Technical Note

Design and Fabrication of a New Expandable Transtibial Liner with Manual Volume Control: A Prototype

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ABSTRACT

Diurnal volume changes is one of the main factors influencing socket fit in transtibial prosthesis and causing pressure problem issues. Embedded bladder liners have been recently a potential approach to deal with this problem. The aim of this technical note was to introduce a new transtibial silicone liner designed based on hybrid socket theory.

To make expandability in the liner, an integrated wax structure was constructed over the selected areas of the positive model and then removed after lamination process. In addition, a mechanical system with manual control was designed to fit the liner with the residual limb volume by pumping the water in or out of the liner through connective tubes.

The results showed that this new design had high reliability in maintaining identical surface pressures after volume changes in laboratory trials. Therefore, it seems that selective expandability of this liner would accommodate residual limb volume fluctuations without disturbing effect on preliminary pressure pattern.

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Keywords

Amputation Stumps; Lower Extremity; Transtibial; Volume Fluctuation; Liner; Bladder; Silicones

Introduction

The socket-liner complex is a major part of transtibial prosthesis, designed to capture the shape and volume of residual limb (RL) and also makes a comfortable load bearing [1]. A proper socket fitting is related to the quality of interface pressure, adequate suspension and wearer satisfaction [2]. However, daily RL volume fluctuations may cause failure in fitting and pressure distribution problems.

Research has shown that daily volume fluctuations can change the proper pattern of the weight distribution between socket and residual limb [3] and may leads to stump abrasion ulcers, pain and eventually prosthesis abandonment [4]. The traditional accommodative methods such as adding pads or changing the number of socks had shown nonacceptable solutions [5]. An approach, which is used recently, is inserted expandable bladders to compensate volume fluctuations of residual limb. However, a handful of laboratory and commercial use of such designs have been introduced, the evidence has shown that they didn't have ap-

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propriate functionality [6-8]. These methods may include localized bladders without connection together or an overall bladder, encompassing whole of RL. It seems that the first bladder method has been designed based on patellar tendon bearing (PTB) theory so that it is characterized by specific surface loading. The second one has been designed according to total surface bearing (TSB) theory, denying the local pressure. It seems that both these designs have advantages and disadvantages; therefore, it was important to make a new design based on hybrid socket theory which included all advantages of both designs [9].

As above, the authors believe that inserting an expandable bladder for selective areas in residual limb where can tolerate the pressure in terms of type of tissues, may be an appropriate solution. Therefore, this bladder should be able to accommodate with RL fluctuating and make a greater contact with stump surfaces. This paper intends to introduce a transtibial liner design, including an integrated wide bladder with mechanical volume adjustability and to indicate the function of this bladder in a libratory on a model of transtibial RL.

Material and Methods

Design and making an expandable liner

As a first step, an experienced prosthetist took a cast of right non-diabetic transtibial RL of a 39 year-old man according to Otto Bock vacuum method for preparing a positive mold. He was recruited from Department of Orthotics and Prosthetics in the University of Social Welfare and Rehabilitation Science and signed written consent form before starting the process. The amputee had used a modular prosthesis with foam (Pelite) liner and supracondylar suspension, previously. Afterwards modification was done as total surface bearing theory and the stump measurement was matched with the positive. A negative copy was tested to achieve best fitting.

Before producing the liner, the areas of RL mostly covered with muscles where expected to change volume [10], were selected and marked on the mold. Then, a layer of wax (Bilkim Co, Izmir, Turkiye), using 1.3 mm width sheets, was formed over the completely marked area. A cylindrical rod (20 mm diameter, 30 mm height) was extruded off the bottom and a number of wax strips connected this rod to proximal part (Figure 1A). These parts were built for next tube connections and conducting fluid to the liner, respectively. Finally, the structure of wax material was melted and carefully separated from the mold.

In the second stage to prepare the expandable soft liner and rigid plastic socket, vacuumed lamination method and silicone material were used for both of them (Shore 10, RTV, Shimie Afsoon Co, Tehran, Iran). To do this, we pulled a PVA bag and 5 layers of Parisian thin elastic nylon stockings (Code 6242221, Germany) over the mold. Then, the prepared wax structure was carefully placed on the right position again and another 5 layers of the same stocking were pulled over.

The mixed 1:1 AB silicone material was poured into the PVA bag and pushed down gently through the stockings. After 24 h passed, an acrylic resin was laminated over the liner as commonly accepted process for fabricating of socket. To remove the wax, we made a hole through the distal rod and placed the liner in the boiling water. Finally, three silicone tubes (4 mm diameter) were glued into the canal by a silicone adhesive (Selsil, Turkey). One of them was inserted to the inner surface of the liner through which the air could be evacuated during donning and others were entered into the intermediate part for flowing the fluid (Figure 1B).

Design and Fabrication of volume adjustment system

The control system was designed based on mechanical approach so that the user can subjectively fit the liner and socket according to

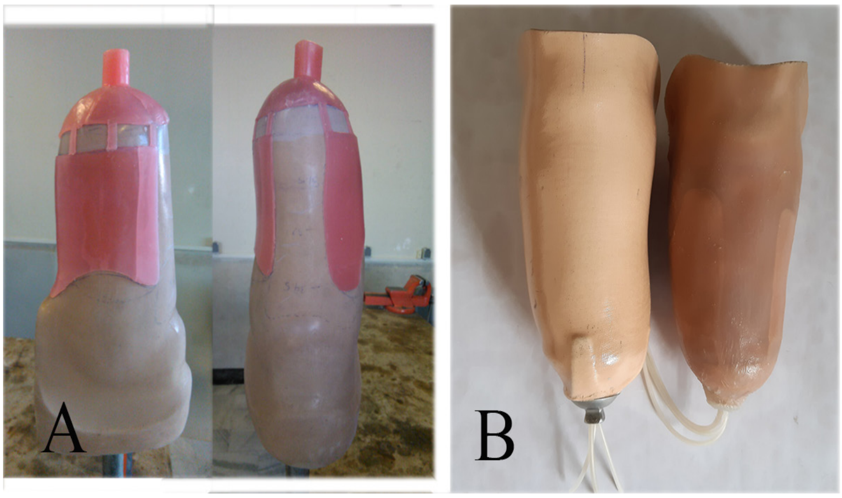

Figure 1: Process of making expandable liner. Wax structure formed over the positive. Medial and Anterior view (A). The liner and its socket after lamination. Tubes were passed through a hole into the pyramid (B)

own optimal RL pressure distribution. In addition, the amputee could increase or decrease the volume of the water inside the liner when don or doff the prosthesis, respectively. We used water as a fluid because it is more available, lighter, less expensive and healthier than other fluids.

The structure was made of an aluminum body (European 7075-T6), attached to the socket pyramid adapter at proximal and held the pylon at the distal (Figure 2).

The water container was a hollow through the aluminum body, and the exterior of which is covered by a graded polyethylene sheet in frontal view. In order to prevent water leakage, a rectangular rubber gasket was attached between the body and the sheet. The capacity of the container was a maximum of 100 ml. and three channels were connected to it. One channel was for filling the container with water and second and third channels were for pumping and draining water into and out of the liner, respectively.

Water pumping mechanism made up a round cylinder with piston and M5 threaded bearing cap (DSNU/MA, Festo, Germany), which was anteriorly installed on the body and two non-return valves (H-Qs-6 Festo Germany). The first valve was screwed to bottom of the container via a 90-degree connection (06 an male flare to 06 an male flare, Persian Sanat, Iran) and the other was also screwed to the round cylinder via a 08 male to 06 female reducer and a T connector (Persian Sanat,Tehran, Iran). Furthermore, two barbed L-fitting rotatable 360° were added to the distal side of both valves and silicon tubes were used to these parts of liner.

A one-way flow control (Zarin Tarash, Isfahan, Iran) was installed on the body to evacuate the air whenever the amputee put the liner in order to make a total contact stump fitting. Opening water evacuation valve screwed on the lateral side would extract the water liner inside to the container.

To operate the system, after rolling on the liner, the socket should be secured in place by staples. Optimal stump-socket fitting can be achieved through pumping the water up to the liner. To prevent drainage, water valve has to be closed during donning the liner and socket, although it can be opened to evacuate the inside liner air at the beginning. Opening the water valve and pushing the stump against the inner side of the socket decrease the high pressure on the limb or let doffing the prosthesis.

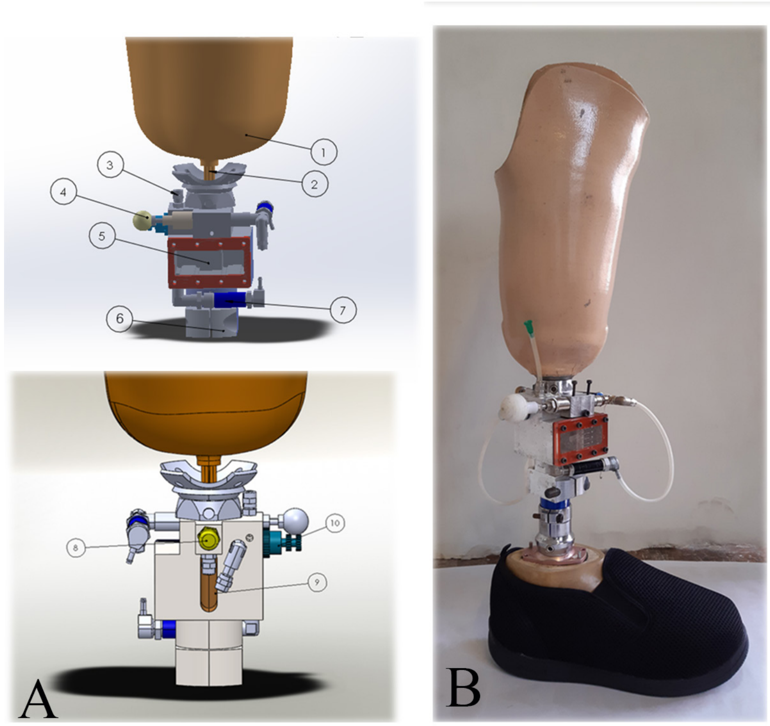

Figure 2: Volume adjustment system. SolidWorks design (A): expandable liner (1), connective tubes (2), water injection channel (3), pumping piston (4), water container (5), tube clamp (6), one-way valve (7), air evacuation valve (8), track for silicone tubes (9), water evacuation valve (10). Pumping system assembled between foot unit and socket (B).

Discussion

Residual limb volume change is one of the main issue, affecting pressure distribution between socket and RL. To solve this problem, the socket walls must be displaced or the inner liner volume should be changed. Thus, an expandable liner may be a good solution. In this article, we introduced a new silicone liner with a mechanical control system.

Several studies have been conducted to quantify the pressure pattern of the stump-socket interface [11-14]. However, a few reviews confirmed that the prosthetic fitting is highly subjective [15-17]. Accordingly, this current liner was designed in order to regulate the fluid pressure by amputee based on own comfortable fitting. In a recent study, volume adjustment was accomplished through small pneumatic inserts, yet air supply added weight, in addition to complicated control [8].

Another advantage of our design was the embedded bladder, set selectively in contact with stump surfaces. Therefore, it seemed that increasing the fluid in the liner after likely RL volume loss might preserve pressures as comfortable as it needed in these areas. On the other hand, it may prevent stress concentration on the limb and eliminate the disadvantage of local and separate bladders used in many models.

In order to estimate the efficacy of this liner at restoring the predetermined pressure pattern on RL after volume changes, mean pressure values of a three-step experiment were recorded. To do this, a phantom transtibial model of foam material was inserted in the assembled prosthesis while pressure pads (Novel Pliance, Germany) were maintained by cellophane in 5 different areas, which included anterior distal, medial flare, anterior lateral, popliteal and bottom of the limb. A pressure jack was used to force the limb in right position similar to standing state of an amputee. At the first step, the limb had same dimensions as the modified positive; however, in the next two stages to simulate volume changes, the limb circumferentially decreased 2.5 and 5 percent, respectively. The test conditions were very similar in the experiments and each test was repeated five times (Figure 3).

Results showed that mean pressures (ranged from 3 to 21 kilopascal) had same trends based on different areas in each experiments. More over the results indicated that the expandable liner had high reliability (Table 1). Consequently, volume accommodation capability of this new design and also hybrid theory were approved. Therefore, it may improve socket fitting in whom RL fluctuate diurnally.

Although in this study we concentrated on liner fabrication and the fluid adjustment mechanism, it would be helpful if silicone thickness was considered and controlled based on volume fluctuation and pressure-sensitive zones with necessary alternative methods. It is desirable that the control system would be as simple and small as possible. It is completely apparent that further research is needed to evaluate the clinical applicability of this design with real transtibial participants.

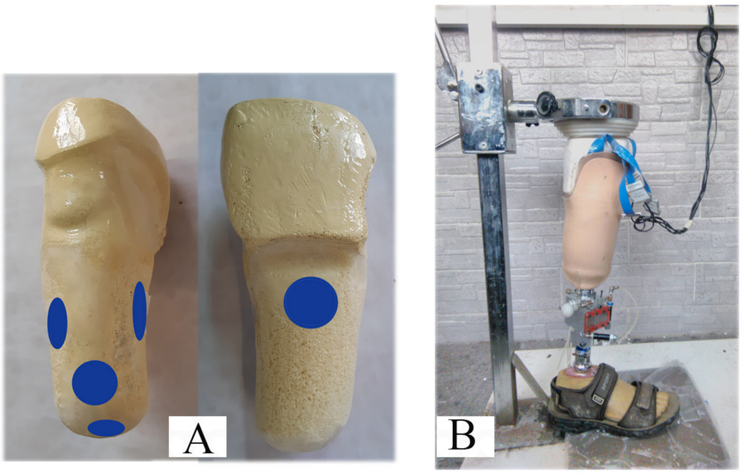

Figure 3: Reliability test measurement. Sensor locations on the limb (A), new liner in experimental trial. Black array shows force applied on the prosthesis, which was controlled by a bathroom scale beneath it (B).

Table 1: Interclass correlation coefficient of different areas under variable test conditions.

Variable	Sensor location	ICC
Mean pressure	Anterior distal tibia	0.99
	Medial flare	0.98
	Anterior lateral	0.99
	Posterior proximal	0.98
	Limb bottom	0.99

Conclusion

A novel expandable transtibial liner with mechanical control was designed according to hybrid load bearing theory to accommodate diurnal limb fluctuations. The experimental results suggested that this new liner was able to remain with the same pressure pattern in spite of artificial limb volume changes. Consequently, it is possible to test this liner on real

RL and also may helpful in clinical applications and good fitted sockets.

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Conflict of Interest

None

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