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Assess and Investigate the Current Techniques, Challenges and Material Innovations in the Design and Fabrication of prosthetic and Orthotic (P&O) Devices

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Abstract

Additive manufacturing (AM), often known as 3D printing, has emerged as a transformative technology with applications in a variety of industries, including the medical field. Traditional manufacturing techniques are labor-intensive, time-consuming and material-wasting. Additive manufacturing has the potential to solve these problems by using digital technologies. Recently, the field of Prosthetics and Orthotics (P&O) has witnessed significant developments due to digital technologies. The aim of this review paper is to investigate and evaluate the existing technologies, materials and challenges in the design and manufacturing of prosthetic and orthotic devices. This study also offers a comprehensive review of technologies, processes, barriers, limitations and the future of additive manufacturing in the prosthetic and orthotic field. This study highlights the main barriers to additive manufacturing including high costs, post-processing, large-scale production, slow speed, training and skills, material limitations and standard compliance. The study also identified the advanced materials such as nanomaterials, biomaterials and ceramics that are sustainable and recyclable materials on which researchers and organizations are focusing. Additionally, multi-material printing, recyclable materials, automation, smart materials, 4D printing and high speed are the latest trends in additive manufacturing. Furthermore, this study offers future recommendations, emphasizing the use of modern technologies such as additive manufacturing, biocompatible materials, and user-centered design techniques. This comprehensive analysis is a valuable tool for researchers, medical professionals, and stakeholders who are striving to improve the prosthetic and orthotic field.

Keywords: Additive Manufacturing; 3D Printing; Prosthetic Devices; Orthotic Devices; Prosthetics and Orthotics (P&O), Traditional Manufacturing of Prosthetics and Orthotics Devices.

1. Introduction

An estimated 1.3 billionpeople or 16% of the global population experience disability [1]. More than one billion people (about 15%) of the world's population live with some form of disability, of whom nearly 200 millionexperience considerable difficulties in functioning in normal life [2]. The global disabled population is increasing due to aging, chronic conditions, malnutrition, war, landmines, violence, road traffic accidents, diseases, domestic and occupational injuries and other causes often related to poverty[3]. These issues are creating an overwhelming demand for health and rehabilitation services. Nowadays, there is a growing need for Prosthetics and Orthotics and many disabled people require advanced prosthetic and orthotic devices[4].Globally the market value of the Prosthetics and Orthotics industry is approximately USD 8.75 billionin 2024 and is expected to grow $13.94 billion from 2024 to 2034[5]. Globally, 1.5 million people undergo amputations mostly lower limbs each year[6]. Amputation is the action taken to surgically remove a part of the body following trauma, disease, or congenital conditions and is the leading reason for the use of prosthetic devices[7].The medical sector has a separate specialized field named prosthetics and orthotics is addresses these problems of increasing disability issues and provides rehabilitation devices and parts to the population suffering from these problems.According to WHO, prostheses and Orthotic are assistive devices to help people with disabilitiesand are designed to replace missing body parts and supports and

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align for improved mobility of function[8].Additive manufacturing techniques fabricate the parts directly fromCAD-designed part models using a layer-by-layer additive fabrication process until the final part or device is completed[9], [10].Over the years, AM has evolved and expanded in various industries, including aerospace[11],[12] automotive[13], [14]and medical[15], [16].The medical sector uses various 3D printing techniques and materials because 3D printing offers benefits such as customization, reduced waste, cost efficiency, faster production and the production of complex geometries that are challenging to achieve with traditional manufacturing methods[17]. The aim of this investigate the existing technologies and processes in the design and fabrication of prosthetic and orthotic aids. This study also identifies the challenges, barriers, materials, limitations and future of additive manufacturing in the Prosthetic and Orthoticfield.

2. Research Gap

Nowadays, organizations adopting additive manufacturing technology in their manufacturing processes due to increasing competition. Additive manufacturing has notable benefits including creating complex designs, lightweight design devices, high precision, reduce material waste, time and cost has transformed the Prosthetic and Orthoticsector. Past studies in the Prosthetic and Orthoticfield have analyzed the additive manufacturing technologies, materials, barriers, limitations and challenges separately but the combination of these parameters is still absent. In prosthetic and orthotic fields, the integration of additive manufacturing technology is still in the initial stage and remains unexplored. In the literature, comparative analysis is absent on AM challenges, technologies, future trends, traditional techniques and material selection together as shown in Table 1. This review paper offers a comprehensive analysis, of developments, barriers, limitations and potential paths in the design and fabrication of prosthetic and orthotic devices. This study gives a deeper understanding of traditional and digital technologies i.e. AM in the manufacturing of prosthetic and orthotics devices.

The table demonstrates the research gap of this study. This stable shows that no study considered these all parameters (technologies, materials, barriers, challenges, comparison of traditional and additive manufacturing, limitations and future) of additive manufacturing. This creates a gap that needs to be fulfilled to understandingthe in-depth role of additive manufacturing in the prosthetic and orthotics field.

3. Motivation and Need of this Study

A comprehensive analysis of AM technologies, processes, materials, challenges, and limitations is lacking together in the Prosthetic and Orthotic(P&O) field that makes practitioners identify the most effective technologies in the design and manufacturing of Prosthetic and Orthoticdevices in order to improve their performance. Addressing this gap could create a comprehensive understanding of the combined effect and offer helpful insights to the prosthetic and orthotic industries. The results of this study also help in identifying the needs and give transformative solutions in the Prosthetic and Orthoticfield. This study will offer a distinct roadmap for the future and assist in recognizing the limitations, opportunities and unexplored areas.

Table 1. Contribution of Table from Past Studies

Authors	Additive Manufacturing Technologies	Materials	Challenges	Traditional Manufacturing	Limitations and Future Studies
[18]	✓		✓		
[19]	✓			✓	
[20]		✓	✓		
[21]	✓		✓		
[22]	✓	✓			
[23]	✓			✓	
[24]	✓		✓		
[25]	✓				✓
[26]	✓			✓	
[27]	✓		✓		
[28]	✓	✓			
[29]	✓		✓		
[30]	✓	✓		✓	
[31]	✓	✓			
[32]	✓		✓		✓
[33]	✓	✓		✓	
[34]	✓	✓			
[35]	✓	✓		✓	
[36]			✓		✓

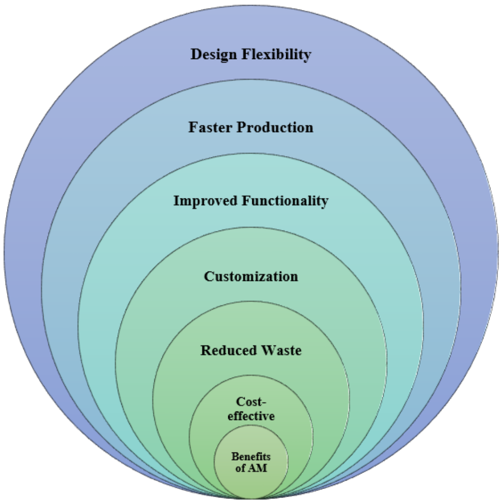

Figure 1. Benefits of AM in the Prosthetic and Orthosis Field (Source: [37])

4. Aim and Objectives

To investigate and identify the existing technologies and techniques in the design and manufacturing of prosthetic and orthotic devices is the aim of this study. The following are the objectives of this study:

1. To investigate and evaluate the current/existing technologies and techniques in the fabrication of prosthetic and orthotic devices.
2. To examine the key challenges in the implementation of additive manufacturing in the fabrication of prosthetic and orthotic devices.
3. To investigate and identify the traditional and advanced materials used in the manufacturing of prosthetic and orthotic aids.

5. Research Methodology

A comprehensive literature review was employed to identify and analyze the current techniques, barriers, challenges and materials used in the design and fabrication of P&O devices.

5.1. Selection Criteria

The literature review conducted in this article was initiated with the downloading and selecting of the related research papers. This process started with the keyword search on "Additive Manufacturing", "3D Printing", "Orthotic and Prosthetic", "P&O devices fabrication", "Current technologies in P&O design, "additive manufacturing in P&O", "Challenges in P&O devices", "3D Printing and digital design in P&O", and "Materials used in P&O aids", was performed on literature published between 2000 and 2025. The platforms from which the papers were accessed/downloaded e.g. Web of Science, PubMed, IEEE Xplore, JSTOR, Google Scholar, Scopus, and Springer Link. A totalof 300 papers were accessed and downloadedamong them related 182 papers were selected for this study. As per the paper selection criteria for the present research, included papers should be of the last 20 years, and must be available in English language. Furthermore, to ensure the inclusion of high-quality sources, only peer-reviewed journal articles, and conference proceedings. Studies that did not address the role of additive manufacturing or 3D printing technologies in the design and fabrication of prosthetic and orthotic devices were excluded.

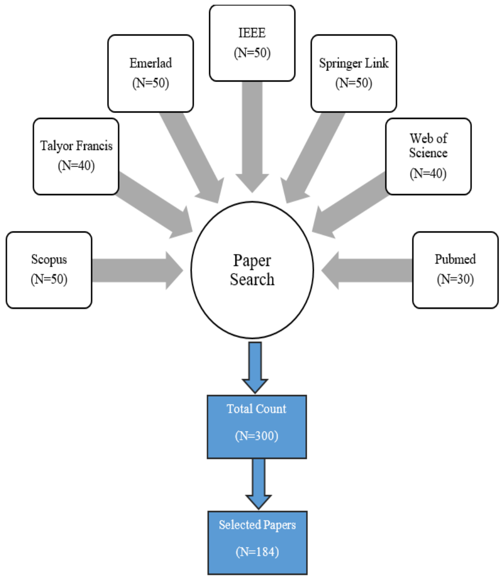

Figure 2. The diagram representing the selection process of the research papers included in this research paper.

6. Literature Review

6.1. Additive Manufacturing (AM)

Additive manufacturing is the innovative, digital and advanced technology of Industry 4.0 [38]. Additive manufacturing also known as three-dimensional (3D) printing or rapid prototyping is a technique that creates objects from 3D data in a layer-by-layer manner using a digitally controlled machine[39], [40], [41]. The ASTM andISOdivided AM into seven different processes vat photopolymerization, material jetting, binder jetting material extrusion, powder bed fusion, sheet lamination, and direct energy deposition[42]. Each process is limited to one type of material [43].3D printing is a rapidly growing technology that is transforming the medical industry[44]. AM has been extensively adopted by the medical industry, ranging from surgical planning to providing a physical model of the operation area, training, and prosthetics and orthotics among others[39], [45].This study highlights the potential of 3D printing in enhancing the value of prosthetics and orthoticsby critically examining the current practices, techniques, and technologies used in the design and manufacturing of prosthetic and orthotic devices, exploring advancements like 3D printing and smart technologies.

6.2. Additive Manufacturing forProsthetic and Orthotic (P&O) Devices

According to the World Health Organization, Orthoses also known as braces, are assistive devices that support joints through alignment, stabilization, or assisting weakened musculature[8]. Orthoses are categorized into different types, such as lower limb orthoses (e.g., foot orthosis, ankle-foot orthosis, knee orthosis), upper limb orthoses (e.g., wrist-hand orthosis), and spinal orthoses (e.g., back braces, splints) and Cervical Orthosis[33]. According to WHO, prostheses are devices that are used to restore the functionality of missing body parts [46]. Upper limbs, lower limbs, transtibial, trans-radial and trans-femoral are the types of prostheses[47]. According to the World Health Organization, there are 40 million amputees in the developing world, with barely 5% accessing any type of prosthetic care [48].Traditional methods have been used for a long time for the fabrication of prosthetic and orthotic devices which are labor-intensive, time-consuming, waste-generated and expensive[49]. Additive manufacturing is the innovative technology of the fourth industrial revolution that allows rapid manufacturing, high accuracy, high customization, lightweight parts and low cost [30].In the prosthetic and orthotic industry, design for AM has been able to increase the level of personalized devices that help clinicians create new designs. As a result, additive-manufactured devices become customizable, rapidly manufactured and available. This has led to prosthetic and orthotic industry shiftsto digital technology where medical professionals are exploring digital design techniques i.e. scanning, CAD, and 3D printing[50]. Software modeling, 3D scanning and additive manufacturing are the future of the Prosthetic and Orthoticindustry that transformed the processes of technicians, clinicians and healthcare care professionals by providing customized and sustainable techniques for patients and staff [51]. Customization, repeatability and cost-effectiveness are the three main benefits of DfAM that reduce waste, manufacturing time and involvement of humans as compared to traditional manufacturing [52]. Combining CAD with CAM is the widely used approach to replace the traditional manufacturing process in the prosthetic and orthotic field [35]. Components are the common mechanical parts of prosthetic and orthotic aids i.e. pylons, joints, foot shells,etc where whereas interfaces are custom-made parts that fit against the body of a patient for function and comfort [8]. There isa large number of materials in the market that are used in additive manufacturing for the manufacturing of customizable products. Different techniques of AM are available for the different materials to manufacture the products [53]. The selection of materials is an important process in the design and manufacturing of products in various applications [54]. Polymers are the commonly used material in the manufacturing of the products but durability strength and long use are the main challenges of these materials [55]. Selective laser sintering, fused deposition modeling, vat photopolymerization, material jetting, sheet lamination, binder jetting and material extrusion are the existing techniques of additive manufacturing that can be used to manufacture prosthetic and orthotic devices by using appropriate material [30].Fusion deposition modeling is the commonly used technique of additive manufacturing due to the use of low-cost materials. ABS, PC, polymers and Nylon are materials that are used in FDM[56]. This technique is successfully used in the manufacturing of prosthetics and orthotic industries such as lower limb orthosis, hand prostheses, and facial prostheses[56]. Selective laser sintering is the economicaltechnique of AM that is used for the manufacturingof strong and lightweight components [57].Stereolithography is the technique used to manufacturehigh-accuracycomponents and interfaces by using resins [58]. Material jetting is the technique used for creating complex geometrieswith high accuracy and surface finishes using resins [59].

Figure 3: Features in the Design of Orthotic and Prosthetic Devices (Adopted: [60])

6.3. Traditional and Additive Manufacturing of Prosthetic and Orthotic Devices

Traditional manufacturing is a manual-based process such as casting, and molding.Traditional manufacturing of Prosthetics and orthosis is time-consuming, labor-intensive, lying to waste, and geometrical inaccuracies and geometrical deviation [61]. The traditional manufacturing process of prosthetics and orthotics begins with assessing the patient’s needs, taking detailed measurements, and capturing the geometry of the affected body part [62]. The mixture of plaster of Paris is used for the measurement by wrapping around the affected limb. A plaster cast is created as a negative mold, which is then filled with plaster to form a positive mold. After several hours’ plaster is removed to produce the limb/s shape. Then in the next step se of vacuumed forming and make adjustments in order to best fit. After that trial and hit methods are used to any modifications. The device is then fitted to the patient to ensure comfort and functionality, with necessary adjustments made[63]. Finally, the device undergoes quality checks, and the finished product is delivered to the patient along with usage and maintenance instructions.Traditional manufacturing needs highly skilled workers and relies on manual processes that lead to waste, poor customization, less precision, long production times and inefficiencies[64]. These challenges and limitations are responsible for failing the comfort and functionality of prosthetic and orthotic devices. Additive manufacturing provides a digital workflow that includes scanning the affected body parts using CAD software and then manufacturing the parts in 3D[65]. Additive Manufacturing offers numerous advantages, including greater precision, design flexibility, shorter manufacturing times, high customization, advanced designs, and reduced time that are difficult to achieve through traditional manufacturing[66]. AM has also had drawbacks and faces challenges throughout in scanning, file conversion and digital extraction. The accuracy of the model depends on several parts such as scanning quality, the accuracy of the printer and digital cleaning[67]. Quality is the main parameter in the manufacturing of devices that play a main role in achieving performance [68], [69]. AM does not always give the clinical accuracy i.e. scanning quality, digital modeling scanning, and precision of the device that affect the final fit[70]. Undoubtedly, AM gives an accurate digital model but if errors are not controlled in the starting it doesn't give the accuracy of the patient fit model. According to Creylman et al., (2012), additive manufacturing with Selective Laser Sintering enables accurate, customized products with greater comfort and fit than conventional methods. It allows for quicker production, material optimization, and the integration of advanced features such as sensors [71]. Wang et al., (2021) compared traditional manufacturing of AFOs with AM. Findings showed that the traditional methods are time-consuming, have less accuracy, high waste, and require skills.In traditional and additive manufacturing modification is the main step. The adjustments modifications and fit issues are solved manually in traditional manufacturing while in additive manufacturing digital modification is needed[63]. Once the product is printed then it is more difficult to modify the digital model. During the scanning phase, the errors may affect the final model. Material selection, cost, durability and strength are the main issues in additive manufacturing.Despite this, additive manufacturing is a powerful technique in the manufacturing of prosthetic and orthotic devices as it offers mass customization, a shortened manufacturing process, good repeatability and design flexibility[72]. Additive manufacturing is the disruptive technology that may replace the traditional manufacturing methods that are time labor-intensive and time-consuming [33]. AM processes use finite element analysis to optimize the mechanical and functional performance of the devices[73], [74]. Maintaining the design durability by optimizing material distribution is possible througha topological approach that is not achieved by traditional techniques [33]. With the help of additive manufacturing material parts are manufactured that are functional, durable and environmentally friendly which is impossible to achieve through traditional manufacturing processes.

6.4. Materials Used in Prosthetic and OrthoticDevices

Additive manufacturing enables the manufacturing of customized parts, complex geometries, faster production and reduced material waste by using numerous innovative materials. The unique properties such as mechanical and thermal properties, of different materials are responsible for the quality and performance of the products [75], [76], [77]. The increased demand for lightweight materials has shifted the focus of many researchers in different applications such as medical, aerospace, biomedical and automotive industries [78].Material selection is critical for Prosthetic and Orthotic device functionality because it has to fulfill performance requirements and be cost-effective, particularly for low-income amputees [79]. The selection of the right material assures the patient comfort, mechanical performance, durability and biocompatibility of the aids.The cost of materials has a significant effect on overall manufacturing costs, so it is critical to choose materials that are economical and appropriate for customized production in additive manufacturing methods [80].Material properties play an important role and there are different innovative materials are available that are used in the fabrication of devices by using additive manufacturing processes. Today, a variety of materials are available in the applications of AM but there is still a need to develop new materials in the design of devices[33]. Further research is ongoing in the development of innovative materials [81]. Polymers, composites, metals, thermoplastics, resins, plastics, ceramics, and bioactive glass are the commonly used materials in additive manufacturing. Metals were used over the years in the manufacturing of the implants but corrosion and lack of strength were the main issues faced in these materials[82]. To overcome these issues, stainless steel was introduced in 1920 and has great corrosion resistance [81]. Cobalt chromium, titanium and stainless steel alloys are the most commercial materials used in the manufacturing of the implants [83], [69]. In the past, sockets were made of materials that were produced and treated for long-term stability, such as wood, leather, latex, and metal. Steel has been replaced in pylons by lightweight metals such as titanium and aluminum, with carbon fiber developing as a recent and lightweight alternative. In biomedical, Titanium is the most effective material in the manufacturing of prosthetic and orthotic devices due to its strong nature [84], [85]. Composites are important materials in the manufacturing of these devices due to their strong mechanical and thermal properties [86], [82], [78], [87]. Glass is the most common and extensive reinforcement material of polymers due to their outstanding thermal and mechanical properties [88]. Thermoplastics, resins, and reinforcing (carbon fiber, glass fiber) are the main categories of composites that have been used in modern developments for improved durability and performance of prosthetic devices [89].Another study revealed that polymers and metals are now widely used in orthotics because of their strength and versatility [90]. Prosthetics are made of lightweight materials such as wood, rubber, lightweight metals (titanium, aluminum), carbon fiber, and plastics. These materials provide ease and comfort for the amputees [91]. Thermoplastic sockets showed good strength, slightly higher than PLA's ultimate strength in prosthetic and orthoticdevices [92]. Thermoplastics are nowadays very useful because of their durability, flexibility and mold ability in the manufacturing of orthotic devices [93].Thermoplastic and carbon fibers were used in the fabrication of thesedevices due to their strength and comfort properties as stated by Patel [94]. Silicone polypropylene, polyurethane and silicone along with nanocomposites give great biocompatibility, durability and patent satisfaction [95]. General used materials in additive manufacturing are plastics [96]. Nowadays, the research is focused on new materialsthat are biocompatible and can quickly heal[97]. Nano materials are the advanced material that transforms AM by increased mechanical, thermal and conductivity [98], [99]. The latest invention that is widely spread and used in clinical applications is the bio-active glass [83]. Detailed specifications and materials used for the fabrication of Prosthetic and Orthotic devices are shown in Table 1.

6.5. Past Studies on Additive Manufacturing in the Prosthetics and Orthotics Field

Table 1 shows the fabrication techniques, prosthetic and orthotic devices, software and materials used in past studies.

Table 1. Overview of Digital Techniques, Fabrication and Materials Used in P&O Devices

Author	Year	Devices	Digital fabrication Software	Techniques	Material
[100]	2025	Ankle Foot Orthosis, Foot Orthosis	CAD	3D Printing	PLA
[101]	2025	Ankle Foot Orthosis	Autodesk Meshmixer	Fusion Deposition Modeling	Polyethylene Terephthalate Glycol
[102]	2024	Prosthetic Foot	CAD	Beam Finite Element	Carbon Fibers
[9]	2024	Wrist Hand Orthosis	CAD	FDM	Nylon
[103]	2023	Partial Hand Prosthesis	CAD	3D Printing	PLA, ABS
[104]	2023	Ankle Foot Orthosis	Solidworks	FFF	TP, Polymer, Carbon Fibers
[105]	2022	Ankle Foot Orthosis	Autodesk Fusion 360, CAD	FDM	ABS
[94]	2022	Ankle Foot Orthosis	Autodesk	FDM	PLA
[106]	2021	Arm and Forearm orthosis	CAD, CAM, Meshmixer, VGStudio MAX	FDM	Plastic
[107]	2021	Wrist, Hand and Finger Orthosis	SolidWorks, Desktop 3D®, CAD	3D Printing	TPU, PLA
[108]	2020	Transtibial Prosthesis	CAD	FDM	TP, Polypropylene
[109]	2019	Spinal Orthoses	Rodin4D, CAD	Vacuum Forming	Polyurethane Foam
[110]	2019	Foot Orthosis	CAD	FDM	ABS, Plastic
[111]	2018	Arm Splint	CAD	FDM	PLA, ABS, PC
[112]	2018	Thumb Splint	CAD	Fused Filament Fabrication	ABS
[113]	2017	Thumb Orthoses	CAD,,Open-Source Software	3D Printing, FFF	PLA
[114]	2016	Hip Orthosis	Free software, MatterControl, CAD	Rapid Prototyping, FDM	PLA, Polymer
[65]	2016	Foot Orthoses, Ankle Foot Orthoses, Prosthetic Sockets	3D scanner, Tracer® CAD software	SLA, FDM	Carbon Fiber, Resin
[115]	2015	Foot Orthoses	CAD, COBRA	Selective Laser Sintering	Nylon And PA
[116]	2015	Prosthetic Hand	CAD	Dual-Extrusion Printing, Multi-Material Fabrication	TPE and PLA
[117]	2014	Wrist Orthosis	Polygonal Surface software	FDM	ABS,Plastic
[71]	2012	Foot and Ankle-Foot Orthoses	CAD	SLS	PLA

6.6. Advantages, and Challenges in Materials Used in the Prosthetic and Orthotic

The advantages and Challenges of numerous materials and their mechanical properties are shown in detail in Table 2. Tensile strength is the maximum pulling amount of material which measures the maximum force that material can bear [118], [119], [120]. The ratio of stress to strain is known as the modulus of elasticity [121].

Table 2. Advantages, Mechanical Properties and Challenges of Materials

Category	Materials	Advantages	Challenges	Material Properties	References
Metals	Stainless steel	Corrosion Resistance, High Strength and Affordable	High Density, Welding Issues and Low Thermal Conductivity	Tensile strength: 490-620MPa Elastic Modulus: 190 GPa	[122],[123],[98],[124],[125]
	Titanium Alloy	Strong, Lightweight and comfortable	Expensive, Difficult to Print	Tensile strength: 900-950 MPa Elastic Moduluos:110 GPa	[122],[123],[126], [127]
	Cobalt chromium alloy	Corrosion Resistance, High Stiffness, and Wear Resistance	Expensive and Brittle	Tensile strength: 800-1000MPa Elastic Modulus: 70 GPa	[122],[123]
Polymers	Acrylonitrile Butadiene Styrene (ABS)	High Resistance, Toughness and Durable	Lower Biocompatibility and Wrapping During Printing	Tensile Strength:40-50 MPa Elastic Modulus:2.0-2.5GPa	[128],[129]
	Polylactic Acid (PLA)	East Printable, Cheap and Bio gradable	Poor Fatigue Resistance and Brittle	Tensile Strength: 50-70 MPa Elastic Modulus: 2.7-3.5 GPa	[130],[131], [132]
	Thermoplastic Polyurethane (TPU)	Abrasion-resistant and High Flexibility	Low Stiffness and Difficult to Press	Tensile Strength:30-55 MPa Elastic Moduluos:20-50 GPa	[133],[91]
	Polypropylene(PP)	Chemical Resistant, Fatigue Resistant and Flexible	Harder to Print, Low Surface Energy	Tensile Strength:24-40 MPa Elastic Modulus:1.5-2.0 GPa	[134],[135],[136]
Ceramics	Aluminia	High Hardness and Wear-resistant	Brittle and Fracture Prone	Tensile strength: Low Elastic Modulus:380 GPa	[137]
	Bioactive Glass	Supports Bone Integration	Brittle and Low-strength	Tensile strength: 40-70 MPa Elastic Modulus: 80GPa	[138], [139]
Biocompatible Polymers	Polyether Ether Ketone (PEEK)	Excellent Mechanical Properties and Biocompatible	Very Expensive, Hard to Print	Tensile strength: 90-100MPa Elastic Modulus:3.6GPa	[140],[141]
Thermoplastics	Nylon	Flexible,Strong and abrasion-resistant	Hygroscopic	Tensile strength: 75 Elastic MPa Modulus:2.5 GPa	[142],[23]
	Polycarbonate (PC)	Very Strong, High Heat Resistance and Impact Resistant	Wrapping Risk, High Printing Temperature	Tensile strength: 60-70 MPa Elastic Modulus: 2.4 GPa	[128],[35]
Resins	Photopolymer resins	Smooth finish, High precision	Less durable, brittle	Tensile strength:40-60MPa Elastic Modulus:2.5GPa	[65]
Glass	Bio glass	Bioactive and stimulates bone growth	Low tensile strength and very brittle	Tensile strength:30-70MPa Elastic Modulus:35-45GPa	[137]

6.7. Literature Key Findings of Prosthetic and Orthotic Devices in Global Perspectives

A comprehensive overview, summary, and key findings across countries in past studies are defined in Table 3.

Table 3. Summary of the literature, findings of P&ODevices across different countries

Author	Countries	Findings	Limitations
[27]	Singapore	The integration of digital technology in Prosthetics and orthotics was examined in this study. According to the findings, 44% of P&Os incorporate digital tools, with 3D scanning and digital imaging.	A small sample size, low response rates in the survey and internet difficulties are limitations of the study.
[143]	Pakistan	This study examined the current state of 3D printing in Pakistan. The findings showed some obstacles including legal concerns and a lack of local production using FDM technology and highlighted the need for proactive legislation and investment in healthcare innovation.	Medical 3DP in Pakistan is limited due to import restrictions and long approval processes. Supportive policies and investments can help expand medical 3DP in the country.
[144]	Global	The global issue of amputation is discussed in this paper. It investigates how digital technologies, such as CAD/CAM, photogrammetry, and additive manufacturing, can revolutionize the cost, scalability, and effectiveness of prosthetic care.	The main limitations of this study were the high cost and strength of 3D printing materials.
[4]	Tanzania, Malawi, Sierra Leone And Pakistan	This study compares the experiences of Prosthetic and Orthoticservice delivery in low-income countries as reported by local practitioners. The findings indicated common challenges, such as poor knowledge, limited access, and the need for further learning and professional development.	Prosthetic and Orthotictraining must be aligned with country regulations and prosthetic services should be integrated intothe medical system in low-income countries to enhance awareness and prioritization by the government.
[145]	Malaysia	This study designed and created a dynamically controlled prosthesis that improves performance. The findings revealed that the new design improves functionality and energy by incorporating a spring-based ankle joint and gear-based knee joint.	Postural stabilization and fall risk were reported to be lower in static platform situations. Future work should focus on enhancing the model accuracy, correcting motion analysis deviations and postural stability.
[30]	Canada	This paper examined the current developments in polymer-based AM for P&O devices. Comparing AM to traditional methods, the study revealed that AM enhances design and production efficiency and reduces prosthetics costs by 56–95%, particularly in socket manufacturing.	The limitations of this study, including the limitation of materials and a lack of education, training and skills for 3D-printed devices restrict their development in the Prosthetic and Orthoticbusiness.
[146]	Belgium, Italy, and the Netherlands	This study uses action research in Belgium, Italy, and the Netherlands to assess workflows that integrate 3D printing into the delivery of assistive devices.	The modelwas designed for European nations, and they don't work well in non-European countries and other legal systems. Cultural and economic disparities are not addressed.
[135]	United States of America	In order to develop an AFO with the right amount of stiffness, this study intended to measure the biomechanical ankle stiffness. The findings demonstrated the great reliability and security of AFO stiffness in meeting the needs of the majority of adults.	Limitations of the study included limited testing with different people, variations in geometric parameters, the requirement for human trials for validation and ignored complicated biomechanical aspects.
[147]	Poland	In this study, Velcro straps, screws, and magnets were tested as joining in wrist orthoses made using 3D scanning and additive manufacturing.	Durability issues with magnetic fastenings and the lack of long-term user trials are the limitations of this study.
[148]	South Africa	The study demonstrated that 3D printing technology in Sierra Leone can potentially create affordable and effective prostheses.	Short follow-up time and small sample size were among the study's limitations, which confined its adaptability and long-term assessment.
[149]	Netherlands	The study emphasized the use of 3D printing in upper-limb prostheses to establish sustainable business models that increase the quality of life and economic value.	The study has significant limitations, especially the financial analysis, which is hindered by the difficulty in obtaining cost and data.
[150]	South Korea	This study examined the user preferences for prosthetic hands by categorizing users into three lifestyle groups; weight-conscious, dexterity-focused, and price-sensitive. The results indicated that Class 1 users prefer 3D-printed prosthetics and reducing weight and improving functionality were the preferences of Class 2 and Class 3.	One of the study's limitations is that some participants had no prior knowledge of prosthetic hands, which might have affected their preferences. Due to the limited availability of 3D-printed prostheses, the study also depended on data that is not available widely.
[151]	Ecuador	This study investigated the use of flexible and rigid materials in 3D printing to produce affordable orthotic and prosthetic devices including foot drop orthotic and a transtibial prosthesis. This study discovered that 3D printing significantly lowers the cost of these devices,	One of the study's limitations of this study is that the patients were still getting used to the transtibial prosthetic device throughout rehabilitation, therefore it was

		particularly in underdeveloped countries.	impossible to evaluate its ability to move.
[152]	Bangladesh	This study evaluated patient satisfaction and experiences with 3D-printed splints at hand therapy for comfort, fit, and efficiency during the recovery period of hand injuries.	A small sample size and a geographical focus were among the study's limitations.
[34]	Russia	To enhance rehabilitation and the quality of life for people with disabilities, this study focused on creating digital technologies for the production of prosthetics and orthoticsin Russia. The findings indicated that these technologies allow customized products and improve the quality of care.	Geopolitical obstacles and boundaries that restrict the availability of digital technologies are the main limitations of the study.
[153]	France, Australia, Italy, the USA, the UK, the Czech Republic	The purpose of this study was to investigate the potential and applications of AM as a rehabilitation tool. The findings emphasized that AM enhances mobility, flexibility, and efficiency and promotes multidisciplinary collaboration in rehabilitation procedures.	The high cost of AM equipment, limited access to technology, and the need for specialized training for successful deployment are some of the limitations of this study.
[154]	Vietnam	The study examined the developments in the design and production of prosthetic sockets, by integrating digital manufacturing techniques in Vietnam. The findings indicated that digital manufacturing techniques provide quicker production and cost-effective prosthetic sockets.	The durability of 3D prosthetic sockets was the major limitation of this study. One of the biggest problems in low-middle-income nations like Vietnam is the lack of access to 3D prosthetics.

7. Challenges and Barriers in The Fabrication of Prosthetic and Orthotic Devices

Previous studies have identified several clinical and technological challenges to the successful integration of 3D printing in prosthetics and orthotics[155][156]. 3D printing technology in the Prosthetic and Orthoticindustry faced several challenges including technological limitations, high production costs, material limitations, high equipment costs, limited data, poor customization, regulation and standardization issues, and patient feedback investigated by Huang, (2024) [28]. The selection of appropriate printing technology, materials, and their compatibility for skin application are among the technological challenges[157].According to Barrios-Muriel et al. (2020), manufacturing errors, high initial cost, insufficient experience, material limitation, patient satisfaction, regulation and standardization problems, and resistance to adapt were the main challenges in the integration of AM [35].I.Ahmed et al., (2022) investigated a study in Pakistan and found that limited financial availability, lack of government support, limited data, private insurance resistance and limited response were the main challenges in the adoption of3D Prosthetic and Orthoticdevices [29].Another study stated that the main challenges were clinician training and the use of 3D technology in traditional procedures which are the major difficulty in the fabrication of prosthetic and orthoticdevices [20]. Amin Mirkouei and BishalSilwal (2017) stated that the lack of standardized measurements for designing and manufacturing Prosthetic and Orthoticdevices was the main challenge of this study [158]. High cost, maintenance needs of 3D Prosthetic and Orthoticdevices, low durability, and selection of material were the main challenges investigated in this study [159].According to Binedell et al., (2020), cost, lack of experience & skills, accessibility and effectiveness of advanced technology are the main barriers found in the integration of AM in the Prosthetic and Orthoticindustry [27]. Another study found that high initial cost, need for training, and clinical workflows are the main issues with the use of 3D printing in the fabrication of orthosis [160]. Jin et al., (2015) [19] stated that digital design and financial situation were the main barriers to customization that need to be overcome and this study was also supported by Chen et al., (2016) [65]. Barriers such as limited accessibility, less skilled clinicians, and high cost remained significant challenges in this study [161]. Liaqat et al., (2021) carried study in Pakistan and identified that there is a lack of job opportunities in the government sector, absence of fixed salaries, lack of government setup, no awareness and support for professionals are the main barriers that hindering the advancement of prosthetic and orthotic field [162]. Lack of funding, service efficiency and shortage of skilled professionals are the main barriers to the implementation of 3D printing in the prosthetic and orthotic field [24]. Some studies found that material limitations, high cost, lack of training and less accessibility were the main barriers to widespread in the prosthetic and orthotic field [163], [164], [165].

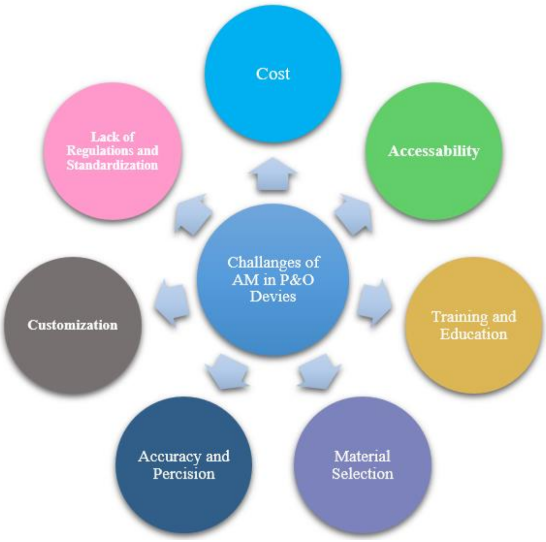

Figure 6. Challenges of AM in the Prosthetic and Orthotic Field (Adopted from [37])

8. Discussion

Additive manufacturing is an emerging technology and has a significant contribution to the medical field nowadays. In the medical field, with the help of AM different tools, instruments, medical implants, braces, and crowns are created according to the needs. The findings of this review study indicated improvements in digital fabrication technologies such as additive manufacturing. By enhancing the effectiveness, customization and accuracy of Prosthetic and Orthoticdevices, these technologies enable to production of lightweight, durable, robust and anatomically optimized solutions[30]. Digital techniques allow rapid prototyping, high accuracy and mass customization of these devices as compared to traditional manufacturing methods which are based on manual craftsmanship[166], [167]. Despite these advantages, several barriers and challenges restrict the widespread adoption of these modern technologies. The high cost of manufacturing technologies and materials is the one of biggest issues highlighted in the literature[168], [169], [170], [171]. The initial investment is needed for 3D printers, scanners, CAD software and materials that might be restricted especially for clinics, rehabilitation and institutions in low-income countries[172]. These financial challenges and barriers restrict accessibility which results in differences in the accessibility of high-quality Prosthetic and Orthoticsolutions[173]. Furthermore, newer materials like biocompatible smart materials are not widely used due to issues regarding cost, approval and clinical validation[62], [174], [175]. The absence of regulatory and standardization frameworks governing the use of digital manufacturing techniques in the Prosthetic and Orthoticindustry is another main challenge[176]. Guidelines for patient-specific customization, quality control measures, and biomechanical validation procedures are necessary for the integration of additive manufacturing and 3D scanning[177], [178]. According to literature, current regulatory agencies are sluggish to adjust to these new emerging trends resulting in a gap in global standards and regulations. Lack of technical skills is another significant obstacle that poses severe effects on innovation[179]. Many specialists, Prosthetists,orthotists and rehabilitation professionals might not be familiar with digital tools, CAD modeling, or additive manufacturing processes[180]. Due to this gap, bridging the gap between clinical application and engineering achievements requires intensive training programs and interdisciplinary collaboration[33], [181]. To further overcome these obstacles, the literature emphasizes the value of interdisciplinary cooperation between engineers and policymakers[182]. [183], [184].

9. Conclusion

Additive manufacturing is a new tool that democratizes the design and production process and manufactures advanced and customized devices in a more accessible and adaptable way. Medical application of 3D printing technology is growing at a rapid rate and becoming integrated into the delivery of patient care. Prosthetic and Orthoticis one associated medical field, where the combination of innovations in 3DP and medical imaging, have been developed for a range of users. Prosthetics and orthotics (P&O) design is being revolutionized by additive manufacturing, which provides increased accessibility, efficiency and customization. By offering portable, useful reasonably priced substitutes for conventional devices, the combination of 3D printing, and cutting-edge biomaterial has greatly enhanced patient care. However, the widespread adoption is hampered by expensive costs, difficult by high costs, difficulty regulations and lack of established standards. This review examined the current trends, methods, difficulties and materials advancements in Prosthetic and Orthoticmanufacturing using 3D printing. To increase the viability of contemporary Prosthetic and Orthoticmanufacturing, future research must concentrate on creating affordable digital fabrication methods, high-performance, sustainable materials and reliable clinical validation tests. Further study is required to improve accuracy, confirm 3D scanning techniques, and create consistent standards even as development occurs. These issues can be resolved by additive manufacturing which has the potential to completely revolutionize Prosthetic and Orthoticsolutions and raise user standards worldwide.In conclusion, despite the enormous potential of digital manufacturing technologies to completely transform the creation and manufacturing of orthotic and prosthetic devices, high cost, technological advancements, material selection, policy reforms, training, and skills prevent their widespread adoption. The future of Prosthetic and Orthoticdevice fabrication can shift towards increased accessibility, efficiency, and patient-centered innovation globally by encouraging interdisciplinary collaboration and investing in research-driven solutions.

Conflict of Intrest

There was no conflict of interest among the authors of this study.

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