

Reference

Axel Rütz¹, Tom DiBello², Chris Toelle³, Bea Hemmen⁴, Jason Wening⁵, Eric Weber⁶, Frank Braatz⁷, Tobias Winkler⁸, Friedemann Steinfeldt⁹, Marina Umari¹⁰, Rüdiger Rupp¹¹, Sebastian Seyler¹², Alexander Krebs¹³, Shane R. Wurdeman¹⁴

¹Katholisches Klinikum (Catholic Hospital) Koblenz-Montabaur, Koblenz, Germany;

²Hanger Clinic, Houston, Texas, USA

³Hanger Clinic, Sarasota, Florida, USA

⁴delante Kenniscentrum (Adelante Rehabilitation Center), Hoensbroek, The Netherlands;

⁵Hanger Clinic, Chicago, Illinois, USA;

⁶Hanger Clinic, Seattle, Washington, USA;

⁷Zentrum für Healthcare Technology der Privaten Hochschule Göttingen (Center of Healthcare Technology of the Private University of Göttingen), Göttingen, Germany

⁸Berlin Movement Diagnostics, Berlin, Germany;

⁹Johannesbad Raupennest GmbH & Co. KG, Altenberg, Germany;

¹⁰Pohlig GmbH, Traunstein, Germany

¹¹Universitätsklinikum Heidelberg (University Hospital of Heidelberg), Zentrum für Orthopädie, Unfallchirurgie und Paraplegiologie (Center for Orthopedics, Trauma Surgery, and Paraplegiology), Heidelberg, Germany;

¹²BG Klinikum Hamburg GmbH (Workmen's Compensation Hospital), Zentrum für Rehabilitationsmedizin (Center for Rehabilitation Medicine), Hamburg, Germany;

¹³Orthopädisches Spital Speising (Orthopedic Hospital Speising), Vienna, Austria;

¹⁴Hanger Institute of Clinical Research and Education, Austin, TX, USA.

A microprocessor stance and swing control orthosis improves the risk of falling, mobility, and function of individuals dependent on a knee-ankle-foot orthosis for ambulation.

Journal of Disability and Rehabilitation. 2023;pp.1-14. doi:

10.1080/09638288.2023.2258342; [open access](https://www.tandfonline.com/doi/epdf/10.1080/09638288.2023.2258342?needAccess=true).

<https://www.tandfonline.com/doi/epdf/10.1080/09638288.2023.2258342?needAccess=true>

Products

C-Brace and KAFO (Locked KAFO, Posterior-Offset KAFO and SCO)

Major Findings

With C-Brace compared to traditional KAFOs (Per Protocol Analysis):

→ Improvement in balance

Primary outcome: Berg Balance Scale (BBS)

mean improvement 3.6 ± 6.1 , [p=0.00006]

→ 80% reduction in falls

Falls mean reduction -3.9 ± 17.7 [p=0.00047]

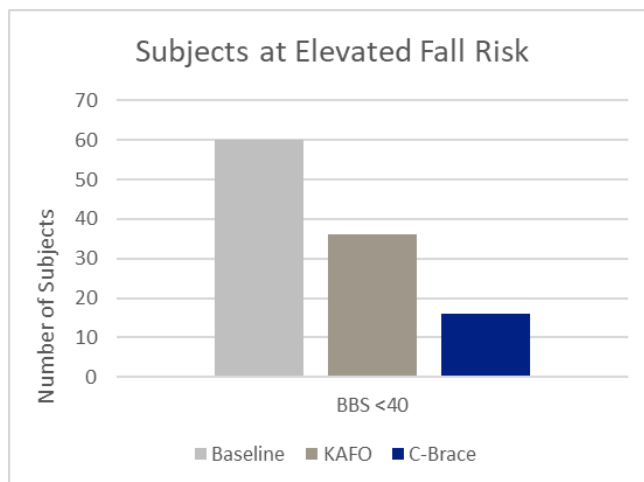
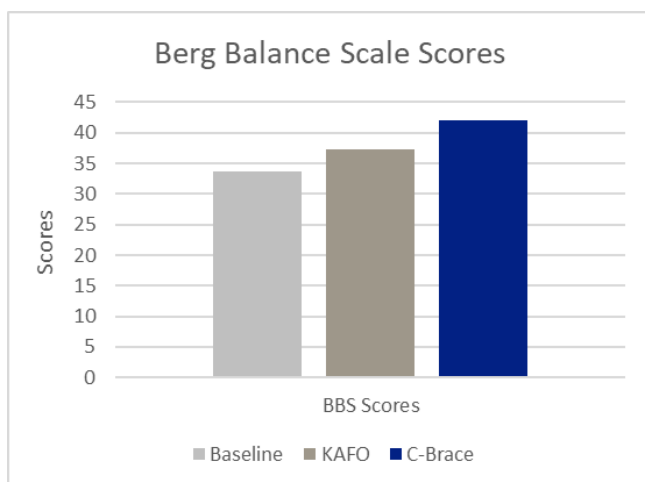
→ Reduction in number of multiple fallers

C-Brace: 11, KAFO: 24, [p=0.004]

→ Reduction in number of subjects at elevated risk of falling

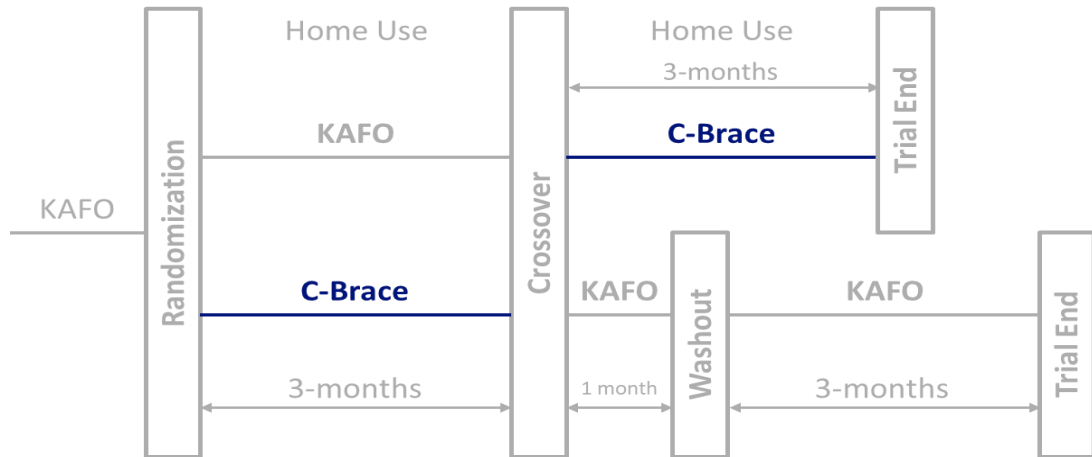
BBS score < 40: C-Brace: 12, KAFO: 25, [p=0.00361];

ABC < 67: C-Brace: 31, KAFO: 48, [p=0.0008]



Population	Subjects:	Intention to treat (ITT): 102 / Per-Protocol (PP): 69 KAFO users w/ quadriceps weakness
	Previous Orthosis:	Locked KAFO (ITT: 39%, PP: 34%), Posterior-offset KAFO (ITT: 25% / PP: 24%), SCO (ITT: 33% / PP: 42%), Other (ITT: 3%)
	Etiology:	Polio/Post-Polio Syndrome (PPS), Spinal Cord Injury (SCI), Lumbar Disc Herniation (LDH), Multiple Sclerosis (MS), Muscular Dystrophy (MD), Traumatic Brain Injury (TBI), West Nile Virus.
	Mean age:	ITT: 55.8 ± 13.8yrs / PP: 55.5 ± 13.6yrs

Study Design Interventional, randomized, crossover design:



Results

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

Category	Outcomes	Results for C-Brace		Sig.*
Functional tests – Safety	<u>BBS</u> mean differences (primary outcome)	C-Brace - KAFO	ITT: 3.5 ± 8.1 / PP: 3.6 ± 6.1	++
		C-Brace - BL	ITT: 6.8 ± 9.7 / PP: 7.4 ± 7.7	++
	<u>BBS</u> <40 number of subjects (% sample)	C-Brace - KAFO	ITT: -20 (19.6%) / PP: -13 (18.8%)	--
		C-Brace - BL	ITT: -44 (43.1%) / PP: -25 (36.2%)	--
Functional tests - Level Walking	<u>DGI</u> mean differences	C-Brace - KAFO	ITT: 1.0 ± 3.7 / PP: 2.4 ± 2.8	++
		C-Brace - BL	ITT: 2.4 ± 3.6 / PP: 2.9 ± 3.4	++
	<u>6MWT</u> mean differences	C-Brace - KAFO	ITT: 0.2 ± 54m / PP: 0.0 ± 0.1m	0
		C-Brace - BL	ITT: 9 ± 63m / PP: 0.03 ± 0.2m	0
Clinical effects – Falls, risk and fear of falling	<u>Falls</u> mean differences	C-Brace - KAFO	ITT: -3.4 ± 17.0 / PP: -3.9 ± 17.7	--
		C-Brace - BL	ITT: -5.0 ± 22.4 / PP: -5.8 ± 23.9	--
	<u>Multiple fallers</u> , number of subjects (% sample)	C-Brace - KAFO	ITT: -13 (12.7%) / PP: -13 (18.8%)	--

Category	Outcomes	Results for C-Brace		Sig.*
Clinical effects – Falls, risk and fear of falling	<u>Fear of Falling</u> – Indoors, mean differences	C-Brace - KAFO	ITT: -1.1 ± 3.2 / PP: -1.3 ± 3.0	--
		C-Brace - BL	ITT: -0.8 ± 3.5 / PP: -1.0 ± 3.1	--
	<u>Fear of Falling</u> – Outdoors, mean differences	C-Brace - KAFO	ITT: -1.0 ± 3.4 / PP: -1.1 ± 3.5	--
		C-Brace - BL	ITT: -1.1 ± 3.2 / PP: -1.3 ± 3.2	--
	<u>ABC</u> mean differences	C-Brace - KAFO	ITT: 7.0 ± 26.3 / PP: 11.3 ± 22.7	++
		C-Brace - BL	ITT: 5.8 ± 22.3 / PP: 8.9 ± 21.8	++
	<u>ABC</u> <67 number of subjects (% sample)	C-Brace - KAFO	ITT: -25 (24.5%) / PP: -17 (24.6%)	0, --
		C-Brace - BL	ITT: -31 (30.3%) / PP: -17 (24.6%)	-, --
Clinical effects - Stairs	<u>SAI</u> – downstairs mean differences	C-Brace - KAFO	ITT: 1.5 / PP: 1.3	++
		C-Brace - BL	ITT: 2.0 / PP: 1.8	++
Clinical effects - Activity, Mobility, Activities of Daily Living (ADLs)	<u>RNLI</u> mean differences	C-Brace - KAFO	ITT: 2.8 ± 16.4 / PP: 3.6 ± 16.8	+, ++
		C-Brace - BL	ITT: 1.8 ± 17.3 / PP: 2.3 ± 16.4	++, +
	<u>WLQ-25</u> mean differences	C-Brace - KAFO	ITT: -2.1 ± 21.5 / PP: -5.6 ± 16.6	0, --
		C-Brace - BL	ITT: -8.4 ± 27.4 / PP: -12.2 ± 31.6	--
Satisfaction - Preference, Quality of Life (QoL)	<u>OPUS</u> – Lower Extremity Functional Status, mean differences	C-Brace - KAFO	ITT: 2.0 ± 5.2 / PP: 2.5 ± 4.5	++
		C-Brace - BL	ITT: 3.1 ± 6.2 / PP: 3.1 ± 6.2	++
	<u>OPUS</u> – Quality of Life, mean differences	C-Brace - KAFO	ITT: 0.6 ± 5.2 / PP: 1.8 ± 4.5	0, ++
		C-Brace - BL	ITT: 1.1 ± 6.2 / PP: 1.6 ± 5.8	+, ++
	<u>SF-36</u> : Physical functioning mean differences	C-Brace - KAFO	ITT: 12.6 ± 29.2 / PP: 15.9 ± 26.6	++
		C-Brace - BL	ITT: 14.3 ± 25.9 / PP: 16.3 ± 25.6	++
	<u>SF-36</u> : Emotional well-being mean differences	C-Brace - KAFO	ITT: 3.2 ± 15.0 / PP: 4.4 ± 11.5	++
		C-Brace - BL	ITT: 2.5 ± 13.1 / PP: 2.5 ± 9.7	++
	<u>SF-36</u> : General Health mean differences	C-Brace - KAFO	ITT: 4.1 ± 14.0 / PP: 4.8 ± 14.3	0, ++
		C-Brace - BL	ITT: 2.4 ± 18.1 / PP: 3.6 ± 17.0	+, ++
	<u>SF-36</u> : Health change mean differences	C-Brace - KAFO	ITT: 10.1 ± 29.5 / PP: 10.3 ± 30.3	++
		C-Brace - BL	ITT: 9.5 ± 28.3 / PP: 9.8 ± 29.0	++
	<u>SF-36</u> : Energy/fatigue mean differences	C-Brace - KAFO	ITT: 5.8 ± 19.0 / PP: 5.7 ± 18.3	++
		C-Brace - BL	ITT: 4.4 ± 19.6 / PP: 5.5 ± 16.2	++
	<u>SF-36</u> : Bodily pain mean differences	C-Brace - KAFO	ITT: 2.7 ± 25.2 / PP: 3.0 ± 20.2	0
		C-Brace - BL	ITT: 3.9 ± 22.7 / PP: 2.2 ± 22.7	++, 0
	<u>SF-36</u> : Role limitations emotional mean differences	C-Brace - KAFO	ITT: 4.5 ± 36.7 / PP: 4.9 ± 38.3	0
		C-Brace - BL	ITT: 6.7 ± 38.7 / PP: 4.5 ± 37.6	+, 0
	<u>SF-36</u> : Role limitations physical mean differences	C-Brace - KAFO	ITT: 5.7 ± 39.8 / PP: 6.3 ± 39.9	0
		C-Brace - BL	ITT: 15.9 ± 34.5 / PP: 15.9 ± 35.8	++
<u>SF-36</u> : Social functioning mean differences	C-Brace - KAFO	ITT: 1.7 ± 25.7 / PP: 2.6 ± 25.9	0	
	C-Brace - BL	ITT: 1.2 ± 19.0 / PP: 0.8 ± 18.6	0	

Category	Outcomes	Results for C-Brace		Sig.*
Health Economics - Utility	EQ-5D-5L (Utility Index) mean differences	C-Brace - KAFO	ITT: 0.009 ±0.18 / PP: 0.03 ± 0.17	0, ++
		C-Brace - BL	ITT: 0.02 ± 0.17 / PP: 0.03 ± 0.17	++

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

BL = Baseline

ABC = Activity-specific Balance Confidence Scale; **BBS** = Berg Balance Scale; **DGI** = Dynamic Gait Index ; **EQ 5D 5L** = European Quality of Life 5 Dimensions 5 Level Version; **OPUS** = Orthotic and Prosthetic User Survey; **RNLI** = Reintegration into Normal Living Index; **SAI** = Stair Assessment Index; **SF-36** = Short Form Health Survey; **WLQ-25** = Work Limitation Questionnaire; **6MWT** = 6 Minute Walk Test;

Author's Conclusion

"This study showed that the microprocessor stance and swing control orthosis C-Brace resulted in significant and clinically meaningful improvements in balance, risk of falling, actual falls, performance-based function, patient-reported function, utility, reintegration into normal living, and, ultimately, quality of life in a population of traditional KAFO users with increased risk of falling. Thus, the C-Brace is a viable option to improve safety, mobility, and quality of life of users of different types of traditional KAFOs." (Rütz et al., 2023)

© 2023, Otto Bock HealthCare Products GmbH ("Otto Bock"), All Rights Reserved. This article contains copyrighted material. Wherever possible we give full recognition to the authors. We believe this constitutes a 'fair use' of any such copyrighted material according to Title 17 U.S.C. Section 107 of US Copyright Law. If you wish to use copyrighted material from this site for purposes of your own that go beyond 'fair use', you must obtain permission from the copyright owner. All trademarks, copyrights, or other intellectual property used or referenced herein are the property of their respective owners. The information presented here is in summary form only and intended to provide broad knowledge of products offered. You should consult your physician before purchasing any product(s). Otto Bock disclaims any liability related from medical decisions made based on this article summary.