Reference

Bart Raijmakers[1,2], Merel Anne Brehm[1,2], Frans Nollet[1,2], Fieke Sophia Koopman[1,2]

Safety, walking ability, and satisfaction outcomes of the NEURO TRONIC stance-control knee-ankle-foot orthosis (SCKAFO): A comparative evaluation to the E-MAG active SCKAFO

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Products

E-Mag Active

Major Findings

With E-Mag Active compared to Neuro Tronic:

→ Significant differences in gait kinematics and kinetics appear in 2 parameters

- Maximal ankle power in terminal stance increased significantly by 120% with the Neuro Tronic compared with the E-Mag Active (p = 0.003).
- Frontal knee moment during single stance decreased significantly by 26% with the Neuro Tronic compared with the E-Mag Active (p = 0.008).

→ No significant differences were observed in any of the spatiotemporal parameters

→ Experienced walking effort improved significantly in favor of the Neuro Tronic (p = 0.014)

- All other items of perceived effectiveness with standing and walking ability and overall perceived effectiveness did not differ between E-Mag Active and Neuro Tronic.

→ Higher mean comfortable treadmill speed with the Neuro Tronic compared to E-Mag Active

- Treadmill speed increased significantly by 19% during challenging walking tests with the Neuro Tronic compared to the E-Mag Active (p = 0.029).

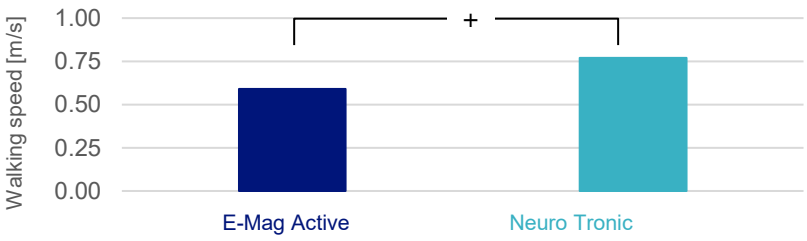


Figure 1: Mean comfortable walking speed on the treadmill during challenging walking tests

→ The median reported number of falls was significantly lower for the Neuro Tronic than for the E-Mag Active (p = 0.034)

→ Both are equally safe in terms of knee joint locking/unlocking during adaptive walking on an instrumented treadmill

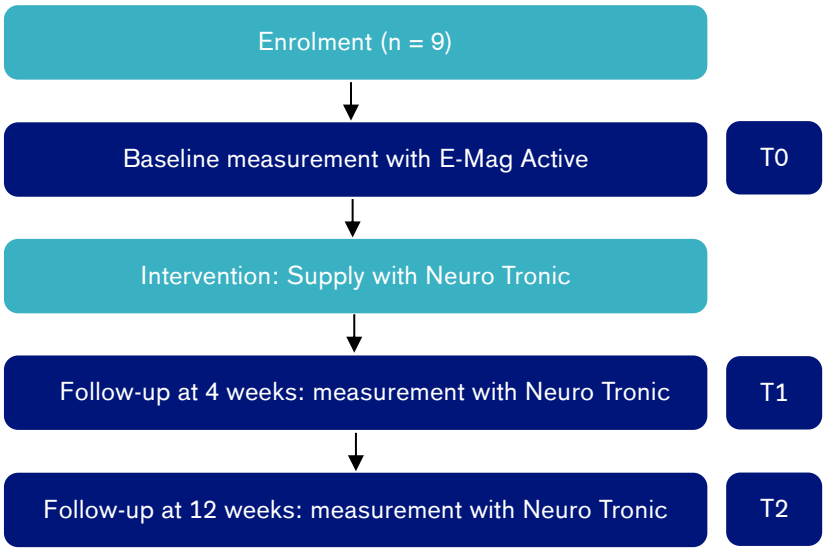
Population

Subjects:	9 (8males, 1female)
Previous orthosis:	Stance-control Knee-ankle-foot orthoses (SCKAFO, E-Mag Active) with solid ankle joint (n = 1) or hinged dorsiflexion-stop (n = 8)

Frequency of orthosis use:	6-7 days a week (n = 6), 4-5 days a week (n = 1), 2-3 days a week (n = 2)
Indication:	Muscle weakness of the lower extremity (incl. quadriceps) due to neuromuscular disorders; Poliomyelitis (n = 8) Postradiation lumbosacral plexopathy (n = 1)
Mean age:	60.3 ± 10.5 years

Study Design

Prospective, uncontrolled, interventional:



The measurements include tests on an interactive treadmill to assess knee joint function during walking under challenging conditions, a 3D gait analysis, a 6-minute walk test (6MWT) to determine net energy consumption (EC), an in-house questionnaire on perceived effectiveness, and the Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology (D-QUEST) to assess participant satisfaction.

Differences between the E-Mag Active and Neuro Tronic were analyzed between the baseline measurement (T0) and the 12-week follow-up (T2).

Results

Functions and Activities						Participation	Environment
Biomechanics – Static Measurement	**Biomechanics – Gait analysis**	X-Rays	EMG	Functional tests	**Clinical effects**	**Satisfaction**	Health Economics

Category	Outcomes	Results for E-Mag Active compared to Neuro Tronic	Sig.[a]
Biomechanics – Gait analysis*	Spatiotemporal parameters	No significant differences	0
	Max. ankle power in terminal stance [W/kg]	Increased significantly with Neuro Tronic compared with E-Mag Active	++

Neuro Tronic	E-Mag Active
0.77 ± 0.32	0.35 ± 0.12

Category	Outcomes	Results for E-Mag Active compared to Neuro Tronic	Sig.[a]
	Frontal knee moment during single stance [Nm/kg]	Decreased significantly with Neuro Tronic compared with E-Mag Active **Neuro Tronic**: 0.23 ± 0.15 — **E-Mag Active**: 0.31 ± 0.16	––
	Sagittal and frontal ankle and knee and hip kinematics and kinetics	No significant differences	0
Knee joint Function	Knee joint locking failure (LF) [%]	No significant differences, LF did not occur with either of them **Neuro Tronic**: 0 ± 0 — **E-Mag Active**: 0 ± 0	0
	Knee joint unlocking failure (ULF) [%]	Lower with Neuro Tronic compared with E-Mag Active, but not significantly **Neuro Tronic**: 9.9 ± 8.6 — **E-Mag Active**: 13.9 ± 11.6	–
	Mean comfortable treadmill speed [m/s]	Increased significantly with Neuro Tronic compared with E-Mag Active **Neuro Tronic**: 0.77 ± 0.32 — **E-Mag Active**: 0.35 ± 0.12	++
Clinical effects – Net EC	Mean comfortable walking speed during 6MWT [m/s]	No significant differences	0
	Net EC [J/kg per meter]	Lower by 8,2% with Neuro Tronic compared with E-Mag Active, but not significantly **Neuro Tronic**: 3.38 ± 0.75 — **E-Mag Active**: 3.68 ± 0.81	–
Satisfaction	Median interquartile range of perceived effectiveness on walking effort	Improved significantly with Neuro Tronic compared with E-Mag Active **Neuro Tronic**: 4.0 (3.0-6.0) ** — **E-Mag Active**: 3.0 (2.0–5.0) **	++
	Perceived effectiveness with standing and walking ability	No significant difference	0
	Overall perceived effectiveness	No significant difference	0
	Mean score of satisfaction (orthosis- & service-related)	No significant difference	0
	Median reported number of falls	Significantly lower for Neuro Tronic than for E-Mag Active **Neuro Tronic**: 0.0 (0.0–3.5) — **E-Mag Active**: 1.0 (0.0–10.0)	––

[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
*3D gait analysis was performed on only 8 subjects because 1 subject was unable to walk without walking aid at the follow-up measurement.

Category	Outcomes	Results for E-Mag Active compared to Neuro Tronic	Sig.[a]

[**]Scores range from 1 to 7 with 7 being the most positive score.

Author's Conclusion

"Our small-sized study in adults with knee instability due to lower extremity muscle weakness indicates that in terms of knee joint safety, evaluated in a laboratory setting, the E-MAG Active SCKAFO and the NEURO TRONIC SCKAFO have comparable outcomes. The net EC reduced by 8.2%, but not significantly, with the NEURO TRONIC SCKAFO compared with that with the E-MAG Active SCKAFO, and perceived walking effort was in favor of the NEURO TRONIC SCKAFO. Larger controlled randomized studies are warranted to compare differences in effectiveness between devices." (Raijmakers et al., 2024)

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