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Original Article

The effect of a novel thoracolumbar brace on spinal alignment in Parkinson's disease: a pilot study

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Abstract. [Purpose] Individuals with Parkinson's disease (PD) experience postural dysfunction, which can contribute to pain and an increased risk for falls. One method with limited research for addressing postural dysfunction is bracing. The objective of this pilot study was to establish the immediate impact of a novel thoracolumbar brace on postural alignment in individuals with PD. [Participants and Methods] This study utilized a single-participant randomized A-B design. Participants were included if they had a diagnosis of PD were 50–80 years of age, reported difficulty with posture, but were able to ambulate within their home and the community. Ten kinematic assessments of posture were completed in each phase. The primary outcome measure was postural alignment at the neck, trunk, and hip/knee. An analysis of postural stability and experience wearing the brace was also completed. [Results] Nine out of ten participants demonstrated at least one statistically significant change in a posture variable, but postural stability was variable across participants. [Conclusion] This pilot study demonstrated that the brace functioned as expected bringing postural alignment into a more neutral or extended position at the trunk and hip/knee. Further research on the long-term effect of the brace needs to be completed to determine its clinical value.
Key words: Orthotics, Posture, Parkinson's disease

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INTRODUCTION

Individuals with Parkinson's disease (PD) experience a variety of motor and cognitive symptoms secondary to dopamine loss, however, one of the most prevalent symptoms, across disease stages, is abnormal posture[1)]. The most common postural dysfunction is a stooped posture with moderate flexion of the knees and trunk, with elbows bent[2)]. These postural dysfunctions are associated with pain, kyphosis, falls, and can cause chronic dysfunction of the vertebral column or the surrounding structures[3)]. Together, these problems limit participation by individuals with PD in meaningful activity, roles, and occupations[4)]. The pathophysiology of axial postural dysfunction in PD is not well understood, but a number of different causes have been proposed including: axial rigidity, weakness, myopathy, poor muscle control and dystonia[5)]. Recent postural studies hypothesized increased postural angles were a result of axial rigidity and weakness of the erector spinal muscles[6)]. Additional evidence for myopathy has been found with electromyography, muscle imaging, and muscle biopsy in patients with PD[7–9)]. The subsequent postural abnormalities put patients at risk for musculoskeletal pain, which has been reported by 70% of individuals with PD[10)]. Abnormal posturing has also been linked to an increased risk for falls[11, 12)].

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Several interventions have been developed to specifically address abnormal posture for individuals with PD including corrective exercise programs[13], tai chi[14], balance training[15], external sensory cueing, and external focus instructions[16]. While these interventions have demonstrated varying success, many focus on extrinsic cueing or sensory feedback as a means to remediate abnormal posture. An alternative is to directly target the orthopedic changes that come secondary to PD through a mechanical adjustment via bracing. Some studies have looked at bracing with home exercise programs for individuals with a severe presentation of anteriorly flexed posture, called camptocormoia, and have found positive results[17, 18]. However, both these studies focus on individuals with camptocormia, and thus further investigation on the use of bracing across the variety of postural impairments that may present in individuals with PD is warranted. Due to the impact that abnormal posturing has on individuals with PD and the limited amount of research available on the use of orthotics in this population, this pilot study investigated the immediate effect of a thoracolumbar orthosis to change posture in early-stage Parkinson's disease by answering the following questions:

1) Does a novel thoracolumbar brace change posture in individuals with PD, as measured by head and spinal alignment? Are changes also observed in measures of postural stability?

2) Does novel thoracolumbar brace restrict performance of typical activities in individuals with PD?

Answering these questions will demonstrate if the brace operates as intended, which is needed to consider further investigation of this device.

PARTICIPANTS AND METHODS

This study implemented a single-subject A-B design (A phase=no brace, B phase=brace) with random assignment of phase order to decrease the potential effect of fatigue on study outcomes. This design was selected due to the pilot nature of the study and the potential variability in the participants. This study was approved by the Duquesne University IRB after full board review (Protocol Number 2015/06/7). All participants provided written consent.

A total of 10 participants were enrolled in and completed this pilot study. Ten participants were thought to be sufficient for this study as power in single subject design is dependent on the number of data collection points per phase not the number of individuals in the study[19]. Participants were recruited through local support and exercise groups. To participate, persons needed to be between 50–80 years of age, have a diagnosis of PD and report difficulty with posture. All participants were able to ambulate independently in home and community with no more than intermittent use of a cane and could tolerate five minutes of standing and/or walking. Participants were excluded if they had 1) limited thoracolumbar spinal flexibility, 2) another neurological diagnosis, 3) history of surgery in the last 3 months, 3) chest pain or shortness of breath at rest or with activity, 4) severe orthostatic hypotension or high or low blood pressure, 5) a resting heart rate <50 or >100 bpm or 6) a waist circumference that would prevent the brace from fitting. Only 1 potential participant was not included in the study due to low blood pressure. Recruitment began in September 2015 and ended June 2016. See Table 1 for participant characteristics.

The brace used in this study is known as the CALIBRACE (Abilife Inc.; Pittsburgh, PA, USA). It was designed through a collaborative process of community and professional stakeholders at a local University. This novel brace was designed for persons with PD specifically, using a tension system that aims to depress and retract the shoulders. The version of the brace that was tested in this study was made of a flexible material with one metal stay in the back to support the tensioning system (Fig. 1). The primary investigator an occupational therapist with 11 years of experience was trained on measuring for and fitting the brace based on torso length and waist size. Participants wore the brace for no more than 40 minutes during data collection.

Intake measures were completed to allow for descriptive analysis of factors that may impact the brace's effectiveness. Demographics and comorbidities were gathered including length of diagnosis, medications, and number of falls in the last month. The Activities Specific Balance Confidence Scale (ABC) was used to measure balance confidence and has been validated for use with individuals with PD[20–22]. Additionally, the Berg Balance Scale (BBS) was used in order to assess static

Table 1. Descriptive characteristics for individual participants

Participant	Gender	Age	Self-reported time since diagnosis	Thoracolumbar flexibility (cm)	Activity specific balance scale (Total/100)	Berg balance scale (Total/56)
1	M	56	4 years	6	83.13	51
2	M	67	10 years	8	86.88	52
3	M	73	8 months	6	85	40
4	M	67	4 years	9	93.13	46
5	M	73	Unknown	8	93.13	47
6	F	69	2–3 years	8.5	93.75	52
7	M	63	7–8 years	11	86.88	50
8	M	68	2 years	6	98.13	50
9	M	65	4 years	10	79.38	50
10	M	77	12 years	7	93.13	45

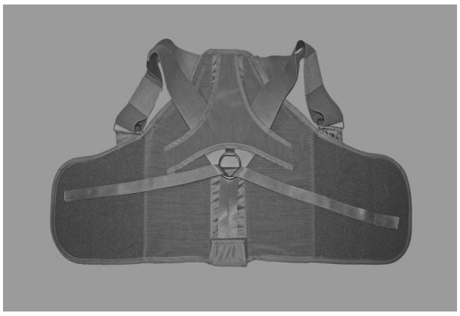


Fig. 1. Image of thoracolumbar brace (CALI-BRACE).
Brace was designed to depress and retract the shoulders using a flexible material.

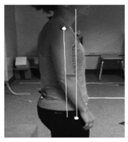
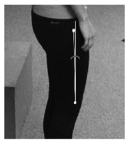
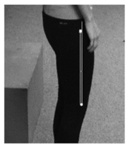
Variable	Points included	Example
Neck Angulation (Degrees)	External auditory meatus, Acromioclavicular joint	
Neck Translation (Inches)	External auditory meatus, Acromioclavicular joint	
Trunk Angulation (Degrees)	Acromioclavicular joint, Greater trochanter of femur	
Trunk Translation (Inches)	Acromioclavicular joint, Greater trochanter of femur	
Hip/Knee Angulation (Degrees)	Greater trochanter of femur, Lateral epicondyle of femur	
Hip/Knee Translation (Inches)	Greater trochanter of femur, Lateral epicondyle of femur	

Fig. 2. Postural alignment variables.

and dynamic balance[23, 24]. Scoring for this tool was completed via video by an experienced physical therapist with five years of clinical practice. Lastly, participants provided feedback on their experience using Likert scale and open-ended questions.

The following outcome measures were used to evaluate postural alignment and postural stability. Kinematic assessment of posture, the primary outcome of interest, was completed using a photographic method. This has been identified as a reliable method to measure posture[25]. A series of ten photo sets per phase were taken from three different views at a standardized distance of 8 feet from the participant. Participants were instructed to stand on a mark on the floor with a comfortable position looking straight ahead. Pictures were captured and digitized through a tablet-based application called PostureScreen Mobile (PostureCo Inc.; Trinity, FL, USA). The PostureScreen Mobile application also provided a target-like display to ensure that the photos were level. Three body segments were assessed for alignment: 1) neck position, 2) trunk position, and 3) hip/knee position. Both angulations and translations were analyzed bilaterally to determine which variables would be most beneficial in a larger trial. See Fig. 2 for variables analyzed.

A Bertec Model N60209, Type 4060A, six-degree of freedom force plate (Bertec; Columbus, OH, USA) was used to collect data on postural stability as an outcome of secondary interest. During this assessment, participants were asked to complete three 10-second trials of static standing with eyes open and then again with eyes closed, an adaptation of the protocol used by Cham and colleagues[26]. Root mean square of the center of pressure (COP RMS) and velocity (COP VEL) in both sagittal and coronal planes were measured.

A coin was flipped to determine if the baseline or intervention phase would occur first. After participants had been screened and consented to the study descriptive measures were completed. The participant was then prepared for the photographic assessments. Participants were asked to change into form-fitting clothing and reflective markers were placed by an experienced physical therapist on the individual's pelvis (e.g., bilateral anterior and posterior superior iliac spine), torso (e.g. bilateral T8 ribs), neck (e.g., spinous process of C7/T1, episternal notch), upper and lower extremities (e.g., acromioclavicular joint, greater trochanter, lateral epicondyle of the femur, medial and lateral malleoli, anterior tibialis tendon at ankle). These markers were placed to assist with digitization of the photos and increase reliability[27, 28]. If participants were starting with the intervention phase, the brace was fitted and then the markers were placed.

Next, the photographic assessment of posture was completed in standing as described in the outcomes section. In between each photographic assessment, participants completed either items from a modified version of the Physical Performance Test[29] (i.e., writing a sentence, turning in a circle, etc.) or a trial from the postural stability assessment. A total of ten photographs were captured in each phase. Participants completed these procedures twice, one time without the brace (A) and one time wearing the brace (B).

Data captured in the Posture Screen Mobile application were digitized according to the parameters provided in the application by the primary investigator, who has established excellent to good (ICC= 0.88–0.99) intra-rater reliability in a neurotypical population[28]. Data were then entered into Microsoft Excel® spreadsheets. Time-series charts were then made for each variable. The postural assessment data were examined for autocorrelation. If a variable was determined to be autocorrelated it was excluded from further analysis; this only occurred twice.

C-statistic analyses were run on data that were not auto-correlated. These tests evaluated individual participant changes over time[19]. Participants had 10 data points regarding posture in each phase. If a participant had a missing variable due to an obscured marker, this data point was replaced with the phase average value of this variable. The alpha level for all tests was set at 0.05 for a two-tailed test. Effect sizes were calculated using the Cohen's D method with a pooled standard deviation for outcomes that were found to be statistically significant.

A data analysis program using Python (Python Software Foundation; Beaverton, OR, USA) was created by AbiliLife and was used to process postural stability data. The program was developed based on the calculation presented by Cham and colleagues[25]. Data from the postural stability assessment were used to calculate: 1) the mean center of pressure location (COP RMS), and 2) mean center of pressure velocity throughout the 10 second trial (COP VEL). Both variables were calculated in the anterior/posterior and medial/lateral directions. For each individual, the three trials were averaged together and treated as a single measure for that individual. Comparisons were completed between brace on and brace off in both eyes open and eyes closed conditions. Postural stability data for the first two participants were excluded due to a calibration error leading to analysis of only eight participants for this set of data. A two-tailed paired t-test with alpha set at 0.05 and both group and individual Cohen's effect size calculations were performed. Due to the expected variability of response, individual analyses were run to better observe potential changes that might be obscured in group analysis.

Data from descriptive measures (i.e., ABC, BBS) were entered into Microsoft Excel (Microsoft Corp.; Bellevue, WA, USA) and placed into a master table with primary outcomes in order to examine unique cases or underlying trends. Similarly, data from the questionnaire was analyzed with frequencies to capture participants' feedback on Likert-scale questions and open-ended responses were organized into categories.

RESULTS

Of the ten participants enrolled in the study, nine were male and one was female. The average age of the participants was 67.8 years. Only one participant reported falls at home in the last month. Self-reported time since diagnosis ranged from 8 months to 12 years. The average score on the ABC was 89.25/100. For additional details see Table 1.

Nine out of 10 participants demonstrated at least one statistically significant change in at least one postural alignment variable. Mean differences and Z-scores for all variables are presented in Supplemental Materials Tables 1–3. Effect sizes for statistically significant variables are presented in Table 2.

Four participants presented with observed changes in the hip/knee translation variable and in these instances the changes observed indicated a more neutral hip position (i.e., value closer to zero) when wearing the brace. A total of three participants demonstrated changes in trunk position via angulations or translations, and all three participants demonstrated more extension when compared to not wearing the brace. Three participants demonstrated changes in head position in either angulations or translations. These data reported greater flexion angles or larger anterior displacements when wearing the brace.

Overall postural displacement measured by COP RMS was larger in the anterior-posterior direction for all eight participants under all conditions. There were no statistically significant differences observed at a group level between brace on and brace off in any condition. After individually testing all of the postural displacement variables in the anterior-posterior and medial-lateral directions, only one participant demonstrated statistically significant changes in postural displacement with the brace on. All other means were not found to be significant and effect size analysis was consistent with these findings. See Supplemental Materials Tables 4–7 for all postural sway analyses.

Majority of participants (7/10) agreed or strongly agreed that the brace was comfortable. In addition, all participants agreed or strongly agreed that they envision wearing the brace for one to two hours, however only 60% agreed or strongly agreed that they could see themselves wearing the brace for three to four hours. Open ended responses from the participants indicated that some liked the sensory experience of the brace (n=9) as well as the design (n=6). Areas of improvement included: lack of comfort in a specific area (n=5), the aesthetics of the brace (n=3), and uncertainty regarding effectiveness (n=1). Some participants wanted the brace to do more to mechanically pull the shoulders back (n=2) or provide more low back support (n=1).

Table 2. Variables at/or below level of statistical significance for postural alignment

Participant	Phase order	Variable	Side	Phase A	Phase B	Mean difference	Cohen's D
				Mean ± SD	Mean ± SD		
PD02	A, B	Hip/Knee Angulation	Left	−7.67 ± 1.43 dg	−5.27 ± 1.43 dg	−2.40 dg*	1.76
		Hip/Knee Translation	Left	−1.91 ± 0.35 in	−1.29 ± 0.35 in	−0.62 in*	1.85
PD05	A, B	Neck Translation	Right	2.34 ± 0.48 in	3.19 ± 0.35 in	−0.85 in*	−2.06
PD06	A, B	Hip/Knee Angulation	Left	−4.03 ± 1.63 dg	−0.75 ± 1.56 dg	−3.28 dg*	−2.17
		Hip/Knee Translation	Left	−1.28 ± 0.52 in	−0.30 ± 0.48 in	−0.98 in*	−2.07
PD07	A, B	Trunk Angulation	Left	−6.49 ± 1.67 dg	−9.70 ± 0.50 dg	3.21 dg*	3.56
		Trunk Translation	Left	−2.70 ± 0.84 dg	−4.07 ± 0.21 dg	1.37 dg*	3.5
PD09	A, B	Hip/Knee Translation	Left	−0.86 ± 0.48 dg	−0.14 ± 0.38 dg	−0.72 dg	1.74
				Phase B	Phase A		
				Mean ± SD	Mean ± SD		
PD01	B, A	Neck Translation	Right	7.41 ± 0.47 in	6.13 ± 0.23 in	1.28 in*	3.61
PD03	B, A	Neck Angulation	Left	37.82 ± 3.19 dg	30.46 ± 5.15 dg	7.36 dg*	1.77
		Neck Translation	Left	5.72 ± 0.55 in	4.38 ± 0.80 in	1.34 in*	2.36
		Hip/Knee Translation	Left	1.41 ± 0.50 in	2.09 ± 0.53 in	−0.68 in*	1.36
PD04	B, A	Trunk Translation	Left	−1.54 ± 0.61 in	−0.16 ± 0.63 in	−1.20 in*	−2.23
PD10	B, A	Trunk Translation	Right	5.22 ± 0.75 in	6.43 ± 0.57 in	−1.21 in*	−1.99

*p-value was less than 0.05. Negative values represent extension and positive values represent flexion.

DISCUSSION

This pilot investigation of a thoracolumbar brace for individuals with PD found that 90% of the participants demonstrated at least one statistically significant change in a posture variable. No statistically significant changes in postural sway were observed across conditions at the group level. In addition, most participants found the brace comfortable enough to wear for two hours at a time, although several recommended adjustments to the straps and style of the brace.

Only one participant (PD03) had statistically significant changes observed at two locations (i.e., neck and hip) when wearing the brace. Additionally, on postural sway measures PD03 demonstrated the only significant changes in center of pressure displacement with eyes open in anterior-posterior and medial-lateral directions. PD03 was a male who had only had a diagnosis for 8 months but presented with the lowest BBS score in the sample (40/56) and limited thoracolumbar flexibility of 6 cm. His ABC score was an 85/100. In contrast, the 8th participant (PD08), demonstrated no statistically significant changes with the brace for postural alignment. Furthermore, during postural sway measures PD08 demonstrated improvements when wearing the brace in all variables except medial-lateral with eyes closed, but none were found to be significant. PD08 had his diagnosis for 2 years, and similarly had thoracolumbar flexibility of 6 cm. However, PD08 had a BBS score of 50/56 and an ABC score of 98.1/100 demonstrating greater balance and balance confidence. Both participants had the same phase order. A comparison of these two cases suggests that the brace may be of greater benefit to individuals with decreased balance and balance confidence. In this study, exclusion criteria were set that limited the level of balance impairment of participants. Future investigations with the brace should consider inclusion of individuals with decreased balance as the brace may be of greater benefit to these individuals in modifying their posture and influencing postural stability.

It should be noted that in the four participants who demonstrated two or more statistically significant changes, all of them had changes at the same body segment in both angulations and translations. This suggests that in future studies the number of variables measured could be reduced as it is likely that changes observed in one measurement would also be seen in the other. Conversely, there appeared to be a lateralization of effect with 11/15 statistically significant changes occurring on the left side. One possible reason for this could have been that the left sided pictures were the last to be taken and therefore impacted by fatigue. Other possible explanations include hand dominance and side of greater weakness due to PD. These were not initial factors of consideration and therefore these data were not collected. Future studies should collect data on these factors and possibly consider taking all photos at the same time point.

Of the participants who demonstrated statistically significant changes, the majority of the effect sizes were large (i.e., greater than 0.80)[30]. This further suggests that the brace could provide improvement postural alignment for individuals with Parkinson's disease. One unexpected finding was that those with changes to neck position, appeared to demonstrate an increase in neck flexion, which was opposite of what was anticipated. This may be due to how the mobile application calculates neck position via the external auditory meatus and the acromion of the shoulder. If the brace functioned as intended, by retracting the shoulders and the head position remained the same, this would increase the amount of flexion angle and translation reported.

The findings of this pilot study demonstrate that the brace at two joint segments functioned in the manner in which it was anticipated. This is consistent with previous research in persons with PD who have greater postural impairments[17, 18]. While the brace did demonstrate changes to postural alignment, changes in postural stability were variable across the sample. This may be expected with a small sample size; however, it may also be reflective of the limited time of application. While participants wore the brace for the longest time when postural stability was tested, research with individuals with orthopedic limitations suggests that a larger dosage over a longer period of time is needed to see changed in postural stability[31, 32].

This study does present with limitations, the first of which was the A-B design. A third reversal phase would have allowed for more confidence that the brace was the mechanism of action. The randomization approach was intended to reduce the impact of not having a third phase by demonstrating change regardless of phase order. The second limitation is that the markers may have shifted over time and others fell off during testing. As noted in the methods, an experienced physical therapist was present to place all markers and fix those that may have fallen off, potentially reducing the amount of error. Finally, the short wear time of the brace and the specific criteria for participants to be included in the study are limitations that impact the external validity and should be addressed in future research.

This study was a necessary first step in understanding the potential impact of a novel thoracolumbar brace for individuals with PD. Further research on the impact of the brace on functional outcomes when worn over longer periods of time is necessary to determine its therapeutic value.

Presentation at a Conference

Part of this work was presented at the 2016 World Congress of Neurorehabilitation in Philadelphia, PA. There was not a published abstract from this conference.

Funding and Conflict of interest

No specific funding was received for this work. AbiliLife provided the braces and an analysis program for use in the study. Representatives from the study also provided input on the study design and outcomes of interest. Dr. Bleakley assisted in the development of the device used in this study and was a member of the board for AbiliLife without compensation. The board was dissolved in 2017. All others have no financial conflicts of interest.

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