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E-MAG Active

Quality for life

Clinical Study Summaries

This document summarizes clinical studies conducted with the E-MAG Active. The included studies were identified by a literature search made on PubMed and within the journal *Medizinisch Orthopädische Technik*.

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Table of content:

1 Overview table

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g. gait analysis, clinical effects, satisfaction, etc). By clicking on underlined categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

Reference		Category						
		Functions and Activities						Participation
Author	Year	Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction
Schröder	2018		1			1		1
Total number: 1		0	1	0	0	1	0	1

2 Summaries of categories

On the following pages you find summaries of categories researched in several studies (e.g. gait analysis, clinical effects, satisfaction, etc.). At the end of each summary you will find a list of reference studies contributing to the content of the particular summary.

Biomechanics – Gait analysis

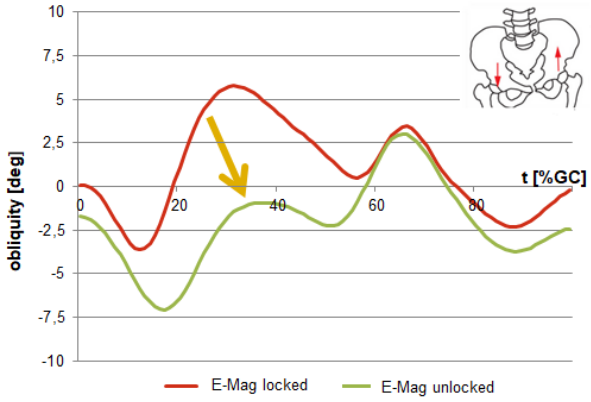
Major Findings

With E-MAG Active in unlocked mode (vs. locked mode):

→ significantly increased walking speed (0.06m/s; p < 0.05)

→ anatomically normalized knee flexion angle (57° at 70% gait cycle)

→ significantly reduced hip hiking



Hip hiking reduced

6 out of 8 patients

Schröder et al., 2018

Clinical Relevance

Patients with total or partial weakness of knee extensors are usually fitted with a Knee Ankle Foot Orthoses (KAFO) with a manually locked knee joint that provides safety while walking and can be released for sitting down. Those orthoses restore basic walking capabilities but have considerable disadvantages compared to normal walking (Bernhardt et al. 2006; Irby et al., 2005; Schmalz et al, 2005). Patients with locked KAFOs force compensatory movements to avoid stumbles when walking. They use hip hiking and vaulting (unnatural plantar flexion during mid-stance on the sound side) to provide sufficient toe clearance during swing (Zacharias et al., 2012).

Stance Control Orthoses (SCOs), like the E-MAG Active, were introduced to mitigate these limitations: they provide a locked knee stance, but enable free knee flexion during the swing phase. Therefore, a more natural gait pattern is offered preventing the sound side from higher or inappropriate loads due to compensatory movements. Overloading of the sound limb can result in secondary diseases such as osteoarthritis.

Biomechanical 3D gait measurements are conducted to determine joint angles, moments and load on the joints, so that differences in gait patterns between locked KAFO and E-Mag Active can be determined objectively.

Summary

When walking with E-MAG Active, we found an average knee flexion angle of 57°± 15° during swing phase at about 70% of gait cycle, which is in line with the results of previous studies that found knee swing flexion angles between 29° and 65° across their subject samples (Hebert et al., 2005; Irby et al., 2007; Moreno et al., 2008; Schmalz et al., 2005; Yakimovich et al., 2006; Zissimopoulos et al., 2007). Physiologically, humans walk with a knee flexion angle of about 65° between 40-

75% of the gait cycle, representing an important contributor to sufficient toe clearance of the swinging leg (Götz-Neumann, 2006; Perry, 2003).

As the orthotic knee joint allows for bending and thus sufficient toe clearance during swing, compensatory movements are reduced with E-MAG Active. Especially, hip hiking was reduced in 6 out of 8 subjects based on the angle of pelvis tilt (obliquity) in the coronal plane. Additionally, vaulting was reduced in 2 out of 3 subjects based on the sagittal angle and moment of the ankle. (Schröder et al., 2018)

These results are in accordance with previous studies. Zissimopoulos, et al. (2007) and Irby, et al. (2007) showed significantly reduced pelvic obliquity on the orthotic side with the SCO compared to a locked orthosis. Schmalz, et al. (2005) reported that the pelvic movement when walking with an SCO was comparable to that of healthy subjects. Irby, et al. (2007) described a significant reduction in vaulting of the sound side with an SCO, and Hebert & Liggins (2005) reported even no unnatural sound side plantar flexion at all in the middle of the stance phase.

SCOs, like E-MAG Active, show clear benefits over locked KAFOs, like more physiologic gait pattern, faster walking speed, lower metabolic energy consumption and reduced compensatory movements (Bernhardt et al. 2006; Davis et al., 2010; Irby et al., 2005; McMillan et al., 2004; Sabelis et al., 2007; Schmalz et al, 2005.

References of summarized studies

Schröder, S.; Pröbsting, E.; Schmalz, T.; Kannenberg, T.; Stinus, H. (2018). Functional walking capacity of subjects with paralyzed knee extensors while walking with an SCO in locked vs unlocked mode. *Physical Medicine and Rehabilitation Research, 3 (2)*: 1-6. DOI: 10.15761/PMRR.1000168

Other References

Bernhardt, K. A., Irby, S. E., & Kaufman, K. R. (2006). Consumer opinions of a stance control knee orthosis. *Prosthetics and orthotics international, 30(3),* 246-256.

Davis, P. C., Bach, T. M., & Pereira, D. M. (2010). The effect of stance control orthoses on gait characteristics and energy expenditure in knee-ankle-foot orthosis users. *Prosthetics and orthotics international*, *34*(2), 206-215.

Götz-Neumann Kirsten (2006) Gehen verstehen. Ganganalyse in der Physiotherapie. Publisher Thieme, 2nd Edition.

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Irby, S. E., Bernhardt, K. A., & Kaufman, K. R. (2005). Gait of stance control orthosis users: the dynamic knee brace system. *Prosthetics and orthotics international*, *29*(3), 269-282.

Irby, S. E., Bernhardt, K. A., & Kaufman, K. R. (2007). Gait changes over time in stance control orthosis users. *Prosthetics and orthotics international*, *31*(4), 353-361.

McMillan, A. G., Kendrick, K., Michael, J. W., Aronson, J., & Horton, G. W. (2004). Preliminary evidence for effectiveness of a stance control orthosis. *JPO: Journal of Prosthetics and Orthotics*, *16*(1), 6-13.

Moreno, J. C., Brunetti, F., Rocon, E., & Pons, J. L. (2008). Immediate effects of a controllable knee ankle foot orthosis for functional compensation of gait in patients with proximal leg weakness. *Medical & biological engineering & computing*, *46*(1), 43-53.

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Schmalz, T.; Blumentritt, S.; Drewitz, H. (2005). Gangphasenabhängig entriegelnde versus gesperrte Beinorthesen – Biomechanische und metabolische Untersuchungen. Unlocking versus locking leg orthosis during gait performance - Biomechanical and metabolic case studies. *Medizinisch Orthopädische Technik, 125(3)*, 67-74.

Yakimovich, T., Lemaire, E. D., & Kofman, J. (2006). Preliminary kinematic evaluation of a new stance-control knee–ankle–foot orthosis. *Clinical biomechanics*, *21*(10), 1081-1089.

Zissimopoulos, A., Fatone, S., & Gard, S. A. (2007). Biomechanical and energetic effects of a stance-control orthotic knee joint. *Journal of Rehabilitation Research and Development*, *44*(4), 503-513.

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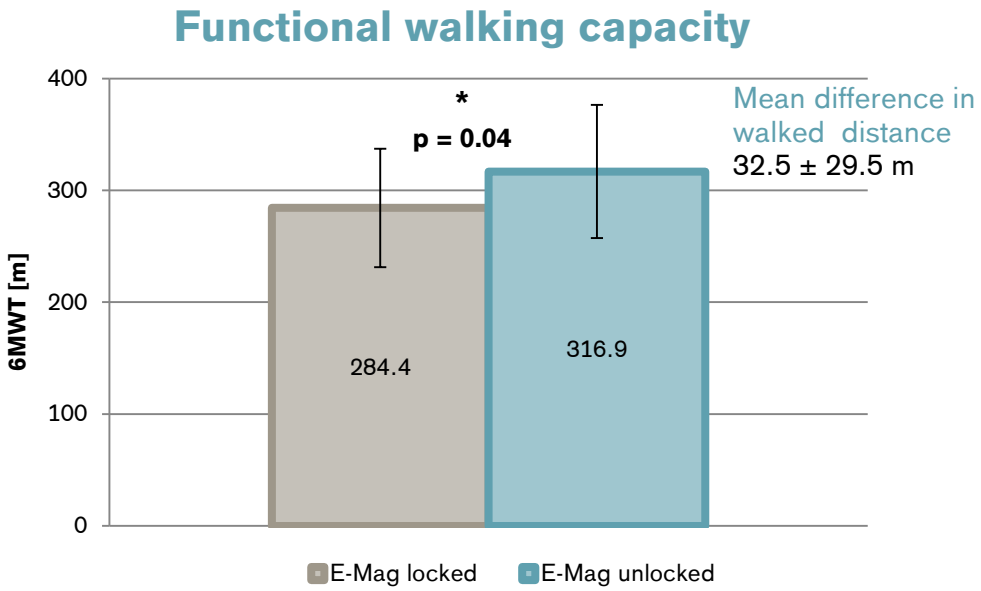
Functional tests

Major Findings

With E-MAG Active in unlocked mode (vs. locked mode):

→ significantly increased walking distance in the 6-minute walk test (+32.5 ± 29.5 m)



Schröder et al., 2018

Clinical Relevance

The aim of E-MAG Active is to enable independent and safe ambulation. It provides the required safety by locking the knee joint for stance and automatically unlock during swing phase. This has influence on activity, mobility, participation and, therefore the overall well-being of the user.

Timed walk tests are validated measures of physical performance and overall mobility in patients with various medical conditions (Rossier & Wade, 2001), including incomplete spinal cord injury (Jackson et al., 2008), post-polio syndrome (Flansbjer & Lexell, 2010) and lower limb amputations. In subjects with lower limb amputations, the distance walked is well correlated with daily activity and indicative for substantial functional limitations in daily life (Gremeaux et al., 2012).

Summary

The results of the study by Schröder et al. (2018) show that subjects walked significantly slower in the locked mode compared to the unlocked mode of E-MAG Active. The average difference in walking speed between the orthotic modes was bigger in the 6MWT with 0.09 m/s than in the gait analysis with 0.06 m/s.

In the literature, five studies reported comparable parameters determined in 3D gait measurements. In those studies, subjects demonstrated a significantly faster or at least a tendency toward faster walking speed between 0.06 m/s and 0.1 m/s with the SCO compared to a locked KAFO (Bernhardt et al., 2006; Davis et al., 2010; Irby et al., 2007; McMillan et al., 2004; Schmalz et al., 2005).

With the E-MAG Active in the locked condition, subjects were significantly restricted in their functional walking capacity as demonstrated by a mean 32.5 m reduction in the distance walked in 6 minutes (Schröder et al., 2018). This difference and thus the effect of the SCO mode on the functional walking capacity is close to the reported minimal clinically important differences (MCID) for incomplete SCI (36 m)

(Forrest et al., 2014) and stroke rehabilitation (34.4 m) (Eng & Dawson, 2004) and is also comparable to the effect of a 3-months physical therapy program in polio survivors (40 m) (Bertelsen et al., 2009). Using the E-MAG Active, subjects reached almost exactly the normative value of 316.8 m reported for subjects after 12 months of rehabilitation after an incomplete spinal cord injury (Ditunno et al., 2007).

Thus, it can be concluded that walking with an orthosis with a locked knee joint results in a significantly reduced functional walking capacity as compared to walking with the E-MAG Active.

References of summarized studies

Schröder, S.; Pröbsting, E.; Schmalz, T.; Kannenberg, T.; Stinus, H. (2018). Functional walking capacity of subjects with paralyzed knee extensors while walking with an SCO in locked vs unlocked mode. *Physical Medicine and Rehabilitation Research, 3(2)*: 1-6. DOI: 10.15761/PMRR.1000168

Other References

Bernhardt, K. A., Irby, S. E., & Kaufman, K. R. (2006). Consumer opinions of a stance control knee orthosis. *Prosthetics and orthotics international, 30(3),* 246-256.

Bertelsen, M., Broberg, S., & Madsen, E. (2009). Outcome of physiotherapy as part of a multidisciplinary rehabilitation in an unselected polio population with one-year follow-up: an uncontrolled study. *Journal of rehabilitation medicine*, *41*(1), 85-87.

Davis, P. C., Bach, T. M., & Pereira, D. M. (2010). The effect of stance control orthoses on gait characteristics and energy expenditure in knee-ankle-foot orthosis users. *Prosthetics and orthotics international*, *34*(2), 206-215.

Ditunno Jr, J. F., Barbeau, H., Dobkin, B. H., Elashoff, R., Harkema, S., Marino, R. J., ... & Deforge, D. (2007). Validity of the walking scale for spinal cord injury and other domains of function in a multicenter clinical trial. *Neurorehabilitation and neural repair*, *21*(6), 539-550.

Eng, J. J., Dawson, A. S., & Chu, K. S. (2004). Submaximal exercise in persons with stroke: test-retest reliability and concurrent validity with maximal oxygen consumption1. *Archives of physical medicine and rehabilitation*, *85*(1), 113-118.

Flansbjer, U. B., & Lexell, J. (2010). Reliability of gait performance tests in individuals with late effects of polio. *PM&R*, *2*(2), 125-131.

Forrest, G. F., Hutchinson, K., Lorenz, D. J., Buehner, J. J., VanHiel, L. R., Sisto, S. A., & Basso, D. M. (2014). Are the 10 meter and 6 minute walk tests redundant in patients with spinal cord injury?. *PloS one*, *9*(5), e94108.

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Irby, S. E., Bernhardt, K. A., & Kaufman, K. R. (2007). Gait changes over time in stance control orthosis users. *Prosthetics and orthotics international*, *31*(4), 353-361.

Jackson, A., Carnel, C., Ditunno, J., Read, M. S., Boninger, M., Schmeler, M., ... & Donovan, W. (2008). Outcome measures for gait and ambulation in the spinal cord injury population. *The journal of spinal cord medicine*, *31*(5), 487-499.

McMillan, A. G., Kendrick, K., Michael, J. W., Aronson, J., & Horton, G. W. (2004). Preliminary evidence for effectiveness of a stance control orthosis. *JPO: Journal of Prosthetics and Orthotics*, *16*(1), 6-13.

Rossier, P., & Wade, D. T. (2001). Validity and reliability comparison of 4 mobility measures in patients presenting with neurologic impairment. *Archives of physical medicine and rehabilitation*, *82*(1), 9-13.

Schmalz, T.; Blumentritt, S.; Drewitz, H. (2005). Gangphasenabhängig entriegelnde versus gesperrte Beinorthesen – Biomechanische und metabolische Untersuchungen. Unlocking versus locking leg orthosis during gait performance - Biomechanical and metabolic case studies. *Medizinisch Orthopädische Technik, 125(3)*, 67-74.

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Satisfaction

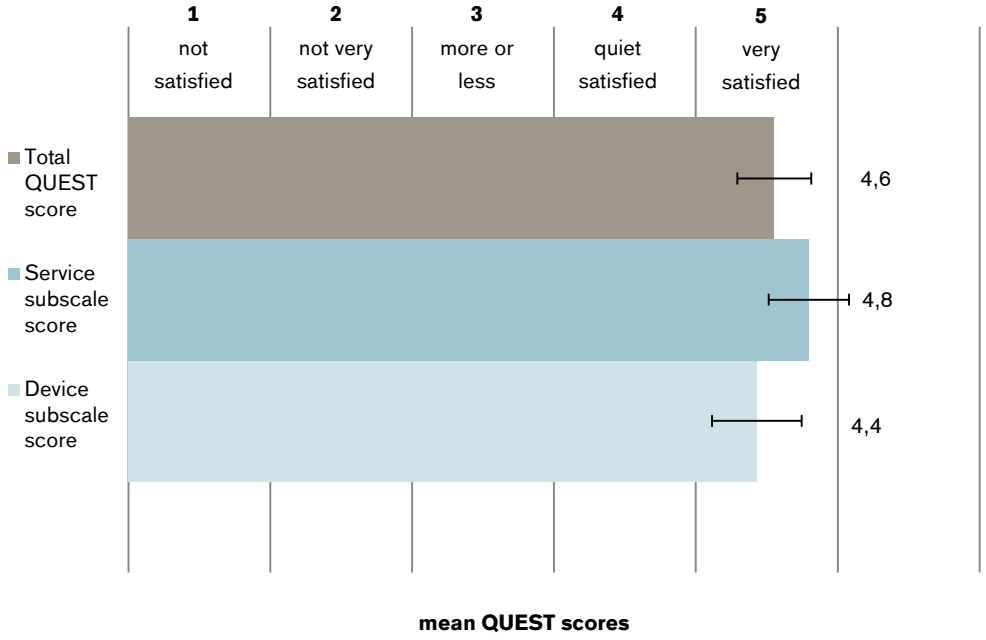
Major Findings

With E-MAG Active in unlocked mode (vs. locked mode):

→ high patient satisfaction, evaluated with the QUEST (Quebec user evaluation of satisfaction with assistive technology)

- Device subscale score: 4.4 ± 0.3
- Service subscale score: 4.8 ± 0.3
- Total QUEST score: 4.6 ± 0.3

Patient satisfaction with QUEST



Schröder et al., 2018.

Clinical Relevance

For enabling disabled people to live independently and safely within the community, assistive technologies are playing an important role. However, studies of the non-use of assistive technologies suggest that on average a third of all devices provided are not used (Scherer, 2002). The lack of consumer involvement in the selection process or consumer dissatisfaction with the device were shown as predictors of non-use (Wielandt & Strong, 2000). A number of problems have been identified as reasons for non-use: inadequate performance of the product; poor function of the product; difficulty in operating the product; and the high cost of the products and their maintenance (Goodacre & Turner, 2005). Obtaining user perspectives is therefore fundamental to address these issues.

Summary

The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) (Demers et al 1996) is a self-administered questionnaire used to evaluate user satisfaction with a wide range of assistive technologies. It assesses user satisfaction with both the specific assistive device and the service relating to device use.

The participants´ satisfaction with the E-Mag Active was surveyed using the QUEST (2.0). The ratings of the Device subscale score, Service subscale score and Total

QUEST score had a mean value > 4 points, which represents a very high overall satisfaction. (Schröder et al., 2018)

As far as the importance of the satisfaction items for the patients is concerned, safety was selected most often (7 times) with an average rating of 3.8, followed by adjustments and effectiveness (each selected 3 times) with mean ratings of 4.8 and 4.6, respectively. The items ease of use, comfort, repairs/servicing and professional service were selected twice each; whereas durability, service delivery and follow-up service were only selected once each.

References of summarized studies

Schröder, S.; Pröbsting, E.; Schmalz, T.; Kannenberg, T.; Stinus, H. (2018). Functional walking capacity of subjects with paralyzed knee extensors while walking with an SCO in locked vs unlocked mode. *Physical Medicine and Rehabilitation Research, 3(2)*: 1-6. DOI: 10.15761/PMRR.1000168

Other References

Demers, L.; Weiss-Lambrou, R.; Ska, B. (1996). Development of the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST). *Assistive Technology, 8*, 3-13.

Goodacre, L. & Turner, G. (2005). An investigation of the effectiveness of the Quebec user evaluation of satisfaction with assistive technology via a postal survey. *British Journal of Occupational Therapy, 68(2)*, 93-96.

Scherer, M. (2002) The change in emphasis from people to person: introduction to the special issue on assistive technology. *Disability and Rehabilitation, 24(1/2/3)*, 1-4.

Wielandt, T.; Strong, J. (2000). Compliance with prescribed adaptive equipment: a literature review. *British Journal of Occupational Therapy, 63(2)*, 65-75.

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3 Summaries of individual studies

On the following pages you find summaries of studies that researched E-MAG Active. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of each summary you also can read the original study authors' conclusions.

Reference

Schröder, Sarah; Pröbsting, Eva; Schmalz, Thomas; Kannenberg, Andreas; Stinus*, Hartmut

Ottobock SE & Co. KGaA, Department of Research, Duderstadt, Germany.
*Specialist in orthopaedics, Orthopaedicum Northeim, Germany.

Functional walking capacity of subjects with paralyzed knee extensors while walking with an SCO in locked vs unlocked mode

Physical Medicine and Rehabilitation Research 2018, 3 (2): 1-6

DOI: 10.15761/PMRR.1000168

Products

E-MAG Active

Major Findings

With E-MAG Active in unlocked mode (vs locked mode):

→ significantly increased walking speed (0.06m/s; p < 0.05)

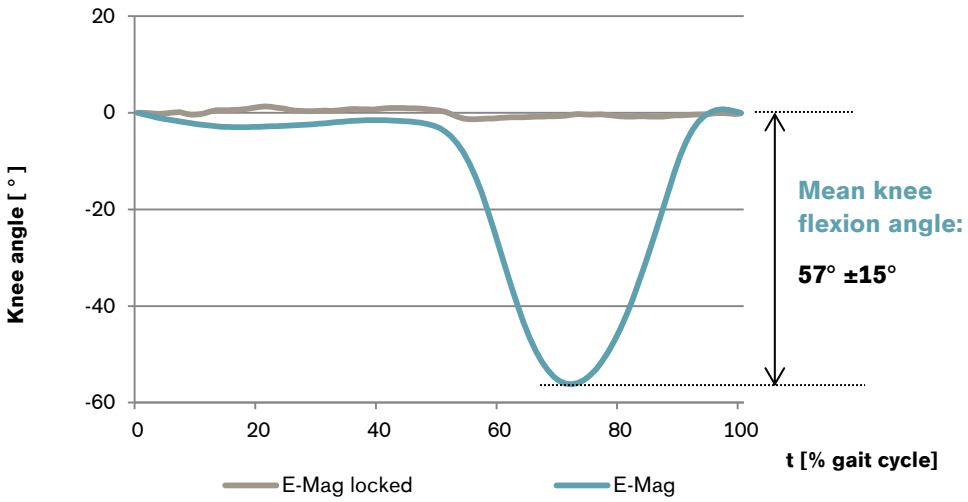
→ significantly increased walking distance in the 6-minute walk test (+32.5 ± 29.5 m)

→ significantly reduced hip hiking

→ high patient satisfaction, evaluated with the QUEST (Quebec user evaluation of satisfaction with assistive technology)

- Device subscale score: 4.4 ± 0.3
- Service subscale score: 4.8 ± 0.3
- Total QUEST score: 4.6 ± 0.3

Mean knee flexion angle of 57° at about 70% of the gait cycle



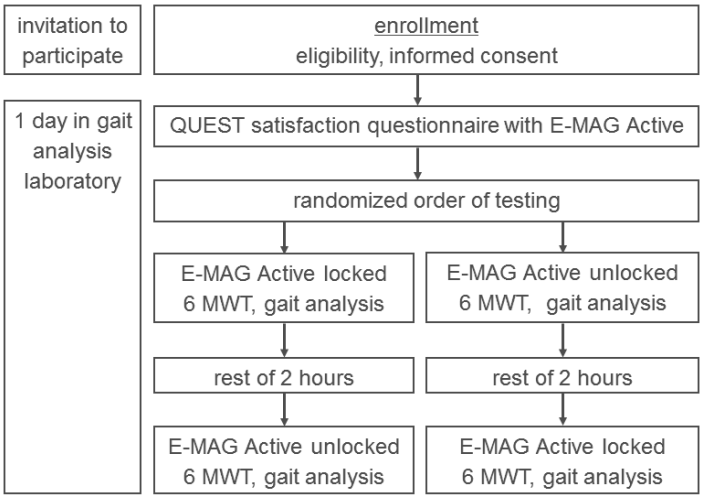
During walking with E-Mag Active in unlocked mode (blue curve) there is a mean knee flexion angle of 57° at about 70% of the gait cycle, compared to full extension of the knee in the locked knee condition (brown curve).

Population

Subjects:	8 (5 male, 3 female)
Mean age:	46.9 ± 19.0 years
Mean body mass:	80.0 ± 11.5 kg
Use of E-MAG Active:	since 3.3 ± 1.6 years
Etiologies:	Incomplete spinal cord injury (4 patients) Poliomyelitis (3 patients) Myopathy (1 patient)

Study Design

Randomized 2x2 crossover design with intra-individual control:



Intervention: to walk with E-MAG Active in locked and unlocked mode.

Results

Functions and Activities | Participation

Biomechanics – Static measures | **Biomechanics – Gait analysis** | **X-Ray** | **EMG** | **Functional tests** | **Clinical effects** | **Satisfaction**

Category	Outcomes	Results for E-MAG Active in unlocked mode (vs. locked mode)	sig.*
Biomechanics – Gait analysis	Walking speed	**The walking speed was significantly faster with E-MAG Active in unlocked mode**	++

	E-MAG Active locked	E-MAG Active unlocked
walking speed [m/s]	0.88	0.94

Gait symmetry was marginally improved with E-MAG Active in unlocked mode

	E-MAG Active locked	E-MAG Active unlocked	
difference in stride length [m]	0.05	0.3	+
difference in stance phase length between orthotic and contralateral side [%GC]	7.3	6.5	+

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction

Category	Outcomes	Results for E-MAG Active in unlocked mode (vs. locked mode)	sig.*
	Knee flexion angle	During walking in the unlocked mode, there was a mean knee flexion angle of 57° ± 15° at about 70% of the gait cycle compared to full extension of the knee during walking in the locked condition.	n.a.
		Every subject showed an increased knee flexion angle during swing in the unlocked mode within a range between 31° and 80°.	
	Compensatory movements	Compensatory movements were reduced with E-MAG Active in the unlocked mode.	n.a.
		Hip hiking was reduced in 6 out of 8 subjects based on the angle of pelvis tilt (obliquity) in the coronal plane.	
		Vaulting was reduced in 2 out of 3 subjects based on the sagittal angle and moment of the ankle	
Functional tests	Functional walking Capacity "6-minute walk test"	**In the locked mode, subjects walked a shorter distance in the 6MWT than in the unlocked condition. The difference in the distance walked of 32.5 ± 29.5 m was statistically significant (p = 0.04).**	++

	E-MAG Active locked	E-MAG Active unlocked
distance [m]	284.4 ± 53.0	316.9 ± 59.6

Satisfaction	QUEST score	"Quebec user evaluation of satisfaction with assistive technology, Version 2.0" (QUEST 5-point rating scale: 1 = "not satisfied at all"; 2 = "not very satisfied"; 3 = "more or less satisfied"; 4 = "quiet satisfied"; 5 = "very satisfied")	
		QUEST scores showed a high overall satisfaction with the E-MAG Active in unlocked mode	n.a.

score	rating
device subscale score	4.4 ± 0.3
service subscale score	4.8 ± 0.3
Total QUEST score	4.6 ± 0.3

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

Author's Conclusion

"Compared to the unlocked condition, the locked mode imposed a clinically meaningful restriction to the functional walking capacity on the subjects. Therefore, fitting of an SCO [stance control orthosis, E-MAG Active] may be considered beneficial in individuals dependent on a KAFO [knee-ankle-foot-orthosis] to improve their functional walking capacity." (Schröder et al. 2017)

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