrahedral
Include Mesh Auto Loops:	Off	
Jacobian points	4 Points	6 Points
Element Size	11.9056 mm	11.9056 mm
Tolerance	0.595 mm	0.5 mm
Mesh Quality Plot	High	High

3.3 Mesh verification and validation of the AFO FE model

The present FE mode was verified for adaptative mesh in the ABAQUS observed by default from SolidWorks. The Jacobian standard mesh with 4 points was adopted. The mesh element size was 11.9056 mm. The deviations of the von Mises stress in different locations were varied between 0.59 mm [7]. The elastic energy of the AFO calculation approach has been adopted to analyse its deformation behaviour under loading conditions using Eq.1.

$$E= (1/2)\ F*d \tag{1}$$

where **F** stands for force and **d** the displacement.

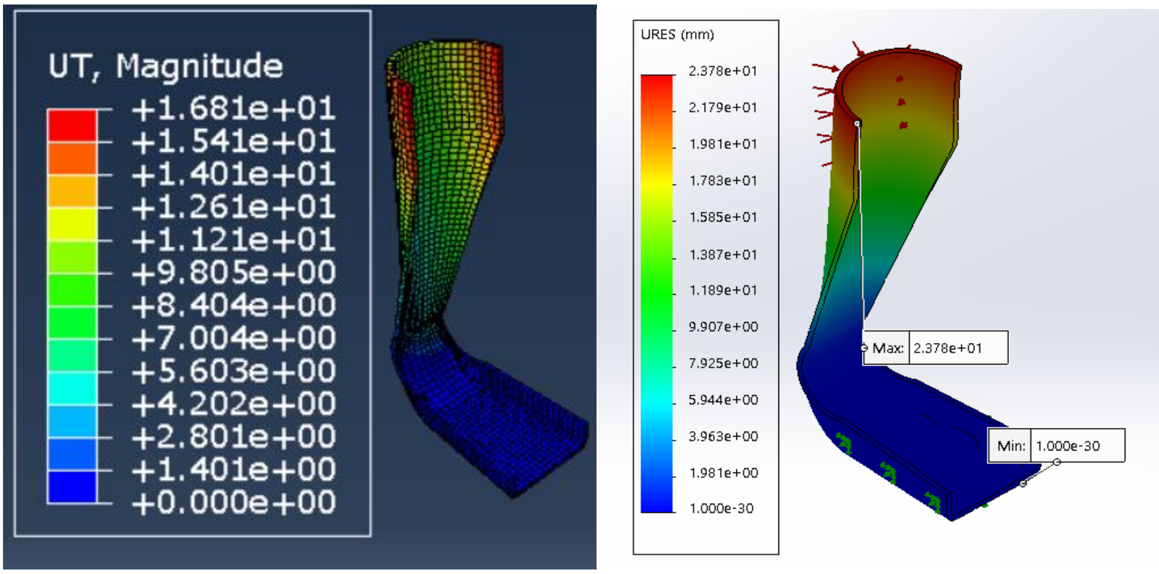
As the objectives of this current research was to examine the performance of the mentioned materials and select the best one depending on their behaviour when used for AFO. FEA simulation was used to predict the behaviour of AFO for each material in real life to save time and experimental test wastes. The stationary boundary conditions were placed as the ground contact section of the foot part in the real walking conditions of how the patients feel while walking. The homogeneous mesh was required to run the simulation and isotropic at any cross-section. The element mesh size was reduced to 1.2 mm (equivalent to 2500 meshes) [13].

CHAPTER 4. RESULTS AND DISCUSSION

This study discusses the clinical application of a three-dimensional FE model of the human foot and ankle. The simulation was conducted using the 3D model designed in SolidWorks and imported into ABAQUS. FE analysis was initially performed in SolidWorks and then validated in ABAQUS using different materials. The aim was to evaluate the effect of mechanical external forces applied to the devices, assuming the patient is in motion during various medical treatments. AFOs made of Polypropylene (PP), Carbon Fiber Reinforced Polymer (CFRP), and Polylactic Acid (PLA) materials were analyzed under full-contact conditions with null ground reaction. Stress analysis of the ankle joint was investigated using both FE and experimental analyses. However, this study was limited to FE analysis due to the focus on the materials used in the ankle.

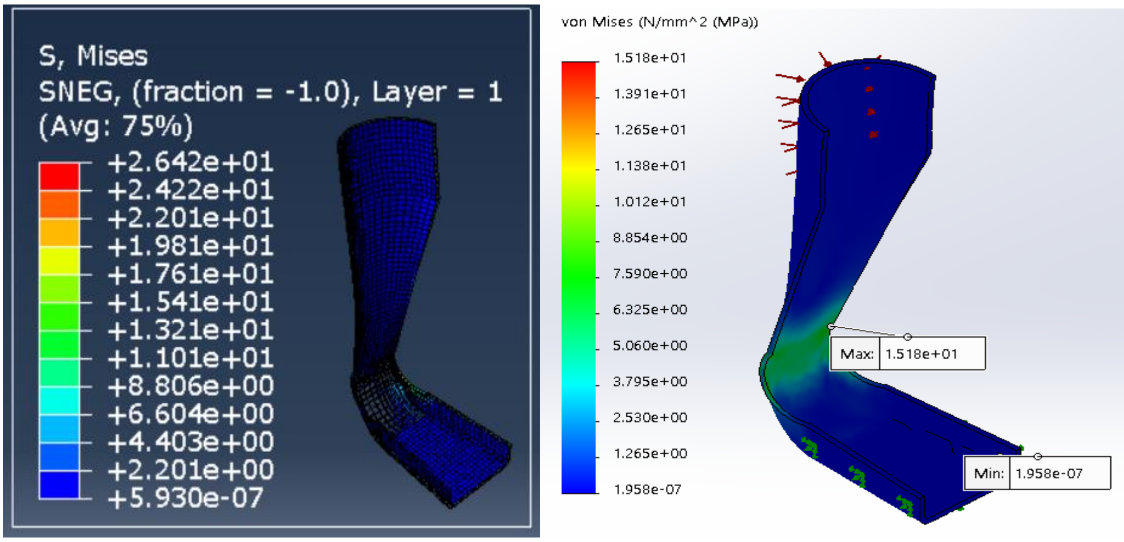
4.1 Finite element analysis of the different materials of the AFOs

The analysis of the effect of materials on AFO devices utilized a 3D FE model with different material properties. Polypropylene cross-linked (E=600MPa, yield strength of 0MPa) and CFRP (8300 MPa, yield strength of 139.043 MPa) were employed. For both maximum and minimum von Mises stress and displacement, the maximum stress was observed to be proportional to the maximum displacement. This indicates that areas of the AFO experiencing maximum stress correspond to minimal deflection strain, while areas with minimal stress exhibit maximum displacement [28]. The results of this study demonstrate that stress in AFO devices changes with variations in materials but remains consistent in the same locations of the device, as illustrated in Fig. 4.1-6 (a) and (b) for displacement and Von Mises stress comparison.



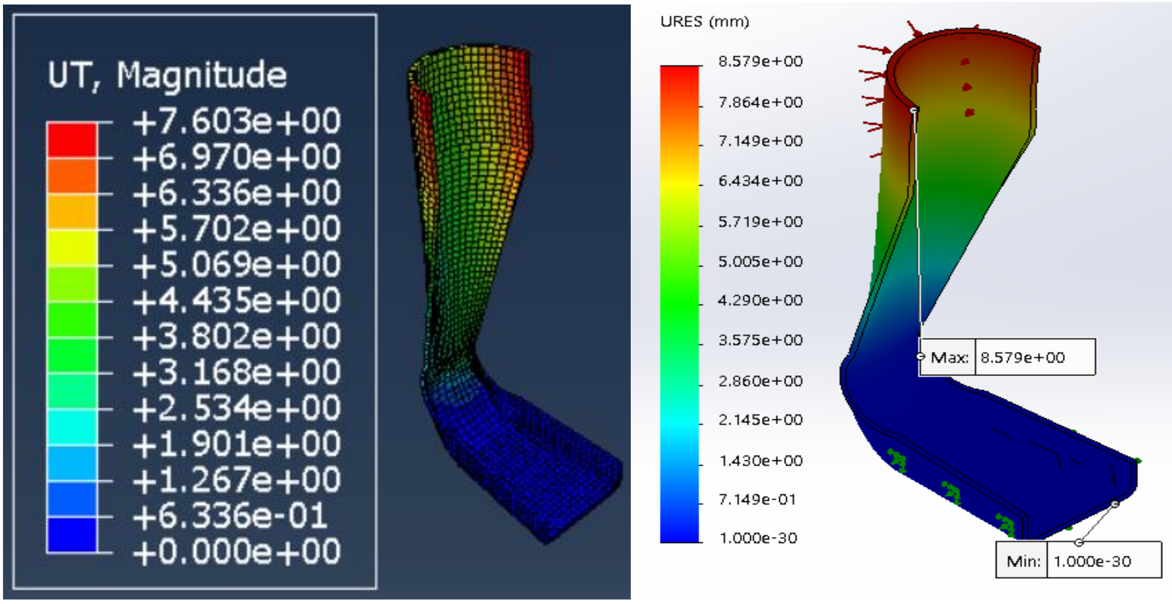
(a) (b)

Figure 4. 1. PP Study for Displacement from (a) ABAQUS, (b) Solidworks



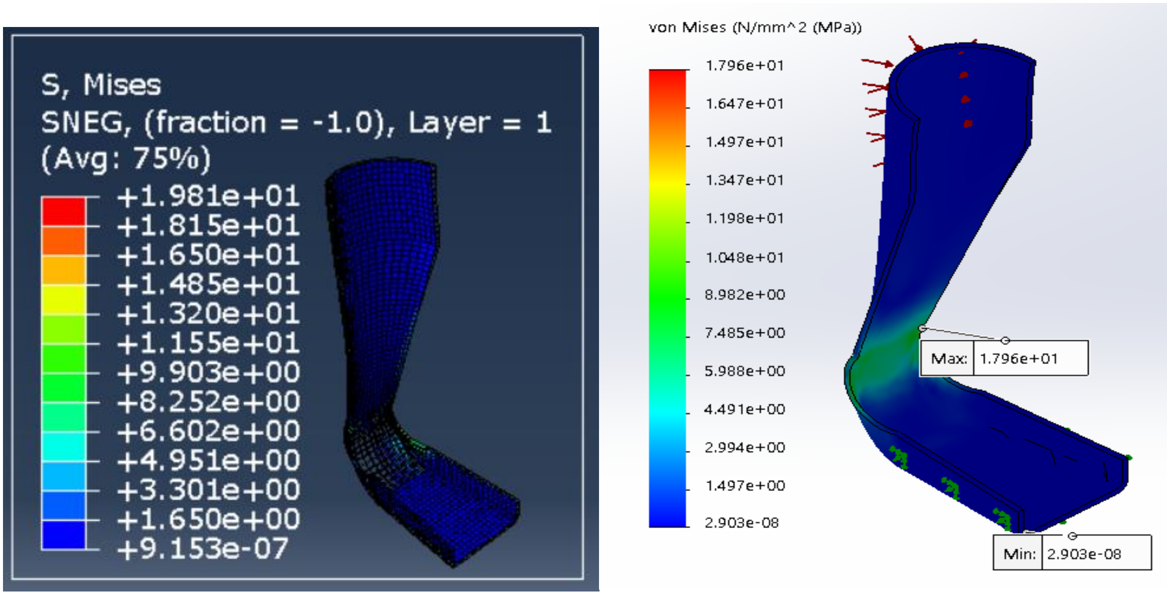
(a) (b)

Figure 4. 2. PP Study for stress from (a) ABAQUS, (b) Solidworks



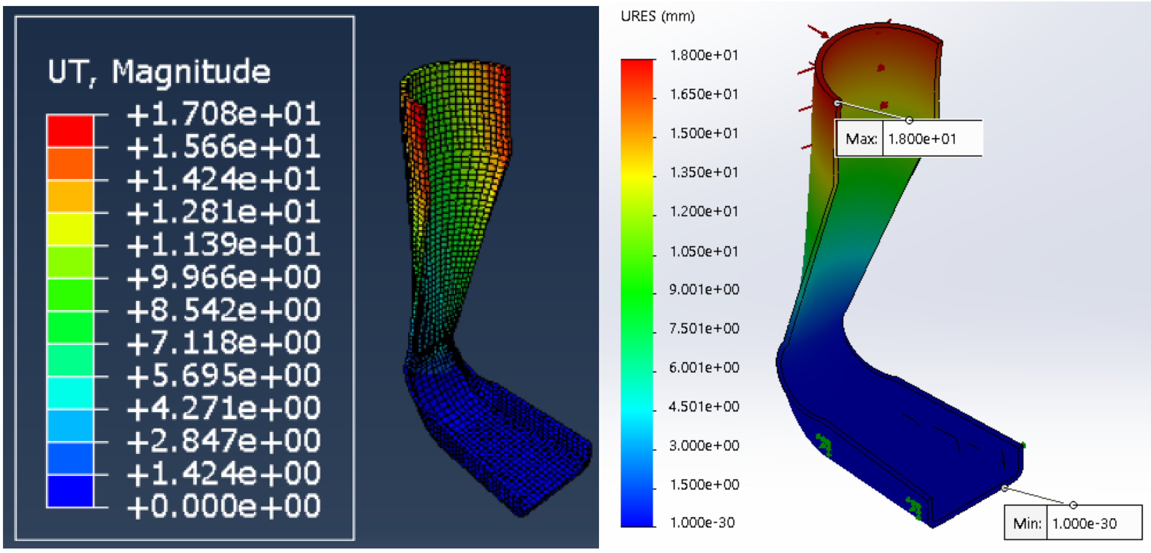
(a) (b)

Figure 4. 3. CFRP Study for Displacement from: (a) ABAQUS, (b) Solidworks



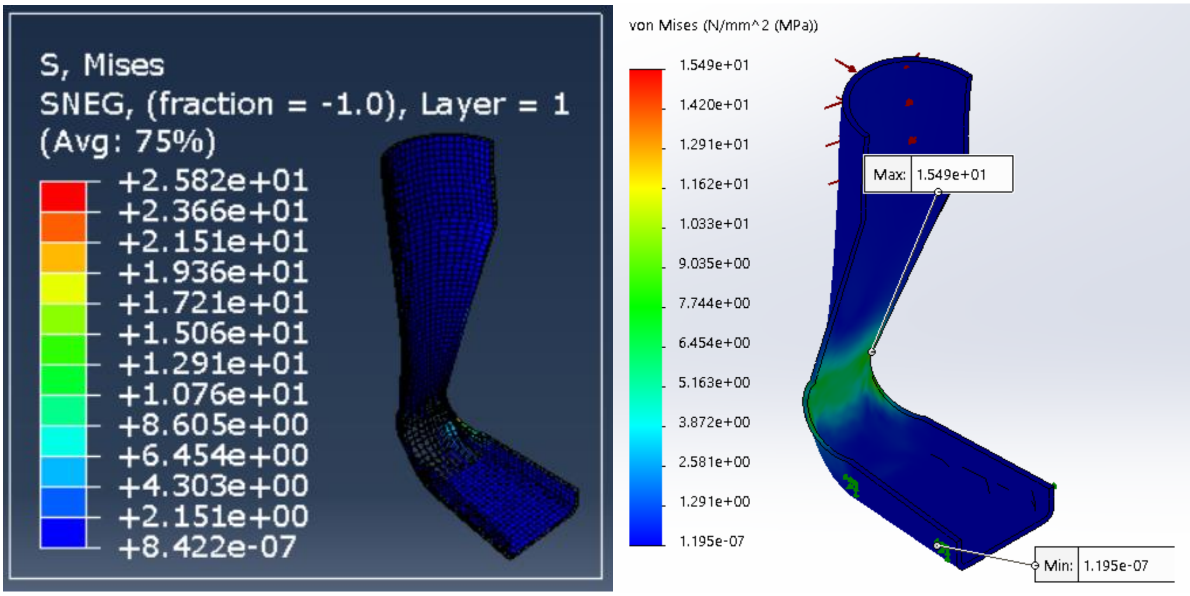
(a) (b)

Figure 4. 4. CFRP Study for stress from: (a) ABAQUS, (b) Solidworks



(a) (b)

Figure 4. 5. PLA Study for Displacement from: (a) ABAQUS, (b) Solidworks



(a) (b)

Figure 4. 6. PLA Study for Stress from: (a) ABAQUS, (b) Solidworks

This present study deals with the development of a 3D FE model of an AFO considering a simplified mode; in terms of materials, geometry and loading conditions. The effect of the material properties of the devices on stress distribution across the geometry and deflection were studied separately [28].

4.2 Effect of materials properties on the AFO FE model

4.2.1 Von Mises Stress

The finite element analysis package ABAQUS was used in foot-ankle FEM analysis. The effect of material properties of AFO on von Mises stress is presented in Figure. 4. 1- 6 for PP, CFRP and PLA materials. From the Figures. 4.2,4.4, and 4.6, it can show that the whole stress is concentrated on the ankle area for both analysis in SolidWorks and ABAQUS. The CFRP showed higher resistance with lowest concentration of the von-Mises stress of 19.8 MPa, followed by PP with 26.4 MPa and the less resistance to the stress was PLA with highest concentration of the von-Mises stress of 25.8 MPa. The key simulation results for stress are provided in Table 4.1. In some studies, a bigger element mesh size was used to discretize the foot ankle geometry complex, which might be inadequate to represent well the complexity of the device geometry. Results of the present study indicate that the stress in AFO devices changes as materials change but on the same location areas of the device as shown in Fig. 4.2,4.4, & 4.6 (a) and (b). The maximum von Mises stress was 9.243e+09 N/m^2 for a dorsal ankle foot orthosis in the gait cycle [27].

4.3 The stress and strain-rate effect in the mechanical properties on AFO

The effects of different strain rates on the mechanical properties of PP, CFPR and PLA materials on the AFO mechanism depend on the modelled solid model using von Mises. They are strain-dependent for both the elastic modulus and the strength.

- Displacement and von Mises stress

The impact of the material properties of AFOs (ankle-foot orthoses) on displacement stress is shown in Figures 4.1-6, which cover three types of polymers: polypropylene (PP), carbon fiber-reinforced polymer (CFRP), and polylactic acid (PLA). The deformation caused by stress was also analyzed.

Figures 4.1, 4.3, and 4.5 demonstrate that most of the deformation or displacement occurs around the top of the ankle for both SolidWorks and ABAQUS simulations. CFRP had the highest resistance to deformation, with the least deformation (7.603 mm). PP followed with 16.81 mm of deformation, while PLA had the least resistance to deformation with 17.08 mm and the highest stress concentration (25.82 MPa). Simulation results for deformation are in Table 4.1.

The maximum deformation of the conventional modified PLA was 1.5 mm, and the maximum stress was reported as 81.35 MPa [8]. This suggests the chosen design is much more durable than articulated AFOs [8]. Comparing PP and PLA, the maximum deformation was quite similar, while CFRP showed a notable difference. This confirms CFRP is the best material in terms of resistance to mechanical forces experienced by patients using the device.

Additionally, because CFRP is denser than PLA, an AFO made from carbon fiber is lighter in weight. Therefore, using CFRP in AFO fabrication can improve the device's performance and efficiency under the same working conditions. However, testing AFOs in real-world scenarios using these materials could not be carried out due to logistical issues and a lack of proper equipment.

The maximum pressure on a normal foot ranges from 0.159 to 1.98 [20]. The maximum deflection obtained was 45, 49, and 15 for ABS, Nylon 6/12, and PEEK, respectively, while for PLA-C, it was 49.67 [20]. A vertical stress of 600 N was applied to the contact areas of the foot surface, totaling 483.55 mm^2. Finite Element Analysis (FEA) was conducted to simulate vertical loading under neutral position conditions, with total weights of 5 N, 10 N, and 490 N in the horizontal (X), yaw (Y), and vertical (Z) directions, respectively. The results are presented in Table 4.1 [20].

Table 4.1. Comparative study of alternative materials used for AFO 3D model analysed

Materials	Loads (N)			Displacement (mm)		Max stress (MPa)	
	X	Y	Z	SolidWorks	ABAQUS	SolidWorks	ABAQUS
PP	5	10	490	12.378e+01	1.681 e+01	1.518e+01	2.642e+01
CFRP	5	10	490	8.57e+00	7.603 e+00	1.796e+01	1.981e+01
PLA	5	10	490	1.800e+01	1.708e+01	1.549e+01	2.582e+01

The total deformation obtained in ABAQUS for the AFO made of PLA was 0.3 mm at the top area. The corresponding equivalent von Mises stress for the PLA AFO at the ankle section was 0.242 MPa. Similar maximum total deformation was reported for conventional AFOs made of PLA in ANSYS simulations, with a value of 0.2 [26]. Likewise, the maximum equivalent stress reported in ANSYS simulations was 91.37 MPa in PLA [26]. For AFOs made of polypropylene sheet tramline, the maximum displacement reported was 9.05 mm, with a peak von Mises stress of 10.94 MPa in the anteroposterior direction [4].

In the ABAQUS analysis, AFO displacements were 8.51 mm, 9.05 mm, and 10 mm for PP, PLA, and CFRP, respectively, as shown in Figures 3.6 to 3.11. Similar displacement values were obtained in SolidWorks simulations. The von Mises stress in the AFOs was 15.19 MPa, 51.2 MPa, and 50.00 MPa for PP, PLA, and CFRP, respectively, in ABAQUS, as shown in Figures 4.1-6. Similar stress values were obtained in SolidWorks simulations. In the 3D AFO model, stress was designed to distribute homogeneously in the 4 mm shell of the devices. Most of the stress appeared on the lower parts of the ankle section for all three materials used in the analyses.

The AFO finite element simulation was validated in the SolidWorks model using the same properties and selected materials, and the behavior remained consistent, as shown in Figures 4.1-6. After partitioning the section, the complex shapes were meshed, and then all parts were assembled together. Subsequently, the FEM model was obtained in ABAQUS, using the same mesh size as in the SolidWorks meshing of the AFO. The analysis was conducted by applying a load, setting boundary conditions, and fixing constraints on the AFO device. A downward force of 490 N, 5 N in the forward direction, and 10 N in the y-direction were applied to the foot part.

The finite element model of the AFO consisted of a combination of hexahedral and tetrahedral mesh elements. The AFO model comprised 2500 elements and 11000 nodes, with mesh metric quality having a minimum value of 5.0e-003, a maximum value of 5 mm, and a standard deviation value of 0.1. The AFO device was made of PP, PLA, and CFRP materials. The objective was to determine the stresses induced and the deflection of the AFO under static conditions. The AFO was analyzed in a stationary state, with a static load applied to a fixed point on the surface, assuming no ground reaction was involved in the analysis. To understand the behavior of the AFO (ankle-foot orthosis) under static conditions, a finite element analysis was performed with a constant load of 490 N (for an individual weighing 80 kg) applied to the top of the orthotic device. The load was applied to a fixed point on the surface using MPC (Multi-Point Constraints).

After the simulation, the maximum and minimum displacements and stress levels were recorded. Figures 4.1-6 show the FEA results for the resulting displacements and von Mises stresses in the AFO device. The maximum stress was concentrated in the area of the foot known as the corn section, while the maximum displacement occurred at the top part of the AFO. The results closely align with reported maximum stress levels of 31.26 MPa and maximum displacement of 4.97 mm, with a deflection of 0.95. The hybrid AFO made with carbon fiber-reinforced polymer (CFRP) was found to be more convenient to use compared to AFOs made of polypropylene (PP) and polylactic acid (PLA) [4].

CHAPTER 5. CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

This study aimed to evaluate the mechanical performance of AFO devices based on their fabrication materials for biomedical utilization. The analysis involved modeling, simulation, and comparison of the foot-ankle complex for medical usage using ABAQUS and SolidWorks. A 3D FE model of the AFO was developed based on dimensions obtained from literature review and using appropriate loading parameters for a standard person weighing 70 kg, along with materials recommended in previous research. Polypropylene (PP), Carbon Fiber Reinforced Polymer (CFRP), and Poly Lactic Acid (PLA) materials were evaluated based on displacement and strain curves derived from FE simulations. Design modifications and fixture adjustments were performed to ensure the accuracy of the AFO 3D FE model. The study concluded that AFOs made of CFRP material exhibited superior performance with deflection values of 7.603 mm and 8.579 mm, and stress values of 1.981e+01 MPa and 1.796 e+01 MPa from ABAQUS and SolidWorks simulations, respectively. The stress and displacement analysis of the 3D FE model, along with literature review, confirmed that AFOs made of CFRP are highly resistant and suitable for fabrication or experimental analysis of orthotic devices. Identified deflections provide crucial data for material selection. For PP and PLA, the predicted deflection during simulation did not significantly differ between them and were twice as much as the deflection observed with CFRP, making CFRP the preferred material for utilization.

5.2 Recommendations

1. In the medical field:

- Prioritize the use of CFRP in AFO fabrication due to its proven resistance to displacement and stress, leading to the creation of more durable and effective devices.
- Gather patient feedback regarding comfort and performance to guide future AFO designs, promoting customization based on individual needs for better support and satisfaction.
- Conduct long-term clinical testing of AFOs made with different materials to ensure their safety, effectiveness, and long-term performance in real-world scenarios.

2. Academically:

- Research alternative materials such as ABS, PETG, PA12, PEEK, Nylon 6/12, and PC to expand options and foster innovations in AFO design.
- Investigate new design techniques and foster interdisciplinary collaboration to drive advancements in AFO research and development.

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