Smart Orthotics!
A Rehabilitative Knee Orthotic for Classifying Irregular Gaits

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ABSTRACT
Uncorrected knee mobility issues can develop and lead to more concerning conditions such as arthritis, and getting the proper treatment for these issues can be expensive and time-consuming. To address these problems, we introduce a method for assisted out-patient knee recovery, applying common sensor technology to widely used, cheap and accessible knee braces. The smart knee brace is an off-the-shelf soft knee brace, augmented with an inertial measurement unit (IMU), flex sensor, haptic feedback, and onboard processing to display gait information and other metrics to a user interface. The result is a low-cost wearable sensor platform that has the potential to aid patients and physical therapists in improving the quality of life of those wearing knee orthotics by reducing the number of in-person checkups with health practitioners.

1. INTRODUCTION
The process of recovering from knee injuries is a critical and demanding one that requires continuous monitoring and evaluation. A knee exam can detect inflammation, fluid accumulation, tendon tenderness, cartilage tears, and laxity [1]. Imaging tests like an X-ray, CT scan, ultrasound, or MRI may be required in addition to physical examinations [18] and these scans are expensive to conduct. Knee rehabilitation is also important following surgery, and entails stretching, strengthening, and extending the knee's range of motion as a part of the healing process [2]. Physical therapists must also monitor the patient while they perform these exercises [20] which adds yet another cost that the recovering patient must bear.

To address this, our team has developed a smart knee brace system that incorporates a mobile application to guide our users through a smooth recovery process. The smart knee orthotic is able to target both of these clinical needs, by enabling more knee assessments and rehabilitation exercises to take place at home rather than at a medical facility with the possibility for physicians and physical therapists to provide their medical expertise. The ultimate goal for this project is to produce a smart orthotic device that is affordable yet effective, and can provide real-time interventions to the patient.

2. BACKGROUND
Our initial literature review explored existing implementations of knee braces in research settings to determine choice of sensor hardware, metrics extracted through data processing, and clinical needs targeted by researchers.

In [4], researchers used stretch sensors to create a smart knee brace, but they also added two IMUs to the tibia and femur. The brace can detect flexion and extension using its stretch sensors, and can measure angular displacement with the help of its IMUs (gyroscope, accelerometer, and magnetometer).

A crucial signifier of injury, especially when it comes to an ACL rupture, is gait asymmetry. Previous research in investigating gait in injuries have found several factors such as stance percentage and flex to detect asymmetry in a person's gait [15].

Since understanding gait phases is very important in understanding the degree of asymmetry in a user, sensing can be a useful tool in identifying specific portions of the cycle [16]. Typical sensors utilized in gait analysis can include IMUs or sensing fabrics that are highly applicable for rehabilitation, and analyzing sensing data has been proven to be effective in providing gait phase information.

An analysis of the gait phases and cycles can be done solely with IMUs and signal processing [10]. One can acquire various aspects of the gait such as swing time, stance time, stride length, gait speed, etc. Being able to track these can be crucial for understanding the mobility health of a person [9]. Another factor that could help with a better understanding of gait phases is cadence. Certain cadences thresholds can be helpful in improving gait analysis and can aid in understanding different aspects of the gait phases for an average human [7].

Interventions can be helpful in speeding up recovery or reducing the risk of further injury. One significant intervention that can be helpful in both aspects is vibration therapy. Vibration therapy has been proven to demonstrate various benefits for mobility issues such as ACL injuries through a multitude of studies [11] [12] [13] [14]. A survey on this topic has shown that it can increase knee strength, raise movement speed, and improve range of mobility in the leg. The effects of vibration are best delivered at a low-stimuli yet high frequency. In our context, Vibration therapy (VT) can benefit our smart knee brace by improving muscle, tendon, and bone tissue health.

3. SMART KNEE BRACE

3.1 Physical Device
In our approach to a smart knee orthotic, we based our prototype on a cheap, widely available, and flexible knee orthotic. We augment the orthotic by fitting it with a ESP32-S2 microcontroller, flex sensor, IMU, and haptic motor.

The Esspressif ESP32-S2 is equipped with a Wi-Fi interface, and is able to host a wireless access point and web server to display the UI on a user's smartphone/computer via a web browser. We use the Adafruit Feather variant as it provides a solderless connection for the I2C bus via a Qwiic connector. All sensors in our prototype are connected using this interface. There is also a JST connector for connecting a 1-cell Li-ion rechargeable battery. For the purposes of testing, a portable USB power bank was used, but we anticipate using an integrated battery in future to significantly reduce weight.

The IMU chosen is the BNO085, which provides raw sensor data (accelerometer, gyroscope, magnetometer). It also provides advanced signals like absolute quaternion angles, step count, and activity classification via sensor fusion algorithms running on an integrated ARM M0 processor. The sensor updates its reports at a rate of 100 Hz, which is the same as that of the iPhone. This allows us to design algorithms using iPhone IMU data and apply them to BNO085 data.

We designed and built a flex sensor in an effort to control the form factor and output range of the sensor. We used a piezoresistive material called Velostat; the resistance of the material decreases when mechanical strain is applied, which occurs when the material is pressed, bent, or twisted. The sensor consists of 4 small strips of Velostat between two strips of copper tape and wire, and is sealed using electrical tape. It is placed into a felt pocket that is sewn into the inside of the knee brace. The pocket helps keep the flex sensor close to the kneecap while moving, which improves the quality of the signal, and also aids in user comfort.

Using a voltage divider resistor arrangement, the microcontroller measures the resistance of the sensor via its analog inputs. The sensor is connected to an external analog-digital converter (ADC) as using the built-in analog reading functions can cause slowdowns on the processor. The ADC used is the PCF8591 module which has 4 channels and 8-bit resolution.

To implement vibration therapy, a haptic motor is placed on the knee directly under the patella. Vibrations on this portion of the knee propagate internally to patellar ligament, MCL, PCL, ACL, and menisci. It is attached using a double-sided adhesive tape and connected to a haptic motor controller. Two controls are implemented – a solid, high intensity buzz, and a medium buzz.

To build the prototype, the ESP32, sensors, and actuators are fitted on the device with yarn; we feel that this pliable mounting approach would interfere less with the function of the knee and brace. They are connected to the ESP32 via the Qwiic interface, which simplifies cable management due to the ability to daisy-chain modules and adjust physical locations as needed.

Figure 1. Physical overview of smart knee orthotic.

3.2 Gait Analysis

Signal processing and analysis of the gait information is critical to the success of our proposed design. In the early stages of data collection and testing, we used an iPhone attached to the knee to collect preliminary gait information with the PhyPhox app. The accelerometer data was noisy and only sufficient to determine if the user was actually moving. The gyroscope data was more promising, and we focused specifically on the axis of the gyroscope associated with the plane of the swinging knee; referred to as the "swing axis". A subset of the data collected is shown in Figure 2.

We attempted to segment these results into gait swing and stance phases and determine the duration of each phase. This was inspired by [9] as longer stance times indicate inconsistencies in gait cycles. This can be seen in Appendix Figure 1. However, we determined that this signal is too inconsistent and sparse in real-time and would not work in our uses to determine gait abnormalities.

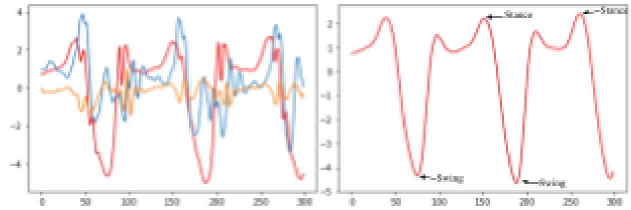


Figure 2. On the left is raw gyro data from all axes; on the right, we extract and filter gyro data along the swing axis. The double peaks and dip are used to determine stance and swing cycles.

Flex data proves to be a much more trustworthy method of measuring knee laxity; there is a lack of need for a ground-truth normal gait (which would be helpful for the swing axis measurements), and it gives insight into the actual knee angle instead of acceleration. The voltage read by the ADC is inversely proportional to the pressure applied. When the user is limping, the knee is flexing significantly less than expected, leading to a lower variance of knee flexion data. An example of this can be seen within Figure 3.

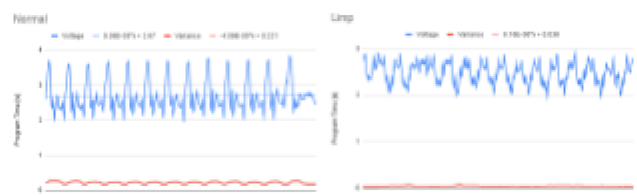


Figure 3. Example normal walk vs limp flex sensor readings.

The specific implementation is worth noting here. Due to the lack of resources on the ESP32, it was critical to meet memory requirements and make all operations real-time. We apply a sliding window rolling-buffer mean and variance calculation using Welford's online approach [17], which works with constant-time operations without recomputation. The size of the sliding window was chosen to be 25 elements, since according to [7] this is a quarter of a full gait cycle (a swing of both legs).

Our peak detection approach takes inspiration from a Stack Overflow algorithm detailed in [6], in which a threshold variance is selected for finding peaks; we augment this with a delta function that ensures that the peak is an inflection point. To ensure unnecessary time is not spent reading values off the I2C bus, we include a strict update rate for every value (primarily 100 Hz), so that no process can block the ESP32's main thread. This way we can seamlessly extract, analyze, and display data to the user without extensive use of limited computing resources.

Another metric tracked by the knee brace is step counting. Although the IMU provides its own implementation of step counting, through testing we determined that the IMU may be double counting steps as the step counter report generated by the IMU counts for every positive peak. We suspected that this is because the IMU is intended to be mounted above the waistline. We instead implemented our own step counter; two steps are counted for every full gait cycle, which consists of a double peak followed by a negative dip.

3.3 User Interface

The primary user interface for the smart knee brace uses a webpage hosted by the ESP32 microcontroller on a local network. We initially planned to use a variant of the ESP32 that had Bluetooth connectivity so that we could develop a mobile application for the user interface. However, at the time of purchasing, the product was unavailable, so we pivoted to a Wi-Fi and web-based solution.

The ESP32 sends data to the website via a WebSocket connection, which is a protocol with lower overhead than standard HTTP, so it is well-suited for sending real-time data. Unlike HTTP, it also supports bidirectional communication, so any inputs the user makes on the website are passed to the ESP32 over the same WebSocket connection. It is also fully supported by regular browser JavaScript (JS), which was a bonus because we did not want to use any sort of JS framework like Node. Data from the sensors is sent as a JS object notation (JSON) string to the client, which is parsed to update plots and text on the website. All the UI components run asynchronously so that the main thread of the ESP32 can be solely used for signal processing.

The CanvasJS library is used to plot data like the flex sensor and gyroscope readings. We tested other libraries like Highcharts and Chart.js, but found that the performance of CanvasJS was superior due to fewer stutters when updating the plot with new data. We used the ESP32 filesystem (LittleFS/SPIFFS) to store all web source files including CanvasJS directly on the device. The file system allows for normal use without any internet access, but has a limited capacity of just 1.5 MB.

Three signals are plotted on two real time charts. First is the gyroscope swing axis readings, which have been processed using the window filter algorithm described earlier. When the user moves their leg forward or backward, the signal increases and decreases respectively. The second plot displays two readings, both associated with the flex sensor. First is the raw reading which displays the current voltage drop through the flex sensor on a scale of 0 to 5V (ADC analog voltage). The window filter algorithm is applied to this signal to compute the variance in knee flexion, and the variance is also shown on the same plot.

Other data that would not be visualized well when plotted is displayed as text on the webpage. This includes the step counter we implemented, as well as the gait classification that uses the flex sensor variance to classify gait as normal or limp/abnormal. To allow the user to control the device, the webpage features buttons for input. One button toggles the visibility of the plots, in case the user does not need to monitor the real time readings from the sensor. There are also 3 other buttons that enable/disable the haptic motor or change the strength of the vibration. The webpage when under use is shown in Appendix Figure 2.

4. Results

4.1 Gait Analysis Results

Throughout this project we followed a test-driven development approach, rapidly modifying our design and implementation as new discoveries and analyses were made. Some of these changes, including the application of flex sensor variance data instead of swing-axis peak detection, have already been mentioned in Section 3.2. To use the IMU, we would need a calibration sequence for every user to determine their threshold for asymmetrical gait and determine if they're improving from there.

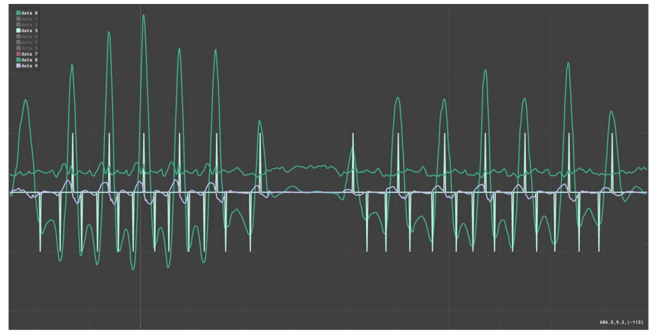


Figure 4. IMU data (green; high peaks) superimposed with peak detections (light blue), deltas (pink), and flex data (green; central)

In Figure 4, we see the result of the data processing described in Section 3.3. The first half of the data displays the user walking normally while the latter portion shows the user limping. Notice the lower intensity peaks in the limp data; although this is visually a valid indicator, we can't quantify the difference when moving to new users. Although the stance percent and peak ratio are displayed on the UI, these signals are ultimately not suitable for gait classification. This is also impacted by extraneous factors like walking speed and changes in direction. When we noticed this, we shifted focus to a flex-sensor based approach.

To further improve the classification of asymmetric gaits we performed user testing to find the optimal variance threshold. After four user tests (results in Table 1), where participants were asked to walk normally and walk with a limp, we asserted that the variance of knee flexion data is the key indicator of gait abnormality. The user bends the knee minimally when limping compared to normal laxity. This is not incredibly obvious from an initial visual inspection but is apparent in Figure 4.

Based on the results from this small sample size we implement a threshold of 0.14 to classify abnormal gait patterns. This value is the average of the normal variance and flex variance above, and from further user testing with the same subjects, proves to be an effective measurement. We may further tune this value in the future with more participants, and can also tailor them based on user health data (e.g. height, weight, walking pattern).

Table 1: User testing results. We notice a significant drop in flex variance when the user is limping.

User #	Height (in)	Normal Flex Variance (V)	Limp Flex Variance (V)
1	68	0.365	0.061
2	69	0.174	0.021
3	71	0.221	0.038
4	75	0.179	0.036
Mean	**70.75**	**0.235**	**0.039**

4.2 User Testing

After this, we collected 9 total user testing results. We were limited in the amount of people we could gather data from because of the involvement of wearing the orthotic and interacting with the web tool in the reduced time we had. We presented the participants with four questions:

- Comfort: How noticeable are the sensors in comfort on top of the knee orthotic?
- Performance: How successfully was the application able to provide crucial information about mobility health?
- Frustration: How insecure, discouraged, irritated, stressed or annoyed were you when acquiring information about your mobility health?
- Recovery: How successful do you think the app would be in helping long-term rehabilitation for your mobility health?

When evaluating comfort we couldn't necessarily measure whether the overall device is comfortable, as many people feel discomfort while wearing orthotics (Appendix Figure 3). Instead, we decided to measure whether participants noticed the addition of sensors while wearing the orthotic. We found that some people have commented that they could not feel the sensors at all while others stated that it was extremely noticeable. The participants may have misinterpreted the question as asking whether the sensors themselves are visible.

A major result is that users find the web tools to be useful and effective in displaying their mobility health as shown on Appendix Figure 4. Our participants also find our web tool easy to use and frustration-free. The participant data shows a median frustration score of 2, where 1 indicates no frustration on a scale of 10. Users find the web tools to be useful and effective long-term in displaying their mobility health throughout their recovery process. Figures demonstrating user testing results can be found in the appendix.

Some participants mentioned that the flex sensor is "relatively comfortable" compared to a brace without sensors attached. Additionally, a user with a genuine mobility injury stated that the vibration effect from the haptic motor actively "numbed the pain of [her] injury".

Overall, our results have shown that our minimal viable product for a knee orthotic was effective in achieving our final goal of providing useful mobility health data during rehabilitation. We have successfully created a working prototype that actively assists users with irregular gait patterns which doesn't impact the form or function of the original brace.

5. Future Works

The smart knee orthotic prototype we developed has the potential to be expanded beyond what was accomplished in this project. An interactive application built on the smart knee brace platform can gamify exercise by using the smart knee orthotic as a form of input to a game. This idea is inspired by [3] where researchers built a rehabilitation/exercise game that can be played while wearing the knee brace. Gamifying this process would engage users during rehabilitation exercises.

Additional sensors can also be incorporated to provide more comprehensive information about a patient's knee rehabilitation health, such as temperature sensors to detect potential inflammation in the knee. Other algorithms can also be implemented that compute metrics such as walking speed, double support time, and amount of time spent standing. A more powerful processor that supports onboard machine learning allows for state-of-the-art algorithms that can be used to make diagnoses fully locally.

More advanced manufacturing techniques can also be used to make a more integrated smart orthotic. Conductive materials and flexible circuit boards can be used to improve flexibility, comfort, and reduce visibility of the electronics. Incorporating other technologies that can modify the rigidity of the brace or provide treatment to the knee by applying heat or cooling are also potential future endeavors. Moving beyond the knee, our platform and sensing methodologies can also be adapted to other areas where orthotics are commonly used, such as elbows, shoulders, and ankles.

6. Conclusion and Reflection

Our project involved the creation of a smart knee orthotic with sensors that collected data on mobility health. We also developed a UI that provided users with updates and aided them in their mobility rehabilitation.

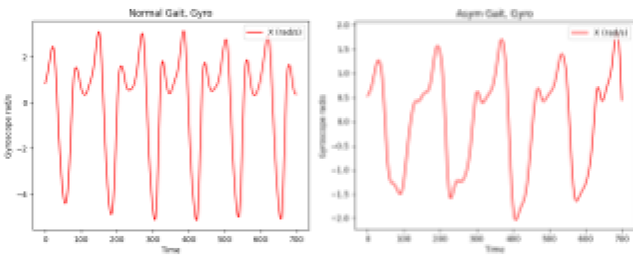
We encountered several obstacles that impeded us along the way, but were successful in achieving our objective. We initially intended to employ machine learning techniques for gait analysis. It was quickly evident that signal processing was better suited and faster for our intended functionality. Although we abandoned this route early on, additional data would have been helpful to enhance the accuracy and generalizability of our approach, thereby increasing its effectiveness.

A Bluetooth module was not procured in time for our hardware suite since the specific device was out of stock. As a result, we opted to rely entirely on a Wi-Fi-based approach. There are several advantages to the Wi-Fi approach, including enhanced security and improved accessibility from a wider range of devices, but the Bluetooth module would have had a higher update rate and imposed less memory overhead on the ESP32.

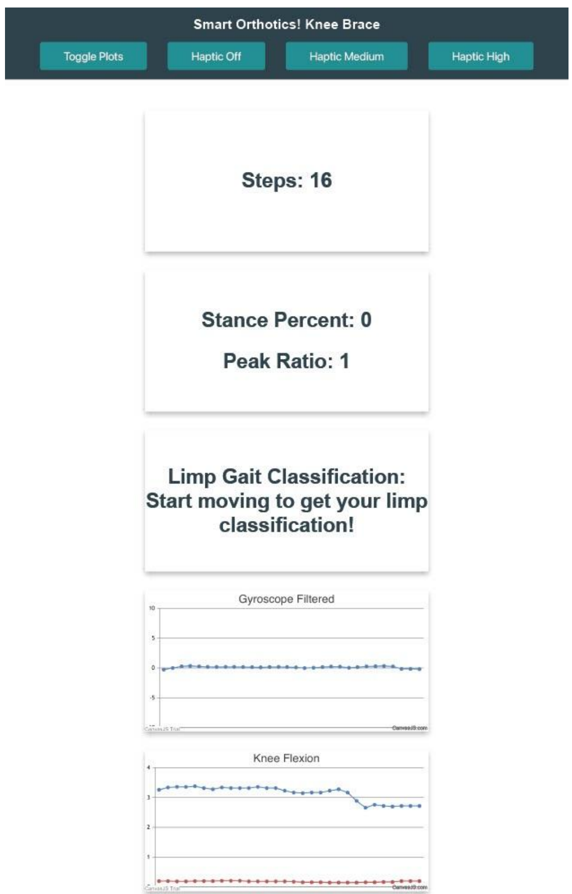
Due to the time constraints of a semester-long class project, we were also unable to track the rehabilitation progress of real-world patients. Nevertheless, our user testing surveys revealed that the data provided holds significant potential for everyday individuals. Further investigations into the long-term effects of VT are necessary, particularly in determining the optimal locations for haptic motor placement. This area of inquiry remains a potential avenue for future research.

Although we were unable to fully realize our initial vision for the project implementation, we were able to accomplish our primary project objective. Our revised approaches presented advantages not evident in our original ideas. Our smart knee orthotic has the potential to aid patients in long-term rehabilitation while reducing both time and cost associated with in-person visits. Rehabilitation is often a lengthy and challenging process; monitoring progress and identifying issues that require medical intervention can be crucial for maintaining long-term mobility health.

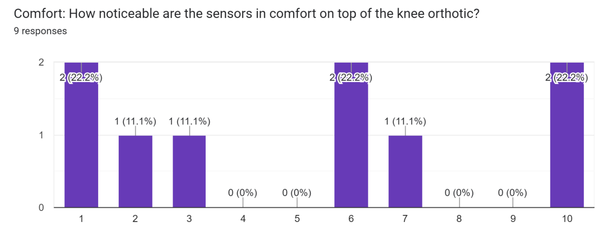
7. Appendix



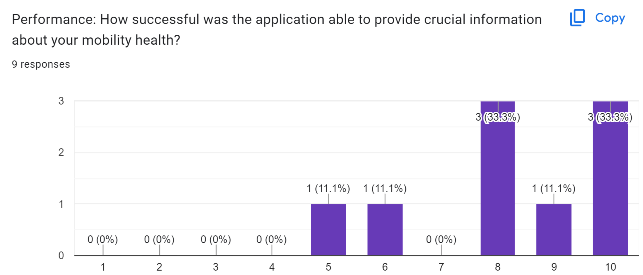
Appendix Figure 1. Example asymmetric gait juxtaposed with a normal pattern. Notice the variation in the double peak intensity and frequency.



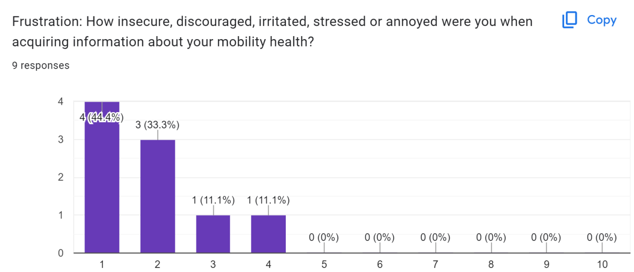
Appendix Figure 2. Web UI for the Smart Orthotic knee brace displaying sensing information and gait classification.



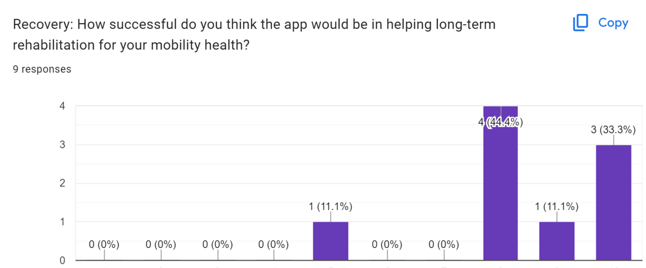
Appendix Figure 3. Users score 1 for "Not noticeable" and 10 for "Very noticeable". The median for comfort is 5.



Appendix Figure 4. Users score 1 for "Failure" and 10 for "Success". The median for performance is 8.



Appendix Figure 5. Users score 1 for "Not frustrating" and 10 for "Very frustrating". The median for frustration is 2.



Appendix Figure 6. Users score 1 for "Not successful" and 10 for "Successful". The median for recovery is 8.

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