

## Reference

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## Experts´ perceived patient burden and outcomes of knee-ankle-foot-orthoses (KAFOs) vs. microprocessor-stance-and-swing-phase-controlled-knee-ankle-foot orthoses (MP-SSCOs)

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## Products

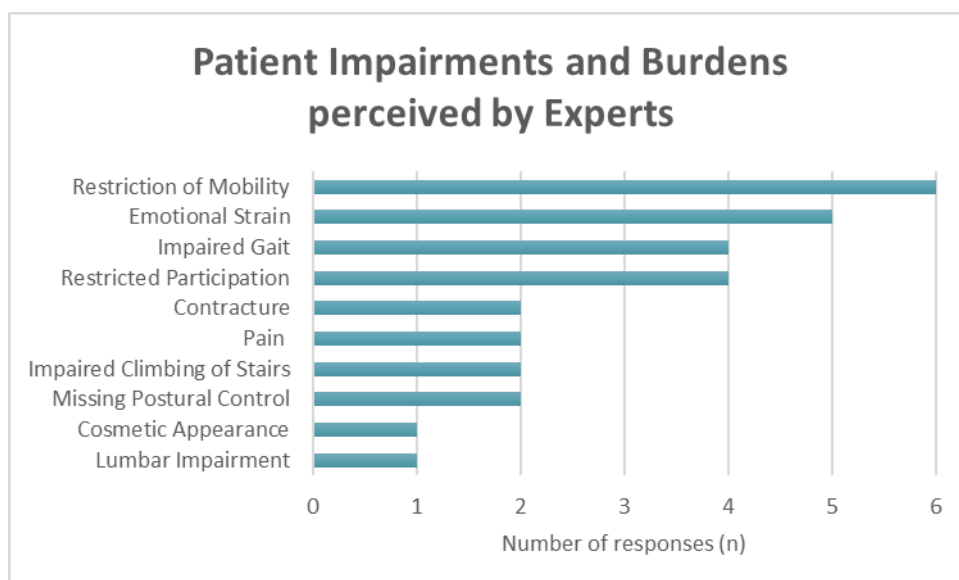
### KAFOs vs MP-SSCOs (C-Brace)

## Major Findings

Eight clinical experts (4 physicians and 4 orthotists) who had a long-term experience in prescribing, fitting and rehabilitation care for both KAFO and MP-SSCO users were interviewed.

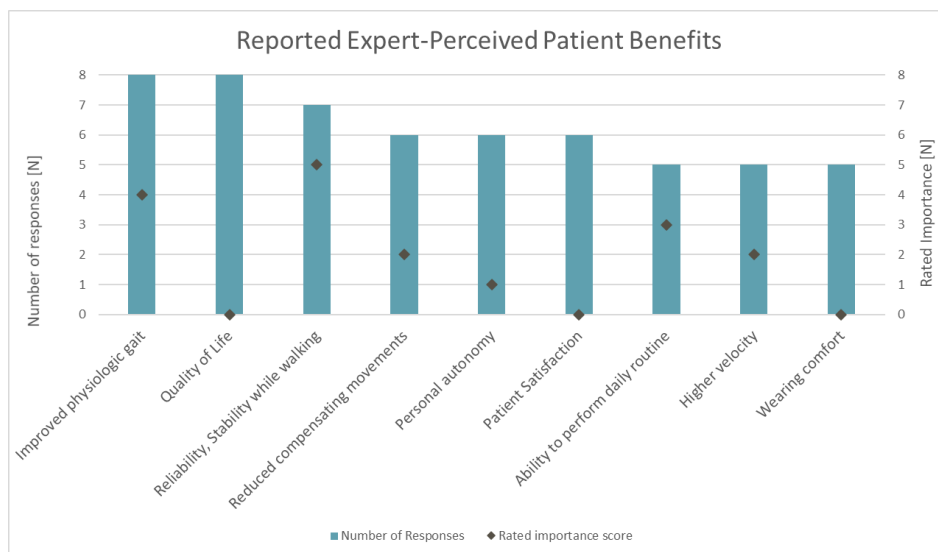
→ **87% clinical experts observed a relevant change in the rehabilitation process when using MP-SSCOs.**

→ **Restriction of mobility was the leading observed patient burden**



→ **Impaired climbing of stairs obtained the highest expert-observed frequency of impairments**

→ **Quality of life, improved gait pattern followed by high reliability of the orthosis were the most relevant observed potential patients benefits**



→ **Gait analysis was reported as the most relevant patient outcome criteria followed by number of falls, participation, and walking distance. Wearing KAFOs and stance control orthoses without microprocessor control (SCOs) are associated with long-term consequences. Lumbar disorders with a locked knee joint was considered as the most relevant item, followed by muscular atrophy.**

Population		
Subjects		8 Clinical experts from Germany were interviewed
Qualifications		4 Physicians; 4 Orthotists
Products		On average each study centre prescribed or delivered 49.9 KAFOs per year and 13.3 MP - SSCOs (C-Brace only) since product availability
Patient Population		Study experts reported a patient population that included patients with incomplete paraplegia (18%), peripheral nerve lesions (20%), poliomyelitis (41%), post-traumatic lesions (8%) and other disorders, including stroke sequelae (13%)
Mean age		not reported.

Study Design	
Interview:	An observer-based semi-structured telephone interview with <b>clinical experts</b> from eight centres in the field of KAFO/MP-SSCO fitting was conducted. Each expert was interviewed for approximately one hour and the information collected in the interviews was transcribed and a content-analysis approach was applied.

## Results

Category	Outcomes	Results for KAFOs vs MP-SSCOs (C-Brace)	Sig.*
Burden of Disease	Restriction of Mobility	<ul style="list-style-type: none"> <li>In terms of expert-observed burden on patients due to impairment, "restriction of mobility" ranked highest among the queried three most serious items (n=6). Second highest was restriction of mobility (90 out of 0-100 scale).</li> <li>In addition, impaired climbing of stairs obtained the highest expert-observed frequency (100 out of 0-100 scale with 100 denoting the highest frequency)</li> </ul>	n.a.
	Emotional Strain	<ul style="list-style-type: none"> <li>Emotional strain was the response with the second highest frequency (n=5)</li> </ul>	n.a.
Patient Benefits of C-Brace	Quality of Life (QoL)	<ul style="list-style-type: none"> <li>Quality of life and improved gait pattern were the most relevant expert-reported patient benefits (n=8)</li> </ul>	n.a.
	Improved Gait Pattern	<ul style="list-style-type: none"> <li>100% of experts (n=8) reported improved gait pattern as most relevant domain of observed potential patients benefit from optimal delivery of orthotic care</li> </ul>	n.a.
	Safety	<ul style="list-style-type: none"> <li>High reliability and stability of the orthosis were important expert-reported patient benefits (n=7)</li> <li>Estimated fall frequency reduces with MP-SSCOs compared to KAFOs :               <ol style="list-style-type: none"> <li>KAFO/SCO:                   <ul style="list-style-type: none"> <li>In total, falls were reported to occur in 71.5 percent of patients at a combined annual frequency of 7.0 fall events per year.</li> </ul> </li> <li>MP-SSCO:                   <ul style="list-style-type: none"> <li>In total, falls were observed to occur in 7.2 percent of all patients with an annual frequency of 2.2 fall events.</li> </ul> </li> </ol> </li> </ul>	n.a.
Rehabilitation	Rehabilitation Process	<ul style="list-style-type: none"> <li>87% experts observed a relevant change in rehabilitation process and structure when using MP-SSCOs</li> </ul>	n.a.
	Indication and diagnosis	<ul style="list-style-type: none"> <li>50% of the experts considered a correct indication and diagnosis as a key challenge for patient rehabilitation in orthotic care, and in particular for MP-SSCO</li> </ul>	n.a.
	Patient education	<ul style="list-style-type: none"> <li>57% highlighted a more intensified initial education phase</li> <li>The need for patient education (intensive support and guidance, especially for understanding and using the functionality of the orthosis) was emphasized by 38%, even more (43% experts) considered the understanding of the potential of the orthosis by the patient to be very essential</li> </ul>	n.a.
Long-Term Consequences of KAFO	Lumbar disorders	<ul style="list-style-type: none"> <li>Excessive lumbar loading with lack of trunk stability is an adverse effect associated with wearing KAFOs and SCOs</li> <li>Lumbar disorders impairment with a locked knee joint are the most relevant observed long-term consequences (n=4; highest frequency, 100 out of 0-100 scale with 100 denoting the highest frequency)</li> <li>Hyperlordosis/scoliosis was reported as a long-term consequence by 1 expert</li> </ul>	n.a.

Category	Outcomes	Results for KAFOs vs MP-SSCOs (C-Brace)	Sig.*
	Muscular Atrophy	Muscular atrophy was the second most observed long-term consequences by experts (n=3; frequency=75 out of 0-100 scale)	n.a.
	Forearm crutches	Physical discomfort due to forearm crutches was mentioned by one expert (n=1; frequency is 25 out of 0-100 scale)	n.a.

**KAFO** Knee Ankle Foot Orthosis; **MP-SSCO** microprocessor stance and swing phase controlled orthosis; **QoL** Quality of Live; **SCO** Stance Control Orthosis;

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

### Author's Conclusion

"Patients with muscular knee instability following neuromuscular or central nervous system injuries or conditions who use KAFOs/SCOs are suffering from restricted mobility, emotional strain and impaired gait patterns.

Advanced orthotic technology might contribute to better QoL of patients, improved gait patterns with subsequent reduction of long-term consequences and perceived reliability of the orthosis. In terms of safety, a substantial decrease in the frequency of falls with MP-SSCO compared to non-microprocessor-controlled KAFOs was reported.

Advanced orthotic devices may enhance physical and psychological health and well-being by enabling patients to pursue their daily routines. In selected patients who are unable to be fitted with non-microprocessor-controlled KAFO/SCO, mobility might be regained through MP-SSCOs with the additional benefit of spending less time in a wheelchair or even discontinuing its use.

Advanced orthoses require even more interdisciplinary rehabilitation with a standardized outcomes assessment comprising instruments for gait analysis and assessing the number of falls as well as individual participation in activities of daily living." (Brüggenjürgen et.al 2022)

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