Training Outcomes from the C-Brace® Retrospective Registry

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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. Data on the training and training outcomes based on the chart reviews are presented to characterize C-Brace training which was used as a guide in the development of the C-Brace Prospective Registry.

METHODS

Case Report Forms (CRFs) 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. A training CRF was developed to collect information on training and training outcomes focused on key functions of C-Brace (e.g. donning/doffing, getting up from a seated position, sitting down in a chair loading both legs, descending ramps step-over-step, descending stairs step-over-step and resting while standing).

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.

Nine (9) subjects had documented results from their training sessions in the clinic charts. The training duration from first to final training date was available for 6 subjects with an average of 39.2 (17-64) days. The number of training sessions was noted for 5 subjects with an average of 5.2 (3 to 6) sessions.

All 9 subjects were able to don/doff the C-Brace; for 5 it was noted that they could do so independently. All 9 subjects could get up from a seated position; for 5 it was noted that they could do so independently. All 9 subjects could descend both stairs and ramps with a step-over-step pattern; for 2 it was noted that they could descend ramps without using a handrail, and for 3 it was noted that they could descent stairs without using a handrail.

12 subjects in the study had some outcome measures at both baseline and follow up. While 10 of 12 subjects had clinically meaningful improvements in at least 1 outcome measure, only 4 of these also had documentation regarding training, so the impact of training on outcomes could not be assessed.

DISCUSSION

For some clinics, off-site training resulted in documentation being unavailable to this registry. For this reason, our results cannot be used to estimate the proportion of C-Brace patients that are getting training. However, of those that had training documentation, the number of sessions is consistent with Ottobock recommendations for training and physical therapy based on established YouTube videos.

Training outcomes were consistent with those published by Schmalz et al [Ref 1], in which all subjects were able to demonstrate a reciprocal gait ambulating down stairs and ramps. Schmalz reported that none of the subjects were able to use reciprocal gait pattern down stairs with their previous orthoses; such data for previous orthoses was not available in this registry. While it was reported in this registry that 3 of the 9 subjects were able to walk down stairs without the use of the handrail, it should be noted that the C-Brace Instructions for Use includes a caution that the handrail should always be used when walking down stairs with the C-Brace.

CONCLUSION

Results from this retrospective registry revealed that all C-Brace subjects with documented training were able to demonstrate the ability to utilize the key features of the C-Brace, including the ability to walk down stairs and ramps with reciprocal gait. Future research is warranted to determine the impact of training on clinical outcomes.

REFERENCES

1. Schmalz T., et al. *Med Orth Tech* 125 (2005) 3, 67-74.

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