

Bridging the Commercialization Gap in 3D-Printed Lower-Limb Prosthetics: A Lab-to-Market Framework

Vishwa Prasath
Department of Mechatronics
Engineering
Rajalakshmi Engineering College
Chennai, India
vishwaprasath12@gmail.com
ORCID: 0009-0007-0450-7334

Abstract—Additive manufacturing (AM) has significantly reduced costs and lead times in upper-limb prosthetics; however, load-bearing lower-limb prostheses face ongoing challenges in clinical adoption. The widespread use of 3D-printed transtibial and transfemoral sockets is hindered by two primary factors: the structural limitations of single-material polymers under dynamic ground reaction forces and the reliance on traditional, labor-intensive plaster-casting workflows. This paper systematically reviews the mechanical and operational limitations of current 3D-printed prosthetic interfaces and proposes an integrated digital manufacturing framework. Mechanical evaluations from the literature demonstrate that while standard fused deposition modeling (FDM) polymers frequently fail below the ISO 10328 ultimate load standard of 3840 N [11], structural parity with traditional laminated composites can be achieved through finite element analysis (FEA) guided topology optimization, hybrid multi-material architectures (PA12/TPU) [10], and cement-based post-processing reinforcements [1]. Furthermore, to reduce the subjectivity of manual fabrication, this paper outlines a digital pipeline. By combining artificial intelligence (AI) optical scanning for automated geometric design [13] with dynamic pressure mapping [12] to generate zero Poisson's ratio metamaterial lattices, studies indicate that peak interface pressures can be significantly reduced [3]. Ultimately, scaling advanced prosthetics in low- and middle-income countries (LMICs) [15] requires transitioning from decentralized standalone hardware to a closed-loop digital supply chain.

Keywords—3D printing, additive manufacturing, lower-limb prosthetics, biomechanics, finite element analysis, metamaterials.

I. INTRODUCTION

The historical evolution of prosthetic devices has transitioned from rigid structural replacements into highly integrated bionic systems. Early artificial interfaces, crafted from wood, leather, and iron, served primarily for cosmetic restoration and basic mobility [9]. Subsequent advancements introduced mobile hinges, body-powered pulley networks, and surface electromyography (EMG) configurations to translate muscle contractions into active grip patterns. Today, the convergence of additive manufacturing (AM), artificial intelligence (AI), and advanced structural materials provides new avenues for customization. The advent of additive manufacturing has initiated a paradigm shift in prosthetic production, offering a rapid, cost-effective alternative to

traditional methods while enabling high levels of geometric customization [5]. Because the residual limbs of individual amputees possess unique geometric morphology and tissue sensitivities, mass-produced interfaces are clinically limited, requiring highly customized fabrication [7].

Despite this technological progress, the widespread deployment of advanced robotic prostheses is constrained by operational and financial barriers. Commercial bionic limbs command high costs, with multi-articulating upper-limb systems ranging from \$60,000 to over \$100,000 [9]. These costs are compounded by legacy manufacturing workflows that are labor-intensive and highly dependent on localized technician craftsmanship. The traditional manufacturing cycle, which relies on manual physical measurements, plaster casting, mold modifications, and vacuum-forming, introduces significant inefficiencies by necessitating repeated clinical fittings and multi-week production timelines [15]. AM offers a streamlined alternative. By replacing manual tracking with a digitized pipeline encompassing 3D scanning, computer-aided design (CAD), and automated layer-by-layer material extrusion, studies have reported reductions in manufacturing turnaround times by up to 75% [7].

Furthermore, the operational decentralization of AM enables the utilization of high-performance thermoplastics via fused deposition modeling (FDM), dropping individual component raw costs to between \$300 and \$1,200 [6]. This has yielded widespread global deployment of lightweight, open-source upper-limb devices, where minimal load configurations protect components from premature mechanical degradation [9].

However, lower-limb prosthetics present a distinct biomechanical challenge. Unlike upper-limb replacements, a lower-limb transtibial or transfemoral interface serves as the primary load-bearing shock absorber for the human body under severe, cyclic dynamic forces [11]. While desktop polymers like polylactic acid (PLA) and acrylonitrile butadiene styrene (ABS) offer weight reduction and personalization flexibility, they possess poorer fatigue resistance compared to traditional metals or laminated composites [4]. This renders them prone to warping, delamination, and interlaminar cracking under structural

stress. For this technology to transition from laboratory protocols to global clinical standardization, the industry must address both the mechanical degradation of materials under dynamic human loads and the inefficiencies of current clinical workflows.

To systematically review these challenges, the remainder of this paper is organized as follows: Section II examines the operational and economic bottlenecks of traditional socket fabrication. Section III analyzes the mechanical failure profiles of FDM polymers under multi-axis gait cycle simulations. Section IV explores advanced multi-material and composite reinforcement solutions, and Section V outlines an integrated, sensing-to-manufacturing framework to scale long-term clinical adoption.

II. THE TRADITIONAL MANUFACTURING AND OPERATIONAL BOTTLENECKS

To contextualize the current limitations in clinical adoption, the prosthetics industry can be evaluated through the lens of business process reengineering (BPR) [14]. Traditional orthotics and prosthetics (O&P) workflows are highly dependent on subjective manual fabrication. The standard clinical model is divided into distinct administrative and clinical phases: initial patient engagement, physical anthropometric assessment, manual mold fabrication, vacuum thermoforming, and repeated dynamic alignment fitting sessions. This localized sequence introduces inefficiencies into the medical supply chain. Observational workflows indicate that traditional plaster-of-Paris casting and hand-carving require approximately 1 hour of practitioner time and 1.5 hours of technician labor per socket, resulting in an average fulfillment delay of four to eight weeks per patient [7].

These operational delays create socioeconomic barriers, leaving only 5% to 15% of amputees in low- and middle-income countries (LMICs) with access to proper prosthetic care [15]. In developing regions, such as rural Vietnam, patients face significant geographic isolation [2]. Because traditional manufacturing relies on iterative plaster modifications, patients must frequently make multiple long-distance trips to centralized urban clinics for trial adjustments. The cumulative costs of travel and accommodation can exceed the manufacturing cost of the device itself, leading to widespread clinical disuse and muscle atrophy [2]. Furthermore, manual casting lacks objective digital data logs; if a plaster positive mold fractures or a patient experiences subsequent limb volume fluctuations, the entire clinical workflow must be restarted.

To overcome these inefficiencies, clinics have begun adopting decentralized digital shape capture pipelines. The integration of accessible optical hardware, ranging from white-light scanners to smartphone-based sensors, allows clinicians to generate precise three-dimensional digital limb models in 15 minutes, requiring approximately 10 minutes of CAD preparation [7]. Implementing this digital front-end eliminates physical plaster shipping, manual mold carving, and the dependence on technician subjectivity. Field

deployments of this workflow at remote healthcare facilities demonstrate significant improvements in supply chain economics [6]. By shifting clinical data collection to digital cloud networks and executing local fabrication via fused filament fabrication (FFF), the cost of a patient-specific socket body can drop to approximately \$20 [6]. Fully assembled, this brings the final price of a customized prosthesis to roughly \$170—a fraction of the \$5,000 to \$100,000 price tags associated with traditional commercial systems [6], [9].

Despite these operational efficiencies, transitioning to a fully digital workflow introduces technical trade-offs that limit clinical adoption. While standard FDM printers reduce practitioner hands-on time, they can require 8 to 12 hours to deposit a plastic socket shell [7]. To match traditional diagnostic socket turnaround times, manufacturing centers must deploy high-flow systems equipped with large nozzle diameters (e.g., 2.5 mm) to print a solid 4 mm thick polyethylene terephthalate glycol (PETG) socket shell in under 1.5 hours [7]. More critically, empirical testing shows that these rapid, single-material digital sockets exhibit a 32% reduction in ultimate failure strength when directly compared to traditionally laminated composite sockets [7]. Consequently, while digitalization resolves clinical time delays, it introduces material vulnerabilities that must be mitigated to ensure structural integrity under real-world loads.

III. MECHANICAL FAILURE ANALYSIS (THE ENGINEERING BOTTLENECK)

For 3D-printed lower-limb prostheses to transition from laboratory prototypes to clinical execution, they must withstand significant, repetitive ground reaction forces. Under standard ISO 10328 testing protocols, a lower-limb socket must safely tolerate specific static proof and ultimate failure loads. For example, a standard transtibial socket must sustain an ultimate threshold of 3840 N, while P5 to P8 structural classifications demand safe load management for patient masses of 100 kg and beyond [11]. Mechanical evaluations reveal that monolithic, unoptimized 3D-printed polymer shells experience a 32% reduction in ultimate failure strength compared to traditional laminated composites, frequently failing below these ISO limits [7]. Sockets printed with a uniform 3 mm wall thickness using standard filaments typically suffer brittle fractures near 2000 N, experiencing interlaminar delamination parallel to the print deposition layers [11].

To address these structural vulnerabilities, manufacturing parameters must shift from uniform extrusion to finite element analysis (FEA) guided topological optimization. By simulating internal stresses prior to fabrication, critical weakness zones can be identified, allowing for a selective increase in wall thickness - from 3 mm up to 6 mm - specifically in high-stress regions [11]. For specific materials such as Raise3D PLA, this variable-thickness redesign effectively doubles the ultimate load capacity of the socket, enabling it to surpass the 3840 N ISO compliance threshold while minimizing overall weight addition [11].

To fully understand the root cause of these mechanical failures, static load limits must be contextualized within the dynamic biomechanics of the human gait cycle. FEA simulations demonstrate that the heel-strike phase is the most structurally critical loading condition [11]. During heel-strike, body weight transfers abruptly, generating peak impact forces that concentrate elevated von Mises stresses directly at the posterior-distal region of the socket [11].

Table I: Mechanical Property and Safety Factor Breakdown of Single-Material Polymers.

Material Classification	Elastic Modulus (GPa)	Yield Strength (MPa)	Max Von Mises Stress (MPa)	Safety Factor (SF)	Total Deformation (mm)
Polycarbonate (PC)	2.180	61.93	36.49	1.697	7.95
Polyethylene Terephthalate (PET)	2.898	52.44	37.65	1.393	6.02
Polyamide 6 (PA6) / Nylon	1.111	43.13	41.20	1.047	16.01

Source: Data compiled from [8]

As detailed in Table I, when single-material 3D-printed architectures are subjected to dynamic heel-strike forces, they exhibit a clear trade-off between structural rigidity and failure susceptibility. While rigid materials such as polycarbonate (PC) provide superior safety margins ($SF = 1.697$), flexible engineering plastics prioritized for patient comfort, such as polyamide 6 (PA6), deform up to 16.01 mm. This operates near critical structural limits ($SF = 1.047$) and accelerates material fatigue [8].

A systematic review of historical mechanical data further clarifies these structural limitations. An evaluation comparing 15 3D-printed sockets against 26 standard laminated sockets across distinct testing alignments (e.g., Neo, Current, and Gerschutz) demonstrates that single-material polymer configurations are highly vulnerable to localized stress concentrations [4]. Across testing protocols, structural failures consistently aggregate at the distal end of the socket and the pyramid attachment plate interface [4]. Bending moments generated during dynamic walking cause the edges of metal adapters to act as geometric stress risers, propagating cracks through the distal polymer curvature. While 3D-printed configurations can achieve structural parity with laminated alternatives for lower P5 to P7 patient weight classes, they exhibit higher failure rates under high-load P8 conditions [11]. However, when optimal material selection is paired with FEA-driven variable thickness at these distal attachment points, the probability of failure decreases significantly, allowing optimized 3D-printed sockets to safely sustain P8 loading levels [11].

IV. ADVANCED MATERIAL AND SURFACE COATING REINFORCEMENTS

To address the trade-off between structural rigidity and

patient comfort without increasing the prosthesis's overall weight profile, manufacturing can utilize advanced multi-material hybrid architectures. Because a rigid exterior is required to manage dynamic ground reaction forces ($GRF = M(g+a)$) while a soft interface is necessary to isolate tissue from shear stress, dual-extrusion approaches are highly effective. Recent structural evaluations validate a double-wall configuration, pairing a stiff 3 mm outer shell printed from high-toughness nylon 12 (PA12, tensile strength = 50 MPa) with a flexible 2 mm inner liner printed from thermoplastic polyurethane (TPU) [10]. Digital workflows can further optimize this assembly using advanced topology software to generate internal lattice geometries, reducing total socket weight by up to 30% while maintaining load-bearing capacity [10].

Under high-load finite element simulations representing a 120 kg equivalent mass, loads applied to critical anatomical junctions, specifically the patellar tendon, medial tibial flare, and fibular shaft, demonstrate the efficacy of this hybrid approach [10]. Depending on the specific socket design iteration, the rigid PA12 shell limits deformation to a range of 0.88 mm to 1.55 mm, maintaining peak stresses well below failure limits to ensure structural integrity [10]. Conversely, the elastic TPU liner compresses up to 65.85 mm, maximizing the surface contact area across the residual limb to provide secure suspension and impact mitigation while keeping the overall assembly lightweight [10].

However, because multi-material polymer extrusion remains susceptible to interlaminar shear failure along the print deposition planes, advanced post-processing reinforcement layers are often required. To evaluate the efficacy of these methods, FDM polymer sockets have been tested with specialized high-strength fiber wet layups and high-density surface sprays [1].

Table II: Mechanical Comparison of Post-Processing Socket Surface Reinforcements.

Reinforcement Coating Group	Mean Yield Strength (MPa)	Mean Young's Modulus (MPa)	Microstructural Surface Features (SEM)
Control Group (Uncoated PLA+)	0.0567	21.5333	Patchy, non-uniform material distribution
Fiberglass Fiber (with Epoxy)	0.0500	23.2350	Rough surface texture, high matrix-fiber friction
Carbon-Kevlar Fiber (with Epoxy)	0.1613	27.1733	Sparse fiber distribution, high microstructural porosity
Carbon Fiber (with Epoxy)	0.3800	89.1100	High uniformity, seamless matrix integration
Cement Surface Spray	0.4767	90.3333	Flawless surface uniformity, zero visible pores

Source: Data compiled from [1]; units reflect axial compression test output from Ramlee et al. 2024.

As demonstrated by the mechanical testing data in Table II, applying an optimized post-processing surface layer significantly alters the load-bearing capacity of the printed device [1]. While carbon fiber fabrics provide substantial

structural reinforcement, the highest static mechanical performance is observed with a multi-layer cement spray coating [1]. Applying this sprayed cement coating increases socket yield strength by **88.05%** and elevates Young's modulus by **74.20%** relative to standard 3D-printed controls [1]. Scanning electron microscopy (SEM) confirms the microstructural origin of this enhancement: whereas manual fiber hand layups introduce internal porosity and sparse fiber tracking, a sprayed cement application creates a highly uniform, pore-free surface envelope [1]. This coating distribution encapsulates the underlying print layer lines, thereby arresting crack initiation [1].

Despite these mechanical improvements, a notable experimental limitation exists: these reinforcements were evaluated exclusively under axial compression to simulate the mid-stance gait phase [1]. Because real-world biomechanics subject the socket to continuous multi-axis bending, torsional twisting, and cyclic fatigue, high-stiffness coatings pose a risk for brittle fracture over prolonged use. Therefore, while post-processing maximizes compressive strength, translating these enhanced materials into clinical practice requires a comprehensive, data-driven digital framework.

V. PROPOSED FRAMEWORK: A LAB-TO-MARKET STRATEGY

To resolve current limitations in scalability, the prosthetics industry requires a transition from localized, labor-intensive manufacturing to a decentralized digital workflow. A primary operational bottleneck is the reliance on the subjective expertise of clinical personnel during plaster casting. To standardize this process, clinical intake can incorporate AI-driven optical 3D scanning. Recent clinical studies utilizing geometric deep learning models, such as DiffusionNet, have automated the socket design process [13]. Trained on historical datasets of 116 patient scans, these AI models achieved a mean geometric deviation of 2.51 mm from expert-crafted sockets [13]. In clinical trials evaluating 10 amputees, traditional manual sockets yielded comfort scores of 7.1/10, which were comparable to AI-generated sockets at 6.6/10, showing no statistically significant difference [13]. Nevertheless, developers must ensure highly diverse training datasets; trials have reported challenges in accommodating unusually narrow residual limbs, indicating limits in AI generalization for anatomical outliers [13].

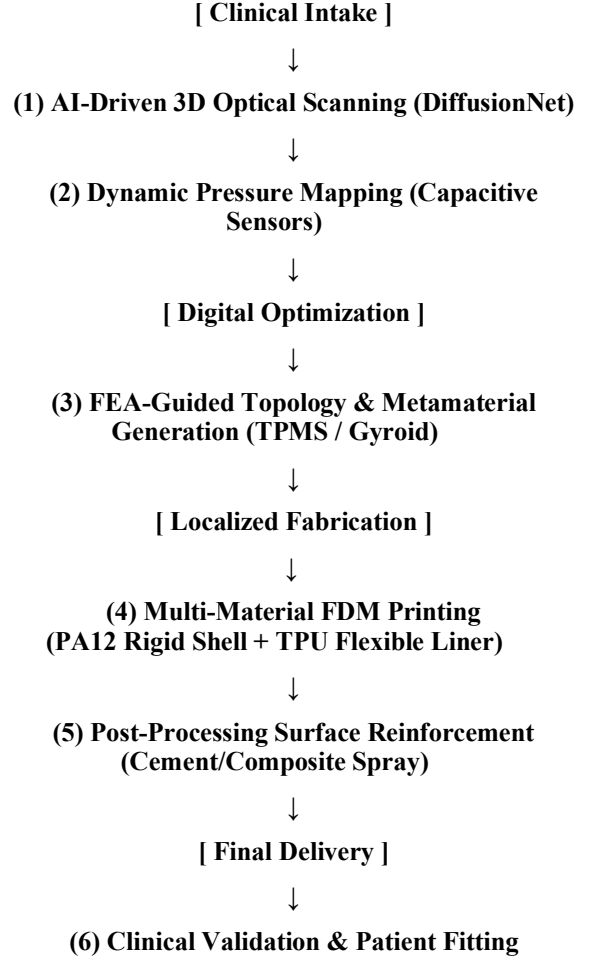


Fig. 1. Integrated Sensing-to-Manufacturing Digital Workflow

Furthermore, a standardized digital scan captures only static geometry. To achieve functional optimization and circumvent structural vulnerabilities, the workflow can incorporate dynamic 3D pressure mapping and advanced topology [12]. Using wearable capacitive sensor liners, dynamic contact pressures can be mapped, identifying peak pressures up to 7500 kPa during loading conditions such as ramp descent [12]. Rather than printing a socket with a uniform solid thickness, this pressure data can dictate the generation of density-graded triply periodic minimal surfaces (TPMS) [12]. By utilizing a customized Gyroid lattice infill, where high-pressure zones receive thicker lattice walls, finite element analysis demonstrates a 1600% increase in energy absorption during standing and a 1290% increase during walking compared to solid sockets [12]. However, it is important to note that both energy absorption metrics (1600% standing and 1290% walking) are derived from a proof-of-concept study involving a single participant (N=1); consequently, larger clinical trials are necessary to fully validate these findings [12].

To further mitigate stress in critical anatomical regions (such as the patellar tendon), this digital pipeline can integrate zero Poisson's ratio metamaterials directly into the socket wall [3]. Because zero Poisson's ratio structures compress vertically without bulging laterally into surrounding tissue, they absorb ground reaction forces without introducing

localized friction [3]. Studies demonstrate that embedding these metamaterials reduces peak interface walking pressures by 11.7% (from 145 kPa to 128 kPa) while improving bilateral knee joint symmetry during deep squatting from 0.992 to 0.999 [3].

Ultimately, standardizing this AI-driven, pressure-mapped workflow is critical for scaling advanced prosthetics globally, particularly in LMICs where only 5% to 15% of amputees have access to care [15]. By reducing the raw socket production cost to approximately \$20 (as discussed in Section II), additive manufacturing addresses financial barriers while enabling remote fitting for rural populations [6]. In contrast, technology deployment must be managed carefully. Systematic reviews of 3D-printed deployments in developing regions indicate that while upper-limb devices have undergone initial testing, there is a marked absence of lower-limb solutions due to stringent load-bearing requirements [15]. Even in upper-limb trials, field tests showed failure rates exceeding 50% within weeks due to material fatigue, compounded by a lack of local CAD expertise [15]. Therefore, scaling load-bearing lower-limb technology requires a comprehensive digital supply chain where FEA and AI modeling are processed remotely, allowing local hubs to focus on executing reinforced FDM prints and patient fitting.

VI. CONCLUSION

The transition of advanced robotic prostheses from laboratory prototypes to a globally scalable medical standard is constrained by manual, artisan-based clinical workflows. As discussed, relying on traditional plaster-casting methodologies creates financial barriers and multi-week production delays [9] that limit access to functional care for many amputees, particularly in low- and middle-income countries (LMICs) [15]. While the digitization of the clinical workflow via optical scanning and CAD manipulation reduces practitioner labor times from hours to minutes [7], executing these designs via low-cost additive manufacturing introduces structural limitations [4], [7]. Although production costs can be reduced to approximately \$20 [6], these cost savings are negated if the device experiences interlaminar delamination during the peak stresses of the heel-strike phase [11].

To address these limitations, the industry must leverage the unique topological capabilities of 3D printing rather than treating it as a direct replacement for traditional lamination. Evidence confirms that 3D-printed lower-limb sockets can sustain high-load P8 categories and surpass the ISO 10328 ultimate load threshold of 3840 N when monolithic polymers are replaced by optimized architectures [11]. By utilizing FEA to selectively reinforce high-stress distal attachment points [11], deploying double-wall PA12/TPU hybrid materials to balance rigidity with comfort [10], and applying cement-based surface coatings to arrest crack propagation [1], manufacturers can substantially mitigate the structural weaknesses of FDM printing.

Furthermore, integrating advanced software can automate complex elements of prosthetic design. Geometric deep

learning models can replicate expert clinical shaping within a 2.51 mm margin of error [13], while dynamic pressure mapping dictates the placement of zero Poisson's ratio metamaterials and density-graded Gyroid lattices [3], [12]. These internal geometries act as localized shock absorbers, reducing peak interface walking pressures by 11.7% and improving bilateral gait symmetry [3]. Ultimately, scaling load-bearing prosthetics requires a closed-loop digital supply chain. By processing AI modeling and FEA remotely while localized clinical hubs execute optimized FDM printing and patient fitting, the medical device industry can deliver customized, structurally validated interfaces to a broader global market.

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