Reference

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The C-Brace® microprocessor-controlled stance and swing orthosis improves safety, mobility, and quality of life at one year: Interim results from a prospective registry

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Products

C-Brace

Major Findings

After 1 year following C-Brace fitting compared to baseline condition:

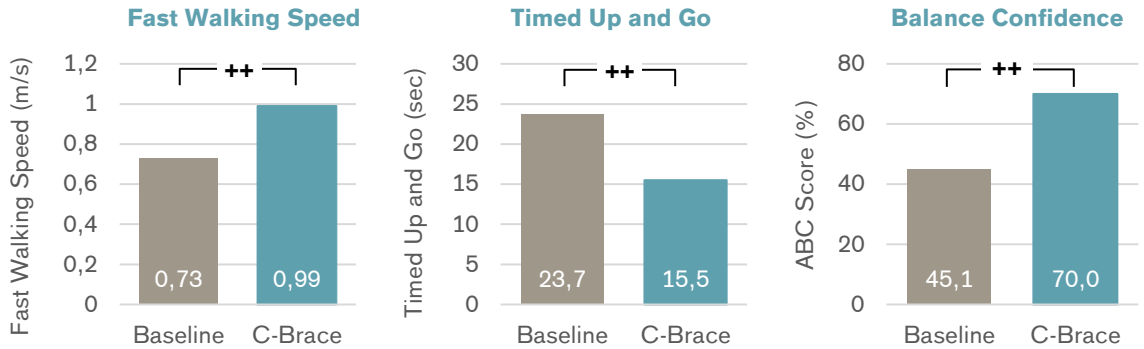
→ **36% improvement in walking speed**
Fast Walking Speed (FWS) improved by 0.26 ± 0.33 m/s (p < .0001)

→ **35% improvement in functional ability and reduced fall risk**
Timed up and go (TUG) time reduced by 8.1 sec ± 14.6 sec (p < .0001)
47% fewer patients at risk of falling (TUG time above 13.5-sec cutoff)

→ **Improvement in patient-perceived balance confidence and reduced fall risk**
ABC improved by +24.9 ± 25.8% (p < .0001)
46% fewer patients at risk of falling (ABC score below 67% cutoff)

→ **91% reduction in actual falls**
Baseline: 33 ± 77. C-Brace: 3.0 ± 5.6 (p = .0005)

→ **33% improvement in quality of life**
Health Utility Index (HUI) from EQ-5D-5L improved by +0.20 ± 0.21 (p < .0001)



++ statistically significant (p< 0.05)

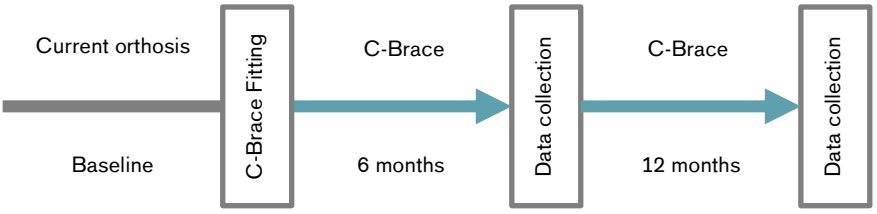
Population

Subjects:	46 (17 female) w/ indication for KAFO
Previous orthosis:	SCO: 28%, AFO: 28%, Locked KAFO: 20%, None: 11%, Polycentric or posterior offset KAFO: 7%, Knee orthosis: 4%, Unknown: 2%.

Underlying conditions:	Spinal Cord Injury (SCI): 33%, Polio/Post-polio syndrome (PPS): 20%, Trauma: 7%, Iatrogenic: 7%, Muscular Dystrophy (MD): 2%, Traumatic Brain Injury (TBI): 2%, Herniated Disk: 2%, Other (n=1 each): 20%
Mean age:	51.8 ± 16.4 yrs
Involvement:	Unilateral: 80%, Bilateral: 20

Study Design

Prospective, international registry:



NOTE: The C-Brace Registry includes annual follow ups for 3 years. Primary outcomes were evaluated at 12 months with 6-month data carried forward for missing 12-month follow ups.

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. Baseline	Sig.*
Functional tests	Fast Walking Speed (FWS) measured by the 10-meter Walk Test.	**36% improvement in FWS, increasing by +0.26 ± 0.33 m/s, from 0.73 ± 0.34 to 0.99 ± 0.42.**	++
		16 subjects (40%) moved up at least one ambulatory class (e.g., from household ambulator to limited community ambulator)	n/a
	Timed up and Go (TUG)	**35% improvement in TUG, decreasing by 8.1 ± 14.6 s, from 23.7 ± 17.5 to 15.5 ± 10.2.**	++
		47% fewer subjects at increased fall risk	n/a
Clinical effects	Falls	**91% reduction in falls, dropping from 33 ± 77 at baseline to 3.0 ± 5.6 at follow up**	++
	Falls (multiple fallers)	**90% reduction in falls among those that fell more than once, dropping from 50 ± 90 at baseline to 4.4 ± 6.4 at follow up.**	++
	Activity-specific Balance Confidence (ABC)	**55% improvement in patient-perceived balance, ABC increasing by +24.9 ± 25.8%, from 45.1 ± 21.1 to 70.0 ± 7.5.**	++
		46% fewer subjects at increased fall risk	n/a
	PROMIS Pain Interference (PI)	**14% reduction in consequences of pain, PI T-score dropping by -8.8 ± 9.7, from**	++

Category	Outcomes	Results for C-Brace vs. Baseline	Sig.*
		61.3 ± 12.8 to 55.0 ± 9.5.	
	Numeric Pain Rating Scale (NPS)	**23% reduction in average NPS (-1.1) driven by reductions in the affected leg (-1.4), affected ankle (-1.0), sound hip (-1.2), sound ankle (-2) and sound foot (-1.5).**	++
	Patient-specific Functional Scale (PSFS)	**169% improvement in PSFS score, increasing by +3.6 ± 2.3 points on a 0-10 point scale, from 2.1 ± 1.2 at baseline to 5.7 ± 2.4 at follow up.**	++
Health Economics	EQ-5D-5L QoL Health Utility Index (HUI)	**33% improvement in HUI, +0.20 ± 0.21, from 0.61 ± 0.24 to 0.82 ± 0.13, driven by improvements in mobility, usual activities and pain dimensions.**	++
	EQ-5D-5L QoL Visual Analog Scale (VAS)	**Improvement of +12.1 ± 21.4 in VAS score, from 69.1 ± 21.5 to 78.8 ± 14.7.**	++

[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
[b] p value after post hoc Bonferroni correction did not
significance set at $p<0.05$; trends set at $0.1>p>0.05$
effect sizes classified by authors as small (<0.3), moderate (>0.3 and <0.5) or large(>0.5)

Author's Conclusion

"Several significant and clinically meaningful improvements were observed in a widely diverse sample of individuals with indication for a KAFO after 1-year of real-world use with the C-Brace, a microprocessor stance and swing control orthosis. Among the clinical improvements were increased fast walking speed, walking capability, and patient-perceived balance confidence which translated into a reduction in risk of falling and actual falls. Further improvements included reductions in relevant functional status limitations, pain, and pain interference, and a meaningful improvement in quality of life. The results of this prospective observational registry provide additional evidence that the C-Brace is an effective option to improve safety, mobility, and quality of life for patients needing the support of a KAFO for walking." (Lundstrom et al., 2024)

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