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A controlled clinical trial of a clinically-tuned powered ankle prosthesis in people with transtibial amputation

BiOM (Bionic powered ankle-foot prosthesis)

With BiOM compared to conventional, unpowered prosthesis (UNPWR) as well as age and gender-matched control participants without amputation (CONTROL):

→ K4 subjects are more likely to improve energy costs than K3 subjects

K4: -4% cost of transport (COT) with BiOM compared to UNPWR
K3: +5.4% COT with BiOM compared to UNPWR

No differences in cost of transport over all subjects

<table>
<thead>
<tr>
<th>Subject group</th>
<th>Cost of transport [J/Nm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>BiOM</td>
<td>0.3</td>
</tr>
<tr>
<td>UNPWR</td>
<td>0.4</td>
</tr>
<tr>
<td>CONTROL</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Population

Subjects: 9 unilateral, transtibial amputees (all males)
Previous prosthetic foot:
- Powered: BiOM (2)
- Unpowered: Renegade (3), Trustep, Re-Flex Rotate, LP Rotate, Veri-Flex (1 each)
Amputation causes: Trauma
Mean age: 45.3 ± 14.5 years
MFCL: K3 (3), K4 (6)

Study Design

Interventional, randomized crossover trial:

After fitting and tuning (>45 min), participants practiced walking over ground until they felt comfortable with the device (>15 min required).
Participants were instructed to walk along an 8-m walkway at their comfortable speed, whereby they were not informed that their speed was being measured. Evidence of a stable speed was required, which consisted of at least five consecutive practice trials where speed varied within ±5% of the running mean. Energetic costs were measured using a lightweight portable metabolic system as participants walked on a treadmill.

### Results

<table>
<thead>
<tr>
<th>Functions and Activities</th>
<th>Participation</th>
<th>Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level Walking</td>
<td>Stairs</td>
<td>Ramps, Hills</td>
</tr>
<tr>
<td>Level Walking</td>
<td>Preferred walking speed [m/s]</td>
<td>No differences with BiOM compared to UNPWR (-2.3%) and CONTROL (0%).</td>
</tr>
<tr>
<td>Metabolic Energy Consumption</td>
<td>Oxygen consumption (VO$_2$) [mL/min/kg]</td>
<td>No differences with BiOM compared to UNPWR (+1.4%) and CONTROL (+9%).</td>
</tr>
<tr>
<td>Cost of transport (COT) [J/Nm]</td>
<td>No differences with BiOM compared to UNPWR (0.7%) and CONTROL (6.6%).</td>
<td>0</td>
</tr>
</tbody>
</table>

Subgroup analysis:
With BiOM, K4 subjects (-4%) are significantly more likely to improve COT than K3 subjects (+5.4) % compared to UNPWR.

* no difference (0), positive trend (+), negative trend (−), significant (++/−), not applicable (n.a.)

### Author's Conclusion

“...Although group mean performance benefits for this study cohort were much smaller than shown in previous work tests of user characteristics revealed that the subgroup of users with a K4 functional classification in this study did show performance benefits, whereas the K3 subgroup did not. The K4 users demonstrated a mean 4.0% decrease in COT and a 5.4% increase in preferred speed with the powered ankle, whereas the K3 users, as a group, showed performance deficits (a mean 5.4% increase in COT and a 1.4% decrease in preferred speed). Increased physical adaptability among users with a higher functional classification may have allowed them to adapt their gait to improve performance with little practice. Correspondingly, study cohorts of high-functioning active-duty military members users show the largest performance benefits for a powered prosthesis in the literature. Our data suggest that, without device-specific training, performance benefits from a powered ankle may be realized by only users with high functional classification. ...” (Gardinier et al., 2017)