Reference

Gardinier ES, Kelly BM, Wensman J, Gates DH.

School of Kinesiology, University of Michigan, Ann Arbor, MI, USA.

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

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Products

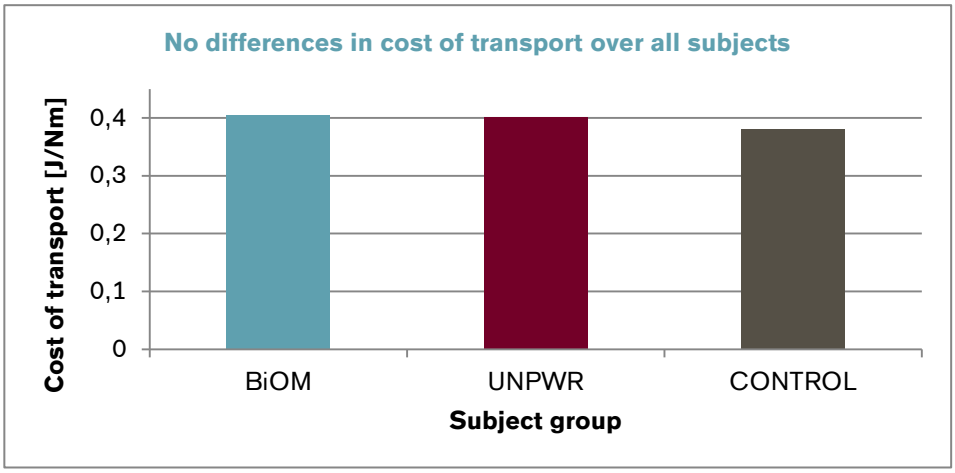
BiOM (Bionic powered ankle-foot prosthesis)

Major Findings

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

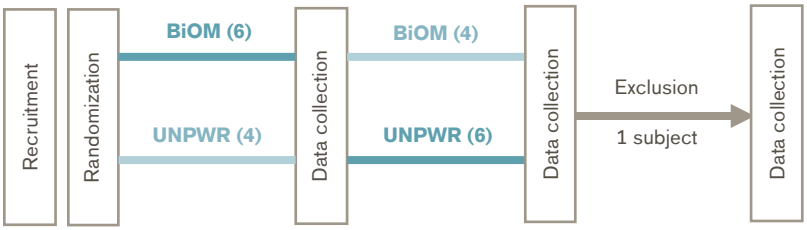


Population

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

Functions and Activities						Participation			Environment
Level walking	**Stairs**	**Ramps, Hills**	**Uneven ground, Obstacles**	**Cognitive demand**	**Metabolic energy consumption**	**Safety**	**Activity, Mobility, ADLs**	**Preference, Satisfaction, QoL**	**Health Economics**

Category	**Outcomes**	**Results for BiOM vs UNPWR vs CONTROL**	**Sig.***
Level Walking	Preferred walking speed [m/s]	No differences with BiOM compared to UNPWR (-2.3%) and CONTROL (0%).	0
Metabolic Energy Consumption	Oxygen consumption (VO_2) [mL/min/kg]	No differences with BiOM compared to UNPWR (+1.4%) and CONTROL (+9%).	0
	Cost of transport (COT) [J/Nm]	No differences with BiOM compared to UNPWR (0.7%) and CONTROL (6.6%). Subgroup analysis: **With BiOM, K4 subjects (-4%) are significantly more likely to improve COT than K3 subjects (+5.4) % compared to UNPWR.**	0

* 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)