Biomechanical Evaluation of Three Dimensionally Printed Passive Transfemoral Leg Socket Compliance with ISO 10328: A Comparison of Two Different Designs

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Abstract: *Malaysia's need for 200,000 prosthetic legs demands efficient production processes and three-dimensional (3D) printing can potentially address this. Despite the advantages of pin-lock sockets in below-knee prosthetics, research on their application in transfemoral amputations remains limited. This study designs and compares conventional and pin-lock prosthetic leg sockets for transfemoral amputees using 3D scanning, modeling, and printing. Conventional and pin-lock transfemoral leg sockets at 6 mm were designed using 3-Matic software. Their biomechanical properties were tested via ISO 10328 compression testing on the Instron 8874 machine. Results indicated that pin-lock sockets had higher average Young's modulus (36.27%) and yield strength (43.53%) compared to conventional designs. However, ultimate compressive strength (UCS) showed no statistically significant difference between the designs ($p > 0.05$). Practical benefits like user stability and comfort might favor the pin-lock design. Future research should consider larger sample sizes and additional gait phases for comprehensive evaluation.*

Keywords: passive prosthetic leg; transfemoral amputee; 3D printing

1. INTRODUCTION

The loss of a lower limb can be a life changing experience that influences an individual's capacity and ability to carry out their daily tasks [1]. Lower limb amputation can be classified into transfemoral (above-knee) and transtibial (below-knee) amputations. Transfemoral amputation involves the removal of the lower limb starting from above the knee, whereas transtibial refers to the removal of the lower limb starting below the knee, to the foot [2,3]. As the loss of a lower limb greatly affects an individual's life quality, both physically and mentally, experts recommend the immediate use of postoperative prosthesis [4], which in turn facilitates early mobilization thus enhancing physical and mental health of lower limb amputees [5].

The prosthesis specific for transfemoral and transtibial amputees is known as prosthetic leg, which can be further categorized into active and passive. Active prosthetic legs are powered by motors as external source for mobilization [6]. These prosthetics provide better walking speed, better sitting comfort, and lower infection rates [7]. Nevertheless, active prosthetic legs are notably higher in cost and weight [8]. In comparison, passive prosthetic legs are body-powered, which do not depend on external sources for mobilization.

Therefore, it is lightweight and lower in cost compared to active prosthetic legs [9]. However, studies indicate that poor socket design can lead to discomfort and medical issues such as skin irritations and blisters, underscoring the importance of using materials that offer good air circulation, strength, comfort, and shock absorption [10,11]. Furthermore, the thickness of the socket is a critical parameter; while thicker sockets can cause discomfort, thinner sockets risk mechanical integrity [12].

Transfemoral amputations account for approximately 26% of lower limb amputations [13]. This demographic, though smaller compared to transtibial amputees, highlights a critical gap in research and development of suitable prosthetic leg socket designs. Among the various designs, the conventional and the pin-lock sockets are most prominent, with the latter demonstrating superior biomechanical strength in compression tests [14]. It is important to note that the leg socket, a crucial component of the prosthetic leg, directly affects gait stability and overall comfort, making its design and material selection pivotal [15,16].

Another critical aspect of prosthetic socket design is its suspension system, particularly the pin-lock mechanism. The primary types of suspensions include suction sockets, seal-in liners, and locking liners with pins that secure the socket to the residual limb. Each suspension type is closely linked to the functional capabilities, skin health, and mobility of the user [17]. Research by Rahmawati et al. [18] highlights the significance of suspension types by evaluating four transfemoral patients who used Silesian belt suspension and silicone liner with lanyard suspension over a week. The study measured speed and stride length to assess the impact on patient cadence, revealing that Silesian belt suspension yielded cadence values closest to normal, underscoring the importance of effective suspension in enhancing mobility [18]. While pin-lock suspensions have been widely utilized, suction and elevated vacuum suspensions have garnered increased attention since their introduction [19]. According to Gholizadeh et al. [20], suction suspension is often viewed as less favorable compared to seal-in liners, as the latter results in reduced sweating, pain, odor, and irritation. Despite the existing literature on various suspension systems, there is a notable lack of focused research on pin-lock suspension, which is a relatively new addition to the prosthetic industry.

Given the increasing demand for prosthetic devices, particularly driven by conditions such as diabetes mellitus, there is an urgent need to explore innovative fabrication techniques. Three-dimensional (3D) printing emerges as a promising alternative to traditional methods, addressing issues such as production time, precision, and the need for skilled technicians [21,22]. Recent advancements in 3D printing technology provide new possibilities for lower extremity prosthetic development, offering new hope for amputated patients. 3D printing in recent years has progressively developed providing solutions in many industries including the healthcare industry, especially prosthetic leg manufacturing.

This study aims to design and biomechanically evaluate 3D-printed transfemoral prosthetic leg sockets, specifically comparing conventional and pin-lock designs through compression testing to determine their compressive stress, strain, Young's modulus, and yield strength. This study focuses on the development and evaluation of 3D-printed passive conventional and pin-lock prosthetic leg sockets, using AutoDesk Meshmixer, 3-Matic, and AutoCAD Tinker CAD. The two designs were modeled and printed with Polylactic acid+ (PLA+). The study biomechanically assessed the prosthetic sockets through compression testing.

2. METHODOLOGY

2.1 Three-dimensional Scanning of Subject's Residual Limb

A 32-year-old man with transfemoral amputation on the left leg was selected as the subject for this study. The man weighs 60 kg and 177 cm tall, with cause of amputation due to a road accident. The residual limb was scanned using a handheld three-dimensional (3D) scanner (Sense 3D, Version 2, 3D Devices, Inc., USA)[23]. With wired connected to a laptop, the optically scanned structure was transferred to Sense software, which was launched prior to scanning. To ensure a precise 3D model of the limb, the scanning process operated in consistent motion [23]. The resulting scanned model was edited to obtain only the necessary part of the residual limb (see Fig. 1).

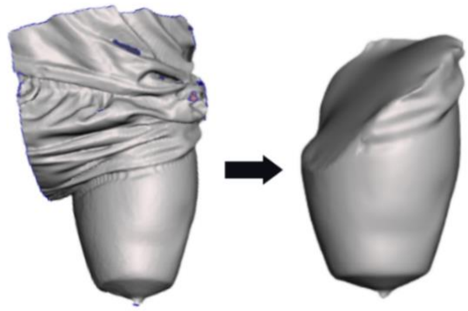

Fig. 1. Residual limb editing process using Sense software. The patient was wearing liner during the scanning.

2.2 Three-dimensional Design and Printing of Prosthetic Sockets

The modified part of the residual limb from the previous process was imported in the form of stereolithography (STL) file into a computer aided design (CAD) software called AutoDesk Meshmixer (Autodesk, Inc., USA). The surface of the modified was carefully traced and later imported into 3-matic software (Materialise N.V., Belgium) in STL format. This traced layer was then used as a guide in preparing a patient-specific prosthetic socket design. The thickness of the socket was set to 6 mm, which was offset from the imported layer. The generated design was classified as the conventional design. Fig. 2 shows the overall process of developing the conventional socket design, while Fig. 3 shows the thickness dimension of the socket. On the other hand, a similar approach was done for the pin-lock design, however with the addition of the pin-lock system at the base of the socket using AutoCAD Tinker CAD (Autodesk, Inc., USA), which can be seen in Fig. 4 and Fig. 5. Fig. 6 shows the finalized designs before proceeding to 3D printing.

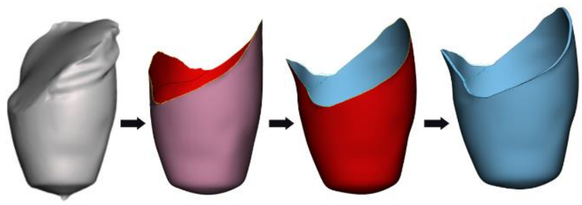

Fig. 2. Conventional transfemoral socket design process using AutoDesk Meshmixer (Autodesk, Inc., USA) and 3-matic software (Materialise N.V., Belgium).

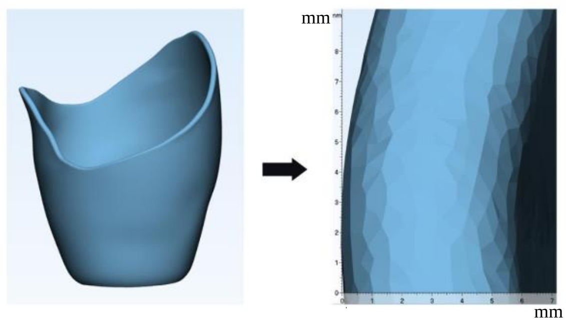

Fig. 3. Finalized design of conventional transfemoral socket (left) and the measurement of the thickness of socket (right).

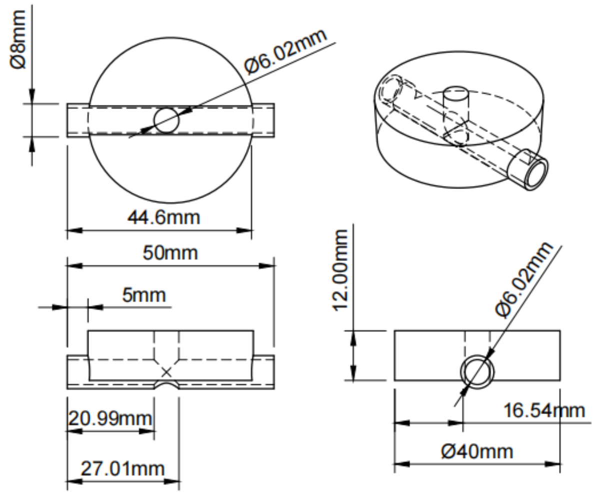

Fig. 4. Pin-lock system design using AutoCAD Tinker CAD (Autodesk, Inc., USA).

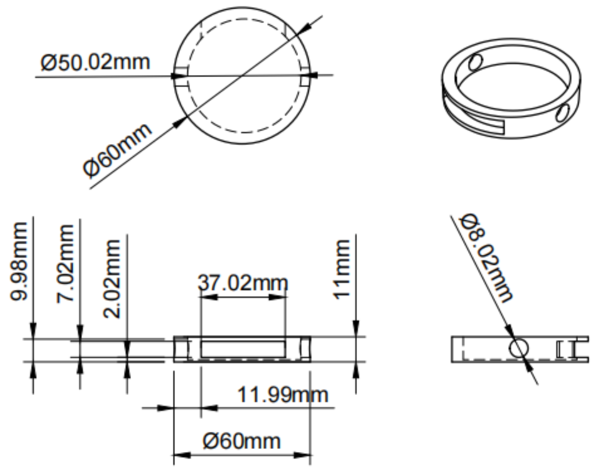

Fig. 5. Pin-lock system cover design using AutoCAD Tinker CAD (Autodesk, Inc., USA).

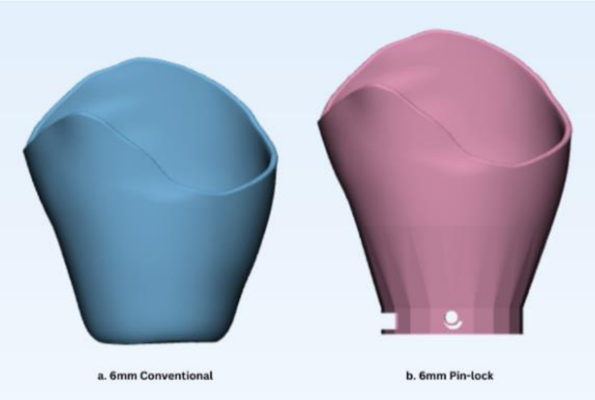

Fig. 6. Finalized transfemoral prosthetic socket designs.

The finalized sockets were fabricated using a fused deposition modelling (FDM) 3D printer due to its convenience and ease of use [24], specifically Ender-5 Pro 3D printer (Creality, Shenzhen Creality 3D Technology Co. Ltd., China). The designs were sliced using the Ultimaker Cura 5.3.1 slicing software (Creality, Shenzhen Creality 3D Technology Co. Ltd., China) prior to printing. The printing parameters were set using polylactic acid (PLA+) as the socket material[25], and 0.4 mm nozzle diameter [26] with 40% infill density [27]. The following table displays the setting of the nozzle and printing bed temperature for the material used (see Table 1). To ensure smooth printing process, the nozzle was inspected weekly to avoid clogging, and an interval of two hours were implemented between each printing process to prevent overheating. A total of six samples were fabricated with three samples for each design.

Table 1. Specifications adopted for 3D printing using PLA+ filaments [14]

Components	Specifications
Nozzle temperature (℃)	210
Bed temperature (℃)	60

2.3 Mock Stump Development

A mock stump that resembles the subject's residual limb structure was needed for the biomechanical evaluation. In this study, the solutions used in fabricating the stump were tap water, polyurethane (PU) 8013-A and 8013-B (Dongguan Yucheng Resin Technology Co. Ltd., China) with a 2:1:1 ratio, respectively. Table 2 describes the composition of the mock stump mixture solution used in the study. A femur bone model was also used to complete the mock stump structure. Fig. 7 shows the completed mock stump embedded in the prosthetic socket. The resulting mock stump, weighing 5.16 kg, was then used in the compression testing of both conventional and pin-lock transfemoral prosthetic sockets.

Table 2. Mock stump solution composition.

Composition	Amount (ml)
Tap water	5160
PU 8013-A	2580
Pu 8013-B	2580

Fig. 7. Developed mock stump in conventional transfemoral prosthetic socket.

2.4 Compression Test

Both prosthetic socket designs were subjected to compression test, simulating the mid-stance phase according to International Standards Organization (ISO) 10328, using Instron 8874 universal testing machine (Illinois Tool Works Inc., Norwood, USA). The developed mock stump was inserted into the sockets to mimic the mid-stance phase and axially compressed downwards by the load cell at a rate of 3 mm/min [14]. The testing was stopped one minute after a constant reading was obtained. Fig. 8 depicts the setup for the compression test.

Fig. 8. Compression test setup on Instron 8874 testing machine (Illinois Tool Works Inc., Norwood, USA).

The data from the compression test were load (N), extension (mm), and time (s). For data analysis, stress (σ) and strain (ε) were calculated by inserting the load and extension values into the stress and strain formula, respectively.

$$\sigma = \frac{\text{Load (N)}}{\text{Original Area (mm}^2\text{)}}$$

$$\varepsilon = \frac{\text{Extension (mm)}}{\text{Original Length (mm)}}$$

The base area of the conventional socket is the interface between the residual limb and the socket, where the load was exerted for weight bearing [28]. A One-Way ANOVA test was also conducted to determine the significance in compression strength between the two designs.

3. RESULTS AND DISCUSSION

3.1 Three-dimensional Printed Sockets

The total duration of printing a single conventional socket was two days, while the pin-lock version required an additional eight hours due to the incorporation of the pin-lock system into the conventional structure. All samples were successfully printed and adhered to the intended specifications. Fig. 9 displays examples of the printed conventional and pin-lock sockets.

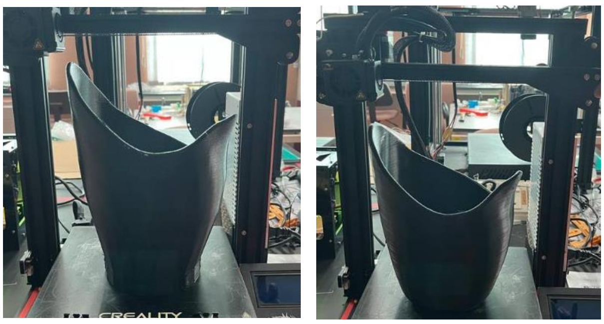
Fig. 9. Printed conventional (left) and pin-lock (right) sockets.

3.2 Stress and Strain

The recorded maximum load of the conventional and pin-lock design of transfemoral sockets were 2.94 kN and 3.50 kN, respectively. This showed that the pin-lock system designed for the transfemoral prosthetic socket exhibits greater strength than the conventional design under applied forces. This finding is consistent with another study [14] which confirmed that the pediatric above-knee pin-lock socket is biomechanically stronger than traditional sockets.

The stress-strain curves of both designs were plotted as shown in Fig. 10 and Fig. 11. Pin-lock socket samples were found to exhibit greater mean compression stress values compared to all conventional samples (see Table 3). Higher stress value increases the socket's mechanical integrity at greater loads, while lower strain sustains its rigidity longer during compression [29].

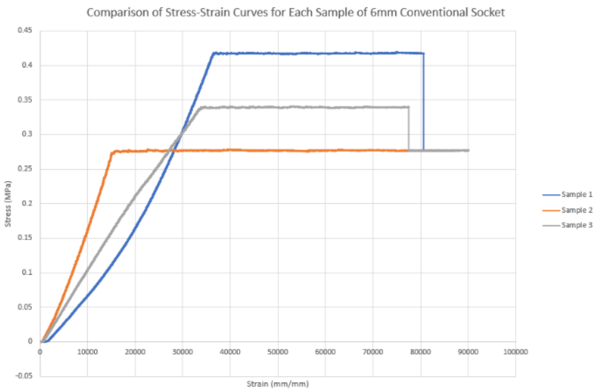

Fig. 10. Stress-strain curve of conventional design.

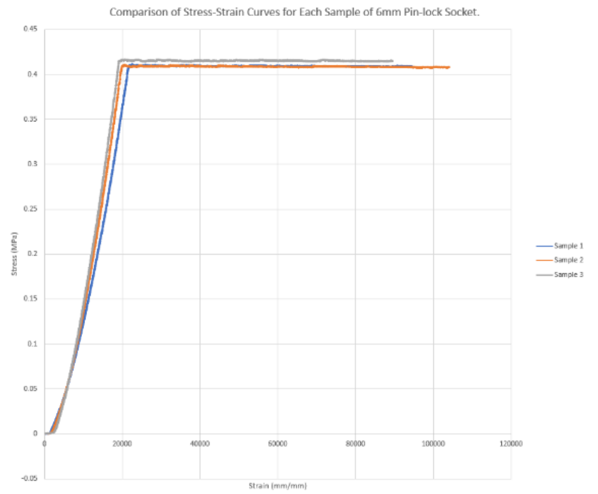

Fig. 11. Stress-strain curve of pin-lock design.

Table 3. Compression stress and strain of both designs.

Socket design	Sample	Compression stress (MPa)	Compression strain ($x10^{-3}$ mm/mm)
Conventional	1	0.3010	5.8309
	2	0.2504	3.0214
	3	0.2682	3.0214
	Mean	**0.2731**	**3.9580**
Pin-lock	1	0.3521	3.9886
	2	0.3606	3.6926
	3	0.3595	3.4506
	Mean	**0.3574**	**3.7110**

It is observed that the pin-lock sockets showed higher durability than the conventional sockets, being 30.86% stronger. Comparatively, the pin-lock design showed slightly lower strain value than the conventional design, with 6.24% difference.

3.3 Young's Modulus and Yield Strength

Data obtained of Young's modulus and yield strength are tabulated in Table 4. Pin-lock sockets exhibited a higher mean Young's modulus compared to conventional designs, indicating that conventional sockets have weaker compressive strength. Integrating the pin-lock system into the design, which secures the liner worn by the user to the prosthetic socket, provides the socket with greater stability to withstand higher loads due to its increased weight compared to the conventional design without the pin-lock system. The average elastic modulus of the pin-lock socket samples was 36.27% higher than that of the conventional designs. A similar pattern was observed in the comparison of yield strength, with the pin-lock design being 43.53% higher than the conventional design. This indicates that the pin-lock socket design can withstand more load before permanently deforming, as pointed out by Phillips and Craelius [30].

Table 4. Young's Modulus and Yield Strength of samples during compression testing.

Socket design	Sample	Young's modulus (MPa)	Yield strength (MPa)
Conventional	1	0.011	0.270
	2	0.012	0.280
	3	0.013	0.300
	Mean	**0.012**	**0.283**
Pin-lock	1	0.017	0.380
	2	0.017	0.430
	3	0.016	0.410
	Mean	**0.017**	**0.407**

Higher young's modulus implies that the socket has higher resistance to deformation when exerted under load, which is important for its durability and use in the long term. This is highly beneficial for active users who subject their prosthetic sockets to more frequent and higher loads [31]. Meanwhile, increasing the socket's yield strength can enhance its endurance against higher stress before experiencing permanent deformation. Over time, this property is desired to ensure the long-term functionality of the prosthetic sockets. Greater resistance to deformation is crucial to ensure the user's comfort and balance during movements. As demonstrated by other literature [32-35], it is worth to note that the biomechanical analysis and computer aided design are the best tools to simulate the behavior of biomedical devices as demonstrated in this study.

3.4 Ultimate Compressive Strength

One-Way ANOVA test was conducted to compare the ultimate compressive strength (UCS) of the conventional and pin-lock designs (see Table 5). The analysis revealed that there was no statistically significant difference between the two designs, with a p-value of 0.18 and an F-value of 2.63 (p > 0.05). The mean compressive strength of the conventional socket was 0.35 MPa (SD = 0.07), while for pin-lock socket was 0.41 MPa (SD = 0.03). This suggests that both designs offer similar performance under compressive loading conditions. Despite the lack of statistical significance, the practical aspects of each design should be considered. For example, the pin-lock design might offer better user stability or comfort, which are not captured by compressive strength alone.

Table 5. One-Way ANOVA analysis of UCS comparison between conventional and pin-lock sockets.

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	0.006513	1	0.006513	2.625914	0.180448	7.708647
Within Groups	0.00992	4	0.00248			
Total	0.016433	5				

Several factors might explain the lack of significant difference observed. One of the limiting factors of this study is the material of the mock stump due to its less accuracy in representing the human residual limb. In addition, the sample size was small, hence, not enough to detect any significant difference between the two designs. Future research could explore other gait phases and include a larger sample size to provide a more comprehensive comparison. Understanding the long-term performance and user satisfaction with each design would also be valuable.

4. CONCLUSION

This study evaluated and compared the biomechanical performance of conventional and pin-lock transfemoral prosthetic leg sockets using 3D printing technology. The findings revealed that although pin-lock sockets exhibited significantly higher average Young's modulus (36.27%) and yield strength (43.53%) compared to conventional sockets, the ultimate compressive strength (UCS) did not show a statistically significant difference between the two designs (p > 0.05).

Despite the lack of significant difference in UCS, the pin-lock design may offer practical advantages such as improved user stability and comfort, which are crucial for the overall functionality and satisfaction of prosthetic users. Future research should focus on larger sample sizes and evaluate additional gait phases to gain a more comprehensive understanding of the performance differences between the two socket designs. Nevertheless, this study also demonstrated that 3D printing technology shows great potential for manufacturing prosthetic leg sockets. The low cost of fabrication and lightweight material, combined with customized designs, can potentially enhance user experience. Future studies could further elucidate the potential benefits of pin-lock sockets in real-world applications.

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