

Reference

Hahn A, Sreckovic I, Reiter S, Mileusnic M.

Ottobock Healthcare Products, Vienna, Austria.

First results concerning the safety, walking, and satisfaction with an innovative, microprocessor-controlled four-axes prosthetic foot.

Prosthet Orthot Int. 2018 Jun;42(3):350-356.

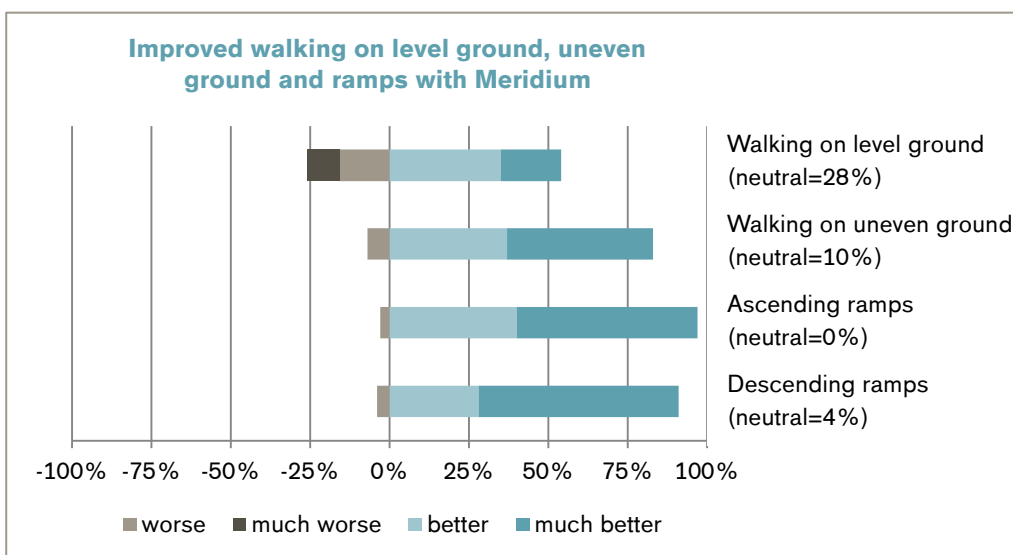
Products

Meridium

Major Findings

With Meridium compared to previous prosthetic foot:

- **Improved walking on level ground (54% of subjects) and uneven ground (82%) as well as ramp ascent (97%) and descent (91%)**
- **Increased safety and stability while standing and walking for more than 45% of the users.**
- **The use of Genium seems to significantly increase the preference of Meridium for transfemoral amputees.**

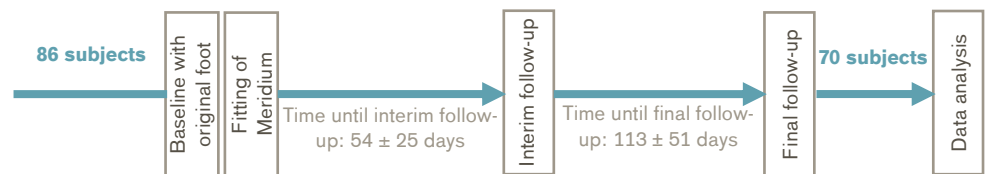


Population

Subjects:	70 subjects (at 44 international prosthetic clinics) - 77% male, 23% female - 64% Transtibial amputation, 36% Transfemoral amputation or kneedisarticulation
Previous prosthetic foot:	85% Carbon fiber feet, 7% Microprocessor controlled feet, 4% SACH, 2% SAFE, 2% Single axis feet
Amputation causes:	66% Trauma, 13% Cancer, 13% Vascular Disease, 5% Infection, 3% Congenital
Mean age:	45.6 ± 13.7 years
Mean time since amputation:	13.9 ± 13.6 years
MFCL:	63% K3, 37% K4

Study Design

Observational, prospective study:



“For 70 participants (81%), at least one patient questionnaire was completed. Therefore, data on 70 participants were used for analysis. Average Meridium use was 106.3 ± 57.04 days. To investigate effects related to trial duration, stratification for time of use differentiated between those having worn Meridium for less than 70 (46 ± 15 days; 51% participants) and for more than 70 (136 ± 35 days; 49% participants).

Fear of falling and number of falls and stumbles during the observation period were recorded. Comparative evaluations were recorded on 5-point Likert scales indicating “much better with Meridium,” “better with Meridium,” “no difference with Meridium,” “worse with Meridium,” and “much worse with Meridium.” Questions regarding pain, concentration, and exertion used the terms “more” and “less.”

Responders are classified as subjects who experienced “better” or “much better” performance with Meridium.” (Hahn et al, 2018)

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 Meridium vs				Sig.*		
Level Walking	Normal walking speed		Responders: 54% - Improved rating when using Meridium more than 70 days (61% responders) - Strong correlation to subject's preference and satisfaction.				n.a. ++ ++		
	Slow walking speed		Responders: 53% Strong correlation to subject's preference and satisfaction.				n.a. ++		
	Fast walking speed		Responders: 38%				n.a.		
	Walking with small steps		Responders: 29% Strong correlation to subject's preference and satisfaction.				n.a. ++		
	Toe clearance		Responders: 53%				n.a.		
	Exertion during walking		No difference in exertion during walking.				n.a.		
Stairs	Stairs ascent		Responders: 37%				n.a.		
	Stairs descent		Responders: 52%				n.a.		
Ramps, Hills	Ramp ascent		Responders: 97% (incl. 57% Much better) Improved rating when using Meridium more than 70 days (97% responders incl. 73% Much better)				n.a. ++		
	Ramp descent		Responders: 91% (incl. 63% Much better) Improved rating when using Meridium more than 70 days (91% responders incl. 76% Much better)				n.a. ++		

Category	Outcomes	Results for Meridium vs	Sig.*
	Ramp standing	Responders: 86%	n.a.
Uneven ground, Obstacles	Walking on uneven terrain	Responders: 82% Strong correlation to subject's preference and satisfaction.	n.a. ++
Cognitive Demand	Concentration while walking	No difference in concentration while walking.	n.a.
Safety	Safety	<u>Standing</u> : 51% responders	n.a.
		<u>Walking</u> : 49% responders Strong correlation to subject's preference and satisfaction.	n.a. ++
	Stability	<u>Standing</u> : 54% responders	n.a.
		<u>Walking</u> : 46% responders - Improved rating when using Meridium more than 70 days (58% responders) - Strong correlation to subject's preference and satisfaction.	n.a. ++ ++
	Stumbles	35% of the subjects reported fewer stumbles, 32% reported no change, and 33% reported an increase in the number of stumbles with Meridium.	n.a.
Falls	23% of the users reported fewer falls, 72% reported no difference, and 5% reported more falls with Meridium.	n.a.	
Preference, Satisfaction, Quality of Life (QoL)	Preference	40% of the users would prefer Meridium over their previous foot.	n.a.
		Prosthetists would recommend Meridium for 59% of the subjects.	n.a.
		50% of the above-knee amputees preferred Meridium. Preference in those using Meridium for longer than 70 days was strongly correlated to the use of Genium.	n.a. ++
	Satisfaction	50% of the users were satisfied with Meridium.	n.a.
	Comfort	<u>Walking</u> : 60% responders Improved rating when using Meridium more than 70 days (72% responders)	n.a. ++
<u>Standing</u> : 53% responders <u>Sitting</u> : 67% responders		n.a. n.a.	
Pain	No difference regarding back pain as well as pain in the residual and sound limb.	n.a.	

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

Author's Conclusion

"First fittings with Meridium showed that users perceived benefits and prosthetist recommended the device. Alignment and the use of the software were rated appropriate for routine use. Meridium seems to be preferred by amputees with a preference for natural walking and the requirement of safely and comfortably negotiating uneven terrain and slopes. Subject's preferences do not correlate with amputation level, age, and mobility grade. In transfemoral amputees, the use of Genium seems to significantly increase the perception of walking-related benefits offered by Meridium. Individual assessment and trial fittings seem to be essential to identify responders to the new foot." (Hahn et al, 2018)

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