# SOFTWARE DEVELOPMENT OF A BIOFEEDBACK DEVICE FOR GAIT EVALUATION AND ASYMMETRY CORRECTION

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Omar Rojas

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I, THE UNDERSIGNED MEMBER OF THE COMMITTEE,
HAVE APPROVED THIS THESIS

# SOFTWARE DEVELOPMENT OF A BIOFEEDBACK DEVICE FOR GAIT EVALUATION AND ASYMMETRY CORRECTION

BY

Omar Rojas

I-Hung Khoo, Ph.D    Electrical Engineering Department

California State University, Long Beach

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# ABSTRACT

SOFTWARE DEVELOPMENT OF A BIOFEEDBACK DEVICE FOR GAIT EVALUATION AND ASSYMMETERY CORRECTION

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We developed a portable device, named ‘WalkEven’, that can measure, analyze, and correct gait asymmetry. Our device collects data in real time on a patient with the purpose of evaluating and improving asymmetrical gait, which is usually exhibited in patients with stroke or certain neurological disorders. For example, a stroke patient usually places more weight on the healthy side resulting in a longer swing time of one leg compared to another. This asymmetrical gait has a detrimental impact on gait pattern and increases the risk of falling, thus proper gait retraining is crucial. Our device can measure the weight distribution that the patient exerts on each foot and the gait characteristics including gait and swing times of both legs to determine asymmetry. Real-time feedback is then provided in the form of audio and electro-tactile feedback to correct gait asymmetry.

TABLE OF CONTENTS

## LIST OF FIGURES

FIGURE Page

# CHAPTER 1

# INTRODUCTION

Gait is the manner of how animals and people move using their limbs. In humans, the gait is the manner in which they use their legs to move. Every individual has a unique gait, their own specialized manner in how they walk. A person's gait begins when the heel of one foot makes contact with the ground, also referred to as the heel strike, and ends with the same foot making contact with the ground. There are three steps in a person's gait, allowing each leg to experience the two different phases that make up a gait. There is the stance and swing phase in a person's gait. When a person takes a step, lifting their foot in the air and moving forward, this is referred to as the swing phase. The swing phase begins with a foot lifting off of the ground, referred to as the toe off in this study, and ends with the same foot's heel strike.  While one foot is in the air, the other foot is firmly on the ground, providing balance as the body moves forward. The foot that is on the ground is considered to be in the stance phase. Stance phase begins with the heel strike of one foot and ends when the same foot lifts off of the ground. During one gait, both legs of the person will go through a stance and swing phase. Swing phases typically consist of 40% of the person's gait while stance phases will consist of the other 60% of the gait time.

Gait asymmetry is when the ratio of swing-to-stance differs from each leg. One example is that the time spent during the stance phase on one leg is less in comparison to the other leg. The same can be said with swing as it is not limited to the stance phase. Gait asymmetry has been noted in stroke patients, patients with other neurological disorders, or patients that have experienced physical trauma. Our group focuses on creating a device to help stroke patients with their gait asymmetry with later iterations of our device being able to help other patients as well. The issue with gait asymmetry is the loss of balance, increased risk of falling, walking being a difficult task, and certain muscle deformities due to improper weight allocation when walking. With our device we plan to improve a patient's gait by making it more symmetrical.

The WalkEven device works by taking readings from customized insoles that are embedded with sensors that interface with a microcontroller; raw data is analyzed and processed to determine the gait parameters in real time. The microcontroller, an Arduino Mega 2560, is housed inside a compact enclosure that is attached to the patient's waist. The wireless capability is achieved by two XBee modules – one connected to the microcontroller and the other to the computer. Each insole contains force-sensitive sensors (FSRs), three for the heel piece and three for the toe piece. The insoles are designed to be adjusted to fit any shoe size. The average force readings from the FSR are analyzed by the microcontroller using our pre-programmed algorithms and the results are sent wirelessly to the host Windows based computer to be displayed to the user at the end of the data collection session. The real-time feedbacks are in the form of electrical pulses delivered to the patient's thigh of the unaffected leg as well as an audio tone. The feedbacks are designed to reduce the swing time or increase the stance time of the affected leg to achieve a more symmetric gait.

# CHAPTER 2

## LITERATURE REVIEW

Before developing the device, we looked at papers that were similar with what we wanted to accomplish with our device. Other research teams have looked into the concept of creating a device used to correct gait asymmetry. In the paper titled *Interactive Gait Training Device "Walk-Mate" for Hemiparetic Stroke Rehabilitation,* the team focused on using auditory cues to generate a walking rhythm for patients to follow. The sounds the patient would hear would signify in what phase of their gait they should be in real time. The team behind the paper *Wearable Shoe-Based Device for Rehabilitation of Stroke Patients*, presented their device which was a shoe embedded with sensors, enabling them to collect data pertaining to a patient gait. The device is meant to be worn throughout the day detecting if the patient was walking, sitting, or participating in any dynamic activity. The main purpose of this device was to collect information that would contribute to the work being conducted in this field of study, correcting gait asymmetry. As of now there are commercially available devices that detect gait information. Physical therapists are currently using these devices to help patients improve their gait.

The inspiration for our device came from the papers *A Wireless Sensory Feedback System for Real-Time Gait Modification* by C. Redd, *Design of an insole embedded foot pressure sensor controlled FES system for foot drop in stroke patients* by S. Sabut, and *Utilization of a lower extremity ambulatory feedback system to reduce gait* asymmetry *in transtibial amputation gait* by L. Yang. Each of these papers proposed the idea of a feedback system to improve gait asymmetry. The devices are wireless, able to analyze a patient's gait, and give feedback. In the feedback system in Redd's device, there was an auditory sound that went off when the symmetry ratio for the patient's gait was determined to be too low. The device in Sabut's paper delivered an electro tactile response when the gait was determined to be asymmetrical. The device in Yang's team relied more on a visual display to show the patient's gait information in real time. Another valuable concept in Yang's paper was the equation for the asymmetry ratio. This ratio was the numerical representation of how asymmetrical a patient's gait was. This equation was adopted to our project so that we would have a way to give a value to a person's symmetry when it came to their gait. The feedback systems described in the papers gave us inspiration and a starting point in how to fix asymmetry in a patient's gait.

# CHAPTER 3

## HYPOTHESIS/RESEARCH DESIGN

We approached handling the issue of gait asymmetry with focusing on how to make the gait more symmetrical. The solution that we came up with was to focus on the two different phases that make up the gait for a patient. The idea we had was to make either the swing or stance phase for a patient take up the same amount of time for both legs. If we can make one phase symmetrical than the other phase would follow suit. This lead to the idea of a biofeedback system. This is the one component of our device that would set it apart from others. There are other devices that measure gait, swing, and stance time, however, few have a biofeedback feature. The biofeedback is in the form of an audio and electro-tactile feedback. This biofeedback is how the device will correct gait asymmetry in patients. The important aspect of the biofeedback is that the patient will be able to notice exactly when, during their gait cycles, their walk has become asymmetrical. The biofeedback would trigger during one of the two phases that make up the gait; the swing or stance phase. The whole process can be seen as a closed-loop control system. The system being the patient's gait and the feedback being the biofeedback system.

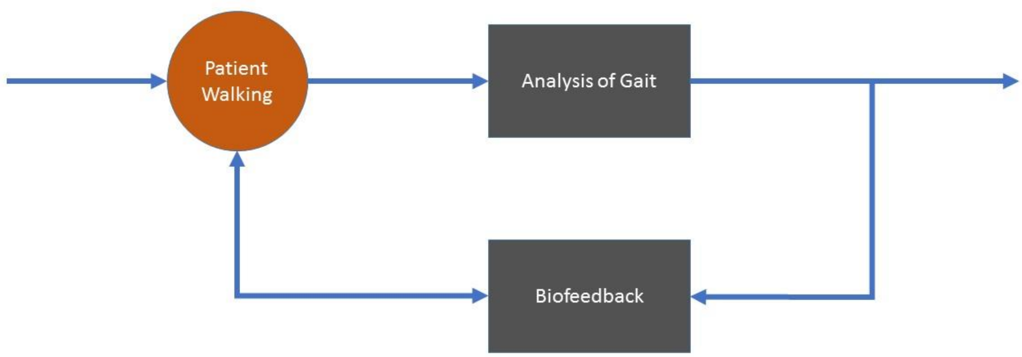


*Figure 1: Closed Loop Feedback Diagram*

CHAPTER 4

METHODS

Summary

The WalkEven device is controlled by an Arduino Mega 2560 microcontroller with information being sent from specially designed soles that have been embedded with force sensitive resistors (FSRs). The soles get the pressure information from the patient wearing them and send it to the Arduino. The Arduino is able to process the information from the FSRs and knows which part of the gait cycle it is in.

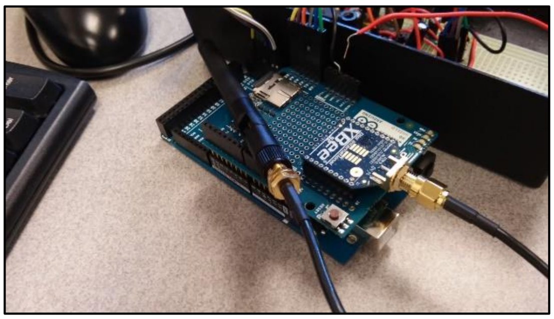

*Figure 2 Force Sensitive Resistor*

*Figure 3 Force Sensitive Resistor*

There are numerous functions within the Arduino that can be activated by a graphical user interface (GUI) designed for the device. These functions range from saving features, troubleshooting, electro tactile adjustment, zeroing, and adjusting threshold. The GUI can run on any computer running Windows. The communication between the GUI and the device is wireless giving the patient increased mobility. The software features of the WalkEven device will be broken into sections and explained.

Interpreting Information from the FSRs

The software for the WalkEven device begins with deciphering the information being sent from the FSRs. There are a total of 12 FSRs among the soles, 6 for each foot.

There are 3 FSRs placed around the ball of the foot and the other three are placed around the heel of the foot. These FSRs pick up the pressure information from the patient's foot as they walk. The information is sent to the Arduino in terms of voltage. A test was done on the FSRs to find the correlation between the amount of voltage sent and the weight that was placed on it.

The test we did was to place known weights on top of the FSR and the voltage that was sent to the Arduino was recorded. The calibration had to be done with each FSR.

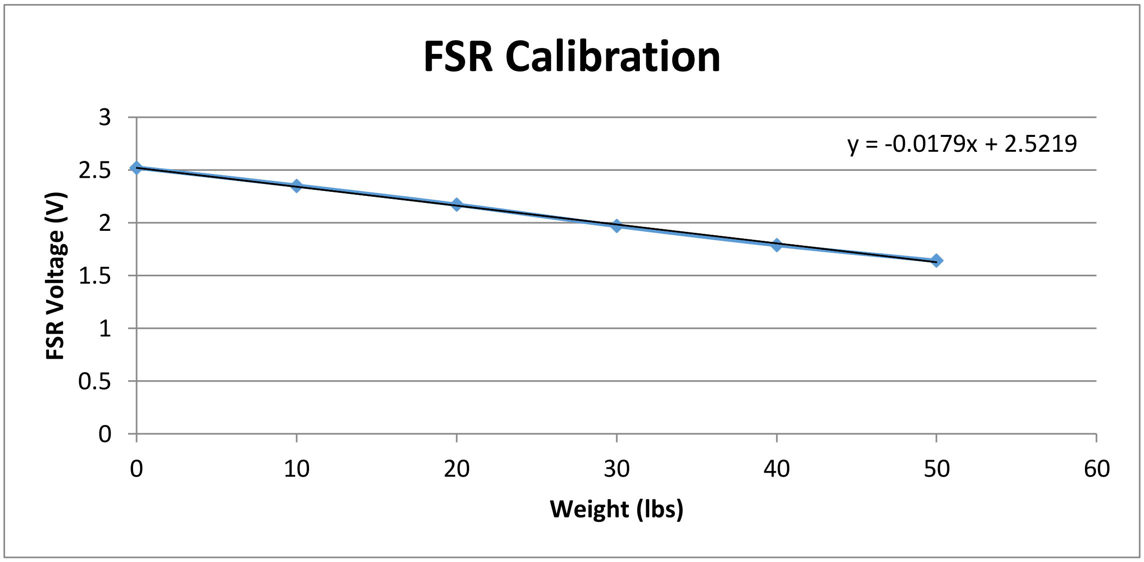


*Figure 4 Force Sensitive Resistor*

The process was done with weights varying from 10lbs to 50lbs. The information gathered showed a linear relationship and an equation was derived for each one.

<u>Heel Strike and Toe Off</u>

With the information from the FSRs, the device is able to know what part of the gait cycle the patient is in due to the heel strike and toe off. The start and end of the swing and stance phase is dependent on these two occurrences; when the heel strikes the ground and when the toe leaves the ground. Swing phase begins with toe offs and ends with heel strikes. The stance phase begins with heel strikes and ends with toe offs. Gait cycles begin with a heel strike and end with the same foot enacting another heel strike. The Arduino has been programmed to look for these occurrences. The FSRs that are placed around the heel of the soles are tasked to monitor the heel strikes, while the FSRs on the ball of the foot are tasked to monitor the toe offs.

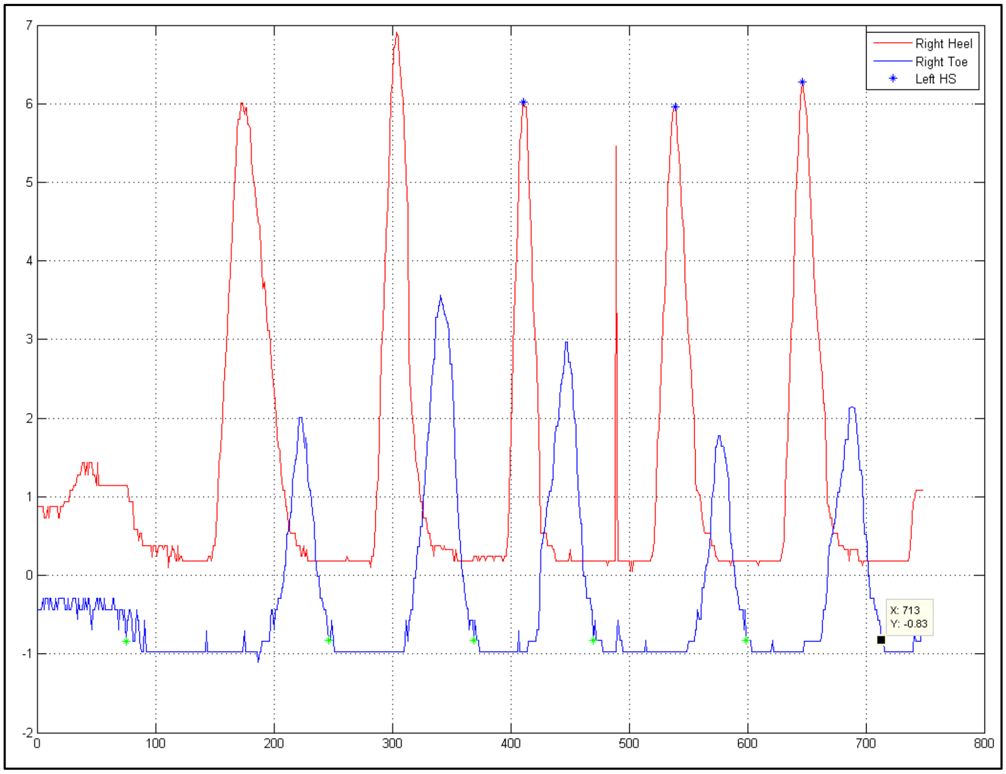


*Figure 5 Readings from FSR Over Time*

When plotted on a graph versus time it is easier to see exactly what the Arduino is looking for. In *Figure 5*, the red line represents the total sum of the FSRs located around the heel on a particular foot. The blue line represents the total sum of the FSRs located on the ball on a particular foot. When the red line peaks, that is when a heel strike has occurred. When the blue line takes on a flat line shape, that is when a toe off has occurred. There are additional software filters programmed into the Arduino to determine a true heel strike and toe off, such as thresholds values.

## Zeroing

The threshold values for each individual are different from one another. To customize these values, the WalkEven has a zeroing function. The threshold values is how the device is able to detect the peaks and flat lines as noted in Figure 5. Once the device notices the values going beyond these threshold values, it knows that either a heel strike or a toe off is about to occur. The device is calibrated to adjust to a specific subject with this feature. The zeroing function begins with the patient being instructed to lift their left foot for 5 seconds and then to lift their right foot for 5 seconds. The patient is then instructed to walk for a few meters and then stop. When the patient is lifting each foot, the Arduino is taking samples of the FSR values in the toe and heel of each foot. From these samples, the lowest value is selected for the heel and toe off for each foot. The values are then saved as the minimum toe off values. During the walking portion of the zeroing function, the Arduino is averaging the heel strike values detected during the walking. . The device is also acquiring information about the peak values detected on the toe area. The values acquired during the zeroing function are the: minimum toe values (minT), minimum heel values (minH), average heel strikes (avgHS), and the average toe peak values (avgTP) are used to calculate the threshold values. The toe off threshold value is calculated as follows :$ToeOff\ Threshold = minT + (avgTP - minT)SF$. SF is a scaling factor.The heel strike threshold value is calculated as follows: $Heel\ Strike\ Threshold = \frac{1}{2}(minH + avgHS)$. These threshold values allows the biofeedback to activate at the appropriate times and for the gait analysis to be more accurate.

## Acquiring Gait, Swing, and Stance Times

When the device is in recording mode, the times for the gait, swing, and stance can be acquired. In recording mode, the patient is asked to walk and the device is able to collect data from the patient's walk.

The flowchart in *Figure 6* shows the process of how the gait time is acquired. The voltage values from the FSR is sent to the device to change into units of pounds. The device waits until a heel strike has been detected, triggering the timer for the gait time. The device waits for another heel strike from the same foot. Once the second heel strike is detected, the timer for gait time ends. The elapsed time from the start of the timer to the end of the timer is the gait time for that current gait cycle. The data is then saved to the SD card.

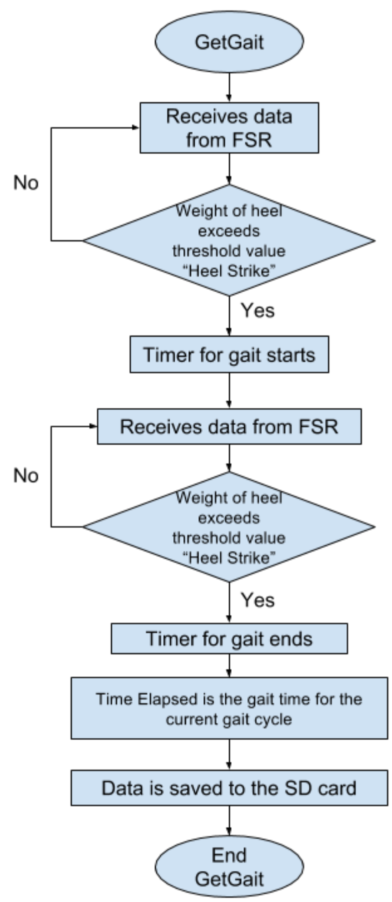


*Figure 6 Flowchart for GetGait*

The flowchart in *Figure 7* shows how the swing time is acquired. The process is very similar to how gait time is required except for when the timer starts and ends. The timer for the swing starts when a toe off is detected. The timer runs until a heel strike is detected from the same foot. The elapsed time is saved as the swing time. The swing time is then subtracted from the gait time to get the stance time.

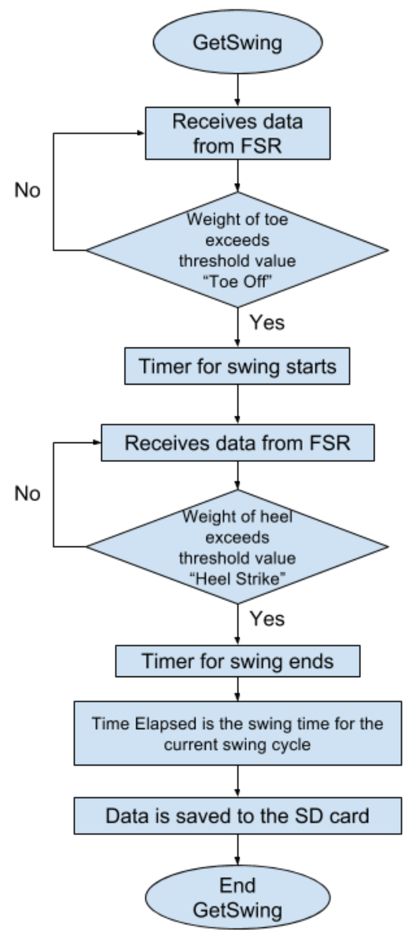


*Figure 7 Flowchart for GetSwing*

The recording process collects data from both legs and is able to end at any time. The process can be stopped when the "END" button is pressed on the GUI. Once the process is stopped, the average values for gait, swing, and stance are displayed to the user. The individual cycles and FSR data are all saved onto the microSD card for later analysis.

## Saving and Wireless Capabilities

There is an attachment on the Arduino, called a shield, which expands the capabilities of the Arduino. In the case of the WalkEven device, the shield allows for saving and wireless capabilities. The shield has a slot for a MicroSD card and another space reserved for a wireless module. The Xbee was selected as the wireless module to be used for the device as the connectivity is simple and direct. There is a directory system implemented in the saving structure of the device. This allows files pertaining to subjects to remain separate from each other. The directory makes navigation through the saved files easier. The files that are saved consist of gait cycles times, swing times, stance times, and other information relating to gait. The raw data is collected from the FSR and saved so if there was ever an error to occur with the real time processing of the device, the raw data can then be referenced to see what actually occurred during a certain test.

## GUI

A GUI was designed to control the WalkEven device. The purpose behind the GUI was to make the device intuitive. One of the end goals is to make this device user friendly. The GUI is able to run on any device running Windows. As seen in *Figure 8* the GUI is user friendly with certain guidelines that are noted on the form itself. From this interface the user is able to interact with the device in various ways. Troubleshooting can be accessed form this GUI as well to investigate the source of any errors if it were to occur. The GUI was designed to be versatile and to adjust any settings that would be beneficial for the optimal usage of the WalkEven device.

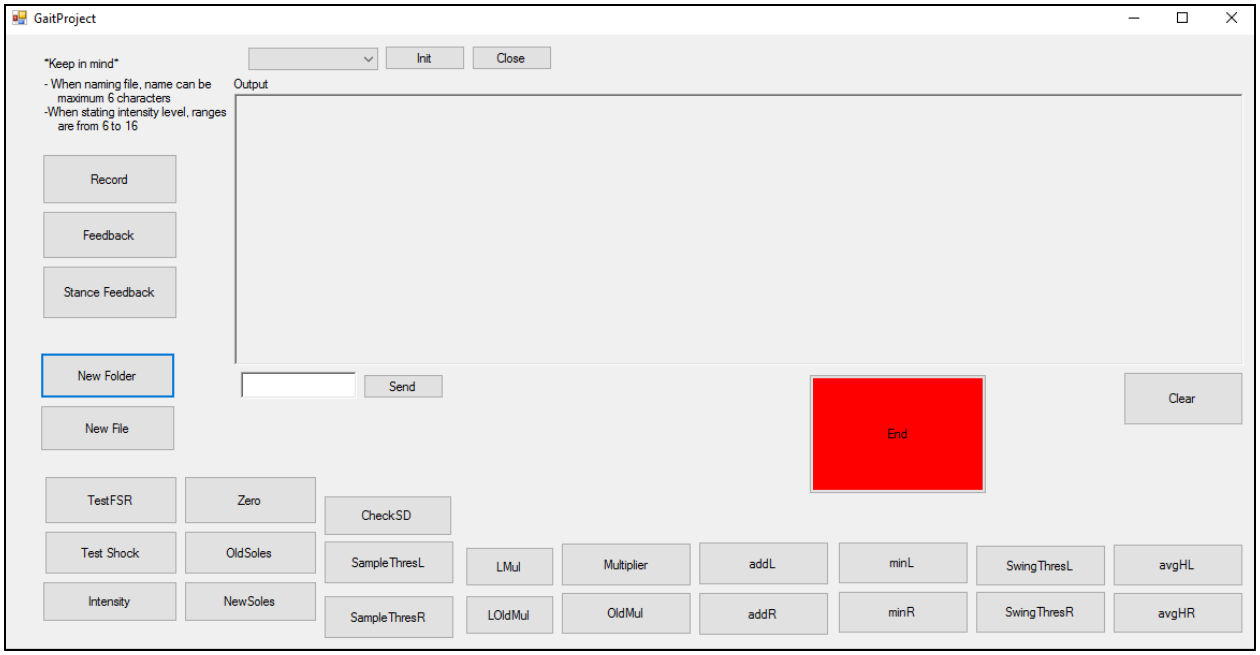


*Figure 8 GUI for WalkEven Device*

There are numerous buttons on the GUI but each one will be explained. Starting from the top are the "init" and "close" button. The drop down menu to the left of them list the communication (COM) ports that are available to connect to. The COM port is how communication is passed between the device and the GUI. Once a COM port is selected the "init" button opens the connection between the GUI and the device. The "close" button ends communication between the two. Once the connection is established the user can begin to create a directory for the saved files on the microSD card. The "New Folder" is where the user creates a new folder in which all the files relating to a single patient would be saved in. The "New File" button is to create folders underneath the main folder for the same patient. The purpose for the "New File" button is to be able to distinguish files containing gait information from different trials. The "Send" button sends what is typed into the text box, located to the left, to the device. The "Zero" button initiates the zeroing function of the device. The "TestFSR" button allows us to see the voltage values the FSRs are sending to the Arduino and from these values we can pinpoint the FSRs that are not working properly. The "OldSoles" and "NewSoles" buttons are to switch the FSR equations according to the soles we used. As mentioned before, each FSR has a unique equation that converts the voltage value it sends the Arduino to pounds. When the soles were switched the equations within the code had to be changed as well, hence the reason for the sole-switching button. The buttons "TestShock" and "Intensity" buttons were used for adjusting the electro tactile response to a comfortable level for the patients. The "CheckSD" button was to see if the files were saved properly onto the microSD card. The "End" button was to end functions such as when the device is recording gait information or when the device's feedback modes were on. The "Feedback" button activated the swing feedback, while the "Stance Feedback" activated the stance feedback. The "Clear" button clears all text information in the output textbox coming from the device. The rest of the buttons deal with certain parameters within the algorithms for detecting gait and its phases. Each button links to a variable in the code to that can be adjusted to better fit the patient using the device.

## Biofeedback

The biofeedback used in the device are the swing and stance feedback. The end result for both of these biofeedbacks is to correct gait asymmetry, but in a different approach. In our recordings, it has been noticed that there is a similar pattern found in stroke patients showing gait asymmetry. In regular patients, the ratio between stance and swing with respect to the gait cycles is that swing takes up 40% of the gait while stance takes up the other 60%. The ratio is not correct with stroke patients. In stroke patients, their affected leg tends to have fast stance times and slow swing times. By focusing on the swing phase or stance phase, the overall gait can be corrected.

The swing feedback main objective is to reduce the amount of time the affected leg spends during its swing phase. To set a baseline time for the affected leg to reach, the patient's gait is recorded. Through the recording process of the device, the parameters for the gait can be found for both legs, affected and the normal. The swing time from the normal leg is chosen to be the baseline time for the affected leg to reach. Once the swing feedback is initiated, the patient begins to walk. The difference here is that when the device notices that the swing time for the affected leg goes beyond the normal leg swing time that was set, the biofeedback goes off. The biofeedback is an auditory sound from the speaker and the electro tactile response. Both of these biofeedback are to encourage the patient to end their swing cycle to match the time of the normal swing time. The feedback turns off when a heel strike on the affected foot is detected. Heel strikes mark the end of a swing phase. The benefit of the swing feedback is that the patient begins to understand the amount of time that should be allocated to the affected foot during the swing phase. The flowchart in *Figure 9* gives a visual of how the swing feedback operates. The feedback can be stopped at any moment by pressing the "END" button on the GUI. During the swing feedback, the device is recording the gait, swing, and stance cycles along with the information for the FSRs.

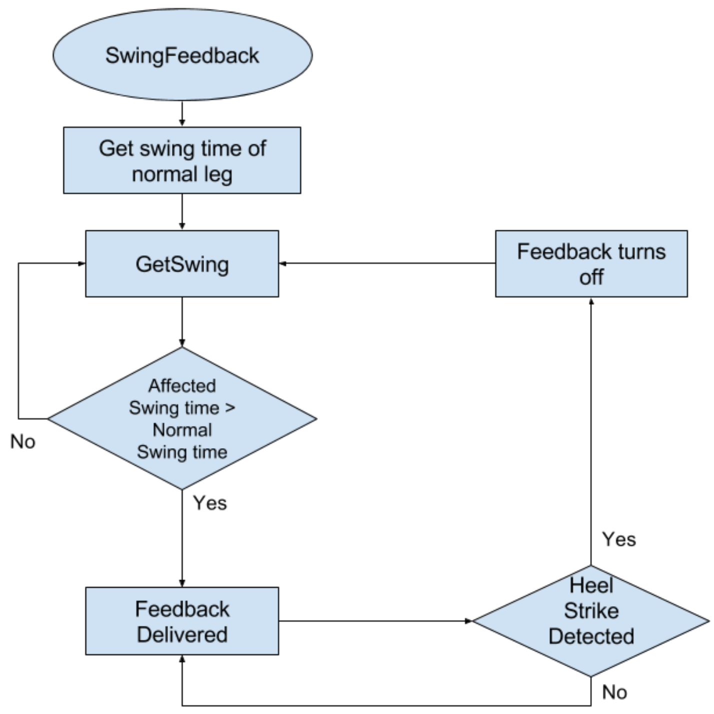


*Figure 9 Flowchart for Swing Feedback*

The stance feedback main objective is to increase the amount of time the affected leg spends during its stance phase. The baseline time chosen for this feedback is the stance time for the normal leg, which is acquired through the recording function. Once the stance feedback mode is initiated, the biofeedback activates during the stance phase of the affected leg. The feedback starts when a heel strike is detected on the affected leg. An auditory sound emits from the speaker and goes for the duration of the baseline time. The patient is supposed to exit the stance phase once the sound stops. The sound gives the patient knowledge on how much time he or she should spend during the stance phase on the affected foot. The flowchart in *Figure 10* shows visually how the stance feedback process goes. Similar to recording and swing feedback, this function can be stopped at any time by pressing the "END" button.

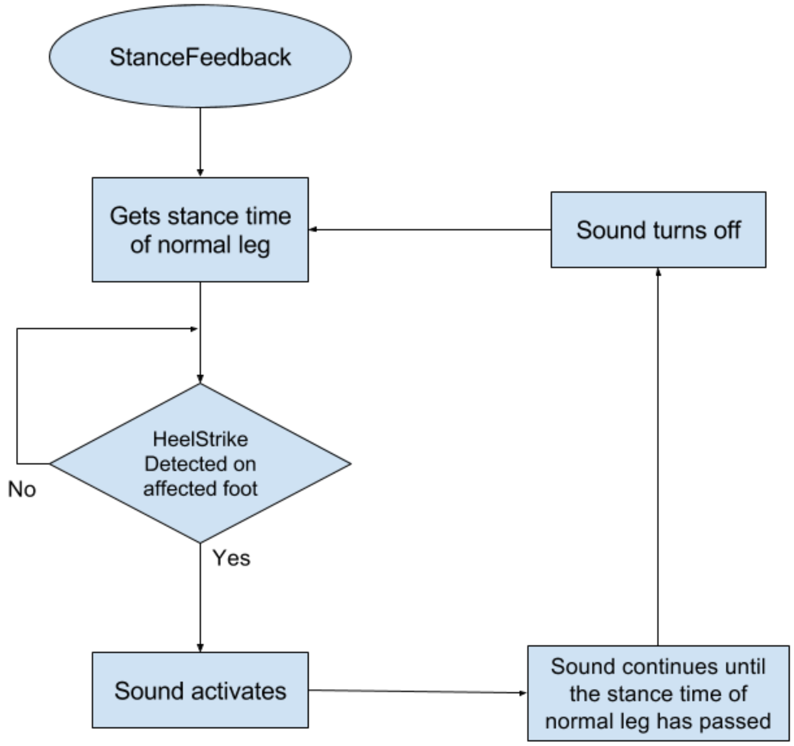


*Figure 10 Flowchart for Stance Feedback*

The main idea behind both feedbacks is to give knowledge to the patient about their own gait in real time, therefore, the patient can learn about their own gait. They know when their swing phase goes for too long or when their stance phase goes too short.

## Latest Work

Recent updates to the WalkEven device include hardware interrupts, a timer interrupt, and a balance test.

The hardware interrupts are for verification testing with a medical device called Zenomat. The Zenomat is able to pick up information pertaining to a patient's walk. There was a need for syncing the recording from both devices so that the information could be compared correctly. There is a sync signal from the Zenomat that sends a high signal when it starts recording. The device is set so that when it encounters this high signal, it marks that moment with a timestamp. When the Zenomat is done collecting information, a low signal is sent. The time when the Zenomat is done collecting information is marked with another timestamp. The timestamps generated by the device make note of the start and end time and that allows for the synchronization between the two devices. Another measurement for marking the start and end of collecting information is through lasers. The lasers are placed so that they trigger when the subjects step onto the mat and when the subjects leave the mat. When the lasers are tripped, they send a high signal. The device is programmed to mark the moments the lasers are tripped with timestamps and is able to differentiate which laser was tripped first and last. The lasers allows spatial parameters such as stride length to be calculated.

A timer interrupt was incorporated into the device so that the sample rate stays at a constant rate. The interrupts used were from a community library that can be found on the Arduino community website, Timer1. Through the libraries of Timer1, interrupts can be set at certain intervals. For the purpose of our device, the interrupts are set to 20 milliseconds. When the timer interrupts are activated, it allows the device to save information. The interrupts are in place to set the device to save at a rate of 20 milliseconds.

The balance test is a new feature in where the patient's weight allocation is shown. The reason for this test is to check the patient's weight displacement on their feet. The test can detect if there is more weight allocated to one foot compared to the other. The information is displayed on a community made GUI made available to the public called GUINO. GUINO allows the information of the weight test to be seen in the form of bars. With the visual representation of the bars, the subjects undergoing the weight test can see which foot has more or less weight and make the appropriate adjustments so that both feet share the same amount of weight displacement.

CHAPTER 5

RESULTS

Verification

In order for our device to be able to be used on stroke patients, it had to be validated. To validate our device, we compare the results of our device to a commercial device called MobilityLab. MobilityLab is able to record and collect gait information. MobilityLab uses accelerometers, gyrometers, and magnetometers to detect gait information. We had four healthy subjects wear our device and MobilityLab, and recorded their gait. The results were analyzed and compared and are shown in the figures below.

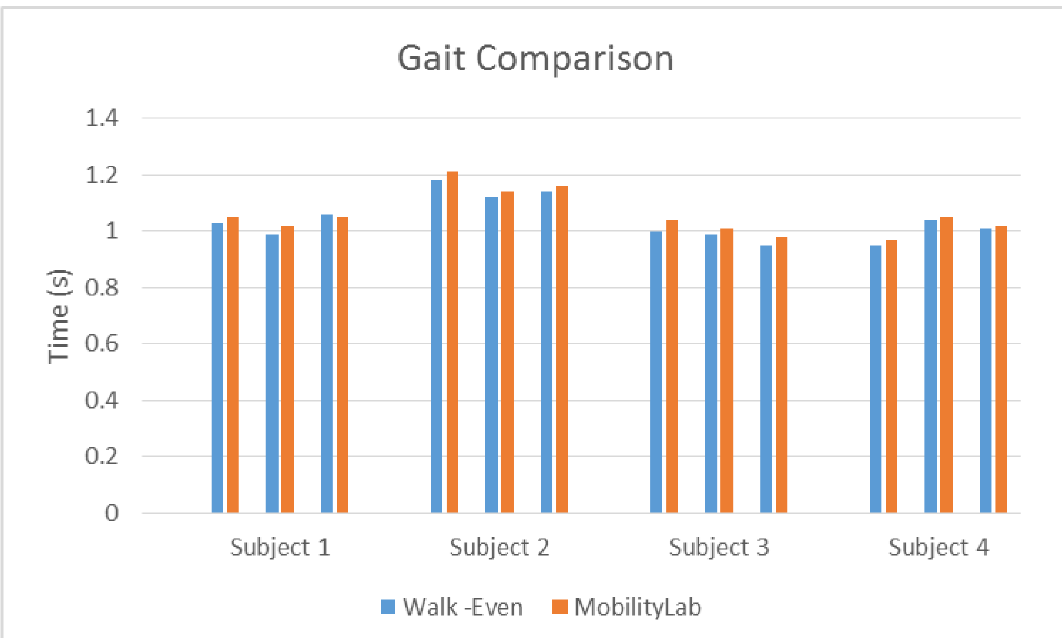


*Figure 11 Graph comparing Gait times between WalkEven and MobilityLab*

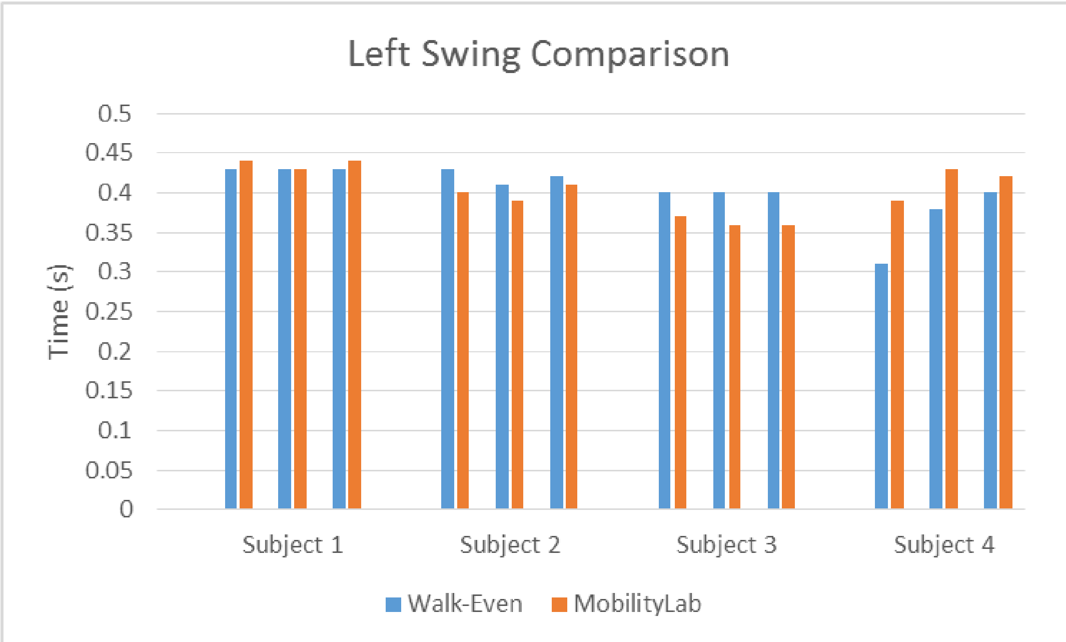


*Figure 32 Graph comparing Left Swing times between WalkEven and MobilityLab*

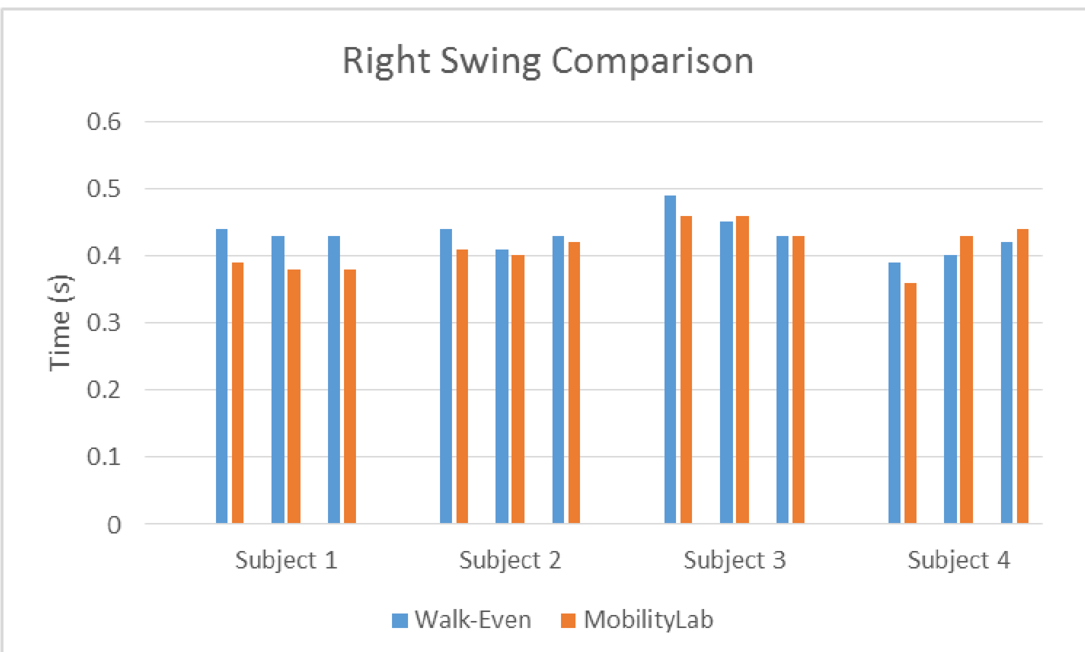


*Figure 13 Graph comparing Right Swing times between WalkEven and MobilityLab*

## Clinical Trials

After validating our device, we moved on to clinical trials. The clinical trials took place over 8 weeks. We had four stroke patients, both male and female in the age group of 30-70 years old. The patients were tested twice a week. The test consists of three phases: pre-training, training, and post-training. Pre-training was to collect three separate walks to collect gait information. The gait information from the pre-training were then used to establish the correct baseline times for the biofeedback. Training lasted for 20 minutes with the biofeedback on during the whole duration. Post-training occurred afterwards to record gait information for another three trials. The variable used to determine the asymmetry ratio for the patient was calculated using this equation, $Asymmetry\ Ratio = 1 - \frac{stance\ \ time\ of\ affected\ side}{stance\ time\ of\ normal\ side}$. The closer the asymmetry ratio got to zero, the more symmetrical the gait is. The figure below shows our results as we graph the progress of the patients during the eight weeks. The three points where we kept track of the asymmetry ratio were pre-test, retention, and post-test. Pre-test was taken a week before any training began. Retention was taken when the patient was in the middle of the eight weeks, having been exposed to the device for at least four weeks at this point. Post-test was taken a week after the eight weeks to see if any of the training was retained by the patients.

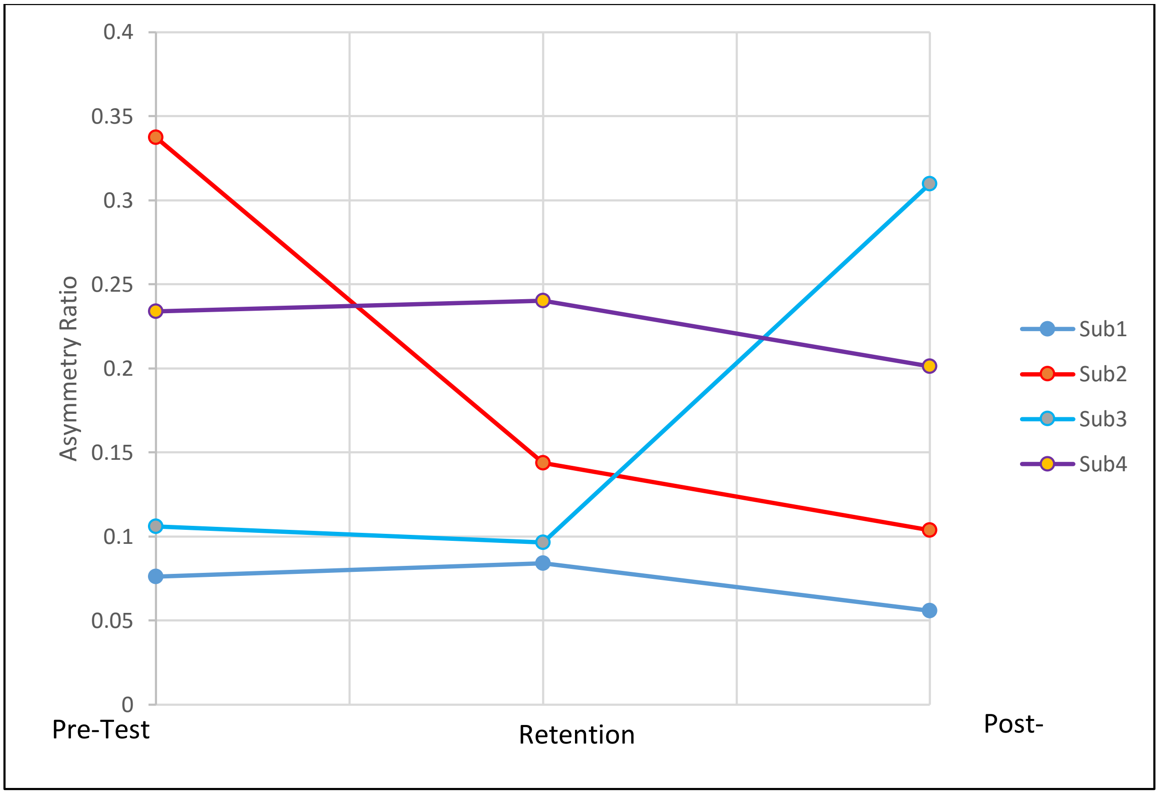


*Figure 14 Results from Clinical Trials*

# CHAPTER 6

# CONCLUSIONS

From the verification and clinical trials, the WalkEven device has proved to be a successful device for dealing with gait asymmetry. The results from the validation process showed our device is correct in the values it gathers from a patient's gait. There were some small variation among the recorded values from the trials, but those were expected. MobilityLab's device uses accelerometers, gyrometers, and magnetometers to analyze gait. Our device relies on the readings given by the FSRs. Given that the two devices use their own approach to measure gait, the similarities in times gave confidence to the values WalkEven was gathering.

The real test of our device was the effectiveness of the biofeedback. The biofeedback was the innovative design feature of our device. There are many commercial devices that can collect gait information, but ours was one that gave real time gait information to the patients through our biofeedback system. The results from the eight week clinical trial showed improvement in three of the patients' asymmetry ratio. The fourth patient that did not show improvement can be explained. There were some days during the 8 weeks that patients felt more tired than usual and that was reflected in the results. The previous readings from the fourth patient showed that they did have improvement in their gait asymmetry ratio.  After reviewing the final results, we feel justified in saying our device can help patients to make their gait more symmetrical.

The devices will go through improvements and more testing with the years to come. There was another clinical trial that took place a few months after the first clinical trial. The recent clinical trial was looking at the effectiveness of the stance feedback as the first clinical trial focused more on the effectiveness of the swing feedback. The comparison for another medical device as mention before, Zenomat, is currently being analyzed to see if our device is as accurate to that one. There are improvements that can be made to the software of the device. The weight test will be more refined for the next iteration. The bar graphs for the weight test will be incorporated in the current GUI so that everything can be concise in one GUI rather than switching between two different ones. The timer interrupts are another area where improvements can be made. The 20 millisecond interrupts vary in their times by a small margin of roughly .6 milliseconds. Ideally, the interrupts should stay at a constant 20 milliseconds. To solve this issue, a stronger processor than the one on the Arduino should be considered. With a stronger processor, the device will be able to multitask and make the 20 milliseconds a reality. Another idea to look into is to graph the FSR information in real time. This would give a more detailed look into a patient's gait.

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