Original Research Article

Comparison study of the prosthetics interface pressure profile of air splint socket and ICRC polypropylene socket for upper limb prosthetics

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ABSTRACT

This study examined the interface pressure differences at the stump socket between an ICRC polypropylene socket and an air splint socket for a common wearer of transhumeral amputee using F-socket transducers. Two F-socket sensors arrays were attached to the residual limb. The subject was asked to complete the following tasks: Normal position, stand in a normal position without conducting any motion and shoulder movements, flexion/extension and abduction. The results revealed that the interface pressure applied using ICRC polypropylene socket was maximize at the end distal of the residual limb and give more pressure contact to any shoulder movements. Conversely, while using air splint socket, the socket was able to auto-adjust for required socket fitting even for any change while doing shoulder movements. Our result demonstrated how the comparison of pressure applied at the stump socket may lead in chosen the suitable prosthetic’s socket for the amputee. The impending development of an auto-adjusted socket that uses air splint system will provide the prosthetic socket with a less contact pressure at the residual limb.

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1. Introduction

It is generally known and accepted between amputees and prosthetists that a poor socket fitting will entail that the stump loses volume daily [1]. The amputee’s socket interface plays a major role in defining the comfort level of the user. The method by which the socket is attached to the residual limb is extremely important [1–6]. Upper-extremity prostheses must be suspended throughout the entire range of motion as well as being able to tolerate loads during normal use [7–10]. The procedure involves a lot of force and brings pressure at the surface between the socket and the limb [11].

Among the different types of the prosthetic socket that can be implemented, are the harness socket [1,9,12–14], self-suspending technique [15–17], suction and vacuum socket [18], and silicon liners [19], all of which utilize polypropylene as prime material to design prosthetics socket. Basically, the
polypropylene is used to structure the main socket by referring to the guidelines from the International Committee of the Red Cross (ICRC) [20]. Socket materials and fabrication have changed over the years from leather and wood, to rigid polyester laminates, to flexible thermoplastics, and composite reinforced frames [1,3].

Although a few devices and research for prosthetics socket can be found in the literature, none have previously focused on the interface pressure at the socket through the use of ICRC polypropylene socket and air splint socket to the amputee. The purpose of this study is to compare the interface pressure at the socket as the amputee used two different sockets, an air splint socket and an ICRC polypropylene socket, to perform common shoulder movements that involve the normal position, flexion/extension and abduction.

1.1. ICRC polypropylene socket

ICRC polypropylene socket was implemented by referring to guidelines from the International Committee of the Red Cross. The ICRC preferred to develop its own technique instead of buying ready-made orthopaedic components, which are generally too expensive and unsuited to the contexts in which the organization works. The cost of the materials used in ICRC prosthetics devices is lower than that of the materials used in appliances assembled from commercial ready-made components [20].

The process of ICRC polypropylene making involves; casting, polypropylene draping, assemble and shaping. The casting, rectification and alignment methods used to correspond to international prosthetic and orthotic (P&O) standards of practice and are therefore not described in the ICRC manufacturing guidelines. The measurement process involves several tools such as length calliper, universal anterior–posterior–medial-lateral calliper, standard tape, spring tape, circumferential tape, and weight scale.

1.2. Air splint socket

The air splint prosthetic socket system was implemented by combining the air splint with a pressure sensor that the user controls through the use of a microcontroller [5,6]. The modular construction of the system developed allows the pressure sensors that are placed inside the air splint socket to determine the required size and fitting for the socket used (refer Fig. 1) [5,6].

The air splint socket system basically uses a pressure sensor [7], which is placed on the surface of the air splint socket, to transfer any pressure data to the microprocessor and microcontroller-based system as the input data. The pressure sensor is one of the most accurate and reliable measurement tools available to determine any contact pressure between the residual limb and the socket surface [6,7]. The pressure sensors use the received pressure wave to retain the input of contact within 0–100 kPa in order to maintain the air splint system pressure accordingly to clinical principle [11]. If the pressure increases more than 40 kPa, the blood system will be interrupted [11]. With the air splint system, the patient does not need to worry about changing the socket size and fitting, since the socket will change the size and fit accordingly within the desired contact of the residual limb.

The pressure sensor that functions as the input will then send the generated data to the microcontroller system that is placed inside the upper elbow part. This part of the transhumeral also consists of an oscillometric pump that will generate the air volume that is required for the air splint or otherwise maintain it at 40 kPa [11]. The power supply for the system comes from 9 V batteries, which are widely available, lightweight and long lasting.

The new prosthetic component was conceived to overcome the limitations imposed at the socket. The development mechanism is the result of a rigorous approach, which made it possible to optimize the functionality of the socket. The articulation consisted of the air splint, which replaced the thermoplastic as the main socket part. The air splint incorporated a silicon liner surface in order to provide the residual limb with increased gripping force. For their own comfort and satisfaction, the amputee can use a stocking net or add another silicon liner to the residual limb; this depends on the user themselves, since the air splint socket system will adjust the size according to the required size and fitting.

The electronic parts were placed at the bottom part of the air splint socket. The microcontroller, the power supply and the motor controller were placed together at a convenient joint that could be readily accessed if there was a need for service or reboot. The socket was also fitted with a USB cable port that could allow the user to restart or reboot the system in the event of any problems.
2. Methods

Based on data pertaining to transhumeral amputees from the Department of Biomedical Engineering, University of Malaya, only one amputee under their rehabilitation unit is still undergoing rehab training. First the subject was fitted with ICRC polypropylene socket, then continue with the air splint socket. Two F-socket sensors arrays 9811E (supplier a) were attached to the residual limb (refer Fig. 2). The subject was asked to complete the following tasks: normal position, stand in a normal position without conducting any motion and shoulder movements, flexion/extension and abduction.

2.1 Ethical statements

All human tests protocols were approved by the University of Malaya Medical Centre Ethics committee under reference number of 829.15, and each subject’s written, informed consent was obtained before data collection. The ethical was approved by a group of expertise in medical and clinical area, clinicians, research scientists, and patients. The approval process involves a presentation, guidelines, limitation, discussion about the pros and cons of the research.

2.2 Subject

University Malaya Medical Centre reported that while many transhumeral amputees register to use the prosthetics hand, the majority of registries never complete the full rehabilitation procedure [5]. This is usually due to the limitation of the need that can be done by the prosthetics and having pain at the socket while wearing the prosthesis. The subject who participated in the study did so on a voluntary basis and gave prior written informed consent.

The subject of the study was a 45-year-old male who suffered from a trauma on the right hand. His hand need to be amputated after involved in terrible accident of rolling machine. His hand only remained 40% of the length of his above elbow. His limb was moderately scarred with graft coverage presented. He had already worn the prosthetic device for approximately a year and replaced it twice as a result of changes in his body size and weight.

2.3 Experimental setup

The study was done at Brace and Limb Laboratory, University of Malaya in conjunction with University Malaya Medical Centre. First, the subject was fitted with the ICRC polypropylene socket. After the test for the ICRC polypropylene socket had been performed, the subject was fitted with the air splint socket and wore this device for 1 h before the data collection activity began (refer Fig. 3). All the procedure of socket making and fitting involves the Certified Prosthetics and Orthotics (CPO) which is recognized by International Society of Prosthetics and Orthotics (ISPO).

The subject was provided with two new prostheses consist of 8 × 14 System Inner Hand for wrist movements and 12K33 Elbow Component for elbow movements (both from Ottobock),

Fig. 2 – Two F-socket sensors arrays 9811E were attached to the residual limb.

Fig. 3 – The subject with the air splint socket. The socket than connected with the below elbow part.
(supplier b), each of which incorporated a different socket: (a) the air splint socket and (b) the ICRC polypropylene socket.

Two F-socket sensors arrays 9811E were attached to the residual limb. The sensor arrays were positioned on the anterior, posterior, medial and lateral aspects of the residual limb. The posterior sensor was positioned approximately 1 cm above the posterior trim-line of the socket. To prevent sensor arrays displacement, the residual limb was covered with a cellophane cover. This sensor arrangement provided a pressure map that covered 90% of the residual limb.

Tekscan software version 6.51 was used to record the interface pressure. A Tekscan pressure bladder was used to equilibrate and calibrate the sensor arrays (refer Fig. 4). Sensor arrays were placed inside the bladder and, according to the manufacturer’s instructions, were subjected to a pressure of 100 kPa [11]. Details regarding the kinematics, kinetics’ model and analysis of the system and pressure analysis are described in previous work by the authors [5,7,11].

3. Results

The analyses of data for two-interface pressure were performed for the two prosthetics socket. Table 1 represents the mean peak pressure values observed. For the ICRC polypropylene socket, the pressure contributed by wearing the prosthetic was distributed over the surrounding the residual limb, the mean peak pressure at the anterior surface (92.7; SD: 2.6) in comparison to the posterior (56.1; SD: 4.5), medial (49.3; SD: 7.4) and lateral (73.9; SD: 7.2). The trials for air splint socket give a less mean peak pressure.

<table>
<thead>
<tr>
<th>Suspension type socket type</th>
<th>Anterior mean (SD)</th>
<th>Posterior mean (SD)</th>
<th>Medial mean (SD)</th>
<th>Lateral mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICRC polypropylene socket</td>
<td>92.7 (2.6)</td>
<td>56.1 (4.5)</td>
<td>49.3 (7.4)</td>
<td>73.9 (7.2)</td>
</tr>
<tr>
<td>Air splint socket</td>
<td>36.0 (2.2)</td>
<td>33.8 (3.1)</td>
<td>36.0 (3.7)</td>
<td>37.8 (2.9)</td>
</tr>
</tbody>
</table>

4. Discussion

Residual limb and socket interface pressure is considered to be of high significance when assessing the biomechanics of the dissimilar socket designs [21,22]. Measuring the degree of these pressures is a direct technique that can be used to evaluate the comfort and fit of the socket [5,6,11]. Two different interface socket systems for transhumeral prosthesis were examined in this study: an ICRC polypropylene socket and a new air splint socket.

As recorded for ICRC polypropylene socket, almost all trials showed that the pressure came from the residual limb that attached to the prosthetic's socket. The maximum pressure recorded was at the end distal of the residual limb on the anterior part. The pressure may be due to the contact of the humerus bones and active muscle stiffed covered by skin that was still active in generating the motion.

Even before the trials begin, the initial pressure was detected at almost all part of the anterior, posterior, medial and lateral parts. Based on the average result, it shows that the subject experienced pressure by wearing the ICRC polypropylene socket even without the below elbow part. Moreover, the body needed a lot of rehabilitations and trainings for the muscle in order for it to get used to the prosthesis socket [23-26]. Consequently, the shoulder size will increase, and muscles would be unbalanced to each other [11,12,22]. The socket itself was not well-attached to the amputee but relied more on the soft stockinet [23-26]. The pressure was found to be increased after a few trials showing that the subject was not comfortable to wear the prostheses. As a result, he refused to wear it longer and, based on his feedback, he usually wore it for 2 h per task. The results showed that the area that was being pressured on was increased. The weight of the prosthesis also contributed to the impact of the pressure. Increasing the weight, will increase the force applied, which will directly increase the pressure. Based on the anthropometry theorem, the prosthetic hand was much heavier than the normal hand [7]. The socket weight and design can contribute to decrease the overall prosthetics hand since other parts such as the arm, motor and cable cannot be directly changeable [1,2].

For the air splint socket, the distribution of maximum pressure was only found constantly at all regions. However, the pressure applied was not due to wearing the prosthesis but due to the placement of the sensor. The results also showed that the area of pressure was detected in a small point only. The weight of the air splint socket gave a small contact pressure, but the weight was still relevant as it was lighter than that of the ICRC polypropylene socket [7].

It is proven that ICRC polypropylene socket gave the pressure to the person that wore it due to the socket and the weight of the prosthesis itself. On the other hand, the air splint
socket showed that the socket was comfortable to be worn by the amputee. At the same time, the pressure occurred due to the sensor displacement rather than the socket and the weight of the air splint socket. Based on these results of the experiment, it was proven that the newly developed air splint socket was designed in line with according to the need and the comfort of the amputee.

In comparison to the other type of prosthesis, the harness socket can create discomfort [23–26], frustration, or difficulty in donning, restriction in range of motion (ROM) [7], and contralateral brachial plexus pressure, which can potentially lead to deviate wearing the prosthetic.

Each motion lead to changeable of muscle, skin and bone structure [1,2]. Whenever amputee do any movements or task, it involve the changing in residual limb volume. But the socket remains static and some area inside the socket will produce a great pressure between the residual limb and the socket [11]. The ICRC polypropylene socket remains static and not changeable with the residual volume which occurs lost in doing daily life activities. The air splint counters this problem, since it is dynamically auto-adjusting into size following the residual limb size and shaping.

Few factors that can impact the socket size are control diet, hydration and activity levels [2]. Hence inappropriate diet and hydration may increase or decrease the body weight and length, which will directly change the size that is most suitable for the prosthetic. Volume loss of the residual limb ranges from 4 to 10%, with approximately 90% of this loss occurring within the first 2 h of the workday [1,2]. This shows how the relationship between changes in socket and the rehabilitation needs to be maintained on an hourly basis. Frequent changes to the socket might be too expensive to be viable and consultation with the rehabilitation unit may not be easy to maintain regularly; almost 80% of prosthetic users do not attend appointments and are lost to follow up [2]. However, the air splint socket eliminates most of the problems that need to be considered. As long as the socket is well bonded with the amputee’s residual limb, it will maintain the desired size and fit, even when the amputee engages in daily life activities. No matter how sophisticated the device, if the patient feels uncomfortable and cannot control the placement of the terminal device, the result will be the rejection of the prosthesis [5].

4.1. Study limitation

This study does not allow for generalizations to be made pertaining to the use of ICRC polypropylene socket and air splint socket. Further limitations of the current study relate to the fact that a laboratory setting was utilized that could only allow for the simulation of limited tasks. The study of internal kinetic factors such as force and motion also need to be considered. The prosthesis required the distribution of a lot of force to the shoulder, and this could also interrupt the condition of the socket change. There is also a need to broaden the comparisons between existing products, such as myoelectric’s socket, as opposed to focusing only on ICRC polypropylene socket. No measurements were taken during the passive range of the transhumeral part while the subject was wearing and not wearing his prosthesis. A measure of the amputee’s subjective experience of comfort and qualitative feedback comparing the socket designs would yield information to the prosthetics and orthotics area.

5. Conclusion

In this study, the subject’s ICRC polypropylene socket maximizes the pressure distribution of the socket. The air splint socket might reduce the pressure within the interface of residual limb in comparison to the ICRC polypropylene socket. This is particularly important during the daily life activities and may reduce the pain and discomfort at the residual limb in comparison to the ICRC polypropylene socket. Clinical investigation between the prosthetic’s socket may lead to further research and development in choosing the most comfortable socket to be worn by the users.

Suppliers

b. F-Scan, Tekscan, South Boston, USA

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