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Development and Technical Validation of a Gait-Synchronised Vibratory Stimulation System for Patients with Parkinson's Disease

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Abstract—An essential consequence of Parkinson's disease is the disruption of the normal walking pattern, manifested by specific abnormalities within the gait cycle. The absence or impairment of the proprioceptive feedback mechanism in muscles is associated with a noticeable decline in voluntary motor activities. The significant relation between Parkinson's freezing of gait and gait characteristics provides motivation to research the influence of vibratory activation on proprioception during walking.

Objective: The goal of this study is to develop and technically validate a vibratory system designed to provide gait-cycle-synchronised vibratory stimulation on lower limb muscles, and assess the different influences of synchronised and non-synchronised vibration concerning cadence and perceptions of facilitated walking in both healthy subjects and individuals with Parkinson's disease.

Methods: A vibratory system was developed based on a Raspberry Pi, 3 IMU sensors and 8 cylindrical vibrators. Build on a custom PCB board, software was developed using the ROS2 framework to be able to vibrate the motors both using custom commands or automatically based on the subjects gait cycle. An adaptive frequency oscillator was implemented to synchronise the subjects' angular velocity data with the corresponding gait percentage. Two protocols were performed to validate the technical aspects of the system and to determine the effect of vibratory stimulation on both body posture and gait cycle characteristics. The influence on body posture was measured using a forceplate while vibrating individual leg muscles. The effect on cadence and perceptions of facilitated walking was determined by using different randomised gait-synchronised and non-gait-synchronised vibrations while walking with a self chosen pace. The developed system was technically validated in both healthy subjects and Parkinson's disease patients.

Results: A functional, compact and wearable vibratory stimulation system was developed. The system is able to capture angular velocity data from both shanks at a frequency of 40 Hz, and detect the main gait events to be able to sync vibratory stimulation with the lower limbs muscles activation. During the technical validation, while no major impact on cadence was observed as a consequence of either synchronised or non-synchronised vibratory stimulation, distinctions in subjects' proprioceptive perceptions were identified through the implementation of varied vibratory stimulation timings.

Index Terms—Parkinson's disease, vibratory stimulation, gait, synchronisation, adaptive frequency oscillator

I. INTRODUCTION

Parkinson's disease (PD) is a widespread neurological disorder estimated to affect a substantial global population, ranging from 7 to 10 million individuals [1]. It imposes a significant

physical and mental burden on patients, their families and an economical payload for healthcare systems worldwide [2], [3]. Among the primary challenges faced by individuals with PD, irregularities in walking patterns and the occurrence of freezing of gait (FOG) are one of bigger concerns [4]. These issues are prevalent across all stages of the disease and are characterised by difficulties in maintaining a consistent gait, with additional sudden episodes of gait freezing [5]. There exists no definitive cure for PD. The overarching goal of managing this condition is to facilitate the independence of patients for as long as possible while mitigating disability [1]. Consequently, there is a need for ongoing research and the development of novel therapeutic interventions to enhance the management of Parkinson's symptoms, especially through non-invasive interventions.

Gait abnormalities and FOG in PD

Typical abnormalities to the gait cycle as a result of motor dysfunctions of PD are shuffling gait and impaired balance (e.g. postural instability) [6]. Additional physiological characterizations of PD gaits are slowing of gait, reduced step length, reduced arm swing and loss of disassociated arm and trunk movements [7].

The control of both posture and locomotion requires the seamless integration of sensory information originating from visual, vestibular, and proprioceptive sources, all of which are processed by the central nervous system [8], [9]. Specially, limited proprioception of body posture and motion may decrease smooth and coordinated movement [10]. Based on the findings of a lack of proprioceptive sensation, the identification of PD shifted from solely a motor disorder to the broader cognitive and sensorimotor domain [11].

Another major symptom that contributes to falls [5] and a diminished quality of life for PD patients are FOG occurrences [12]. FOG is characterised by "a short period of inability to generate effective forward stepping motions with lack of any known cause other than Parkinsonism or high-level gait disorders." [13], often described by patients as the sensation of both feet being stuck to the floor. These episodes typically endure for approximately 10 to 30 seconds, after which patients resume walking relatively smoothly [14], [15]. Research has indicated that there is a notably higher occurrence of FOG episodes in a home environment, which may be attributed to the automatic motor acts commonly performed in familiar surroundings. To the contrary, in clinical settings or healthcare environments, individuals with Parkinsonism experience

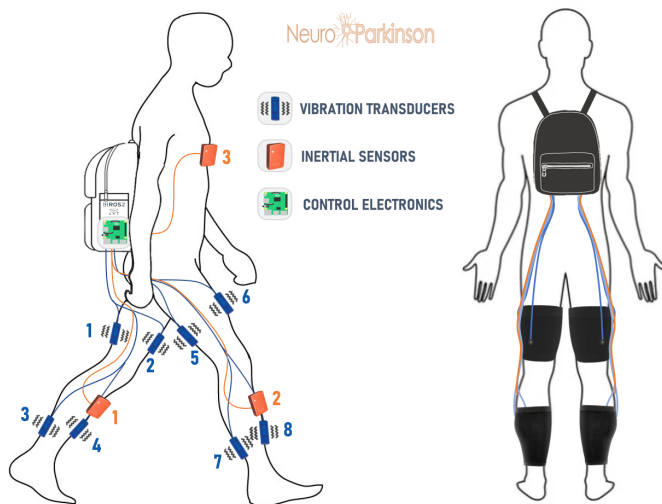


Fig. 1: Overview of the wearable NeuroParkinson system consisting of eight vibration motors and three IMU sensors, integrated in a compact bag-pack and wearable sleeves.

fewer freezing episodes [16]. The most important features of FOG that have a relationship with gait characteristics are (1) trembling of the legs to prevent the freezing [17], (2) an increase in cadence (steps/minute) while the step length decreases [18], and (3) drop-foot, causing the patient having trouble lifting the foot to a sufficient height to make a proper step. Hausdorff et al. have suggested that the inability to regulate cadence is a general gait disturbance in PD patients experiencing FOG [17]. Nieuwboer et al. suggested that the difference between trembling and actually coming to a freezing seems to be a result of the continued reduction of stride length before freezing while the cadence remains consistent [18]. This suggests that a stabilised step length and cadence should be maintained, as excessive deviations lead to a disruption of locomotion.

Because of this prominent relation between FOG and the gait characteristics, proprioceptive feedback of leg muscles is proposed as a new innovative way to support PD patients in their daily living environments.

Vibratory stimulation as proprioceptive feedback

In the context of locomotion and walking, it is crucial to acknowledge the role played by proprioceptive feedback. This feedback is derived from muscle spindles in the regulation of locomotor behavior. The absence or impairment of this feedback mechanism is associated with a noticeable decline in voluntary motor activities, consequently leading to a reduction in the functional capacity of walking [9]. The brain perceives the input from muscle spindles activated by the vibration as an indication of muscle elongation. The proprioceptive information originating from the difference in muscle-spindle length may thus result in anatomical muscle or posture adjustments during walking, which indicates an interesting potential non-invasive support method for altering the walking pattern of PD patients.

The humans perception of altering muscle spindle lengths as a result of vibratory stimulation was examined if it was

sufficient enough to create alterations in both body posture and the control and anatomical regulation of lower limb muscles during walking.

High-frequency vibration can enhance movement speed by placing the motor cortex in a “ready-to-move” state [19]. This suggests that the moment of initiating this motor cortex state is of importance during muscle activation patterns. A modification in vibratory activation may impact proprioceptive receptors differently than in unstimulated walking, leading to an adjustment in the voluntary motor feedback system. Consequently, motor activities could undergo adaptations to the vibrational stimuli, thereby influencing alterations in body locomotion. These variations in stimuli may emphasize the significance of the precise timing of muscle activation during walking and illustrate the effects of either pre- or postponed vibratory stimuli.

Previous research, has investigated the influence of vibratory stimulation as a method to influence the proprioception of subjects, assessing the effects on posture and walking speed [20], [21], [22].

Ivanenko et al.’s experimental setup for the walking protocol involved subjects performing trials on a treadmill, with speed control implemented using both fixed and subject-dependent settings. Vibratory stimulation was applied to agonist-antagonist muscle pairs of both the upper leg and lower leg. Constant continuous vibration as well as phasic vibratory stimulation was applied. The phasic vibration was synchronised with the subjects’ gait cycle, monitored through footswitches detecting heel-strikes. Vibratory stimulation of the Hamstrings muscles elicited the most prominent effect on both body posture and walking speed. However, the effects of vibrations on each leg muscle were assessed only when stimulated at the initiation of the swing phase (40% of the gait cycle) or the stance phase (90% of the gait cycle). Consequently, there was limited insight into the activation of vibratory stimulation immediately before or after the initial muscle engagement.

Prado et al. recently conducted analogous walking trials on a treadmill to investigate the effects of more precisely timed vibratory feedback and the immediate after-effects of vibratory feedback during overground walking [23]. They enhanced the gait analysis and were able to divide the gait cycle into smaller subdivisions, enabling more precise application of phasic vibrations per muscle. Their results suggested that both types of vibration affect the subjects’ gait, although their effect on cadence varies between the different types of vibrations. Their statement that the strategy of when and where the vibration is applied can impact gait is used as frame of reference in this study.

To the best of our knowledge, there are also limited studies [21] that comprehensively explore both the impact of phasic gait-synchronised vibratory stimulation on various gait characteristics, as well as its potential to alter walking patterns and reduce FOG episodes of PD patients.

NeuroParkinson project

Utilizing the insights derived from the research conducted by Ivanenko et al. and Prado et al., this study executed analo-

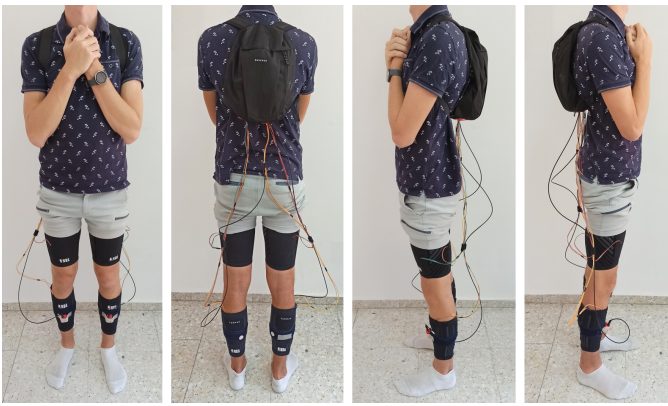


Fig. 2: A healthy subject wearing the improved NeuroParkinson system.

gous experimental protocols. However, this research primarily focused on the application of vibratory stimulations with the specific objective to enhancing the locomotion of PD patients in daily-life environments, an extension from the objectives pursued by the mentioned researchers.

The research into the impact of vibratory stimulation during the gait of individuals diagnosed with PD is conducted within the NeuroParkinson project, administered at the Centre for Automation and Robotics (CAR) in Madrid, has the primary goal of developing a system for improving gait and managing FOG occurrences in PD patients by stimulating the afferent sensory pathways through vibratory stimulation. The project further seeks to demonstrate the underlying mechanistic foundations of this innovative therapeutic modality. The anticipated outcome of this project is that afferent neurostimulation may serve as a potential substitute or complement to conventional pharmacotherapeutic approaches for managing FOG episodes.

II. THESIS HYPOTHESIS AND GOALS

In this thesis, performed as part of the broader NeuroParkinson project, we have the goal of developing a vibratory system and technically test it for the investigation if the effect of synchronised, phasic vibratory stimulation to lower limb muscles exceeds the influence of non-synchronised vibration with respect to cadence for walking healthy subjects and PD patients.

Our primary hypothesis is that gait-synchronised stimulation would exert a decrease in cadence variance by PD patients during walking compared to no vibratory stimulation. Additionally, we expect that gait-synchronised vibratory stimulation exerts a more pronounced influence on the walking patterns in PD patients when compared to non-synchronised stimulation, as this rhythmic stimulation might affect both physical and mental behaviour. Consequently, distinct variations in the subjects' perceptions of facilitated walking are expected across the various types of vibratory stimulations.

Two protocols were performed during this study. A Posture protocol was executed to validate the technical functionalities of the system and to assess the impact of singular-location

vibratory stimulation, specifically targeted at either a muscle belly or a muscle tendon, on body posture. A Walking protocol was executed to evaluate the impact of diverse vibratory stimulation patterns on the walking gait.

Therefore, we assessed the impact of vibratory stimulation applied to lower limb muscles on temporal gait parameters, specifically focusing on cadence. In this study, the cadence was defined as the number of steps per leg per minute. This was done by performing technical validations with data of both healthy and PD subjects to assess the quality and the effect of the system, and performing actual on-site trials with both subject groups.

Objective Posture protocol

Muscle vibration techniques have often been used in the examination of proprioceptive effects. The application of vibrations of adequate amplitude and frequency to a muscle or tendon primarily triggers the activation of the primary spindle endings, which are connected to the prominent Ia afferent fibers [24]. It has been shown that the primary endings of the muscle spindles are distinctively sensitive to low-amplitude vibrations, whereas the secondary endings and Golgi tendon organs show lower sensitivity, as their response is primarily elicited by larger amplitudes [25].

The Posture protocol was performed to explore potential alterations in posture as a result of the brain's interpretation of the vibrated muscle's length as being "elongated" [24]. Consequently, the brain might compensate for this perceived elongation by initiating movements in the opposite direction of the muscle's anatomical location. Therefore, by stimulating both the muscle belly and tendon, a distinction in posture is expected that will indicate the most effective vibratory stimulation location.

Given the dissimilarity in results across various studies regarding the optimal location for vibratory stimulation [26], [20], the process of identifying the most optimal stimulation site has been reexamined in this study. The findings of this protocol enabled the identification of the most optimal vibratory locations, including muscle location and muscle structure, which induced the most substantial posture changes. These observed effects on body posture potentially served as indicators of effective stimulation locations during the execution of the Walking protocol.

Objective Walking protocol

The Walking protocol consisted of applying various vibratory stimulation sequences and precisely synchronising these stimulations with the subjects' gait cycles. The influence of vibratory effects on step cadence, the decrease of cadence variance, and the experienced sensation of facilitated walking were studied.

Allowing the subjects to determine their own pace, inducing different (off-)timed vibrations, a voluntary change in cadence was expected as a result of the subjects' desire to match the vibrations' rhythm. Although previous studies did show effects in cadence for healthy subjects [22], [27], [20], the primary aim of incorporating healthy subjects into this study was to

undertake a technical validation of the system and to enhance its functionality. Additionally, their subjective assessments of vibration and walking characteristics were correlated with the different stimuli given by the system. The subsequent trials conducted with PD patients served to illustrate the impacts of the developed system on their gait patterns. Because of the influence of vibratory stimulation on the muscle response, one of the main objectives of the Walking protocol was to identify the most influential start moment for stimulation during the walking process: directly at the body's muscle activation, 10% before or 10% after the initial muscle activation.

Future objective

Based on the data acquired through the protocols implemented in this study, the overarching aim of the NeuroParkinson project is to ascertain whether the application of this developed vibratory system can effectively diminish the frequency and duration of FOG incidents in individuals with Parkinson's disease during walking. This reduction is anticipated to be achieved through the targeted vibratory stimulation of lower limb muscles, aligning with the gait cycles of the patients, as described in this study.

System Requirements

To assess the efficacy of the complete system, a set of requirements have been established involving both the hardware and software components. These requirements served as guiding principles throughout the developmental process.

Hardware:

- **Non-invasive:** the system must be entirely non-invasive, ensuring that it does not lead to any enduring side effects resulting from vibratory over-stimulation.
- **Self-attachment:** all system components should be attachable by the subjects themselves, even those who experience mobility challenges due to PD.

Software:

- **Real-time gait analysis:** the software must possess the capability to detect and analyze the subject's walking pattern in real-time, with an emphasis on gait event recognition.
- **Adaptability to PD-related anomalies:** the software should retain its ability to recognize gait events even when subjects show various PD-related walking anomalies, such as drop-foot and shuffling.
- **Pause recognition:** the software should be able to identify pauses in the walking pattern to prevent over-stimulation by the vibration motors.

Based on the experience of preliminary research performed in the NeuroParkinson project, the following additional preferences were defined for the development of the system:

- **ROS2 framework with Python:** The software should be developed within the Robot Operating System 2 (ROS2)

framework, utilizing Python as the scripting language. Using the ROS2 framework enables this system to be easily compatible with, and adjustable to other developments and systems using the same framework.

- **Main hardware component:** The main hardware component of the system should be based on the Raspberry Pi platform.
- **Supervisor control:** The system should grant supervisors the capability to easily terminate any software execution or vibratory stimulation to ensure the safety of the subjects.

Based on these requirements and preferences, initially a system was designed to fulfill dual functions: detecting the gait cycle and administering vibratory stimulation to agonist-antagonist muscle pair locations of the upper and lower leg. This system was complemented by the development of complementary software, resulting in the creation of a compact, portable, and stand-alone system (Figure 1).

III. METHODS

A. Hardware and Software

A custom made system has been designed for the purpose of monitoring the gait cycle during walking and applying vibratory stimulation to various lower limb muscles, as illustrated in Figures 1 and 2. Complement software has been developed using Python and the ROS2 framework, resulting in a compact and portable system optimised for hardware control.

The main hardware components of the NeuroParkinson system consisted of:

- 3 IMUs (Adafruit - BNO055): to detect body posture changes and lower limb movement.
- 8 vibratory motors (Precision Microdrives - 307-103.005): to transduce vibratory stimulation to the leg muscles.
- 8 motor drivers (Adafruit - DRV2605L): to enable individual motor activation.
- 2 multiplexors (Adafruit - TCA9548A I2C): to enable simultaneously communication with the IMUs and motors; one for the IMUs and motors respectively.
- RaspBerry Pi 4B (RPi): single-board computer to allow communication of datastreams and activation of sensors and motors.

All components were connected to a custom custom printed circuit board (PCB), powered by an external powerbank (Figure 3).

The control software employed for the operation of the NeuroParkinson system has been specifically developed for this project. This software framework was founded on the ROS2 framework and was mainly scripted in Python. The central components of this software, responsible for governing all hardware facets and coordinating the processing unit responsible for their operation, consisted of the following elements:

- **IMU Publisher (RPi):** The RPi functions as a publisher of IMU data. The IMU data is transmitted to a dedicated ROS2 topic, which is subsequently accessible from a PC.

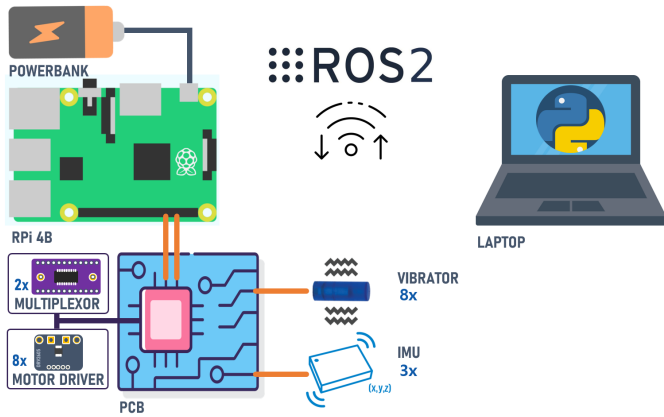


Fig. 3: Hardware configuration for both the Posture and Walking protocol. Consisting of: Raspberry Pi 4B (RPI), custom printed circuit board (PCB), 8 motor drivers (Adafruit - DRV2605L), 2 multiplexors (Adafruit - TCA9548A I2C), 3 IMUs (Adafruit - BNO055) and 8 vibration motors (Precision Microdrives).

- **MotionRecorder (PC):** Operating from the PC, this component is tasked saving the IMU data stream and transmitting motor activation data back to the RPi for the Posture protocol.
- **GaitStimulator (PC):** Operating from the PC, this component is tasked with receiving and processing the IMU data stream for the Walking protocol. Beyond the task of data recording, it is responsible for analysing the gait cycle in real-time, predicting the TO events, performing the Adaptive Frequency Oscillator (AFO) process and transmitting motor activation data back to the RPi for the Walking protocol.
- **Motor Activator (RPI):** simultaneously to publishing the IMU data the RPi will collect any instructions to manage the activation of all connected motors.

This software architecture optimised system performance by offloading computationally intensive tasks to a more robust CPU on the PC, while the RPi was configured to focus on the continuous collection and publication of IMU data, as well as the activation of motors. This division of tasks ensured that the RPi operated with minimal script execution, thereby facilitating uninterrupted data collection and motor control without undesirable interruptions or delays.

In this experimental setup, vibratory stimuli were generated utilizing direct current (DC) motors equipped with an eccentric component fixed to the shaft, which was enclosed within a plastic tube. To improve rigidity, vibratory stimulation and prevent mechanical malfunctions, after testing the Precision Microdrives model 304-116 an upgrade of the motors was made to model 307-103.005 (8.7 mm in diameter, 25.1 mm in length, displaying a typical normalised amplitude of 7G).

The vibratory stimulus frequency was set at 80 Hz through voltage control [22], [25]. The orientation of the vibrator's cylinder axis was aligned perpendicular to the presumed direction of muscle fibers.

B. Subjects

The following inclusion criteria for healthy subjects have been maintained:

- Age between 18 – 80 years.
- Sufficient cognitive skills: able to follow simple instructions.

The following inclusion criteria for PD patients have been maintained:

- Age between 18 – 80 years.
- Sufficient cognitive skills: able to follow simple instructions.
- Modified Hoehn and Yahr between and including stage 1 – 4 (or a similar score using a local practitioner's scale).

Prospective participants, individuals from both the healthy and PD populations, were subject to exclusion based on the following predefined criteria:

- Inability to sustain continuous walking on a level surface at a consistent pace for a duration of 10 minutes, without active external support (walking stick or crutches permitted solely for safety reasons). Temporary interruptions caused by episodes of FOG were tolerated during this assessment.
- Behavioral problems of an extent that may impede normal subject cooperation as assessed by the treating physician.
- Coexisting medical conditions that significantly impair walking ability, visual acuity, or cognitive function (e.g., cerebral palsy, cardiac comorbidity, frequent epilepsy), to a degree that renders individuals unsuitable for study participation, as determined by the attending physician.
- Visual impairments of a nature that would interfere with the capacity to independently execute the prescribed Walking protocol.

Four healthy subjects, comprising three males and one female (ages $23-44 \pm 10$ years old), performed the Posture protocol.

In addition to multiple healthy subjects that serve as Technical Validation subjects, the angular velocity data of three additional PD patients have been used to improve the system during the Technical Validation. However, only the IMU data containing their gait patterns was utilised as a validation signal, with the subjects not wearing the NeuroParkinson system. Consequently, an assessment of the system's technical precision was feasible, but there was an absence of data regarding the subjects' subjective perceptions of the vibratory stimuli.

The Walking protocol involved a total of 10 healthy subjects consisting of 6 males and 4 females, ages 23-72 years (average 42 ± 20 years old). Additionally, 1 PD patient participated (male, age 55) and, due to limited access to PD patients, two essential tremor (ET) patients (female age 62 and male age 76) participated. Despite they suffered from their neurological disorder, they did not show significant impairments in their walking capabilities. In any case, they were represented within the PD category, taking into account their ET indication. These subjects engaged in the experimental trials while wearing the complete NeuroParkinson system, allowing for the caption of

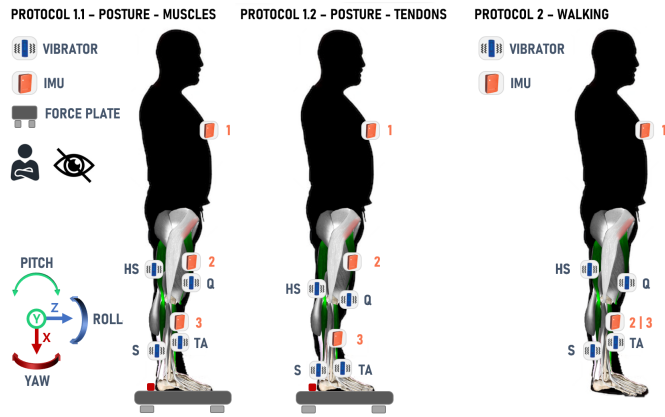


Fig. 4: Position of vibrating devices and inertial sensors for both the muscle and tendon location of the Posture protocol (left) and the Walking protocol (right). During the Posture protocol, the subjects kept their arms crossed in front of their body with their eyes closed.

their gait patterns and the administration of vibratory stimuli via the integrated motors.

C. Protocols

Two different protocols were performed. Initially, a Posture protocol was conducted with a cohort of healthy participants to test the vibratory system and to validate the influence of vibratory stimulation applied to specific leg muscles and tendons on body posture, as performed by previous studies. Subsequently, a Walking protocol was carried out, involving both healthy subjects (to serve as a Technical Validation group) and patients diagnosed with PD.

Posture Protocol

Experimental setup

The healthy subjects performed the Posture protocol while standing inside on a flat leveled force place (BTS Bioengineering – P-6000) without additional balancing aid (e.g. railing or crutches). Vibrating actuators were placed bilaterally on four leg muscles: hamstrings (*biceps femoris*) (HS), quadriceps (*rectus femoris*) (Q), soleus (S), tibialis anterior (TA).

Three IMUs (Adafruit – BNO055) were placed on the upper and lower body to analyse the posture and movement of the body:

- IMU 1 was placed in the center of the sternum to detect the posture of the upper body.
- IMU 2 was placed on the anterior side of the left upper leg.
- IMU 3 was placed on the left tibia bone.

The IMU sensors were positioned such that the Z-axis of the gyroscope coincided with the sagittal axis, so that the IMUs measured the pitch orientation of the shank, thigh and sternum around the Y-axis (Figure 4).

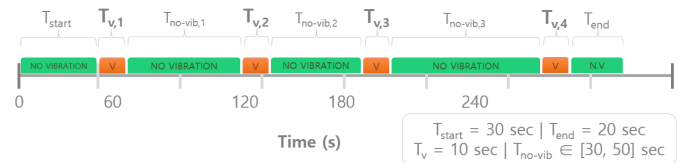


Fig. 5: The structure for the Posture trial for each specific muscle/tendon combination. The recovery interval (T_{no-vib}) between vibratory stimulation periods was characterised by random values drawn from a uniform distribution ranging between 30 and 50 seconds. Each trial started with an initial period of 30 seconds without any vibratory stimuli.

Data acquisition

The orientation data was captured using three IMUs operating at a sampling frequency of 40 Hz. Simultaneously, reaction forces and the positional coordinates of the center of mass relative to the ground were collected through the usage of a force plate. The sampling frequency of the force plate data was set at either 250 Hz or 800 Hz, depending on the specific measurement locations¹.

Protocol

During the trial, participants maintained a closed-eye posture with their arms crossed in front of their thorax. They were instructed to ensure continuous contact of their heels with the ground without their feet shifting throughout the trial. Participants received specific instructions not to resist any perturbations introduced during the trial. The trial started with a signal for participants to perform three consecutive knee bends, serving as an indicator for the initiation and synchronisation of both the IMU data collection and the measurement of reaction forces. Following this, participants were instructed to maintain a stationary, upright posture, whereafter for a duration of 30 seconds no vibratory stimuli were applied (Figure A2).

Over a period of 3.5 minutes, participants underwent four 10-second periods of vibratory stimulation targeting individual muscle groups, followed by intervals of non-vibratory conditions of varying durations. Notably, both the right and left legs were subjected to vibratory stimulation targeting the same muscle group concurrently.

Each trial consisted of nine distinct conditions, incorporating all possible combinations of vibratory stimulation locations within the muscle belly (-B) and muscle tendon (-T). In detail, the conditions performed were the absence of vibration (baseline) as well as vibratory stimulation applied to the hamstrings (HS-B, HS-T), quadriceps (Q-B, Q-T), soleus (S-B, S-T), and tibialis anterior (TA-B, TA-S).

The trial is composed of a structure comprising non-vibratory phases (lasting between 30-50 seconds, randomly allocated) alternated with four vibration intervals lasting 10 seconds each (Figure 5). During the non-vibration recovery periods, no explicit instructions or signals were given to the

¹Locations: Hospital Niño Jesus, Madrid (250 Hz); IRF La Salle, Madrid (800 Hz)

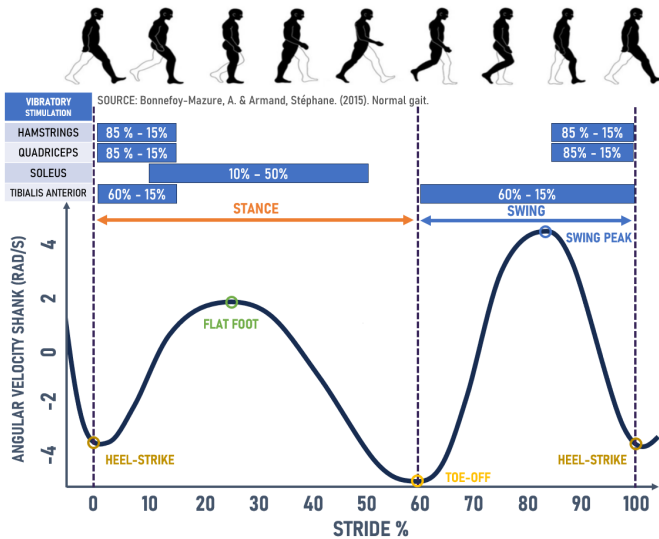


Fig. 6: Main gait cycle events with respect to the corresponding gait phase percentages. The muscle activation is based on stride percentages [28], [29].

subjects. Following the completion of each individual trial, which did not exceed a maximum duration of 4 minutes, the participants had a one minute break.

Walking protocol

Experimental setup

The subjects performed the Walking protocol on a flat level private road, ensuring they could walk without interruptions. Similarly as in the Posture protocol, the HS, Q, S and TA muscles were stimulated. The sensor and motor locations were identical as indicated in the Posture protocol (Figure 4). While the angular orientation of the torso (IMU 1) can provide additional posture data, it is not mandatory for the primary measures of cadence.

Data acquisition

The monitoring process focused on the use of two IMUs fixed to the shanks. These IMUs recorded angular velocity data at a rate of 40 Hz, enabling the tracking of subjects' gait cycle.

Protocol

A trial of the Walking protocol contained both gait-synchronised and non-synchronised (continuous) vibratory stimulation. This trial was performed to determine the effects of vibratory stimulation synchronised with the subject's gait cycle on both the walking pattern and the perception of facilitated walking. Cadence served as the primary metric for evaluating alterations in the walking pattern. In addition to cadence, Swing Time and Stance Time were the measures to detect inter-gait cycle changes. Five distinct conditions were used for the Walking protocol, all integrated into a single trial: (1. No Vibration) the absence of stimulation (baseline), (2. Synchronised) gait-synchronised stimulation,

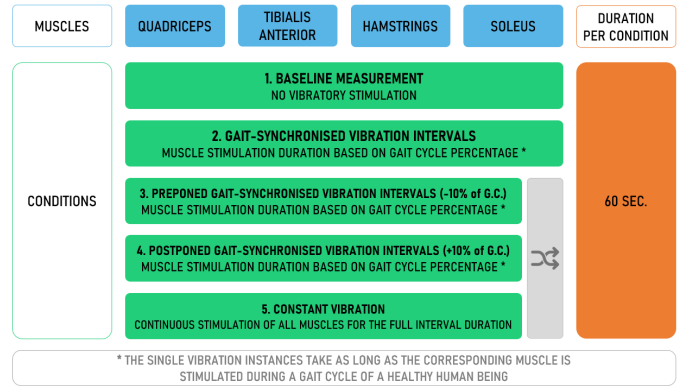


Fig. 7: Overview of the muscle groups, conditions and interval duration of the Walking protocol. Each condition is consecutively performed for 60 seconds, with the order of the Preponed, Postponed and Constant conditions randomised during each trial.

(3. Preponed) preponed gait-synchronised stimulation, (4. Postponed) postponed gait-synchronised stimulation and (5. Constant) constant (non-synchronised) stimulation. An overview of these various conditions, detailing the muscle groups and the respective duration of intervals, is visually presented in Figures 7 and 6.

To ascertain the optimal onset and duration of vibratory actuation, a segment of the trial has been conducted wherein vibrations were synchronised in real-time with the subject's gait cycle (Synchronised). This synchronization ensured that stimulation coincides with the precise moment when the corresponding muscle was naturally activated during walking. The timing of this activation was determined based on gait phase percentages, as established in the research of Bonnefoy-Mazure and Armand [29], which characterizes normal gait patterns. Additionally, another segment of the trial featured activation occurring just prior to or following the natural activation point (Preponed and Postponed). This pre- and post-gait-synchronised condition initiated vibratory stimulation 10% of the gait cycle duration earlier or later than the muscle activation percentage determined in the Synchronised condition.

To assess the impact on the main measures due to continuous vibrations (Constant) on various leg muscles, a part of the trial will be conducted wherein the anterior and posterior muscle groups receive constant stimulation. This approach allows for the examination of how constant vibration of each muscle group affects cadence. The objective of this evaluation is to identify the vibration type and duration that exerts the most substantial influence on walking performance in PD patients when subjected to vibratory stimulation.

Signal processing

Real-time angular velocity data of each shank was processed to determine the activation of each individual vibration motor. Since each leg was equipped with its own IMU and four vibration motors, two distinct signal processing scripts operated simultaneously during the trials; one script dedicated to each

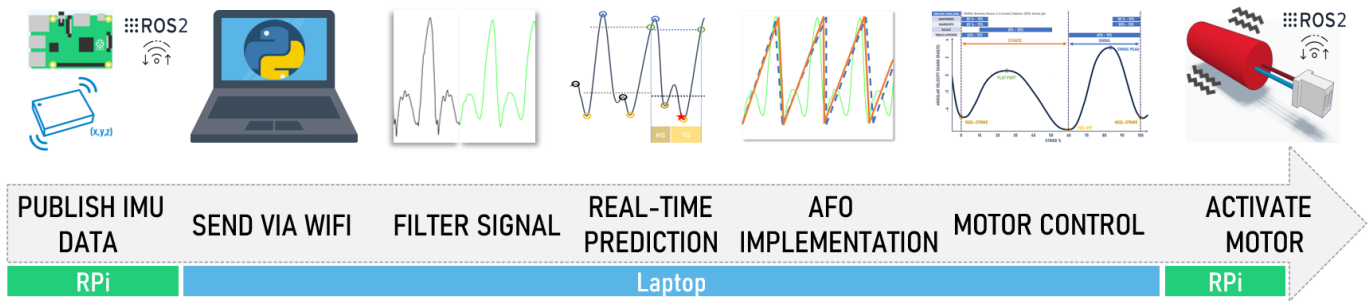


Fig. 8: Processing timeline of the RPi and PC per IMU sample.

leg. The comprehensive processing timeline per IMU sample is visually depicted in Figure 8.

The primary objective of this processing workflow is to extract the real-time gait cycle phase and frequency, utilizing an Adaptive Frequency Oscillator (AFO) [30]. The AFO functioned to synchronize the system's activity, more specifically the gait cycle phase, with the external time-varying IMU's angular velocity signal as guiding signal. Subsequently, the resulting gait cycle phase information was utilised to trigger the vibration motors precisely at the appropriate moments in the gait cycle.

The initial step involved the measurement and wireless data-transfer of the IMU signal, which was collected and transmitted at a frequency of 40 Hz by the RPi within the ROS2 environment. Subsequently, the PC collected each frame of this signal as it was published. The collected IMU signal was subjected to a two-step filtering process. Firstly, any abrupt spikes were removed to ensure data quality. Following this, the signal was further filtered using a first-order band-pass filter characterised by cutoff frequencies set at 0.1 - 4 Hz [31]. By performing the processing at a sample frequency of 40 Hz, an average delay of one sample, equivalent to 25 milliseconds, was observed as a consequence of this filtering procedure. This band-pass filter configuration served to attenuate important frequency components and thereby prevent the introduction of additional peaks that disturbed the detection of peaks corresponding to gait cycle events.

This filtered signal was the input signal for the automated detection of the different gait cycle events: the swing peak (SW), heel-strike (HS), flat foot (FF) and toe-off (TO). A custom made algorithm was designed that detected the different gait events based on peak detection of distinctive inter-gait cycle characteristics 6).

Given that the AFO needs a periodic event as input to correct its calculated phase and compensate for any irregularities in the IMU data patterns [32], the TO event was used as binary input. The selection of the TO event was grounded in its inherent recognizability as a distinctive occurrence within a typical walking pattern (Figure 6).

At the start of the experiment, a calibration phase spanning a duration of five seconds was initiated. Subsequent to this calibration phase, an analysis of all gait events, including swing peaks, heel-strikes, flat-feet, and toe-offs was conducted and used as references for forthcoming events during new gait cycles. For each of these events, distinctive threshold

values were initiated to quantify the next events within the gait cycle. These threshold values are based on the average IMU signal values of the corresponding events during the calibration period. By lowering each threshold value by a fixed event-specific factor, future events could be detected in real-time once the IMU signal would trespass the corresponding threshold value, even if there was a (subtle) change in signal (Figure 9).

Following the calibration period, these threshold values were continuously updated on a per-frame basis based on the mean value of multiple previous events. The calibration was considered to be successful if all three gait events were distinguishable within at least two complete gait cycles within the five-second calibration period.

Following the brief calibration period, the subsequent actual HS, FF and TO events were detected in a semi-real-time fashion, as they were determined at the end of every gait cycle. Utilizing information from the preceding SW and TO events, the system became capable of predicting the timing of the TO event for each successive gait cycle. This enabled the system to achieve real-time localization prediction of the TO events, a critical aspect used to synchronize the AFO with the ongoing IMU signal.

The ultimate output of the AFO was a refined gait cycle phase, which assumes values within the range of 0 to 100. This phase was synchronised with the gait cycle percentages to ensure the highest possible accuracy with respect to the actual real-time gait cycle. In each frame of operation, the activation instants of the vibration motors were cross-referenced with the phase information provided by the AFO. Based on this synchronization, the motors were then activated or deactivated as needed, with the corresponding instructions send through ROS2 message publication back to the RPi. Ultimately this resulted in gait-synchronised vibratory stimulation based on the angular velocity of the shank of that leg. A technical overview of all processes of the AFO is described in Appendix D.

IV. RESULTS

The findings from this research covered both an analysis of the technical specifications of the system, including both software and hardware components, as well as the quantitative results originating from the execution of both protocols. Supplementary results and complementary figures are presented in the appendix for further reference.

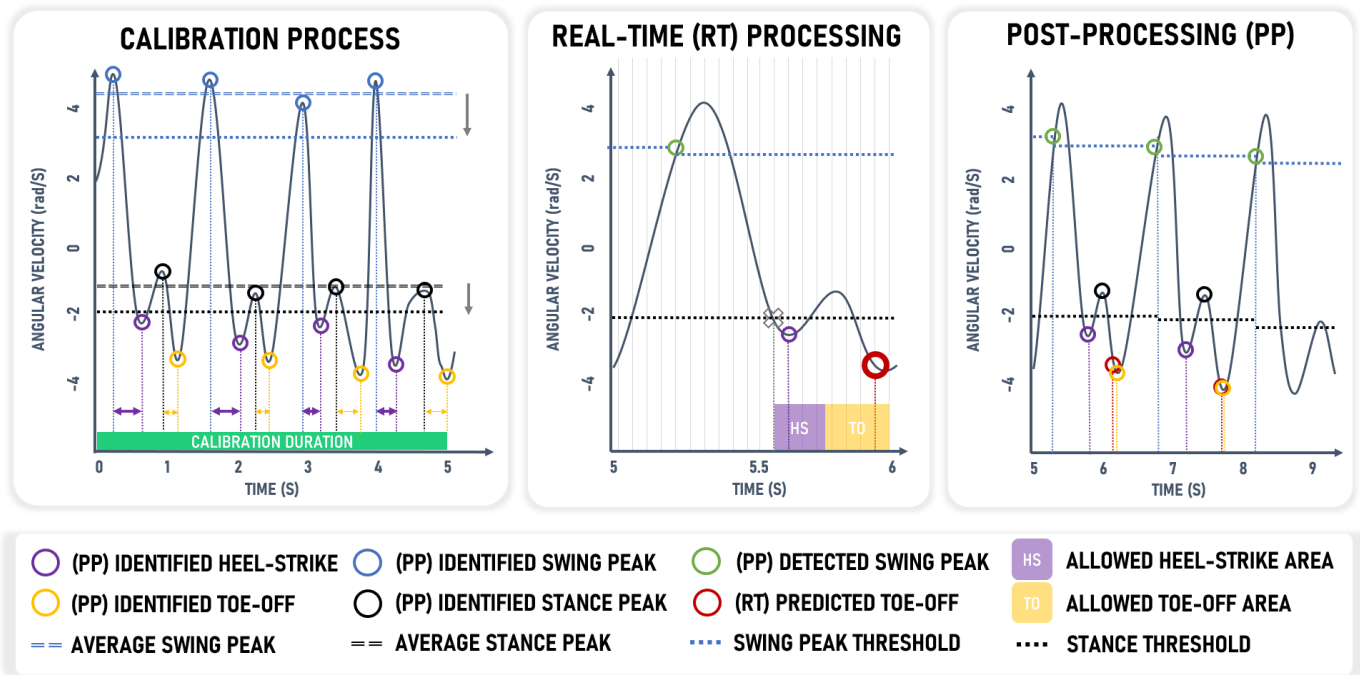


Fig. 9: Simplified overview of the real-time peak prediction system and post-processing peak detection. After initialising the swing peak threshold and stance peak threshold, these thresholds were updated every gait cycle. Based on the previous offsets of the identified toe-off locations with respect to the detected swing peak, a real-time toe-off prediction was made to provide accurate input for the AFO.

A. Posture protocol - Healthy subjects

The results of the Posture protocol were based on the COM movement along the Z-axis of the force plate and the subjects' perception of their posture. Due to the minor variations in posture, which consequently resulted in a substantial noise-to-signal ratio within the IMU's pitch data, none of the IMU data was included in the analysis of the Posture protocol.

Force plate data (Figures 10 and 11, male subject, 23 years old) revealed only marginal alterations in the COM across all subjects (Figure A10) both during vibration and non-vibration periods. No unambiguous change was visible during the vibrational periods (green) throughout the trial for all muscle locations. These changes remained confined to a range of one centimeter per vibrational period.

Vibration of shank muscles did not significantly change the perception of body posture, whereas thigh muscle vibration elicited a mainly forward perception (Figure A11). Besides the unanimous forward leaning perception during hamstring belly vibrations, also vibrations of the quadriceps belly and tendon induced a forward leaning perception.

The application of vibratory stimuli to the muscles of the shank did not yield significant alterations in the perceived orientation of the body's posture. Conversely, vibrations applied to the thigh muscles predominantly elicited a forward-leaning perceptual response. Vibrations affecting the hamstring belly consistently provoked an unanimous perception of forward inclination, while similar forward-leaning perceptions were also observed in response to vibrations applied to the quadriceps belly and tendon. In general, the participants reported a greater perception of influence resulting from vibratory stimulation applied to the muscle bellies as compared to stimulation

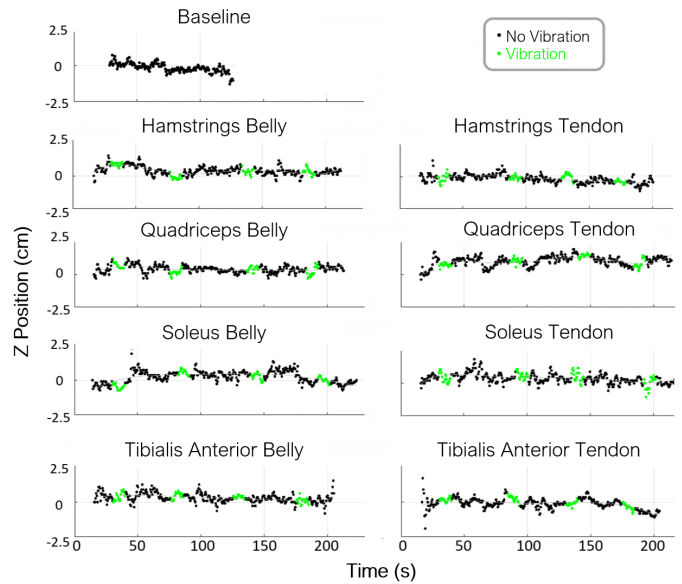


Fig. 10: Centre of mass positions along the Z-axis of the force plate per muscle group during the Posture protocol performed by a healthy subject. Each vibration period (green) lasted for 10 seconds. Non-vibration periods (black) lasted a random duration between 30-50 seconds. All measurements started at zero displacement based on the initial COM of that measurement.

applied to the muscle tendons (Figure 12).

The individual muscles failed to show influence upon the COM alterations as a result of vibratory stimuli (Figures A10 and A11).

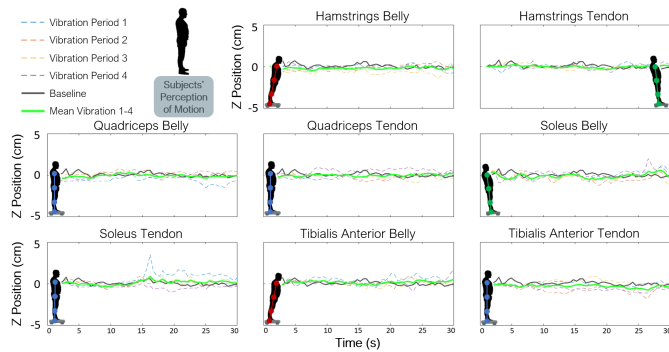


Fig. 11: Centre of mass positions along the Z-axis of the force plate per muscle group during the vibration periods of the Posture protocol performed by a healthy subjects, including the baseline (no vibrations) and the mean displacement during vibrations per muscle group. The subjects’ personal perception of posture is indicated as silhouette.

Subjects Perception of Motion per Muscle Belly or Tendon								
	HS-B	HS-T	Q-B*	Q-T*	S-B	S-T	TA-B	TA-T*
		1	1	1		3	2	2
	4	1	2	2	2		1	
		1			2	1		1
	1						1	
Nr. of Subjects: 4	Nr. Movement Perceptions Muscle Belly		12		Nr. Movement Perceptions Muscle Tendon		7	

* Data not present in 1 subject

Fig. 12: Overview of the subjective perceptions of posture from the subjects during the Posture protocol. Each number indicates the amount of subjects perceiving the corresponding posture per muscle belly or tendon vibration.

B. Technical Validation - Healthy and PD subjects

The Technical Validation was an evaluation of the hardware components’ quality and the precision of the real-time analysis software. Based on technical evaluations and iterative designs the new system was developed that has been used for the Walking protocol (Figure 2).

Given that the ROS2 IMU publisher operated at a frame-rate of 40 Hz, it is anticipated that the RPi’s average processing time would be approximately 25 milliseconds per frame (Figure 15). The Python script executed on the PC during the trial exhibited an average processing time of 1.5 milliseconds per frame. This fell well within the acceptable range of up to 25 milliseconds per frame to ensure uninterrupted 40 Hz processing. In contrast, the same processing performed by the RPi took an average of 5 milliseconds per frame.

Validation of the prediction algorithm involved a comparative analysis between the predicted time points of the TO peaks in real-time and the detected TO peaks obtained through post-processing. In addition, the gait phase values corresponding to

the Swing peak events and Heel-Strike events were compared to the expected percentages derived from the gait-cycle events illustrated in Figure 6. This validation was conducted for both the walking pattern of a healthy subject (Figure 13) and that of multiple PD patients.

For the walking pattern of healthy subjects, the average real-time prediction error per condition of 60 seconds was found to be within 2.7% of the duration of a gait cycle of that subject, equivalent to an absolute error of ± 0.032 seconds. Due to the combination of prediction error and the error margin associated with the AFO process, the average computed gait phase error concerning the true gait phase was 0.05 ± 0.03 seconds.

As a result, the average gait phase percentage corresponding to the swing peak event was approximately 85%, which closely aligned with the expected value of $\pm 80\%$ [28], [29]. Similarly, the average gait phase percentage associated with the heel-strike event was approximately 97%, with the anticipated values being 100% (or 0%).

Due to the prediction system and the performance of the AFO, the timing for the activation of vibratory stimuli performed on a high level of precision. The deviation per vibration period was minimised to a few milliseconds prior or after the intended period (Figure 14).

In the case of the three PD subjects, it was observed that the mean real-time prediction error fell within a range of 0.02 ± 0.01 seconds. Furthermore, the mean gait phase percentage associated with the swing peak event exhibited an approximate value of $83\% \pm 2.3\%$. Similarly, the mean gait phase percentage corresponding to the heel-strike event demonstrated an approximate value of $97\% \pm 1.0\%$.

The integration of all IMU sensors and vibratory motors within the compression sleeves, along with the merging of all associated cables, has resulted in a wearable system that is both compact and resilient. This integration has led to a reduction in signal distortions and a decrease in hardware connection malfunctions (Figure 2).

C. Walking protocol - Healthy subjects

Based on the Posture protocol results, it was determined that only muscle belly location would be stimulated during the Walking protocol. Among the cohort of ten healthy subjects, it was observed that eight individuals either showed no effect on their cadence or experienced a decline during each vibrational condition in comparison to the No Vibration condition. One participant consistently demonstrated an increase in cadence across all conditions, while another subject displayed both increments and decrements in cadence across the vibrational conditions (Figure 16). On average, the average data across all vibrational conditions indicated a decrease of 1 step per minute per leg (Figure 18).

In addition to the evaluation of cadence, an analysis of the inter-gait cycle was performed by assessing the Swing time and Stance time within each gait cycle. It was observed that all healthy subjects exhibited no consistent alterations in the Swing/Stance ratio as a direct consequence of vibrational stimuli (Figure 19 and A14).

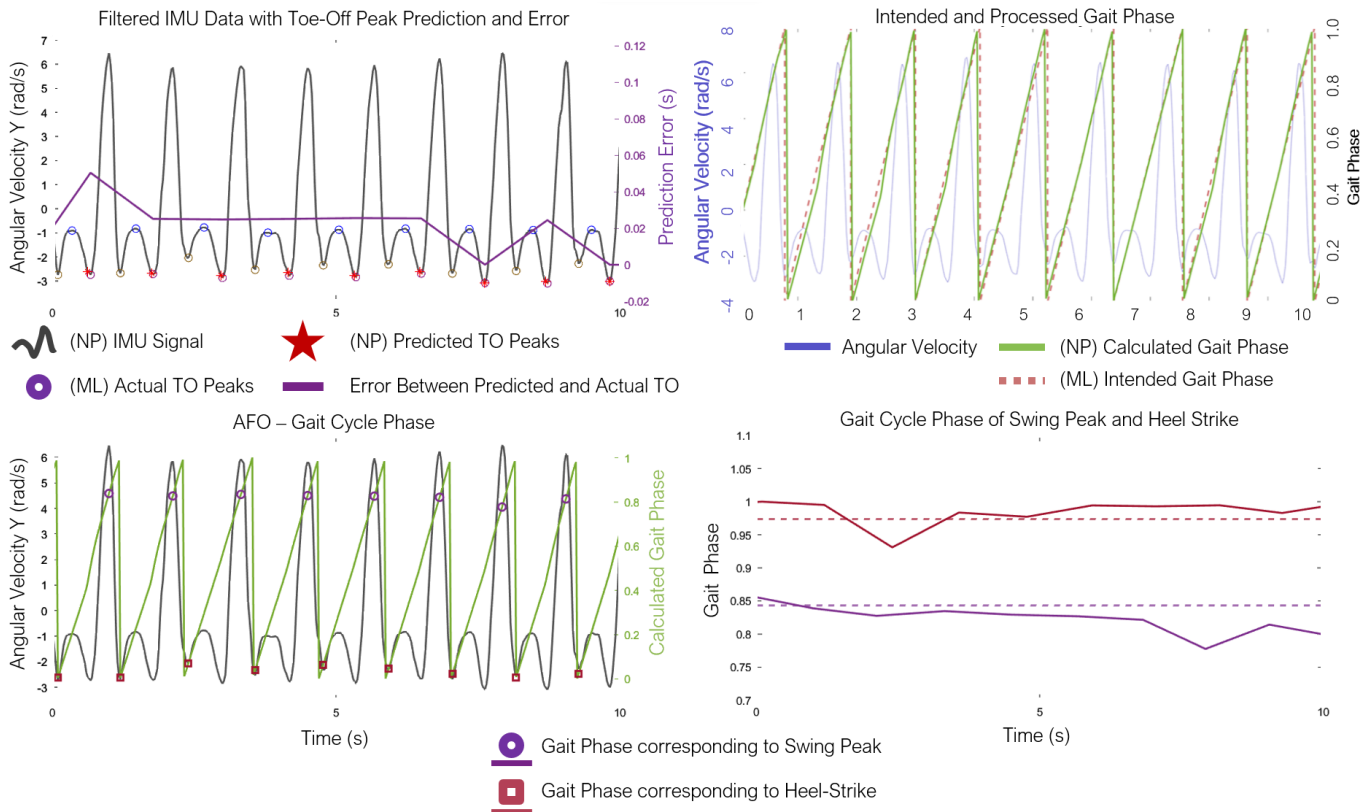


Fig. 13: Overview of the prediction and AFO algorithm validation based on the walking pattern of a healthy subject. (Top Left) The mean error between the predicted and actual TO peaks was 0.018 seconds (2% of the average gait cycle duration). (Top Right) The error between the AFO calculated Gait Phase compared to the intended Gait Phase was about 25 milliseconds. (Bottom) The average gait phase percentage for the Swing Peak was 85% whereas $\pm 80\%$ was expected. The average gait phase percentage for the Heel-Strike was 97%, whereas 100% (or 0%) was expected.

D. Walking protocol - PD patients

The two ET subjects showed a decline in cadence for all vibrational conditions, whereas the PD subject showed a small increase for the Synchronised condition and a decrease in the Preponed, Postponed and Constant conditions (Figure 17). The Preponed condition showed the biggest decline in cadence: one to three steps per minute per leg decline (Figure 18).

In line with the results of healthy subjects, the PD subjects did not show any unambiguously effect on Swing/Stance-ratio (Figure 19).

E. Subjects' Perception of Vibration and Cadence

Throughout the experimental trials, the majority of subjects communicated their subjective perceptions regarding the vibratory stimuli and the resultant impact of these vibrations on their walking cadence. These subjective insights were quantified (Figure 20). A distinction was established based on the presence of vibrations in the upper and lower extremities, taking into consideration the varying activation durations of different muscle groups during a gait cycle.

Vibrations applied to the upper muscles during the Synchronised and Preponed conditions were observed to be less prominently perceived compared to the vibrations applied to the lower muscles. Conversely, the Postponed and Constant conditions elicited the most pronounced vibrational perception

among the majority of the subjects. Regarding the perception of cadence, half of the subjects reported an increased sensation of walking at a higher pace during the Postponed and Constant conditions.

In addition to the quantitative metrics, transcriptions of verbal remarks were documented to provide supplementary information of the observed effects for each subject.

The following subjective remarks were given by the Healthy subjects during the trials, with some individuals expressing similar responses:

- "The Constant vibration gives a pleasant and relaxing feeling while walking." (3x)
- "The Constant vibration gives a pressing, sleeping or uncomfortable feeling on the muscles." (3x)
- "I have the urge to walk faster during the Postponed or Constant condition." (4x)

Subsequently, the following subjective remarks were given by the PD subjects during the trials, with some individuals expressing similar responses:

- "With all vibration conditions, I have the feeling of being able to walk better in a straight line." (1x)
- "I have the feeling that I walk faster during the Postponed or Constant condition. Also, it feels easier to lift my foot, to raise my leg and make a step." (1x)

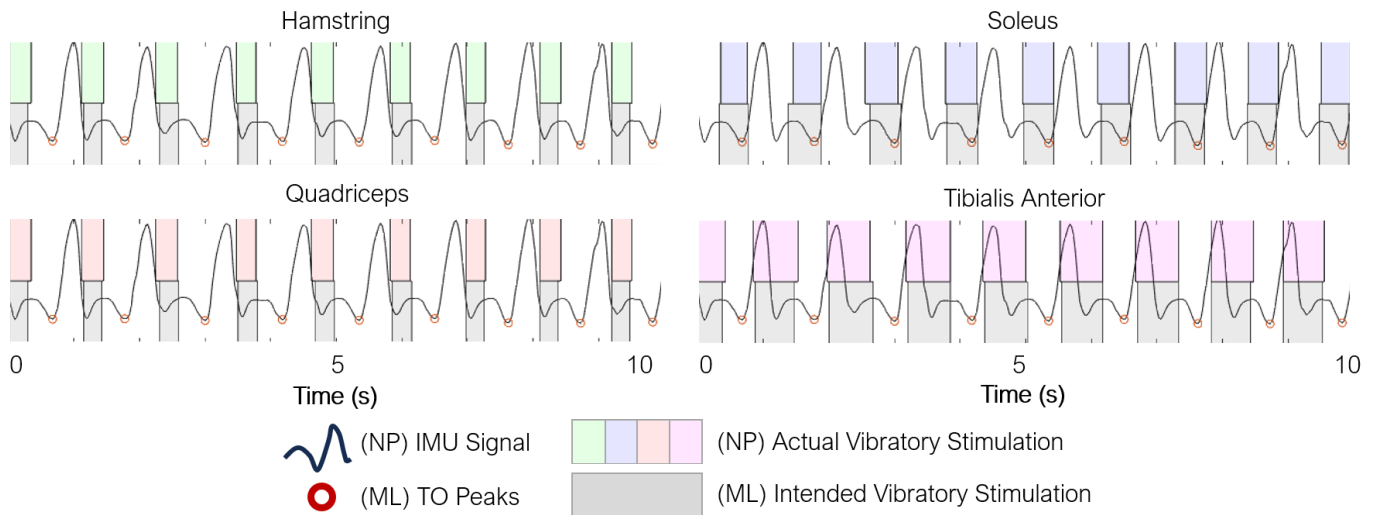


Fig. 14: Overview of the AFO and motor vibration algorithm validation based on the walking pattern of a healthy subject. The upper bars represent the periods of vibrations computed by the NeuroParkinson (NP) AFO. The lower bars depict the intended periods of vibration determined based on the gait cycle percentages calculated using Matlab (ML).

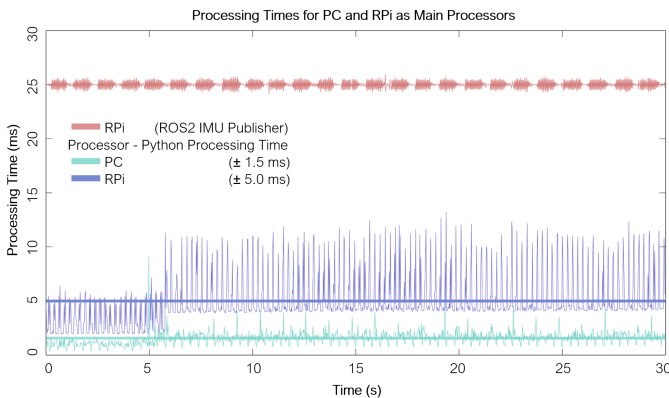


Fig. 15: Processing time of the RPi to measure and publish the IMU data (red) and the processing times for the PC (green) and RPi (blue) as main processors for processing every frame.

- "Although I feel the vibrations, I do not notice a difference in walking speed." (1x)

V. DISCUSSION

The results show that multiple subjects had the perception of an alternating gait cycle between the different types of vibration. For the Postponed and Constant vibration types an increase in facilitated walking was perceived by over half the subjects, confirming our hypothesis regarding the effects of vibratory stimulation on gait walking perceptions. For almost all healthy subjects, a small decrease in cadence was observed for all types of vibration. The limited set of PD subjects showed no major difference in absolute cadence for the different vibration types. However, the subjective perception of facilitated walking showed positive insights into potential contributions of both phasic and constant vibratory stimulation. These perceptions might indicate a decrease in cadence variance and FOG occurrences as expressed in the projects' objective.

A. Posture protocol

The research involving the application of vibrational stimuli to various lower limb muscles was conducted within the Posture protocol. Vibrators were placed perpendicular to the associated muscles to maximise the impact of the mechanical vibrating force on the mechanoreceptors compared to parallel placed vibrators. With respect to body posture, vibrations applied to anterior muscles were anticipated to result in forward-leaning motions, while vibrations directed at posterior muscles were expected to induce backward-leaning motions [27] as a result of the perception of muscle elongation. However, contrary to previous research findings [20], no prominent influence on body posture was found based on the COM recordings (Figure 12).

The occurrences of forward-leaning perceptions following both anterior and posterior muscle stimulation contradicted the hypothesis of counteracting leaning behaviors [27]. Also, the unanimous perception of forward leaning as a result of stimulating the Hamstrings contradicts the results from Ivanenko et al. [20], that showed backwards leaning.

However, the limited results suggested that the impact on the perception of motion appears to be more pronounced when muscle bellies were stimulated as opposed to muscle tendons (Figure 12). Consequently, adjustments have been made to the stimulation locations for the Walking protocol, with a focus on exclusively stimulating muscle bellies.

The majority of performed studies stimulating muscle tendons over muscle bellies [22], [19], [24], [33], [34], although different studies suggest muscle belly stimulation is beneficial [35]. The results of the Posture protocol showed with limited participants a larger perception of motion after stimulating muscle bellies compared to tendon stimulation (Figure 12). In order to determine the different and most optimal effects of synchronised muscle stimulation on muscle bellies or tendons, more trials should be performed using different stimulation locations.

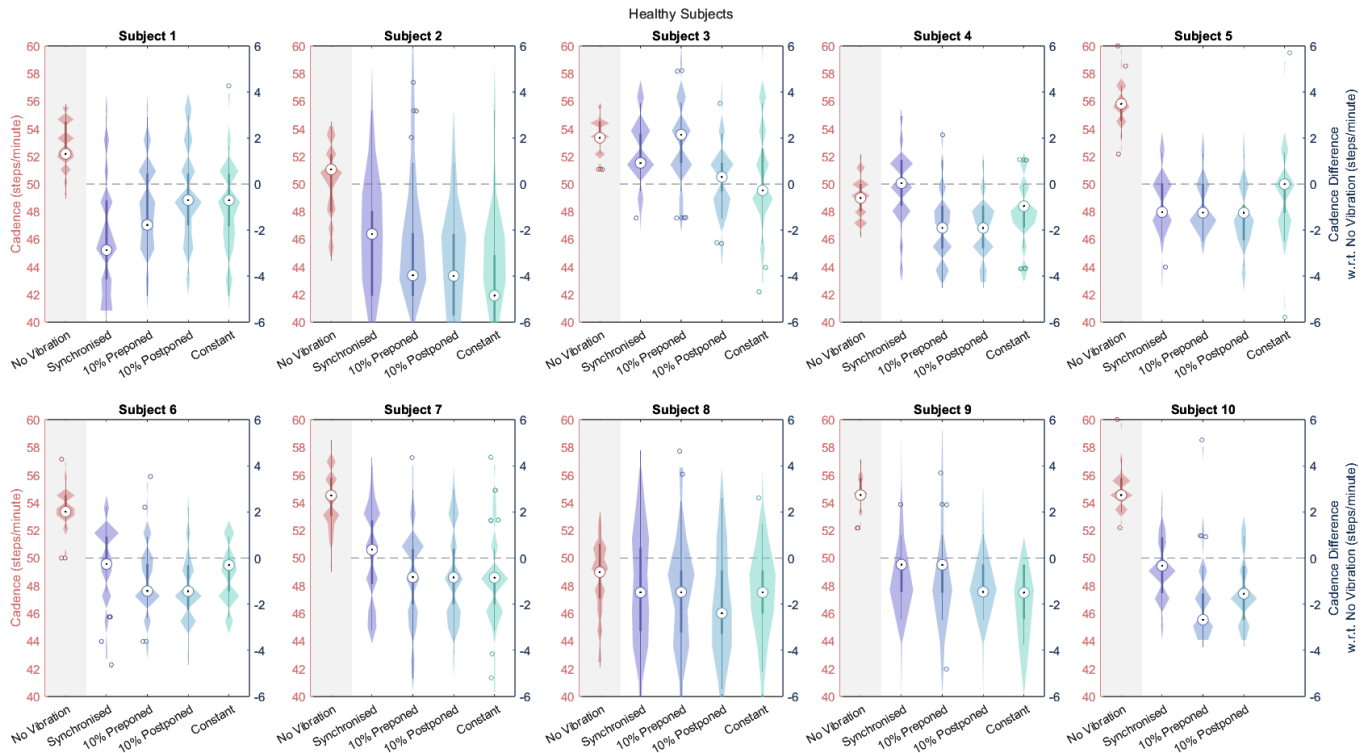


Fig. 16: Boxplots of the analysed cadence per healthy subject during the Walking protocol. The first boxplot shows the absolute cadence during the No Vibration condition. The boxplots on the right indicate the cadence difference of the corresponding vibration condition with respect to the mean cadence during No Vibration.

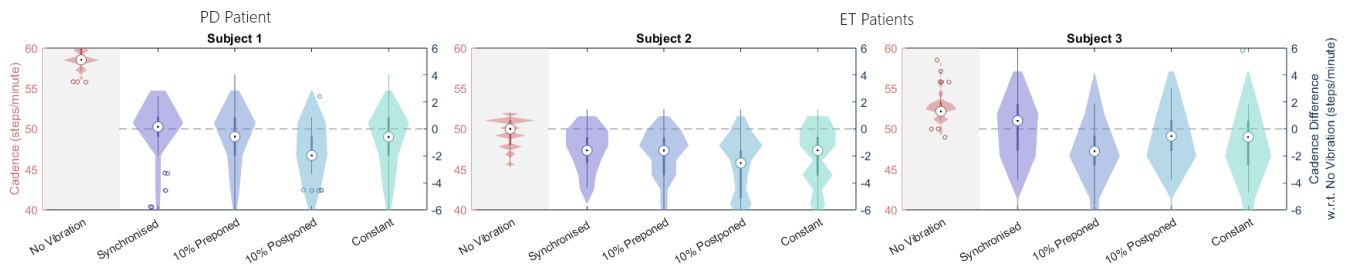


Fig. 17: Boxplots of the analysed cadence per Parkinson and Essential Tremor patient during the Walking protocol. The first boxplot shows the absolute cadence during the No Vibration condition. The boxplots on the right indicate the cadence difference of the corresponding vibration condition with respect to the mean cadence during No Vibration.

During analysis of the IMU recordings obtained during the Posture protocol trials, it has been determined that the IMU data did not offer precise and valuable information to support or refute the protocol objective. The noise-to-signal ratio observed for the subtle movements of the trunk and lower limbs was too prominent, which made it impractical to extract meaningful data from these measurements. Therefore, all drawn conclusions were based on the COM measurements and on the subjects perception of motion.

B. Technical Validation

The initial results of the Technical Validation from the tests with healthy subjects looked promising. It was proven that the hardware was functioning properly once the gait-cycle detection and AFO are activated.

The main evaluation criteria for the hardware components revolve around their robustness and the ease with which the system can be applied to the human body. The enhanced system (Figure 2) demonstrated remarkable robustness, enduring repeated use by various subjects across multiple trials without experiencing malfunctions. The integration of compression sleeves significantly improved the system's usability, substantially reducing the time required for attaching and removing the system. Furthermore, the PCB showed no indications of deterioration or faulty component connections throughout the assessment.

The primary evaluation criteria for assessing the quality of the software included several key aspects, including processing times, the accuracy of the gait cycle prediction system, and the precision of the AFO.

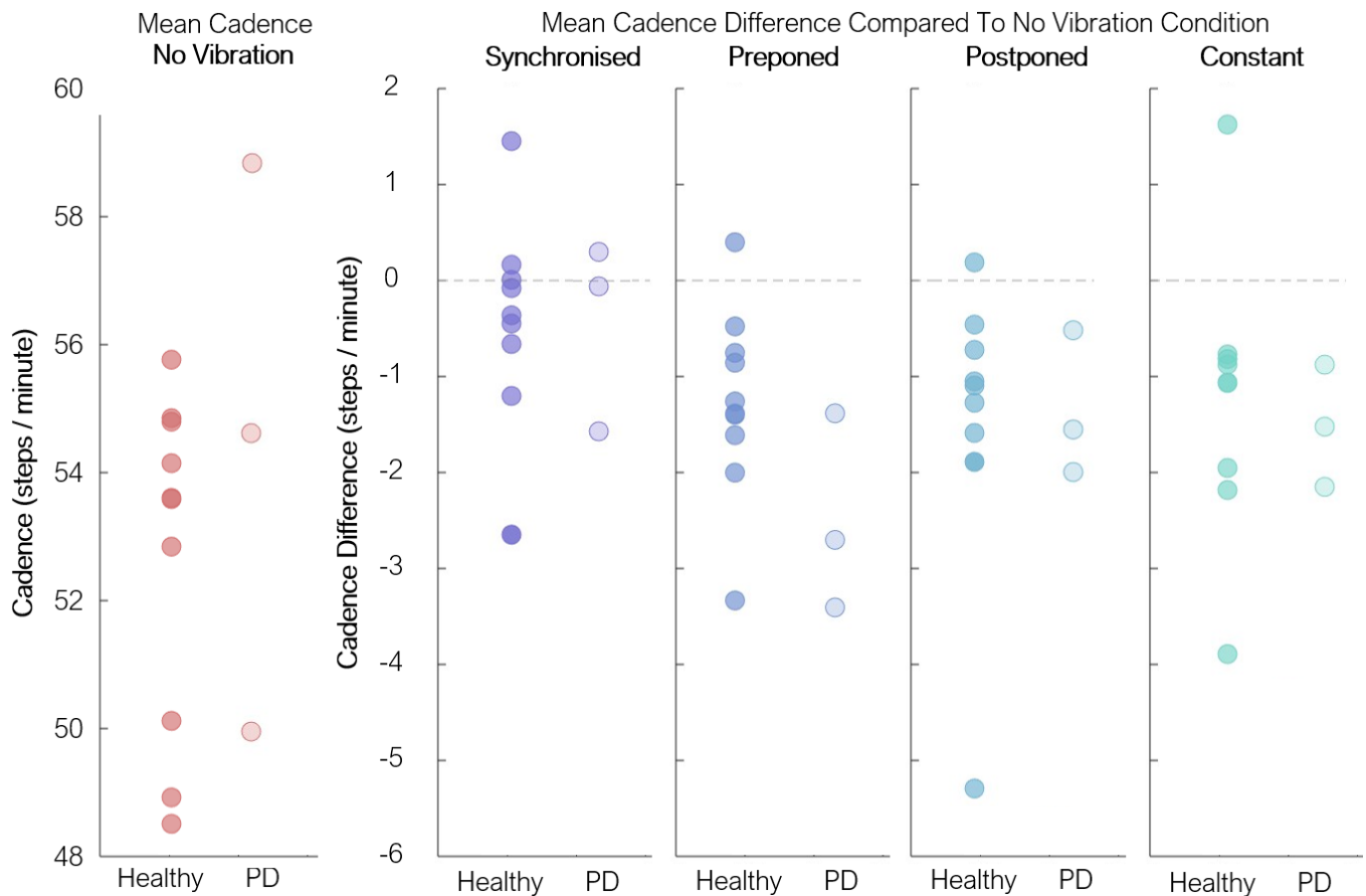


Fig. 18: The first plot shows the average cadence (steps per leg / minute) during the No Vibration condition of all healthy (left) and PD (right) subjects. The other conditions show the average cadence difference with respect to the average No Vibration cadence per subject.

Processing time: The computational capabilities, including the processing power and subsequent processing times of both the Raspberry Pi and the PC, were of great importance in determining the quality of the data-stream. These metrics were crucial indicators of software efficiency and overall performance. Several factors contributed to the software's efficiency, including the processes executed by the RPi, those by the PC, and the efficacy of wireless data transmission between the two controllers.

Ideally, the average processing time for the RPi should have been aligned with the expected value of 0.025 seconds, considering the sampling frequency of 40 Hz. Any deviation from this benchmark attributed to potential delays in ROS2 communication, which subsequently impacted the IMU sampling rate. Such variations in frame rate had repercussions on the precision of the peak-prediction process, affecting the accuracy of the system's performance.

Initially, a sample frequency of 40 Hz was used to ensure the prevention of delays in both data transmission and data processing. The gait-cycle analysis and AFO prediction system were calibrated based on this initial sample frequency to attain optimal performance of the entire system. However, optimizing the software through the implementation of a higher sample frequency for both the IMU collection and signal processing has the potential to capture more details in

the gait cycle and therefore reduce vibratory activation errors in the system [36].

Owing to the latency associated with wireless Wi-Fi transmission, certain trials exhibited deviations from the specified sampling frequency of 40 Hz for recording IMU data (Figure A12). In specific instances, individual frames required up to 23 milliseconds for transmission to the personal computer, leading to observed inconsistencies in the operation of the prediction algorithm. Consequently, not every gait cycle throughout the entire trial contained the anticipated 40 frames. Nevertheless, upon recovery of the original 40 Hz sampling rate, the system was capable of re-calibrating its prediction parameters, facilitating accurate and intended predictive performance.

To ascertain the upper limit of the sample frequency that could be accommodated by both the RPi and the PC without introducing disruptions that could obstruct the processing of the IMU signal, an additional hardware assessment was performed (Figure A13). When the PC is exclusively used for executing the main processing script, a sample frequency of 100 Hz can be achieved. However, if the RPi is also utilised as the primary processing unit, a maximum sample frequency of 60 Hz can be sustained before significant delays in data acquisition become evident. Ultimately, to ensure the development of a standalone system maintaining a user-

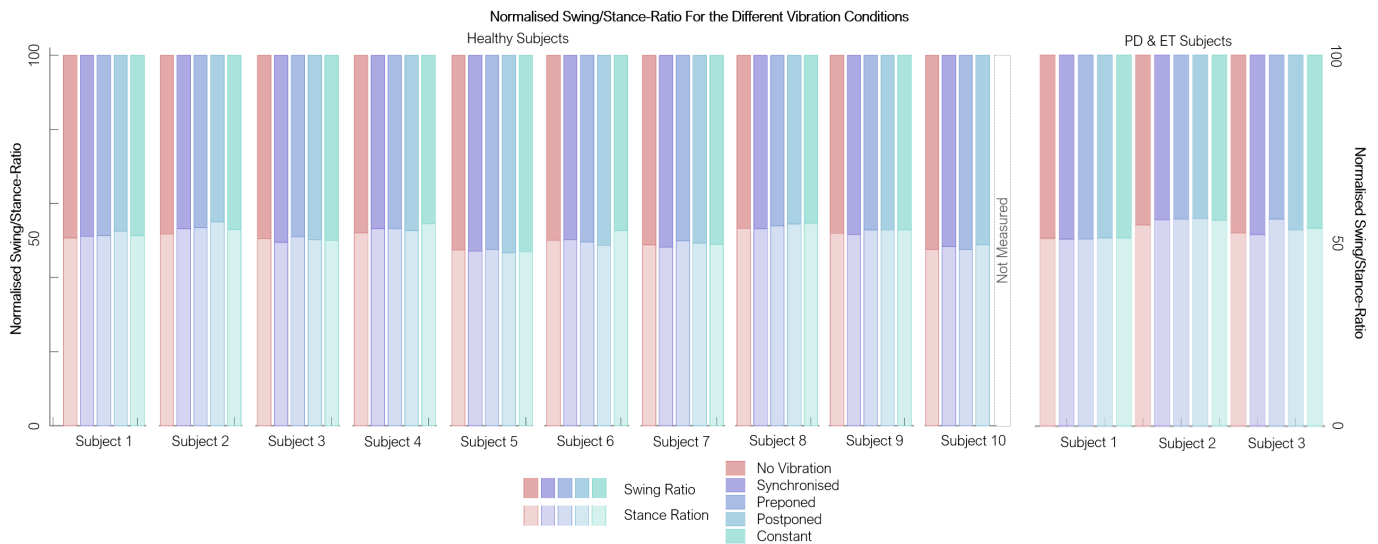


Fig. 19: Normalised Swing/Stance-ratio for Healthy and PD subjects for all different conditions.

Subjects' Perception of Vibration and Cadence

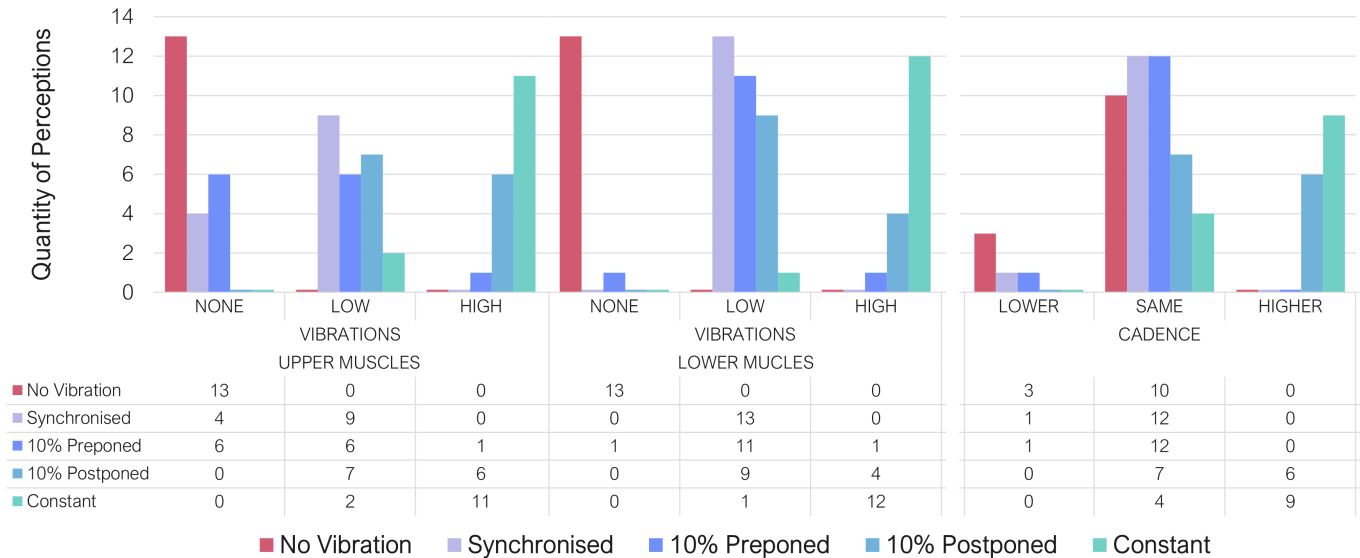


Fig. 20: Bargraphs indicating the subjects' perception of the vibratory stimulation and cadence change for both the upper and lower leg muscles for the different vibration conditions during the Walking protocol.

friendly operation, the entirety of processing tasks should be executed by the RPi. Striking a balance becomes inevitable in this context, involving considerations for an increased sample frequency to enhance signal processing quality. However, this must be achieved without creating potential complications arising from hardware limitations.

Prediction system: During the development of the custom gait cycle analysis system, an approach was chosen for the automated identification of gait cycle events, utilizing a dynamic threshold method. While alternative methodologies employing machine learning techniques have demonstrated comparable accuracy in gait event detection [37], the design of the initial system for this study prioritised simplicity, requiring minimal computational resources and minimised the necessity for expertise in machine learning algorithms. Given the di-

verse scope of this study, and the absence of gait data from individuals with PD during the initial system development, a deliberate decision was made to use a method capable of analysing various input signals, thereby ensuring flexibility and applicability in diverse upcoming trials. As the dynamic threshold method adapts to every individual subject during the calibration phase, no large datasets or pre-learning methods are required.

Gait patterns in individuals with impairments exhibit a variability not observed in healthy gait patterns, and the accurate detection of gait phases during impaired walking may create distinct challenges. Consequently, as additional data on PD gait patterns becomes available, refinements to the gait analysis system are recommended; mainly focusing on the unique characteristics of PD-related gait abnormalities.

It is essential to acknowledge that despite these necessary adjustments, the fundamental functionalities of the designed system can be retained, preserving its utility and offering valuable features for synchronised vibratory stimulation in individuals with impaired gait.

For the actual prediction system, the toe-off event has been selected to function as main synchronisation event for the AFO. During preliminary gait cycle tests, the TO event showed consistency and was most of the time identifiable in the gait cycle signal, even for deviating walking patterns.

AFO precision: The main disadvantage of adaptive frequency oscillators is that they require precise parameter tuning to quickly synchronize with the human periodic motion [38]. In order to achieve synchronised stimulation, it was observed that the switch on/off time for an 80-Hz vibration motor took approximately 20 milliseconds [39]. To account for this mechanical delay, adjustments were made to the AFO system, enabling it to activate each stimulation 1% of the gait cycle in advance. Given the average gait cycle duration of 1.2 seconds for healthy subjects, this corresponded to an anticipated vibration duration of approximately 12 milliseconds.

The comparison results (Figure 14) show the alignment between the AFO's vibration timings and the intended timings based on the gait cycle percentages of a healthy subject. The precision of the generated vibrations was the result of an iterative calibration process involving both the AFO and the vibration system. It is important to note that these calibrations primarily relied on data obtained from healthy subjects.

Still the results of the Technical Validation showed an average AFO error offset of 5% for the swing peak and 3% for the heel-strike event (Figure 13). Although multiple studies performed AFO validations based on hip or knee angles [40], [41], [42], [43], the study from Eslamy et al. [44] showed an AFO validation based on shank angles. They presented an average RMSE gait phase error of 3% over a span of 10 gait cycles.

The observed discrepancy in the AFO gait phase, resulting in a few percentages deviation, was likely attributed to the cumulative effects arising from various factors including the pre-processing of angular velocity data. The introduction of timing errors during signal filtering, the fluctuating AFO input signal, and timing inaccuracies inherent in the TO prediction system collectively contributed to a cumulative error in the AFO gait phase.

Prospective enhancements to the prediction system and AFO parameters could be made by a broader dataset encompassing gait patterns derived from both healthy individuals and those with PD. Building upon the results of Zhang et al., the incorporation of an additional machine learning layer may serve to rectify potential errors introduced by the AFO. The machine learning system offers a more precise estimation of walking frequency, thereby potentially improving the corrective capabilities of the overall system [40].

C. Walking protocol

Vibration-induced muscle-spindle input is interpreted by the brain interprets as muscle elongation [34]. Hence, the question

arises concerning the apparent lack of substantial effects or the presence of weak effects when applying vibration to lower limb muscles during walking on cadence. It is probable that locomotion executed on a level and stable surface predominantly relies on the automatic generation of motor patterns for walking [27]. In contrast to previous studies [20], [23], this study conducted all trials outdoors, avoiding the utilization of a treadmill. This decision was motivated by the aim to align the walking environment more closely with the real-life settings encountered by PD patients in their daily activities. It was anticipated that these outdoor settings may eventually provide a more representative portrayal of the effects of vibratory stimulation on FOG compared to controlled indoor trials [16].

Ivanenko et al. demonstrated that the continuous vibration of hamstrings muscles induced more substantial increments in walking speed than phasic stimulation during both swing and stance phases [20]. Prado et al. observed a small yet significant increase in cadence during both continuous and timed vibrations [23]. In contrast, the findings of this study did not show the anticipated increase in cadence in response to either timed or continuous vibrations. It is noteworthy that Prado et al. considered additional parameters such as step length and stride length in their analysis. Given that an unaltered cadence does not necessarily imply an absence of changes in step length, the inclusion of this metric in future trials may enhance the comprehensiveness of the analysis. Despite the absence of a cadence increase, it is important to acknowledge that improving stride length can still benefit PD patients as a potential strategy to minimise trembling and instances of FOG [18].

D. Limitations and Future Work

One of the primary objectives of the NeuroParkinson project is the creation of a handheld device tailored for use in the everyday environments of Parkinson's patients, removing the necessity for the presence of medical personnel to facilitate the application of the system's components. This study has demonstrated the potential and validation of the developed vibratory stimulation system toward achieving this objective. To ensure the optimal functionality of this system, future efforts should include additional tests and developments.

Spatial parameters: Elevating or stabilizing cadence in individuals with PD holds potential benefits for improving their gait. The involvement of healthy subjects in this study primarily served to assess the operational efficacy of the developed system, given their absence of walking pattern abnormalities. Consequently, the anticipated changes in cadence were mainly expected within the PD subject group. However, due to the unavailability of precise measurement tools, spatial parameters were not recorded during the trials of this study.

Including measurement tools to capture step length would enhance the spatial parameter analysis. Additionally, adjusting the trial design to investigate the impact of vibratory stimulation on consciously manipulated cadence could also offer valuable insights. The present analysis focused solely on voluntary and self-selected walking speeds. By introducing intentional cadence variations during trials, the study could

show the effects of vibratory stimulation on gait parameters associated with dynamically adjusted walking speeds [19].

FOG occurrences: Due to limited amount of PD patients that could be measured within the time-span of this project, insufficient data was present to analyse and determine the effect of the vibratory stimulation on FOG occurrences. Once further developed, the same system can be utilised to assess also the influence of the same vibratory stimulation on FOG occurrences. Research can be performed to explore whether this vibratory stimulation could potentially facilitate the easing of FOG among individuals diagnosed with PD, promoting a faster resolution of FOG episodes and maintaining their unobstructed gait during walking.

The potential efficacy of vibratory stimulation was shown through the subjective feedback provided by the PD patient during the Walking protocol, wherein they expressed a perception of "ease in lifting the foot, raising the leg, and initiating a step". Given that some primary challenges in PD include an increased risk of falling [5], tremors [17] and drop foot, the reported sensation of facilitated foot lifting suggests a plausible enhancement in gait as an outcome of the vibratory stimulation intervention.

The existing software of the current system was designed to identify interruptions in walking, whether deliberate stops or instances of freezing. Enhancing the software with a functionality to differentiate these events would enable the administration of specific vibratory stimulations during FOG. Consequently, the NeuroParkinson project hypothesis states that the implementation of timed and freeze-dependent vibrations may lead to a reduction in both the frequency and duration of FOG episodes.

Vibratory adaptation: Several participants reported perceiving the continuous vibrations as 'pressing,' inducing a sensation of 'sleepiness,' or a general discomfort. Despite the shorter actual duration of vibrations in the gait-synchronised vibration, it is of importance to determine the optimal utilization of vibratory stimulation without eliciting discomfort for the participants. The adaptation of proprioceptive feedback systems to vibratory stimulation over time, involving receptor adaptation, has been recognised in previous studies [45]. This phenomenon could be attributed to the tendency of individuals to ignore the constant vibratory signal while monitoring the natural sensory signal [33].

Additional future research should determine whether muscles undergo optimal adaptation to prolonged vibrations by this system. The outcomes of the continuous vibrations within the Constant condition can be analysed to determine if there exists a variation in the primary measures following multiple instances of uninterrupted vibratory stimulation in contrast to shorter vibratory pulses. This examination aims to elucidate the maximum duration of vibratory stimuli that remains effective for leg muscles during walking, without the subject perceiving a discomfort during walking.

VI. CONCLUSION

A compact, wearable, and non-invasive system was designed to administer vibratory stimulation to the lower limb

muscles. Employing this system in walking trials involving both healthy individuals and PD subjects revealed varying objective and subjective outcomes in relation to cadence and perceived facilitation of walking. Despite the general trend of decreased cadence induced by most vibration types, the Postponed Synchronised and Constant vibration types showed a perception of facilitated walking in more than half of the subjects. Supplementary observations made during the trials underscored the effects of vibratory stimulation administered to the upper and lower legs on locomotion perceptions. PD subjects emphasised the possible improvement in gait movement due to the muscle-specific and timed vibratory stimulation.

Utilizing angular velocity data obtained from both shanks, a real-time toe-off prediction system was developed through gait cycle analysis. This system included the angular velocity data and the real-time prediction signal as input for an adaptive frequency oscillator, subsequently enabling the determination of real-time gait phase percentages. The stimulation of the Hamstrings, Quadriceps, Soleus, and Tibialis anterior muscles on both legs was achieved based on the calculated gait phase percentages.

The Technical Validation of the prediction and vibratory system emphasised its usability as a compact, standalone system applicable walking in daily-life environments. Future research may involve the integration of additional sensors to further investigate the impact of vibratory stimulation on cadence and various spatial gait parameters. Additionally, the potential of the system to assess and minimise freezing of gait occurrences in Parkinson's disease patients could be explored in future trials.

AUTHORS' CONTRIBUTION

Tom Busink developed the NeuroParkinson - GaitStimulator software and corresponding protocols, performed the software scripting, the experiments, initial GUI design and the protocols. Jorge Quijorna Santos designed and developed the control electronics PCB board and contributed during experiments. Julio Salvador Lora Millán supported the initial implementation of the AFO. Eduardo Rocon and Cristina Bayón conceived and coordinated the research. All authors contributed to the critical discussion of the project development.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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VII. APPENDIX

A. Documentation

The attached NeuroParkinson Docs folder contains an interactive and comprehensive documentation and manual for all the Python and Matlab scripts included in the NeuroParkinson package. This documentation is designed to provide step-by-step guidance, enabling external researchers to effectively execute all necessary software components for conducting trials with the NeuroParkinson system. It should equip researchers with the essential insights and instructions required for successful utilization of the system. However, a fundamental understanding of the ROS2 system is recommended as a prerequisite for working with this documentation.

B. Hardware

The iterative process of system design led to the development of various versions with distinct characteristics. The initial system, designed for the Walking protocol, is illustrated in Figure A1. Following extensive testing and the exploration of potential improvements, the second version of the hardware system was created, and this version was used during the actual trials. Figure 2 provides a visual representations of the 2nd version of the system and its configuration when utilised with a subject.

The 3D model representation of the PCB board with accessory case is depicted in Figures A3 and A4.

The models of Figures A5 - A9 show the (iterative) development of the hardware components and their casings. All models are made in Tinkercad [<https://www.tinkercad.com/>], wherefore some models have been printed and used as 3D models in the project.



Fig. A2: Healthy subjects performing the Posture protocol synchronisation process (left) and the actual protocol (right).



Fig. A1: Healthy subjects test of the initial system (V1) to analyse its performance during the Walking protocol.

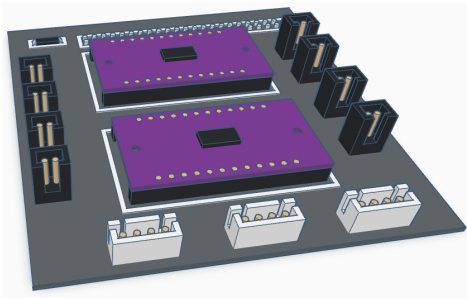


Fig. A3: Improved PCB Board model (V2) with 3 IMU connections (white) and 8 motor connections (black).

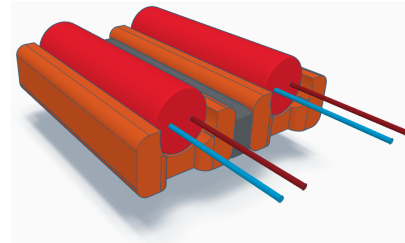


Fig. A7: Two vibrators (Precision Microdrives – 304-116) in 3D-printer casings separated by self-adhesive foam used in the Posture protocol.

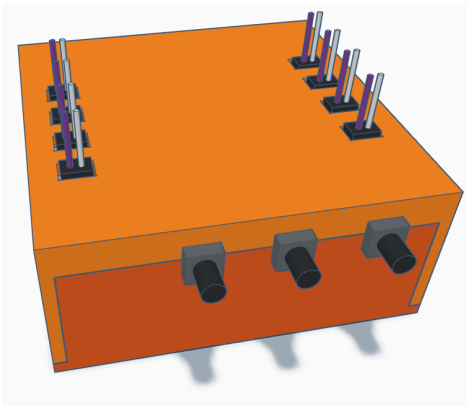


Fig. A4: 3D-printed PCB case model including 3 IMU connections and 8 motor connections corresponding to the connections in Figure A3.

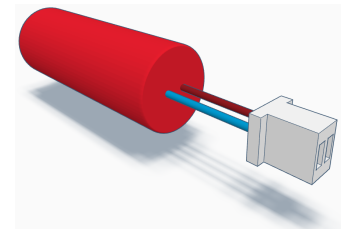


Fig. A8: Vibrator (Precision Microdrives – 307-103.005 with Molex 51021 connector) used in the Walking protocol. Most Molex connectors have been disassembled to increase robustness of the vibrator connectors.



Fig. A5: IMU (Adafruit BNO055) in 3D-printed casing. Used in the Posture protocol.

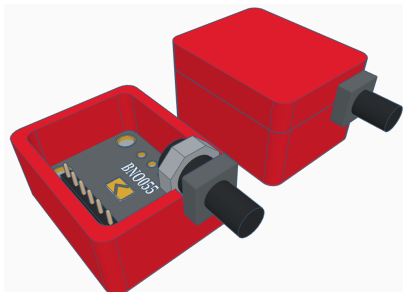


Fig. A6: IMU (Adafruit BNO055) in 3D-printed casing. Updated version with new connector used in the Walking protocol.

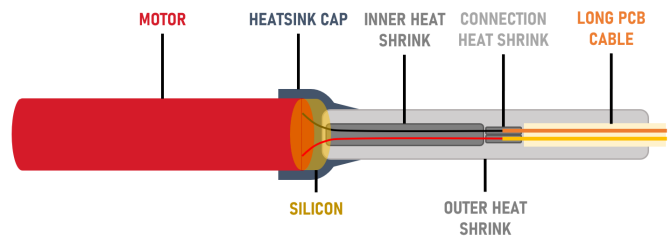


Fig. A9: Vibrator connection to prevent cable malfunctions due to mechanical wear.

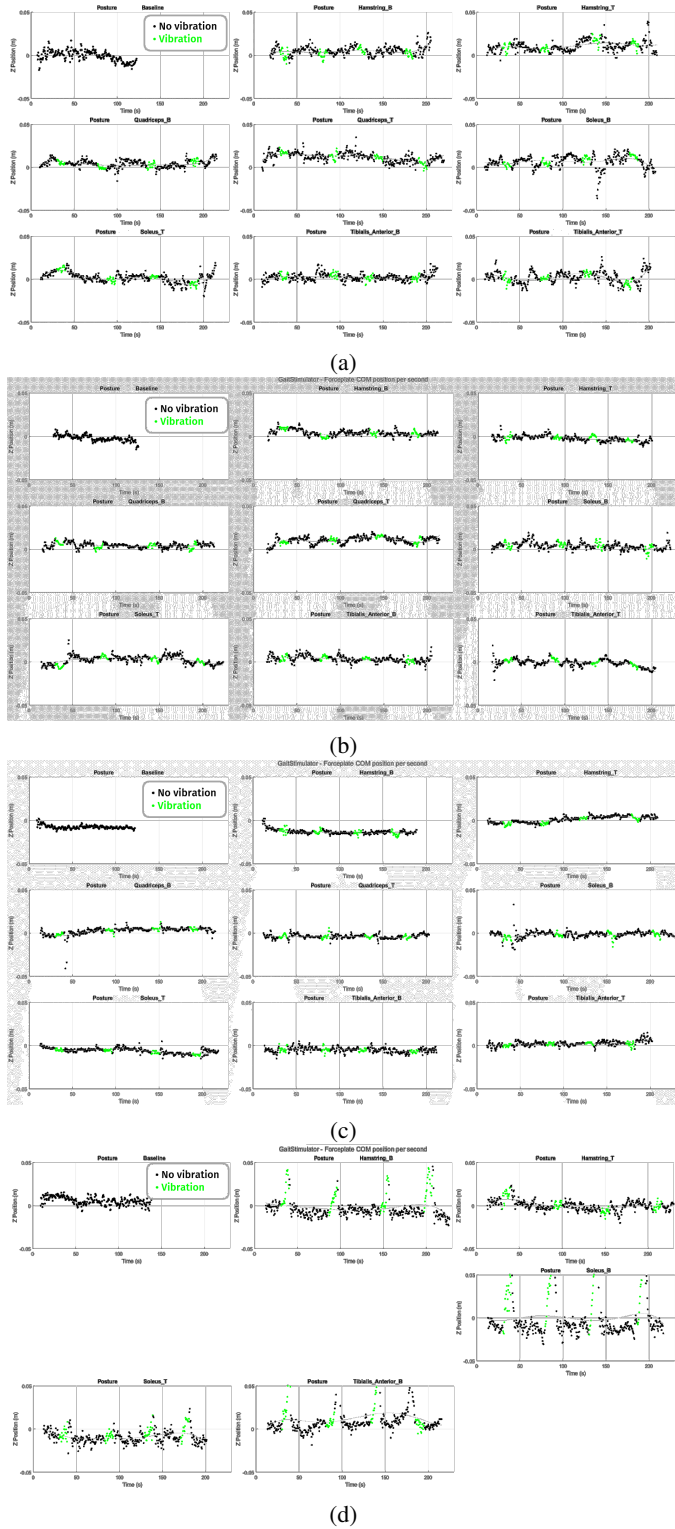


Fig. A10: COM positions along the Z-axis of the forceplate for subjects one (a) to four (d) per muscle group during the entire Posture protocol. Each vibration period (green) lasted for 10 seconds. Non-vibration periods (black) lasted a random duration between 30-50 seconds. All measurements start at zero displacement based on the initial COM of that measurement.

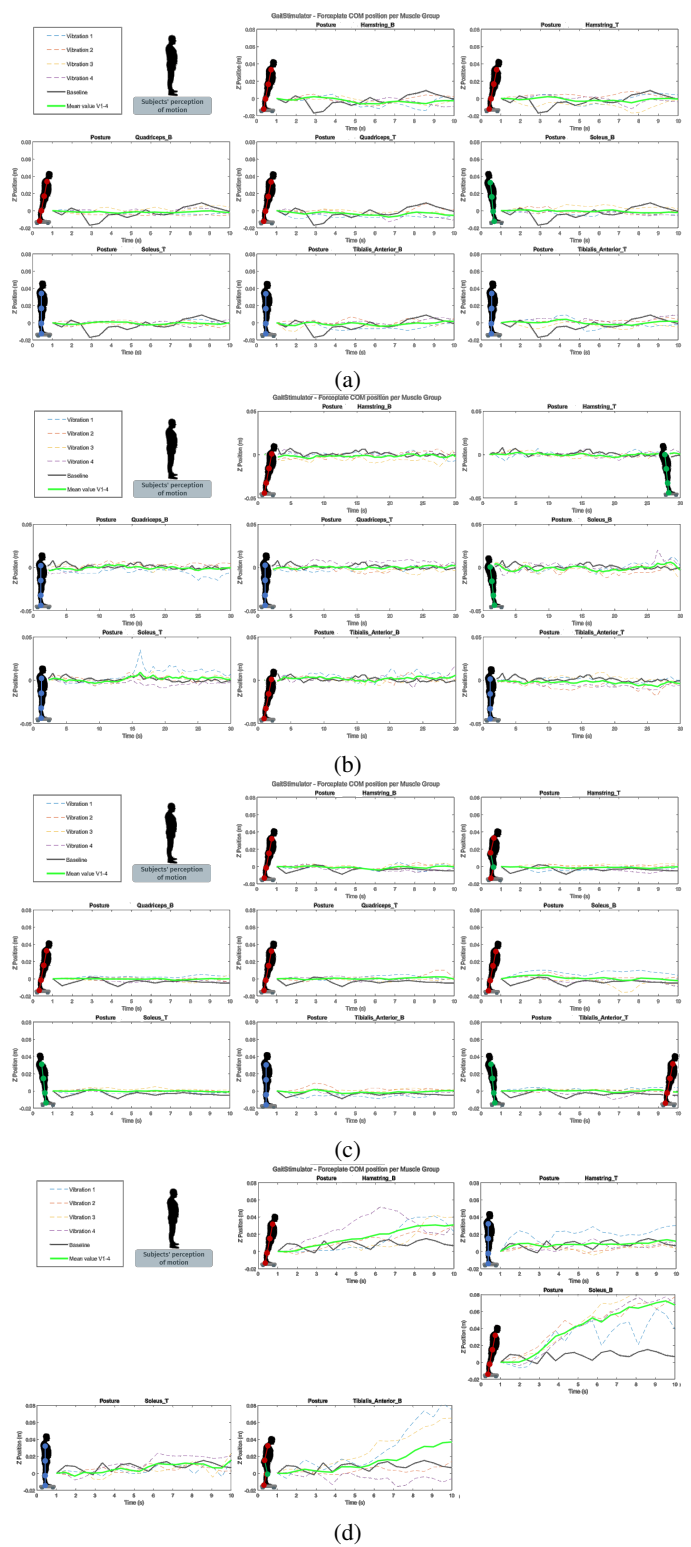


Fig. A11: COM positions along the Z-axis of the forceplate for subjects one (a) to four (d) during the vibration periods of the Posture protocol, including the baseline (no vibrations) and the mean displacement during vibrations per muscle group. The subjects' personal perception of posture is indicated as silhouette.

C. Additional Results

The force plate results of the Posture protocol of all four subjects are depicted in Figures A10 and A11.

The results of the analysis regarding the processing times of the PC and Raspberry Pi are depicted in Figures A12 and A13.

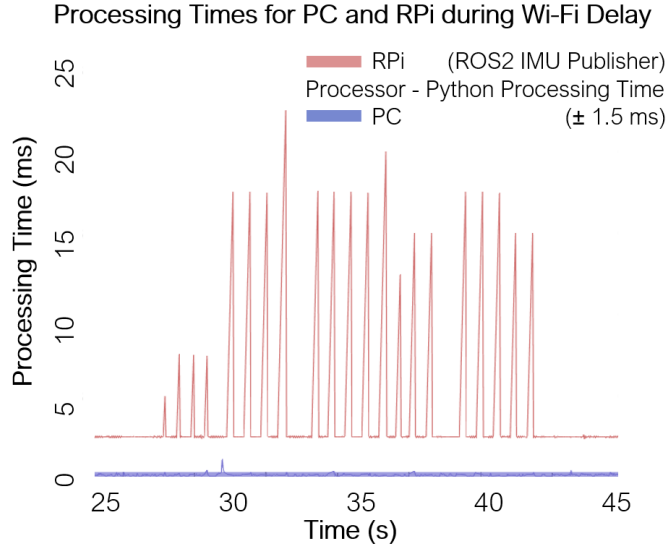


Fig. A12: Processing times per frame of the ROS2 IMU Publisher, executed by the RPi (red) and the processing time of the PC, responsible for conducting all calculations for each frame (blue). The average processing time for the RPi should align with the expected value of 25 milliseconds, considering the sampling frequency of 40 Hz. Starting from 28 seconds, delays in WiFi-communication caused an increased processing time for subscribing and publishing the IMU data, resulting in a decreased FPS.

D. AFO Phase Synchronisation

The Adaptive Frequency Oscillator is employed to continuously extract the phase and frequency of the subject's gait in real time. To initiate the AFO process effectively, the subject should have been walking for a minimum duration of five seconds. This prerequisite ensures that the real-time toe-off prediction becomes sufficiently accurate to serve as reliable input for the AFO synchronization process.

TABLE I: Overview of the variables used in the AFO equations.

Variables	Description
θ	Shank angle
φ	Oscillator phase
ω	Oscillator frequency
η	Learning constant
ε	Coupling strength
α, β	Fourier constant
σ	Phase of gait cycle
f	Frequency of gait cycle
N_f	Number of Fourier coefficients

To extract the phase of the gait cycle, the shanks' angular velocity is utilised, which is derived from the filtered IMU data. The oscillator's input is defined as the signal error $e(t) = \theta_m(t) - \theta_{rec}(t)$, where $\theta_m(t)$ represents the angular velocity and $\theta_{rec}(t)$ signifies the angular velocity estimated after performing a real-time finite-term Fourier decomposition. In this context, five pairs of Fourier coefficients α_k and β_k (indexed by k) are used. These coefficients are continually updated and calculated based on the following equations, with a learning constant η set to a value of 8:

$$\theta_{rec} = \sum_{k=0}^{N_f} (\alpha_k \cos(k\varphi) + \beta_k \sin(k\varphi)) \quad (1)$$

$$\dot{\alpha} = \eta \cos(k\varphi) e(t) \quad (k = 0, \dots, N_f) \quad (2)$$

$$\dot{\beta} = \eta \sin(k\varphi) e(t) \quad (3)$$

The output of the AFO includes both the phase and the frequency. To achieve this, several steps are taken: First, the derivatives of the phase and frequency of the oscillator are computed (using equations 4 and 5). In this process, the coupling strength parameter ε is set to a value of 0.5. Subsequently, the phase and frequency of the oscillator are normalised (according to equation 6). The reason for this transformation of variables is twofold: For the phase, it is interpreted such that 0 represents the start of the current gait cycle, and 1 represents the start of the subsequent cycle. For the frequency, the change of variables enables it to be interpreted as cycles (or steps) per second, described in Hertz (Hz).

$$\dot{\varphi} = \omega - \varepsilon e(t) \sin(\varphi) \quad (4)$$

$$\dot{\omega} = -\varepsilon e(t) \sin(\varphi) \quad (5)$$

$$\sigma(t) = \frac{\varphi(t)}{2\pi}, f(t) = \frac{\omega(t)}{2\pi} \quad (6)$$

Building upon the concept introduced by Van Dijk et al. in their work [46], the phase is refined using TO events as a reference point. This step is necessary because the gait phase obtained through prior operations may not reliably align with a TO event when $\sigma = 0$. To achieve this correction, the system adjusts the phase by applying an offset acquired upon the detection of a TO event. The corrected phase is computed by subtracting this offset from the raw phase. This correction process ensures that the gait phase is accurately synchronised with TO events, enhancing the precision of the system's phase tracking.

$$\sigma_c = \sigma - \rho \quad (7)$$

In the provided equation, ρ represents the offset of the phase that needs to be determined, σ_c corresponds to the corrected phase, and σ signifies the raw phase. The correction process is specifically aimed at synchronizing a phase value of 0 with the TO events within the gait cycles. It's important to note

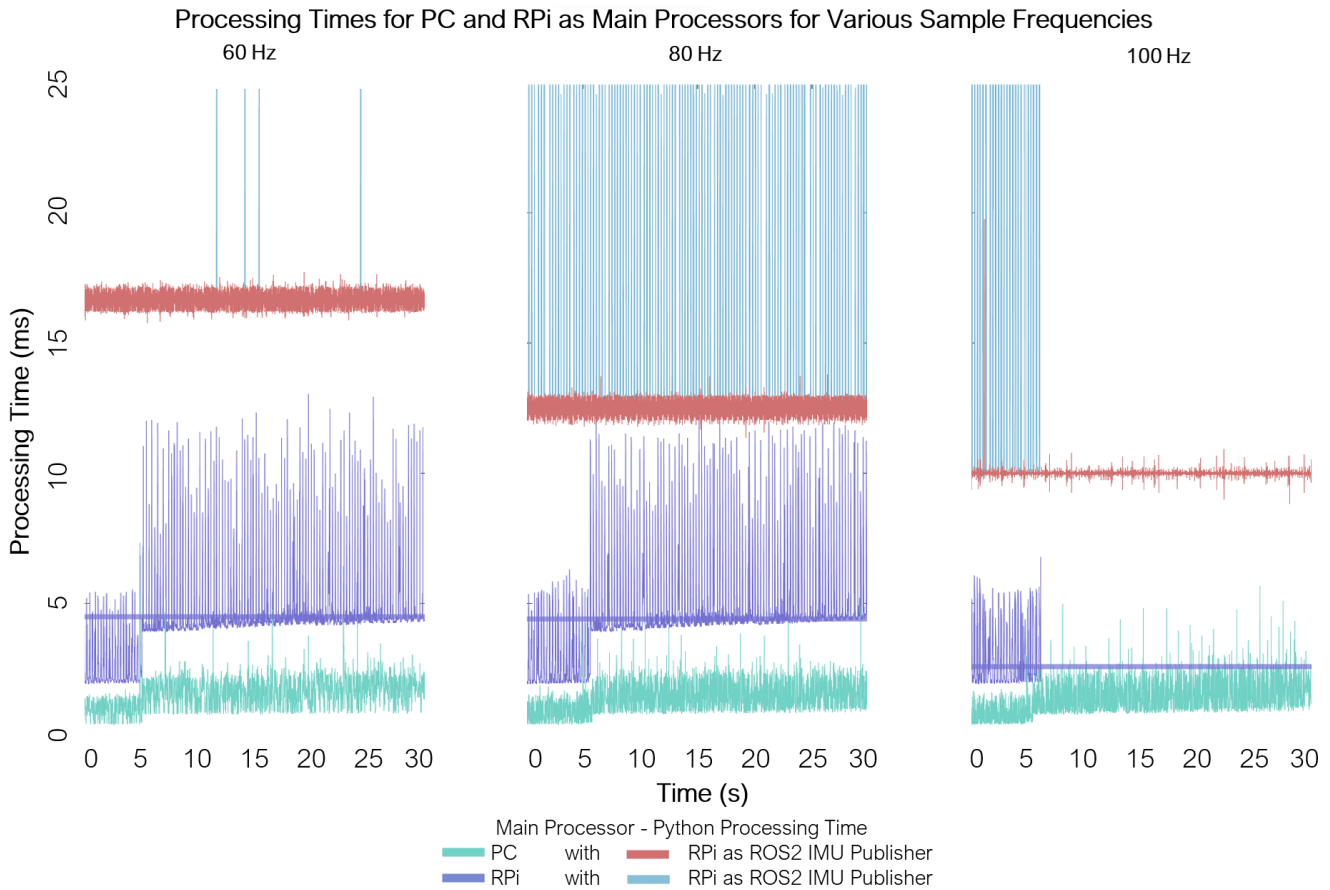


Fig. A13: The processing times per frame for the ROS2 IMU Publisher and the primary processing script were evaluated across various sample frequencies of 60 Hz, 80 Hz, and 100 Hz. A delay in data acquisition and publication becomes apparent on the RPi starting from the 80 Hz sample frequency (light blue). At 100 Hz, the RPi was unable to execute the primary processing script effectively due to the increased delay, resulting in an inconsistent IMU signal.

that, at this stage of the process, a phase value of zero at a TO event doesn't indicate the starting point of the gait cycle, as the gait cycle's 0% phase is defined at a HS event. To align the current phase start with the start of the actual gait cycle percentages (starting at each HS event), the total phase value is reduced by 0.6 (60%). This adjustment is made because the TO event typically occurs at approximately 60% of the start of the actual gait cycle [28], [29]. After this processing, the phase output of the AFO should be in line with the actual gait phase of the gait cycle.

In real-time, when a TO event is predicted, the phase value at that particular moment is utilised as the offset for correction. To ensure a smooth and gradual phase correction without abrupt changes in the corrected phase value, it is essential to apply a low-pass IIR (Infinite Impulse Response) Butterworth filter. This filter has an order of 1 and a cut-off frequency of 0.5 Hz applied.

In summary, this module for gait phase detection processes data recorded from the IMU, utilizes the TO prediction algorithm, calculates the gait phase using the AFO algorithm, and ultimately synchronizes the gait phase with the predicted TO events. This comprehensive process ensures accurate and synchronised tracking of the gait phase throughout the walking cycle, without the requirements to have knowledge about

complex AI / Neural Networks that should be trained to detect real-time gait events.

E. Usage Artificial Intelligence

During the preparation of this work, ChatGPT 3.0 is used to revise grammatical errors and improve sentence structures. No actual new content, values or statements are produced by AI. After using this service, the content is thoroughly reviewed and edited as needed, taking full responsibility for the final outcome.

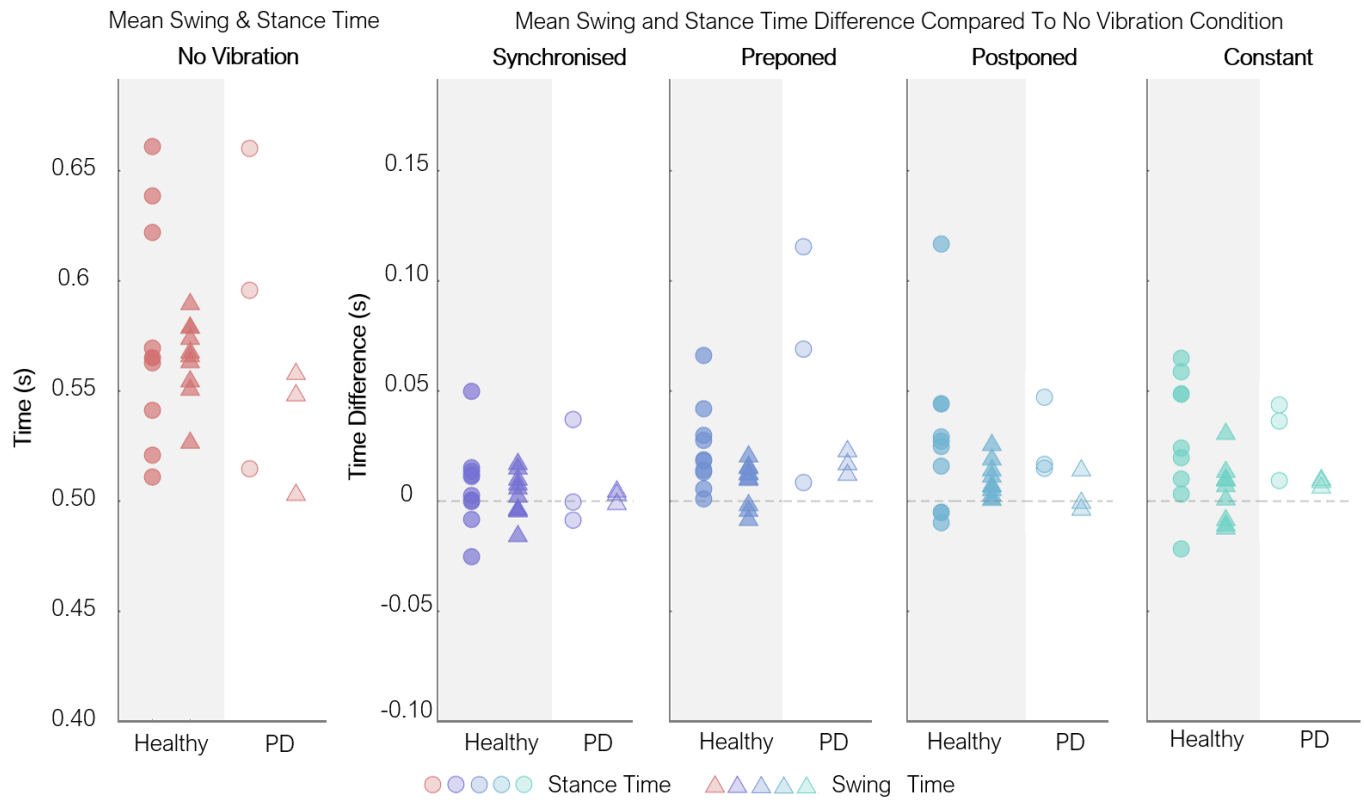


Fig. A14: The first plot shows the average absolute Swing Time and Stance Time (seconds) during the No Vibration condition of all healthy (left) and PD (right) subjects. The other conditions show the average Swing and Stance Time difference with respect to the average corresponding No Vibration time of that subject.