Clinical study

Changes in interface pressure and stump shape over time: preliminary results from a trans-tibial amputee subject

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Abstract
Interface stresses and stump shape were measured during sessions over a two-month interval on a trans-tibial amputee subject. Results from thirteen transducer sites monitored during four sessions showed greater interface pressure changes over time at anterior sites than at lateral or posterior locations. There was a trend of decreased pressure with stump swelling and increased pressure for stump atrophy. During one session in which stump shape was monitored over a 23.1 min interval after ambulation, stump swelling was localised. Swelling tended to increase in the regions of initial enlargement, as opposed to redistributing through different areas over time. Regions of swelling were anterior lateral and posterior proximal, areas of thick underlying soft tissue. Identification of localised areas of swelling and atrophy and understanding of their effects on interface pressures could be used to improve individual socket design.

Introduction
Changes in interface stress can affect the long-term fit and performance of a prosthesis. An alteration in stress distribution can concentrate stresses in load-intolerant areas. A number of researchers have quantified interface stresses, though only two investigators (Appoldt et al., 1968; Sanders et al., 1998) considered time-dependent changes. In both of those studies, session to session interface stress changes over weekly intervals were higher than those induced by substantial alignment modifications. Limb atrophy or swelling may account for alterations in stress distributions. Researchers have attempted to quantify volume change post-operatively so as to establish appropriate stabilisation protocols (Fernie and Holliday et al., 1982; Golbranson et al., 1988). However, assessment of both shape and interface stress changes simultaneously has not been conducted.

The purpose of this research was to conduct an initial study to monitor changes in both interface stresses and stump shape over time. If a correlation was demonstrated on a single trans-tibial amputee subject, then efforts to establish correlations common across large populations should be pursued. Clinical guidelines could then be established to use the data to design sockets so that limb atrophy and swelling do not concentrate interface stresses.

Methods
The unilateral trans-tibial amputee subject selected for this study was 28 years of age, 180.3cm in height, and 65.8kg in mass. His left limb was amputated as the result of a traumatic injury fifteen months prior to this study, and he had no other abnormalities. His stump was of length 14.5cm from the patellar tendon to the distal tibia, and his stump circumference at the tibial condyles was 32.0cm. The thermoplastic socket used was of total contact patellar-tendon-bearing design fitted with a nylon sheath. The subject did not distal end bear. The prosthesis was completed with a Seattle™ Ankle and Seattle LiteFoot.

Interface stresses were measured using custom-designed sensors as described previously (Sanders et al., 1998). Briefly, holes were drilled through the socket at thirteen sites of clinical interest and of low to moderate socket

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Table 1. Transducer locations on the stump.

<table>
<thead>
<tr>
<th>Site name</th>
<th>Transducer location</th>
</tr>
</thead>
<tbody>
<tr>
<td>anterior lateral proximal</td>
<td>at the level of the tibial tubercle, lateral side</td>
</tr>
<tr>
<td>anterior medial proximal</td>
<td>at the level of the tibial tubercle, medial side</td>
</tr>
<tr>
<td>anterior lateral mid-limb</td>
<td>mid, anterior tibial border, lateral side</td>
</tr>
<tr>
<td>anterior medial mid-limb</td>
<td>mid, anterior tibial border, medial side</td>
</tr>
<tr>
<td>anterior lateral distal</td>
<td>distal stump, anterior tibial border, lateral side</td>
</tr>
<tr>
<td>anterior medial distal</td>
<td>distal stump, anterior tibial border, medial side</td>
</tr>
<tr>
<td>lateral proximal</td>
<td>lateral femoral epicondyle</td>
</tr>
<tr>
<td>lateral mid-limb</td>
<td>fibular neck</td>
</tr>
<tr>
<td>lateral distal</td>
<td>lateral distal stump</td>
</tr>
<tr>
<td>lateral-posterior distal</td>
<td>midway between the lateral distal fibula and distal calf (on the border between lateral and posterior groups)</td>
</tr>
<tr>
<td>posterior proximal</td>
<td>centre of the popliteal fossa, on the posterior or longitudinal mid-line</td>
</tr>
<tr>
<td>posterior mid-limb</td>
<td>mid-calf, on the posterior longitudinal mid-line</td>
</tr>
<tr>
<td>posterior distal</td>
<td>distal calf, on the posterior longitudinal mid-line</td>
</tr>
</tbody>
</table>

curvature (Table 1). Transducers with circular sensing surfaces of diameters 6.35mm were positioned in mounts of the socket at these locations such that they were flush with the inside socket surface. Transducer non-linearity was less than 2.2%. A modular force sensor and signal conditioning unit positioned beneath the socket (Sanders et al., 1997) was used to identify heel contact and toe off. Cables extended from the transducers and sensor to a lightweight belt pack connected via a thin cable to a computer data acquisition system. In data processing, steps were segmented into stance and swing phases, then the maximal stance phase pressures determined for each step. Only maximum stance phase pressures were analysed in this initial study.

A custom-designed silhouetting shape sensor (Schreiner and Sanders, 1995) was used to measure stump shape. A digital video camera mounted on the end of a motor-driven aluminium beam took 17 images as it was rotated around the stump. Images were thresholded to obtain the boundaries of the stump and then the boundaries used to construct three-dimensional shapes. B-spline surface equations were used (Zachariah et al., 1996). Shapes from different scans were aligned using a linear least-squares minimisation process (Hafner et al., 1998) on the distal 75% of the slices. The top slices were not used because slight changes in knee flexion during the scanning process caused error. Maximal error in volume assessment from the shape sensor and the reconstruction methods was 2%. Error in the alignment method cannot be specified since there was no standard reference; the shapes were aligned based on the least-squares minimisation criteria.

Internal review board approval was obtained for all procedures. At the outset of a session, the subject sat with his prosthesis donned for a 10 min interval to reach a homeostatic condition. He then removed his prosthesis, and the stump was imaged with the silhouetting shape sensor. Three scans were taken. The instrumented prosthesis was then donned, and the subject was allowed trial walking to become accustomed to the prosthesis. Interface stresses were then monitored in three 20 s walking trials in a 20.7m hallway with at least 8 acceptable steps collected in each trial. A metronome was used to control cadence to 56 steps/min (1.46m/s walking speed). Data collection sessions were conducted on Days 1 (mid-June), 37, 43, and 57 of the study. In a fifth session, residual limb shape data were collected after 27 min of walking. Data were taken at 1.2, 4.6, 10.4, 15.8, and 23.1 min after doffing the prosthesis.

Results

All transducers performed properly in all sessions and demonstrated minimal drift over the course of each session. The stump was imaged successfully in at least 1 of the 3 scans in each of the first 4 sessions and successfully in all
Fig. 1. Mean interface pressures and standard deviations (bars) at anterior, lateral, and posterior transducer sites are shown for the four study days. Lat=lateral; med=medial; prox=proximal; mid=mid-limb; dist=distal; post=posterior.
Results from the 13 transducer sites indicate the subject tolerated much load in the mid-limb regions, particularly anteriorly and laterally (Fig. 1), a result consistent with the non-distal end bearing socket design. Posterior sites demonstrated lower variability (standard deviation/mean) within the same session than other transducer locations. Anterior sites demonstrated higher variability than other locations. Posterior sites also demonstrated lower variability from session to session. There were substantial pressure changes at both the anterior lateral mid-limb and the anterior medial mid-limb sites for Day 1 compared with other sessions, consistent with the long time interval between Day 1 and the other sessions. No other sites, however, showed this trend.

There was a trend of reduced interface pressures for an enlarged stump (Fig. 2). While the session on Day 37 had the highest volume, it had the lowest pressures at seven of the 13 sites: anterior lateral proximal, anterior medial proximal, anterior lateral distal, lateral proximal, lateral mid-limb, posterior proximal, and posterior mid-limb. It experienced highest pressures only at the anterior medial distal site. The session on Day 43 had the smallest stump but the highest pressures at 4 sites: anterior lateral distal, lateral proximal, lateral mid-limb, and posterior proximal. It experienced lowest pressures only at the anterior lateral proximal site.

There was not a trend of increased pressure for increased local cross-sectional area (Fig. 3). Though the session on Day 37 demonstrated the largest distal stump, it did not experience the largest distal stresses. Though the session on Day 43 demonstrated the smallest distal stump, it did not experience the lowest interface pressures there.

Intra-session stump shape data collected after ambulation demonstrated results consistent with clinical expectation in that the stump enlarged over time. The volume vs. time data fit well to a third-order polynomial equation (Fig. 4). Areas of local enlargement were concentrated in the

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Fig. 2. Stump volumes as measured by the optical scanner are shown for the four study days.

Fig. 3. Cross-section area differences comparing Day 1 results with those from the other study days are shown. The stump extends from distal to proximal from the left side to the right side of the figure.
Fig. 4. Stump volumes before ambulation and at four time points after ambulation for a single session are shown. The prosthesis was doffed at time '0'.

anterior lateral and posterior proximal areas (Fig. 5), regions with thick underlying soft tissue layers. As expected, few to no regions experienced stump shrinkage. Comparison of stump shape before vs. immediately after walking demonstrated comparable volumes (volume before walking: 958.4cm$^3$; volume 1.2 min after doffing: 962.8cm$^3$). Yet a redistribution of tissue occurred as a result of the applied interface loads, as shown in the stump swelling and shrinkage images in the first row of Figure 5. The total stump volume increase at 23.1 min after doffing the prosthesis was 3.7%.

Discussion

The result of higher interface stresses for a reduced stump volume and lower interface stresses for an increased stump volume might suggest this socket was designed to accommodate the larger volume. When the limb reduced in volume (Day 43) stress concentrations were induced at local sites. With an enlarged stump (Day 37) contact surface area increased thus reducing interface pressures. Further, localised swelling did not necessarily correspond to a localised pressure increase. Thus

<table>
<thead>
<tr>
<th>SWELL</th>
<th>SHRINK</th>
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<tbody>
<tr>
<td><img src="image1" alt="Swell Medial Posterior View" /></td>
<td><img src="image2" alt="Shrink Medial Posterior View" /></td>
</tr>
<tr>
<td><img src="image3" alt="Swell Frontal View" /></td>
<td><img src="image4" alt="Shrink Frontal View" /></td>
</tr>
<tr>
<td><img src="image5" alt="Swell Lateral Posterior View" /></td>
<td><img src="image6" alt="Shrink Lateral Posterior View" /></td>
</tr>
</tbody>
</table>

Fig. 5. Areas of stump swelling and shrinkage are shown comparing shapes after ambulation with the shape from before ambulation.
during socket fitting maintenance, the stump must be considered as a whole and all areas taken into consideration. Other features besides stump volume change that were not monitored could also have influenced interface stress results such as changes in stump soft-tissue mechanical characteristics or changes in gait style. However, because the subject was an experienced prosthesis user walking at the same cadence for all sessions, substantial changes in gait style were unlikely.

The low variability in interface pressures at posterior sites and the high variability at anterior sites compared with other locations is consistent with clinical expectation. Thick soft tissues posteriorly help to redistribute the load more evenly from one step to the next and from one session to the next than anterior sites with thin soft tissue covering. Anterior tissues are thus much more susceptible to trauma than are posterior tissues.

Consistent with Fernie's data (Fernie and Holliday, 1982), results here do not demonstrate a consistent volume reduction over time. Non-consistent volume reduction indicates that other factors besides time influence stump atrophy and swelling. Factors such as interface stress distributions should be considered.

Data on changes in stump shape after walking potentially could be useful clinically. Highly dynamic localised areas of change could be identified and accommodated for in prosthetic socket design as well as subsequent maintenance and fit. Further, potentially the patient's rate of stump swelling could be assessed. If a time constant in a fit equation of volume-time data could be established, a number indicative of swelling rate could be determined. Extensive testing on a large subject population would be needed to develop clinically-useful test procedures that may influence trans-tibial socket design.

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REFERENCES


