

## Reference

Altenburg, B.<sup>1</sup>, Ernst, M.<sup>2</sup>, Maciejasz, P.<sup>3</sup>, Braatz, F.<sup>4</sup>, & Bellmann, M.<sup>5</sup>

# Analysis of a Novel Prosthetic Foot Design: A Clinical and Biomechanical Evaluation

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## Products

### Evanto

## Major Findings

With Evanto compared to established ESR feet:

### → Enhanced shock absorption without added joint loading

- Heel compression increased by +24% ( $p = 0.030$ ), indicating enhanced shock absorption
- Contributes to reported improvements in terrain adaptability alongside with increased range of motion
- No differences were found in contralateral knee loading

### → Higher biomechanical performance with Evanto compared to the patients' everyday foot with more dynamic gait pattern (greater forward propulsion, increased push-off energy)

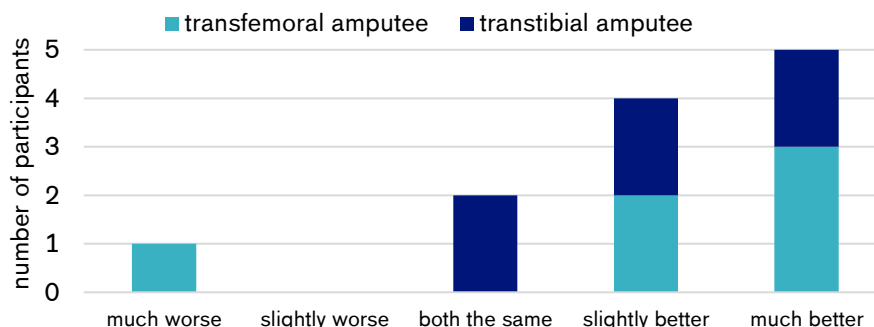
- Significantly greater anterior-posterior ground reaction force peaks (transfemoral amputees: +14%,  $p = 0.028$ ; transtibial amputees: +13%,  $p = 0.046$ )
- Increased ankle power by +21% ( $p = 0.010$ )
- Increased ankle ROM by +14% ( $p < 0.001$ )

### → Improved functional walking performance using Evanto compared to the patients' everyday foot

- Increased average 6-MWT distance by +6% ( $\Delta 23.5 \pm 18.0$  m,  $p = 0.004$ )

### → Strong user preference of Evanto, but no clinically meaningful change in patient reported outcomes

- Improvement in PLUS-M was statistically significant but not clinically relevant ( $\Delta 0.8 \pm 1.0$ ,  $p = 0.038$ ) what may be attributed to already high initial mobility with the patients' everyday foot
- Change in ABC scale was neither statistically significant nor clinically relevant difference, possibly because there was not much room for improvement
- 75% of participants preferred the Evanto foot over their everyday ESR foot ( $p = 0.021$ )
- Highlighted with Evanto were improved shock absorption, smoother rollover, enhanced adaptability when walking on uneven terrain



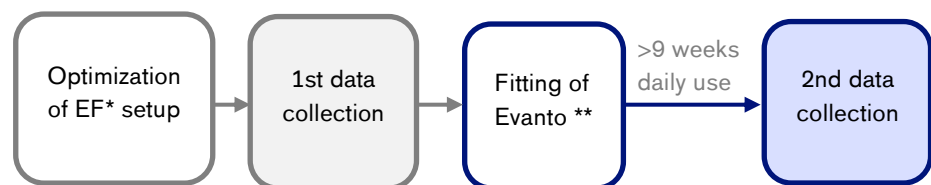
**Figure 1.** Foot preference: Rating of the Evanto foot compared to the participants' everyday foot regarding suitability in individual everyday life at the end of the study.

<b>Population</b>	Subjects:	12 subjects completed the study (14 enrolled), female (5), male (7)
	Amputation Level:	unilateral TTA* (6) and TFA* (6)
	Previous prosthesis:	<b>Knee:</b> Genium (2), Genium X3 (3), C-Leg 4 (1) <b>Foot:</b> <u>Ottobock</u> : Triton (5), Taleo Side Flex (2), Taleo (2), Triton Low Profile (1), Challenger (1); <u>Össur</u> : Proflex Align (1) (at least 3 years of experience with ESR foot and MPK)
	Amputation causes:	n.a.
	Mean age:	TTA: 51 ± 6 years; TFA: 56 ± 4 years
	Mean time since amputation:	TTA: 25 ± 14 years; TFA: 25 ± 9 years
	MFCL:	K3 (9), K4 (3)

\* TTA = transtibial amputee; TFA = transfemoral amputee

## Study Design

Cross-sectional study design:



\* EF = everyday foot, that the patients use

\*\* study foot = Evanto, with the same prosthetic socket as in the old setup

The participants' everyday foot was inspected and optimized if needed. Next, the first data collection was carried out. Thereafter the participants received the study foot Evanto. After 1 week of everyday use, the prosthesis was adjusted if necessary. Then an accommodation period of at least 9 weeks followed, subsequently followed by the same procedure of data collection with the new setup.

For the data collection a gait analysis with self-selected speed on level ground was performed.

## 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 vs. everyday foot <sup>b</sup>	Sig. <sup>a</sup>				
Level Walking	6-MWT (m)	<p>The distance covered increased significantly by +6% (<math>\Delta 23.5 \pm 18.0</math> m, <math>p = 0.004</math>, <math>d = 0.32</math>) on average with Evanto compared to the EFs.</p> <p>All, except one subject, walked further with Evanto (subject #5: longer distance with the EF (Challenger, Ottobock)).</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>EF</th> <th>Evanto</th> </tr> </thead> <tbody> <tr> <td>390 ± 60 m</td> <td>413 ± 61 m</td> </tr> </tbody> </table>	EF	Evanto	390 ± 60 m	413 ± 61 m	++
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Category	Outcomes	Results for Evanto vs. everyday foot <sup>b</sup>	Sig. <sup>a</sup>									
	Prosthetic Limb Users Survey of Mobility Scale (PLUS-M)	T-score increased with using Evanto by $+0.8 \pm 1.0$ , which reached statistical significance ( $p = 0.038$ , $d = 0.10$ ).										
		<table border="1"> <thead> <tr> <th></th> <th>EF</th> <th>Evanto</th> </tr> </thead> <tbody> <tr> <td></td> <td><math>59.7 \pm 6.5</math></td> <td><math>60.5 \pm 6.2</math></td> </tr> </tbody> </table>		EF	Evanto		$59.7 \pm 6.5$	$60.5 \pm 6.2$	++			
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	Activities Specific Balance Confidence Scale (ABC)	No significant difference between the different feet.	0									
	Ground Reaction Force (GRF) (%BW)	Anterior-posterior GRF: The maximum acceleration on the prosthetic side for TFA significantly increased +14% ( $p = 0.028$ , $d = 0.39$ ) and TTA 13% ( $p = 0.046$ , $d = 0.50$ ) with Evanto compared with the EF.										
		<table border="1"> <thead> <tr> <th></th> <th>EF</th> <th>Evanto</th> </tr> </thead> <tbody> <tr> <td>TFA</td> <td><math>12.4 \pm 4.0</math> %BW</td> <td><math>14.5 \pm 3.3</math> %BW</td> </tr> <tr> <td>TTA</td> <td><math>13.7 \pm 1.9</math> %BW</td> <td><math>15.7 \pm 3.0</math> %BW</td> </tr> </tbody> </table>		EF	Evanto	TFA	$12.4 \pm 4.0$ %BW	$14.5 \pm 3.3$ %BW	TTA	$13.7 \pm 1.9$ %BW	$15.7 \pm 3.0$ %BW	++
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	Ankle Power (W/kg)	Significant increase in ankle power on the prosthetic side of +21% ( $p = 0.010$ , $d = 0.51$ ) for the entire group using Evanto.										
		<table border="1"> <thead> <tr> <th></th> <th>EF</th> <th>Evanto</th> </tr> </thead> <tbody> <tr> <td></td> <td><math>1.5 \pm 0.4</math> W/kg</td> <td><math>1.9 \pm 0.5</math> W/kg</td> </tr> </tbody> </table>		EF	Evanto		$1.5 \pm 0.4$ W/kg	$1.9 \pm 0.5$ W/kg	++			
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	Ankle Range of Motion (ROM) (°) <sup>c</sup>	significant ROM increase of +14% ( $p < 0.001$ , $d = 2.95$ ) on the prosthetic side using Evanto										
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	Heel Compression (mm)	<u>TFA</u> : more heel compression at the beginning of stance with Evanto <u>TTA</u> : less uniform for this parameter → decreased heel compression for two subjects while using Evanto <u>Average</u> : significant increase of ~3 mm (+24%, $p = 0.030$ , $d = 0.75$ )										
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	Spatiotemporal Gait Parameters	Similar results for Evanto and EF for the following parameters: <ul style="list-style-type: none"> <li>• Gait velocity</li> <li>• Stance phase duration asymmetry</li> <li>• Step length asymmetry</li> <li>• Vertical Ground Reaction Force (1<sup>st</sup> &amp; 2<sup>nd</sup> peak)</li> <li>• Knee torque (1<sup>st</sup> positive peak)</li> <li>• Ankle torque</li> </ul>	0									

Category	Outcomes	Results for Evanto vs. everyday foot <sup>b</sup>	Sig. <sup>a</sup>
Preference, Satisfaction, Quality of Life (QoL)	Foot preference	Individual foot selection: Clear preference for the Evanto ( $p = 0.02$ ): <ul style="list-style-type: none"> <li>9 participants favored Evanto (75%)</li> <li>1 participant favored EF (8%)</li> <li>2 participants had no preference (17%)</li> </ul>	++

<sup>a</sup> no difference (0), positive trend (+), negative trend (-), significant (++/--), not applicable (n.a.); significance set at  $p < 0.05$ ; trends set at  $0.1 > p > 0.05$

<sup>b</sup> effect sizes of Cohen's d: small ( $< 0.3$ ), moderate ( $> 0.3$  and  $< 0.5$ ) or large ( $> 0.5$ )

<sup>c</sup> sagittal ankle range of motion (ankle ROM): range from maximum plantarflexion (after foot strike) to maximum dorsiflexion (before foot off)

### Author's Conclusion

"This study demonstrated that the novel low-profile prosthetic foot (SF), featuring a unique load transmission mechanism, can achieve biomechanical and clinical performance comparable to, and in some aspects exceeding, that of established ESR feet. Objective gait analyses revealed no adverse effects on contralateral limb loading, while dynamic gait parameters such as forward propulsion and ankle power output improved among prosthetic users. The clinical outcome measure 6MWT indicated statistically significant functional benefits. Additionally, the majority of participants preferred the SF for everyday use, highlighting improved terrain adaptation and shock absorption. These findings suggest that the SF may be a valuable alternative for K3 prosthesis users, especially in cases where reduced build height or enhanced heel adjustability are required. Further studies with larger cohorts are warranted to confirm these results" (Altenburg et al., 2025)

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