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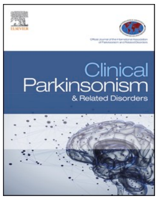

Short Communications

Do sensorimotor insoles improve gait safety in patients with Parkinson's disease on a short scale?

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ABSTRACT

Introduction: Parkinson's disease (PD) often leads to gait abnormalities, increasing the risk of falls and affecting daily life. Sensorimotor insoles aim to enhance foot sensitivity, potentially improving gait stability.

Methods: This study examined whether there are short-term effects of sensorimotor insoles on neural activation (measured by EEG), kinematic gait parameters (speed, cadence, step length, and step-length variability), and subjective gait stability in PD patients. Sixteen individuals suffering from PD completed a gait task while wearing sensorimotor and placebo insoles, respectively.

Results: The results showed no significant changes in kinematic parameters with the sensorimotor insoles. Subjective ratings of gait stability and attentional control of gait improved on average with the sensorimotor insoles, but again did not reach statistical significance. There was no significant reduction in alpha-band activity, indicating no improvement in sensorimotor processing.

Conclusion: The immediate impact of sensorimotor insoles on sensorimotor processing and gait characteristics in PD patients remains inconclusive. The small sample size limited the statistical power, highlighting the need for larger studies to comprehensively assess efficacy. Further research should investigate the long-term effects and potential benefits on disability measures in PD patients.

1. Introduction

Parkinson's disease (PD) is a common neurological disorder characterized by motor impairments. One of the affected aspects is gait which leads to decreased mobility and an increased risk of falls, disability, morbidity, and mortality in PD patients [1]. Individuals with PD exhibit various changes in gait compared to age-matched controls, including alterations in walking speed, step length, cadence, head-torso control, single support time, and arm swing. Moreover, spatial and temporal gait parameters are more variable and asymmetrical in PD patients compared to healthy individuals [1]. Aside from these kinematic changes, deviations in the structural and functional aspects of gait-related brain activity have been reported. In several studies, habitual walking showed increased cortical activity in PD patients compared to control groups (young or older adults) or baseline conditions (standing or sitting). In particular, regular walking led to greater activation of the prefrontal cortex (PFC), the supplementary motor areas (SMA), the premotor cortex (PMC), and the primary sensorimotor cortex [SMC; e.g., [2]]. Furthermore, correlations have been found between increased PFC activity and gait parameters [e.g., [2]]. In most cases, cortical activity was analyzed using electroencephalography (EEG). Changes in the power of the low-frequency bands in the EEG signal have been associated with abnormalities in motor function. Specifically, PD patients showed increased activity in the theta band (4–7 Hz), indicating poorer somatosensory information processing, as well as associated increased activity in the upper alpha band (10–12 Hz), reflecting higher utilization of cognitive resources, i.e. more cognitive attention [3].

Related to the diminished sensorimotor processing in individuals with PD, it has been observed that they often also experience reduced

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foot plantar sensitivity and that this correlates with an increased risk of falls [4]. Cutaneous mechanoreceptors in the human foot play a role in providing somatosensory feedback and thereby contribute to balance and gait control. As a consequence, one potential solution to address the fall risk is the use of specialized sensorimotor stimulating insoles, which are designed to enhance the sensitivity of the low-threshold skin receptors on the sole of the foot through a stimulation via textured surface elements [for a review see [4]]. This somatosensory stimulation aims to improve the transmission of pressure- or vibration-induced stimuli to the central nervous system. Consequently, it is hypothesized that sensorimotor integration for the control and regulation of postural and locomotor tasks will be enhanced [5], leading to improved gait stability.

Corresponding studies conducted in individuals with PD have confirmed the positive effects of sensorimotor insoles on various gait parameters such as gait speed, step length, cadence, and gait variability [for a review see [4]], while others have not observed any effects [for a review see [6]]. Most of the studies have looked at immediate effects, but gait adaptations are likely to build up over longer timescales. Since the neural stimulus for such adaptive processes could plausibly be detected immediately, supplementing kinematic measures with neural measures may facilitate the detection of short-term adaptations. However, to date, no study has looked at neural and behavioral effects of sensorimotor insoles in combination. A study by Kenny and colleagues [7] examined the use of textured insoles in young, healthy subjects in comparison to placebo insoles in bipedal stance. Neural results showed that centro-parietal cortical activity in the upper alpha band was reduced by the sensorimotor insoles, accompanied by a reduction in center-of-pressure fluctuations. This can be interpreted as an amplification of the incoming sensorimotor information by the foot stimulation.

The present study aims to investigate the effects of sensorimotor stimulating insoles on kinematic and neural parameters in patients with PD. Participants were asked to repeatedly complete a gait task while wearing their own shoes with two different types of insoles (placebo vs. stimulating). Additionally, to mitigate any residual effects, participants completed the same task without any insoles in between the two conditions, serving as a washout period.

We expected the following effects on cortical brain activity when wearing stimulating insoles compared to wearing placebo insoles:

- a reduction in the upper alpha band (parieto-central/occipital), reflecting an increase in sensorimotor processing
- a decrease in the theta band (fronto-central), indicating less attentional processing (i.e. less use of cognitive resources)

We also expected the cortical changes to be reflected in an improvement in kinematic parameters during free walking. Specifically, we expected wearing the stimulating insoles to result in

- a higher gait speed.
- a reduction in the step frequency (cadence).
- an increase in step length.
- a reduction in step-length variability.

Wearing the stimulating insoles should also influence the subjective perception of gait stability.

2. Methods

2.1. Participants

Sixteen patients (12 males, 4 females) with a clinical diagnosis of idiopathic PD according to the clinical criteria of the Movement Disorders Society [1] were recruited. All patients gave written informed consent to participate in the study, which has been approved by the Ethical Review Board of the University of Marburg. Patients aged between 44 and 73 years ($M = 60.25$; $SD = 8.26$). They had no higher-order cognitive deficits (MoCA < 26; [8]) and no clinical signs for polyneuropathy. They were classified into mild to moderate stages of the disease (stages I-II according to [9], and scored between 2 and 43 of the motor section of the UPDRS scale; $M = 16.25$, $SD = 11.30$). They were not severely restricted in walking, i.e. did not require walking aids such as walking sticks, rollators, etc. The patients were tested while on their medication.

Due to technical problems, only 10 participants were available for EEG data analyses and only 14 for gait stability estimations. The full data set could be analyzed kinematically.

2.2. Task and procedure

Participants performed a modified timed-up-and-go test (TUG test) at a self-selected habitual walking speed over a walking distance of 18 m. At the turning point, an obstacle in a distance of 9 m had to be circumnavigated. The task was executed in a randomized fashion, with blocks of 10 trials under each of the two distinct insole conditions: stimulating insoles (Stim), and placebo insoles (Placebo). Moreover, participants completed 10 trials wearing their regular shoes and insoles (Norm) as a washout phase between the experimental conditions in order to reduce the risk of carryover effects with the crossover design used.

Two pairs of individualized insoles were manufactured individually for each patient by a local orthopedic shoe technician (according to Jahrling [10]). The insoles were characterized by prominent functional elements, which were placed on a flexible EVA carrier layer (ethylene vinyl acetate, 3 mm) either in the proximal, medial and lateral longitudinal arch, as well as retrocapital in the distal transverse arch and under the toe berries. Placebo insoles consisted of the same support layer and had the same colored top cover as the stimulating insoles.

After completing the gait sequences in each condition, participants were asked to rate their individually perceived gait stability using a visual analogue scale (VAS) with the poles “very unsteady” and “very safe”.

2.3. EEG recordings and analyses

Brain activity was continuously recorded using a mobile EEG system with 32 active Ag/AgCl electrodes (Live-Amp, BrainProducts GmbH) positioned according to the international 10–20 system. Averaged mastoids served as reference for all electrodes. Since an active electrode system was used, impedance was kept below 10 kOhm.

EEG frequency bands upper alpha (10–12 Hz) and theta (4–7) were analyzed using EEGLAB (free open-source add-on for MATLAB) with standard pipelines for pre-processing (filtering, referencing, artifact rejection) and analysis (time/frequency analyses). For details see Supplementary materials.

2.4. Kinematic recordings and analyses

Gait behavior was recorded using a marker-based optoelectrical motion capture system (32-camera Vicon Vantage V5 / Vero v1.3 system, Vicon Motion Systems, UK) and the Vicon Nexus 2.15 software. The Vicon Plug-in Gait lower body model with four additional markers on each lower arm was used, in which a total of 24 reflective markers are attached to the person (directly on the skin or on tight-fitting clothing) using double-sided adhesive tape. The markers were positioned on defined anatomical landmarks.

As dependent kinematic variables, gait speed, cadence, step length, and step-length variability were determined and analyzed using self-written algorithms in MATLAB (version R2021). For details see Supplementary Materials.

2.5. Statistical analyses

Method-specific toolboxes were used for the statistical hypothesis testing of the EEG and behavioral data (MATLAB R2021, JASP 0.18.3.0). The analyses were based on recommendations for 2-phase crossover designs [11]. For each target variable, the sums or differences of the measured values from the first and last used insole were calculated. U-tests were then used to test for the negligibility of carryover effects (using the sum values) or to analyze the acute effects of the two test insoles (using the difference values between Placebo and Stim).

3. Results

3.1. Brain activity

We looked at two specific frequency bands of brain activity (alpha band and theta band) associated with sensorimotor processing. Fig. 1A shows a comparison between the Stim and Placebo insoles for the alpha band, which indicates whether sensorimotor processing is more inhibited (top) or more activated (bottom). There were a few more patients for whom the Stim insole led to a deterioration (inhibition of sensorimotor processing). Statistically, however, neither a positive nor a negative effect of the sensorimotor insoles could be clearly demonstrated ($W = 19$; $p = 0.171$; *biserial rank correlation* = 0.583).

Fig. 1B shows how much attention is paid to walking (again comparing the Stim insoles to the Placebo insoles). It can be observed that most patients used more cognitive resources when wearing the sensorimotor insoles (top) and that walking was not so much automated (bottom). The statistical p-value of the difference measure (Stim vs Placebo), however, missed significance ($W = 21$, $p = 0.067$; *biserial rank correlation* = 0.75).

3.2. Gait

Gait characteristics did not differ between insole conditions. No statistically significant changes were observed for the Stim insoles compared to the Placebo insoles (all p values > 0.5) gait speed ($M_{\text{Stim}} = 1.2$, $SD_{\text{Stim}} = 0.2$, $M_{\text{Placebo}} = 1.2$, $SD_{\text{Placebo}} = 0.2$; in m/s), cadence ($M_{\text{Stim}} = 106.8$, $SD_{\text{Stim}} = 7.1$, $M_{\text{Placebo}} = 107.2$, $SD_{\text{Placebo}} = 8.0$; in steps/min), step length ($M_{\text{Stim}} = 0.69$, $SD_{\text{Stim}} = 0.11$, $M_{\text{Placebo}} = 0.69$, $SD_{\text{Placebo}} = 0.11$; in m), and step-length variability ($M_{\text{Stim}} = 5.24$, $SD_{\text{Stim}} = 1.3$, $M_{\text{Placebo}} = 5.24$, $SD_{\text{Placebo}} = 1.4$; in %).

In terms of gait stability ratings, we found that most people rated their subjective gait stability higher with the Stim insoles than with the non-simulating Placebo insoles (top in Fig. 2B), although this was not statistically significant ($W = 37$, $p = 0.108$; *biserial rank correlation* = 0.54).

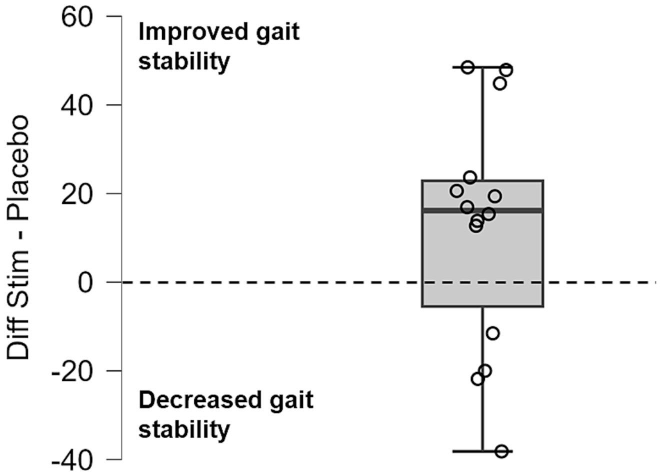

Fig. 2. Comparison of the sensorimotor stimulating insoles (Stim) with the non-stimulating insoles (Placebo) for subjective gait stability. Box plots and individual data (circles) of differential ratings, indicating whether gait is rated more safe (top) or more unsteady (bottom).

4. Discussion

To the best of our knowledge, this study is the first to examine the short-term effects of wearing sensorimotor stimulating insoles in patients with PD on both kinematic and neurophysiological measures. It had been expected that the sensorimotor stimulation would give rise to neural reorganization of attentional control (indicated by changes in the theta band) and cerebral sensorimotor processing (indicated by changes in the alpha band) and that this would lead to improvements in gait patterns and/or a feeling of safer gait. However, neural adaptations could not be statistically confirmed when the insoles were worn. Similarly, gait stability ratings did improve on average with a large effect size, but not statistically significantly.

Regarding kinematic measures, we found that gait was also not differently influenced by the insoles. For the measures that we hypothesized to be influenced by changes in sensorimotor processing (gait speed, cadence, step length, and step-length variability), we did not find any differences between conditions.

A limitation of our study is the small sample size which was attributed to technical and methodological issues encountered throughout the experiment. Consequently, our study lacked statistical power to demonstrate efficacy. However, the observed average changes with

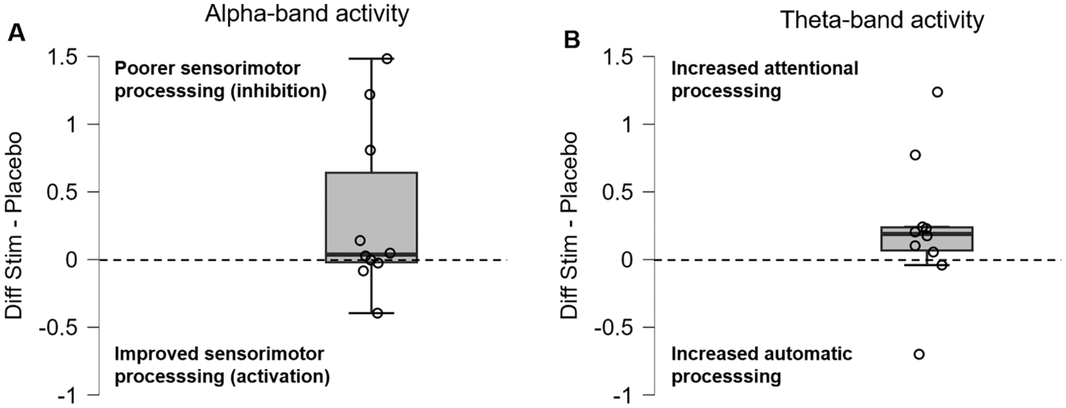

Fig. 1. Comparison (by difference measure of EEG bands) of the sensorimotor stimulating insoles (Stim) with the non-stimulating insoles (Placebo). A: Box plots and individual data (circles) of differential activity in the alpha band, indicating whether processing is more inhibited (top) or more activated (bottom). B: Box plots and individual data (circles) of differential activity in the theta band, indicating whether processing is more attention driven (top) or more automatic (bottom).

large effect sizes for the theta-band activity and the subjective ratings of gait stability suggest that these measures may be worth investigating in a larger study with sufficient statistical power. In contrast, changes in gait parameters are assumed to occur only after a familiarization period. Therefore, investigating longer-term effects should be a future aim. Additionally, as plantar skin afferents are particularly important in unforeseen situations, such as tripping, where plantar information is used to initiate compensatory movement strategies [12], effects could be provoked when using perturbation paradigms.

CRediT authorship contribution statement

Lisa K. Maurer: Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Visualization, Writing – original draft, Writing – review & editing. **Heiko Maurer:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Manuel König:** Writing – review & editing, Writing – original draft, Validation, Resources, Conceptualization. **Marlena van Munster:** Writing – review & editing, Project administration, Investigation, Resources, Conceptualization. **Saskia Haen:** Writing – review & editing, Resources, Project administration, Methodology, Investigation. **David J. Pedrosa:** Conceptualization, Investigation, Methodology, Project administration, Resources, Writing – review & editing.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Manuel Koenig reports equipment (sensorimotor insoles) was provided by a local podiatrist (footpower Gießen). Manuel Koenig reports a relationship to footpower Gießen that includes: employment. All other authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.prdoa.2024.100290.

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