Compression Testing and Thermal Assessment on Newly Developed Universal Design (Kedidi) of Prosthetic Leg Socket: A Patient-Specific Study

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Compression Testing and Thermal Assessment on Newly Developed Universal Design (Kedidi) of Prosthetic Leg Socket: A Patient-Specific Study

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Abstract: *Prosthetic leg is a common assistive device for amputee patients in their daily living activities. With the current changes of design and materials, researchers tend to conduct more research to improvise the socket for betterment of users. The aimed of this study is to evaluate a newly developed prosthetic leg, namely as Kedidi, in terms of mechanical integrity and thermal conditions of the residual skin. A total of three sizes have been developed; 11-, 12- and 13-inch diameter of socket, where a volunteer was acquired in this study. The compression testing of socket was done according to ISO10328:2016 structural testing of lower-limb prostheses, where an axial load was applied to the socket until maximum load. A thermal imaging camera was used to capture the skin's temperature of the volunteer at the residual limb areas. From the results, it is found that the maximum load obtained was 3961.39N for the 13-inch diameter of socket. Meanwhile, the temperature of skin found to be similar with the one from literature, where the maximum value was at 35.35℃. In conclusion, this newly developed Kedidi socket is a comparable to the conventional prosthetic socket and literature.*

Keywords: prosthetics leg; transtibial prosthetics; compression testing; kinematics for prosthetics, residual limb.

1. INTRODUCTION

Lower limb prosthetics play an important and crucial role and restoration for amputee patients to improvise the quality of life in daily living activities [1, 2]. This assistive device is not mean for a cosmetic or aesthetic values, but it is mean everything for them. Among the essential components of a prosthetic leg in the market, the socket serves as the critical interface and intermediate platform between the residual limb and the artificial limb, hence this will significantly be contributing both comfort and functionality that drive the users forward [3]. Traditionally, there are two prominent socket designs have been widely adopted, including (a) the Patellar Tendon Bearing (PTB) and (b) the Total Surface Bearing (TSB) sockets [4]. The PTB socket design focuses on distributing the load through pressure-tolerant areas, particularly around the patellar tendon, allowing relief in pressure-sensitive zones [5]. On the other hand, the TSB design promotes a more uniform pressure distribution across the entire surface of the residual limb, often providing better suspension and increased comfort for various users [6]. While each design has its advantages, they also present limitations in terms of biomechanical support and long-term wearability, driving the need for continuous design innovations that accommodate both structural integrity and user-centered comfort [2, 7-9].

Despite the mechanical and biomechanical advancements in prosthetic socket design, issues related to compressive strength and thermal comfort remain pressing challenges and need to be investigated further to improvise design, where at the same time could be a beneficial to the users in the future [1, 10-12]. Many studies from the literature have shown that inadequate compressive strength could compromise the socket's durability and structural integrity, thus potentially endangering user safety during dynamic movements [2]. It is worthy highlighted that thermal discomfort plays another major contribution, stemming from heat buildup and sweat accumulation on the skin. This has emerged as a primary factor affecting user satisfaction and prosthetic acceptance [11, 13]. To be noticed, excessive heat and moisture within the socket could lead to skin irritation, pressure sores, and an overall decrease in prosthesis usage time. Thermal comfort is thus not merely a matter of convenience, but a determinant of long-term prosthetic wearability and limb health [14]. Therefore, heat dissipation becomes a greater challenge and necessitates design modifications that address both thermal regulation and load-bearing capacity [15].

In response to these ongoing challenges, the present study introduces a newly developed universal design of a prosthetic leg socket, known as the "Kedidi" socket, with a focus on patient-specific customization. This study aims to evaluate the compressive strength and thermal performance of the Kedidi socket through a comprehensive experimental assessment. Specifically, the objective is to examine whether the Kedidi design can address the structural limitations and thermal discomfort reported in prior research, thereby offering an improved alternative for daily prosthetic users. By combining mechanical testing with thermal assessments, this research contributes to the development of more resilient and comfortable prosthetic socket designs, tailored to individual patient anatomy and usage conditions. The findings from this study are anticipated to guide future advancements in prosthetic engineering and promote higher adoption rates among amputees seeking improved quality of life through enhanced prosthetic solutions.

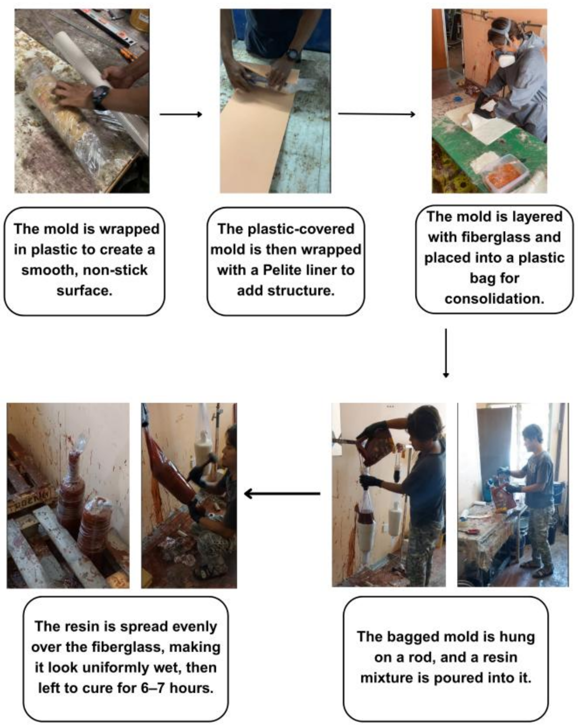
2. MATERIALS AND METHODS

2.1 Patient Recruitment

A volunteer transtibial amputee (gender: male, age: 25 years old, limb: transtibial residual limb) was recruited in this study. The volunteer has read all the protocols and agreed to contribute to this study where a consent form have been signed before the study begin. In this study, all procedures and protocol have been approved by UTM Research Ethics Committee with an approval number UTMREC-2023-24.

2.2 Socket Development

The Kedidi socket was developed based on a universal design principle with adaptability to anatomical features. The final socket prototype was fabricated using fiberglass composite material with a liner. A total of three sample size of socket were developed, which were 11-, 12- and 13-inch diameter.



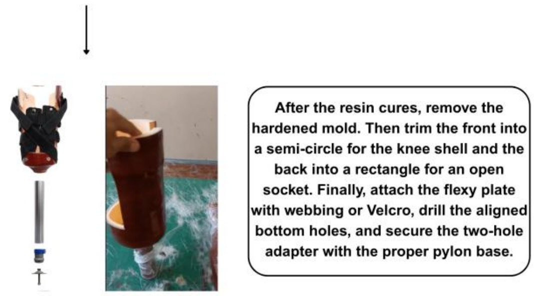


Fig. 1. A flow that illustrated the process of socket development

2.3 Compression Testing

Prior to compression testing, a mock residual limb was developed in the laboratory, followed ISO10328:2016 structural testing of lower-limb prostheses [13]. This standard encompasses the testing procedures, the loading conditions and other specifications for prosthetics leg structural assessment. The following Fig. 2 shows the flow of the mock residual limb development process, where this process is necessary prior to the compression testing. In this study, UTM SCALEBONE product was used to mimic the knee joint of human leg whereas a combination of femur and tibia bone that connected each other. Next, the socket was encapsulated with plaster of paris (PoP) in order to develop a cavity for the next pouring process. Once the cavity is done, polyurethane (PU) resin was poured onto it to finally develop a mock residual limb, where this procedure was done in a fume hood, within 20 minutes curing time. A cube structure of PU was also developed at the top and bottom of the sample to be able to fix on the universal testing machine during the testing procedures.

Fig. 2. A flow that illustrated the process of developing mock residual limb.

Compression testing was conducted to assess the mechanical integrity of the Kedidi socket under axial loading condition. The setup of the jig and load rates followed ISO10328:2016 structural testing of lower-limb prostheses. In this study, a static proof (ultimate strength) was chosen as it is one of the types of tests that incorporated in ISO 10328 standard. For passing the static proof test, the prosthetics sample must retain the structural soundness and not endure a permanent deformation exceeding 5 mm between distal and proximal loading point [16, 17]. Fig. 3 shows the setup condition for the compression testing. During the testing, the applied load was risen gradually at rate 100 N/s – 250 N/s until it reached maximum load, whereas test was done with Instron 8874 model. Subsequently, the setup was observed to detect any failure. In case there was no failure, the load was gradually increase until the setup eventually failed. For every socket sample testing, the mock residual limb was inspected to identify any damage that may affect the loading transmission to the socket sample. This same procedure was used to test socket size of 11-, 12- and 13-inch diameter. Load-displacement curves were recorded, and the compressive strength was calculated from the peak force.

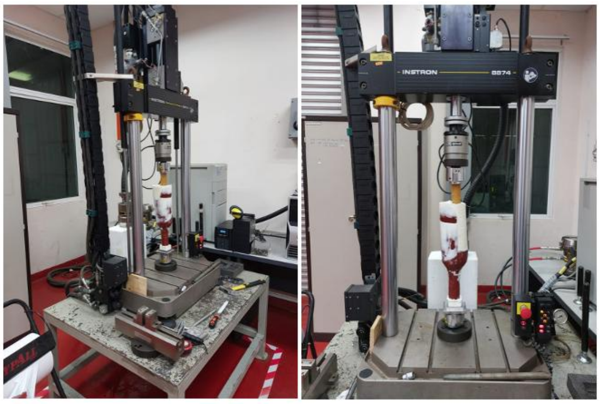


Fig. 3. Sample attached with Instron 8874 machine for compression testing procedure according to ISO10328:2016.

2.4 Fitting Testing

Prior to the thermal assessment, the volunteer was asked to wear the prosthetics leg (Fig. 4) to ensure all parts have been completely fitted to the leg. Some minor modifications of the liner were done if the socket was not fitted, according to user's acceptance. If the participant satisfied with the fitting conditions, next procedure of thermal assessment is carried on.

Fig. 4. A fitting test of the socket to the residual limb of the patient.

2.5 Thermal Assessment

Thermal imaging assessment was done to observe temperature of the residual limb before and after donning the prosthetics leg. In this study, both conventional and newly developed prosthetic leg (Kedidi) were tested in the laboratory, using thermal imaging system by Infrared Cameras Inc. (USA). Before the assessment is conducted, the room temperature was set at a constant value, 24°C and the volunteer was explained about the activities. The volunteer who is transtibial amputee, wore the socket before activity begin and stand at a distance of 0.50-0.80m from the camera for the first data acquisition. Then the volunteer was asked to walk at 6m distance for about three rounds, and the images were taken at the end of the activity when he removed the prosthetics leg. During the assessment, minimum and maximum temperatures were observed and recorded [18]. Fig. 5 shows the flow of thermal imaging assessment procedure in this study.

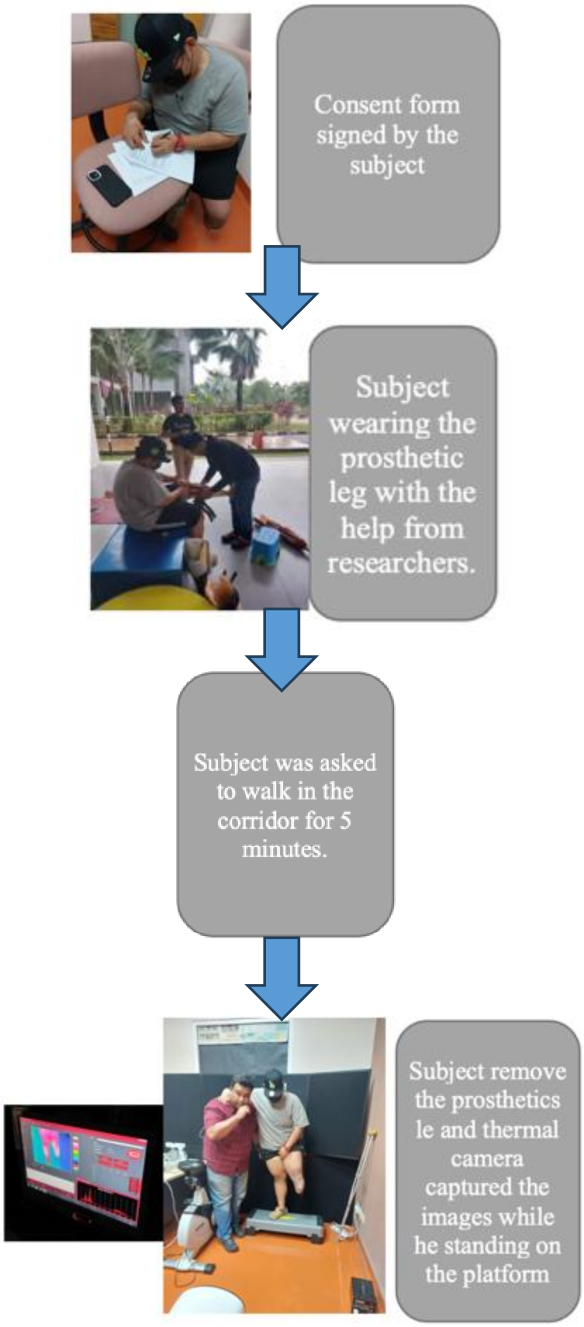


Fig. 5. A flow that illustrated the process of thermal imaging assessment.

3. RESULT AND DISCUSSION

3.1 Compression Testing

Fig. 6 shows a graph of Load (N) versus Compression Extension (mm) for socket 11-, 12-, 13-inch diameter, respectively. From the graph, it illustrated that the compression extension is increasing when the load is increasing, thus this suggested that it behave likes a linear-elastic properties. All specimens exhibited consistent mechanical behaviour with no signs of premature failure or crack propagation during the compression testing. Deformation was observed at the proximal end, consistent with expected load concentration zones in transtibial socket designs. These findings suggest that the Kedidi socket's composite construction offers robust mechanical performance comparable to or exceeding conventional sockets, which typically range between 2500 – 3000 N in compressive strength [4].

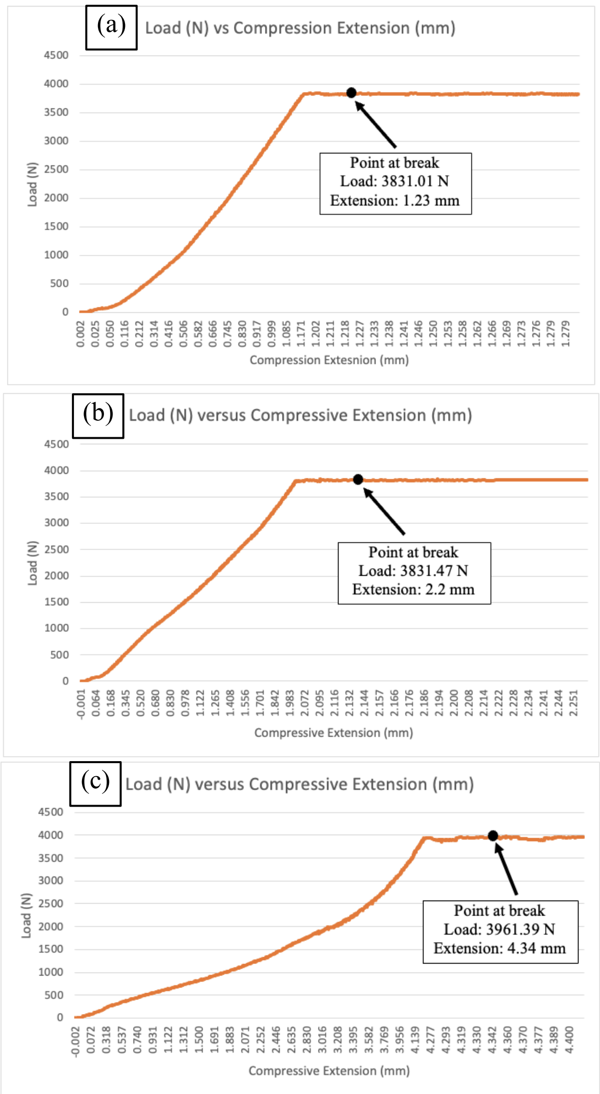


Fig. 6. A graph of Load (N) versus Compression Extension (mm) for socket 11, 12 and 13 inch, respectively.

The following Table 1 shows a summary of the results from the compression testing. To be noted, all specimens break at the load of 3800N and above. A minor difference between size of 11- and 12-inch diameter, approximately around 0.01% difference. Meanwhile, a total of 3.33% difference have been found for the sample size of 12- and 13-inch diameter. In addition, high value of load at break implies that the socket has higher resistance to the applied load, thus indicating that the socket is stronger. This is highly important to be highlighted that active users who use their prosthetics leg may subject more load on the socket, thus high chances of failure might be occurred in the future [9].

Table 1. Summary of the results from compression testing

Socket Size (Inch)	Load at Break (N)	Compressive Extension at Break (mm)
11	3831.01 ± 24.22	1.23 ± 0.12
12	3831.47 ± 45.71	2.20 ± 0.22
13	3961.39 ± 77.19	4.34 ± 0.29

3.2 Thermal Assessment

3.2.1 Conventional Prosthetics Leg

Fig. 7 and 8 show the thermal distribution area of superficial skin of the residual limb for conventional prosthetic leg, before and after activity, respectively. From the assessment, the results were recorded as minimum (min), average (avg), maximum (max) and standard deviation (std). From the distribution, it is found that maximum temperature (32.87°C) recorded before donning was at the front of residual limb. Meanwhile, the maximum temperature after the activity was found at 34.78°C. To be noted, the higher temperatures were found at the front side as compared with the back side of the residual limb. This indicates that special attention should be made on the front design of socket to reduce the skin's temperature, to avoid complications in the future.

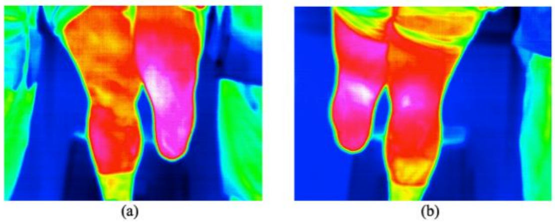


Fig. 7. Thermal images of the (a) front and (b) back side of the residual leg before activity begin.

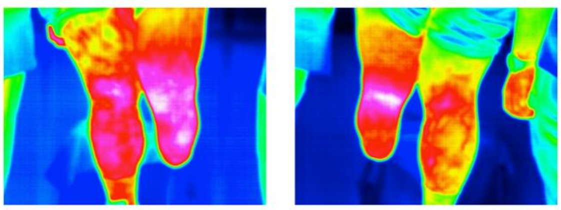


Fig. 8. Thermal images of the (a) front and (b) back side of the residual leg after subject removed the prosthetics leg once activity was done.

3.2.2 Kedidi Prosthetic Leg

Fig. 9 and 10 show the thermal distribution area of superficial skin of the residual limb for Kedidi prosthetic leg, before and after activity, respectively. It is found that the front side contributed larger temperature value as compared with the back side. Before donning and activity, the maximum temperature was at 31.22°C. Meanwhile after the activity, the skin's temperature was recorded at 35.02°C. As similar with conventional prosthetic leg, it is found that higher temperatures occurred at the front side, where this is crucial information to be highlighted that design modification or materials selections should be made properly to reduce the temperature to avoid complications in the future.

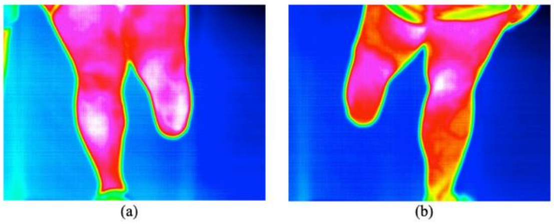


Fig. 9. Thermal images of the (a) front and (b) back side of the residual leg before activity begin.

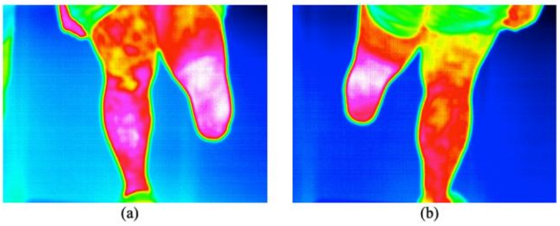


Fig. 10. Thermal images of the (a) front and (b) back side of the residual leg after subject removed the prosthetics leg once activity was done

Table 2 and 3 summarise the results of the temperature at the front and back sides of the residual limb for both the conventional and Kedidi prosthetic socket. Comparing the two designs, the Kedidi socket recorded a slightly higher temperature at the front side (35.02°C) compared to the conventional design (34.78°C). This represents a minimal percentage difference of 0.68%, suggesting no significant thermal variation between the two designs. However, when comparing pre- and post-activity temperatures, the Kedidi design exhibited a more pronounced increase at approximately 4-6°C, a trend consistent with previous findings [15]. In contrast, the conventional socket showed a smaller temperature change of only 1-2°C. This suggests that the conventional design and its materials are significantly superior to the Kedidi socket in terms of thermal performance on the skin.

Table 2. Summary of the results of temperature for front side of residual limb

Temp (°C)	Conventional		Kedidi	
	Pre	Post	Pre	Post
Min	21.12	21.81	19.24	20.12
Ave	31.08	31.18	29.05	32.08
Max	32.87	34.78	31.22	35.02
SD	0.92	1.51	1.39	1.57

Table 3. Summary of the results of temperature for back side of residual limb

Temp (°C)	Conventional		Kedidi	
	Pre	Post	Pre	Post
Min	22.83	20.47	20.26	19.72
Ave	29.64	30.03	27.75	31.86
Max	30.82	32.12	30.67	35.35
SD	0.63	0.95	0.95	1.73

In general, this study aimed to evaluate the newly developed Kedidi prosthetic socket in terms of mechanical integrity – following ISO10328:2016 standards for structural testing of lower-limb prostheses- and thermal performance by assessing skin temperature for improved air circulation. A study by Cutti et al. [15] investigated the thermal conditions of unilateral transtibial amputees using a thermal camera and reported a mean post-activity temperature of 35.02°C, which is consistent with the temperature observed for the Kedidi socket in this study. Another key finding from Cutti et al. was that the temperature difference before and after activity ranged from 1-6°C- a trend similarly observed in the current study. These temperature variations are likely due to the materials used in the current study, where a further study should be conducted to assess the properties of that materials. A previous study by Peery et al. [19] suggested that socket material significantly affects the magnitude of temperature increase, with thermoplastic sockets inducing higher temperature rises compared to carbon-fiber alternatives. Not much literature was found on the study of materials, therefore, a comprehensive investigation should be conducted in the future to evaluate different materials for prosthetic leg socket application [20, 21].

It is worth to mention that this study has limitation. First and foremost, there was only one volunteer in this study. To obtain more comprehensive results, the study should include more volunteer as suggested by other studies [15, 19]. Another limitation of study is regarding the number of activities for thermal assessment. In the future, it is suggested that many activities should be considered, i.e walking, jumping, climbing and cycling as demonstrated by literature [2, 22]. One of the most important to be highlighted here is the combining of conventional and three-dimensional (3D) printing technology should be considered in the future [1, 18, 20, 23]. This could enhance the design improvement and perhaps the outcomes will be more favourable.

4. CONCLUSION

This study shows that potential of newly developed Kedidi socket for the amputee leg patients in the future. From the results, it can be concluded that the mechanical integrity and thermal condition is acceptable for the users.

5. ACKNOWLEDGEMENTS

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