Original Article
http://mjiri.iums.ac.ir
Medical Journal of the Islamic Republic of Iran (MJIRI)

Med J Islam Repub Iran. 2024 (19 Aug);38.94. https://doi.org/10.47176/mjiri.38.94

A New Socket Prototype Design with a Heat-Exchanging Metal Layer for Individuals with Below-knee Amputation

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Received: 18 May 2024 Published: 19 Aug 2024

Abstract

Background: Individuals who have undergone lower limb amputation often struggle with excessive heat and sweating in their prosthetic sockets. This is due to the closed environment of the socket, which disrupts the body's natural cooling mechanisms and can lead to increased skin temperature, sweating, and various skin problems. This study aimed to develop a new socket to alleviate heat buildup in those with below-knee amputation.

Methods: A positive residual limb model of a below-knee amputee was used to create a new socket made of copper metal through electroforming. A cooling system was programmed so that if the temperature exceeded a predetermined threshold, the system would be activated to prevent further temperature increase. The participant wore the conventional and new socket with the cooling system, and his residual limb skin temperature was monitored using a temperature data logger.

Results: Implementing the new socket led to a significant 5°C to 6°C reduction in temperature within the socket, greatly enhancing thermal comfort and reducing heat sensation for the users.

Conclusion: By incorporating the new socket and cooling system, substantial reductions in heat accumulation within the prosthetic socket can be achieved.

Keywords: Prosthetic socket, Temperature, Below-knee amputation, Electroforming, Active Cooling System, Heat Reduction

Conflicts of Interest: None declared
Funding: None

Cite this article as: Farhoudi M, Hajiaghaei B, Saeedi H, Babaee T. A New Socket Prototype Design with a Heat-Exchanging Metal Layer for Individuals with Below-knee Amputation. *Med J Islam Repub Iran.* 2024 (19 Aug);38:94. https://doi.org/10.47176/mjiri.38.94

Introduction

There are multiple factors contributing to the occurrence of lower limb amputations. According to data, there are approximately 1.9 million individuals living with amputations in the United States (1). By 2050, this number is expected to be over 3.6 million, with lower-limb amputees comprising about 65% of the total (2).

A prosthetic limb is the key to the rehabilitation of those with lower limb amputation. An excellent prosthetic limb with a favorable socket-residual limb fit is required to determine the usefulness of the prosthesis. The primary function of the prosthetic socket is to establish a structural connection between the residual limb and the prosthesis. Additionally, it should effectively distribute pressure during standing and movement while minimizing pistoning action and displacement between the limb and prosthesis. (3). Despite advancements in socket manufacturing, surrounding the residual limb inside the socket leads to an increase in heat and sweating inside the socket. This can lead to complications such as skin inflammation, bacterial infections,

↑What is "already known" in this topic:
Despite advancements in socket manufacturing, surrounding the residual limb inside the socket leads to increased heat and sweating. This can lead to complications such as skin inflammation, bacterial infections, inflammation of hair follicles, skin pimples, cellulitis, blisters, increased moisture on the skin's surface, friction, and, ultimately, skin wear.

→What this article adds:
As an alternative approach, we propose using copper metal to construct prosthetic sockets because of its high thermal conductivity, effectively dissipating heat and facilitating heat transfer out of the socket.

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inflammation of hair follicles, skin pimples, cellulitis, blisters, increased moisture on the skin's surface, friction, and ultimately skin wear (4). Klute et al researched the thermal conductivity of materials used in socket and liner production. Although these products offer high biomechanical efficiency in the market, they act as insulators that trap heat around the residual limb. As a result, sweating occurs along with increased heat (5). Ghoseiri and Safari conducted a review study that showed approximately 53% of lower limb amputees experience issues related to heat and sweating within their prosthetic sockets (6).

When internal body temperature rises due to factors such as increased metabolism or external influences, 4 mechanisms are employed by the skin to dissipate heat into the environment to maintain core body temperature (7). Evaporation is the primary mechanism for heat dissipation during physical activity, leading to decreased skin temperature. However, in those with lower limb amputation using a prosthesis, the prosthetic socket disrupts these cooling mechanisms due to its enclosed space and direct contact with the skin of the residual limb, which may increase skin temperature and perspiration (7). Perry et al demonstrated that even a slight increase of 1° to 2° in socket temperature can cause discomfort for users (8). Therefore, managing heat stress and preventing skin perspiration is crucial, as failure may discourage prosthesis usage (6, 9). This product development and evaluation study aimed to investigate the usefulness of a new socket design with a heat-exchanging metal layer for those with below-knee amputation.

Developing prosthetic sockets using materials that facilitate effective heat transfer is vital. Reducing the temperature within the socket enables prolonged prosthesis usage and improves quality of life (10). Nurhanisah designed an air-flow prosthetic socket utilizing natural fibers to optimize its usability. This study examined the impact of various fenestration patterns on limb temperature in a below-the-knee amputee (11). This approach increased stresses on the socket wall and compromised its strength; therefore, it was deemed unsuitable (4). Another potential solution lies in utilizing nanotechnology to address heat issues within prosthetic sockets. Nanoparticles or carbon nanotubes have significantly improved heat transfer efficiency (12). Zhi reported that incorporating just 1% of carbon nanotubes into poly methyl methacrylate resin while manufacturing prosthetic sockets increases thermal conductivity by 3-fold (13). However, concerns over the safety of nanomaterials exist, as they could be released onto the skin over time, resulting in skin irritation, allergic reactions, or other adverse effects. Therefore, further research is necessary to investigate these materials' stability and potential toxicity (14). Switching from thermoplastic to carbon fiber as the socket material is unlikely to significantly impact temperature or perspiration levels within the residual limb since both materials possess similar thermal conductivity properties (15). To address these challenges, a prototype of a new socket incorporating a heat-exchanging metal layer and cooling system was designed and constructed. Its performance was evaluated during the clinical stage using a below-knee amputee as a test subject. This study hypothesized that the new socket can assess and measure temperature changes inside the prosthetic socket of the individual being studied during different phases. This was achieved by utilizing a control program in the clinical stage to prevent the temperature inside the socket from rising.

Methods

Socket Design

We utilized the positive residual limb model of an individual who had a below-the-knee amputation to create a new socket made of copper metal through electroforming (Figure 1). The construction process involved several stages (Table 1). Following construction, the socket's strength was assessed in a physics laboratory and deemed sufficient and stable.

Copper Electroforming

The process entails using electricity to deposit positive copper ions onto a negatively charged mold. This is achieved by immersing the mold into a salt solution containing copper electrolyte composed of copper sulfate and sulfuric acid (16). Subsequently, the mold is separated or dissolved from the copper metal, leaving only the copper form. A unique technique was developed by utilizing a silicone mold with a hollow interior that can be filled with wax or another material. By sprinkling silver particles on the mold surface, it became conductive. The mold was then placed into the electrolyte bath at an appropriate angle and fixed at a distance of 8 to 10 cm from the anode to ensure an even layer of copper. A current intensity of 4 amps and a voltage of 12 volts were used. The process took approximately 6 days to achieve the desired thickness and strength. The mechanical engineer has checked and confirmed the final thickness and strength of the socket for this purpose. Electroforming is a secure and stable process that produces high precision and elegance when all instructions are followed correctly (17). This method does not change in dimensions due to shrinkage and distortion after production (17). The metal produced through this method is exceptionally pure and possesses outstanding qualities compared to impure metals because of its refined crystal structure. Multiple layers of metal created through this process can be molecularly bonded to one another or different substrate materials, creating complex structures with excellent durability

Figure 1. A new socket with a heat-exchanging metal layer and filled mold with silicone top(left); the final socket (Right)

Table 1. Steps of making a copper socket with the electroforming method

1) Visit the below-knee amputee and evaluate the exit and entry criteria by answering the questionnaire.
2) Molding of the remaining member of the individual
3) Conventional correction of the mold and preparation of a negative mold, followed by checking it on the person
4) Lay material with four layers of socks on the positive mold.
5) Construct a hard socket and coat it with silicone all around the inner wall of the socket
6) Fill the silicone mold with any filler material (wax was used in this study)
7) Remove the hard socket from the silicone mold.
8) Conduct the surface on the silicone mold with silver spray.
9) Place the mold in the electrolyte bath to perform the electroforming process.
10) Make a new socket on a silicone mold by Electroforming method.
11) Remove the silicone mold from the copper socket.
12) Pour material on the new socket to create a profile on it and add more strength.

and strength (18).

External Frame

An outer frame was utilized to enhance the strength and durability of the new socket. The construction of this frame involved placing material on the copper socket. To create it, 3 layers of socks and 1 layer of carbon socks were applied to the copper socket. The material was laid down after positioning the 4 horns at the end of the socket. It was then cut into a suitable shape to ensure that both the copper socket remained exposed and the weight of the socket did not increase.

Cooling System

Upon completing the planning and construction phase, we implemented a cooling system to enhance the performance of the new socket in terms of cooling capabilities (19) (Figure 2). To achieve this, we employed a thermoelectric cooler (TEC1-12704) measuring 0.4 × 4 × 4–cm, connected to a heat sink measuring 2.5 × 5.5 × 10–cm, and a small 12-volt fan measuring 1 < 5 × 5–cm. The fan was secured to the heat sink using 2 screws, and both were then connected to the thermoelectric cooler using silicone glue. Including a heat sink and fan with a thermoelectric cooler was essential to prevent overheating and potential damage to the component, thereby increasing its lifespan and efficiency. By employing these components, excess heat is dissipated effectively. An Arduino Uno microcontroller board was utilized to construct the cooling system (20). This particular board is based on the ATmega328 microcontroller and has various features such as a USB port, power jack for power supply input, ICSP header, and reset button. With just a single USB cable connection to the computer or an AC-to-DC adapter or battery for power supply, this board can be efficiently utilized. Operating within a 6 to 20-volt voltage range, the Arduino Uno board's programming was carried out using open-source software that employs the C/C++ programming language for coding purposes. The microcontroller board was specifically programmed as a closed-loop control program utilizing the PID algorithm. It can measure temperature information through thermistors and activate the cooling system based on predetermined temperature thresholds (21). Each sensor had a resistance of 10 KΩ within a range of -40°C to +125°C with a resistance of ±1%°C at room temperature (25°C). A temperature display connected to the microcontroller board showcased the average temperature recorded by the sensors. The temperature data are stored using an Arduino Data Logging Shield on a memory card. The cooling system consisted of 2 parts: Part (A) included a thermoelectric cooling element (19), heat sink (22), and fan (22) affixed behind the copper socket using silicone glue, while Part (B) involved microcontrollers, thermistors, and data loggers placed inside a box connected to electricity via an adapter to measure and reduce temperature. The second part was worn by the participant on his waist using a waist bag to reduce the overall weight of the prosthesis (20). The system's operation involved defining a specific temperature set point within its control circuitry. When the average temperature inside the socket exceeded this set point value, the system would activate automatically to prevent further temperature rise (21).

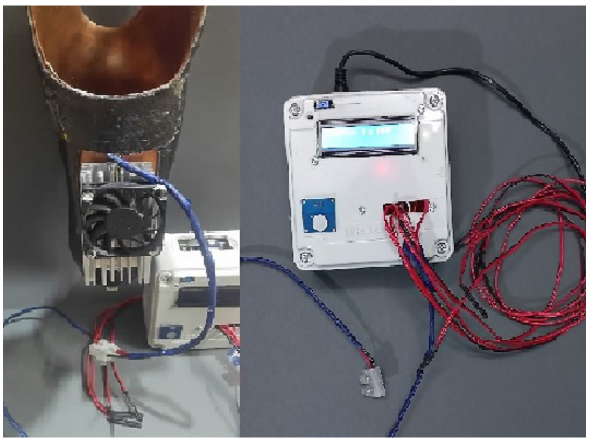

Figure 2. Cooling system components, part (A) included a thermoelectric cooling element, heat sink, and fan, and part (B) consisted of microcontrollers, thermistors, and data loggers placed inside a box

Clinical Examination

This study was supported by the research committee of Iran University of Medical Sciences (No. IR.IUMS.REC.1401.515). Before the study, we comprehensively explained the research and its objectives to the participant and obtained written consent. The amputation was congenital, and the person had approximately 25 years of experience using a prosthesis, wearing one for about 12 to 13 hours daily. The participant had no skin problems or wounds on his residual limb, which was in a healthy condition. The person's prosthesis had a Patellar Tendon Bearing Supracondylar suspension system(PTB SC), with a gel

[DOI: 10.47176/mjiri.38.94]

liner interface between the socket and the stump that was 3 mm thick. Moreover, he did not smoke, had no cardiovascular or breathing issues, and had normal blood flow in the stump. He did not use extra socks for a better fit, as both sockets fit perfectly. However, he did experience discomfort due to heat and sweating inside the prosthesis socket, particularly during summer. After creating the new socket, the researchers in this study compared its performance to the conventional socket that the participant initially had. Before beginning the tests, the participant wore the new socket and walked with it for 2 consecutive days to become accustomed to using it. The participant was asked to wear the conventional and new socket with the cooling system. After fabricating the desired socket, we scheduled a visit to the prosthetic laboratory within 6 days for data collection. The participant would arrive at a specified time during the day and be asked to rest for 30 minutes in the test environment without wearing prostheses. This allowed them to adapt to the conditions and temperature of their surroundings. Throughout all testing stages, we maintained a constant ambient temperature of 29°C. Thermistors were strategically placed on areas of the patient's residual limb with higher temperatures than bony regions (20). These sensors were positioned on the residual limb's medial, anterolateral, posterior (popliteus muscle mass), and posterodistal side. After proper placement, we proceeded with the initial evaluation step, which consisted of 4 stages. Initially, the skin temperature of the participant's residual limb was recorded while not wearing the prosthesis. The data obtained during the initial phase of the experiment, where the participant did not wear the socket and remained seated for 5 minutes, were used to determine the surface temperature values of the residual limb's skin. Subsequently, the temperature was measured while wearing the prosthesis in a seated position after 1 minute and again after 15 minutes (8). In the third step, the participant walked on a treadmill for 3 minutes to establish a desired speed (20) (1m/sec, 500 m distance) and then continued walking for 15 minutes while wearing the prosthesis. The temperature recorded during the last minute of these 15 minutes was analyzed. Finally, in the fourth step, the participant's residual limb skin temperature was measured while sitting and wearing the prosthesis for 15 minutes, with analysis focused on the last minute of this timeframe (10).

The measured temperature was collected through a data logger and stored in the computer. The data record was done automatically through the programming of the microcontroller, which includes 2 commands: (1) measuring temperature and (2) decreasing the temperature. Moreover, calculations were performed for each thermistor to determine average temperatures and trend lines when using 2 types of conventional and new sockets. In the steps when the prosthetic socket is on the residual limb, 2 subjective evaluations were conducted before and after wearing the prosthesis to assess the thermal sense and thermal comfort of the participant. The thermal sensation is a conscious feeling of the amount of heat, typically categorized as cold, cool, slightly cool, neutral, slightly warm, warm, and hot based on personal assessment. Thermal comfort is the overall sensation of warmth or coolness experienced by the body. It is described as a state in which the brain perceives the heat level in the surroundings to be satisfactory, as assessed through personal judgment. The participant was asked to rate his thermal sense and comfort based on the American Society of Heating, Refrigerating, and Air-Conditioning Engineers and Bedford scales, respectively (19, 23).

Statistical analysis is a crucial method for assessing the effectiveness of interventions at an individual level. Various standard techniques are employed for data analysis, including visual graphs like line graphs and bar graphs, which are widely used to present data and highlight patterns. Bar graphs are also used to illustrate average results in each intervention phase. However, visual analysis, particularly examining line graphs to identify patterns of change, is a critical statistical method in the current research. Criteria such as level, trend, stability, and variability are assessed. Another method used is the effect size index, which measures it based on the percentage of non-overlapping data. It can also be used in comparative analyses, such as the Mann-Whitney U test or analysis of variance, which serve as additional statistical methods to compare data in these studies. The evaluations were conducted using SPSS and Microsoft Excel software Version 2016.

Results

The temperature measured by the sensors at the fifth minute was used to evaluate the surface temperature of the residual limb. The results showed that a temperature of 28.98 corresponds to the distal region as the coldest. In contrast, a temperature of 30.54 corresponds to the anterior-lateral region as the warmest part of the residual limb. The findings are displayed in Figure 3.

The results regarding the average temperature in all 3 modes of the conventional socket, the new socket without the cooling system, and the new socket with the cooling system active showed a significant decrease in temperature when using the new socket. Table 2 illustrates the results of these recorded temperatures. The evaluation of the average temperature of each sensor showed that wearing the new socket resulted in a noticeable decrease in temperature compared with the conventional socket. Furthermore, there was a distinct change in the temperature level and trend immediately after wearing the new socket, which aligned with the research objectives. This information can be found in Figure 4.

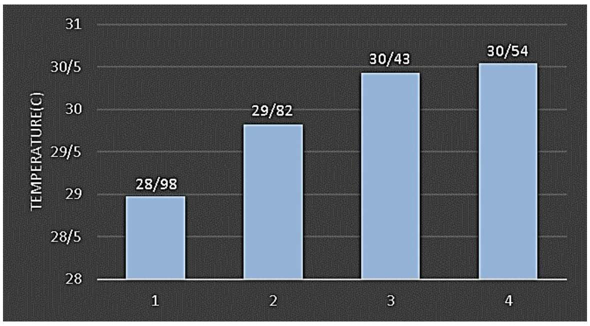

Figure 3. Residual limb skin temperatures (°C) for all 4 thermistors for (1): posterodistal, (2): medial, (3): posterior (popliteus muscle mass), and (4): anterolateral side (without the prosthesis)

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Table 2. The average temperature inside a new socket and a conventional socket

Socket type	1st	2nd	3rd	4th
Conventional socket	29	30.69	34.79	34.37
New Socket (Cooling system Off)	28.72	29.38	31.53	30.43
New Socket (Cooling system On)	28.42	28.66	29.17	28.25

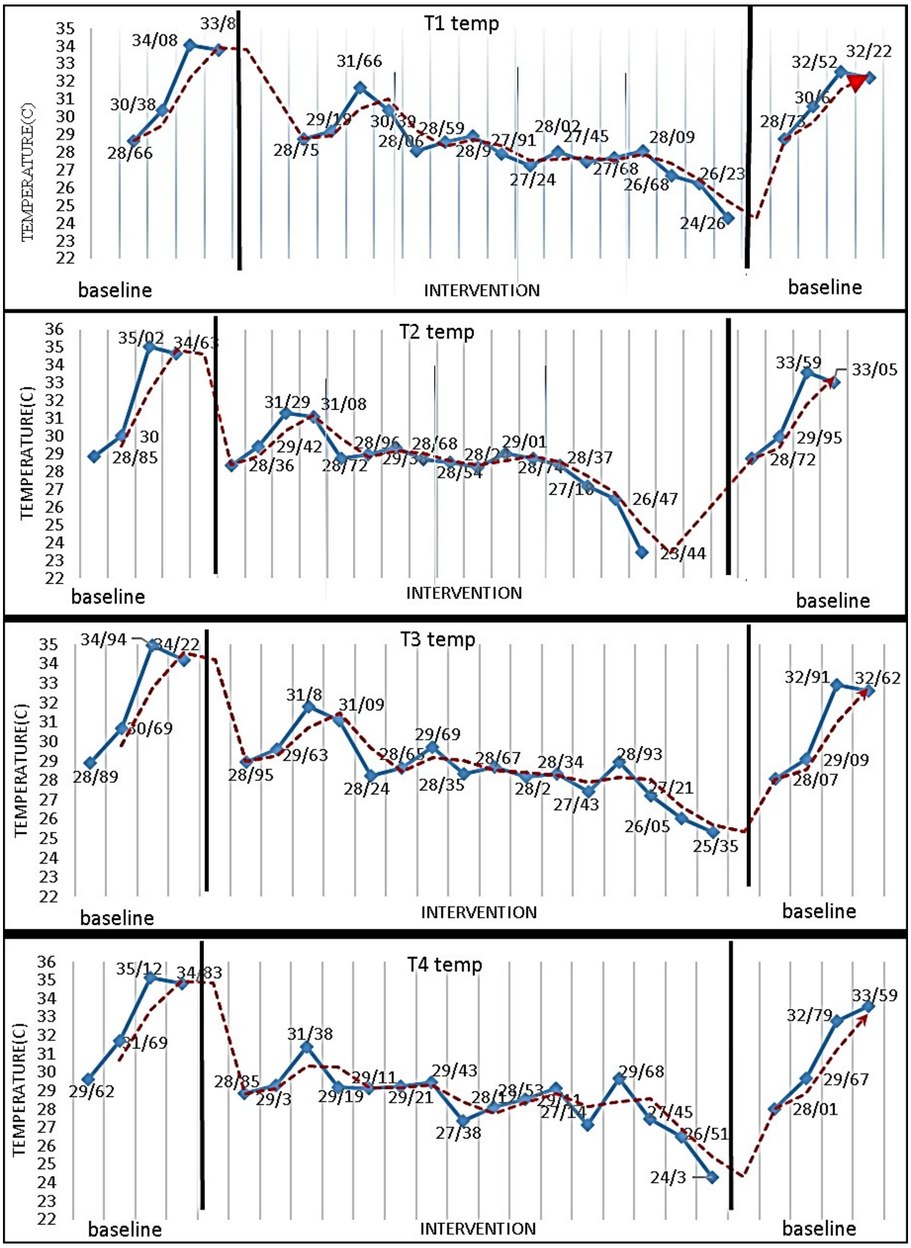

Figure 4. Average temperature of each thermistor and trendline during conventional socket and new socket

The results of the evaluation of an amputee's thermal sensation after wearing 2 types of new and conventional sockets showed that wearing the new socket with a cooling system made the person feel less hot. In terms of the thermal comfort experienced by the amputee after wearing both types of sockets, the evaluations indicated that the person reported higher levels of comfort when wearing the new socket with the cooling system. This suggests that the person experiences more comfort and less heat in this state. The results of thermal sense and thermal comfort before and after wearing the prosthesis are shown in Figure 5.

Discussion

We investigated the impact of a newly designed socket, equipped with a heat-exchanger metal layer and a cooling system, on reducing the temperature inside the socket for those with below-knee amputations. As an alternative approach, we propose using copper metal to construct prosthetic sockets because of its high thermal conductivity,

[DOI: 10.47176/mjiri.38.94]

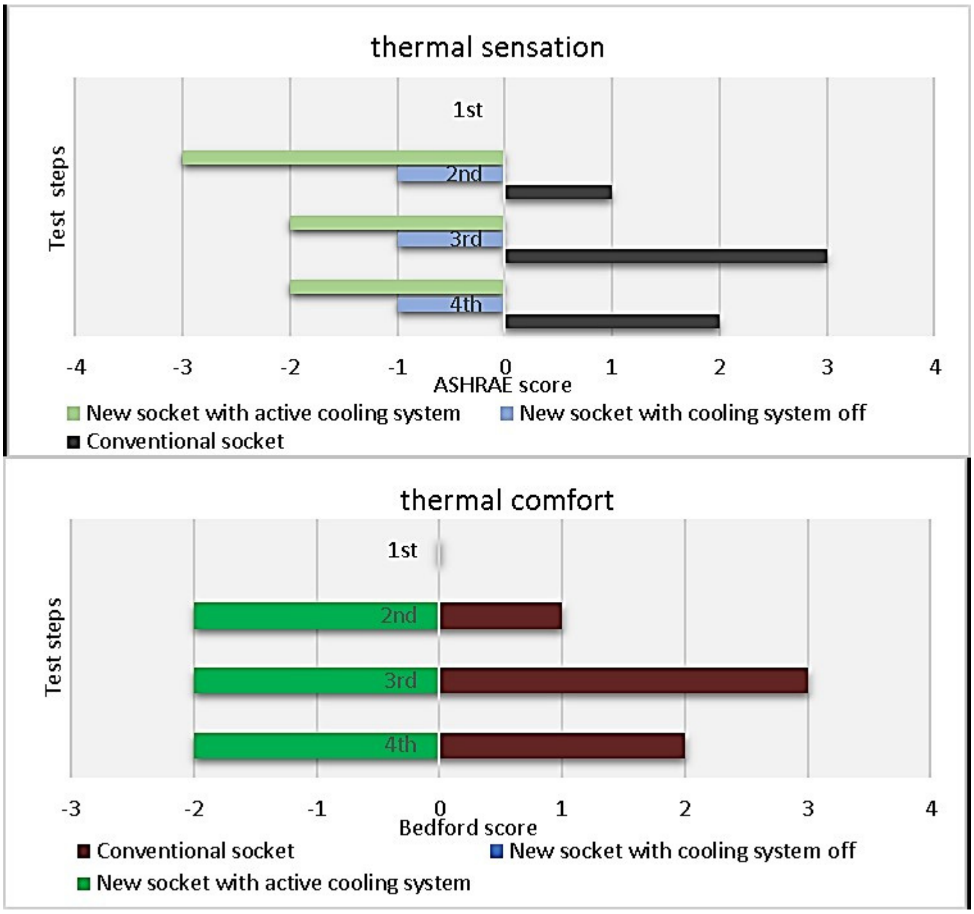

Figure 5. The results of thermal sensation and thermal comfort assessment when using two types of sockets

which effectively dissipates heat and facilitates heat transfer out of the socket. Integrating the new socket design with a cooling system holds significant clinical relevance, as it can significantly decrease heat accumulation within the prosthetic socket, a common problem of amputees, thus possibly improving the overall comfort, wearability, and compliance to prosthetic use among this population. Nonetheless, it is essential to note that the present study was conducted as a preliminary feasibility analysis, and thus, the efficacy of this system within a clinical context necessitates further evaluation through research involving a larger sample size. Through multiple measurements of skin temperature on the residual limb without wearing the prosthesis, we obtained an average temperature of 29.94°C ± 0.8°C. Ghoseiri also conducted a study where they measured surface temperatures on the residual limb skin and reported an average temperature of 29.08°C ± 0.6°C. Their study consisted of 2 phases (A1 and A2), and in phase A1, they found that the skin temperature on the residual limb was approximately 29.69°C, which closely aligns with our findings (19). Peery et al, on the other hand, stated that the average skin temperature was about 31.4°C ± 1.3°C (8). According to Elizabeth Hoff's research, a 59-year-old person's residual limb skin temperature averaged 29.5°C ± 0.9°C after wearing a standard socket for 60 minutes. This information was obtained using 16 thermistors (24).

In another study by Mathur et al that involved measuring residual limb skin temperature during 35 minutes of activity with a below-knee prosthesis at an ambient temperature of 25°C, they found that the surface temperature of the residual limb skin, 1 minute after wearing the prosthesis, was approximately 29°C (25). Considering these findings, it appears that a temperature ranging from 29°C to 30°C is a more realistic average for residual limb temperature compared to the study by Perry.

During the testing, it was observed that when the individual wore the conventional socket, the temperature of the remaining limb inside the socket increased by 5.8°C compared to its original temperature. Even after resting on a chair for 15 minutes after a session on the treadmill, the temperature only decreased by 0.42°C. Interestingly, when tested with a new socket that did not have an active cooling system, the temperature increased by a maximum of 2.8°C compared to its initial temperature. After resting for 15 minutes, the temperature inside this new socket decreased by 1.1 degrees Celsius. Comparing these 2 types of sockets revealed that at the final stage of testing, the residual limb's temperature inside the new socket was nearly 4°C lower than in the conventional socket. Consequently, there is a significant disparity in thermal performance between these 2 types of sockets.

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During the period when the cooling system was functioning, the findings indicated that after the initial resting phase, there was a slight rise in the average recorded temperature from 28.42°C to 28.66°C (an increase of 0.2 degrees). Subsequently, after 15 minutes of walking on the treadmill, the temperature escalated to 29.17°C—an increase of 0.75°. Then, at the end of the final rest period, the temperature dropped to 28.25°C—(a decrease of 0.17°. This outcome was remarkable, as it demonstrated that the maximum temperature increase was <1° and ultimately, by the end of the experiment, the average temperature was even lower than its initial value. When comparing the maximum temperature in the new socket with the active cooling system compared to the conventional socket, the results showed that the temperature has decreased by 5.62°C.

The findings regarding the feeling of heat and comfort about the new socket revealed that not only did the person not experience any heat, but they also felt cool. This greatly satisfied the person using it. The size of the cooling system was appropriate, taking into account that the microcontroller part was placed in a box on the person's waist in a waist bag, and the cooling part was hidden from view on the back wall of the socket. The person fully accepted the aesthetics of the new socket. The weight of the socket without the cooling system was the same as a conventional socket, with the difference lying in the weight of the cooling element, heat sink, and fan located behind its wall. One limitation of this study is that amputees can only walk briefly without risking injury while wearing thermistors. However, James Williams mentioned in a study that conducting temperature studies lasting multiple hours is feasible but conducting experiments lasting multiple days or weeks requires reliable temperature sensors that participants can apply and remove independently. Additionally, data collection systems need to have sufficient battery life and storage capacity for continuous data collection and recording (20). Another common limitation in prosthetic thermal comfort research is having small participant sizes; thus, efforts should be made to find ways to safely encourage more participation within this community.

Conclusion

The socket developed in this research has effectively decreased the temperature within the socket during various stages. It is anticipated that this innovative socket will greatly alleviate heat-related issues by efficiently cooling the socket. Consequently, it will enhance the individual's prosthesis utilization and overall quality of life.

Authors' Contributions

Conceptualization and design: All authors; Methodology: All authors; Data collection and analysis: Mahboobeh Farhoudi and Behnam Hajiaghaei; Writing original draft: Mahboobeh Farhoudi; Revisions and editing: All authors; Resources: All authors; Supervision: Behnam Hajiaghaei and Taher Babaee.

Ethical Considerations

The study complied with the Declaration of Helsinki 2018 and was approved by the Ethics Committee of the Iran University of Medical Sciences, Tehran, Iran (Code: IR.IUMS.REC.1401.515).

Acknowledgment

The authors express their gratitude to the participants who participated in this study.

Conflict of Interests

The authors declare that they have no competing interests.

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