

Reference

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Microprocessor Controlled Knee Ankle Foot Orthosis (KAFO) vs. Stance Control vs. Locked KAFO: A Randomized Control Trial

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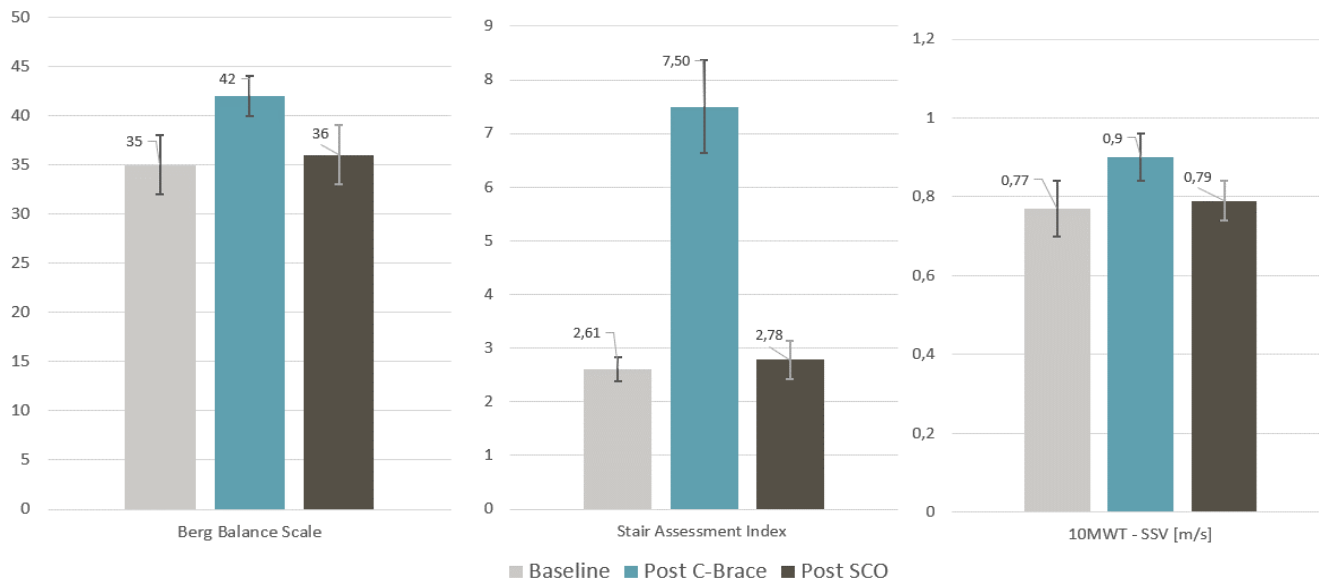
Products

C-Brace

Major Findings

With C-Brace compared to unilateral KAFO or Stance Control Orthosis (SCO):

- ➔ Sign. Improvements in mobility and gait
Increased self-selected walking speed (10MWT, 6MWT)
Increased independence during descending stairs
- ➔ Sign. Improvements in static and dynamic balance
Increased BBS (scores < 40 associated with 100% fall risk)
Increased FGA scores
- ➔ Improvements in quality of life and satisfaction
- ➔ Sign. Reduction of self-reported falls
with C-Brace (5) versus SCO (38) or locked KAFO (15)



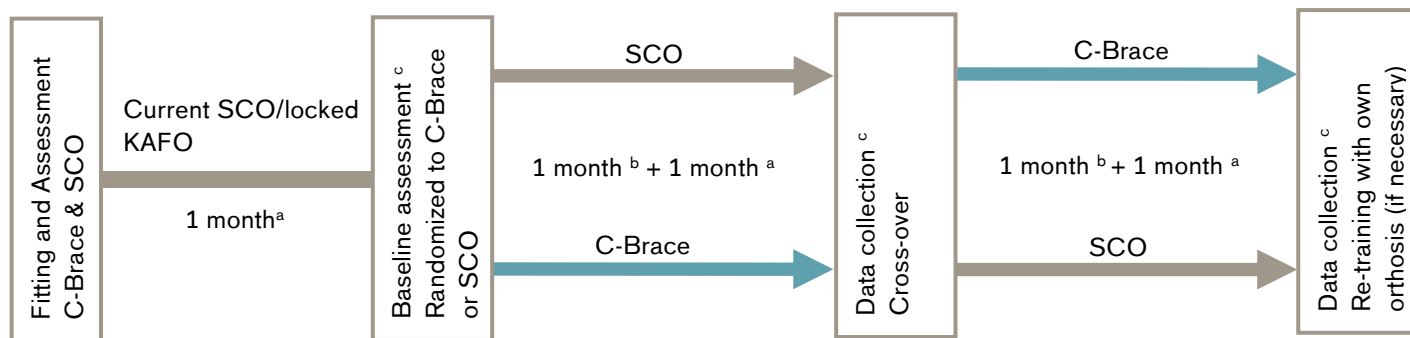
SSV = self-selected velocity; Error bars denote standard deviation

Population

Subjects: 18
Previous orthosis: SCO (n=5)
Locked KAFO (n=13)
Epidemiology: Poliomyelitis (n=9)
Peripheral nerve injury (n=2)
Traumatic SCI (n=4)
West Nile encephalitis (n=1)
Peripheral neuropathy (n=1)
Traumatic brain injury (n=1)
Mean age: 54.6 ±12.9yrs

Study Design

Randomized cross-over Trial:



^a home-use with community mobility monitoring

^b 6 training visits in 1st month

^c functional and subjective assessments

Results

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

Category	Outcomes	Results for C-Brace vs SCO			Sig.
		Baseline	Post-C-Brace	Post-SCO	
Functional tests	6MWT [m]	278.64 (29.13)	331.25 (27.25)	300.71 (31.44)	*p=0.013
	10MWT-SSV [m/s]	0.77 (0.07)	0.90 (0.06)	0.79 (0.05)	*p=0.023 #p=0.019
	10MWT-FV [m/s]	1.03 (0.10)	1.14 (0.08)	1.04 (0.09)	P>0.05
	FGA	14.89 (1.11)	19.16 (0.70)	14.89 (1.03)	*p=0.002 #p=0.001
	Berg Balance Scale	35 (3)	42 (2)	36 (3)	*p=0.01 #p=0.007
	5xSST [s]	21.8 (3.16)	22.03 (2.13)	22.58 (2.92)	p>0.05
	Cross Walk Test [s]	27.87 (3.33)	23.41 (2.52)	25.68 (2.16)	p>0.05
Ramps and stairs	HAI (descension 10° ramp)	6.16 (0.74)	7.39 (0.53)	5.94 (0.54)	*p>0.05 #p=0.029
	SAI (descension flight of stairs)	2.61 (0.23)	7.50 (0.86)	2.78 (0.35)	*p<0.001 #p<0.001
	Ramp up [s]	20.74 (3.14)	16.07 (1.56)	21.70 (3.79)	p>0.05
	Ramp down [s]	23.05 (4.10)	17.51 (2.29)	27.89 (7.19)	p>0.05
	Stairs up [s]	41.40 (9.14)	39.10 (5.85)	44.13 (10.94)	p>0.05
	Stairs down [s]	39.39 (5.27)	36.87 (4.87)	44.58 (10.16)	p>0.05
Clinical Effect	mFES	8.11 (0.40)	7.91 (0.46)	7.72 (0.42)	p>0.05
	Falls	15	5	38	-

Satisfaction	OPUS-QoL	59.34 (2.33)	62.65 (2.74)	58.19 (2.28)	*p=0.02 #0.003
	OPUS-LE function	47.80(1.54)	49.05 (1.59)	48.00 (1.53)	p>0.05
	OPUS- Satisfaction w. Device	52.10 (2.47)	49.15(1.57)	48.26 (2.20)	p>0.05
	WHOQOL-Physical Health	63.56 (5.44)	70.94 (4.60)	67.44 (4.79)	*p= 0.037
	WHOQOL-Psychological	78.5 (3.34)	78.89(4.57)	76.11 (4.87)	p>0.05
	WHOQOL-Social relationships	75.72 (4.59)	79.22 (4.33)	78.5 (3.93)	p>0.05
	WHOQOL-Environment	78.94 (3.93)	83.11 (3.55)	78.0 (4.54)	p>0.05

SSV = self-selected velocity; FV = fast velocity; FGA = Functional Gait Assessment; 5xSST = 5 Times Sit to Stand Test; HAI = Hill Assessment Index (descension of 10° ramp and flight of stairs) ; mFES = Modified Falls Efficacy Scale; OPUS = Orthotic and Prosthetic User's Survey; QOL = Quality of Life; SAI = Stair Assessment Index (descension of 10° ramp and flight of stairs); WHOQOL = World Health Organization Quality of Life;

* indicates comparison with baseline; # for comparison between SCO and C-Brace

Author's Conclusion

"The MPO, a knee-ankle-foot orthosis that dampens loaded knee flexion and speed adapted control of knee flexion and extension during the stance and swing phase, may allow improved gait speed, endurance, static & dynamic balance, quality of life, health status and reduced self-reported falls for individuals with lower-extremity impairments, due to increased safety and participation in their community. Users within a wide range of walking speed and postural stability may benefit from using the MPO." (Deems-Dluhy et al. 2020)

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