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Original article

Impact of a microprocessor-controlled knee-ankle-foot orthosis in community ambulators with quadriceps insufficiency fitted with an SCO: a randomized crossover trial

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ABSTRACT

Background: Community ambulators with quadriceps insufficiency generally use stance control orthoses (SCO) but show limitations in mobility and daily activities.
Objectives: This study compared the impact on mobility of SCO and the C-Brace, an innovative microprocessor-controlled orthosis. We used the PLUS-M™ 12-item self-questionnaire and analyzed the effect on quality of life, endurance, balance confidence, participation, satisfaction, and psychosocial adjustment.
Methods: This international multicenter randomized crossover trial was conducted in 17 rehabilitation centers from two European countries. Community ambulators (ie, ability to walk at 3 km/h) were fitted with the C-Brace and their SCO, in a randomized sequence (2-week transition period). The impact of each orthosis was assessed after 2 months of use in real-life conditions through six self-questionnaires and a walking test.
Results: We recruited 38 participants with quadriceps insufficiency (26 males; 12 females; mean age 52.3; SD 12.8). The analysis on the per-protocol (PP) cohort ($n = 30$) showed that the mobility score (PLUS-M) significantly improved (+21.5 %; $p < 0.001$) with the C-Brace. Similarly, the EQ-5D utility significantly improved (+27.2 %; $p < 0.001$), as well as the health scores (+21.6 %; $p = 0.002$). The 6MWT score was significantly

Abbreviations: ABC, Activities-specific Balance Confidence; AE, Adverse events; BMI, Body mass index; ITT, Intention To Treat; KAFO, Knee-ankle-foot orthosis; mITT, Modified Intention to treat; PIADS, Psychosocial Impact of Assistive Devices Scale; PO-KAFO, Posterior Offset Knee-Ankle-Foot-Orthosis; PP, Per-protocol; PSFS, Patient-Specific Functional Scale; QUEST, Quebec User Evaluation of Satisfaction with Assistive Technology; SCO, Stance control orthoses

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($p < 0.001$) improved by 65.9 (SD 84.2) meters (+19.5 %). Balance, functional, and user satisfaction scores also showed significant improvement ($p < 0.001$), and the global PIADS score improved by +60.0 % on the [-3; +3] scale. Moreover, the C-Brace led to a significant ($p = 0.005$) decrease in the use of walking aids when walking outdoors. Safety has been reported as the most important satisfaction criterion for participants. In all, 86.7 % of participants preferred the C-Brace to their SCO.

Conclusions: Community ambulators with limited knee stability in the stance phase could benefit greatly from this microprocessor-controlled KAFO to improve their outdoor mobility and facilitate completion of daily activities.

Introduction

Quadriceps insufficiency related to the paralysis of knee extensors or paresis is caused by neuromuscular or neurological diseases such as post-polio syndrome, spinal cord injury and multiple sclerosis. Quadriceps insufficiency leads to severe disability and may require the use of a knee-ankle-foot orthosis (KAFO) for walking. People who are at high risk of falling are generally equipped with a locked KAFO (LKAFO). Otherwise, a KAFO with posterior offset (PO-KAFO) is used, providing a free swing phase and avoiding knee flexion during the stance phase as long as the load line is anterior to the knee center. Unlike these traditional orthoses, stance control orthoses (SCO) integrate an automatic knee locking and unlocking system. The SCOs are mainly used by active people, able to manage a free swing phase, looking for a high level of mobility and a safe locking system to move in indoor and outdoor conditions. Unlike LKFOs users who are forced to walk with a locked knee, SCO users can walk with a swing phase on flat ground, avoiding hip hiking strategy, leg circumduction, or vaulting gait [1−4]. However, SCOs have not shown a reduction in energy expenditure [5] and controlled knee flexion on uneven ground, downstairs, or downhill [6]. SCOs users face restrictions in mobility, transportation, and daily activities, including family and social life, sports, and leisure [7].

The C-Brace is a microprocessor stance and swing control orthosis (MP-SSCO). The resistance of knee flexion and extension during the stance and swing phases is adjusted based on sensor signals providing knee angle variation under load. The orthosis restores the damaged eccentric actions of knee extensors, dampening knee flexion during the initial stance phase and loading response, absorbing the shock at heel strike, allowing one to sit down naturally, and to walk safely on uneven ground, downstairs, or downhill [8].

Previous research studies showed that the C-Brace improves gait speed, endurance, as well as static and dynamic balance [6,8−10]. However, the benefits of C-Brace in the specific group of community ambulators, who usually use a SCO, have not been confirmed yet.

The main objective of this study was to compare the impact of the SCO and the C-Brace on mobility in community ambulators, using the PLUS-M™ 12-item self-questionnaire, to provide clinical evidence to Health Authorities in charge of reimbursement decisions. C-BRACE was compared with SCO as it is the most common orthosis provided to community ambulators with quadriceps insufficiency. In addition, we also compared the impact of both orthoses on QOL, endurance, balance confidence, participation, satisfaction, and psychosocial adjustment.

Material and methods

Design

This research is an international multicenter randomized crossover trial in which the participants served as their own control.

Regulatory and ethical aspects

The study received the authorization from the National Agency for the Safety of Medicines and Health Products (*L'Agence nationale de sécurité du médicament et des produits de santé*, ANSM) on February 16, 2022 (N° IDRCB 2022-A00116−37). The study was also approved by the ethics committee in France (*Comité de protection des personnes in Ile de France*) on March 10, 2022, and by the ethics committee of Göttingen in Germany (*Ethik-Kommission der Universitätsmedizin Göttingen*) on June 24, 2022. License fees have been paid to EuroQol Research Foundation for the use of EQ-5D-5 L.

Assessed devices

Participants compared two devices:

- Stance Control Orthoses (SCO): knee, ankle, foot orthoses from different manufacturers (ie, E-Mag Active manufactured by Otto Bock, SPL-Basko by Basko Healthcare, Neuro Tronic by Fior & Gentz). SCO offers a locked stance phase and free swing phase, but the knee remains extended during the stance phase and totally unlocked for sitting down.
- C-Brace: microprocessor-controlled stance/swing KAFO manufactured by Otto Bock HealthCare Product GmbH, first commercialized in 2010, improved in 2017 with reduced weight (1000 g versus 1400 g) and height (193 mm versus 280 mm). Based on a 3D sensor technology and complex algorithms, the microprocessor detects situations (sitting, standing, walking), analyses gait, and adjusts (100 Hz) knee flexion and extension resistances accordingly.

Study location and duration

A total of 17 specialized orthopedic centers with experience in SCO participated in the study (see the list of author affiliations). The participants were enrolled from the 29th of April 2022 to the 31st of August 2022. The study was conducted between April 29th, 2022 (date of first enrollment) and April 17th, 2023 (last follow-up visit).

Participant selection criteria

The inclusion criteria for the participants were the following:

- Person with quadriceps insufficiency, confirmed by the assessment of muscle strength on the 0 to 5 MRC (Medical Research Council) scale, used in people with neuromuscular or neurological disease, including polio survivors [11].
- Person using a SCO for at least 3 months, walking with a swing phase on a flat ground, without walking aids, or with one cane or one crutch.
- Person with the ability to walk at 3 km/h (measured with a 10-meter walk test) with the SCO in unlocked mode. A walking speed measurement with a cut-off value of 3 km/h was chosen to identify community ambulators based on the observational study of Brehm et al. conducted in polio survivors, reporting 6- walking distances for house walkers (275 m, 2.75 km/h), limited community ambulator (323 m; 3.25 km/h) and full community walker (385 m; 3.85 km/h) [12].
- Person with a stable stance phase on the contralateral side, even if the limb was affected by some loss of motor control, for instance, checked by asking the participant to stand on one leg with the knee fully extended, then partially bent.

The exclusion criteria concerned people who were incompatible with the protocol of the study and those with contraindications for C-Brace (Appendix A).

The calculation to determine the number of subjects required for the trial was performed by QUANTA MEDICAL VCLS (Soft SAS® version 9.4 Procedure POWER), considering an approximated normal distribution, bilateral paired Student *t*-test, and risk of $\alpha = 0.05$ in a randomized crossover design. The hypothesis was an improvement of the primary outcome measure (PLUS-M™), higher than the minimum detectable change of 5.36 suggested by Hafner et al. [13], from an initial score estimated at 50.1 (5.9) based on internal data from the promoter (not published) collected within the Medical Device Regulation Surveillance of the SCO E-Mag Active. Considering a 15 % loss of participants during follow-up, the size of the cohort to be enrolled was initially set to a minimum of 36 participants.

Study process and design

Potential participants were identified in the patient databases from the participating neuro-orthopedic centers. The people who met the inclusion criteria were then contacted by the investigating physicians and invited to participate in the study. Participant enrollment, clinical evaluations, and data collection were ensured by the investigators. After obtaining their written consent, each participant was randomly assigned, by the electronic Case Report Form (eCRF), to the CB/SCO or the SCO/CB arm, ie, the order in which the 2 orthoses were fitted differed depending on the study arm. A custom-made KAFO orthosis with C-Brace joint was manufactured for each participant and then returned to the manufacturer after the trial period. The SCO used by participants was their personal orthosis.

For each orthosis, the follow-up period lasted 2 to 3 months (the study protocol included a margin of 4 weeks). Between the 2 follow-up periods, a minimum of a 2-week transition period was required during which participants used their SCO. In the SCO/CB arm, the transition period was necessary to adjust the C-BRACE orthosis with the participant before the trial; in the CB/SCO arm, this period was necessary to ensure that the participant was confident walking again with his/her SCO before the assessment period started. A 2-week duration was considered necessary, with no impact on results in the event of a longer transition period. In all, 2 evaluations were performed, one at the end of each follow-up period.

Several rehabilitation sessions were provided to participants after receiving the C-Brace orthosis. The protocol imposed a minimum of 4 h of rehabilitation. As participants were experienced SCO users accustomed to walking with a free swing phase, they could learn to walk with the C-Brace in just a few hours. However, the rehabilitation duration could be extended according to the needs of participants. Indeed, the frequency and number of rehabilitation sessions were left to the decision of the investigating physicians. The rehabilitation exercises were conducted according to a standard protocol.

When using an SCO, the orthotic knee joint is locked during the stance phase. With C-Brace, participants were taught how to use safely and naturally the flexion of the knee during the stance phase in different conditions such as standing, sitting up and down, walking on flat and uneven surfaces, on slopes and stairs altering steps (Appendix B). After the C-Brace follow-up period and the re-fitting of participants with their SCO, a 1-h rehabilitation session was required with the SCO to ensure that the participants could use their orthoses safely again.

Data collection

The data was collected and processed via the electronic Case Report Form (eCRF) set up by EVAMED, a certified external Contract Research Organization. A Data Management Plan and several controls were set up to prevent incoherent data. The eCRF was completed and validated by the main investigator in each participating center. The paper questionnaires completed by the participants were scanned and downloaded into the eCRF by the investigators.

Primary outcome measures

Mobility questionnaire - PLUS-M™ 12-item. The mobility of participants (ie, the ability to move intentionally and independently from one place to another) was assessed with the PLUS-M™ 12-item self-questionnaire, available in French and German (www.plus-m.org). It was initially developed for users of external prostheses who face the same challenges as KAFO users [14]. PLUS-M™ questions assess the respondents' perceived ability to carry out basic (ie, walking a short distance indoors) and complex activities (ie, hiking for long distances over uneven ground) that require the use of both lower limbs. The PLUS-M™ 12-item short form provides a t-score that ranges from 21.8 to 71.4. A higher score is representative of better mobility.

Secondary outcome measures

Quality of life questionnaire - EuroQol - 5 Dimensions - 5 levels (EQ-5D-5 L). The EuroQol - 5 Dimensions - 5 levels (EQ-5D-5 L) is a scale developed by the EuroQol group in 2009. The EQ-5D-5 L scale was preferred to other instruments as it is a globally used and validated tool to assess health-related quality of life, allowing comparisons with the global population. This scale, available in French and German, includes 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, rated on 5 levels, from "no problems" to "extreme problems" [15]. The health status is defined by an index value ranging from 0 (meaning a state as bad as being dead) to 1 (meaning full health). This score was computed based on French or German value sets, depending on the participant's country [16]. The EQ-5D-5 L also includes a Visual Analogue Scale (EQ-VAS) to record participants' self-rated health, from 0 ("the worst health you can imagine") to 100 ("the best health you can imagine").

Endurance - 6-min walk test (6MWT). The 6MWT is a functional walking test to evaluate the distance that a person can walk on an even ground floor within 6 min. The 6MWT is a reliable instrument used with polio survivors and users of SCO or C-Brace orthoses [4,9,17,10,18].

Balance confidence - simplified Activities-specific Balance Confidence (ABC-s). The simplified version of the Activities-specific Balance Confidence (ABC-s) scale is a self-report measure of the perceived balance confidence an individual has while completing various ambulatory activities. This study used the simplified version of the ABC-s, developed and translated into French in 2007 [19–22]. The scale includes 15 items and evaluates confidence on 4 levels from "very confident" to "not at all confident." The global score, ranging from 0 to 45, is then converted into a percentage. A higher score represents better confidence. The German version was constructed for the study, from the available German version of ABC (16 items), removing the last item ("walk on ice sidewalks"), according to the simplified ABC-s version.

Participation - Patient-Specific Functional Scale (PSFS). PSFS is a person-specific measure of participation for important functional activities in people with musculoskeletal disorders [23]. Participants identified three activities that are important to them but are either unable to perform or are challenging, as a result of their disability. Participants were asked to rate their current ability to complete these activities using an 11-point scale, where 0 is "cannot perform the activity at all" and 10 is "can perform the activity fully." Due to the study design, activities monitored with the PSFS focused on the social, familial, and professional lives of participants. Activities such as competitive sports, running, and water activities were excluded because these activities are not possible or allowed with either the SCO or the C-Brace.

Satisfaction - Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0). User satisfaction was evaluated with the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) available in French and German [24]. Participants evaluated their satisfaction level with the technology of their assistive device (8 items) and services (four items). The self-questionnaire also allows participants to state the criteria that are most important to them. The mean satisfaction value can be calculated on a scale ranging from 1 to 5, with 1 being "Not at all satisfied" and 5 being "Very satisfied". The final QUEST score is the average obtained for all 12 items. Technology and services subscores can also be calculated. A better score is indicative of better satisfaction.

Psychosocial adjustment - Psychosocial Impact of Assistive Devices Scale (PIADS). The Psychosocial Impact of Assistive Devices Scale (PIADS) is a 26-item questionnaire available in French and German, which assesses the effects of an assistive device on functional independence, well-being, and quality of life from the disabled person's point of view [25–27]. Each item is rated on a 7-point Likert scale ranging from −3 (maximum negative impact) to +3 (maximum positive impact). Items are spread among 3 sub-scales titled "Competence," "Adaptability," and "Self-esteem." A higher score relates to a better psychosocial adjustment. The PIADS was administered only once, after the use of the C-Brace, as the scale directly measures the difference between the two devices.

Additional data. At the end of the 2-month trial period, the investigator asked the participant to estimate the average frequency of use of the orthosis during the last month, in number of days per week and number of hours per day. At the end of the study, the participants were asked whether they preferred their SCO or the C-Brace orthosis.

Statistical analysis

Study cohorts

Statistical analyses were performed on three cohorts:

- Intention To Treat (ITT) cohort: participants enrolled and randomized during the inclusion period.
- Modified ITT (mITT): participants of the ITT cohort who started the C-Brace trial phase.
- PP cohort: participants without any major deviation from the protocol, including missing data on the primary outcome measure; inclusion criteria not respected; missing inclusion date; missing follow-up visit date; missing C-Brace fitting date; missing data on safety items; use of SCO <60 days; use of C-Brace out of range (ie, between 60 and 92 days); wash out period <15 days.

An exploratory analysis was conducted on four sub-groups (participants initially walking with or without walking aids and participants with or without contralateral deficiency) in order to discuss the interest in conducting further research.

Statistical tests

Statistical analyses were performed by EVAMED using RStudio software version 2022.02.1 + 443 and R language version 4.1.2 (2021−11−01). The Shapiro-Wilk test was used to check the normal distribution. Depending on the distributions, Fisher's test, Student's T-test, Welch's T-test, and the Wilcoxon Mann-Whitney test were used to compare quantitative variables. The Independence Chi-2 test and Fisher's exact test were used for qualitative variables. A paired Student's T-test or Wilcoxon signed rank test was used to compare two paired samples depending on the distribution of the difference. McNemar's test was used for dichotomous variables. A p-value under .05 was considered statistically significant.

Crossover analyses

Crossover analyses (test of carry-over, period, and treatment effects) on quantitative variables were performed using methods described in Hills & Armitage (crossover parametric analyses) and Koch et al. (crossover nonparametric analyses) [28,29]. Crossover analyses on binary endpoints were performed using Prescott's method, as described by Jones & Kenward [30].

Missing data

Missing data were not replaced (Table 2). They were not considered for the percentage calculation and for statistical tests.

Results

Characteristics of the participants

In this study, a total of 38 participants (32 in France, 6 in Germany) were enrolled (ITT; $n = 38$) and randomized in 2 arms (Fig. 1). One ($n = 1$) participant withdrew from the study immediately after enrollment. The remaining 37 participants, ie, the mITT cohort, used the C-BRACE orthosis at least once. However, ($n = 6$) participants quit the study before the final assessment, due to an adverse event ($n = 5$) or loss to follow-up ($n = 1$). One ($n = 1$) participant completed the study with major deviations regarding trial duration. In all, 30 participants completed all assessments without any major deviation from the protocol (PP; $n = 30$). The demographic data of the ITT and PP cohorts are presented in Table 1. The participants' flow diagram of the ITT, mITT, and PP cohorts is presented in Fig. 1.

Difference between randomized groups

No significant differences were detected between the 2 randomized groups (CB/SCO and SCO/CB) in the PP cohort according to age, height, weight, body mass index (BMI), activity levels, etiologies, affected side, types of SCO, muscle strength, and muscle spasticity.

Trial durations and use of orthoses

In the PP cohort, the mean trial durations were 73.6 days (SD 7.2) with the C-Brace and 75.1 days (SD 15.6) with the SCO (Table 2). Most participants reported that they used the C-Brace every day (21/30; 70 %) and >8 h per day (18/30; 60 %). The SCO was also mostly used every day (19/30; 63 %) and >8 h per day (16/30; 53 %).

The transition period duration was 15 days in the CB/SCO arm and 34 days in the SCO/CB arm. Delays in C-Brace orthoses fabrication occurred in both arms, but impacted the duration of the transition period in the SCO/CB arm only.

Primary and secondary outcome measures

The results are summarized in Table 3 for the mITT and PP cohorts. There were no significant carry-over effects and no significant period effects for any of the 7 outcome measures. The analysis focuses on the PP cohort.

Mobility - PLUS-M™ 12-item

The PLUS-M mobility score significantly ($p < 0.001$) improved by + 9.9 points (+21.5 %) with the C-Brace ($M = 55.9$; SD 8.5) in comparison with SCO ($M = 46.0$; SD 6.4).

Quality of life - EQ-5D-5 L

The quality of life, measured with the EQ-5D-5 L Utility score, was significantly ($p < 0.001$) improved with the C-Brace ($M = 0.880$; SD 0.106) compared to SCO ($M = 0.692$; SD 0.296). The EQ-VAS health score was also significantly ($p = 0.002$) higher with the C-Brace ($M = 76.3$; SD 17.4) compared to SCO ($M = 63.0$; SD 21.8).

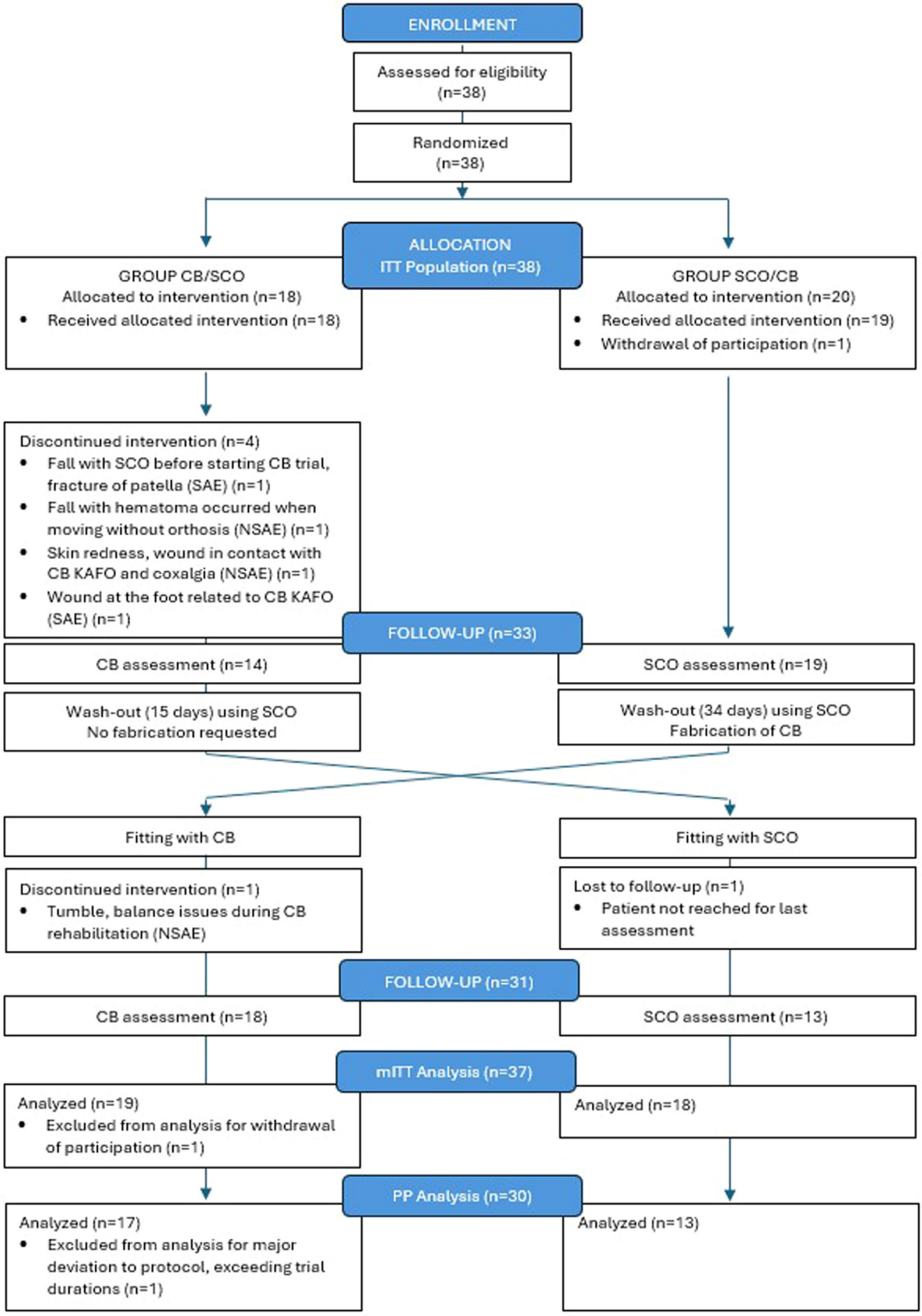

Fig. 1. Participants flow diagram.

Table 1
Demographic data for the ITT and PP cohorts.

	ITT cohort (n = 38)	PP cohort (n = 30)[b]
Sex		
Female, n (%)	12 (31.6)	10 (33.3)
Male, n (%)	26 (68.4)	20 (66.7)
Age at enrollment (years), Mean (SD) [Min - Max]	52.3 (12.8) [30.7−83.0]	50.8 (11.3) [30.7−83.0]
Height (cm), Mean (SD [Min - Max]	170.9 (10.4) [147.0 −197.0]	170.5 (10.3) [150.0 −197.0]
Weight w/o orthosis (kg), Mean (SD [Min - Max]	75.3 (14.9) [47.5−105.0]	75.7 (15.1) [47.5−105.0]
Body Mass Index (kg/m^2), Mean (SD [Min - Max]	25.8 (4.5) [17.9−35.6]	26.0 (4.8) [17.9 - 35.6]
Employment status		
Professional activity, n (%)	16 (42.1)	14 (46.7)
No professional activity, n (%)	11 (28.9)	10 (33.3)
Retired, n (%)	11 (28.9)	6 (20.0)
Sport / Leisure / Hobbies		
Yes, n (%)	27 (71.1)	22 (73.3)
No particular sport/leisure/Hobby, n (%)	11 (28.9)	8 (26.7)
Activity level (ICF-WHO)		
ICF d4602 / K2, n (%)	22 (57.9)	17 (56.7)
ICF d4608 / K3, n (%)	16 (42.1)	13 (43.3)
Main living environment		
Urban, n (%)	25 (65.8)	20 (66.7)
Rural, n (%)	13 (34.2)	10 (33.3)
Etiology		
Poliomyelitis, n (%)	20 (52.6)	16 (53.3)
Spinal cord injury, n (%)	2 (5.3)	1 (3.3)
Ponytail syndrome, n (%)	1 (2.6)	1 (3.3)
Isolated traumatic affection of lower limb, n (%)	4 (10.5)	3 (10.0)
Other [(a)], n (%)	11 (28.9)	9 (30.0)
Side affected (fitted with SCO)		
Left, n (%)	20 (52.6)	16 (53.3)
Right, n (%)	18 (47.4)	14 (46.7)
Type of orthosis (SCO)		
E-Mag Active, n (%)	30 (78.9)	25 (83.3)
SPL-Basko, n (%)	7 (18.4)	4 (13.3)
NEURO TRONIC, n (%)	1 (2.6)	1 (3.3)
Contralateral side		
No deficiency, n (%)	32 (84.2)	26 (86.7)
Ankle foot orthosis (AFO), n (%)	0 (0)	0 (0)
Orthopedic shoe, n (%)	2 (5.3)	2 (6.7)
Orthotic insole, n (%)	3(7.9)	1 (3.3)
Orthotic heel pad, n (%)	1 (2.6)	1 (3.3)
Other disabilities		
Yes, n (%)	6 (15.8)	5 (16.7)
No, n (%)	32 (84.2)	25 (83.3)
Muscle strength (Janda scale)		
Hip extensors, Mean (SD) [Min - Max]	3.0 (1.5) [0.0−5.0]	2.9 (1.5) [0.0−5.0]
Hip flexors, Mean (SD) [Min - Max]	2.6 (1.4) [0.0−5.0]	2.6 (1.4) [0.0−5.0]
Knee flexors, Mean (SD) [Min - Max]	2.6 (1.6) [0.0−5.0]	2.3 (1.6) [0.0−5.0]
Knee extensors, Mean (SD) [Min - Max]	1.3 (1.2) [0.0−4.0]	1.2 (1.1) [0.0−3.0]
Plantar flexors, Mean (SD) [Min - Max]	2.1 (1.7) [0.0−5.0]	1.9 (1.8) [0.0−5.0]
Dorsi flexors, Mean (SD) [Min - Max]	1.9 (1.9) [0.0−5.0]	1.7 (1.9) [0.0−5.0]
Muscle spasticity (Modified Ashworth Scale)		
Knee extensors at 0, n (%)	36 (94.7)	29 (96.7)
Knee extensors at 2, n (%)	2 (5.3)	1 (3.3)
Plantar flexors at 0, n (%)	36 (94.7)	29 (96.7)
Plantar flexors at 2, n (%)	2 (5.3)	1 (3.3)

(a) Other etiologies : Stroke; operated left deficient cruralgia ; Guillain-Barre ; retroperitoneal liposarcoma with psoas muscle lesion ; Lyme disease ; polytrauma ; multiple sklerosis. No missing data.
(b) In PP cohort, no significant differences were detected between randomized groups (CB/SCO and SCO/CB) according to age, height, weight, body mass index, activity levels, etiologies, affected side, types of SCO, muscle strength, and muscle spasticity.
ITT: Intention to treat, PP: per protocol, SCO: stance control orthoses.

Endurance - 6MWT

The distance covered during the 6 min was significantly ($p < 0.001$) improved with the C-Brace (M = 404.3; SD 126.4 m) in comparison with SCO (M = 338.4; SD 108.5 m).

Balance Confidence - simplified ABC-s

The ABC-s score measuring balance confidence was significantly ($p < 0.001$) improved with the C-Brace (M = 83.6; SD 17.6) in comparison with SCO (M = 54.8; SD 21.5).

Participation - PSFS

The PSFS score significantly ($p < 0.001$) improved with the C-Brace (M = 7.0; SD 2.6) in comparison with SCO (M = 2.9; SD 1.8). Activities focused on mobility challenges encountered in daily life, such as: “play with children in the garden;” “walk without walking aids;” “walk downstairs and upstairs;” “walk on ramps;” “biking;” “hiking on uneven ground;” “walking for a long time (>1 h);” “reduce concentration on each step during walking,” “carry out bags,” “practicing sport activities,” “carrying a baby or child when walking,” etc.

Table 2
Duration of the trial period and frequency of use of the devices.

	SCO	C-Brace
Time of use of the device in the trial (days)		
Mean (SD)	75.1 (15.6)	73.6 (7.2)
Median	70.5	72.5
Q1 - Q3	63.0 - 83.8	70.0 - 76.8
Min - Max	60.0 - 126.0	63.0 - 91.0
Weekly use of the device		
Every day, n (%)	19 (63.3)	21 (70.0)
5 to 6 days per week, n (%)	4 (13.3)	2 (6.7)
3 to 4 days per week, n (%)	1 (3.3)	3 (10.0)
1 to 2 days per week, n (%)	3 (10.0)	2 (6.7)
<1 day per week, n (%)	1 (3.3)	2 (6.7)
The participant stopped using the orthosis, n (%)	2 (6.7)	0 (0)
Daily use of the device		
>12 h per day, n (%)	11 (36.7)	8 (26.7)
From 8 to 12 h per day, n (%)	5 (16.7)	10 (33.3)
From 5 to 8 h per day, n (%)	6 (20.0)	5 (16.7)
From 1 to 5 h per day, n (%)	4 (13.3)	6 (20.0)
Less than 1 h per day, n (%)	4 (13.3)	1 (3.3)

No missing data. SCO: stance control orthoses.

Satisfaction - QUEST 2.0

The QUEST score used to measure global satisfaction significantly ($p < 0.001$) improved with the C-Brace ($M = 4.5$; SD 0.4) in comparison with SCO ($M = 4.0$; SD 0.6). Satisfaction regarding the device and the services provided was higher with the C-Brace (+0.6 points) than with SCO (+0.4 points). The most important items reported by participants were safety, effectiveness, and weight after the use of C-Brace. In contrast, after the use of the SCO, the main items were safety, effectiveness, and comfort.

Psychosocial adjustments - PIADS

Global score on the PIADS scale, which measured the psychosocial adjustment after participants were fitted with the C-Brace, improved by 1.8 points; SD 0.6, on the [−3; +3] scale.

Participant preference

At the end of the study, 87 % of participants (PP: 26/30) preferred the C-Brace, and only 13 % (PP: 4/30) preferred the SCO.

Use of walking aids indoors and outdoors

No significant change was observed in indoor conditions regarding the use of walking aids, as 80 % (24/30) of participants had the same walking aid habits with SCO and the C-Brace. However, participants significantly reduced ($p = 0.005$) the use of walking aids in outdoor conditions with the C-Brace, as 30 % (9/30) of participants did not require aids anymore (Table 4).

Rehabilitation hours with the C-Brace

The mean duration of rehabilitation was 6.5 h (SD 4.4 h, Min = 4 h, Max = 25 h).

Table 3
Results for primary and secondary outcomes.

	mITT ($n = 37$)			PP ($n = 30$)		
	SCO	C-BRACE	*p*-value	SCO	C-BRACE	*p*-value
PLUS-M T-score						
Mean (SD)	45.8 (6.3)	56.0 (8.5)	<0.001	46.0 (6.4)	55.9 (8.5)	<0.001
Min ; max	34.9 ; 64.5	36.4 ; 71.4		34.9 ; 64.5	36.4 ; 71.4	
Missing data, n(%)	*5 (13.5)*	*4 (10.8)*		*0 (0.0)*	*0 (0.0)*	
EQ-5D-5 L, Mean (SD)						
EQ-5D-5 L Utility score	0.698 (0.289)	0.874 (0.110)	<0.001	0.692 (0.296)	0.880 (0.106)	<0.001
Missing data, n(%)	*5 (13.5)*	*4 (10.8)*		*0 (0.0)*	*0 (0.0)*	
EQ-VAS (Health score)	62.0 (21.4	75.9 (17.8	0.0016	63.0 (21.8	76.3 (17.4	0.0018
Missing data, n(%)	*6 (16.2)*	*4 (10.8)*		*1 (3.3)*	*0 (0.0)*	
6MWT, Mean (SD)	332.9 (108.8)	395.8 (125.1)	<0.001	338.4 (108.5)	404.3 (126.4)	<0.001
Missing data, n(%)	*5 (13.5)*	*4 (10.8)*		*0 (0.0)*	*0 (0.0)*	
ABC-s, Mean (SD)	55.5 (21.3)	82.7 (18.2)	<0.001	54.8 (21.5)	83.6 (17.6)	<0.001
Missing data, n(%)	*5 (13.5)*	*4 (10.8)*		*0 (0.0)*	*0 (0.0)*	
PSFS, Mean (SD)	3.1 (1.9)	6.9 (2.5)	<0.001	2.9 (1.8)	7.0 (2.6)	<0.001
Missing data, n(%)	*5 (13.5)*	*4 (10.8)*		*0 (0.0)*	*0 (0.0)*	
PIADS, Mean (SD)						
PIADS - Global score		1.7 (1.1)			1.8 (1.1)	
Missing data, n(%)		*6 (16.2)*			*1 (3.3)*	
PIADS - Competence sub-score		1.7 (1.1)			1.8 (1.1)	
Missing data, n(%)		*6 (16.2)*			*1 (3.3)*	
PIADS - Adaptability sub-score		1.8 (1.2)			1.8 (1.2)	
Missing data, n(%)		*4 (10.8)*			*0 (0.0)*	
PIADS - Self-esteem sub-score		1.6 (1.1)			1.7 (1.0)	
Missing data, n(%)		*5 (13.5)*			*0 (0.0)*	
QUEST 2.0, Mean (SD)						
QUEST - Global score	4.0 (0.7)	4.5 (0.4)	<0.001	4.0 (0.6)	4.5 (0.4)	<0.001
Missing data, n(%)	*5 (13.5)*	*6 (16.2)*		*0 (0.0)*	*1 (3.3)*	
QUEST - Technology sub-score	3.7 (0.7)	4.4 (0.4)		3.8 (0.7)	4.4 (0.6	
Missing data, n(%)	*5 (13.5)*	*6 (16.2)*		*0 (0.0)*	*1 (3.3)*	
QUEST - Services sub-score	4.5 (0.6)	4.8 (0.4)		4.5 (0.6)	4.9 (0.3	
Missing data, n(%)	*5 (13.5)*	*4 (10.8)*		*0 (0.0)*	*0 (0.0)*	
3 most important items						
Safety, n (%)	27 (84.4)	25 (78.1)		25 (83.3)	23 (76.7)	
Effectiveness, n (%)	18 (56.2)	17 (53.1)		18 (60.0)	17 (56.7)	
Comfort, n (%)	12 (37.5)	12 (37.5)		10 (33.3)	–	
Weight, n (%)	–	12 (37.5)		–	11 (36.7)	
Missing data, n(%)	*5 (13.5)*	*5 (13.5)*		*0 (0.0)*	*0 (0.0)*	
Participant preference, n (%)	4 (12.9)	27 (87.1)		4 (13.3)	26 (84.6)	
Missing data, n(%)		*6 (16.2)*			*0 (0.0)*	

mITT: Modified Intention to Treat; PP: per protocol; SCO: stance control orthoses.

Table 4
Change in the use of walking aids.

	PP cohort (n = 30)	p
Indoor		
Walking with 1cane with SCO but not with C-BRACE, n (%)	4 (13.3)	0.3340
Walking with 2 canes with SCO but not with C-BRACE	1 (3.3)	
Same walking aids habits with C-BRACE and with SCO, n (%)	24 (80.0)	Fisher
Use of walking aids (1 or two canes) with C-BRACE but not with SCO, n (%)	1 (3.3)	
Outdoor		
Walking with 1 cane with SCO but not with C-BRACE, n (%)	7 (23.3)	0.005
Walking with 2 canes with SCO but not with C-BRACE, n (%)	2 (6.7)	
Same walking aids habits with C-BRACE and with SCO, n (%)	21 (70.0)	Fisher
Use of walking aids (1 or two canes) with C-BRACE but not with SCO, n (%)	0 (0)	

No missing data. PP: per protocol; SCO: stance control orthoses.

Adverse events

Serious and non-serious adverse events were defined, categorized, and reported by the investigators according to the European regulation of clinical trials (EU) MDR2017/745. During the study, 29 adverse events (AEs) for 16 different participants were reported. The list of AEs is presented in Appendix C. Ten events occurred when using SCO (35 %), and 19 events occurred when using the C-Brace (66 %). Among the AEs, 24 were qualified as non-serious adverse events, and five were qualified as Serious Adverse Events. Among the five participants who had to definitively interrupt the study after an adverse event: two were injured after a fall when using the SCO or when moving without an orthosis; one participant had balance issues, pain, and fatigue, during the rehabilitation phase with the C-Brace; and, two participants presented skin redness and wounds on different areas in contact with the custom-made C-Brace orthosis.

Discussion

Our results show that the C-Brace significantly improved mobility, participation, and quality of life in community ambulators with quadriceps insufficiency. In outdoor conditions, there was a significant reduction in the use of walking aids with C-Brace. At the end of the study, a vast majority of participants (87 %) preferred the C-Brace rather than their SCO.

This study has potential limitations and biases. The self-questionnaires used here are not validated for people with quadriceps insufficiency using a KAFO, due to a lack of literature and research in this field. The primary outcome measure is not validated. As the primary objective was to measure the impact of C-BRACE on mobility in active SCO users, facing restrictions mainly in outdoor conditions, the use of a self-questionnaire measuring the perceived difficulties encountered in activities of daily life was more relevant than using a functional test performed in indoor conditions. However, self-questionnaires used in orthotics (OPUS-LEFS, PROMIS-PF, LEFS) were not available in French. PLUS-M™ was the only questionnaire available in French and in German, adapted to assess perceived ability to carry out indoor and outdoor activities that require the use of both lower limbs without showing ceiling effects in active walkers. More recently, Balkman et al. reported the limitations of existing questionnaires to assess mobility in orthotics and developed a new tool based on the scoring system of PLUS-M [31]. However, this tool was unavailable when our research started.

Concerning the comparator, it is composed of 3 different orthoses, offering stance control obtained by a mechanical (SPL-Basko) or an electronic (Neuro Tronic, E-Mag Active) locking system. This heterogeneity is nevertheless minimized by the same gait pattern provided to the users (free swing phase, locked stance phase) and by a significant representation of E-Mag Active (25/30; 83 %) covered by public reimbursement in France since 2018. Neuro Tronic was still not covered by public reimbursement in France at that time and was used by German participants only. The SPL-Basko was reimbursed in France in 2011 and was less available at the time of the study. Thus, the results obtained with C-Brace should be nuanced when compared to SCOs in general, as most orthoses were E-Mag Active in this research.

Rehabilitation with C-Brace may require a different number of sessions depending on the participant's needs, and this variability may impact the results. This potential bias is considered acceptable, as it would favor the comparator if some participants did not receive sufficient rehabilitation with the C-Brace. The person's ability to properly use the SCO orthosis was assessed during the inclusion phase, and no rehabilitation was provided before the trial period, as it was the participant's orthosis.

We cannot rule out the possibility that some participants were in a process of abandoning their SCO during the study, which would favor the C-Brace. We also cannot exclude that some participants were not perfectly fitted with the SCO, as 7 AEs were reported, even though there was a walking test at the inclusion visit. A wrong alignment or setting of the knee joint can, for instance, alter the proper functioning of the locking system. Nevertheless, these possible biases seem to be limited, considering the high score of satisfaction at the QUEST (4.0 on 5.0) measured with the SCO during the study.

All results are equally positive in mITT and PP cohorts. As there is a significant amount of missing data in the mITT cohort due to discontinued interventions (n = 6) and loss of follow-up (n = 1), to avoid bias related to missing data, the discussion focuses on results in the PP cohort, where the amount of missing data is negligible.

Mobility was assessed with the PLUS-M scale, measuring the difficulties in moving. This dimension was completed by a 6-min walking test measuring endurance, and an assessment of balance confidence with the ABC-s scale. The PLUS-M score was improved by + 9.9 points (+21.5 %) with the C-Brace. Further research should be conducted to confirm the clinical relevance of this improvement. The 6MWT was improved by 65.9 meters with the C-Brace. This improvement is certainly related to the microprocessor-controlled swing phase provided by C-Brace, not by SCO. There is no MDC defined for KAFO users or for such highly functional participants. However, the improvement is above the MDC (45.8 meters) proposed by Lam et al. for people with incomplete spinal cord injuries [32] or the MDC (58.21 meters) proposed by Perera et al. for geriatric people [33]. Still, individuals fitted with the C-Brace do not perform the 6MWT as fast as healthy adults with similar BMI (26) and age (51), who would walk, in theory, 558 m (women) and 640 m (men) based on the equations of Enright et al. [34]. In contrast to our results, the 6MWT was not improved with C-Brace among indoor and limited community walkers [10]. It suggests that C-Brace may support a comfortable walking speed over a longer distance in community ambulators only. Balance confidence, measured with the ABC-s self-questionnaire, was significantly improved ($p < 0.001$) by 29 %. With an ABC-s score of 55 %, under 67 %, the people fitted with a SCO can be considered as a population at risk of falling according to Lajoie et al. [35]. With the C-Brace, the ABC-s score was >80 % and the risk of falling was reduced. This result is consistent with the study of Ruetz et al., who also reported a reduced risk of falling with the C-Brace [10]. Improvement of balance confidence is important for people with quadriceps insufficiency, as reported by Raijmakers et al. in polio survivors, where most participants use the KAFO to improve stability when walking (73 %) or standing (64 %) [36].

The impact on participation was assessed with the PSFS scale, a reliable tool in community-dwelling older adults, people with knee dysfunction, or lower limb amputation [37–39]. PSFS scores significantly ($p < 0.001$) improved with the C-Brace. Items differ from one person to

another, but as these were important activities of daily life, difficult to manage with the SCO from the participants' own perspective, we consider these improvements to be clinically relevant.

These measurable changes in mobility and participation significantly impacted the quality of life of participants. The EQ-5D-5 L Utility score significantly ($p < 0.001$) improved with the C-Brace, reaching a value (0.880) close to values reported for the French cohort (0.905) by Gautier et al. [40,32] or for the German cohort (0.88) by Grochtdreis et al. [41]. Ruetz et al. also reported an improved (but not significant) EQ-5D-5 L Utility score with the C-Brace (0.752) compared to conventional KAFO or SCO (0.727), in a cohort (mean age 55.5) with a moderate activity level and a high risk of falling [10]. Results from the PIADS questionnaire are consistent with the EQ-5D-5 L improvements and confirm the positive psychosocial effects of the C-Brace in the 3 sub-dimensions "competence," "adaptability," and "self-esteem." The 7-point Likert scale of the PIADS, ranging from −3 (maximum negative impact) to +3 (maximum positive impact), facilitates the use of this instrument in clinical practice as it is administered only once. However, the absence of scores before and after does not allow statistical tests to be carried out on the difference and limits interpretation.

The global satisfaction for the C-Brace significantly improved when compared to SCO, confirming the participants' satisfaction concerning the functionalities of the C-Brace despite its additional weight (1 Kg). With both devices, the two most important criteria of satisfaction for participants were safety and effectiveness. This is to be expected in community ambulators, as these aspects are very important in outdoor activities performed in challenging environments. However, the weight of the orthosis remains a significant concern for participants, as it is mentioned as the third most important criterion in the C-Brace assessment. Regarding the SCO, the third criterion was "comfort," certainly related to the static and locked stance phase, and the lack of shock absorption during heel strike.

An exploratory analysis showed that with the C-Brace, improvements in mobility were similar for participants initially walking with aids ($n = 14$; difference in PLUS-M t-score of 10.1; SD 12.4) or without aids ($n = 16$; difference in PLUS-M t-score of 9.7; SD 7.5 points). It also showed that the mobility of the 26 participants with no contralateral deficiency improved with the C-Brace (difference in PLUS-M t-score of 11.5; SD 9.8 points) whereas no improvement was noted in the 4 participants with a contralateral deficiency at the foot, users of orthopedic shoes ($n = 2$), insole ($n = 1$) or heel pad ($n = 1$), (difference in PLUS-M t-score of −0.0; SD 1.3 points). However, the mean scores of all the secondary outcome measures improved in these 4 participants: EQ-5D-5 L Utility (+0.300; SD 0.502), EQ-5D-5 L Health score (+20.8; SD 31.1), ABC-s (+11.7; SD 9.0), PSFS (+1.7; SD 1.2), QUEST 2.0 (+0.1; SD 0.6), PIADS (+0.6; SD 1.5), 6MWT (+52.2; SD 51.6). The sample was too small to conduct statistical tests; nevertheless, it suggests that other outcomes (quality of life, safety, confidence, satisfaction) may be more important than mobility for persons with contralateral deficiency. Further studies with a greater number of participants with this profile could provide insights into these results.

The inclusion criteria excluded community ambulators with bilateral quadriceps insufficiency to ensure a homogenous sample for the study. Nevertheless, people with bilateral deficiency fitted with the C-Brace on both affected limbs might benefit from the technology, and this possibility warrants further studies.

The number of AEs (29) reported in 16 participants is quite high compared to the number of participants enrolled in this study ($n = 38$). However, 83 % of AEs were qualified as non-serious. Some events had a possible, probable, or causal relationship with the study intervention, whether during the C-Brace trial (13) or during the SCO follow-up (7). The higher number of AEs with C-Brace is due to the use of the new orthosis in new conditions, including during rehabilitation exercises. The controlled flexion of the knee generates constraints between the leg and the KAFO, increasing the risk of skin redness and pain when the KAFO is not perfectly adjusted. The number of AEs with SCO is lower, given that these were the usual orthoses of the participants and were worn for at least 3 months before the beginning of the study. As such, all the fitting and rehabilitation issues had already been solved before the research. Nevertheless, the high number of AEs due to the knee joint (5) or the KAFO (2) suggests a low reliability of the SCO. The causes of AEs for SCO and the C-Brace were identified and resolved during the study.

The improvement in mobility in real-life conditions is consistent with biomechanical studies that have shown improved functional abilities to negotiate slopes and stairs with C-Brace in comparison with traditional KAFOs [6,8]. Previous randomized crossover trials compared C-Brace with KAFOs in people with all levels of mobility [9] or in people with low mobility grades and high risk of falls (BBS <45) [10]. Although these studies also report improvements in balance, functional mobility, and quality of life, their results cannot be directly compared with our findings because our research only focuses on a specific group of community ambulators (walking speed > 3 km/h) who use SCO. A 3-month follow-up study on C-Brace users [7] and a post-market survey after 2 years [42] reported improvements in perceived safety, experienced falls, and difficulties encountered in performing daily life activities. A recent registry on community ambulators using C-Brace for 1 year confirmed significant improvement of walking speed, dynamic balance, perceived safety, frequency of falls, and quality of life. Rehabilitation and gait training play a key role in helping people modify gait patterns when switching from their SCO to the C-Brace orthosis, especially regarding the additional dampening function during the stance phase. Rehabilitation programs should incorporate outdoor exercises (eg, stairs, ramps, uneven ground) and daily life activities to help people overcome obstacles or tasks requiring physiological gait or a standing position.

The C-Brace is a non-motorized knee joint articulation restoring eccentric actions of knee extensors, supporting walking on uneven ground, downhill, downstairs, and sitting down. This eccentric passive help is also repeatedly recognized positively by C-Brace users to facilitate standing up from a chair. Further research may assess the benefit of developing powered KAFO orthoses that support an active extension of the knee, to improve walking accelerations, standing up from a chair, or climbing hills and stairs.

Conclusions

This multicenter and international randomized crossover clinical trial asked 38 community ambulators with a quadriceps insufficiency to test and compare 2 knee-ankle-foot orthoses: their SCO and the C-Brace. Our results show that the C-Brace significantly improved mobility, endurance, confidence, participation, satisfaction, psychological adjustment, and quality of life in this population. Moreover, the C-Brace led to a decrease in the use of walking aids when walking outdoors, even though safety has been reported as the most important satisfaction criterion for participants. In all, community ambulators requiring the use of KAFO for walking could greatly benefit from the use of the C-Brace orthosis to improve their outdoor mobility and facilitate completion of daily activities. Further studies including people with bilateral quadriceps insufficiency are an interesting prospect to assess the possible advantages of the C-Brace for this population.

Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the authors did not use AI-assisted technologies in the writing process.

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Data availability

Data will be made available on request.

Conflict of interests

F. Genêt, A. Ruetz, and F. Braatz were part of the scientific advisory board for this study and received financial compensation (FG, AR) or institutional financial compensation (FB) for their contribution to study design, protocol review, and study report. They participated in the critical review of the manuscript. The other authors contributed to the research as investigators and have no conflicts of interest to disclose.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.rehab.2025.102057.

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