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Title
Analysis of patient-reported musculoskeletal pain with use of a powered ankle-foot component.

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Summary
In an online survey, 41 unilateral transtibial amputees using a powered prosthetic foot daily reported significant improvements in knee pain, low-back pain, Knee Injury and Osteoarthritis Score and Oswestry Disability Index compared to a recall for their previous passive carbon fiber foot.

Introduction
Lower limb amputees often ambulate with a compensatory gait pattern, favoring their intact side with increased load through their sound knee (Gailey, 2008 & Esposito, 2016). Powered ankle-foot systems providing push-off (Esposito, 2016) were shown to result in decreased user's gait asymmetry patterns (Grabowski, 2013) with the potential to unload the sound side knee. This study aimed to determine if a powered ankle-foot system decreases knee and back pain, when compared to a passive energy storage and response (ESAR) carbon fiber foot.

Methods
250 patients who had been fitted with an Empower or BiOM foot were invited via email to participate in an IRB-approved online survey. Sixty-three individuals responded (response rate 25.2%). 57 unilateral transtibial amputees with an average age of 53.5 years were included in data analysis. Six responses of subjects with bilateral amputation were excluded.
Survey data collected: demographics, relevant health history, three 0-10 point numerical rating scales (NRS) for pain (sound side knee, amputated side knee, lower back), Socket Comfort Score, Knee Injury and Osteoarthritis Outcome Score (KOOS), Oswestry Disability Index (ODI) for low-back pain. Surveys were distributed via email, with a link to the survey done through Qualtrics® survey software. Responses were anonymous and de-identified.

Data analysis: Signed-rank tests were performed on the differences in outcomes. To account for possible recall bias, a sensitivity analysis for the difference in pain ratings was also performed.

Results

Forty-one of the 57 respondents (71.9%) claimed to be regular users of a powered ankle-foot mechanism and reported statistically significant and clinically meaningful improvements of 50% each in sound and amputated side knee pain as well as 33% reduction in low-back pain (Table 1).

To account for a possible pain recall bias, a sensitivity analysis demonstrated that these improvements would still be statistically significant if subjects had overrated their past pain with the passive carbon fiber foot by 36% (sound side knee), 28% (amputated side knee), or 33% (low-back pain), respectively.

The Knee Injury and Osteoarthritis Score (KOOS) showed a significant improvement with use of the powered prosthetic foot moving from a median of 76.6 (range 21.9-100) to 89.1 (range 25-100; $p<0.001$). Likewise, the Oswestry Disability Index (ODI) for low-back pain improved highly significantly from a median of 18 (range 0-80) to 8 (range 0-56; $p<0.001$). P-Values indicate strong statistical significance in both cases. Patients who had stopped using the powered ankle-foot component at some point for weight, limited battery life or lack of waterproofness, did not recall any improvements in musculoskeletal pain, KOOS or ODI scores.

Conclusion

Individuals using the powered foot were found to have statistically significant and clinically meaningful reductions in knee and low-back pain when compared to passive feet. Although there are more factors that influence pain, no difference was found in socket comfort scores, suggesting the difference can be attributed to the prosthetic foot. One limitation of the study was that subjects had to recall past pain with their previous foot. It has been found that patients tend to recall worse past pain than reported in concurrent ratings. However, the sensitivity analysis showed that results would still have been statistically significant if subjects had overestimated the differences in pain between the feet by 50-72%.

The data suggests that use of a powered ankle-foot component may reduce knee and low-back pain in transtibial amputees. Future research should address a possible correlation with improved gait symmetry and investigate musculoskeletal pain prospectively.

References

Gailey R. Review of secondary physical conditions associated with lower-limb amputations and long-term prosthesis use. J Rehab Res Dev 2008;45:15-30.

Grabowski AM, D´Andrea S. Effects of a powered ankle-foot prosthesis on kinetic loading of the unaffected leg during level-ground walking. J NeuroEng Rehabil 2013;10:49-60.

Russell Esposito E, Aldridge Whitehead JM, Wlken JM. Step-to-step transition work during level and inclined walking using passive and powered ankle-foot prostheses. Prosthet Orthot Int 2016;40(3):311-319.

Image: Table 1_Pain Ratings_2476.png

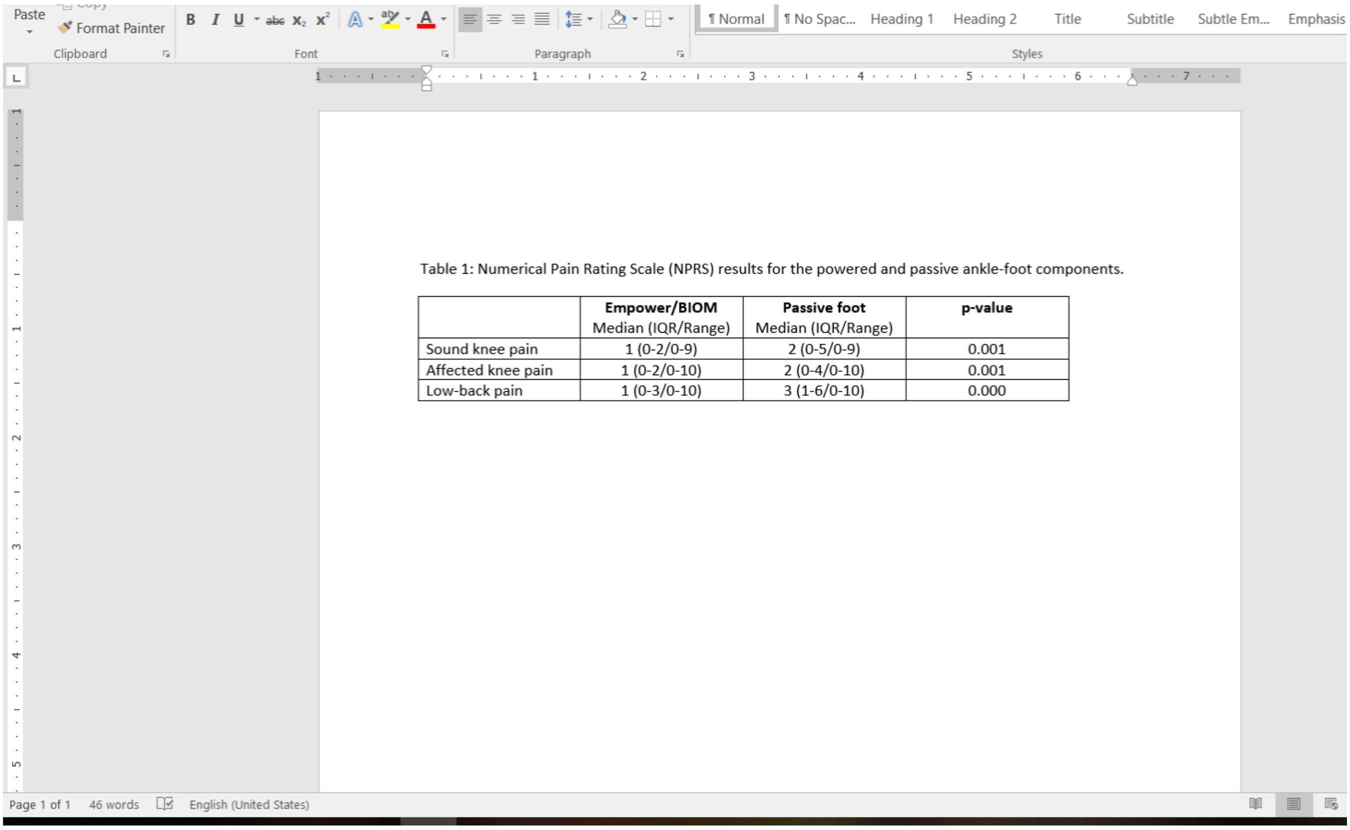

Table 1: Numerical Pain Rating Scale (NPRS) results for the powered and passive ankle-foot components.

	Empower/BIOM Median (IQR/Range)	**Passive foot** Median (IQR/Range)	**p-value**
Sound knee pain	1 (0-2/0-9)	2 (0-5/0-9)	0.001
Affected knee pain	1 (0-2/0-10)	2 (0-4/0-10)	0.001
Low-back pain	1 (0-3/0-10)	3 (1-6/0-10)	0.000