



Effectiveness Results from the C-Brace[®] Retrospective Registry

Russ Lundstrom, MS, Alicia Drain, BS, Andreas Kannenberg, MD, PhD
Ottobock, Austin, Texas

INTRODUCTION

The C-Brace Orthotronic Mobility System is a microprocessor-controlled Stance and Swing Controlled Orthosis (SSCO) developed to overcome the limitations of KAFOs that do not offer damped knee flexion during weight-bearing or dynamic swing control. A retrospective registry was designed: (1) to gather safety and effectiveness data from patients that have been fitted with a C-Brace (2) to discover what assessments are routinely performed at clinics as a part of evaluating C-Brace patients. Effectiveness results from the chart reviews are presented to characterize potential patient benefits and to guide in the selection of measures to be used in the C-Brace Prospective Registry.

METHODS

Case Report Forms were developed to collect data for a variety of outcome measures based on discussion with prospective sites. Planned outcome measures at Hanger included the Timed Up and Go (TUG), Fast Walking Speed (FWS), and Berg Balance Scale (BBS), an Activity of Daily Living Questionnaire (ADLQ) and the Activities-specific Balance Confidence (ABC) Scale. IRB approval for the retrospective chart review and waiver of informed consent was obtained for each participating investigator. Baseline data was collected for outcome measures using a previous orthosis or no orthosis if subjects were not using an orthosis. Patient questionnaires were also mailed to patients by the Hanger clinics and completed questions made available for additional data collection to provide long-term, patient-reported outcomes.

RESULTS

Data was collected from 19 subjects having been fitted with a C-Brace at 14 clinics. Subjects were 5 female/14 male with an estimated mean age of 49.7 years and mean weight of 204 (125-272) lbs. 10 subjects were fitted for the left leg, 8 for the right, and 1 for bilateral fitting. The data collected for outcome measures represented a mean follow-up duration after C-Brace fitting of 6.4 (0-27.8) months.

The baseline (B/L) and change (Chg) scores for each of four outcome measures are summarized in the table below.

Outcome	FWS	BBS	ADLQ (Mobility)	ABC
	m/s	score	score	%
n	7	7	10	10
Cut-off	0.1	4	1	15%
Avg B/L	1.1 ± 0.50	44.9 ± 7.5	1.2 ± 1.13	37 ± 24%
Avg Chg	0.22 ± 0.26	1.57 ± 0.98	1.4 ± 1.38	15 ± 23%
Med FU	3 mos	3 mos	15 mos	15 mos

Cut-off scores were established for each outcome measure to determine the level of change from baseline that would be considered clinically meaningful. Clinically meaningful improvements were observed based on the mean change scores for FWS, ADLQ Mobility subscale and ABC. TUG results are not presented, since only 4 subjects had data at both baseline and follow up.

DISCUSSION

Clinically meaningful changes compared to baseline were observed in 10 of 12 subjects (83%) that had efficacy data at both baseline and follow-up. 5 of 7 (71%) of subjects had a clinically meaningful change in FWS. One had a clinically meaningful decline (>0.1 m/s slower), but this subject was already walking at 1.74 m/s at the time of C-Brace fitting. No information on gait quality in this subject was available.

Subject	FWS	BBS	ADLQ (Mob)	ABC	FU (mo)	👉?
0204	■	□	□	■	1	✓
0208	□	□	■	■	1/12*	✓
0212	□	□	■	□	24	✓
0213	□	□	■	■	18	✓
0214	□	□	□	□	12	
0216	■	□	■	■	6	✓
0217	□	□	■	□	18	✓
0220	□	□	□	■	30	✓
0222	■	□	□	■	24	✓
0224	■	□	□	□	6	✓
0301	■	□	□	□	3	
0302	■	□	□	□	3	✓

■ = clinically meaningful improvement

■ = clinically meaningful decline, □ = no change

□ = no data

*FWS & BBS assessed at 1 mo; ADLQ & ABC at 12 mos.

CONCLUSION

Results from this retrospective registry revealed that the majority of C-Brace subjects have demonstrated clinically meaningful improvements in outcome measures. FWS and ABC, in particular, appear to be sensitive outcome measures in the majority of subjects with implications for use in the planned prospective registry. The immediate orthotic effect was mixed in patients, which highlights the importance of training and accommodation before clinically meaningful improvements can be observed.

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