A wearable device to monitor the gait of patients with Multiple Sclerosis

Medical Technology Innovation Course

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Department of Mechanical and Process Engineering

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1 Research, Understanding & Awareness of Problem / Need Statement

Multiple sclerosis (MS) is a chronic autoimmune inflammatory neurological disease affecting the central nervous system [1]. It targets myelinated axons in nerves, causing varying degrees of damage to both myelin and axons [2]. A 'relapse' refers to temporary inflammation for at least 24 hours, resulting in worsened or new symptoms [3]. Relapses range from a few days to several months, followed by complete or partial recovery. This deterioration in nerves is characterised by numbness in limbs, unsteady gait, inability to walk, visual impairments, vertigo, and extended fatigue [4]. These symptoms contribute to an impedance in motor functions: from the estimated 2.8 million people affected by MS worldwide [5], 75% experience a significant walking disturbance [6]. The mean age at diagnosis is 32, MS prevailing predominantly in women, with a 2:1 ratio.

Despite the high number of MS cases, making it the 3rd most common neurological disorder, its causes are still somewhat unclear. Existing research points to a complex interplay between genetic predisposition and environmental factors [7], low vitamin D levels [8], smoking [9], and the Epstein-Barr Virus [10]. Current diagnostic methods are being continually improved to enable an earlier detection of MS and to better the understanding of the disease's early stages. The most common tool for observing MS is with Magnetic Resonance Imaging (MRI), by examining scans of demyelinated nerves. It must be noted that no cure to MS exists, although treatment to mitigate the disease's progression, frequency and magnitude of relapses, is available.

MS treatment may be classified in 3 methods [11]: acute relapse management (ARM), disease modifying treatments (DMTs), and symptomatic treatments. ARM involves corticosteroids to reduce inflammation during relapses. For severe cases, treatments like plasmapheresis are considered. DMTs reduce relapse frequency, slow the disease's progression, and prevent new MRI-detected disease activity. These therapies include various forms such as injectables, oral medications, and infusion treatments, each with different mechanisms of action and effectiveness. The choice of a DMT depends on individual factors like the type and severity of MS, patient health, potential side effects, and lifestyle preferences. Symptomatic treatments target specific MS symptoms, including fatigue, depression, spasticity, pain, bladder and sexual dysfunctions. Thus, the evolution of MS is highly varied and unpredictable [12], underlining the importance of a personalised treatment plan for each patient. Moreover, monitoring its progression is challenging. This is where Stride steps in.

2 Define Need & Design Evaluation Criteria

Monitoring MS mainly consists of regular clinical visits where patients perform tests assessing their neurological functions, including the Kurtzke Expanded Disability Status Scale (EDSS) [13], the Nine-Hole Peg Test (NHPT) [14], Timed 25-Foot Walk Test (T25-FW) [15], MRI scans of the brain and spinal cord, and the Optical Coherence Tomography [16] for retina and optic nerve imagery. The EDSS measures the neurological impairment with a scale ranging from 0 (no impairment) to 10 (severe impairment) every 0.5 increments, assessing mobility, sensory functions, and cognitive abilities. The NHPT measures finger dexterity. The T25-FW quantifies leg performance based on a 25-foot marked course, where the patient is instructed to walk as quickly and safely as possible.

To gain a more practical understanding of the tests used when assessing MS patients, our team reached out to neurologist Dr. Med. Giulio Disanto from the Ente Ospedaliero Cantonale in Lugano. Dr. Disanto confirmed the use of EDSS and T25-FW tests when assessing MS patients' ambulation, as well as others like the 2- and 6- Minute Walk Test. However, he voiced concern on the time these tests required, limiting the amount carried out during the patient visit, and only offering snapshots of the patient's motor capabilities every 4-6 months. Furthermore, these tests do not provide a complete overview of the patient's ambulation, where parameters such as walking speed, daily step count, or more sophisticated gait analyses detailing weight distribution and balance are not available.

Through research and discussions with Dr. Disanto, it became clear that monitoring MS is challenging due to standardised methods, reduced time frames of measured results, and impractical clinical visits. This, coupled with the aforementioned symptoms affecting mobility, resulted in the following problem statement: to create a personalised monitoring of MS, by continuously extracting highly significant and accurate data from the patient's gait. The design criteria for our device were:

a) Precise and accurate: The recorded data from the patient's gait should be highly precise, accurate, repeatable, and objective, to derive reliable conclusions.
b) Comprehensive metrics and models: The collected data should be pertinent and aid in distinguishing the various stages of the disease and the corresponding optimal treatment.
c) Robust and reliable: The device should be resistant to external disturbances that could potentially damage it and work continuously for 16 hours before being recharged.
d) Non-invasive: The device will be easily integrated to the patient by being non-invasive, removing the risk of surgery and minimising the stress associated with its use for the patient.
e) Comfortable and discrete: Since the patient will wear the device for entire days, it should be comfortable, easily attachable, and minimalist in its design to not attract unwanted attention.
f) Affordable: It's price should be low to benefit a maximum number of MS patients.
g) Easy-to-use: The device's functionality should be intuitive to the patient, with easy data transfer to the patient's phone for the visualisation of key metrics and models by the doctor.
h) Data Protection: Patient data should be encrypted, accessible to patient and doctor, and regularly backed up on Stride's servers. It must adhere to EU GDPR and US HIPAA regulations.

3 Ideation - Technology and Research

From our problem statement, the team decided to focus on modelling patient gait on a daily basis. Although many smart watches and smartphones are readily available nowadays, they lack in comprehensive-ness when measuring gait parameters. For example, [17] after applying machine learning models and neural network-based models, was only able to accurately determine basic gait metrics like step length, swing time and stance time. A more complete measuring of patient gait is with infrared (IR) markers and cameras, but these being in controlled environments, are obsolete for our application.

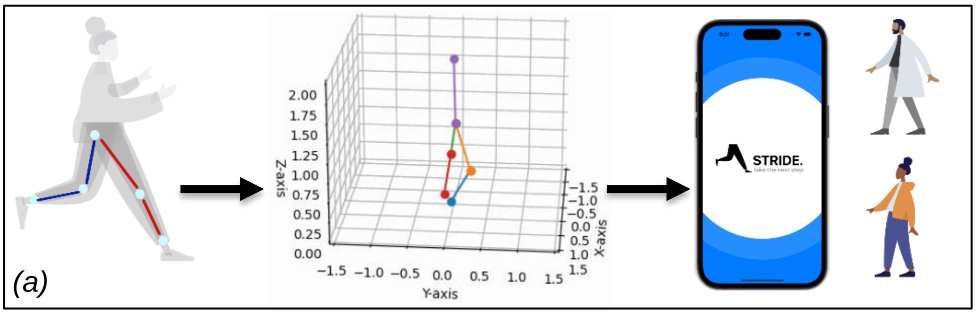
To solve for uncontrolled environments, Inertial Measurement Units (IMU) were considered. An IMU consists of an accelerometer, a gyroscope, and a magnetometer, which measure accelerations, angular rotations and magnetic fields. Searching online, companies like IMeasureU [18], Driveline [19], and Plantiga [20], implement IMUs in straps, armbands, and soles respectively, to measure the corresponding accelerations and forces for athletes. However, none of these companies had implemented a “connected” system, able to accurately measure the user’s lower-limb kinematics.

Scientific literature on wearable sensors measuring gait introduced IMU devices better suited for our application. [21] and [22] described devices tailored to athletes and explained the methods and calculations used for extracting the IMU’s data, such as Kalman filters to remove noise. [23], [24] and [25] presented an IMU wearable system to classify user tasks, where low-cost IMUs were placed on the shank, thigh, and hip. [23] echoed a threefold higher cumulative error in smartwatches than its own wearable system, due to the reliance on wrist kinematics rather than lower-limb kinematics. [24] detailed a low-cost portable motion and force measurement system, characterised by IMU sensors placed on the shoes, shank, thighs, and hip, with additional force sensors in the shoes’ sole.

4 Team Design Concepts

To validate our assumptions based on our research, a prototype device was developed. The devised process to monitor patient gait was to (1) measure the patient’s joint accelerations with IMUs (2) build a kinematic model from the raw accelerations (3) extract key gait parameters from this model and display them on the Stride App to the patient and doctor. This is illustrated in Figure 1a.

From previous work [25] and for practicality, five IMUs placed on the hip (1), knee (2), and ankle (2). This satisfied our criteria (b) and (e) by creating a detailed kinematic model at every joint, whilst also being comfortable and easily attachable via Velcro straps. We considered having sticky patches for attachment, but Velcro straps seemed the most user-friendly, supported by the fact many runners jog with similar straps. The IMUs were fixed in place via 3D printed boxes inserted in the straps to record more accurately, fulfilling criteria (a) and (c), as shown in Figure 1b.



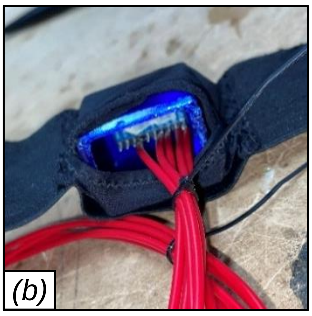


Figure 1: (a) Measuring patient gait step-by-step process, (b) 3D-printed IMU support box.

We thought of adding EMG sensors to capture heart pulsations and muscle activity. Although this could provide information on the patient's metabolic effort, it would also require the monitoring of oxygen consumption, either invasively or non-invasively, going against our criteria (d) and (e).

If our final design is to have Bluetooth communication between all IMU sensors for criteria (g), we used I^2C cable communication for simplicity and due to time constraints. An issue we had was that the I^2C protocol only allows serial communication, meaning the Arduino Nano microcontroller only read one IMU. This issue was solved by rapidly cycling through the addresses associated with the IMUs (0x68, 0x69), resulting in a 20Hz data collection frequency (Appendix A1).

For the prototype, the IMU's calibrated accelerations were read from the Arduino's Serial Port and processed in Python (Appendix A2). The x,y,z accelerations are integrated twice from Euler's method to determine their corresponding positions, as seen in Figure 2. The positions are grouped in vectors, which by applying forward kinematics creates a kinematic model of the patient (Appendix A3).

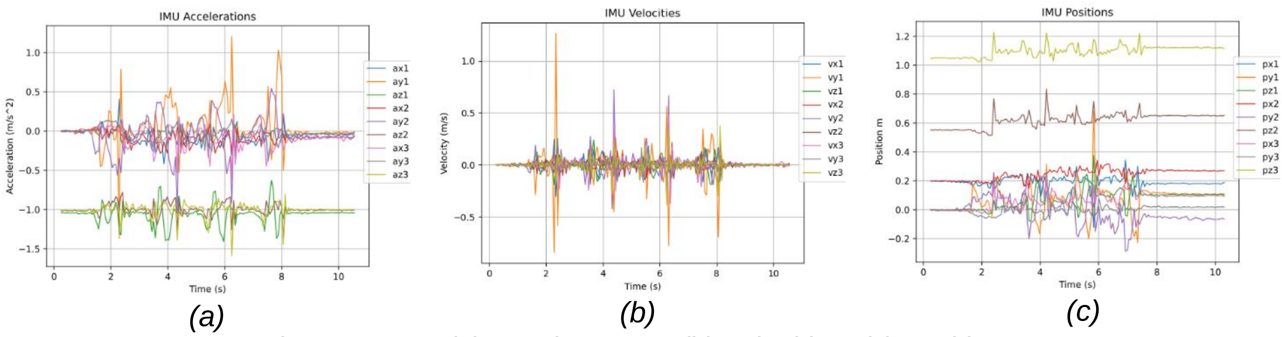


Figure 2: IMU (a) accelerations, (b) velocities, (c) positions

Inspired by Novartis' "Ekiva-MS" app, we added a feature in the Stride App where the patient can record their symptoms and daily impressions.

5 Final Solution & Outcome Scenarios

Our final solution is a wearable system, composed of five IMU sensors integrated in Velcro straps, which measures patient gait continuously throughout the day. It provides comprehensive MS gait metrics via the Stride App once the user syncs their device in the evening. The IMUs monitor the gait precisely and accurately, providing personalised data for patients, which allows for a better treatment plan. Figure 3 exemplifies the full gait model, allowing for extraction of countless metrics.

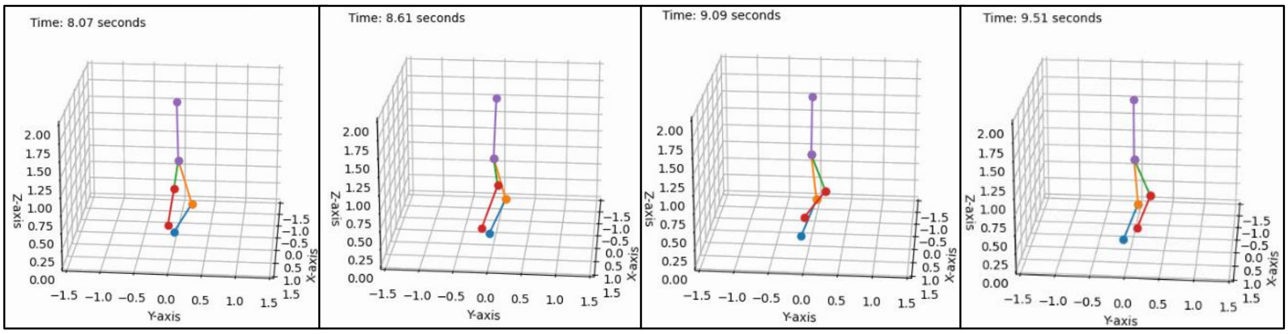


Figure 3: A kinematic model of patient gait calculated with IMU readings.

The daily measurements are transferred via Bluetooth from the device to the patient's phone, processed and securely stored via external servers managed by Stride, and readily available on the Stride App to patient and doctor, as seen in Figure 4a. The device itself is robust to external disturbances, non-invasive, comfortable, and discrete by its small size, location, and easily removable via Velcro straps. Figure 4b presents a prototype of our device worn by a student.

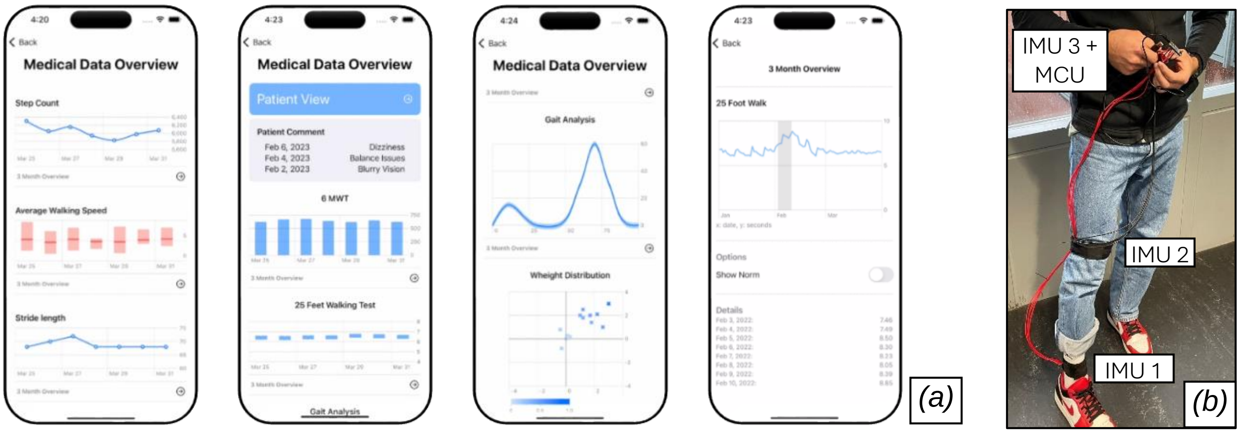


Figure 4: (a) Key metrics displayed on the Stride App, (b) Prototype of Stride's wearable device.

Our first prototype, considering its numerous improvements, indicated our idea was technically feasible by modelling the gait quite accurately, as observed with the kinematic model. Adding a Kalman filter would remove the 'jittery' behaviour of the simulation by removing noise. As per literature, we observed the IMUs suffered from 'drift', which is the accumulation of small errors in the accelerometer and gyroscopic measurements. This could be reduced by mapping the IMU's readings to measurements from a motion capture system (IR markers, cameras) acting as a ground truth via a machine learning model. A regular recalibration of the gyroscopes would also reduce drift.

We put an emphasis on the simplicity of our design to make sure it is affordable and available to most MS patients. This would help reduce the yearly USD 85.4 billion cost related to MS in the United States [26]. Our prototype (I^2C cable communication) costs CHF 32.00, and our final product (Bluetooth communication) would cost CHF 76.50 (Appendix A4), due to the added Bluetooth and microcontrollers modules, increasing the frequency of measurements from 20 to 60Hz. Upgrading all electrical components and selecting better-quality fabric would make our device more accurate and comfortable, albeit increasing its cost. Additional costs would be incurred for the external servers on which the data is processed and stored, as well as for the Stride App. Our device itself would have no significant environmental implications, apart from our servers being energy consumptive.

Stride could become the new standard in the field of MS. Its continuous accurate monitoring capabilities of patient gait allows for a personalised tracking of the disease, helping both patient and doctor in understanding MS and determining the most suitable treatment. Stride's priority, aside from delivering the most accurate and affordable wearable device, will be to ensure secure and private handling of patient's data. We believe Stride could revolutionise the field of MS, and be extended to other neurological diseases, such as Parkinson's Disease and Amyotrophic Lateral Sclerosis.

6 References

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6.1 Appendix A1 – Reading and Calibration of IMU 1,2,3

https://github.com/MattJmt/MTI-Gait-Kinematics/blob/main/MPU9250_calibration/MPU9250_calibration.ino

6.2 Appendix A2 – Reading of Serial Port, Acceleration -> Position, Forward Dynamics

https://github.com/MattJmt/MTI-Gait-Kinematics/blob/main/Serial.py

6.3 Appendix A3 – Model of Virtual Kinematics

https://github.com/MattJmt/MTI-Gait-Kinematics/blob/main/Model.py

6.4 Appendix A4 – Bill of Materials

Prototype (I^2C Communication):

Description	Unit Cost	Quantity	Amount
Arduino Nano	5.50 CHF	1.00	5.50 CHF
IMU 6-Axis MPU6500	2.50 CHF	5.00	12.50 CHF
Dupont Cable Male-Female, 10pcs	0.50 CHF	2.00	1.00 CHF
Dupont Cable Male-Male, 10pcs	0.50 CHF	2.00	1.00 CHF
Cable Mini-USB	2.00 CHF	1.00	2.00 CHF
Velcro Straps	1.40 CHF	5.00	7.00 CHF
5V Power Supply, HLK-PM01	3.00 CHF	1.00	3.00 CHF
		Total	**32.00 CHF**

Final Product (Bluetooth Communication):

Description	Unit Cost	Quantity	Amount
Arduino Nano	5.50 CHF	5.00	27.50 CHF
IMU 6-Axis MPU6500	2.50 CHF	5.00	12.50 CHF
Cable Mini-USB	2.00 CHF	1.00	2.00 CHF
Velcro Straps	1.40 CHF	5.00	7.00 CHF
Bluetooth Module	2.50 CHF	5.00	12.50 CHF
5V Power Supply, HLK-PM01	3.00 CHF	5.00	15.00 CHF
		Total	**76.50 CHF**