Abstract:
This study aims to investigate the pain-pressure relationship of the residual limb and the interface pressure at the prosthetic socket-residual limb interface during walking. Load was indented to different regions of the residual limb through Pelite and polypropylene indenters connected to a force transducer until pain was just perceived. A finite element (FE) model was built simulating the indentation process to evaluate the pressure distribution beneath the indenter upon indentation. Results suggested that pain is triggered when the applied peak pressure overshot a certain threshold. A second FE model was built to predict the socket-limb interface pressure, considering friction/slip and pre-stress produced by donning the limb into a shape-modified socket which were commonly ignored in previous models under simplifying assumptions. The predicted interface pressure was in the range of previous clinical pressure measurement and was below the thresholds causing pain. In future investigations, more subjects will be involved for the pain-pressure relationship and more analysis on interface pressure under different conditions, such as alignment, walking speed and style, will be performed.
INTRODUCTION

Amputees may complain of pain at the residual limb while wearing their prostheses. High pressure applied onto the limb which is not particularly tolerant to loadings is a major cause of the pain (Mak, et al., 2001). Finite element (FE) modeling has been identified as a useful tool to understand pressure distribution between the residual limb and prosthetic socket. However, the accuracy and efficiency of a model depend much on the model establishment. Simplifying assumptions, such as ignoring the friction/slip at the limb-socket interface and the pre-stresses produced by donning the limb into a shape-modified socket, were commonly made in previous FE models (Zhang, et al., 1995).

The predicted interface pressure at the limb-socket interface is of little clinical value if there is a lack of knowledge of the pressure tolerance of the residual limb. There were few investigations studying the pain response to stresses applied onto the limb. Those investigations, however, focused on one particular region of the limb or the global response of the stump to external load. Quantitative pressure tolerance over different regions of the residual limb have not received much attention.

The objective of this study was to investigate the relationship between applied pressure and pain perception of different regions of the residual limb and to build a FE model studying the pressure at limb-socket interface considering the frictional/slip conditions and pre-stresses.

METHOD

1. Pressure-pain relationship

Load tolerance, defined as the minimum force inducing pain, over eleven different regions of the residual limb of a transtibial amputee was studied using indentation method. Force was applied normal to the test regions with a circular, flat-ended indenter of 10mm diameter connected to a force transducer until the subjects reported the onset of pain. The test regions were those require relieves at prosthetic sockets including tibial tuberosity, mid-shaft of tibia, fibula head, distal ends of fibula and tibia and those where higher magnitude of force is applied within a socket, including mid-patellar tendon, medial tibial flare, mid-shank of fibula, popliteal muscle, anterolateral and anteromedial tibia.

Each test region was tested with two different stiffness of indenting materials, namely Pelite- a relatively soft material which is often used as liner and polypropylene- an engineering thermoplastic. The order of the use of indenting materials was randomized. The subjects were not told they were tested with two different indenting materials. Before the test started, all test regions were marked to ensure the indenter was pressing on the same regions for different tests.

A FE model was built, based on the limb geometry and load tolerance of the subject, to simulate the indentation test so that the pressure distribution underlying the indenter could be studied. Magnetic resonance images (MRI) were obtained from the residual limb of the subject. Each test region was isolated for FE analysis using a fine mesh. A circular disc of diameter 10mm was created and aligned flat onto each test sites. The material properties of different regions of the stump and the two indenting materials were adopted from the literature. The soft tissue surrounding was given fixed boundaries. Load tolerance, obtained from the indentation test, was input to the model to load the
indenting material. The FE analysis was performed in ABAQUS version 6.4.

2. Prediction of pressure at prosthetic socket-residual limb interface during walking

A FE model was developed for the same subject to determine interface stress. The geometries of the bones were obtained from the MRI of the subject. The residual limb surface was obtained by digitizing a loose plaster cast using the BioSculptor™ system. ShapeMaker™ 4.3 was used to prepare the geometry of the prosthesis by applying rectification template to the digitized cast and adding a shank blended into the socket end. The geometry of the prosthetic foot was based on direct measurement of a SACH foot. The foot was partitioned into two for the regions of wooden keel and the surrounding rubber foam. The shank end and the top surface of the prosthetic foot were tied. The Young’s modulus of socket and shank in its entirety, soft tissue, bones, keel and rubber foam were assumed to be 1500MPa, 200kPa, 700MPa and 5MPa respectively. Poisson’s ratio of 0.45 was assigned to soft tissue and 0.3 to other materials.

The residual limb and socket were modeled as two separate structures and their contact was simulated considering pre-stress when the limb was donned into a shape-modified socket and friction/slip. There were two phases in the analysis. The first phase was to simulate the interaction produced by donning the limb into the prosthetic socket by fixing the external surfaces of the prosthesis together with the bones and moving the penetrated limb surface onto the inner surface of the socket. The required pre-stresses were calculated.

At the second phase, the pre-stresses calculated in the first phase were kept. The fixed boundary constraint previously added to the prosthesis was removed. External loadings were applied at the prosthetic foot to simulate the participating subject walking at heel strike, loading response and heel off of gait based on our gait analysis data. Coefficient of friction of 0.5 was assigned for socket-limb interface. The model was analyzed in ABAQUS 6.4.

RESULTS AND DISCUSSION

Load tolerance had been measured over different parts of the body in previous studies and the measuring technique using indentation test was similar to that employed in this study. Little attention, however, was paid to the load tolerance of the residual limb. In this investigation, load tolerance of different regions the residual limb against two different stiffness of indenters was measured. It was found that load tolerance was significantly higher with softer indenting material Pelite than polypropylene at all the test regions. The recorded load tolerance values were used to load the two indenters against the soft tissues in the FE model. As expected, peak pressure appeared at the edge of the indenters and pressure gradually fell towards the center of the indenter. The model revealed that the peak pressure over the same test region indented by the two different indenters with when pain was initiated were very close. Table 1 shows the load tolerance and peak pressure of five of the test regions. The closeness in magnitudes of peak pressure under the two indenters when pain is just initiated suggests each test site bears a threshold which is pressure-related and the thresholds are site-dependent. Pain is initiated if the induced peak pressure exceeds those thresholds.
The next focus would be put on the prediction of interface pressure at socket-limb interface. High pressure was predicted falling on patellar tendon, anterolateral tibia, anteromedial tibia and popliteal depression regions where socket undercuts were made. The patterns of the pressure distribution were similar among the three different loading conditions; but differ in peak stress values as shown in Figure 1. The predicted pressure values over the four regions were in the range of the clinical measurements (Zhang, et al., 1998).

As the predicted interface pressure was lower than the thresholds inducing pain, it is predicted that pain would not occur for normal walking of the subject. This is consistent with the verbal report by the subject indicating no pain was perceived during the uses of the prosthesis. The interface pressure, however, could be much influenced by the socket rectification scheme, mal-alignment, body weight, walking speed and style of the amputee. More analysis in interface pressure under different situations conditions will be preformed. More subjects will be involved studying the relationship between pain and pressure. Our goal is to predict socket fit with the help of computational models.

Table 1. Load tolerance and peak pressure of five selected test sites

<table>
<thead>
<tr>
<th>Regions</th>
<th>Indenting materials</th>
<th>Load tolerance (N)</th>
<th>Peak pressure (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Popliteal muscle</td>
<td>Pelite</td>
<td>57</td>
<td>0.81</td>
</tr>
<tr>
<td>Mid-patellar tendon</td>
<td>Pelite</td>
<td>54</td>
<td>0.72</td>
</tr>
<tr>
<td>Medial tibial flare</td>
<td>PP</td>
<td>54</td>
<td>0.77</td>
</tr>
<tr>
<td>Anteromedial tibia</td>
<td>Pelite</td>
<td>60</td>
<td>0.69</td>
</tr>
<tr>
<td>Anterolateral tibia</td>
<td>Pelite</td>
<td>57</td>
<td>0.71</td>
</tr>
</tbody>
</table>

CONCLUSION

A FE model was built predicting the limb-socket interface pressure, considering friction/slop and pre-stress which were commonly ignored in previous models. It is that suggested that pain is triggered when the applied peak pressure exceeded a certain threshold.

REFERENCE

