# PARKIBIP Feedback Wearable Rehabilitation Device: Market Analysis and Enhancements

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*Abstract*— **Rehabilitation counteracts motor deficiencies in gait disorder of Parkinson's Disease (PD) patients. PARKIBIP is a wearable feedback device that aims to offer a continuous and personalized rehabilitation tool for such people. A survey and external study of PARKIBIP suggest design enhancements. Exploration of its industrial potential shows direct competitors, a first step to conclude that PARKIBIP is suitable for Technological Transfer to a company for commercial dissemination. PARKIBIP is both a home treatment helping device and a clinical data & feedback capture terminal for the electronic medical record. Being wearable technology, PARKIBIP stands out in the present global context as an affordable robotic element with feedback capability connected to the patient's mobile phone.**

***Keywords—Parkinson's disease, Wearable device, Gait Analysis, Rehabilitation.***

## I. INTRODUCTION

### A. Clinical context.

Parkinson's disease (PD) is an irreversible neurodegenerative disorder that slowly and progressively affects the Central Nervous System (CNS) by introducing several motor (e.g. bradykinesia, rigidity, and resting tremor) and non-motor (e.g. anxiety, altered bladder function, sleep disorder) impairments [1], [2]. At the moment it is the second most prevalent neurodegenerative disease worldwide, after Alzheimer's disease, and it is proved to increase its prevalence after the age of 60 [3], [4].

Currently the clinical treatment of PD is segmented into pharmacological, surgical, and rehabilitative measures, all focused on improving the symptoms the disease carries. However, the use of dopaminergic drugs has been shown to lose effectiveness over time, the combination of physiotherapy and rehabilitation is one of the most promising approaches to PD [5].

Based on the clinical context and the available technology, the goal of this study is to revise the potential to commercialize our recent project, PARKIBIP, and its possible enhancements.

### B. Gait disorder in Parkinson's Disease.

The presence of a gait disorder is a primary symptom of PD, causing the increased possibility of falling and diminishing the patient's independence and life quality [6], [7]. The normal gait disturbance is also known as rigid hypokinetic gait and is characterized most commonly by a flexed posture, increased rigidity, limb tremor, altered spatial-temporal and gait phase parameters (e.g. decrease in step length and walking speed, variability in between strides, slowing down, feet shuffling or a delayed onset of walking) [8]–[11], and freeze of gait (FoG) (paroxysmal interruption of the stride or a marked reduction of feet forward motion) [12], [13].

As the disease progresses, a great part of the symptoms become resistant to the pharmacological and surgical treatments [14]. However, it is studied that rehabilitation based on gait retraining could help to counteract this [5]. In addition, visual or acoustic stimuli could significantly increase the effectiveness of this therapy [15], [16].

Nevertheless, obtaining a clinical evaluation with reliable results can be very complex and impractical. As clinicians can only rely upon evidence from sporadic sessions, and in addition, motor dysfunctions progress, objective analysis is very difficult to perform. Therefore, it is essential to find an accurate way of obtaining clinical evaluation and monitor symptoms continuously to obtain optimum results.

Gait analysis (GA) is used to obtain the necessary kinematic, kinetic, and spatial-temporal parameters to get to the desired evaluation, as they objectively reflect the patient's normal walking ability [17]. The best way to collect this data is using optical movement analysis systems based on cameras (3D-GA). These systems are very adequate to measure gait characteristics in terms of precision and repeatability; however, the tests require to be executed in a laboratory environment with high-cost equipment, with specialized personnel [18], [19] .

In parallel, wearable technology has gained advances that resulted in measuring devices capable of evaluating human movement using sensors connected to the body. The gait parameters obtained with these instruments are useful indicators to characterize PD, as for instance to quantify the stage of the disease of the subjects [9], [20].

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### C. *PARKIBIP: step by step gait stimulation.*

Taking into account the lifelong neurodegenerative nature of the disease and that the rehabilitation and the exercise-based therapy should be performed on a long-term basis and during daily routine in order to achieve a maximum efficiency [21], [22]; an important clinical gap was found.

A potential clinical breakthrough was recently designed, PARKIBIP [23], [24] to address the problem of interactive rehabilitation of PD in prolonged autonomous sessions.

The proposed solution is a wearable feedback device that offers a continuous and personalized therapy for people in this condition. This device consists of two Inertial Movement Unit (IMU) sensors inserted on two braces which are placed on the patient's ankles (Fig. 1.) and the sessions are guided with an Android mobile application that connects to the sensors via Bluetooth [24].

Fig. 1. PARKIBIP elastic ankle band with the IMU sensor. Image from [22].

## II. METHODS

### A. *PARKIBIP study.*

A formal revision of the references used during the development of PARKIBIP was done to understand better its original aspects.

The second step was an on-site practical evaluation of PARKIBIP functionalities, directed by the developers of the instrument. Additionally, all the possible configurations of the application (e.g. stimulation at each step, only when FoG occurs, only one type of stimulation) were revised.

### B. *Industrial potential analysis.*

To examine the potential this device has in the industry, it is important to analyze the market size and target buyers. For this the global and local burden of PD was studied.

Moreover, risk management should be applied throughout the entire life-cycle of the apparatus to identify, estimate, evaluate and control or mitigate any risks related with the use of the device as well as to monitor the actions taken to eliminate or minimize those risks. It is also important to classify PARKIBIP following the registration stipulations stated at the interested places. Once this is evaluated, it will be determined if the device should opt for the Technological Transfer to industry or not.

Furthermore, a brief but concise survey was shared with potential users of PARKIBIP to obtain interdisciplinary opinions about the instrument. The survey was mailed to professionals from Uruguay, Spain and Chile (physiotherapists, physicians, biomedical engineers, etc). .

### C. *Analysis of competitors.*

For the industrial potential analysis to be completed, it is crucial to understand if PARKIBIP has any competitors that could eclipse their objectives or its commercialization.

A competitive analysis was conducted to compare competitors against PARKIBIP's specifications and identify possible wins. Devices that were not wearable or did not make use of sensorial stimulation were discarded. The following parameters were examined:

- The creation of a clinical record.
- How it interacts with the patient.
- Sensor type.
- Connection type.
- Stimulation type: acoustic, visual, or sensorial.
- Level of customizability.
- Usability (at the clinic or at home).
- Price estimation.

The results were exposed in a table and compared between them.

## III. RESULTS

### A. *PARKIBIP study.*

PARKIBIP consists of two IMU sensors inserted on two braces, which are then placed on the patient's ankles(Fig.1). These sensors are connected by Bluetooth to the PARKIBIP Android app, which monitors the patient's sessions.

The selected IMU sensor model (MetaMotionR) consists of an accelerometer and a gyroscope, apart from a magnetometer and a vibratory unit. PARKIBIP analyzes and identifies the phases of gait and emits vibrational and acoustic stimuli. This stimulation (vibration + "BIP" sound) offers the possibility of performing the therapy sessions in a domestic setting. The protocol in PARKIBIP is established by the clinician in charge of the specific patient. Further details are available in the original thesis and are now being included in the patent application [24].

At the on-site trial of the device, the results were successful. PARKIBIP showed to correctly identify the phases of gait (Heel Strike and Toe-Off) and was able to stimulate when necessary. The global COVID-19 pandemic situation hindered the prototype from being tested clinically on a longer term with volunteers from the Asociación Uruguaya de Parkinson (AUP) [25].

The level of the vibrational and acoustic signals is perfectly perceivable and adjustable. The results of each session are displayed on graphs that show the activity of both legs.

TABLE 1: PARKIBIP AND COMPETITORS: DEVICES FOR MONITORING AND REHABILITATION FOR PD PATIENTS

| **Parameter** | **Devices** | | | | | | |
|---|---|---|---|---|---|---|---|
| | ***Walk with path*** | ***NexStride*** | ***Honda Walking Assist Device*** | ***Kinesia360*** | ***SISMO-NEURO*** | ***deFOG*** | ***PARKIBIP*** |
| ***Clinical record*** | No | No | No | Yes: Web Portal | No | No | Yes: CDA |
| ***Patient interaction*** | Visual laser beam | Tempo indication (tics) and laser beam | Walking assistance based on patterns | App (daily diary for monitoring) | Vibratory impulse when FoG | Wireless headset with acoustic cues | App, vibratory and acousting signals. |
| ***Body location*** | Shoe attachment | Walking poles or canes | Hip belt with leg motors. Approx. 2.7 kg | Wrist and ankle bands | Ankle socks | Shoe attachment | Ankle braces |
| ***Sensor type*** | No sensor: laser indication for next step | No sensor: metronome | Hip angle sensor | Non specified | Accelerometer, on one foot only | Accelerometer, gyroscope. | Acceleromete, gyroscope, magnetometer |
| ***Connection Type*** | No App | No App | No App | Bluetooth | Bluetooth | Bluetooth | Bluetooth |
| ***Stimulation Type*** | Visual | Acoustic and visual | Sensorial (moves you) | No stimulation | Sensorial (vibration) | Acoustic | Acoustic and sensorial |
| ***Customizability*** | Adjustable visual cue | Adjustable tempo and visual cue. | 3 training modes | Daily monitoring tool | FoG detection | FoG detection | Gait analysis monitoring and stimulation. Customizable to therapy need. |
| ***Usability*** | Domestic | Domestic | Clinic and domestic | Domestic | Domestic | Domestic | Clinic and domestic |
| ***Price*** | 884$ | 499 $ | Non specified | Clinical trial | Not commercialized | Not commercialized | 500 - 1000 $ |

The measurements with PARKIBIP where compared to the Openshoe (Open source project for creating an embedded foot-mounted inertial navigation system (INS) implementation) database [26]. PARKIBIP's processing differ only by a root mean square error (RMSE) of 0.0214 using 12.239 observations [24].

### B. *Industrial potential analysis.*

At the Movement Disorder Society (MDS) Virtual Congress 2020 a research with the objective of estimating the current number of individuals living with PD globally was exposed. The results showed the approximation of 9.4M population with PD globally in 2020 [27], being significantly higher than the previously reported 6M PD cases in 2016 by The Global Burden of Disease Study [28].

According to the numbers provided by the AUP, the prevalence of PD in Uruguay is 1.36/1000, with the average age at 75 years [25].

The classification of PARKIBIP for a possible registration showed that, as it is non-invasive, it corresponds to a Class I device, following the regulations set by the Uruguayan government and MERCOSUR [29]. This matches the regulations set by the European Commission (93/42/CEE) [30] and the Food and Drug Administration (FDA) [31].

The survey was answered by a limited number of professionals. All replies were supportive, confirming their interest in counting on a device such as PARKIBIP for their work in rehabilitation of PD patients.

### C. *Analysis of competitors.*

The selected competitors are shown in Table 1, where it is possible to see their different features.

It is important to state that there are more studies comparing the use of wearable technologies for PD treatment but there is no evidence of their commercialization [32], [33]. The six compared competitors in Table 1 were selected because they reflect different types of devices, either commercialized or prototype.

The first two devices found on Table 1, Walk with path [34] and NexStride [35], do not have a sensor to analyze the gait of the patient. These devices work with visual and acoustic stimulation in order to activate the motor cortex of the brain and this way help the user to continue walking (e.g. in case of FoG). Another interesting competitor is Honda Walking Assist [36], a training device attached to the hip and legs of the user that transfers a motor force to help the movement of the patient's inferior limbs. Kinesia360 [37] is another device, which by using wearable sensors it monitors the consumer's activity during the day, keeping a diary through a tablet application and storing this in a web portal.

The two devices that resulted being more resembling to PARKIBIP were deFOG [38] and the NEURO-SISMO project [39], both of which consist of wearable sensors on the ankles with some type of stimulation guided by a mobile application, however there is no evidence that these prototypes have been commercialized. The authors of deFOG obtained a patent based on their idea [40]. PARKIBIP is the only device with both vibration feedback as well as spoken words triggered by a protocol based on instant by instant real time analysis of gait. A feedback that mimics the Physiotherapist's oral support during rehabilitation sessions.

The reports of manufacturers of similar devices and academic prototypes do not generally include detailed evaluation from a clinical point of view. Nevertheless, a pilot trial on the use of a smartphone App and sensors to prevent FoG episodes showed good results [41]. The group using the prototype improved balance control and quality of life parameters compared to the control group. One study described 0.3 decrease in the Unified Parkinson's Disease Rating Scale (UPDRS) after 17 months of use by 300 patients of a wearable technology device [42].

## IV. PROPOSED ENHANCEMENTS

The principal design limitation that was found during the study of PARKIBIP was that the use of uniquely one sensor per limb at ankle length, does not provide the clinicians all the information that could be of interest for a proper rehabilitation session. At ankle height, the sensors do not consider the range of movement of both user's feet, which would be helpful to understand for a better reinstruction of the gait.

Foot placement plays an important role in balance control and an improper positioning could increase the likelihood of falls, insecurity of the patient and a slower progress of the therapy [43][44].

The proposed enhancement for the design of PARKIBIP would be the addition of another identical IMU sensor on each of the patient's feet (e.g. attached to the shoes) which, with the same technology as the ones on the ankle braces, will identify the feet's range of motion and its position. The fusion of the information obtained by the sensors would deliver fuller data for the treatment.

An alternative for obtaining the foot placement details would be the introduction of smart insoles, pads that the user introduces in their shoes and are equipped with IMU and pressure sensors. The insoles provide more information than just the IMU sensors, as they include additional data extracted from the pressure sensors. Studies demonstrate that this alternative offers optimistic results with complete information about gait analysis [45][32].

## V. DISCUSSION

### A. *Industrial potential analysis.*

In relation with the analysis for industrial potential, considering the global burden of the disease it is possible to affirm that the market in which the device would be commercialized has a considerable size. Also, if the increasing life expectancy is kept in mind, it suggests that this market only grows with time. As the prevalence of PD is after the age of 60, and with a growing number of the elderly population, the presence of PD worldwide will spread.

Furthermore, it is important to consider that PARKIBIP is a Class I device, which means that it is safe for its domestic use and does not need a special formation for its utilization. It is very important to point this out, as currently the COVID-19 pandemic situation has forced people to stay home and self-isolate, specially the geriatric sector, as they are population at risk and would be more likely to have complications with the virus. The creation of alternative methods for therapy from home is very important at this point in time to avoid sedentary lifestyles (which would degrade in a considerable way the possible progresses of the patient), saturation of hospitals and unnecessary possible infections with COVID-19.

Moreover, although the limited dissemination and answers so far of the survey impeded the generation of reliable statistics respecting the commercial implementation of PARKIBIP, the few obtained answers served as exterior opinions from possible future users of the device. The inclination towards the use of the device obtained from most of the responses encouraged us to think that it could be a promising tool for treating people suffering from PD.

### B. *Analysis of competitors.*

The competitors' analysis highlighted that PAKRIBIP is clearly not the first invented device to improve the gait of PD patients. There are several studies and some commercialized options that also utilize wearable technologies to focus on the treatment. Nevertheless, the analysis identified competitors which are the most resembling to our device (deFOG and the NEURO-SISMO prototypes). Apart from not being commercialized yet, they principally focus on identifying and act against only one feature of the gait disorders PD provokes, FoG, whilst for PARKIBIP the stimulation in case of FoG is just one of its possible options, allowing the device to reach a wider audience and standing out against the competitors.

As well as this, the instant feedback PARIBIP offers its users seems to be a distinctive feature among all its competitors. This could be an important attraction for physiotherapy professionals who could use PARKIBIP as a repetition tool for their own patient stimulation strategies, including their own wording. PARKIBIP would carry the therapist's words, strategies, and reactions directly into patient's everyday lives, a clear advantage during pandemic times, and also *post-pandemia*.

It is also remarkable to claim that as the size of the potential industrial market this prototype pertains to is considerable, it could have an important impact on it, even with the existence of parallel projects with similar objectives. Despite of the fact that currently PARKIBIP is more competent than other options, the rise of devices with equal features could occur, but as the burden of PD worldwide is extensive and increasing with time, there is an encouraging industry in which all those devices could co-exist successfully.

### C. *Enhanced PARKIBIP.*

The introduction of another sensor to obtain information about feet movement and positioning enriches the prototype with useful information for the clinicians, allowing them to offer a better treatment to the patient, and therefore boost the user's quality of life. It would be useful to compare the practicality of the use of insoles (which could limit the footwear during the sessions)versus the simple use of sensors attached to the shoes. The insoles could offer more data than the attachments, but it should be investigated if this is additional data is significantly useful or redundant.

In addition, the way PARKIBIP is designed has the capability to be versatile and new configurations can be easily added. This is very favorable as it is possible to update continuously the software as technology advances. This is also advantageous for the clinicians as it allows them to personalize the therapies depending on the patient's needs. It could be a promising feature to focus each therapy taking into account the rest of the person's health condition (e.g. the presence of other hindering illnesses as a heart condition could be).

It is also worth mentioning that, as the use of this device in earlier stages of PD would help to have a slower degeneration with regard to the patient's mobility, it would be also significantly appealing for after surgical interventions in PD. The rehabilitation therapy in combination with the surgery and possible pharmacological treatment would significantly counteract the symptoms resulting life-renewing for the patients, especially for the youngest generation.

Last but not least, the use of wearable technologies diminishes the possible costs of the device, lowering the final price, making it more affordable for the users, reaching out to a wider audience and bringing this tool closer to more people.

The use of PARKIBIP at home is also a way to increase considerably the effect of rehabilitation, since the limited number of sessions can be augmented by daily interactions with a rehabilitation protocol enacted by PARKIBIP.

## VI. CONCLUSION

The extensive and growing market with potential users, the low risks for the patients during the sessions and the lack of existing commercialized competitors with significant similarities, as well as the versatile features of the device and the constructive enhancements it could add, brings to light that PARKIBIP is a prototype with an exciting future. Moreover, the current pandemic situation with an increasing need for clinical domestic alternatives and the optimistic statements from the professionals about the use of the device, leads us to be convinced that it is an eye-opening instrument that would remarkably improve PD patient's lifestyle and quality. Also, the use of wearable technologies which decrease the final price, brings this tool to a wider range of people.

To conclude, we encourage the further development of the prototype in pursuit of the Technologic Transfer to a company ready to get their feet wet with this promising device.

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