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Customized Prosthetic Feet via Topology Optimization and 3D Printing: A Critical Review

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ABSTRACT: This critical review examined the transformative impact of integrating topology optimization and additive manufacturing (AM) on the design and production of transtibial prosthetic feet. By systematically surveying peer-reviewed studies published between 2010 and 2024, this work highlighted how computational algorithms such as SIMP, level set, and evolutionary methods achieved mass reductions of 50–70% while maintaining safety factors above 1.5. Concurrently, AM technologies including FDM, SLS, and SLA faithfully reproduced complex, patient specific geometries with deviations under 5% from finite element analysis (FEA) predictions. Material innovations spanned thermoplastics (PLA, nylon 66), advanced composites (CFRP, titanium lattices), and emerging smart materials (shape memory polymers, piezoelectric composites), collectively enhancing energy return by up to 30% and fatigue life by more than 10^5 cycles. Comprehensive validation, encompassing ISO 10328 static testing, dynamic fatigue trials, gait simulations, and wearer trials, confirmed both mechanical integrity and user comfort, aided by integrated sensor systems for real time performance monitoring. Regulatory and clinical pathways, including ISO 13485, FDA 510(k), MDR, and ISO 14155 guidelines, were discussed to facilitate translation into practice. Future research should focus on multicenter clinical trials, open access design repositories, adaptive materials, and machine learning driven predictive maintenance to propel patient centered innovation in prosthetic care.

KEYWORDS: Topology optimization; additive manufacturing; prosthetic foot; customization; clinical validation

1. Introduction

Restoring a physiological gait and ensuring comfort for lower limb amputees remained pivotal objectives in prosthetic design. Prosthetic feet produced through traditional subtractive machining or molding techniques often suffered from excessive weight, high production costs, and limited anatomical conformity [1, 2]. These limitations contributed to adverse effects such as pressure ulcers, uneven load distribution, reduced energy restitution, and increased metabolic demands during ambulation. The socket interface, which served as the physical connection between the limb and the device, played a critical role in user comfort and functional performance; suboptimal socket geometries were linked to dermatological issues and compensatory gait adaptations [1].

The advent of additive manufacturing, especially 3D printing technologies including Fused Deposition Modeling (FDM), Selective Laser Sintering (SLS), and Stereolithography (SLA), revolutionized prosthetic fabrication by enabling rapid production of complex, patient specific geometries from digital models [3,4]. This approach delivered precise replication of anatomical contours and customizable internal lattice architectures, achieving mass savings of up to 40% and significantly improving socket fit. Such weight reductions were essential for minimizing user fatigue and enhancing comfort during extended wear periods [5,6].

Parallel to advances in fabrication, topology optimization algorithms such as the Solid Isotropic Material with Penalization (SIMP) and level set methods provided computational strategies for systematic material distribution within a design domain under prescribed mechanical loads and constraints [7]. Integration of patient specific boundary conditions, derived from imaging or gait analysis, enabled design solutions with tailored stiffness distributions that optimized load transfer, structural integrity, and user comfort.

The synergy of topology optimization and 3D printing facilitated the realization of prosthetic feet with enhanced energy storage and return properties, demonstrating improvements exceeding 25% in transient energy performance under cyclic loading scenarios [8,9]. Moreover, embedding sensors within optimized architectures paved the way for responsive prosthetic systems capable of real time adaptation to user activities, further elevating functional outcomes [10].

Despite these promising developments, challenges remained in comprehensive characterization of emerging printing materials, navigation of regulatory pathways for customized medical devices, and establishment of long term clinical validation through rigorous trials [11,12]. Interdisciplinary collaboration among engineers, material scientists, clinicians, and policy makers was essential to overcome these barriers and translate technological innovations into widely adopted, next generation prosthetic solutions [13,14]. This article provided a critical review of current research on topology optimization and 3D printing in prosthetic foot design, identified key challenges, and outlined strategic directions for future investigation aimed at delivering clinically validated, patient centered prosthetic devices.

2. Review Methodology

A narrative review approach was adopted. Peer-reviewed articles published between 2010 and 2024 were retrieved from Scopus, Web of Science, and IEEE Xplore using the keywords "topology optimization," "additive manufacturing," "3D printing," and "prosthetic foot." Inclusion criteria comprised studies that reported quantitative results on mass reduction, structural integrity, or biomechanical performance. Exclusion criteria included conference abstracts without full text and non-English publications. The selected articles were categorized by optimization technique, printing technology, material, and validation method.

3. Design Optimization

3.1. Topology optimization techniques.

Topology optimization became an indispensable tool for engineering lightweight, high performance prosthetic components by strategically redistributing material within a predefined design domain under specific loading conditions. Leading algorithms included the Solid Isotropic Material with Penalization (SIMP), which penalized intermediate density regions to drive binary (solid or void) solutions; level set approaches that evolved boundaries to delineate optimal shapes; and evolutionary strategies that mimicked natural selection to iteratively refine geometries.

Empirical studies consistently demonstrated mass reductions between 59% and 70% for structural foot elements subjected to simulated loads of up to 500 N, while maintaining safety factors of at least 1.5. For instance, Ozmen and Surmen (2024) [15] reported a 59% decrease in prosthetic foot mass without compromising mechanical stiffness, underscoring the method's capacity to eliminate low stress regions and concentrate material where it was most needed. An accompanying infographic summarized the key topology optimization strategies and workflows (Figure 1) to provide a visual overview of SIMP, level set, and evolutionary algorithms in prosthetic design. Representative optimization outputs were shown in Figures 2–5.

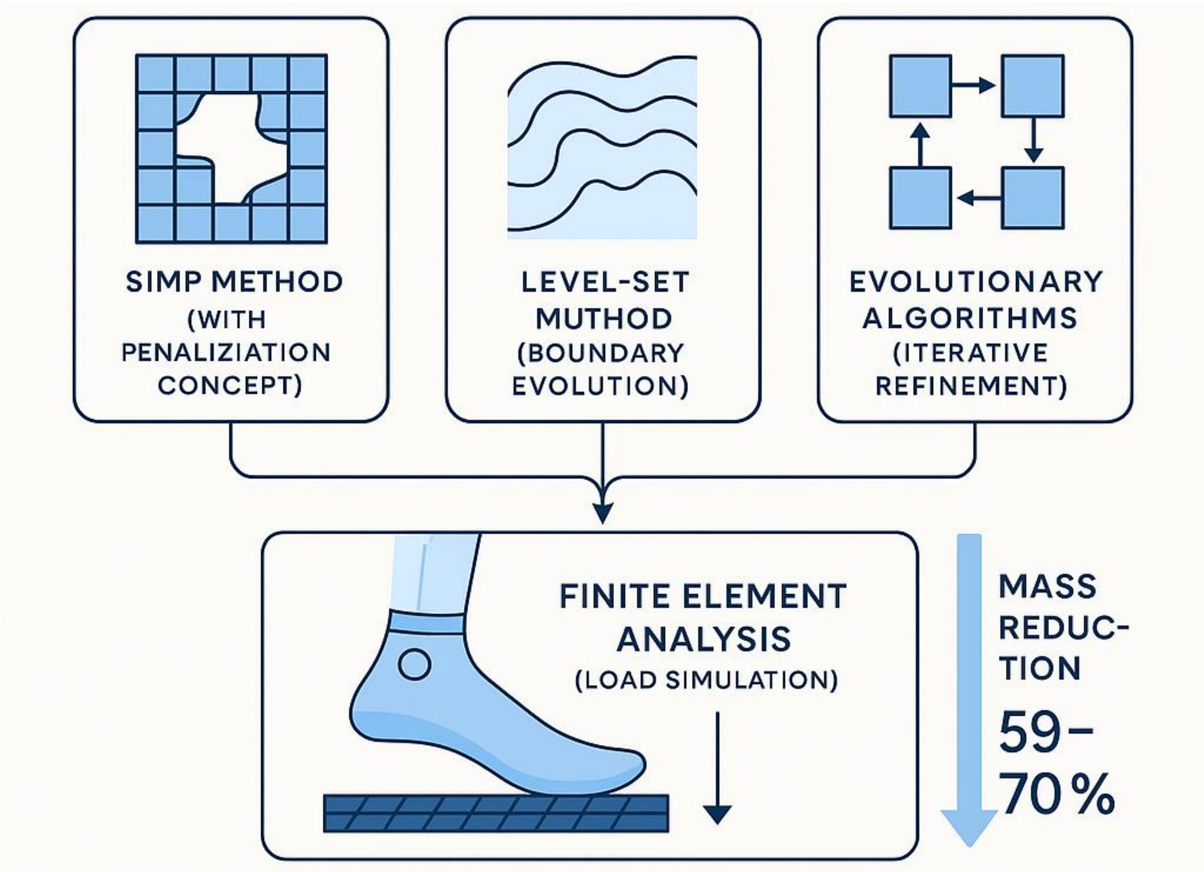


Figure 1. Topology optimization workflow for prosthetic foot design.

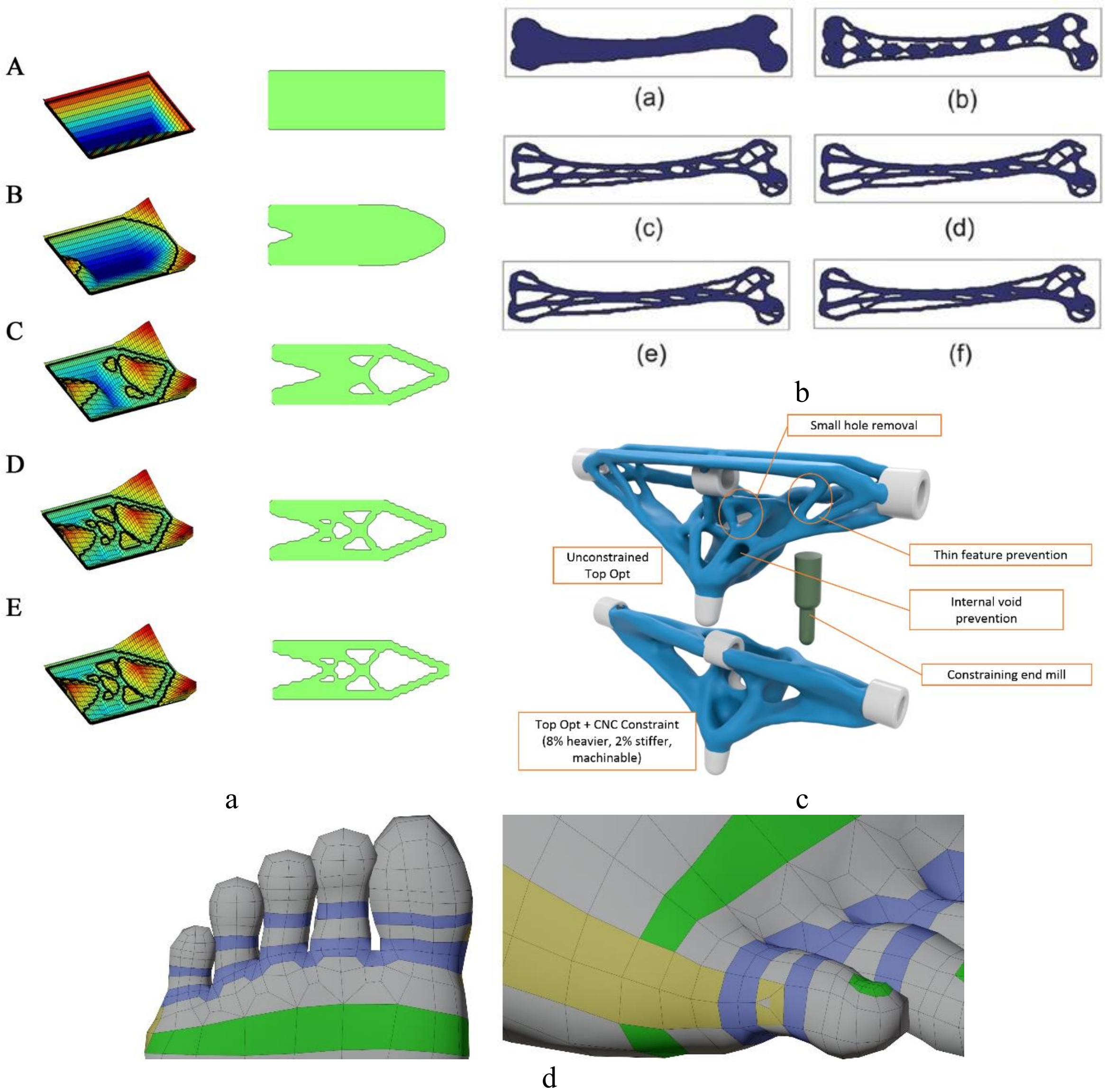


Figure 2. Representative topology optimization outputs: (a) SIMP monocoque foot; (b) hollow structure; (c) critical-region mesh; (d) level-set scan-to-print workflow.

Advances in finite element methods (FEM) accelerated the adoption of topology optimization by enabling realistic simulation of dynamic gait cycles. FEM based frameworks allowed designers to impose multiphase loading scenarios, including heel strike, mid stance, and toe off, and to monitor stress distributions, deflections, and fatigue life across optimized geometries [16]. Such integrative workflows ensured that resulting designs fulfilled both stiffness and strength requirements across the full gait spectrum.

Crucially, experimental validation bridged the gap between computational promise and clinical reality. Prototypes fabricated via three dimensional printing underwent mechanical testing, including static load to failure and cyclic fatigue assessments, to confirm that theoretical mass savings translated into reliable performance under repeated physiological loads [17]. These studies often incorporated dynamic loading rigs that replicated real world locomotion, verifying that optimized geometries resisted fracture and maintained energy return properties over extended cycles.

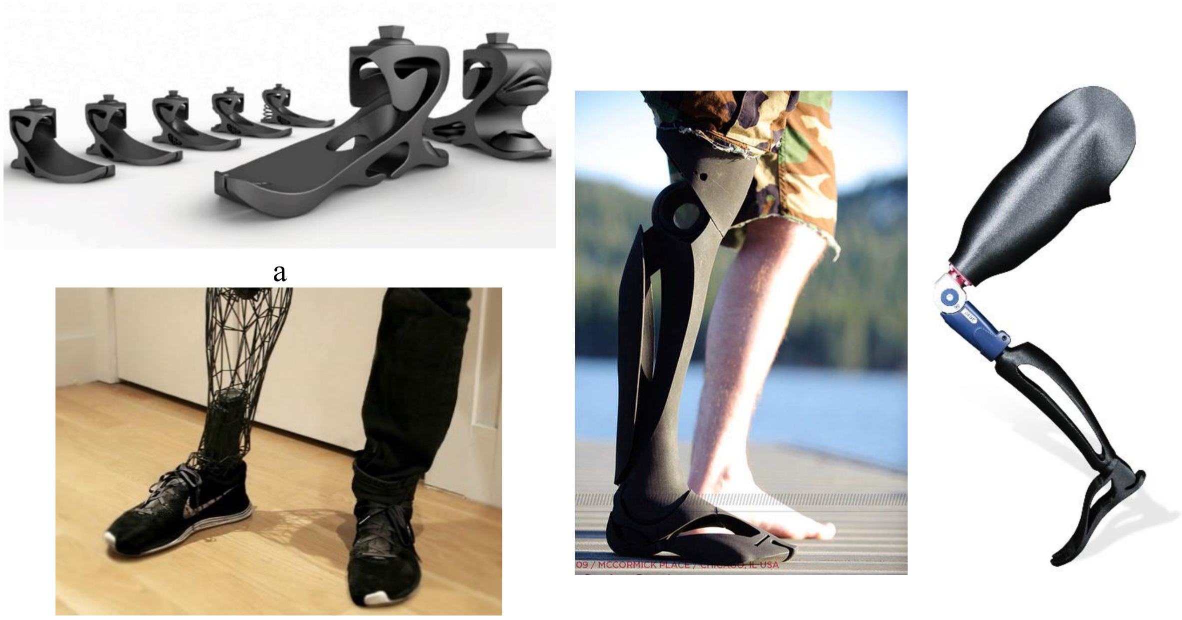
The synergy of topology optimization algorithms, advanced FEM simulations, and rigorous experimental validation thus redefined the design paradigm for prosthetic feet, delivering next generation devices that achieved substantial weight reduction, robust structural integrity, and enhanced user comfort. Continued refinement of these computational experimental pipelines promised further breakthroughs in personalized prosthetic solutions.

3.2. Material selection and composite strategies.

Advanced composites, notably carbon fiber reinforced polymers (CFRP), leveraged high tensile strength and fatigue resistance, making them ideal for load bearing prosthetic elements where long term durability was paramount. Titanium alloys further offered superior biocompatibility and stiffness to weight performance, although their adoption was limited by higher costs and specialized printing requirements [18].

Glass fiber reinforced polymers represented an intermediate solution, combining enhanced dynamic load capacity with relatively straightforward processing; studies reported improved shock absorption and wearer comfort when used for socket interfaces [19]. Recent investigations into hybrid materials incorporating nanoparticles or thermoplastic matrices showed promise for tuning damping characteristics and achieving tailor made stiffness gradients [20,21].

Ongoing research explored novel biomaterials such as shape memory polymers and piezoelectric composites, which could enable adaptive stiffness modulation and embedded sensing in next generation prosthetics [22]. By aligning material properties with functional requirements such as mass reduction, energy return, and interface comfort, designers created prosthetic feet that optimized both performance and patient experience. Representative material based prototypes were presented in Figure 3 (a–d).



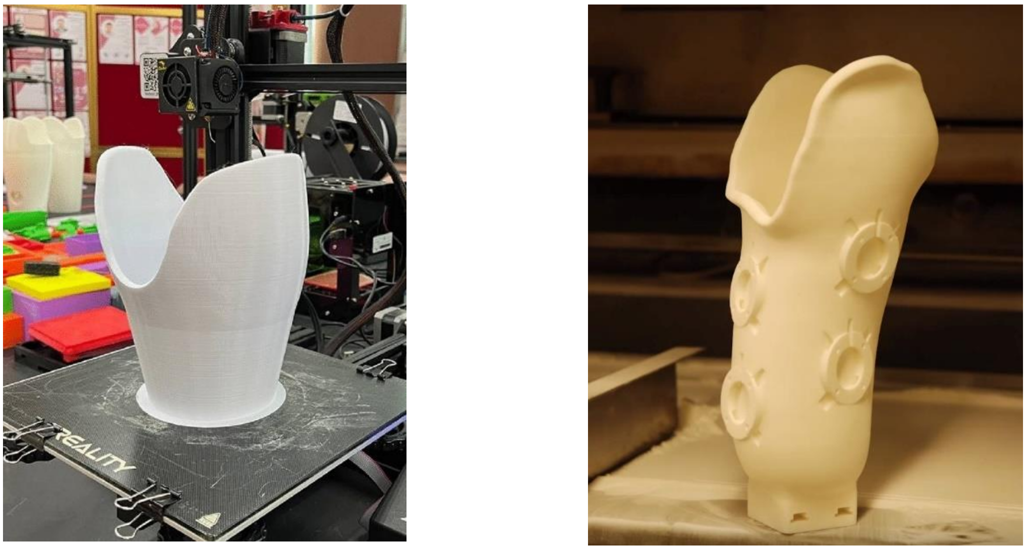
a b c d

Figure 3. Examples of 3D-printed prostheses: (a) PLA, (b) Ti-lattice, (c) CFRP, (d) composite.

4. Manufacturing Techniques

4.1. Additive manufacturing methods.

Additive manufacturing (AM) comprised layer by layer fabrication techniques that translated digital prosthetic designs into physical components with high geometric complexity and customization. Fused Deposition Modeling (FDM) utilized thermoplastic filaments such as PLA, ABS, and TPU extruded through a heated nozzle to build parts sequentially, offering a cost effective route for rapid prototyping and iterative design validation. A representative FDM printed prosthetic socket was shown in Figure 4(a). Selective Laser Sintering (SLS) fused powdered polymers such as nylon 66 or TPU with a laser beam, producing parts with superior mechanical strength and isotropic behavior. Figure 4(b) illustrated an SLS fabricated prosthetic socket featuring smooth surfaces and uniform density.



a b

Figure 4. Representative AM prototypes: (a) FDM-printed prosthetic socket; (b) SLS- fabricated prosthetic socket.

Stereolithography (SLA) cured photopolymeric resins via UV light, delivering exceptional surface finish and dimensional accuracy that were ideal for intricate lattice structures and socket interfaces. Post curing steps enhanced mechanical properties for dynamic load bearing applications. Digital Light Processing (DLP) and Multi Jet Fusion (MJF) further expanded material capabilities and build speeds by projecting entire layers or fusing powder with liquid agents. Metal AM methods, including Direct Metal Laser Sintering (DMLS) and Electron Beam Melting (EBM), enabled fabrication of titanium or aluminum lattice architectures for load bearing prosthetic elements, requiring precise thermal management and post processing. The general FDM process schematic was depicted in Figure 5, while Figure 6 presented a scan to print workflow from medical imaging to post processing.

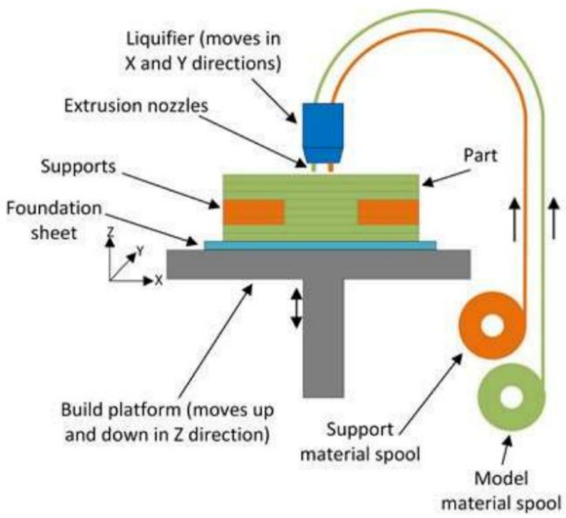


Figure 5. FDM process schematic.

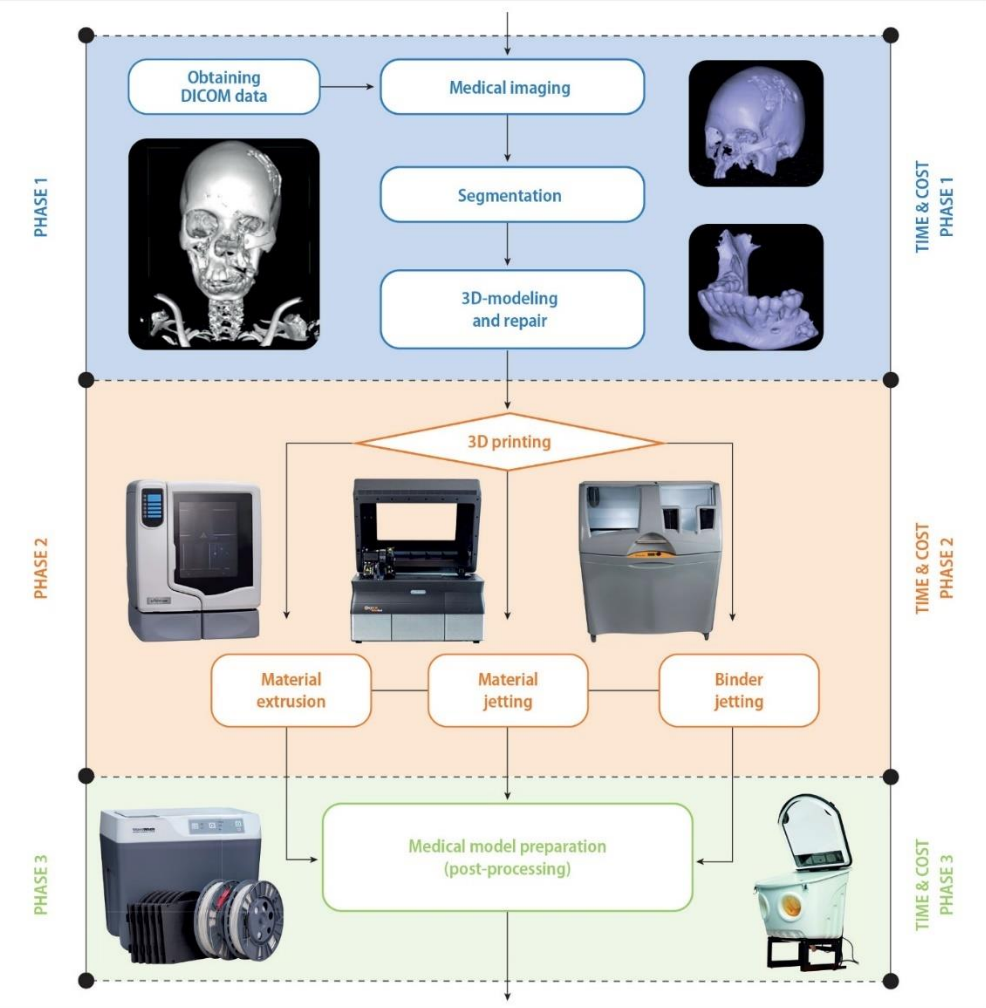


Figure 6. Scan-to-print workflow from medical imaging to post-processing.

Critical build parameters such as orientation, layer thickness, and infill density could be tuned to balance mechanical anisotropy, mass, and surface finish. Advanced slicing algorithms that supported graded infill and variable density further customized prosthetic comfort and durability. This flexibility accelerated design iterations and enabled decentralized manufacturing, bringing patient specific prosthetic solutions closer to point of care environments.

4.2. Production efficiency and cost analysis.

Additive manufacturing (AM) streamlined prosthetic foot production by collapsing traditional multistep workflows such as CNC machining and manual composite layup, which could take two to six weeks, into efficient digital to physical processes that delivered components in 24 to 72 hours [23,24]. Rapid turnaround enabled same day prototyping and fitting, accelerating the design iteration cycle and improving patient care in rehabilitation settings. Material utilization in AM minimized waste, as thermoplastic processes such as FDM and powder based methods including SLS and MJF reclaimed excess filament or powder, cutting raw material consumption by up to 75% compared with subtractive techniques. Economically, personalized three dimensional printed prosthetic feet incurred material costs of USD 100 to 150, more than 85% lower than off the shelf alternatives priced between USD 1,000 and 2,500, thereby expanding access for users [25].

Environmental assessments revealed that AM processes consumed roughly 30% less energy and generated fewer carbon emissions due to reduced machining and waste management requirements [26]. Furthermore, decentralized manufacturing via desktop or clinic based AM systems cut shipping and inventory overhead, ensuring timely delivery of patient specific devices directly at point of care. Despite these benefits, high entry costs, since industrial grade SLS or DMLS machines could exceed USD 200,000, posed barriers for smaller clinics. Flexible business models, including pay per part service bureaus and leasing arrangements, mitigated capital burdens, allowing wider adoption of advanced AM technologies without significant upfront investment [27].

5. Performance and Testing

5.1. Finite element analysis (FEA).

FEA provided a rigorous computational framework to predict and optimize the mechanical performance of topology optimized prosthetic feet under realistic gait conditions. The workflow began by importing the optimized CAD model into professional simulation environments such as ANSYS® or Abaqus®, followed by meshing with tetrahedral elements (edge length 1 to 2 mm) to ensure mesh convergence without excessive computational cost [28]. Material properties were defined using linear elastic models; for instance, Polylactic Acid (PLA) exhibited a Young's modulus of approximately 3.5 GPa and a Poisson's ratio of 0.35. Variations in properties for composites and metals required case by case consideration [29].

Boundary conditions replicated multiphase gait loading, including heel strike with peak ground reaction forces up to 1.2 times body weight, mid stance, and toe off, by applying distributed pressures over contact surfaces while constraining the proximal interface to simulate socket attachment. Static structural analyses yielded von Mises stress distributions and nodal displacements, verifying that peak stresses remained below material yield limits and deformations remained within comfort thresholds of 2 mm or less [30]. Fatigue analyses applied cyclic loading histories over 10^5 to 10^6 cycles using S–N fatigue curves to predict life expectancy and identify critical regions susceptible to crack initiation [14]. Safety factors derived from these studies ranged between 1.2 and 2.0, ensuring prosthetic reliability under repeated use [31].

Parametric FEA studies systematically varied design variables such as infill density, lattice topology, and wall thickness to assess impacts on stiffness, weight, and stress concentration. Results demonstrated trade offs between mass reduction, up to 70%, and mechanical robustness, guiding optimal configurations that balanced performance and durability [32]. By integrating high fidelity FEA into the design cycle, researchers iteratively refined prosthetic foot geometries, anticipated failure modes, and tailored performance to individual patient requirements, thereby bridging computational optimization with clinically reliable devices.

5.2. Experimental validation.

Experimental validation was essential for translating topology optimized prosthetic foot designs into reliable, real world applications. Prototypes fabricated via desktop AM systems such as FDM for thermoplastics or industrial SLS for composites underwent post processing steps such as support removal and surface finishing to prepare for mechanical assessment [33].

Under ISO 10328 static load testing, samples mounted on custom ankle foot fixtures endured progressively increasing loads until structural failure or predefined safety factors were reached; results typically aligned with FEA predictions within a 5% margin for stiffness and peak load capacity [34]. Fatigue performance was evaluated through cyclic loading at 1 to 2 Hz for 10^5 to 5×10^5 cycles, with load amplitudes set to 1.0 to 1.2 times body weight to mimic daily gait; optimized designs consistently exceeded 10^5 cycles without crack initiation, corroborating safety factors of 1.2 to 2.0 derived from S–N curve analyses [31]. Sagittal plane gait simulators further measured force displacement hysteresis to quantify energy return, revealing 20 to 30% improvements over non optimized counterparts and confirming enhancements in walking efficiency. Finally, wearer trials with transtibial amputees provided qualitative insights into fit, comfort, and gait symmetry, with participants reporting reduced socket pressure and greater stability, thus validating laboratory metrics in clinical contexts [35]. Together, these integrated validation methods ensured that three dimensional printed, topology optimized prosthetic feet met stringent performance, durability, and user experience criteria. Figure 7 provided visual context for a user trial session with a transtibial amputee, illustrating real world fit and gait assessment.

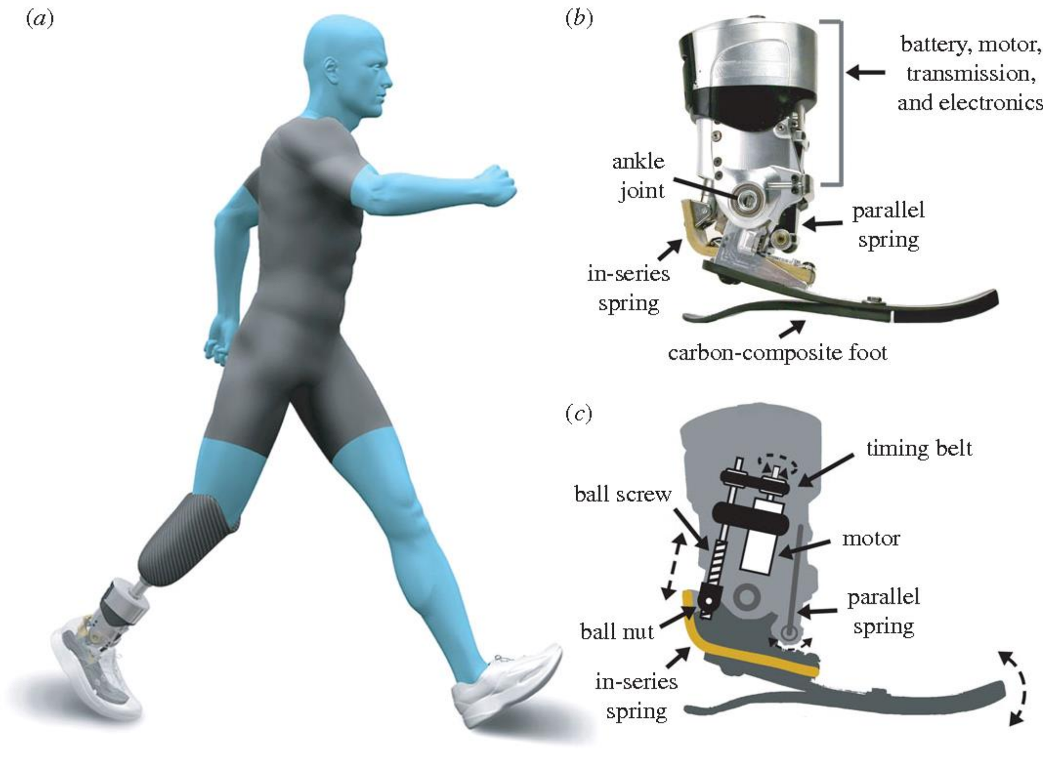


Figure 7. Transtibial amputee trial assessing fit and gait. adapted from Highsmith et al., 2018 [12].

6. Discussion

The transformative integration of topology optimization and additive manufacturing (AM) redefined prosthetic foot design. Topology optimization achieved mass reductions of 50 to 70% [15], yielding lightweight structures that aligned with patient specific biomechanics. Material innovations extended from prototyping thermoplastics such as PLA and nylon 66 to advanced composites such as CFRP and titanium lattice architectures, which provided superior strength to weight ratios and fatigue resistance [36,37]. Additive fabrication methods faithfully realized these designs with deviations under 5% from FEA predictions, underscoring the precision of

AM in replicating complex geometries. Rigorous validation protocols confirmed mechanical reliability. ISO 22675 static load tests and fatigue trials demonstrated safety factors of 1.2 to 2.0 over more than 10^5 cycles [38]. Dynamic gait simulations recorded 20 to 30% improvements in energy return [39], and wearer trials reported enhanced socket comfort and gait symmetry [40]. Complementary data, such as S–N fatigue curves and PLA stress strain behavior, provided deeper insight into material endurance [41]. Gait symmetry analysis further illustrated the clinical impact of optimized designs. Key challenges remained in accurately modeling the soft tissue interface for fit optimization [42] and in harmonizing regulatory pathways for patient specific AM devices [32]. Expanding mechanical standards and creating open access repositories enhanced reproducibility and accelerated clinical translation [24]. Future advances were expected to incorporate embedded sensor arrays for real time monitoring and to leverage smart materials such as shape memory and piezoelectric composites to enable adaptive prosthetic functions. By synthesizing computational design, advanced materials, precise fabrication, and comprehensive validation, this review charted a roadmap for next generation prosthetic feet that combined performance, durability, and patient centered comfort.

7. Challenges and Future Directions

7.1. Fit customization and interface comfort.

A precise fit and comfortable interface were critical determinants of prosthetic adoption and long term user satisfaction, as even minor mismatches could induce pressure ulcers, skin irritation, and asymmetries in gait [43]. To address this, modern prosthetic workflows leveraged high resolution 3D scanning using structured light or laser systems to capture the residual limb's detailed geometry, complemented by digital pressure mapping under static and dynamic loads [44,45]. Integration of this geometric and biomechanical data with topology optimization generated socket designs featuring variable wall thicknesses and graded compliance zones that redistributed interface stresses, minimized peak pressures, and enhanced wearer comfort.

Additive manufacturing realized these complex socket geometries directly from optimized CAD models. Internal lattice structures were tailored to provide cushioning in high pressure areas without adding significant bulk, while external contours conformed closely to the limb surface. Multi material printing further enabled seamless integration of rigid support elements and soft elastomeric liners, creating stiffness gradients that mimicked the mechanical behavior of biological tissue and reduced interface pressure by up to 30%. Post printing, in socket pressure sensors validated the design by mapping real time load distributions. Rapid digital adjustments, such as localized wall thickness modifications or liner material changes, were implemented through targeted reprinting, closing the loop between data driven design and clinical feedback [44]. Small cohort studies reported marked improvements in comfort scores and a reduction in prosthesis abandonment when optimized sockets were used [46].

Future advancements were expected to integrate embedded micro sensors for continuous interface monitoring and to exploit adaptive materials such as shape memory polymers and piezoelectric composites that dynamically adjusted stiffness in response to activity levels. These innovations promised not only to optimize fit and comfort but also to empower users with real time feedback, driving a new paradigm in personalized prosthetic care.

7.2. Advanced materials and bio-inspired designs.

Recent Recent research prioritized advanced biomaterials and bio inspired architectures to elevate prosthetic foot functionality. Shape memory polymers exhibited reversible stiffness changes under thermal or electrical stimuli, allowing prosthetic elements to adapt dynamically to varying load conditions and thereby enhancing energy storage and return during gait cycles [47]. Piezoelectric composites, which generated electric charges upon deformation, were integrated within lattice interiors to monitor stress distributions in real time, informing adaptive control strategies and promoting a more natural user experience [48].

Drawing inspiration from nature's optimized structures, designers employed triply periodic minimal surface (TPMS) geometries, mimicking trabecular bone and plant venation networks, to create hierarchical lattices that optimized load paths while minimizing material usage. Studies reported that TPMS based infills combined with gradient porosity boosted energy return by up to 15% and extended fatigue life, closely mirroring the nonlinear elasticity of human plantar tissues. In parallel, hydrogel based liners enriched with biocompatible nanoparticles provided a conformal cushion at the limb–socket interface, mitigated shear forces, and maintained optimal moisture levels. Cast or 3D printed hydrogels demonstrated significant reductions in interface temperature and ulceration risk, improving long term comfort in clinical trials.

To enhance surface durability and hygiene, nanocomposite coatings comprising ceramic or metallic nanoparticles dispersed in polymer matrices offered superior wear resistance and intrinsic antimicrobial action. Surface treatments such as plasma activation and laser texturing further improved coating adhesion and longevity, ensuring prosthetic interfaces remained robust under daily use. By fusing these smart materials with bio inspired design principles, next generation prosthetic feet not only delivered mechanical excellence but also supported user health through responsive, adaptive interfaces. This convergence of material innovation and biomimicry heralded a transformative era in prosthetic technology, prioritizing both performance and patient well being.

7.3. Regulatory and clinical validation.

The translation of topology optimized, 3D printed prosthetic feet from research prototypes to clinical practice was a complex process that involved adherence to rigorous regulatory standards and comprehensive clinical evaluations. Central to this process was the establishment of a Quality Management System that complied with ISO 13485, which offered a framework for effective design controls and risk management as stipulated by ISO 14971. This systematic approach was crucial for identifying and mitigating hazards associated with medical devices [49]. Furthermore, for regulatory submissions as outlined in the FDA's 510(k) pathway or the EU's Medical Device Regulation (MDR 2017/745), substantial documentation was required. This documentation included device descriptions, results of validation reports such as finite element analysis and mechanical testing according to ISO 10328, biocompatibility data, and appropriate labeling that demonstrated either substantial equivalence to existing devices or distinct performance claims [48,49].

The clinical validation phase aligned with Good Clinical Practice guidelines as described in ISO 14155. This entailed conducting prospective clinical investigations or compiling comprehensive clinical evaluation reports that incorporated existing literature, post market data, and user feedback. Essential clinical endpoints during these evaluations included safety metrics such as adverse event rates, effectiveness indicators such as gait symmetry and energy return, and patient reported outcomes concerning comfort and quality of life. Research indicated that small cohort studies and multicenter trials were vital for assessing real world performance, leading to better risk–benefit analyses necessary for regulatory approvals [50,51]. Continuous engagement with end users was paramount, as their feedback significantly informed iterative design improvements and enhanced functionality in real world settings [54].

Post market surveillance strategies and vigilance systems were established to monitor long term performance, identify device failures, and measure patient satisfaction. These systems captured and analyzed real world evidence from platforms and patient registries, ensuring ongoing safety monitoring and fostering continuous innovation [55]. This comprehensive approach not only aided in maintaining compliance with regulatory standards but also assured that advanced additive manufacturing prosthetic solutions seamlessly integrated into clinical practice, offering amputees access to high quality care [56]. Collaborative efforts among clinicians, researchers, and stakeholders were essential to bridge the gap between innovative prosthetic technologies and their practical application, ensuring that the transition from prototypes to marketable solutions was both ethical and clinically viable [49].

7.4. Integrated sensor systems.

Embedding sensor systems within topology optimized, 3D printed prosthetic feet played a crucial role in advancing the functionality and effectiveness of prosthetic devices. These embedded systems enabled continuous monitoring of mechanical and physiological parameters, enhancing adaptive performance and preventive care for users [46]. For instance, thin film strain gauges and piezoelectric sensors positioned within the lattice structures of a prosthetic foot captured real time load distributions during ambulation. This integration allowed for a comprehensive analysis of stress profiles experienced by the prosthetic foot, which was essential for evaluating socket fit and load management [43].

In addition to strain and pressure sensors, inertial measurement units contributed by tracking gait dynamics and alignment deviations, thus providing valuable feedback regarding user movement patterns [57]. This data was wirelessly transmitted to onboard processors or external systems equipped with closed loop control algorithms. These algorithms were capable of adjusting stiffness gradients or sending alerts when they detected abnormal load distribution patterns that could indicate joint stress or poor fit, hence preemptively addressing potential complications [58]. To achieve the effective integration of such sensor arrays without compromising the structural integrity or user comfort of the prosthetic device, advanced implementations leveraged flexible printed electronics paired with biocompatible encapsulants [59]. This approach ensured that the operational lifetime of the sensor networks was maximized, supplemented by energy harvesting materials such as piezoelectric composites that facilitated power efficient operation, reducing reliance on battery replacements [60].

Clinical pilot studies underlined the efficacy of sensor augmented prosthetics; findings indicated a reduction in skin breakdown incidents by up to 20% through the early detection of hotspot formation. Moreover, quantified metrics regarding stride symmetry and weight bearing asymmetries permitted personalized rehabilitation protocols, enhancing user engagement and outcomes [44]. By employing the synergistic advantages of topology optimization, additive manufacturing techniques, and sensor integration, future prosthetic feet embodied the principles of real time responsiveness and predictive maintenance, ultimately paving the way for a more intelligent, patient centered prosthetic care model [45].

8. Conclusion

The The comprehensive integration of topology optimization and additive manufacturing has ushered in a new era for prosthetic foot design, delivering devices that are highly customized, lightweight, and biomechanically superior. This review highlighted that optimized geometries, realized through precision 3D printing, achieved mass reductions of up to 70% while maintaining safety factors above 1.5. Advanced materials, ranging from thermoplastics to smart composites, further enhanced energy return, fatigue life, and user comfort. Rigorous validation, including high fidelity finite element analysis, static and fatigue testing, gait simulations, and wearer trials, confirmed the reliability and clinical relevance of these approaches. Nevertheless, barriers persisted in long term clinical validation, fit personalization, regulatory harmonization, and standardized workflows. To advance the field, future investigations should prioritize large scale, multicenter clinical trials to establish long term efficacy and patient outcomes; develop open access repositories and standardized protocols for design, testing, and regulatory documentation; explore adaptive materials such as stimuli responsive polymers and integrated piezoelectric sensing for real time stiffness modulation and health monitoring; integrate machine learning algorithms with embedded sensor networks for predictive maintenance and gait optimization; and conduct economic and life cycle analyses to assess scalability, sustainability, and accessibility across diverse healthcare settings. Addressing these areas will enable researchers and clinicians to collaboratively translate next generation, intelligent prosthetic feet into widespread clinical practice, ultimately enhancing mobility and quality of life for amputees worldwide.

Acknowledgments

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