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. The goal should be to capitalize on the experience of others rather than 'reinventing the wheel'. There is no harm in adopting a proven design if it serves the purpose. Time thus saved can be better utilized in more challenging design activities. Some designs can very well be based on one's own experience with some modification as necessary.

This chapter contains various research/review papers, articles, and theories based on design procedure, material selection, technique, analysis & testing of prosthetic and orthotic elements.

The research is aimed at discovering and understanding the underlying mechanism of the particular structure for the investigation work. The investigational data will be analyzed both quantitatively and qualitatively to identify parameters.

Engineering structures are designed to provide reliable performance with a minimum number of breakdowns and minimum repair costs. In the past, in high-tech sectors such as the aerospace industry, chemical processing units, manufacturing industry, and production systems, performance constraints were almost always associated with the application of the material.

However, these elements must be able to withstand deformation and resist failure during a working life of thirty to forty years.

Composite Materials are being developed and made with two kinds of objectives;

- To enhance the performance efficiency and material properties
- To design materials with combinations of preferred properties

❖ **Enhancement of performance efficiency and properties**

The earlier products of composite materials which are in wide-scale use today developed with high specific properties like higher specific strength and higher modulus. All the improvements are achieved by choosing lightweight matrices like polymers and reinforcing them with reinforcement fibers of high specific properties arranged in specific geometrical patterns.

- **Materials with combinations of preferred properties**

When a product is made, the material system used should have to fulfill several functional, physical, and mechanical property requirements. It is now possible within limits to create composite materials with combinations of desired properties.

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 behavior. This advantage gives it flexibility in many industrial applications.

The key advantages of matrix polymers (Fry, 1986) are their low cost, comfort of handling, chemical resistance & low density. Low resistance, modulus, and operating temperature, on the other hand, limit its application. Thermoplastic polymers, thermosetting polymers, elastomers, and their mixes are the polymers used in composites.

Thermoplastics (Olabisi & Adewale, 2016) are made up of molecular chains that are either linear or branched and have strong intramolecular bonds but weak intermolecular interactions. They have a semi-crystalline or amorphous structure and may be reconstructed using heat and pressure. Polypropylene, polystyrene, nylon, polyethylene, polyacetal, polyamideimide, polyetheretherketone, polysulfone, polycarbonate, polyphenylene sulphide, and polyetherimide are just a few examples.

Thermosetting (Pascault & Williams, 2013) resins have a cross-linked or networked structure in which all molecules are covalently bound. When heated, they do not soften but decompose. They can no longer be reformed after they have been cross-linked. Polyesters, epoxies, polyimides, melamines, silicones, and phenolic resins are common examples. Elastomers (Ikeda, Mamiya, & Yu, 2007) are polymers with viscoelastic properties and generally have significantly lower modulus and higher yield strength than other materials.

2.2 PROSTHETICS AND ORTHOTICS TECHNOLOGICAL DEVELOPMENT

To suit the functional demands of the person, the prosthetic must be a unique combination of acceptable materials, location, design, and construction. Orthotics can be used on many different parts of the body, including the upper and lower limbs, the skull, and the spine. Orthotics have recently been developed to drastically realign the bones of the skull in newborns with positional plagiocephaly.

The brace can be worn on a variety of body parts, including the upper and lower extremities. To suit the practical demands of the person, restoration must be a one of a kind blend of materials, location, design, and construction. Study of the composition and operation of biological systems as a design model and construction of materials and machines. A human attempt to copy the characteristics of God's creation to improve his design. The objective for most of the new prosthetic designs is to replace the motion of natural limbs as closely as possible for some expected ambulation and provide comfort for the wearer.

A flexible action foot, a strong composite pylon, and a socket adapter are all part of the lower leg prosthetic. As shown in Figure 2.1 a pylon is an internal cylindrical rod that supports the amputee's foot at the distal end and connects to the shaft at the proximal end. The remaining limb's socket is a plastic chamber that fits the exterior shape of the remaining limb and binds the prosthetic to the amputee. (Levangie & Norkin, 2011)

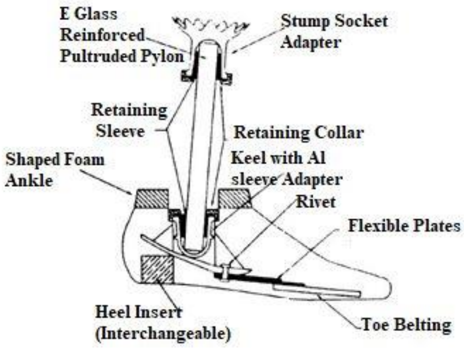


Figure 2.1: New prosthetic cross-section diagram (Michael & Bowker, 2004)

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 as shown in Figure 2.2.

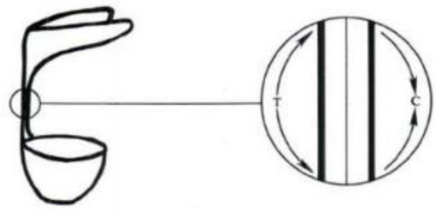


Figure 2.2: Stresses distribution on socket wall (Current, Kogler, & Earth, 1999).

Increasing the distance between the inner and outer walls is directly related to increased resistance to fracture, fatigue, and breakage. The angle of the fiber concerning the applied stress is important to achieve the highest level of fracture toughness in the composite structure. This can be achieved by applying the composite in the form of a mat or knit, thereby arranging the composite fibers at multiple levels.

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

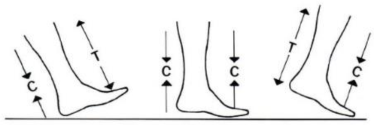


Figure 2.3: The forces transmitted through the anterior and posterior aspects during the walking cycle (O&P Virtual library)

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)

The morphology of the lower leg is usually documented using a molded box or a foam impression box in the creation of ankle and foot orthotics in footwear. The use of carbon fiber dates back to the 20th century when doctors and engineers were looking for a lighter load-bearing material. Fiber Reinforced Plastics (FRP) (Che, Saxena, Han, Guo, & Ehmann, 2014) are composite materials made by incorporating a high strength, high modulus fiber like glass fiber, and carbon fiber into the plastic materials. CFRP is a very light, flexible, and durable material that allows for the integration of energy return systems.

Although these materials have superior strength-to-weight properties compared to structural metals, they are expensive to manufacture and environmentally friendly. Traditional composites used in joint prosthetic sockets include acrylic, glass, and carbon fiber, which generate harmful gases and dust during manufacturing. Orthotic devices and prosthetics are structured using a variety of fibers such as cotton, nylon, glass, and carbon. This study focuses on the acetabular region and emphasizes the leg prosthetic. This is because they are often modified and replaced with nature-based biocomposites. (Antoniac, 2016)

Plant fiber is a renewable resource that is durable, reusable, affordable, low bulk, and high strength-to-weight ratio. Lingo's cellulosic (plant-based) biofibers consume much less energy to produce and are easily biodegraded when no material is needed. (Black & Hastings, 2013)

(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)

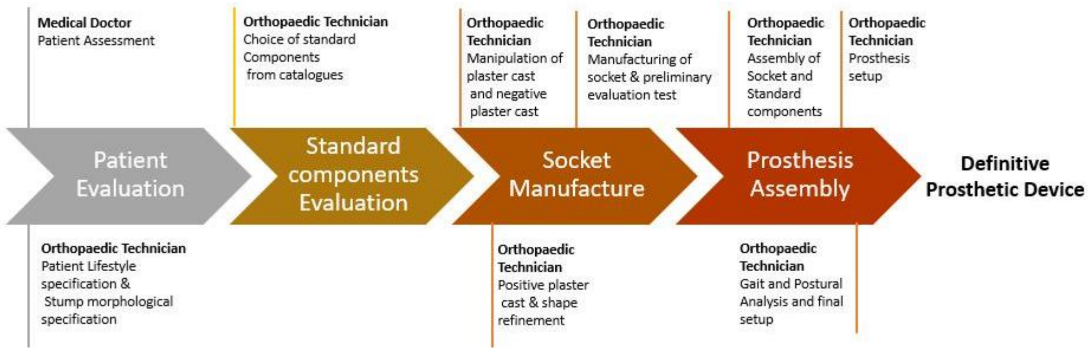


Figure 2.4: Traditional manufacturing workflow for a modular prosthetic (Colombo & others, 2014)

In general, the technique for designing a socket for a prosthetic begins by making a positive cast of the patient’s remaining limbs (Figure 2.5). This socket manufacturing method is used in this study because it is a stack of multiple layers of material. One of the layers used to give the laminated bushings maximum strength is fiberglass. There are other techniques for making sockets, including vacuum casting techniques. (Abd Al-razaq, Resan, & Ibrahim, 2016)

Figure 2.5: Traditional fabrication process of the prosthetics socket

Prosthetics can be created in two ways: endoskeletal and exoskeleton (Figure 2.6). The way it is done depends on the level of activity of the patient. In the endoskeleton method, the mast tube is wrapped in soft, skin-colored foam and shaped to fit healthy limbs. In the exoskeleton method, a hollow calf-shaped sleeve is placed between the socket and the foot to fill a dense, hard foam.

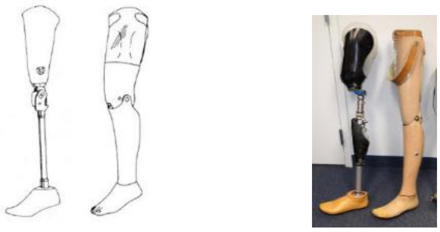


Figure 2.6: Fabrication methods (O&P Virtual library)

Currently commercially produced prosthetic ranges between Rs. 3,50,000 to Rs. 4,50,000. Given this considerable amount, many people in need of prosthetics cannot afford them and cannot lead a limited life. From the reference (Figure 2.7), Ossur Talux Foot price is around 2.18 lakh/piece and the P & O Rehab Center prosthetic hand price is around 2.5 lakh/piece.

Figure 2.7: Prosthetic foot (Ossur Talux) and hand (P & O Rehab Center)

Conventional orthotic manufacturing covers the typical process (Figure 2.8) starting from measuring, placing markers, molding, positive mold, drying, correcting and polishing, removing negative mold, heating thermoplastic, removing mold, and initial fitting.

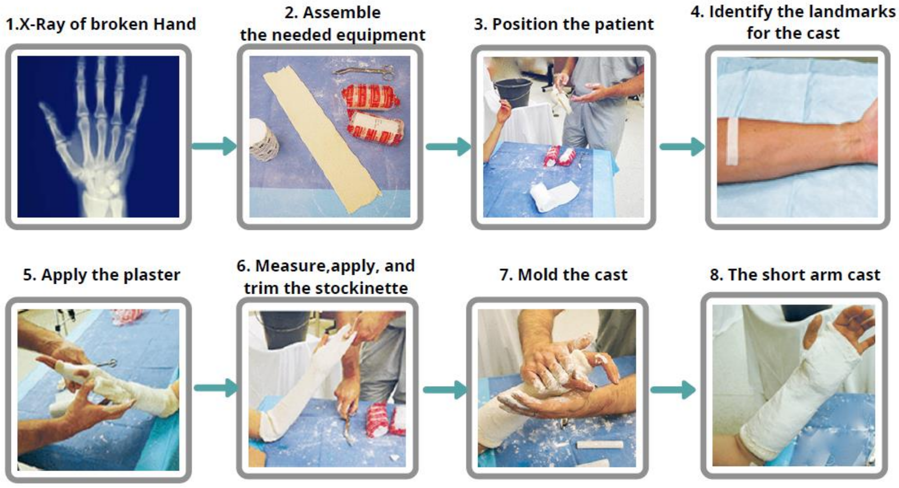


Figure 2.8: Broken arm process steps

Due to the challenge of the market, prosthetic manufacturers are currently making changes on several levels; some of which involve the selection of materials used in the rolling development of the socket or assembly.

(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. There was no failure after 2.5 million cycles of fatigue testing on a specialized walking machine (Figure 2.9 & Figure 2.10). (Nair, Hanspal, Zahedi, Saif, & Fisher, 2008)

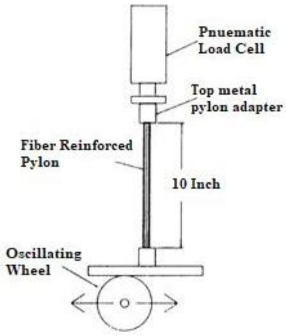


Figure 2.9: Schematic of pylon fatigue test

(a) (b)

Figure 2.10: Prosthetic test frame (a) Fixed angle test frame b) Test frame with a roller mechanism

To choose the proper material for use in the pylon, compression, bending fatigue, and static torsion tests are done on several rod and tube materials. E-glass and carbon fiber reinforced epoxies, vinyl esters, and draw-formed and compression-formed polyester solid rods were among the materials chosen for testing. (Symington, Banks, West, & Pethrick, 2009)

2.3.2 Prosthetic/Orthotic systems by advanced manufacturing method

Charles Hull invented a new manufacturing technique in 1984 compared to the traditional manufacturing process. Working at 3D Systems Corporation, Hull was a pioneer in the solid imaging process known as Stereolithography and his patents allowed him to create solid objects from layers of UV-sensitive resin. (Wohlers & Gornet, 2014)

3D printing (Redwood, Schöffer, & Garret, 2017) is a layered modeling process based on the principles of inkjet printing. With this technology (Figure 2.11), it is possible to make 3D products using various materials. Rather than removing material from huge materials as in a CNC milling machine, products are constructed layer by layer.

Figure 2.11: Corporation orientation chart for 3D printing (Lipson & Kurman, 2013).

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. These prosthetics usually cost less than a few hundred dollars and will be a viable option for those who significantly improve their lives.

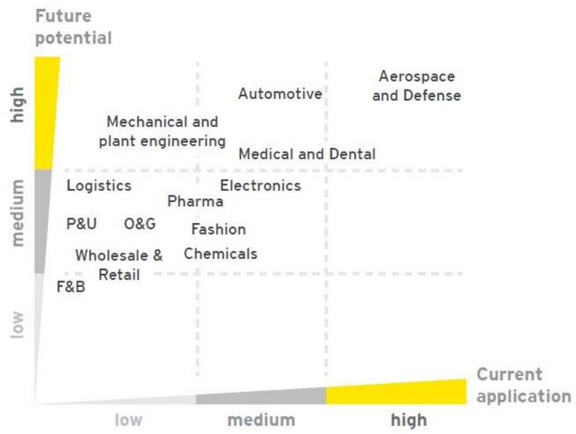


Figure 2.12: Current application and future potential of 3D printing by industry (3D Printing in the Electronics Supply Chain /source-today)

3D printing is very convenient because it allows you to manufacture individual parts at a lower cost. Depending on the medical structure and accessibility, the production of a standard prosthetic can take weeks or months. As 3D printing continues to transform the manufacturing industry (Figure 2.12) (Campbell, Williams, Ivanova, & Garrett, 2011), doctors want to help 30 million people around the world who need prosthetics and orthotics.

(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. Because of the strict craft control, the filament is free from impurities and won't block the nozzle, which is important for printing. The vacuum package can keep the filament safe during transportation.

Owing to its stability, the products printed are less likely to be deformed. It is harmless to humans and eco-friendly. After opening it, the filament can be stored for more than 3 weeks without any damage and enjoy a stable printing effect.

Figure 2.13: Filament spools

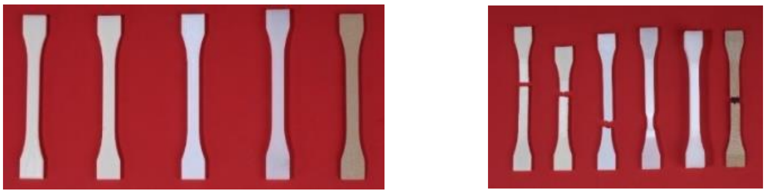
ABS, PLA, and their many mixtures are the most prevalent FDM 3D printing materials (Figure 2.13). Advanced FDM printers (Table 2.1) may also print with specialist materials that have increased heat resistance, impact resistance, chemical resistance, and stiffness. (Dizon, Espera Jr, Chen, & Advincula, 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)



(a) Before testing (b) After testing

Figure 2.14: Test specimens 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 2.14). Tensile experiments on 3D printed materials are summarized in Table 2.2. (Decuir, Phelan, & Hollins, 2016)

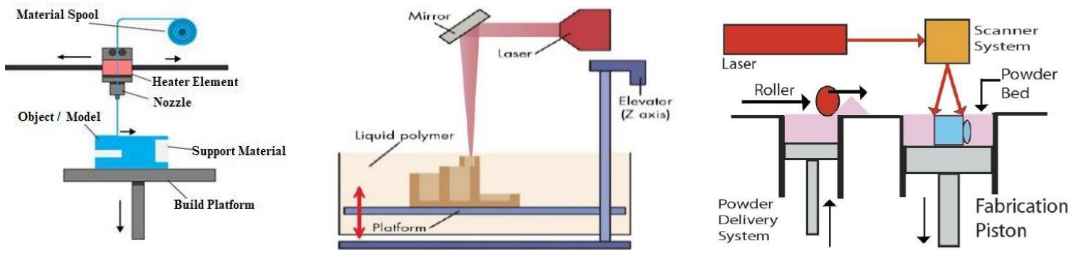
Table 2.2: Tensile testing for 3D printed materials

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. This can force the user to live with a broken prosthetic or adopt a unique solution that could compromise its calibration, causing secondary damage.

Creating a traditional prosthetic can take weeks or months, but creating a 3D-printed prosthetic takes just one day, making it more accessible. Traditional prosthetics are notorious for being awkward due to socket discomfort. The 3D prosthetic is more comfortable because it is more customizable to the user. Some of the additive manufacturing (Wong & Hernandez, 2012) processes (Figure 2.15) are listed below;



(a) (b) (c)

Figure 2.15: Additive manufacturing process (Molitch-Hou, 2018) (a) FDM (b) SLA (c) SLS

I. Fused Deposition Modelling (FDM)

FDM (Vyavahare, Teraiya, Panghal, & Kumar, 2019) deposits the material in layers according to the "additive" concept as shown in Figure 2.15 (a). The flow may be switched on and off by feeding an untied plastic filament or wire into the extrusion nozzle. A numerical controller allows the nozzle that is heated to melt the material, to move horizontally and vertically.

II. Stereolithography (SLA)

In the layered molding technique known as Stereolithography (Huang, Qin, & Wang, 2020), layers of objects are constructed one at a time using liquid bats, UV-curable photopolymer “resins” and UV lasers as shown in Figure 2.15 (b). The laser beam traces the cross-section of the part design on the surface of the liquid resin for each layer.

III. Selective Laser Sintering (SLS)

SLS (Schmid, Amado, & Wegener, 2014) is an additive manufacturing process that fuses minute bits of plastic powder, metal ceramics, or glass into a single block with the required 3D shape using extremely powerful lasers (such as carbon dioxide lasers) as shown in Figure 2.15 (c).

Each technology has its strengths and weaknesses during the manufacturing process. The choice of raw materials required processing speed and resolution, and the necessary cost and performance for the intended application all affect the manufacturing technique choice.

There is interest in using 3D printing in the medical profession after a thorough assessment of the literature in the sector. The implementation of 3D printing in dentistry (Dawood, Marti, Sauret-Jackson, & Darwood, 2015) solves some of the problems commonly encountered in traditional dentistry.

Traditional dental practices can be very uncomfortable for patients, often a time-consuming process. Valuable time is spent waiting for the molded material to set and harden. Although advances have been made in the process of mouth shaping, the process is still relatively slow. One of the challenges in creating a dental cast using a traditional cast is understanding the anatomy of the oral soft tissue.

Today, however, the accuracy, speed, and precision of 3D printing are the main reasons why it is practiced in high-risk areas of dentistry (Mahamood, Khader, & Ali, 2016), prosthetic development, and surgery. 3D printing transforms each of these areas into a more digital process.

Figure 2.16: Application of 3D Printing

3D printing allows users to create specific shapes and sizes to achieve a highly customizable restoration. Prosthetics 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 2.16 & Figure 2.17. (Aherwar, Singh, & Patnaik, 2013)

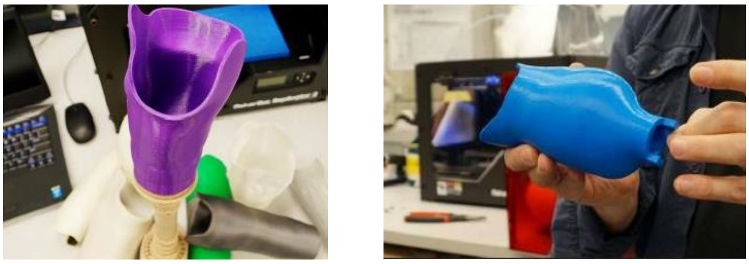


Figure 2.17: 3D printed prosthetics

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

Computational techniques can have a significant impact on improving product design, analysis, and manufacturing. FEM is also increasingly used in biomechanical analysis of human bones, tissues, and organs. These models' numerical stresses are analyzed for vertical equilibrium using finite element analysis software.

The prosthetic fabrication process does not involve the prosthetic or the patient because the device is manufactured to the exact size, shape, and durability specifications required. The patient then receives a prosthetic optimized for the patient's needs. The schematic diagram of the design and analysis process is shown in Figure 2.18.

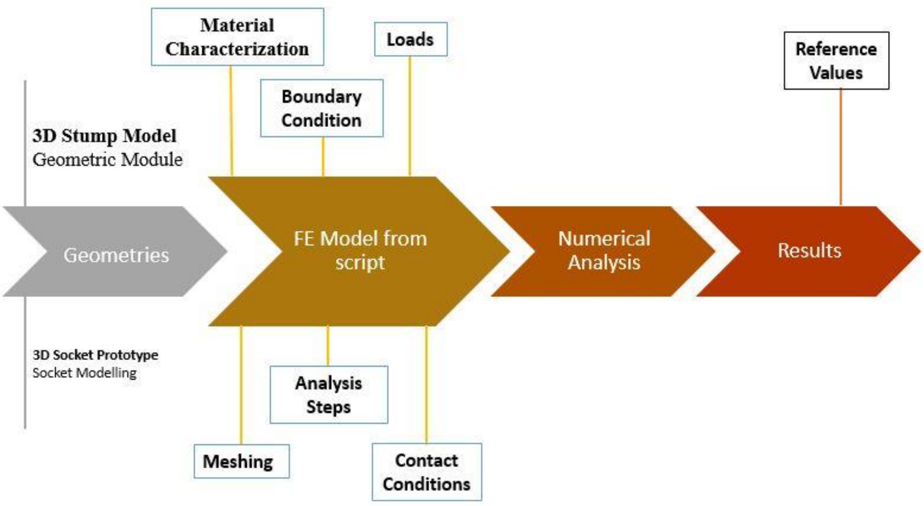


Figure 2.18: Integrated FE analysis procedure within the design platform (Colombo & others, 2014)

To optimize the biomechanical adaptation of the orthotic device to the patient, the goal of the current study is to create analytical techniques to assess Ankle Foot Orthotic (AFO) designs using FEA.

This task's specific purpose is to first create a flexible modeling process that produces a realistic 3D asymmetric finite element model of the Prosthetic/Orthotics for a particular patient, according to a set of application-defined design parameters.

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 molds.
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	Aluminum / 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 prosthetics.
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 favorable speeds.
9	Bose, Vahabzadeh, &	Bone	Biomaterials	3D printing	Choosing the right binder for 3DP remains a challenge and may require extensive

	Bandyopadhyay , 2013				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 molds	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 personalized 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 utilized 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 0.79 kg to 0.30 kg. 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	Aluminum alloy/ plastic nylon	3D printing	Based on human gait data, the motorized 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 stabilized by rods and clamps was utilized 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 utilized 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 molding	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.

Some articles' brief overviews relating to our research activity are listed below as case studies;

(a) Modeling and simulation in the design process of a prosthetic foot (Tryggvason, Starker, Lecompte, & Jónsdóttir, 2017)

The right range of stiffness in the location of joints and spring components for varied prosthetic jobs and loads is one of the issues in prosthetic design (Figure 2.19). This necessitates the development of an adaptive mechanism that replicates the stiffness features of a physiological foot through the use of real-time adaptive control that alters the stiffness reactively based on the user's demands.

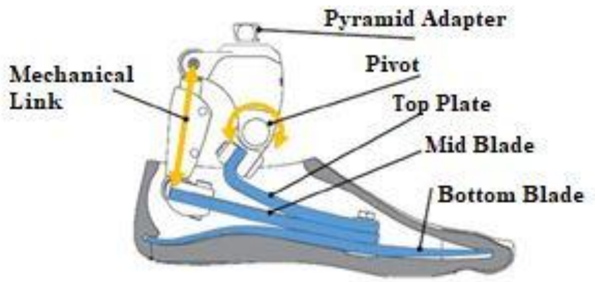


Figure 2.19: Prosthetic foot model schematic

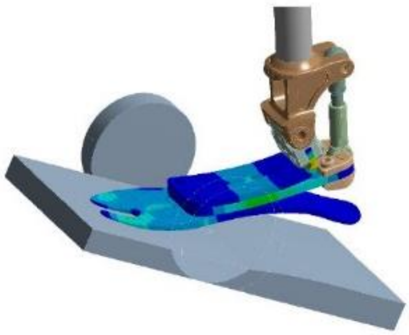


Figure 2.20: The FE model in 3D, exhibiting equivalent stresses in flexible components

The ongoing study must show a relationship between these mechanical traits and various groups of persons who have had amputations. The FE simulation model (Figure 2.20), on the other hand, has a significant connection with the machine test findings.

(b) Design, Modeling, and Optimization of a prosthetic runner blade (Upender, Srikanth, Karthik, & Kumar, 2018)

The design of the blade runner (Figure 2.21) is very important for biomedical engineering, which involves the science of applying mechanical engineering to achieve the best results.

Figure 2.21: CAD geometry of runner blade

Since the selected material is carbon fiber, its properties are defined in the Solid Works material data interface. After meshing, the model was imported into Solver (ANSYS) for analysis.

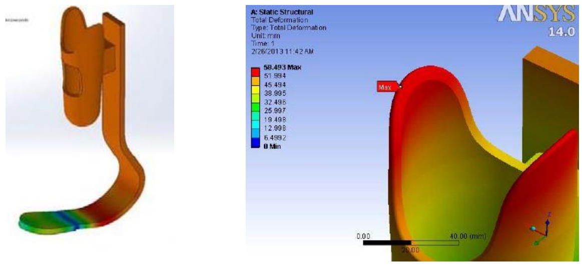


Figure 2.22: A closer view of total deformation on the runner blade

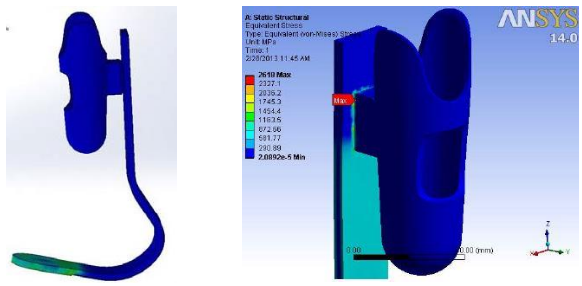


Figure 2.23: A closer view of total equivalent stress on runner blade

Thus, the required results of stress and strain concentration values are obtained as shown in Figure 2.22 & Figure 2.23. Finally, based on these values, the design was modified for optimal performance.

(c)The Mechanical response and parametric optimization of Ankle-Foot devices (Smith, 2016)

The goal of this work was to better understand the design characteristics of existing prosthetics through mechanical testing and to develop a model that has been numerically optimized for a walking style.

(a) (b)

Figure 2.24: Ankle-Foot Devices (a) Renegade prosthetic foot (b) Tailor-Made prosthetic foot

A single-axis compression test was performed on the Freedom Innovations Renegade and Tailor Made legs to determine deflection, stiffness, and energy return during quasi-static loads at fifteen selected angles on an ideal load model with and without their aesthetic cover.

Renegade and Tailor Made (Figure 2.24) are proven to have excellent energy return performance and excellent storage capacity when pushed at 20°. This paper provides a framework for the design optimization process by performing parametric finite element analysis on a representative leg model.

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 favorable to plaster, a sink with plaster catch, and a non-slip surface.

FDM’s ability to create complex products with high accuracy in a short time allows it to liberate the hands of engineers from a variety of occupations. The use of additive manufacturing, in particular, is generating a revolution in rehabilitation engineering by printing personalized P&O devices.

While several authors have emphasized the benefits of 3D printing technology in the production of orthotic devices, little research has focused on the design of cervical orthotic devices. This might be due to the complexity of the orthotic device design and the lack of readily available off-the-shelf orthotic devices to meet the patient's needs. Table 2.4 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 mold for AFO injection molding would eliminate any concerns associated with anisotropy in 3D-printed components, however, the expense of the mold 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.

Some articles related to our research work are mentioned below as case studies;

(a) ***A narrative review: commonly used types and recent developments in Ankle-Foot Orthotics*** (Choo & Chang, 2021)

By bringing the heel into touch with the ground during the stance phase, AFO prevents foot drag during the swing phase of walking, maintains clearance between the foot and the ground (DeBoer, Hosseini, & Rossa, 2022), and maintains postural stability. Plastic AFOs, hiking boots, UD-Flex, and carbon fiber AFOs are the most often utilized AFOs in the clinical context.

In addition, new types of AFOs have been developed to make up for the shortcomings of these traditional AFOs, such as AF servos, TurboMed, 3D printing AFOs, and Kenaf composite AFOs as shown in Figure 2.25.

(a) (b) (c)

Figure 2.25: Ankles- current trends in foot orthotics (a) AF Servo, (b) TurboMed, and (c) 3D printed AFO

Compared to traditional AFOs, recently developed AFOs, depending on the type, are more durable, have shorter manufacturing times, have better molding capacity, are easier to wear, and have a better appearance.

(b) ***A review of orthotics and prosthetics, with a focus on the possibility of Kenaf composites as substitute constituents for ankle-foot orthotics*** (Shahar, et al., 2019)

This article deals primarily with the possibility of replacing AFO materials with materials currently on the market.

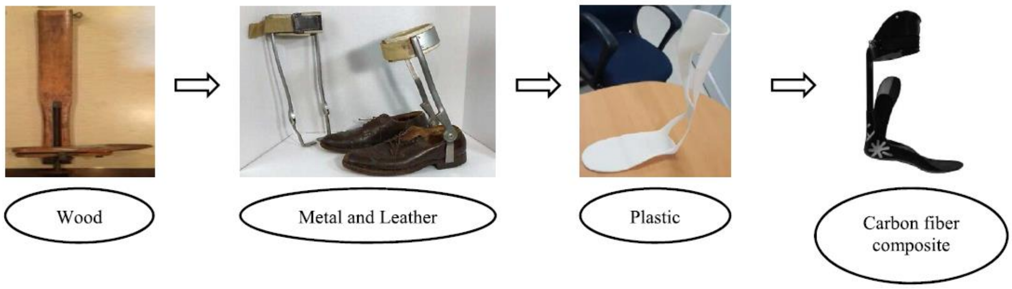


Figure 2.26: The evolution of AFO materials

AFO’s current consumer and research materials comprise wood, metal, leather, plastic, and carbon fiber composites (Figure 2.26). When all of these materials are compared, It is determined that carbon composite, with its low weight, high strength, and high rigidity, is the material most suited for AFO. However, the cost of its basic materials is prohibitively expensive, prompting researchers and manufacturers to utilize more plastic.

Nowadays, Additive Manufacturing is popular because of its adaptable and optimal design, as well as its long-term cost-effectiveness (Shahar, et al., 2019). To reduce existing production times and costs, future research may use natural fiber composites in additive manufacturing using 3D printing technologies.

(c) *A Comparison of Ankle-Foot Orthotic manufacturing using conventional and Additive manufacturing* (Shahar, Sultan, Shah, & Safri, 2020)

Thermoformed polymer sheets are commonly used in AFO production because they are inexpensive, light, easy to shape, and visually beautiful. As a result, they are highly sought after in the area of orthopaedics. PMCs are the subject of extensive studies to reduce polymer consumption and look at environmentally friendly orthotics.

Researchers have also started to use PMC in the AM to boost production speed and flexibility in AFO design. This shows that AM has great potential for AFO development and might replace CM in terms of cost-effectiveness, ease of manufacture, decreased manufacturing time, and a tensile strength comparable to thermoformed polymers utilized in the CM process.

(d) *Customized assistive technology is produced using 3D modeling and printing methods* (Lee, et al., 2019)

3D printing technology is widely employed in medicine and has altered numerous medical treatment paradigms. The main advantage of 3D printing is that it is easy to produce personalized materials at a low cost.

The 3D-printed orthotic is designed to be printed using fused filament fabrication. A non-toxic, resilient, and highly flexible thermoplastic elastomer was used as the impression material. The entire procedure, from 3D scanning through 3D printing, is shown in Figure 2.27.

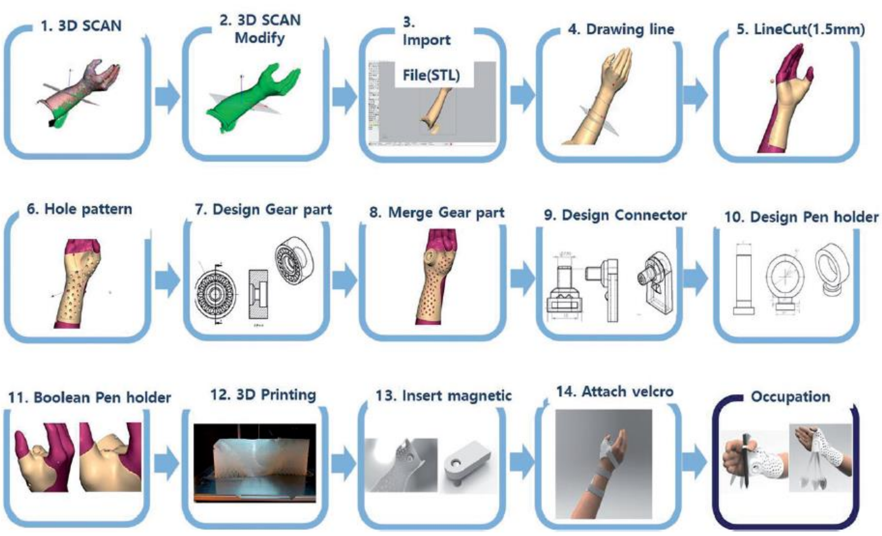


Figure 2.27: Process from 3D scanning to 3D printing

The 3D-printed orthotic was a success for the patient because it was comfortable and easy to use.

2.5 PATENTS

2.5.1 Patents related to prosthetic elements

(a) Patent: - US10857007B2 (Michael Thomas Wilson, 2016)

Titled: - Coupling for a prosthetic device

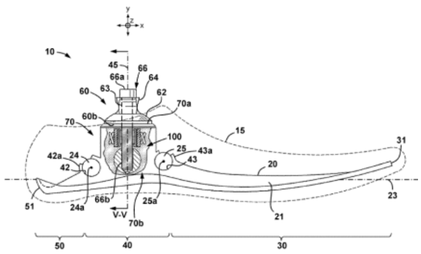


Figure 2.28: Side partial c/s view of an embodiment of a prosthetic foot

Disclosure - The cited document describes a prosthetic foot with a longitudinal axis keel as shown in Figure 2.28. The keel body consists of a heel portion, a forefoot portion, and an ankle portion positioned between the heel and forefoot portions. The ankle component has a housing with a central axis that is vertically orientated. Furthermore, the prosthetic foot comprises a connection assembly that is housed within the ankle portion's housing. A bearing member is disposed about the central axis, a support sleeve is disposed about the bearing member, and an embedding member is disposed about the support sleeve.

Problem: The cited document uses a complex structure and comprises multiple components which may be difficult for the user to handle with a severe disability. Though the cited document includes a keel having a longitudinal axis, it didn't specify whether the user can climb or use stairs or walk on uneven ground.

Solution: The subject of the current innovation is a prosthetic, which is a single unit of curvature shaped like a human structure, which allows the user to easily climb stairs and uneven ground without losing balance. The present invention provides the advantage of multiaxial dynamic foot stability with the energy storage capacity of high-profile dynamic feet. There is another advantage to having a prosthetic that allows true medial-lateral rotation.

(b) Patent: - US10772741B2 (Friesen, 2020)

Titled: - Prosthetic Foot

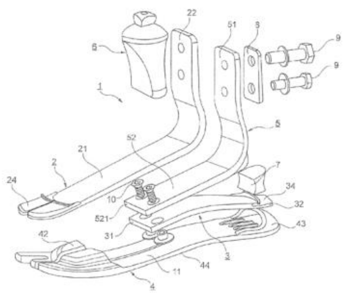


Figure 2.29: Prosthetic foot in an exploded view

Disclosure - The cited document shows a prosthetic foot with springs in the forefoot, springs in the heel, and springs in the sole as shown in Figure 2.29. The sole spring is connected to the heel spring and forefoot spring. The sole spring has a receptive facility for the forefoot spring and heel spring, where the receptive spring i.e. heel spring and forefoot spring can be fitted. The heel spring is connected to the forefoot spring through an articulating element, and the articulating element extends forward along the forefoot spring at least through one of its parts.

Problem: The cited document uses a complicated structure and comprises multiple components which may be difficult for the user to handle with a severe disability. Though in the cited document the base spring is connected to the heel spring and to the forefoot spring, it didn't specify whether the user can climb or use stairs or walk on uneven ground without losing balance.

Solution: The invention relates to a novel single-unit prosthetic foot that can absorb shocks developed during walking with efficient energy transfer between heel strike and toe thrust and improved stability. The present invention provides the stability benefits of a multi-axis foot with the energy storage capabilities of a highly configurable dynamic foot. There is another benefit to having a prosthetic foot that allows true medial rotation.

(c) Patent: - US10369019B2 (Clausen, 2019)

Titled: - Prosthetic foot with enhanced stability and elastic energy return

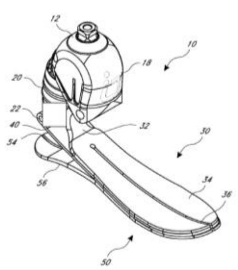


Figure 2.30: Perspective view of an embodiment of a prosthetic foot

Disclosure - The cited literature reveals a prosthetic foot consisting of one fixed element and two or more flexible elements as shown in Figure 2.30. The fixture may include a connector configured to connect the fixture to a user or other dummy device. Two or more flexible elements may be rotated to the fixed element using swivel joints so that the flexible element can both rotate and flex concerning the fixed element when the prosthetic is in contact with the ground.

Problem: The cited document provides the design of a prosthetic foot but due to its complex structure, it may be difficult for the user to handle a severe disability. Although in the cited document there is one fixed element and two or more rotatable flexible elements that are connected through rotations, it didn't specify whether the user can climb or use stairs or walk on uneven ground without losing balance.

Solution: The technological advancement in the present invention relates to a novel single-unit prosthetic foot in which the mounting bracket structure above the top surface of the prosthetic foot model holds the snubber ball connection with the prosthetic foot adaptor for the multiaxial rotation ankle. The present invention provides the stability benefits of a multi-axis dynamic foot with the energy storage capabilities of a highly configurable dynamic foot. There is another advantage of having an adjustable prosthetic leg that will allow the manufacturer or user to select the range of side-to-side rotation that best suits the user's needs. 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.

(d) Patent :- WO2020012504A1 (Gosakan , 2020)

Titled: Pyramidal Prosthetic Foot

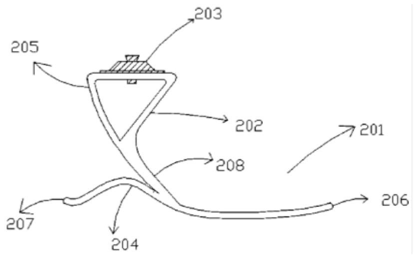


Figure 2.31: Exemplarily illustrates a prosthetic foot with a heavy metallic connector

Disclosure - The cited document discloses a prosthetic foot that comprises a hollow triangular lightweight top section that is an integral part of a first leaf spring that originates from a top portion to the toe of the prosthetic foot as shown in Figure 2.31.

The prosthetic foot further comprises a second leaf spring. The second leaf spring originates from the heel to the toe.

Problem: Though the cited document comprises a hollow triangular lightweight top section that is an integral part of a first leaf spring that originates from a top portion to the toe of the prosthetic foot, it didn’t specify whether the user can climb or use stairs or walk on uneven ground without losing balance.

Solution: The subject of the current innovation is a prosthetic foot comprising a hollow rectangular lightweight top section that is an integral part of the *novel single-unit prosthetic foot structure*. The present invention provides the stability benefits of a multi-axis dynamic foot with the energy storage capabilities of a highly configurable dynamic foot. There is a further advantage to having an adjustable prosthetic foot to select a range of medial-lateral rotation and also varus-valgus movement like the anatomical subtalar joint to accommodate the uneven terrain. Even as per the foot size of the patient the die can be trimmed to a smaller foot size. Attempts will be made in the die for the higher thickness of shaft, and blade for ultra-heavy amputee patients 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).

(e) Patent:- WO2020012319A1 (Huot, 2020)

Titled: - Prosthetic Foot

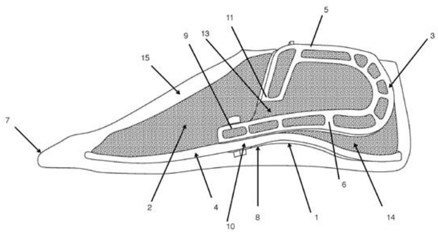


Figure 2.32: Complete prosthetic foot (cross-sectional view) that includes the keel

Disclosure - The document proposes a prosthetic foot having an internal keel and an encapsulating substance as shown in Figure 2.32. To ensure that the prosthetic's behavior is as close to that of a healthy human foot as feasible. The materials and design of the keel allow strain energy to be stored and released during the proper stages of the gait cycle. In some areas, elastomeric foams are used as safety components to prevent keel overloading. Because it has the shape of a human foot, the keel is preferred surrounded by two types of foam to fill internal space and as a cosmetic element.

Problem: The cited document uses a complex structure and comprises multiple components which may be difficult for the user to handle with a severe disability. Though the cited document includes a keel embedded in a material, it didn't offer the flexibility of a cost-effective material and the related lifetime of the material.

Solution: The present invention is related to a novel single-unit prosthetic foot structure where the static structural simulation results show that considering carbon fiber material for a prosthetic foot structure has the lowest deformation value and highest natural frequency. The present invention provides the stability benefits of a multi-axis dynamic foot with the energy storage capabilities of a highly configurable dynamic foot. There is a further advantage to having a prosthetic foot of different materials like carbon fiber suitable for heavy load situations and other polymer materials like UHMW-PE/ Nylon / Delrin which has a low production cost and is lightweight.

2.5.2 Patents related to Orthotics elements

(a) Patent: - US 2021/0298937 A1 (Schuind, 2021)

Titled: - Custom medical splint or brace fabrication for immobilization of a specific region of a patient's body portion

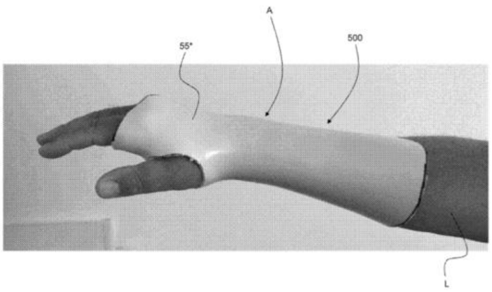


Figure 2.33: Photographic illustrations of a resulting splint or brace

Disclosure: The referenced document describes a technique for producing a personalized medical device that incorporates a brace to immobilize a certain region of a patient's body as shown in Figure 2.33. The personalized medical device is created using the following operations: (a) producing a 3-D mold of a piece of the patient's body part that includes the chosen location where the desired medical item will be installed; (b) establishing the intended medical device's three-dimensional form across the designated location; and (c) making a two-dimensional template related to the stated 3-D shape, which reflects the 3-D form of the desired medical device unfolding in a two-dimensional format.

Problem: Traditional custom orthotics manufacture is a time-consuming and labor-intensive process. The cited document uses direct molding of a splint or braces onto the relevant portion of the patient's body part is also known as such in the art and widely applied in practice using e.g. mineral plaster casting materials, thermoformable materials or resin-impregnated fabric materials.

Solution: The present invention relates to wrist orthotic devices that use FDM techniques because of their versatility, weight and time savings, and cost-effectiveness in optimizing complex shapes.

(b) Patent: - US20210187153A1 (Xiang, 2021)

Titled: - Adjustable external fixing brace

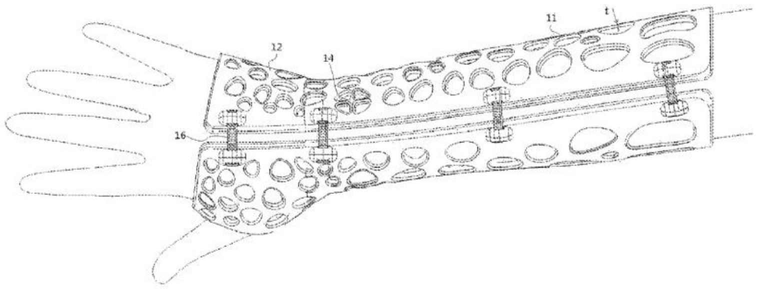


Figure 2.34: Schematic views of an adjustable external fixation brace

Disclosure - The cited document discloses a medical fixing brace, which is characterized in that it is a mesh-shaped plate provided with several large ventilation openings and injection molded from a shape memory material as shown in Figure 2.34. On both the front and rear surfaces of each side of the mesh plate in proximity to the transverse edges, several mounting holes used for connecting an engaging fitting apparatus are provided symmetrically along the plate-shape structure or several mounting holes for connecting an engaging fitting are provided on at least one surface. The thickness of the mesh-shaped plate is thinned at the mounting holes; and, provided within the mounting holes are some parts for mounting the engaging fitting apparatus. The fixing brace has no coating layer, allows with the large hole structure thereof the direct viewing of condition changes, and prevents the occurrence of post-traumatic complications; clamping tightness can be adjusted throughout a treatment, compression on soft tissues is maintained, and fixing effects are great; the fixing brace can be used on either the left or right, operation is simple for a physician. The material used for the fixing brace is nonabsorbent and has no padding structure, dries quickly after a shower, provides great comfort, and prevents the occurrence of itchiness and dermatitis.

Problem: The cited document uses the injection molding process for the development of the adjustable external fixing support, in which the shape memory mesh plate with the large openings distributed thereon is formed in a mold at one time. Furthermore, under static conditions, the final result acquires shape and might create blisters on the subject's skin.

Solution: The present invention related to the patient-specific optimized wrist brace is prepared by the FDM technique. This is the process of manufacturing customized orthotic device parts directly from CAD data according to patient requirements, without the use of parts-dependent tools. Scanning requires only one person and a laptop or PC. You do not need to be in a specific workplace because the scanner is portable. This is especially important when the subject is immobile or difficult to relocate, and it is a substantial improvement over the traditional plaster method.

(c) Patent:- US20210205109A1 (Whiteside, 2021)

Titled: - Flexible ankle foot orthotic

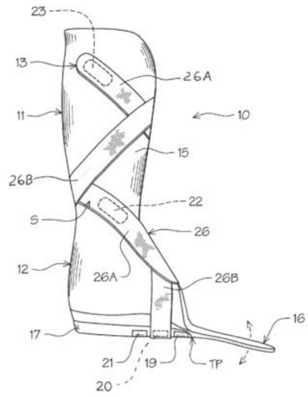


Figure 2.35: Medial side elevation view of the AFO

Disclosure - An ankle and foot orthotic comprising an integrated flexible yielding material to offer active or passive influence of foot and ankle position via direct adjustable elastomeric overlaying strap is disclosed in the given document (Figure 2.35).

The orthotic extends over the lower limb having multiple strap attachment and tensioning points there along with or without a non-yielding buildup extending the heel and sole portion on which multiple strap fixation repositionable points are transversely positioned in spaced parallel, horizontal, and diagonal orientation to one another and method of manufacturing the ankle and foot orthotic.

Problem: The mentioned article employs the plastic molding approach for the construction of the ankle-foot orthotic, which is a more time-consuming and labor-intensive production process.

Solution: The present invention, which relates to the creation of ankle-foot orthotic devices employing FDM techniques, has the potential to significantly improve the orthotic device manufacturing process through reduced manufacturing periods, faster morphology acquisition, and increased patient comfort.

(d) Patent:- US20200281801A1 (Karlovich, 2020)

Titled: - Mobility assistance device

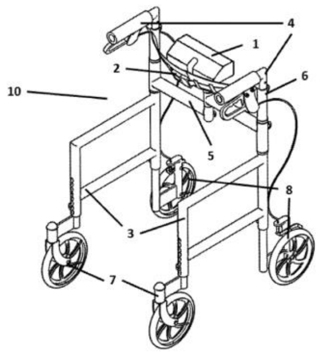


Figure 2.36: Exemplary perspective view mobility assistance device

Disclosure - The cited document discloses a mobility assist device with first and second frames, articulated arm mechanisms coupled to the first and second frames, situated on the user's left and right sides as shown in Figure 2.36. A pivoted backup unit or walker coupled to the frame then transfers at least a portion of the user's weight from the legs and transfers the weight to the first and second frames via the user's hips or pelvis, which allows the user to stand and work for a long time without the user's arm holding the frame.

Problem: The cited document uses a lightweight motorized version that can only be used in "auxiliary walking mode". In assisted walk mode, the user is powered by the hub wheel and the device walks on its own without a footrest.

Solution: The novel concept of the 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.

(e) Patent:- US20200000673A1 (Morgan, 2020)

Titled: - A support frame

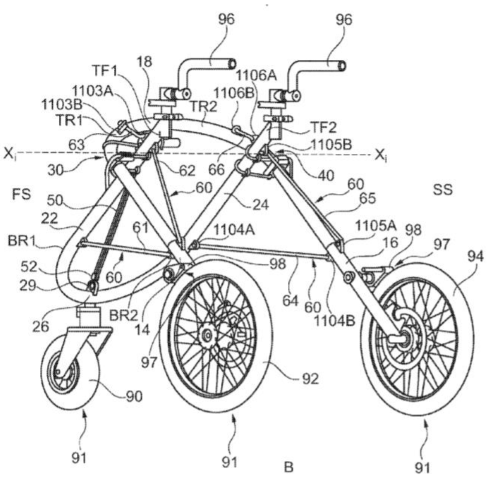


Figure 2.37: Isometric view of an embodiment of the support frame

Disclosure - The given publication describes a support frame (Figure 2.37) with an outer frame and an inner frame coupled on both a first and second side by flexible fixed-length tension members and an adjustable-length tension member. The support frame can be deployed or collapsed, with the flexible fixed-length tension members under tension when deployed and slack when collapsed. This is accomplished by adjusting the length of the adjustable length tension member. The outer and inner frames rotate relative to one another around an axis of rotation x, which is formed by a first and second hinge member.

Problem: The cited document relates to a collapsible posterior walking frame such as may be used only concerning a human requiring physical support.

Solution: The present invention related to the 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. Additionally, 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.