International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2024: 7.101

Advancing Prosthetics and Orthotics Through 3D Printing Technology: A Review of Clinical and Technical Outcomes

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Abstract: ***Additive manufacturing (AM), commonly known as 3D printing, is transforming prosthetics and orthotics (P&O) by enabling patient-specific design, rapid iteration, and distributed fabrication. A review of peer-reviewed studies (2015-2025) on 3D-printed prosthetic sockets, upper limb devices, and orthoses - particularly ankle-foot orthoses (AFOs) - demonstrates growing technical and clinical maturity. Evidence indicates that 3D-printed devices can achieve technical feasibility and, in selected cases, comparable clinical performance to conventionally fabricated counterparts. Sockets and AFOs produced using PA12 or similar polymers can meet ISO 10328 static strength standards when design and print parameters are optimized, though fatigue performance data remain limited. Clinical investigations report equivalent or improved gait outcomes and patient satisfaction, with notable advantages in customization, reproducibility, and turnaround time. Overall, 3D printing is evolving from a prototyping tool to a viable manufacturing method for targeted P&O applications. Future progress will depend on standardized testing protocols, well-defined regulatory frameworks, and high-quality clinical trials focusing on durability and long-term outcomes.***

Keywords: 3D printing, additive manufacturing, prosthetics, orthotics, regulatory framework

1. Introduction

Additive manufacturing (AM), or 3D printing, represents a paradigm shift in the fabrication of prosthetic and orthotic (P&O) devices. By replacing traditional manual and subtractive fabrication with digital, layer-by-layer additive processes, AM enables a fully integrated workflow from 3D scanning and computer-aided design (CAD) to point-of-care production and on-demand customization [1–3]. This digital continuum allows clinicians and engineers to design patient-specific devices that are lighter, reproducible, and ergonomically optimized while reducing turnaround time and material waste compared to conventional plaster-based or lamination methods [4,5].

Over the past decade, the increasing affordability of fused deposition modeling (FDM), selective laser sintering (SLS), and stereolithography (SLA) technologies has driven the clinical adoption of AM in prosthetics and orthotics [6]. Applications now span from upper-limb prosthetic components and transtibial sockets to ankle-foot orthoses (AFOs) and spinal orthoses, with early reports indicating that AM-based devices can achieve equivalent biomechanical and functional outcomes to conventionally fabricated alternatives [7,8].

In prosthetics, particularly socket fabrication, AM offers distinct advantages in digital reproducibility and the ability to rapidly iterate socket shape for optimal fit and comfort. However, variability in mechanical performance, limited long-term fatigue data, and lack of universally accepted design standards continue to constrain clinical integration [9]. In orthotics, especially AFOs, studies have demonstrated promising outcomes, including improved gait parameters, reduced production time, and enhanced patient satisfaction [10–12].

Despite this progress, translation from laboratory feasibility to large-scale clinical deployment remains incomplete. Key barriers include inconsistent mechanical testing methodologies, absence of standardized regulatory frameworks, and limited randomized clinical trials evaluating long-term durability and patient outcomes [13,14]. Therefore, a consolidated narrative review synthesizing both technical and clinical evidence is timely to identify where AM in P&O has matured and where critical research gaps remain.

2. Methods (Review Approach)

A narrative review approach was adopted to integrate evidence from engineering, biomechanics, and rehabilitation studies given the heterogeneity of designs and outcome measures in this emerging field. Literature searches were performed using PubMed, Scopus, and Google Scholar databases for publications between January 2015 and August 2025. The following keywords and Boolean combinations were applied: (“3D printing” OR “additive manufacturing”) AND (“prosthetics” OR “orthotics” OR “socket” OR “AFO” OR “upper limb” OR “lower limb”) AND (“clinical outcomes” OR “biomechanical” OR “ISO 10328” OR “mechanical testing”).

Inclusion criteria:

- Peer-reviewed English-language studies on external P&O devices fabricated via 3D printing.
- Reports including quantitative data on structural or biomechanical testing, gait analysis, or patient-reported outcomes (PROs).
- Systematic reviews and meta-analyses summarizing AM in P&O.

Exclusion criteria:

- Conceptual, simulation-only, or non-empirical studies.
- Internal implants, dental prostheses, or non-limb assistive devices.
- Conference abstracts or duplicated reports.

Data extraction focused on device type, printing technology, material, structural testing (ISO 10328 compliance, ultimate strength, fatigue), gait and kinematic outcomes, patient satisfaction, turnaround time, and reported costs. The review also examined mentions of standards, regulatory pathways, and clinical validation frameworks. Key scoping and systematic reviews were used as evidence anchors [1–5,15,18], complemented by recent clinical and technical studies [6–17,19–25].

3. Technical Outcomes

3.1 Standards and Structural Integrity

ISO 10328 [24] remains the foundational benchmark for evaluating the structural integrity of lower-limb prosthetic components, specifying loading conditions that simulate stance and swing phase forces for different user weights and activity levels. Recent adaptations have extended ISO-aligned testing to transtibial sockets fabricated through additive manufacturing (AM), enabling meaningful comparison between polymer-based and laminated composite designs. A PLoS ONE systematic review of 3D-printed sockets [12] reported that numerous geometries fabricated in PA12, PETG, and reinforced PLA meet or closely approach static load thresholds under ISO loading configurations, particularly when print orientation and infill patterns are optimized. However, fatigue resistance, impact tolerance, and environmental stability (e.g., exposure to moisture, UV, and temperature cycles) remain under-explored.

An exploratory Medical Engineering & Physics *study* [13] demonstrated that customized test fixtures and "worst-case configuration" protocols—such as distal load application and offset alignment - yield more reproducible static load testing results. These emerging ISO-aligned methodologies are critical for regulatory acceptance and inter-laboratory reproducibility. Future structural validation should integrate cyclic fatigue testing, fracture surface analysis, and digital traceability to ensure clinical safety in definitive-use devices.

3.2 Materials and Processes

In orthotic fabrication, selective laser sintering (SLS) of nylon PA11 and PA12 remains the dominant method for definitive clinical devices due to its favorable mechanical anisotropy, smooth surface finish, and predictable post-processing behavior [5–7,8]. Fused-filament fabrication (FFF/FDM) continues to be widely adopted in low-resource and point-of-care settings because of its low cost and equipment accessibility. Studies comparing materials such as PLA, PETG, nylon, and carbon-fiber-reinforced filaments indicate trade-offs between stiffness, ductility, and fatigue performance [3,8,19,20].

Recent workflow studies demonstrate that digital design scripting enables embedding of lattice zones, variable wall thicknesses, and localized ventilation within a single print, effectively integrating biomechanics into geometry [5,8]. Such parametric control allows the fabrication of compliant mechanisms—an emerging frontier for patient-specific dynamic orthoses. However, process variables (temperature, humidity, cooling rate) still affect interlayer adhesion and long-term durability. Developing validated material property databases for AM polymers used in prosthetics and orthotics is therefore an immediate research priority [9,14,18].

3.3 Accuracy, Repeatability, and Fit

Digitally driven workflows—using 3D scanning, parametric modelling, and automated toolpath generation - substantially improve repeatability and version control in socket and orthosis production. This digital traceability contrasts with artisanal workflows, where minor manual variations can alter fit and alignment [2,4,10,11]. Scoping reviews highlight that AM facilitates versioned device histories, where each iteration can be digitally archived, compared, and reprinted with identical geometry, improving both patient follow-up and quality assurance [15,17]. Nonetheless, there remains no consensus on standardized test geometries or benchmarking models for comparing scanner accuracy, print fidelity, or fit validation across studies. Variability in scanning protocols, smoothing algorithms, and mesh resolution continues to hinder cross-study reproducibility [10,11]. Research into quantitative fit metrics (e.g., shape deviation mapping, pressure distribution correlation) is essential to establish evidence-based definitions of "fit quality" in digital P&O manufacturing [12,13].

4. Clinical Outcomes

4.1 Ankle-Foot Orthoses (AFOs)

Across multiple systematic and scoping reviews [5,7,15,17], patient-specific 3D-printed AFOs have demonstrated clinically meaningful improvements in gait velocity, stride length, and ankle dorsiflexion during stance compared to conventional thermoplastic devices. Evidence is particularly strong in post-stroke and neuromuscular populations, where lightweight SLS nylon AFOs provided equivalent or superior functional outcomes and user satisfaction [9,10,20,21]. Studies also note improved aesthetic acceptance and reduced manufacturing lead time (often <48 hours from scan to delivery).

Figure 1: 3D Printed AFO

However, meta-analytic interpretation remains constrained by small sample sizes, heterogeneous gait measurement tools, and limited long-term follow-up. While short-term gait metrics show promise, fatigue, creep, and wear performance of printed polymers over months of daily use remain insufficiently reported [14,18]. Longitudinal trials evaluating mechanical degradation and patient adherence are therefore needed.

4.2 Prosthetic Sockets

The PLoS ONE review [12] synthesizes evidence indicating that 3D-printed transtibial sockets can achieve ISO aligned static strength and functional adequacy but emphasizes the paucity of integrated clinical-technical datasets linking material/process variables to user comfort, skin integrity, and device longevity. Early clinical evaluations demonstrate comparable fit and suspension quality to laminated sockets, often at reduced turnaround time and with digital reproducibility advantages [5,6,9,12].

Figure 2: 3D Printed Trans-tibial socket

Recently, ISO-aligned fixture design and static test methods [13,24] have been proposed to harmonize mechanical reporting and facilitate regulatory approval. Future studies should prioritize multisite trials with standardized gait analysis, pressure mapping, and skin health assessments to validate 3D-printed sockets as definitive not merely experimental solutions [12,14,15].

4.3 Upper-Limb Devices

Narrative and scoping reviews [4,5,16,22] document the expanding role of AM in upper-limb prosthetics, especially in paediatric and low-resource contexts. 3D printing enables rapid, low-cost customization, simplified repairs, and integration of aesthetic personalization (e.g., superhero themed designs). Community-based initiatives such as *Enabling the Future* have democratized access to functional yet inexpensive prostheses.

Figure 3: 3D Printed U/L Device

However, these devices typically prioritize accessibility over longevity; durability, grip force, and service pathways require systematic evaluation before formal clinical adoption [14,22]. Future research should address fatigue testing, ergonomic optimization, and certification frameworks for paediatric use devices [18,22].

5. Practical Considerations for Clinics

5.1 Workflow and Turnaround Time

End-to-end digital workflows - 3D scan → CAD → print → fit—can reduce production time from days to hours, enabling near-real-time device iteration [2,4,5,10,11]. The ability to reprint archived designs for adjustments or replacements reduces remakes and enhances clinical efficiency [15]. Integration of distributed manufacturing hubs may further decentralize production, improving access in remote or resource-limited settings [21,23].

5.2 Cost and Accessibility

While initial investment in SLS printers, CAD software, and scanning systems is significant, labour and material savings yield cost parity at moderate to high production volumes [2,5,8,23]. FFF/PLA-based systems lower the entry threshold for small clinics but entail greater variability in mechanical reliability. Economic models show that per-unit cost reduction correlates strongly with production volume and in-house expertise [23].

5.3 Design Freedom and Biomechanics

AM allows engineers to embed functional gradation of stiffness, lattice infills, and localized compliance zones that mimic biological limb behaviour [5,8,9,14]. Optimization frameworks now permit balancing stiffness, comfort, and weight for enhanced energy return and pressure distribution—particularly beneficial in AFOs and dynamic response prostheses [2,5,8]. This “geometry as function” paradigm represents one of AM’s most distinctive clinical advantages.

5.4 Hygiene and Skin Health

SLS nylons (PA11/PA12) demonstrate low water absorption, high wear resistance, and compatibility with standard disinfectants [5,8]. However, micro-porosity and rough surface textures in FFF prints may harbour moisture or bacteria, emphasizing the need for post-processing (sanding, vapor smoothing, sealing). Few clinical trials report dermal microclimate data - skin temperature, humidity, and Ph which are critical to assessing comfort and dermatological safety [2,8,9].

5.5 Safety, Standards, and Regulation

Clinical integration of AM devices requires robust traceability - linking digital design files, printer logs, and material batches to patient records [12,13,24]. For definitive prostheses, documenting ISO 10328-compliant testing, weight classification, and printer calibration parameters supports regulatory compliance [13,24]. International frameworks (e.g., ISO 22523, FDA guidance, and EU MDR 2017/745) are gradually adapting to AM, but local harmonization remains incomplete. There is a pressing need for regulatory training modules tailored to P&O clinicians and labs transitioning to AM workflows [23,25].

6. Limitations of the Evidence

Despite rapid progress, overall evidence quality remains moderate. Most published studies employ small sample sizes (<20 participants), short-term follow-up (≤6 months), and inconsistent outcome metrics. Fatigue and environmental durability testing are rarely included, and patient-reported outcomes (PROs) are collected less frequently than mechanical data [9,10,12,15]. Moreover, cross-study comparisons are hindered by heterogeneity in geometries, print technologies, and materials [5,7,8,14,18]. Comprehensive risk–benefit analyses and cost-effectiveness studies are essential to inform healthcare policy and reimbursement decisions [23,25].

7. Future Directions

The next phase of additive manufacturing (AM) integration in prosthetics and orthotics (P&O) should focus on establishing standardized, ISO-aligned test geometries for sockets and ankle-foot orthoses (AFOs) that incorporate cyclic fatigue protocols to assess long-term durability [13,14,18,24]. Multi-site ring trials are essential to ensure inter-laboratory reproducibility and calibration consistency [15,16], while prospective, comparative clinical studies should employ harmonized gait metrics and validated patient-reported outcome (PRO) instruments to strengthen clinical evidence [9,10,12,17]. Research must also advance hybrid and multi-material constructions that allow stiffness tuning and energy return without compromising safety margins [8,14,18]. Furthermore, implementation studies should address point-of-care manufacturing logistics, workforce training, and cost-effectiveness to support real-world scalability [2,3,23]. Finally, regulatory harmonization that aligns additive manufacturing standards (ISO/ASTM 52900 series) with prosthetic-specific safety norms (ISO 10328, ISO 22523) will be vital [24,25]. Achieving these goals will require close collaboration among clinicians, material scientists, and regulatory bodies to ensure safe, scalable, and equitable adoption of AM technologies in clinical P&O practice [5,6,22].

8. Conclusion

3D printing has evolved from a prototyping novelty to a clinically viable fabrication method for selected prosthetic and orthotic applications - most notably PA12 SLS ankle-foot orthoses and increasingly, transtibial sockets meeting ISO-referenced static strength criteria. The clearest advantages today are reproducible customization, digital traceability, and the ability to encode biomechanical function within geometry. However, long-term fatigue performance, standardization, and regulatory clarity remain key challenges.

To transition from research to routine practice, the field must move toward harmonized mechanical testing, transparent regulatory frameworks, and multicentre clinical trials assessing durability and patient outcomes. If these challenges are met, additive manufacturing could redefine P&O practice by enabling a globally scalable, data-driven, and patient-centered fabrication ecosystem.

Conflicts of Interest

The author declares no conflicts of interest.

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