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Original Research Article

Additively manufactured patient-specific transtibial prosthesis for enhanced biomechanical performance and comfort

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Abstract: Affordable transtibial prosthetic solutions often lack optimal gait mechanics, thermal comfort, and structural customization. In contrast, advanced prosthetics provide improved performance but remain economically inaccessible for many users. This work presents the design and development of a patient-specific transtibial prosthesis fabricated using additive manufacturing techniques to improve comfort, adaptability, and biomechanical performance while maintaining affordability. A digital workflow is adopted where Computed Tomography (CT) scan data of the residual limb is used to design a customized prosthetic socket. The socket is fabricated using fused filament fabrication (FFF) with Polylactic Acid (PLA) and incorporates ventilation features to reduce perspiration and skin irritation. Structural reinforcement is introduced in the socket–pylon interface to address anisotropic strength characteristics of FFF components. A lightweight carbon fiber pylon replaces the conventional stainless-steel pylon to reduce overall prosthesis weight. The ankle–foot assembly consists of a hybrid PLA– Thermoplastic Polyurethane (TPU) structure with two degrees of freedom, including plantarflexion-dorsiflexion at an articulated ankle joint with a safe motion range and compliant bending at the toe region. Stiffness of the foot structure can be customized according to user requirements by modifying TPU printing parameters. The proposed design demonstrates the potential of additive manufacturing for developing patient-specific, affordable, lightweight, and biomechanically responsive transtibial prosthetic systems.

I. Introduction

Lower limb amputation significantly affects mobility, independence, and quality of life. Transtibial amputations represent a substantial proportion of lower-limb amputations worldwide. Access to affordable and functional prosthetic limbs remains a major challenge among low-income populations, where cost remains the primary constraint in prosthetic adoption. The Jaipur Foot (a well-known transtibial prosthesis developed in Jaipur, India), Solid Ankle Cushioned Heel (SACH) foot and other similar entry level prostheses are widely used due to their affordability and availability through government and charitable initiatives [1], [2], [3], [4]. While they provide basic mobility, several limitations have been reported such as:

- Limited ankle articulation
- Suboptimal gait mechanics
- Heat retention and perspiration causing discomfort
- Skin irritation and abrasion during prolonged use

On the other hand, advanced prosthetics available globally incorporate energy-storing, carbon fiber structures and articulated ankle mechanisms resulting in enhanced comfort, improved gait biomechanics, and walking efficiency. However, their high-cost limits accessibility for economically disadvantaged populations.

Recent advances in additive manufacturing provide opportunities for developing low-cost, customized prosthetic devices [5], [6]. Additive manufacturing combined with a digital design approach enables rapid fabrication, geometric customization, and integration of functional features such as ventilation structures and variable stiffness elements [7], [8].

The present work focuses on the design and development of a patient-specific transtibial prosthesis using a fully

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digital workflow and additive manufacturing techniques. The design incorporates customized socket geometry for enhanced fitting, improved ventilation through air vents to reduce perspiration and discomfort during prolonged usage, redesigned socket-pylon interface to account for anisotropic strength characteristics associated with additive manufacturing. A lightweight carbon fiber pylon is employed to reduce overall prosthesis weight as compared to conventional stainless-steel pylons. The ankle-foot assembly is designed as a hybrid structure incorporating Polylactic Acid (PLA) for structural support and Thermoplastic Polyurethane (TPU) for compliant mechanism [9], [10]. This provides two degrees of freedom, including an articulated plantarflexion–dorsiflexion at the ankle joint and compliant bending at the toe region, allowing improved biomechanical response during walking. The stiffness can also be customized according to user requirements by modifying the printing parameters.

This integrated digital design and manufacturing approach enables the development of a customizable, lightweight, and mechanically adaptable transtibial prosthesis aimed at improving comfort and functional performance for users.

II. Design objectives

The following objectives were considered for the design of transtibial prosthetic system:

- Patient-specific socket geometry for improved comfort.
- Low-cost manufacturing suitable for resource-constrained settings.
- Improved thermal comfort through ventilation features.
- Reduced overall prosthesis weight.
- Controlled ankle articulation for improved gait mechanics.
- Adjustable stiffness to accommodate different user weights.
- Structural reliability for daily use.

III. Design and development

A digital design workflow along with material extrusion based additive manufacturing was adopted to achieve user specific customization, repeatability and affordability.

III.I. Residual limb data acquisition

Data acquisition of residual limb for design of prosthesis can be done through 3D scanning of the residual limb or through Computed Tomography (CT) scan. Both methods are reliable and proven. The choice of scanning method can be determined based on availability of the technology and cost of services involved. However, in both methods post processing of the data plays a crucial role specifically for scan obtained through CT.

Figure 1: Shows the prosthetic user going through CT scanning process for data acquisition of residual limb.

A CT scan of the residual limb obtained by Philips Incisive CT, manufactured by Philips healthcare, Netherlands was used to capture the anatomical geometry of the residual limb as shown in Fig. 1, The open source software 3D Slicer was used to develop the mesh model of the residual limb from DICOM (Digital Imaging and Communications in Medicine) data as illustrated in Fig. 2.

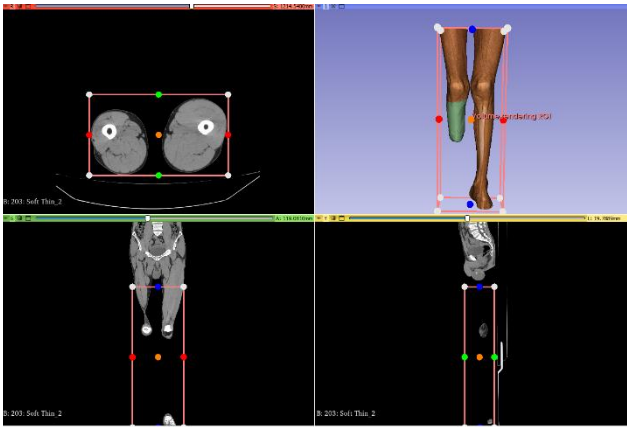

Figure 2: Shows the CT scanned data of residual limb along with volume rendered 3D View in 3D Slicer.

The obtained mesh model was further segmented, and mesh corrections were performed in Autodesk Meshmixer to remove artifacts and ensure smooth geometry, as shown in Fig. 3**.**

III.II. Digital modelling

Patient specific socket and liner conformally fitting onto the residual limb were designed in Autodesk Meshmixer (3.5.0, 1/6/2025) as shown in Fig. 4(a), surface smoothing was performed. Modifications were made such that load is distributed in pressure tolerant regions and no loading happens in pressure intolerant areas as illustrated in Fig. 4(b).

Figure 3: Mesh model of residual limb.

The mesh file of designed socket was further imported into Autodesk Fusion 360 for design of lower part of the socket consisting of provision for air ventilation and interface with the pylon. It was observed that the conventional design of pylon-socket interface is more prone to failure with material extrusion based additive manufacturing due to anisotropic mechanical properties introduced by weak interlayer bonding [11], [12], [13]. A completely new interface of socket-pylon was designed, unlike bolting in conventional prosthetics in the proposed design the pylon fits in the pocket created in the socket as shown in Fig. 8, to improve the structural strength of prosthetic limb. Five air vents were added onto the periphery of the socket to improve airflow and reduce perspiration within the socket, as illustrated in Fig. 5.

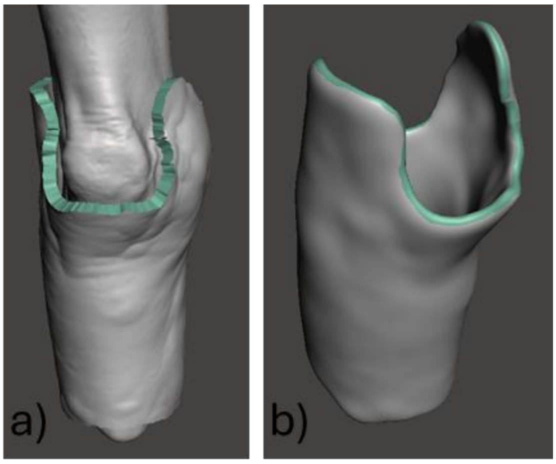

Figure 4: Socket designed over residual limb (a) Raw conformal design (b) Smoothed and modified design.

Figure 5: Complete socket design with air vents

Considering the size of user's foot, a prosthetic foot was designed in Autodesk Fusion 360, this new design of foot consists of two degrees of freedom. The primary degree of freedom was achieved through an articulated joint replicating the ankle joint and allowing the plantarflexion and dorsiflexion to ensure the articulation in safe range a design feature is added in the joint to limit the articulation within ±10.5° [14]. As illustrated in Fig. 6, Two TPU blocks are added in the articulated joint to act as a spring, and stiffness of both these blocks can be modified by changing the infill structure to achieve required stiffness according to the user's weight and activity level. Secondary degree of freedom at the toe region was achieved by a compliant mechanism due to hybrid PLA-TPU design as shown in Fig. 7, where TPU provides flexibility and PLA provides structural integrity. The complete assembly of the prosthetic limb developed using the proposed design approach is shown in Fig. 8**.**

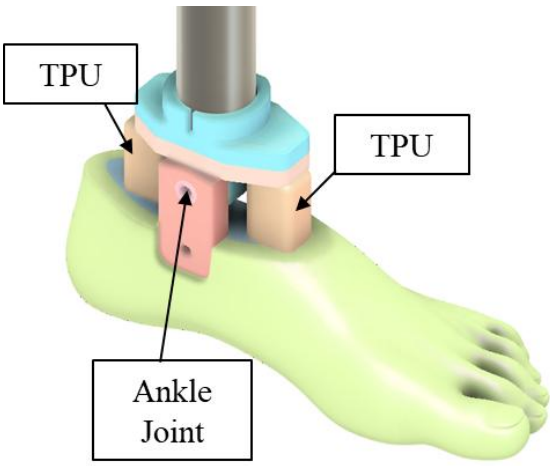

Figure 6: Shows the articulated ankle joint along with TPU blocks to act as a spring with customizable stiffness as per user

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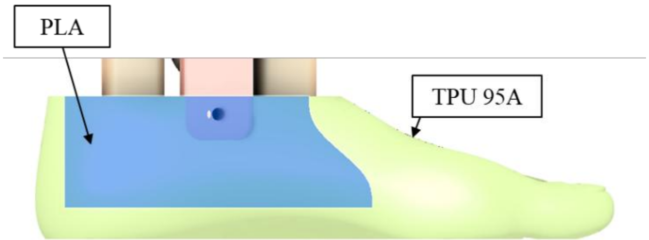

Figure 7: Shows the hybrid PLA-TPU design of foot for bending of toes, blue region represents PLA

Figure 8: Shows the complete assembly design of the prosthetic limb

III.III. Additive manufacturing

Since low-cost manufacturing was an objective to ensure affordability, the material extrusion based Fused Filament Fabrication (FFF) technology was considered with PLA and TPU materials for fabrication of the socket and foot [15] specifications of PLA and TPU material used are mentioned in Table 3 & Table 4 respectively. Additive manufacturing process parameters mentioned in the Table 1. and Table 2 were selected based on the literature review, ensuring the structural strength, low weight of prosthesis, and users weight and activity level to modify the stiffness of TPU. OrcaSlicer software was used to slice the designs and Omega 300 3D printer manufactured by Rudrabots Private Limited was used for 3D printing. The final prosthetic limb fabricated using the proposed design and additive manufacturing process is shown in Fig. 9**.**

Table 1: Additive Manufacturing Process Parameters for Socket

Material	Polylactic Acid (PLA)
Nozzle Size	0.8mm
Layer Height	0.16mm
Infill Density	20%
Infill Pattern	Gyroid
Wall Thickness	1.6mm
Top/Bottom Thickness	0.8mm
Nozzle Temperature	220°C
Bed Temperature	60°C
Print Speed	80mm/sec

Table 2: Additive Manufacturing Process Parameters for Foot

Material	Polylactic Acid (PLA) & Thermoplastic Polyurethane (TPU)
Nozzle Size	0.4mm
Layer Height	0.12mm
Infill Pattern	Gyroid
Infill Density	50% for PLA 18% for TPU
Wall Thickness	1.2mm
Top/Bottom Thickness	0.6mm
Nozzle Temperature	220°C
Bed Temperature	60°C
Print Speed	100mm/sec

Table 3: Specifications of PLA Filament

Material	Polylactic Acid (PLA)
Filament Diameter	1.75 mm
Brand	eSun
Density	1.24 gram/cm^3
Tensile Strength	27 MPA
Flexural Strength	101.2 MPA
Heat Distortion Temperature	60 °C

Table 4: Specifications of TPU Filament

Material	Thermoplastic Polyurethane (TPU)
Filament Diameter	1.75 mm
Brand	eSun
Density	1.12 gram/cm^3
Shore Hardness	87A
Shock Resistance	7 (KJ/m^2)

IV. Results and discussion

To meet the objectives of design and development of an affordable, light weight and reliable transtibial prosthetic limb which provides an enhanced gait cycle and comfort.

Figure 9: Shows the complete prosthetic limb developed using proposed design.

Patient specific socket geometry was achieved by designing a conformal socket over the design of residual limb. To meet these requirements while maintaining low-cost manufacturing, PLA was selected for socket, carbon fiber for pylon, PLA and TPU for foot.

For additive manufacturing, the FFF process was selected, the issue with FFF process and PLA material was weak interlayer bonding, resulting in anisotropy. With conventional design of socket where the pylon is bolted using an adapter as shown in Fig. 10, there were high chances of failure due to stress concentration and interlayer shear failure. Considering the same a new interface of socket and pylon was designed to distribute the load more uniformly and increase the structural integrity is shown in Fig. 11. Further to improve the thermal comfort air vents were placed on the periphery of the socket to ensure air flow inside the socket.

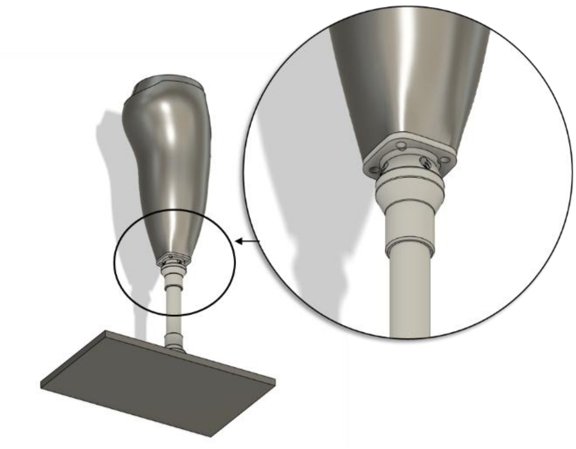

Figure 10: Shows the bolting region of conventional prosthetic socket and pylon.

Figure 11: Shows the improved design of socket-pylon interface, designed considering additive manufacturing process.

Whereas for pylon conventionally available 3K roll wrapped carbon fiber tube with outside diameter of 30mm and 5mm thickness was selected to limit the weight and ensure strength.

Human gait cycle requires coordinated motion at both the ankle and forefoot during walking. During the gait cycle heel strike requires controlled plantarflexion, mid stance requires slight dorsiflexion and toe off requires bending of forefoot. To address these requirements the proposed prosthetic foot incorporated two degrees of freedom, achieved through a combination of an articulated ankle joint and a compliant forefoot, resulting in smoother and more natural gait pattern.

Figure 12: Shows the ankle joint and compression of TPU blocks (a) Shows the Dorsiflexion and (b) Shows the Plantarflexion.

The articulated ankle joint allows dorsiflexion as shown in Fig. 12(a) and plantarflexion as shown in Fig. 12(b) along with the safety mechanism restricting the motion in ±10.5°. The articulated joint features two TPU blocks acting as compliant springs, allowing the modification of stiffness to account for users' weight and activity level, by changing the additive manufacturing process parameters.

The hybrid design of foot allowed bending of forefoot during toe off phase as shown in Fig. 13, this further enhanced the biomechanical response of the prosthetic limb during walking.

Thus, the proposed prosthetic design introduces several improvements compared with conventional low-cost systems a key comparison of the same is also presented in table 5.

Figure 13: Shows the compliant bending of forefoot.

Table 5: Comparison of features between conventional low-cost prosthesis and proposed design

Feature	Conventional Low-Cost Prosthesis	Proposed Design
Socket fabrication	Manual plaster casting	CT-based digital modeling
Ventilation	Limited	Integrated air vents
Weight	Higher	Reduced via carbon fiber pylon
Ankle motion	Limited	Controlled articulation
Foot stiffness	Fixed	Customizable via TPU structure

V. Conclusions

This study presented the design and development of a patient-specific transtibial prosthesis using an integrated digital workflow and additive manufacturing approach. The proposed system incorporates a customized prosthetic socket designed from Computed Tomography (CT) scan data, enabling improved anatomical conformity and pressure distribution. Ventilation features were integrated within the socket structure to enhance thermal comfort and reduce perspiration-related discomfort during prolonged use. To address the anisotropic mechanical behavior associated with fused filament fabrication (FFF), a redesigned socket–pylon interface was developed to improve load distribution and structural reliability. In addition, a lightweight carbon fiber pylon was utilized to reduce the overall weight of the prosthetic system compared to conventional stainless steel pylons.

The prosthetic foot was designed as a hybrid PLA–TPU structure providing two degrees of freedom, including controlled plantarflexion–dorsiflexion at the articulated ankle joint and compliant bending at the forefoot. The integration of TPU elements enables customization of stiffness according to the user's weight and activity level through modification of additive manufacturing parameters. This approach enables a mechanically adaptable prosthetic system capable of improving gait biomechanics while maintaining affordability. Overall, the proposed design demonstrates the potential of additive manufacturing for developing customizable, lightweight, and cost-effective transtibial prosthetic systems that address several limitations of conventional low-cost prostheses. Future work will focus on experimental validation through mechanical testing, fatigue analysis, and gait evaluation to further assess the functional performance and long-term reliability of the developed prosthetic limb.

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Author's statement

Conflict of interest: The authors declare no conflicting interests. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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