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# Design and Mechanical Evaluation of 3D-Printed Hybrid Transtibial Prosthetic Sockets Using Finite Element Analysis

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## Abstract

**Background:** A prosthetic socket serves as a vital interface between a patient's residual limb and the prosthetic device, playing a key role in enhancing quality of life during prosthetic rehabilitation. The design and material composition of the socket significantly influence patient comfort, safety, and long-term functionality.
**Aims:** This study introduces a novel transtibial prosthetic socket design concept utilizing additive manufacturing techniques with two materials: Polyamide 12 (PA12) for structural integrity and Thermoplastic Polyurethane (TPU) for inner comfort, aiming to improve biomechanical performance and user comfort.
**Methods:** The socket design integrates both PA12, recognized for its ISO-compliant safety in socket fabrication, and TPU, chosen for its flexibility and skin-friendliness. Additive manufacturing methods, including Fused Deposition Modelling (FDM) and Selective Laser Sintering (SLS), were employed in fabrication. Biomechanical validation was conducted using the Radcliffe principle for stump-socket force analysis. Additionally, bio-based modelling and mathematical simulations were utilized to optimize the socket design, including surface pressure mapping on the residual limb.
**Results:** The dual-material socket demonstrated potential improvements in mechanical strength and patient comfort. Surface pressure mapping allowed for precise evaluation of load distribution, confirming the design's effectiveness in reducing peak pressure points and improving fit.
**Conclusion:** Digital fabrication technologies, particularly additive manufacturing, offer promising avenues for customized, biomechanically sound prosthetic socket design. The integration of PA12 and TPU enhances both safety and comfort, suggesting a valuable direction for future prosthetic development and theoretical research in digital health technologies.

**Keywords:** Additive manufacturing; Fuse deposition modelling; Prosthetic socket; Selective laser sintering

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**Introduction**

The loss of a limb's natural function following an amputation causes several mobility-related difficulties. Additionally, it interferes with activities of daily living and has a significant negative psychological impact on amputees. Trauma is the leading cause of amputation worldwide [1]. Non-traumatic amputations are commonly caused by diabetic gangrene, malignant tumors, osteomyelitis, and neuropathic lower limb ulcers. As per the article Epidemiology and outcome of non-traumatic lower limb amputees, published in 2023, below knee amputation accounts for 48.29% of all lower limb amputations [2]. A prosthetic socket is a crucial component of a prosthetic limb. It is a custom-designed part made to fit an individual's residual limb, providing a comfortable and secure interface between the residual limb and rest of the prosthetic device. To distribute the user's weight evenly, avoid discomfort, and permit natural movement, the socket's fit and design are crucial. The socket experiences repetitive loading during a typical gait cycle, and actions like jumping and running can result in even more rapid loading. The need to sustain such high-impact forces calls for a high-strength prosthetic socket, but at the same time, the socket should be flexible and skin-friendly to avoid skin irritation on the patient's residual limb.

The conventional method of fabricating a prosthetic socket involves plaster-casting, followed by modifications to the plaster mould [3]. Once the modifications are made, the sockets can be fabricated using durable materials such as thermoplastics and laminated materials. Despite their widespread availability worldwide, patient feedback has identified a lack of comfort and accuracy in conventional prosthetic sockets [4]. Recent technological advancements have made digital modifications a key factor in transforming the prosthetic industry. This approach offers several notable advantages, including high accuracy, the capacity to create complicated geometries, flexibility in material experimentation, digital data transfer, and remote access [5]. However, identifying an appropriate material for prosthetic applications in digital socket fabrication continues to be an area of ongoing research [6], [7].

Sabeti et al. 2018 [6] compared sockets made from Polyamide 12, recycled Polyamide 12, and Polylactic Acid (PLA). They observed that the sockets made from Polyamide 12 and recycled Polyamide met the minimum ISO standards for ultimate strength. However, the PLA sockets that were printed in the x-z direction underwent failure before reaching the ultimate strength. Marinopoulos et al. 2021 [7] concluded that socket strength can be significantly improved with proper design. They observed that the sockets fabricated using FDM of PLA material develop interlayer cracks on the application of load that progresses to socket failure. Kim et al. 2022 [8] observed that the failure points come near major load-bearing areas and the distal end of the prosthetic sockets. They concluded that the sockets made from PLA and PP using 3D printing technology possessed insufficient strength to be used in prosthetic socket applications. In their research, they recommended that reinforcement with composite materials and suitable post-processing techniques can improve the strength capabilities of these materials. Stelt

et al. 2022 [9] observed that the sockets made from PLA could sustain lower values of mechanical stress compared to composite materials. They concluded that by incorporating Fused Deposition Modelling (FDM) technology in fabrication, the vulnerability of transversely loaded specimens primarily resides in the resistance of the union between layers. This aspect emerges as the weakest link within the structural integrity of the produced components.

As per these studies, authors can say that the adoption of 3D printing in the prosthetic field started with FDM technology and PLA material because of its biocompatibility and being metabolically unharmful. This faced many challenges in terms of its low load-bearing strength and inter-layer adhesion. The adoption of selective laser sintering (SLS) provided sockets with improved load-bearing capabilities. PA12 is a compelling material for the prosthetic industry because of its higher strength properties. The high-strength PA12 socket proposed a new challenge of discomfort to the patient because of its hard surface and high stiffness. To deal with it, professionals add a soft interface in between the patient's stump and socket.

This paper introduces a formalized design concept for a prosthetic socket crafted via additive manufacturing, incorporating two distinct materials: PA12 and TPU. The central idea revolves around evolving from the past and utilizing the concept of Stefano Botta [10]. The design aims to develop a transtibial double-wall socket consisting of an inner flexible layer and an outer rigid layer.

The rest of the paper is structured as follows: Section II describes socket design, fabrication, biomechanical analysis of stump socket forces, and strength testing using simulation. Section III elucidates the results. Finally, Section IV draws the conclusions.

## Methods

### Socket Design and Fabrication:

Advanced technologies like computer-aided designing and manufacturing are increasingly being used to shorten the process of creating and manufacturing prosthetic sockets. Using the ability to create organic shapes and manufacture complicated structures quickly, additive manufacturing can help minimize time and can create more complex geometries.

The socket was digitally designed from 3D scan data of a transtibial amputee, obtained using a non-contact, light-based hand-held 3D scanner, the Artec Leo. The 3D scan was imported into organic modeling or sculpting software, Freeform, to model and create the socket, utilizing a haptic feedback device to finalize the design. The socket was created in two different layers of 2 mm and 3 mm, respectively, with a clearance of 0.8 mm for easy donning. The final socket file was then exported as an .stl file for 3D printing.

The design emphasizes on achieving a lightweight socket and cost-effective fabrication by introducing geometric structures. These structures were created using nTop, Release 4.1, nTop Inc. software. These structures were created in accordance with the patient's anatomy, and they may contain pressure-sensitive sections of the patient's stump.

Moreover, a geometry-based design reduced weight by up to 30% without a significant loss in strength, showcasing the design's efficiency. The process of socket design and fabrication is demonstrated in **Figure 1**.

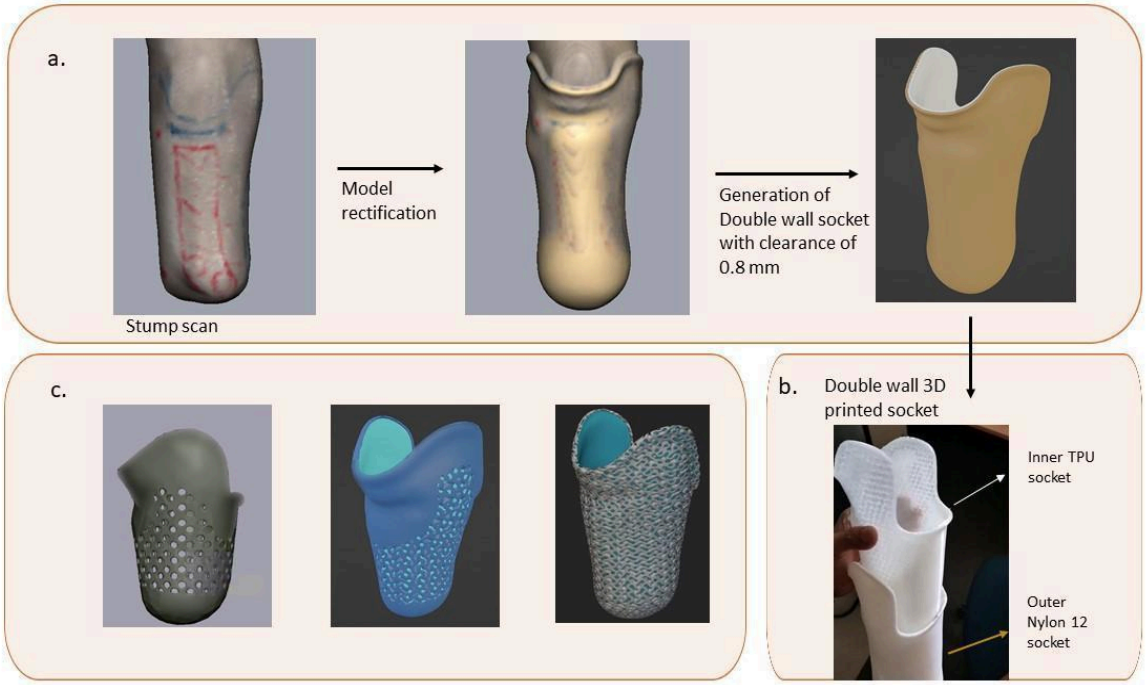



***Figure 1**: a.) Process of digital designing of socket; b.) 3D printed double wall socket; c.) Geometry-based socket designs*

**Analysis of Stump-Socket Forces**

Radcliffe made the first attempt in 1961 to explain force patterns of a transtibial patellar tendon bearing stump-socket contact [11]. Radcliffe investigated a stump-socket force distribution pattern that changes during the gait cycle and is influenced by the socket fit, prosthesis alignment, muscle action, and the angular location of the stump concerning the ground reaction force (GRF). Radcliffe assumed that a below-knee amputee with a stump of at least average length might be expected to walk in the same way as a normal person.

In addition to the antero-posterior forces, the medial-lateral forces which Radcliffe proposed, are relatively similar throughout the gait cycle. GRF's have a medial inclination due to the horizontal acceleration of the centre of gravity. As a means to counteract this medial inertia, stabilising forces are established in the lateral distal and proximal medial tibia.

**Ground Reaction Forces**

When the foot comes into contact with the ground during gait as a result of the force applied to the ground, ground reaction forces (GRF) occur that counteract the force of gravity. These forces can be described simply according to Newton's law by equation [12],

$$GRF = M(g + a)$$

Where GRF is the ground reaction force, (g) is the gravitational acceleration, (a) is the vertical acceleration of the centre of mass (COM), and (M) is the person's body mass. Because (M) and (g) are constants, variations in the magnitude of GRF are solely determined by changes in vertical acceleration.

At the heel strike phase of the gait, the knee joint is fully extended and the GRF passes anterior to the knee joint. Immediately following the heel strike, the knee goes towards 15° of flexion and the GRF passes from a location anterior to the knee joint to a position posterior to the joint. In the mid-stance phase, the knee again goes towards extension and the flexion angle changes from 15° to 5°. The GRF acts anterior to the knee. During the heel-off phase, the knee returns to a fully extended or neutral position, with GRF acting anteriorly. The knee flexes 30° during toe-off, and the GRF passes behind the knee. In different phases of the gait cycle, the change of GRF from anterior to posterior and posterior to anterior causes significant pressure at the patellar tendon, anterior distal tibial, and popliteal area.

**Digital Simulation:**

In this study, three different trans-tibial sockets of different materials were tested for load-bearing capabilities in Ansys® Academic Research Mechanical, Release 2022.1.0 software. The maximum displacement and stress were evaluated in the Ansys Workbench.

**Testing Parameters:**

The sockets were aligned vertically with the Z-axis of the Ansys workspace. The distal end of the socket, where it is joined with the adaptor, is used as fixed geometry as shown in **Figure 2a**.

The patellar tendon, popliteal area, medial tibial flare, the lateral shaft of the fibula, and distal end redundant tissue (for total contact socket) are major load-bearing areas of the stump that transmit the body weight to the ground via socket. The net load of 120 Kg (with safety factor of 1.5 of an 80 Kg patient) was applied in these regions, as shown in **Figure 2b**, to perform the static simulation [13].

The material characteristics of the considered materials are shown in **Table 1.** The lower density of PA12 is one of its most advantageous characteristics, as it results in a high strength-to-weight ratio. The tensile strength of PA12 is comparatively high, making it suitable for load-bearing applications. In contrast, the larger deformations of TPU provide a cushioning effect upon load application. Thus, the integration of an outer PA12 socket with an inner TPU socket offers the patient both robust weight-bearing capacity and comfortable cushioning.

***Table 1**: Material properties of PA 12 powder, PA 12 filament and TPU 95A filament*

| S.no. | Mechanical Properties | PA12 (SLS) | PA12 (FDM) | TPU 95A |
|---|---|---|---|---|
| 1. | Density (g/cc) | 0.95 | 1.012 | 1.2-1.24 |
| 2. | Young modulus (MPa) | 1850 | 1370 | 9.5 ± 0.4 |
| 3. | Tensile strength (MPa) | 50 | 50.81 | 29.3 ± 2.8 |
| 4. | Elongation at break (%) | 6 | 165.41 | 330 ± 15 |

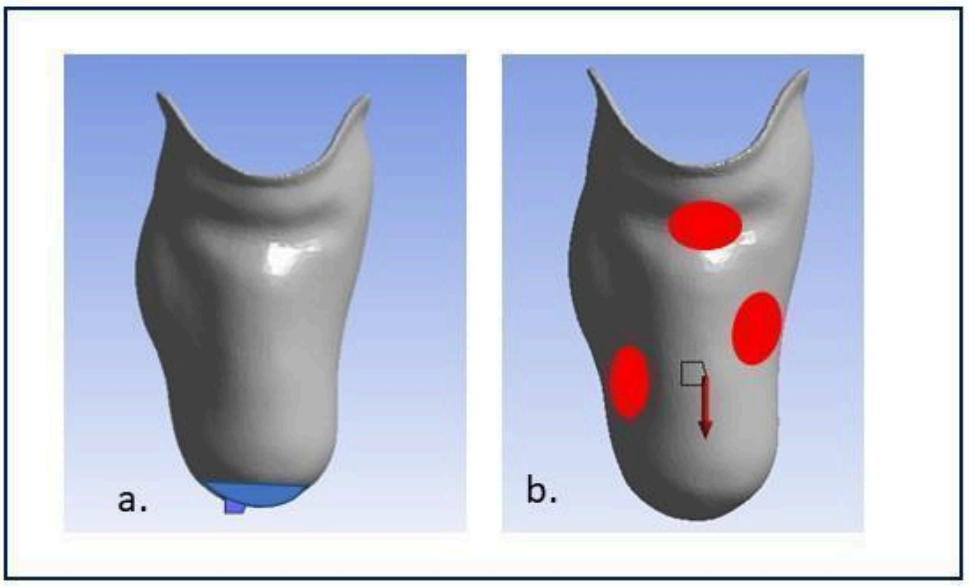



***Figure 2**: Socket Testing Parameters. a.) Fixed region of socket; b.) Load bearing regions of a socket*

**Results**

The application of load causes deformation in the sockets, leading to induced stress. The digital simulations performed in Ansys Workbench show a pictorial representation of the stress and deformation in each region. **Figure 3a** illustrates the deformation induced in socket 1, ranging from 0 to 1.5486 mm, displayed using a colour gradient map to represent the area. It shows that the socket undergoes maximum deformation at the supracondylar part of the socket.

Similarly, **Figure 3b** illustrates the stress induced in socket 1, ranging from 0 to 9.0058 MPa, displayed using a colour gradient map to represent the area. It shows that the maximum stress generates at the distal end of the sockets, i.e., around the socket-adaptor interface. The stress is well below the ultimate tensile strength of the PA12, making the

design safe.

The stress and deformation that occurred in all the three sockets, under the same boundary conditions are recorded in **Table 2**. All three sockets come out to be safe design solutions for prosthetic sockets. This analysis underscores the efficacy of combining PA12 and TPU materials in prosthetic socket design. Irrespective of the specific design, PA12 consistently exhibits elevated maximum equivalent stress, indicating its capacity to deliver exceptional structural strength and durability. Conversely, TPU demonstrates notably greater total displacement, reflecting its superior flexibility and adaptability. These characteristics enhance user comfort by accommodating anatomical variations. This complementary pairing ensures that the external PA12 layer bears the primary load, while the internal TPU layer mitigates impact and adapts to dynamic movements. The results suggest that this material combination effectively balances strength and comfort, rendering it a dependable option for prosthetic socket applications. Furthermore, variations in design influence stress and displacement values, underscoring the adaptability of this material combination to diverse configurations without compromising its overall performance.

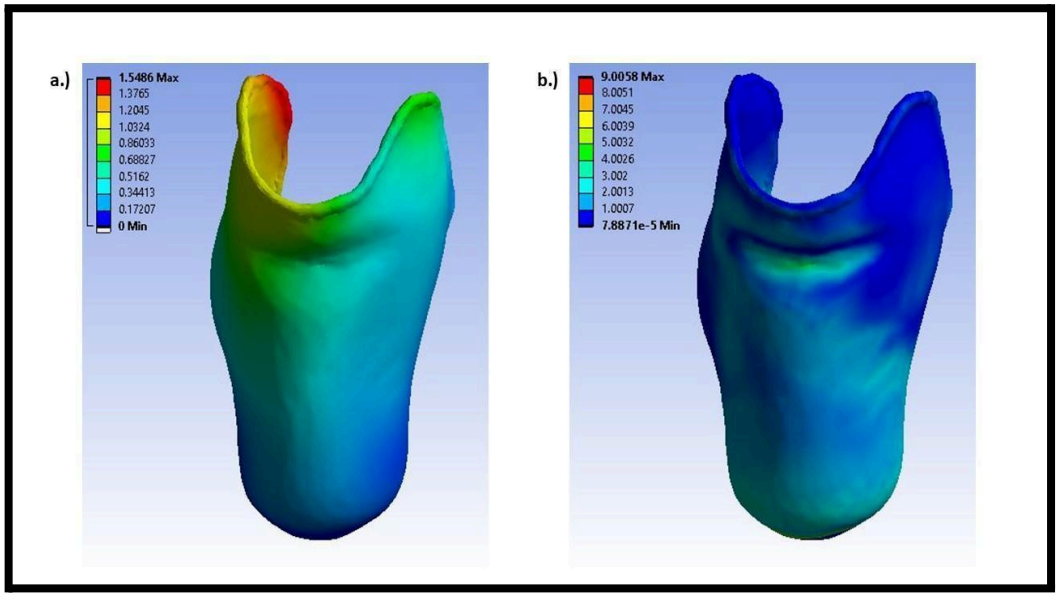



***Figure 3**: Results of simulation, showing a.) displacement and b.) stress in the socket*

***Table 2**: Maximum stress and displacement induced in sockets*

| S. no | Socket | PA12 3 mm outer socket | | TPU inner socket | |
|---|---|---|---|---|---|
| | | Max. Eq. Stress (MPa) | Max. Total Displacement (mm) | Max. Eq. Stress (MPa) | Max. Total Displacement (mm) |
| 1 | **Socket 1** | 13.7 | 0.8869 | 5.921 | 37.553 |
| 2 | **Socket 2** | 4.4786 | 1.2939 | 3.2614 | 51.146 |
| 3 | **Socket 3** | 9.0058 | 1.5486 | 5.6246 | 65.848 |

**Discussion**

As shown in **Table 2,** PA12 consistently demonstrates high maximum equivalent stress (4.48–13.7 MPa) values across all three socket designs, with the highest stress recorded at 13.7 MPa in Socket 1. Despite this, the stress levels remain well below the ultimate tensile strength of PA12 which is 50 MPa, as shown in **Table 1**, confirming that the sockets do not reach critical stress thresholds under the applied loading conditions. This indicates that PA12, serving as the outer shell, effectively supports the mechanical load, ensuring the structural integrity of the socket. The socket preserves the stump shape and alignment under loading, thereby minimizing structural deformation. Conversely, TPU exhibits significantly higher total displacement (37.55–65.85 mm) values, particularly in Socket 3 (65.848 mm). This confirms its ability to deform elastically and increase contact area along the limb. These large displacements reflect the material's inherent elasticity and flexibility. Such behaviour is advantageous in prosthetic applications as it allows the socket to conform to the user's limb, enhancing fit, comfort, and adaptability during dynamic movements. The controlled deformation allows the inner wall to accommodate daily limb-volume fluctuations by undergoing about 5–10 percent elastic strain, reducing the need for frequent sock adjustments. This compliance helps to reduce localized pressure points and improve long-term wearability.

The double-wall design can improve suspension, ease of donning and doffing, and accommodation of residual-limb volume changes compared with existing silicone or gel-based liners and rigid-socket systems. Unlike silicone or gel-based liners, which often rely on distal pin-lock suspension because their soft, low-friction surfaces alone cannot consistently resist traction forces during gait, the TPU layer distributes pressure more evenly, creating a **"grip-without-pressure"** effect and contributing to suspension through elastic recoil. The inner wall can deform by approximately 1- 3 mm and tolerate elastic strain of about 5 - 10%, loads are spread across a broader surface and pressure concentrations at bony prominences are reduced. As a result, suspension is achieved across the entire socket- limb interface rather than at a single distal anchor point, helping limit pistoning and distal traction.

The existing silicone or gel-based liners often require good hand dexterity to wear properly. In contrast, the inner TPU socket, which is designed to match the geometry of the outer shell, is easier to don. The small design clearance between the two walls facilitates easier donning and doffing by allowing the outer socket to roll over the flexible inner layer.

Overall, the results show that the stress induced in the sockets during digital simulations is well below the ultimate strength of the material, making it suitable for load bearing of the patient. The sockets made from PA12 show higher rigidity and those made of TPU show higher flexibility. Based on the results, we can infer that the PA12 sockets are capable of sustaining the load reaction being applied on it during activities of daily living. The inner layer of TPU provides a cushioning effect towards the human body, making it a more comfortable design. The flexible nature of TPU provides resistance against impact

While 3D printing technology holds immense promise in enhancing socket manufacturing processes and the current simulations provide valuable insights into maximum stresses and displacements under static conditions, the long-term load-bearing capacity of 3D printed sockets remains uncertain. The study does not address material degradation due to repetitive stress, wear and tear, loss of suspension over time, the effects of repeated donning and doffing, or variations in patients with specific activity levels. Future work will focus on the experimental validation of the socket under cyclic loading conditions, involving repeated application of loads to simulate real-life use, as well as fatigue testing to evaluate how the PA12 and TPU layers may weaken or fail under prolonged, repetitive stress. The authors emphasize the necessity for thorough evaluation through patient trials to gain insights into the long-term durability and comfort of the socket under real-world conditions. The evaluation involves testing sockets with diverse participants across activities like walking, running, and stair climbing, combining performance data with feedback on comfort, usability, and stability. This holistic approach will allow researchers to identify potential areas for improvement and further optimize the design. If the results are positive, the design could become a widely recommended option for prosthetic sockets, providing individuals with limb differences a more comfortable and functional solution.

**Conclusion and Recommendation**

This research introduced a novel methodology for designing and evaluating the mechanical performance of prosthetic sockets. The fundamental discovery was that the double wall socket design exhibited exceptional functionality and could effectively withstand the necessary loads. This design has the potential to transform the manufacturing of prosthetic sockets, offering a more customized and comfortable fit for individuals with limb differences.

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