Summary
of
The Ph.D. Thesis

Entitled

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

By

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CHAPTER 1
INTRODUCTION

Biomechanical engineering is the application of mechanical engineering principles and biological understanding to better understand how these fields intersect and how they may be used together to potentially improve people's quality of life.

1.1 Prosthetics and Orthotics (P&O)

A prosthesis is an artificial device that substitutes a missing body part that may have been lost due to an accident, sickness, or a congenital ailment. (Behrend, Reizner, Marchessault, & Hammert, 2011). The term "orthosis" refers to an exterior gadget used to alter the functional and anatomic characteristics of the muscular and skeletal systems.

Artificial limbs are classified into four categories. Transtibial, transfemoral, transradial, and transhumeral. A trans-radial prosthetic is a prosthetic limb that replaces a lost arm below the elbow. A transhumeral prosthetic is an artificial limb that replaces an arm that has been amputated above the elbow. A transtibial prosthetic is a prosthetic limb that replaces a lost leg below the knee. A transfemoral prosthetic is a prosthetic limb that replaces a lost leg above the knee. The essential components of the modular transfemoral prosthetic are shown in figure 1.1.

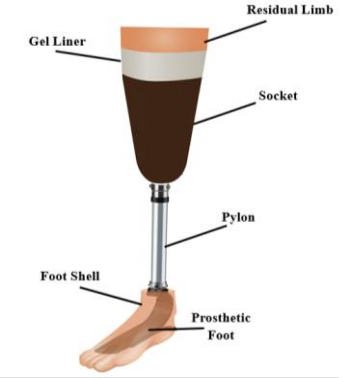


Figure 1.1: Arrangement of main elements of prosthetic (Stuart Mason Dambrot, May 2016)

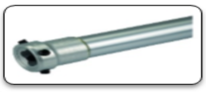
The primary function of employing the main key elements of prosthetic devices is discussed shortly below.

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.

The creation and manufacturing of external orthotics as a measure of a patient's therapy requires accuracy and ingenuity. Common orthotic interventions include spinal jackets, neck, footwear, insoles, braces, splints, calipers, etc. (Patel & Gohil, 2022)

1.1.1 Materials used for P&O devices

The body consists of intimate parts that, if lost, cannot fully be replaced. Fortunately, researchers all across the universe are attempting to replace each component of the body to transform all of us becoming cyborgs. Figure 1.2 depicts some of the technologies that aid in the P&O of the human body. (Shahar, et al., 2019) (Hench & Polak, 2002)

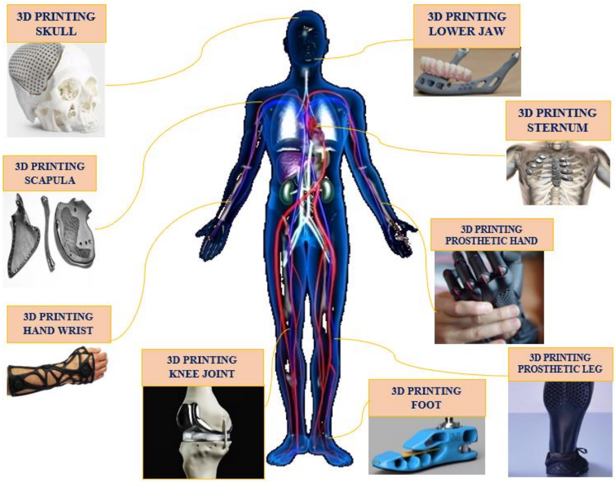


Figure 1.2: P&O assistive devices in the human body (Patel & Gohil, 2022)

1.2 Composite materials

A composite material is a substance system made up of a mixture or combination of two or more macro components that differ in structure and chemical composition and are insoluble in each other. (Jones, 2018)

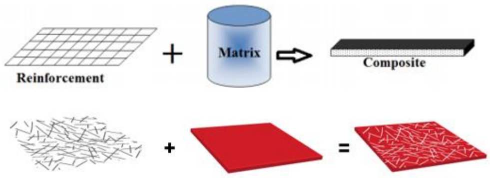


Figure 1.3: Constituents of Composite Material

1.2.1 Classification of composite material

Depending upon the family of material used, the matrix system composites are classified into;

a) Polymer Matrix Composites (P.M.C)
b) Metal Matrix Composites (M.M.C)
c) Ceramic Matrix Composites (C.M.C)

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 as 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.

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.(Mellor, Hao, & Zhang, 2014) (Piyush Patel, Piyush Gohil, 2021).

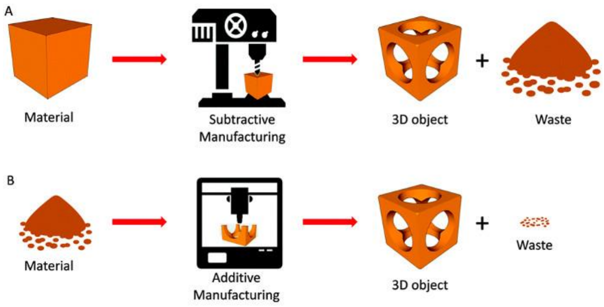
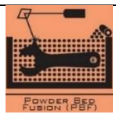
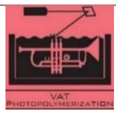
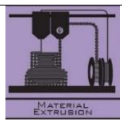
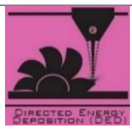


Figure 1.4: Subtractive vs Additive Manufacturing (Chen Cheng & Wang , 2020)

Seven groups of Additive Manufacturing as indicated by ASTM F2792 standards are recorded below in table 1.1.

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

AM Process	Schematic diagram	Strengths	Typical Materials
Powder Bed Fusion		• Significant complication; • The powder acts as a support material; • A diverse variety of materials.	Sand, plastics, metals, ceramic powders
Vat Photo polymerization		• Extreme precision and intricacy; • Smooth surface finish; • Large construction area.	Photopolymer Resins with UV Curability
Binder Jetting		• Full-color printing is possible; • There is high output; • A variety of materials are used.	Sand, metal, ceramic, glass, and powdered plastic
Material Jetting		• A high degree of precision; • Full-color components are possible; • Multiple materials are possible in a single part.	Wax, polymers, and photopolymers
Sheet Lamination		• Rapid volumetric growth rates; • Allows for combinations of metal foils, including embedding components; • Relatively inexpensive (non-metals).	Paper, plastic, and metallic foils and tapes
Material Extrusion		• Multiple colors are possible; • It is inexpensive and practical; • It can be used in an office context; • The parts are structurally sound.	Thermoplastic slurries, liquids, and pellets; filaments; and pellets
Directed Energy Deposition		• Highest single-point deposition rates; • No direction or axis restrictions; • Effective for repairing and adding features; • The use of numerous substances in a single component.	Metal wire and powder in conjunction with ceramics

CHAPTER 2
LITERATURE REVIEW

Literature gives a clear view of work such as papers, and theories related to the topic and helps in determining the proper aim of the research work.

2.1 Polymers and its composites

After modification with functional fillers and reinforcements, polymer composites (Landel & Nielsen, 1993) have been found to exhibit excellent friction and wear behaviour. The key advantages of matrix polymers (Fry, 1986) are their low cost, comfort of handling, chemical resistance & low density. Thermoplastic polymers, thermosetting polymers, elastomers, and their mixes are the polymers used in composites.

2.2 Prosthetics and Orthotics technological development

To meet the functional demands of the person, the prosthetic must be a one-of-a-kind mix of appropriate materials, location, design, and manufacture. Orthotics can be used on many different parts of the body, including the upper and lower limbs, the skull, and the spine. A flexible action foot, a strong composite pylon, and a socket adapter are all part of the lower leg prosthetic. (Levangie & Norkin, 2011).

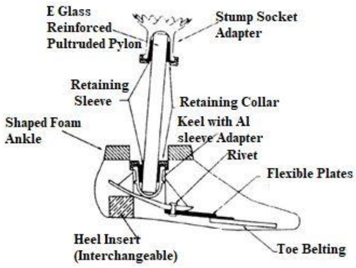


Figure 2.1: New prosthetic cross-section diagram (Michael & Bowker, 2004)

When using orthopedic instruments, the associated major stress and force assessments are very helpful in selecting and applying the correct composite. Since the weight is transmitted through the wall of the socket, the outer surface is subject to a constant tensile load and the inner wall is equally subject to the opposite compressive load (figure 2.2).

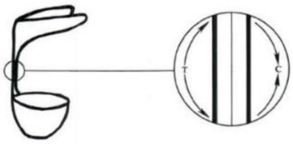


Figure 2.2: Stresses distribution on socket wall (Current, Kogler, & Earth, 1999).

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.

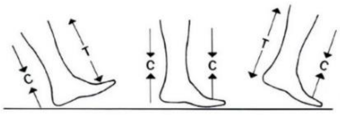


Figure 2.3: The forces transmitted through the anterior and posterior aspects during the walking cycle (O&P Virtual library)

Normal walking incorporates the stance phase with one leg and the swing phase with the other as shown in figure 2.3. Muscles must resist gravity, accelerate or decelerate impact forces, and contract to overcome tread resistance.

2.3 Material, manufacturing, and testing of Prosthetic / Orthotics systems by traditional methods and Advanced manufacturing methods

2.3.1 Traditional Prosthetic/Orthotics systems

(a) Material:

Different metals are used for prosthetics. Aluminum, titanium, magnesium, copper, steel, and many more. Composites have several advantages over steel, which have inherent design limitations, are difficult to transport, are expensive, are susceptible to corrosion, and have high maintenance costs (Ramakrishna, Mayer, Wintermantel, & Leong, 2001).

(b) Manufacturing:

The design and manufacture of prosthetics are still done manually and rely heavily on prosthetic know-how (skill and experience). This subjective and static assessment results in a high rate of non-conforming prosthetics, increasing costs and delays. The traditional design process, depicted in figure 2.4, can be divided into four main stages (Jaimes, et al., 2018).

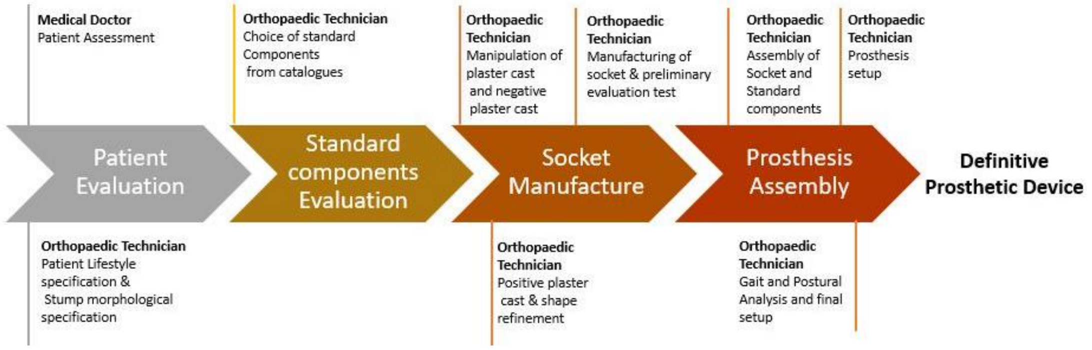


Figure 2.4: Traditional manufacturing workflow for a modular prosthetic (Colombo & others, 2014)

(c) Testing:

Flexible composite panels are used in the foot design to enable a seamless transition from heel to finish in the gait cycle. Extensive testing of the new member's components has demonstrated its durability and dependability.

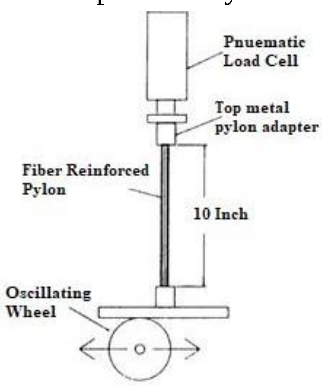


Figure 2.5: Schematic of pylon fatigue test

2.3.2 Prosthetic/Orthotic systems by advanced manufacturing method

3D printing (Redwood, Schöffer, & Garret, 2017) is a layered modeling process based on the principles of inkjet printing. A commercially produced prosthetic currently costs between Rs 3,50,000 and Rs 4,50,000. Given this significant amount, many people who require prosthetics cannot afford them and must live with limitations. 3D-printed prosthetics (Ten Kate, Smit, & Breedveld, 2017), on the other hand, are cheap and affordable.

(a) Materials:

The stability of the filament diameter (1.75±0.02mm) can ensure the printing extruder is out of blocking and slipping and it is important for printing a smooth product.

Figure 2.6: Filament spools

ABS, PLA, and their many mixtures are the most prevalent FDM 3D printing materials (figure 2.6). Advanced FDM printers (Table 2.1) may also print with specialist materials that have increased heat resistance, impact resistance, chemical resistance, and stiffness (Dizon, Espera Jr, Chen, & Advincula, 2018).

Table 2.1: Specific properties of 3D printing polymers

Material	Property				
	Technical Name	**Chemical Formula**	**Melting Temperature (°C)**	**Tensile Strength (MPa)**	**Density** (g/cm^3)
ABS (Yang, Grottkau, He, & Ye, 2017)	Acrylonitrile Butadiene Styrene (ABS)	$(C_8H_8)x\cdot(C_4H_6)y\cdot(C_3H_3N)z)$	220-270	46	1.06
PLA (Hsueh, et al., 2021)	Polylactic Acid(PLA)	$(C_3H_4O_2)$ n	180-220	50-70	1.24
PA (Zhang, Fan, & Liu, 2020)	Polyamide (PA)	$C_{12}H_{26}N_2O_4$	220	76	1.13
HIPS (Kaveh, Badrossamay, Foroozmehr, & Etefagh, 2015)	High Impact Polystyrene (HIPS)	$(C_8H_8)N$	210-249	53	1.04
PET (Woern, et al., 2018)	Polyethylene Terephthalate (PET)	$(C_{10}H_8O_4)n$	260	152	1.56

(b) Testing:

Tensile testing of materials (Van Der Klift, et al., 2016), including metals and plastics, is the most essential testing strategy for testing mechanical properties. This information is essential for designers and quality professionals to accurately predict the performance of their end applications. This data is fundamental to developing new materials and expanding applications (Letcher & Waytashek, 2014).

Figure 2.7: Test specimen before and after testing (Pernica, et al., 2021)

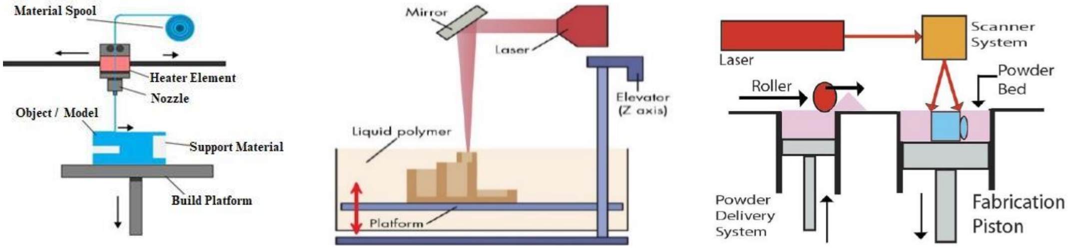
For both test methodologies, specimens are evaluated at room temperature (23 °C) at an average rate of 5 mm/min. The stress is calculated using the dimensions of the breakpoint measured before the test (figure 2.7). Tensile experiments on 3D printed materials are summarised in Table 2.2 (Decuir, Phelan, & Hollins, 2016).

Table 2.2: Tensile testing for 3D printed materials

Material	Maximum Strain	Maximum Stress (N/mm^2)
ABS – M30 (Fischer, 2011)	0.12	30.2
ABS+ Dim EL (Torrado, et al., 2015)	0.06	28.7
Polycarbonate (Cantrell, et al., 2017)	0.09	60
Undraped Copolymer (Singh, Ramakrishna, & Berto, 2020)	0.5	27.3
Draped Copolymer	0.5	28.1
Laminated Resin	0.07	262.5

(c) Manufacturing:

A child between 4 and 16 years old, grows 5 to 7 cm per year, so a child's prosthetic must be replaced every 6 to 12 months compared to 3 to 5 years for adults. Repairing a damaged prosthetic can cost more than buying a new limb. Creating a traditional prosthetic can take weeks or months, but creating a 3D-printed prosthetic takes just one day, making it more accessible. Some of the additive manufacturing (Wong & Hernandez, 2012) processes are listed below;



(a) (b) (c)

Figure 2.8: Additive manufacturing process (Molitch-Hou, 2018) (a) FDM (b) SLA (c) SLS

3D printing allows users to create specific shapes and sizes to achieve a highly customizable restoration. Prosthetic have been used successfully for dentures, dental prosthetic, hip, femur, and knee reconstruction and continue to develop as a viable and preferred option for prosthetics as shown in figure 2.9 (Aherwar, Singh, & Patnaik, 2013).

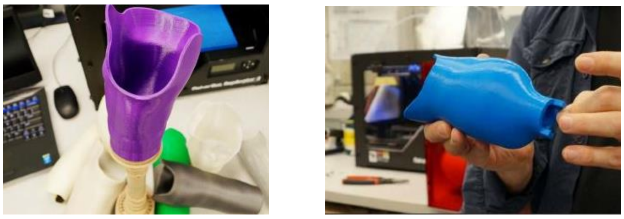


Figure 2.9: 3D printed prosthetics

Therefore, as natural 3D printing continues to develop, 3D prosthetics will become mainstream and transform the field (Rengier, et al., 2010).

2.4 Case studies on prosthetic and orthotics elements using finite element analysis, design optimization, and development process

2.4.1 Case studies on prosthetic elements

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 is now on the market is displayed in Table 2.3 below.

Table 2.3: Research on currently utilized materials and techniques for prosthetic devices

Sr No.	Author, Year	Body Element	Material	Method	Results
1	Tay, Manna, & Liu, 2002	Prosthetic Socket	Composite material	Fused Deposition Modeling	Realistic socket fabrication and clinical trials have confirmed the viability of FDM technology.
2	Dayal Udai & Nath Sinha, 2017	Prosthetic limbs socket	N.A.	CAD Modeling	This method will be useful for clinical assessment, training/research in record keeping, and the transfer of manual editing skills to a CAD/CAM system.
3	Hsu, Huang, Lu, Hong, & Liu, 2010	Transtibial Prosthetic Socket	Carbon fiber	Fused Deposition Modeling	Traditionally, prosthetic sockets are made from repeated plaster casts of a stump, which is fully dependent on the manual abilities of a Prosthetist who should be skilled in the replication and modification of stump moulds.
4	Gebhardt, Schmidt, Hötter, Sokalla, & Sokalla, 2010	Dental part	Metal powder	Selective laser melting	SLM is an excellent technology for producing dental components. For best results, materials databases should be built separately for each material and preferably for similar geometries.
5	Lenka, Choudhury, & others, 2011	Socket for a trans-tibial prosthetic	Composite material; propylene	FEM	The results summarize that embedding local fit features into the socket wall can be an effective method to distribute peak stress zones and also reduce the contact pressure between the stump and the socket.
6	Colombo, Facoetti, Regazzoni, & Rizzi, 2013	Lower limb prosthetic	Aluminium / stainless steel/titanium/carbon	CAD Modeling	The final trial of the exchange patient confirmed that a whole system is a good approach for the virtual design of lower limb prosthetic.
7	Al-Khazraji, Kadhim, & Ahmed, 2012	Lower limb prosthetic socket	Composite material	Vacuum molding technique	The findings indicate that altering the kind of reinforcement has a considerable impact on the measured attributes.
8	Sengeh & Herr, 2013	Prosthetic Socket	3D Printing materials	3D printing	Observed that maximum contact pressure in the fibula region of peaks 1 and 2 was reduced by 17% and 15%, respectively, compared to conventional sockets while participants using VIPr sockets walked at favourable speeds.
9	Bose, Vahabzadeh, & Bandyopadhyay, 2013	Bone	Biomaterials	3D printing	Choosing the right binder for 3DP remains a challenge and may require extensive optimization before producing high-quality parts.
10	Maji, Banerjee, Banerjee, & Karmakar, 2014	Hip prosthetic	Biomaterials	Rapid Prototyping	Today, advanced AM technologies such as LENS and EBM can be used to manufacture custom prosthetics.
11	Leddy, Belter, Gemmell, & Dollar, 2015	Prosthetic fingers	Composite	3D printed moulds	Synthetic fingers have the highest stiffness with the lowest weight compared to other fingers tested, as well as customizability and lower cost.
12	Cahill, 2016	Prosthetic devices	3D Printing materials	Fused Deposition Modeling	This project demonstrates the feasibility of using laminated molding to create an inexpensive and durable prosthetic for use in companion animals.
13	van Gaalen, et al., 2016	Hip Implant	Ti-6Al-4V	Metal Additive Manufacturing	This modular design enables you to simply implant and test several sensors in your implant, providing real-time information on the implant's performance and condition.

14	Sato, Togo, & Yamanaka, 2016	Prosthetic (Socket and Prosthetic blade)	Nylon12/ powder ASPEX-PA2	Laser Sintering	The purpose of this research is to provide mass-personalized products to a wider range of people rather than providing customized products to specific people.
15	Chen, Jin, Wensman, & Shih, 2016	Orthotic and prosthetic	Nylon 11/Nylon 12/PP	Additive Manufacturing	Proven AM technique for creating personalised lower limb FOs, AFOs, and prosthetic sockets that fit well and are durable.
16	Greene, Lipson, Soe, & Mercado, 2016	Prosthetic hand	ABS/PLA	Additive Manufacturing	After a series of tests, the prosthetic was able to carry groceries, carry a cell phone, throw a tennis ball, and open the door.
17	Szostakowski, Smitham, & Khan, 2017	Prosthetic parts	Plaster of Paris	Traditional	Certain hazards can be reduced by using the proper throwing technique. It is important to let the patient know what goes wrong with the cast.
18	Ten Kate, Smit, & Breedveld, 2017	Limb prosthetic	ABS/PLA	3D printing	The overview (58 devices) describes the device's general parameters, mechanical and kinematic specs, and the 3D printing technique utilised in the hand.
19	Hawes, Wentworth, & Ma, 2017	Prosthetic hand	ABS/TPU	Additive Manufacturing	Manufacturing the fingers and palms from TPU filament gave the prototype an adaptive grip as opposed to a more rigid structure provided by hard materials like ABS.
20	Radosh, Kuczko, Wichniarek, & Górski, 2017	Prosthetic hand	ABS	Fused Deposition Modeling	Design operations for this type of product can be standardized and then automated using intelligent CAD models, significantly reducing overall product preparation time and costs.
21	Garg, Pathak, Tangri, Gupta, & others, 2016	Prosthetic finger	Silicones	Traditional method (wax pattern fabrication)	When the finger prosthetic is uniquely sculpted and stained in situ under a range of lighting conditions, this step of restoration is most successful.
22	Rhyne, Post, Chesser, Roschli, & Love, 2017	Transhumeral Prosthetic	ABS/Polyetherimide	Additive Manufacturing	The prosthetic could be printed from polyetherimide, which has nearly triple the tensile strength of ABS.
23	Rochlitz & Pammer, 2017	Foot Prosthetic	ABS	Fused Deposition Modeling	The 3D printable prosthetic design presented in this article shows that such ABS filament products can be a cost-effective solution for moderately active amputees.
24	Tao, Ahn, Lian, Lee, & Lee, 2017	Prosthetic foot	PLA	Fused Deposition Modeling	Finally, reduce the weight of the prosthetic from 0.79kg to 0.30kg. 62% of weight loss plays an important role in achieving patient satisfaction.
25	Cherelle, et al., 2017	Bionic feet	N.A.	Rapid Tooling	Experiments on a treadmill demonstrated the impacts of a resettable overrunning clutch and enhanced EEA when walking on flat and hilly terrain.
26	Cuellar, Smit, Breedveld, Zadpoor, & Plettenburg, 2019	Prosthetic hands	Polylactic acid(PLA)	3D printing	The prosthetic can be 3D printed on an inexpensive FDM machine and can be gripped in various ways.
27	Upender, Srikanth, Karthik, & Kumar, 2018	Prosthetic runner blade	3D Printable materials	3D printing	The required results of stress and strain concentration values are obtained. Finally, based on these values, the design is modified for optimal performance.
28	Tappa & Jammalamadaka, 2018	Customized implants	Biomaterials	Bioprinting	There is a great research need to fabricate new biofilm-forming agents with tunable and functionally reversible biological properties at the site of application.
29	Türk, Einarsson, Lecomte, & Meboldt, 2018	Prosthetic	Carbon fiber-reinforced polymers	Additive Manufacturing & autoclave layup process	The limitation of the manufacturing method is the thermo mechanical stability of the AM polymeric components under the autoclave pre-treatment condition.
30	Geierlehner, Malferrari, & Kalaskar, 2019	Medical devices	Biomaterials	3D printing	This study shows the potential to obtain 3D scans of the hand that can then be used to design a custom 3D-printed medical device.
31	Heinrich, et al., 2019	Biomedical components	Biomaterials	4D bioprinting	3D bioprinting offers great flexibility for fabricating functionally and structurally related biomimetic and volumetric tissues.

32	Alkhatib, Mahdi, & Cabibihan, 2019	Prosthetic hand	ABS/PLA	3D printing	The results were used to calculate the mechanical properties that could be used to design and manufacture products from these materials.
33	Salomão, Santos, & Junior, 2019	Dental implants	Cement	Traditional	An interdisciplinary approach that combines prosthetic and periodontal procedures has proven to be efficient and improve aesthetic results.
34	Oleiwi & Hadi, 2021	Prosthetic feet	Composite	Traditional	Carbon fiber and glass combined with an epoxy resin base will provide medium efficiency with durability, lightweight and energy return to amputee patients.
35	Park, Ahn, Lee, & Lee, 2020	Motorized Prosthetic leg	Aluminium alloy/ plastic nylon	3D printing	Based on human gait data, the motorised prosthetic is ideally constructed while retaining structural safety under boundary circumstances, with its knee motion coordinated with normal human stride through the PD controller.
36	Javanmard, Mohammadi, & Mojtahedi, 2020	Nasal prosthetic	Plaster of Paris / Silicon	Traditional	A nasal prosthetic supported by two implants positioned in the nasal floor and stabilised by rods and clamps was utilised to restore the defect following incisional surgery in this clinical report.
37	Kumar & others, 2020	Biomedical components	Biomaterials	3D printing	This study reports important existing literature on the design and fabrication of biomedical components using metallic and non-metallic materials.
38	Vignesh, et al., 2021	Biomedical implants	Biomaterials	3D printing	Implants manufactured using AM technology have greater biocompatibility than conventional procedures and play a vital role in the bioprinting of complex organs due to their enhanced features.
39	Balaramakrishnan, Natarajan, & Sujatha, 2021	Prosthetic feet	Hyper-elastic/ orthotropic and isotropic linear elastic	Finite element analysis	The suggested numerical model may be utilised to offer thorough a priori insights into biomechanical factors that influence prosthetic features when walking.
40	Lecomte, et al., 2021	Variable stiffness foot	Composite	Traditional	In this study, mechanical tests and FEM successfully characterized the prosthetic and reflected the biomechanical response of humans during gait as measured by motion analysis.
41	Naseri, Mohammadi Moghaddam, Gharini, & Ahmad Sharbafi, 2020	Hydraulic prosthetic foot	Carbon	Traditional	A hybrid mechanism that essentially acts as a clutch has been developed for the H2AP, expanding the range of motion of the damper and reusing the stored energy while the damper is disengaged.
42	Vinay, et al., 2022	Passive ankle-foot prosthetic	N.A.	Finite element analysis	The structural analysis demonstrates that the unit can withstand a vertical load of 800 N with a FOS of 1.5.
43	Oleiwi & Hadi, 2021	Prosthetic socket	Composites and thermoplastics	Traditional	The best-laminated composite has three layers of jute plus four layers of carbon, depending on the result.
44	McDonald, et al., 2021	Below-knee prosthetic	Composite/Spring steel	Traditional	All participants showed decreased active hip joint activity of the prosthetic limb when walking with flexible toe joints.
45	Dillingham, Kenia, Shofer, & Marschalek, 2022	Transfemoral Prosthetic	Composite/Steel	Injection moulding	In this short-term feasibility study, an instantly adjustable prosthetic provided a safe, comfortable, and functional gait to people who lost a limb as a result of blood exchange.
46	Yan, Chen, Cheng, & Wang, 2022	Prosthetic hand	Nylon	3D printing	The results show that the soft hand can grasp many objects and the ab/d joint allows the soft hand to perform many human-like hand gestures.

2.4.2 Case studies on orthotics elements

This section briefly discusses the design and development of orthotics using traditional and AM processes. Traditional P&O device production techniques are still primarily manual and require the knowledge of an orthopedic surgeon to generate high-quality products. However, these production methods are often unpleasant for the patient. Traditional techniques of capturing foot and ankle morphology can be time-consuming and expensive, especially when producing AFOs (Patel & Gohil, 2022), as they require specialist equipment like a casting room, furniture that is favourable to plaster, a sink with plaster catch, and a non-slip surface. Table 2.4 summarizes studies on existing materials and production processes for AFOs, wrists, and other assistive devices.

Table 2.4: Work has been done on the materials and techniques currently utilized in AFOs, hand, wrist, and other assistive devices.

Sr. No	Author, Year	Body Part	Material	Method	Results
1	Yoo, Kim, Han, & Bogen, 2005	Knee braces & wrist	Hyper-elastic materials	Surface parameterization	The experiment's findings demonstrate how successfully geometric and biomechanical analysis may be used in the computer-aided design of medical assistance equipment.
2	Jain, Dhande, & Vyas, 2011	AFO	N.A.	3D virtual model	This study showed how a personalized, user-friendly dynamic AFO may be developed with the ability to provide anatomic mobility for the long-overdue historical clubfoot deformity repair in newborn infants.
3	Font-Llagunes, Pàmies-Vilà, Alonso, & Lugrís, 2011	knee-ankle-foot orthotic	Thermoplastic Material	Design and simulation approach	The approach is effective in terms of computing, and it produces findings that are helpful for choosing actuators when designing active orthotics.
4	Paterson & Bourell, 2012	Wrist splints	ABS	FDM	The software prototype was quite simple to use and navigate for all participants.
5	Stier, Simon, & Reese, 2015	AFO	Carbon fiber reinforced composite	FEA	It is possible to infer that the provided method is well suited for quantitatively obtaining global and local findings for AFOs without the requirement for extra tests or parameter fitting.
6	Jin, He, & Shih, 2016	AFO	Common thermoplastic Material.	FDM	Structure optimizations are used on the AFO portion to minimize the support structure while maintaining strength.
7	Kalami, Khayat, & Urbanic, 2016	Hand brace & Finger design	NinjaFlex and ABS	Bead-Based Deposition Processes	The surface quality of AM-fabricated products may be rough, especially if they feature curved surfaces with inclination angles close to zero.
8	Walbran, Turner, & McDaid, 2016	AFO	ABS	3D printing	The stiffness testing machine results demonstrated that the final AFO design had good structural integrity.
9	Totah, Kovalenko, Saez, & Barton, 2017	AFO	Polyethylene (PE)	Optimization Algorithms	An optimization framework may be used to automate a component of the decision-making process and arrive at a quantitatively optimal solution.
10	Baronio, Volonghi, & Signoroni, 2017	Hand orthotic	ABS	FDM	Aside from being utilized on either the right or left hand, the final product may be useful as a palmar support in the acquisition of the dorsal side of the hand.
11	Cazon, Kelly, Paterson, Bibb, & Campbell, 2017	Wrist splint	Vero White Plus and Tango Black Plus	PolyJet AM	The current study contends that, from a technological standpoint, the AM splint design achieves the same or even greater level of performance in displacements and stress values than the traditional low-temperature thermoplastic technique, and is therefore a viable solution to splint design and fabrication.
12	Cha, et al., 2017	AFO	Thermoplastic Material	FDM	According to the kinematic analysis, the normal AFO made the ankle more dorsiflexed during the swing phase, whereas the 3DP AFO and no AFO made the ankle the least dorsiflexed.
13	Chen, Zi, Wang, Li, & Qian, 2021	AFO	Smart materials	3D printing	The authors discussed the biomechanics of normal and abnormal human gaits, followed by an overview of currently available AFOs. Finally, the authors evaluated the present AFOs' shortcomings as well as their future research and development prospects.
14	Dal Maso & Cosmi, 2019	AFO	PLA	3D printing	Designing a 3D-printed mould for AFO injection moulding would eliminate any concerns associated with anisotropy in 3D-printed components, however, the expense of the mould fabrication might raise the AFO cost.

15	Schmitz, Mori, Gamba, Nohama, & de Souza, 2019	Wrist-Hand Orthotic	PETG	FDM	This orthotic enhanced the patient's fit, comfort, and functional hand abilities.
16	Shahar, et al., 2019	AFO	Kenaf composites	3D printing	The findings indicate that Kenaf composite has the potential to be used in AFO manufacture because of its tensile strength, which is nearly similar to PP tensile strength.
17	Lee, et al., 2019	Assistive device	PLA	3D printing	Assistive devices that were 3D printed functioned better than ready-made alternatives.
18	Harte, 2020	Hand Orthotic	Thermoplastic Material	Traditional	With references to the appropriate literature, the novel design presented expands on previous notions of dynamic traction orthotics. It serves as a template for future investigation into the design's qualities.
19	Jones, Cancio, Stanley, Truax, & Gower, 2021	Radial and ulnar wrist orthotic	Thermoplastic Material	Traditional	The U-WACO and R-WACO designs may increase comfort, compliance, and functional capacity to execute everyday chores while providing targeted rest and recuperation of the anatomical structure(s) at the radial and ulnar portions of the wrist that have been overused or traumatized.
20	Chu, Wang, Sun, & Liu, 2022	Thumb orthotic	TPE material	3D printing	The orthotic offers more hand movement freedom and stronger support than the standard, manually created orthotic.
21	O'Brien, et al., 2021	Fingers	ABS	3D printing	Aspects of both 3D-printed prototypes suggested future advancements; however, mechanical methods to reduce the force required at the wrist to engage the grip remain necessary.
22	Sarma, et al., 2020	AFO	PLA, polypropylene, and ABS	3D printing	This study describes a motorized AFO that may be used as an assistive device for those who are impaired. It is low in weight, which gives support and improves interaction with the human body.
23	Portnoy, et al., 2020	Finger orthotic	ABS	3D printing	The 3D-printed orthotic was substantially lighter than the manual orthotic, although the preparation time was longer.
24	Ali, Smagulov, & Otepbergenov, 2021	AFO	Carbon Fiber/ Nylon 12	FDM	The typical adapted model with Nylon 12 is shown to be far more sustainable than the articulated form with carbon fiber.
25	Totah, Menon, Gates, & Barton, 2021	Ankle brace	Thermoplastic Material	3D printing	When an AFO operates throughout a range of motion at a set speed, the nondestructive, automated SMApp measures torque and angle.
26	Wang, et al., 2021	AFO	Traditional Material	Manual fabrication method	These findings might be used to improve teaching procedures, allow therapists to view and track their changes, and develop reference maps for digital manufacturing.
27	Eddison, Healy, Buchanan, & Chockalingam, 2022	AFO	Thermoplastic Material	Manual fabrication method	This categorization is necessary for more effective evidence-based therapy.
28	Ranjan, Kumar, Kundu, & Moi, 2022	Various field	3D printing materials	3D printing	The uses of 3D printed items include goods composed of various materials and 3D printing procedures.
29	Darwish, Al-Qady, El-Wakad, Farag, & Darwish, 2022	Dental	Biodegradable polymers	3D printing/ 4D printing	Creating surgical models for viewing and training, as well as printing patient-specific implants and tissues, and organs.
30	Kumar & Chhabra, 2022	Orthotic Devices	Biodegradable	Additive manufacturing	This article discusses the possible advantages of using the AMT for topologically personalized orthotic production and offers a sustainability angle for the medical industry.

CHAPTER 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. 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 insufficient P&O infrastructure, are overly centralised, and produce insufficiently to fulfil demand.

Figure 3.1: Human prosthetic and orthotic elements

However, very few studies are dedicated to investigating the optimization of biomimetic structural design. Still, there is a gap in the 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.

3.2 Problem definition

India has the largest young traumatic amputee population in the world. There are private clinics/ Multi-National Companies in the country only a few can afford and make use of their availability. Because of variations in growth and weight, the human body changes with time, so it is necessary to **replace and adjust** the P&O regularly. This means that the P&O elements may not be used for long periods. 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 the 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.

Therefore, cost-efficient prosthetic parts 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 advanced manufacturing using polymer/composite.

So to overcome such problems and limitations, the research area will be covered on the topic entitled *"Investigations on Prosthetics / Orthotics elements developed from polymers and its composites".*

3.3 Need for study

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

Based on the field survey, India does not have any K3 and K4 level foot manufacturing units widely. (India has only K1 and K2 level foot manufacturing units). 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.

There is a scope for the development of Prosthetics / Orthotics elements through the latest advanced manufacturing technique e.g. Additive manufacturing, CNC Machines, etc.

3.4 Research objectives

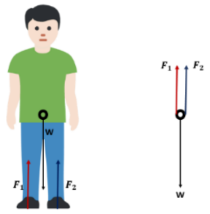
Various methods have been proposed to overcome the difficulties faced by early researchers and introduce new types of techniques. Therefore, this research proposes new and cheaper materials that retain the properties required in the medical field.

The objectives of the present research are:

- To investigate patients' specific needs for prosthetics and orthotics elements 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 purposes.
- To evaluate P&O elements utilizing a variety of computational software tools.
- To highlight and project polymers/composite as a material for the development of various P&O elements.
- To develop 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.

CHAPTER 4
HUMAN BODY ANTHROPOMETRY

The primary area of anthropology called anthropometry (Easterby, 2012) examines how to measure body parts and other physical traits to identify variations between people and groups. Numerical simulations of biological and physical processes are used to get force data and analysis on the human leg.



(a) Force acting on a person (b) FBD of person

Figure 4.1: External forces acting on the human body during standing

To solve biomechanical problems, four essential body segment data are required: mass, length, center of mass, and radius of gyration. As seen in figure 4.2, the pertinent body segments are typically arranged in a structure known as a link segment model.

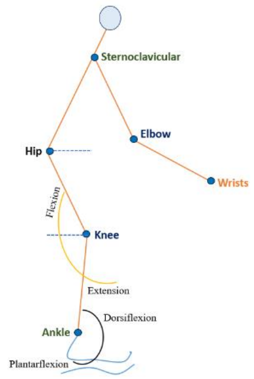


Figure 4.2: Link segment model

4.1 Segment length

A set of typical segment lengths is expressed in terms of body height, which is illustrated in figure 4.3 (Drillis & Contini, 1966).

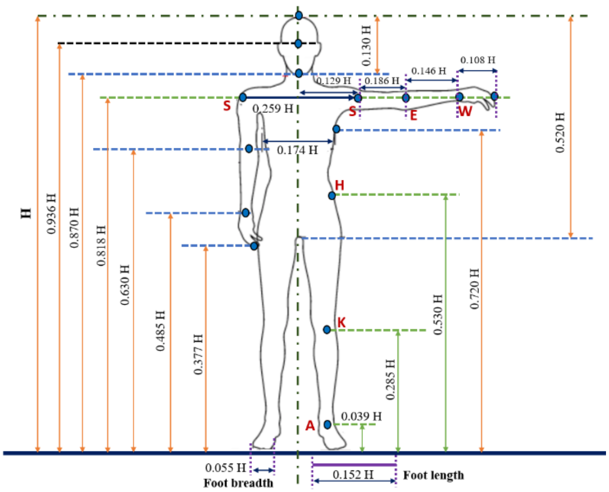


Figure 4.3: Anatomical structures length as a proportion of total body height H

4.2 Segment mass and center of mass

Table 4.1 displays an average set of anthropometric measures for each human segment's mass and the position of the mass center.

Table 4.1: Anthropometric data of the human body (Winter, 2009)

Segment	**Segment weight/Total body weight**	**Center of Mass/ segment length**		**Radius of gyration / Segment length**			
		Proximal	*Distal*	*C of G*	*Proximal*	*Distal*	*Density*
Hand	0.006 M	0.506	0.494 P	0.297	0.587	0.577 M	1.16
Forearm	0.016 M	0.430	0.570 P	0.303	0.526	0.647 M	1.13
Forearm and hand	0.022 M	0.682	0.318 P	0.468	0.827	0.565 P	1.14
Upper arm	0.028 M	0.436	0.564 P	0.322	0.542	0.645 M	1.07
Total arm	0.050 M	0.530	0.470 P	0.368	0.645	0.596 P	1.11
Foot	0.0145 M	0.50	0.50 P	0.475	0.69	0.690 P	1.1
Leg	0.0465 M	0.433	0.567 P	0.302	0.528	0.643 M	1.09
Foot and leg	0.061 M	0.606	0.394 P	0.416	0.735	0.572 P	1.09
Thigh	0.100 M	0.433	0.567 P	0.323	0.54	0.653 M	1.05
Total leg	0.161 M	0.447	0.553 P	0.326	0.56	0.650 P	1.06

4.3 Properties of density, mass, inertia & radius of gyration

The human body is composed of several sorts of tissue, with each having distinctive densities. Compact bone has a relative density that is more than 1.8. Drillis and Contini (1966) suggested the following formula for ponderal index c as a function of the body's density d (Winter, 2009).

$$d = 0.69 + 0.9c \text{ kg/liter} \qquad \text{………………. (Eqn. 4.1)}$$

Where $c = h / (w^{1/3})$, h = height in meter and w = weight in kg.

4.4 Forces and moments in shoulder joints

The joint force varies from the inter-segment force in that the forces generated from the activity of the muscles across the joint must be included in the calculation. When no muscles are active, the joint force equals the inter-segment force. 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 4.4. The arm has a total mass of 4.0 kg, with the center of mass placed at the shoulder joint.

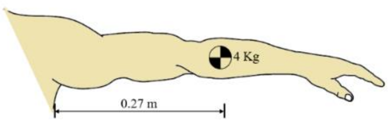


Figure 4.4: Arm held out straight to the side

Figure 4.5 depicts both of them on the free-body diagram. Because the arm segment is in static equilibrium, the total of all forces should be zero. Vertical components are added together, with upwards regarded as positive.

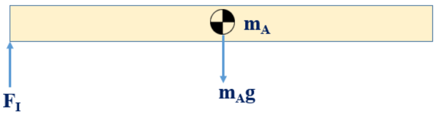


Figure 4.5: Free body diagram of arm

$$\sum Fv = F_I - m_A g = 0 \quad \text{..........................(Eqn. 4.2)}$$

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;

$$F_I = m_A g \quad \text{........................ (Eqn. 4.3)}$$

$$F_I = 4 * 10 = 40 \text{ N}$$

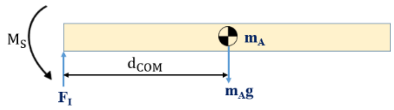


Figure 4.6: Free body diagram of the arm including moments

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

$$\sum M = M_S - m_A g * d_{COM} = 0 \quad \text{..................... (Eqn. 4.4)}$$

$$M_S = m_A g * d_{COM}$$

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

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

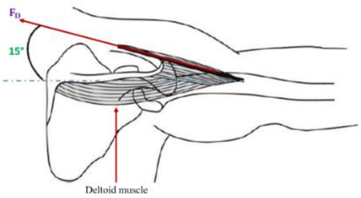


Figure 4.7: Deltoid muscle force

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 center and applies a force at 15 degrees to the arm segment as shown in figure 4.7.

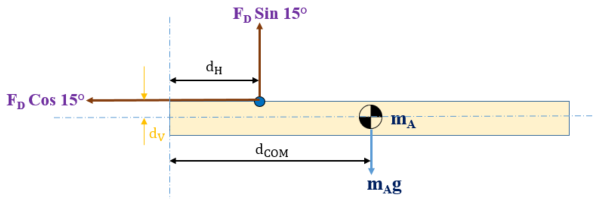


Figure 4.8: FBD representing forces generating moments near the center of the shoulder joint

Using rotational equilibrium at the shoulder joint's axis;

$$\sum M = F_H\, d_V + F_V\, d_H - m_A g\, d_{COM} \quad \text{..................... (Eqn. 4.5)}$$

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

$$F_D \cos 15°\, d_V + F_D \sin 15°\, d_H - m_A g\, d_{COM} = 0$$

$$F_D = m_A g\, d_{COM} / (\cos 15°\, d_V + \sin 15°\, d_H)$$

$$= 389 \text{ N}$$

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.

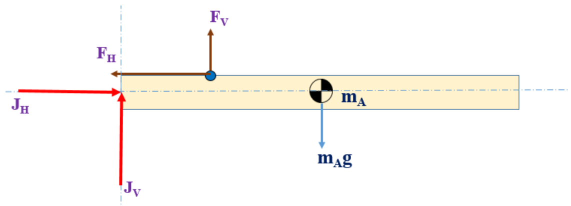


Figure 4.9: FBD includes components of deltoid muscle force and joint force

Figure 4.9 shows an FBD of an arm segment with vertical and horizontal deltoid muscle force components.

Adding up the horizontal forces:

$$\Sigma F_H = J_H - F_H = 0 \qquad \text{……………………. (Eqn. 4.6)}$$

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

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

Adding up the vertical forces:

$$\Sigma F_V = J_V + F_V - m_A g = 0 \qquad \text{……………………. (Eqn. 4.7)}$$

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

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

$$J = \sqrt{J_H^2 + J_V^2} \qquad \text{……………… (Eqn. 4.8)}$$

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

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

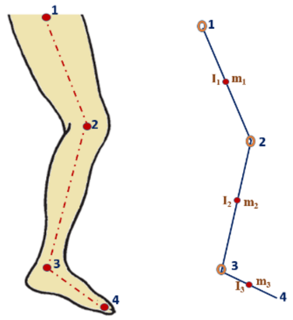
$$\tan\theta = J_V / J_H \qquad \text{……………………. (Eqn. 4.9)}$$

$$\theta = 9.2°$$

As a result, the shoulder joint force operating on the arm segment is 380 N in a 9.2° relative to the 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.

4.5 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.



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

Figure 4.10: Relationship between anatomical and link-segment model

Consider the rigid rod in figure 4.11, which is pivoted at point X and has the potential to spin in the paper's plane.

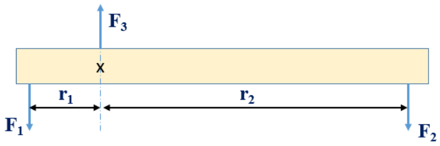
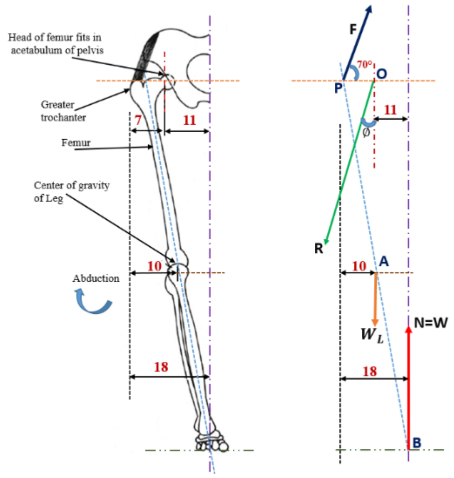


Figure 4.11: A rigid rod that may freely spin around a center at position X

If the algebraic sum of all torques is zero, the rod is in equilibrium:

$$\sum_i \tau_i = \sum_i r_i F_i = 0. \quad \text{(Eqn. 4.10)}$$

The force analysis for a person standing with one leg is mentioned in figure 4.12. At a 70° appropriate angle, the greater trochanter is subjected to the resultant force (F) of the abductor's muscles. The greater trochanter is roughly 18 cm from the midline, approximately 10 cm horizontally from the leg's center of mass, and approximately 7 cm vertically from the center of the femur's head in an average person. As seen in figure 4.12 (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 the leg

Figure 4.12: Human leg anatomy with force analysis

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

$$W_L = W/7 = 112.07 \text{ N}$$

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

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

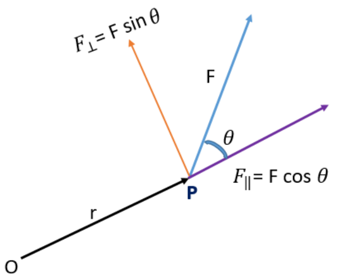


Figure 4.13: An element at point P is subjected to a force F

In the figure 4.13, an element is allowed to spin around point O. The horizontal components of the forces are:

$$\sum F_H = F\cos(70°) - R_H \qquad \text{............... (Eqn. 4.11)}$$

The forces' vertical components are:

$$\sum F_V = F\sin(70°) - R_V - \frac{W}{7} + W \qquad \text{............... (Eqn. 4.12)}$$

$$\sum \tau = -F\sin(70°) * 7 - \left(\frac{W}{7}\right) * (10-7) + W * (18-7) \qquad \text{............... (Eqn. 4.13)}$$

$$6.57\ F = 10.57W$$

$$F = 1.6\ W \qquad \text{............... (Eqn. 4.14)}$$

Now, R_H and R_V may be calculated using Equations 4.11 and 4.12.

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

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

$$R = \sqrt{R_H^2 + R_V^2} = 2.4\ W \qquad \text{............... (Eqn. 4.15)}$$

The angle $\emptyset$ is calculated from tan ($\emptyset$) = $\mathbf{R_H/R_V}$ and is found to be:

$$\emptyset = 13°$$

The solution to all of these equations is:

$$F = 1.6\ W$$

$$R = 2.4\ W$$

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

$$F = 1.6\ W = 1.6 * 784.5 = 1255.2\ N$$

$$R = 2.4\ W = 2.4 * 784.5 = 1882.8\ N$$

As a result, there is a gap in the development of foot anthropometry, which may serve as a baseline for the design of prosthetic and orthotic elements. Foot anthropometry has demonstrated that foot proportions vary greatly between individuals, and the significance is that the design of footwear, including prostheses, must take these variations into account to attain the required fitness. This set of calculations concentrates on estimating height and predicting patient weight based on foot dimensions/measurements.

CHAPTER 5
DESIGN & SIMULATION APPROACH OF PROSTHETIC FOOT

The complete technique for designing and analyzing multiple K-level human foot models is covered in this chapter. For material optimization data, many factors are analyzed on the foot structure model.

5.1 Design approach

The detailed design and development process of the prosthetic elements is mentioned below in figure 5.1. This includes research, analysis, and a complete understanding of the end user (Razzouk & Shute, 2012).

CONCEPTUALIZATION

Analysis of how the foot should work, Research on present works on prosthetic foots, Improvement on present works, Data collection

DESIGN APPROACH

Get dimension of patient (Anthropometry measurements), Design calculation for force and stress analysis, Modeling process

SIMULATION APPROACH

Material and shape optimization through software tools, structural analysis for various parameters

Figure 5.1: Design and simulation flow chart

5.2 Participatory approach

The purpose of this study is to gather information regarding the present model utilized by patients. A patient survey was conducted to obtain background information regarding the use of P&O elements during the various visit and one of the sample is illustrated in figure 5.2.

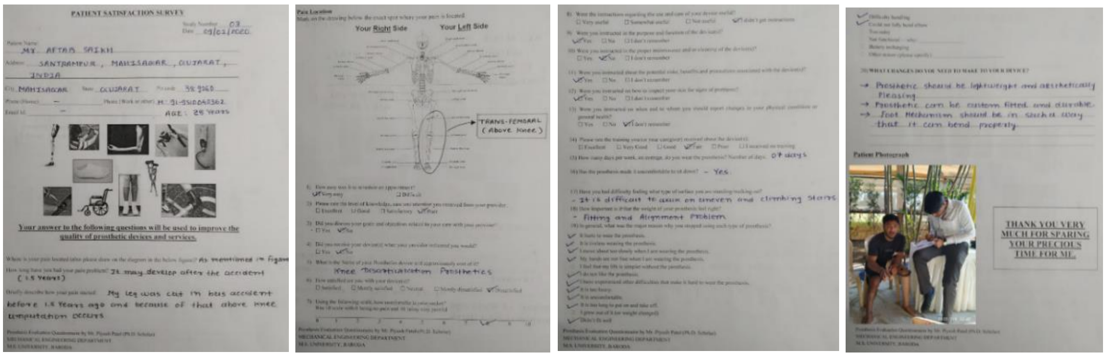


Figure 5.2: Patients feedback form 1

5.3 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 commercial plan can address in terms of customer value and market potential, design thinking is a discipline.

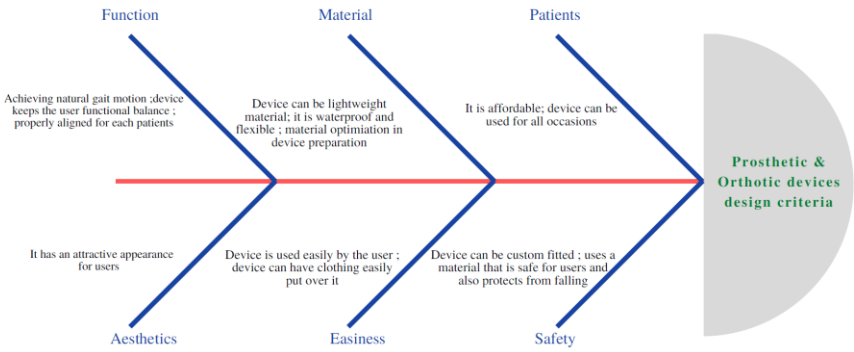


Figure 5.3: Prosthetic and orthotic devices design criteria

Most traditional prosthetics are integral structures, and the foot cannot be as flexible and convenient as a human foot. The main reason is that human feet are arch-shaped, and their toes can support activities. Therefore, we need a bionic mechanical foot to satisfy patients' desire for a highly flexible prosthetic. The design of these prosthetics depends on their functionality. Various configuration models of the prosthetic foot are developed as shown in the figure 5.4 to figure 5.9.

The purpose of the first utility model 1 and 2 is to provide a prosthetic foot, based on the existing bionic prosthetic foot, to further improve the cushioning and shock absorption effect of the prosthetic foot on the ground during walking.

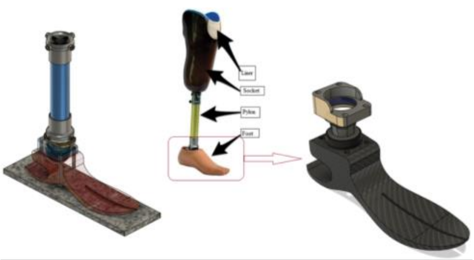


Figure 5.4: Prosthetic foot model 1

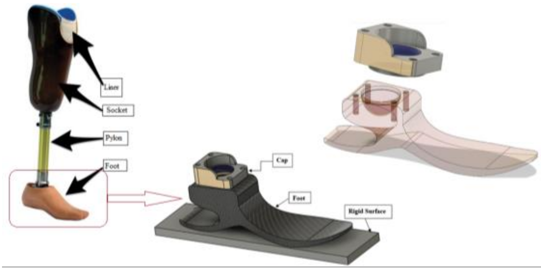


Figure 5.5: Prosthetic foot model 2

The second alternative conceptual design models 3 and 4 are developed for reducing the maximum stress and for increasing the strain energy. In the design modification instead of a single unit structure, extra plates are attached to the foot structure mechanism as described in the figure 5.6. A block of rubber imparted some unique properties to the foot piece additionally enabling the amputee to squat.

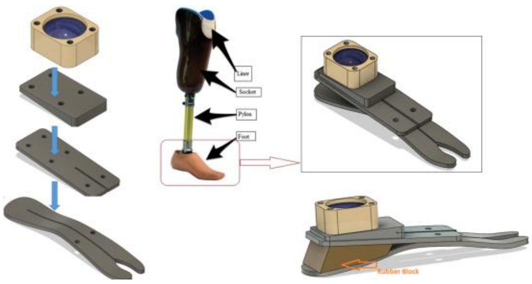


Figure 5.6: Prosthetic foot model 3

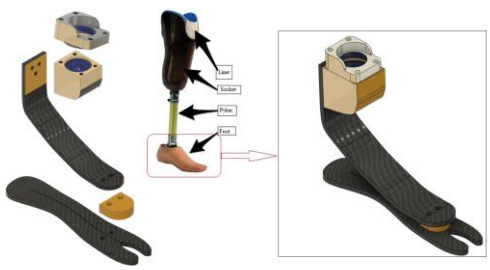


Figure 5.7: Prosthetic foot model 4

Because of shifts in mindset and much more advanced prosthetic technology, many people having physical deficiencies are engaging in a broader range of sports than before.

Figure 5.8: Prosthetic foot model 5

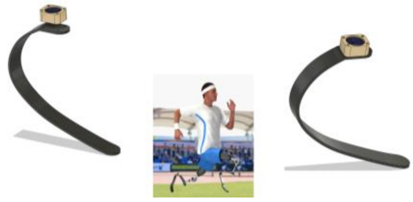


Figure 5.9: Prosthetic foot model 6

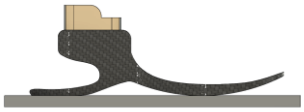
Advanced prosthetic devices for running are usually curved blades (Upender, Srikanth, Karthik, & Kumar, 2018) shape as shown in the third alternative conceptual design models 5 and 6. This provides a nice balance of flexibility and strength to withstand high-impact activities like sprinting and jumping.

5.4 Simulation approach

The different prosthetic foot analysis (Rochlitz & Pammer, 2017) stages are described to get the basic idea in different load situations. Gait has been separated into parts that allow us to describe, interpret, and assess the events that are taking place. A gait cycle is described as two consecutive occurrences of the same limb, which is frequently the lower extremity's first contact with the supporting surface.

a) Prosthetic foot “heel strike” analysis
b) Prosthetic foot “mid stance” analysis
c) Prosthetic foot “toe off” analysis

(a) Heel strike



(b) Mid-stance

(c) Toe-off

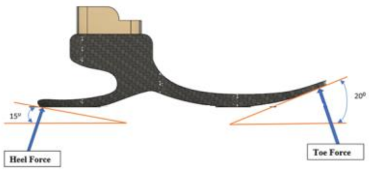


Figure 5.10: Prosthetic foot analysis stages

The results for each stage of the methodology have been tabulated and discussed in chronological order below. The midstance phase is reproduced by totally constricting the toe and heel to the platen. A same magnitude vertical load is applied to the foot in a downward motion.

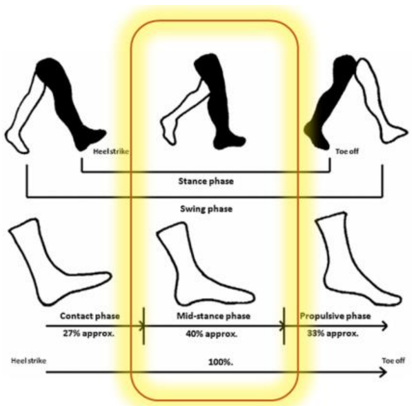
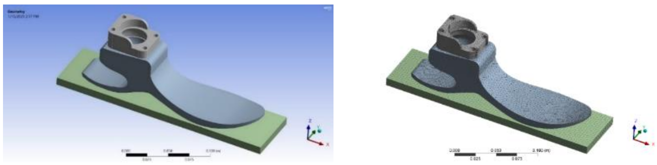


Figure 5.11: Prosthetic foot model 2 in “mid-stance” situation



(a) CAD geometry (b) Mesh model

Figure 5.12: Prosthetic foot model 2 geometry during midstance situation

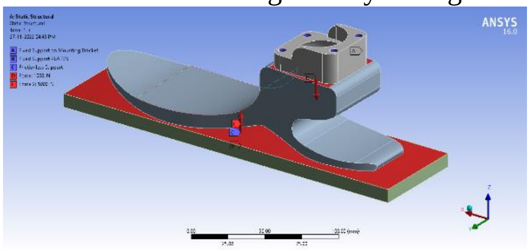


Figure 5.13: Static structural simulation of prosthetic foot model 2 during midstance situation

Table 5.1: Midstance analysis on prosthetic foot model 2

Sr no.	Materials	Total deformation(Hz)	Total deformation (mm)	Equivalent stress (MPa)	Strain energy(mJ)
1	**ABS**	446.56	0.09735	8.9925	0.002324
2	**ABS+PC PLASTIC**	443.01	0.09693	8.9863	0.002218
3	**ACETAL RESIN**	422.71	0.09587	8.9686	0.001946
4	**CARBON FIBER**	1078	0.07392	22.691	0.001593
5	**NYLON 6/6**	335.28	0.10268	9.0049	0.003685
6	**PEEK**	504.95	0.09409	8.8455	0.001478
7	**PET**	433.79	0.0958	8.9871	0.001933
8	**PLA**	489.83	0.09468	8.9266	0.00164
9	**UHMW-PE**	1363	0.090459	18.284	0.002472

Simulation results data by considering the optimization in the material for the prosthetic foot model 2 is mentioned in table 5.1. 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 midstance simulation.

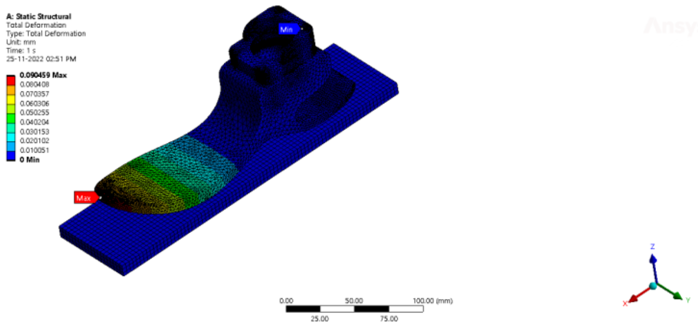


Figure 5.14: Total deformation in mm for prosthetic foot model 2 during midstance simulation

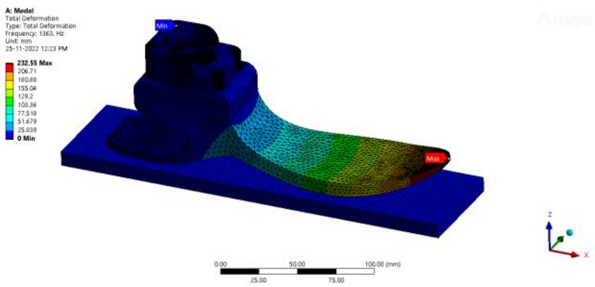


Figure 5.15: Total deformation in Hz for prosthetic foot model 2 during midstance simulation

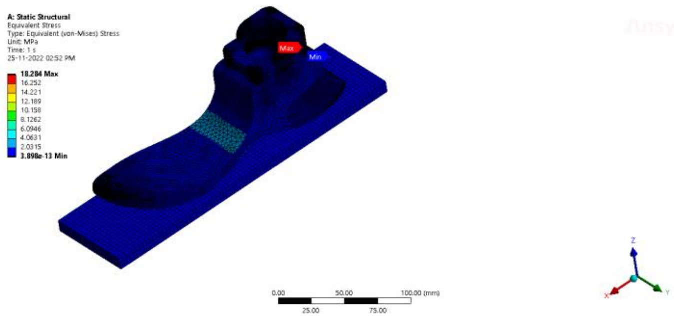


Figure 5.16: Equivalent stress for prosthetic foot model 2 during midstance simulation

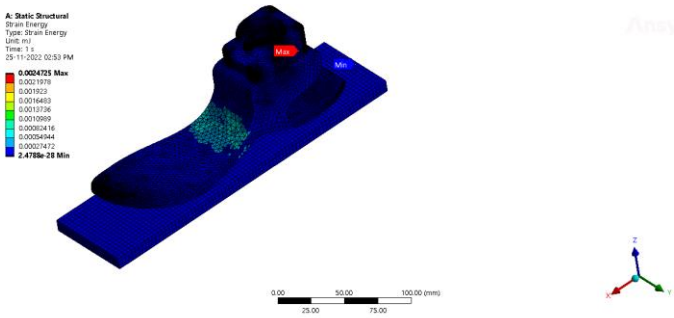


Figure 5.17: Strain energy for prosthetic foot model 2 during midstance simulation

Table 5.2: Midstance analysis on prosthetic foot model 2

Sr no.	Materials	Total deformation (Hz)	Total deformation(mm)	Equivalent stress (MPa)	Strain energy(mJ)
1	ABS	446.56	0.09735	8.9925	0.002324
2	ABS+PC PLASTIC	443.01	0.09693	8.9863	0.002218
3	ACETAL RESIN	422.71	0.09587	8.9686	0.001946
4	CARBON FIBER	1078	0.07392	22.691	0.001593
5	NYLON 6/6	335.28	0.10268	9.0049	0.003685
6	PEEK	504.95	0.09409	8.8455	0.001478
7	PET	433.79	0.0958	8.9871	0.001933
8	PLA	489.83	0.09468	8.9266	0.00164
9	UHMW-PE	1363	0.090459	18.284	0.002472

Table 5.3: 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

Table 5.4: Toe-off analysis on prosthetic foot model 2

Sr no.	Materials	Total deformation (Hz)	Total deformation (mm)	Equivalent stress (MPa)	Strain energy (mJ)
1	ABS	492.04	0.014	16.079	0.00132
2	ABS+PC PLASTIC	487.99	0.0133	16.079	0.001258
3	ACETAL RESIN	465.08	0.01163	16.08	0.001102

4	**CARBON FIBER**	590.54	0.0032	16.21	0.000444
5	**NYLON 6/6**	370.64	0.02278	16.074	0.00209
6	**PEEK**	556.54	0.0087	16.115	0.000818
7	**PET**	476.57	0.01153	16.069	0.0011
8	**PLA**	538.29	0.0096	16.085	0.000925
9	**UHMW-PE**	1613.3	0.003536	54.322	0.00263

According to the 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;

- 1st natural frequency for all phase analyses (midstance /heel strike / toe-off) is very large compared 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 1st mode in midstance: 1363 Hz; heel strike: 595.85 Hz and toe-off: 1613.3 Hz.

(b) UHMW-PE material has the highest strain energy in mJ (heel strike: 0.001874; toe-off: 0.00263; midstance: 0.002472)

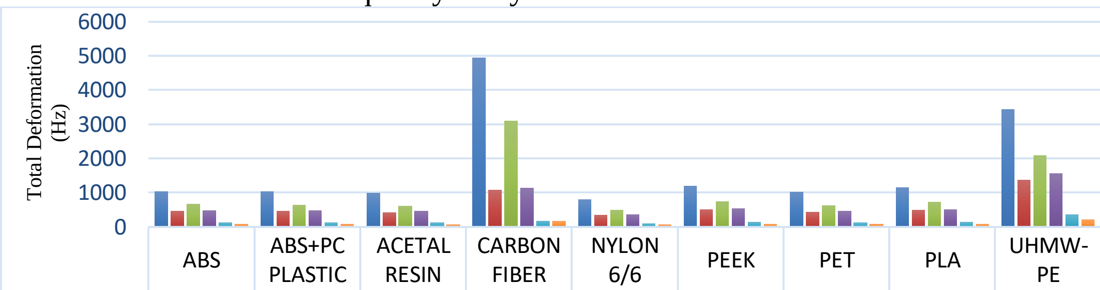
(c) Carbon fiber material has the lowest deformation values compared to other materials in all midstance (0.07392 mm) and toe-off (0.0032 mm) phase analyses and for heel strike (0.002459 mm) UHMW-PE material is suitable.

(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.

5.5 Simulation data summary for various prosthetic foot models

Various parameters analysis is conducted on the foot structure model for material optimization data as shown in tables. Through modal analysis, the result shows that the natural frequency (1363 Hz) of the model 2 is the 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.

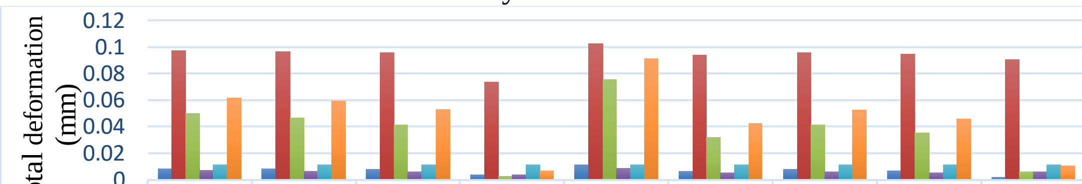
Table 5.5: Frequency analysis of various foot structure models



	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

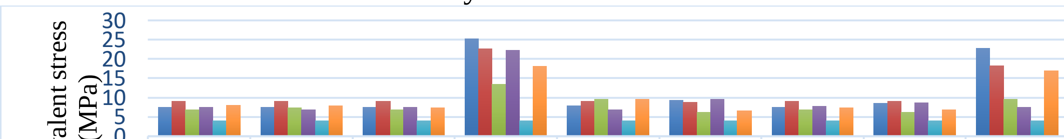
The total deformations by considering different materials of the models were calculated in ANSYS software tools for various configuration models. The minimum total deformation was observed to be 0.002020 mm for UHMW-PE material for prosthetic foot model 1 as mentioned in table 5.6.

Table 5.6: Deflection analysis of various foot structure models



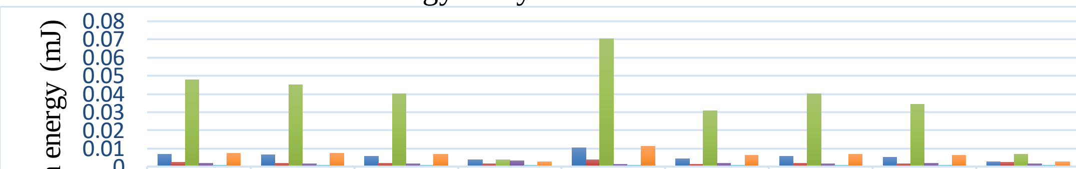
	ABS	ABS+PC PLASTIC	ACETAL RESIN	CARBON FIBER	NYLON 6/6	PEEK	PET	PLA	UHMW-PE
Model 1	0.0084	0.00817	0.00755	0.00371	0.01103	0.0064	0.007524	0.006817	0.0020207
Model 2	0.09735	0.09693	0.09587	0.07392	0.10268	0.09409	0.0958	0.09468	0.090459
Model 3	0.0499	0.04696	0.04152	0.00261	0.07561	0.03191	0.04131	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

Table 5.7: 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

Table 5.8: 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

The desirable values of the effective parameters for various prosthetic foot structure models are mentioned in table 5.9.

Table 5.9: Prosthetic foot model analysis data (midstance 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 behaviour of a prosthetic foot across different walking circumstances.

5.6 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 split type prosthetic foot model 2 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 structures used previously.

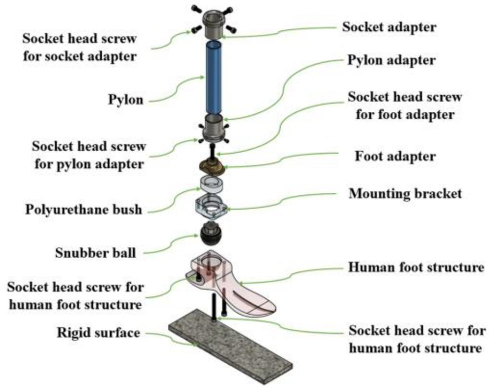
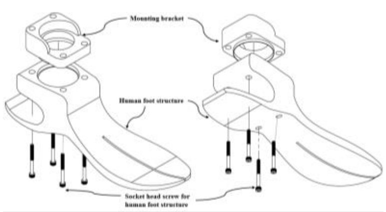


Figure 5.18: Exploded view of the multiaxial foot-ankle mechanism



(a) NE isometric view (b) SE isometric view

Figure 5.19: Exploded view of human foot structure assembly

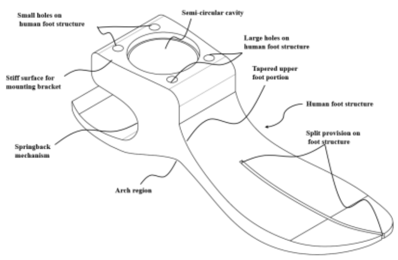


Figure 5.20: Perspective view of human foot structure

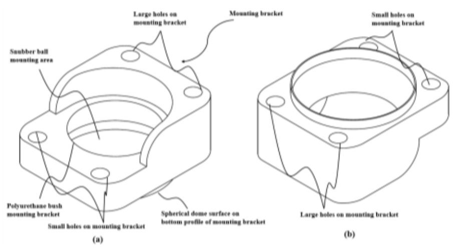


Figure 5.21: NE and SE isometric view of the mounting bracket

Figure 5.22 shows the transparent assembled view of the multiaxial foot-ankle mechanism. The snubber ball is inserted in the semi-circular cavity for the multiaxial rotation ankle. The mounting bracket is placed over the snubber ball and is connected to the stiff surface of the mounting bracket by the socket head screw for the human foot structure from the bottom side of the small holes on the human foot structure to the large holes of the mounting bracket and large holes on human foot structure to the small holes on the mounting bracket.

Polyurethane bush is inserted into the extended part of the snubber ball up to the polyurethane bush mounting area placed above the mounting bracket to bear the weight. The foot adapter is connected to the snubber ball and fixed with the help of a socket head screw for foot adapter. The pylon adapter is mounted on the foot adapter and tightened with the socket head screw for the pylon adapter at four points. The socket adapter is mounted on the pylon and tightened with the socket head screw for the socket adapter at four points. Pylon joins the socket adapter, with the pylon adapter acting as the human femur and/or tibia and fibula, depending on the amount of amputation.

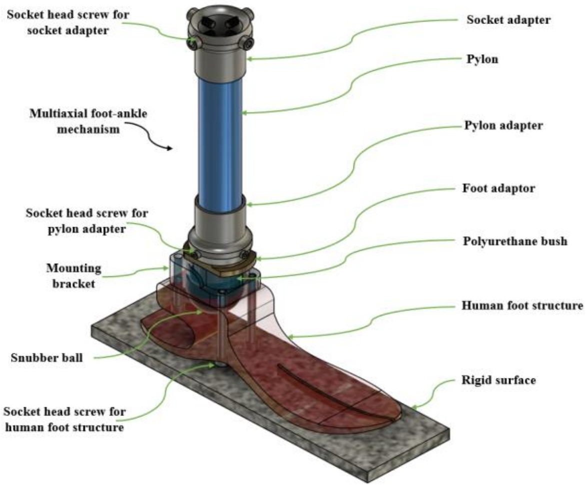


Figure 5.22: Transparent assembly view of the multiaxial foot-ankle mechanism

Figure 5.23 depicts a transparent view of a human foot structure constructed according to the principles of the current approach, in which the human foot structure, mounting bracket, socket head screw for the human foot structure, polyurethane bush, and snubber ball are all assembled.

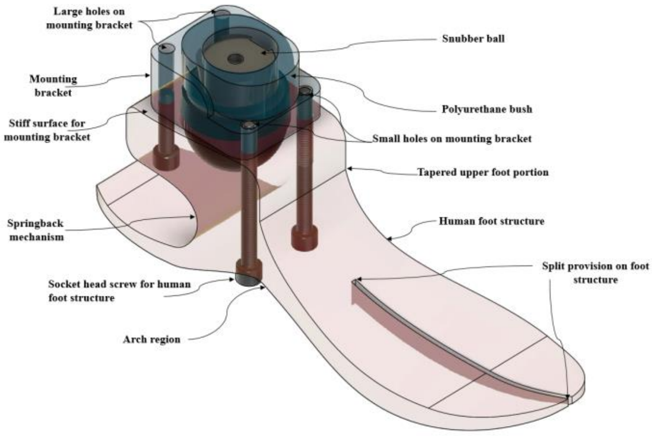


Figure 5.23: Perspective transparent view of human foot structure assembly

CHAPTER 6
DEVELOPMENT & TESTING OF NOVEL PROSTHETIC FOOT

This chapter discusses the detailed procedure for the development and testing of a novel prosthetic foot model for lower limb amputation level patients as per their requirements. Based on the best design data available, a prototype model was created using 3D printing technology. Finally, the manufacturing process for the prosthesis foot structure is completed by using a 3 Axis Vertical Milling Center machine. 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.

6.1 The development process of novel prosthetic foot

The medical professional is continually on the lookout for innovative, cutting-edge technology that might improve traditional processes. As a result, the combination of 3D scanning and additive manufacturing has already made progress into the healthcare industry (Gibson, et al., 2021).

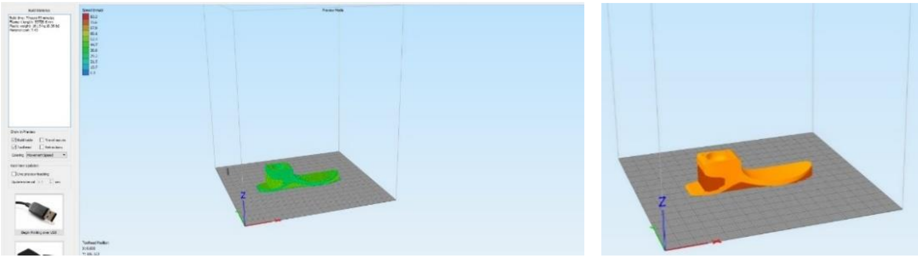


Figure 6.1: Slicing tools for prosthetic foot model

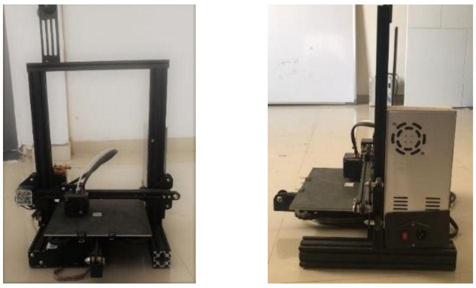


Figure 6.2: FDM machine (Ender-3 V2)

Table 6.1 displays the technical parameters of the 3D printer machine.

Table 6.1: Machine specifications for FDM

Sr. No.	*Specification Data*	*Value of Data*
1	Technology for modelling	FDM
2	Size of machine	475*470*620 mm
3	Dimension of printing	220*220*250 mm
4	Diameter of the filament	1.75 mm
5	Filament	ABS/PLA/TPU/PETG
6	Hot bed temperature	≤100 ℃
7	The layer thickness	0.1-0.4 mm
8	Print accuracy	±0.1 mm
9	Slicing software	Simplify 3d/Cura
10	Power source	Input AC 115V/230V; Output DC 24V 270W
11	Supporting OS	MAC/Windows XP/7/8/10
12	Mode of operation	Online or SD card offline

Figure 6.3: Prototype model of the prosthetic foot

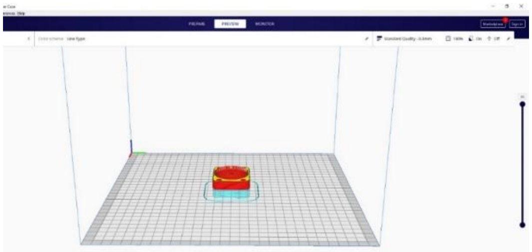


Figure 6.4: Slicing tools for the mounting bracket

Figure 6.5: Prototype model of the mounting bracket

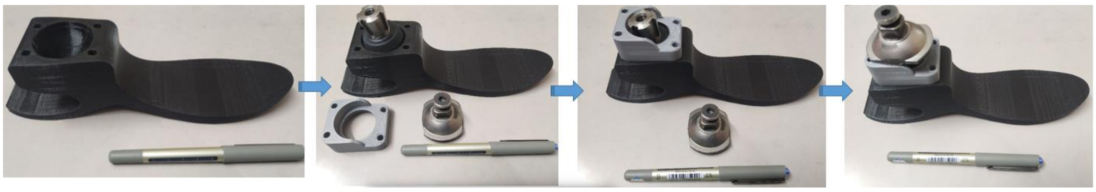


Figure 6.6: Prosthetic model assembly process

Using this approach, the designer and manufacturer may enhance the production of prototype parts and offer their innovative, high-performing, zero-defect product to the market in the shortest amount of time at the lowest feasible cost.
For the development of prosthetic human foot structures, Ultra High Molecular Weight Polyethylene (UHMWPE) can be used because it possesses the best qualities, featuring exceptional toughness and durability, great abrasion resistance, superior chemical protection, minimal wettability, and ease of fabrication with cheap manufacturing costs. Delrin, a material with outstanding impact and creep resistance, good dimensional stability, great machinability, high fatigue endurance, chemical resistance, and high strength and stiffness qualities, may be used to make the mounting bracket. Injection molding is the best production method with delrin/nylon 6 material for low-cost community projects and prosthetics.
Using a 3 Axis Vertical Milling Center device, the prosthetic foot manufacturing (Dhokia, et al., 2017) process is finally completed.

S. No.	DESCRIPTION OF REQUIREMENT	REQUIRED
1	**Technical Specification**	
1.1	**Capacity**	
1.1.1	Length of table	700 min
1.1.2	Width of table	400 min
1.1.3	Max load on table	300 kg
1.1.4	X travel	700 mm min
1.1.5	Y travel	400 mm min
1.1.6	Z travel	300 mm min
1.2	**Machine Spindle**	
1.2.1	Spindle Speed	Min 8000 Rpm
1.2.7	Main Spindle Power	7Kw or more
1.2.8	Spindle taper	ISO/BT/SK 40/50
1.3	ATC	15 min
1.4	**Accuracy**	
1.4.1	Positional accuracy	0.01 mm in full length
1.4.2	Repeatability	0.005 or better
1.5	**Coolant System**	
1.5.1	Tank capacity	Min 100 Ltr
1.5.2	High presuure filtration system	Min 20 Bar with filteration system
1.6	**Axis drive and Control**	
1.6.1	Digital controlled drive and motors	**For all Axis**
1.6.2	Guide way	**LM guide way**
1.6.3	Rapid Speed	**Min 20m/min**
1.6.4	Feed rate	**Min 6m/min**

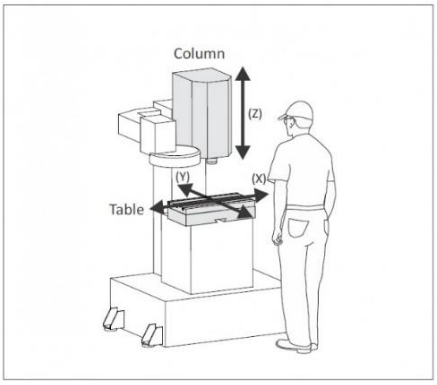


Figure 6.7: Vertical Milling Center with 3 Axis

Table 6.2: Raw material datasheet

Sr No	Raw Material (Size: 350 x 75 x 75) mm^3	Approx. Cost (Rs.)
1	UHMW-PE	1650
2	Delrin	1200
3	Nylon	1700
4	Carbon Fiber	40000 - 45000
5	Teflon	3000 - 4000

The Ultra High Molecular Weight Polyethylene (UHMWPE) material (Li & Burstein, 1994) is selected for the preparation of the prosthetic foot model as per its desirable material properties. The raw material of size 350 x 75 x 75 mm^3 is considered as per the final product size of the foot structure model as shown in figure 6.8.

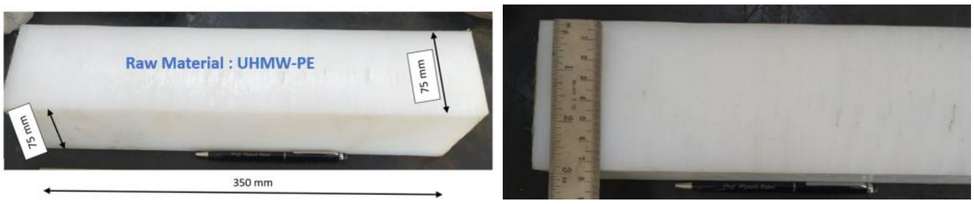


Figure 6.8: UHMW-PE raw material block

The material block is mounted on the fixture device as shown in figure 6.9 and the manufacturing process for the prosthetic foot is completed in approximately 8 hours by using a 3 Axis Vertical Milling Center machine.

Figure 6.9: Machining process of prosthetic foot model

Figure 6.10: A realized model of a prosthetic foot

The material block is mounted on the fixture as shown in figure 6.11 and the manufacturing process for the mounting bracket is completed in approximately 3 hours by using a 3 Axis Vertical Milling Center machine.

(a) Machining process (b) A realized Model

Figure 6.11: Mounting bracket

The foot adapter is connected to the snubber ball and fixed with the help of a socket head screw for the foot adapter as shown in figure 6.12.

Figure 6.12: Prosthetic foot with foot adapter

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 6.13.

Figure 6.13: Sole treaded on the bottom side of the prosthetic foot

The pylon adapter is mounted on the foot adapter and tightened with the socket head screw for the pylon adapter at four points as shown in figure 6.14.

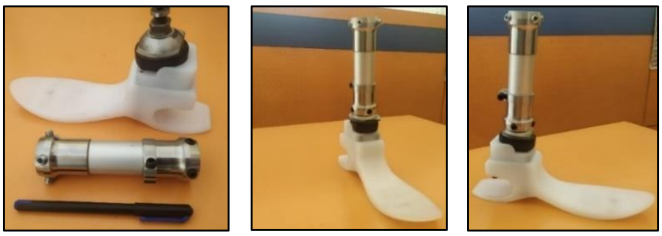


Figure 6.14: Pylon adapter is mounted on the foot adapter

The effects of a non-articulated Solid Ankle Cushion Heel (SACH) and a multiaxial foot-ankle mechanism on the performance of low-activity users are of special interest to professionals in amputee rehabilitation. By comparing these two prosthetic feet, the goal of this study is to evaluate the potential benefits brought about by the increased degrees of freedom afforded by the multiaxial foot.

SACH foot has a stiff foot with no ankle articulation, where the heel absorbs stress and the forefoot simulates dorsal flexion. The SACH foot offers adequate shock absorption properties for restricted walkers because of its big heel cushion, but it is not suited for moderate to high-activity prosthetic users who want to perform more than home duties due to its lack of flexibility and inability to tolerate uneven terrain. According to the following fundamental prosthetic foot features, our studies demonstrate that a multiaxial foot is a substantial alternative option to the typical SACH foot:

- An amputee can accommodate the foot on uneven terrain easily ascending/ descending on-ramps using a multiaxial foot. The design of the multiaxial foot structure 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 a 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 can absorb the shocks developed during ambulation as well as maintain 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 multiaxial foots for this purpose. It is always desirable that the mass will be as least as conceivable without relinquishing strength and stiffness.

Table 6.3: 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 sizes (table 6.3) are considered for the comparative analysis and a standard pylon adapter of 45 mm length is used for the assembly process as shown in figure 6.15.

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

Figure 6.15: Weight of pylon with adapter

The socket aims to offer structural stability to the prosthetic where it meets the residual limb. It may also have suspension features to keep the prosthetic in place. The weight of various required elements for a socket is mentioned in table 6.4.

Table 6.4: 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 6.16: Weight of socket elements

As shown in table 6.5, various prosthetic foot structures are taken into account for weight analysis.

Table 6.5: Weight of various foot structures

Prosthetic Foot Element Name	Weight (gm.)
Novel foot structure	190
3D printed foot structure	112
SACH foot structure	309
NIAGARA foot	364

Figure 6.17: 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 6.6. The mass of the SACH foot structure is discovered to be 309 grams and the mass of the novel foot structure after optimization is found to be **190 grams**. The development efforts by considering design optimization in novel prosthetic foot structure show that there is a weight reduction of approximately 61.5 % in comparison with the SACH foot structure.

Table 6.6: Mass comparison of prosthetic foot structure

Elements	SACH foot structure assembly (grams)	Novel foot structure assembly (grams)
Prosthetic foot structure mass	309 (76.5 % of total mass)	**190** (38.46 % of total mass)
Others elements mass	95	304
Total mass	404	494

Figure 6.18: Assembly weight of novel and SACH prosthetic foot elements

The main element of the foot-ankle mechanism is the human foot structure which is the base for the stability of the patients and better control in all terrain. Elements (table 6.7) other than the present development like socket elements and pylon mechanism are assembled to get the required functionality.

Table 6.7: Novel prosthetic foot structure mechanism details

PYLON SIZE **Element Name**	**PYLON 1** **Weight (gm.)**	**PYLON 2** **Weight (gm.)**	**PYLON 3** **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**

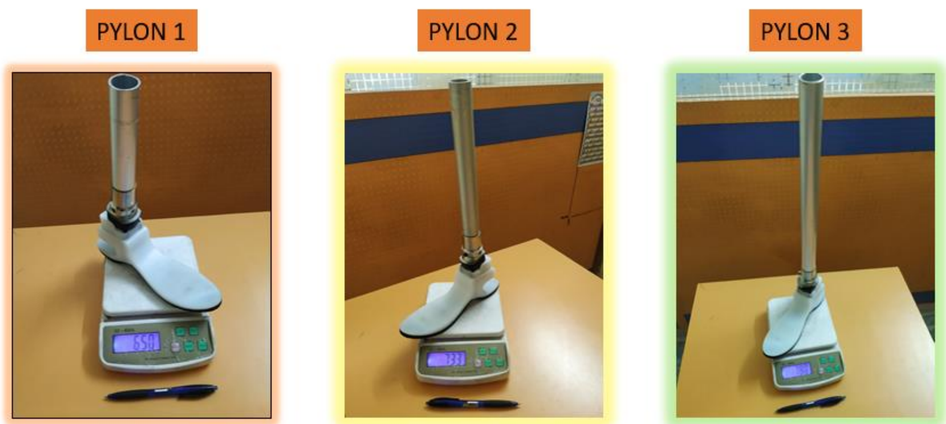


Figure 6.19: Novel prosthetic foot structure with various pylon elements

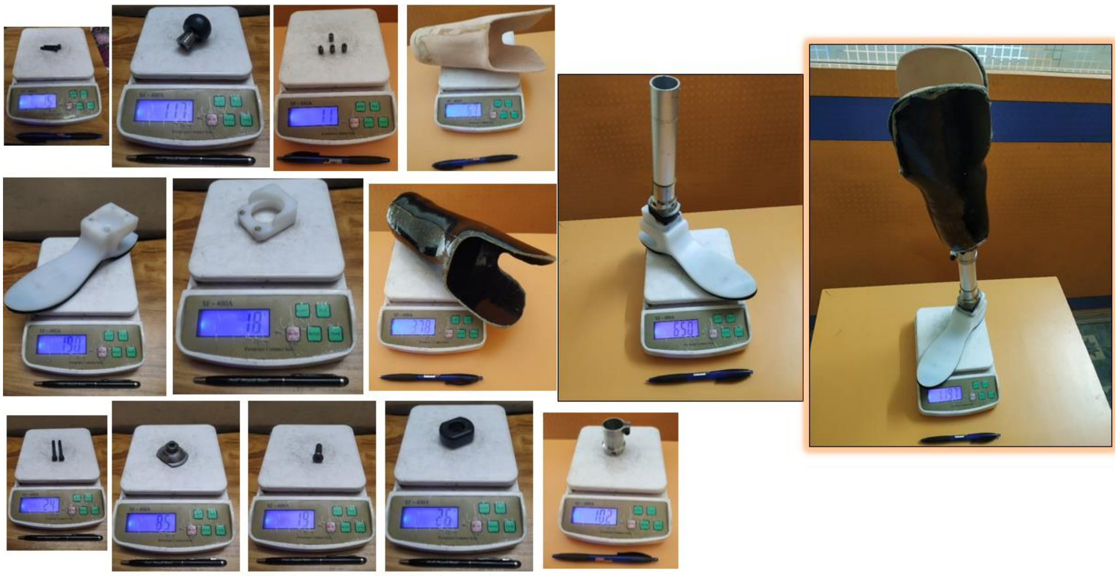


Figure 6.20: Weight for novel prosthetic foot structure using pylon1

Figure 6.21: Weight of novel prosthetic foot structure with various pylon sizes

The most basic type of non-articulated foot is the single-axis foot. The name is 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 6.8: SACH prosthetic foot structure mechanism details

PYLON TYPE **Element Name**	**PYLON 1** **Weight (gm.)**	**PYLON 2** **Weight (gm.)**	**PYLON 3** **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 6.22: SACH prosthetic foot structure with various pylon elements

Figure 6.23: Weight for novel prosthetic foot structure using pylon 2

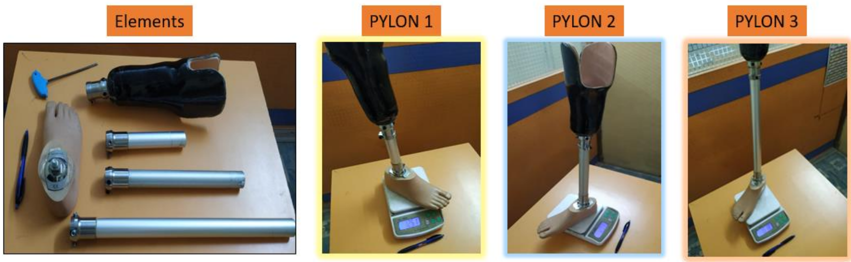


Figure 6.24: Weight of SACH prosthetic foot structure with various pylon sizes

The development efforts including design optimization in the 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 are considered for the evaluation of the patient.

6.2 The gait cycle's phases

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 the prosthetist as per the comfort of the patients it is fitted properly as shown in figure 6.25.

Figure 6.25: Socket fitting process on patients

During lower limb prosthetics, patients often return to the clinic for some alterations and adjustments. This iterative process and the ongoing changes in prosthetic socket comfort and function can be a major cause of frustration for both the amputee and the rehabilitation team.

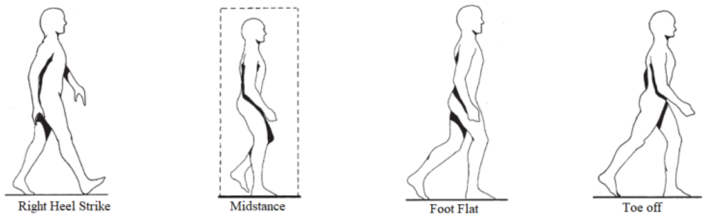


Figure 6.26: The stance phase of the right lower limb's gait cycle

A standardized physical examination of the lower limbs is done throughout the session to determine anthropometry and passive range of motion, and standardized clinical films are captured. As indicated in figure 6.27, the foot and ankle have a variety of joints that move during walking.

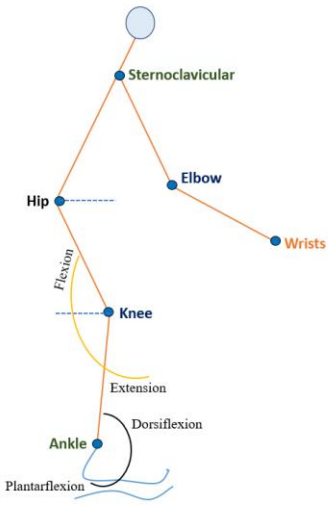


Figure 6.27: Human body stick diagram for pointing movement

- An ankle angle > 90° denotes plantarflexion while an ankle angle < 90° denotes dorsiflexion.
- A knee angle > 180° denotes hyperextension while a 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 (-).

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

6.3 Testing of novel prosthetic foot element below knee amputation level patients

Gait analysis is an assessment of gait style by observing a patient walking in a straight line. Video gait analysis is increasingly being utilized to evaluate a subject's motor patterns to aid in the diagnosis of medical issues, improve sports performance, and/or monitor therapeutic measures such as gait retraining and shoe adjustments.

Figure 6.28 depicts Kinovea, a video annotation tool designed to analyze human body movement. It includes utilities for capturing, slowing down, comparing, annotating, and measuring video motion. The tools built into this software allow the observer to calculate the joint angle and obtain other measurements as required.

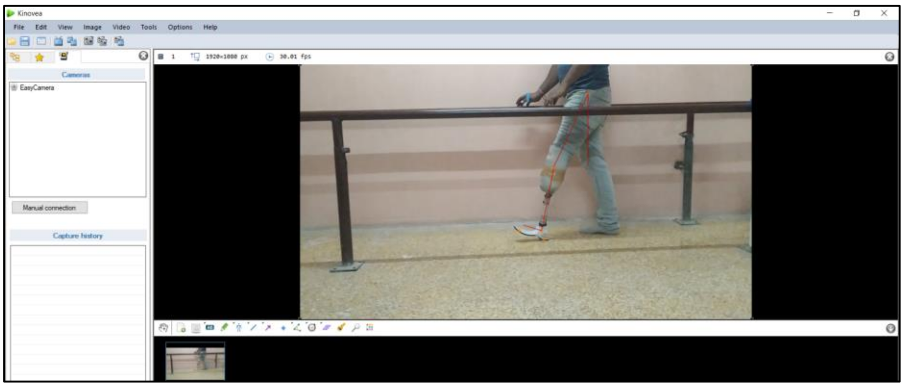
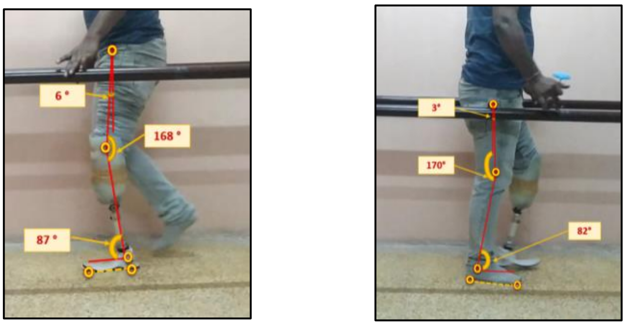


Figure 6.28: GUI of Kinovea for patient motion analysis

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 6.29 respectively.



(a) Left leg (b) Right leg

Figure 6.29: 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 6.30 to figure 6.32 respectively. 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.

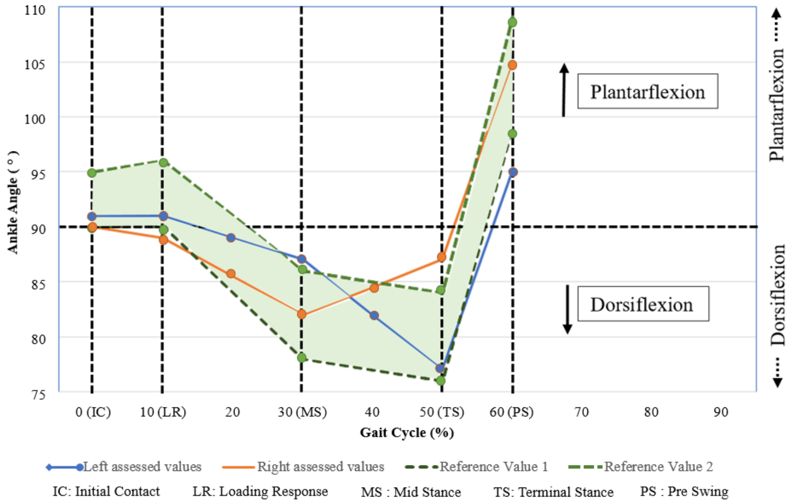


Figure 6.30: Graphs for the lateral views of the gait cycle: Ankle angle (Novel prosthetic foot)

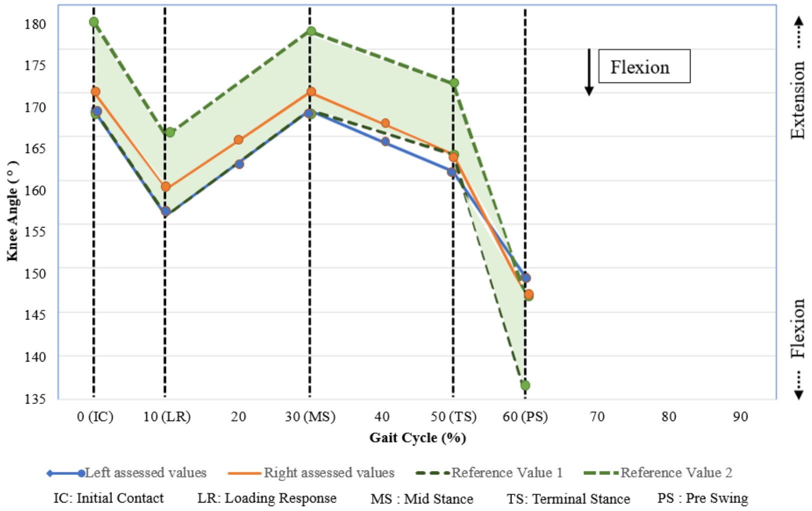


Figure 6.31: Graphs for the lateral views of the gait cycle: Knee angle (Novel prosthetic foot)

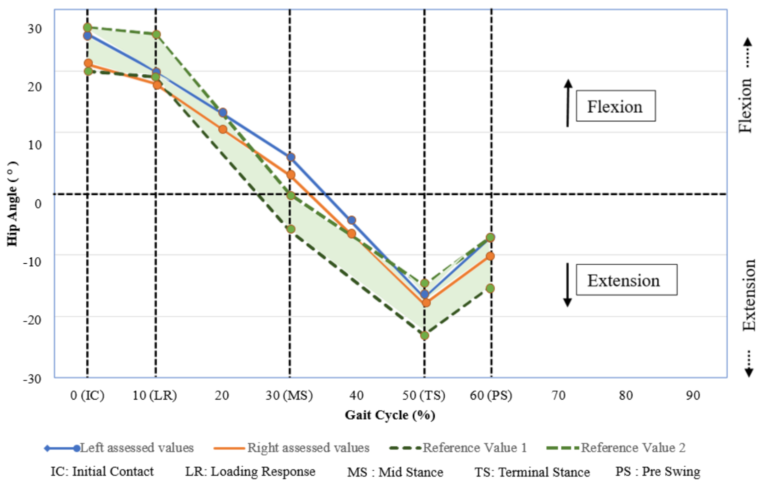


Figure 6.32: Graphs for the lateral views of the gait cycle: Hip angle (Novel prosthetic foot)

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 6.9.

Normal Patient

Patient with Senator Foot

Patient with Novel prosthetic foot

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 6.33: Patient case studies data

Table 6.9: 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 6.34.

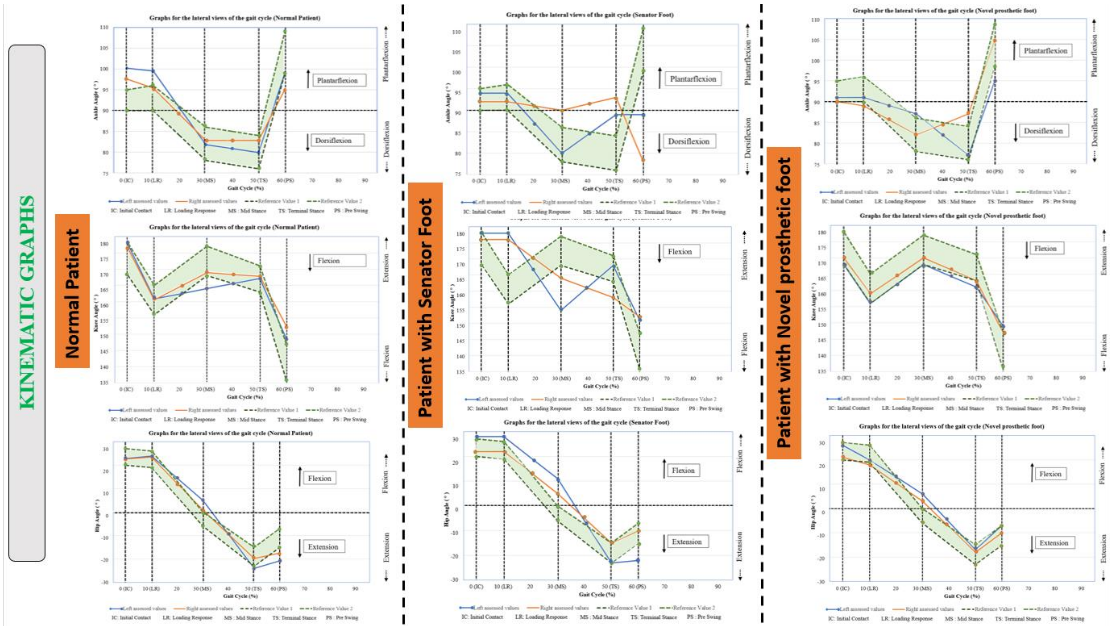


Figure 6.34: Kinematic graph for patient's lateral view position

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, and allowing proper operation according to the patient's requirements.

CHAPTER 7
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.

7.1 Human orthotic elements

AFO materials (Shahar, et al., 2019)have steadily evolved through time from various materials as shown in figure 7.1.

Figure 7.1: 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).

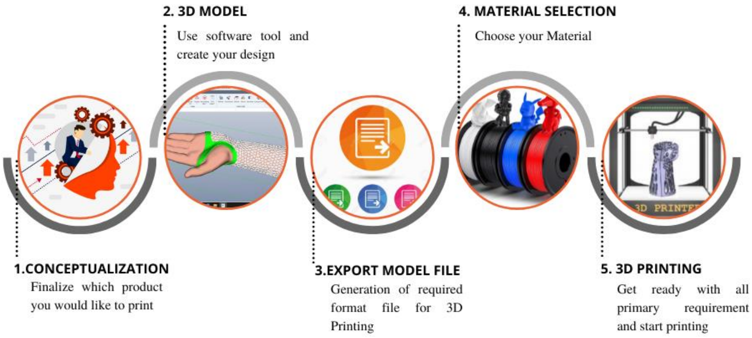


Figure 7.2: 3D printing process flow

Table 7.1: 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 • physical skill • physical endurance • Problem-solving abilities	• Operating and creating skills for 3D software
Steps in manufacturing	• Cast creation using landmark identification • Cast correction • Molding technique • Trimming and cutting of edges	• 3D imaging • Modelling • 3D printing tool for slicing • 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)

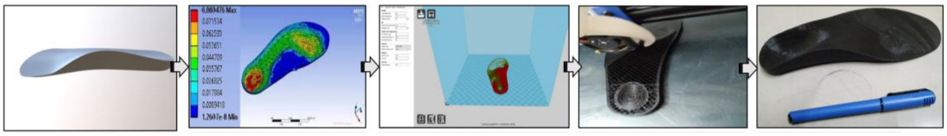


Figure 7.3: Design and development process of the Orthotics Foot Shell Model

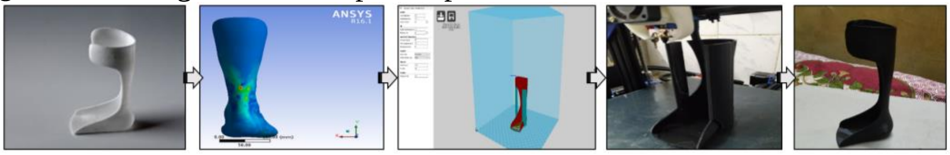


Figure 7.4: Design and development process of the Ankle Foot Orthotic Model

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.

7.2 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. Both online surveys and face-to-face interviews (figure 7.5) were conducted to collect data necessary for the study (Susmartini, Herdiman, & Priadythama, 2021) (Sarker, Karim, Ahamed, Sultana, & Islam, 2020).

Figure 7.5: 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. 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 7.6.

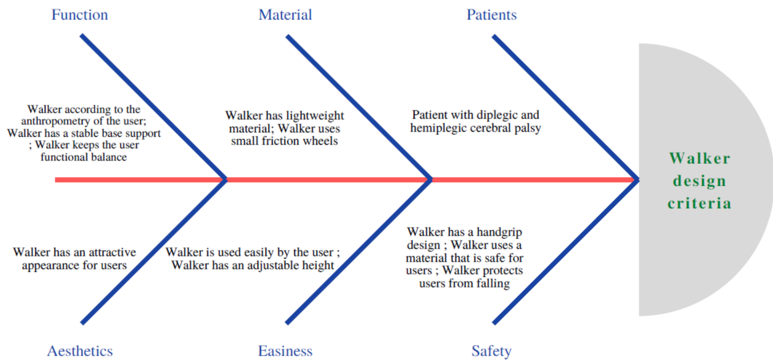


Figure 7.6: Walker design criteria (Lestari, Susmartini, & Herdiman, 2020)

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.

7.2.1 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.

- 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 7.7 & 7.8 for standing and sitting position respectively.

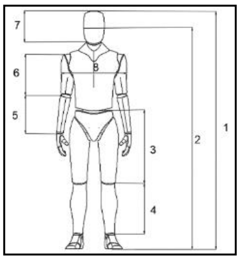


Figure A

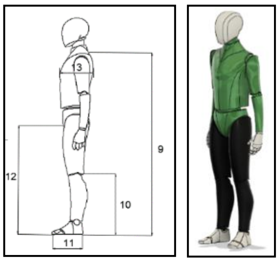


Figure B

Figure 7.7: Measurements in standing posture

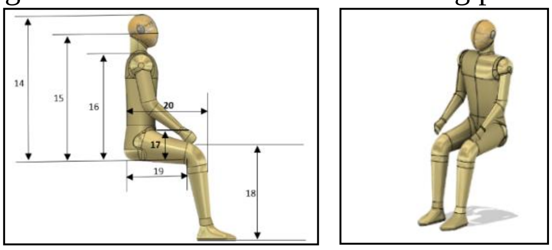


Figure C

Figure 7.8: Measurements in sitting posture

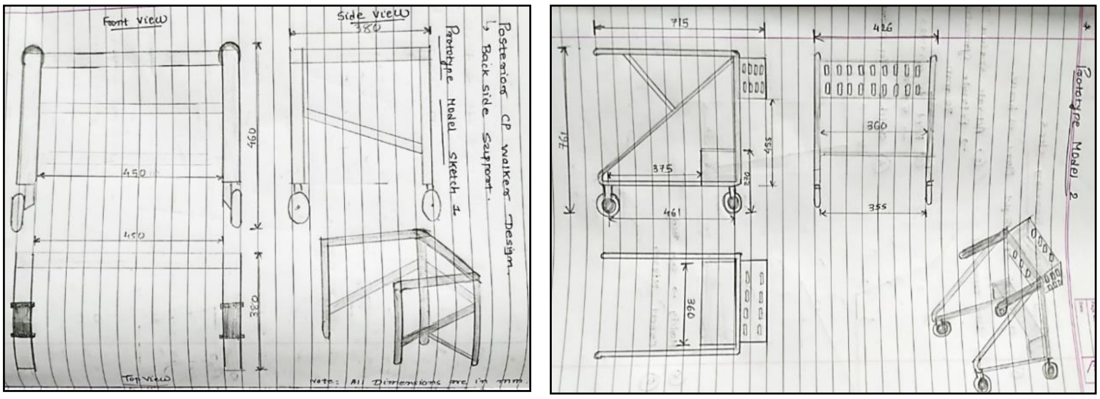
Table 7.2: Anthropometric Measurements (Farooqui & Shahu, 2016)

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 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 7.9.



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

Figure 7.9: 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 7.10 to figure 7.12.

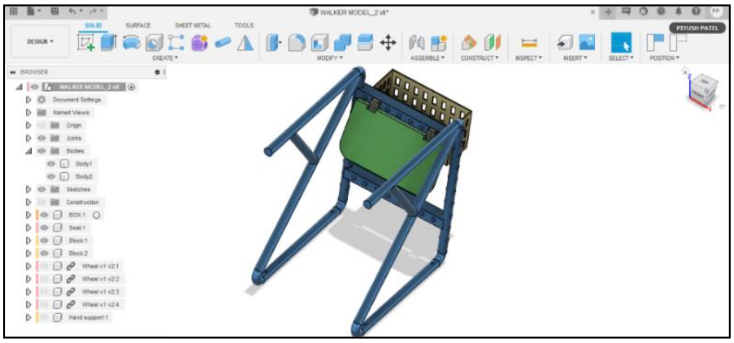


Figure 7.10: CP walker design process

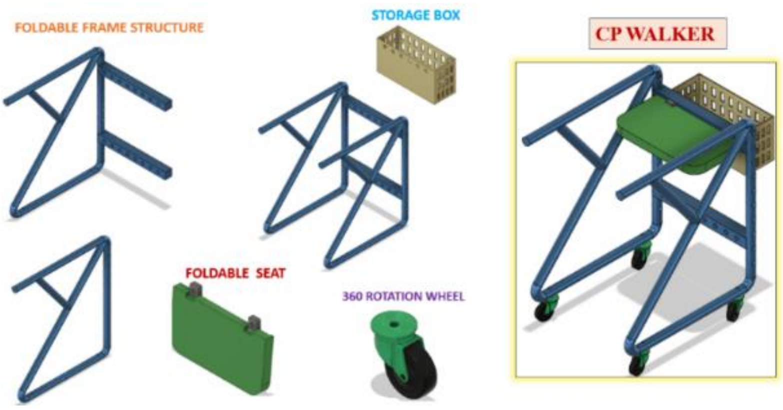


Figure 7.11: CP walker components

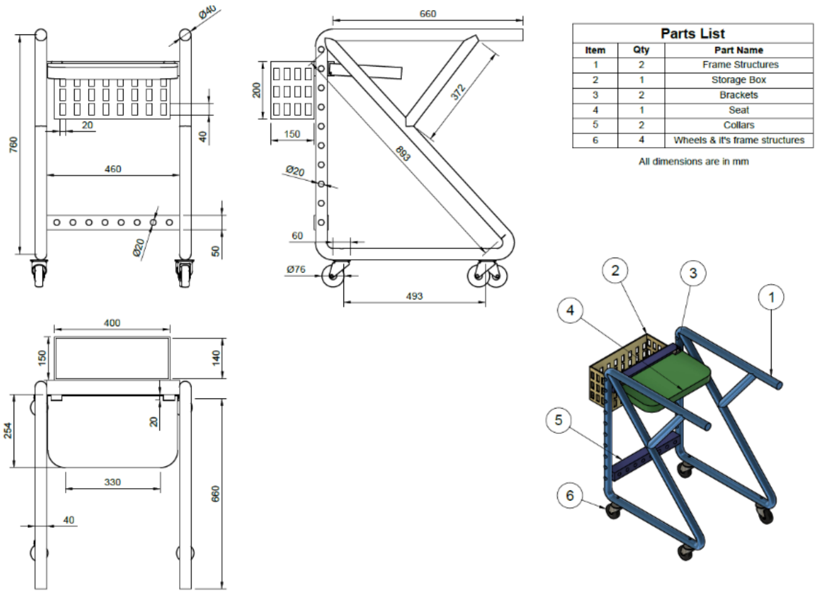


Figure 7.12: CAD drawing of CP walker model

Table 7.3: 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 7.13 & 7.14.

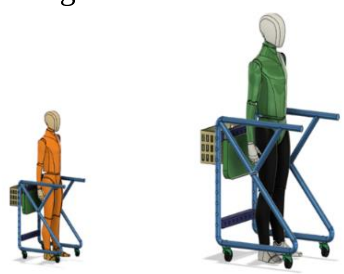
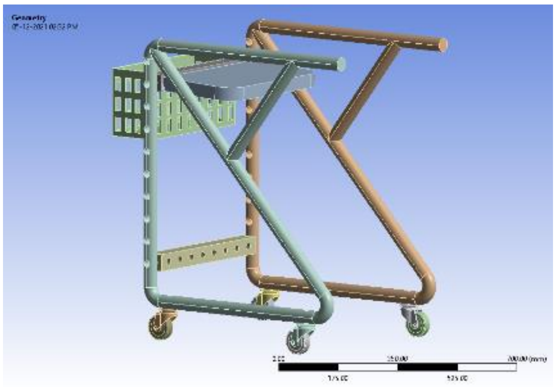


Figure 7.13: Standing Position

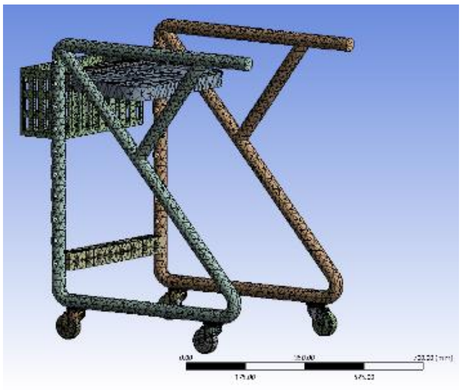
Figure 7.14: Sitting position

- Simulation approach

Finite element modeling is used to develop a walker design and investigate its stability as shown in figure 7.15.



(a) CP walker CAD geometry



(b) CP walker mesh model

Figure 7.15: CP walker CAD model

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 7.4 and table 7.5.

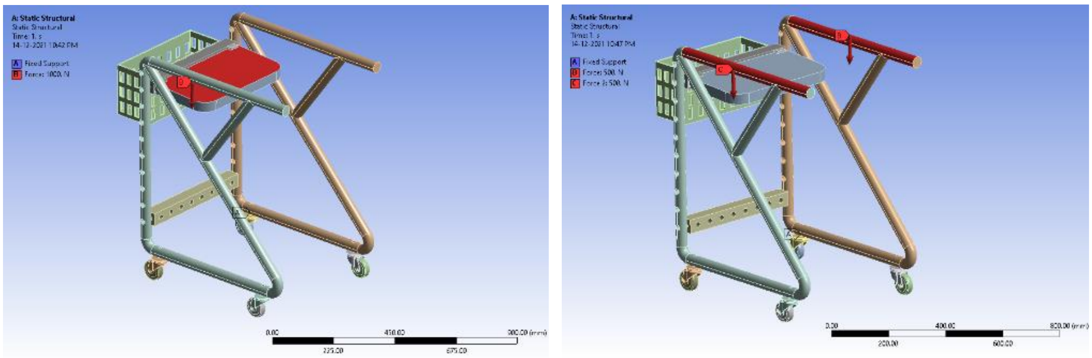
Table 7.4: CP walker material analysis data (Child weight)

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 7.5: 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

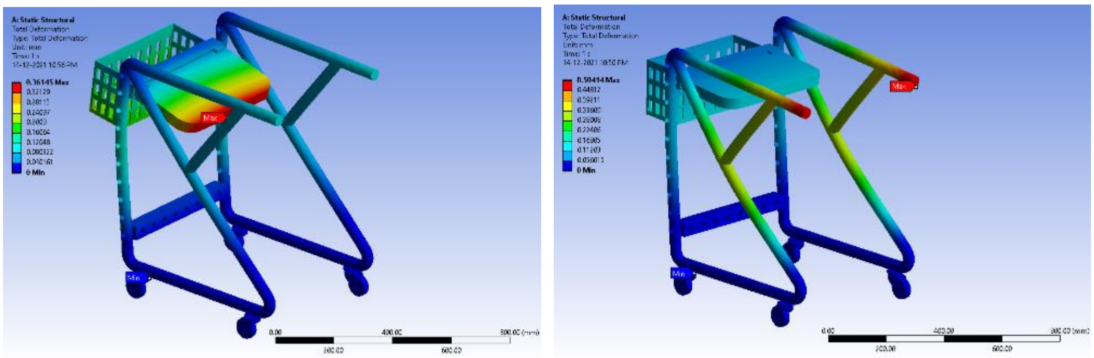
Therefore, from the observation data preferable material for the mainframe structure is **Aluminum**, and the rest of the elements are made from different materials as shown in table 7.3.



(a) Sitting position (b) Standing position

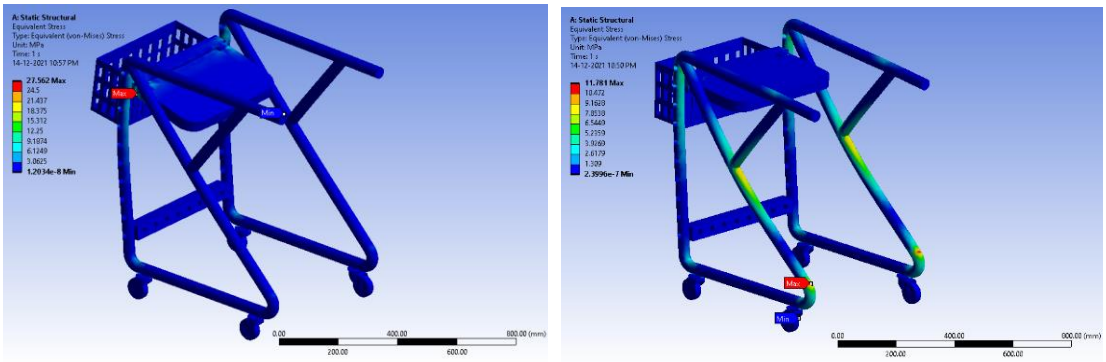
Figure 7.16: Static structural simulation for the weight of adult as 100 kg

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 7.17 and 7.18.



(a) Sitting position (b) Standing position

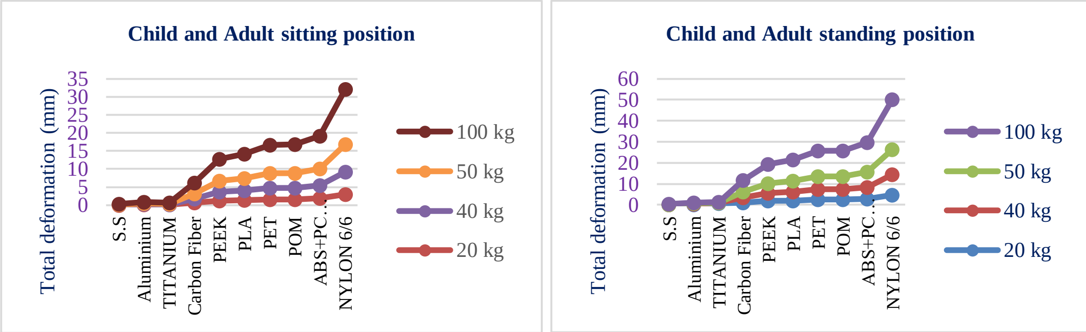
Figure 7.17: Total deformation for the weight of an adult is 100 kg



(a) Sitting position (b) Standing position

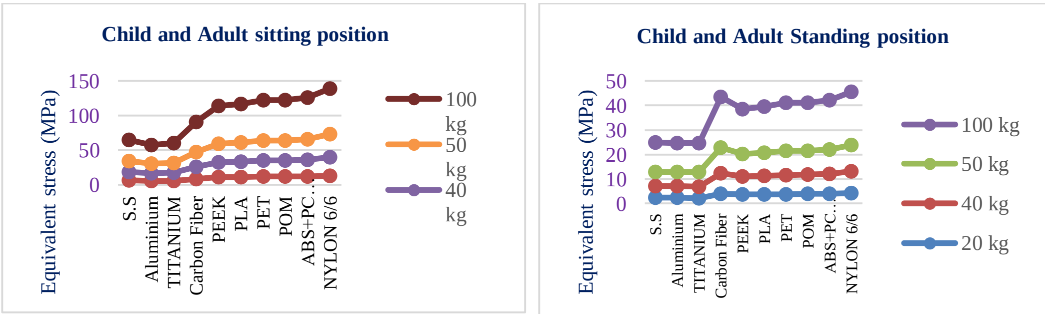
Figure 7.18: Equivalent stress for the weight of an adult is 100 kg

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 7.19 and 7.20.



(a) Sitting position (b) Standing position

Figure 7.19: Total deformation for various materials



(a) Sitting position (b) Standing position

Figure 7.20: Equivalent stress for various materials

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.

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.

CHAPTER 8
BRIEF RESEARCH METHODOLOGY

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 elements can 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 the above demands in view, research studies have been conducted on developing optimized P&O elements. The use of Advanced Manufacturing in medical element manufacturing has risen in prominence over the last several decades as the prospects for this technology have expanded significantly. This thesis work goes over the complete approach for designing, analysing, developing, and testing innovative prosthetics and orthotics based on the needs of the patient. It is our responsibility to assist humanity by providing high-quality P&O elements at a reasonable price.

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. As a result, the P&O elements could not be functional for an extended length of time. The requirement for this continual alteration or adaptation may be great if expensive materials are being utilized. However, relatively few research have focused on the optimization of biomimetic structure 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 elements are manufactured using plaster molds, which require multiple patient visits, take 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. Additive manufacturing is an advanced layer-based manufacturing process that fabricates customized prosthetics and orthotics to patient requirements directly from computer-aided design data without using part depending tools. Nowadays 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 extensively used finite element techniques for the simulation and optimization of various design concepts proposed for P&O elements. The optimized design is manufactured & realized and may undergo successful tests & evaluation proposed for novel prosthetic foot models 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. To obtain the technology for complex and low-cost artificial limbs, the links between gait analysis and prosthetic biomechanics must be strengthened. The study provided here exhibits an understanding of gait analysis for application in prosthetic creation and assessment of performance. The result of simulation and testing is reported and found to be close conformance.

According to the survey, another design and simulation technique was used for the orthotics aspects to take into account the basic needs of the patients. A minor attempt is made to develop and analyse the AFO element and the CP walker. This thesis work goes into the depth of these challenges and envisages the development of lightweight, compact and very low development cycle time from concept to realization for the Orthotics elements.

All children are made up differently and have cerebral palsy in different parts of their bodies. Therefore, there is a need for a 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 the sitting and standing position of patients in the ANSYS workbench for the total deformation and stress equivalent of the different materials. Based on the findings of the research, the 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 customized design approach with specified performance characteristics efficiently and cost-effectively.

CHAPTER 9
KEY FINDINGS

The goal of this research finding was to create low-cost prosthetic and orthotic components according to the needs of the patients. This presents a comprehensive description of the study's findings in order to provide a clear picture of what was observed after data processing.

Identification and application of innovative manufacturing techniques in healthcare engineering were explored throughout this research. An attempt has been made through this research to study global and indian health issues and identified some basic elements required in the field of prosthetics and orthotics. Customized P&O elements are the main requirements because the human body varies over time owing to changes in development and weight, the prosthetic must be replaced and adjusted regularly. This means that the P&O elements may not be used for long periods.

The methodology was developed through this research for the development of customized P&O elements using advanced manufacturing techniques.

9.1 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. Another advantage of having an adjustable prosthetic foot is that it allows the manufacturer or user to choose the range of medial-lateral rotation that is most suited to the wearer's demands. 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.

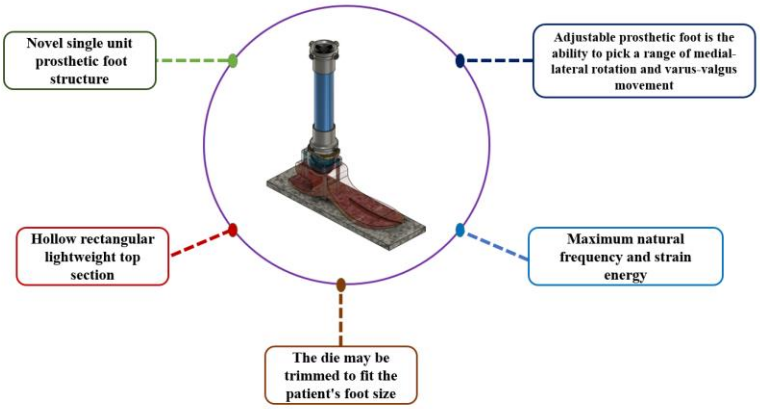


Figure 9.1: Multiaxial dynamic foot's device features

The current novelty is about a prosthetic foot comprising a hollow rectangular lightweight top section that is an integral part of the novel single-unit prosthetic foot structure. 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 the higher thickness of shaft, and blade for ultra-heavy amputee patients-where countries like the US have heavy patients weighing 400 to 500 lbs (same will be used with filler for routine amputee patients with a weight limit up to 120kg).

Various parameters analysis is conducted on the foot structure models for material optimization data as described in detail in Chapter 5 (Section 5.5 Simulation data summary for various prosthetic foot models).

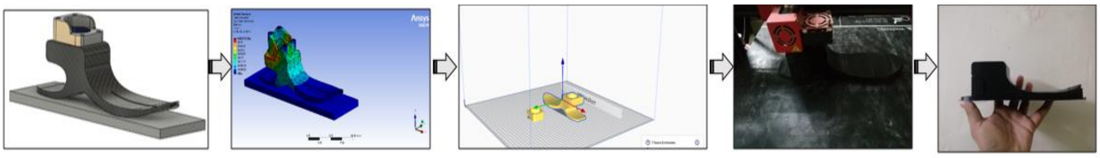


Figure 9.2: Design and development process of the prosthetic foot model 1

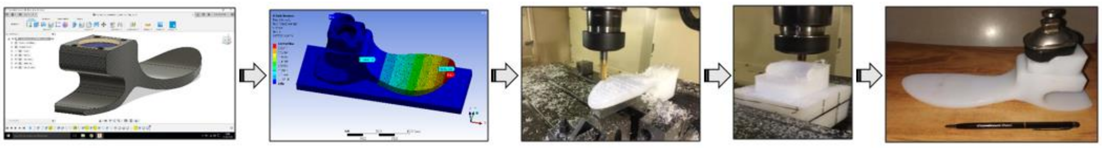


Figure 9.3: Design and development process of the prosthetic foot model 2

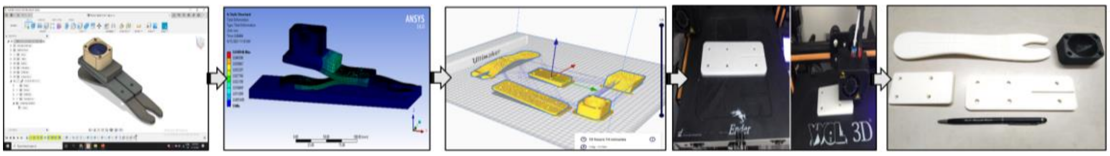


Figure 9.4: Design and development process of the prosthetic foot model 3

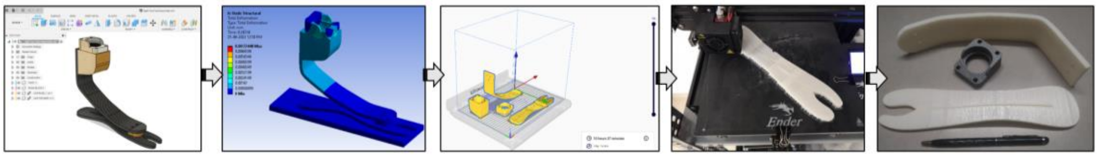


Figure 9.5: Design and development process of the prosthetic foot model 4

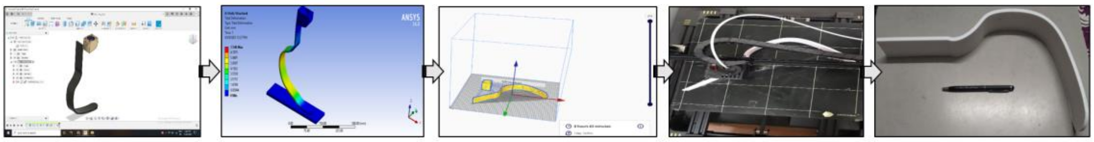


Figure 9.6: Design and development process of the prosthetic foot model 5

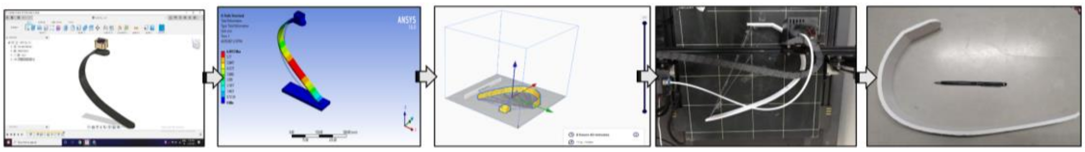


Figure 9.7: Design and development process of the prosthetic foot model 6

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.

Figure 9.8: Development and testing process for a novel prosthetic foot

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.

9.2 Result and discussion for orthotics elements

Individual orthotics devices are traditionally created using plaster moulds, which necessitate many patient visits and demand a significant amount of labour and time to construct. As a result, our primary focus is on the process of rapidly designing and constructing lightweight structural components while simplifying the production process. The creation of a methodology for the construction of tailored human orthotics foot shell, wrist brace, ankle foot orthotic, and CP walker utilising an advanced manufacturing approach is studied in this part.

The AFO and flex foot prosthetic parts 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 parts and about 10 hours for flex-foot prosthetics.

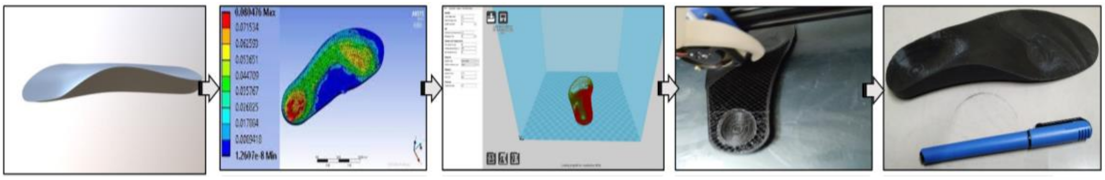


Figure 9.9: Design and development process of the orthotics foot shell model

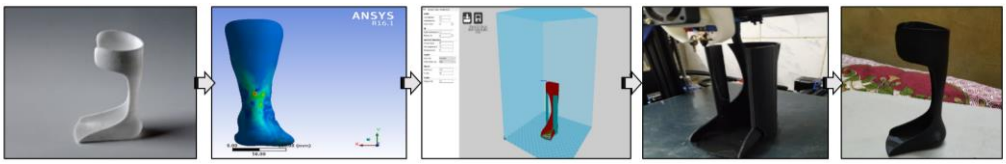


Figure 9.10: Design and development process of the Ankle Foot Orthotic model

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.

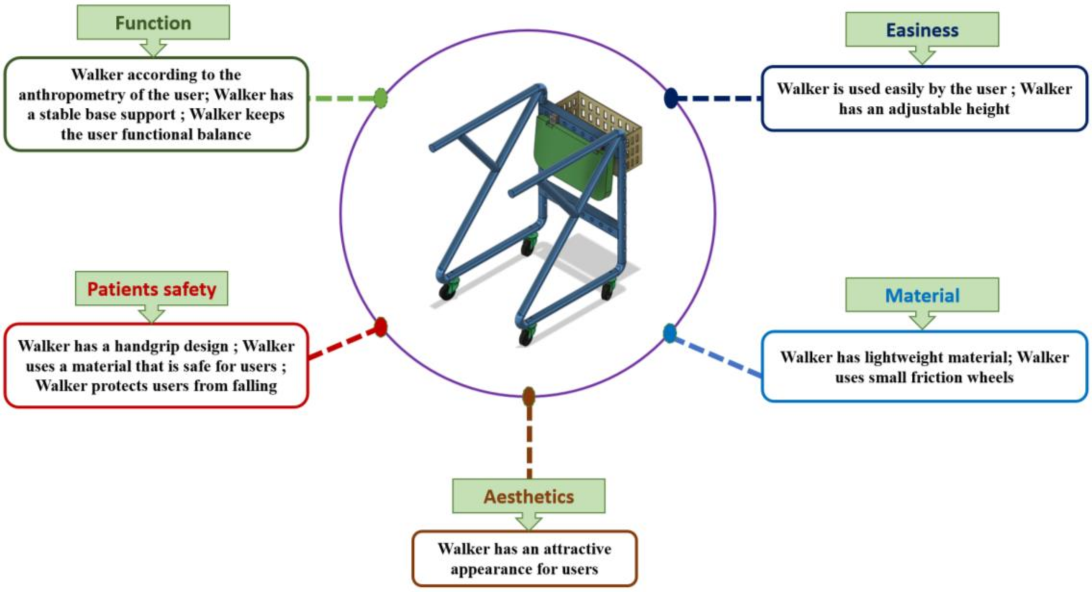


Figure 9.11: Walker device features

The novel concept of the CP walker is designed as a multipurpose device, it can be reconfigured with four main functions: standing and walking mode, standing and sitting mode, floor sitting mode, and wheelchair mode. The floor sitting mode can be accessed by mounting the seat with collar on the bottom most position.

The device has a wide range of features, including a variety of removable accessories such as a light frame structure with various adjustable and customizable components for height adjustment, and a storage box for personal items, including independently adjustable handles and/or ergonomic grips.

CHAPTER 10
CONCLUSION

This thesis discusses the detailed procedure for the design, analysis, and development of various K-level human foot models. Identification and application of innovative manufacturing techniques in healthcare engineering were explored throughout this research.

- Based on the mass comparison data it is observed that the unique foot design is lighter than prior prototypes while preserving structural integrity and permitting optimal functioning according to the patient's needs. The mass of the SACH foot structure is discovered to be 309 grams and the mass of the novel foot structure after optimization is found to be 190 grams. The development efforts by considering design optimization in novel prosthetic foot structure show that there is a weight reduction of approximately 61.5 % in comparison with the SACH foot structure.
- Based on the literature and analysis carried out in this research it is revealed that the most recent advancement is a novel single-unit prosthetic foot that can absorb shocks during ambulation while also effectively transferring energy between heel strike and toe-off and enhancing stability.
- Based on the experimental evaluation and analysis it is observed that an amputee can adapt their foot to uneven ground and effortlessly mount and descend ramps. By pasting the sole treaded on the bottom side of the prosthetic foot, an amputee can walk/ambulate without a foot shell and participate in water activities such as beach/swimming.
- Based on the design optimization process it is established that the current innovation concerns a prosthetic foot that has a hollow rectangular lightweight top component that is a vital component of the new single-unit prosthetic foot development. Another advantage of having an adjustable prosthetic foot is the option to select a range of medial-lateral rotation and varus-valgus movement to adapt to uneven terrain, comparable to the natural subtalar joint.
- Based on the patient requirement and the survey data, flexibility is incorporated in the foot structure model related to die preparation. It can be reduced to a smaller foot size based on the patient's foot. Attempts may be made in the die for a thicker shaft and blade for ultra-heavy amputee patients, where nations such as the United States have heavy patients weighing 400 to 500 lbs (the same will be utilized with filler for routine amputee patients with a weight limit of up to 120kg).
- Based on the market survey and the analysis data it is recognized that prosthetic foot made of various materials provides additional benefits, including carbon fiber for heavy load circumstances and other polymer materials like UHMW-PE/nylon/delrin that are lightweight and have low production costs.
- Parametric analysis is conducted on the foot structure model for material optimization. Based on the simulation, the result shows the natural frequency (1363 Hz) of the model 2 is the maximum for UHMW-PE material. So for the preparation

of the foot structure, this material may be selected for the best performance of the prosthetic foot model. Based on the simulation it is established that the 1st natural frequency for all phase analyses of prosthetic foot models (midstance /heel strike / toe-off) is very large compared to the average human walking frequency of 2-3 Hz.

- Based on the patient motion analysis it is observed that a graphical depiction of the gait analysis's multiple measured parameter values for ankle, knee, and hip angles reveals that the data are within the acceptable range of the standard reference data for the patient's lateral view position when wearing the unique prosthetic foot model.
- Based on the manufacturing process it is established that the AFO and flex foot prosthetic elements are manufactured on FDM machines with PLA material. The process is finished in less than 7 hours, with AFO sections averaging 10-15 minutes of hands-on time and roughly 10 hours for flex-Foot prosthetics. To put it another way, employing 3D printing to construct a P&O device for a patient takes far less time than traditional procedures.
- Based on the design criteria and shortcomings of previous walker designs, a walker design that can meet the user's requests is designed. To create a walker design and test its stability, finite element modelling is performed. Based on the simulation data the maximum stress caused by the aluminium walker is 13.781 MPa in the sitting position and 11.781 MPa in the standing position, the lowest value among the materials tested. As a result of the observation data, aluminium is the preferred material for the mainframe structure of the CP walker device.

CHAPTER 11
RECOMMENDATIONS / SUGGESTIONS

The future is definitely on combining high-end technology in prosthetic and orthotic elements. Already 3D printing is available in the creation of almost all devices. Now a lot of prototypes are developing in neuroprosthetics.

Myoelectric/ bionic arms are very popular but not affordable to the majority of people due to their high prices. As a result, several prototypes are now being developed in this regard. Developing low-cost myoelectric arms, for example. If myo arms are available at an affordable price that will be a great help for many people because mechanical upper limb prostheses require a lot of manual power to operate and are not smooth as well.

Since bionic/myoelectric appliances are heavy, plans can be made to build lightweight orthotic and prosthetic devices. Water-resistant prosthetic and orthotic components can be designed so that patients can use them while bathing and swimming.

Furthermore, the usage of prosthetic and orthotic devices may be done by employing variable parameters specified in smart devices to obtain the desired indication. By installing software in the smartwatch and feeding it a certain walking speed, the smartwatch may beep an alarm if an inappropriate amount of pressure is applied.

The current work can be expanded in the following ways:

- Artificial intelligence in prosthetic and orthotic rehabilitation.
- The final designs obtained can be verified experimentally.
- By monitoring underfoot pressures during walking, Force Sensitive Resistors (FSRs) can be utilized to kinetically evaluate human gait.
- In the future, it is intended to compare the changing effects produced by using various types of materials for the enhancement of P&O devices using the AM technique.
- It is proposed to design a motorized sensor-based hand splint for stroke patients who are wheelchair-bound for activities of daily living.
- There are many technological shortfalls or limitations, such as for paraplegics due to spinal cord injury, where reciprocating gait orthosis is used but is not easily available, or for CP with diplegia children cases where crouch gait is very common and difficult to control with existing passive knee systems.
- Active orthotic knees are rarely accessible to meet the needs of patients and are also expensive. It is proposed to create cost-effective customized devices made with low-cost technologies, which are greatly needed.

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LIST OF PUBLICATIONS

a) Research paper in the journals

1) **Piyush Patel**, Piyush Gohil (May 2022). “Custom orthotics development process based on additive manufacturing”, Materials Today: Proceedings, Volume 59, Part 3, 2022, Pages A52-A63.
   DOI: https://doi.org/10.1016/j.matpr.2022.04.858.
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2) **Piyush Patel**, Piyush Gohil (August 2021). “Role of additive manufacturing in medical application COVID-19 scenario: India case study”, Journal of Manufacturing Systems, Volume 60, 2021, Pages 811-822.
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3) Design and Simulation Approach of Cerebral Palsy Pediatric Standard Walker (Elsevier Journal*: Medicine in Novel Technology and Devices*: Manuscript No: MEDNTD-D-23-00002R1: Under Review Process)

4) Design, Analysis and Development of Prosthetic and Orthotic elements by Additive Manufacturing process (Springer Journal: *Biomedical Engineering Letter:* Manuscript No:BMEL-D-23-00319 : Under Review process)

5) Design, Analysis, Development and Testing of Novel Prosthetic foot model for lower limb amputation level patients (Elsevier Journal: Composite communication, Manuscript No: COCO-D-23-00508: Under Review 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

NATIONAL INSTITUTE OF TECHNOLOGY RAIPUR
(An Institute of National Importance)

SECOND INTERNATIONAL CONFERENCE ON MATERIALS AND TECHNOLOGIES

MaterialTECH2022

28th –29th January, 2022

Certificate

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)

NITRR/Conference/MaterialTECH2022/MM49

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Dr. Neha Gupta (Organizing Secretary)
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c) Book chapter

1) **Piyush Patel**, Piyush Gohil, Vijay Parmar (July 2021). "Bio Composite Material: Review and its Applications in Various Fields", Encyclopedia of Materials: Composites, Elsevier, 2021, Pages 80-93, ISBN 9780128197318, https://doi.org/10.1016/B978-0-12-819724-0.00011-2.

d) 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)

Office of the Controller General of Patents, Designs & Trade Marks
Department of Industrial Policy & Promotion,
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Government of India

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APPLICATION TYPE	ORDINARY APPLICATION
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APPLICANT NAME	1 . Mr. PIYUSH THAKORBHAI PATEL 2 . Dr. PIYUSH PRAGJIBHAI GOHIL 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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(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

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