ottobock.

C-Brace: Clinically proven advantages.

Re-defining the standard of care.

Information for healthcare professionals

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1. Introduction.

C-Brace is the world's first microprocessor-controlled stance and swing phase control orthosis (SSCO®). Because the ***C-Brace*** controls flexion and extension resistances during the entire gait cycle and provides knee flexion under load, it provides 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.

2. Differentiation of treatments.
Limitations of conventional KAFOs.

For decades, 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 (SCO) 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[8-10]. From these reviews, we can conclude SCOs provide the following benefits:

- Reduction or elimination 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
- Major limitation of research: level walking only with nearly constant stride length

3. *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.

4. *C-Brace*: Groundbreaking outcomes of a landmark study.

New evidence & opportunities.

In a significant new study, ***C-Brace*** continues to redefine the standard of care.

The world's first microprocessor-controlled stance & swing phase control orthosis (SSCO) system, *C-Brace* has already demonstrated a range of functional advantages for diverse patient types.
Now, a robustly designed study has shown that this unique device delivers superior outcomes for patients dependent on conventional knee-ankle-foot orthoses (KAFOs) across a range of clinically meaningful endpoints.[1]

This compelling evidence was generated by the largest-ever international, randomized, controlled, multi-center, crossover evaluation of ***C-Brace*** versus KAFO.
Outcomes from this groundbreaking study show that ***C-Brace*** significantly improves patients' safety compared with conventional mobility aids, while also enhancing their mobility, lower limb function, and quality of life.

Study design & endpoints[1].

Head-to-head: *C-Brace* vs KAFO

In this study, KAFO-dependent individuals at elevated risk of falling were randomized to KAFO/***C-Brace*** or ***C-Brace***/KAFO use for three months with each orthosis. Participants in both groups achieved consistently superior outcomes with ***C-Brace***.

Investigators concluded that these outcomes are likely attributable to ***C-Brace***'s stumble recovery and controlled knee flexion during weight bearing, and that the benefits of these functions will have a substantial positive impact on patients' every-day lives.

Cohorts & analyses

Intent-to-Treat (ITT) analysis: 102 participants
The ITT analysis reflects results expected under real-life conditions, including treatment failures, lost patients, and non-compliant individuals. All participants originally randomized to a treatment group were included in this analysis, whether or not they finished the study as planned. **Unless otherwise noted, all the following outcomes are based on this "real-world" analysis.**

Per Protocol (PP) analysis: 69 participants
The study's PP analysis reflected results obtained under ideal conditions and with full compliance, including both treatment failures and participants who experienced improved outcomes. These outcomes are available in the pull study publication.

All participants:
- High risk of falling at screening (BBS <45)
- Active, compliant individuals who had used a KAFO for ≥3 months prior to randomization and committed to using the ***C-Brace*** ≥1 hr/day for 5 days/week

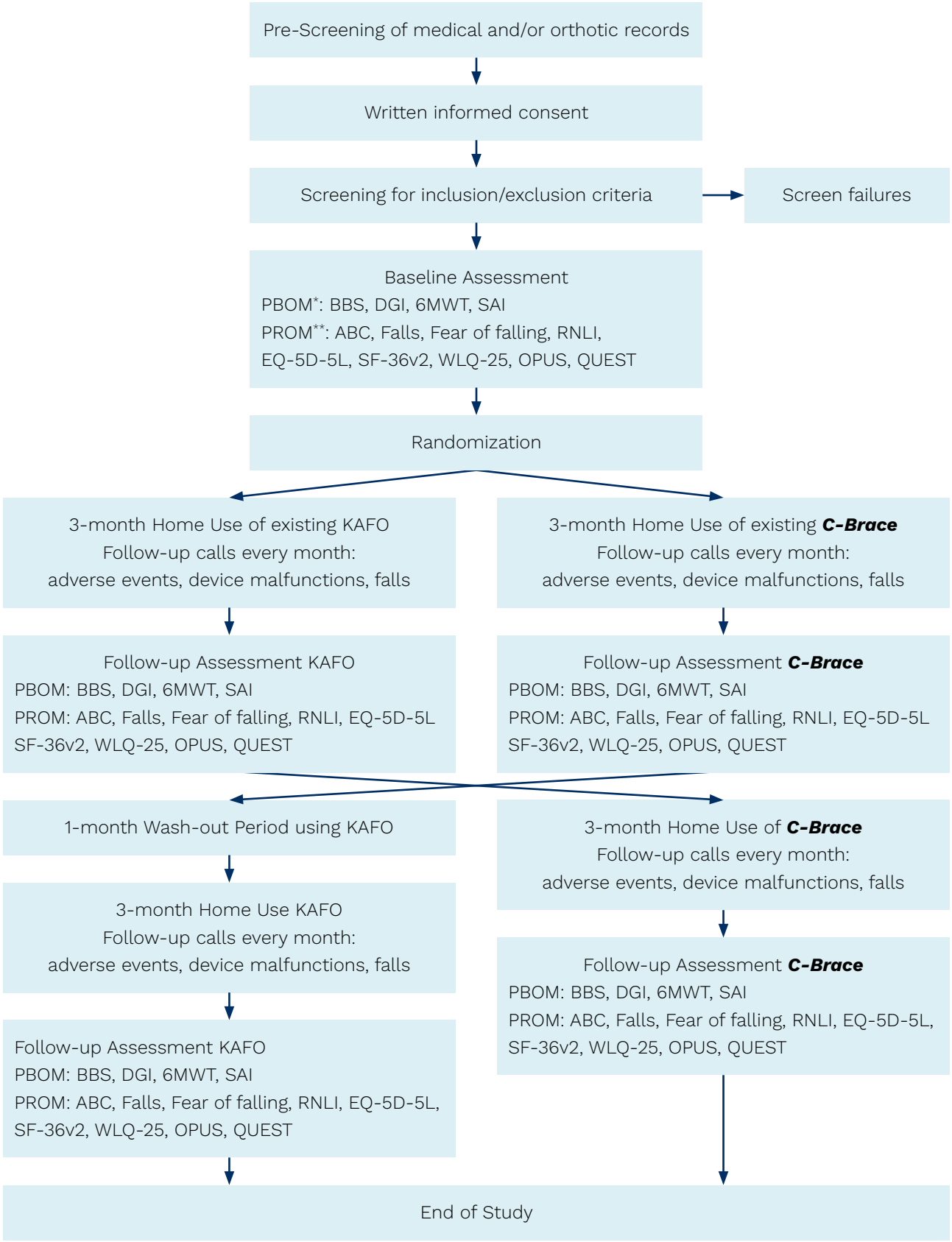
Endpoints & instruments*

Primary
- Static balance and risk of falling: Berg Balance Scale (BBS)

Secondary
- Balance confidence: Activity-Specific Balance Confidence (ABC) Scale
- Falls: Documented by participants in a falls diary
- Mobility: Dynamic Gait Index (DGI) & Stair Assessment Index (SAI)
- Function: Orthotics & Prosthetics User Survey (OPUS)
- Health-related quality of life: SF-36

*** With significant outcomes**

Randomized crossover study design



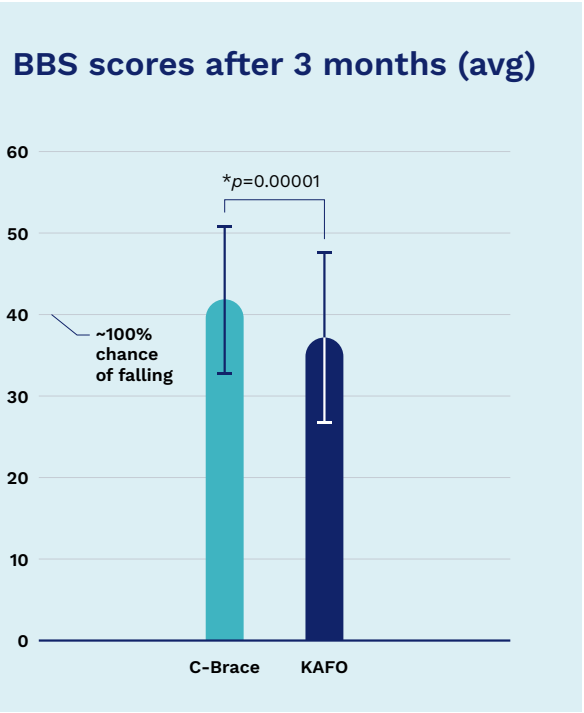
* *Performance Based Outcome Measures*
** *Patient Reported Outcome Measures*

Improved balance & reduced fall risk.[1]

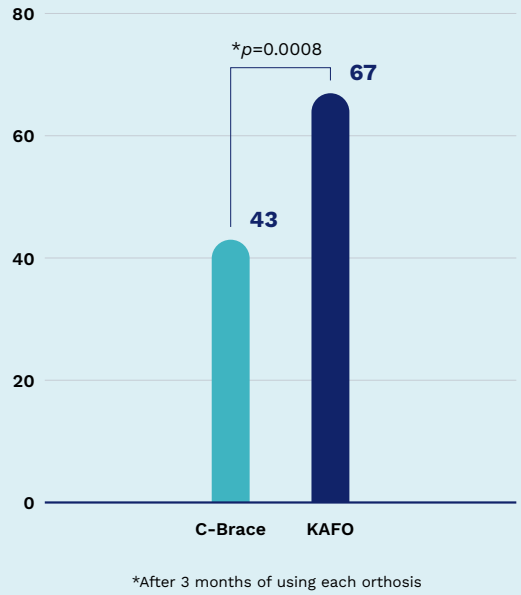
After using *C-Brace* for 3 months, participants were at significantly lower risk of falling (p<0.00001).
Ottobock's SSCO system significantly increased patients' BBS scores*, indicating meaningfully increased safety in both real-world and clinically controlled scenarios.

***About BBS scores**

- Clinical instrument consisting of 14 movement tasks used to assess static balance and fall risk
- Score range of 0-56
- Scores <45 indicate increased fall risk
- Scores <40 indicate an almost 100% risk of falling

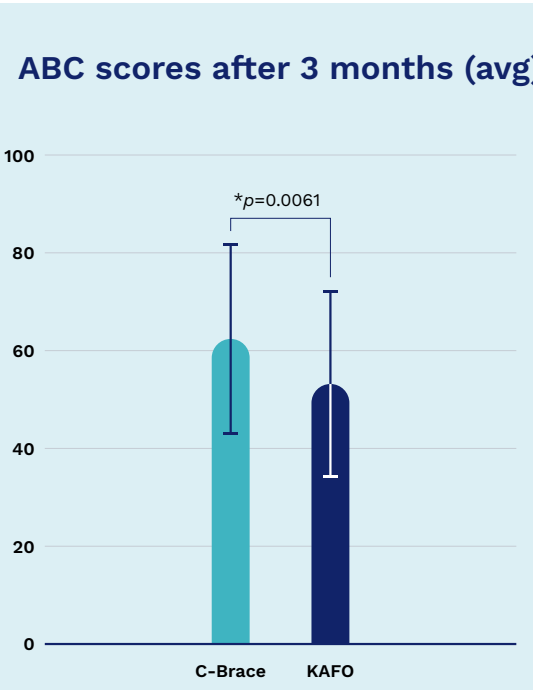


C-Brace significantly reduced the number of participants at high risk of falling.*
In 3 months of use, ***C-Brace*** is significantly more effective at protecting users from potentially injurious events.



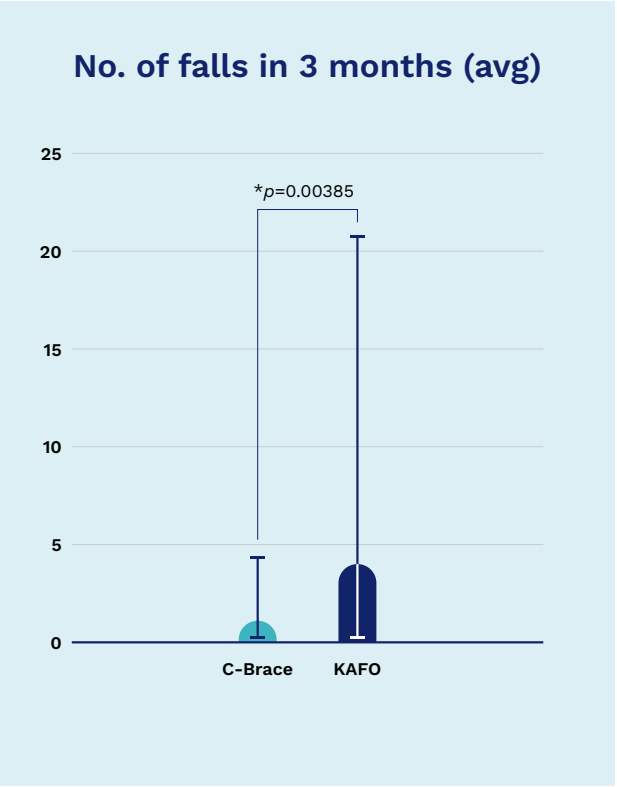
Participants also reported significantly more activity-specific balance confidence after using _C-Brace_.
Assessed via the Activity-Specific Balance Confidence (ABC) scale, which measures 16 ADLs on a 0-100 scale.

Greater scores represent better balance confidence. Scores <67 indicate increased fall risk.

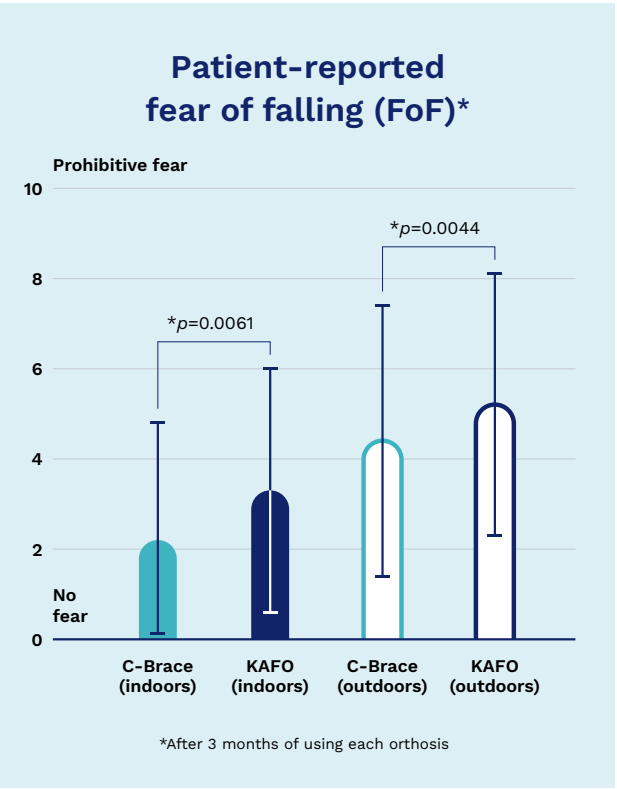


Fewer falls.[1]

During the study, participants using *C-Brace* fell far less often than participants using a conventional KAFO.
In fact, participants using ***C-Brace*** reported up to 80% fewer falls than participants using a KAFO, marking a significant reduction from both baseline and vs KAFO (p=0.00002).



Compared to KAFO use, *C-Brace* use significantly reduced participants' fear of falling (FoF).*
Indoors and outdoors, ***C-Brace*** helped patients feel more confident navigating a variety of ADLs and everyday environments.

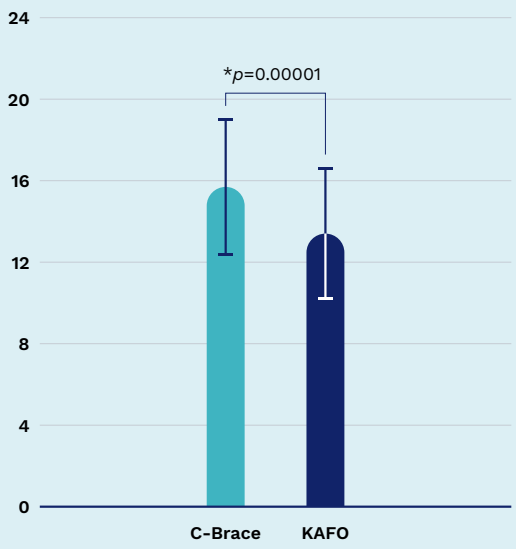


Greater mobility.[1]

After using *C-Brace*, participants demonstrated significantly improved balance during walking tasks.
Scores on the Dynamic Gait Index (DGI) indicate that ***C-Brace*** greatly enhanced participants' ability to adapt their balance in response to external demands or additional motor tasks while walking.

- Higher scores represent better balance and walking function (max score of 24).
- Scores <19 indicate elevated fall risk.

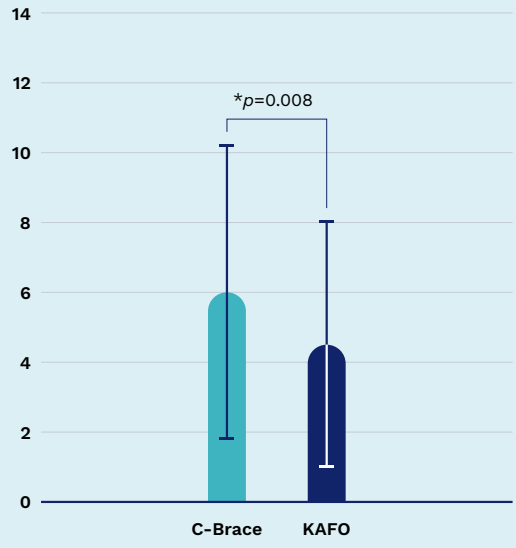
Mobility after 3 months (DGI)



C-Brace also significantly increased patients ability to descend stairs.
Scores on the Stair Assessment Index (SAI) show that walking downstairs was substantially easier for participants after using ***C-Brace***.

- Higher scores represent greater ability to descend stairs
- 0 = Unable to descend stairs
- 13 = Step-over-step pattern without rail or assistive device

Avg ability to descend stairs (SAI)*



*After 3 months of using each orthosis

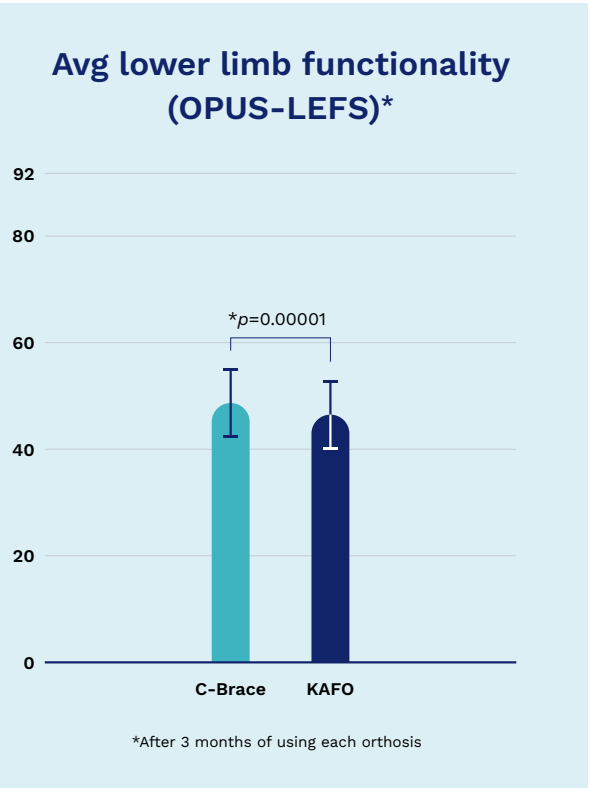
Improved lower limb function.[1]

After using *C-Brace*, a wide range of ADLs were easier for participants to complete.
Responses to the Orthotics & Prosthetics User Survey (OPUS) showed a significant improvement in lower extremity functional status (LEFS) once participants had used ***C-Brace*** for 3 months.

- OPUS-LEFS assessment covers a comprehensive range of 20 ADLs.
- Higher scores represent greater orthotic function.

Activity types assessed by OPUS-LEFS

- Personal hygiene/dressing
- Balance
- Indoor ambulation
- Outdoor ambulation
- Donning/doffing
- Rising/sitting/standing
- Managing tasks while walking



Enhanced quality of life.[1]

C-Brace use led to significant patient-reported improvements in a range of health-related domains.

Multi-dimensional QoL improvements (SF-36)

In the following domains, the ITT analysis indicates that ***C-Brace*** delivered significantly greater improvements than KAFO.

Physical function (p=0.00003)
- ***C-Brace*** 44.3±23.3
- KAFO 31.1±23.8

Emotional wellbeing (p=0.032)
- ***C-Brace*** 58.2±23.8
- KAFO 54.2±23.8

Health change (p=0.004)
- ***C-Brace*** 56.5±26.4
- KAFO 48.0±26.0

Energy/fatigue (p=0.003)
- ***C-Brace*** 56.8±20.1
- KAFO 52.3±20.3

Bodily pain (p=0.003)
- ***C-Brace*** 59.5±26.7
- KAFO 57.4±24.8

Role limitations (physical, p=0.00017)
- ***C-Brace*** 51.0±41.2
- KAFO 44.9±43.2

5. Real-world Evidence from the *C-Brace* Registry.

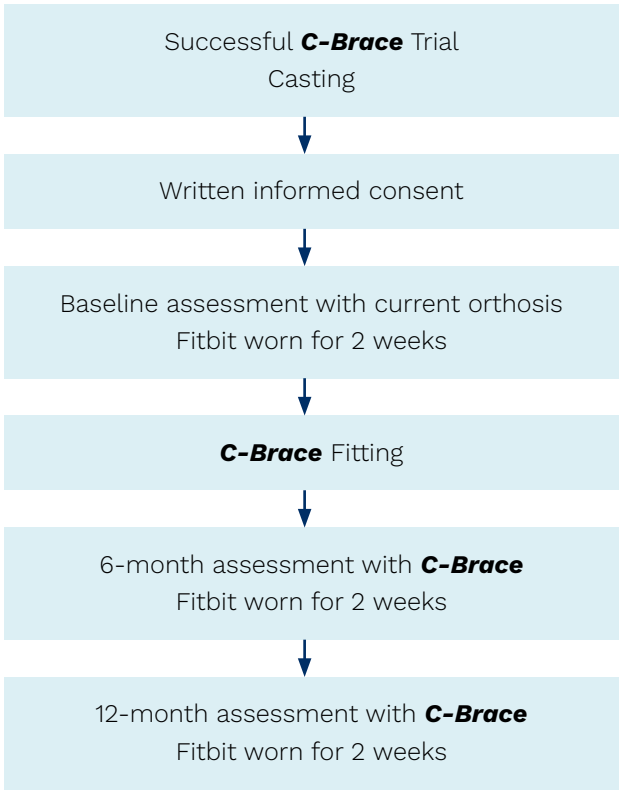
Study design & outcome measures.

Assessment of the *C-Brace* in routine clinical practice[2]

In this observational registry, participating sites follow best-practice standard of care and assess outcomes before and after ***C-Brace*** fitting in routine clinical practice. Any patient having had a successful assessment with the ***C-Brace*** Trial Orthosis (DTO) and having been casted for ***C-Brace*** fitting may be invited to participate.

Interim results from this international registry were recently published provide real-world evidence that the ***C-Brace*** results in significant and clinically meaningful improvements in a widely diverse sample of individuals with indication for a KAFO 1-year after fitting.

Simple follow-up schedule
After giving informed consent, participants undergo baseline testing with their current orthosis at the DTO fitting or any time prior to the ***C-Brace*** definitive fitting. They are assessed with the ***C-Brace*** again at 6 months and 12 months after the fitting.



Outcome measures & instruments

Primary
- Fast Walking Speed (FWS): 10-meter or 25-foot walk test
- Walking ability and balance: Timed Up and Go (TUG)
- Balance confidence: Activity-specific Balance Confidence (ABC) Scale

Secondary
- Goal attainment: Patient-specific Functional Scale (PSFS)
- Activity: Daily Step Counts via Fitbit*
- Static balance and risk of falling: Berg Balance Scale (BBS) (optional)*

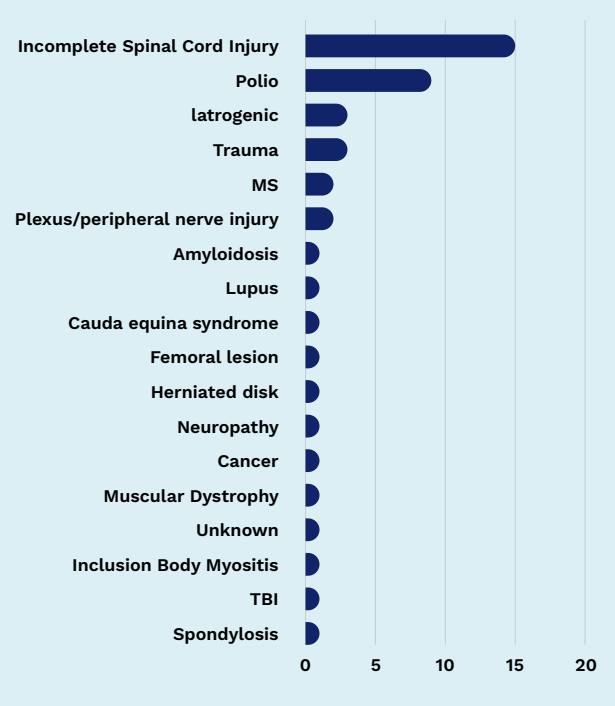
Exploratory
- Pain intensity: Numeric Pain Rating Scale (NPRS)
- Manual Muscle Test (MMT)*
- Quality of Life: EQ-5D-5L
- Consequences of pain: PROMIS Pain Interference

** Not yet analyzed for publication*

Diverse sample of participants in the Registry

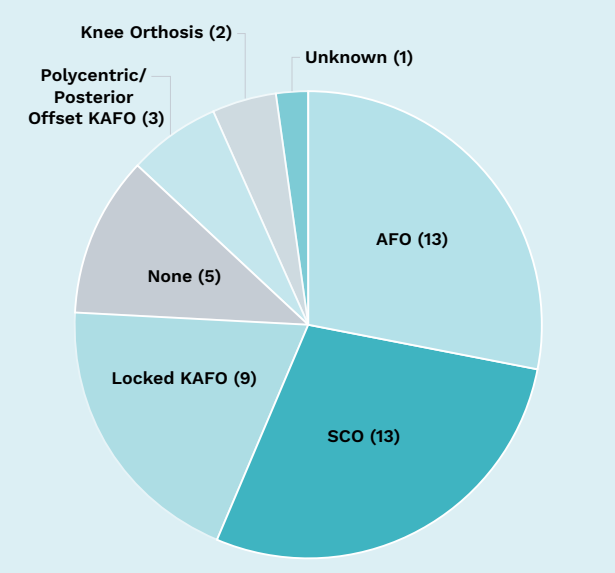
Participants in the registry had a variety of causes for muscle weakness with an indication for Knee Ankle Foot Orthosis

Subjects	46 (17 female)
Mean age	51.8 years [22-83]
Affected side	19 left
	18 right
	9 bilateral
Mean weight	178 [58-270] pounds



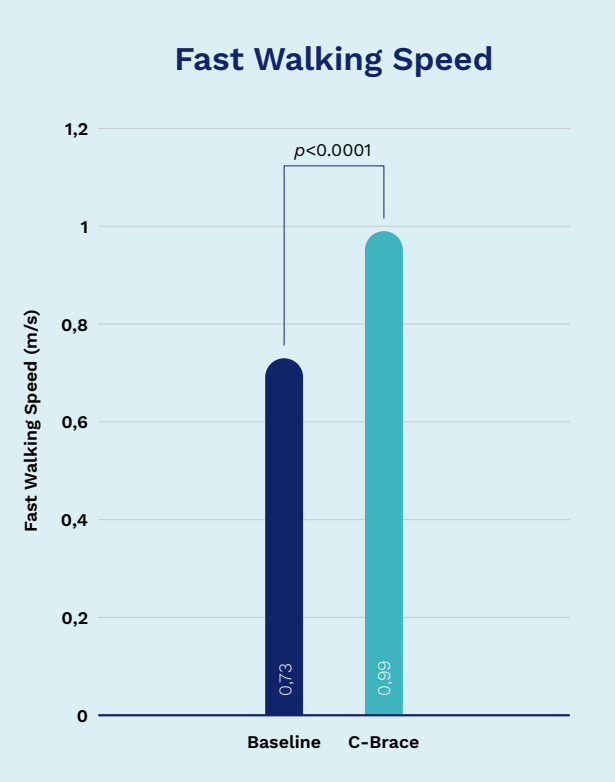
Most participants were wearing a traditional KAFO prior to *C-Brace* fitting

- 25 (54%) were wearing either a stance-controlled orthosis (SCO), a Locked KAFO or other KAFO.
- 5 (11%) were fit with the ***C-Brace*** as their first orthosis



Improved walking speed

1 year after *C-Brace* fitting, participants had a 36% improvement in fast walking speed compared to the baseline condition.
Fast walking speed improved by 0.26 m/s on average.
At follow up, 16 participants (40%) moved up at least one ambulation class*



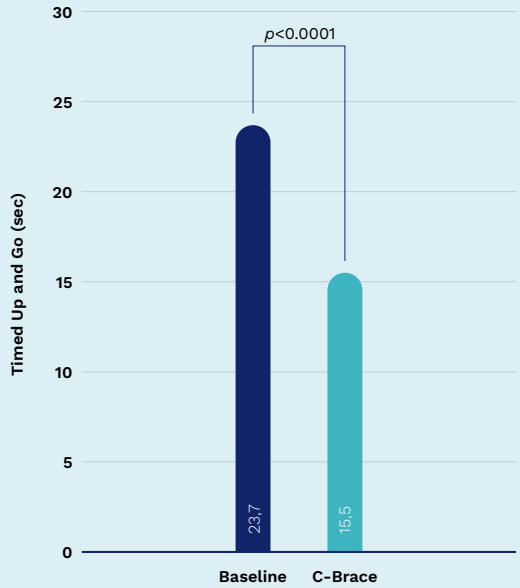
*** Ambulation classes according to Perry:**

< 0.4 m/s	Household ambulator
0.2 – 0.8 m/s	Limited community ambulator
> 0.8 m/s	Full community ambulator

Improved mobility, balance confidence and reduced fall risk.

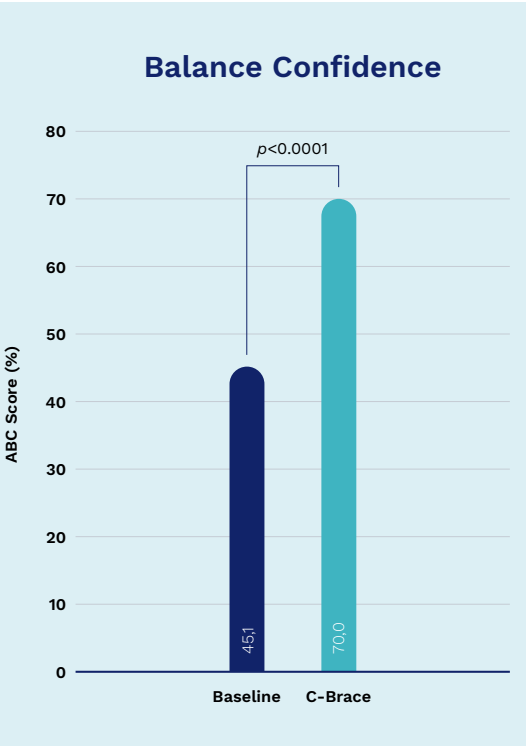
Participants had lower TUG times with the *C-Brace* indicating increased balance and walking ability and reduced fall risk.

- Timed up and go (TUG) times reduced by 8.1 sec.
- 47% fewer patients at risk of falling (TUG time above 13.5-sec cutoff)



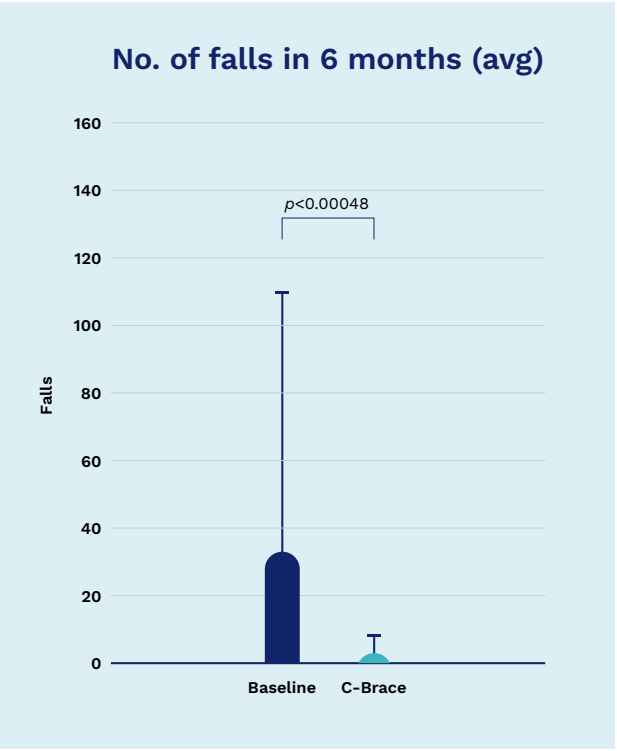
Participant had increased ABC scores indicating increased balance confidence and reduced fall risk.

- ABC scores improved by 24.9%
- 46% fewer patients at risk of falling (ABC score below 67% cutoff)

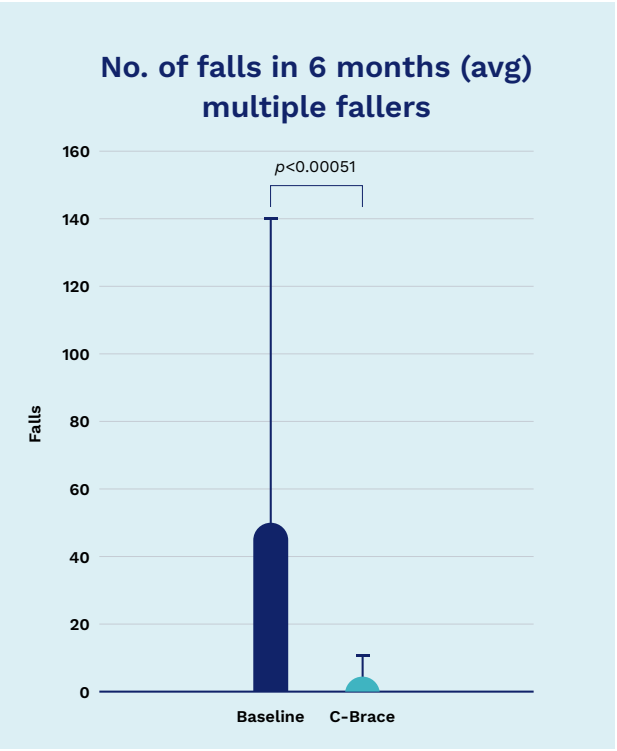


Fewer falls.

Participants fell far less often after *C-Brace* fitting compared to baseline.
91% fewer falls in the previous 6 months with ***C-Brace*** compared to baseline dropping from an average of 33 at baseline to 3 at follow up.



86% of participants that fell more than once in the previous 6 months (multiple fallers), showed a clinically meaningful reduction in falls after *C-Brace* fitting*
Among multiple fallers there was a 90% reduction in falls, dropping from 50 at baseline to 4.4 after ***C-Brace*** fitting.

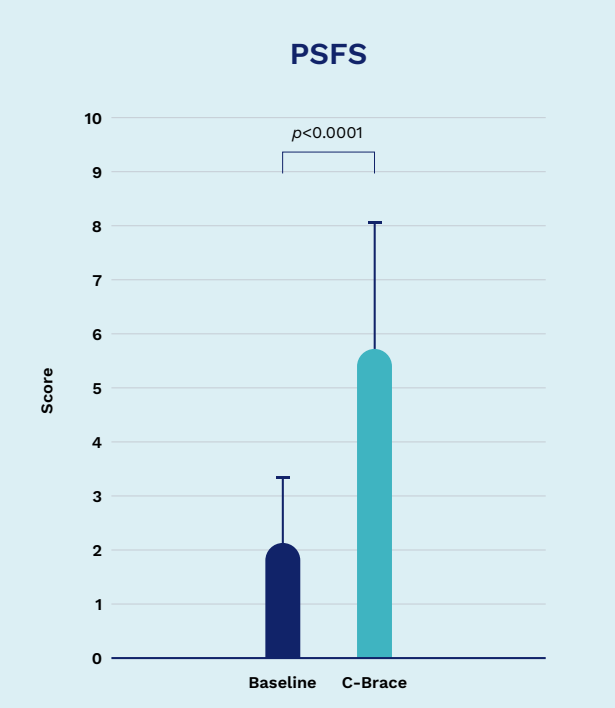


** A 25% reduction in fall frequency is considered clinically meaningful.*

Achievement of individual goals.

Participants made significant process reaching their individual goals* 1 year after *C-Brace* fitting compared to baseline

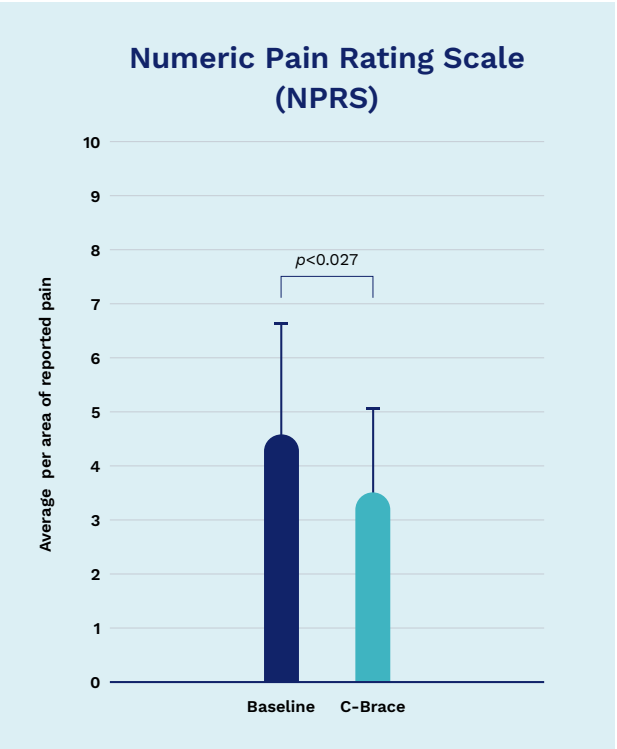
169% improvement in PSFS score, increasing by an average of +3.6 points on a 0-10 point scale with ***C-Brace*** compared to baseline.



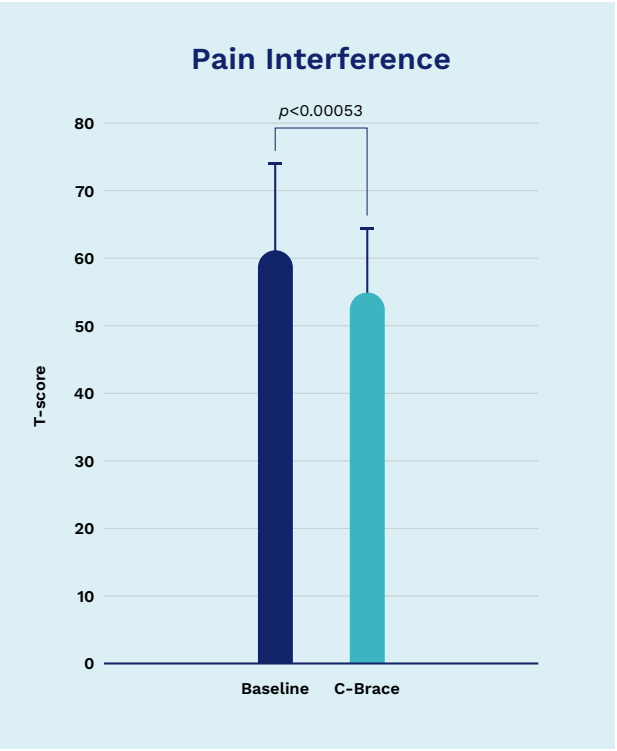
** Patients set a variety of individual goals as depicted in this word cloud*

Reduced pain and the interference of pain with daily life.

Participants reported less pain after *C-Brace* fitting compared to baseline
23% reduction in the average NPRS score per area of reported pain driven by reductions in pain in the affected leg, affected ankle, sound hip, sound ankle and sound foot.



Participants reported less pain interference
14% reduction in PROMIS Pain Interference T-score*, dropping by 8.8 points on average.



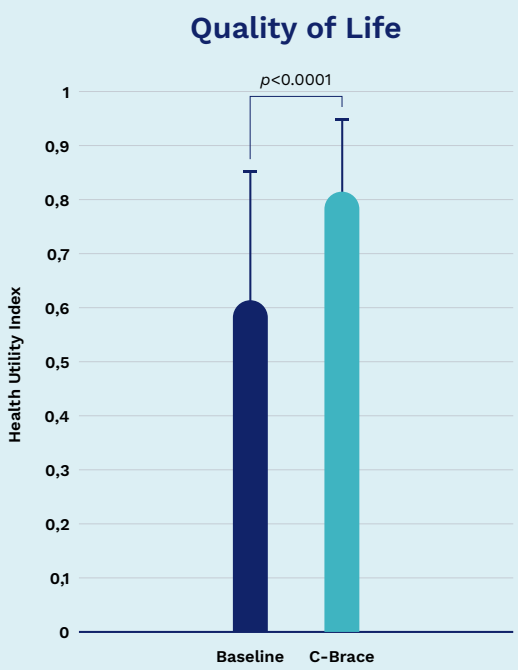
* *A T-score is a conversion of scores on a test to a standardized scale with a mean of 50 and standard deviation of 10.*

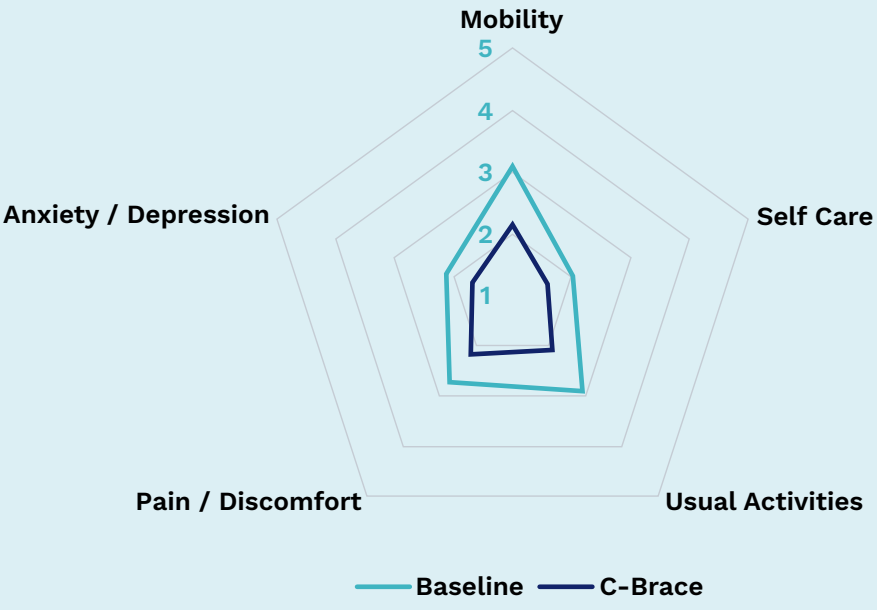
Enhanced quality of life.

***C-Brace* use led to significant improvements in the Health Utility Index (HUI) mapped from the EQ-5D-5L scores**

33% improvement in HUI, +0.20 on average, driven by improvements in mobility, usual activities and pain dimensions.

- Higher raw scores on the individual dimensions represent greater problems in the dimension
- Higher HUI scores indicate better health, 1 being perfect health and 0 being worst health
- Maps for HUI are geographically specific; participants from the US were indexed using US tables and those from the EU based on EU tables





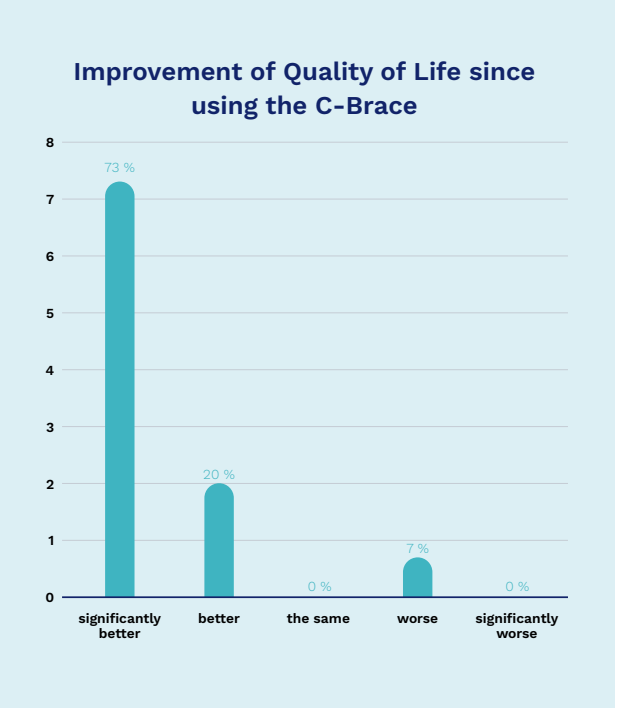
6. Additional clinical key findings.

Patients' burden using microprocessor-stance-and-swing-control knee-ankle-foot orthoses and outcomes compared to those with prior traditional knee-ankle-foot-orthosis" (Brüggenjürgen et al., 2024).[3]

A structured cross-sectional survey was conducted in 6 orthotic and prosthetic clinics in Germany. 21 individuals who had been using ***C-Brace*** for at least 6 months and previously used a locked KAFO/SCO/no orthosis prior to ***C-Brace*** answered an online survey that comprised various topics including mobility/functionality, participation, safety, pain, satisfaction, and quality of life.

With ***C-Brace*** compared to traditional KAFOs:

- Improved perception of safety
- Significantly greater general perception of safety (KAFO: 6.4 vs. ***C-Brace***: 3.8 on a 10-point scale [lower scores indicate greater perceived safety])
- Significantly decreased fear of falling (KAFO = 3.4 points, ***C-Brace*** = 1.5 points on a 5-point scale)
- Reduction in falls (Mean number of falls (outliers excluded) significantly decreased from 12.1 falls per year with KAFO to 0.5 falls with the ***C-Brace***)
- Significant reduction in restrictions to activities of daily living (ADLs) (Significantly greater ability to perform ADLs in 3 out of 4 ADL situations)
- Reduction in pain impact on daily life (On a Likert scale of 1 to 5, pain impact on daily living decreased significantly from 3.7 with KAFO to 1.7 with ***C-Brace***)
- Improvements in Quality of Life (QoL) (73% reported significant better and 20% better QoL with ***C-Brace***)



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 (SCO) or locked KAFO[4]. Baseline assessments were performed with previous orthosis (locked KAFO or SCO), ***C-Brace*** assessments were performed after at least 7 weeks of wearing.

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

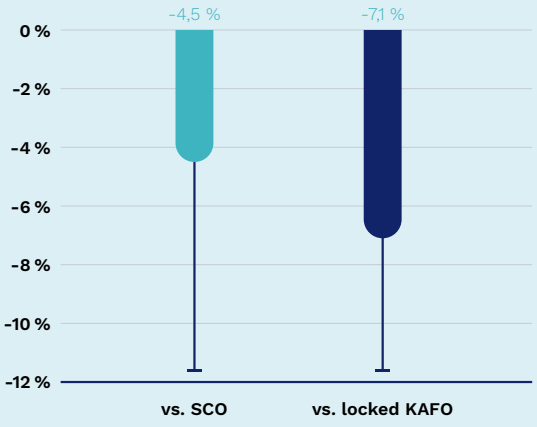
Another gait laboratory study conducted in 5 subjects measured the oxygen (O2) consumption while walking* and assessed safety after forced stumbles[1].

Results with *C-Brace* showed:

- 2 of 3 subjects previously wearing SCOs had reduced O2 costwalking on level ground with the ***C-Brace***
- Both subjects previously wearing locked KAFOs showed reduced energy cost 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.

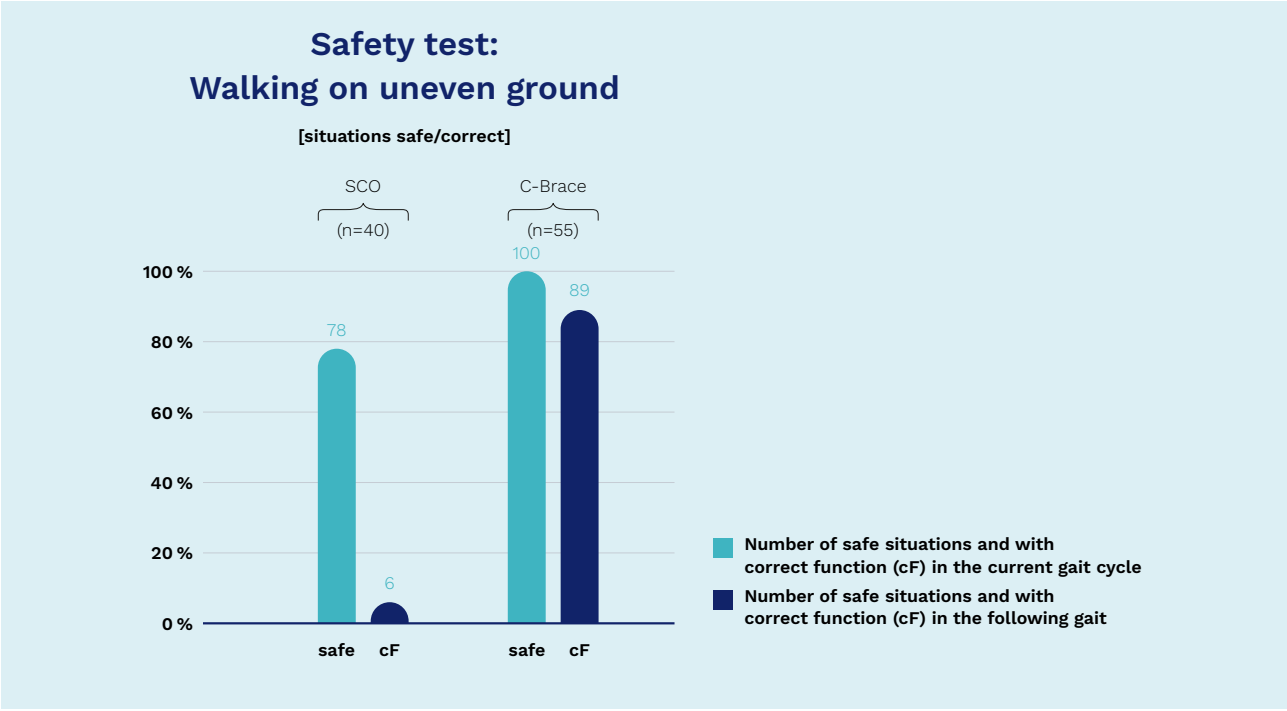
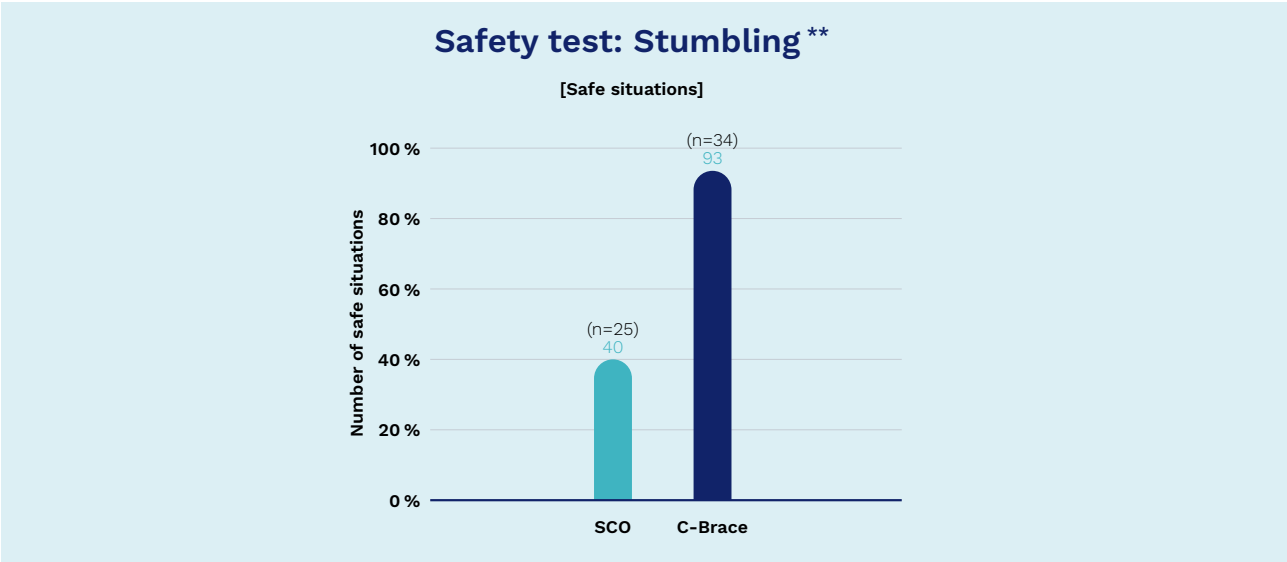


Chart “Safe situations”: 60 % of the stumbles simulated with the SCO would have likely resulted in a fall, whereas only 7% would have with the ***C-Brace***.



** 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.

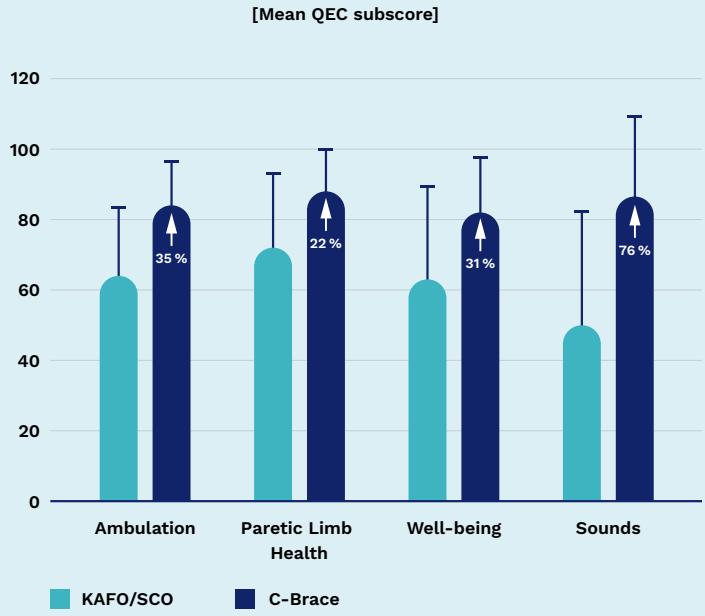
Multi-center observational study

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[6]. 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



* *(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.*

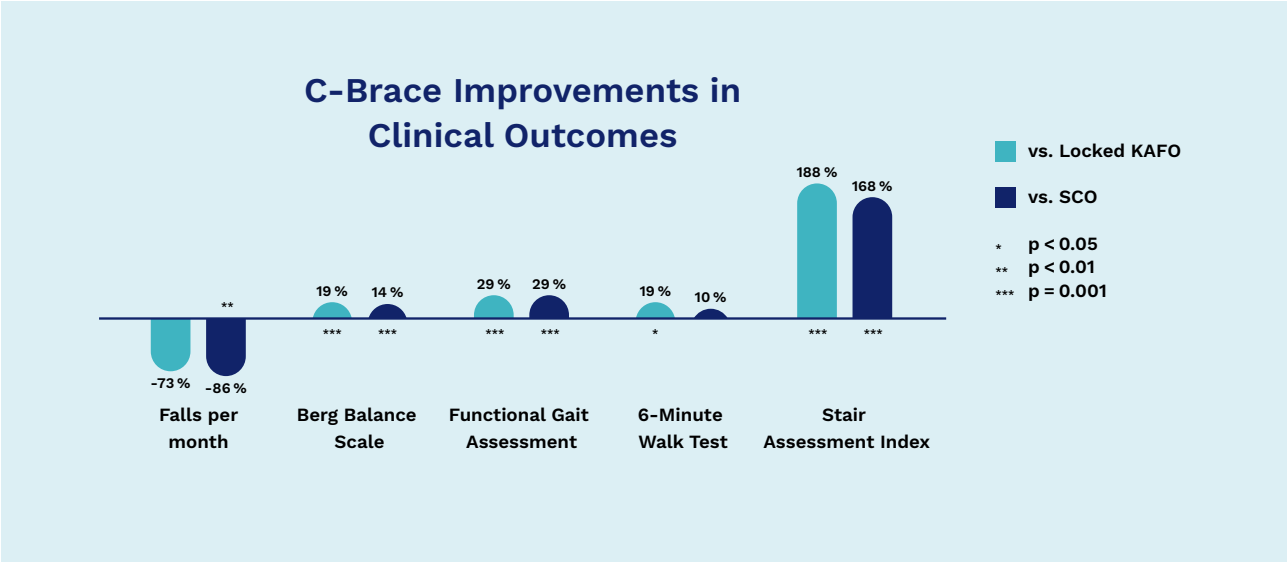
Comparative effectiveness (vs. conventional KAFOs).

Randomized Control Trial (RCT) (Shirley Ryan Ability Lab)

Eighteen subjects wearing locked KAFOs or SCOs completed a study to compare locked KAFOs, SCOs and the ***C-Brace*** in each subject[7]. For each brace, subjects had one month of training and one month of home use before assessments.

Results with *C-Brace* showed:

- Significantly 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



References.

C-Brace studies

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SCO studies

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