AN EVALUATION PROTOCOL FOR BELOW-KNEE SOCKET SELECTION -- A FINITE ELEMENT APPROACH WITH PAIN-PRESSURE TOLERANCE

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INTRODUCTION

The socket, as the interface between amputee and prosthesis, plays an essential role in transmitting loads. With the introduction of patella-tendon-bearing (PTB) socket, the biomechanical concept has been integrated into the socket development. However, to fabricate a fitted socket still relies on the experience of the prosthesist, because it is difficult to predicate the load transfer pattern based on the static shape of the stump. It is possible leading the loads over-concentrated on certain regions of the stump with improper rectifications.

Adding more contact area between the stump and the socket is a way to prevent the load concentration problem. Total-Surface-Bearing (TSB) socket, using a perfect matched liner with the stump shape, pushes the size of contact area to its limit [1]. This design concept seems to offer better biomechanical effect than the PTB socket. However, the study of Hachisuka showed that TSB socket is still no the perfect choice [2]. What this indicated is that no single type of socket design could fit all patients and the pre-evaluation, especially from the biomechanical viewpoint, is important and finite element (FE) analysis is considered as a promise pre-evaluation tool. Beside the evaluation tool, a biomechanical index to reveal each individual's judgment of socket fitting has to be determined. Pain of amputee has been proposed in some papers as the evaluation index. But up to now, no study, as far as we know, has integrated the pain information with FE outcomes to evaluate the biomechanical fitting of sockets. Most of the previous FE studies on below-knee (B-K) sockets were focused on the influences or sensitivities of various design parameters, and the results were presented without considering the variations within amputees.

The objective of this study is to combine the Pain-pressure tolerance (PPT) information with FE analysis to investigate the fitness of the PTB and TSB sockets for a selected amputee and assess the ability of this approach as a pre-evaluation tool for B-K socket selection.

MATERIALS AND METHODS Geometry and materials of the FE mesh model

A male weighted 48 kg with right B-K amputated was selected in this study. The FE model of PTB socket with stump was built based on the 3mm-interval transverse CT images and meshed with brick elements. The surface-to-surface contact elements were employed at the stump-socket interface. The entire PTB model consisted of 14776 elements (including 1251 contact elements) and 14904 nodes. The TSB FE model was established with the stump CT image and a 5mm offset of the stump outer shell to represent the liner of TSB socket and the mesh consisted of 12320 elements (including 1247 contact elements) and 12368 nodes.

The major materials of these stump/liner FE models could be identified as the bone, soft tissue and the soft liner. Two loading conditions were investigated in this study, i.e., the static stand on both legs (Half Body Weight, HBW) and the single leg stand (Full Body Weight, FBW) on the stump. All nodes on the outer layer of the soft liner for both sockets were fixed as the boundary conditions to simulate a hard socket condition.

Indentor test for Pain-pressure threshold and tolerance

A self-developed handheld indentor device, which included a digital meter to provide the deformation of the soft tissue and a load cell to detect the applied loading, was used to measure the pain information. During the test, the examiner maintains the indentor perpendicular to the test region and applies the load as slow as possible on the subject (1mm/sec roughly). The pain-pressure threshold (PTH) is achieved at the load when the subject begins to feel pain. The PPT is reached at the load when the subject cannot bear the pain. In total, five regions (patella tendon, medial condyle, fibular head, popliteal fossa and stump end) were tested for five successful measurements. The recorded force-displacement curve during test for each region was also utilized to obtain the Young's Modulus of soft tissue.

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Interface pressure measurement with force sensors

Force sensing resistance (FSR) sensors (Interlink electronics, Camarillo, CA) were used in this study to measure the interface pressure between the stump and liner under static stand on both legs (HBW). There were five sensors placed at expected high-pressure regions (patella tendon, medial condyle, fibular head, popliteal fossa and stump end) and placed on the stump with tapes. The sampling rate of the sensors was 1/3 Hz. On each sensor, three measured pressures were recorded and averaged for each load phase.

RESULTS

The values of PTH and PPT were shown at Table 1. Both the measured (from FSR sensor) and the simulated averaged interface pressure for the two sockets under HBW loading were listed in Table 2. The measured pressure values were at the same order with the averaged pressures from simulation. The distributions of the simulated interface pressure for both sockets were shown in Figure 1. For PTB socket, the peak pressure was 253 KPa and the peak shear stress was 126 KPa both occurred at the lateral region near fibular head. For the TSB socket, the simulated pressure distribution was quite uniform except at the stump end region. The peak pressure and shear stress occurred at the stump end with a value of 240 KPa and 60 KPa respectively.

DISCUSSION

In previous studies of the socket biomechanics, the focus was on an absolute sense, i.e., directly comparing the stress values without considering the variations within subjects. In our opinion, this approach was only halfway for a successful evaluation because the socket will eventually applied on subject. In the review article of Mak et. al., it is stated that the final goal of the socket/stump interface investigations was to set up an optimal type of socket for every B-K subjects[3]. This objective is difficult, if possible, to achieve due to the complicated mechanical behaviors of interface as well as the large variations on socket design and on individual subjects. In this study, a more practical target was selected for the interface investigation, i.e., to employ as an evaluation tool by combining with the PPT values of individual subject. The PPT index might not be the perfect choice to fully reflect the characteristics of each individual but it is easy to measure and, conceptually, should be a major link to the subjective feeling of socket fitness.

When comparing, in an absolute sense, the interface stress outcomes between PTB and TSB sockets of this study, it is identified that the performances is almost the same since the peak stress values are very close. However, if PPT data are involved in the comparing, the superior of the TSB socket for this subject become obvious since the difference between the peak stress and PPT is much larger in the PTB design. Nevertheless, the large safe margin (PPT divided by the peak stress) values for these two sockets should provide an indication of good fitting of both sockets and this is confirmed in the filed evaluation of these two sockets.

To conclude, a contact FE simulation integrated with the PPT data of each individual should be able to provide a fist step of socket pre-evaluation. The current results indicated that a fitted socket should have a large safe margin. However, a precise value of this safe margin for a fitted socket should be determined by more subjects.

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FIGURES/TABLES



Figure1. (up) the pressure distribution for PTB socket (low) the pressure distribution for TSB socket

Table1. PTH and PPT at different regions

	Fibular	Medial	Popliteal	End of	f Patella
	head	condyle	fossa	stump	tendon
PTH (kPa)	599.6 ±8 2.6	555.2±132.2	503.2 ±134.2	396.3 ±154.5	919.6 ±161.7
PPT (kPa)	789.8±143.0	651.0 ±11.1	866.6	547.6 ±109.1	1158. ±2 03.2

Table2. Average pressures at different regions with PTB and TSB socket in FE simulation and sensor measurement

	Anterior	Posterior	Medial	Lateral	Stump end
Average pressure of PTB	28.4	22.2	34.2	18.4	
from FE model (k Pa)					
Average pressure of PTB	24.8	16.0	25.4	12.6	
from measurement (k Pa)					
Average pressure of TSB	17.5	14.1	16.3	16.0	26.1
from FE model (k Pa)					
Average pressure of TSB	16.2	16.7	12.7	15.8	21.5
from measurement (k Pa)					