Reference

Pawel Maciejasz[1], Tymoteusz Budny[2], Michael Sauer[3], Marina Umari[4], Jürgen Korber[5], Jennifer Ernst[6,7], Bjoern Altenburg[1], Andreas Hahn[8] and Frank Braatz[7,9]

User preference and patient benefits of a novel energy storing and return foot: A randomized, cross-over clinical trial

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Products

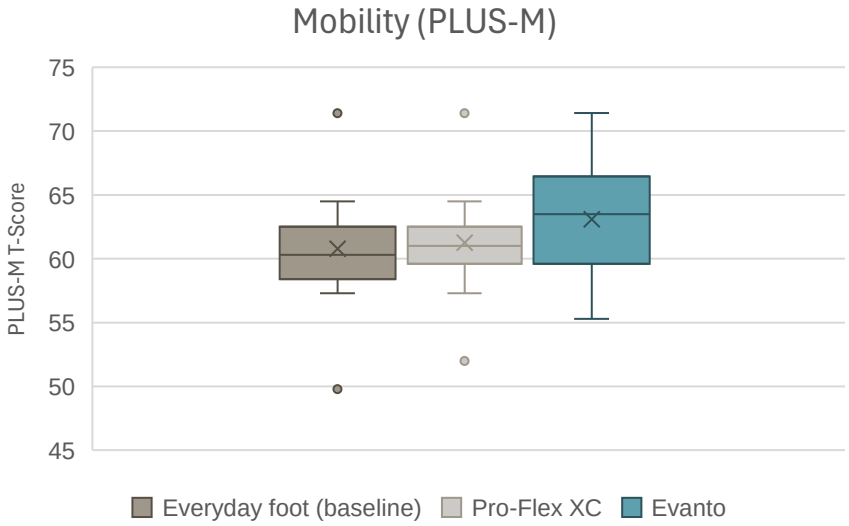
Evanto vs. Pro-Flex XC vs. everyday ESAR

Major Findings

With Ottobock 1C70 Evanto compared to the currently used everyday ESAR (energy storing and returning) foot:

→ Improved perceived mobility

- Significant mean improvement of 2.3 ± 2.8 of the PLUS-M T-Score [p= 0.0007, d_z = 0.84]. For 25% of participants this improvement was higher than the minimal detectable change (MDC(90) = 4.5).



Mobility shown as the mean PLUS – M T-Score value for Evanto, Pro-Flex XC and the everyday used foot.

→ Improved walking experience

- 95% of participants rated walking up slopes easier
- 85% of participants rated standing more flexible
- 85% of participants rated the heel strike more comfortable

With Ottobock 1C70 Evanto compared to Pro-Flex XC and the current everyday ESAR:

→ Higher foot preference

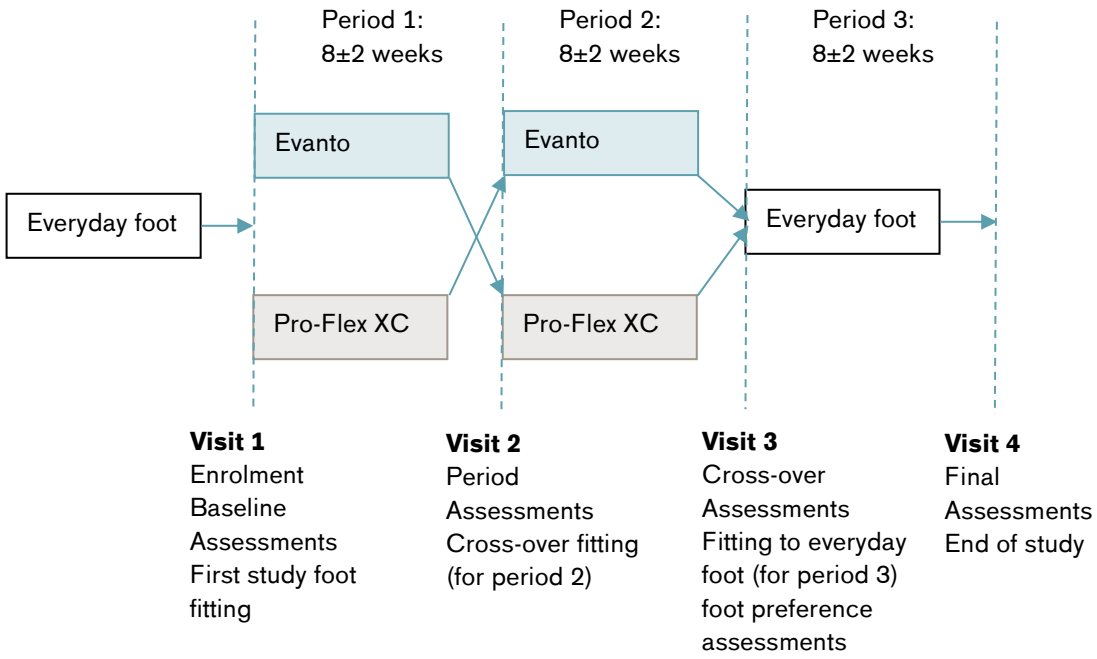
- Evanto was the most preferred foot overall (55% of participants) and for many activities, e.g., walking on inclines (85%) and over uneven terrain (70%).

Population

Subjects:	20 transtibial amputees (12 male, 8 female)
Amputation causes:	Trauma (8), Infection (4), Vascular or diabetes (4), Congenital (2), Cancer (2)
Mean age:	53.6 ± 15.0 years
Mean time since amputation:	14.0 ± 14.3 years
MFCL:	K3 (all; inclusion criteria)
Current everyday ESAR foot:	Össur Pro-Flex XC (8), Ottobock Taleo (5), Ottobock Trias (3), Össur Pro-Flex LP (1), Össur Pro-Flex LP Torsion (1), Össur Pro-Flex Pivot (1), Össur Vari-Flex (1)

Study Design

Interventional, multicenter, randomized, cross-over design:



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 Evanto	Sig.*
Activity, Mobility, Activities of Daily Living (ADLs)	Mobility - PLUS-M T-Score (21.8-71.4; confirmatory outcome)	**Mean differences ±SD (Effect size):** Evanto vs. ESAR BL: 2.3 ± 2.8 (p= 0.0007 (d_z = 0.84) Evanto vs. Pro-Flex XC: 1.8 ± 4.0 (d_z = 0.47)	++ +

Category	Outcomes	Results for Evanto	Sig.*
	Balance confidence - Activities specific Balance Confidence (ABC) Scale (0-100; exploratory outcome)	Score while wearing Evanto (91.4 ± 6.8) was higher than while wearing ESAR BL (91.0 ± 7.2) and Pro-Flex XC (90.8 ± 8.6), but lower than ESAR Final (92.9 ± 6.2).	0
	Walking experience	≥ 50% participants agreed with 21 out of 22 custom statements about the improved walking experience with Evanto as compared with their ESAR feet.	n.a.
		Highest agreement rates were for easier walking up slopes (95%), more flexible standing with secure stance (85%) and more comfortable heel strike (85%).	n.a.
Safety	Number. of falls (exploratory outcome)	Number of falls while wearing Evanto (0.3 ± 0.7) was roughly the same as for ESAR Final (0.3 ± 1.1) and higher than for the other tested feet (0.2 ± 0.4 and 0.1 ± 0.2 for ESAR BL and Pro-Flex XC, respectively).	0
	Fear of falling (0-10, the lower the score the better, confirmatory outcome)	Score while wearing Evanto (0.5 ± 1.1) was the lowest among the tested feet.	0
Preference, Satisfaction, Quality of Life (QoL)	Satisfaction - Extent of meeting amputees' prosthetic foot needs (0-10, confirmatory outcome)	**Mean differences ± SD (Effect size):**	
		Evanto vs. ESAR at BL: 0.8 ± 2.8 (d_z = 0.29)	0
		Evanto vs. Pro-Flex XC: 1.2 ± 2.7 (d_z = 0.42)	+
	Preference	Evanto was the most preferred foot overall (preferred by 55% of participants). For each or the investigated activities including walking, sport specific activities and ADLs the preference ratio for Evanto was higher than for any other tested foot.	n.a.
		The highest preference ratios for Evanto were observed for walking on inclines (85%), walking on declines (70%), and walking on uneven terrain (70%).	n.a.
	Pain - highest reported pain (0-10, the lower the score the better, confirmatory outcome)	**Mean differences ±SD (Effect size):**	
		Evanto vs. ESAR at BL: -0.4 ± 2.9 (d_z = 0.14)	0
		Evanto vs. Pro-Flex XC: -0.7 ± 2.5 (d_z = 0.26)	0
	Residual limb pain (0-10, the lower the score the better, confirmatory outcome)	Score while wearing Evanto (0.9 ± 1.5) was lower than the one for ESAR Final (2.0 ± 2.1) and Pro-Flex XC (1.8 ± 2.5), but higher than ESAR BL (0.8 ± 1.6).	+
	Sound limb pain (0-10, the lower the score the better, confirmatory outcome)	Score while wearing Evanto (0.9 ± 1.5) was the highest among the tested feet.	0
	Lower back pain (0-10, the lower the score the better, confirmatory outcome)	Score while wearing Evanto (1.5 ± 2.5) was the lowest among the tested feet.	0

Category	Outcomes	Results for Evanto	Sig.*
	Pain in the neck and shoulder area (0-10, the lower the score the better, confirmatory outcome)	Score while wearing Evanto (1.0 ± 1.7) was roughly the same as for ESAR BL and higher than for the other tested feet.	0
	Phantom limb pain (0-10, the lower the score the better, confirmatory outcome)	Score while wearing Evanto (1.1 ± 1.9) was the lowest among the tested feet.	0
	Pain interference (0-10, the lower the score the better, confirmatory outcome)	Score while wearing Evanto (0.8 ± 1.3) was lower than the one for ESAR Final (1.7 ± 2.4) and Pro-Flex XC (1.7 ± 2.5), but higher than ESAR BL (0.5 ± 0.8).	+
	Health utility value - EQ-5D-5L (-0.661-1, exploratory outcome)	Score while wearing Evanto (0.97 ± 0.5) was the highest among the tested feet	0
	Current health – EQ-5D-5L (0-100, exploratory outcome)	Score while wearing Evanto (89.4 ± 9.9) was the highest among the tested feet	0

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
Significance set at $p<0.05$ and for confirmatory outcomes further adjusted for multiple comparisons (Benjamini-Hochberg procedure); trends set at $0.1>p>$adjusted α (confirmatory objectives) or <0.05 (exploratory objectives)
Effect sizes (d_z) classified by authors as small (<0.3), moderate (>0.3 and <0.5) or large (>0.5)
SD – Standard deviation, **ESAR** - currently used everyday energy storing and returning foot, **BL** – Score during baseline assessment, **Final** - Score during final assessment

Author's Conclusion

"The novel foot, despite its compact design, offers several advantages compared with the other tested feet. The most profound benefits seem to be walking on uneven terrain and slopes easier that might result from high multiaxial compliance and comfortable heel strike with more perceptible shock absorption that is related to adjustable elastic foam elements. At the same time, in none of the investigated activities and outcomes, the novel foot was assessed significantly worse than the other feet. This was confirmed by the highest overall preference of the novel foot (55%) among the tested feet and improved perceived mobility as measured by PLUS-M, for which the difference as compared with the everyday foot at baseline was highly significant."

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