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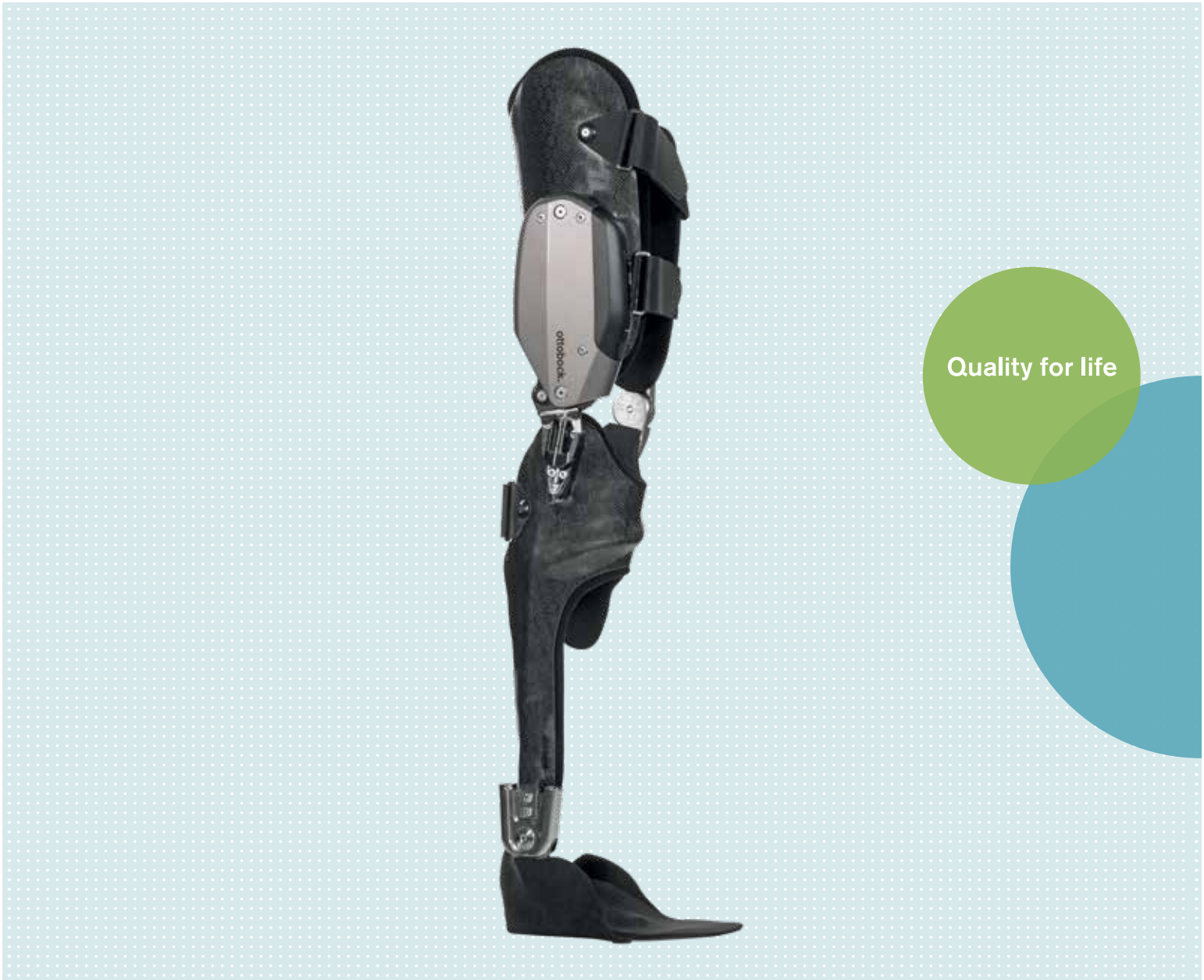
C-Brace®: Clinically proven advantages

Redefining the standard of care



Introduction

C-Brace is the world's first microprocessor-controlled stance and swing phase control orthosis (SSCO®) system. Because the C-Brace controls flexion and extension resistances during the entire gait cycle and provides knee flexion under load, it delivers more support for activities of daily living (ADLs) compared to conventional knee ankle foot orthoses (KAFOs). Furthermore, the Active Stumble Recovery in the C-Brace provides patients with a greater feeling of safety during these ADLs. These benefits have been shown in several studies, which are summarized in the following sections.

Differentiation of treatments

Limitations of conventional KAFOs

For centuries, patients with weakness of knee stabilization muscles have been prescribed KAFOs to keep the knee from collapsing, and allowing patients to walk. KAFOs with locked or posterior offset orthotic knee joints have long been the standard orthotic devices.

Locked knee joint

Locked KAFOs lock the knee for both the stance and swing phases. For this reason, the patient must walk with a fully extended or “stiff” leg. The locked KAFO allows for safe standing and walking on level ground, but limitations include the following:

- Limited foot clearance requires compensation: hip hiking, increased pelvic obliquity, circumduction during swing, and vaulting during stance
- Slower walking speed, increased metabolic energy requirement
- Safety concerns on uneven terrain, slopes, and stairs
- Reciprocal hill or stair descent impossible

Posterior offset knee joint

The design of a posterior offset orthotic knee and ankle joint with a dorsiflexion stop, prevents the orthotic knee joint from collapsing during the entire stance phase and allows for safe standing and walking on level ground. During the swing phase, the orthotic knee joint is free permitting the calf to swing forward. Limitations include the following:

- The orthotic leg must take the first step – knee flexion must be provided by the sound leg
- Increased effort to overcome the knee flexion moment; walking becomes exhausting and uncomfortable
- Does not accommodate standing or walking on uneven terrain
- Reciprocal hill or stair descent impossible

Stance Control Orthoses (SCOs)

In contrast to the standard KAFOs described above, stance control orthoses use various technical switching mechanisms to lock the orthotic knee joint and unlock it at the end of the stance phase. The switching between stance and swing phase may be provided by different technical mechanisms. These orthoses allow for safe and comfortable walking on level ground with a nearly constant stride. Limitations include the following:

- Knee may fail to switch to a locked position, resulting in knee collapse or failure to unlock for swing
- Uneven terrain makes full extension difficult, which is required to switch to locked or unlocked position
- Orthotic leg must always make the first step; knee flexion must be provided by sound leg
- Reciprocal hill or stair descent impossible
- Difficult to sit (especially for bilateral users)

Clinical evidence for SCOs

Three systematic reviews have been published summarizing patient benefits for orthotic devices to treat knee instability, two specifically related to SCOs [6–8]. From these reviews, we can conclude SCOs provide the following benefits:

- Reduction or elimination of compensatory movements for walking on level ground (↓pelvic obliquity, hip hiking, and circumduction on the orthotic side)
- Increased walking speed
- Decreased mechanical stress to the sound limb
- Increased patient satisfaction vs. locked KAFOs
- Mixed results regarding reduction in energy consumption
- Limitation of research: level walking only with nearly constant stride length

C-Brace key features & benefits

- **Stance Flexion Resistance** – provides resistance against knee flexion allowing controlled partial flexion during weight bearing. This facilitates descending stairs and ramps with reciprocal gait.
- **Stumble Recovery** – high knee flexion resistance, activated by microprocessor swing control, allows patients to recover safely after a trip or stumble.
- **Walking Backward** – safety and stability while walking backward.
- **Real-time Gait Analysis** – the microprocessor receives sensor information 100 times per second.
- **Intuitive Stance Function** – allows patients to stand in locked position with slight knee flexion and rest while standing securely.
- **Sitting/Standing** – automatically detects when patients sit, providing progressive resistance for sitting in a controlled manner. Also detects sitting position to allow the brace to be in a relaxed position in confined spaces and to prepare for standing.
- **MyModes** – programmable for training during initial use, walking on all terrains and activity-specific needs of the patient.

Clinical results

Normalized gait

Biomechanical study

A gait lab study was conducted in 6 subjects to compare the biomechanics after fitting with the C-Brace to the biomechanics with orthoses previously worn, either stance controlled orthoses or locked KAFO [2]. Assessments were performed after at least 7 weeks of follow up.

The results with C-Brace showed:

- More physiologic knee flexion during both stance and swing phases
- Reduced knee and hip joint loading with the C-Brace, especially for locked KAFO wearers
- All subjects in the study were able to achieve step-over-step descent of stairs and ramps

Metabolic energy consumption & safety

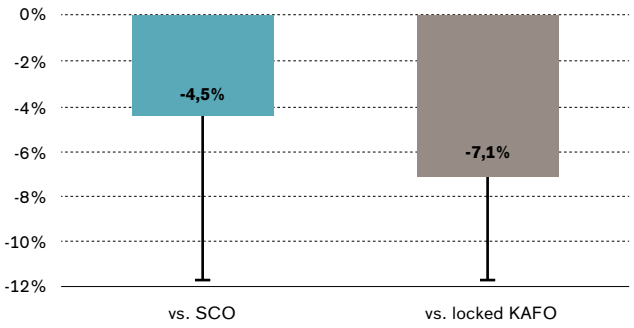
Another gait laboratory study conducted in 5 subjects measured the oxygen (O2) consumption while walking* and assessed safety after forced stumbles [1].

Results with C-Brace showed:

- Two of 3 subjects previously wearing SCOs had reduced O2 cost (7 %) walking on level ground with the C-Brace.
- Both subjects previously wearing locked KAFOs showed reduced energy cost (4 and 10 %) walking on level ground.

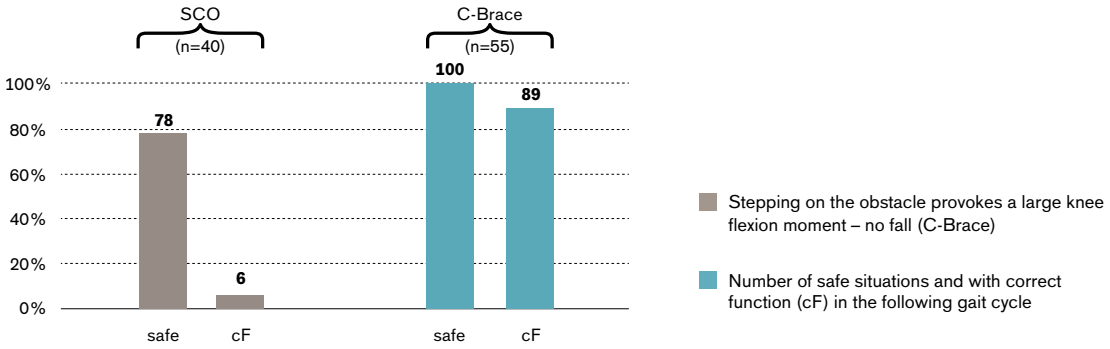
Reduced Energy Expenditure for Level Walking with C-Brace vs Conventional KAFO

[Change in O2 Cost of Walking]



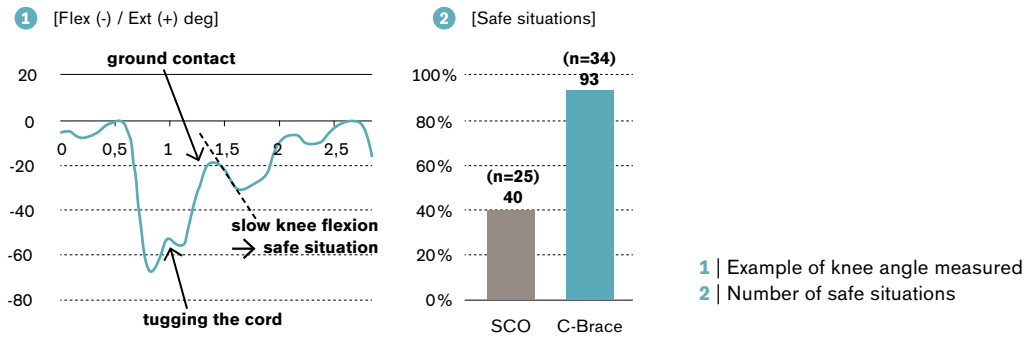
While walking on uneven ground, SCOs proved to be safe in 78% of the tests and worked correctly (release of free swing) in only 6% of the subsequent gait cycles. C-Brace proved to be safe to 100% and correctly switched from stance to swing in 89% of the subsequent gait cycles.

Safety test: Walking on uneven ground
[situations safe/correct]



60% of the stumbles simulated with the SCO would have likely resulted in a fall, whereas only 7% would have with the C-Brace.

Safety test: Stumbling**



* spiroergometry measurement of oxygen consumption during level walking on a treadmill or outside

** stumbles simulated while subjects were wearing a safety harness by pulling a cord affixed to the ankle

Improvements in quality of life

Multi-center observational study

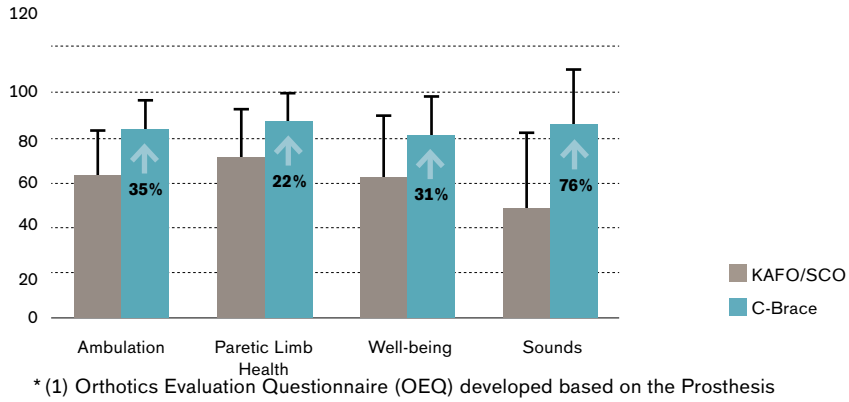
A pilot observational study was conducted including 13 subjects (1 bilateral) wearing either locked KAFOs (5) or SCOs (8) for an average of 24 years [3]. Subjects completed two questionnaires* prior to C-Brace fitting at least 3 months after home use.

Results with C-Brace showed:

- Improvements in orthotic function and quality of life, specifically in perceived ambulation, paretic limb health, well-being and sounds.**
- Increase in comparative safety for performing 59 % of activities of daily living (ADLs) assessed.
- Reduction in perceived difficulty for 53 % of ADLs assessed.

Increased Orthotic Evaluation Questionnaire scores in 4 subdomains

[Mean QEC subscore]



* (1) Orthotics Evaluation Questionnaire (OEQ) developed based on the Prosthesis Evaluation Questionnaire including 81 questions measuring perceived orthotic function and quality of life and (2) an Activities of Daily Living Questionnaire (ADL-Q) in which subjects rated comparative safety and difficulty of 45 ADLs.

** Less bothersome noise such as squeaking or clicking.

Improved function and safety

Multi-center retrospective chart review

Chart reviews were conducted at 14 clinics to review C-Brace fittings and clinical outcomes [5]. Twelve (12) subjects had outcomes data gathered at both baseline and follow-up ranging from 1 to 27.8 months after fitting. Ten (10) of 12 subjects showed clinically meaningful improvements in at least one outcome measure.

The following improvements in average scores were observed after C-Brace Fitting:

- Increase of 0.22 m/s in fast walking speed.
- Increase of 15 % in patient-perceived balance.*
- The total score doubled for the ease of performing ADLs** with a 109 % improvement in the mobility domain.

Activity-specific Balance Confidence (ABC) Score,
*Activities of Daily Living Questionnaire (ADL-Q), p<0.01
**

Prospective registry interim results

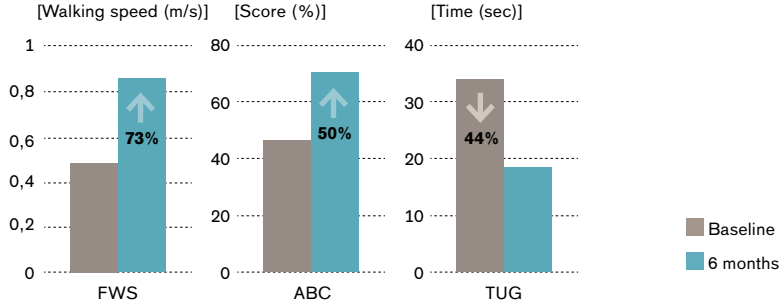
Sixteen (16) clinics are currently participating in a prospective registry to evaluate the effectiveness of the C-Brace [9]. An interim analysis was done including 9 subjects followed for 6 months.

Results after C-Brace fitting showed:

- Average Fast Walking Speed increased by 0.36 m/s (↑73 %)
- Patient-perceived balance (ABC score) increased by 50 %
- Timed Up and Go test decreased by 14.9 seconds (↓44 %)

The C-Brace registry is ongoing with the aim of 65 subject enrollments followed a minimum of one year after fitting.

Clinical Outcomes at Baseline and 6-months after C-Brace



Comparative effectiveness (vs. conventional KAFOs)

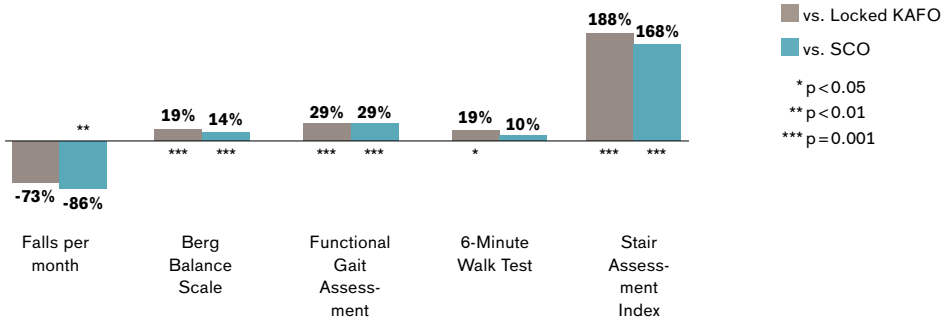
Randomized cross-over trial (Shirley Ryan Ability Lab)

Eighteen (18) subjects wearing locked KAFOs or SCOs completed a study to compare locked KAFOs, SCOs and the C-Brace in each subject [4]. For each brace, subjects had one month of training and one month of home use before assessments.

Results with C-Brace showed:

- Fewer falls vs. SCO (2.1 → 0.3 per mo) and a trend vs. locked KAFOs (1.1 → 0.3 per mo)
- Higher Berg Balance Scale (BBS) scores vs. locked KAFO and SCO indicating reduced risk of falling
- Improved Functional Gait Assessment scores
- Improved 6-min Walk Test vs. locked KAFOs
- Improvement in the Stair Assessment Index

C-Brace Improvements in Clinical Outcomes



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