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Effects of osteopathic manipulative treatment vs. osteopathic cranial manipulative medicine on Parkinsonian gait

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Abstract

Context: Sixty thousand people are diagnosed with Parkinson's disease (PD) each year, making it the second most common neurodegenerative disorder. PD results in a variety of gait disturbances, including muscular rigidity and decreased range of motion (ROM), that increase the fall risk of those afflicted. Osteopathic manipulative treatment (OMT) emphasizes the central role of the musculoskeletal system, which could be ideal for addressing the somatic dysfunction associated with neurodegeneration in PD. The close anatomical relationship of structures implicated in PD within the skull and the increased frequency of strain patterns raise the question of whether osteopathic cranial manipulative medicine (OCMM) can improve gait performance by improving circulation to the affected nervous tissue. However, there have been few studies in recent years that explore the effects of a standardized OMT protocol on Parkinsonian gait characteristics, and there have been few studies that include OCMM techniques.

Objectives: This study aims to determine whether a single session of OMT or OMT + OCMM can improve the gait of

individuals with PD by addressing joint restrictions in the sagittal plane and by increasing ROM in the lower limb.

Methods: The following study is a two-group, randomized controlled trial in which individuals with PD (n=45) and age-matched healthy control participants (n=45) were recruited from the community. PD participants were included if they were otherwise healthy, able to stand and walk independently, had not received OMT or physical therapy (PT) within 30 days of data collection, and had idiopathic PD in Hoehn and Yahr stages 1.0–3.0. PD participants were randomly assigned to one of three experimental treatment protocols: a 'whole-body' OMT protocol (OMT-WB), which included OMT and OCMM techniques; a 'neck-down' OMT protocol (OMT-ND), including only OMT techniques; and a sham treatment protocol. Control participants were age-matched to a PD participant and were provided the same OMT experimental protocol. An 18-camera motion analysis system was utilized to capture 3-dimensional (3D) position data in a treadmill walking trial before and after the assigned treatment protocol. Pretreatment and posttreatment hip, knee, and ankle ROM were compared with paired t-tests, and joint angle waveforms during the gait cycle were analyzed with statistical parametric mapping (SPM), which is a type of waveform analysis.

Results: Individuals with PD had significantly reduced hip and knee extension in the stance phase compared to controls (32.9–71.2% and 32.4–56.0% of the gait cycle, respectively). Individuals with PD experienced a significant increase in total sagittal hip ROM ($p=0.038$) following a single session of the standardized OMT-WB treatment protocol. However, waveform analysis found no significant differences in sagittal hip, knee, or ankle angles at individual points of the gait cycle following OMT-WB, OMT-ND, or sham treatment protocols.

Conclusions: The increase in hip ROM observed following a single session of OMT-WB suggests that OCMM in conjunction with OMT may be useful for improving gait kinematics in individuals with PD. Longitudinal studies

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over multiple visits are needed to determine the long-term effect of regular OMT and OMT+OCMM treatments on Parkinsonian gait characteristics.

Keywords: cranial manipulative treatment; osteopathic manipulative treatment; Parkinson's disease.

Parkinson's disease (PD) is the second most common neurodegenerative disease and is currently estimated to affect 1 million Americans, with 60,000 new diagnoses being made each year (<https://www.parkinson.org/Understanding-Parkinsons/Statistics>) [1]. Individuals with PD are three to nine times more likely to fall than healthy adults, with two-thirds of them falling recurrently [2, 3]. Falling/gait disturbance is a major contributor to PD disability [3], doubles the direct medical costs of PD [4], and is associated with an increased risk of death [5]. Therefore, treatment options that reduce fall risk are important to examine.

Reduction of joint range of motion (ROM) in the sagittal plane is a prevailing feature of Parkinsonian gait and fall risk. Gait analysis has found that people with PD have a significantly slower walking velocity, decreased stride length, and decrease in ROM at the ankle, knee, and hip joints compared to controls [6–10]. The gait deficits identified in individuals with PD have a significant role in increasing fall risk [11]. A reduction of maximal hip extension in the terminal stance phase and a reduction in plantar flexion of the ankle at toe-off reflects a more conservative gait pattern with less propulsive drive, which would contribute to the slower walking velocity and step length seen in PD. A slower walking velocity and decreased step length have been associated with increased fall risk in elderly populations [12], yet they are not the only indicators for increased fall risk in individuals with PD [11]. Sufficient vertical foot clearance may not be maintained in Parkinsonian gait due in part to a decreased ROM of the knee joint. This can have important implications for walking on irregular surfaces or obstacle avoidance [9], because insufficient foot clearance can result in a trip and subsequent fall. In individuals with PD, increasing the functional mobility of the lower-limb joints by increasing ROM could reduce fall risk and increase walking velocity.

It is important to understand what treatments may be useful in improving motor function or lessening the impact of gait disturbances in individuals with PD. Osteopathic manipulative treatment (OMT) emphasizes the central role of the musculoskeletal system, which could be ideal for addressing the somatic dysfunction associated with neurodegeneration and muscular rigidity in PD. A recent literature review concluded that OMT has demonstrated efficacy in addressing some symptoms of PD, although

the number of studies is limited [13]. Wells et al. [14] were the first to explore the influence of a single OMT session on the gait characteristics of 20 individuals with PD. They hypothesized that OMT could break the cycle of muscle tension and muscle, fascial, and tendon shortening that contributes to decreased joint ROM and postural instability [14]. The study showed that those with PD exhibited a significantly increased stride length and increased upper and lower limb segment velocities following OMT [14]. A pilot study has since examined the effects of multiple sessions of a standardized OMT protocol on nine individuals with PD over a period of 6 weeks and found a significant improvement in motor function as measured by the Movement Disorders Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS) [15], yet it did not examine functional mobility (i.e., walking).

Much of the attention in addressing PD gait through OMT has been aimed at the lower body and trunk. PD is a disorder of the basal nuclei, and any interruption of the arterial supply may contribute to an accelerated disease progression in individuals with PD. Therefore, attention to the head, neck, and central nervous system should be considered during OMT. Cranial strain and somatic dysfunction of the upper cervical spine and occiput may influence the substantia nigra, the site of PD-associated neurodegeneration. If so, an increase in circulation to the nervous tissue may counteract these effects and mitigate the signs and symptoms of PD. A retrospective study performed by Rivera-Martinez and colleagues [16] recorded the somatic dysfunction and strain patterns found in 30 individuals being treated for PD and found an increased frequency of occipitoatlantal and occipitomastoid compressions compared to an age-matched healthy control group. The dysfunctions identified by Rivera-Martinez and colleagues [16] could potentially originate from a stooped Parkinsonian posture with flexion at the head, torso, and lower extremities, and cranial dysfunction at the occiput may have a significant effect on the substantia nigra. An increased frequency of somatic dysfunctions in individuals with PD, and the close anatomical relationship of structures implicated in PD within the skull, raise the question of whether osteopathic cranial manipulative medicine (OCMM) can improve gait performance by improving circulation to the affected nervous tissue [13, 17, 18].

The purpose of this study was to determine whether OMT is a viable adjunctive treatment for improving the walking mechanics of patients with PD, and whether the addition of OCMM to the OMT protocol would further improve gait. It was hypothesized that individuals with PD will exhibit decreased ROM at the hip, knee, and ankle joints when compared to a healthy control group, and

that the application of a standardized OMT protocol will improve Parkinsonian gait by decreasing rigidity, as evidenced by an increase in the ROM of the hip, knee, and ankle joints. Additionally, it was hypothesized that the addition of OCMM to the treatment protocol will further improve gait kinematics compared to an OMT protocol focused only below the head and neck.

Methods

This study was approved by the North Texas Regional Institutional Review Board (IRB Project #2016-097). The study was funded by a grant from the American Osteopathic Association (Grant No. 191611706). The study was post-hoc registered with ClinicalTrials.gov (NCT04946760).

Prior to the study, written and informed consent was obtained from all participants by the authors (R.M.P. and K.L.H.). Participants were compensated \$50 each for a one-time visit. If a participant arrived in good faith for testing but was disqualified by the investigator (e.g., scores <26 for PD group and <24 for control group on the MMSE and/or >3.0 on the Hoehn and Yahr Scale [PD]), he or she was paid \$10 for their participation.

Subject recruitment and inclusion/exclusion criteria

The present study is a two-group, randomized controlled trial in which individuals with idiopathic PD (n=45) and age-matched healthy participants (n=45) were recruited from the community through senior living centers, churches, independent living residences, appropriate PD-related events, and the University of North Texas Health Science Center (UNTHSC) on-campus clinic between December 2016 and September 2019. Participants were recruited from these locations via flyers, University Daily News, and word of mouth, and screening for inclusion/exclusion criteria was conducted over the phone. Participants were included in the study if they were above the age of 18 years, otherwise healthy and injury-free outside of their PD diagnosis, abstained from any OMT or physical therapy (PT) within the past 30 days (self-reported), and were able to stand and walk independently without the use of assistive devices. Further, for those with PD, participants were included if they had a neurologist-diagnosed idiopathic PD in Hoehn and Yahr stages 1.0–3.0. Participants were excluded if they had cognitive impairment as defined by the Mini-Mental State Examination (<26 for PD and <24 for controls).

Study design and data collection

Data were collected utilizing an 18-camera Motion Analysis System (Motion Analysis Corp, Santa Rosa, CA) integrated with a dual-belt treadmill V-Gait Computed Assisted Rehabilitation Environment Network (CAREN, DIH Technology Inc., Norwell, MA) sampled at 120 Hz and 1200 Hz, respectively. A chest harness tethered overhead to a steel safety system could support the participant's entire body weight in the event of a fall (Figure 1).

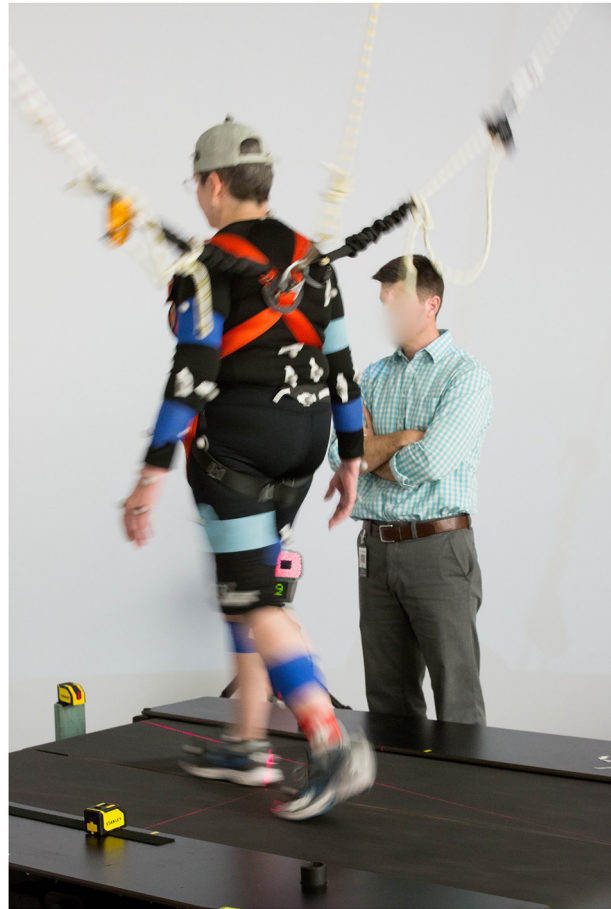


Figure 1: Photo of a 63-year-old woman with PD in the motion capture system.

After consenting, participants drew a letter from a basket to identify randomization into one of three treatment groups (15 letters each). The study design included a sham, standardized OMT neck down (OMT-ND), and standardized OMT whole-body including OCMM (OMT-WB) protocols (Figure 2). After written informed consent was obtained, participants underwent a baseline assessment of clinical measures and neurological evaluations including the Mini-Mental State Exam, the UPDRS, and Hoehn and Yahr Stage (H&Y). Each participant's natural walking speed was then calculated by timing a short walk over 20 feet overground distance and was utilized to set the initial treadmill speed. Participants then donned a harness, had 54 markers placed on key anatomical landmarks based on a modified Helen Hayes full-body marker set, and underwent a short static and dynamic calibration phase for the motion capture system before completing a variety of tasks. This study examined the walking task only. During the walking task, the treadmill was set at the participant's natural walking speed and adjusted to match the participant's comfortable habitual walking pace. Once adjusted, the participant walked for 30 s at this pace.

After the baseline assessment, participants received an OMT or sham treatment protocol (Appendix A) from a board-certified neuromusculoskeletal medicine and osteopathic manipulative medicine (NMM/OMM) osteopathic physician (K.L.H. and R.S.). Following are brief descriptions of the OMT-ND, OMT-WB, and sham protocols.

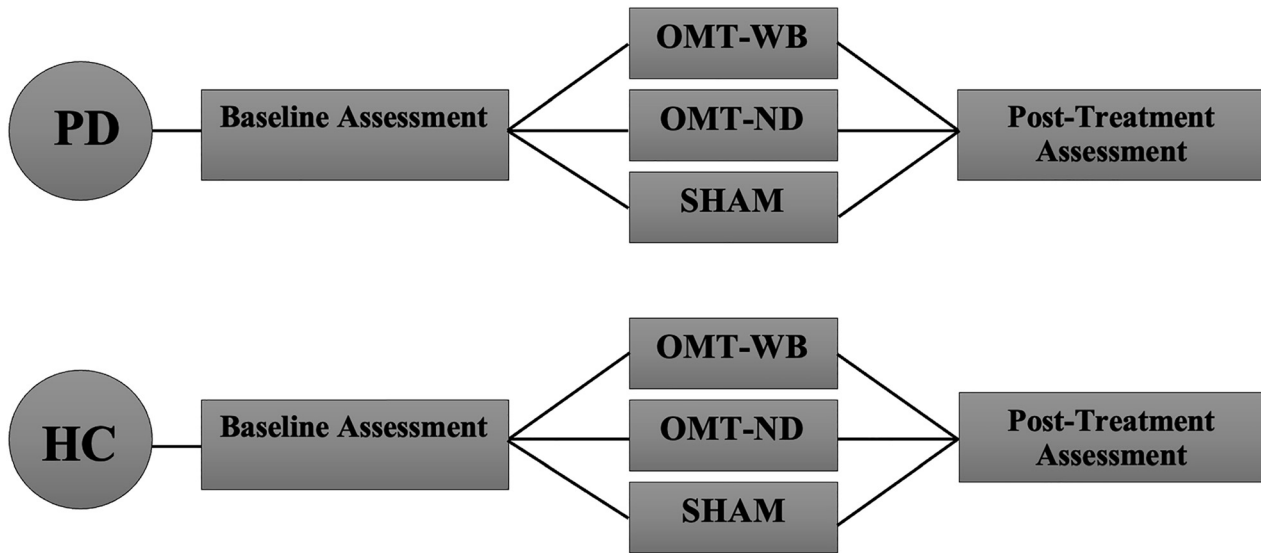


Figure 2: Study design. PD, Parkinson’s disease; HC, healthy control; OMT-WB, osteopathic manipulative treatment whole-body protocol; OMT-ND, osteopathic manipulative treatment neck-down protocol.

- **OMT-ND:** The neck-down protocol took into consideration previous relevant studies [14, 19]. OMT was utilized bilaterally on the following areas with one or more techniques including myofascial release, articular, muscle energy, and balanced ligamentous tension. The OMT-ND protocol lasted approximately 20–25 min and targeted the cervical, thoracic, and lumbar spine, shoulder girdle, sacroiliac joint, innominates, leg musculature (including psoas, piriformis, hamstring, and adductors), and ankles.
- **OMT-WB:** This protocol included all of the techniques in the OMT-ND protocol, but it also included techniques focused on expected cranial dysfunction [16]. The OMT-WB protocol lasted approximately 25–30 min and included the following: evaluation for strain patterns, occipitoatlantal decompression, sphenobasilar synchondrosis decompression, occipitomastoid suture V-spread, temporal bone balancing, and venous sinus drainage techniques.
- **Sham:** The sham protocol consisted of an examination of the subject’s active and passive ROM in the spine and extremities, and it tested the same joints that were treated with OMT. The subject was similarly positioned in sitting, supine, and lateral recumbent positions but did not receive active intervention. To provide a sham for the OMT-WB protocol, the subject lied supine with the physician’s pronated hands supporting the dorsal aspect of the patient’s head. The sham procedures were conducted for approximately 20–25 min.

Following receipt of an OMT or sham protocol, each participant underwent the same data collection procedures as outlined above.

Data processing

Visual3D (C-Motion, Germantown, MD) was utilized to create a virtual 3-dimensional (3D) model from the motion capture data. In Visual3D, a previously created model template containing pre-defined body segments and joints was applied to the position data of the reflective markers. This model is then applied to the walking trial of the

participant so that joint angles can be calculated utilizing standard inverse dynamic calculations for each time point in the gait cycle.

MATLAB (Mathworks, Inc., Natick, MA) was utilized to time-normalize the resulting joint flexion angle data at the hip, knee, and ankle to 100% of the gait cycle including both the stance and swing phases. Heel strike was utilized for the delineation of gait cycles, which was defined based on the coordinate-based treadmill algorithm outlined by Zeni and colleagues [20].

$$t_{\text{Heel Strike}} = -(Z_{\text{heel}} - Z_{\text{sacrum}})_{\text{max}}$$

The use of this coordinate-based treadmill algorithm for defining gait events eliminates the need for force plate data. Force plate data in studies involving individuals with gait abnormalities can be inaccurate, especially in cases in which a shuffling gait may result in insufficient vertical foot clearance during the swing phase, registering a ‘heel strike’ before the limb has finished its recovery.

Five gait cycles from the middle of the walking trial were extracted and averaged for each participant to overcome normal stride-to-stride variability [21]. The participant’s self-identified dominant limb, defined by which leg the participant would utilize to kick a ball, was utilized for the analysis because in individuals with PD who present asymmetrically, the dominant-side is found to be affected first in both right- and left-handed individuals [22]. ROM was calculated for each lower-limb joint as the maximum flexion of the joint subtracted by the maximum extension, or minimum flexion, during one full gait cycle and averaged for the five extracted gait cycles.

Statistical analysis

Demographic and clinical measures were analyzed between the three experimental groups (SHAM, OMT-WB, OMT-ND) utilizing one-way analysis of variance (ANOVA) and Hedge’s *g* effect size (Table 1). To examine the baseline differences in gait between PD and healthy control participants, statistical parametric mapping (SPM) independent *t*-tests [23] were performed on the pre-treatment (prior to receipt of

Table 1: Control and PD (mean \pm SD) participant demographics.

Control (n=43)	OMT-WB (n=15)	OMT-ND (n=15)	Sham (n=13)	P- Value
Age, years	66.9 \pm 11	68.2 \pm 9.5	65.2 \pm 8.0	0.719
Height, cm	176.1 \pm 10	169.5 \pm 11	175.0 \pm 7.6	0.149
Mass, kg	84.9 \pm 25	76.5 \pm 12	85.7 \pm 18	0.364
M/F	10M/5F	7M/8F	9M/4F	–
PD (n=41)	OMT-WB (n=15)	OMT-ND (n=14)	Sham (n=12)	P- Value
Age, years	67.9 \pm 12	70.2 \pm 8.0	63.5 \pm 7.7	0.214
Height, cm	170.9 \pm 8.8	168.6 \pm 12	173.9 \pm 15	0.539
Mass, kg	80.8 \pm 21	75.7 \pm 18	93.4 \pm 23	0.094
Hoehn and Yahr	1.97 \pm 0.7	1.68 \pm 0.8	2.13 \pm 0.7	0.290
UPDRS	19.9 \pm 11	14.7 \pm 8.4	24.1 \pm 7.0	0.039*
M/F	10M/5F	5M/9F	10M/2F	–

* $p < 0.05$ – Mean \pm SD OMT-ND and SHAM UPDRS scores are significantly different. OMT-ND, osteopathic manipulative treatment neck-down protocol; OMT-WB, osteopathic manipulative treatment whole-body protocol; PD, Parkinson's disease; UPDRS, Unified Parkinson's Disease Rating Scale. OMT-ND, osteopathic manipulative treatment neck-down protocol; OMT-WB, osteopathic manipulative treatment whole-body protocol; PD, Parkinson's disease; ROM, range of motion. *Effect size less than 0.2 is a negligible effect, Greater than or equal to 0.2 is a small effect, Greater than or equal to 0.5 is a medium effect, Greater than or equal to 0.8 is a large effect. Bold values were statistically significant.*

OMT-WB, OMT-ND, or SHAM protocol) joint angle waveforms. To examine the effect of the OMT protocols on lower-limb joint motion, pre- and post-treatment ROMs were compared utilizing paired t -tests, and SPM paired t -tests were utilized to compare pre- and posttreatment gait cycle-normalized joint angle waveforms. Data was compared individually for PD and control experimental groups. To compare the effects of each treatment protocol SPM one-way ANOVAs were utilized to compare joint angle waveforms between treatment groups in both the pre- and post-treatment conditions. All statistical analysis was performed in MATLAB with a significance level set at $p = 0.05$. Post-hoc analysis was performed with a Bonferroni correction.

SPM was chosen for this study because it allows for a continuous comparison of all data points in the gait cycle waveform. The continuous nature of time series data presents a unique challenge for analysis and has traditionally been analyzed in a discrete manner in biomechanics by reducing the waveform to key events within the time series for direct comparison, but this can neglect most of the waveform and overlook significant differences found in portions of the gait cycle [24]. SPM considers the continuity of time series data and avoids data reduction and potential bias that can be introduced through discretization.

Results

While a total of 90 individuals were recruited for the study, data collection errors resulted in missing or unusable marker position data for six participants. The final sample

sizes included 41 individuals with PD and 43 age-matched controls (Table 1).

No significant differences were found between the treatment groups for age, height, and mass in both the controls and PD groups (Table 1). The Hoehn and Yahr scores were not significantly different between the PD treatment groups, yet the UPDRS total score was significantly greater in the sham treatment group than the OMT-ND treatment group.

The PD and control participants' pretreatment hip and knee angle waveforms differed significantly at 32.9–71.2% and 32.4–56.0% of the gait cycle, respectively (representing the mid-to-terminal stance). No significant differences were found between PD and control pretreatment ankle angle waveforms (Figure 3).

Comparison of PD pretreatment and posttreatment joint ROM revealed a significant increase in hip ROM following administration of the OMT-WB protocol (Table 2; $p = 0.038$). No significant differences in hip ROM were found after the OMT-ND or sham protocols, and no significant differences were found at the knee or ankle joint for any treatment group. In healthy controls, no significant differences were found in joint ROM. No significant differences were found in the hip, knee, or ankle joint waveforms following OMT-WB, OMT-ND, or sham treatment protocols in PD or controls (Figure 4).

SPM found no significant differences in pretreatment joint angle waveforms between treatment groups at the hip, knee, or ankle joints in PD or controls. SPM found no significant differences in posttreatment joint angle waveforms between groups at the hip, knee, or ankle joints in PD or controls (Appendix B).

Discussion

The purpose of this study was to determine the effects of OMT and OMT + OCMM on Parkinsonian gait kinematics to evaluate if OMT and OCMM techniques are possible adjunctive treatments for individuals with PD. The main finding of this study was that hip ROM significantly increased following the OMT-WB protocol; however, no significant differences were present in the lower-limb joint angle waveforms after the application of either the OMT-WB or OMT-ND treatment protocols for individuals with PD.

This study found that before treatment, hip and knee angles in the sagittal plane were significantly different between PD and control individuals. Waveform analysis revealed that individuals with PD exhibited a significant reduction in hip extension, supporting the findings of

PD vs. Control

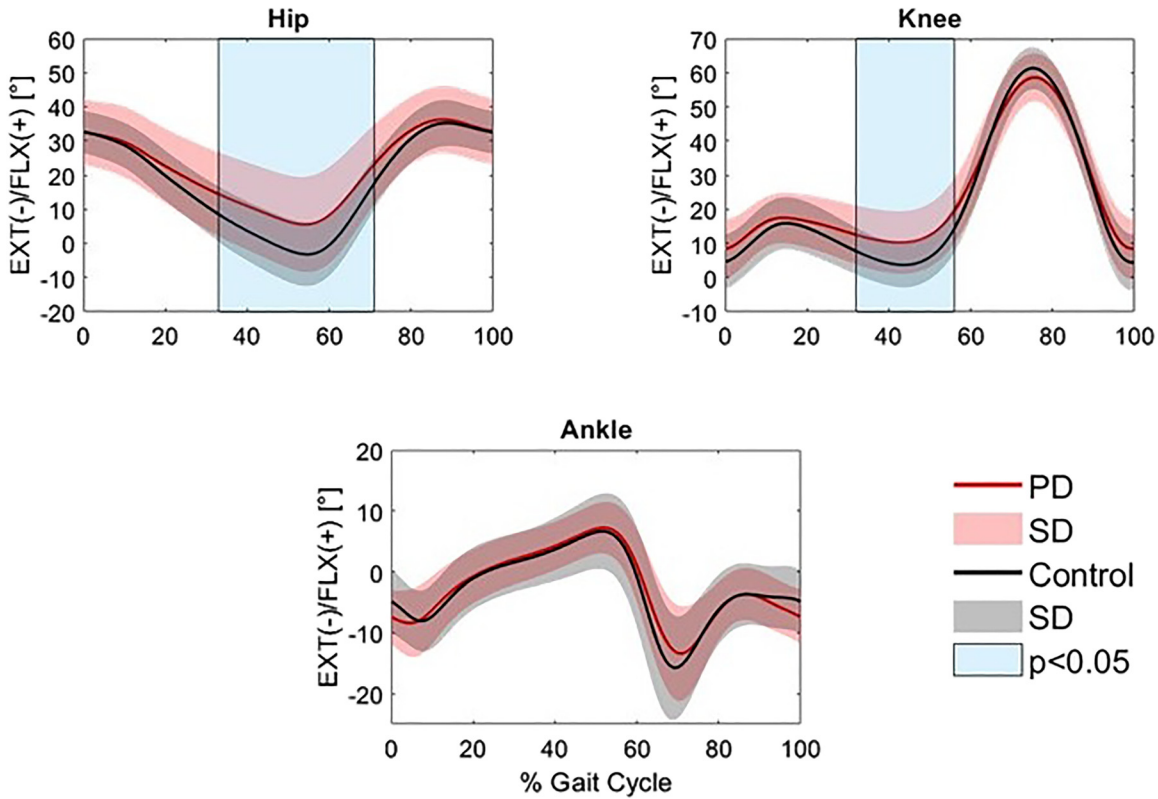


Figure 3: Statistical parametric mapping (SPM) analysis of PD (n=41, red) vs. age-matched healthy control (n=43, black) pretreatment sagittal plane joint angles presented with ± 1 standard deviation cloud; Y axis: Joint extension denoted by – degrees (EXT [–]) and flexion by + degrees (FLX [+]); X axis: % gait cycle from heel strike.

Table 2: Control and PD (mean \pm SD) pre- vs. posttreatment ROM.

Control		Pretreatment ROM (°)	Posttreatment ROM (°)	p-Value	Hedge's g
OMT-WB	Hip	39.1 \pm 8.6	40.4 \pm 7.2	0.151	0.159
	Knee	59.0 \pm 9.8	58.3 \pm 9.5	0.370	-0.077
	Ankle	23.7 \pm 6.1	24.2 \pm 5.9	0.517	0.088
OMT-ND	Hip	39.6 \pm 5.0	39.1 \pm 4.1	0.428	-0.062
	Knee	64.1 \pm 4.9	63.8 \pm 4.7	0.705	-0.069
	Ankle	24.4 \pm 4.5	24.3 \pm 3.8	0.87	-0.026
Sham	Hip	38.5 \pm 5.3	39.0 \pm 6.2	0.721	0.079
	Knee	58.9 \pm 5.3	60.9 \pm 6.5	0.086	0.323
	Ankle	23.9 \pm 5.9	24.0 \pm 4.5	0.905	0.022
PD		Pretreatment ROM (°)	Posttreatment ROM (°)	p-Value	Hedge's g
OMT-WB	Hip	29.1 \pm 10.8	31.4 \pm 9.8	0.038*	0.226
	Knee	48.1 \pm 9.7	49.4 \pm 11.2	0.153	0.117
	Ankle	20.3 \pm 6.1	21.5 \pm 6.0	0.148	0.182
OMT-ND	Hip	32.4 \pm 6.2	32.4 \pm 5.0	0.963	-0.009
	Knee	54.3 \pm 9.4	54.9 \pm 9.5	0.516	0.062
	Ankle	23.5 \pm 6.0	23.7 \pm 6.8	0.868	0.023
Sham	Hip	33.2 \pm 7.8	33.7 \pm 9.0	0.609	0.068
	Knee	56.7 \pm 9.2	60.6 \pm 9.5	0.071	0.399
	Ankle	24.2 \pm 7.8	24.5 \pm 6.6	0.726	0.040

*p<0.05.

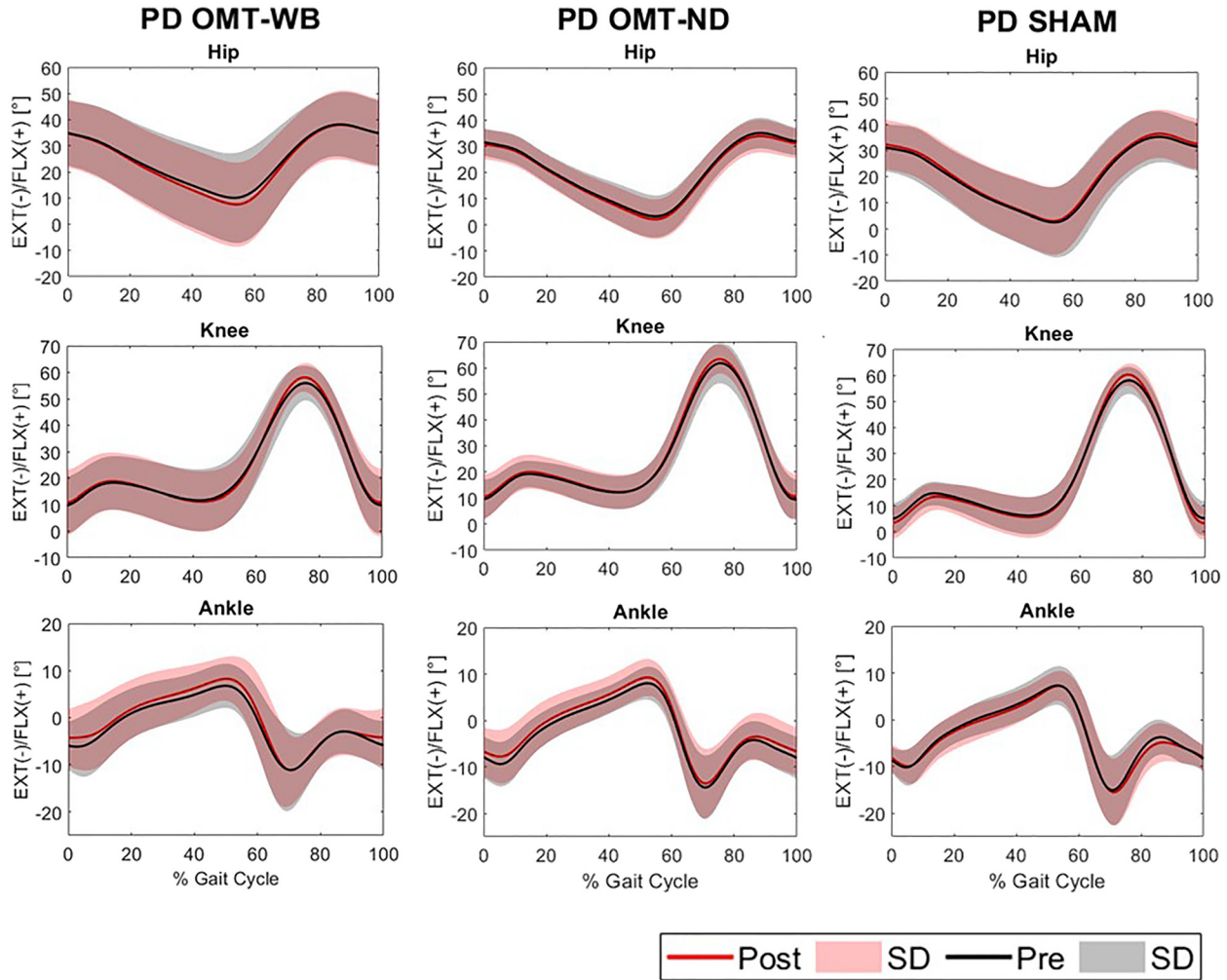


Figure 4: Statistical parametric mapping (SPM) analysis of sagittal joint angles pre- vs. post-OMT-WB, OMT-ND, or sham treatment for the PD experimental group; Y axis: Joint extension denoted by – degrees (EXT (–)) and flexion by + degrees (FLX (+)); X axis: % gait cycle from heel strike.

Kyeong et al. [10], who found that those with PD suffer a reduction in maximal hip extension in the stance phase. Additionally, this study found that knee extension is significantly reduced in individuals with PD during the stance phase compared to controls. The reduction of hip and knee extension in the stance phase in PD reflects a more conservative gait pattern in which double-limb support time and stability are prioritized. Addressing the identified restrictions in hip and knee ROM throughout the gait cycle may be important for improving joint kinematics during walking and decreasing fall risk.

An increase in hip ROM was identified in individuals with PD following receipt of a single standardized OMT-WB treatment protocol, which included OMT and OCMM techniques. This ROM increase was not identified following the OMT-ND or sham protocols, which raises important questions about the role of OCMM in improving Parkinsonian

gait. Our results suggest that an OMT-WB protocol may be important for addressing cranial strain patterns and somatic dysfunction of the upper cervical spine and occiput, including the increased frequency of occipitoatlantal and occipitomastoid compressions identified by Rivera-Martinez and colleagues [16], acutely improving ROM in individuals with PD through increased circulation to the affected nervous tissue [17, 18].

Waveform analysis performed in Figure 4 found no significant differences in joint angle waveforms following the OMT-WB, OMT-ND, or sham protocols. The results are contrary to our expectation that waveform analysis would provide insight regarding the increased stride length identified by Wells et al. [14] following a single session of OMT in individuals with PD. The lack of statistical significance in our analysis of joint angle waveforms may be attributed to large variability within the treatment groups,

particularly the OMT-WB treatment group, which can be visualized by the SD clouds plotted in the first column of Figure 4. This variability is likely due to a wide range of disease progressions within the randomized treatment group, and future studies may choose to examine the effects of OMT on Parkinsonian gait by progression of motor impairment as measured by the Hoehn and Yahr stages or the UPDRS scale.

SPM one-way ANOVA was utilized to compare pre-treatment joint waveforms between the experimental groups, which were not significantly different among the PD participants or controls. Establishing an equal baseline between the groups allowed for a later comparison of posttreatment joint waveforms between them. Again, no significant differences were found, indicating that no one treatment protocol significantly influenced sagittal hip, knee, or ankle angles more than another.

Limitations

This study had several limitations, the impact of which were mitigated through our research design. Standardized OMT protocols were utilized despite traditional osteopathic treatment principals, which champion a thorough evaluation and personalized treatment to address identified somatic dysfunction, limiting the application of our findings to a clinical setting. However, standardization of the OMT protocol is important because it allows for meaningful comparisons within the treatment groups and contributes to reproducibility of our results.

To allow for administration of the OMT protocol, the reflective markers were removed and re-applied for the posttreatment gait analysis. Our analysis relied on accurate marker placement on each subject before and after treatment, and to mitigate the risk associated with removal and reapplication of the markers, trained staff utilized key anatomical landmarks as marker placement references and the same staff member applied the markers pre- and post-treatment as suggested by prior studies [25]. Any deviation in the placement of the reflective markers on an individual before vs after treatment may have altered the results.

Unlike some other studies, we did not diagnose or record specific somatic dysfunctions. A chart on our protocol form (see Appendix) allowed for recording of the severity of somatic dysfunction in each region assessed.

Finally, this study examined the effects of a single session of OMT and OCMM on Parkinsonian gait. Future studies should be performed to determine if OMT may be helpful in the longitudinal treatment of PD patients' gait mechanics. Although this certainly allowed for a larger sample size to be

obtained, future studies should examine gait after several sessions to determine the effect of OMT and OCMM on the progression of motor and gait impairment in PD. Longitudinal studies will increase the relevance of the results for osteopathic physicians who manage PD over many visits.

Conclusions

This study results support our hypothesis that OMT is a viable adjunctive treatment option to improve walking mechanics in PD. Furthermore, the addition of OCMM to the OMT protocol appears to further improve gait. Waveform analysis found that individuals with PD in the OMT-WB group exhibited significantly reduced hip extension in the mid-to-late stance phase and reduced knee extension in the stance phase compared to controls (32.9–71.2% and 32.4–56.0% of the gait cycle, respectively). Individuals with PD experienced a significant increase in sagittal hip ROM following a single session of the standardized OMT-WB treatment protocol. However, waveform analysis found no significant differences in sagittal hip, knee, or ankle angles throughout the gait cycle following OMT-WB, OMT-ND, or sham treatment protocols.

This study provides valuable insight into potential effects of OMT on Parkinsonian gait and adds to the small but growing base of research surrounding the effects of OCMM in treating disorders of the central nervous system. By continuing to evaluate the effects of treatments such as OMT and OCMM on Parkinsonian gait, we hope to eventually identify whether OMT can assist osteopathic physicians in slowing the progression of gait/motor dysfunction in adults with PD, thereby decreasing the risk of falls and injuries.

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personnel compensation (10% of which was protected time), 4% participant compensation, 5% general supplies and equipment maintenance, and 4% travel costs. All participants were compensated for their time.

Author contribution: R.M.P. and K.L.H. provided substantial contributions to study conception and design, acquisition of data, and oversight during data processing and analysis; Z.T. processed/analyzed the data and drafted the article; S.M. provided substantial contributions to acquisition of data, and data processing/analysis techniques; all authors gave final approval of the version of the article to be published; and all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Competing interests: None reported.

Informed consent: All participants in this study provided written informed consent prior to participation.

Ethical approval: This study was reviewed and approved by the North Texas Regional Institutional Review Board (IRB project number: 2016-097). The study was registered post-hoc at clinicaltrials.gov (identifier: NCT04946760).

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