AOPA Member Article

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Journal of Rehabilitation and Assistive Technologies Engineering
Volume 11: 1–13

DOI: 10.1177/20556683241269539
journals.sagepub.com/home/jrt
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The C-Brace® microprocessor controlled stance and swing orthosis improves safety, mobility, and quality of life at one year: Interim results from a prospective registry

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Abstract

Introduction: The C-Brace microprocessor-controlled stance and swing control orthosis has been shown to improve function, mobility, and quality of life. A systematic registry to gather long-term, real-world safety and effectiveness data in patients fit with a C-Brace has not been performed.

Methods: International multicenter registry. Patients undergoing routine C-Brace fittings were assessed at baseline and 1 year after fitting. Primary outcomes were fast walking speed (FWS) measured by 25-foot or 10-meter walk test, Timed Up and Go (TUG) and the Activity-specific Balance Confidence (ABC) Scale. Secondary and exploratory outcomes included the Patient-specific Functional Scale (PSFS), falls, pain, PROMIS Pain Interference (PI), and quality of life.

Results: 48 subjects with 1-year baseline and follow up data were analyzed. With the C-Brace, FWS improved by + 0.26 ± 0.33 m/s ($p < .0001$), TUG by −8.1 ± 14.6 sec ($p < .0001$), and ABC by + 24.9 ± 25.8% ($p < .0001$). Mean falls reduced from 33 ± 77 to 3.0 ± 5.6 ($p = .0005$). PSFS increased by 3.60 ± 2.34 points ($p < .0001$). Outcomes for pain, PI and quality of life showed significant improvements with the C-Brace.

Conclusion: The C-Brace is an effective option to improve safety, mobility, and quality of life for patients needing a KAFO for ambulation.

Keywords

Rehabilitation, lower limb paresis, knee-ankle-foot orthosis, knee ankle foot orthosis, EQ-5D, walking speed, timed up and go, Activity-specific Balance Confidence

Introduction

Approximately 1.7% of the population of developed countries live with some form of paralysis in the extremities.[1,2] Partial or total paralysis of the lower extremities impacts the biomechanics of gait and, therefore, functional mobility. Paralysis is caused by a variety of ailments including damage to the central nervous system (CNS) such as spinal cord injury (SCI), traumatic brain injury (TBI), and stroke, damage to the peripheral nerve pathways caused by trauma, iatrogenic means, or peripheral

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neuropathies, and by neuromuscular disease such as poliomyelitis and post-polio syndrome, motor neuropathies, and muscular dystrophies.[2] Unresolved dysfunction of the lower extremity due to any cause which is left untreated or treated sub-optimally results in reduced mobility and the ability to independently complete activities of daily living (ADLs) which therefore leads to activity reduction, reduced social participation, psychosocial problems, and deleterious health effects due to inactivity.[3–6]

The standard of care for neuromuscular instability of the knee is the knee-ankle-foot orthosis (KAFO).[7,8,2] There are several types of KAFOs including locking, posterior offset, and stance control orthoses (SCOs).[2] Locking KAFOs (LKAFOs) have a mechanism which restricts motion in full extension which is locked by the user for walking and standing and unlocked by the user to sit.[2,9] Posterior offset KAFOs (PO-KAFOs) provide knee stability in stance through built-in stops in the orthotic knee joint to produce a stabilizing knee extension moment throughout stance.[2] SCOs also have mechanisms which restrict motion in full extension or partial knee flexion during stance, but are operated mechanically or electronically using different trigger mechanisms, such as knee and/or ankle angle or thigh-segment angle to lock or unlock the orthotic knee joint.[2,10] The commonality of these designs is the full extension of the knee in stance phase of gait. Full extension throughout the gait cycle is not natural, however. For users of LKAFOS, this leads to an asymmetrical gait pattern and gait deviations such as hip hiking, circumduction, and vaulting to compensate for reduced toe clearance during swing.[9] While SCOs and PO-KAFOs may reduce or even eliminate these compensations for level ground walking, they still lack the ability to provide knee flexion during weight bearing, which introduces another significant deficit compared to nature gait.[8] Asymmetric loading of proximal and contralateral joints results in structural damage, discomfort, pain, and contributes to reductions in activity over time.[11] Traversing ramps, stairs, uneven terrain, and other non-level activities are also suboptimal with the knee locked in extension. These factors lead to decreased safety for the user, particularly for PO-KAFOs and SCOs.[12] These traditional KAFO designs also do not have controlled swing phase or stumble recovery. So, if the patient stumbled and the KAFO did not reach the fully locked position, it would offer no support and increase the likelihood of the patient falling.

The C-Brace® [Ottobock SE & Co. KGaA, Duderstadt, GER] is a microprocessor (MP) stance and swing control orthosis with a hydraulic knee joint which provides responsive flexion and extension resistances based on sensor inputs which respond to a variety of movement patterns.[2] In addition, sensors in the knee joint detect when the patient has stumbled and subsequently activate the stumble recovery function which effectively locks the knee at its current angle to allow weight bearing for a corrective step to regain balance. By allowing for controlled knee flexion during weight bearing, the joint is designed to promote increased activity and safety through nearly physiologic gait on all types of terrains.

Several benefits reported for the C-Brace in the literature include significantly improved balance, reduced falls and risk of falling, faster walking speed, improved walking function, and higher quality of life than with the traditional KAFOs.[2,13] Another study found significant improvements in patient-reported overall orthotic function, ambulation, paretic limb health, well-being, as well as ease and safety of performing more than 20 different ADLs.[14] However, these studies all evaluated effectiveness over periods of 3 months or less, had strict inclusion and exclusion criteria, did not include individuals without previous orthotic use in the past, and were not completely reflective of the clinical setting. The generalizability of these findings to the full population with lower extremity dysfunction longitudinally is unknown.

Therefore, the international C-Brace Prospective Registry was established to collect longitudinal safety and real-world effectiveness data of typical C-Brace users. The C-Brace Registry is the first longitudinal registry to assess the effectiveness of a microprocessor-controlled stance and swing control orthosis. The purpose of this study was to provide an interim analysis of results for the primary outcome measures and several exploratory measures. It was hypothesized that a representative sample of C-Brace users would experience improved walking speed, functional mobility, and balance confidence 1 year following C-Brace fitting.

Methods

The C-Brace Prospective Registry protocol was approved by WCG IRB (#20150567) in the United States (US) and the Ethics Committee of University of Medicine, Goettingen (20/10/18) in Germany (Table 1). The first subject was enrolled April 1, 2016 and this interim analysis included all those subjects enrolled through October 31, 2023. As of this date, 51 sites have initiated, 47 in the US and 4 in Germany. Of these, 38 are active and 13 are inactive. The Registry is listed on ClinicalTrials.gov (NCT04640584).

Potential subjects are identified during the C-Brace fitting process at participating clinics. The fitting process includes a successful test with the functional C-Brace trial tool, casting, evaluating fit with a test orthosis, and fit of the definitive orthosis. The trial tool consists of a fully functional, programmable C-Brace knee joint with adjustable splints, straps, and foot part which allows for a short-term, in-house fitting in the clinic to check whether the potential study participant was able to initiate swing and utilize controlled knee flexion during weight bearing. It is not

Table 1. EC and IRB approvals.

Approval number	Country	Ethics committee/Institutional Review Board
20/10/18	Germany*	Ethics Committee of University of Medicine, Göttingen
20150567	United States	WCG IRB, Puyallup, Washington

suitable for home use per industry standards. The following inclusion criteria for the Registry were designed to permit all subjects for whom the clinician decides to fit a C-Brace to be invited to participate: a successful test with the trial tool, having been casted for the C-Brace, the ability to communicate, provide feedback, understand and follow directions during the study, and willingness to provide informed consent. Exclusion criteria include geographic inaccessibility to participate in the study and lack of casting for the C-Brace. Following written informed consent, demographic information, a standard medical history, and fitting information are collected.

Subjects then completed a baseline data collection with their existing orthosis or current ambulatory condition in the participating clinic. Standardized outcome measures (OMs) are described below. Step Activity Monitoring (SAM) was recorded using a Fitbit Zip for 2 weeks after each data collection. These assessments repeated at follow-up visits 6 months and 1-, 2- and 3-years following fitting of the definitive C-Brace. Due to the longitudinal nature of this Registry, high attrition was expected. To mitigate attrition, sites were given a window before or after the target date in which data could be attributed to a visit per protocol. The windows were three and six months for the 6-month visit and annual visits, respectively. The primary endpoint for the study was the 1-year visit. Data was monitored by the Sponsor [Otto Bock HealthCare LP, Austin, TX, USA] according to ISO 14155 standards.

Outcome measures

Primary outcome measures (OM) for the Registry were (1) fast walking speed (FWS) as measured by the 10-meter Walk Test (10mWT) or 25-foot Walk Test, (2) walking ability as measured by the Timed Up and Go (TUG) and (3) patient-perceived balance confidence as measured by the Activity-specific balance confidence (ABC test).

The 10mWT is a performance-based OM designed to assess self-selected walking speed and fastest possible walking speed (FWS).[15] In this study, only the FWS speed was evaluated and recorded. Use of assistive devices was also recorded. Walking speed has been used to predict ambulatory levels with speeds < 0.4 m/s being considered "household ambulators," 0.4 – 0.8 m/s being "limited community ambulators," and > 0.8 m/s being "unlimited community ambulators."[16–18] Walking speed greater than 1.32 m/s has been considered sufficient to cross a street safely.[19] When space was not available, the protocol allowed for the 25-foot walking test was able to be used.

The Timed Up and Go test (TUG) is a performance-based OM quantifying functional mobility and risk of falling.[20] The test requires subjects to stand up from a chair, walk three meters, turn 180°, return to the chair, turn 180° again, and then sit down in the chair. Cut-off scores of 10-13.5 seconds have been used to identify patients at risk of falling.[21–24] The MCID for the TUG is 3.4s for the population, post lumbar surgery.[25]

The ABC scale is a patient-reported OM to evaluate confidence in performing various ambulatory activities on a scale from 0% (no confidence) to 100% (complete confidence) without losing balance or becoming unsteady.[26] Scores for each of the 16 items were collected and a total average percentage was calculated. Scores <67 indicate an increased risk of falling.[26] The MDC is reported as 11 points.[27]

Secondary outcomes measures were[1] the Patient-specific Functional Scale (PSFS),[2] daily step counts as measured by a FitBit, and[3] the Berg Balance Scale (BBS). Only the results for PSFS are reported in this manuscript.

The Patient-Specific Functional Scale (PSFS) is a self-report measure aimed at identifying functional status limitations that are most relevant to individual patients.[28] The PSFS is a reliable, valid, and efficient measure for detecting clinical change in persons with low back pain and knee dysfunction.[29] Patients were asked to identify three to five activities that they are having difficulty or are unable to perform because of their injury/condition. For the specified activities, patients were then asked to rate their ability to perform each activity at that time (0–10 numerical scale) with '0' being unable to perform the activity, and '10' being able to perform the activity at the same level as they could prior to the injury/condition onset.

Exploratory OMs for the Registry included frequency of falling, the Numerical Pain Rating Scale (NPS), the PROMIS Pain Interference Short Form 6a (PI), and quality of life as measured by the EQ-5D-5 L. Fall frequency was collected by asking subjects to recall the number of falls in the previous 6 months. The NPS is a patient-reported OM of a single dimension of pain.[30] Subjects who reported pain were asked to rate the intensity over the last 24 hours on a scale 1-10, 1 being 'very mild' and 10 being 'the worst possible pain imaginable'. 'No pain' could also be selected. Subjects were asked to rate the pain of their low back, lower extremity joints, and feet. If the subject had low back pain which radiated down into either leg, subjects were asked to rate the leg pain. If assistive devices were used, pain was rated in any additional affected joint of the upper extremities. The MCID

for pain in multiple musculoskeletal conditions is 1.0 for a clinically meaningful change.[31]

The PI is a patient-reported OM reporting the degree to which pain interferes with six activity areas.[32] Potential responses were assigned a numerical value and included 1 for 'not at all', 2 for 'a little bit', 3 for 'somewhat', 4 for 'quite a bit', and 5 for 'very much'. Raw scores are converted to a T-score with a mean of 50 and a standard deviation of 10.

The EQ-5D-5 L is a patient-reported OM developed by the EuroQol Group to evaluate health-related quality of life (QoL).[33] The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five levels: 'no problems', 'slight problems', 'moderate problems', 'severe problems', and 'extreme problems'. The subjects were asked to indicate health state in each dimension by ticking the box next to the most appropriate statement level resulting in a numerical condition code. The condition code is indexed according to location of the clinic in the US or Europe to a numerical equivalent 0 to 1.[34] The subjects also rated their overall health on a visual analog scale (VAS) between 0 and 100, with 0 being 'worst health possible' and 100 being 'perfect health'.[34]

Data analysis

Sample size calculations were performed at project inception using data from multiple sources. The largest sample size calculated was 55 patients required to have 80% power to detect a difference of 4 seconds between baseline and follow-up scores on the timed up and go (TUG) test with alpha of 5% using Wilcoxon's matched pairs signed ranks test.[25] A standard deviation of 10 seconds was used for the calculation. Attrition of 20% was expected at the primary endpoint for a target sample of 66 subjects. This work is an interim analysis of the ongoing Registry project.

Data analyses were primarily descriptive in nature. Categorical variables (such as gender) were summarized by absolute and relative (percentages) frequencies. Continuous variables (such as age) were summarized by the mean, standard deviation, and minimum and maximum values observed. In addition, changes in continuous measures of effectiveness (such as walking speed and timed up and go scores) were evaluated by subtracting baseline from follow-up scores. The mean and standard deviation were used to summarize change scores.

The significance of differences between baseline and follow-up scores were tested using paired t-tests if the data were normally distributed and the Wilcoxon's matched pairs signed rank if not. The Hochberg method was used to adjust alpha for the multiple primary OMs as one family, thereby limiting the family-wise alpha to 5%. In this method, p-values were ranked from highest to lowest for each endpoint tested. If the highest p-value was $\leq .05$, all null hypotheses were to be rejected in that family and no further adjustments were made. If, however, the highest p-value was $> .05$, alpha was adjusted to 2.5% (alpha/2). The remaining p-values had to be $\leq .025$ in that group in order to be statistically significant. Adjustment of alpha were continued in this manner within the family of primary effectiveness endpoints. Two-tailed p-values $\leq$ the Hochberg adjusted alpha would indicate statistical significance. Each variable was analyzed separately. The primary effectiveness objectives were to characterize the improvement in primary OMs with the C-Brace compared to baseline measurements when assessed 1 year after the initial fitting.

Dependent variables at follow-up with the C-Brace were expected to be improved from baseline without the C-Brace. In statistical terms, the null (H_0) and alternative hypotheses are:

H_0: $\mu_{\text{Baseline}} = \mu_{\text{Follow-up}}$ versus H_A: $\mu_{\text{Baseline}} < \mu_{\text{Follow-up}}$

Where μ_{Baseline} is the dependent variable at baseline and $\mu_{\text{Follow-up}}$ is the mean dependent variable at follow-up.

If the difference in mean of a dependent variable at follow-up was in the predicted direction and the 2-tailed p-value was $\leq$ the Hochberg adjusted alpha, the null hypothesis was rejected in favor of the alternative hypothesis. For each variable analyzed, only valid values were included in the analysis. In instances where the 1-year follow-up data is not available, the 6-month data were carried forward.

The Registry includes some subjects who enrolled immediately following completion of other prospective studies related to C-Brace. For subjects who entered from a randomized crossover study of KAFO users initially fit with a C-Brace, their Registry enrollment and baseline visits were conducted immediately after they exited the trial.[2] The target date for their first follow-up was set 6-months after the baseline data collection if they ended the trial in C-Brace arm or 3 months after the baseline if they exited the trial in the KAFO arm. Target dates for annual follow-up visits were set 6 months thereafter.

Results

In total, n = 91 subjects had been enrolled in the study. This included 22 subjects from a large crossover study of KAFO and SCO users fit with a C-Brace and 1 subject from another C-Brace study in France. As of the data cutoff date, 12 subjects had follow-ups not yet due, 21 dropped out, 11 had missing follow-up visits, and one subject had missing baseline data resulting in 46 subjects available for analysis (Figure 1). Demographic information is shown in Table 2. Regarding the use of walking aids, 40 subjects (87%) reported needing a walking aid to walk at baseline. Based on the preference for using a walking aid for the

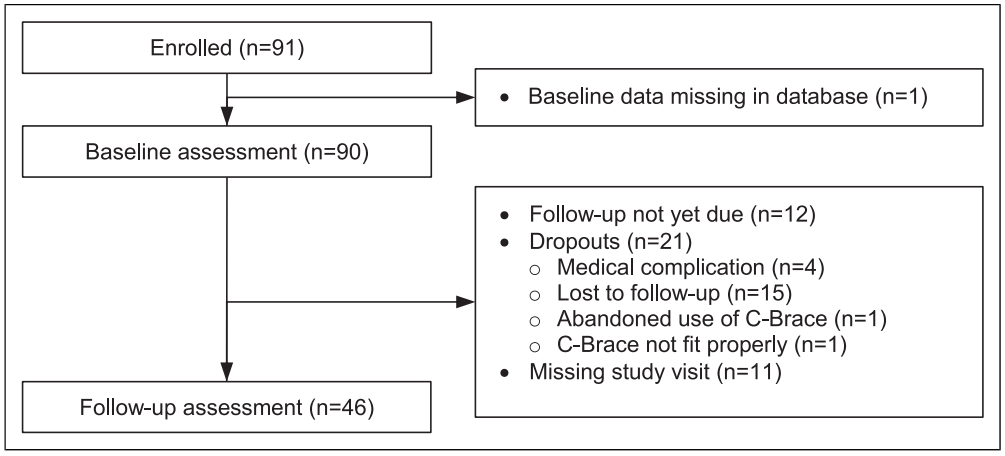

Figure 1. Data Flow.

performance-based testing at follow-up, 24 subjects (52%) still required a walking aid, but 22 subjects (48%) no longer required one for the test.

For the primary OMs, 40 subjects had performance measures at both baseline and follow-up and 46 subjects reported their balance confidence as measured with the ABC (Table 3). The fastest possible walking speed (FWS) significantly increased 0.26 m/s ($p < .0001$) between baseline and 1-year with the average speed at follow-up nearly reaching 1 m/s (Figure 2). Based on the measured gait speeds at baseline, 9 subjects (23%) were household ambulators, 12 (30%) were limited community ambulators, 15 (38%) were community ambulators and 4 (10%) were safety able to cross a street. At follow-up, 16 of subjects (40%) moved up at least one ambulation level. Times for the TUG were significantly faster, decreasing by 8.1 seconds ($p < .0001$) between baseline and 1-year. At baseline, 32 subjects (80%) had TUG times > 13.5 sec indicating an increased risk of falling. At follow-up, only 17 (43%) were at risk of falling. The mean ABC score significantly increased by 24.9 percentage points ($p < .0001$) between baseline and 1-year. Based on ABC scores, 35 subjects (76.1%) were at risk of falling at baseline with scores < 67%. At follow-up, only 19 (41.3%) were at risk of falling. Using Hochberg's method, the highest p-value for the three primary endpoints evaluated as a family was for the TUG. Since this p-value was <0.05, all null hypotheses were rejected, and no further adjustments were made.

For the PSFS, 33 subjects had data available at both baseline and follow-up (Table 3). In these subjects, the average PSFS score more than doubled from 2.1 at baseline to 5.7 at follow-up, an average improvement of 3.6 ($p < .0001$).

For falls, 42 subjects had data available at both baseline and follow-up (Table 3). In these subjects, the average number of falls in the previous 6 months was reduced by 91% at 1-year with the median falling from 3 to 1. Of these subjects, 30 (71%) reported having a fall in the past 6 months at baseline which was reduced to 23 subjects (55%) at 1-year. Regarding multiple fallers, 24 subjects (57%) reported having multiple falls in the past 6 months at baseline. There were 16 (38%) subjects still reporting multiple falls, although there were significantly fewer falls on average at 1-year.

For pain, 38 subjects provided NPS data at both baseline and follow-up (Table 3). Of these, 31 subjects (82%) reported having pain at baseline in over four areas of the lower limb on average. The number of subjects reporting pain at follow-up increased slightly to 32 (84%) at 1-year. However, the average NPS per area of reported pain decreased by 23% at 1-year compared to baseline ($p = .02$). This reduction in average pain was driven by reductions in pain in the affected leg (−1.4), affected ankle (−1.0), sound hip (−1.2), sound ankle (−2), and sound foot (−1.5). For subjects using assistive devices, 9 subjects (24%) reported having pain in the upper extremities at baseline, and this remained unchanged at 12 months. The average NPS score per upper limb area decreased by only 5%. Pain interference (PI) measured with the PROMIS was reduced by 14% between baseline and 1-year ($p < .001$). A moderate correlation (r = 0.51) was found between the change in PI and the average NPS per area of reported pain ($p < .001$) (Figure 3).

Quality of life as measured by the EQ-5D-5 L was available in 38 subjects at baseline and follow-up (Table 3). The Health Utility Index (HUI) increased from 0.61 at baseline to 0.82 at follow-up, an average increase of 0.20 ($p < .0001$). While the change in the HUI was driven by marked reductions in the scores for rated problems in three dimensions, Mobility [-1.5, ($p < .0001$)], Usual Activities [-1.1, ($p < .0001$)], and Pain [-0.88, ($p < .0001$)], all dimensions were significantly different including Self-Care [-0.53,($p = .0024$)] and Anxiety and Depression [-0.55, ($p < .0002$)] (Figure 4). In addition, the

Table 2. Demographics.

	Analysis sample (n = 46)	
Mean age (± SD) [years]	51.8 ± 16.4 [22-83]	
Gender	Male:	29 (63%)
	Female:	17 (37%)
Mean weight (± SD) [kg]	79.3 ± 22.2 [26.3-122]	
Underlying conditions	iSCI:	15 (33%)
	Polio/PPS:	9 (20%)
	Trauma:	3 (7%)
	Iatrogenic:	3 (7%)
	MS:	2 (4%)
	Plexus/peripheral nerve injury:	2 (4%)
	MD:	1 (2%)
	TBI:	1 (2%)
	Herniated disk:	1 (2%)
	Other (n = 1 each):	9 (20%)
Work/employment status	Working:	23 (50%)
	Unemployed:	7 (15%)
	Retired:	16 (35%)
Side/bilateral orthosis	Left:	19 (41%)
	Right:	18 (39%)
	Bilateral:	9 (20%)
Previous orthosis	SCO:	13 (28%)
	AFO:	13 (28%)
	LKAFO:	9 (20%)
	None:	5 (11%)
	Poly/PO-KAFO:	3 (7%)
	KO:	2 (4%)
	Unknown:	1 (2%)
Use of walking aids	Axillary Crutches:	3 (6%)
	Cane:	14 (30%)
	Quad Cane:	1 (2%)
	Forearm Crutches:	4 (9%)
	Wheelchair:	1 (2%)
	Walker:	3 (6%)
	Other:	1 (2%)
	Multiple:	13 (28%)
	None:	6 (13%)

SD: standard deviation; PPS: post-polio syndrome; iSCI: incomplete spinal cord injury; MS: multiple sclerosis, MD: muscular dystrophy; TBI: traumatic brain injury; LKAFO: locked KAFO; PO-KAFO: posterior-offset KAFO; SCO: stance control orthosis; AFO: ankle foot orthosis; KO: knee orthosis.

overall health reported by the Visual Analog Scale (VAS) was 69.1% at baseline and 78.8% at follow-up, an increase of 14% (p = .002).

Discussion

The International C-Brace Prospective Registry was established to collect longitudinal safety and real-world effectiveness data of typical C-Brace users. The hypothesis that a representative sample of C-Brace users would experience improved walking speed, functional mobility, and balance confidence 1 year following C-Brace fitting was fully supported. Significant improvements were made in all the primary effectiveness outcomes including the fastest-possible walking speed, TUG, and ABC. Additional improvements in other outcome measures were also noted including falls, pain, pain interference, PSFS, and EQ-5D-5 L.

The most important prerequisite of any mobility-assistive device is to provide the user safety and prevent injuries.[35] However, evidence regarding safety of these devices is limited. The performance of the C-Brace assessed by the primary measures demonstrated its longitudinal safety because the OMs have direct correlations to safety thresholds for multiple etiologies. When assessing FWS, subjects moved from unsafe community ambulation speeds to exceed 0.7 m/s, a speed indicative of increased risk of adverse events like falls, to nearly 1.0 m/s on average, the commonly held threshold for safe community ambulation and into the range of normative walking speed data for multiple age groups.[36–38] In addition, the primary purpose of assistive devices and orthoses is to improve user performance of particular tasks.[39] In the case of the C-Brace, the tasks are walking and performing ADLs. Results here show the mean improvement in gait speed meets or exceeds MCIDs and MDCs for multiple etiologies similar to those of users in this study including SCI (0.13), CVA (0.13), MS (0.26), and Parkinson's Disease (0.25).[40–44] Further, users experienced a movement from limited community ambulation to independent community ambulation when compared to an established threshold for patients with SCI.[45]

When assessing functional mobility with the TUG, subjects moved from slower than fall-risk thresholds for multiple etiologies including hip OA, vestibular disorders, and Parkinson's disease as well as elderly adults to faster than or in proximity to these thresholds.[21–24,46] The mean reduction was greater than both the MDCs of 2.9s and 3.5s for patients with CVA and Parkinson's Disease, respectively, as well as the MCID of 3.4s for subjects after lumbar surgeries, all etiologies represented in this sample.[47,48,25,35] Baseline TUG results in this sample, 23.7 ± 17.5s, are higher than those reported by Lemay & Nadeau for individuals with SCI, 17.0s ± 18.7s, and paraplegia, 19.7s ± 25.9s with the difference exceeding the published MCIDs.[49] In the literature, the TUG has strong negative correlations with the 10mWT and BBS for SCI and CVA patients as well as the elderly.[45,20,49,50] Correspondingly, the TUG results here show similar improvement to the FWS in this work and to findings of the BBS[51] reported by Ruetz et al., which showed a BBS improvement of 3.6 points in that study of the C-Brace.[2]

When assessing patient-reported balance confidence, scores improved from below to above or near fall-risk thresholds of 58%-67% for elderly adults, and multiple

Table 3. Results.

Outcome	Sample size	Baseline (BL)	C-Brace (6-12M FU)	Change	*p*-value C-Brace vs. BL
Primary Outcomes					
FWS [m/s]	n = 40	0.73 ± 0.34	0.99 ± 0.42	+0.26 ± 0.33	0.000014
TUG [s]	n = 40	23.7 ± 17.5	15.5 ± 0.2	−8.1 ± 14.6	0.00007*
ABC [%]	n = 46	45.1 ± 21.1	70.0 ± 7.5	+24.9 ± 25.8	<0.00001
Safety Outcomes					
Falls	n = 42	33 ± 77 median: 3	3.0 ± 5.6 median: 1	−30 ± 74 median: −2	0.00048*
Falls (multiple fallers)	n = 28	50 ± 90 median: 6	4.4 ± 6.4 median: 1	−45 ± 87 median: −4.5	0.00051*
Secondary Outcomes					
PSFS	n = 33	2.13 ± 1.24	5.72 ± 2.36	3.60 ± 2.34	<0.00001*
Exploratory Outcomes					
PROMIS PI [T-Score]	n = 42	61.3 ± 12.8	55.0 ± 9.5	−8.8 ± 9.7	0.00053
NPS – Average per area of reported pain	n = 38	n = 31 (82%) 4.57 ± 2.07	n = 32 (84%) 3.51 ± 1.57	−1.06 (−23%)	0.027**
EQ-5D-5 L HUI	n = 38	0.614 ± 0.237	0.815 ± 0.133	0.200 ± 0.206	<0.00001*
EQ-5D-5 L VAS	n = 38	69.1 ± 21.5	78.8 ± 14.7	12.1 ± 21.4	0.00157*

Means ± SD including all subjects for non-pain outcomes and the subset of subjects reporting pain either at baseline or follow up for NPS.
*Wilcoxon signed rank test used, since the data was not normally distributed; all other *p*-values are for t-tests.
**Unpaired t-test all other *p*-values are for paired t-tests.

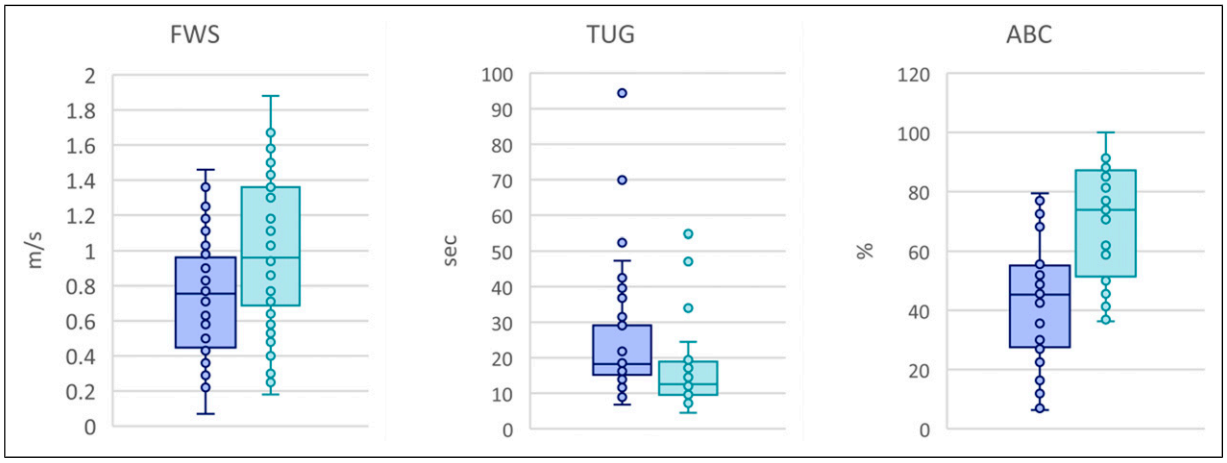

Figure 2. Results for primary outcome measures.

etiologies including 55%–69% for Parkinson's Disease, and 40% for MS between baseline and 12-months.[52,26,53–55] Overall, mean improvement exceeded the MDCs of 11.1% - 14% for multiple etiologies.[27,53,43] The ABC scores here show a similar improvement pattern to the FWS and TUG which is interesting because the ABC does not typically correlate more than adequately with gait speed and TUG times when evaluated in multiple etiology groups. This could be caused by previous comparisons being conducted with single etiologies which are more prone to physiologic balance changes than this more heterogenous sample. While walking speed, functional mobility, and balance confidence are related, they are separate constructs. This

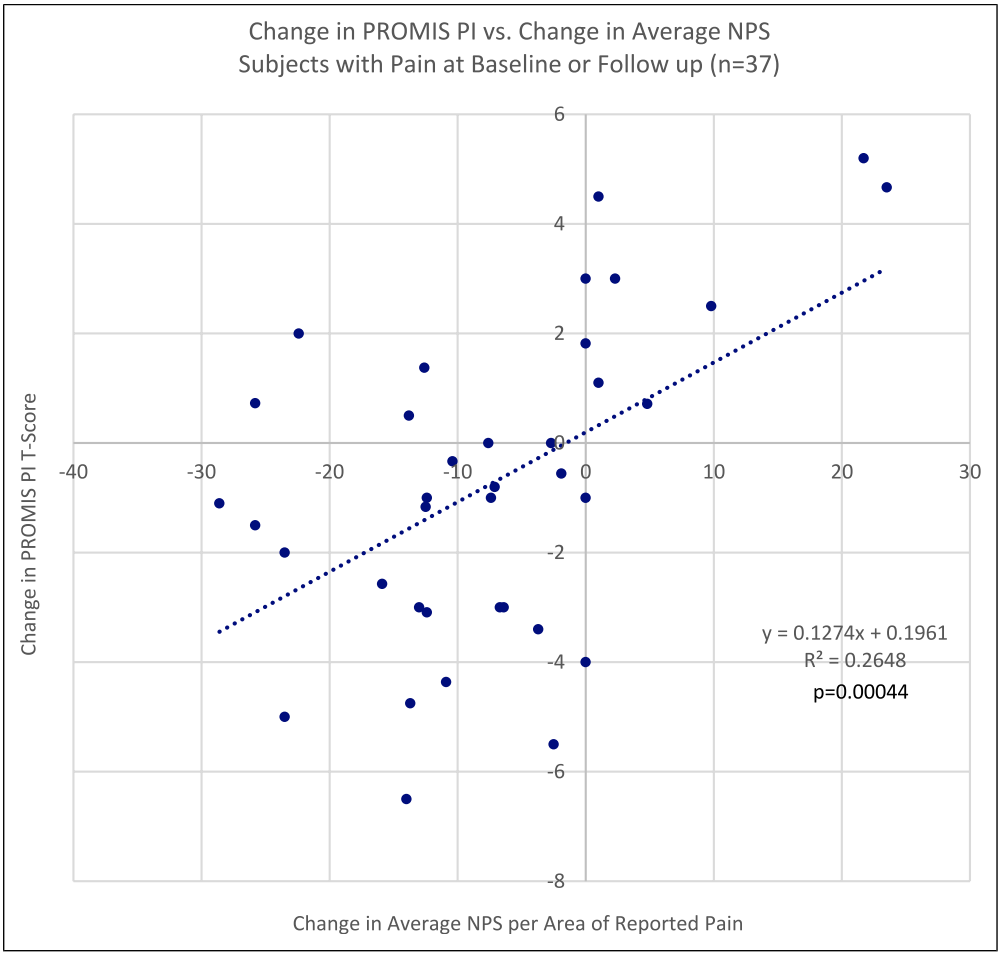

Figure 3. PROMIS PI vs. Average NPS.

pattern of improvement in multiple domains was also noted in the previous C-Brace study by Ruetz et al. who found a mean improvement of 11.3% for the ABC with the C-Brace between 3 months of C-Brace and KAFO home use which was accompanied by improvements in the BBS and dynamic gait index (DGI), for example.[2] Ruetz et al. also observed 24.5% of that sample move from below the 67% ABC fall-risk threshold to above it; a slightly higher percentage of this Registry sample crossed above this threshold (39.1%). Main differences between Ruetz et al. and this study are the study duration, but also that all the subjects in that sample were already using KAFOs whereas this sample includes subjects wearing AFOs or no orthosis experience. The results here indicate the C-Brace can offer lasting improvements over time to individuals who are not full-time KAFO users, or orthosis users at all.

The improvement relative to performance and confidence fall-risk thresholds translated to a reduction in falls which persisted over time. These findings are similar to those found by Ruetz et al. who reported a reduction of 3.4 falls over a three-month period of C-Brace use compared to KAFOs and a 54% reduction in the proportion of multiple fallers, which was similar to the findings here.[2] Those findings are similar to a study by Deems-Dluhy et al. who found a reduction in 10 to 33 falls with the C-Brace compared to locked KAFOs or SCOs over a one-month period in a diverse sample of 18 KAFO/SCO users, although this was not statistically significant in that study. Much attention has been given to fall prevention as a safety statistic in recent years due to associated healthcare cost and mortality. The Centers for Disease Control and Prevention reports $50B in costs associated with non-fatal falls and $754M with fatal falls in the United States each year.[56] A systematic review on fall cost in the elderly reported associated costs ranging from $1,059 to $42,840 per event before inflation.[57] with approximately $5,765 of that event cost being attributed to emergency department visits, approximately $17.3 B annually.[58] Falls account for approximately one-third of injury-related emergency department visits in the US each year overall, with the proportion of visits

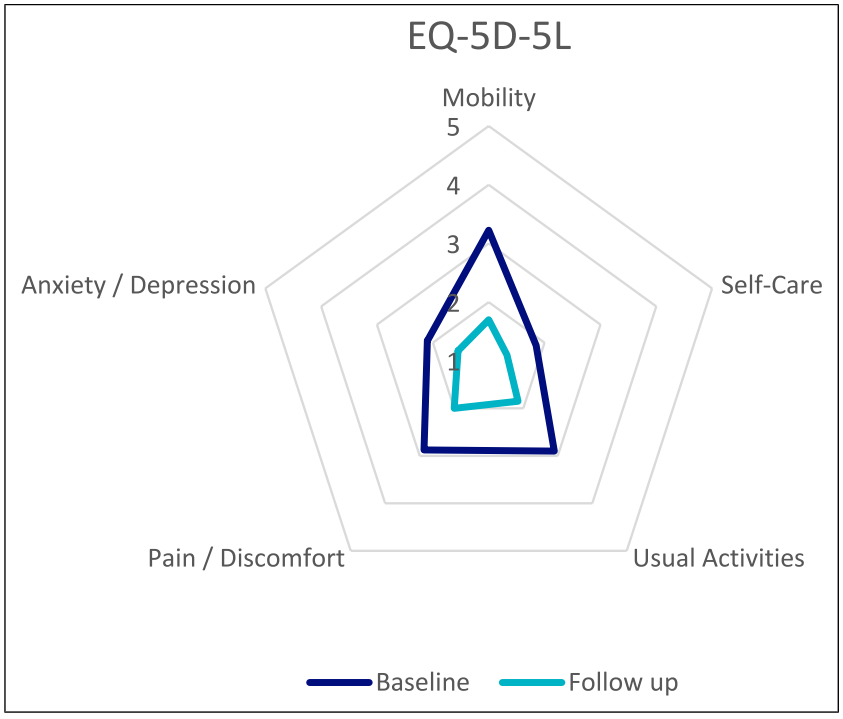

Figure 4. EQ-5D results.

attributable to falls increasing with age and level of dependency.[58–60]

In addition to the safety and performance improvements, subjects in the Registry also experienced reduced average pain, which was driven by reduced pain in multiple areas and joints including the affected leg and ankle and the sound hip, ankle, and foot at 1 year. Subjects are moving from some type of compensatory pattern where muscular and positional imbalances are common to a more biomimetic pattern which acutely causes discomfort, but leads to pain reductions over the long term.[61,62] For individuals with various pathologies and different levels of compromised neuromusculoskeletal systems who have acclimated to imbalanced muscular activation patterns over the course of months to several decades, the one to 3 month home-use period used in previous studies may have been too short to realize this change.[9,62] Pain has a significant influence on QoL worldwide, but especially in the US where it is the single most important dimension of the EQ-5D index.[63] Reductions in pain can have meaningful impact not only in the lives of individual patients but also the general healthcare system because pain is responsible for higher costs annually than diabetes and heart disease in the US and globally.[64]

The degree of activity limitation a condition introduces to an individual also impacts QoL and is widely used as a primary indicator of successful rehabilitation for patients with neuromuscular conditions.[65–67] The results of the PROMIS-Pain Interference scale and PSFS in the Registry show an improvement in factors contributing to activity limitation and patient-reported specific function at 1-year. These results are similar to findings of Reutz et al. who reported a significant increase of 15.9 points in the SF-36 physical functioning scale, 6.3 in the role limitations - physical scale, and 2.5 in the OPUS-LEFS.[2] The previously mentioned increase in balance confidence and function and the reduction in pain contributed to the improvement in perceived function also. In contrast to the results of Ruetz et al. where the bodily pain index of the SF-36 reported was not statistically different after 3 months, there was a significant reduction in the raw scores for the pain dimension of the EQ-5D-5 L in this study. All these factors contribute to overall QoL which is reflective of the improvement in EQ-5D-5 L at 1 year with the C-Brace. These results are consistent with other studies comparing the C-Brace to traditional KAFO use as well. Deems-Dluhy et al. reported statistically significant improvements in the OPUS-QoL and WHOQoL-physical health scale after 1 month and Ruetz et al. reported statistically significant improvements in the SF-36 following 3 months of C-Brace use. The combination of these findings demonstrates the superiority of the microprocessor-controlled stance-and-swing KAFOs to traditional KAFOs and SCOs in a variety of patient groups.

Limitations

An inherent limitation in observational studies is the lack of input control, such as etiology specificity of the sample and variety in the history and length of orthotic use. Different etiologies have different progressions and different prognoses for improvement independent of C-Brace use which may have affected results at various timepoints. These factors lead to a lack of generalizability of the findings to any particular disease group. The amount of physical therapy and gait training could also not be controlled. However, these conditions are representative of the real-world patient population who may benefit from using the C-Brace and reflect the clinical environment.

Similarly, 43% of subjects in this sample did not report previous use of a KAFO including five subjects who reported no use of any orthosis. While all subjects were indicated for a KAFO at time of C-Brace fitting, they may have benefitted from a KAFO of another class. However, their entire orthotic experience is unknown. For example, they may have unsuccessfully trialed an AFO or KAFO in the past. Additionally, prescription of other device types may have been inappropriate for their unique presentation. Again, these conditions are representative of the real-world clinical environment.

In addition, attrition is often high in longitudinal and observational studies. As the study period increases, so does the opportunity for dropout and adverse events. Subjects move or do not feel the need to return, for example. The study implemented several mitigation measures to reduce this including indicating the 1-year visit as the primary endpoint and allowing the possibility of using 6-month data to fill missing 1-year data when not available. The presence of the COVID-19 pandemic during this period may have exacerbated attrition mechanisms and/or impacted results as well. While the pandemic reduced activity in the population overall, its effect on participation and performance in this study was not specifically evaluated and remains unknown.

Conclusion

Several significant and clinically meaningful improvements were observed in a widely diverse sample of individuals with indication for a KAFO after 1-year of real-world use with the C-Brace, a microprocessor stance and swing control orthosis. Among the clinical improvements were increased fast walking speed, walking capability, and patient-perceived balance confidence which translated into a reduction in risk of falling and actual falls. Further improvements included reductions in relevant functional status limitations, pain, and pain interference, and a meaningful improvement in quality of life. The results of this prospective observational registry provide additional evidence that the C-Brace is an effective option to improve safety, mobility, and quality of life for patients needing the support of a KAFO for walking.

Contributorship

RL & AK conceived the study. RL was involved in protocol development, gaining ethics approval, patient recruitment, data analysis, and reviewed and edited the manuscript. TK wrote the first draft of the manuscript, and was involved in patient recruitment and reviewed and edited the manuscript, AM was involved in data analysis and patient recruitment, BP was involved in ethics approvals and patient recruitment. KH was involved in developing the protocol and data analysis. AK reviewed and edited the manuscript. All authors approved the final version of the manuscript.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: RL, TK, AM, BP, & AK are employees of subsidiary companies of Ottobock SE & Co. KGaA, the manufacturer of the C-Brace. KH has received consultancies from Otto Bock HealthCare LP.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was funded internally by Ottobock SE & Co. KGaA and its subsidiaries.

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