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Integration of Additive Manufacturing in Prosthetics and Orthotics

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ABSTRACT

Additive manufacturing (AM), commonly known as 3D printing, has transformed the fabrication of prosthetic and orthotic devices by enabling rapid, cost-effective, and customized production across a diverse range of materials. By tailoring geometry and material composition to individual anatomy, AM has improved fit, function and patient comfort while reducing production time and cost compared with traditional casting and CNC-milling workflows. This review summarizes the core AM technologies used in Prosthetics and Orthotics (P&O)-fused deposition modelling, selective laser sintering, and stereolithography-alongside their principal material families, and traces their clinical application in orthoses, prosthetic sockets and finite-element-guided device design. It further discusses the emerging role of 4D printing, in which materials are engineered to change shape or properties in response to environmental stimuli, and outlines an early concept of 5D printing that adds embedded information as a fifth dimension for actively responsive P&O devices. Five recent case studies illustrate how AM is already improving access to prosthetic care, particularly in low-resource settings. The review closes with a critical assessment of the material, regulatory, and intellectual-property barriers that must be addressed for AM to be adopted at scale in P&O practice, and proposes a systematic framework spanning body-part scanning through to final printing.

Keywords: Additive manufacturing, 3D printing, 4D printing, Rapid prototyping, Customization, Prosthetics, Orthotics

INTRODUCTION

Orthotic and Prosthetic devices have existed for many centuries, providing immobilization, support, correction, or protection for musculoskeletal injuries and dysfunction [1]. A prosthesis replaces an absent or deficient limb segment, while an orthosis supports an existing one. Manufacturing approaches evolved through the twentieth century-for example, tinted rubber-based plastic coatings were introduced in the 1970s to improve the comfort and appearance of orthoses but the introduction of additive manufacturing technologies (AMT) in the early 1980s, beginning with stereolithography (SLA), marked a turning point. Subsequent techniques such as fused deposition modelling (FDM), laminated object manufacturing (LOM), selective laser sintering (SLS), and material jetting expanded the manufacturing toolkit substantially.

The concept of 4D printing was introduced in 2013 by Tibbits at MIT as “3D printing plus time”: structures whose shape or properties change under stimuli such as temperature, pH, or an electromagnetic field after they are printed [2]. Building on this, we outline a nascent concept of 5D printing, in which a fifth dimension-information-is embedded in the printed structures so that they can interact with and cause deliberate change in, its environment during use, rather than only responding passively to it. For P&O applications, such actively responsive, shape-morphing structures could in principle support gait augmentation and orthopaedic rehabilitation in humans and animals alike, although this remains largely a conceptual extension of 4D printing rather than an established clinical technology.

Rapid prototyping techniques (RPT) are now driving a broader change in orthotic and prosthetic manufacturing because individualized devices must conform closely to complex anatomy to avoid pressure injuries, blistering, and discomfort [3]. RPT has already been applied to spinal braces, exoskeleton components, and passive orthoses, and its low cost, short lead time, and high dimensional accuracy make it attractive for an industry that has traditionally relied on hand-crafted, specialist-dependent fabrication [4,5]. In the conventional workflow, a specialist acquires the limb morphology using foam or plaster moulds, produces a positive model by CNC milling, and manually adjusts the device to fit-a process that can take several weeks and cannot reproduce complex surface geometries or mixed material thickness. The RPT alternative begins instead with 3D scanning of the patient, followed by CAD/CAE-based design and direct AM fabrication, which can cut production time to a matter of days [6]. AM is now used across medicine more broadly, including surgical instruments, drug-delivery devices, tissue scaffolds, dental implants, and prosthetic and orthotic devices [7-9].

Classification of Additive Manufacturing Process

AM processes are commonly grouped by feedstock form into solid-, powder-, and liquid-based systems (Figure 1). Solid-based methods include LOM, FDM, wire-arc AM, and electron-beam freeform fabrication; powder-based methods include SLS, electron-beam melting, selective laser melting, and laser metal deposition; and liquid-based methods include SLA, digital light processing (DLP), and material jetting [10]. Polymers remain the dominant P&O feedstock, being compatible with all three process families and offering a favourable balance of mechanical, thermal, and biocompatible properties [11]. Figure 2 provides an overview of Principal process parameters associated with fused deposition modelling, stereolithography/digital light processing, and selective laser sintering.

The generic AM workflow (Figure 3) begins with a CAD model that is converted to a standard tessellation language (.stl) file, sliced into two-dimensional cross-sections, and then built layer by layer; the resolution of the .stl file and ambient temperature/humidity both influence final part quality. In FDM, a thermoplastic filament is heated to a semi-solid state and deposited through a nozzle that follows a G-code toolpath; nozzle and bed temperature, and layer height, govern the resulting mechanical properties [12]. SLS instead selectively sinters thermoplastic powder with a laser, while SLA/DLP cure a photosensitive resin layer-by-layer using UV light. Commercially available FDM, SLS, and SLA machines span a wide range of build volume, layer resolution (as fine as 1-40 µm depending on process), and material compatibility; a representative comparison compiled from manufacturers' specifications is given in Table 1, and a general classification of the polymer families available for each process is given in Table 2.

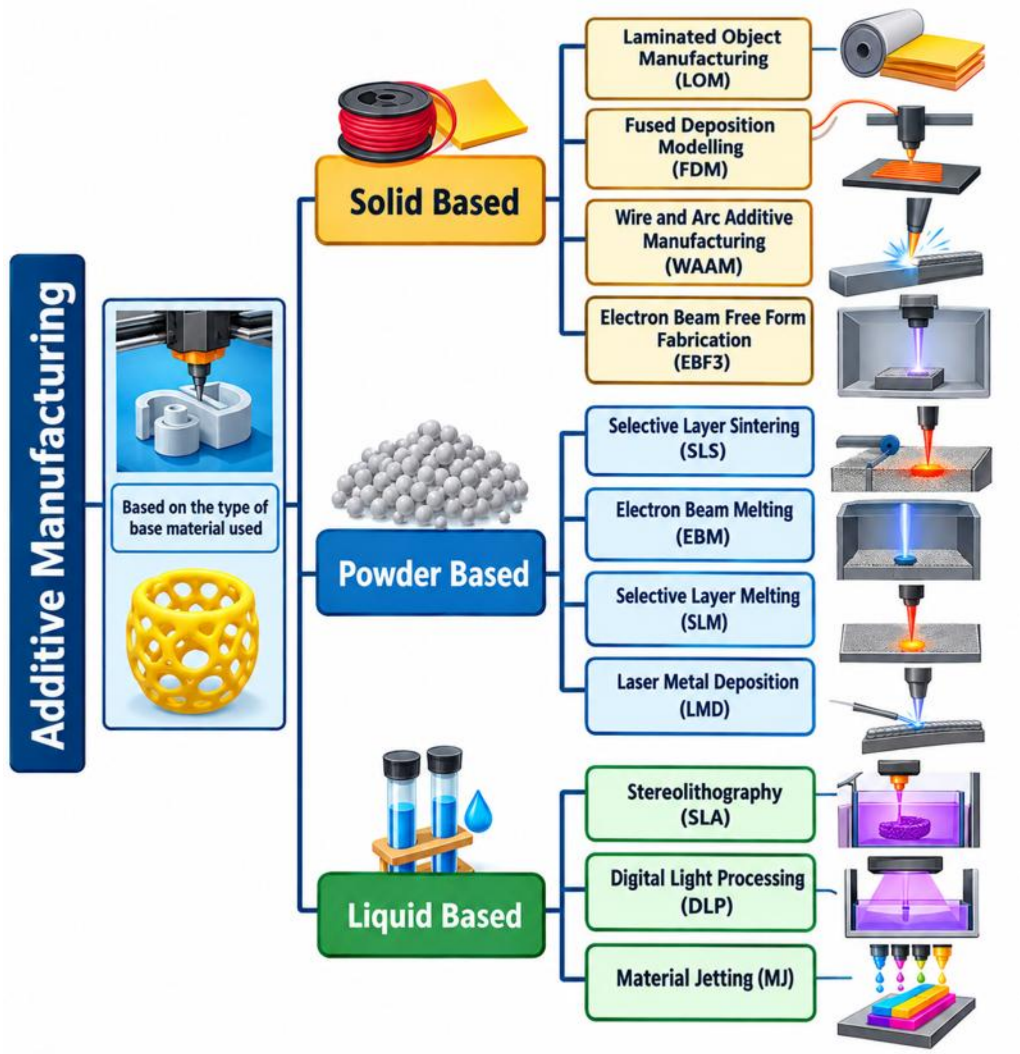

Figure 1. Classification of additive manufacturing techniques based on feedstock type. Solid-based processes include Laminated Object Manufacturing (LOM), Fused Deposition Modelling (FDM), Wire Arc Additive Manufacturing (WAAM), and Electron Beam Freeform Fabrication (EBF3). Powder-based processes include Selective Laser Sintering (SLS), Electron Beam Melting (EBM), Selective Laser Melting (SLM), and Laser Metal Deposition (LMD). Liquid-based processes include Stereolithography (SLA), Digital Light Processing (DLP), and Material Jetting (MJ). The illustration is conceptual and does not represent specific commercial products.

Material choice is governed by process-specific requirements: FDM depends most on filaments rheology and the elastic modulus/strain behaviour needed to avoid buckling under the feed mechanism; SLS depends on powder particle size/shape distribution (typically 20-80 µm) and thermal behaviour within a well-defined sintering window between onset melting and onset crystallization temperatures; and SLA/DLP depend on resin viscosity, curing kinetics, and optical absorption at the cure wavelength [13]. Representative thermal properties for common FDM filaments and SLS powders are summarized in Tables 3 and 4.

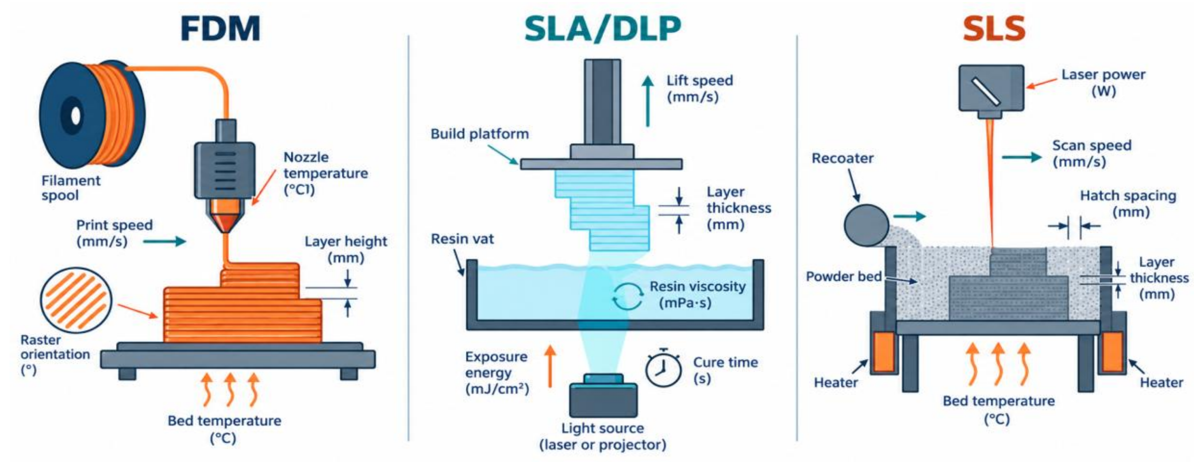

Figure 2. Conceptual depiction of Principal process parameters associated with fused deposition modelling, stereolithography/digital light processing, and selective laser sintering. FDM parameters include nozzle and bed temperatures, print speed, layer height, and raster orientation. SLA/DLP parameters include resin viscosity, exposure energy, cure time, lift speed, and layer thickness. SLS parameters include laser power, scan speed, hatch spacing, bed temperature, and layer thickness.

Figure 3. Generic digital workflow for additive manufacturing of prosthetic and orthotic devices, beginning with patient or object scanning and proceeding through digital modelling, design optimization, STL export and slicing, machine setup and printing, post-processing, and completion of the final device.

Table 1. A representative comparison of commercially available industrial-grade FDM, SLS, and SLA 3D printers. Information is collected from the supplier's website.

AM Technology	Printer	Build Volume (mm)	Layer Thickness (mm)	Compatible Materials
FDM	Stratasys F900	914 x 609 x 914	0.127-0.5	PLA, ABS, PEEK, Nylon, ULTEM
FDM	Roboze Argo 500	500 x 500 x 700	0.025-0.2	PLA, ABS, PEEK, Nylon, ULTEM
FDM	Ultimaker S5	330 x 240 x 300	0.02-0.25	PLA, ABS, Nylon
SLS	Formlabs Fuse 1	165 x 165 x 300	0.1	PA12, PA11, TPU
SLS	EOS Formiga P110 Velcis	200 x 250 x 330	0.06-0.12	PA12, PA11, TPU, TPE
SLS	3D Systems ProX SLS 6100	381 x 330 x 460	0.08-0.15	PA12, PA11, TPU, PP
SLA	Formlabs Form 2	145 x 145 x 175	0.025-0.1	Standard resin, Castable, Biocompatible
SLA	3D Systems ProX 950	1500 x 750 x 550	0.05	Standard resin, Castable, Clear
SLA	DWS XPRO S	300 x 300 x 300	0.01	Standard resin, Biocompatible, Flexible

Table 2. A general classification of the polymer material families available for FDM, SLS, and SLA/DLP printing, grouped by structural class.

AM Technique	Material Class	Representative Materials
FDM (filament)	Semi-crystalline thermoplastics	PEEK, PP, PLA, TPU, PA6, PA12, POM, PET
FDM (filament)	Amorphous thermoplastics	PEI, PC, ABS, PMMA, PS, HIPS, PEKK
SLS (powder)	Semi-crystalline thermoplastics	PA12, PA11, PA6, PEEK, PEK, PEKK
SLS (powder)	Amorphous thermoplastics	PC, PMMA, PS, PSU, PES
SLA/DLP (resin)	Polyester-based resins	PPF, PLA, PCL
SLA/DLP (resin)	Polycarbonate-based resins	PTMC, PTMC/Gelatin
SLA/DLP (resin)	Polyether-based resins	PEG, PEG/Chitosan, PEO/PEG

4D and Magneto-Responsive Printing Toward a 5D Concept

Since Tibbits' original definition, 4D printing has attracted growing interest for structures that actively change shape under an external stimulus once printed. (Figure 4) A widely explored route for P&O-relevant 4D structures is magneto-responsive printing, in which a magnetic filler (e.g. carbonyl iron powder, iron oxide, or Nd-Fe-B particles) is incorporated into the filament, powder or resin before printing, enabling the finished part to bend, grip or fold under an applied magnetic field [14,15]. Comparable shape-memory behaviour has also been demonstrated in soft, hydrogel-elastomer 4D-printed systems [16]. These approaches remain largely at the laboratory-demonstration stage, but point toward P&O devices that could dynamically adjust stiffness or shape to a user's gait cycle or environment rather than being fixed at the time of fabrication.

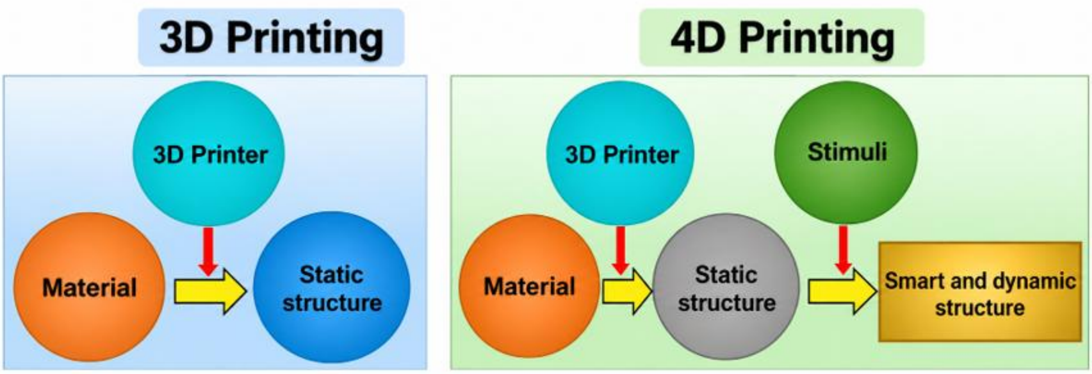

Figure 4. Conceptual distinction between 3D and 4D printing. Conventional 3D printing produces a structure with fixed geometry and properties after fabrication, whereas 4D printing uses stimulus-responsive materials capable of changing shape or properties over time in response to heat, moisture, light, or a magnetic field.

Table 3. Melting temperature and glass transition temperature of common thermoplastic filaments used in FDM.

Material	Tm (°C)	Tg (°C)	Printing Temp. (°C)	Degradation Temp. (°C)	Ref.
ABS	100-105	100-105	230-260	350-450	17
PLA	150-180	55-65	190-230	250-350	18
PET	245-260	75-85	230-260	350-450	19
PP	160-170	-20 to -5	220-250	300-450	20
PA6	215-225	45-55	250-280	350-450	21

Table 4. Melting temperature, onset melting temperature, onset crystallization temperature, and sintering window of common thermoplastic powders used in SLS.

Material	Tm (°C)	Tm,onset (°C)	Tc,onset (°C)	Sintering Window (°C)	Ref
PA12	185.6	178.0	158.6	19.4	22
PA11	202.9	189.2	168.3	20.9	23
TPU	144.4	122.2	123.9	1.7	23
PC	167.1	157.0	121.9	35.1	24
PP	182.3	177.1	151.3	19.5	25

Additive Manufacturing in Orthotics

Interest in computer-aided prosthetic and orthotic design dates back to the early 1960s, and a formal workflow using body scanning, CAD, and AM has since been outlined for both device classes [26]. SLS- and FDM-fabricated ankle-foot orthoses (AFOs) have shown outcomes broadly comparable with traditionally fabricated equivalents across several studies: AM - made running insoles improved comfort and injury-prevention metrics over three months of use [27]; SLS-fabricated passive-dynamic AFOs matched the stiffness of conventionally made devices after computational and destructive-test validation [28]; and gait analysis in eight subjects with unilateral drop foot found no significant difference between AM-fabricated and clinically accepted thermoplastic AFOs [29,30]. AM-fabricated AFOs are now commercialized for indications including clubfoot and rheumatoid arthritis, and for relieving peak plantar pressure [31,32,33,34]. Figure 5 illustrates representative examples of 3D-printed orthotic and prosthetic devices, including a prosthetic socket, AFO, wrist orthosis, cranial and spinal orthoses, and a customized foot insole, several of which use lattice infill to reduce weight while preserving structural support and ventilation.

Figure 5. Conceptual examples of additively manufactured prosthetic and orthotic devices, including a transtibial prosthetic socket, ankle-foot orthosis, wrist-hand orthosis, cranial remoulding orthosis, thoracolumbosacral orthosis, and custom foot orthosis. The illustrated devices are generic concepts and do not represent specific commercial products

Additive Manufacturing in Prosthetics

A prosthetic socket must transfer load between the residual limb and the prosthesis while remaining comfortable, and its shape is deliberately not an exact replica of the limb because soft tissue is unevenly suited to load-bearing. Conventional fabrication relies on a positive mould of the limb, iterative hand-rectification, and trial fitting-an experience-dependent process whose quality can only be judged after the device is built. AM instead allows the design to be evaluated computationally before fabrication: transtibial sockets (Figure 6) produced by SLS and FDM from CAD models have shown comfort, step symmetry, and interface pressures comparable with definitive sockets made conventionally, including designs with built-in compliant features over bony prominences [35].

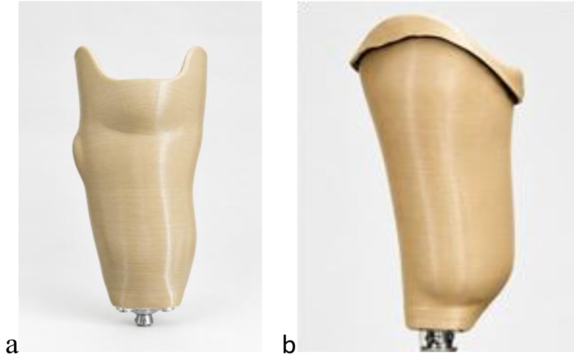

Figure 6. Transtibial **(a)** and transfemoral sockets **(b)** produced by FDM technique of Additive Manufacturing at AIIPMR in the Department of Prosthetics and Orthotics

Finite-Element Analysis of Prostheses and Orthoses

Finite-element analysis (FEA) has been used in prosthetics and orthotics design since the late 1980s to predict tissue stress distribution, load transfer, and the interface biomechanics ahead of fabrication, supporting topology optimization of the final printed geometry [36]. Applications include predicting the cross-sectional strut dimensions and breaking resistances of AM-fabricated AFOs, multi-objective optimization of AFO stiffness against metabolic cost, and simulation of donning, gait-cycle contact pressure, and shear stress at the residual-limb/socket interface using models reconstructed from MRI data (Figure 7). Across these studies, accounting for material inertia and friction between soft tissue and bone measurably changes predicted interface stresses, underscoring the value of patient-specific FEA for identifying the risk of deep-tissue injury before a socket is printed.

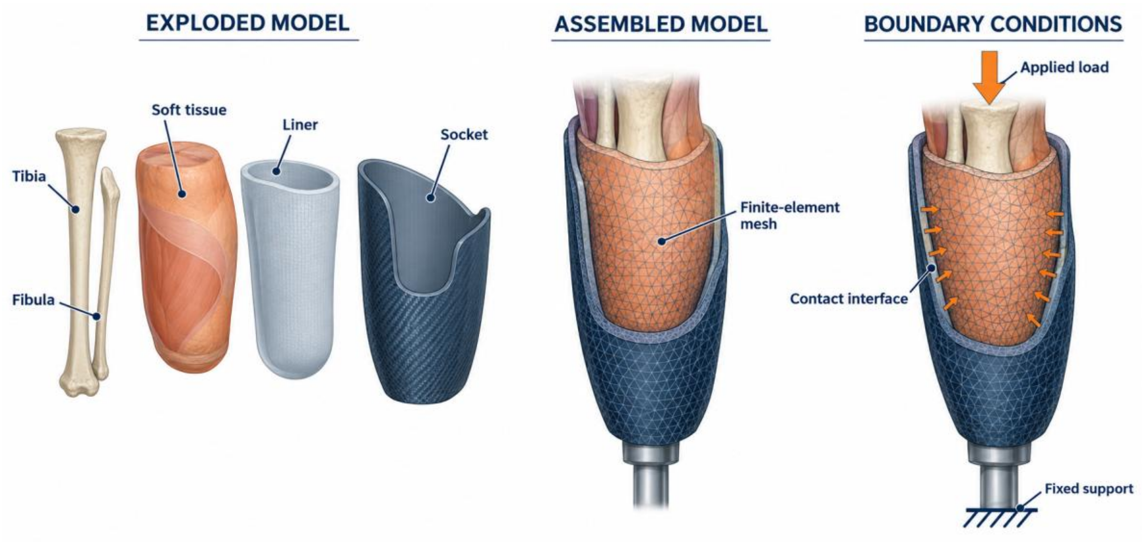

Figure 7. Schematic finite-element representation of a transtibial residual limb and prosthetic socket. The exploded model identifies the tibia, fibula, soft tissue, liner, and socket; the assembled model illustrates finite-element meshing; and the boundary-condition model shows the applied load, limb–socket contact interface, and distal constraint. The illustration is conceptual and does not represent patient-specific clinical data.

Recent Case Studies in 3D-Printed Prosthetics and Orthotics

A number of recent case studies illustrate how AM is already improving access to prosthetic care.

Low-cost scanning and socket fabrication: A smartphone-based scanning workflow was used to design and print below-knee prosthetic sockets on low-to mid-end 3D printers, reducing dependence on specialized imaging equipment and personnel while maintaining functional fit [37].

Paediatric prosthetic hands: An economical, 3D-printed upper-limb prosthesis was fabricated for children, whose rapid growth otherwise makes conventional replacement costly; the design supported user-friendly modification as the child grows [38].

Resource-limited settings: In rural Sierra Leone, handheld 3D scanners and desktop printers were used to fabricate patient-specific splints and braces, producing four well-received aesthetic prostheses, though long-term material availability and repair capacity remained open concerns [39].

Task-specific upper-limb devices: A user-engagement-driven design process produced 3D-printed prosthetic attachments for specific activities such as playing an instrument, demonstrating the value of modular, user-driven design over general-purpose prosthetic hands [40].

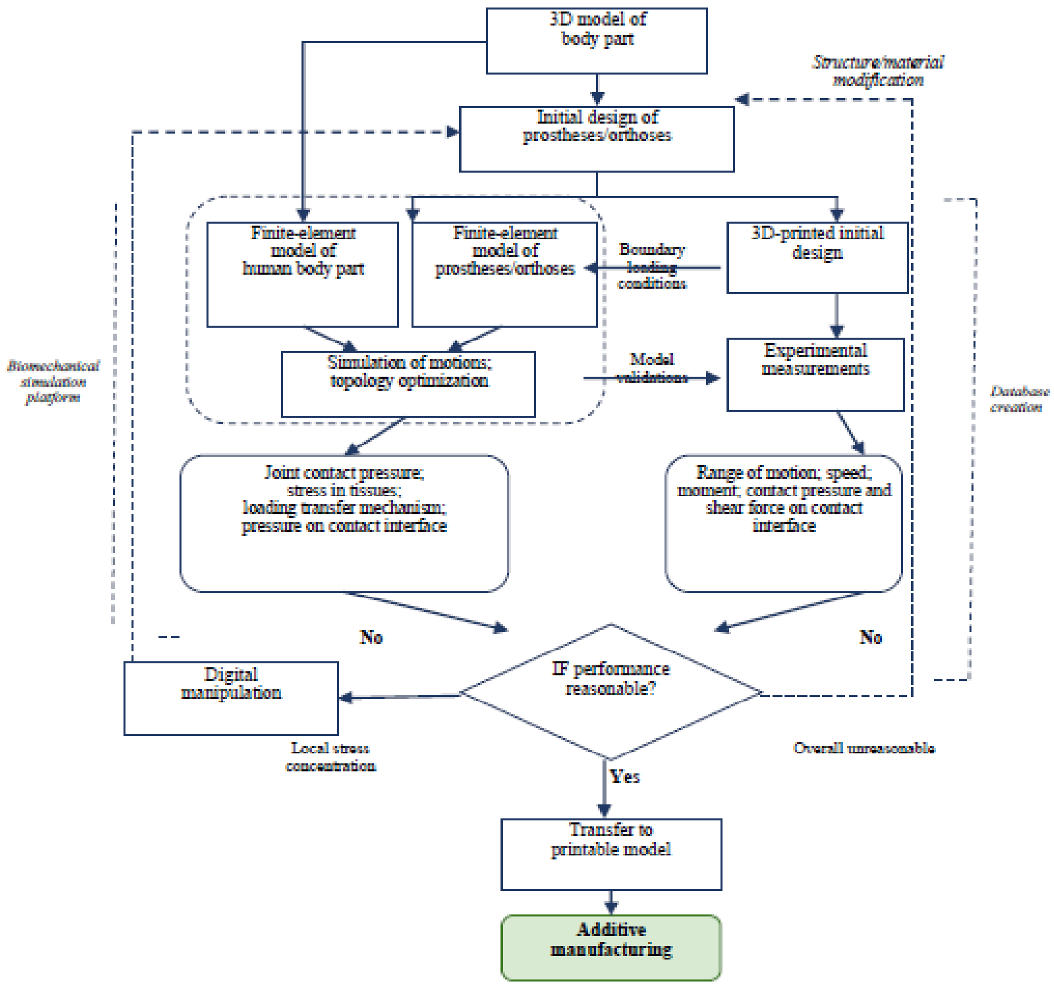

Figure 8. A proposed systematic framework for the additive manufacturing procedure in prosthetics and orthotics, spanning patient scanning through to final device printing. The design is evaluated in parallel through a biomechanical simulation platform and a physical prototyping/testing platform (database creation), converging on a performance decision before the model is transferred for additive manufacturing.

Remote fitting: A remotely fitted, 3D-printed transradial prosthesis achieved functional performance comparable with a standard device, although patient-reported satisfaction was lower, pointing to the need for improved material selection and mechanical reinforcement in remote-fitting workflows [41].

Current Limitations, Material Constraints, and Regulatory Hurdles

Despite this progress, AM adoption in P&O faces material, regulatory, and structural barriers. Many commonly used print materials still lack the durability, biomechanical compatibility, or cost efficiency needed for widespread clinical use, and replicating the elasticity and load distribution of human tissue remains difficult; multi-material printing, needed for devices with both soft and rigid zones, is still confined largely to high-end systems [42]. The regulatory landscape for 3D-printed medical devices is still evolving, with unclear design-control and quality-assurance standards for personalized devices, particularly regarding safety, sterilization, and process validation-a challenge shared across EU, USA, and India [43]. AM's reliance on digital patient-specific files also raises intellectual-property and data-protection questions that traditional manufacturing did not need to address, since such files can be copied and redistributed far more readily than a physical mould.

At the same time, falling printer costs and open-source designs are broadening access: entry-level printers now bring basic prosthetic and orthotic fabrication within reach of small clinics, and localized, on-demand production can shorten supply chains and reduce dependence on centralized manufacturing, which is particularly valuable in low-resource or logistically constrained settings [44].

CONCLUSION:

This review has covered the principal AM fabrication technologies, design methodologies, material options, and functional evaluation approaches relevant to Prosthetics and Orthotics, together with the regulatory and material barriers that currently limit their wider adoption. One recurring gap in the literature is the absence of a single framework spanning the full process from initial patient scanning to a final adaptable device; Figure 8 proposes such a framework, covering scanning of the affected body part through to 3D printing of the finished device.

Looking ahead, three trends are likely to shape the field. First, smart and 4D-responsive materials-shape-memory alloys, magneto-responsive polymers, and variable-stiffness composites-may enable prosthetic elements that adapt push-off and energy return to the terrain rather than behaving as fixed-stiffness components. Second, prosthetic control is increasingly borrowing from robotics and machine learning, with gait-phase recognition models moving from laboratory to clinical use to support smoother, more responsive powered devices. Third, continued integration of AI-assisted design, smart sensing, and regenerative bioprinting could extend AM's role from passive structural fabrication toward more actively adaptive P&O care. Realising this potential will depend on resolving the material, regulatory, and intellectual-property questions raised above, ideally through closer collaboration between researchers, regulators, and industry.

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