INTRODUCTION
Residual limb shape change occurs both throughout the day, and over the lifetime of a socket. Persistent shape changes in a limb are often accommodated with prosthetic socks (D’Silva 2014) or padded inserts. If shape changes are large, a new socket may need to be fabricated. A socket insert may be able to extend the life of a socket by decreasing the number of socks worn and better matching a clinically desirable socket. The purpose of this study was to evaluate the feasibility and accuracy of hard inserts fabricated with a 3D printer. We also investigated integrating sensors into the inserts for potential outcomes monitoring.

METHOD
Five people with transtibial amputation wore a test prosthesis consisting of an enlarged duplicate of their practitioner prescribed socket plus a 3D printed insert. Subjects’ normal prostheses were digitized with a precision 3D scanner (Platinum Arm, Faro). The scanned socket shape was digitally enlarged using a CAD program (Geomagic, 3D Systems) by applying a uniform offset of 1.8mm. A test socket was then fabricated using the enlarged profile (Fig. 1). A socket insert was created in CAD as the difference between the scanned original and the enlarged duplicate socket profiles. The insert was fabricated with a 3D printer (Objet30 Pro, Stratasys) from a rigid polymer with properties similar to Delrin®.

Subjects wore the enlarged duplicate socket with insert for four weeks. The inside surface was scanned at the beginning and end of the four-week wear period. Insert geometries were then compared to participants’ original socket geometries using a custom Matlab script (Sanders 2011).

RESULTS
For the five subjects tested fit quality (i.e., difference between the insert and original socket shape) improved over the four-week wear period. Compared to the original socket total volume, new inserts were 0.36% smaller (mean radial error -0.11±0.23 mm) while worn inserts were 0.09% smaller (mean radial error -0.03±0.15 mm) (Table 1). Over the four-week trial period, no signs of abnormal fatigue or failure were noted. Sensors integrated into the inserts showed good durability and low signal noise (Fig. 2).

Table 1: Shape comparisons between installed inserts and the original socket shape (n=5).

<table>
<thead>
<tr>
<th>Radial Error (mm)</th>
<th>Vol Error (%)</th>
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</thead>
<tbody>
<tr>
<td>New</td>
<td>Worn</td>
</tr>
<tr>
<td>1</td>
<td>-0.12 ± 0.16</td>
</tr>
<tr>
<td>2</td>
<td>-0.13 ± 0.19</td>
</tr>
<tr>
<td>3</td>
<td>-0.09 ± 0.18</td>
</tr>
<tr>
<td>4</td>
<td>-0.04 ± 0.25</td>
</tr>
<tr>
<td>5</td>
<td>-0.19 ± 0.36</td>
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</tbody>
</table>

DISCUSSION
This study showed that 3D printed inserts for prosthetic sockets are both feasible and accurate. There may be a break-in period for the inserts since they tended to seat in place with use. Sensors integrated effectively into the inserts and may prove useful for outcome assessment.

CLINICAL APPLICATIONS
3D printers are becoming increasingly available that offer similar precision to the model used in this study for a fraction of the cost. Thus, it may soon be possible to fabricate inexpensive inserts and extend the life of a socket.

Inserts in this study were designed with a uniform thickness. However, non-uniform inserts could likely be customized to the patient using design software (e.g. OMEGA® Tracer; Canfit®). Regional shape changes may further enhance socket fit.

REFERENCES

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