International Journal of Health Sciences and Research
Volume 14; Issue: 11; November 2024
Website: www.ijhsr.org
Case Study *ISSN: 2249-9571*

Design and Performance Evaluation of Biofeedback Foot Orthosis to Inhibit Tremors on the Patients with Parkinson's Disease

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DOI: https://doi.org/10.52403/ijhsr.20241117

ABSTRACT

INTRODUCTION: Parkinson's disease (PD) is a progressive neurological disorder that affects the motor system, leading to symptoms such as tremors, rigidity, bradykinesia (slowness of movement), and postural instability. The incidence and prevalence increase with advancing in age, around 1% of people over the age of 60 years. As one of the hallmark features of Parkinson's disease which is most prevalent among majority of the people is the tremors and freezing of gait (FOG) which has a severe impact on the patient's gait and mobility. Hence leading to the distinctive gait abnormalities that can affect person's quality of life. With the progression in the severity and with the increasing age it has led to the dependency of the patients on the care givers and to the family members for the daily living activities. This paper presents a development of new low-cost biofeedback foot orthosis to suppress the tremors and freezing of gait (FOG) with the incorporation of vibration mechanism. As the vibration mechanism has a positive impact in suppressing tremors in the patients.
AIM: To develop an orthosis that provides biofeedback through vibration mechanism to inhibit tremors and freezing of gait (FOG) on the patients with Parkinson's disease.
METHODOLOGY: In this study a patient with Parkinson's disease has been taken and he has been prescribed with orthosis. After this the development of the prototype design, which includes design specifications, components and vibration mechanism after this an orthosis has been developed which has an incorporation of vibration motors which allows to send stimulus to the brain by which the patient get attentive enough so that they can perform their daily living activities and then the trial of the orthosis on the patient was done. The orthosis has been tested on one patient and he has been selected as per the Yohn & Yahr scale for determining the severity of the Parkinson's disease and pretest data was taken using Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) without the biofeedback orthosis and then the orthosis has been installed into the patient's footwear and after that post test data was taken and data analysis was done.
RESULTS: The biofeedback foot orthosis has improved the patient's gait cycle via suppression of tremors and also there has been a decrease in the freezing of gait episodes. By this, the patient's quality of life has been increased drastically and has made them to lead a healthy lifestyle.
DISCUSSION & CONCLUSION: This study showed improved results in user's satisfaction and has also led to tremor suppression which has improved patient's gait cycle and reduction

in the freezing of gait (FOG) episodes. In this study we developed a biofeedback foot orthosis to inhibit tremors on the patients with Parkinson's disease. With the incorporation of vibration mechanism it acts as a powerful proprioceptive stimulus, strongly affecting the motion perception of not only healthy people but also patients with Parkinson's disease or various other neurological disorders. In this study, we investigated the effect of biofeedback foot orthosis made up of high temperature thermoplastic (HTTP) sheet and concluded that it is effective in improving patient's gait cycle and also it can be worn with the normal footwear to their workplace. Further, the research can be conducted with a large sample size and increased intervention period.

Keywords: Parkinson's disease, Vibration mechanism, tremors & freezing of gait (FOG).

INTRODUCTION

Parkinson's disease (PD) is a common neurological disorder that affects people worldwide, with about 6.3 million cases globally[1]. The disease was first identified by James Parkinson in 1817. It is a long-term, progressive condition that gradually worsens over time and primarily impacts the brain's ability to control muscle movements[2]. Parkinson's disease leads to difficulties in coordinating and controlling muscles, but it is not contagious or fatal. In a small number of cases, genetics may play a role in developing the disease. Parkinson's disease usually begins around age 60, though it can start earlier. About 5 to 10 percent of cases are "early onset," where symptoms appear before age 50[3,4]. These early onset cases are often linked to specific genetic mutations. The disease is more common in men than women, although it can also affect younger people[5,6].

The most common clinical symptoms of PD are tremor, rigidity, akinesia, bradykinesia, postural instability, and freezing of gait[7]. These symptoms not only serve as key indicators for the diagnosis of PD but also significantly affect the daily lives and safety of those living with the condition. As one of the hallmark features of Parkinson's disease which we are considering is the tremors which has an severe impact on the patient's gait and mobility[6,7]. Hence leading to the distinctive gait abnormalities that can affect person's quality of life[8]. These challenges are indirectly associated with numerous unfavorable outcomes, such as high risk of falls, memory loss and even mortality[8-12].

Despite the wide range of medical interventions aimed at rehabilitating individuals with Parkinson disease often continue to suffer from severe gait and balance issues. As the condition progresses, a person's changed stride may cause falls and fractures, increasing the risk of death. Thereby, escalating the risk of mortality and leading to a growing dependence to others. As the severity of the disease escalates, the patient increasingly lose confidence in their ability to initiate movement, further complicating their condition. Parkinson's disease often begins in old age and worsens gradually over time.

Although the early signs and symptoms of Parkinson's disease can vary greatly, 70% of patients have tremor when they are first diagnosed. Tremors in Parkinson's disease (PD) are one of the primary marker symptom and often one of the first signs that alert individuals and healthcare providers to the possible presence of the disease[13,14]. Slow, rhythmic tremors usually begin in one hand, foot, or leg and later spread to both sides of the body in Parkinson's disease (PD). In the context of Parkinson's disease, tremors are most commonly seen as resting tremors, which means they occur when the muscle is relaxed and not engaged in active movement. Patients find tremor distressing because it is observable to others and can be unpleasant or aesthetically debilitating[15]. A severe form known as "freezing episodes," is experienced by certain patients[17]. It may be partially caused by deficiencies in motor plan access. Parkinson's disease patients may experience irregular gait with retropulsion, which can

result in falls backward. Forward falls may result from the stooping posture combined with a fast, festinating walk[16].

All these motor symptoms-Tremor, rigidity, bradykinesia, and postural instability occur as "direct effects" of Parkinson's disease. Since there is no way to manage every motor symptom, our primary focus here is on managing motor symptoms and in that specifically the tremors. A wide range of surgical and pharmacological treatments are also available to manage Parkinson's disease, offering patients various options to alleviate symptoms and improve quality of life, but these have a detrimental effect on the patient's life.

Physical therapy exercises and activities can sometimes be physically demanding for patients with PD, leading to fatigue, muscle soreness, or discomfort, especially for those with existing mobility issues[10]. Certain exercises or movements in physical therapy sessions may pose a risk of falls for PD patients, particularly those with balance and coordination issues. Therapy sessions may also evoke feelings of frustration or helplessness if progress is slow or if symptoms worsen[11-13].

All the available orthoses for patients with Parkinson's disease (PD) involves the use of various supportive devices designed to improve mobility, enhance stability, and reduce the risk of falls, which are common concerns for individuals with Parkinson disease[18].

There are various orthotic interventions like shoes with a wide base, low heels, and non-slip soles can help improve stability and reduce the risk of falls. Shoes that are easy to put on and take off are also beneficial. Another advanced technology for compensating tremors includes vibratory Insoles that can be placed inside the shoes and provide vibratory feedback directly to the soles of the feet[19]. In order to help patients overcome instances of freezing of gait, the vibration can be adjusted in accordance with the intended step, typically via motion sensors or manual controls[20]. Also various assistive devices for mobility are being used like the canes or other assistive devices equipped with a laser pointer can help overcome freezing episodes by providing a visual cue to step over, facilitating the initiation of movement[21].

While orthotic devices significantly help manage mobility and stability in Parkinson's disease (PD) patients, current devices often fail to cope up to the unique movement and posture challenges specific to these patients. A major gap exists due to the lack of customization, which is crucial given the fluctuating symptoms of PD, such as varying muscle tone and rigidity.

Many orthotic solutions do not adjust dynamically to these changes, leading to patient rejection. Devices that require manual adjustment can be difficult for PD patients with limited coordination and some like Parkinson disease shoes for tremor suppression as they have complicated working mechanism. Current vibratory orthoses are often bulky and aesthetically unpleasing, limiting their use outside the home and impacting social engagement[22]. Moreover, there's a scarcity of user-friendly designs that are easy for patients to put on, take off, or adjust independently. Existing orthotics also fall short in specifically targeting PD-related gait abnormalities or in providing feedback to enhance walking stability and stride continuously.

This study attempts to fill these gaps by developing a tremor suppression orthosis for the patients with Parkinson's disease by enhancing their independence and facilitating their engagement in daily activities.

The tremor suppression orthosis incorporates vibratory sensors to generate biofeedback vibrations which may improve proprioception and hence, improve balance and address the issue of freezing gait. Further, the goal of this study is to create a device that is not only functional but also usable and aesthetic to enhance the acceptability for the people with Parkinson disease.

MATERIALS & METHODS

In this study, a patient with Parkinson's disease has been taken. The patient is 65 years old; he has been diagnosed with Parkinson's disease. He also has the episodes of freezing of gait (FOG) and resting tremors very frequently. The patient cannot walk for longer duration of time and he also experiences very frequent imbalances while walking. The patient and his family wanted some assistance so that the patient could walk without and fear and lead a heathy lifestyle. Criteria for the subject with Parkinson's disease included a Hoehn & Yahr stage 3(indicating moderate disease), ability to ambulate with assistance (patient uses quadripod cane) and a demonstrated ability to follow directions in either English or Hindi languages.

The patient was explained in detail about the whole procedure and also consent was taken from the patient. Then patient's Pretest data was taken through QUEST 2.0 questionnaire. The patient walked for 15 minutes.

After choosing the best suited shoe (one size bigger than the normal length), then the orthosis is being embedded inside the patient's footwear and then post-test data was taken through QUEST 2.0 questionnaire. The patient walked for 15 minutes, then data analysis was done.

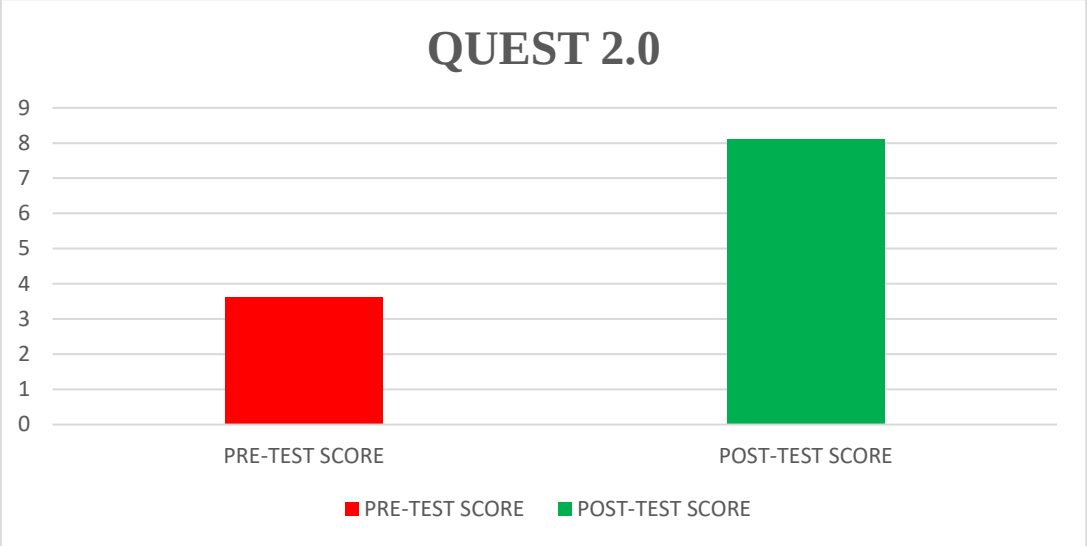
RESULT

A durable biofeedback foot orthosis to inhibit tremors on the patients with Parkinson's disease was developed effectively which is cost-effective and aesthetically pleasing so that the patient could perform his day to day activities independently and can lead a healthy lifestyle. This orthosis improves patient's gait cycle and also lowers the frequency of freezing of gait (FOG) episodes. The Pre-test score was 3.625 which moves towards more or less satisfied and Post-test was 8.125which moves towards totally satisfied.

Table 1: - Average score of Pre-Test & Post-Test of Biofeedback Foot Orthosis

TOTAL	PRE-TEST SCORE	POST-TEST SCORE
QUEST 2.0	3.6	8.1

Graph 1: - Graphical Representation Of Pre-Test & Post Test Score Of The Biofeedback Foot Orthosis



DISCUSSION

Parkinson's disease (PD) is a progressive neurological disorder that affects the nervous system, leading to a wide range of motor impairments. Common symptoms include tremors, muscle rigidity, bradykinesia (slowness of movement), postural instability, and gait abnormalities, all of which significantly affect patients' daily functioning and quality of life. As the disease advances, maintaining balance becomes increasingly difficult, exposing individuals to a higher risk of falls due to impaired reflexes. Tremors, which usually begin in the hands, can spread throughout the body and, when they reach the lower limbs, result in severe gait impairments such as festinating gait, freezing of gait, and an increased likelihood of falls. The study aims to develop an innovative device to address these issues. It focuses on a non-invasive solution that integrates biofeedback technology with vibratory stimulation. The goal is to reduce tremors and improve stability by delivering targeted vibrations to the plantar region of the foot. This helps patients maintain focus, stability, and balance during their daily activities, thereby improving their mobility, reducing fall risks, and encouraging social participation. Vibratory stimulation has shown great potential in reducing the intensity of Parkinsonian tremors. Existing research supports the efficacy of vibrations in managing motor symptoms, with studies reporting improvements in both tremor suppression and quality of life. Significant contributions to tremor orthoses research include Roberto J. Páez Salgado and Team developed a device that produces vibrations opposing the frequency of hand tremors (6-9 Hz) in Parkinson's patients. Using video analysis software and frequency sensors, they found that counteracting tremors with vibrations resulted in significant improvements in motor control and a reduction in tremor intensity[23].

Adibah M. Zulkefli and Team designed an intelligent glove using vibratory feedback and gyroscopic forces to manage resting tremors. Equipped with motors, a rotating brass disc, and a gyroscope, the glove reduced tremors by 50% to 90%, depending on the tremor frequency (3-7 Hz). This glove offered an effective solution to stabilize the hands, improving the comfort and functionality of patients[24].

Jiancheng Mo and Ronny Priefer, in their review of tremor management, they explored medical devices as alternatives to traditional drug treatments. Their research highlighted the limitations of current pharmacological approaches and the promise of non-invasive devices for tremor suppression, such as wearable orthoses, electrical stimulation systems, and assistive devices for activities like feeding. These technologies represent a

shift toward safer, more effective management of Parkinson's symptoms[25].

T. Busink's developed a system that synchronized vibrations with the patient's gait cycle using sensors and vibrators attached to the legs. Although the vibrations did not significantly alter walking speed, many participants reported improved comfort and ease of movement, suggesting that vibrations positively influence the walking experience, even without measurable changes in gait metrics[26].

Thus, the findings support the fact that by the incorporation of the vibratory mechanism to the plantar region of the foot has a very advantageous impact on the patient's tremor suppression drawback leading to the freezing of gait patterns. Hence, with the application of vibration mechanism has found to have a advantageous impact on patient's with Parkinson's disease to cope up with their day to day barriers and also to allow them to engage in their jobs and also allow them to be socially available.

This study represents a pivotal step towards harnessing orthotic technologies for tremor management in Parkinson's Disease, offering promising avenues for enhancing patient care and quality of life. This study presents significant advancements in treating Parkinson's disease by introducing a novel, non-pharmacological device that utilizes vibratory feedback to suppress tremors. This biofeedback foot orthosis targets the plantar region, aiming to enhance mobility and stability for patients, thus reducing the risk of falls and improving their ability to perform daily activities independently. The device holds promise not only in improving patients' quality of life by allowing greater social engagement and activity but also represents a pivotal step in Parkinson's disease management, offering a potential alternative to traditional drug therapies. This research could also pave the way for broader applications in treating other neurological disorders with similar symptoms.

CONCLUSION

The biofeedback foot orthosis presents a promising avenue for improving the lives of people with Parkinson's disease. By utilizing targeted vibrations, it addresses key motor challenges such as tremor suppression, gait improvement, and fall prevention. The device enables patients to carry out daily activities more independently, thereby enhancing their overall well-being and social participation. This study not only offers a step forward in orthotic technologies but also provides a glimpse into the future of neurological care, where wearable devices play a crucial role in managing chronic conditions effectively. Further research and clinical trials are essential to optimize the design, validate its long-term benefits, and explore its potential applications for broader neurological use cases.

Declaration by Authors

Acknowledgement: None

Source of Funding: None

Conflict of Interest: The authors declare no conflict of interest.

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How to cite this article: Gouri Sharma, Yashika Kumar. Design and performance evaluation of biofeedback foot orthosis to inhibit tremors on the patients with Parkinson's disease. *Int J Health Sci Res.* 2024; 14(11):166-172. DOI: *https://doi.org/10.52403/ijhsr.20241117*

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