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The Role and Future Directions of 3D Printing in Custom Prosthetic Design †

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Abstract: The advent of 3D printing technology has revolutionized various manufacturing sectors, including the medical field, particularly in the production of prosthetic limbs. Traditional prosthetic manufacturing processes are often time-consuming and expensive, causing amputees to endure long waiting periods and high costs. In contrast, 3D printing offers a rapid, cost-effective alternative, enabling the creation of custom-made prosthetics tailored to the specific needs and measurements of each wearer. Integrating 3D printing technology into prosthetics and orthopedics has ushered in a new era of customization and innovation. This advanced approach facilitates the creation of personalized prosthetics and bone replacements tailored to individual patients' needs. With the latest advancements in software and 3D printing, the use of custom orthopedic implants for complex surgical cases has gained significant popularity. This paper explores the advantages of using 3D printing for prosthetic limb production, highlighting its ability to significantly reduce the production time and costs while maintaining high functionality and quality. By leveraging 3D scanning and computer-aided design (CAD), precise digital models of a patient's residual limb can be created, ensuring a perfect fit and improved comfort. Additionally, the flexibility of 3D printing allows for the incorporation of advanced materials and design features, enhancing the durability and performance of the prosthetics. The study also examines the potential for 3D printing to democratize access to prosthetic care, especially in low-resource settings. The affordability and accessibility of 3D printers, coupled with open-source designs, empower local communities and healthcare providers to produce prosthetics on demand, reducing dependency on centralized manufacturing facilities. By addressing the current limitations and challenges, including material constraints and regulatory hurdles, this paper highlights the transformative impact of 3D printing on the prosthetics industry.

Keywords: 3D printing; custom prosthetics; orthopedic implants; personalized medicine; bone replacement; additive manufacturing

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1. Introduction

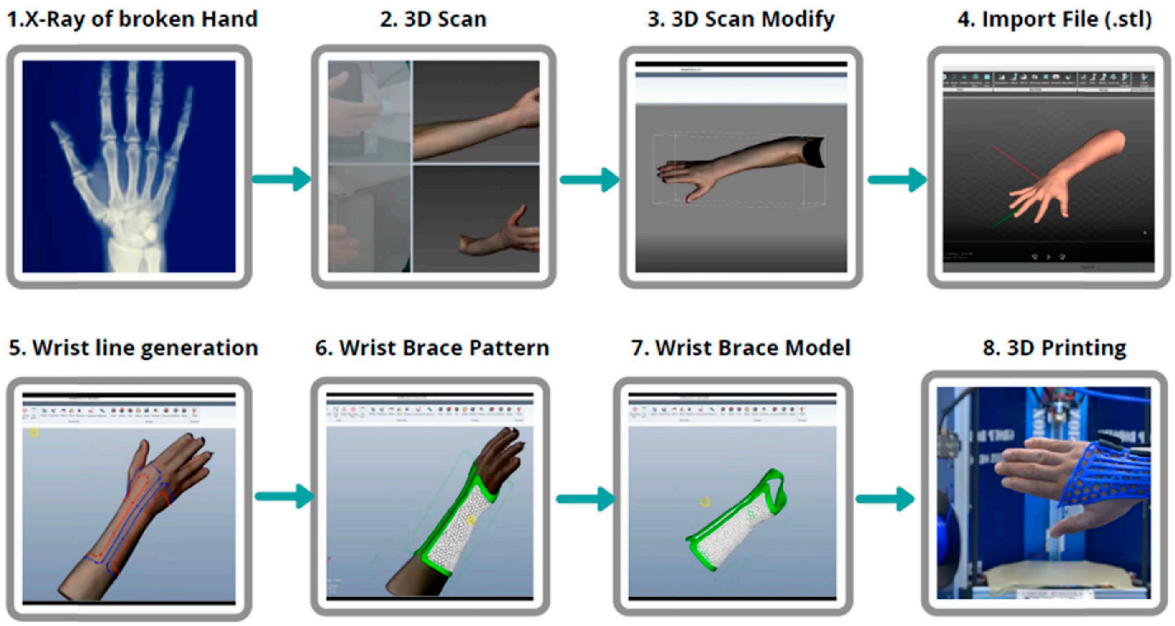
The applications of 3D printing in the production of medical implants have rapidly evolved into a thriving industry. This growth is driven by advancements in material design, which have expanded the range of printable materials, and by improvements in 3D printer technology, enabling the creation of complex biological structures at a microscopic scale. 3D printing allows for the efficient use of materials such as plastics and metals to create intricate designs [1]. Anatomical models are among the most widely used applications in the medical field, with medical computer-aided design (CAD) software (Autodesk Fusion 360) and low-cost 3D printers becoming increasingly accessible, allowing more hospitals

to establish 3D printing laboratories. Surgeons can reduce operating time and improve patient outcomes by using 3D-printed models for pre-surgical preparation. The potential for 3D printing to innovate and solve long-standing medical challenges is immense [2,3]. Advancements in additive manufacturing (AM) technologies have introduced new usable materials, making 3D printing an integral part of AM. This technology encompasses 3D scanning, printing, and various design software tools. Several businesses now produce high-grade, biocompatible materials, including high-performance thermoplastics and metals, for medical applications. As the range of 3D printable materials and deposition techniques expands, unique 3D-printed electronic medical devices are being developed for human use. This requires advanced additive manufacturing capabilities to print electronics of any shape. Additionally, 3D-printed structures can be used for drug and cosmetic testing. Personalized medicine is another significant advantage, allowing drugs to be tested on 3D-printed organs made from patient tissue, thereby reducing the need for harmful treatments, like chemotherapy. The advent of 3D printing technology has revolutionized the production of prosthetic limbs, offering a highly customizable and cost-effective alternative to traditional methods. This technology leverages computer-aided design (CAD) software to create precise digital models of prosthetic components, which are then fabricated layer by layer using various materials, such as plastics, metals, and composites. The ability to tailor prosthetics to the specific needs of each patient significantly enhances comfort and functionality, thereby improving the quality of life for amputees. Moreover, 3D printing reduces the production time and costs, making high-quality prosthetics more accessible to a broader population, including children and individuals in low-resource settings. As 3D printing technology keeps improving, the future of prosthetic limb production looks even more promising. It will bring smarter designs, better technology, and more eco-friendly solutions, while also reducing mechanical weaknesses in metal parts made through sintering. [4,5]. Prostheses and orthoses are critical assistive devices that help individuals with disabilities meet their biomechanical needs. Prostheses replace missing body parts, typically for lower or upper limbs, while orthoses, also known as braces, support and modify the structural and functional characteristics of the musculoskeletal system. The traditional custom manufacturing of prostheses and orthoses involves labor-intensive processes, like plaster casting, which, while effective, result in high costs, material waste, and variability in product quality depending on the skill of the technician. In contrast, additive manufacturing (AM), or 3D printing, offers a more efficient, cost-effective alternative, enabling the customization to individual patient needs with significantly reduced material waste [6,7]. AM allows for the creation of complex geometries, precise replication, and integration of multi-materials, enhancing product performance and functionality. Despite the advantages of AM, its adoption in prosthetic and orthotic manufacturing remains slow due to challenges such as limited scientific evaluations of product functionality, lack of standardized metrics, and regulatory uncertainties. However, AM is considered a disruptive technology, with the potential to replace traditional methods, particularly in the context of producing personalized, high-performance devices. This paper emphasizes the need for a systematic framework integrating AM into prosthetic and orthotic designs, highlighting advancements in computational analysis, materials, and multi-material technologies to optimize the functional performance of these devices [8–10].

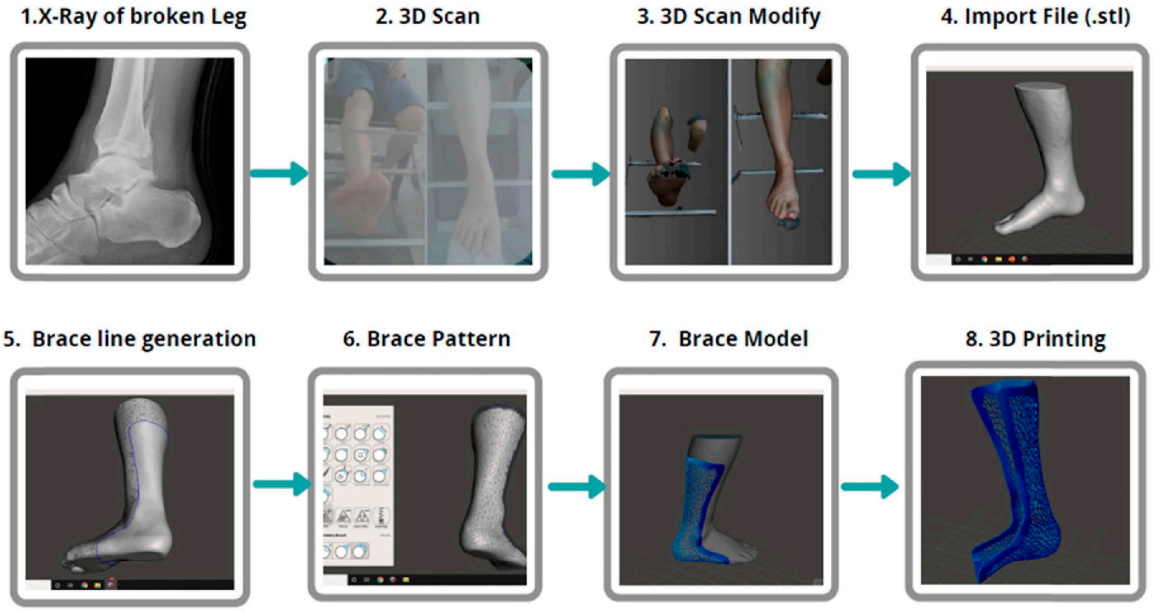
2. Traditional Prosthetic Manufacturing Processes

Traditional prosthetic limb production involves several labor-intensive steps, beginning with the patient visiting a prosthetist to take anthropometric measurements. A cast mold is created by wrapping plaster bandages around the affected body part, and a positive mold is made by pouring plaster into the negative cast. The prosthetic or orthotic

device is then fabricated by heating and vacuum-forming sheets of thermoplastic onto the positive plaster mold, which is trimmed into the correct shape after cooling. Additional modifications or components may be added based on the load-bearing requirements of the body [11]. Accessories and straps are attached to finalize the product, and fitting visits are necessary for further adjustments to ensure comfort and functionality. This process is material-intensive, time-consuming, and highly dependent on the prosthetist's skill, making it difficult to achieve consistent results [5,11]. In contrast, additive manufacturing (AM) offers a more efficient and customizable approach to prosthetic limb production. AM technologies, such as stereolithography (SL), fused deposition modeling (FDM), and selective laser sintering (SLS), allow for the creation of complex structures with reduced time and labor costs. These technologies enable precise replications of existing products and the integration of multiple materials and functions, enhancing product performance and reducing the need for assembly [12]. AM's flexibility and precision make it a disruptive technology capable of replacing many conventional manufacturing processes, particularly those that are time-consuming and require individual customization. The advantages of AM are further enhanced by specific technologies, like finite-element analysis, which optimize mechanical characteristics and functional performance. Topology optimization allows for the efficient distribution of materials while maintaining design stiffness, which is impossible in traditional methods. Multi-material technologies advance AM by enabling the production of components with complex geometries and added functionality, improving product performance in terms of stiffness, functionality, and environmental adaptation. However, combining dissimilar materials in AM can pose challenges due to differences in thermal expansion and contraction, which are not issues in traditional fabrication [12–14]. SL, FDM, and SLS are the three primary AM technologies. SL, the oldest AM technique, uses a high-powered laser to convert photosensitive liquid into a 3D solid plastic layer by layer, offering high geometrical accuracy but limited material options and high costs. FDM creates 3D objects by extruding and depositing melted thermoplastic filaments layer by layer, providing cost-effectiveness and ease of use but with lower dimensional accuracy and resolution. SLS fuses powdered materials using a laser, offering a wide range of materials and no need for support structures, but resulting in porous and mechanically weak metal components. Table 1 shows a comprehensive comparison of the features of stereolithography (SL), fused deposition modeling (FDM), and selective laser sintering (SLS) technologies [15–17]. Figure 1 illustrates the design and production process for creating custom 3D-printed braces for a broken wrist and leg. The process begins with obtaining an X-ray of the injured area, either the hand or the leg, to assess the specific nature of the injury. Following this, a 3D scan is performed on the injured part, capturing its precise dimensions and shape. The scanned model is then modified to ensure that the design will provide the necessary support and fit. The final modified design is exported in the STL file format, which is suitable for 3D printing. For both the wrist and leg braces, the next step involves generating a brace line on the digital model, highlighting the areas that need structural reinforcement. This is followed by the creation of the brace pattern, which is specifically designed to meet the patient's needs. The brace model is then created, which incorporates all the necessary adjustments for comfort and support. Finally, the 3D model is sent to a 3D printer, which produces a custom-fitted brace that can be worn by the patient.



(a) Design process sequence for custom wrist



(b) Design process sequence for leg brace

Figure 1. Advance manufacturing process for orthotics development. Reprinted from *Materials Today: Proceedings, Vol. 59*, Piyush Patel and Piyush Gohil, *Custom orthotics development process based on additive manufacturing*, Pages A52–A63, Copyright (2022), with permission from Elsevier [18].

Table 1. Comparison of the features among SL, FDM, and SLS technologies, highlighting their respective advantages and disadvantages in prosthetic limb production [19–21].

Feature	Stereolithography (SL)	Fused Deposition Modeling (FDM)	Selective Laser Sintering (SLS)
Process Overview	Uses a UV laser to cure liquid resin layer by layer into a solid object.	Melts and extrudes thermoplastic filament through a nozzle, depositing it layer by layer.	Uses a laser to sinter powdered material into a solid structure layer by layer without requiring a support structure.

Table 1. *Cont.*

Feature	Stereolithography (SL)	Fused Deposition Modeling (FDM)	Selective Laser Sintering (SLS)
Material Options	Photopolymers (resins), limited to liquid state materials.	Wide range of thermoplastics (PLA, ABS, PETG, TPU, etc.).	Nylon, polyamide, and composites (e.g., nylon with carbon fiber or glass-filled materials).
Surface Finish	Produces smooth, high-resolution surfaces ideal for aesthetic prosthetic components.	Surfaces can be rough or require post-processing to smooth, depending on layer thickness and nozzle quality.	Excellent surface quality with minimal post-processing required, suitable for complex designs.
Strength and Durability	High resolution but less durable than thermoplastics; resins may be brittle and prone to cracking under stress.	Durable and flexible thermoplastics offer strong performance; however, strength depends on filament quality and print settings.	Produces durable and functional parts with good mechanical properties, including resistance to wear and impact.
Precision and Accuracy	Extremely precise, with high levels of detail, making it ideal for intricate designs.	Moderately precise; precision depends on nozzle size and printer calibration.	Highly precise, with the ability to handle complex geometries and fine details.
Speed	Slower than other methods due to the curing process; ideal for small, detailed parts but not for large-scale production.	Generally faster, particularly for simpler designs; ideal for prototyping.	Moderate speed; faster than SL for large builds but slower than FDM for simple parts.
Cost of Equipment	High initial costs due to advanced hardware and the need for specific materials (resins).	Low to moderate; affordable entry-level printers are widely available.	Expensive, with industrial-grade machines dominating the market.
Material Cost	High; specialized resins are more expensive than thermoplastics.	Low to moderate; thermoplastic filaments are widely available and affordable.	Moderate to high; powdered materials can be more costly, especially for specialized applications.
Ease of Use	Requires expertise to handle resins safely and operate the machine; post-curing is also necessary.	User-friendly and widely accessible; ideal for beginners and low-tech environments.	Requires technical expertise for setup and operation; safety precautions are needed for handling powders.
Environmental Impact	Resins are less eco-friendly and can be hazardous if not disposed of properly.	Filaments, like PLA, are biodegradable and more eco-friendly; however, others, like ABS, produce fumes during printing.	Powder waste can be recycled to an extent, but the overall environmental impact depends on the material usage and disposal practices.
Applications in Prosthetics	Excellent for creating aesthetic components, such as cosmetic covers and lightweight decorations.	Ideal for rapid prototyping, preliminary designs, and the cost-effective production of simple prosthetic parts.	Well-suited for functional and structural components, such as load-bearing prosthetic frames or complex joints.
Advantages	- High resolution and detail for intricate designs.- Smooth surface finish reduces post-processing. - Ideal for small, detailed, and aesthetic components.	- Cost-effective and accessible. - Wide material availability. - Flexible design options for prototypes and low-stress parts.	- Superior mechanical properties. - No need for support structures, enabling complex geometries. - Durable, functional parts suitable for long-term use.
Disadvantages	- High material and equipment costs. - Limited material strength and durability. - Requires expertise in handling and post-curing.	- Limited surface finish quality; often requires post-processing. - Less suitable for high-stress or complex load-bearing parts.	- High equipment and material costs. - Requires technical expertise and industrial setup. - Not as accessible for small-scale or individual users.
Future Potential	Advancements in resin materials to improve durability and reduce costs may expand its applications in prosthetics.	Continuous improvements in filament quality and printer precision could make FDM more suitable for functional prosthetic components.	Expanding material options and reducing machine costs could make SLS more accessible, enabling the widespread use of both functional and aesthetic prosthetic components.

3. Advantages of 3D Printing in Prosthetic Design

The application of 3D printing in prosthetic designs has introduced significant advancements, redefining how prosthetic devices are manufactured, customized, and delivered. This transformative technology addresses several traditional challenges, providing unparalleled benefits in terms of speed, cost, and customization, as shown in Figure 2. In this section, its primary advantages were discussed below.

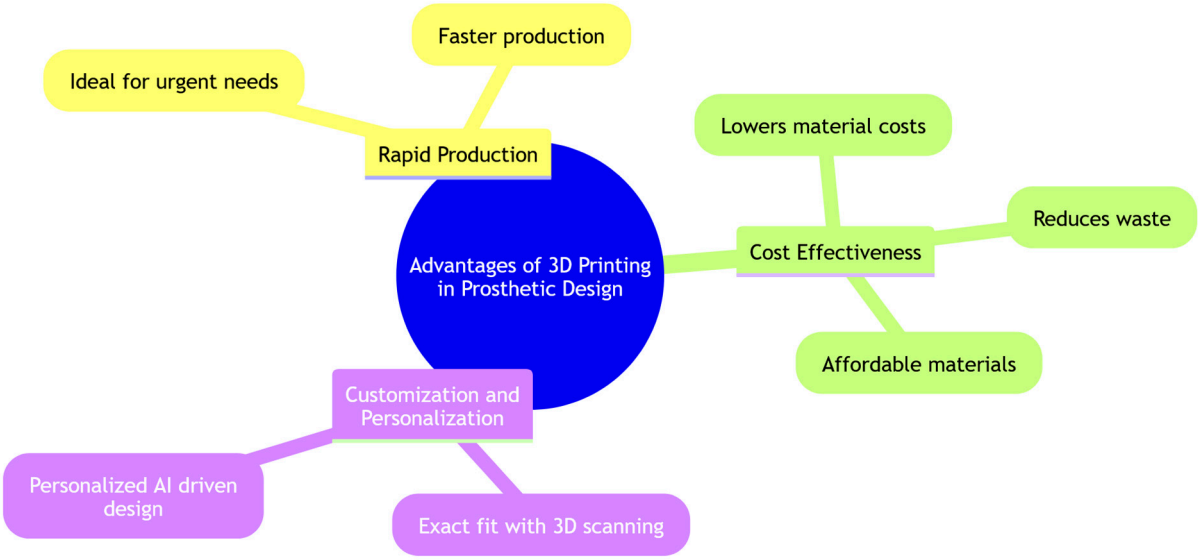


Figure 2. Advantages of 3D printing in prosthetic design.

3.1. Rapid Production

3D printing significantly accelerates the production of prosthetic devices by eliminating traditional manufacturing steps, like molding and manual assembly. Using digital blueprints, it directly fabricates parts, reducing the production time and making it ideal for urgent situations. This technology is particularly beneficial for addressing the needs of growing children who require frequent replacements or for providing rapid support to patients in disaster-stricken areas.

Studies have shown that 3D printing can cut manufacturing times by up to 75% compared to conventional methods, with some cases achieving same-day prosthetic delivery. The use of high-speed printers and advanced polymers further enhances the production speed without compromising quality. In humanitarian contexts, this capability is transformative, enabling the swift delivery of functional prosthetics to those in need, significantly improving their quality of life [5,10].

3.2. Cost-Effectiveness

Traditional prosthetic manufacturing involves expensive materials, labor-intensive processes, and multiple fitting appointments, making it inaccessible for many individuals. In contrast, 3D printing reduces costs by utilizing affordable materials, like PLA (polylactic acid) and ABS (acrylonitrile butadiene styrene), while minimizing material waste. The digital nature of 3D printing eliminates the need for molds and manual machining, significantly lowering the production overheads. This affordability increases access to prosthetics, particularly in underserved populations and resource-constrained settings, such as rural healthcare facilities and low-income regions [22].

3.3. Customization and Personalization

Perhaps the most transformative advantage of 3D printing in prosthetic design is its ability to offer unparalleled levels of customization and personalization. Using advanced 3D scanning technologies, prosthetists can capture the exact anatomical dimensions of a patient's residual limb, creating devices that fit perfectly and cater to individual functional and aesthetic needs. This contrasts sharply with traditional prosthetics, which often involve standardized designs and may require multiple adjustments for an optimal fit [23]. A recent breakthrough in this area, highlights the transformative potential of integrating artificial intelligence and 3D printing in prosthetic design [23]. The study underscores how these

technologies are not only revolutionizing the creation of prosthetic limbs by reducing costs through 3D printing but are also enhancing functionality through AI-driven advancements. Innovations such as bionic limbs with brain–hand communication and constant feedback systems have opened new possibilities for amputees, allowing for improved mobility, comfort, and usability. Furthermore, these advancements address affordability challenges, ensuring that more individuals can access life-changing prosthetic solutions [23].

4. Integration of 3D Printing in Prosthetics and Orthopedics

The integration of 3D printing technology in prosthetics and orthopedics (Figure 3) has redefined the possibilities in personalized healthcare. By enabling precise fabrication, tailored solutions, and innovative approaches to complex challenges, 3D printing is enhancing patient outcomes in unprecedented ways. This section explores its significant contributions across three key areas.

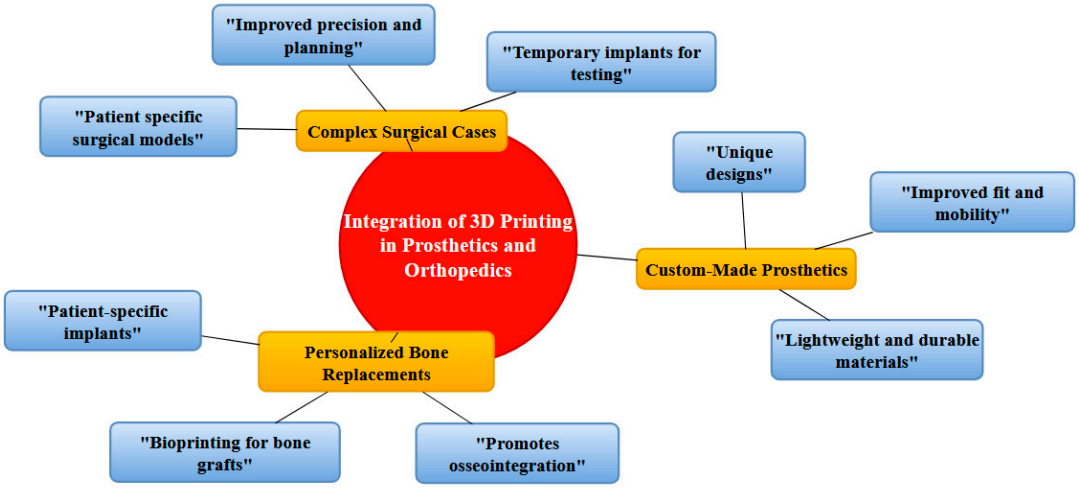


Figure 3. Integration of 3D printing in prosthetics and orthopedics.

4.1. Custom-Made Prosthetics

Custom-made prosthetics are among the most prominent applications of 3D printing in healthcare. This technology allows prosthetists to design devices that are uniquely adapted to the individual's anatomy, functional needs, and aesthetic preferences. Traditional methods often rely on molds and standardized components, leading to compromises in fit and comfort. With 3D printing, precise digital scans of the residual limb can be used to create a prosthetic that fits perfectly, reducing pressure points and enhancing mobility [5,6].

Recent advancements in additive manufacturing have significantly enhanced its application across various fields, particularly in healthcare. Research highlights how the integration of high-performance metals and polymers, alongside improvements in multi-material printing capabilities, has enabled the production of intricate and valuable finished goods. In the medical domain, additive manufacturing has revolutionized tissue engineering and regenerative medicine by providing precise control over the internal structure of porous materials, allowing for the creation of specialized scaffolds. Additionally, this technology supports the development of customized implants and prosthetics, improving biocompatibility, patient comfort, and clinical outcomes. The flexibility in design and rapid prototyping offered by additive manufacturing also allows for quick iterations and adjustments, catering to individual needs, such as anatomical changes or unique patient requirements. As the technology continues to advance, with improvements in printing speed, resolution, and scalability, its potential to transform personalized healthcare, regenerative medicine, and patient-specific solutions grows even further. These innovations

not only enhance functionality and comfort but also contribute to cost-effectiveness and sustainability through waste reduction and efficient material usage [24].

4.2. Personalized Bone Replacements

One of the groundbreaking applications of 3D printing in orthopedics is the production of personalized bone replacements. Complex bone injuries, congenital deformities, and conditions like osteosarcoma often require precise and robust solutions that conventional implants struggle to provide. 3D printing offers a way to fabricate patient-specific implants that mimic the exact structure, size, and density of natural bone [1,5].

Three-dimensional (3D) additive manufacturing has transformed orthopedic oncology by enabling advanced solutions for bone reconstruction and tumor management. For instance, 3D-printed titanium alloy implants have revolutionized bone reconstruction by offering customizable options for various anatomical regions. These implants are not only durable but can also be designed with porous structures to support osseointegration, enhancing the integration of the implant with surrounding bone tissue. Furthermore, 3D printing facilitates personalized approaches to surgical planning through the creation of precise bone and tumor models and tailored surgical instruments, significantly improving surgical accuracy and outcomes. While metal implants dominate current applications, bioprinting, a cutting-edge form of 3D printing, shows immense potential for future advancements. Experimental developments in bioprinting aim to create biodegradable scaffolds and bone grafts infused with bioactive materials, potentially enabling biological bone reconstruction. These innovations hold great promise for personalized, effective treatments in orthopedic oncology, particularly in cases involving complex bone defects or reconstructive surgeries after tumor removal [25].

4.3. Use in Complex Surgical Cases

Additive manufacturing (AM) has emerged as a game-changing approach in the design and production of prosthetic and orthotic (P&O) devices, offering patient-specific solutions without the need for traditional, labor-intensive equipment. By utilizing advanced 3D printing techniques, unique P&O elements can be rapidly designed and manufactured with precise control over material properties and structural performance. For example, carbon fiber materials have demonstrated exceptional performance in prosthetic foot models, exhibiting desirable characteristics, such as high natural frequency, minimal deformation, and optimal strain energy, making them a preferred choice for high-performance prosthetic applications [13,26]. Traditionally, P&O devices required time-consuming processes involving plaster molds and multiple patient visits. In contrast, 3D printing enables the production of lightweight and functional devices, like AFOs and Flex-Foot prostheses, in significantly less time. With the use of PLA materials on FDM machines, the manufacturing process for an AFO can be completed in under 7 h, with minimal hands-on effort, while Flex-Foot prostheses can be produced in about 10 h. This streamlined workflow not only reduces the production time but also simplifies the overall manufacturing process, making it more accessible and efficient. As the field evolves, future advancements aim to explore alternative materials to further enhance the performance and functionality of P&O devices. The integration of AM in P&O design and production represents a paradigm shift, delivering faster, more cost-effective, and personalized solutions that improve patient outcomes and satisfaction. This innovative approach is set to redefine the standards of care in prosthetics and orthotics [26].

5. Technological Advancements

The use of 3D scanning and computer-aided design (CAD) in prosthetics and orthopedics has significantly enhanced the precision and efficiency of device creation. 3D scanning captures the detailed dimensions of a patient's body part or residual limb, creating a digital representation that serves as the foundation for design and manufacturing. This process eliminates the need for traditional molds and physical casts, which are time-consuming and often less accurate [27].

Once the 3D scan is completed, the CAD software is employed to refine the design of the prosthetic or orthopedic device. Engineers and prosthetists can manipulate the digital model to incorporate features such as anatomical alignment, weight distribution, and functional enhancements. The flexibility of CAD allows for the easy iteration and optimization of designs, ensuring that the final product meets the patient's unique requirements. Recent studies demonstrated how 3D scanning and CAD reduced the fabrication time for prosthetics by over 50% while also improving the overall accuracy of the designs. This integration of technology has become a standard practice in modern prosthetic and orthopedic production [27,28]. The creation of precise digital models is a cornerstone of modern 3D printing technology in prosthetics and orthopedics. These models are generated from the data captured during the scanning process, ensuring a high level of fidelity to the patient's anatomy. Precision is critical, as even minor inaccuracies can lead to discomfort, reduced functionality, or potential complications. Digital models allow for advanced simulations to test the performance of the prosthetic or orthopedic device before physical production [27]. Engineers can evaluate factors like stress distribution, range of motion, and load-bearing capabilities, optimizing the device to perform reliably under real-world conditions. Additionally, these models are easily stored and modified, enabling efficient updates or adjustments as the patient's needs evolve. Recent advancements have further enhanced the precision of digital modeling. AI-driven modeling algorithms were used to analyze patient-specific data to automatically optimize the design for improved functionality and durability. This level of precision has contributed to higher success rates and better patient outcomes in both prosthetics and orthopedics [29]. One of the most significant benefits of integrating 3D scanning and CAD in prosthetic and orthopedic design is the improved fit and comfort for the patient. Traditional manufacturing methods often rely on standardized or semi-custom solutions that could lead to pressure sores, irritation, or poor alignment. By contrast, 3D scanning captures the exact contours of the patient's body, ensuring a customized fit that enhances comfort and usability. Moreover, the use of CAD allows for the incorporation of ergonomic features tailored to the individual. Adjustments for specific activities, such as running, climbing, or everyday walking, can be integrated seamlessly into the design. This level of personalization significantly improves the patient's experience and quality of life [27,29].

5.1. Material and Design Flexibility

The adoption of advanced materials in 3D printing has revolutionized prosthetics and orthopedics, offering significant advantages over traditional materials, such as wood, aluminum, and basic polymers, which are often heavy, prone to wear, and lack customization options. With 3D printing, materials like thermoplastic elastomers, carbon fiber-reinforced polymers, and biocompatible metals, such as titanium, are now widely used. These materials provide enhanced flexibility, durability, and weight reduction. For instance, thermoplastics offer flexibility, while carbon fiber composites are lightweight yet strong, improving the handling and functionality of prosthetics. Moreover, bioprinting advancements allow for the integration of materials mimicking human tissue properties, enhancing integration and performance. Research has demonstrated that advanced materials in 3D-printed prosthetics

can reduce weight significantly while maintaining or improving structural integrity [5,22]. In addition to material innovation, 3D printing enables the incorporation of intricate design features previously unattainable with traditional manufacturing methods. Complex geometries, lattice structures, and anatomically tailored shapes can now be achieved with precision. These designs improve the functionality, aesthetics, and ergonomics of devices. For example, lattice structures reduce weight without compromising strength, enabling more natural movement and comfort in prosthetics. In orthopedics, porous designs in bone implants promote osseointegration, facilitating faster and more effective healing. Furthermore, personalized features like embedded sensors for monitoring pressure points or stress levels can now be included to enhance patient care. Patient-specific enhanced designs improve mobility and significantly reduce the need for frequent adjustments [28,29].

5.2. Durability and Performance

Durability and performance are critical factors in prosthetic and orthopedic devices, and 3D printing has introduced significant improvements in these aspects. Devices made using advanced materials and optimized designs exhibit superior resilience against daily wear and tear. Unlike traditionally manufactured devices, which may degrade quickly or require frequent replacements, 3D-printed alternatives are designed for prolonged use. For example, carbon fiber-reinforced prosthetics produced through 3D printing demonstrate high tensile strength and reduced risk of failure under stress. In orthopedic implants, 3D printing enables the creation of structures that mimic the mechanical behavior of natural bone, reducing the likelihood of fractures or misalignment [30]. Research has shown that 3D-printed prosthetics and implants have a significantly longer lifespan compared to traditional devices, with fewer instances of mechanical failure. This enhanced durability not only improves patient satisfaction but also reduces long-term costs associated with repairs and replacements. The integration of advanced materials, innovative designs, and improved durability in 3D-printed prosthetics and orthopedics has transformed patient care, delivering solutions that address functional challenges while enhancing quality of life and long-term outcomes [29,30].

6. The Evolution of Materials in Prosthetics

The evolution of materials used in prosthetics (Figure 4), showcasing a transition from traditional materials to advanced 3D-printed options. Initially, wood was used for prosthetic limbs, providing basic functionality but with limited comfort and flexibility. Over time, metal and leather became more common, offering enhanced durability and support. The next phase saw the introduction of plastic, which provided greater customization, lighter weight, and more comfort for users. The use of composite materials represents the latest advancement, combining strength, flexibility, and lightweight characteristics, often achieved through 3D printing for more personalized and efficient prosthetic designs. Early prosthetics were constructed from wood and metal due to their availability and basic structural properties [31]. The introduction of synthetic polymers in the 1900s, such as silicone, polyurethane, and thermoplastic gels, greatly enhanced the realism, comfort, and functionality of prosthetics [32]. Over the last 40 years, the use of composite materials, which are lightweight and structurally resistant, has become increasingly prevalent, particularly in dynamic prosthetic components, like feet and knee joints [33,34]. In modern prosthetics, metals like titanium and cobalt-chrome alloys are commonly used for their strength, corrosion resistance, and biocompatibility [35,36]. Advanced polymers, such as polypropylene and polyethylene, are valued for their fatigue resistance, ease of shaping, and ability to mimic natural tissue properties [37]. Ceramics and composite materials are particularly important in dental prosthetics due to their durability and aesthetic quali-

ties. Recent developments in biomimetics have enabled the creation of prosthetics that closely replicate biological appendages, enhancing both functionality and user comfort [38]. The early applications of 3D printing in prosthetics were focused on rapid prototyping, offering the ability to create patient-specific devices using medical imaging, which facilitated better fit and comfort [24,39,40]. Initially relying on basic polymers, 3D printing in prosthetics has evolved to include high-performance metals, ceramics, and bio-resins, improving mechanical properties, durability, and biocompatibility [41–44]. Hybrid materials, such as combinations of polylactic acid (PLA) with bio-resins, have been developed to strengthen prosthetic structures while improving user comfort. Additionally, tactile sensing materials, like polydimethylsiloxane (PDMS), have been utilized to enhance the haptic experience [45,46]. The materials and technologies used in prosthetics have evolved from basic wood and metal to advanced composites, polymers, and metals, significantly improving the functionality, customization, and accessibility of prosthetic devices [31,38,47,48].



Figure 4. The evolution of materials [18]. Reprinted from *Materials Today: Proceedings, Vol. 59*, Piyush Patel & Piyush Gohil, *Custom orthotics development process based on additive manufacturing*, Pages A52–A63, Copyright (2022), with permission from Elsevier.

7. Design Considerations for 3D-Printed Prosthetic and Orthopedic Solutions

3D printing technology has revolutionized the design and manufacturing of prosthetic and orthopedic devices, offering numerous advantages, such as customization, reduced production costs, and the possibility of integrating advanced technologies. These benefits have led to the adoption of 3D-printed prosthetics and orthotics in clinical settings, but several key design considerations (Figure 5) must be addressed for optimal outcomes.

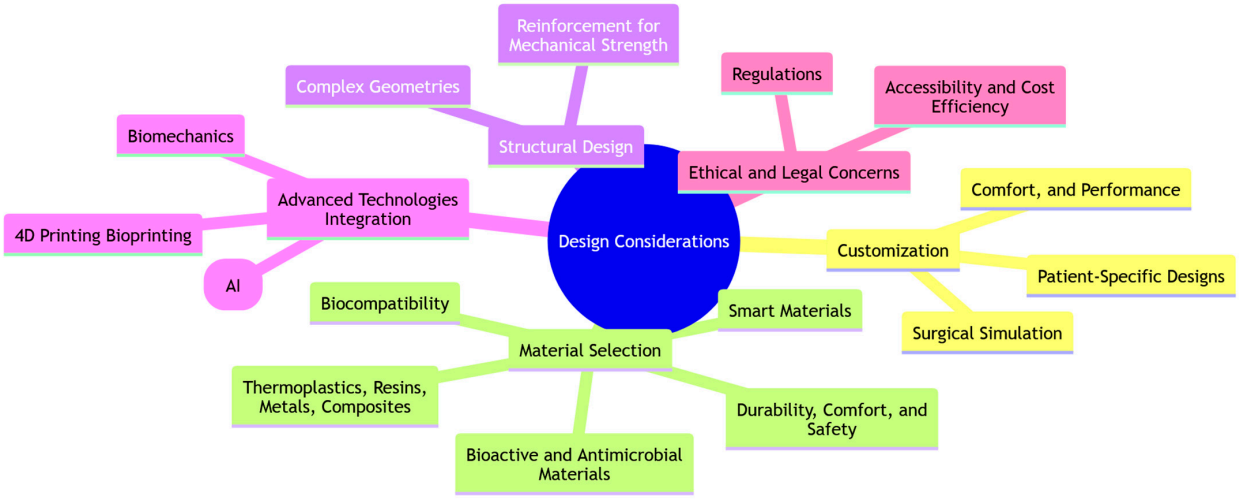


Figure 5. Design considerations for 3D-printed prosthetics.

7.1. Customization and Personalization

One of the most significant advantages of 3D printing is the ability to create patient-specific designs that address individual anatomical and functional needs. Customization enhances the fit, comfort, and performance of prosthetic and orthotic devices, ultimately leading to better patient outcomes [49]. Additionally, 3D printing facilitates preoperative planning and surgical simulation, which is particularly useful for complex cases, such as pelvic fractures and oncological surgeries. By allowing surgeons to simulate procedures beforehand, 3D printing helps to ensure more precise and personalized interventions [50–52].

7.2. Material Selection

The materials used in 3D printing play a critical role in determining the durability, comfort, and safety of prosthetic and orthopedic devices. Common materials include thermoplastics, resins, metals, and composites, each with varying mechanical properties, such as strength, flexibility, and resistance to wear. Biocompatibility is also essential, ensuring that the material does not cause adverse reactions in the body [15,43]. Recent advancements in material science have introduced bioactive and antimicrobial materials, which improve the functionality of implants by promoting osseointegration and preventing infection [53]. Moreover, smart materials with characteristics such as shape memory, electrical conductivity, and antibacterial properties are being explored to enhance prosthetic devices further [53,54].

7.3. Structural and Functional Design

3D printing allows for the creation of complex geometries and porous structures, which are particularly beneficial for orthopedic implants. These structures support osseointegration, improving the stability of implants in bones and enhancing the healing process [55]. In the case of prosthetics, structural reinforcement is essential to ensure mechanical strength. For example, reinforcing the distal end of prosthetic sockets can significantly improve their durability and performance under stress [56].

7.4. Integration with Advanced Technologies

Another major consideration in the design of 3D-printed prosthetics is the integration of biomechanics and artificial intelligence (AI). Biomechanics ensures that the prosthetics meet the functional needs of patients by considering factors such as weight distribution, movement, and comfort [57]. The incorporation of AI into the design and manufacturing process also enhances personalization, optimizing the fit and function of the devices. Emerging technologies such as robotic rehabilitation devices and assistive systems for post-stroke and spinal cord injury rehabilitation are gaining traction, offering new possibilities for patient recovery [49]. The future of 3D printing in prosthetics and orthopedics appears promising. Innovations such as 4D printing, which involves materials that change shape over time, and bioprinting, which enables the creation of biological tissues, offer exciting possibilities for enhancing prosthetic solutions [49]. These advancements may lead to even more functional and adaptable devices, offering greater support and comfort for patients. By focusing on these key design considerations—customization, material selection, structural design, cost efficiency, integration with advanced technologies, and addressing ethical and legal concerns—3D-printed prosthetic and orthopedic solutions can be optimized to provide the best possible outcomes for patients [49,57].

8. Some Recent Case Studies on 3D-Printed Prosthetics

Customized Prosthetic Sockets. In resource-constrained communities, one of the primary challenges in prosthetic development is the lack of access to advanced imaging and

fabrication technologies. Obtaining an accurate digital representation of the residual limb is essential for ensuring a proper fit, yet traditional scanning methods can be costly and require professional expertise. To address this, researchers have developed a smartphone-based scanning technique that captures digital limb data and predicts the mechanical functionality of prosthetic sockets printed under various conditions. A case study conducted by Lee et al. (2024) demonstrated how below-knee prosthetic sockets were successfully designed and produced using low- to mid-end 3D printers [58]. This approach significantly enhanced accessibility by reducing reliance on highly specialized professionals while maintaining functional integrity in the prosthetic design [58].

Prosthetic Hands for Children. Children frequently outgrow prosthetic devices, requiring frequent replacements that can be costly for families. Traditional prosthetics, while functional, lack affordability and accessibility, especially in developing regions. A case study by Francis et al. (2021) demonstrated the successful fabrication of an economical upper-limb prosthesis using additive manufacturing techniques [59]. This study highlighted how affordable, lightweight, and functional prosthetic hands could be customized and printed for children, ensuring that they receive prosthetic support without financial burden. The research also emphasized design flexibility, allowing for user-friendly modifications as the child grows [59].

Prosthetics in Resource-Limited Settings. Healthcare systems in low-income and rural areas often struggle to provide high-quality prosthetic devices due to financial constraints, lack of infrastructure, and limited access to specialists. Researchers in Sierra Leone explored the feasibility of integrating 3D printing into prosthetic care in resource-limited settings. According to van der Stelt et al. (2020), handheld 3D scanners and desktop 3D printers were used to manufacture patient-specific prosthetic devices, including splints and braces [60]. The study successfully produced four aesthetic prostheses, which were well received by patients. However, the research also noted that long-term sustainability remains uncertain, particularly due to material availability, repair challenges, and regulatory concerns [60].

Upper-Limb Prosthetics for Specific Tasks. Standard prosthetic hands are designed for general daily activities, but many users require specialized prosthetic designs tailored to specific tasks or occupations. Hofmann et al. (2016) explored the role of user engagement in prosthetic design, emphasizing collaborative prototyping with end-users [61]. The case study highlighted how 3D printing was leveraged to create prosthetic devices for activities such as playing the cello and using a knife. The results demonstrated that modular, user-driven designs enable individuals to regain function in ways that traditional prosthetics do not accommodate. This research reinforced the importance of personalized prosthetic solutions and the potential for greater independence and quality of life through additive manufacturing [61].

Prosthetic Supply Chain Enhancement. In many regions, delays in prosthetic production and delivery are common due to supply chain inefficiencies. The adoption of 3D printing in prosthetic manufacturing has the potential to revolutionize supply chain dynamics by offering on-demand production, reduced material waste, and localized fabrication. A study by Al-Masa'fah et al. (2024) examined the integration of additive manufacturing in Jordan's prosthetic supply chain, revealing enhanced efficiency, patient empowerment, and environmental sustainability [22]. The study emphasized that 3D printing minimized lead times, allowing for faster delivery and customization while also reducing transportation and storage costs [24].

Remote Fitting of Prosthetics. One of the significant challenges in prosthetic rehabilitation is the time gap between amputation and prosthesis fitting. Delayed prosthesis fitting can lead to muscle atrophy, mobility limitations, and psychological distress for amputees. To address this, researchers explored the potential of remote prosthetic fitting

using 3D-printed transradial prostheses. In a case study by Copeland et al. (2022), a remotely fitted, 3D-printed prosthesis demonstrated superior functional performance compared to standard prosthetic devices [62]. However, patient satisfaction levels were lower due to concerns regarding durability and long-term comfort. The study emphasized the need for improved material selection and mechanical reinforcement to enhance prosthetic longevity [62].

Prosthetic Hands with Soft Joints. Traditional prosthetic hands often suffer from limited flexibility and high mechanical rigidity, making fine motor tasks difficult for users. Researchers have explored thermoplastic polyurethane (TPU)-based soft joints to enhance dexterity and energy efficiency in prosthetic hand designs. A study conducted by Vedi et al. (2024) demonstrated the successful implementation of TPU in 3D-printed prosthetic hands, enabling more natural movement while maintaining cost-effectiveness [37]. The experimental results confirmed high accuracy and improved the energy efficiency, validating the feasibility of low-cost, customizable prosthetic hands for individuals in low-resource settings. This advancement paves the way for more adaptable and user-friendly prosthetics, particularly for individuals requiring greater grip strength and precision [37].

9. Current Limitations, Material Constraints, and Regulatory Hurdles of 3D Printing in Prosthetics

Despite its transformative potential, 3D printing in prosthetics and orthopedics faces notable limitations and challenges. Material constraints remain a significant barrier, as many commonly used materials lack the durability, biomechanical compatibility, or cost-efficiency required for widespread application. While advanced materials such as carbon fiber composites and biocompatible polymers show promise, they often come with higher costs and limited accessibility, particularly in low-resource settings [2,3]. Additionally, replicating the complex properties of human tissues, such as elasticity, flexibility, and load distribution, remains a technical challenge. Multi-material printing, essential for creating prosthetics with varied functional zones (e.g., soft and rigid sections), is still confined to high-end printers, further limiting scalability. These constraints underscore the need for continued material innovation to bridge the gap between functionality and affordability [5,7]. Regulatory hurdles also pose significant challenges to the integration of 3D printing in healthcare. The regulatory landscape for 3D-printed medical devices is still evolving, with ambiguous standards for safety, efficacy, and quality assurance creating uncertainty for manufacturers. Personalized devices, while highly beneficial, often fall outside traditional regulatory frameworks, necessitating new testing protocols and approval processes. This can delay market entry and discourage innovation, particularly for smaller manufacturers. To address these challenges, collaborations between researchers, regulatory bodies, and industry stakeholders are essential. By fostering material innovation, streamlining approval pathways, and developing standardized guidelines, the 3D printing sector can overcome these barriers and unlock its full potential to transform prosthetics and orthopedics [5,63].

The key challenges and considerations regarding material constraints and regulatory hurdles in 3D printing for prosthetics include the following:

9.1. Material Constraints

Limited Material Options. The field of 3D printing for prosthetics is still evolving, with a significant bottleneck being the lack of suitable polymers, biomaterials, hydrogels, and bioinks that are both functional for 3D printing and biocompatible [53,64,65]. Materials often lack the necessary mechanical strength, printability, and functionality required for durable and effective prosthetic devices [53,64,65].

Mechanical Functionality. The mechanical properties of 3D-printed prosthetics are highly dependent on the printing conditions, which can be a significant issue, especially in resource-constrained settings with limited access to high-end 3D printing technology and materials [58,66].

Processing Challenges. There are difficulties in processing materials into self-supporting devices with tunable biomechanics, optimal structures, and appropriate degradation rates [53,64]. Ensuring consistent material properties and optimal printing parameters, such as build orientation and laser power, is crucial for quality assurance [58,65].

9.2. Regulatory Hurdles

Regulatory Complexity. The customizability and unique build processes of 3D-printed prosthetics introduce complexities in meeting regulatory standards. This includes challenges in drafting design control models for FDA approval and ensuring manufacturing quality assurance [67,68]. Regulatory frameworks in the EU and USA do not fully account for the differences between 3D printing and conventional manufacturing methods, posing additional challenges for manufacturers [67,68].

Quality Control and Validation. Ensuring the quality of 3D-printed prosthetics involves addressing post-printing considerations such as cleaning, finishing, and sterilization [67,69,70]. Process validation, material selection, and scalability are critical aspects that need to be managed to meet regulatory requirements [67].

Software and Design Control. The control of the computer-aided design of the manufacturing process and the associated software system chain presents additional scientific and regulatory challenges [68]. The cost and complexity of the interface and software for manufacturing prosthetics can be prohibitive, further complicating regulatory compliance [53,69].

10. Affordability and Accessibility of 3D Printers

The decreasing cost of 3D printers has significantly contributed to democratizing prosthetic production. Affordable entry-level 3D printers, capable of producing basic prosthetic components, are accessible even to small clinics and individual users. Advanced medical-grade printers, though more expensive, remain far cheaper than traditional manufacturing equipment. This cost-effectiveness bridges the gap in underserved and resource-constrained regions, where traditional prosthetic manufacturing is either unavailable or prohibitively expensive. The ability to produce functional prosthetics at a fraction of the cost of conventional methods makes life-changing devices accessible to a broader population [71–73].

Open-Source Designs. The rise of open-source designs for 3D-printed prosthetics has enhanced the reach and impact of this technology. Platforms and communities offer free, customizable designs with detailed instructions, enabling individuals and organizations to create prosthetics without specialized expertise. Open-source designs drastically reduce development costs and time, making it possible to produce functional prosthetic hands for under $50. These designs also encourage innovation and adaptation, catering to specific needs like pediatric prosthetics or devices for unique physical activities. Open collaboration and knowledge-sharing models exemplify how technology can address global healthcare challenges by empowering communities to develop cost-effective solutions [71,74].

Local Production and Reduced Dependency. 3D printing enables the local production of prosthetic devices, reducing reliance on centralized manufacturing and long supply chains. Traditional prosthetic manufacturing involves specialized factories, costly shipping, and lengthy lead times. In contrast, 3D printing allows for on-demand production at local facilities, minimizing delays and transportation costs. This localized approach enhances

resilience in areas facing logistical challenges, such as conflict zones or regions affected by natural disasters. It also fosters local economic growth by creating jobs and developing skills in 3D printing technologies. By reducing dependency on external suppliers, 3D printing ensures greater access to essential medical devices, particularly in regions with limited healthcare infrastructure [34]. The convergence of affordable 3D printers, open-source designs, and local production capabilities has revolutionized prosthetic and orthopedic care. These advancements address critical barriers to access, ensuring that even the most vulnerable populations can benefit from transformative medical technologies.

11. Transformative Impact on the Prosthetics Industry

The integration of 3D printing technology has had a transformative impact on the prosthetics industry, reshaping traditional manufacturing processes and improving accessibility for patients worldwide. One of the most significant benefits is the reduction in production time and costs. Traditional prosthetic production often requires labor-intensive processes and expensive materials, leading to high costs and long lead times. In contrast, 3D printing enables rapid production of custom devices at a fraction of the cost. For example, prosthetics that once cost thousands of dollars can now be produced for under 100 USD using affordable 3D printers and materials [72]. This accessibility not only benefits low-income communities but also ensures faster delivery for individuals requiring immediate solutions, such as growing children or patients recovering from trauma. Another transformative aspect is the creation of prosthetics with high functionality and quality. 3D printing allows for intricate designs and complex geometries that are impossible to achieve with traditional methods. Lightweight materials, optimized for strength and durability, contribute to more comfortable and functional devices that align closely with the patient's anatomy. Innovations like lattice structures reduce weight while maintaining strength, and porous implants enhance biological integration in orthopedic applications. As a result, 3D-printed prosthetics offer superior mobility, comfort, and user satisfaction [71,72]. Future directions and potential developments in the industry include advancements in bioprinting for regenerative medicine, the integration of smart sensors for real-time feedback, and the use of AI-driven design tools to further personalize and optimize prosthetics. These developments promise to push the boundaries of functionality, accessibility, and patient-centered care, solidifying 3D printing's role as a cornerstone of innovation in prosthetics [73–75].

12. Conclusions

The advent of 3D printing has undeniably revolutionized the prosthetics industry, offering unparalleled opportunities to improve accessibility, functionality, and customization. By significantly reducing production time and costs, this technology has made prosthetics more affordable and accessible, particularly in underserved and low-income regions. Its capacity to deliver high-functionality devices, tailored precisely to individual needs, has enhanced patient satisfaction and quality of life. Furthermore, innovations such as lattice structures, lightweight materials, and bioprinting continue to push the boundaries of what is possible in prosthetics and orthopedics. Looking ahead, the integration of advanced technologies, like artificial intelligence, smart sensors, and regenerative bioprinting, presents exciting possibilities. However, overcoming challenges such as material constraints and regulatory hurdles will be critical to sustaining and expanding the transformative impact of 3D printing in this field. As these barriers are addressed through innovation and collaboration, 3D printing is poised to remain a cornerstone of progress, reshaping prosthetic care and offering hope to millions worldwide.

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