**SYNOPSIS**

of the Ph.D. Thesis

Entitled

# "INVESTIGATIONS ON PROSTHETICS / ORTHOTICS ELEMENTS DEVELOPED FROM POLYMERS AND ITS COMPOSITES"

Proposed to be submitted in

Partial fulfilment of the Degree of

**DOCTOR OF PHILOSOPHY**

*In*

**MECHANICAL ENGINEERING**

*Submitted by*

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(FOTE/982 Dt. 24-01-2019)

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(JANUARY 2023)

# Certificate

This is to certify that the Synopsis of the thesis entitled **"INVESTIGATIONS ON PROSTHETICS / ORTHOTICS ELEMENTS DEVELOPED FROM POLYMERS AND ITS COMPOSITES"** submitted by **Piyush Thakorbhai Patel** (FOTE/982 dated 24-01-2019) towards the fulfillment of the requirement for work carried out in Mechanical Engineering is a bonafide record of investigations carried out by him in The Department of Mechanical Engineering, Faculty of Technology and Engineering, The Maharaja Sayajirao University of Baroda, Vadodara under the guidance and supervision of Dr. Piyush P. Gohil (Associate professor, Department of Mechanical Engineering). In our opinion, this has attained the standard fulfilling the requirements as prescribed in the regulations of the University.

**Date:**
**Place:**

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Research Supervisor and Guide

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# DECLARATION

I, Piyush Thakorbhai Patel, hereby declare that the work reported in this Synopsis of the thesis entitled, “INVESTIGATIONS ON PROSTHETICS / ORTHOTICS ELEMENTS DEVELOPED FROM POLYMERS AND ITS COMPOSITES” submitted for the award of the degree of Doctor of Philosophy in Mechanical Engineering is original and was carried out by me in the Department of Mechanical Engineering, Faculty of Technology & Engineering, The Maharaja Sayajirao University of Baroda, Vadodara. I further declare that this Synopsis of the thesis is not substantially the same as one, which has already been submitted in part or in full for the award of any degree or academic qualification of this university or any other institution or examining body in India or abroad.

**Date:**
**Place:**

**Piyush Thakorbhai Patel**
**(FOTE/982 Dt. 24-01-2019)**

# ACKNOWLEDGEMENT

At this moment of accomplishment, first of all I pay my obligations to my guide **Dr. Piyush P. Gohil** (Associate Professor, MED) for his immense support and for believing in me more than myself that I could pursue my Ph.D. in the field of Biomedical Engineering. His consistent direction, intellectual insight, and encouragement throughout my research effort allowed me to accomplish my work on time. He not only assisted me in grasping the fundamental principles and practices of the work, but he also motivated me at every turn to improve my way of thinking and approach. His conversations and recommendations contributed to a better implementation of the task. This dissertation would not have been feasible without his unwavering support.

I am also thankful to Dr. Veerendra K. Shandilya (PhD, LPO, BOCPO) for his guidance and constant encouragement throughout this work. I express my special thanks to Dr. Khyati Vansadavala (Prosthetist & Orthotist , RCI No: A51452) for giving me an opportunity to carry forward my gait analysis work in Evolution Healthcare Pvt. Ltd (Surat). I wish to thank Dr. Sagar Naik (CEO & Chief Physiotherapist, Asian Physiotherapy & Research Institute, Surat) for his for suggestions, guidance and sharing experiences. The researcher expresses sincere thanks and gratitude to the participants for their patience and cooperation during the study's completion.

I would like to express my sincere gratitude to the members of the doctoral advisory committee who have corrected me when necessary as well as to all of the faculty in the department of mechanical engineering in particular for their willingness to share their knowledge.

I am also hugely appreciative to Dean of Faculty of Technology and Engineering for his kind support extended throughout the period of the study.

Additionally, I want to convey my sincere gratitude to my friends, coworkers, and last but not least, my family, who have provided their explicit and tacit support for my dissertation effort.

Piyush T. Patel

# ABSTRACT

Investigations on Prosthetics / Orthotics elements developed from polymers and its composites

**Key words:** Advanced Manufacturing; Anthropometric Measurements; Assistive device; CAD; Cerebral Palsy; Customized Design; Gait; Health Care; Material Optimization; Patient's Survey; Pediatric Walker; Prosthetic and Orthotic; Simulation

**Background**

Due to the growing demand from consumers and industries for high performance products, composite materials have recently gained prominence due to their better particular mechanical qualities. Researchers have concentrated on creating ecologically acceptable bio based products from renewable resources as a result of the depletion of non-renewable resources and rising environmental degradation. Biocompatible materials are very useful in the medical field for the various devices.
Rehabilitation procedures enable people to perform more effectively following an injury or sickness. As a result of a rise in fatalities and man-made mishaps, limb amputations to preserve human life are becoming more common. Following limb amputation, the patient becomes totally reliant on the Prosthetic and Orthotics (P&O) device. Healthcare plays an important role in markets and is developing at a quicker rate; it has characteristics that distinguish it from other more traditional sectors and presents problems in both the use of current technology and the creation of new technologies. Medical researchers are looking for new ways to develop healthcare items such as artificial limbs, prosthetics, implants, personalised orthotic devices/customized insoles, foot and surgical-planning models of internal body components that are faster and more exact.

**Objectives**

P & O facilities are accessible in all nations, but services frequently fall short of expectations, both numerically and qualitatively. The majority of low-income nations have insufficient P&O facilities, are overly centralised, and produce insufficiently to fulfil demand. According to the World Health Organization, around 5% of persons who use assistive devices are able to utilise them. P & O practises are not always adequate, equipment quality is frequently poor, and the quantity and qualifications of workers are insufficient to satisfy the demands. The foremost motive of this dissertation work is to categorize the latest knowledge for researchers and highlight the challenges and future directions of research in recent advancements in polymer processing for biomedical applications.
Keeping above demands in view, research studies have been conducted on developing optimized P&O elements. The use of Advanced Manufacturing in medical device manufacturing has risen in prominence over the last several decades as the prospects for this technology have expanded significantly. This research work goes over the

complete approach for designing, analysing, developing, and testing innovative prosthetic and orthotics based on the needs of the patient. It is our responsibility to assist humanity by providing high-quality P&O devices at a reasonable price.

**Method**

The human body varies over time due to fluctuations in weight and growth, thus it is important to replace and modify the P&O frequently. The requirement for this continual alteration or adaptation may be great if expensive materials are being utilised. However, relatively few research have focused on the optimization of prosthetic foot design. There is still a discrepancy between how process parameters are influenced by material performance and design specifications. According to complicated load combinations and structural design standards, several sophisticated manufacturing and analysis procedures must also be taken into account for the maximum factor of safety.

Traditionally, individual P&O devices are manufactured using plaster molds, which require multiple patient visits, takes a lot of effort and time to produce. Therefore, our main attention is the process of designing and developing lightweight P&O elements quickly with a simplification of the manufacturing process. Additive manufacturing is an advanced layer-based manufacturing process that fabricates customized P&O to patient requirements directly from computer aided design data without using part depending tools. Now a days in the rehabilitation field, the use of additive manufacturing processes has been shown to accelerate, facilitate and improve the quality of personalized products.

The works proposed have been extensively uses finite element techniques for simulation and optimization of various design concepts proposed for P&O devices. The optimized design are manufactured & realized and may underwent successful test & evaluation proposed for novel prosthetic foot model for lower limb amputation level patients. A systematic physical examination of the lower limbs is done throughout the session to determine anthropometry, passive range of motion, and clinical films are recorded.

The established kinematic analysis is placed via gait analysis with varied inputs to generate variable outputs, taking into account the prosthetic's typical usage circumstances. The study provided here exhibits understanding of gait analysis for application in prosthetic creation and assessment of performance. The result of simulation and testing are reported and found to be close conformance.

This research work goes into the depth of these challenges and envisages development of light weight, compact and very low development cycle time from concept to realization for the Orthotics devices.

All children are made up differently and have cerebral palsy in different parts of their body. Therefore, there is a need for posterior pediatric walker that can adapt to the various needs of users. Both online surveys and face-to-face interviews were conducted to collect data necessary for the study. The design criteria parameters for a pediatric walker are based on device function, materials, patients, aesthetics, ease of use and safety.

The walker described is analyzed considering sitting and standing in the ANSYS workbench for the total deformation and stress equivalent of the different materials. Based on the findings of the research, design and material are further improved by combining materials and dimensions to fulfil both mechanical requirements in terms of strength and ergonomics for the CP walker.

As a result, the design framework's adaptability would make it simple for a product designer to arrive at a customised design approach with specified performance characteristics in an efficient and cost-effective manner.

**Outcomes**

The following are the key research contributions to knowledge as a result of this research for Prosthetics and Orthotics elements:

1. According to the findings of the review, the final focus was on the design and development of human prosthetic foot structures for below knee amputee patients, as well as a minor attempt to be made for Orthotics element preparation employing advanced manufacturing techniques.
2. Conducted a patient survey to acquire background information on the use of Prosthetics & Orthotics elements (Jaipur foot camp of bhagwan mahaveer vikalang sahayata samiti at shree party plot, Valsad, Gujarat; Asian Physiotherapy & Research Institute, Surat, Gujarat).
3. Developed P&O model using various modeling tools (Autodesk Fusion 360, Autodesk Meshmixer).
4. Outlined a logical process for choosing the optimized parameter to create the personalized various prosthetic foot, orthotics foot shell, wrist brace, ankle foot orthotic, and CP walker.
5. Analyzed P&O elements utilizing a variety of Analysis software tools (ANSYS, Ultimaker Cura, Kinovea).
6. Emphasized polymers/composite as a material for various P&O elements.
7. Developed a simplify lightweight structural components using an advanced manufacturing process (The mass of SACH Foot Structure is discovered to be 309 grams and the mass of Novel Foot Structure after optimization is found to be 190 grams. The development efforts by considering design optimization in Novel prosthetic foot structure shows that there is a weight reduction around approximately 61.5 % comparison with the SACH Foot Structure).
8. Utilized an appropriate advanced production technology for the development of customized P&O elements (Fused Deposition Modeling (3D Printer); 3 Axis CNC Vertical Machining Center).
9. Performed patient testing to evaluate the performance of the Novel Prosthetic foot model for lower limb amputation level patients (Evolution Healthcare Pvt. Ltd, Surat, Gujarat).

# LIST OF ABBREVIATIONS

| Description | | Parameter |
|---|---|---|
| 3D printing | : | 3DP |
| American Society for Testing and Materials | : | ASTM |
| Ankle Foot Orthosis | : | AFO |
| Acrylonitrile Butadiene Styrene | : | ABS |
| Additive Manufacturing | : | AM |
| Aluminum | : | Al |
| Ankle Disarticulation | : | AD |
| Assistance to Disabled Persons for Purchase | : | ADIP |
| Carbon Fiber | : | C |
| Carbon Fiber Reinforced Plastic | : | CFRP |
| Cerebral Palsy | : | CP |
| Computer Aided Design | : | CAD |
| Computer Aided Manufacturing | : | CAM |
| Computer Numerical Control | : | CNC |
| Conventional Manufacturing | : | CM |
| Corporate Social Responsibility | : | CSR |
| Cross Section | : | C/S |
| Design for Assembly | : | DFA |
| Design for Manufacturing | : | DFM |
| District Disability Rehabilitation Centres | : | DDRC |
| Factor of Safety | : | FOS |
| Finger Orthoses | : | FO |
| Finite Element Method | : | FEM |
| Finite Element Analysis | : | FEA |
| Fused Deposition Modeling | : | FDM |
| Geometric Dimensioning and Tolerancing | : | GD&T |
| Gross Motor Function Classification System | : | GMFCS |
| Hand Orthoses | : | HO |
| High Density Polyethylene | : | HDPE |
| High Impact Polystyrene | : | HIPS |
| Low Density PolyEthylene | : | LDPE |
| Multi Axial Foot Mechanism | : | MAFM |
| Magnetic Resonance Imaging | : | MRI |
| Non-Governmental Organization | : | NGO |
| Nylon 6/6 | : | N |

| Description | | Parameter |
|---|---|---|
| Original Equipment Manufacturer | : | OEM |
| Poly Lactic-co-Glycolic Acid | : | PLGA |
| Poly Methyl Meth Acrylate | : | PMMA |
| Polyamide | : | PA |
| Polycaprolactone | : | PCL |
| Poly-Ether-Ether-Ketone | : | PEEK |
| PolyEthylene | : | PE |
| Poly-Ethylene Terephthalate | : | PET |
| Poly-Ethylene Terephthalate Glycol | : | PETG |
| Poly-Lactic Acid | : | PLA |
| Polymer Matrix Composites | : | PMC |
| Poly-Oxy-Methylene | : | POM |
| Poly-Propylene | : | PP |
| Poly-Urethanes | : | PU |
| Poly-Vinyl Alcohol | : | PVA |
| Prosthetics and Orthotics | : | P&O |
| Solid Ankle Cushioned Heel | : | SACH |
| Stainless Steel | : | SS |
| Standard Tessellation Language | : | STL |
| Stereolithography | : | SLA |
| Thermo-Plastic Elastomers | : | TPE |
| Thermoplastic Poly-Urethane | : | TPU |
| Three Dimensional | : | 3D |
| Titanium | : | Ti |
| Ultra-High Molecular Weight Poly-Ethylene | : | UHMWPE |
| Ultra-Violet | : | UV |
| United States | : | US |
| Variable Impedance Prosthetic | : | VIPr |
| Vertical Milling Center | : | VMC |

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# 1. INTRODUCTION

## 1.1 Prosthetics and Orthotics (P&O)

Prosthetic is an artificial device that substitutes a missing body element that may have been lost due to accident, sickness, or a congenital ailment. (Behrend, Reizner, Marchessault, & Hammert, 2011). Orthotics (Lusardi, Jorge, & Nielsen, 2013) is the use of artificial or mechanical devices, such as braces, to limit or help muscles or joints that are damaged or weak from moving. The essential components of the modular prosthetic are shown in figure 1.1.

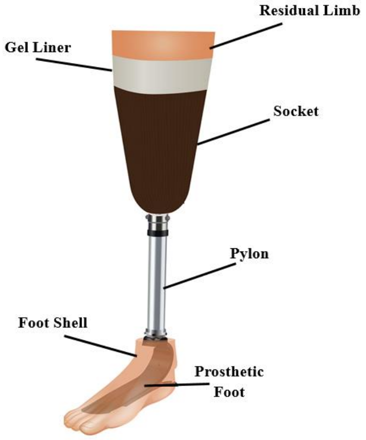



Figure 1.1: Arrangement of main elements of prosthetic

The primary function of employing the main key elements of prosthetic devices is discussed shortly below.

**Liner**

-The liner is a flexible, cushioning material that serves as a protective cover. It decreases mobility and friction between the skin and the socket when worn over your residual limb.

**Socket**

- The socket's aim is to offer structural stability to the prosthesis where it meets the residual limb. It may also have suspension features to keep the prosthesis in place.

**Pylon**

- To complement the residual capacity of lower limb amputees, prosthetic makers have created shock-absorbing pylons to reduce the transient stresses of foot-ground contact.

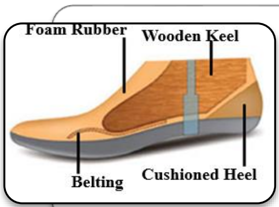
**Prosthetic Foot**

- Prosthetic foot with two or three axes of movement enable more ankle mobility, which helps balance the user when travelling on uneven ground.

**Foot Shell**

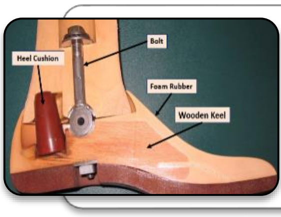
- A purely aesthetic covering for a prosthetic foot that allows for easy walking on uneven terrain.

In general, prosthetic feet can be classified into three categories: Non articulated, Articulated and Dynamic response foot as mentioned in the below list.



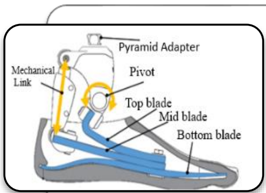

### Non Articulated Foot

- The most basic type of non-articulated foot is the single axis foot. The name refers to a soft rubber heel wedge that simulates ankle motion by compressing under load during the early stages of walking's stance phase. The keel is hard, therefore there is no lateral movement but there is midstance stability. The SACH foot comes in a variety of heel heights.




### Articulated Foot

- They can have a limited range of motion in either the sagittal plane to replicate planter and dorsiflexion motions, or in both the sagittal and frontal planes to model planter & dorsiflexion movements as well as inversion and eversion. There are feet with varying degrees of movement amortisation.




### Dynamic response foot

- Dynamic-response feet are a type of energy-storing prosthetic foot designed for active and moderately active prosthetic users who want to live a normal life. These shoes are made of innovative composite materials such as carbon graphite to give more dynamic movement and function.

To proceed with the design of the elements, it is necessary to classify the patients according to their usual activities. A K-level code technique is used to divide the entities into groups as shown in figure 1.2. The design of these prosthetic varies according to their respective functions.

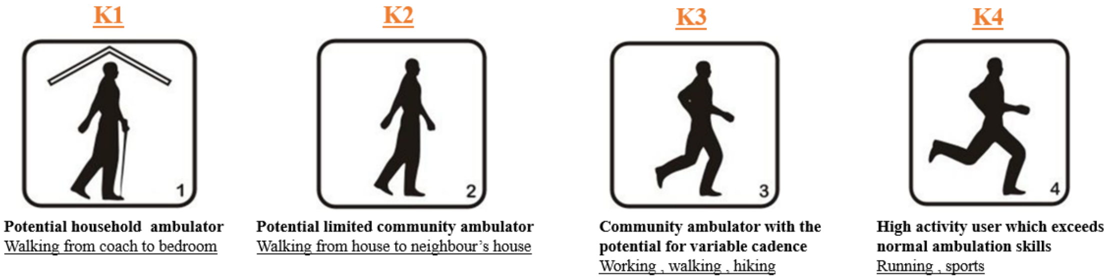



Figure 1.2**.** Functional level (K level) of prosthetic users

Orthotic is a man-made device meant to fulfil a patient's biomechanical (Hamill & Knutzen, 2006) demands. The creation and manufacturing of external orthotics as measure of a patient's therapy requires accuracy and ingenuity. There are a variety of ready-to-use & tailor-made orthotic devices used for many musculoskeletal disorders (Buckle, 2005). Common orthotic interventions include spinal jackets, Neck, footwear, insoles, braces, splints, calipers etc. (Patel & Gohil, 2022)

Depending on the specific patient's demands and the type of device materials are utilized in prosthetics and orthotics. (Vanaei, Parizi, Salemizadehparizi, & Vanaei, 2021) (White, Weber, & White, 1972) (Lipskin, 1971)

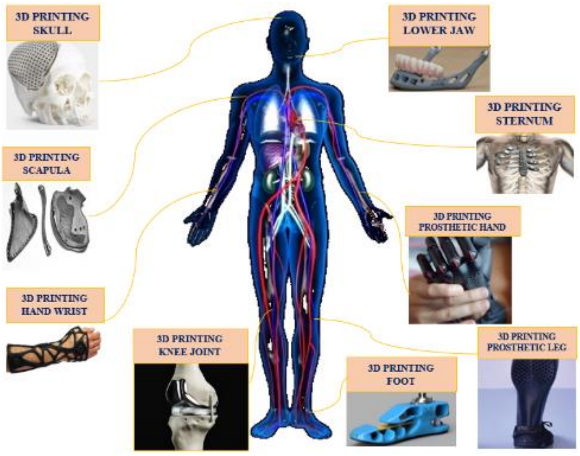



Figure 1.3: P&O assistive devices in human body (Patel & Gohil, 2022)

The body consists of intimate elements that, if lost, cannot fully be replaced. Fortunately, researchers all across the universe is attempting to replace each element of the body in order to transform all of us becoming cyborgs. Figure 1.3 depicts some of assistive devices in the human body. (Shahar, et al., 2019)

## 1.2 Composite Materials

The composite material is described as a combination of two immiscible elements with different structures (figure 1.4), which have the capability to meet the diverse design and requirements with weight savings as compared to the conventional materials. (Tsai & Hahn, 2018)

The significant demands made on engineers to improve performance and reliability at a reduced cost require the ability to understand the mechanical behavior of the material and elements under services conditions. (John, Dean, & Karyn, 1986)

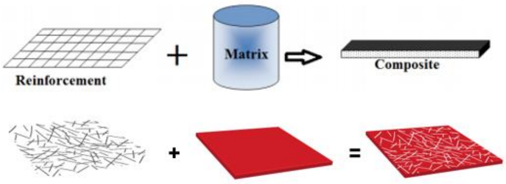



Figure 1.4: Constituents of Composite Material

The advancement of composite materials, yet up 'til now making, has shown up at a period of improvement. Opportunities for what's to come are splendid for a grouping of reasons. The cost of the key constituents is lessening a result of market advancement. The innovation of composite materials (Nicolais, Meo, & Milella, 2011)has encountered fast advancement over the most recent forty years. A portion of the hidden reasons and inspirations for this advancement are;

- Significant progress in materials science and innovation in the zone of fibres, polymer and ceramics (Leszek ́nski, 2006).
- Requirements for smart material for the future of rehabilitation industry (Shreeshan Jena, 2017).
- Development of amazing and advanced mathematical techniques for basic investigation utilizing modem computer technology.

- Characterization techniques for the damage in composite material and enables researchers to devise selection criteria to select the most appropriate technique (Osama Ahmed, 2021).
- 3-D printing composite materials for P&O elements (Wendy Triadji Nugroho, 2021).
- Additive manufacturing has enormous promise for a wider application, particularly in medical, aerospace, and automotive industries (Dipak M.Hajare, 2022).
- Advancements in polymer composites as a pertinent biomaterial for hard tissue applications (Sahil Mehta, 2022)

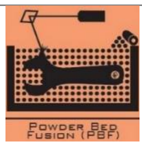
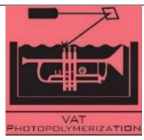
The utilization of customary and new composite materials is actually related to the improvement of assembling procedures. Opportunities for what's to come are splendid for a grouping of reasons. The cost of the key constituents is lessening a result of market advancement. The assembling strategy is getting more affordable as more experience is amassed, systems are improved, and creative methods are introduced. Additionally, the development is eagerly updated by a more energetic time of engineer and scientists practiced and arranged in the field of composite materials.

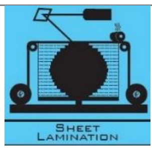
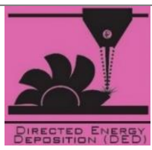
### 1.3 Additive Manufacturing -Evolution

“A layer-based automated manufacturing technique known as "additive manufacturing" (AM) uses 3D CAD data to produce scaled 3D objects without the need for part-dependent tools.

AM's approach to craftsmanship is flexible, adaptable, distinctively adjustable and deeply relevant to most elements of modern creation. (Prakash, Nancharaih, & Rao, 2018) AM's core focus remains on customizing low-volume, high-value items for rapid production. An automated manufacturing technique called AM uses layers to produce scaled 3D things directly from 3D CAD data without the need for tools that depend on specific parts. (Mellor, Hao, & Zhang, 2014). Seven groups of Additive Manufacturing as indicated by ASTM F2792 Standards are recorded beneath in Table 1.1.

Table1.1: Various Additive Manufacturing process (DelVecchio, 2021)

| AM Process | Schematic diagram | Strengths | Typical Materials |
|---|---|---|---|
| Powder Bed Fusion |  | • High level of complication;<br>• Powder serves as a support material;<br>• A diverse variety of materials. | Sand, plastics, metals, ceramic powders |
| Vat Photo polymerization |  | • High level of precision and intricacy;<br>• Smooth surface finish;<br>• Large construction area. | Photopolymer Resins with UV Curability |
| Binder Jetting |  | • Full color printing is possible;<br>• There is high output;<br>• A variety of materials are used. | Sand, metal, ceramic, glass, and powdered plastic |
| Material Jetting |  | • High degree of precision;<br>• Full color elements are possible;<br>• Multiple materials are possible in a single part. | Wax, polymers, and photopolymers |

| | | | |
|---|---|---|---|
| Sheet Lamination |   | • Rapid volumetric growth rates;<br>• Allows for combinations of metal foils, including embedding elements;<br>• Relatively inexpensive (non-metals). | Paper, plastic, and metallic foils and tapes |
| Material Extrusion |   | • Multiple colours are possible;<br>• it is inexpensive and practical;<br>• it may be utilized in an office setting;<br>• The parts have high structural qualities. | Thermoplastic slurries, liquids, and pellets; filaments; and pellets |
| Directed Energy Deposition |   | • Highest single-point deposition rates;<br>• No direction or axis restrictions;<br>• Effective for repairing and adding features;<br>• Multiple materials in a single element. | Metal wire and powder combined with ceramics |

The below table 1.2 summarize the challenges and opportunities by considering the different level sector in the additive manufacturing domain. (Gupta, Weber, & Newsome, 2012)

Table 1.2: The challenges and research needs in Additive Manufacturing (Guo & Leu, 2013) (Seepersad, 2014)

| Levels | Challenges | Research Needs |
|---|---|---|
| ***Material-level*** | • Variation in properties due to recycling of material<br>• Material cross-contamination<br>• Heterogeneity of particle sizes | • Safety guidelines for handling powders and reducing fire and inhalation dangers<br>• Precise control over particle size, mixes, and composition |
| ***Part-level*** | • Optical measuring techniques create a large quantity of point cloud data; new algorithms are required to synthesize this data.<br>• Polishing and post-process machining of free-from geometries is done manually and is costly.<br>• Coordinate measuring instruments struggle to measure freeform surface geometries. | • Post-process finishing to enhance the surface and geometric integrity of free-form surfaces and facilitate the removal of supports;<br>• Standardization of test processes; geometric dimensioning and tolerancing (GD&T); and metrology of AM elements<br>• Design rules and support structure optimization |
| ***Process-level*** | • Need to track multiple process variables<br>• Repeatability is ensured by careful calibration of process machine elements.<br>• Thermal physics is complicated, and modelling is confined to element deformation | • Adoption of best practices, such as post-process cleaning, as standards<br>• Effective and accurate modelling and simulations to foresee future issues<br>• In-process monitoring, sensing and control to guarantee that elements are manufactured according to specification<br>• Process improvement to boost production volume and speed |
| ***Enterprise-level*** | • A number of systems are linked to the cloud or OEM servers.<br>• AM suppliers, design bureaus, and facilities are dispersed | • New ways to hands-on teaching and training to teach the concepts of AM processes to the next generation of users<br>• Logistics and supply chain implications of AM |

| | | |
|---|---|---|
| | throughout several areas. The types and capacities of systems differ amongst facilities.<br>• Traditional production technicians are inexperienced with powder handling. | • Cyber security to guard against digital thread infiltration in AM and preservation of design intellectual property<br>• Safety & Human-factors implications of AM |

The scientific and technological issues related with the development, materials, and metrology of AM products that will influence market acceptance and economic opportunities. (Chen, He, Yang, Niu, & Ren, 2017)

## 2. LITERATURE REVIEW

Literature gives a clear view of work such as papers, theories related to topic and helps in determining the proper aim of the research work. This chapter contains various research/review papers, articles, and theories based on design procedure, material selection, technique, analysis & testing of prosthetics and orthotics elements.

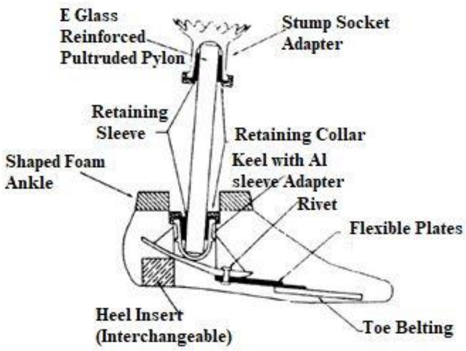



Figure 2.1: Prosthetic cross section diagram (Michael & Bowker, 2004)

The typical step demonstrates seamless function with no indication of body element deficit. The standard walking cycle is separated into two stages: (1) When the foot makes contact with the ground, this is referred to as a stance, and (2) When the foot goes forward in the air, this is referred to as a swing.

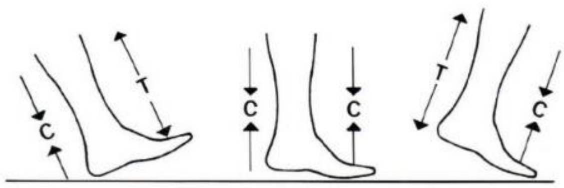


Figure 2.2: The forces transmitted through the anterior and posterior aspects during the walking cycle

Normal walking incorporates stance phase with one leg and swing phase with the other as shown in figure 2.2. Muscles must resist gravity, accelerate or decelerate impact forces, and contract to overcome tread resistance.

The design and manufacture of prosthetic is still done manually and relies heavily on the prosthetic know-how (skill and experience). This subjective and static assessment results in a high rate of non-conforming prosthetic, increasing costs and delays. Due to the challenge of the market, prosthetic manufacturers are currently making changes on several levels; some of which involves the selection of materials used in the rolling development of the socket or assembly.

Charles Hull invented a new manufacturing technique in 1984 compared to the traditional manufacturing process. Creating a traditional prosthetic can take weeks or months, but creating a 3D-printed prosthetic takes just one day, making it more accessible. This literature review contains various research/review papers, articles, and theories based on design procedure, material selection, technique, analysis & testing of prosthetic elements. The documented research on the materials and techniques utilized to make the prosthetic that are now on the market is displayed in Table 2.1 below.

Table 2.1: Research on currently utilised materials and techniques for prosthetic elements

| Year | Author | Body Element | Material | Method |
|---|---|---|---|---|
| **2002** | Francis E.H. Tay et al. | Prosthetic Socket | Composite material | FDM |
| **2008** | Arun Dayal Udai et al. | Prosthetic Limbs Socket | N.A. | CAD Modeling |
| **2008** | L.H. Hsu et al. | Transtibial Prosthetic Socket | Carbon fiber | Fused Deposition Modeling |
| **2010** | Andreas Gebhardt et al. | Dental part | Metal powder | Selective laser melting |
| **2011** | Prasanna Kumar Lenka et al. | Trans tibial prosthetic socket | Composite material; propylene | Finite Element Method |
| **2011** | Giorgio Colombo et al. | Lower limb prosthetic | Aluminium / stainless steel / titanium / carbon | CAD Modeling |
| **2012** | Kahtan Al-Khazraji et al. | Lower limb prosthetic socket | Composite material | Vacuum molding technique |
| **2013** | David Sengeh et al | Prosthetic Socket | 3D Printing materials | 3D printing |
| **2013** | Susmita Bose et al. | Bone | Biomaterials | 3D printing |
| **2014** | Palash Kumar et al. | Hip prosthetic | Biomaterials | Rapid Prototyping |
| **2015** | Michael T. Leddy et al. | Prosthetic fingers | Composite | 3D printed molds |
| **2016** | Benjamin et al. | Prosthetic devices | 3D Printing materials | FDM |
| **2016** | Jolien B. van Gaalen et al. | Hip Implant | Ti-6Al-4V | Metal AM |
| **2016** | Shoichi Sato et al. | Prosthetic (Socket and Prosthetic blade) | Nylon12/powder ASPEX-PA2 | Laser Sintering |
| **2016** | Roland K.Chen et al. | Orthotic and prosthetic | Nylon 11/Nylon 12/PP | Additive manufacturing |
| **2016** | Sean Greene et al. | Prosthetic hand | ABS/PLA | Additive manufacturing |
| **2017** | B. Szostakowski et al. | Prosthetic parts | Plaster of Paris | Traditional |
| **2017** | Jelle ten Kate et al. | Limb prosthetic | ABS/PLA | 3D printing |
| **2017** | Stephen P. Hawes et al. | Prosthetic hand | ABS/TPU | Additive manufacturing |
| **2017** | Aleksandra Radosh et al. | Prosthetic hand | ABS | FDM |
| **2017** | Meenu Garg et al. | Prosthetic finger | Silicones | Traditional method |
| **2017** | Breanna J. Rhyne et al. | Transhumeral Prosthetic | ABS/Polyetherimide | Additive manufacturing |
| **2017** | Bence Rochlitz et al | Foot Prosthetic | ABS | FDM |
| **2017** | Zhen Tao et al. | Prosthetic foot | PLA | FDM |
| **2017** | Pierre cherelle et al. | Bionic feet | N.A. | Rapid Tooling |
| **2018** | Juan Cuellar et al. | Prosthetic hands | Polylactic acid(PLA) | 3D printing |
| **2018** | V.Upender et al. | Prosthetic Runner Blade | 3D Printable materials | 3D printing |
| **2018** | Karthik Tappa et al | Customized implants | Biomaterials | Bioprinting |
| **2018** | Daniel-Alexander Turk et al. | Prosthetic | Carbon fiber reinforced polymers | AM & Autoclave layup process |
| **2019** | Alexander Geierlehner et al. | Medical devices | Biomaterials | 3D printing |
| **2019** | Marcel Heinrich et al. | Biomedical elements | Biomaterials | 4D Bioprinting |
| **2019** | Farah Alkhatib et al. | Prosthetic hand | ABS/PLA | 3D printing |
| **2019** | Gustavo Vargas Da Silva Salomão et al. | Dental implants | Cement | Traditional |
| **2020** | Jawad K Oleiwi et al. | Prosthetic feet | Composite | Traditional |
| **2020** | Kiwon Park et al | Motorized Prosthetic leg | Aluminum alloy/ plastic nylon | 3D printing |
| **2020** | Afrooz Javanmard et al. | Nasal prosthetic | Plaster of Paris / Silicon | Traditional |
| **2021** | Pankaj Kumar et al. | Biomedical elements | Biomaterials | 3D printing |
| **2021** | M. Vignesh et al. | Biomedical implants | Biomaterials | 3D printing |
| **2021** | T.M.Balaramakrishnan et al. | Prosthetic feet | Hyper-elastic/ orthotropic and isotropic linear elastic | Finite element analysis |
| **2021** | Christophe Lecomte et al. | Variable stiffness foot | Composite | Traditional |
| **2022** | Amirreza Naseri et al. | hydraulic prosthetic foot | Carbon | Traditional |

| | | | | |
|---|---|---|---|---|
| **2022** | Vinay B.S et al. | Passive ankle-foot prosthetic | N.A. | Finite element analysis |
| **2022** | Hamad et al. | Prosthetic socket | Composites and thermoplastics | Traditional |
| **2022** | Kirsty A. McDonald et al. | Below-knee prosthetic | Composite/Spring steel | Traditional |
| **2022** | Timothy R. Dillingham et al. | Transfemoral Prosthetic | Composite/Steel | Injection moulding |
| **2022** | Yadong Yan et al | Prosthetic hand | Nylon | 3D printing |

This section briefly discusses the design and development of orthotic using traditional and AM processes. Traditional P&O device production techniques are still primarily manual and require the knowledge of an orthopaedic surgeon to generate high-quality goods. However, these production methods are often unpleasant for the patient.

FDM's ability to create complex products with high accuracy in a short period of time allows it to liberate the hands of engineers from a variety of occupations. While several authors have emphasised the benefits of 3D printing technology in the production of orthotic devices, few research have focused on the design of cervical orthotic devices. This might be due to the complexity of the orthotic device design and the lack of readily available off-the-shelf orthotic devices to meet the patient's needs. Table 2.2 summarizes studies on existing materials and production processes for AFOs, wrists, and other assistive devices.

Table 2.2: Work has been done on the materials and techniques currently utilised in AFOs, hand, wrist, and other assistive devices.

| Year | Author | Body Element | Material | Method |
|---|---|---|---|---|
| **2005** | Taeseung D. Yoo et al. | Wrist and knee braces | hyper-elastic materials | Surface parameterization |
| **2011** | Jain et al. | Ankle foot orthotic | N.A. | 3D virtual model |
| **2011** | Josep M. Font-Llagunes et al. | knee-ankle-foot orthotic | Thermoplastic Material | Design and simulation approach |
| **2014** | Paterson et al. | Wrist splints | ABS | Fused Deposition Modelling |
| **2015** | Bertram Stier et al | Ankle-foot orthotic | Carbon fiber reinforced composite | Finite Element Analysis |
| **2016** | Hamed Kalami et al. | Finger and Hand brace design | NinjaFlex and ABS | Bead-Based Deposition Processes |
| **2016** | Yuan Jin et al | Ankle foot orthotic | Thermoplastic Material | Fused Deposition Modelling |
| **2016** | M. Walbran et al. | Ankle foot orthotic | ABS | 3D printing |
| **2017** | Deema totah et al. | Ankle-Foot Orthotic | Polyethylene (PE) | Optimization Algorithms |
| **2017** | Gabriele Baronio et al. | Hand orthotic | ABS | Fused Deposition Modelling |
| **2017** | Aitor Cazon et al. | wrist splint | Vero White Plus and Tango Black Plus | PolyJet AM |
| **2017** | Yong Ho Cha et al. | Ankle foot orthotics | Thermoplastic Material | Fused Deposition Modelling |
| **2018** | Bing Chen et al. | Ankle foot orthotic | Smart materials and/or shape memory polymers | 3D printing |
| **2019** | Alberto Dal Maso et al. | Ankle foot orthotics | PLA | 3D printing |
| **2019** | Cristiane Schmitz et al. | Wrist-Hand Orthotic | PETG | Fused Deposition Modelling |
| **2019** | Farah Shahar et al. | Ankle foot orthotic | Kenaf composites | 3D printing |
| **2019** | Keun Ho Lee et al. | Assistive device | PLA | 3D printing |
| **2019** | Daniel Harte MClinRes | Hand Orthotic | Thermoplastic Material | Traditional |
| **2019** | Kelly A. Jones et al. | radial and ulnar wrist orthotic | Thermoplastic Splinting Material | Traditional |
| **2020** | Chu et al. | Thumb orthotic | TPE | 3D printing |
| **2020** | L O'Brien et al. | Fingers | ABS | 3D printing |
| **2020** | Tribedi Sarma et al. | Ankle foot orthotics | PLA, PP, and ABS | 3D printing |
| **2020** | Sigal Portnoy MSc et al. | Finger orthotic | ABS | 3D printing |
| **2021** | Md. Hazrat Ali et al. | Ankle foot orthotic | Carbon Fiber/ Nylon 12 | Fused Deposition Modelling |
| **2021** | Deema Totah et al. | Ankle brace | Thermoplastic Material | 3D printing |
| **2021** | Joyce Wang et al. | Ankle foot orthotic | Traditional Material | Manual method |
| **2022** | N Eddison et al. | Ankle foot orthotic | Thermoplastic Material | Manual method |
| **2022** | Rajeev Ranjan et al. | Various field | 3D printing materials | 3D printing |
| **2022** | Lamis R. Darwish et al. | Medical and Dental | Biodegradable polymers | 3D printing/ 4D printing |

## 2.1 Finding from the Literature Review

Now a day's many prosthetics elements are available. According to a field survey, India has few K3 and K4 level foot manufacturing units. (In India, only K1 and K2 level foot manufacturing units exist.) The cost of K3 and K4 level foot devices in other nations is roughly ₹150,000 and ₹ 250,000, respectively. Cost-effective P&O elements made with economical technologies are desperately needed.

The prosthetics mechanism has numerous components, including the foot, socket, pylon, hydraulic unit, rotator, foot shell, knee joint, etc. However, the major focus of the study is on the design and development of novel prosthetic feet. Other prosthetic components, such as 30 mm tube pylons and adapter mechanisms, are available in standard sizes and may be attached to lower limb prosthetic endoskeleton systems.

Development of Orthotics elements using traditional manufacturing process takes long fabrication time and the laborious steps compare to the advanced manufacturing techniques. Now a days in the rehabilitation field, the use of additive manufacturing process has proven to speed up, facilitate and improve the quality of the customized products. This study, hopefully, offers to examine Prosthetics and Orthotics elements by taking into account varied material behavior, design/parameter consideration, customized design, and advanced production employing polymer/composite materials.

# 3. RESEARCH STATEMENT AND OBJECTIVES

## 3.1 Research Motivation

Due to population growth, poverty, illness and violent conflict, the number of people in need of rehabilitation services is increasing every year. Existing rehabilitation services are far from meeting this growing need. In low-income countries, the need for P & O elements is growing significantly. Although it is difficult to obtain numbers on the exact need for prosthetics and orthotics in low-income countries, it is estimated that 24 million people (0.5% of the total population) may need them. Due to illness, accidents, natural disasters, ongoing conflicts and their aftermath, demand is constantly increasing, growing faster than the expansion of P & O services in most countries.

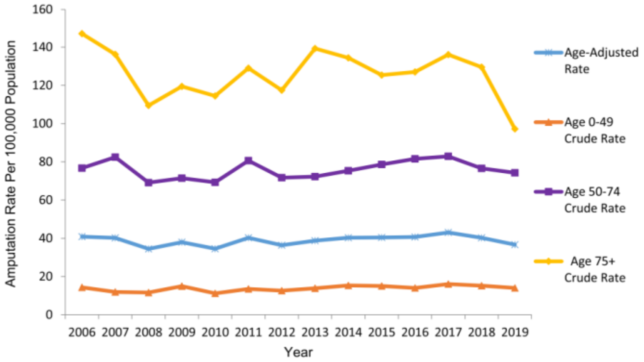



Figure 3.1: Age-adjusted and age-stratified crude amputation rates by year (Essien, Kopriva, Linassi, & Zucker-Levin, 2022)

P & O facilities are available in all countries, but services often do not meet the needs, both quantitatively and qualitatively. The majority of low-income countries have too few P & O facilities, too centralized, and too little production to meet demand. According to the World Health Organization, perhaps 5% of people who need assistive devices can use them. The P & O techniques used are not always appropriate, the quality of the equipment is often poor, and the number and qualifications of staff are not sufficient to meet the needs.

Because the human body varies over time owing to changes in development and weight, the prosthetic must be replaced and adjusted on a regular basis. This means that the prosthetic may not be usable for long periods of time. If the materials used are expensive, the need for this constant change or adjustment can be high. For overcoming poor functionality and controllability of previous prosthetic devices, biomimetic approach has appeared as a suitable for considering novel forms and functions closer to biological models.

Ongoing research in the field of bioengineering has improved a model of a prosthetic that closely reproduces the functioning of a real biological modal by improving the safety and accessibility of prosthetic limb manufacturing. The study's findings are based on the compatibility of current and projected material characteristics, helping to provide more cost-effective and environmentally friendly alternatives while maintaining the properties required for prosthetic devices. This outcome is likely to assist patients and carriers who lack this important skill to live independently at a young age.

However, very few studies are dedicated to investigating the optimization of biomimetic structural design. Still, there is a gap in dependencies of process parameters on design requirements and material performance. Some of the complex analysis and manufacturing procedures should also be considered, taking into account the combination of complex loads and the maximum factor of safety subject to design criteria. Further mechanical and biocompatibility testing, as well as complete economic analysis are needed. Therefore, the biomaterial used as an alternative must function in the same way. Developing country like India alone reports of more than 0.5 million amputees and figure as large as 2350 is added about every year. According to the World Health Organization, India has the greatest number of road accidents in the world.

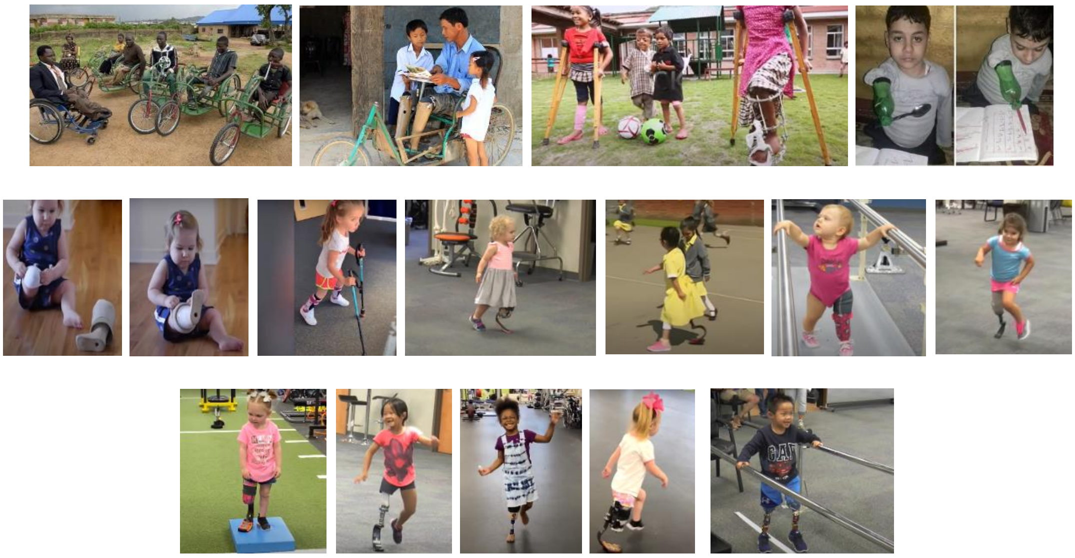


Figure 3.2: Human prosthetic and orthotic elements

## 3.2 Problem Definition

India has the largest number of young traumatic Amputee population of the world. As India being a developing country, the highest number of prosthetic/ Aids & appliances fitting are done free of cost through various Schemes of Government of India like ADIP/ Sarwa Sikha Abhiyaan/ Assistive schemes/CSR. National Institutes/ State Government Centers/DDRC/ Charitable Institutions/ NGOs play also a major role. Also there are Private Clinics/ Multi-National Companies in the country only few can afford and make use of their availability.

Because of variations in growth and weight, the human body changes with time, it is necessary to **replace and adjust** the P&O on a regular basis. This means that the P&O elements may not be usable for long periods of time. If the materials used are **expensive,** the need for this constant change or adaptation can be high.

However, very few studies are dedicated to investigating the optimization of biomimetic structural design. Still, there is a gap in dependencies of process parameters on **design requirements** and **material performance**. Some **complex manufacturing** and **analysis processes** also need to be considered for the maximum factor of safety according to complex load combinations and structural design criteria.

Table 3.1: Applicability of manufacturing process for various engineering materials

| Basic Category of Materials | Primary forming processes (Additive) | | Deforming processes (Formative) | | Material Removal Processes(Subtractive) | | Joining Process (Consolidation) | | Property changing processes |
|---|---|---|---|---|---|---|---|---|---|
| | Traditional | Advanced | Traditional | Advanced | Traditional | Advanced | Traditional | Advanced | Traditional |
| Metals | A | B* | A | A | A | A | A | A | A |
| Alloys | A | B* | A | A | A | A | A | A | A |
| Polymers | A | A | B | B | B | A | B | B | C |
| Ceramics | A | C | C | C | B | A | B | C | C |
| Composites | A | C | C | C | B | A | B | B | C |

The above table 3.1 gives information about applicability of different manufacturing process to different types of Engineering Materials. Here we can see A Means Widely Used, B : Not Frequently Used, C : Not Used, * : Under Research Stage. Now regarding polymer only **Property changing processes, Heat Treatment Process** is not very common for polymer. Rest all A & B. So this table gives you an overview of the process that are dedicated for Processing of Polymer. Now for Composite no of 'c' are there. Only two process are widely used for Composite. Rest are not frequently used or under the research stage. Therefore the topic becomes even more important as engineer that we should know that what are the processes that are being used for polymer based composite.

Therefore, cost-efficient prosthetic elements which are created using **Economical technology** are significantly needed. Hopefully, this study proposes to investigate Prosthetics and Orthotics elements by considering different material behaviour, design/parameter consideration, customised design and advance manufacturing using polymer/composite. So to overcome such problems and limitations, the research area will be cover on the topic entitled *"Investigations on Prosthetics / Orthotics elements developed from polymers and its composites".*

### 3.3 Need of Study

The highest amputee population are of lower limbs where transtibial /Below Knee are more in numbers. Most amputees in India are K3 level ambulator with prosthetic, where they constantly walk on uneven terrain. Here is the need for low cost multi-axial prosthetic foot to negotiate farm land/staircases/ ramps/ uneven road surface.

Based on the field survey, India does not have any K3 and K4 level of foot manufacturing unit widely. (India has only K1 and K2 level foot manufacturing unit). The cost of K3 and K4 level foot devices which are available in other countries are approximately 1, 50,000 ₹ and 2, 50,000 ₹ respectively.

Multiaxial foot-ankle mechanism is designed in such a way that it will be fitted on Lower limb prosthetic endoskeleton system with 30 mm tube pylon and adapter worldwide. There is a scope of development of Prosthetics / Orthotics through latest advanced manufacturing technique e.g. Additive manufacturing, CNC Machines, etc.

Optimization and parametric study in terms of dimensional of Prosthetics / Orthotics with a combination of various materials is not found adequately in literature. For a Prosthetic foot design it should be light in weight so that it can mimic maximum motions as of anatomical foot.

### 3.4 Research Objective

Various methods have been proposed to overcome the difficulties faced by early researchers and introduce new types of techniques. Therefore, this research proposes new materials that are cheaper but retain the properties required in the medical field.

The objectives of the present research are:

- To investigate patient's specific needs for prosthetics and orthotics as per requirements.
- To carry out a patient survey for obtaining basic information regarding the use of P&O elements.
- To create a P&O model using various modeling tools.
- To adopt suitable parameters for the development of P&O elements for analysis purpose.
- To evaluate P&O elements utilizing a variety of computational software tools.
- To highlight and project polymers/composite as a material for development of various P&O elements.
- To develop a simplified lightweight P&O elements.
- To adopt suitable advance manufacturing techniques for the development of tailor-made P&O elements.
- To conduct patient testing for the evaluation of the performance of the Novel prosthetic foot.

## 4. HUMAN BODY ANTHROPOMETRY

The biomechanical model of the human body is used to determine the moments and forces acting on joints as shown in figure 4.1. In biomechanics, the body segment parameters are of particular importance. To solve biomechanical problems, four essential body segment data are required: length, mass, centre of mass, and radius of gyration.

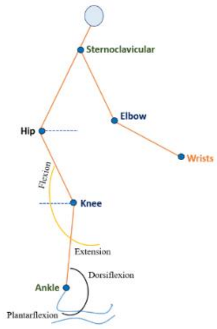



Figure 4.1: Link segment model

The most essential body dimension is the length of the segments among each joints. A set of typical segment lengths expressed in terms of body height, which is illustrated in figure 4.2 (Drillis & Contini, 1966).

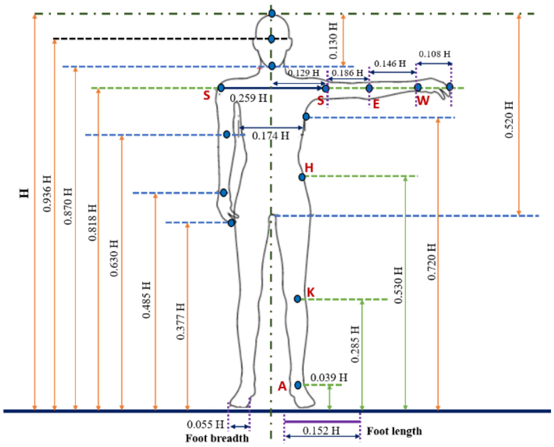



Figure 4.2: Anatomical structures length as a proportion of total body height H

## 4.1 Forces and moments in shoulder joint joints

To demonstrate the distinction between joint force and inter-segment force, examine the forces at the shoulder joint when the arm is stretched out straight to the side, as illustrated in figure 4.3. The arm has a total mass of 4.0 kg, with the centre of mass placed at the shoulder joint.

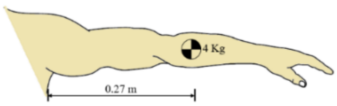



Figure 4.3: Arm held out straight to the side

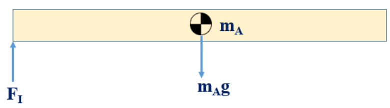



Figure 4.4: Free body diagram of arm

Vertical components are added together, with upwards regarded as positive.

$$\sum Fv = F_I - m_A g = 0 \qquad \ldots\ldots\ldots\ldots\ldots\ldots\ldots \text{(Eqn. 4.1)}$$

Where; $F_I$ is the inter-segment force at the shoulder joint; $M_A$ is the mass of the whole arm (4.0 kg), and g is the acceleration due to gravity (10 m/s).

Thus the inter-segment force at the shoulder joint can be calculated by;

$$F_I = m_A g \qquad \ldots\ldots\ldots\ldots\ldots\ldots\ldots \text{(Eqn. 4.2)}$$

$F_I = 4 * 10 = 40$ N

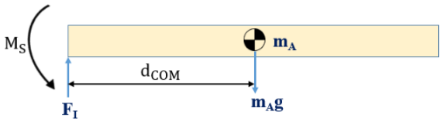



Figure 4.5: Free body diagram of arm including moments

Thus, the times about the shoulder joint are added together.

$$\sum M = M_S - m_A g * d = 0 \quad \text{……………………. (Eqn. 4.3)}$$

$$M_S = m_A g * d$$

$$M_S = 4 * 10 * 0.27 = 10.8 \text{ N.m}$$

Where: $M_S$ is the moment around the shoulder joint, and d is the distance from the shoulder joint.

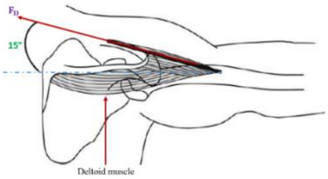



Figure 4.6: Deltoid muscle force

As a result, to maintain the arm segment in place, a moment of magnitude 10.8 Nm is required. This moment is caused by internal forces created by muscle action and ligaments. We will assume that the moment is exclusively produced by the deltoid muscle, which is inserted 7 cm distal and 1 cm superior to the shoulder joint centre and applies a force at 15 degrees to the arm segment as shown in figure 4.7.

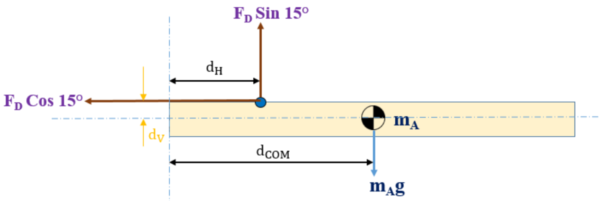



Figure 4.7: FBD representing forces generating moments near the centre of the shoulder joint

Using rotational equilibrium at the shoulder joint's axis;

$$\sum M = F_H d_V + F_V d_H - m_A g\, d_{COM} \quad \text{……………………. (Eqn. 4.4)}$$

Where: $F_H$ is the deltoid muscle's horizontal component of force; $d_V$ is the deltoid muscle's insertion's vertical displacement with respect to the shoulder joint; $F_V$ is the deltoid muscle's vertical component of force; and $D_H$ is the deltoid muscle's horizontal displacement with respect to the shoulder joint.

$$F_D \text{Cos } 15° d_V + F_D \text{Sin } 15° d_H - m_A g\, d_{COM} = 0$$

$$F_D (\text{Cos } 15° d_V + \text{Sin } 15° d_H) - m_A g\, d_{COM} = 0$$

$$F_D = m_A g\, d_{COM} / (\text{Cos } 15° d_V + \text{Sin } 15° d_H)$$

$$= (4*10*0.27) / (\text{Cos } 15° * 0.01 + \text{Sin } 15° * 0.07)$$

$$= 10.8 / (0\ 0096593 + 0.018117) = 389 \text{ N}$$

The magnitude of the components is calculated as follows:

$$F_H = F_D \cos 15° = 389 * \cos 15° = 376 \text{ N}$$

$$F_V = F_D \sin 15° = 389 * \sin 15° = 101 \text{ N}$$

To maintain the arm segment in rotational equilibrium, the force exerted by the deltoid muscle must be around 390 N.

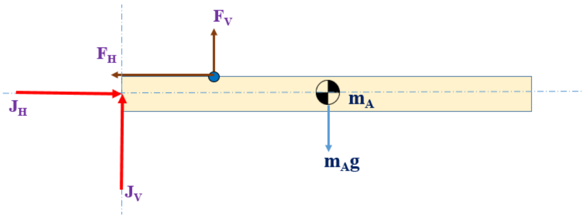



Figure 4.8: FBD includes components of deltoid muscle force and joint force

Figure 4.8 shows a FBD of an arm segment with vertical and horizontal deltoid muscle force components. To counterbalance the pressures operating on the arm segment and keep it in static equilibrium, the joint force must include both a horizontal and a vertical component.

Adding up the horizontal forces:

$$\Sigma F_H = J_H - F_H = 0 \quad \text{…….…………… (Eqn. 4.5)}$$

Where: $J_H$ is the combined force's horizontal component.

$$J_H = F_H = 376 \text{ N}$$

Adding up the vertical forces:

$$\Sigma F_V = J_V + F_V - m_Ag = 0 \quad \text{…….…………… (Eqn. 4.6)}$$

$$J_V = -F_V + m_Ag = -101 + 4.0 \times 10 = -61 \text{ N}$$

Now Pythagoras' theorem may be used to determine the size of the joint force:

$$J = \sqrt{J_H^2 + J_V^2} \quad \text{…………..…. (Eqn. 4.7)}$$

$$J = \sqrt{376^2 + 61^2}$$

Calculating the joint force's angle θ with respect to the horizontal,

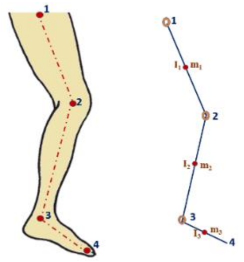
$$\tan\theta = J_V / J_H \quad \text{…….…………… (Eqn. 4.8)}$$

$$\theta = 9.2°$$

As a result, the shoulder joint force operating on the arm segment is 380 N in a 9.2° relative to horizontal plane. When the joint force is evaluated to the inter-segment force of 40 N acting vertically, it is evident that there is a significant difference.

### 4.2 Forces and torque in leg joints

Mathematical models of physical and biological systems are used to get force data and analysis on the human leg. In a link segment model, the forces operating on a body segment may be divided into three categories: inertia forces, internal forces, and external forces.



(a) Anatomical model (b) Link-segment model

Figure 4.9: Relationship between anatomical and link-segment model

If the body is in rotational motion, a different circumstance must be applied to the forces. In rotational equilibrium, the object either does not rotate or rotates at a steady pace.

Considering the rigid rod in figure 4.10, which itself is pivoted at point X and possesses the ability to spin in the plane of the paper. At $r_1$ and $r_2$ distances from the pivot and perpendicular to the rod, $F_1$ and $F_2$ forces are imparted to the rod within the the paper's plane. To maintain translational equilibrium, the pivot imparts the appropriate force $F_3$ to the rod. If $F_1$ and $F_2$ are both perpendicular to the rod, they are said to be parallel. Additionally, they must be parallel to $F_3$, as translational equilibrium demands that $F_3$ equals $F_1 + F_2$.

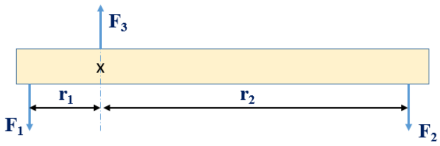
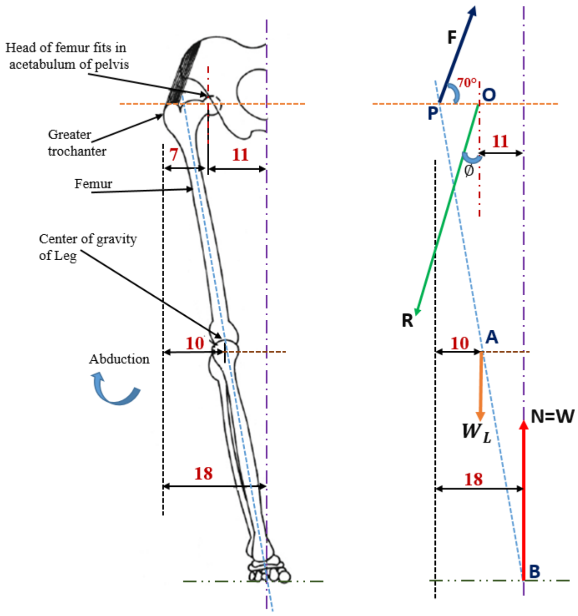



Figure 4.10: A rigid rod that may freely spin around a center at position X

The rod is in equilibrium state if the algebraic sum of all torques is zero:

$$\sum_i \tau_i = \sum_i r_i F_i = 0. \qquad \text{(Eqn. 4.9)}$$

The force analysis for a person standing with one leg is mentioned in figure. The weight of the person (W) is equal to the normal force (N) of the floor on the foot, which operates under the centre of gravity for the entire body of the person. At a 70° appropriate angle, the greater trochanter is subjected to the resultant force (F) of the abductor muscles. The greater trochanter is roughly 18 cm from the midline, approximately 10 cm horizontally from the leg's centre of mass, and approximately 7 cm vertically from the centre of the femur's head in an average person. As seen in the figure 4.11 (b), the weight of the leg $W_L$ is typically approximately 1/7 of the person's weight (Hobbie & Roth, 2007) (Lunn, Lampropoulos, & Stewart, 2016).




(a) Human leg anatomy (b) F.B.D. of force acting on leg

Figure 4.11: Human leg anatomy with force analysis

Where F represents the net force of the abductor muscles acting on the greater trochanter, R represents the force of the acetabulum acting on the head of the femur, N represents the upward force of the floor acting on the bottom of the foot, and $W_L$ represents the weight of the leg acting vertically downward at the leg's centre of gravity ($W_L \approx W/7$).

If a person mass 80 kg, the weight of the leg is approximately 784.5 N.

$$W_L = W/7 = 112.07\ N$$

Because the person is stationary, the vertical and horizontal elements of the forces, as well as the total torque, are all equal to zero.

$$\sum F_H = 0\ ;\ \sum F_V = 0; \sum \tau = 0$$

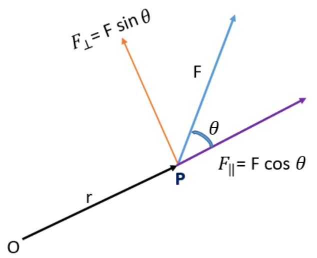



Figure 4.12: An element at point P is subjected to a force F

In figure, an element is allowed to spin around point O. Although it applies in any direction at point P, force F, which is positioned in the plane of the paper. The planes of the paper is determined by the vectors r and F if they are not parallel.

The horizontal components of the forces are:

$$\sum F_H = F\cos(70°) - R_H \quad \text{………..…. (Eqn. 4.10)}$$

The forces' vertical components are:

$$\sum F_V = F\sin(70°) - R_V - \frac{W}{7} + W \quad \text{…………..…. (Eqn. 4.11)}$$

$$\sum \tau = -F\sin(70°) * 7 - \left(\frac{W}{7}\right) * (10-7) + W * (18-7) \quad \text{…………..…. (Eqn. 4.12)}$$

$$6.57\ F = 10.57W$$

$$F = 1.6\ W \quad \text{…………..…. (Eqn. 4.13)}$$

Now, $R_H$ and $R_V$ may be calculated using Equations 4.10 and 4.11.

$$R_H = F\cos(70°) = 1.6\ W\ (0.342) = 0.55\ W$$

$$R_V = F\sin(70°) + \frac{6}{7}W = 1.6\ W\ (0.94) + 0.86\ W = 2.36\ W$$

$$R = \sqrt{R_H^2 + R_V^2} = 2.4\ W \quad \text{…………..…. (Eqn. 4.14)}$$

The angle ∅ is calculated from: tan(∅) = $R_H/R_V$ and is found to be:

$$\boldsymbol{\emptyset = 13°}$$

The solution to all of these equations is:

F = 1.6 W

R = 2.4 W

If the person with a mass 80 Kg has a weight of about 784.5 N then force acting on greater trochanter of femur and reaction force acting at Head of femur fits in acetabulum of pelvis is calculated from above equations.

F = 1.6 W = 1.6 * 784.5 = 1255.2 N

R= 2.4 W= 2.4 * 784.5 = 1882.8 N

## 5. DESIGN & SIMULATION APPROACH OF PROSTHETIC FOOT

Design thinking is a field that combines designer sensibility and approaches with what is technically achievable and what viable business tactics may convert into customer value and market potential (Tschimmel, 2012). The detail design and development process of the prosthetic elements are mentioned in the below figure 5.1. This section includes research, analysis, and a complete understanding of the end user (Razzouk & Shute, 2012).

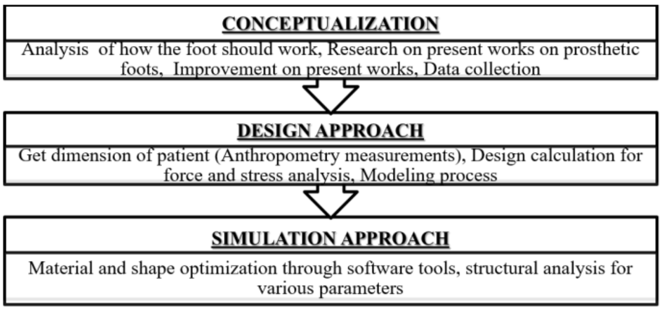



Figure 5.1: Design and simulation flow chart

### 5.1 Participatory Approach

The purpose of this study is to collect information about the current model used by patients. Both online surveys and face-to-face interviews were conducted to collect data necessary for the study. Patient survey was conducted as illustrated in figure 5.2 obtain background information regarding the use of P&O elements during the visit at Jaipur foot camp, valsad on 9th January 2020.

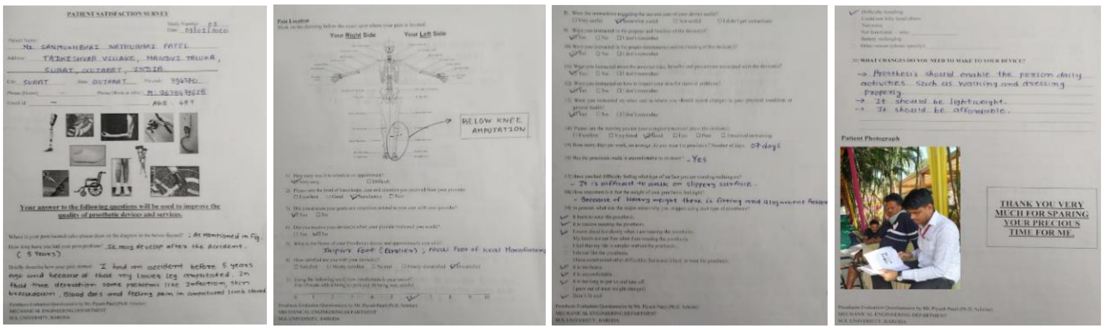



Figure 5.2: Patients Feedback form 1

However, in many countries components are still imported, especially when it comes to designed and finished prosthetic. Hopefully, this study proposes to fill this gap by showing alternatives for making much cheaper prosthetic. Therefore, cheap prosthetic elements as well as other devices (figure 5.3) manufactured with economical technology, are certainly in great demand.

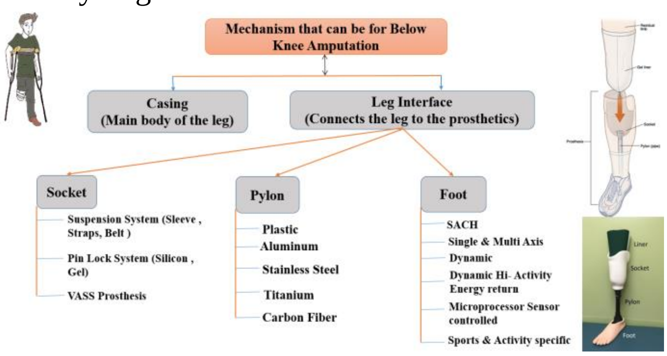



Figure 5.3: Below knee amputation mechanism

❖ Project scope

- Create several designs and analyze the optimal design using CAD program / stress analysis
- Developing a prototype
- To design analysis and testing of components which is light in weight, low cost, precisely manufactured and perfectly assemble to perform the intended function
- Create a design that appeals to many people
- Making a design of Prosthetic and Orthotics devices in such a way that manufacturing process will be simplified

❖ Realistic constraints

- Every amputation is different and a prosthetic may not be comfortable or suitable for everyone
- 3D printing is possible only on a narrow range of materials

The human factor plays a large role in developing devices suitable for use by patients. Human design focuses on creating designs that meet users' capabilities, constraints and requirements. For example, environmental factors and ergonomics have a huge influence on the design of human elements.

## 5.2 Alternative Prosthetic foot models design approaches

To connect people's demands (Resan, Ali, Hilli, & Ali, 2011) with what is technologically possible and what a workable business plan can address in terms of customer value and market potential, design thinking is a discipline (figure 5.4).

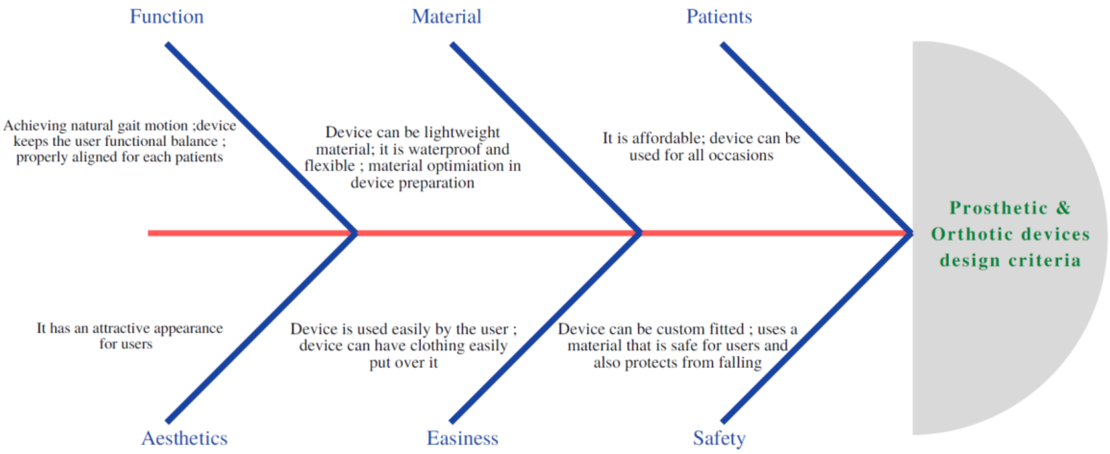



Figure 5.4: Prosthetic and Orthotic elements design criteria

Differently designed prosthetic foot are well recognized in the arts (Srikanth & Bharanidaran, 2017). The many conventional designs have attempted to address a number of prosthetic foot constraints. As a result, having a prosthetic foot that combined the stability benefits of a multi - axial dynamic foot with the energy storage characteristics of a good dynamic foot would be advantageous.

The purpose of the first utility model 1 and 2 is to improve the cushioning and shock absorption effect of the prosthetic foot on the ground during walking. Prosthetics CAD models are designed in "Autodesk Fusion 360" software as shown in figure 5.5 & 5.6.

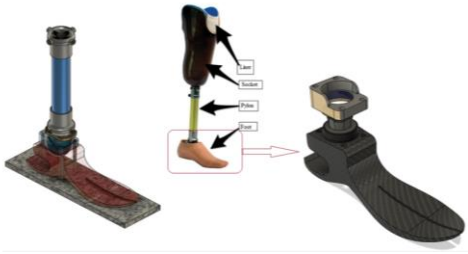


Figure 5.5: Prosthetic foot Model 1

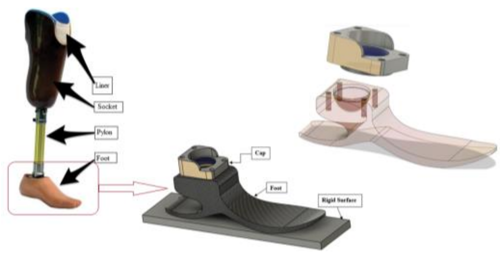


Figure 5.6: Prosthetic foot Model 2

The second alternative conceptual design model 3 and 4 are developed for reducing the maximum stress and for increasing the strain energy as shown in figure 5.7 & 5.8. In the design modification instead of a single unit structure, an extra plates are attached in the foot structure mechanism as described in figure. A block of rubber imparted some unique properties to the foot piece additionally enabling the amputee to squat.

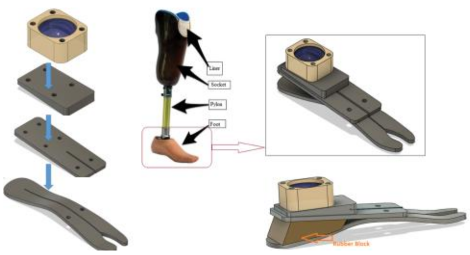


Figure 5.7: Prosthetic foot Model 3

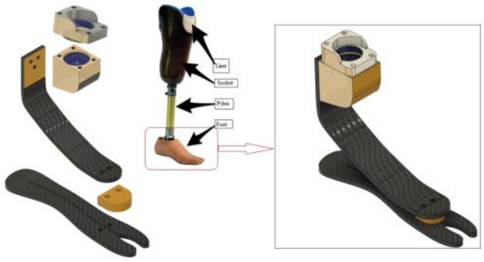


Figure 5.8: Prosthetic foot Model 4

The third alternative conceptual design model 5 and 6 are developed for high activity users (K4 Level) as shown in figure 5.9 & 5.10.

Figure 5.9: Prosthetic foot Model 5

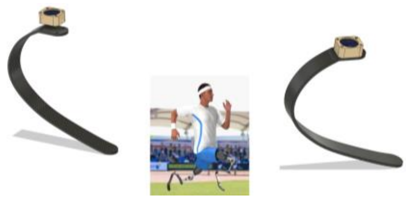
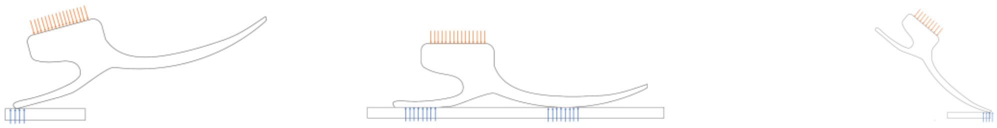


Figure 5.10: Prosthetic foot Model 6

Advanced prosthetic devices for running are usually a curved blade (Upender, Srikanth, Karthik, & Kumar, 2018) shape as shown in third alternative conceptual design models. This provides a nice balance of flexibility and strength to withstand high-impact activities like sprinting and jumping.

### 5.3 Simulation approach

The computer simulations were performed to determine the performance of the prosthetic model in the three major phases of the gait cycle as shown in figure 5.11. These simulated scenarios consisted of a heel strike, a stance phase, and a toe-off.



(a) Heel strike (b) Mid stance (c) Toe off

Figure 5.11: Prosthetic foot analysis

Finite Element Analysis (FEA) is further carried out discreetly, accounting three major phases the human foot undergoes during a gait cycle. The results for different stages in the methodology have been tabulated and discussed below in a chronological sequence. Initially the Heel strike simulation data results for prosthetic foot model 2 are mentioned with detail description. The FE static structural analysis is conducted on an ANSYS Workbench. On the basis of the geometry model (figure 5.12), an FE mesh model (figure 5.13) is built with ANSYS auto meshing techniques.

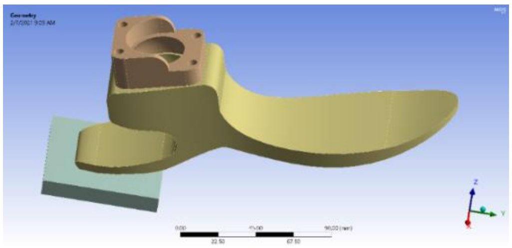


Figure 5.12: Prosthetic foot model 2 geometry during Heel strike situation

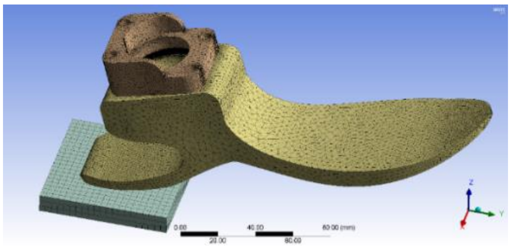


Figure 5.13: Prosthetic foot Mesh model 2 during Heel strike situation

The main elements of the prosthetic foot model assembly preparation are mounting bracket (Cap) and foot structure. The mounting bracket is made from delrin in all configuration of the prosthetic foot models. Frictionless contact between the base plate and the foot cover allowed the prosthetic to flex freely. The reaction forces in the fixed support at the proximal end of the prosthetic pylon are then determined.

Due to the low walking pace, only a static transfer without an inertial effect and the influence of gravity are considered; consequently, the fixed support reaction forces and the Ground Reaction Force (GRF) should be equal in size and opposing in orientation. In the case of the most weight bearing scenario, a vertical force of 1000 N is given to the foot (Omasta, Paloušek, Návrat, & Rosickỳ, 2012).

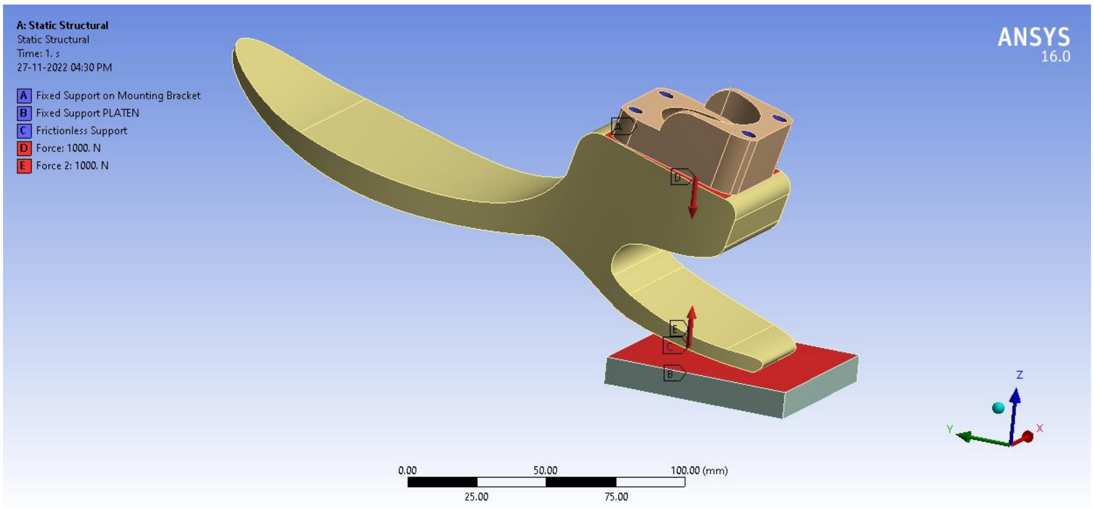



Figure 5.14: Static structural simulation of Prosthetic foot model 2 during Heel strike situation

Table 5.1: Heel strike analysis on Prosthetic foot model 2

| Sr no. | Materials | Total deformation (Hz) | Total deformation (mm) | Equivalent stress (MPa) | Strain energy (mJ) |
|---|---|---|---|---|---|
| 1 | ABS | 179.65 | 0.01028 | 8.0485 | 0.00098609 |
| 2 | ABS+PC PLASTIC | 178.19 | 0.009793 | 8.0528 | 0.00093959 |
| 3 | ACETAL RESIN | 169.89 | 0.0085314 | 8.0697 | 0.00082101 |
| 4 | CARBON FIBER | 213.57 | 0.002867 | 14.553 | 0.00028197 |
| 5 | NYLON 6/6 | 135.19 | 0.016631 | 7.9983 | 0.0015791 |
| 6 | PEEK | 203.18 | 0.006386 | 8.0444 | 0.000611 |
| 7 | PET | 174.16 | 0.0084673 | 8.09 | 0.0008177 |
| 8 | PLA | 196.7 | 0.007118 | 8.086 | 0.000687 |
| 9 | UHMW-PE | 595.85 | 0.002459 | 50.798 | 0.0018742 |

The findings of the mode shape analysis were obtained by modal analysis. The modal analysis results aided us in determining the natural frequency of the foot at various stages of the gait cycle. Total deformation, equivalent Von- Mises stress, and strain energy data for each step are detailed in the timeline below.

Simulation results data by considering the optimization in the material for the Prosthetic foot model 2 is mentioned below. As per the simulated data the UHMW-PE material is suitable for the preparation of the Prosthetic foot model 2 as per the applied loading situation in heel strike simulation.

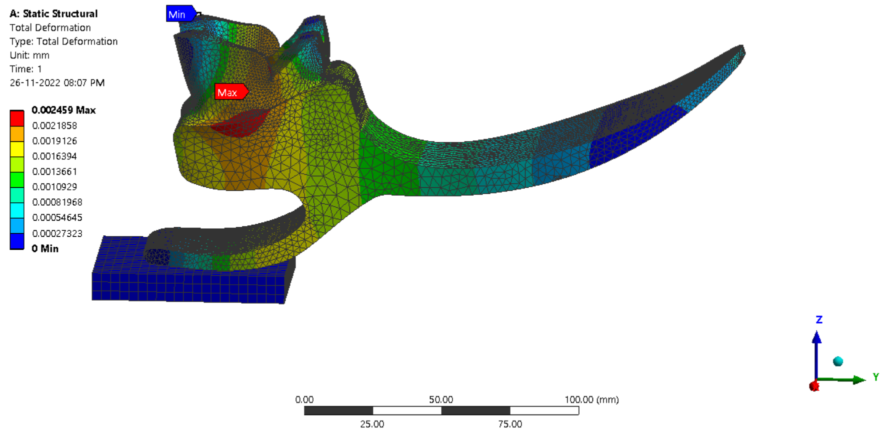



Figure 5.15: Total deformation in mm for Prosthetic foot model 2 during Heel strike simulation

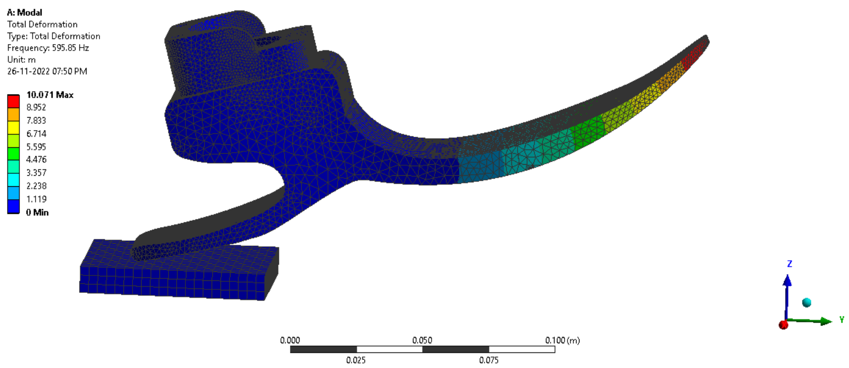



Figure 5.16: Total deformation in Hz for Prosthetic foot model 2 during Heel strike simulation

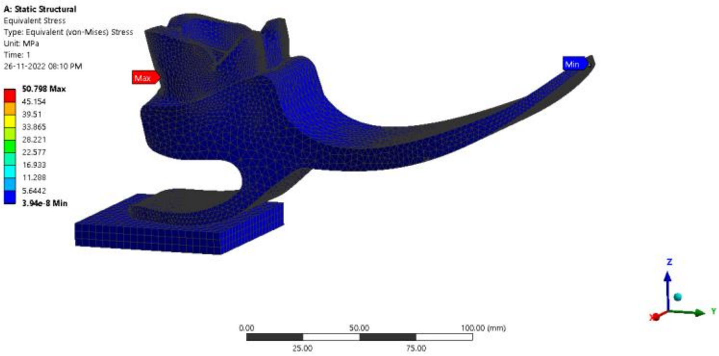



Figure 5.17: Equivalent stress for Prosthetic foot model 2 during Heel strike simulation

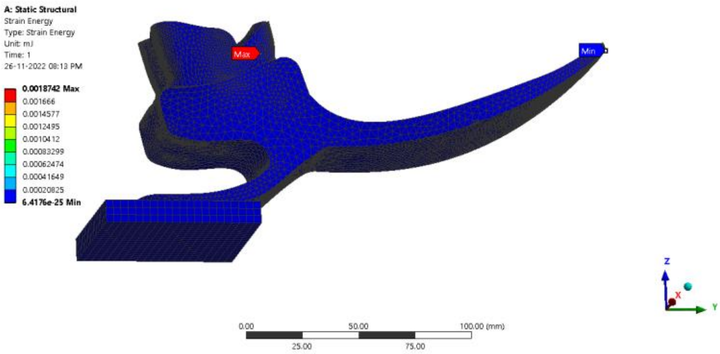



Figure 5.18: Strain energy for Prosthetic foot model 2 during Heel strike simulation

## 5.4 Simulation data summary for various prosthetic foot models

According to static structural and modal analysis of prosthetic foot model 2 for all phases (mid stance / heel strike / toe off), the conclusions are listed as follows;

- $1^{st}$ Natural frequency for all phase analysis (Midstance /Heel strike / Toe-off) is very large compare to the average human walking frequency of 2-3 Hz.
- As per different material analysis data;

**(a)** UHMW-PE material has the highest Natural frequency for all phase analyses. Natural frequency value for the $1^{st}$ mode in Midstance: 1363 Hz; Heel strike: 595.85 Hz and Toe-off: 1613.3 Hz.

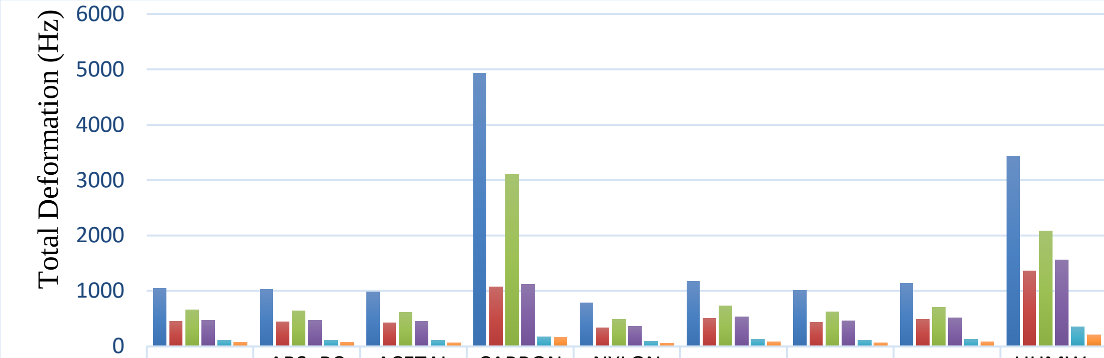
**(b)** UHMW-PE material has highest Strain energy in mJ (Heel strike: 0.001874; Toe-off: 0.00263; Midstance: 0.002472 )

**(c)** Carbon fiber material has the lowest deformation values compare to other materials in all Midstance (0.07392 mm) and Toe-off (0.0032 mm) phase analysis and for Heel strike (0.002459 mm) UHMW-PE material is suitable.

**(d)** PEEK, Nylon 6/6 and PET materials are suitable for the lowest average stress value for Midstance, Heel strike and Toe-off phase analyses.

Various parameters analysis is conducted onto the foot structure model for material optimization data as shown in tables. An element's frequency response is exclusively connected to its own attributes, such as its materials and density (Zhang, et al., 2019). Through modal analysis, the result shows that the natural frequency (1363 Hz) of the Model 2 is maximum for UHMW-PE material. So for the preparation of the foot structure we may select this material for the best performance of the prosthetic foot model.

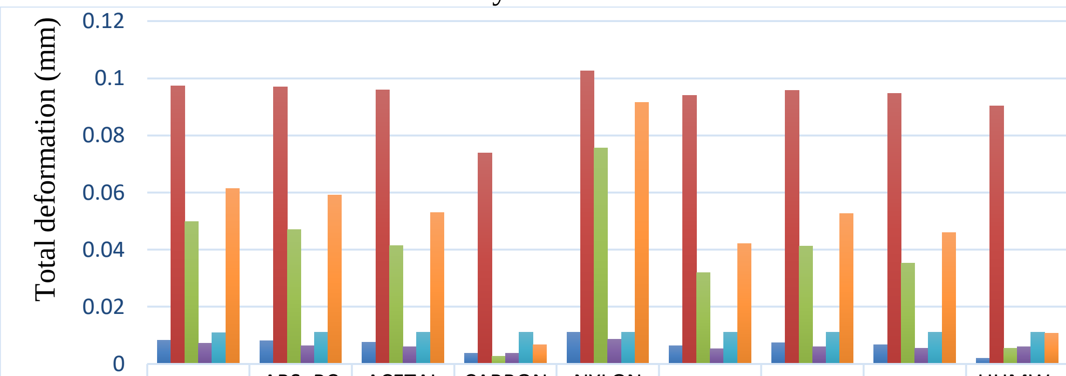
Table 5.2: Frequency analysis of various foot structure models




| | ABS | ABS+PC PLASTIC | ACETAL RESIN | CARBON FIBER | NYLON 6/6 | PEEK | PET | PLA | UHMW-PE |
|---|---|---|---|---|---|---|---|---|---|
| Model 1 | 1040.5 | 1031.9 | 983.41 | 4932.2 | 783.83 | 1176.4 | 1007.8 | 1138.1 | 3429.9 |
| Model 2 | 446.56 | 443.01 | 422.71 | 1078 | 335.28 | 504.95 | 433.79 | 489.83 | 1363 |
| Model 3 | 663.33 | 640.42 | 610.35 | 3103.1 | 486.45 | 730.23 | 625.46 | 706.4 | 2081.6 |
| Model 4 | 471.72 | 467.82 | 445.93 | 1119.5 | 363.27 | 526.14 | 456.88 | 511.9 | 1561.1 |
| Model 5 | 115.35 | 114.33 | 108.76 | 168 | 87.363 | 129.57 | 111.43 | 125.53 | 351.9 |
| Model 6 | 71.674 | 71.076 | 67.725 | 165.25 | 54.022 | 80.869 | 69.432 | 78.347 | 208.71 |

The total deformations by considering different materials of the models were calculated in Ansys software tools for various configuration models. The minimum total deformation was observed to be 0.002020 mm for UHMW-PE material for Prosthetic foot model 1 as mentioned in table 5.3.

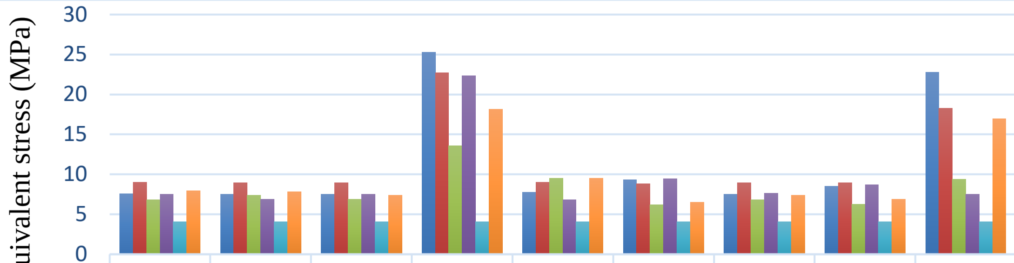
Table 5.3: Deflection analysis of various foot structure models




| | ABS | ABS+PC PLASTIC | ACETAL RESIN | CARBON FIBER | NYLON 6/6 | PEEK | PET | PLA | UHMW-PE |
|---|---|---|---|---|---|---|---|---|---|
| Model 1 | 0.0084 | 0.00817 | 0.00755 | 0.00371 | 0.01103 | 0.0064 | 0.007524 | 0.006817 | 0.0020207 |
| Model 2 | 0.09735 | 0.09693 | 0.09587 | 0.07392 | 0.10268 | 0.09409 | 0.0958 | 0.09468 | 0.090459 |
| Model 3 | 0.0499 | 0.04696 | 0.04152 | 0.00261 | 0.07561 | 0.03191 | 0.04131 | 0.035309 | 0.0056047 |
| Model 4 | 0.00724 | 0.0064 | 0.006 | 0.00377 | 0.0087 | 0.005243 | 0.005988 | 0.005521 | 0.005997 |
| Model 5 | 0.011 | 0.01109 | 0.011099 | 0.0111 | 0.01109 | 0.011102 | 0.01109 | 0.0111 | 0.011119 |
| Model 6 | 0.061478 | 0.05909 | 0.05297 | 0.006786 | 0.091491 | 0.04215 | 0.052739 | 0.045984 | 0.010744 |

Similarly Von-Mises stress was calculated by applying 1000 N for Midstance position of the prosthetic foot structure. The minimum stress was found to be 7.4765 MPa for PET material for prosthetic foot model 1.

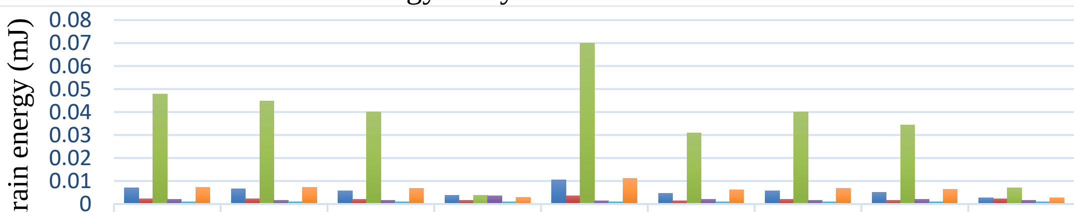
Table 5.4: Stress analysis of various foot structure models




| | ABS | ABS+PC PLASTIC | ACETAL RESIN | CARBON FIBER | NYLON 6/6 | PEEK | PET | PLA | UHMW-PE |
|---|---|---|---|---|---|---|---|---|---|
| Model 1 | 7.5696 | 7.5486 | 7.4864 | 25.289 | 7.7744 | 9.3241 | 7.4765 | 8.5308 | 22.761 |
| Model 2 | 8.9925 | 8.9863 | 8.9686 | 22.691 | 9.0049 | 8.8455 | 8.9871 | 8.9266 | 18.284 |
| Model 3 | 6.8566 | 7.375 | 6.8781 | 13.566 | 9.5337 | 6.1896 | 6.8672 | 6.2459 | 9.428 |
| Model 4 | 7.5111 | 6.9088 | 7.535 | 22.354 | 6.8246 | 9.4593 | 7.5968 | 8.724 | 7.526 |
| Model 5 | 4.0724 | 4.0724 | 4.0721 | 4.0705 | 4.0732 | 4.0716 | 4.0721 | 4.0718 | 4.075 |
| Model 6 | 7.9646 | 7.8205 | 7.4223 | 18.127 | 9.5511 | 6.5367 | 7.4208 | 6.8977 | 16.968 |

The FEM is a versatile numerical method which allows strain analyses of complex foot structures. Prosthetic feet that conserve energy through mid-stance movement and restore it throughout late-stance movement are known as energy-storing prosthetic feet. As per the analysis data the maximum strain energy was found to be 0.01049 mJ for Nylon 6/6 material in Model 1 as mentioned in Table 5.5.

Table 5.5: Strain Energy analysis of various foot structure models




| | ABS | ABS+PC PLASTIC | ACETAL RESIN | CARBON FIBER | NYLON 6/6 | PEEK | PET | PLA | UHMW-PE |
|---|---|---|---|---|---|---|---|---|---|
| Model 1 | 0.00694 | 0.0066 | 0.0059 | 0.00376 | 0.01049 | 0.0046 | 0.005896 | 0.005071 | 0.0027462 |
| Model 2 | 0.002324 | 0.002218 | 0.001946 | 0.001593 | 0.003685 | 0.001478 | 0.001933 | 0.00164 | 0.0024725 |
| Model 3 | 0.04786 | 0.04486 | 0.04001 | 0.003892 | 0.07011 | 0.03093 | 0.04003 | 0.03438 | 0.007146 |
| Model 4 | 0.0021 | 0.0016 | 0.001745 | 0.003536 | 0.0015 | 0.00204 | 0.0017546 | 0.001933 | 0.0017359 |
| Model 5 | 0.001078 | 0.001077 | 0.001076 | 0.001065 | 0.00108 | 0.001074 | 0.001076 | 0.001075 | 0.0010661 |
| Model 6 | 0.007344 | 0.007229 | 0.006896 | 0.002922 | 0.011318 | 0.0062 | 0.006861 | 0.0064496 | 0.002732 |

Table 5.6: Prosthetic foot model analysis data (Mid Stance Situation)

| **Sr no.** | **Effective Parameters** | **Desirable value** | **Prosthetic Foot Model 1** | **Prosthetic Foot Model 2** | **Prosthetic Foot Model 3** | **Prosthetic Foot Model 4** | **Prosthetic Foot Model 5** | **Prosthetic Foot Model 6** |
|---|---|---|---|---|---|---|---|---|
| | | | **Material (Value)** | **Material (Value)** | **Material (Value)** | **Material (Value)** | **Material (Value)** | **Material (Value)** |
| **1** | Total deformation (Hz) | Maximum | Carbon Fiber (4932.2 Hz) | UHMW-PE (1363 Hz) | Carbon Fiber (3103.1 Hz) | UHMW-PE (1561.1 Hz) | UHMW-PE (351.9 Hz) | UHMW-PE (208.71 Hz) |
| **2** | Total deformation (mm) | Minimum | UHMW-PE (0.002020 mm) | Carbon Fiber (0.07392 mm) | Carbon Fiber (0.00261 mm) | Carbon Fiber (0.00377 mm) | ABS (0.011 mm) | Carbon Fiber (0.00678 mm) |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3 | Strain energy (mJ) | Maximum | Nylon 6/6 (0.01049 mJ) | Nylon 6/6 (0.0036 mJ) | Nylon 6/6 (0.07011 mJ) | Carbon Fiber (0.003536 mJ) | Nylon 6/6 (0.00108 mJ) | Nylon 6/6 (0.011318 mJ) |
| 4 | Equivalent stress (MPa) | Minimum | PET (7.4765 MPa) | PEEK (8.8455 MPa) | PEEK (6.1896 MPa) | Nylon 6/6 (6.8246 MPa) | Carbon Fiber (4.0705 MPa) | PEEK (6.5367 MPa) |

This approach may be used in the prosthetic feet design phase to examine the behavior of a prosthetic foot across different walking circumstances.

**5.5 Design for manufacturing of the Prosthetic foot model**

The various configuration models of the prosthetic foot are designed and finally as per the simulation data multiaxial Prosthetic foot model is finalized for the manufacturing process. The present approach is based on the principles of Design for Assembly (DFA) and Design for Manufacturing (DFM), (Madu, 2022)where the foot structure is built as a single unit instead of multiple components and complicated structure used previously.

Figure 5.19 shows an exploded view of the elements of the multiaxial foot-ankle mechanism to understand the associated connection of the device. The main element of the multiaxial foot-ankle mechanism is human foot structure that is the base for the stability of the patients and better control in all terrain.

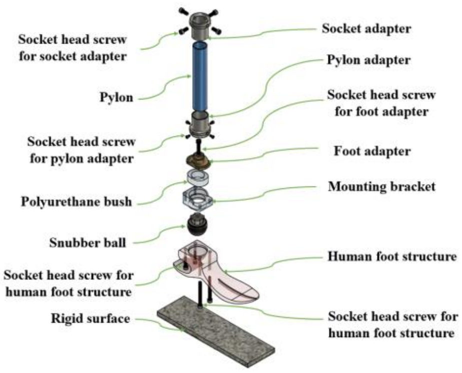



Figure 5.19: Exploded view of the multiaxial foot-ankle mechanism

Elements other than the present development like socket head screw for human foot structure, pylon, foot adapter, polyurethane bush, snubber ball, pylon adapter, socket adapter, socket head screw for foot adapter, socket head screw for pylon adapter, socket head screw for socket adapter are assembled to get the required functionality. The bottom rigid surface is just for alignment where the pylon should always be vertical to 90° for proper weight-bearing distribution. Figure 5.20 shows the assembled view of the multiaxial foot-ankle mechanism where all the required elements are connected in a sequence to the main human foot structure.


Figure 5.20: Assembly view of the multiaxial foot-ankle mechanism

The present design approach is associated with a multiaxial foot-ankle mechanism for prosthetic legs that allow the user to walk on steps or on uneven terrain without losing balance while maintaining stability of the structure. The present approach is made of lightweight material having a foot portion and an attached ankle portion capable of a desired degree of rotation with respect to the prosthetic frame. The approach is an optimization in the prosthetic foot structure design that resembles the human foot surface. The mechanism is designed in such a way that the foot structure will fit on the lower limb prosthetic endoskeleton system with 30 mm pylon tube. The novelty of the present approach lies in the design of the multiaxial foot structure that allows the desired rotation on its axis and offers the freedom to move in a medial-lateral direction.

## 6. DESIGN AND SIMULATION APPROACH OF ORTHOTICS ELEMENTS

This chapter covers the design, material optimization and development process for the Human wrist and foot brace using advanced manufacturing process. In addition, a minor attempt is made to optimize the design of the CP walker based on patient feedback and analysis is performed for the material optimization data for elements.

### 6.1 Human orthotic elements

Orthotic devices that allow people with disabilities or activity impairment to lead a healthier, active lifestyle while engaging in social and everyday activities (Shurr, Michael, & Cook, 2002). AFO materials (Shahar, et al., 2019)have steadily evolved through time from various materials as shown in Figure 6.1.


Figure 6.1: The evolution of AFO materials (Patel & Gohil, 2022)

The design and development of orthotic devices utilizing the conventional lamination moulding method are briefly described in this section. (Patel & Gohil, 2022). Because of the capacity to create complicated items with great accuracy in a short amount of time, Fused Disposition Modelling has freed the minds of professionals from many disciplines. The creation of novel materials and supporting technology like as 3D scanners (Farhan, Wang, Bray, Burns, & Cheng, 2021) has expanded the range of 3D printer uses. The advent of rapid prototyping (figure 6.2), in particular, is generating a transformation in rehabilitative technology by allowing for the creation of one-of-a-kind prosthetic, tissues, implantation, and other products.

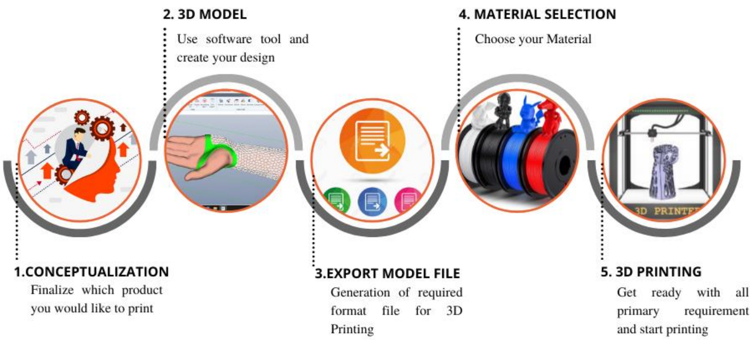



Figure 6.2: 3D printing process flow

Table 6.1: Assessment between traditional and AM process (Patel & Gohil, 2022)

| Parameters | Conventional Approach | AM |
|---|---|---|
| ***Producing period*** | Four weeks | One-Two days |
| ***Rate of production*** | Costly | Economical |
| ***Necessary labour skills*** | • Detail-oriented<br>• physical skill<br>• physical endurance<br>• Problem-solving abilities | • Operating and creating skills for 3D software |
| ***Steps in manufacturing*** | • Cast creation using landmark identification<br>• Cast correction<br>• Molding technique<br>• Trimming and cutting of edges | • 3D imaging<br>• Modelling<br>• 3D printing tool for slicing<br>• 3D Printing |

The creation and manufacturing process consists of four parts. The initial component of a 3D object of a person arm and ankle braces is scanned using a 3D scanner (Lochner, Huissoon, & Bedi, 2012). The second section covers modelling using the 3D programme "Autodesk Meshmixer." The third section discusses configuring the slicing programme with all the necessary settings, and the last section discusses utilizing AM to create personalized wrist and foot braces. (Patel & Gohil, 2022)

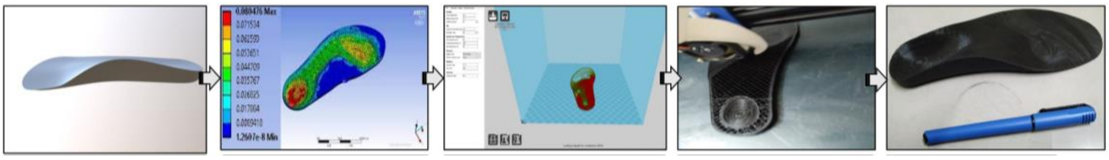


Figure 6.3: Design and development process of the Orthotics Foot Shell Model

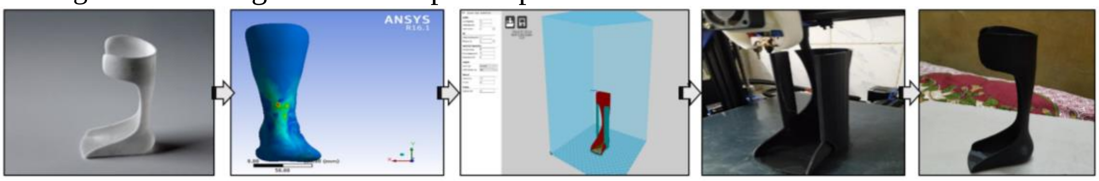



Figure 6.4: Design and development process of the Ankle Foot Orthotic Model

## 6.2 Result and Discussion for Orthotic elements

Rehabilitation procedures enable people to perform more effectively following an injury or sickness. The use of 3D printing in the manufacturing of medical devices has risen in prominence over the last several decades as the prospects for this technology have expanded significantly.

Individual Orthotic devices are traditionally created using plaster moulds, which necessitate many patient visits and demand a significant amount of labour and time to construct. When constructing an individual orthopaedic surgery utilizing current technology, the measures indicated in this report should be taken. The portable imaging system is easy to use that requires only one person and a computational systems. Because the scanner is portable, you are not need to be in a set working area. When the person is immobilized or unable to move, this is a significant improvement over the traditional plaster technique.  It is critical to collect the segments in the right format while creating an orthotic device. The scanned model cannot be used as a positive if it has flaws. No machining is required since the original model must be clean and precise. Editing a 3D scan model may result in a mismatch between the device's surface and the body's surface, resulting in incorrect device design. As a result, our primary focus is on the process of rapidly designing and constructing lightweight structural components while simplifying the production process for considering the above critical process data collection by proper practice to elimination the Errors.

### 6.3 Cerebral Palsy (CP) Walker

Cerebral Palsy is a type of disorder that involves movement and posture. Walking is more effortful for children with CP than their non-disabled peers due to weakness, lack of coordination between muscle groups, flexed posture, poor balance, and altered muscle tone. The Gross Motor Function Classification System (GMFCS) in the case of CP relies entirely on independent movement with a primary focus on sitting and mobility.

Users need access to adaptive hardware that meets specific requirements. All children are made up differently and have CP in different parts of their body. Therefore, there is a need for posterior pediatric walker that can adapt to the various needs of users. Both online surveys and face-to-face interviews (figure 6.5) were conducted to collect data necessary for the study (Susmartini, Herdiman, & Priadythama, 2021) (Sarker, Karim, Ahamed, Sultana, & Islam, 2020).

Figure 6.5: Patients using commercial walkers

User identification design requirements are met using questionnaires. The purpose of this study is to collect information on current pediatric walking aids used by children with CP, or recommended by pediatric therapists, in order to provide future pediatric walkers for children with CP (Rodríguez-Costa, et al., 2021) (George, Levin, & Ryan, 2020). The human factor plays a large role in developing devices suitable for use by children. Human Design focuses on creating designs that meet users' capabilities, constraints and requirements. For example, environmental factors and ergonomics have a huge influence on the design of human elements. This type of design is especially important for walkers to ensure that the child can use the device.

The design criteria parameters for a pediatric walker are based on device function, materials, patients, aesthetics, ease of use and safety as shown in below figure 6.6.

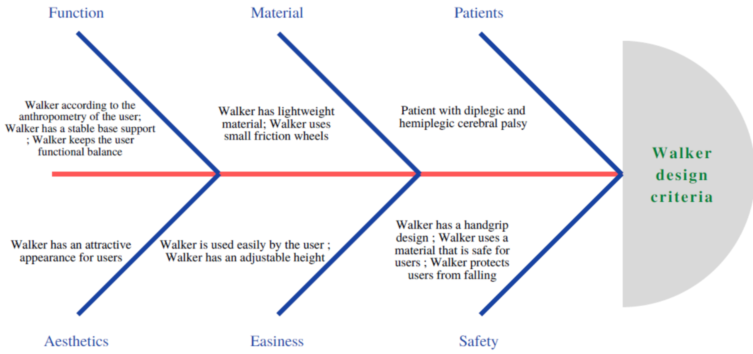



Figure 6.6: Walker design criteria (Lestari, Susmartini, & Herdiman, 2020)

The reliability and validity of the conclusions of the criteria presented in the questionnaire were checked. This is followed by an analysis and description of the design requirements for the pediatric walker.

## 6.4 Design and Simulation approach for CP walker

There are different types of pediatric walkers, but most of the products on the market cannot meet all of patient’s needs. However, this design ignores the rapid growth and typical activities of young children. A user's posture, mobility and sociability are essential factors in a child's development. Proper posture and mobility allow users to develop the skills necessary to walk independently of the walker (Decker, McMahon, Foley, & Nassar, 1919).

- Design approach

Our goal is to develop an adaptable, user-friendly and aesthetically pleasing pediatric walker for the physical and social development of children with CP (Anuar, Selvam, & Mahamud, 2016) (Ismail, 2012). By considering the normal height of the male person (1.763 m), other body elements dimensions are measured for the CP walker structure design as shown in figure 6.7 & 6.8 for standing and sitting position respectively.

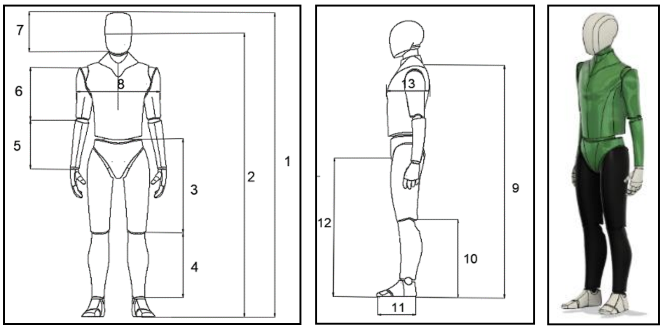



Figure A Figure B

Figure 6.7: Measurements in standing posture

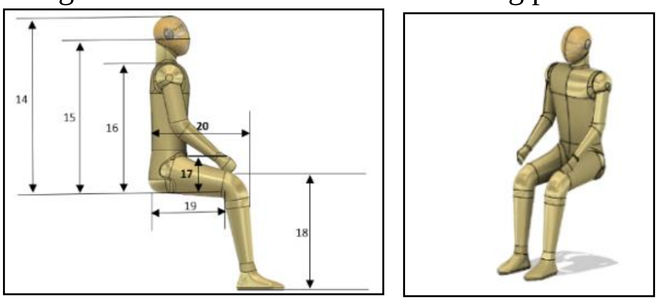



Figure C

Figure 6.8: Measurements in sitting posture

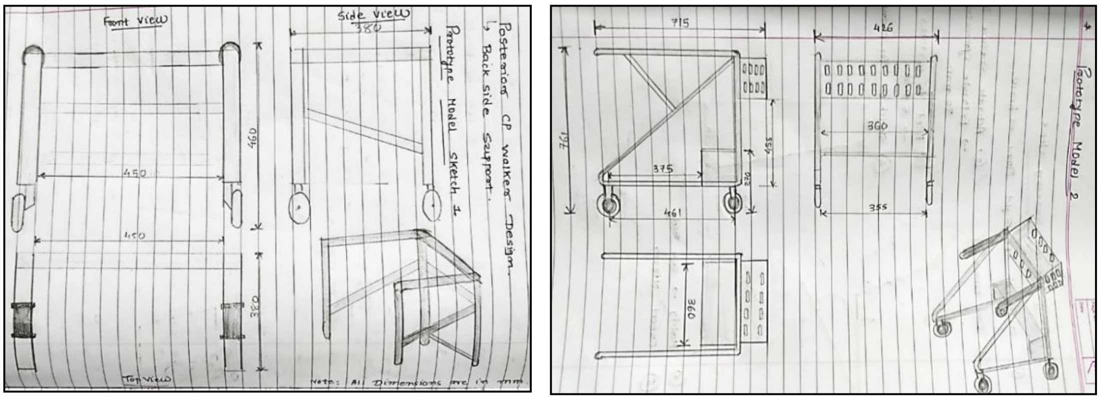
Table 6.2: Anthropometric Measurements (Farooqui & Shahu, 2016)

| Figure no. | Sr no. | Measurements | Human body key sizes (mm) |
|---|---|---|---|
| | | ***A. Measurements in Standing posture*** | |
| **Figure A** | 1 | Height | 1763 |
| | 2 | Eye height1 | 1647 |
| | 3 | Thigh length | 489 |
| | 4 | Calf length | 388 |
| | 5 | Lower arm length | 249 |
| | 6 | Fore arm length | 329 |

| | | | |
|---|---|---|---|
| | 7 | Head height | 234 |
| | 8 | Shoulder width | 453 |
| **Figure B** | 9 | Shoulder height 1 | 1436 |
| | 10 | Tibia height | 466 |
| | 11 | Foot length | 260 |
| | 12 | Perineum height | 830 |
| | 13 | Chest thick | 223 |
| | | ***B. Measurements in Sitting posture*** | |
| **Figure C** | 14 | Sit height | 954 |
| | 15 | Eye height 2 | 838 |
| | 16 | Shoulder height 2 | 628 |
| | 17 | Thigh thick | 137 |
| | 18 | Knee height | 518 |
| | 19 | Sit deep | 480 |
| | 20 | Arm knee distance | 582 |

Based on the design criteria (Wang, Dzul-Garcia, Bolding, & Raybon, 2019) and weaknesses of previous walker designs, a walker design that can meet the needs of the user has been created. One of the advantages of this walker design is that it keeps the user in balance and prevents the user from tipping over. The Walker trainer concept design is called the application of assistive technology (Bartlett, 2017).

The first design was all most similar to the existing design with four legs, four wheels and a rectangular structure surrounding the user. However, we realized that this design did not solve the volume problem and could provide too much mobility, thus being less advantageous and negatively impacting the user's posture. Conceptual designs are created, by traditional drawing, as shown in figure 6.9.




(a) Conceptual model 1 (b) conceptual model 2

Figure 6.9: CP walker prototype

The second design was an iteration of the first design with four legs type frame structure and four swivel wheels. A front swivel wheel provides mobility for the user and a rear wheel provides stability by limiting front wheel movement. The handle with grip controls the user's mobility provided by the rotating wheel. This design reduces the bulk of the device as it better fits the user. You can also adjust the walker as your child grows, including different height positions of foldable seat and frame structure.

The CP Walker CAD model was developed with “Autodesk fusion 360” software, and the process flow for the design and drawing of the main components is shown in the below figure 6.10 to figure 6.12.

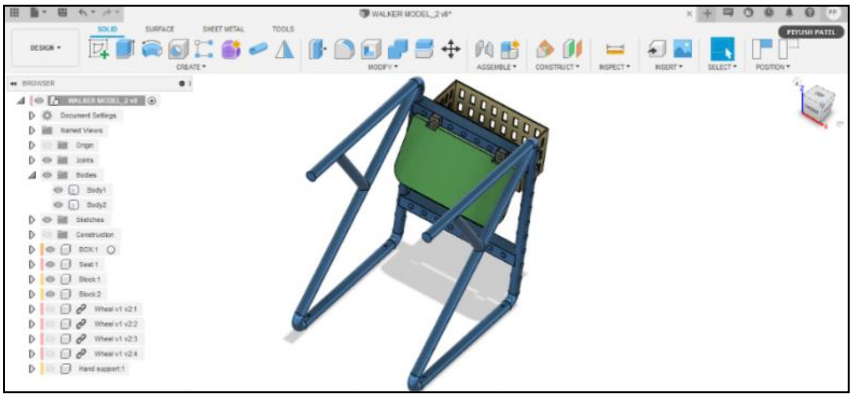


Figure 6.10: CP walker design process

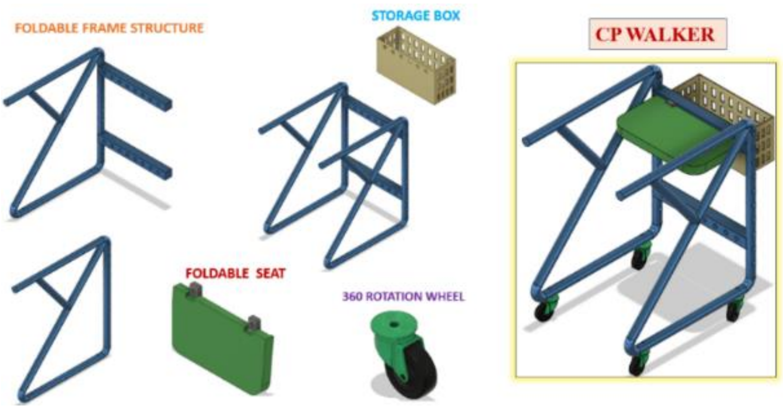



Figure 6.11: CP walker components

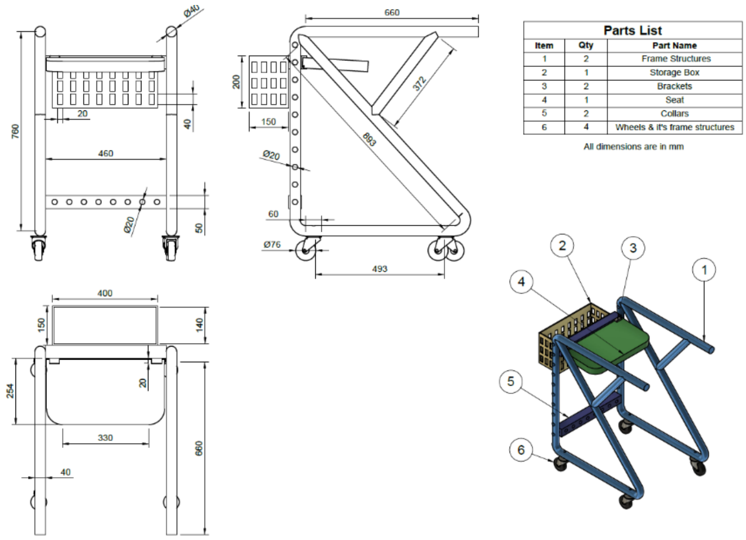



Figure 6.12: CAD drawing of CP walker model

Table 6.3: CP walker elements material details

| CP Walker Elements Details | |
|---|---|
| **A Group Elements list and Materials** | **B Group Elements (Variable Material)** |
| 1) Wheel :Polyethylene | 1) Collar : AL/SS/C/ABS/POM/PLA/PET/PEEK/N/Ti |
| 2) Wheel Frame Structure : Al | 2) Seat : AL/SS/C/ABS/POM/PLA/PET/PEEK/N/Ti |
| 3) Bracket : Al | 3) Frame : AL/SS/C/ABS/POM/PLA/PET/PEEK/N/Ti |
| 4) Storage Box : PLA | |

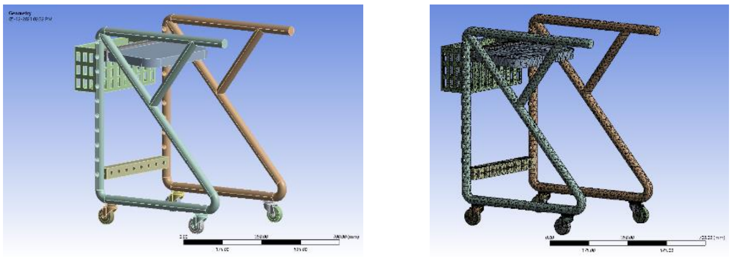
The developed walker has two configuration modes, standing mode and walking mode, as shown in the figure below 6.13 & 6.14.

Figure 6.13: Standing Position

Figure 6.14: Sitting position

- Simulation approach

Finite element modeling is used to develop a walker design and investigate its stability as shown in Figure 6.15. Static structural FEA is implemented to ensure that the walker is manufactured without any concern for the safety of the user.



(a) CP walker CAD geometry (b) CP walker mesh model

Figure 6.15: CP walker CAD model

The side frame is considered the most vulnerable because the normal force exerted by the user across the seat and the normal force exerted in the direction away from the wheel, causes bending stress. Group A components (wheel & its structure, bracket, and storage box) are prepared using common materials as shown in Table 6.3, and the evaluation of various materials for Group B components (frame, seat, collar) is analyzed through static structural modeling. Considering different load situations, such as 20 kg and 40 kg for children and 50 kg and 100 kg for adults, the total deformation and equivalent stresses are calculated for the standing and sitting positions, as shown in Tables 6.4 and 6.5.

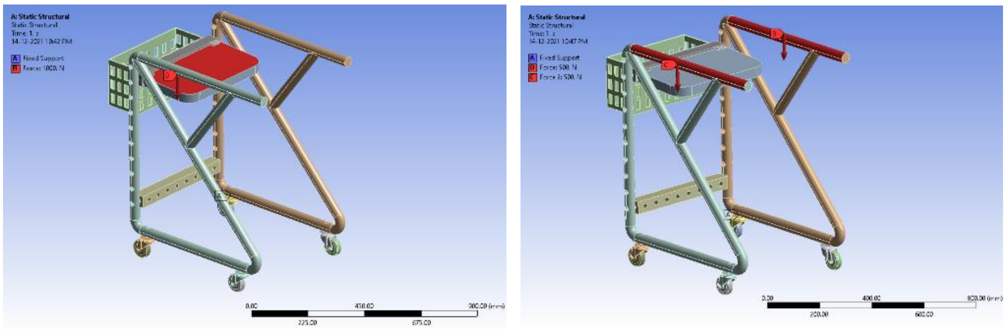
Table 6.4: CP walker material analysis data (Child weight)

| Sr no. | B Group parts (Frame, Seat, Collar) Material list | Child weight | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 20 kg | | | | 40 kg | | | |
| | | Sitting position | | Standing position | | Sitting position | | Standing position | |
| | | *Total deformation (mm)* | *Equivalent stress (MPa)* | *Total deformation (mm)* | *Equivalent stress (MPa)* | *Total deformation (mm)* | *Equivalent stress (MPa)* | *Total deformation (mm)* | *Equivalent stress (MPa)* |
| **1** | **S.S** | 0.02798 | 6.1617 | 0.037296 | 2.3656 | 0.05596 | 12.323 | 0.074591 | 4.7312 |
| **2** | **Aluminum** | 0.07229 | 5.5124 | 0.10083 | 2.3561 | 0.14458 | 11.025 | 0.20166 | 4.7123 |
| **3** | **Titanium** | 0.05428 | 5.7266 | 0.74509 | 2.3445 | 0.10857 | 11.453 | 0.14902 | 4.6891 |
| **4** | **Carbon Fiber** | 0.5816 | 8.6493 | 1.1105 | 4.1447 | 1.1623 | 17.299 | 2.2211 | 8.2893 |
| **5** | **PEEK** | 1.2068 | 10.831 | 1.8379 | 3.6804 | 2.4136 | 21.662 | 3.6757 | 7.3607 |
| **6** | **PLA** | 1.3439 | 11.141 | 2.052 | 3.7806 | 2.6877 | 22.282 | 4.1039 | 7.5612 |
| **7** | **PET** | 1.5905 | 11.63 | 2.4422 | 3.9087 | 3.181 | 23.26 | 4.8844 | 7.8174 |
| **8** | **Acetal Resin (POM)** | 1.6002 | 11.657 | 2.4565 | 3.9242 | 3.2004 | 23.314 | 4.913 | 7.8484 |
| **9** | **ABS+PC** | 1.8276 | 12.031 | 2.8184 | 4.0178 | 3.6552 | 24.061 | 5.6369 | 8.0356 |
| **10** | **Nylon 6/6** | 3.0493 | 13.274 | 4.7707 | 4.3559 | 6.0985 | 26.547 | 9.5415 | 8.7118 |

Table 6.5: CP walker material analysis data (Adult weight)

| Sr no. | B Group parts (Frame, Seat, Collar) Material list | Adult weight | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 50 kg | | | | 100 kg | | | |
| | | Sitting position | | Standing position | | Sitting position | | Standing position | |
| | | *Total deformation (mm)* | *Equivalent stress (MPa)* | *Total deformation (mm)* | *Equivalent stress (MPa)* | *Total deformation (mm)* | *Equivalent stress (MPa)* | *Total deformation (mm)* | *Equivalent stress (MPa)* |
| **1** | **S.S** | 0.06995 | 15.404 | 0.093239 | 5.914 | 0.13991 | 30.808 | 0.18648 | 11.828 |
| **2** | **Aluminum** | 0.18072 | 13.781 | 0.25207 | 5.8904 | 0.36145 | 27.562 | 0.50414 | 11.781 |
| **3** | **Titanium** | 0.13571 | 14.316 | 0.18627 | 5.8614 | 0.27141 | 28.633 | 0.3725 | 11.723 |
| **4** | **Carbon Fiber** | 1.454 | 21.623 | 2.7764 | 10.362 | 2.908 | 43.247 | 5.5527 | 20.723 |
| **5** | **PEEK** | 3.0169 | 27.078 | 4.5947 | 9.2009 | 6.0339 | 54.156 | 9.1893 | 18.402 |
| **6** | **PLA** | 3.3596 | 27.853 | 5.1299 | 9.4515 | 6.7193 | 55.706 | 10.26 | 18.903 |
| **7** | **PET** | 3.9763 | 29.075 | 6.1055 | 9.7717 | 7.9526 | 58.15 | 12.211 | 19.543 |
| **8** | **Acetal Resin (POM)** | 4.0005 | 29.142 | 6.1413 | 9.8105 | 8.0009 | 58.285 | 12.283 | 19.621 |
| **9** | **ABS+PC** | 4.5691 | 30.077 | 7.0461 | 10.045 | 9.1381 | 60.154 | 14.092 | 20.089 |
| **10** | **Nylon 6/6** | 7.6232 | 33.184 | 11.927 | 10.89 | 15.246 | 66.368 | 23.854 | 21.78 |

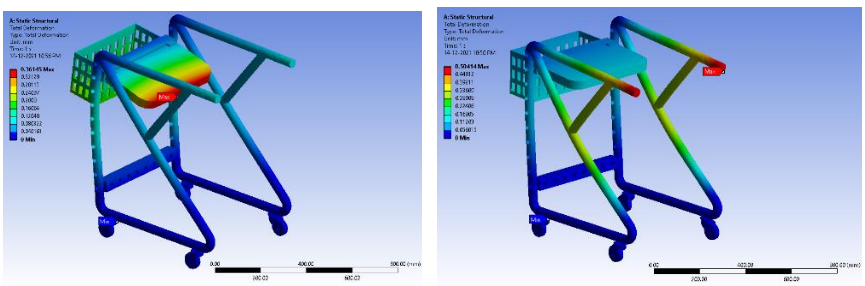
The density of stainless steel, aluminum, titanium, and carbon fiber is 7.5, 2.7, 4.5, and 1.6 g/cm$^3$ respectively. The cost of stainless steel, aluminum, titanium, and carbon fiber is 190, 140, 1600, and 6500 Rs/kg respectively. Therefore, from the observation data preferable material for the mainframe structure is **Aluminum**, and the rest of the elements are made from different materials as shown in Table 6.3. Considering the weight of an adult as 100 kg for impact and dynamic conditions, the total load acting on the seat in the sitting position is considered to be 1000 N and the same load is evenly distributed between frame structures during the standing position as shown in figure 6.16.



(a) Sitting position (b) Standing position

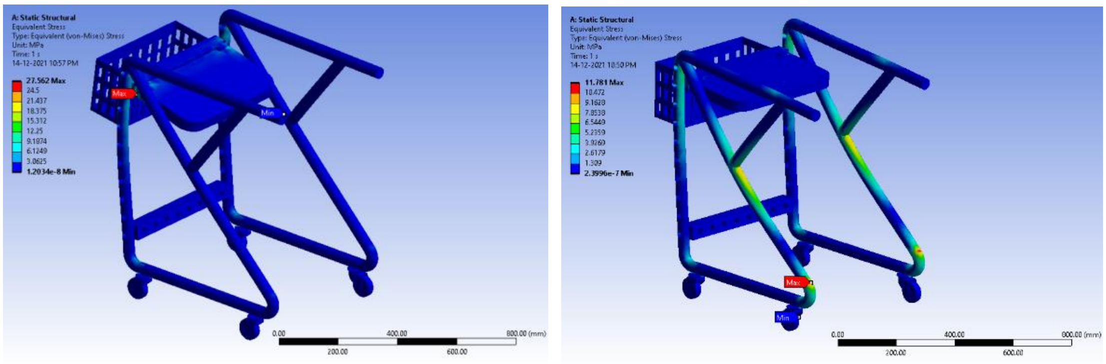
Figure 6.16: Static structural simulation for the weight of adult as 100 kg

The static structural simulation analysis for total deformation and equivalent von-mises stress for aluminum material of the frame and collar components are shown in figures 6.17 and 6.18.



(a) Sitting position (b) Standing position

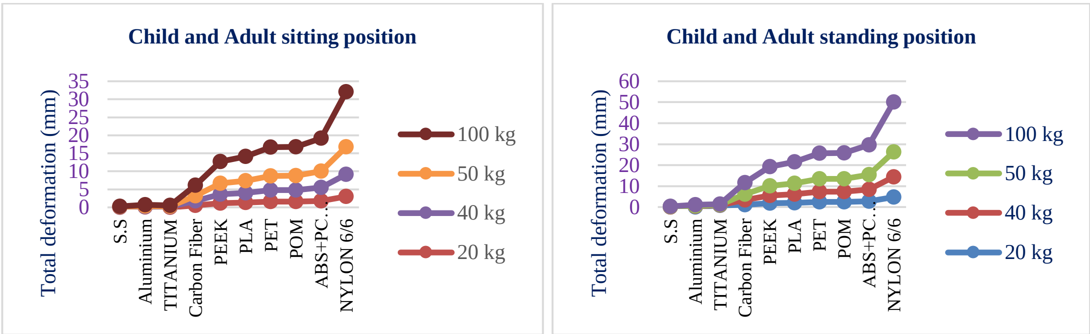
Figure 6.17: Total deformation for the weight of an adult is 100 kg



(a) Sitting position (b) Standing position

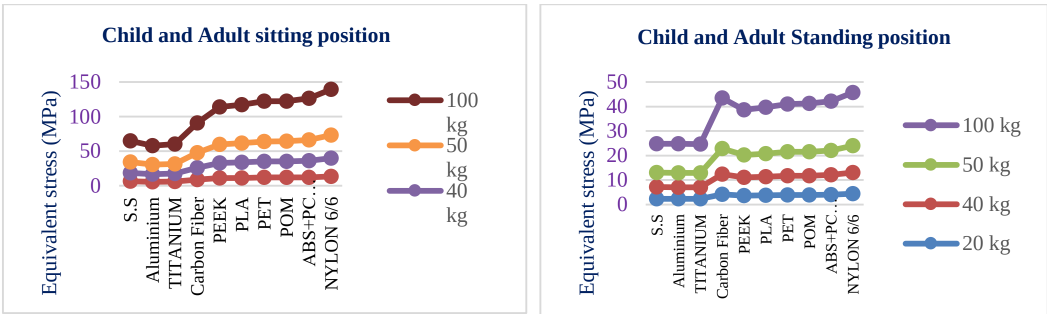
Figure 6.18: Equivalent stress for the weight of an adult is 100 kg

The described walker is analyzed through a static structural simulation process and the effects of total deformation and equivalent stresses of various materials are shown in Figures 6.19 and 6.20.




(a) Sitting position (b) Standing position

Figure 6.19: Total deformation for various materials




(a) Sitting position (b) Standing position

Figure 6.20: Equivalent stress for various materials

### 6.5 Result and discussion for CP walker

A walker design that can satisfy the user's demands has been developed based on the design criteria and shortcomings of earlier walker designs. This walker's balance-preserving features stop the user from toppling over, which is one of its benefits.

There are several things to consider for new product development as mentioned above for a particular medical field. The combination of materials for the final analysis is the result of observing the first four results. Aluminum is the most popular material due to its low cost and ease of processing. Stainless steel is also preferred because it has low CTE and high hardness, but has the disadvantage of being heavier.

To create a walker design and test its stability, finite element modelling is performed. ANSYS is used to investigate the walker's stress and total strain analysis, and the results are displayed in the table. According to the results, the maximum stress induced by the aluminum walker is 13.781 MPa in the sitting position and 11.781 MPa in the standing position, the lowest value compared to the other materials. Therefore, from the observation data preferable material for the mainframe structure of the CP walker device is Aluminum.

## 7. DEVELOPMENT & TESTING OF NOVEL PROSTHETIC FOOT

A prosthetic is a device that replaces one or more functions of the human ankle-foot system. Traditional production processes for prosthetic and orthotic element's wastage of materials is more, take a long time, and are labor-intensive. The benefit of AM technology is that it can overcome these issues. In recent years, developers have released various technologically advanced prosthetic legs, expanding the range of available devices. Therefore, cost-efficient prosthetic elements which are created using economical technology are significantly needed. The main goal of this research study is to design and develop lightweight structural components in such a way that simplifies the manufacturing process.

### 7.1 Development Process of Novel Prosthetic Foot

Designers need to understand the many models that help them find the best solution for engineering design verification. The prototyping phase is a very important phase of new product development and many decisions have to be made to get a quality, defect-free product at the right time with minimal cost. The use of 3D imaging in combination with 3D printing technologies has gained popularity in various medical fields. The figure 7.1 and figure 7.2 below shows the software pipeline for the preparation of a prototype model of prosthetic foot and mounting bracket respectively.

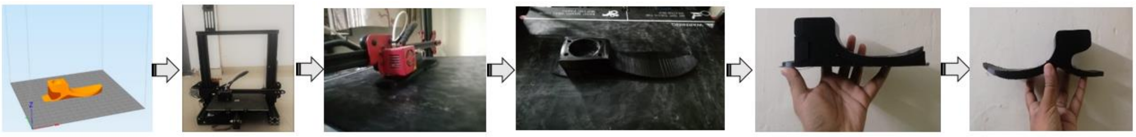


Figure 7.1: Prototype modeling process of prosthetic foot

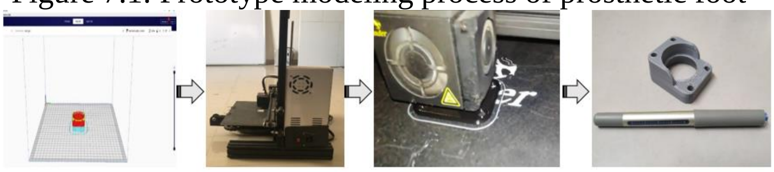


Figure 7.2: Prototype modeling process of mounting bracket

Elements other than the present development like foot adapter, snubber ball, and socket head screw for foot adapter are assembled as shown in figure 7.3 to get the required functionality.

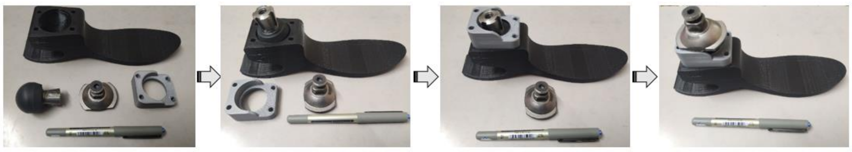


Figure 7.3: Prosthetic model assembly process

Finally, the manufacturing process for prosthetic foot is finalized by using a 3 Axis Vertical Milling Center machine. The material block is mounted on the fixture device and the manufacturing process for prosthetic foot and mounting bracket are successfully completed in approximately 8 hours and 3 hours respectively by using a 3 Axis Vertical Milling Center machine as per process sequence steps mentioned in figure 7.4 and figure 7.5.

Figure 7.4: Machining process of prosthetic foot model

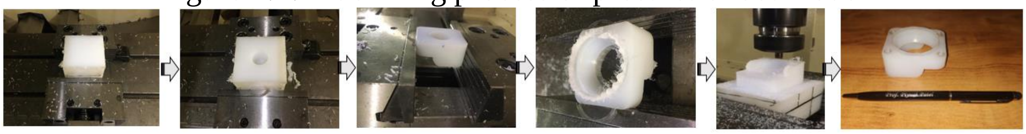


Figure 7.5: Machining process of mounting bracket

Polyurethane bush is inserted to the extended part of the snubber ball up to the polyurethane bush mounting area placed above the mounting bracket to bear the weight. Foot adapter is connected with the snubber ball and fixed with the help of socket head screw for foot adapter as shown in figure 7.6(d). Even an amputee can walk/ambulate without a foot shell and participate in aquatic activities like beach /swimming by pasting the sole treaded on the bottom side of the prosthetic foot as shown in figure 7.6(e).

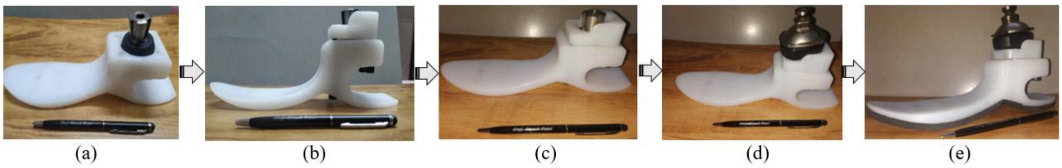



Figure 7.6: Assembly process of prosthetic foot model with bracket

The pylon adapter is mounted on the foot adapter and tightened with the socket head screw for pylon adapter at four points as shown in figure 7.7 (b). The socket adapter is mounted on the pylon and tightened with the socket head screw for socket adapter at four points as shown in figure 7.7 (d). Pylon connects the socket adapter with the pylon adapter playing the same role as the human femur and/or tibia and fibula, depending on amputation level.

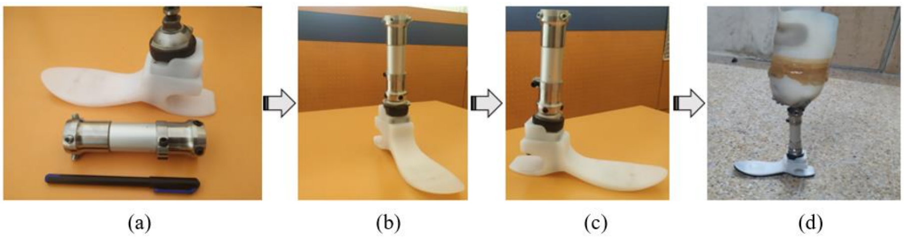



Figure 7.7: Pylon adapter is mounted on the foot adapter

Practitioners in amputee rehabilitation are particularly interested in the impact of a non-articulated Solid Ankle Cushion Heel (SACH) and a multiaxial foot-ankle mechanism on the performance of low-activity users. The purpose of this study is to evaluate potential benefits brought about by the greater degrees of freedom offered by the multiaxial foot by comparing these two prosthetic foot. SACH foot have a stiff foot with no ankle articulation, where the heel absorbs stress and the forefoot simulates dorsal flexion. The SACH foot is a basic, robust, low-cost prosthetic foot alternative for persons who need restricted mobility and have little fluctuation in pace and terrain.

The SACH foot offers adequate shock absorption properties for restricted walkers because to its big heel cushion, but it is not suited for moderate to high activity prosthesis users who want to perform more than home duties due to its lack of flexibility and inability to tolerate uneven terrain.

Our findings show that a multiaxial foot is a significant alternative option to the standard SACH foot as per the following essential features of prosthetic foot:

- An amputee can accommodate the foot on uneven terrain easily ascending/ descending on-ramps using multiaxial foot.
- The design of the multiaxial foot structure that allows the desired rotation on its axis and offers the freedom to move in a medial-lateral direction.
- Even as per the patient size of the foot one size die can be trimmed to smaller size foot.
- The innovation is an optimization in the prosthetic foot structure design that resembles the human foot surface.
- The innovation resembles the human foot surface which is able to absorb the shocks developed during ambulation as well as maintain the balance and stability.
- It relates to a high performance prosthetic foot offering advanced dynamic reaction capabilities.

A detailed examination is performed to assess the weight of SACH and Multi axial foots for this purpose. It is always desirable that the mass will be as least as conceivable without relinquishing the strength and stiffness.

Table 7.1: Pylon and Adapter size details

| **Element Name** | **Length (mm)** | **Weight (gm.)** | **Diameter (mm)** |
|---|---|---|---|
| Pylon 1 | 125 | 70 | 30 |
| Pylon 2 | 235 | 148 | 30 |
| Pylon 3 | 380 | 187 | 30 |
| Pylon Adapter | 45 | 81 | 32 |
| Socket head screw for pylon adapter (M8*14: Hex Socket Set Screw) | 14 | 11 | 8 |

Prosthetic makers have created shock-absorbing pylons to complement the residual capacity of lower limb amputees as well as to reduce the transient stresses of foot-ground contact. Three pylon size (table 7.1) are considered for the comparison analysis and standard pylon adapter of 45 mm length is used for the assembly process as shown in figure 7.8.


*Pylon 1= P1 ; Pylon 2= P2; Pylon 3= P3 ; Pylon Adapter= A; Socket head screw for pylon adapter = S

Figure 7.8 : Weight of Pylon with adapter

The socket's aim is to offer structural stability to the prosthesis where it meets the residual limb. It may also have suspension features to keep the prosthesis in place. The weight of various required element for socket is mentioned in table 7.2.

Table 7.2: Socket elements for BK Patients

| Element Name | Weight (gm.) |
|---|---|
| Socket | 378 |
| Socket Linear | 67 |
| Socket adapter | 102 |
| Socket head screw for socket adapter (M8*12: Hex Socket Set Screw) | 10 |
| Socket Assembly | 557 |


Figure 7.9: Weight of Socket elements

As shown in table 7.3, various prosthetic foot structures are taken into account for weight analysis.

Table 7.3: Weight of various foot structure

| Prosthetic Foot Element Name | Weight (gm.) |
|---|---|
| Novel Foot Structure | 190 |
| 3D Printed Foot Structure | 112 |
| SACH Foot Structure | 309 |
| NIAGARA foot | 364 |


Figure 7.10: Weight of various Prosthetic foot elements

The mass comparison data of SACH and Novel foot structure assembly without pylon and socket elements are mentioned in table 7.4. The mass of SACH Foot Structure is discovered to be 309 grams and the mass of Novel Foot Structure after optimization is found to be **190 grams**. The development efforts by considering design optimization in Novel prosthetic foot structure shows that there is a weight reduction around approximately 61.5 % comparison with the SACH Foot Structure.

Table 7.4: Mass comparison of prosthetic foot structure

| Elements | SACH Foot Structure Assembly (grams) | Novel Foot Structure Assembly (grams) |
|---|---|---|
| **Prosthetic foot structure mass** | 309<br>( 76.5 % of total mass) | **190**<br>(38.46 % of total mass) |
| **Others elements mass** | 95 | 304 |
| **Total mass** | 404 | 494 |


Figure 7.11: Assembly weight of Novel and SACH prosthetic foot elements

The main element of foot-ankle mechanism is human foot structure that is the base for the stability of the patients and better control in all terrain. Elements (Table 7.5) other than the present development like socket elements and pylon mechanism are assembled to get the required functionality.

Table 7.5: Novel Prosthetic Foot Structure mechanism details

| PYLON SIZE | PYLON 1 | PYLON 2 | PYLON 3 |
|---|---|---|---|
| **Element Name** | **Weight (gm.)** | **Weight (gm.)** | **Weight (gm.)** |
| Human Foot Structure | 190 | 190 | 190 |
| Socket Head Screw for Human Foot structure (M4*30) | 15 | 15 | 15 |
| Socket Head Screw for Human Foot structure (M4*50) | 24 | 24 | 24 |
| Snubber Ball | 117 | 117 | 117 |
| Mounting Bracket | 18 | 18 | 18 |
| Polyurethane bush | 26 | 26 | 26 |
| Foot adapter | 85 | 85 | 85 |
| Socket head screw for foot adapter (M7*25) | 19 | 19 | 19 |
| Socket head screw for pylon adapter (M8*14: Hex Socket Set Screw) | 11 | 11 | 11 |
| Pylon adapter | 81 | 81 | 81 |
| Pylon | 70 | 148 | 187 |
| Socket | 378 | 378 | 378 |
| Socket adapter | 102 | 102 | 102 |
| Socket head screw for socket adapter (M8*12: Hex Socket Set Screw) | 10 | 10 | 10 |
| Socket Linear | 67 | 67 | 67 |
| **Novel Prosthetic Foot Assembly** | **1213** | **1291** | **1330** |

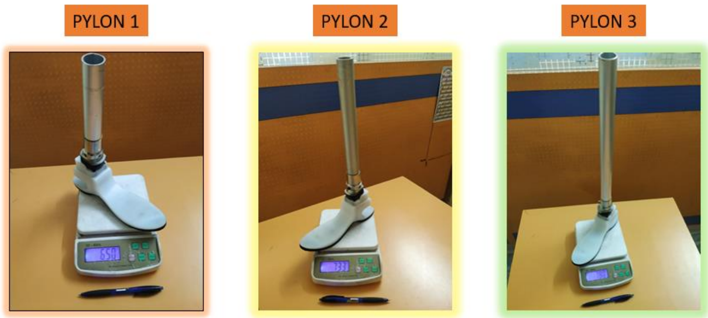



Figure 7.12: Novel Prosthetic Foot Structure with various pylon elements

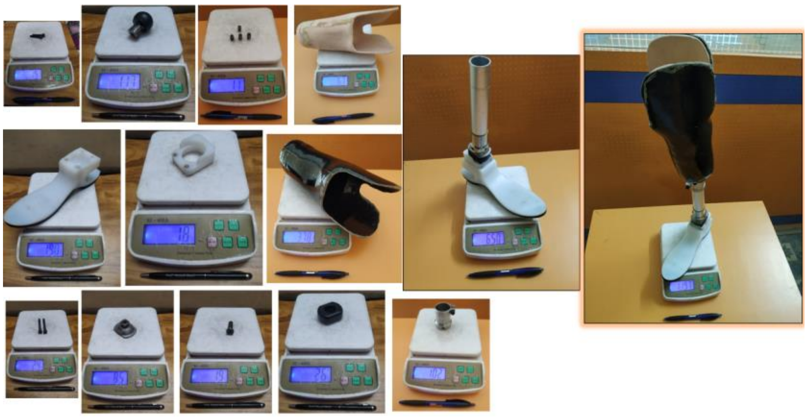


Figure 7.13: Weight for Novel prosthetic foot structure using pylon1


Figure 7.14: Weight of Novel prosthetic foot structure with various pylon size

The most basic type of non-articulated foot is the single axis foot. The name SACH refers to a soft rubber heel wedge that simulates ankle motion by compressing under load during the early stages of walking's stance phase. The keel is hard, therefore there is no lateral movement but there is Midstance stability. The SACH foot comes in a variety of heel heights.

Table 7.6: SACH Prosthetic Foot Structure mechanism details

| **PYLON TYPE** | **PYLON 1** | **PYLON 2** | **PYLON 3** |
|---|---|---|---|
| **Element Name** | **Weight (gm.)** | **Weight (gm.)** | **Weight (gm.)** |
| SACH Foot Structure | 309 | 309 | 309 |
| Foot adapter | 85 | 85 | 85 |
| Socket head screw for foot adapter | 10 | 10 | 10 |
| Pylon | 70 | 148 | 187 |
| Pylon adapter | 81 | 81 | 81 |

| | | | |
|---|---|---|---|
| Socket head screw for pylon adapter (M8*14: Hex Socket Set Screw) | 11 | 11 | 11 |
| Socket | 378 | 378 | 378 |
| Socket adapter | 102 | 102 | 102 |
| Socket head screw for socket adapter (M8*12: Hex Socket Set Screw) | 10 | 10 | 10 |
| Socket Linear | 67 | 67 | 67 |
| **SACH Prosthetic Foot Structure Assembly** | **1123** | **1201** | **1240** |


Figure 7.15: SACH Prosthetic Foot Structure with various pylon elements

Figure 7.16: Weight for Novel prosthetic foot structure using pylon 2

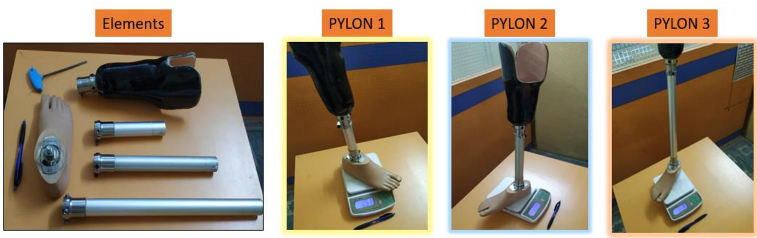



Figure 7.17: Weight of SACH prosthetic foot structure with various pylon size

The development efforts including design optimization in Novel prosthetic foot structure reveal a weight decrease of around 61.5% when compared to the SACH Foot Structure. So finally Novel prosthetic foot elements is considered for the evaluation on patient.

## 7.2 Testing of novel prosthetic foot element on below knee amputation level patients

Gait analysis is an assessment of gait style by observing a patient walking in a straight line. The kinematic system is used to capture the position and angle of joints in gait analysis. The novel prosthetic foot model is connected with the socket and then with the help of prosthetist as per the comfort of the patients it is fitted properly as shown in figure 7.18.

Figure 7.18: Socket fitting process on patients

During the session, a standardized physical examination of the lower limbs is performed to measure anthropometry, passive range of motion and clinical videos are recorded. The kinematic data analysis is conducted for different joint angle observation parameters like ankle angle, knee angle, hip angle, rear foot angle, pelvic drop and knee Ab/Adduction.

There are a number of joints in the foot and ankle that move during walking as shown in figure 7.19. These joints serve critical functions during normal walking. The ankle joint allows the foot to move up (dorsiflexion) and down (plantarflexion), using the muscles located in the front of the leg (the anterior muscle compartment) for upward movement, and the muscles located in the back of the leg (the posterior compartment) to pull the foot back down.

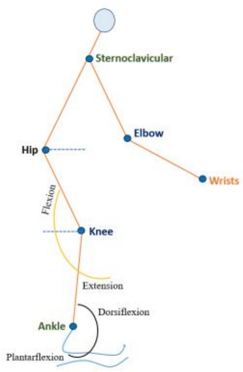


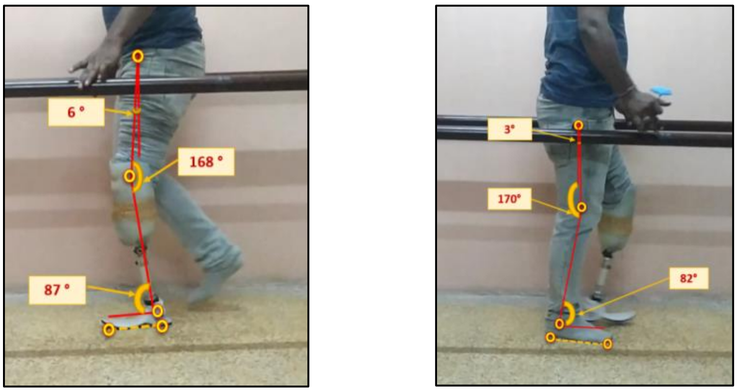

Figure 7.19: Human body stick diagram for pointing movement

GaitON® running gait analysis software is used by clinicians globally for a detailed human motion analysis. Its protocol analyses the lower & upper body motion of the patient's & identifies any biomechanical faults. The various body movements' data analysis are described below;

- Ankle angle > 90° denotes plantarflexion while ankle angle < 90° denotes dorsiflexion.
- Knee angle > 180° denotes hyperextension while knee angle < 180° denotes flexion.
- Hip flexion is shown as (+) and hip extension is shown as (-).
- Rear foot Eversion is denoted as (+) and Rear foot inversion is denoted as (-).

- Contralateral pelvic drop is shown as (+) while ipsilateral pelvic drop is shown as (-).
- Knee Ab/Adduction is (+) when patella is medial to the 2nd toe and (-) when patella is lateral to the 2nd toe.
- All values are free gait speed, phase ending

The novel prosthetic foot model is tailored to the patient, and basic gait analysis data for different viewing angles such as lateral, posterior and anterior are taken into account. The graphical representation of the ankle angle, knee angle and hip angle of the left and right legs is given in the figure 7.20 respectively. In the left leg observation ankle angle is dorsiflexion; knee and hip angle values are in the normal range. For the right leg observation ankle, knee and hip angle values are in the normal range.




(a) Left leg (b) Right leg

Figure 7.20: Patient lateral view mid stance position

In the graphical representation data for the patient's lateral view of gait cycle the different measured parameters values by considering ankle, knee and hip angles are mentioned in the figure 7.21 to figure 7.23 respectively. The different measured parameters values at the specific contact positon like initial contact, loading response, midstance, terminal stance and pre swing are shown in the figure. The reference values points are marked with a green color line and the left & right assessed values are marked with a blue and orange color line as shown in the figure.

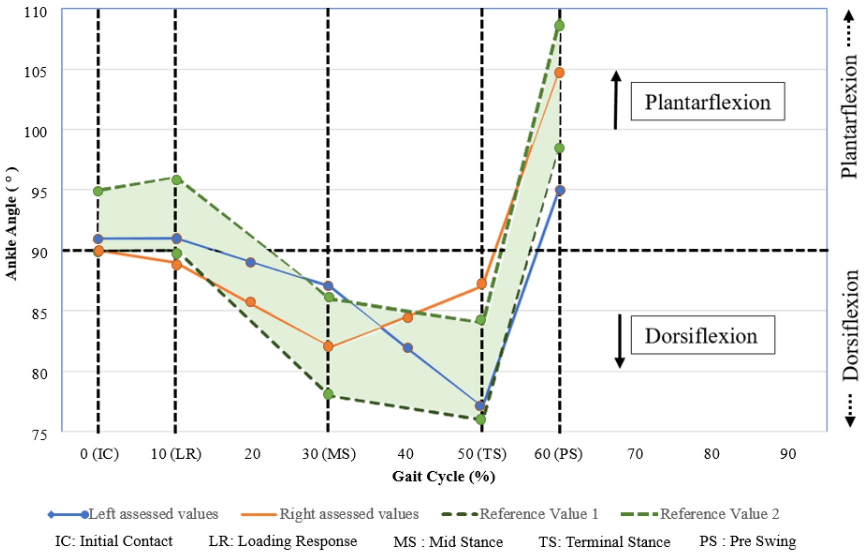



Figure 7.21: Graphs for the lateral views of the gait cycle: Ankle angle (Novel prosthetic foot)

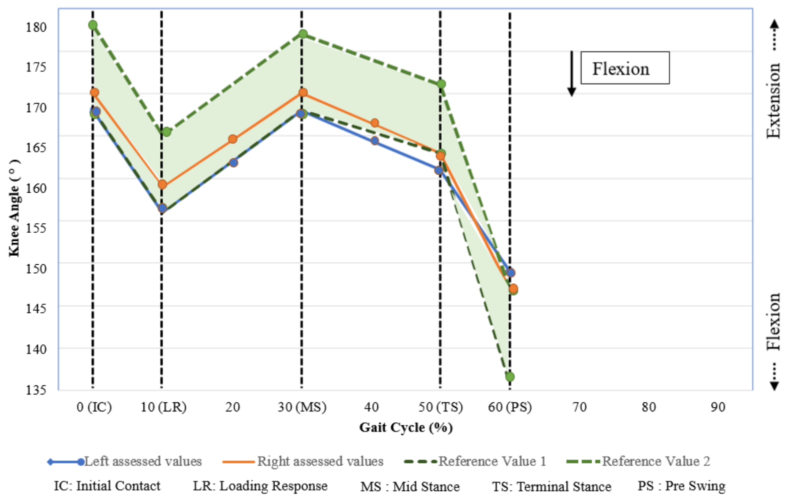



Figure 7.22: Graphs for the lateral views of the gait cycle: Knee angle (Novel prosthetic foot)

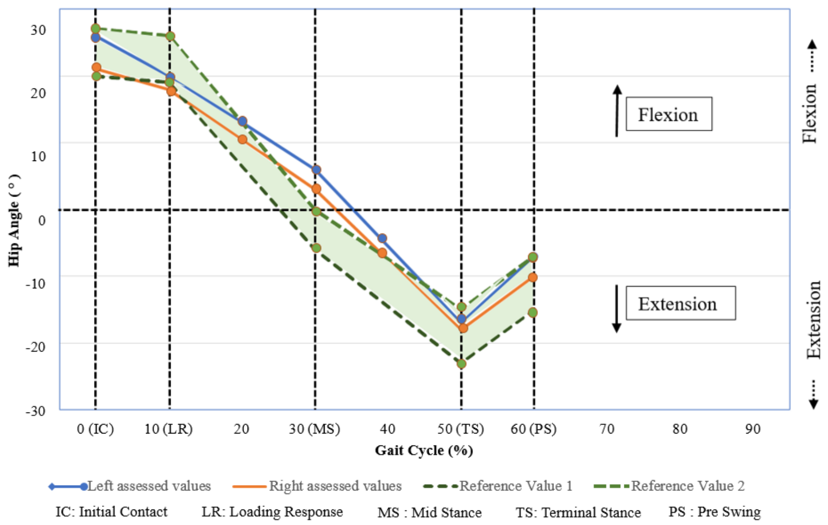
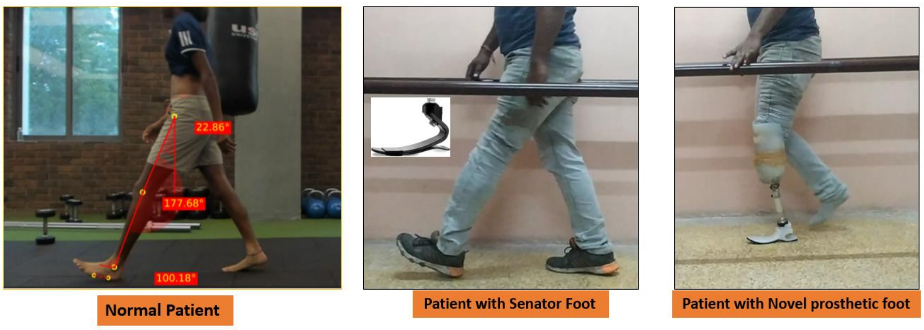



Figure 7.23: Graphs for the lateral views of the gait cycle: Hip angle (Novel prosthetic foot)

According to data analysis from three different case study reports, the final comparative data for normal patients, patients with below-knee amputation wearing Senator's foot, and new prosthetic are summarized in the following table 7.7.




| | |
|---|---|
| Name | Ruju |
| Age(Yrs.) | 27 |
| Weight (kg) | 65 |
| Height (ft) | 5' 4" |
| Gender | Female |
| Clinician | Dr. Mitul Darji (Sports PT) |
| Date of gait analysis | 21-06-2019 |

| | |
|---|---|
| Name | Mr Nikunj Maiskar |
| Age(Yrs.) | 35 |
| Weight (kg) | 85 |
| Height (ft) | 5' 9" |
| Gender | Male |
| Clinician | Dr. Khyati Vansadavala (Prosthetist & Orthotist , RCI No: A51452 ) |
| Date of gait analysis | 23-10-2021 |
| Amputation | A person injured in an accident and his left leg was amputated below knee in 2013 |

Figure 7.24: Patient case studies data

Table 7.7: Patients gait analysis comparison data

**Normal Patient**

LATERAL VIEW

| Ankle Angle[a] | Right | Left | Reference Value |
|---|---|---|---|
| Initial Contact | 90° | 91° | 90° to 95° |
| Loading Response | 89° | 91° | 90° to 96° |
| Mid Stance | 82° | 87° | 78° to 86° |
| Terminal Stance | 87° | 77° | 76° to 84° |
| Pre Swing | 105° | 95° | 99° to 109° |

| Knee Angle[b] | Right | Left | Reference Value |
|---|---|---|---|
| Initial Contact | 170° | 168° | 168° to 178° |
| Loading Response | 159° | 156° | 156° to 165° |
| Mid Stance | 170° | 168° | 168° to 177° |
| Terminal Stance | 163° | 161° | 163° to 171° |
| Pre Swing | 147° | 149° | 136° to 147° |

| Hip Angle[c] | Right | Left | Reference Value |
|---|---|---|---|
| Initial Contact | 21° | 26° | (+) 20° to (+) 27° |
| Loading Response | 20° | 18° | (+) 19° to (+) 26° |
| Mid Stance | 6° | 3° | 0° to (-) 6° |
| Terminal Stance | (-)18° | (-)17° | (-) 15° to (-) 23° |
| Pre Swing | (-)10° | (-)7° | (-)7° to (-)15° |

POSTERIOR VIEW

| Rear Foot Angle[d] | Right | Left | Reference Value |
|---|---|---|---|
| Mid Stance | 3° | 11° | (+) 2° to (+) 6° |

| Pelvic drop[e] | Right | Left | Reference Value |
|---|---|---|---|
| Mid Stance | 3° | 2° | 0° to (+) 5° |

ANTERIOR VIEW

| Knee Ab/Adduction[f] | Right | Left | Reference Value |
|---|---|---|---|
| Mid Stance | (-) 1° | (-) 0.5° | 0° |

**Patient with Senator Foot**

LATERAL VIEW

| Ankle Angle[a] | Right | Left | Reference Value |
|---|---|---|---|
| Initial Contact | 92° | 94° | 90° to 95° |
| Loading Response | 96° | 94° | 90° to 96° |
| Mid Stance | 90° | 80° | 78° to 86° |
| Terminal Stance | 93° | 89° | 76° to 84° |
| Pre Swing | 78° | 89° | 99° to 109° |

| Knee Angle[b] | Right | Left | Reference Value |
|---|---|---|---|
| Initial Contact | 176° | 178° | 168° to 178° |
| Loading Response | 165° | 162° | 156° to 165° |
| Mid Stance | 164° | 154° | 168° to 177° |
| Terminal Stance | 158° | 168° | 163° to 171° |
| Pre Swing | 152° | 151° | 136° to 147° |

| Hip Angle[c] | Right | Left | Reference Value |
|---|---|---|---|
| Initial Contact | (+) 22° | (+) 28° | (+) 20° to (+) 27° |
| Loading Response | (+) 20° | (+) 20° | (+) 19° to (+) 26° |
| Mid Stance | (+) 5° | (+) 11° | 0° to (-) 6° |
| Terminal Stance | (-)15° | (-)23° | (-) 15° to (-) 23° |
| Pre Swing | (-)10° | (-)22° | (-)7° to (-)15° |

**Patient with Novel prosthetic foot**

LATERAL VIEW

| Ankle Angle[a] | Right | Left | Reference Value |
|---|---|---|---|
| Initial Contact | 97.64° | 100.18° | 90° to 95° |
| Loading Response | 95.36° | 99.54° | 90° to 96° |
| Mid Stance | 82.78° | 81.79° | 78° to 86° |
| Terminal Stance | 82.77° | 79.92° | 76° to 84° |
| Pre Swing | 95.13° | 98.99° | 99° to 109° |

| Knee Angle[b] | Right | Left | Reference Value |
|---|---|---|---|
| Initial Contact | 176.53° | 177.68° | 168° to 178° |
| Loading Response | 160.49° | 160.87° | 156° to 165° |
| Mid Stance | 168.88° | 163.99° | 168° to 177° |
| Terminal Stance | 167.8° | 167.13° | 163° to 171° |
| Pre Swing | 152.51° | 148.62° | 136° to 147° |

| Hip Angle[c] | Right | Left | Reference Value |
|---|---|---|---|
| Initial Contact | (+) 22.61° | (+) 22.86° | (+) 20° to (+) 27° |
| Loading Response | (+) 23.39° | (+) 23.91° | (+) 19° to (+) 26° |
| Mid Stance | (+) 0.8° | (+) 4.97° | 0° to (-) 6° |
| Terminal Stance | (-) 19.69° | (-) 24.02° | (-) 15° to (-) 23° |
| Pre Swing | (-) 17.42° | (-) 20.75° | (-)7° to (-)15° |

POSTERIOR VIEW

| Rear Foot Angle[d] | Right | Left | Reference Value |
|---|---|---|---|
| Mid Stance | (+) 15.01° | (+) 15.63° | (+) 2° to (+) 6° |

| Pelvic drop[e] | Right | Left | Reference Value |
|---|---|---|---|
| Mid Stance | (+) 8.53° | (+) 2.75° | 0° to (+) 5° |

ANTERIOR VIEW

| Knee Ab/Adduction[f] | Right | Left | Reference Value |
|---|---|---|---|
| Mid Stance | (-) 0.6° | (-) 1.67° | 0° |

A graphical representation of various measured parameter values for angles at the ankle, knee, and hip shows that the data are within the allowable range of the standard reference data for the patient's lateral view position when wearing the new prosthetic as shown in below figure 7.25.

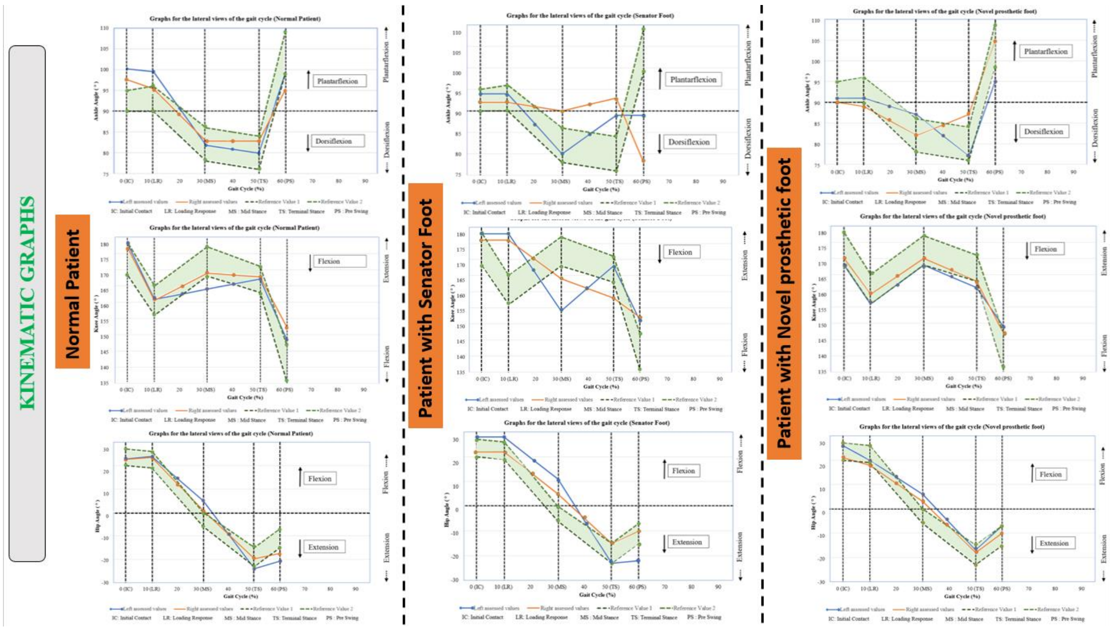



Figure 7.25: Kinematic graph for patient's lateral view position

## 7.3 Result and discussion of patient's test

This study presents the physical design, mechanical properties, and initial gait test of a prosthetic to evaluate the effectiveness of the prosthetic as a design goal. The special feature of this foot is that it allows testing of ankle stiffness over a wide range of motion, similar to physiological ankle stiffness and range of motion. The prosthetic foot element design shows a reduction in weight compared to previous prototypes, maintaining structural integrity, allowing proper operation according to the patient's requirements. The current approach pertains to a revolutionary single unit prosthetic foot that may absorb shocks during ambulation while also transferring energy efficiently between heel strike and toe-off and improving stability.

## 8. RESULT AND DISCUSSION

### 8.1 Result and Discussion for Prosthetics Elements

The current creation combines the benefits of a multiaxial dynamic foot's stability with the energy storage capabilities of a high-profile dynamic foot.

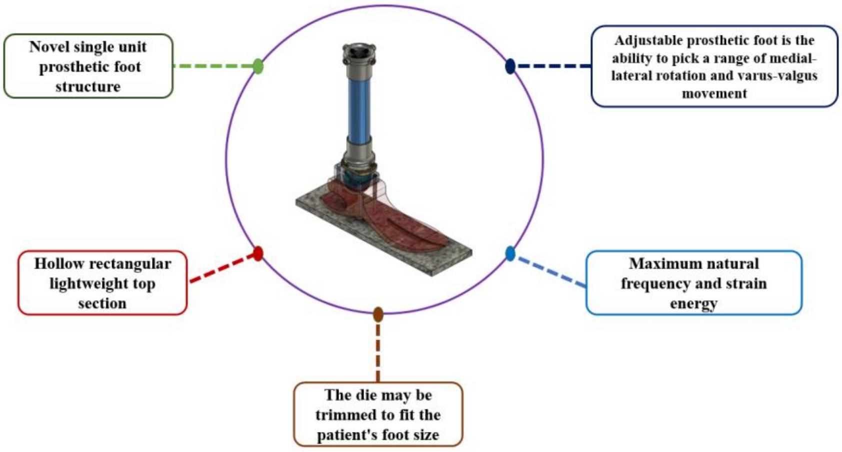



Figure 8.1: Multiaxial dynamic foot's device features

The current novelty is about a prosthetic foot comprising a hollow rectangular lightweight top section that is an integral element of the *novel single unit prosthetic foot structure*. The mass of SACH Foot Structure is discovered to be 309 grams and the mass of Novel Foot Structure after optimization is found to be 190 grams. The development efforts by considering design optimization in Novel prosthetic foot structure shows that there is a weight reduction around approximately 61.5 % comparison with the SACH Foot Structure. Another advantage of having an adjustable prosthetic foot is the ability to pick a range of medial-lateral rotation and varus-valgus movement, similar to the natural subtalar joint, to adapt uneven terrain. Even as per the foot size of the patient the die can be trimmed to a smaller foot size. Attempts will be made in the die for higher thickness of shaft, blade for ultra-heavy amputee patients-where countries like US have heavy patients weighing 400 to 500 lbs (same will be used with filler for routine amputee patients with weight limit up to 120kg). An amputee can accommodate the foot on uneven terrain and can easily ascend/ descend on-ramps. Even an amputee can walk/ambulate without a foot shell and participate in aquatic activities like beach /swimming by pasting the sole treaded on the bottom side of the prosthetic foot.

The present design approach related to novel single unit prosthetic foot structure where the static structural simulation results shows that by considering carbon fiber material for a prosthetic foot structure has lowest deformation value and highest natural frequency. The current innovation combines the benefits of a multiaxial dynamic foot's stability with the energy storage capabilities of a high-profile dynamic foot. There is a further advantage to having a prosthetic foot of different materials like carbon fiber suitable for heavy load situations and other polymer materials like UHMW-PE/ nylon / delrin which has a low production cost and is lightweight. Various parameters analysis is conducted onto the foot structure models for material optimization data as described in details in Chapter 5 (Section 5.4 Simulation data summary for various prosthetic foot models).

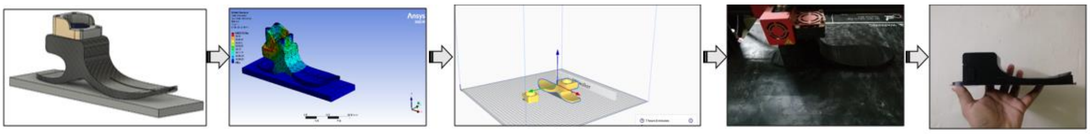


Figure 8.2: Design and development process of the Prosthetic Foot Model 1

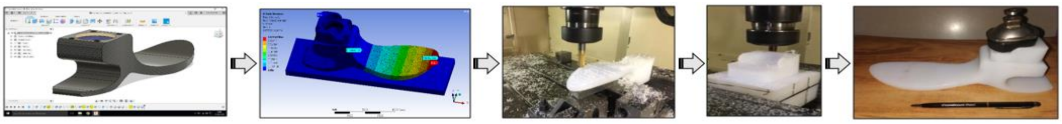


Figure 8.3: Design and development process of the Prosthetic Foot Model 2

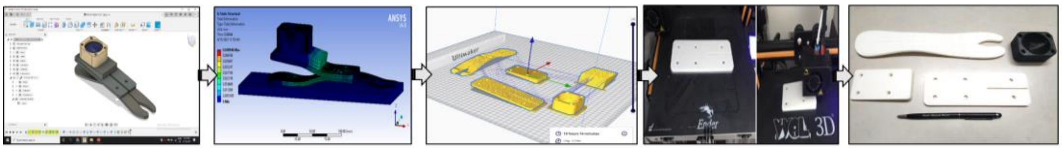


Figure 8.4: Design and development process of the Prosthetic Foot Model 3

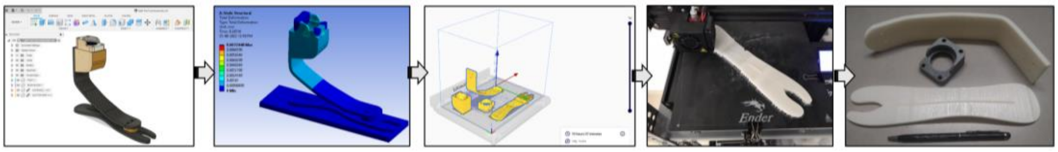


Figure 8.5: Design and development process of the Prosthetic Foot Model 4

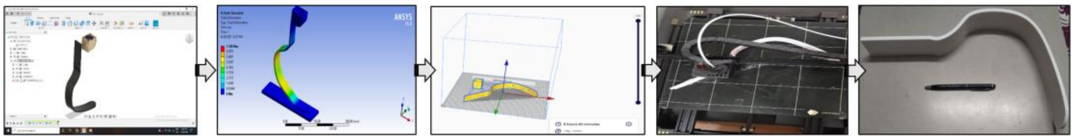


Figure 8.6: Design and development process of the Prosthetic Foot Model 5

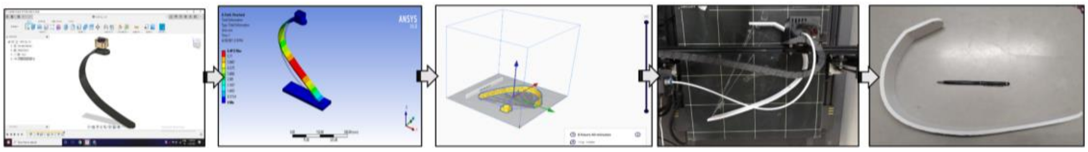


Figure 8.7: Design and development process of the Prosthetic Foot Model 6

Many factors must be considered while building a better physical prototype for any new product, and the same is true when utilising the prototype as a benchmark. Based on these criteria, designers may select an acceptable sort of prototype approach for their new product. Finally, the innovative multiaxial foot mechanism is created with a 3 Axis Vertical Milling Center device and fitted to patients for product assessment. A standardized physical examination of the lower limbs is done throughout the gait analysis to determine anthropometry, passive range of motion, and standardized clinical films are captured as explained in detail in Chapter 7 (Development & testing of novel prosthetic foot).

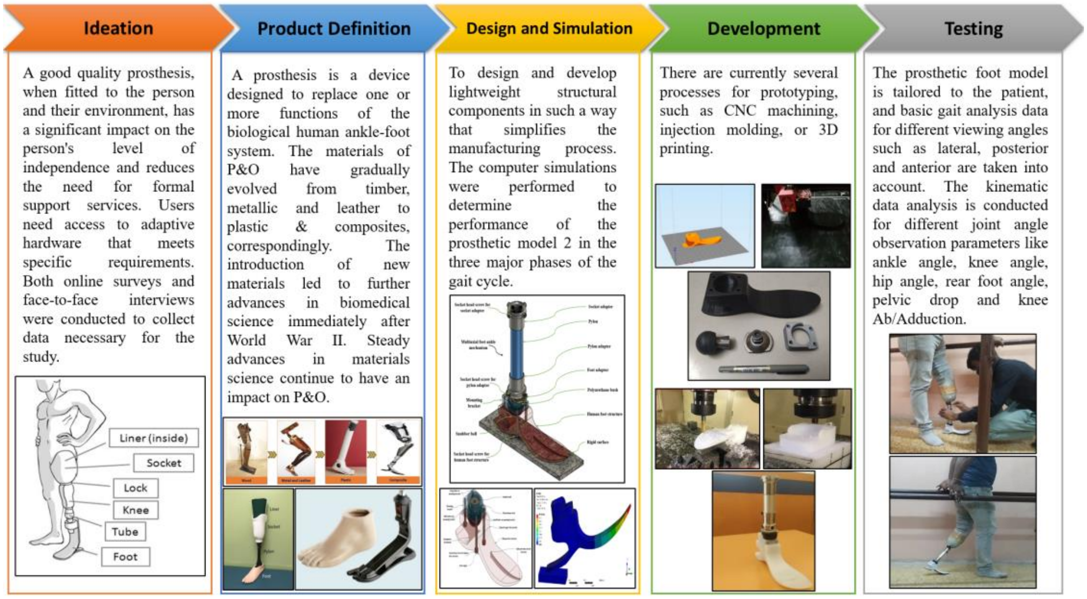



Figure 8.8: Development and testing process for novel prosthetic foot

The special feature of this foot is that it allows testing of ankle stiffness over a wide range of motion, similar to physiological ankle stiffness and range of motion. The novel foot design shows a reduction in weight compared to previous prototypes, maintaining structural integrity, allowing proper operation according to the patient's requirements.

The current development pertains to a revolutionary single unit prosthetic foot that may absorb shocks during ambulation while also transferring energy efficiently between heel strike and toe-off and improving stability.

## 8.2 Result and Discussion for Orthotics Elements

Rehabilitation techniques help people function better after injury or illness. The use of Advanced Manufacturing in medical device manufacturing has grown in popularity over the past decades as the opportunities for this technology rapidly expand. Traditionally, individual P&O devices are manufactured using plaster molds, which require multiple patient visits, takes a lot of effort and time to produce. Therefore, our main attention is the process of designing and developing lightweight structural components quickly with a simplification of the manufacturing process.

The AFO and flex foot prosthetic elements are printed using PLA material on FDM machines. The entire process takes less than 7 hours, with an average hands-on time of only 10-15 minutes for AFO elements and about 10 hours for Flex-Foot prosthetic.

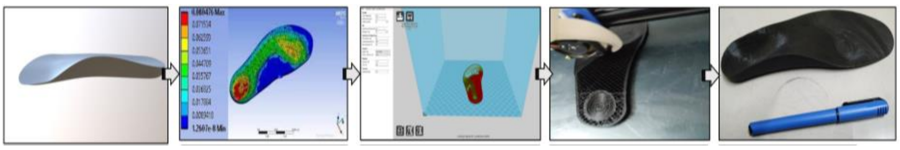


Figure 8.9: Design and development process of the Orthotics Foot Shell Model

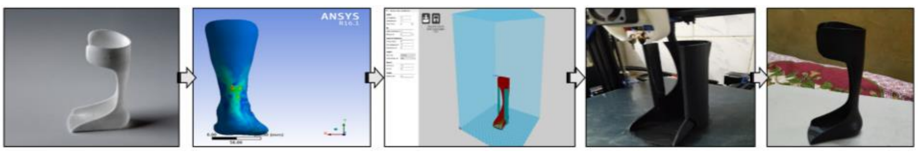



Figure 8.10: Design and development process of the Ankle Foot Orthotic Model

In other words, using 3D printing to create a P&O device for a patient is significantly less time consuming than traditional methods. In the future, it is intended to compare altered effects obtained by using various types of materials for the improvement of the P&O devices by AM method.

Based on the design criteria and weaknesses of previous walker designs, a walker design that can meet the needs of the user has been created. One of the advantages of this walker design is that it keeps the user in balance and prevents the user from tipping over.

The second design was an iteration of the first design with four legs type frame structure and four swivel wheels. A front swivel wheel provides mobility for the user and a rear wheel provides stability by limiting front wheel movement. The handle with grip controls the user's mobility provided by the rotating wheel. This design reduces the bulk of the device as it better fits the user. As your kid grows, you may also make adjustments to the walker, including changing the height settings of the foldable seat and frame structure.

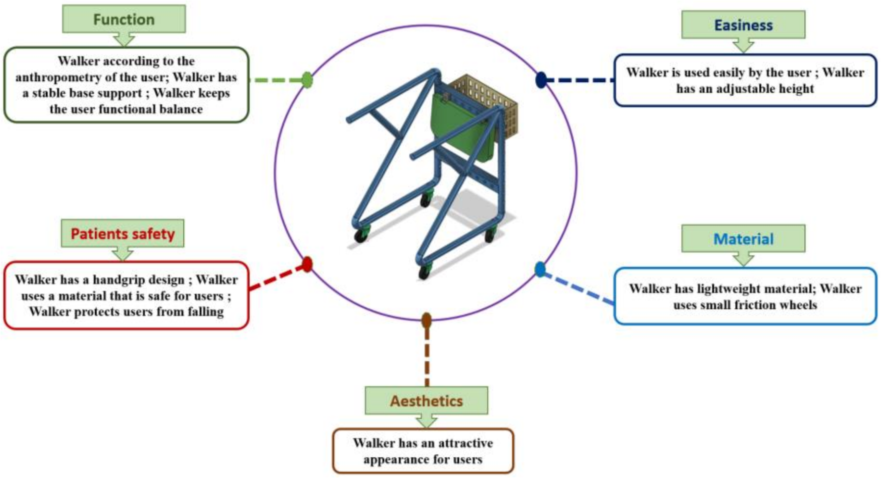



Figure 8.11: Walker device features

Finite element modeling is used to develop a walker design and investigate its stability. The walker's stress and total strain analysis is examined using ANSYS, and the findings are shown in the table. According to the results, the maximum stress induced by the aluminum walker is 13.781 MPa in the sitting position and 11.781 MPa in the standing position, the lowest value compared to the other materials. The static structual simulation analysis for total deformation and equivalent von-mises stress for various material of the frame and collar components are described in chapter 6 (Design and simulation approach of orthotics elements).

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## LIST OF PUBLICATIONS

### a) Research paper in the journals

1) Custom Orthotics development process based on Additive Manufacturing (Elsevier Journal*: Materials Today: Proceedings*) doi.org/10.1016/j.matpr.2022.04.858
2) Bio Composite Material: Review and its Applications in Various Fields (Elsevier: *Encyclopedia of Materials: Composites*) doi.org/10.1016/B978-0-12-819724-0.00011-2
3) Role of Additive Manufacturing in Medical Application COVID-19 Scenario: INDIA Case study (Elsevier Journal: Journal of Manufacturing Systems) doi.org/10.1016/j.jmsy.2020.11.006
4) Design and Simulation Approach of Cerebral Palsy Pediatric Standard Walker (Elsevier Journal*:* Medicine in Novel Technology and Devices: Under Review process)
5) Design, Analysis and Development of Prosthetic and Orthotic elements by Additive Manufacturing process (Elsevier Journal: Materials Today Communications Journal ; Under Submission process)
6) Design, Analysis, Development and Testing of Novel Prosthetic foot model for lower limb amputation level patients (Elsevier Journal: Materials Today Communications Journal ; Under Submission process)

### b) Presenting research work in conferences

1) Custom Orthotics development process based on Additive Manufacturing (International Conference on Materials and Technologies: NIT Raipur)

2) Design and Simulation Approach of Cerebral Palsy (CP) Pediatric Walker (International Conference on Materials and Technologies: NIT Raipur)


NITRR/Conference/MaterialTECH2022/MM48

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MaterialTECH2022

28th –29th January, 2022

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This certificate is presented to

Mr. PIYUSH THAKORBHAI PATEL

for Oral Presentation of Paper Custom Orthotics Development Process Based on Additive Manufacturing. in the International Conference "Material TECH 2022" organized jointly by Department of Metallurgical and Materials Engineering & Department of Mechanical Engineering at National Institute of Technology Raipur, India.

Dr. N V Swamy Naidu (Organizing Secretary) | Dr. Neha Gupta (Organizing Secretary) | Dr Jagadish (Organizing Secretary)


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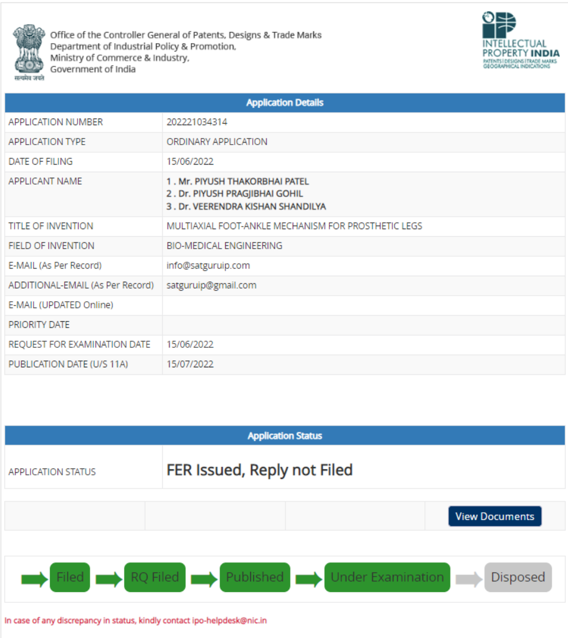
## c) Patent Publications

1) Product **Patent** entitled "Multiaxial foot-ankle mechanism for prosthetic legs" published on 15-07-2022 in Journal Issue No: 28/2022 in Part -1 (Application No: 202221034314)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Government of India

INTELLECTUAL PROPERTY INDIA

**Application Details**

| | |
|---|---|
| APPLICATION NUMBER | 202221034314 |
| APPLICATION TYPE | ORDINARY APPLICATION |
| DATE OF FILING | 15/06/2022 |
| APPLICANT NAME | 1 . Mr. PIYUSH THAKORBHAI PATEL<br>2 . Dr. PIYUSH PRAGJIBHAI GOHIL<br>3 . Dr. VEERENDRA KISHAN SHANDILYA |
| TITLE OF INVENTION | MULTIAXIAL FOOT-ANKLE MECHANISM FOR PROSTHETIC LEGS |
| FIELD OF INVENTION | BIO-MEDICAL ENGINEERING |
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| PRIORITY DATE | |
| REQUEST FOR EXAMINATION DATE | 15/06/2022 |
| PUBLICATION DATE (U/S 11A) | 15/07/2022 |

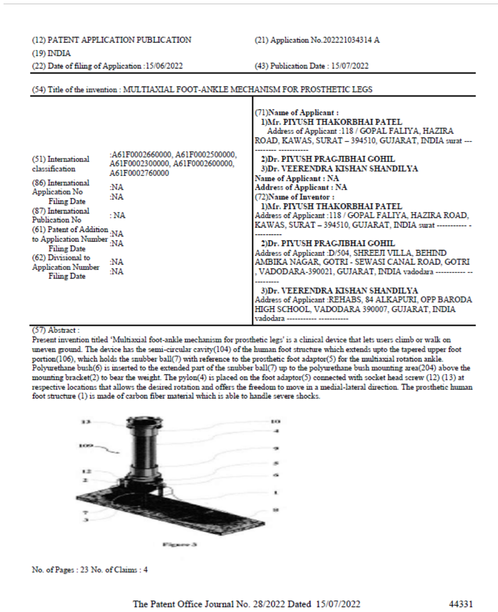
**Application Status**

| | |
|---|---|
| APPLICATION STATUS | FER Issued, Reply not Filed |

View Documents

Filed → RQ Filed → Published → Under Examination → Disposed

In case of any discrepancy in status, kindly contact ipo-helpdesk@nic.in


(12) PATENT APPLICATION PUBLICATION (21) Application No.202221034314 A
(19) INDIA
(22) Date of filing of Application :15/06/2022 (43) Publication Date : 15/07/2022

(54) Title of the invention : MULTIAXIAL FOOT-ANKLE MECHANISM FOR PROSTHETIC LEGS

(51) International classification :A61F0002660000, A61F0002500000, A61F0002300000, A61F0002600000, A61F0002760000
(86) International Application No :NA
Filing Date :NA
(87) International Publication No : NA
(61) Patent of Addition to Application Number :NA
Filing Date :NA
(62) Divisional to Application Number :NA
Filing Date :NA

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(57) Abstract :
Present invention titled 'Multiaxial foot-ankle mechanism for prosthetic legs' is a clinical device that lets users climb or walk on uneven ground. The device has the semi-circular cavity(104) of the human foot structure which extends upto the tapered upper foot portion(106), which holds the snubber ball(7) with reference to the prosthetic foot adaptor(5) for the multiaxial rotation ankle. Polyurethane bush(6) is inserted to the extended part of the snubber ball(7) up to the polyurethane bush mounting area(204) above the mounting bracket(2) to bear the weight. The pylon(4) is placed on the foot adaptor(5) connected with socket head screw (12) (13) at respective locations that allows the desired rotation and offers the freedom to move in a medial-lateral direction. The prosthetic human foot structure (1) is made of carbon fiber material which is able to handle severe shocks.

Figure 3

No. of Pages : 23 No. of Claims : 4

The Patent Office Journal No. 28/2022 Dated 15/07/2022 44331