ottobock.

C-Brace

Quality for life

Clinical Study Summaries

This document summarizes clinical studies conducted with the C-Brace. The included studies were identified by a literature search made on PubMed and within the journals Orthopädie-Technik, Medizinisch Orthopädische Technik, Neurologie & Rehabilitation and Journal of Pediatric Orthopaedics.

Table of content:

1 Overview table

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g. gait analysis, clinical effects, satisfaction, etc). By clicking on underlined categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

Reference		Category						
		Functions and Activities						Participation
Author	Year	Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction
Schmalz	**2016**		x					
Pröbsting	**2016**							x
Total number: 1			1					1

2 Summaries of individual studies

On the following pages you find the summary of the study that researched C-Brace. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of each summary you also can read the original study authors' conclusions.

Reference

Schmalz, T., Pröbsting, E., Auberger, A., & Siewert, G.

Otto Bock Healthcare, Department of Research/Biomechanics, Göttingen, Germany

A functional comparison of conventional knee-ankle-foot orthoses and a microprocessor-controlled leg orthosis system based on biomechanical parameters

Prosthetics and Orthotics International 2016; 40(2): 277-286

Products

C-Brace vs KAFO

Major Findings

With C-Brace compared to KAFO (locked or SCO):

→ Descending stairs and ramps more natural

All subjects that could not walk down stairs and ramps with a step-over-step pattern with the conventional orthosis could do so with C-Brace

Only 17% of subjects needed the handrail when walking down a ramp while 100% needed it with the conventional orthosis

→ Controlled knee flexion while stance phase is possible

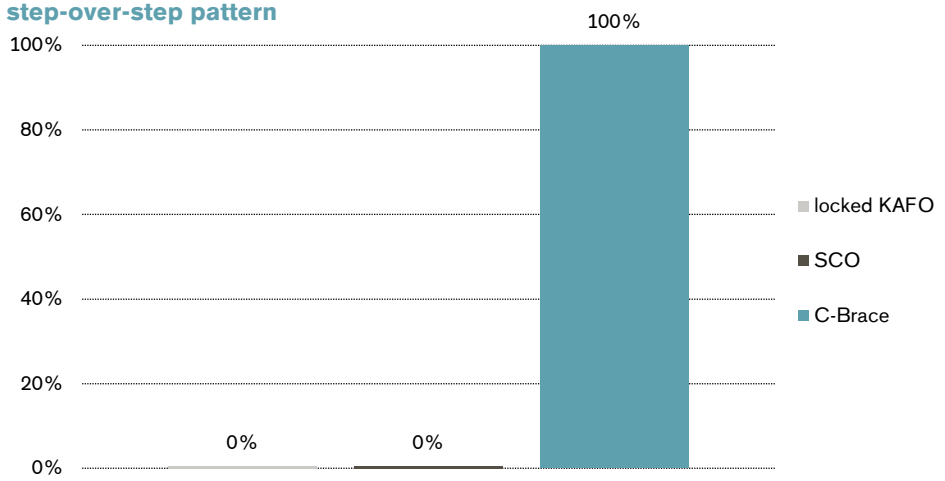
83 % of the subjects used the unique knee flexion function of C-Brace in the stance phase

→ Gait pattern becomes more natural

Knee flexion while swing phase approximates normal physiological level of 65° (vs. 0° with locked KAFO and 74° with SCO)

Compensatory movements are reduced (external hip moment)

Percentage of subjects that could descend stairs with a step-over-step pattern

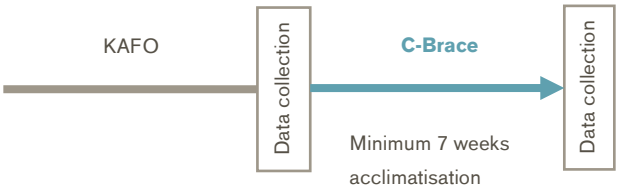


Population

Subjects:	6 subjects (5 unilateral, 1 bilateral)
Previous orthosis:	SCO (4), locked KAFO (2)
Underlying condition:	Polio (2), Incomplete spinal cord injury (2), Disc herniation (1), Incomplete femoral nerve lesion (1)
Mean age:	56 ± 13 years

Study Design

Interventional, pre- to post-test design:



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	Sig.*
Biomechanics – Gait analysis	Level Walking – Video motion analysis	No differences in walking velocity, stride length and step length asymmetry	0
		Four of the six subjects (5 orthotic limbs) used stance phase flexion with C-Brace (previous KAFO: 0 limbs) with a mean knee flexion of 11°	n.a.
		All subjects (all orthotic limbs) used swing phase flexion with C-Brace (previous KAFO: 4 limbs)	n.a.
		In the early stance phase the maximum hip flexion moment of the orthotic limb was higher compared to the SCO and lower in comparison to the locked KAFO (0.72 vs 0.62 vs 0.55)	n.a.
		Immediately before swing initiation the maximum hip extension moment of the orthotic limb is reduced with C-Brace in comparison to SCO and locked KAFO (-0.21 vs -0.36 vs -0.41)	n.a.
		The mean knee flexion moment of the sound limb in the first half of the stance phase is reduced slightly in comparison to SCO (-0.51 vs -0.44) and increased considerably in comparison to locked KAFO (-0.23 vs -0.73)	n.a.
		The knee extension moment slightly increased in the second half of the stance phase in comparison to SCO (0.52 vs. 0.57) and decreased considerably in comparison to locked KAFO (0.49 vs 0.06)	n.a.

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

Category	Outcomes	Results for C-Brace	Sig.*
		The mean hip flexion moment in the early stance phase and the hip extension moment before swing initiation did not change considerably in comparison to SCO (0.73 vs 0.72 and -0.22 vs -0.23) but in comparison to locked KAFO (0.60 vs 1.24 and -0.19 vs -0.02)	n.a.
	Stairs – Video motion analysis	All subjects (100%) were able to descend stairs with a step-over-step technique and handrail use with C-Brace while none of them was able to do this with their previous orthosis	n.a.
	Ramp – Video motion analysis	All subjects (100%) were able to descend a ramp with a step-over-step technique with C-Brace while only four of them could do this with their previous orthosis (locked KAFO: 33%, SCO: 33%) and only with considerable compensatory patterns and the use of a handrail. Only one subject (17%) needed the handrail with C-Brace	n.a.

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

Author's Conclusion

"Overall, the tests showed that the new orthotic functions of the C-Brace for situation-dependent knee flexion in the weight-bearing condition have been used by patients with a high level of confidence. This is demonstrated by the fact that the handrail was not generally used for ambulating on ramps which indicates a clear increase in perceived safety compared to all previously used KAFO mechanisms. Due to the high safety potential, patients will be able to use the C-Brace even if they are not able to use an SCO. In general, patient safety is of utmost importance and should not be compromised by increased orthotic functionality. In this study, two patients who were previously using a locked KAFO and did not qualify for SCO fitting for reasons of safety were able to safely use and benefit from the C-Brace. This illustrates that the C-Brace is able to combine improved orthotic function with sustained orthotic safety." (Schmalz et al. 2014)

↑ Back to overview table

Reference

Pröbsting E, Kannenberg A, Zacharias B.

Otto Bock HealthCare, Department of Clinical Research and Services, Duderstadt, Germany.

Safety and walking ability of KAFO users with the C-Brace® Orthotronic Mobility System, a new microprocessor stance and swing control orthosis

Prosthetics and Orthotics International 2016; Epub ahead of print.

Products

C-Brace vs KAFO (locked SCO)

Major Findings

With C-Brace compared to KAFO (locked or SCO):

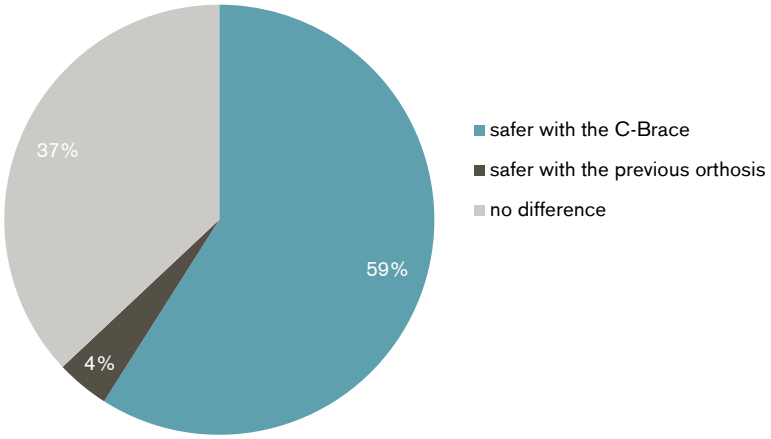
→ Improvement in perceived orthotic function and Quality of life
Compared to all previous orthoses combined, the results of the OEQ demonstrated significant improvements by C-Brace use in the total score

→ ADLs become easier
With C-Brace the patients rated the activities in the domains of family and social life (+24%), mobility and transportation (+41%), sports (+35%) and other activities (+24%) significantly easier than with other KAFOs

Of the responses for perceived comparative difficulty, 54% showed a greater ease of ADL execution with C-Brace

→ ADLs become safer
Of the responses for perceived comparative safety, 59% demonstrated a safer execution of ADLs with the C-Brace

Distribution of the answers for the comparison of perceived safety of the 45 activities of the Orthotic ADLs Questionnaire between the C-Brace and the previous orthoses



Population

Subjects:	13 subjects (12 unilateral, 1 bilateral)
Previous orthosis:	SCO (8), locked KAFO (5)
Underlying condition:	Poliomyelitis (8), incomplete spinal cord injury (3), peripheral lesion of the femoral nerve (1), stroke (1)
Mean age:	57.4 ± 14.4 years

Study Design

Interventional, pre- to post-test design:

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	Sig.*
Satisfaction OEQ (scale 0 to 100)	Ambulation	**all KAFOs: Improved by 38%**	**++**
		SCO: Improved by 32%	**++**
		Locked: Improved from 45%	**++**
	Appearance	all KAFOs: Improved by 3%	+
		SCO: Declined by -8%	-
		Locked: Improved by 27%	+
	Frustration	all KAFOs: Improved by 11%	+
		SCO: Declined by -4%	**-**
		Locked: Improved by 42%	+
	Perceived Response	all KAFOs: Declined by -5%	-
		SCO: Declined by -4%	-
		Locked: Declined by -8%	-
	Paretic Limb Health	**all KAFOs: Improved by 21%**	**++**
		SCO: Improved by 17%	**++**
		Locked: Improved by 29%	+
	Social Burden	all KAFOs: Improved by 6%	+
		SCO: Improved by 1%	+
		Locked: Improved by 13%	+
	Sounds	**all KAFOs: Improved by 52%**	**++**
		SCO: Improved by 53%	+
		Locked: Improved from 44%	+

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

Category	Outcomes	Results for C-Brace	Sig.*
	Utility	all KAFOs: Improved by 8%	
		SCO: Improved by 3%	+
		Locked: Improved by 16%	+
	Well-Being	**all KAFOs: Improved from 73 to 88**	**++**
		SCO: Improved by 21%	+
		Locked: Improved by 29%	+
Satisfaction	Personal Hygiene and Dressing	all KAFOs: Improved by 7%	+
		SCO: Improved by 2%	+
		Locked: Improved by 8%	+
	Family and Social Life	**all KAFOs: Improved by 24%**	**++**
		SCO: Improved by 17%	+
		Locked: Improved by 42%	**++**
	Mobility and Transportation	**all KAFOs: Improved by 41%**	**++**
		SCO: Improved by 26%	**++**
		Locked: Improved by 67%	**++**
	Sports and Leisure Activities	**all KAFOs: Improved by 35%**	**++**
		SCO: Improved by 24%	+
		Locked: Improved by 57%	+
	Other Activities	**all KAFOs: Improved by 24%**	**++**
		SCO: Improved by 8%	+
		Locked: Improved by 63%	**++**

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

Author's Conclusion

"Overall, the tests showed that the new orthotic functions of the C-Brace for situation-dependent knee flexion in the weight-bearing condition have been used by patients with a high level of confidence. This is demonstrated by the fact that the handrail was not generally used for ambulating on ramps which indicates a clear increase in perceived safety compared to all previously used KAFO mechanisms. Due to the high safety potential, patients will be able to use the C-Brace even if they are not able to use an SCO. In general, patient safety is of utmost importance and should not be compromised by increased orthotic functionality. In this study, two patients who were previously using a locked KAFO and did not qualify for SCO fitting for reasons of safety were able to safely use and benefit from the C-Brace. This illustrates that the C-Brace is able to combine improved orthotic function with sustained orthotic safety." (Schmalz et al. 2014)

↑ Back to overview table