

Reference

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Impact of a Powered Prosthetic Ankle-Foot Component on Musculoskeletal Pain in Individuals with Transtibial Amputation: A Real-World Cross-Sectional Study with Concurrent and Recalled Pain and Functional Ratings

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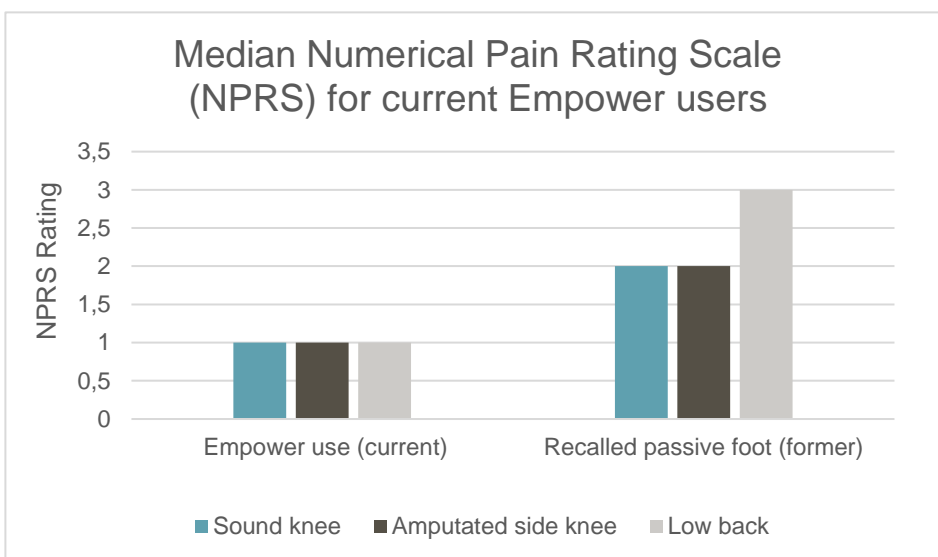
Products

Empower

Major Findings

With Empower compared to passive prosthetic foot:

→ **Significantly lower pain for sound knee, amputated side knee and lower back reported by current Empower users compared to recalled pain with previous passive prosthetic feet**



Population

Subjects: 57 (TT, unilateral, male)
- 41 current Empower users
- 16 former Empower users (current passive foot (PAS) users)

Previous prosthetic foot: n.a.

Amputation causes: Trauma (75.4%), Dysvascular (15.8%), Other (8.8%)

Mean age: 53.5±13.0 years

Mean time since amputation: 13.1±12.1 years

MFCL: n.a.



1. 250 subjects who were previously fit with Empower and had given permission to contact them were invited via email to participate in an online survey.
2. 63 subjects answered all questions of the online survey regarding demographic information, details about their amputation and prosthetic history and patient-reported outcome measures: Socket Comfort Score (SCS); Numerical Pain Rating Scale (NPRS) for sound knee, amputated side knee and lower back; Activity of Daily Living domain of the Knee Injury and Osteoarthritis Outcome Score (KOOS-ADL); Oswestry Disability Index (ODI). Ratings for the current foot were current and ratings for the previously used foot (passive foot in current Empower users, Empower in current passive foot users) were recalled.
3. Of the 63 datasets, 6 of bilateral subjects were excluded and the datasets of 57 unilateral subjects were selected for data analysis.
4. Recalled ratings were analyzed as original ratings and after adjustment for recall bias using recommendations of the scientific literature. In addition, a sensitivity analysis was performed to determine by what maximum percentage the recalled pain could have been adjusted (reduced) while maintaining a statistically significant difference between the Empower and passive feet. Such percentage indicates by what percentage subjects could have overestimated past pain while keeping a statistically significant difference in pain between the feet.

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 Empower vs. passive foot					Sig.*	
Activity, Mobility, Activities of Daily Living (ADLs)	KOOS-ADL (higher scores indicate better function)		Current Empower users (N=41): [median (range)] 89.1 (82.0-96.9) vs 76.6 (65.6-89.1) (p<0.001) <i>after adjustment for bias:</i> 89.1 (82.0-96.9) vs 66.6 (55.6-79.1) (p<0.001)					++	
			Current PAS users (N=16): [median (range)] 84.4 (66.4-93.4) vs 86.7 (75.4-96.9) (p=0.306) <i>after adjustment for bias:</i> 74.4 (56.4-83.4) vs 86.7 (75.4-96.6) (p=0.004)					0	
	ODI (lower scores indicate less activity restrictions)		Current Empower users (N=41): [median (range)] 8 (3-15) vs 18 (7-28) (p<0.001) <i>after adjustment for bias:</i> 8 (3-15) vs 28 (17-38) (p<0.001)					--	

Category	Outcomes	Results for Empower vs. passive foot	Sig.*
		Current PAS users (N=16): [median (range)] 17 (4-23) vs 17(2.5-24) (p=0.858) <i>after adjustment for bias:</i> 27 (14-33) vs 17 (2.5-24) (p=0.007)	0 +
Preference, Satisfaction, Quality of Life (QoL)	Musculoskeletal Pain Group results (NPRS Rating)	Current Empower users (N=41): [median (IQR)] <u>Sound knee pain:</u> 1 (0-2) vs 2 (0-5) (p=0.001) <i>after adjustment for bias:</i> <i>1 (0-2) vs 1 (0-4) (p=0.005)</i> <i>after maximum adjustment (-36%):</i> <i>1 (0-2) vs 1.28 (0-3.2) (p=0.049)</i> <u>Amputated side knee pain:</u> 1 (0-2) vs 2 (0-4.5) (p=0.001) <i>after adjustment for bias:</i> <i>1 (0-2) vs 1 (0-3.5) (p=0.032)</i> <i>after maximum adjustment (-28%):</i> <i>1 (0-2) vs 1.44 (0-2.88) (p=0.037)</i> <u>Low back pain:</u> 1 (0-3) vs 3 (1-6.5) (p=<0.001) <i>after adjustment for bias:</i> <i>1 (0-3) vs 2 (1-6) (p=0.003)</i> <i>after maximum adjustment (-33%):</i> <i>1 (0-3) vs 2.01 (0.72-4.02) (p=0.044)</i> Current PAS users (N=16): [median (IQR)] <u>Sound knee pain:</u> 3.5 (1-6) vs 4.5 (1-6) (p=0.596) <i>after adjustment for bias:</i> <i>2.5(1-5) vs 4.5 (1-6) (p=0.042)</i> <u>Amputated side knee pain:</u> 2 (0.25-4.5) vs 2 (1-4.5) (p=0.931) <i>after adjustment for bias:</i> <i>1 (0.25-3.5) vs 2 (1-4.5) (p=0.230)</i> <u>Low back pain:</u> 3.5 (1.25-5.75) vs 4.5 (1.25-6) (p=0.886) <i>after adjustment for bias:</i> <i>2.5 (1-4.75) vs 4.5 (1.25-6) (p=0.061)</i>	-- -- -- -- -- 0 0 0
	Musculoskeletal Pain Individual results (NPRS Rating)	Patients with moderate or severe pain (NPRS ≥ 3 (N=57)): [number of patients (percentage)] <u>Sound knee:</u> 18 (32%) vs 30 (53%) (p=0.004) <u>Amputated side knee:</u> 14 (25%) vs 25 (44%) (p=0.007) <u>Lower back:</u> 25 (44%) vs 35 (61%) (p=0.012) <u>All 3 body regions:</u> 7 (12%) vs 16 (28%) (p=0.004)	n.a.

Category	Outcomes	Results for Empower vs. passive foot	Sig.*
		<p><u>Patients with pain >3 who improved ≥2 NPRS using the other foot) (N=57):</u> [number of patients with improved NPRS/number of patients with former pain > 3 (percentage)]</p> <p><u>Sound knee:</u> 19/30 (63%) vs 3/18 (17%)</p> <p><u>Amputated side knee:</u> 18/25 (72%) vs 5/14 (36%)</p> <p><u>Lower back:</u> 19/35 (54%) vs 4/25 (16%)</p> <p><u>All 3 body regions:</u> 12/16 (75%) vs 2/7 (29%)</p>	n.a.

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

Author's Conclusion

"Individuals in active daily life with TTA may experience significant and clinically meaningful relief of sound knee, amputated side knee, and low-back pain with the use of a powered ankle foot mechanism. In addition, individuals may also see a reduction in pain-related restrictions in ADL function. However, other factors such as quality of socket fit seem to contribute to the potential clinical benefits as well." (Cacciola et al.2022)

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