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 amputees using F-socket transducers. Two F-socket sensors arrays were attached to the residual limb. The subject was asked to perform 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 socket for the amputee. The impending development of an auto-adjusted socket that uses an 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 [13,14,15], 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

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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 detection 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 retofit. 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 x 14 System Inner Hand for wrist movements and 12K33 Elbow Component for elbow movements (both from Ottobock),