Reference

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Impact of a microprocessor-controlled knee-ankle-foot orthosis in community ambulators with quadriceps insufficiency fitted with an SCO: a randomized crossover trial

Annals of physical and rehabilitation medicine, vol. 69,1 102057. 22 Nov. 2025, doi:10.1016/j.rehab.2025.102057

Products

C-Brace

Major Findings

With C-Brace compared to previous Stance-Control Orthosis (SCO):

→ Significantly improved mobility and endurance

- Significantly improved PLUS-M T-score by 21.3% (+9.9 points) with C-Brace ($p < 0.001$)
- Significantly improved distance covered during the 6MWT by 19.5% (+65.9 meters) with C-Brace ($p < 0.001$)

→ Lower risk of falling

- Significantly improved Activity specific balance confidence (ABC) scale by 52.5% (+28.8 points) with C-Brace ($p < 0.001$)
- Reduced risk of falling with C-Brace, as the ABC score was > 80%

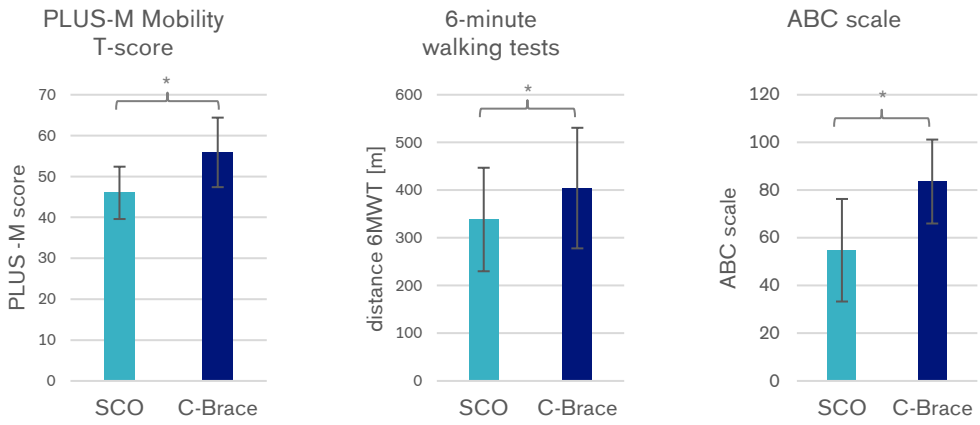


Figure 1: Improvements in the PLUS-M Mobility score, 6-minute walking test (6MWT) and the Activity specific balance confidence scale for C-Brace compared to SCO in the Per Protocol (PP) group. Legend: * $p < 0.001$.

→ Significantly improved participation for important functional activities

- Significantly improved Patient-Specific Functional Scale (PSFS) value by 4.1 points with C-Brace ($p < 0.001$)
- Improvements in ADLs were considered clinically relevant as they were difficult to manage with the SCO from the participants perspective

→ Significantly improved quality of life

- Significantly improved EQ-5D-5L health utility score by 27.2% (+0.19) with C-Brace ($p < 0.001$)
- C-Brace achieved values for the EQ-5D-5L utility score (0.88) reaching close to values reported for French cohort (0.905) and German cohort (0.88) in the literature compared to SCO (0.692)

→ Significant reduction in the use of walking aids with C-Brace (p = 0.005) in outdoor conditions

→ 87% of the participants preferred the C-Brace over their SCO

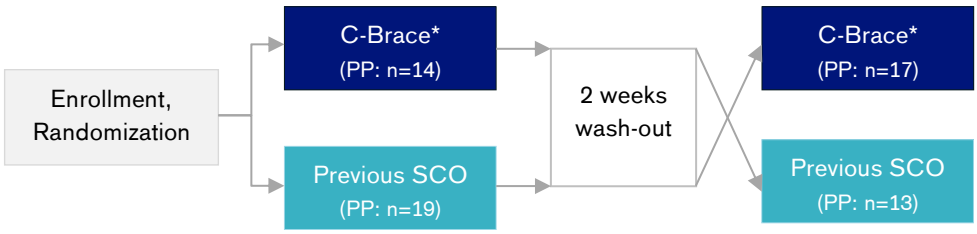
Population

Subjects:	Intention to Treat (ITT): 38 adults (12 female) Per protocol (PP): 30 adults (10 female)
Etiology:	SCO users with quadriceps insufficiency ITT: Polio (20), Trauma (4), SCI (2), Other (12) PP: Polio (16), Trauma (3), SCI (1), Other (10)
Previous SCO	ITT: E-Mag (30), SPL-Basko (7), NEURO TRONIC (1) PP: E-Mag (25), SPL-Basko (4), NEURO TRONIC (1)
Time since SCO use:	At least 3 months
Mean age:	ITT: 52.3 ± 12.8 years PP: 50.8 ± 11.3 years
MFCL:	ITT: 56.7% K2 (n = 22); 43.7% K3 (n = 16) PP: 56.7% K2 (n = 17); 43.7% K3 (n = 13)
Contralateral side (PP):	86.7% no deficiency, 6.7% orthopaedic shoe, 3.3% orthopaedic insoles, 3.3% orthopaedic pad

*SCI=Spinal Cord Injury, Polio=Poliomyelitis

Study Design

International multicenter randomized crossover trial:



*Several rehabilitation sessions are provided after C-Brace fitting. The protocol imposed a minimum of 4h of rehabilitation.

For either SCO or C-Brace, the follow-up period after fitting lasted 2 to 3 months. At the end of each follow-up period, data was collected. After the C-Brace follow-up period and re-fitting with their SCO, a 1h rehabilitation session was required.

A total of 38 participants were enrolled (ITT = 38) and randomized in two arms. 37 participants used the C-Brace at least once. 30 participants completed all assessments without any major deviation from the protocol (PP = 30, C-Brace/SCO = 13 and SCO/C-Brace = 17)

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 C-Brace vs. SCO (PP group)	Sig.[1]
Functional tests	6-min walk test (6MWT) [m]	Significantly longer distance covered during the 6MWT by 19.5% (+65.9 meters) with C-Brace (p < 0.001):	++

C-Brace (PP)	SCO (PP)
404.3 ± 126.4 m	338.4 ± 108.5 m

Category	Outcomes	Results for C-Brace vs. SCO (PP group)	Sig.[1]
	Simplified Activities-specific Balance Confidence scale (ABC scale)	Significantly higher ABC scale by 52.5% (+28.8 points) with C-Brace ($p < 0.001$):	++
		C-Brace (PP): 83.6 ± 17.6 / SCO (PP): 54.8 ± 21.5	
Clinical effects - Mobility	Mobility Questionnaire PLUS-M (primary outcome measure)	Significantly higher PLUS-M mobility T-score by 21.5% (+9.9 points) with C-Brace compared to SCO ($p < 0.001$):	++
		C-Brace (PP): 55.9 ± 8.5 points / SCO (PP): 46 ± 6.4 points	
	Use of Walking Aids	Similar walking aids habits for C-Brace and SCO in indoor conditions for 80% of the participants.	0
		Significantly reduced use of walking aids in outdoor conditions with C-Brace ($p = 0.005$): • 30% (9/30) of the participants did not require aids anymore with C-Brace	++
	Psychological Impact of Assistive Device scale (PIADS)	Improvement in the global score on the PIADS scale by 1.8 points.	n.a.
Satisfaction	Use of orthosis	70% of participants (21/30) reported daily use of C-Brace and 60% (18/30) use it more than 8h per day. The SCO was used daily by 63% (19/30) of the participants and over 8h per day by 53% (16/30).	n.a.
	Satisfaction questionnaire - QUEST 2.0	Significantly improved global satisfaction by 12.5% with C-Brace ($p < 0.001$):	++
		C-Brace (PP): 4.5 ± 0.4 / SCO (PP): 4.0 ± 0.6	
		Higher satisfaction for sub score device (+0.6 points) and the services provided (+0.4 points) with C-Brace than with SCO.	n.a.
		Most important items reported were safety, effectiveness and weight after C-Brace use. After SCO use the main items were safety, effectiveness and comfort.	n.a.
	Preference	87% of participants (26/30) preferred the C-Brace over the SCO. Only 13% preferred the SCO.	n.a.
Satisfaction – Quality of Life	Quality of life (EQ-5D-5L utility score)	Significantly higher EQ-5D-5L utility score by 27.2% with C-Brace ($p < 0.001$):	++
		C-Brace (PP): 0.880 ± 0.106 / SCO (PP): 0.692 ± 0.296	
	EQ-VAS health	Significantly higher EQ-VAS health score by 21.6% with C-Brace ($p = 0.002$):	++
		C-Brace (PP): 76.3 ± 17.4 / SCO (PP): 63 ± 21.8	

Category	Outcomes	Results for C-Brace vs. SCO (PP group)	Sig.[1]
Satisfaction - Participation	Patient-Specific Functional Scale (PSFS)	Significantly improved PSFS score by 4.1 points with C-Brace ($p < 0.001$): C-Brace (PP): 7 ± 2.6 SCO (PP): 2.9 ± 1.8	++
		Activities focused on mobility challenges encountered in daily life, such as: • Playing with children in the garden • Walking without walking aids • Walking downstairs and upstairs • Walking on ramps etc. The improvements with C-Brace were considered clinically relevant, as the activities are difficult to manage with SCO from the participants own perspective.	n.a.

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

Author's Conclusion

"This multicenter and international randomized crossover clinical trial asked 38 community ambulators with a quadriceps insufficiency to test and compare 2 knee-ankle-foot orthoses: their SCO and the C-Brace. Our results show that the C-Brace significantly improved mobility, endurance, confidence, participation, satisfaction, psychological adjustment, and quality of life in this population. Moreover, the C-Brace led to a decrease in the use of walking aids when walking outdoors, even though safety has been reported as the most important satisfaction criterion for participants. In all, community ambulators requiring the use of KAFO for walking could greatly benefit from the use of the C-Brace orthosis to improve their outdoor mobility and facilitate completion of daily activities. Further studies including people with bilateral quadriceps insufficiency are an interesting prospect to assess the possible advantages of the C-Brace for this population." (Genêt et al., 2026)

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