

A Cost-Effective, Thermally Optimized Transradial Prosthesis using Nylon PA12: A Single-Subject Case Study on Mechanical and Functional Validation

Carlos M Carrillo¹ ; Bryan D González¹ ; Thalía D San Antonio¹ 

¹Universidad Técnica de Ambato, Facultad de Ingeniería Civil y Mecánica, Ambato, Ecuador, cmcarrillo@uta.edu.ec, davidgonzalezv03@gmail.com, t.sanantonio@uta.edu.ec

Abstract— Upper limb amputation has a major impact on quality of life; however, the cost of traditional prostheses is often beyond the reach of users in developing economies. Though 3D printing has enhanced accessibility, the commonly used material, PLA, is prone to degradation and generates heat within the socket. This paper describes a single-subject case study concerning the development of a low-cost, thermally optimized transradial prosthesis made from Nylon PA12. The device was designed using a User-Centered Design approach and customized through 3D scanning and validated via Finite Element Analysis (FEA). Most importantly, material properties used in the simulation were not generic but experimentally characterized according to ASTM D638, ASTM D790, and ISO 868 standards. The simulation gave an FOS value greater than 3.0 for the critical load of 300 N. Additionally, flammability testing (ISO 11925-2) and thermographic analysis proved that the Nylon PA12 socket can be considered as safe self-extinguishing thermal insulation. Functional field tests indicated that the participant was able to manipulate industrial tools with a weight of up to 5 kg successfully. These preliminary findings indicate that experimentally characterized Nylon PA12 can be considered as an alternative material for affordable rehabilitation concerning mechanical durability and thermal comfort in low-resource settings.

Keywords— Transradial prosthesis, Additive manufacturing, Nylon PA12, Thermal comfort, FEA.

I. INTRODUCTION

Amputation of the upper limb is a catastrophic problem in public health and rehabilitation physically, since it changes completely the way a person relates to his environment [1]. The loss of a limb affects not only physical functionality but also imposes severe psychological distress and social stigmatization on the amputee, thus affecting the overall well-being of an amputee [2]. In high-income nations, advanced myoelectric and robotic prostheses offer a solution to restore function; however, these devices come with a prohibitive price tag, often ranging from thousands to tens of thousands of thousands of thousands of thousands of dollars. For most amputees living in developing economies, such costs render high-performance rehabilitation inaccessible, perpetuating a cycle of disability and poverty [3], [4].

Because of these systemic financial constraints, Additive Manufacturing (AM) in general, and specifically Fused Deposition Modeling (FDM), has become a disruptive technology within the medical field. It allows decentralized

fabrication of custom prosthetic devices at very low costs compared to traditional manufacturing; hence, 3D printing possibilities democratize access to rehabilitation [5], [6]. This shift in technology made it possible for researchers and hobbyists to build functional hands and arms using cheap desktop 3D printers. Nevertheless, the fast spread of these devices ran into a big bottleneck in material science which limits their clinical viability.

Polylactic Acid (PLA) is still the standard material for low-cost prosthetic prototyping because it is easy to print and biodegradable. PLA would be suitable for visual prototypes or light usage but has critical deficiencies when applied clinically for the long term since it has low thermal stability and high hygroscopicity; hence, it will degrade very fast when subjected to environmental humidity and body sweat [7]. Standard thermoplastics do not have required mechanical properties for manual labor that can lead to early failure of such devices [8]. Most "low-cost" prostheses are therefore short-term solutions since they do not cater to the daily needs of users.

In addition to mechanical failure, another important aspect of prosthetic design that is often ignored is thermal management. For transradial amputees, the prosthetic socket creates a semi-closed microenvironment that can easily trap heat. High temperatures at the interface with the residual limb can lead to excessive sweating, skin maceration, and bacterial growth. These dermatological problems may not be very pleasant but are major causes for abandoning the device; they are primary drivers of device abandonment [2]. Users in tropical climates or industrial working conditions are particularly vulnerable and often must choose between functional restoration and physical comfort.

This study addresses these limitations by proposing a shift toward engineering-grade thermoplastics. Unlike PLA or Acrylonitrile Butadiene Styrene (ABS), Nylon PA12 (Polyamide 12) has a better balance of mechanical properties. It has high tensile strength and high flexibility without fracture, and more importantly, low thermal conductivity [8], [9]. This property allows the material to be an effective thermal insulator as it hinders temperature transfer from the outside to inside environment of a material.

Despite these theoretical advantages, there is a lack of comprehensive literature validating the use of Nylon PA12 in low-cost prosthetics through a rigorous engineering lens. Most

existing studies focus on geometric design rather than material characterization. This paper fills that gap by designing, manufacturing, and experimentally validating a transradial prosthesis made of Nylon PA12. Adopting a User-Centered Design (UCD) methodology, integrating anatomical fitting through anthropometric 3D scanning [10] with structural validation via Finite Element Analysis (FEA) calibrated with experimental data [11]. The primary objective is to demonstrate that by prioritizing thermodynamic comfort and material durability, it is possible to create an affordable rehabilitation solution that is both functional and comfortable for long-term use in developing economies.

II. METHODOLOGY

A. Study design and ethical considerations

This study used experimental case study design within a UCD framework. This approach ensured that geometric and functional specifications met the user's specific anatomical needs. It aligns with ISO 9241-210 standards, prioritizing physical interaction and environmental context [12]. The development took place at the manufacturing and simulation laboratories of the Faculty of Civil and Mechanical Engineering at Universidad Técnica de Ambato.

The study protocol adhered to the ethical principles of the Declaration of Helsinki [13]. Since the research involved a non-invasive functional assessment of a healthy adult volunteer who provided written informed consent, formal approval from an institutional Ethics Committee was not required under the current internal regulations of the Universidad Técnica de Ambato. The participant was fully informed about the study's scope, potential risks, and benefits prior to data collection and consented to the publication of the results and images.

B. Anthropometric digitization and parametric modelling

A non-contact optical metrology was used to capture the residual limb's geometry. This guarantees a fit that minimizes contact pressure and improves suspension. A CR Ferret Pro high-precision 3D scanner generated a point cloud of the stump with accuracy of ± 0.01 mm (Fig. 1). This captured the minute anatomical details needed for the socket interface [14].



Fig. 1 High-precision digital acquisition of the residual limb geometry using the CR Ferret Pro 3D scanner to ensure anatomical socket fit.

Simultaneously, manual measurements were obtained from the user's sound limb to establish baseline dimensions. To restore visual and biomechanical symmetry, the length and volume of the prosthetic forearm were extrapolated using McCallum's body proportion formulas [10]. The data were imported into SolidWorks® 2023 to model the socket and forearm. The design uses "shell" architecture. This reduces weight but maintains enough wall thickness to support the scapular traction harness.

Specifically, the modeling process utilized surface lofting techniques to create smooth transitions between the distal and proximal cross-sections of the residual limb, minimizing friction points. Special attention was paid to the proximal trim line; the edges were filleted with a radius of 5 mm to prevent soft tissue impingement during full elbow flexion. Furthermore, the shell thickness was designed to be variable: reinforced to 4 mm at the distal end to firmly anchor the wrist unit screws and tapering to 3 mm at the proximal opening to reduce total suspended mass without compromising structural stability.

C. Material selection and additive manufacturing

Material selection focused on two needs: mechanical durability and thermodynamic regulation. While PLA is standard for prototyping, Nylon PA12 (Polyamide 12) was chosen for the final component. Nylon PA12 offers better tensile strength and, crucially, low thermal conductivity. This allows it to act as an insulator against environmental heat [8], [9].

The prosthesis was manufactured using Fused Deposition Modeling (FDM). To improve layer adhesion and minimize anisotropy, a typical failure mode for FDM parts, the printing parameters were strictly controlled. These included a nozzle temperature of 250°C, a layer height of 0.2 mm, and 100% infill density in high-stress connection zones [9].

Nylon PA12 processing demands specific attention since it has a tendency for thermal shrinkage which affects dimensional accuracy. A heated bed at 100°C was used with polyamide-specific adhesive to mitigate warping at the build plate interface, a common defect in high-temperature polyamides that compromise part fit. The printer was also kept inside a passive thermal chamber to allow stable ambient temperature during the print cycle of 37 hours. This controlled environment prevented layer delamination caused by rapid cooling drafts, promoting stronger interlayer bonding and reducing mechanical anisotropy in the Z-axis. Finally, a skin-tone resin to seal surface porosity was applied, improving aesthetics and facilitating hygiene [15].

D. Computational simulation and structural validation

Before manufacturing, the design's structural integrity was validated using Finite Element Analysis (FEA) in ANSYS Academic®. The simulation replicated stresses from heavy lifting and daily use. A mesh sensitivity analysis verified convergence. Importantly, the material properties for Nylon PA12 were defined based on the experimental data obtained

from the mechanical characterization (Table I), ensuring the simulation reflected the actual performance of the printed material.

TABLE I
EXPERIMENTAL MECHANICAL PROPERTIES OF 3D-PRINTED NYLON PA12
SPECIMENS

Property	Standard	Average Value	Unit
Tensile Strength (σ_{max})	ASTM D638	26.14	MPa
Elastic Modulus (E)	ASTM D638	1.24	GPa
Flexural Strength	ASTM D790	51.23	MPa
Flexural Modulus	ASTM D790	1.84	GPa
Hardness	ISO 868	85.30	Shore D

The forearm assembly was tested under static loading, starting at 50 N and increasing to a critical load of 300 N at the distal end. This mimics the moment arm effect during lifting [16]. The analysis used von Mises stress distribution to identify stress concentrators and calculate the Safety Factor (SF). Additionally, fatigue failure theories were applied (Modified Goodman and ASME Elliptic) to the connecting shaft of the terminal device to predict the lifecycle of the metal-polymer interface under cyclic loading [17].

E. Experimental characterization and functional testing

The validation phase included material characterization and field testing. Mechanical characterization at the Materials Resistance Laboratory of the Universidad Técnica de Ambato were conducted to ensure the simulation model was accurate. Tensile properties were evaluated according to ASTM D638 [18], and flexural strength followed ASTM D790 [19]. Surface hardness was measured using the ISO 868 (Shore D) standard [20].

Flammability tests were carried out at Mechanical Investigation Laboratory (LIM) to meet standards for safety certification on skin contact under NTE INEN-ISO 11925-2 [21]. These tests measured flames spread and self-extinguishing capability. The rate of heat transfer (Q) through the socket wall was analyzed for thermal validation using thermographic imaging combined with Fourier's law [21] while exposing its outer surface to a controlled heating source.

Functional efficacy was determined by the user's performance in Activities of Daily Living (ADLs). The participant performed standardized tasks such as feeding, dressing, and handling tools with loads up to 5 kg. These tests verified the efficiency of the scapular traction mechanism and the reliability of the standard Hosmer 8X stainless steel hook [22].

III. RESULTS

A. Mechanical and Physical Characterization of Nylon PA12

The experimental characterization of the FDM-printed Nylon PA12 specimens provided the specific material constants necessary for the Finite Element Analysis. The material has an average tensile strength of 26.14 MPa and a flexural modulus of 1.84 GPa, as shown in Table I. The average value from the Shore D hardness test is 85.3, which indicates a high resistance to indentation on the surface; this

property is very important for the durability of the prosthetic socket in industrial environments.

B. Anthropometric Validation and Parametric Fit

The digitization process and later parametric modelling achieved anatomical symmetry, which is an important factor for psychosocial acceptance of the device by the user. Using McCallum's body proportion formulas applied to measurements of the sound limb, theoretical forearm length was calculated to be 63.3 cm. Post-fabrication measurement of the prosthetic assembly gave a length of 63.0 cm; thus deviation is less than 0.5% (Fig. 2) [10]. This small difference supports how precise digital acquisition can be and also that printed devices restore biomechanical balance without causing postural compensation in users.

C. Structural Integrity under Static Loading

The simulation replicated stresses from daily use and heavy lifting. Critically, the material properties in ANSYS were updated with specific experimental data from the ASTM D638 and ASTM D790 tests (Table I), rather than using generic library values. The socket showed no deformation under a normal service load of 50 N. This shows a stable interface between the residual limb and the prosthesis.

At a critical load of 300 N, simulating the worst-case scenario of extreme lifting, the socket maintained a global Safety Factor of 6.96 (Fig. 3). Localized stress concentrations at the points where harness connections are made showed a Safety Factor equal to 3.92; both values exceed the minimum safety threshold for rehabilitation devices [11]. This verifies that shell design is robust against fracture.

D. Thermal Insulation and Material Safety

Improving user comfort in high temperatures was a primary objective. Flammability tests (ISO 11925-2) showed that the printed Nylon PA12 is self-extinguishing. Exposed to a direct flame, vertical flame spread was consistently below 150 mm (average 40–45 mm), with no flaming droplets [21].

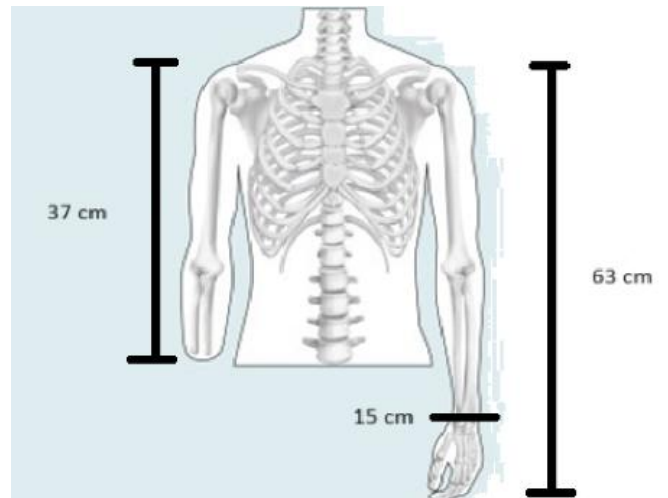


Fig. 2 Patient prosthetic assembly dimensions needed for the application of McCallum's formulas.

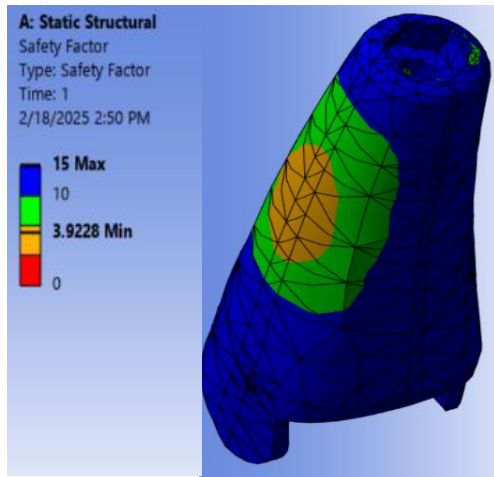


Fig. 3 FEA results showing the safety factors across the prosthetic socket under a critical load of 300 N.

Analysis by thermography confirmed insulating properties for this material; when exposed to its outer surface to approximately $\sim 399^{\circ}\text{C}$ temperature, it kept an internal skin-contact surface within safe ranges between 41.1°C and up to as high as 47.2°C (Fig. 4). This steep thermal gradient supports calculated heat transfer $Q=23.34\text{ W}$ thereby proving that socket acts effectively like a barrier against external heat.

E. Assembly Mechanics and Fatigue Life

The mechanical reliability of the gripping mechanism was evaluated. Fatigue analysis of the stainless-steel connecting shaft, using Modified Goodman and ASME Elliptic criteria, yielded SF of 10.04 and 9.44, respectively [17]. This predicts an extended service life for the metal components, well beyond the clinical obsolescence of the socket itself.

The complete prosthetic system (socket, wrist unit, and hook) was tested under a maximum combined load of 240 N which resulted in an ultimate deformation of just 1.28 mm and an average Safety Factor of 3.14 (Fig. 5). These findings prove that the assembly is sufficiently stiff for accurate handling but has enough elasticity to absorb shocks and avoid brittle failure.

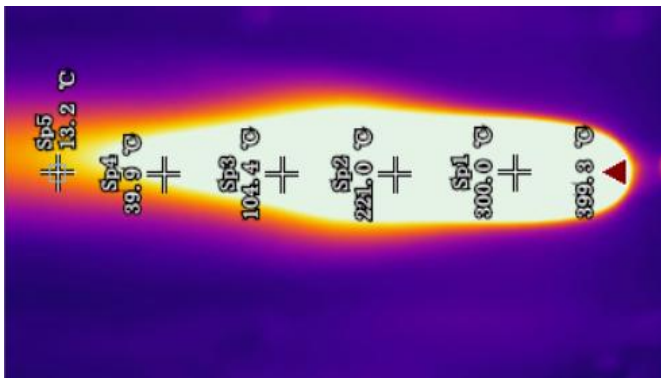


Fig. 4 Thermographic characterization of the Nylon PA12 used to build the socket showing effective thermal insulation properties under point-source heat exposure (399.3°C).

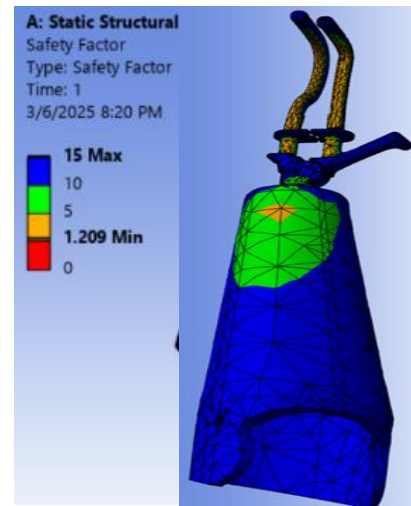


Fig. 5 FEA results for structural simulation of the prosthetic assembly, showing the safety factor under a combined operational load of 240 N.

F. Economic Feasibility Analysis

Field testing confirmed the successful translation of the mechanical design into functional restoration. The scapular traction system demonstrated high responsiveness, allowing the user to execute fine motor tasks such as independent feeding using cutlery and dressing without assistance (Fig. 6a). Crucially, the device demonstrated the structural capacity to handle loads up to 5 kg; furthermore, as illustrated in Fig. 6b, it enabled the effective manipulation of industrial tools within the user's actual work environment, validating the simulation results in a real-world scenario. The specific surface treatment with skin-tone resin facilitated social integration, as reported by the user, and no skin irritation was observed after prolonged use, supporting the biocompatibility of the finished Nylon PA12 surface.

G. Economic Feasibility Analysis

The cost-benefit analysis reveals the disruptive potential of this manufacturing approach for developing economies. The total production cost of the prosthetic system was $\sim \$1,040$ USD (Table II). Notably, 66% of this cost ($\$683$ USD) is allocated to the imported medical-grade stainless steel hook (Model 8X) to guarantee clinical reliability [22]. The custom 3D-printed structural components, however, incurred a material and energy cost of only $\sim \$135$ USD. This model concentrates investment on a durable high-quality terminal device, allowing the custom socket, which requires replacement due to residual limb volume changes or damage, to be replaced for under 15% of the total cost, which is significantly cheaper than traditional lamination.

IV. DISCUSSION

Validating Nylon PA12 as a thermally insulating structural medium diverges from the widespread reliance on PLA in low-cost prosthetics. Previous reviews by Ten Kate et al. [7] and Rahim et al. [8] document the mechanical viability

of FDM printing but note that standard thermoplastics suffer from environmental degradation.



Fig. 6. Functional validation in real-world scenarios: (a) independent dressing capabilities demonstrating fine motor control, and (b) manipulation of industrial work tools.

TABLE II
DETAILED COST BREAKDOWN OF THE PROSTHETIC LIMB, HIGHLIGHTING THE LOW COST OF 3D-PRINTED STRUCTURAL COMPONENT.

Category	Description	Cost (USD)
Energy	Power consumption during printing (37 hours)	1.16
Labor	Design and post-processing	108.68
3D Materials	Nylon PA12 filament, PLA (prototyping), Nozzles	134.00
Hardware	Hosmer Hook (Model 8X), Harness, Cables, Resin	794.75
TOTAL	Complete Prosthetic System	1,038.59

The experimental tensile strength of 26.14 MPa obtained in this study is consistent with typical values for FDM-printed polyamides, which usually lie between 20–40 MPa depending on layer orientation [8]. Although it is lower than the ~50 MPa of injection-molded Nylon, it greatly exceeds the maximum

operating stress of 0.63 MPa reported in the FEA simulations under a 300 N load. In addition to that, the hardness recorded at 85.3 Shore D exceeds High-Density Polyethylene (HDPE) used in prosthetics (~65 Shore D), confirming superior resistance to surface abrasion and impact in industrial environments.

The findings directly address the gap in literature, since the experimental data shows low thermal conductivity in the socket that suggests that PLA is unsuitable for long-term clinical use in high-temperature environments due to its limited thermal insulation compared to the Nylon PA12 socket. This study argues that material selection is as important as geometric design. Mitigating heat transfer reduces device abandonment, a major issue in warm environments [2]. To contextualize these findings against the current standard for low-cost prosthetics, a comparative analysis between the experimental Nylon PA12 data and established literature baselines for FDM-printed PLA is presented in Table III. While PLA often exhibits a higher absolute tensile strength, its inherent brittleness, high hygroscopicity, and poor thermal stability render it inadequate for prolonged clinical use. In contrast, the experimentally characterized Nylon PA12 demonstrates an optimal balance: it maintains sufficient structural integrity (Safety Factor > 3.0) while providing the critical thermal insulation and environmental durability that PLA lacks.

Clinically, the structural results validate a "hybrid" manufacturing model. This bridges the gap between accessible rapid prototyping and medical-grade reliability. The FEA yielded Safety Factors exceeding 3.0, aligning with Tanaka and Glenn's recommendations [11]. Unlike fully 3D-printed hands, which often have mechanical weaknesses, the use of a standard stainless-steel hook ensures the terminal device is strong enough for industrial work. This means that it is possible to reduce costs without necessarily compromising quality. By limiting the 3D printing process to only the custom socket and using standardized hardware for the terminal device, this solution presents a scalable pathway toward rehabilitation that is accessible.

Besides the direct production costs, the proposed manufacturing model provides an important logistical benefit: decentralized maintenance. In conventional prosthetic supply chains, when a socket gets damaged or adjustments are needed due to volume fluctuation, it usually requires shipping the device back to a central fabrication center. This can leave users without their prosthesis for weeks [3]. The digital nature of this workflow allows on-demand replacement; if a socket is broken or if there's some change in limb volume of the user, then that component could be printed locally within 24 hours using a stored digital file. This drastically reduces downtime and indirect economic costs associated with disability by creating a more sustainable rehabilitation ecosystem.

Though this study proves the feasibility of Nylon PA12 through a UCD process, it should be noted by authors that due to functional testing being conducted on only one subject, statistical generalization cannot be made from such results.

Table III
EXPERIMENTAL MECHANICAL PROPERTIES OF 3D-PRINTED NYLON PA12 SPECIMENS.

Property/ Characteristic	Polylactic Acid (PLA) [8], [7]	Nylon PA12 (Experimental Study)	Clinical Implication for Prosthetics
Tensile Strength	~30 – 45 MPa	26.14 MPa	Adequate static strength; PLA risks brittle failure.
Flexural Modulus	~2.5 – 3.0 GPa	1.84 GPa	Nylon absorbs impacts better without fracturing.
Thermal Conductivity	Moderate / High (Acts as a heat trap)	Low (Acts as an insulator)	Nylon improves thermodynamic comfort.
Hygroscopicity & Degradation	High (Degrades rapidly with environmental humidity/sweat)	Low / Stable	Nylon withstands prolonged skin- contact and sweat.
Thermal Stability	Low (Susceptible to warping at ~60°C)	High (Self-extinguishing, stable internal temps up to 399°C exposure)	Nylon prevents heat deformation in industrial settings.

Future work will focus on expanding the sample size to include varying amputation levels. Additionally, regarding the simulation, although the FEA provided robust initial validation using experimental constants, future iterations will incorporate orthotropic material models to more accurately predict Z-axis anisotropy and long-term fatigue behavior under dynamic loading, as suggested by the limitations of FDM technology [23].

V. CONCLUSION

The main aim was to create, manufacture as well as validate a transradial prosthesis that would provide an appropriate balance between mechanical durability and thermal comfort at an affordable price point. It has been proven since standard prototyping plastics were replaced with Nylon PA12 additive manufacturing could yield a functional device capable of enduring industrial rigor [8]. Results confirmed customized socket works efficiently as a thermal insulator. It maintains skin-contact temperatures within a safe physiological range, even under extreme external heat [9].

Mechanical characterization gave an impressive Safety Factor of 3.14 for the whole assembly, which is above recommended standards for rehabilitation [11]. This allowed the user to handle loads up to 5 kg. More importantly, this functional restoration costs about \$1,040 USD which is way less than what laminated body-powered prostheses typically cost conventionally [4], [5].

These results challenge the assumption that thermal comfort is secondary to mechanics in low-cost prosthetics. User acceptance is likely determined as much by thermal regulation as by kinematic function [2]. For clinical management, this "hybrid" model comprising a custom 3D-printed socket and a standardized stainless steel terminal device [22] provides an option that can be scaled easily. It indicates that healthcare systems in developing economies may achieve reductions in procurement costs while maintaining clinical reliability.

Subsequent work should be directed towards destructive testing of printed Nylon PA12 specimens at various orientations for further optimization of safety coefficients.

Longitudinal studies are necessary to monitor dermatological interactions between resin-treated Nylon and residual limb over a long period. This study is, therefore, a step forward in prosthetic manufacturing by demonstrating that cost-effectiveness does not entail compromising the user's quality of life.

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