Manufacturing and Testing Pneumatic Pads Adjustable Socket for A Below-Knee Prosthetic

Ammar Issam Kubba [1,2], Ahmed A Alammar[3]

Authors affiliations:
1) Dept. of Prosthetics and Orthotics Engineering, College of Engineering, Al-Nahrain University, Baghdad, Iraq.
ammarkubba83@gmail.com

2) Honorary research fellow, Dept. of Mechanical Engineering, School of Engineering, University of Birmingham, UK
a.i.s.kubba@bham.ac.uk

3) Centre for Sustainable Cooling, School of Chemical Engineering, University of Birmingham, UK.
a.a.g.alammar@bham.ac.uk

Paper History:

Received: 21st Sep. 2023

Revised: 8th Nov. 2023

Accepted: 24th Dec. 2023

Abstract

The purpose of this research is to manufacture and test adjustable sockets for below-knee amputation. This article studies using the pneumatic–pads for adjustable sockets. The manufacturing of an adjustable socket with pneumatic pads goes through several stages: In the theoretical design of the adjustable socket, the suggested materials were studied for the pneumatic pads, tubes, and pneumatic pump which should be suitable for the suggested application. In the experimental work, using composite materials for manufacturing the socket consisting of perlon and resin to achieve the rigid shape and required flexibility for the prosthetic user with the pneumatic pads. After assembling the adjustable socket parts, the pneumatic pads, the pump and the tubes, the socket were tested for several times on the patient. In the last stage, the pressure between the socket and the residual limb was measured using F-socket, and it was found that the results were: anterior (160kPa), lateral (167kPa), posterior (153kPa) and medial (348kPa). By comparing these results with what was previously studied, the pressure between the socket and the residual limb is within the acceptable range. The design provides good suspension and more adaptability to the change in stump volume. Positive feedback was given by the patient who used the prosthetic for several days as a trial to measure its safety and comfortability.

Keywords: Adjustable Socket, Below-Knee Amputation, Pneumatic -Pads, Prosthesis.

تصنيع و فحص وقب قابل للتعديل بالوسادات الهوائية للأطراف الاصطناعية أسفل الركبة

عمار عصام صالح كبه , أحمد علي العمار

الخلاصة:

الهدف من هذا البحث هو تصنيع واختبار وقب قابل للتعديل للبتر تحت الركبة باستخدام وسادات الهواء. يمر تصميم وتصنيع الوقب القابل للتعديل باستخدام وسادات الهواء في عدد من المراحل. في مرحلة التصميم النظري للوقب القابل للتعديل ، تم دراسة مقترحات انواع الوسائد الهوائية وماهية المواد المستخدمة للوسائد والانابيب ومضخة الهواء المناسبة للمتطلبات التصميمية للمنظومة المقترحة. في العمل التجريبي ، تم استخدام المواد المركبة لتصنيع الوقب القابل للتعديل المكون من البيرلون و استخدام الراتينج للطبقات هو لتحقيق الشكل الصلب وايجاد المرونة المناسبة و التي تساهم في ضمان الراحة لمستخدم الطرف مع وسادات الهواء. وبعد تجميع أجزاء الوقب مع وسادات الهواء والمضخة والأنابيب ، تم اختبار الوقب عدة مرات على المريض. في المرحلة الأخيرة ، تم قياس الضغط بين الوقب والجذعة باستخدام F-socket ، ووجد أن النتائج ضمن حدود المقترحة من الدراسات السابقة للضغط وهي كالاتي, الجهة الامامية (160kPa), الجهة الجانبية (167kPa), الجهة الخلفية (153kPa), الجهة الداخلية (348kPa). ان الطرف المصنع في هذا البحث قد وفر تعليق جيد للطرف وكذلك قابلية للتكيف مع التغيرات الحاصلة في حجم وشكل الجذعة. لذلك يعد التصميم ناجحا بعد تجربته من المريض الذي ابدى ارتياحا كبيرا لاستخدامه ضمن الفترة التجريبية التي كانت لعدة ايام.

1. Introduction

The socket is a crucial interface part located between the prosthetic and the stump of the patient; it is the key element to define if the prosthetic succeeds. It should be customized to fit the amputee's exclusive remaining lower or upper limb. Whenever the socket has an unsuitable shape, the patient will become uncomfortable with the prosthetic, or even it will result in some pain and skin issues.

The prosthesis designs the socket shape based on the unique requirements of a patient and their clinical status. A biomechanical structure will be created by the connection of the patient and the prosthetic. The prosthetic user's daily activities will decide the design requirements of the prosthetic: psychical abilities, occupation, patient's work area, etc. Substituting lost limbs is to make sure that the patient can support himself to stand and move freely without the assistance of any supporting piece of equipment. [1]

Early below-knee socket designs could not support patients' weight-bearing, due to the poorly available material and limited customized socket designs. These sockets were not able to carry all the patient's weight which resulted in shifting the supporting load to the knee or even to the above knee region, so they used other supporting techniques; some side joints and leather thigh corsets. The consciences of the continuous movement between the patient's stump and the socket will result in pain, skin irritations or at least patient discomfort. The prosthesis experts along with biomechanics scholars kept arguing about the need for new socket design technologies or not, these arguments led to the Symposium on Below Knee Prosthetics at the University of California, Berkeley Biomechanics Laboratory in 1957. At this event, cutting-edge technologies related to the socket's designs were presented which led to the design of the patella tendon-bearing socket. This socket is still in use for some patients until now [2]. However, several new designs were developed after this one, such as total surface bearing in the 1990s.

2. Adjustable sockets

An air pneumatic suspension system (APSS) is a devolved total contact socket with a pneumatic suspension system. The interface contact pressure and pistoning were tested for the suggested APSS. A 95% of the contact area or more was verified by the Tekscan F-Scan pressure sensor with a fluctuation of 10kPa or less during the gait cycle phases. The proposed adjustable socket design can improve the pressure distribution on the residual limb, putting on or off the prosthetics, keeping the socket fitted during a wide range of activities, and providing more ability to support any minor changes in the stump volume, and shape. Using pressure sensors to measure air pressure will provide feedback to control the pad volume [3]. A preferred pressure should be suggested and set to the proposed design before placing the residual limb into the socket. Then, when the patient activates the system control switch, the pneumatic pump will deliver the required air to the air bladder until the desired air pressure amount is reached. The pressure will be controlled through several air pressure sensors, which are programmed by microprocessors to keep the pressure in the designed range. In the end, when the patient needs to doff the prosthetic, a button will be pressed to release the air and drop the pressure, and then the residual limb region will be relaxed and it will come out easier from the socket [3].

Adjustable socket by Pneumatic -pads is a method of suspension and adjustable socket through the air pressure between the socket and stump in the below knee amputation. The air is compressed by placing air chambers inside the socket. The patient could don the prosthetic using a liner layer around the stump, and after that push the stump into the prosthetic's socket. The device compresses the required air to the pads which are placed in the designed suspension areas. The adjustable socket allows the amputee to constrict the socket's grasp on the stump. A range of stump sizes can be fitted in an adjustable socket system, in addition, the adjustable socket can fit the stump with volume and shape fluctuations. From the flexibility of adjustment and fitting, the suggested adjustable socket could reduce pain, soft tissue damage, and discomfort [4].

In the study of an adjustable socket for transtibial amputation prosthetic and immediate Fit which was delivered by Dillingham, T., et al (2019); The iFIT socket is unlike the traditional prosthetics. It can be made by the injection of modern polymer which results from a flexible socket that can fit a range of stump shapes. There is no need for grinding out the extra edges of the socket. Some extra alterations can be made by the prosthesis to make the socket more comfortable by adding some pads and liners. A shuttle lock can be used to ensure the prosthetics suspension requirements [5].

A socket interface pressure (SIFP) was used to compare two kinds of sockets in below-knee prosthetics. This study was delivered by Salvador Ibarra Aguila. et al. [2020] [6]. The (SIFP) system measures contact pressure in (6) critical regions of interest (CROI) during specific periods of the gait cycle. The sensors are fitted to the stump at the (CROI) just before fitting the prosthetic sockets. The pressure was observed when the participant was walking on the treadmill along the experiment 10 minutes at 1.4 m/sec. the collected data shows a difference between the peak value of the pressure between the prosthetics sockets.

A 50% or 0.22kgf/cm^2 difference in the collected pressure data at the stance phase in the gait cycle. The SIFP can be utilized by any rehabilitation center that takes care of amputees. The collected data can be used in a wide range of prosthetics testing and development to collect the required data for monitoring the progress of the services provided to the amputee [6].

A self-adjusting socket for a transtibial prosthetic with an automatic control system was suggested by Mbithi and et al. [2022] [7] study. This work shows a control structure that can adapt to a patient's stump by using localized actuators, these actuators were controlled by the suggested control system with the limitations of the safety of the soft tissue breakdown or injuries. A finite element analysis FEA was utilized to select the locations and to find the values of the actuator's locations and the amount of the applied load. The analyses were based on the anatomy-mechanical properties of the stump area, with the tissue risk assessment for the injury data. Several actuators were set to the proposed system to ensure proper socket interface pressure and safe limits to avoid injury [7].

A study aims to assess the reliability of the Bio-sculptor's bio-scanner system in measuring transtibial stump volume variation during a range of daily activities and rest periods [8]. The stump volume was observed by measuring the stump circumference after the prosthetic user walked for 5 to 25 minutes, in five consecutive days. The collected data shows irregularity in the value of stump circumference at several locations of the stump circumference outline. The two amputees who delivered the experiments had a sharp increase in the stump circumference at the distal end of the stump when they finished the five minutes of walking (7.35% change in inactive and 8.83% in active amputees), the collected data of the stump circumference decreased as the amputee practiced more walking. This research shows the implementation of the Bio-scanner device is useful to the typical measurement technique and it could be a different method for measuring the stump's change in volume during daily activity [8].

A study by Sanders et al (2019) aims to find an adjustable socket design based on controlling several panels in the socket using a motor with cables to adjust the location of these panels. The control system is connected to the mobile phone of the prosthetic user so; he/she can control the position socket conditions as comfortably [9]. An Algorithm for the control system and how to operate the motors with their cables for the adjustable socket was developed by Andrew et al (2020) [10]. The technology of using motors with cables to adjust the socket size and control by a mobile phone app was tested by McLean et al (2019), the tests were utilized by recording data from the prosthetic user while walking on the treadmill [11]. Another project by Weathersby et al. (2022) was to test the technology by utilizing several test cycles of monitoring the amputee during sitting -walking- cycling, these periodic test cycles were continued for several minutes [12].

An adjustable socket design using shape memory alloy to sustain interface pressure between the socket and the stump was developed by Wang et al. 2023 [13]. This adjustable socket was designed based on using a slide ring for the socket circumference with several actuators that are based on preserving specific values for interface pressure that controls the socket circumference to maintain the required socket shape and volume.

Finally, Klenow and et al. (2021) listed in their article several modern adjustable socket technologies which are still in development or are already in commercial usage. In this work, four main types of adjustable sockets are presented with their designs and functions [14].

From the above studies, the adjustable socket prosthesis is still in development. A wide range of projects and research are still available to achieve in prostheses. There are many different types of adjustable sockets, including Pneumatic – pads. Due to the lack of previous work on the pneumatic pad system, an adjustable socket design, manufacturing, and testing were investigated for a below-knee prosthetic limb with pneumatic-pads technology.

3. Design and manufacturing the Adjustable Socket

In this work, the traditional socket design was used with a pneumatic-pad system, these pads were added to provide suspension and control of the socket with fluctuations in the size of the stump.

After studying several previous articles to locate the pads, it was found that the best place to place the pads was below areas where total contact is suggested. The areas for adding pads are determined as shown in Figure (1), which shows that the green areas bear pressure, and the red areas cannot be subjected to pressure.

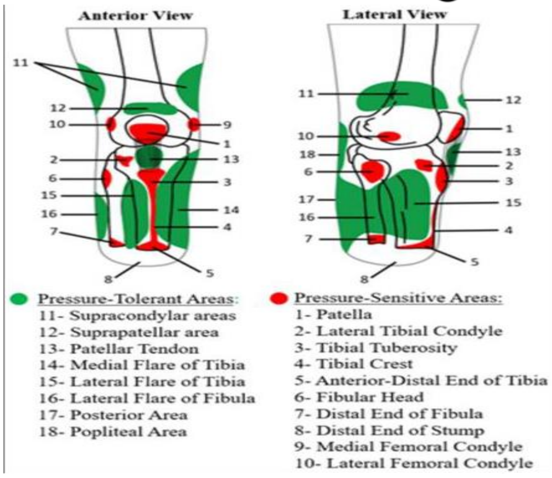

Figure (1): A transtibial stump with the locations of the areas of pressure sensitive and pressure tolerant [15].

The proposed design and manufacturing procedure of the socket involves adding several geometrical improvements to the stump mold to create the required profile of the socket's inner surface. The residual limb model is usually a mold made from plaster, which is created by the negative mold. The process consists of six steps; which can take around two hours each, some of these steps take more time as the molds need to be dry, and the whole process might need two working days to be completed [5].

The following figure (2) shows the steps of manufacturing the prosthesis, from taking the mold to the patient to assembling the artificial limb.

Figure (2): the steps of Assembling the prosthesis.

The design of this modified adjustable socket was established by assembling the pneumatic pad system which is placed behind the socket (pump, valve, tube). The pump and the valve can be easily controlled by the patient due to their position. The pads are located between the solid socket and the soft socket layer. The air passes from the pneumatic pump and the valve to the airbags through rubber tubes to ensure patient comfort. Figure (3) shows the final design of the socket. At the scenario when the patient feels that the socket is not having sufficient suspension, or there is some slipping or movement in the socket during walking, the patient could increase the air pressure in the pads by pumping more air to them using the pneumatic pump. On the other hand, when the patient feels that the socket is applying a lot of pressure on the stump, or the patient needs to get the prosthetic off, the patient could open the valve to let the air goes out of the pneumatic pads to decrease the air pressure.

Figure (3): Adjustable socket assemble.

The pads and the air pump which are utilized in this project were made for a blood pressure device. These parts are selected for the following reasons, they are reliable to be used with the range of pressure that is compatible with the human body. Also, the material from which these parts were made of to be compatible when located near the human skin.

The socket modification procedure is explained in detail below:

1. By using pneumatic pads for giving Adjustable and suspension to the socket.
2. Make two holes to insert the tubes, as described in Figure (4).
3. Two pneumatic pads have been glued inside the socket, glued the pump behind the socket.

Figure (4): modification by the pneumatic pads.

4. F-Socket test

The interface pressure between the stump and the socket areas is measured by the F-Socket device. The collected data from the amputee is measured while walking for a few seconds in different phases of the gait cycle. The utilized data are transferred to a computer to be stored and analyzed. In general, the stump region is separated into four parts in the longitudinal direction as shown in Figure (5), (Anterior, Lateral, Posterior, and Medial). The tests were carried out in the Dept. of Prosthetic and Orthotic, Al-Nahrain University.

Figure (5): F-socket sensor test.

The results of the F-socket tests are shown in the figures (6 to 9) for the four regions.

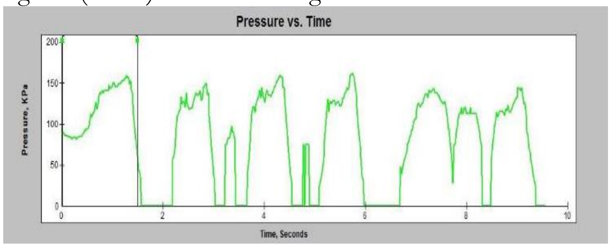

Figure (6): Anterior region.

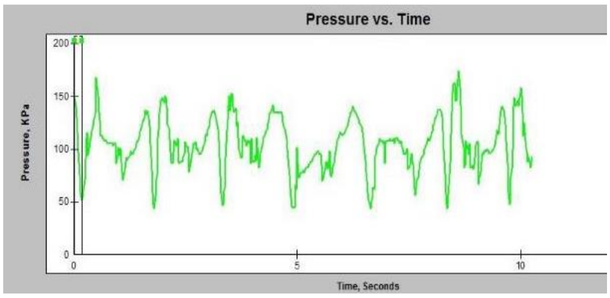

Figure (7): posterior region.

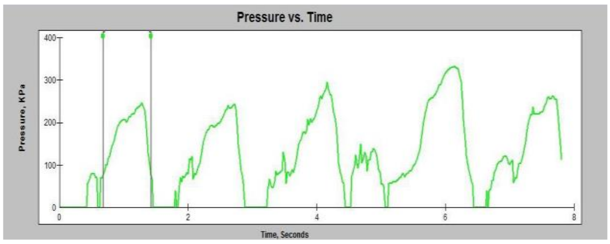

Figure (8): medial region.

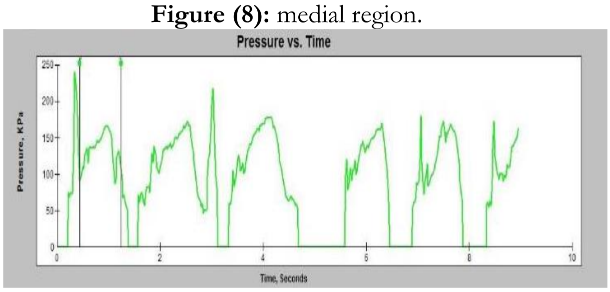

Figure (9): lateral region.

Table 1 lists the maximum contact pressure for each region, the results show that the listed values are in the comfortable zone for the patient [15], which was also confirmed by the patient when he used the prosthesis for several days in a wide range of daily activities.

Table (1): Results of the F-socket tests.

Socket region	**Anterior**	**Lateral**	**Posterior**	**Medial**
Contact pressure kPa	**160**	**167**	**153**	**348**

The results from the F-socket test show a successful socket design. The listed above data represent the interface contact pressure between the socket and the stump, these results should not exceed 350 kPa pressure on the sides and 500 kPa on the posterior. If the pressure increases between the socket and the stamp above the values above, it will lead to patient discomfort and pain, which can lead to socket failure [16].

Also, the patient has used the socket for several days in general daily activities. The patient had the required training for putting in and out the adjustable socket properly. The patient's general experience with using this socket was improved compared to using a regular socket. Using the adjustable socket gives the patient the ability to adjust the interface pressure between the socket and the stump for each activity.

5. Conclusions

There are several conclusions from this work which will be noted as follows:

1- The socket design provides adjustability with pneumatic pads through air pressure providing good suspension and will provide more control from the user on the applied pressure between the stump and the socket.
2- The use of pneumatic pads allows the socket to be adjusted in shape and size of the stump fluctuations.
3- The locations of pneumatic pads were located on the lateral and medial positions because these areas have soft tissue and far from the bones which can carry pressure without causing discomfort or pain to the patient.
4- According to the F-Socket results, the collected interface pressure data from different stump location is safe and comfortable for the patient.

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