Reference

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Patients' burden using microprocessor-stance-and-swing-control knee-ankle-foot orthoses and outcomes compared to those with prior traditional knee-ankle-foot-orthosis

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Products

C-Brace (Microprocessor-stance-and-swing-control knee-ankle-foot orthosis (MP SSCO)) compared to traditional knee-ankle-foot-orthosis (KAFO)

Major Findings

With C-Brace compared to traditional KAFOs:

→ Improved perception of safety

- Significantly greater general perception of safety (KAFO: 6.4 vs. C-Brace: 3.8 on a 10-point scale [lower scores indicate greater perceived safety])
- Percentage of users feeling very safe while standing more than tripled from 21.4% with a KAFO to 76.2% with the C-Brace

→ Significantly decreased fear of falling (KAFO = 3.4 points, C-Brace = 1.5 points on a 5-point scale)

→ Reduction in falls

- With C-Brace, 42.9% of respondents experienced falls compared to 78.6% with KAFO.
- Mean number of falls (outliers excluded) significantly decreased from 12.1 falls per year with KAFO to 0.5 falls with the C-Brace

→ Significantly higher usability rating

- The KAFO was rated "poor" in usability, whereas the C-Brace was rated as "good".

→ Significant reduction in restrictions to activities of daily living (ADLs)

- Significantly greater ability to perform ADLs in 3 out of 4 ADL situations (reciprocal stair descent, ability to walk on an incline, walking at varying speeds)

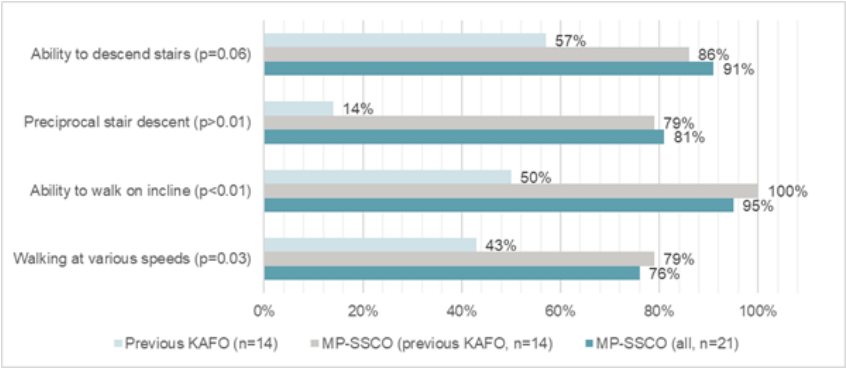

Figure 1: Percentage of respondents able to perform ADLs with previous KAFO, among MP-SSCO users with previous KAFO experience, and among all MP-SSCO users.

→ Improved gait pattern

- With previous KAFO, 92.9% of respondents had poor/ very poor symmetry, while with C-Brace only 9.5% of respondents reported poor symmetry.

→ Reduction in pain impact on daily life

- On a Likert scale of 1 to 5, pain impact on daily living decreased significantly from 3.7 with KAFO to 1.7 with C-Brace.

→ Improvements in satisfaction

- 80% of responders reported C-Brace as superior to their previous orthosis.
- High satisfaction levels were reported (71.4% very satisfied and 23.8% satisfied).

→ Improvements in Quality of Life (QoL)

- 73% reported significant better and 20% better QoL with C-Brace

Population

Subjects:	21
Previous orthosis:	Free swing KAFO/SCO (N=10) Locked KAFO (N=4) No previous orthosis (N=7)
Underlying condition:	Poliomyelitis (N=8) Incomplete Paraplegia (N=4) Neuromuscular disease (N=2) Traumatic brain injury (N=1) Other (N=6) None (N=11)
Mean age:	48.1 ± 14 years (10 female and 11 males)
Mean time utilizing C-Brace:	1.9 years (minimum = 11-month, maximum = 2.9 years)
Mean time KAFO prior C-Brace:	12.5 years

Study Design

A structured cross-sectional survey was conducted in 6 orthotic and prosthetic clinics in Germany. 21 individuals who had been using an MP-SSCO (C-Brace) for at least 6 months, previously used a locked KAFO/SCO/no orthosis prior to C-Brace and were older than 18 years answered an online survey to rate their current and recalled outcomes and experience with their previous or no orthosis, respectively. The survey comprised various topics including demographics, mobility/functionality, participation, safety, pain, satisfaction, and QoL. The questionnaire used Likert scales with 1- to 5-point rating scales for most items, and a 1- to 10-point rating scale for the general perception of safety. The experiences with the current and previous orthoses were compared.

Results

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

Category	Outcomes	Results for C-Brace vs. KAFO			Sig.*
		KAFO (N=14)	C-Brace in previous KAFO users (N=14)	C-Brace in all (N=21)	
Functional tests – Mobility and Functionality	Number of assistive devices used (1= yes, 0 = no)	0.9	0.6	0.4	0
	Usability (range: 1 (very good) to 5 (very poor))	3.9	2.0	2.1	++

Category	Outcomes	Results for C-Brace vs. KAFO			Sig.*
		KAFO (N=14)	C-Brace in previous KAFO users (N=14)	C-Brace in all (N=21)	
	Symmetry of gait (range: 1 (very good) to 5 (very poor))	4.5	2.1	2.2	++
	Ability to descend stairs (range: 1 (very good) to 5 (very poor))	4.0	1.7	1.7	++
	Ability to descend stairs (1= yes, 0 = no)	0.6	0.9	0.9	+
	Reciprocal stair descent (1= yes, 0 = no)	0.1	0.8	0.8	++
	Ability to walk an incline (1= yes, 0 = no)	0.5	1.0	0.9	++
	Walking on various speeds	0.4	0.8	0.8	++
	Activities of daily living (ADLs)	Significant improvement in ADLs – significantly greater ability to perform ADLs in 3 out of 4 ADL situations ((reciprocal stair descent, ability to walk on an incline, walking at varying speeds)			++
Clinical Effect – safety	General perception of safety (range: 1 (completely safe) to 10 (completely unsafe))	6.4	3.8	4.1	++
	Safety while standing (range: 1 (very safe) to 5 (not safe))	2.8	1.6	1.4	0
Clinical Effects – falls, fear of falling	Fear of falling (range: 1 (very low) to 5 (very high))	3.4	1.5	1.8	++
	Falls occurred? (1= yes, 0= no)	0.8	0.4	0.4	0
	Number of falls per year (outliers included)	67.9	1.1	5.3	++
	Number of falls per year (outliers excluded)	12.1	0.3	0.5	++
Clinical Effects - pain	Pain incidence? (1= yes, 0 = no)	0.5	0.3	0.4	+
	Pain intensity (range: 1 (very mild) to 5 (very severe pain))	3.8	2.1	2.8	+
	Pain impact (range: 1 (no impact) to 5 (severe impact))	3.7	1.3	1.7	++
Satisfaction	Orthosis preference	80% of participants reported that C-Brace is superior to their previous orthosis			n.a.
	Satisfaction level	High satisfaction level – 71.4% were very satisfied and 23.8% were satisfied with the C-Brace. Only 4.7% were not satisfied			n.a.
	Quality of Life (QoL)	15 out of 16 who responded on QoL believed that C-Brace positively impacted their QoL			n.a.

Category	Outcomes	Results for C-Brace vs. KAFO			Sig.*
		KAFO (N=14)	C-Brace in previous KAFO users (N=14)	C-Brace in all (N=21)	
		With C-Brace, 73% reported QoL was significantly improved, 20% reported better QoL, and 7% worse QoL			n.a.

* Significance tested is between KAFO users and C-Brace users in previous KAFO users - no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"Individuals with knee instability caused by neuromuscular diseases or central nervous system disorders face limitations and restrictions in mobility, impaired gait patterns, and experience emotional strain when using conventional locked and free-swing KAFOs. The implementation of advanced orthotic technology has the potential to positively impact patient-specific parameters such as fall frequency, fear of falling, pain, activities of daily living, and reliance on other assistive devices. Notably, the use of MP-SSCO resulted in a significant reduction in the frequency of falls compared to conventional KAFOs. When assessing their orthoses, individuals emphasized safety, effectiveness, and weight as the most relevant attributes. In contrast, experts considered dependability and stability as the most crucial aspects. This highlights the importance of involving patients in the orthosis selection process and taking into account the aspects that users rate as most significant. Furthermore, individuals' quality of life was identified as a relevant dimension and an area that could see substantial improvements for KAFOs/SCOs users." (Brüggenjürgen et al. 2024)