Universitat Pompeu Fabra

Biomedical Engineering: Practicum Report

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Abstract

Gait disorder is one of the principal features of Parkinson disease, negatively affecting the independence and lifestyle of the patients. Treatment with rehabilitation counteracts this motor deficiencies. PARKIBIP is a wearable feedback device that aims to offer a continuous and personalized therapy for people in this condition. The objective of this research is, by deeply studying this portable tool, the exploration of the potential industrial development it would have and through the analysis of its possible competition the proposition of improvements for its future evolution.

Key words: Parkinson Disease, Gait disorder,

Contents

1. STUDENT DATA

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2. GENERAL DATA

- **Name and address of hosting institution:** Núcleo de Ingeniería Biomédica (NIB), Hospital de Clínicas Dr. Manuel Quintela of Montevideo, Uruguay. This institution belongs to the Universidad de la República of Montevideo. Av Italia, 11600 Montevideo, Departament of Montevideo.
- **Name of supervisor:** Franco Simini.
- **Initial and final date:** from 01/12/2020 to 05/01/2021.
- **Hours of student work:** 150 hours
- **Income (if any):** There is no income due to performing this practicum in a public institution with lack of funds.
- **Number of ECTS credits:** 6
- **Language in which the practicum was achieved:** Spanish and English
- **Way of contact with hosting institution:** via email (nib@fmed.edu.uy, simini@fing.edu.uy).

3. HOSTING INSTITUTION DESCRIPTION

3.1. HISTORY

The Núcleo de Ingeniería Biomédica (NIB) [1], is an interdisciplinary group formed by the Medical and Engineering Faculties of the Universidad de la República (UDELAR) [2] of Montevideo active in teaching, research and technology transfer in Biomedical Engineering and Medical Informatics (Fig. 3.1).

The background of the NIB goes back to the decades of 1960 and 1970 when Dr. Caldeyro Barcia collaborated with electronic technicians in order to develop devices to amplify biological signals and for fetal heartbeat detection.

In the decades of 1970s and 1980s, business plans for devices for nuclear medicine, clinical neurophysiology and cardiovascular signal monitors were born. In 1984 a descprition of Biomedical Engineering was published in the First National Engineering Meeting by Eng. Franco Simini, which motivates a growing interest in completing their careers with biomedical knowledge by the students.

Around 1987 the first biomedical device prototypes enter in clinical service, and in 1990, the engineering and medical schools of the UDELAR agreed to create the NIB with an equal division of costs. In 1993 Eng. Franco Simini was named as coordinator.

3.2. ORGANIZATION OF THE INSTITUTION

The highest position in the NIB would be the coordinator, occupied by Prof. Eng. Franco Simini. Following this, there are 6 other associate Professors from different departments.

Also, there are 7 assistant teachers, who are completing their academic training apart from coordinating academic courses for the UDELAR (Grade 1 or Grade 2, depending on their formation and time at the NIB).

As mentioned above, the NIB is an institution active in research apart from teaching, which means that each participant of this organism takes an active part in different projects in parallel with the educational part.

In addition, there is obviously an administrative support and external lecturers who collaborate with the NIB.

3.3. MAIN GOALS

The NIB contributes in the education in Biomedical Engineering to face the challenges of medical instrumentation in health institutions. Its participation in undergraduate extension is divided in the contribution to the assistance in this process and the involvement of students in projects from this area.

[1] http://www.nib.fmed.edu.uy/
[2] https://udelar.edu.uy/portal/

3.4. Products/ Outcomes

The main activities carried out by the NIB are:

- Development of projects and implementation of prototypes in support of biomedical investigation in the field of master's degrees and PhD's for clinicians, engineers and other relevant formations.
- Education and investigation in project techniques for national manufacture of biomedical devices as for technological transfer.
- Realization of courses and seminaries linked to Biomedical Engineering and its clinical applications.
- Publication in journals and participation in National and International Congresses for dissemination and update of investigations.

3.5. Existence and role of biomedical engineers in the institution.

As its name suggests, the NIB is a Nucleus of Biomedical Engineering, so it is obvious that there is an existence of biomedical engineers in the institution.

As mentioned beforehand, the main role they have is to investigate and develop innovative ways to improve healthcare, mainly in the country itself, this is by the building of new prototypes for medical devices or by adapting other already existing facilities. On the other hand, they also have they carry out the work of teaching about this field, providing different courses for the students of the Medical and Engineering faculties of the UDELAR and participating in worldwide congresses and events. They work in collaboration with other professionals in the fields of interest.

Figure 3.1: Logos of the hosting institution.

4. TASK DESCRIPTION AND OBTAINED RESULTS

4.1. CONTEXT

As mentioned in the previous section, the NIB collaborates with students from the Engineering and Medicine faculties to develop different types of projects in order to improve healthcare. As I got in touch with Professor Simini, he introduced me to PARKIBIP, the prototype that the two computer engineering students Carlos Huerta and Samuel Sainz were working on for their final thesis, presented on 14th December 2020.

PARKIBIP is a prototype that consists of a mobile application and two inertial measurement unit (IMU) sensors that are localized at ankle level for people suffering from Parkinson's Disease (PD) and have the purpose of re-instructing their gait during a domestic rehabilitation process. The device recognizes and measures the different phases of gait and emits acoustic signals according to established protocols by the physiotherapist or clinician to achieve similar objectives to accompanied walking during physical therapy sessions at the clinic.

This internship aims to study in detail this device, offer possible enhancements and help to take this prototype a step further.

Due to the current global pandemic situation, the major part of the placement had to be developed remotely from home. During the period the practicum lasted I was settled in Montevideo, Uruguay.

4.2. INITIAL OBJECTIVES

The initially established objectives to accomplish during the practicum were the following:

- Study in depth of PARKIBIP.
- Perform an industrial potential analysis and define if it is feasable for the process of Technologic Transfer to a company for its future commercialization.
- Do a competence analysis of similar devices.
- Identify design constraints and propose ways to optimize PARKIBIP.

4.3. AVAILABLE DATA

Before designing the prototype of PARKIBIP, the students did an exhaustive systematic revision based on evidences of the bibliography. This means, that they established a revised selection criteria, with which they picked a large number of related scientific articles (463, to be precise), and continued revising and electing with more specific guidelines every time (as if it was a funnel). Finally they obtained a number of 30 studies with utmost, 22 articles with intermediate and 33 with slight relevance punctuation following the beforehand established criteria.

This detailed collection was saved in a Mendeley library [3] that the students kindly shared with me so I could perform a bibliographic revision on my own, apart from the extensive description of their work (in their thesis document). The rest of the data was reached by the use of open-source search engines as PubMed [4].

4.4. METHODOLOGY

During the whole internship, there were two weekly reunions via Zoom [5]. One with the supervisor and another one with the rest of the NIB team. The first case was to focus only on this practicum and its course, while the second one was to get an update and general view of the state of all the projects that were being developed at that moment at the NIB.

Also, in order to get a good control of the *modus operandi* that was followed, a detailed log was kept, registering the worked hours and how they were invested. The performed study was reflected in the writing of an article, which has to be presented at the 2021 IEEE International Symposium on Medical Measurements and Applications (MeMeA) Congress [6]. Both the log and the article can be found as annexes of this report.

Before being able to study the device, it was necessary to study carefully the clinical context of PD, the gait disorders it brings with it and the consequences for the patients.

4.4.1. STUDY OF PARKIBIP

To understand in depth the functioning of PARKIBIP, the detailed working-report of the authors was revised [1], in addition, there were held video-conferences via Zoom with them in order to obtain a more specific vision of the device. Also, the most outstanding part of the bibliography was revised to enlarge the knowledge.

Once the performance of PARKIBIP was understood, an on-site test was executed. The trial held place at the Engineering Faculty of the UDELAR, directed by the developers of the instrument, and consisted of a try-out simulating the use of the device in a therapy session, from the initialization of the app and the connection of the sensors to different exercises the clinician could propose to the patient. Additionally, all the possible configurations of the app were revised.

4.4.2. INDUSTRIAL POTENTIAL ANALYSIS

In order to examine the potential this device has industrially, it was important to analyse the market size and target buyers. For this the global and local burden of PD was studied.

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 de-

[3] https://www.mendeley.com/
[4] https://pubmed.ncbi.nlm.nih.gov/
[5] https://zoom.us/
[6] https://memea2021.ieee-ims.org/

vice 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 could opt for the technological transfer or not.

Furthermore, a brief but concise survey was developed in order to be disseminated between potential users of PARKIBIP to obtain interdisciplinary opinions of professionals (physiotherapists, physicians, biomedical engineers, etc) in the clinical aspects of PD and who would be using the device in their treatments.

4.4.3. Analysis of competitors

It is crucial to understand if PARKIBIP has any competitors that could eclipse their objectives or its commercialization. Therefore, a deep inspection through the internet was executed to find as many competence as possible to compare with the specifications of PARKIBIP and contrast them. Those devices that were not wearable were dismissed.

The parameters that were examined were the following:

- 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 (adaptable to therapeutic criteria or not).
- Usability (clinical or domestic).
- Price estimation.

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

4.5. Results

PD is an irreversible neurodegenerative disorder that slowly and progressively affects the Central Nervous System (CNS) by introducing motor and non-motor impairments [3]. 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 [4, 5]. If the conventional surgical and pharmacological treatments are complemented with constant and daily rehabilitation and physiotherapy sessions based on retraining gait in PD patients, it could help to counteract this deficiencies [6]. Also, the use of visual or acoustic stimulus during this sessions seem to give good results [7, 8]. Therefore, it is essential to find an accurate way of medical evaluation and a continuous monitoring of the affected subjects in order to obtain optimum results, deriving in the clinical gap they tried to face with PARKIBIP.

The advances of wearable technology have shown to give the possibility to obtain gait parameters that could be useful indicators to characterize PD and quantify the disease's state [9], offering an alternative to the expensive and specialized laboratory equipment that is needed for an effective 3D Gait Analysis.

4.5.1. Study of PARKIBIP

As mentioned beforehand, PARKIBIP consists on two IMU sensors located at braces that are placed at ankle level of each of the patient's legs (Fig. 4.1). These sensors are connected via Bluetooth to the PAKIBIP Android app and via which they will be guided.

The used IMU sensors consist of an accelerometer and a gyroscope, apart from a magnetometer and a vibratory unit. They are capable of analyzing and identifying the phases of gait of the user and emit a sensorial (vibration) and acoustic (currently a "BIP" sound) stimuli during the execution of therapy session protocols established by the clinician in charge [1].

At the on-site trial of the device, the results were positive. PARKIBIP showed to correctly identify the phases of gait of interest (Heel Strike and Toe off) and to be able to stimulate when necessary, in the different possible settings of the app. The level of the vibrational and the acoustic signals are perfectly perceivable and adjustable by the clinician. The results of each session are showed at graphs in which it is possible to see the activity of both legs and notify about when there is movement or pause and the followed trajectory.

By studying it theoretically and seeing its functioning on-site, the principal design limitation that I found 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 could be important to know 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 [10, 11]. At the possible future work section further on (4.7) the proposed enhancement for PARKIBIP will be described.

Figure 4.1: PARKIBIP elastic ankle band with the IMU sensor. Image from [1]

4.5.2. 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 PD global population in 2020[12], being significantly higher than the previously reported 6M PD cases in 2016 by The Global Burden of Disease Study[13]. According to the numbers provided by the Asociación Uruguaya de Parkinson, the prevalence in this country of PD is 1.36/1000, with the average age at 75 years old [14].

The classification of PARKIBIP for a possible registration showed that, as it is a non-invasive device, it corresponds to a Class I device, following the regulations set by the Uruguayan government and MERCOSUR [15].

The dissemination of the survey was unsuccessful, despite of distributing it thoroughly through different fields and locations, to obtain as much interdisciplinary opinions as possible, only 4 replies were received, making it not possible to elaborate detailed statistics.

4.5.3. Analysis of competitors

The most outstanding competitors that were selected were 6 other devices or prototypes. In Table 1 it is possible to see the different features of each competitor.

It is important to state that there were found more studies that compare the use of wearable technologies for PD treatment but there is no evidence of their commercialization of all of them [16, 17].

The six compared competitors in Table 1 were selected because they reflect different types of designed devices with this goal.

The first two devices found on Table 1, Walk with path [18] and NexStride [19], 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 would be Honda Walking Assist [20], this consists on 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 [21] would be another type of device, which by using wearable sensors it would monitor 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 [22] and the project corresponding to NEURO-SISMO [23]. Consisting of wearable sensors at the ankles and some type of stimulation guided by a mobile application. But there is no evidence that these prototypes have been commercialized. The authors of deFOG obtained a patent based on their idea [24].

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 somehow the Physiotherapist oral support during rehabilitation sessions.

TABLE 1: PARKIBIP AND COMPETITORS: DEVICES FOR MONITORING AND REHABILITATION FOR PD PATIENTS							
Parameter	**Devices**						
	Walk with path	***NextStride***	***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 $

4.6. DISCUSSION AND CONCLUSIONS

The existence of a clinical gap here is obvious, and this prototype could help to cover it. The high prevalence of PD, both globally and locally, shows that there is a huge potential market where this device could fit in. Also, the fact that it belongs to a low-risk class, means that it would need to pass less regulations, making it more interesting for a company for considering an investment, both financially and commercially. In addition, the competence analysis showed that we are facing a device that is significantly complete, standing out from its commercialized competitors.

To sum up, the enormous and growing market with potential users, the low risks for the patient's during the sessions and the lack of already commercialized competitors with significant similarities, as well as the versatile features of the device, leads to the idea 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, let me think it is an eye-opening instrument that would remarkably improve PD patient's life style and quality. Also, the use of wearable technologies which decrease the final price, brings this tool to a wider range of people. In brief, I 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.

As the project was developed principally by two computational engineering students, the work was mainly focusing on the more technical part of the functioning of the prototype. With my combined formation acquired in my degree biomedical engineering I was able to have also an additional clinical vision to evaluate the device, because of this I was able to identify the limitation commented beforehand in Section 4.5.1.

The proposed enhancement for the design of PARKIBIP would be the addition of another identical IMU sensor at each of the patient's feet (e.g. attached to the shoes), which with the same technology as the ones at 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.

A very interesting alternative for obtaining the foot placement details would be the introduction of smart insoles, this would be 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 additionally include the data extracted from the pressure sensors. Studies demonstrate that this type of alternatives offer positive results with complete information about gait analysis [16, 25]. This extra data could boost the user's results and life quality. It would be necessary to study the practicality comparing the use of the insoles (which could limit the footwear during the sessions) or the use of the simple attachment of a sensor. The pad could offer more data than the attachment, but it should be considered if this is redundant or significantly useful.

In addition, the way PARKIBIP is designed is to have the capability to be versatile and easily add new configurations, interesting for the clinicians because it permits them to personalize the therapies depending on the patient and its 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).

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 younger ones.

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5. Evaluation

5.1. Skills acquired during the practicum

Some of the skills I have acquired are: knowledge about the nature of PD and one of its principal symptoms: gait disorders.

I have developed better oral communication abilities in public during the reunions with the NIB integrates, which I was very insecure about. Also, I have enhanced my team working skills during this video-calls and the meetings with the students. Moreover, I improved my organizational and commitment skills by working mostly alone and from home.

In addition, I learned in more detail about computer engineering and technical aspects of sensors, apart from data processing competences.

5.2. More relevant competences from the degree used in the practicum

From the degree I used my knowledge acquired during the "Introduction to medical devices and its design" and "Project and innovation management in biomedical engineering" courses taken during last year, as we learned the process of the developing of a biomedical device and its posterior commercialization and the management of this process.

Also, I used the competences to understand signal transformation and filtering learned during the courses about biosignals and systems. The bibliographic searching methods and article writing and reviewing skills acquired at diverse courses of Campus Mar were also used.

It is worth mentioning that the anatomical and physiological classes taken during the degree were fundamental to study the clinical context and understand the purpose of the device.

5.3. Personal evaluation of the practicum

Personally, I found this practicum very nurturing for my educational and professional growth.

It gave me the possibility to learn about the role of biomedical engineers at the institution, and by completing the placement, I was able to participate in the evolution of a highly interesting project, learn about it in detail and use my vision to try to improve it.

My confidence has improved immensely which has allowed me to voice my opinions and make suggestions which I like to think have had a positive impact on the work. I have learned how to handle several tasks at once and to ask for help when needed. I will be able to maintain effective control over project planning and exercise good and efficient problem solving skills as well as applying my new knowledge in my future work.

With the skills I have gained during my internship I will be able to use them in the rest of my career to achieve my goals and obtain my degree.

I would like to continue working on my critical thinking to provide good engineering solutions on drawbacks future projects may present.

5.4. Evaluation of relation with supervisor

The relation with the supervisor was very positive. I was very quickly received with open arms and with the intention to make the practicum experience as good as possible.

The two weekly reunions helped to stay motivated and follow the thread of the practicum, despite of the big load of autonomous work it carried (and with the current pandemic situation, from home), which may could make the internship more burdensome to fulfill.

Also, my supervisor was able to help me when needed and assisted me with suggestions that could improve my performance during the practicum.

5.5. Suggestion for improving the practicum

The main suggestion I have would be to introduce a more applied way to participate, maybe working on-site at the NIB and doing more practical experiments with the project.

However, I am aware of the current global COVID-19 situation and that it was necessary to modify the placement in order to carry it out in a responsible way for everybody's health and do what was in our hand to try to diminish infections.

5.6. Would you recommend this institution for future TFGs or practicums?

Yes, the received treat at the NIB was great and very helpful. It is an institution with very interesting projects and an continuous intention to move forward in healthcare.

Moreover, in my opinion, accomplishing an internship or TFG with an foreign group or company opens your mind about other working and organization methods and boost your professional and human experience.

A. Annex 1: Activity Log

DETAILED SCHEDULE			
DATE	ACTIVITY	HOURS	COMMENTS
01/12/2021	Reunion with tutor	1	8.00-9.00. Activity definition and administration tasks
01/12/2020	Individual study	6	Study of papers with gait analysis in Parkinson.
02/12/2020	Biomedical Engineering class	3	17.00 - 20.00 Muscle fisiology and EMS (hours don't count)
02/12/2020	Individual study	7	PARKIBIP overleaf, Document revision (chapter 1 until 4.7)
03/12/2020	Individual study	6	PARKIBIP overleaf, chapter 4.7-4.12, 5.1-7
03/12/2020	Weekly NIB reunion	1	14.00-15.00. Weekly reunion informing the state of each investigation. NIB participants
03/12/2020	Clinical Engineering class	2	Ventilation systems. Air purification (hours don't count)
04/12/2020	Individual study	7	chapter 5.8-end of document
07/12/2020	Reunion with tutor	1	8.00-9.00. Review of previous study. Email UPF.
07/12/2020	Paper writing and study	6	Abstract definition, start of introduction, bibliographic study
08/12/2020	Individual study	6	Study and comment of final version of the thesis.
08/12/2020	Reunion with students	1	17:30-18:30. Samuel and Carlos.
09/12/2020	Individual study	7	Tecnologic transfer and its request
10/12/2020	Individual study	7	Mendeley. Competitors.
11/12/2020	Weekly NIB reunion	1	7.00-8.00. NIB participants.
11/12/2020	Individual study	6	Bibliographic revision, IMU sensor analysis.
14/12/2020	Reunion with tutor	1	8.00-9.00. Review of individual study. Question resolution.
14/12/2020	PARKIBIP thesis presentation	2	10.00- 12.00. Samuel and Carlos present their thesis.
14/12/2020	Individual study	4	IMU sensor analysis. Market analysis
15/12/2020	Individual study	7	Statistics search (analysis). Paper writing (introduction).
16/12/2020	Individual study	7	Survey preparation. Industrial potential analysis.
17/12/2020	Individual study	6	Article coordination and writing. Questionnaire diffusion
17/12/2020	Weekly NIB reunion	1	14.00-15.00. Weekly reunion informing the state of each investigation. NIB participants
18/12/2020	Reunion with students	1,5	18:30 - 20:00. Personal meeting. PARKIBIP proofs.
18/12/2020	Individual study	5,5	Competitors analysis. Study of enhancements.
21/12/2020	Individual study	6	Industrial potential analysis.
21/12/2020	Reunion with tutor	1	8.00-9.00. Review of article. Proposition of enhancements
22/12/2020	Individual study	7	Bibliographic revision. Paper writing.
23/12/2020	Weekly NIB reunion	1	7.00-8.00. NIB participants.
23/12/2020	Individual study	6	Analysis of survey results. Study of enhancements.
28/12/2020	Individual study	6	Paper writing. Bibliographic revision

28/12/2020	Reunion with tutor	1	8.00-9.00. Paper revision
29/12/2020	Individual study	7	Paper writing. Bibliographic revision
30/12/2020	Individual study	7	Paper writing.
30/12/2020	Weekly NIB reunion	1	14.00-15.00. Weekly reunion informing the state of each investigation. NIB participants
04/01/2020	Individual study	5	Paper writing
05/01/2020	Individual study	4	Paper writing.
05/01/2020	Reunion with tutor	1	13:00-14:00. Paper revision, closure.

Record of working hours

Date	Start	Finish	Hours done	Comments	Total hours:	150
01/12/2021	8.00	15.00	7			
02/12/2020	8.00	15.00	7			
03/12/2020	8.00	15.00	7			
04/12/2020	8.00	15.00	7			
07/12/2020	8.00	15.00	7			
08/12/2020	9.00	18.30	7	Break from 14:00 to 16:30		
09/12/2020	8.00	15.00	7			
10/12/2020	8.00	15.00	7			
11/12/2020	7.00	14.00	7			
14/12/2020	8.00	15.00	7			
15/12/2020	8.00	15.00	7			
16/12/2020	8.00	15.00	7			
17/12/2020	8.00	15.00	7			
18/12/2020	9.00	20.00	7	Break from 14:30 until 18:30		
21/12/2020	8.00	15.00	7			
22/12/2020	8.00	15.00	7			
23/12/2020	8.00	15.00	7			
28/12/2020	8.00	15.00	7			
29/12/2020	8.00	15.00	7			
30/12/2020	8.00	15.00	7			
04/12/2020	9.00	14.00	5			
05/12/2020	9.00	14.00	5			

B. Annex 2: Written Article

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 the revision of the potential to be commercialized of 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 the 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. First, the clinicians will only be able to rely on evidence from sporadic sessions, based on their experience. And on the other hand, the increase of patients' motor dysfunctions throughout the disease will also complicate the analysis.

Therefore, it is essential to find an accurate way of clinical evaluation and a continuous monitoring of the affected subjects 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].

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 included on a long-term base and in the 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 is formed by two Inertial Movement Unit (IMU) sensors which are located at ankle level of each of the patient's legs (Fig. 1.) and the session are guided with an Android mobile application that connects with 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 were revised (e.g. stimulation at each step, only when FoG occurs, only one type of stimulation).

B. Industrial potential analysis.

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

Also, 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 developed in order to be disseminated between potential users of PARKIBIP to obtain interdisciplinary opinions of professionals from Uruguay, Spain and Chile (physiotherapists, physicians, biomedical engineers, etc) in the clinical aspects of PD and who would be using the device in their treatments.

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.

Therefore, a deep inspection through the internet was executed to find as many competitors as possible to compare with the specifications of PARKIBIP and contrast them. Those devices that were not wearable or did not make use of IMU sensors were discarded. The parameters that were examined were the following:

- 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 located at braces that are placed at ankle level of each of the patient's legs (Fig.1). These sensors are connected via Bluetooth to the PARKIBIP Android app and via which they are guided.

The used IMU sensors consist of an accelerometer and a gyroscope, apart from a magnetometer and a vibratory unit. They are capable of analyzing and identifying the phases of gait of the user and emit a sensorial (vibration) and acoustic (currently a "BIP" sound) stimuli during the execution of therapy session protocols established by the clinician in charge [24].

At the on-site trial of the device, the results were positive. PARKIBIP showed to correctly identify the phases of gait of interest (Heel Strike and Toe off) and to be able to stimulate when necessary, in the different possible settings of the app.

The level of the vibrational and the acoustic signals are perfectly perceivable and adjustable by the clinician. The results of each session are showed at graphs in which it is possible to see the activity of both legs and notify about when there is movement or pause and the followed trajectory.

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 PD global population in 2020 [25], being significantly higher than the previously reported 6M PD cases in 2016 by The Global Burden of Disease Study [26].

According to the numbers provided by the Asociación Uruguaya de Parkinson (AUP), the prevalence in this country of PD is 1.36/1000, with the average age at 75 years old [27].

The classification of PARKIBIP for a possible registration showed that, as it is a non-invasive device, it corresponds to a Class I device, following the regulations set by the Uruguayan government and MERCOSUR [28], and matching to the stipulations set by the European Commission (93/42/CEE) [29] and Food and Drug Administration (FDA) [30].

The survey was answered by a limited number of professional health workers of diverse specializations. All replies were positive, confirming their interest in counting on a device such as PARKIBIP for their work in rehabilitation of PD patients.

C. *Analysis of competitors.*

The most possible competitors that were selected were 6 other devices or prototypes. In Table 1 it is possible to see the different features of each competitor.

It is important to state that there were found more studies that compare the use of wearable technologies for PD treatment but there is no evidence of their commercialization of all of them [31], [32]. The six compared competitors in Table 1 were selected because they reflect different types of designed devices with this goal.

The first two devices found on Table 1, Walk with path [33] and NextStride [34], 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 would be Honda Walking Assist [35], this consists on 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 [36] would be another type of device, which by using wearable sensors it would monitor 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 [37] and the project corresponding to NEURO-SISMO [38]. Consisting of wearable sensors at the ankles and some type of stimulation guided by a mobile application. But there is no evidence that these prototypes have been commercialized. The authors of deFOG obtained a patent based on their idea [39].

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 somehow the Physiotherapist oral support during rehabilitation sessions.

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 could be important to know 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 [40][41].

The proposed enhancement for the design of PARKIBIP would be the addition of another identical IMU sensor at each of the patient's feet (e.g. attached to the shoes), which with the same technology as the ones at 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.

A very interesting alternative for obtaining the foot placement details would be the introduction of smart insoles, this would be 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 additionally include the data extracted from the pressure sensors. Studies demonstrate that this type of alternatives offer positive results with complete information about gait analysis [42][31].

V. Discussion

A. *Industrial potential analysis.*

In relation with the analysis for industrial potential, taking into account 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 increases with time. As the prevalence of PD is after the age of 60, and that with a growing number of the elderly population, the presence of PD worldwide will grow too.

Also, it is important to consider that PARKIBIP is Class I device, which means that it does not bring any risks for the domestic use of it nor it needs a special formation for its use. It is very interesting 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 risk patients and would be more likely to have complications with the virus.

The creation of alternative methods for therapy from home are very important at this moment 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 positive 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.*

As it was possible to see at the competitors' analysis, PAKRIBIP is clearly not the first invented device for the improving gait of PD patients. There are several studies and some commercialized options that also make use of wearable

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

Parameter	Devices						
	Walk with path	***NextStride***	***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 $

technologies to focus on the treatment. Nevertheless, the principal identified competitors which are the most resembling to our device (deFOG and the NEURO-SISMO prototype), apart from not being commercialized yet, they principally focus on identifying and act against only one feature of the gait disorders PD provokes, FoG, while 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 compeers.

Moreover, 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 everyday life of patients at home, a clear advantage in pandemic times, and also in post pandemia.

It is also remarkable to claim that as the size of the potential industrial market this prototype pertains to, it could have an important impact on it even when there is an 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 massive 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, permitting them to offer a better treatment to the patient, boosting the user's results and life quality. It would be necessary to study the practicality comparing the use of the insoles (which could limit the footwear during the sessions) or the use of the simple attachment of a sensor. The pad could offer more data than the attachment, but it should be considered if this is redundant or significantly useful.

In addition, the way PARKIBIP is designed is to have the capability to be versatile and easily add new configurations, this is very positive as it is possible to update continuously the software as technology advances. This is also interesting for the clinicians, because it permits them to personalize the therapies depending on the patient and its 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 to mention 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 younger ones.

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

To sum up, the enormous and growing market with potential users, the low risks for the patient's during the sessions and the lack of already commercialized competitors with significant similarities, as well as the versatile features of the device and the constructive enhancements it could add, allow us to think 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 life style and quality. Also, the use of wearable technologies which decrease the final price, brings this tool to a wider range of people.

In brief, 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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