Design of a Wearable Sensor System for the Estimation of Lower Limb Joint Loading

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Abstract

Osteoporosis and low bone mineral density (BMD) are critical issues among adults in the U.S. and physical activity is a known modifiable factor to prevent bone degeneration. For this reason, monitoring bone loading during physical activity is essential to understand its effects on bone formation and BMD. Current monitor systems are only available in laboratory settings and are costly and limit subject mobility. To address this need, a proof of concept wearable sensor system for the estimation of bone loading in the tibia was designed, prototyped, and tested. The sensor system consisted of imbedded force sensing shoe insoles, goniometer angle measurement sensors on the toe, ankle, knee, and hip, and accelerometers on the center of mass of the foot, shank, and thigh. Concurrent testing of our wearable sensor system with a laboratory system was conducted through trials of static and dynamic loading. A 2 tailed paired t-test on the peak force during testing was conducted to assess if there was a statistically significant difference between the sensors. Angle and acceleration measurements were compared to laboratory sensor data and literature to verify expected data. Using literature, collected and measured data and equations of motion, MATLAB script was created to calculate joint reaction forces and moments. These data were used for the estimation of bone loading.

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Authorship

All components of this major qualifying project were contributed to equally by all four team members.

All sections of this report were written, formatted, and edited equally by all four team members.

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Chapter 1: Introduction

Over 10 million adults in the U.S. over the age of 50 have been diagnosed with osteoporosis, and an additional 43 million are affected by low bone mineral density (BMD) [1]. Out of the approximately 100 million adults over the age of 50 in the U.S., 54 million, over half, are affected by osteoporosis or low BMD [2]. In addition, each year in the U.S., two million bone fractures occur due to osteoporosis, and approximately 1 in 2 women and 1 in 4 men over the age of 50 have an osteoporosis-related fracture in their lifetime [1], [3]. Women have a greater risk than men due to thinner bones, and postmenopausal women have an even more significant risk due to decreased estrogen levels, which can result in further bone loss. There are many factors affecting BMD, such as age, family history, and gender, that are fixed and out of an individual's control; however, there is growing evidence of a correlation between BMD and a controllable variable – physical activity [4], [5].

Bone tissue adapts to strain-producing physical activities, or a lack thereof. Studies have shown that a decrease in physical activity may lead to an increase in bone loss and osteoporotic fractures. Studies have shown that the reverse is also true: increased stress on bone tissue from enhanced physical activity increases bone formation and BMD [5]. Despite this, studies have also shown that physical activity patterns tend to decrease during early adulthood, between the ages of 18 and 29, which is a crucial time for bone growth and increasing BMD [7]. Eroding physical activity levels during this period may lead to an increased risk of osteoporosis, bone fragility, and fracture [8].

Since it is known that increased physical activity results in increased bone mass and stronger bones the development of a method to track and calculate joint reaction loads, bone strengthening exercise regimens and estimated injury models have the potential to inform individuals with methods to reduce their risk of osteoporosis and low BMD. Bone loading can be estimated with joint reaction force (JRF) and joint reaction moment (JRM) data. JRF is the equal and opposite force that exists between bones at a joint and JRM is the moment produced at the joint due to the same generated force. During all movements, JRFs and JRMs are the result of a force on the joint.

Bone strain can be directly measured using strain gauges [9], [10]. While this method may be accurate and direct in determining bone loading, it is invasive and typically only used in cadaver testing. Alternatively, joint reaction forces and moments may be calculated with data collected from laboratory

testing [11]. Currently, the gold standard for this laboratory testing involves the use of force plates and three-dimensional motion capture systems. The data collected from the human testing can then be used to calculate JRF and JRM to estimate bone loading.

While the use of the current gold standard accurately measures JRFs and JRMs and is an acceptable approach to estimating bone loading in subjects, the use of force plates and motion capture systems presents several limitations. These systems utilize expensive equipment that requires extensive setup time and calibration. Motion capture systems require a considerable amount of sensor attachments to the subject, and wiring can limit subject mobility. Force plates and motion capture systems restrict the space available for testing, which may require the subject to alter typical movements. This restricted mobility and altered movements can produce data that cannot be generalized to a real-world setting outside of the laboratory [12].

Studies show that certain physical activities, particularly weight-bearing activity, induce bone loading and will increase bone strength while allowing for the prevention of bone degradation [13]. Activities like high impact endurance training and weight lifting load bones in a way that leads to an increase in BMD and strengthens bone [5][13]. A wearable sensor system that collects data for determining JRFs and JRMs would provide researchers and individual feedback regarding activities that increase and/or maintain bone strength by generating adequate bone loading.

This project aimed to create a wearable sensor system that measures skeletal loading during functional physical activities that have been shown to strengthen bone. The sensor system uses accelerometers, pressure sensors, and potentiometers to estimate motion, ground reaction forces, and joint angles. These data can be further utilized to estimate bone loading, described as joint reaction forces and moments. This project focused on data from current technologies used-both from external wearable sensors and literature data from internal sensors. The sensor system was validated by concurrently collecting bone loading data using the gold standard motion capture techniques and the new sensor system prototype across several exercises. The data collected from the sensor system and subject data, such as height and weight, were analyzed with a custom MATLAB script to derive JRFs and JRMs

By creating a system that can be used outside of the lab, a wider range of activities can be monitored without impeding user activity. This sensor system and the data it provides will be able to be applied

to a finite element model (FEM) of the user to estimate tissue strain and ultimately, develop a course of action that includes activities that will better strengthen bone to decrease the risk of fractures due to osteoporosis. In summary, the system can be used in a research setting and allows for the measurement of applied forces and estimate bone loading during activities that have been proven to increase bone loading and therefore increase bone formation. Using the system will allow for researchers and physicians to eventually provide a specific course of action for increasing bone density and strength and therefore decrease the chance of osteoporosis and future fracture. Additionally, the sensor system is portable and compact so that it may be used outside of a laboratory setting and for a variety of activities without impeding the user's motions. It is user friendly as well as adjustable and versatile for the user. The system collects and stores data that may be analyzed through MATLAB and applied in a research setting.

In order to achieve this, preliminary background information was obtained regarding bone mechanics, bone remodeling, joint reaction forces, relevant measurable data, and existing sensors and measurement systems. Design requirements, functions, and features for the system were identified through research and consulting the Project Advisor, Professor Karen Troy, as well as PhD candidate Megan Mancuso. An overall design concept was developed and alternative designs and sensor components were considered and evaluated as to whether they met the determined functions and requirements. A prototype of the final design of the sensor system was fabricated and experimental tests were conducted. Experimental testing was performed using the sensor system prototype as well as laboratory gold standard systems for validation. Design improvements were determined through experimental testing to further meet the needs of the client statement and device features and requirements. Performance limitations of the system and future recommendations were identified to increase the validity and accuracy of the sensor system.

Chapter 2. Literature Review

This chapter presents the clinical and technical background as well as the limitations of current technologies which lays the foundation for the wearable sensor system. Topics covered in this chapter include: the bone remodeling cycle, activities that affect the bone remodeling cycle, and the importance of estimating bone loading. Additional topics include the current gold standards utilized for biomechanical analysis and their limitations.

2.1 Significance

2.1.1 Bone and the Bone Remodeling Process

Bone is a porous mineralized structure of calcified connective tissue forming the major portion of the skeleton and accounts for 15% of the human body [14]. The major functions of the human skeleton is to protect the inner organs and to provide attachment for muscles, tendons, and ligaments so the body can move and function.

There are two types of bone in the human body: cortical bone and trabecular bone. They account for 80% and 20% of the skeletal mass in the human body, respectively. Cortical bone is compact and dense, and it functions to provide mechanical strength and protection. Trabecular bone is porous, less dense, and more elastic and does not possess the same mechanical properties as cortical bone, however it is important for absorbing impacts and transmitting force from the bone surface to the cortical diaphysis, or midsection of the bone. Long bones in the body, such as the tibia and femur, are composed of an outer region of strong cortical bone which is highly resistant to bending and torsion. The internal part of long bone is made of trabecular bone and assists with force transmission as well as metabolic functions.

Both types of bone are in a constant state of remodeling, which allows for the maintenance of the shape, size, quality, and strength of the bone. The bone remodeling cycle is a process that adjusts the architecture of bone based on mechanical or chemical stimuli [8]. Bone remodeling is the process by which bone is being resorbed and replaced, which allows for the maintenance of the shape, quality, and size of the bone. This cycle occurs in every bone of the human body in order to improve the overall

strength of the bone and to prevent the accumulation of old weaker bone, which can fracture easily.

The bone remodeling process has several stages: activation, resorption, reversal, formation, and resting. Overall osteoclasts are responsible for the resorption of old, weaker bone that has come under a mechanical change, while osteoblasts create a new bone matrix that replaces the old resorbed bone [8]. The first phase of the cycle, activation begins when a chemical or mechanical stimuli for the cycle occurs. This stimuli causes osteoclasts to form from the fusion of monocytes and begin to remove bone which activates the next phase of the sequence, resorption. During the resorption phase, newly formed osteoblasts begin to gradually resorb bone. Osteoclasts remove the weak, old bone to make room for osteoblasts to form new bone [14]. Activity during the reversal phase switches from osteoclastic to osteoblastic as cells begin to prepare the surface for new osteoblast which will come and produce new bone to strengthen the bone overall [7]. During the formation phase, osteoblasts refill and form new bone [14]. Newly formed bone mineralized and the cycle concludes with the resting phase in which there is inactivity of bone resorption and formation.

Abnormalities in the bone remodeling cycle can lead to a variety of skeletal disorders. In a homeostatic equilibrium, the rate of bone resorption and bone formation are balanced [8]. This ensures that old bone is continuously replaced by new bone and there is no accumulation of old weaker bone. One skeletal disorder is osteoporosis, which causes bone to become weaker and more likely to break. However, this condition is usually only prevalent in people of older age who have less calcium within their bones. Osteoporosis is when the rate of bone resorption exceeds the rate of bone formation osteoporosis occurs. So not only do is weaker bone accumulating but the body also resorbs bone and does not replace it resulting in bone that are more likely to fracture.

When the body does not stimulate the bone remodeling process the bone resorption rate starts to overcome the bone formation rate. This leads to a condition known as osteoporosis. As mentioned in Chapter 1, osteoporosis is a disease that is characterized

by an individual having low bone mass and low bone density and causes the bones to be brittle resulting in an increased risks of fracture [9].

The tibia is the long bone that runs from the knee to the ankle and when coupled with the fibula makes up the lower leg. The tibia is the most commonly fractured long bone in the body [10]. This is because the tibia is part of the knee which is the largest weight-bearing joint in the body. This, coupled with the lower bone mass and density associated with osteoporosis, makes the tibia a prime fracture candidate. The upper portion of the tibia is the most likely place for the tibia bone to break and it is caused by a force driving the femur into it [11].

2.1.2 Effect of Activity on Bone Remodeling
There are several factors that affect bone and the bone remodeling cycle, however, one known modifiable factor that increases bone mass and bone density is physical activity. Physical activity places necessary stresses on the bones to stimulate the bone formation process that is needed to maintain bone density. With age the amount of physical activity that we perform decreases in both amount and severity. During young adulthood, ages 18-29, activity patterns begin to erode, indicating a decrease in activity. During adulthood, ages 30-64, activity patterns were found to remain stable and at retirement age, age 65+, activity patterns had a slight increase [4]. This leads to less stimulation of the bone remodeling cycle and weaker bones.

2.1.3 Biomechanics and Estimating Bone Loading
A force is defined as a push or pull upon an object resulting in the objects interaction with another object [15][16]. The science of studying the effects forces have on matter particularly motion and deformation is Mechanics. When mechanics is applied to the body to study the effects of forces have on the human body this application is called Biomechanics [17]. Biomechanics is accomplished by defining body segments of the body using anatomical landmarks, these body segments are then used as rigid bodies. Rigid bodies are defined as a body whose size and shape is unaffected by the forces that act upon it [16]. By defining each body segment as a rigid body free body diagrams can be draw of each rigid body. Free body diagrams are diagrams of an object with all

the relevant forces and moments acting on it at any given point of time. By taking these diagrams we can create either equations of equilibrium if focusing on static systems or equations of motion if kinematics are being studied. A free body diagram example can be seen in Figure 2.1.
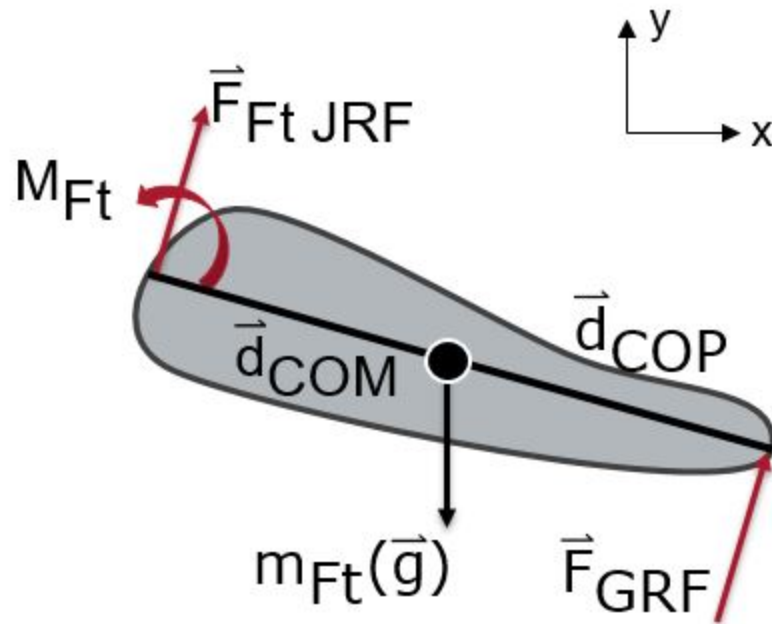
Figure 2.1. Example of a Simple Free Body Diagram of the Foot

Kinematics is the branch of mechanics concerned with the motion of objects without reference to the forces that cause the motion. Kinematic measurements of human locomotion are usually based on the assumption of that body segments are idealized as rigid bodies [18]. Utilizing Newton's second law that any force is equal to the mass of the object multiplied by its acceleration. Measurable values like position of anatomical landmarks are used to calculate the acceleration and velocities of body segments to calculate the forces that act on the rigid bodies during motion.

There are multiple levels of biomechanics ranging from Molecular Biomechanics to Tissue Biomechanics [19]. Biomechanics looks at the effect external forces have on

biological tissues like bones, ligaments, tendons, etc. These external forces cause internal forces to act directly on bones of the skeletal system. These forces that act on the bones directing are called bone loading and the estimation of bone loading is an application of tissue biomechanics that is studied frequently.

To estimate bone loading during any physical activity is done by looking at the intersegmental forces and moments acting on a body segment. Physical activity of any form causes external loads to the whole body which are transmitted to the joints in the form of joint reaction forces (JRF) and moments (JRM). This transmission of joint loads through the bone causes stresses and strain on the tissues. Thus, JRF and JRM are one commonly used as a surrogate measure for bone loading [20]. Using free body diagrams to create equations of motion which then can be used to find the JRF and JRM acting at a joint at any point of time using inverse dynamics. Inverse dynamics is the process of calculating unknown kinematic information using measurable kinematic like velocities, accelerations and position. Using laboratory equipment like force plates and 3D motion capture systems to measure the necessary kinematic information to calculate the JRF and JRM using the equations of motion. There is no way to quantify bone loading accurately without invasive measurements making the best method of estimating bone loading externally is using physics and inverse dynamics to calculate JRF and JRM.

2.2 Current Laboratory Devices and Technology

2.2.1 Devices to Measure Ground Reaction Force

In order to calculate resultant forces on various joints, ground reaction force data has to be collected. For motions where foot strikes occur (ie. walking, running, jumping, etc.) a ground reaction force is produced. The most common way to collect ground reaction force data is through force plates. Force plates are able to measure the force acting on them by strain gauges inside the plates. A strain gauge is a sensor that when a force is applied to will cause the resistance to vary. The gauge is able to convert the forces acting on it into a change in electrical resistance which can be measured and used in biomechanical calculations [33]. These Multiple force plates can be connected to the same software and collect data simultaneously.

In more agile settings, insole tri-axial force transducers can be used to collect force data. In one study on basketball cutting maneuvers, a small section of the insole and midsole were removed to house the transducer flush to the rest of the insole. The basketball sneakers were worn as normal and pressure and shear stress was calculated from the obtained data [15]. Additionally, pressure sensor placed in insoles have been studies to estimate ground reaction forces. In one study, pressure insoles were used to test the force produced due to walking [16].

These devices all allow for the collection of ground reaction force data of the foot during activity. The data collected can be used in tandem with joint angle and acceleration, discussed next, to estimate bone loading.

2.2.2 Devices to Measure Joint Angles and Acceleration

Body motion sensor systems track body kinematics and collect data on body position and location. Common methods to track body motion utilize optical motion capture systems or electromagnetic sensor systems. For more agile settings, goniometers or gyroscopes coupled with accelerometers can also be used. Through further analysis, joint angles and linear acceleration during a motion can be calculated from body motion data.

Optical motion capture systems utilize video to visually record motion through markers placed on the anatomic structures of the subject. System compatible software is used to analyze the captured video to determine body position and location. Systems can either have passive or active markers to capture data. Passive markers reflect light back to the sensors while active markers provide light for the sensor to capture [12]. Electromagnetic systems require sensors on the relevant anatomical structures to define the body's location and produce data on sensor locations with respect to a global zero. This can then be used to determine joint angles by creating vectors for the two body segments that are connected to the joint of interest. The vectors are created using the positions of the anatomical landmarks on the body segments of interest. The vectors are then used to calculate the flexion angle at the specific joint of interest using the dot and cross product of the two

vectors being used. This system is useful for adding as many markers are required, building off the base sensors. A drawback to electromagnetic systems is that the measurement is completed through magnets and it is therefore susceptible to error due to interference by metal objects in the surrounding area.

Optical motion capture systems require camera setup, limiting the area a motion can be performed. Analog goniometers can be placed on a relevant joint with one arm stationary and another one free to move as the joint angle changes to measure two-dimensional angle changes. To provide measurements for three-dimensional angular motion, adapted goniometers can be used [13]. This eliminates the need for an external capture system off the body. Electro-goniometers have two parts containing strain-gauges attached to the segments of the body about the joint of interest. Relative joint angle can be measured and sent to a connected data storage unit [14].

2.3 Limitations and Gap in Technology

Although sensor systems in the laboratory have been verified and validated, they have several limitations and restrictions. These systems have a long setup time and a limited operating range. Device calibration and subject setup in the lab can take upwards of two hours. Electromagnetic sensors have more extensive wiring compared to optical motion capture systems which–limits the mobility of the subject. Additionally, metal present within the operating range will create noise and alter electromagnetic sensor data. While optical motion capture systems are allow subjects to move more freely, the operating range tends to be smaller than EMT systems and are more expensive.

The gold standard utilizes forces plates from companies like Kistler and AMTI which are calibrated by technicians and can cost more than $40,000 and are stationary so the subject have to alter their movements to ensure they will land on the force plate [17]. This often means athletic motions such as cutting force and jumping force data are not accurate to out of lab situations. Lastly, the movements monitored have to fit within the available lab space. This means that movements that require large spaces or specific equipment cannot be monitored.

Since there is currently no way to monitor bone loading outside of the laboratory, daily activities and real-life situations cannot be monitored to understand how daily activities affects bone loading. These data are collected and have to be processed manually to calculate bone loading.

2.4 Summary

Physical activity generates forces and bone loading which causes stress and strain on bones. This loading causes microfractures and mechanical changes within the bone. Bone remodeling occurs through changes in bone geometry and mass in response to the mechanical change to prevent fractures and strengthen bone [2]. Currently, quantifying induced forces on bone is only done in laboratory settings. This process has multiple drawbacks: high expenses, tedious setup procedures, and limited space. Force plates and three-dimensional motion capture systems used to measure forces on bones and are expensive and the motion capture system must be calibrated. Calibration as well as strategic placement of identifying markers requires extensive setup time prior testing and data collection. The laboratory setting also limits the activities that can be performed for testing due to the limited space and force plate setup.

Chapter 3. Project Strategy

This chapter documents the process and justification for refining the project goals, determine and compare sensor options, and arrive at a final design. In order to guide project development, this process follows the engineering design approach. This process begins with the initial client statement. Technical and standard design requirements were established. This allowed for a revisions to the client statement and the outline of a project approach.

3.1 Initial Client Statement

The scope of this project derives from the client statement, which was initially given by the project advisor, Dr. Karen Troy, and is as follows:

Design and implement a method that utilizes worn sensors to estimate joint forces and moments during functional physical activity with the following requirements and details:
1. Focus on off-the-shelf sensor identification, signal processing and integration,
2. Involve human subjects testing and biomechanics analysis for validation, and
3. Be of low cost and easy to use for the wearer.

3.2 Design Requirements (Technical)

Through discussions and advisor meetings, the client statement was developed and the following design requirements – including objectives, functions, constraints, and specifications – were determined and developed.

3.2.1 Design Objectives

The following objectives were identified for the project and sensor system.
1. **Wearable and compact**: The system must be able to be worn by human subjects for verification, validation, and future use. The overall sensor configuration should utilize minimal wiring and pose minimal interference and discomfort to the subject during use. The combined system should weigh less than two pounds. This is of greatest importance; the sensor system must utilize worn sensors in order to measure ground reaction force and joint angles.
2. **Accuracy**: The sensors must provide accurate results throughout testing, verification, and validation. The data provided by the sensors will be used for calculations and further utilized for estimations of bone loading by the researcher, so accuracy overall is essential. For this reason, the sensor system should collect data within 80% accuracy of the laboratory sensors.

3. **Durable**: The sensors must be able to withstand use during multiple activities including gait and load carriage without damaging integrity of the sensors or altering results due to wear or damage. The sensors must provide consistent results throughout testing.

4. **Battery capacity**: The sensors should collect data for at least two hours before requiring charging or battery change. This will allow of the completion of at least one subject test without interruption due to battery capacity.

5. **Portable**: The sensors utilized and worn by the subject must allow for the subject to move freely not attached to any stationary equipment. An onboard power source or charged sensors will be necessary. No external wiring (connections to a computer, outlets, etc.) should be needed.

6. **Ease of use**: Sensors should have a simple setup and calibration for the subject. This includes a limited setup time, less than ten minutes, and limit information content to reduce user error. However, the use of the sensor system should not be oversimplified and diminish system accuracy.

7. **Adjustable**: The sensors utilized should be able to be adjusted to fit the subject. This will allow for testing and use by a larger range of subjects and minimal or simple device modifications. In the scope of this project, the ability of the system to be adjustable to a wide range of subjects was not significant.

Table 3.1 displays a pairwise comparison matrix utilized to weight and rank each of the design objectives.

Table 3.1 Pairwise Comparison of Design Objectives

Objectives	Wearable & Compact	Portable	Ease of Use	Adjustable	Durable	Accuracy	Battery Capacity	Total
Wearable & Compact		1	1	1	1	1	1	**6**
Portable	-1		1	1	-1	-1	-1	**-2**
Ease of Use	-1	-1		1	-1	-1	-1	**-4**
Adjustable	-1	-1	-1		-1	-1	-1	**-6**
Durable	-1	1	1	1		-1	1	**2**
Accuracy	-1	1	1	1	1		1	**4**
Battery Capacity	-1	1	1	1	-1	-1		**0**

3.2.2 Constraints

Several constraints and limitations associated with the project and the sensor system were also identified.

- o **Non-invasive and off-the-shelf sensors**: The sensor system must utilize off-the-shelf sensors and signal integration while being non-invasive. Data collection is limited to non-invasive methods excluding the use of internal sensors such as strain gauges. The sensors used must be able to be purchased or easily assembled by the researcher for use.
- o **IRB approval**: This project will involve voluntary human subject testing and testing procedures will require approval from the WPI Institution Review Board (IRB). Human testing procedures developed and used for the validation of the sensor system must comply with ethical and regulatory guidelines and produce minimal risk to voluntary subjects.
- o **Limited setup time**: The hardware for the sensor system should take no more than 5 minutes to put on and calibrate by the user. This setup time should be minimal such that is does not bother the user and interfere with time for activity.
- o **Limited interference**: The hardware should not interfere with the users' gait cycle or other activities performed and should not cause any discomfort during testing or use. Restricting any of the activities may lead to inaccurate, real-world results.
- o **Accuracy**: Results produced by the sensor system must be accurate in comparison to current gold standard equipment available to the team. In order for the overall system to be used to estimate bone loading, the results produced by the sensors must be within 80% accuracy of the laboratory sensors for calculated data to be relevant.
- o **Data collection, storage, and software compatibility**: The sensors must collect and store data and the data must also be compatible with code produced using MATLAB. The MATLAB code may be altered depending on the data outputs of the sensors.
- o **Timeline**: This project must be completed during the 2017-18 academic year. Based on this, the project must be completed within approximately eight months.
- o **Financial**: The expenses made by the team for this project must not exceed $1000 based on the institution's Biomedical Engineering Major Qualifying Project guidelines.

3.3 Design Requirements (Standards)

The sensor system developed through this project will be used for medical research and human testing. Several ISO standards will need to be addressed and adhered to in the design of this system. The system created for this project will be used for biomechanical research and is classified as a medical and diagnostic device for physical medicine. This research device will also be used for testing on human subjects for this prototype.

The following ISO standards were identified for the scope of this project

1. ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
2. ISO 14155: Clinical investigation of medical devices for human subjects -- Good clinical practice
3. ISO 13485: Medical devices – Quality management systems – Requirements for regulatory purposes
4. ISO 21500: Guidance on project management

The first standard listed is to be adhered to so that the results from our sensor system can be trusted based off following proper testing and calibration standards. The second standard focuses on protecting the safety, wellbeing, and rights of the test subjects to make sure all the results of the investigation and experiments are credible. The third standard focuses on the making sure the medical device demonstrates the ability to provide services that meet both customer and regulatory requirements where they are applicable. The fourth and final standard focuses on good practice in project management so that the project can be performed at the highest level.

3.4 Revised Client Statement

Based on information gathered from the client and technical research surrounding the topic, the initial client statement was revised and is as follows:

Design and produce a prototype of a sensor system that will provide data that can be utilized to estimate bone loading for a research setting. The sensors utilized in the system must be purchased off-the-shelf or easily assembled for use. The sensors must measure ground reaction force and joint angles about the knee and ankle of subjects during functional physical activities. Data collected by the sensors must be utilized to calculate joint reaction forces and moments about the tibia which will be used further to estimate tibia bone loading. The sensor

system should be portable, compact, and easy to use by subjects. The sensors must provide accurate data and results must be verified and validated using current gold standard laboratory equipment available for biomechanical analysis involving human subject.

3.5 Project Approach

In order to provide direction for the completion of this project, several necessary steps were determined in terms of development, implementation, and testing a successful sensor system design.

Research regarding project significance, the current devices and technologies utilizes, and the limitations of these devices played a major role in the design process for the sensor system. Design requirements were also determined and the client statement was revised in order to provide greater scope to the project. Through this research and development of design requirements, several sensors that could be utilized for the system were identified.

Once specific sensors were identified, the design of the sensor system was developed. The configuration for the sensors was determined and sensors and sensor parts were purchased and assembled. The sensor system prototype was finalized and the components were calibrated. A code was also developed using MATLAB to allow collected sensor data to be analyzed.

The sensor components were verified individually and results were compared against gold standard laboratory equipment available. The MATLAB code was verified using data produced by the collected sensor data. Validation of the sensor system was completed through subject testing and the data from the testing was analyzed and measurements were calculated using the MATLAB code.

Following subject testing and data analysis, results of the project were documented and communicated through a project report and a final presentation. Future recommendations were also determined for the project and the sensor system. A lab notebook was also kept during the duration of the project to document design ideas, developments, decisions, and system results. Figure 3.1 displays a work breakdown structure created for the project.
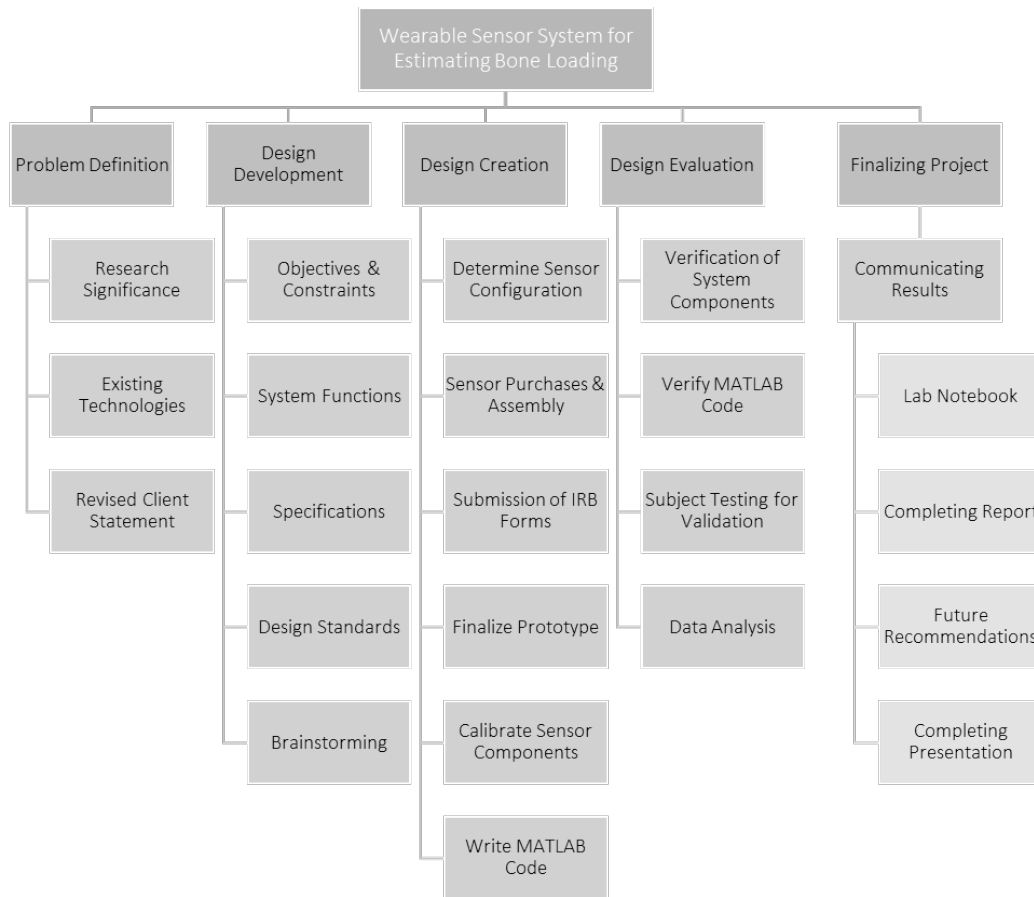
Figure 3.1. Sensor System Project Work Breakdown Structure

Chapter 4. Design Process

This chapter discusses the process followed for generating and evaluating designs. This project aimed to address needs brought about by the project advisor and a needs analysis was conducted and allowed for the generation of design specifications. This chapter further details the brainstorming of preliminary conceptual designs for the sensor system and decisions for the final design of the system. Following sensor selections for the system, a final conceptual design and sensor configuration was determined and a prototype was constructed to begin preliminary data collection.

4.1 Needs Analysis

Following discussions with the project advisor and research regarding bone loading and measuring joint reaction forces and joint angles, requirements for the sensor system were developed.

As discussed in the previous chapter, the sensor components of the system must be able to measure and collect data regarding ground reaction forces, joint angle about the knee and ankle, and acceleration of the foot, shank and thigh. Measuring these data at an appropriate frequency and utilizing sensors that provide a greater degree of accuracy against the current gold standard is crucial in order for the system to achieve its purpose to be used to estimate tibia bone loading. The software or code must be able to analyze the data collected by the sensors and calculate the joint reaction forces and moments about the ankle and knee which will provide data for estimations of tibia bone loading. Figure 4.1 summarizes the overall needs for the sensor system and how the sensor and software components of the system connect.
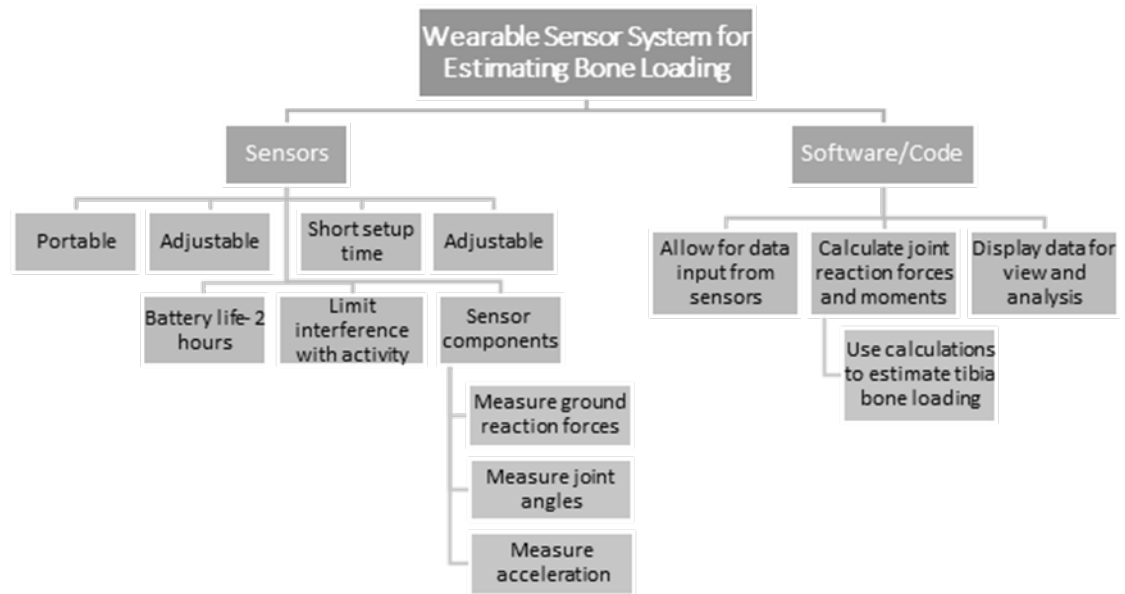
Figure 4.1. Sensor and Software Component Needs

4.2 Design Requirements, Functions (Specifications)

4.2.1 System Functions
In order to further develop the client statement and goals of the project, functions and operations of the sensor system were determined and defined. These were divided into sensor and software functions.

Sensors:
- o Provide up to 2 hours of battery life to allow for setup, testing, and general use. The system may utilize rechargeable or disposable batteries.
- o Measure ground reaction forces during gait and other activities performed during testing and use.
- o Measure joint angle about the ankle and knee during activities performed during testing and use.
- o Measure acceleration of the foot, shank, and thigh during activities performed during testing and use.
- o Collect and store data either internally, on a micro SD card, or through a sensor application (app).

Software (MATLAB script):
- o Provide a simple interface that allows for subject-specific inputs, such as height, body segment lengths, weight, and age, by the researcher.
- o Calculate joint reaction forces and moments about the ankle and knee.

o Provide data that can be used for estimations of tibia bone loading.

4.2.2 Specifications

Several specifications were determined related to sampling and accuracy for the sensor system in order for accurate data to be collected and used for further analyzation.

- o **Sampling Frequency**: Data should be collected at a frequency of 100 Hz and should be collected at the same time points across all sensors utilized.
- o **Recording Time**: Sensors should have the capacity to record and store data for up to 2 hours of use during testing.
- o **Data Storage**: The sensors should be able to store up to 20 megabytes of data in .csv files or in a format that can be easily transferred to a .csv file. This is crucial such that the data can be analyzed by MATLAB.
- o **Accuracy of Force Measurements***: Ground reaction force data collected by respective sensors should be within 90-95% accuracy as compared to the current gold standard available (Force Plates).
- o **Accuracy of Angle Measurements***: Joint angle measurements collected by the sensor system should be within 90% accuracy as compared to the current gold standard available (Polhemus G4 Electromagnetic Tracking system).

* It should be noted that these data may have a greater variance due to offset sampling – a peak or other data point may be collected by the sensor system that is not picked up by the gold standard, or vice versa.

4.3 Theoretical Basis for Design

The theoretical basis for our sensor system is to use physics and kinematics to calculate the forces that act on the knee and ankle joints during gait. This is done by using free body diagrams and inverse dynamics. Free body diagrams (FBD) are diagrams of an object with all the relevant forces and moments acting on it at any given point of time. For the system we created a free body diagram for both the foot and the shank body segments. Figures 4.2 and 4.3 are visual representations of the FBD's of both the foot and shank respectively.
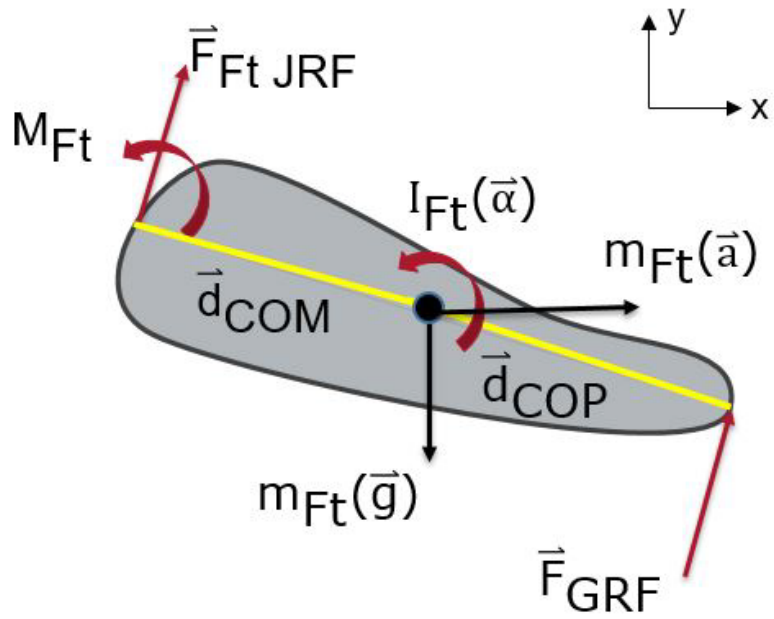
Figure 4.2. FBD of the foot body segment of the lower limb.
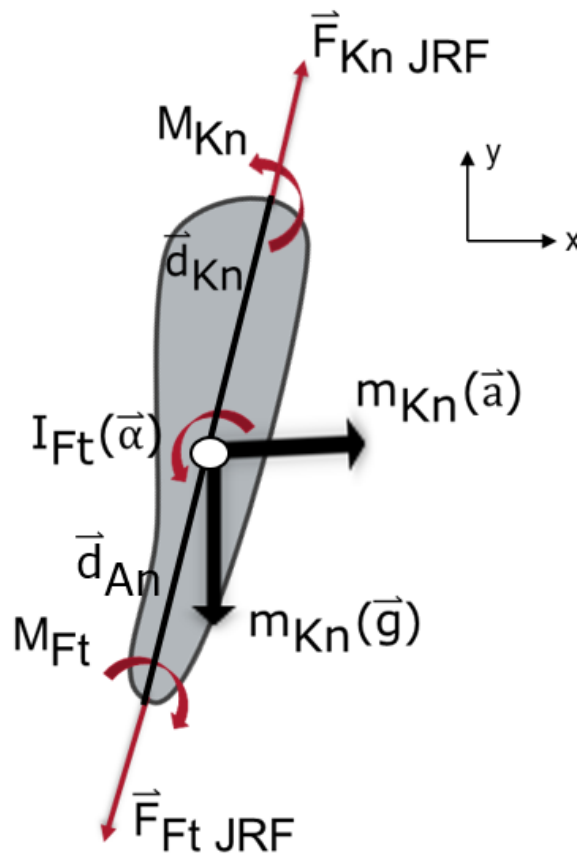
Figure 4.3. FBD of the shank body segment of the lower limb.

From these free body diagrams inverse dynamics is used to created equations of motions with were used to calculate the Joint Reaction Force (JRF) and Moment (JRM) acting on the joint of interest in each body segment. Inverse dynamics is the process of calculating unknown kinematic information using measurable kinematic like velocities, accelerations and position. Using each free body diagrams two equations can be derived to be used to calculate the JRF acting at the ankle and knee joints. These four equations can be seen below with the measured values from the sensor system in red and measured or literature values in blue.

$$\vec{F}_{Ft\ JRF}\begin{bmatrix}x\\y\end{bmatrix} = (m_{Ft}) * \left(\vec{a}_{Ft}\begin{bmatrix}x\\y\end{bmatrix}\right) - F_{GRF}\begin{bmatrix}x\\y\end{bmatrix} - (m_{Ft}) * (\vec{g})$$

$$\vec{F}_{Kn\ JRF}\begin{bmatrix}x\\y\end{bmatrix} = \vec{F}_{Ft\ JRF}\begin{bmatrix}x\\y\end{bmatrix} - (m_{Sh}) * \left(\vec{a}_{Sh}\begin{bmatrix}x\\y\end{bmatrix}\right) - (m_{Sh}) * (\vec{g})$$

$$M_{Foot}\begin{bmatrix}x\\y\end{bmatrix} = (I_{Ft})\ \mathbf{X}\ \vec{\alpha}_{Ft}\begin{bmatrix}x\\y\end{bmatrix} - (d_{Ft})\ \mathbf{X}\ \left(\vec{F}_{Ft\ JRF}\begin{bmatrix}x\\y\end{bmatrix}\right) - (d_{COP\ Ft})\ \mathbf{X}\left(\vec{F}_{GRF}\begin{bmatrix}x\\y\end{bmatrix}\right)$$

$$M_{Kn}\begin{bmatrix}x\\y\end{bmatrix} = (I_{Sh})\ \mathbf{X}\ \vec{\alpha}_{Sh}\begin{bmatrix}x\\y\end{bmatrix} - (d_{An})\ \mathbf{X}\ \left(\vec{F}_{An\ JRF}\begin{bmatrix}x\\y\end{bmatrix}\right) - (d_{Kn})\ \mathbf{X}\left(\vec{F}_{Kn\ JRF}\begin{bmatrix}x\\y\end{bmatrix}\right)$$

Where F=force, m=mass, α =angular acceleration, a=linear acceleration, M=moment, I=moment of inertia, d=distance from center of pressure, Ft=foot, Sh=shank, An=ankle, Kn=knee, $\mathbf{X}$ = cross product, $*$ = scalar multiplication

Using these equations and MATLAB we can create a custom MATLAB script that can then be used to estimate bone loading in the lower limb by using the JRF and JRM acting on the knee and ankle joints during gait. The data collected by our sensor system components can be plugged directly into the MATLAB code as a .csv file and this will then allow our code to calculate the JRF and JRM over one gait cycle. Which was then compared to literature in order to validate the accuracy of the results of our sensor system.

4.4 Preliminary Conceptual Designs

After compiling information regarding design requirements, objectives, constraints, and specifications, several types of sensors as described in Section 2.2, were further researched within the context of this project. The sensors included those that measured ground reaction force, relevant joint angles, and acceleration. This section describes the main sensors that were considered in each category in further detail with regards to the needs of the sensor system. An overall diagram of the project's preliminary design concept is shown in Figure 4.4.

HARDWARE COMPONENT

SOFTWARE COMPONENT

Global reference sensor for the system

Motion tracking sensors on relevant joints

Pressure sensor technology in shoes

software pipeline

wireless

Data transmitted to external computer and run through software/code to estimate joint reaction forces

Calculations of (tibial) joint reaction forces

Estimate bone loading

Further estimate bone loading and allow for application to finite element models of the subjects bone and possibly determine a plan of action to increase bone strength

Figure 4.4. Preliminary Design Concept

4.4.1 Measuring Ground Reaction Force

Tekscan™ In-Shoe Pressure Measurement Solutions: F-Scan System [22]
- Shoe sole with pressure sensors integrated into the material of sole
  - Pressure transducer in them which has a sensing element of a constant area. The element responds to the force applied to the area by fluid pressure. The force applied will deflect the diaphragm inside the transducer and this is then measured and converted into an electrical output. The electrical output can then be calibrated to correspond with the correct pressure being applied and the time. This creates a sensor that can measure the pressure applied to it and then convert it to psi or Newtons using a microprocessor or computer.
- Can be placed directly into persons shoe
- Tethered or Wireless sensor with its own battery
  - Battery Life – 3 Hours
  - Data transmitted via Bluetooth
- Collects data at 100 Hz wirelessly
- Measures normal force and calculates COP

Orpyx® Pressure-Sensing Inserts: SurroSense Rx [23]
- Shoe sole with 8 pressure sensors integrated into the material of the sole

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- Pressure transducer in them which has a sensing element of a constant area. The element responds to the force applied to the area by fluid pressure. The force applied will deflect the diaphragm inside the transducer and this is then measured and converted into an electrical output. The electrical output can then be calibrated to correspond with the correct pressure being applied and the time. This creates a sensor that can measure the pressure applied to it and then convert it to psi or Newtons using a microprocessor or computer.
- Can be directly placed into the persons shoe
- Wireless sensor with its own battery
  - Battery Life – 3 Hours
  - Data transmitted via Bluetooth to cloud in .csv File
- Collects data at 100 Hz wirelessly
- Measures normal force and calculates COP
- Estimates weight and force acting on the insole based on pressure and estimated contact area

Tekscan™ FlexiForce™ Standard Sensors [24]
- Force Sensors that can measure forces being applied to it in one direction
  - Can measure up to 7000 lbs.
- Can be fixated (Glue or Epoxy) to shoe sole at locations of Toe Off and Heal Strike
- Cannot Measure Center of Pressure
- Can collect data at 9.6 KHz when paired with Arduino microprocessor
  - Homemade Insole Pressure Sensors with two embedded sensors: 1 at the ball of the foot and 1 at the heel. This would provide ground reaction force at heel strike and toe off of the gait cycle

4.4.2 Measuring Relevant Joint Angles

Biometrics Twin-Axis Goniometer [25]
- Small Wireless sensor that can measure the angle of a joint using a spring
- Between end blocks is a protective string with a composite wire that has a series of strain gauges mounted around the circumference. As the angle between the two ends changes, the change in strain along the length of the wire is measured and this is equated to angle
- Max Length of Sensor: 1500mm
- Measurement Range +/- 150 Degrees
- Accuracy: ±2° measured over 90° from neutral position
- Data collected and transferred via cable or wirelessly to computer stored in .csv file

- Retail Price: Over $1000

AliMed® Baseline® Digital Absolute Axis™ Goniometer [26]
- Digital goniometer that uses voltage to measure angle the goniometer is making
- Can be attached to subject to measure joint during gait
- Unable to store data and method of data collected and storage need to be created
- Then must be integrated with knee and ankle brace to measure flexion angle

StretchSense™ Stretch Sensors [27]
- Silicone band embedded with Silicon Stretch Sensing elements that are very flexible and elastic
- Elements measure the capacitance in the sensing elements during the exercise and this is to calibrate the sensor to measure angle flexion.
- Can be attached to a knee brace and ankle sleeve with sewing material
- Wireless with own battery
- Data transmitted to phone and stored there in .csv
- Retail Price: Over $1000

Panel Mount 1K Potentiometer from Adafruit [28]
- A voltage divider used to measure electric potential (voltage) and which corresponds with the rotation of the dial on the potentiometer (angle)
- Knee brace integrated with a Potentiometer and Plastic Goniometer to measure Joint angle using the dial of Potentiometer with an Arduino Microprocessor with SD Card reader
- Collects data at 9.6 kHz
- Stores data onto a SD Card (8GB) in .csv File
- Retail Price for all Components (Estimation): $60

4.4.3 Measuring Acceleration

Driving Test Gyroscope by WitMotion [29]
- Wireless electronic device that measures acceleration of an object (i.e. a body segment) in three planes (x,y,z) of motion
- Uses position vectors and derivations to calculate the acceleration
- Measures data up to 100 Hz
- Wireless device that can be attached to a body segment with tape or bands to measure acceleration during motion
- Retail Price: Under $50
- Data transmitted via Bluetooth to laptop and stored there in .csv File

Xsens MTi-G-710 [30]
- Measures orientation, position, velocity, and acceleration of an object in (X, Y, and Z) Directions
- Uses position vectors and derivations to calculate the acceleration
- Maintains sampling frequency of 10 kHz and output frequency up to 2 kHz
- Wireless device that can be attached to a body segment with tape or bands to measure acceleration during motion
- Retail Price: $1,000+
- Data Stored to Cloud Storage in .csv File

Arduino Microprocessor with SD card and Acceleration Module
- Measures orientation, position, velocity, and acceleration by using a microprocessor and acceleration module with gyroscope (Homemade IMU)
- Uses position vectors and derivations to calculate the acceleration
- Maintains sampling frequency of 10 kHz and output frequency up to 2 kHz
- Wireless device that can be attached to a body segment with tape or bands to measure acceleration during motion
- Measures acceleration in X, Y, and Z
- Data stored onto a SD Card (8 GB) in .csv File

4.5 Decision of Final Design

After researching these sensors to further determine their capabilities, design matrices were composed in order to "score" each of the sensors based on the needs and requirements of the sensor system. Tables 4.1, 4.2, and 4.3 are design matrices that score each category of sensors: measuring ground reaction force, measuring joint angle, and measuring acceleration, respectively. The scoring criteria for the matrices is as follows:

- o 1: Sensor exceeded the requirement
- o 0: Sensor met the requirement
- o -1: Sensor did not meet the requirement

Table 4.1 Sensors Measuring Ground Reaction Force

	Tekscan™ F-Scan System	Orpyx® SurroSense Rx	Tekscan™ FlexiForce™ Sensors
Wearable & compact	1	1	0
Portable	1	1	0
Ease of use	0	1	0
Adjustable	0	0	0
Durable	0	0	0
Accuracy	0	0	0
Data collection - sampling frequency	0	1	-1
Data Storage capacity	0	1	-1
Battery Life	0	1	0
Cost	-1	-1	-1
Total:	**1**	**5**	**-1**
Additional notes:	-outside price range	-outside price range	-limitation: accuracy

Table 4.2 Sensors Measuring Relevant Joint Angles

	Biometrics Goniometer	AliMed® Goniometer	StretchSense™ Stretch Sensors	Adafruit Potentiometer
Wearable & compact	1	1	1	0
Portable	1	1	1	0
Ease of use	-1	-1	0	0
Adjustable	0	-1	0	0
Durable	0	-1	0	0
Accuracy	1	-1	0	0
Data collection - sampling frequency	1	0	0	1
Data Storage capacity	0	0	-1	1
Battery Life	1	0	0	1
Cost	-1	1	-1	1
Total:	**3**	**-1**	**0**	**4**
Additional notes:	-outside price range -may not integrate well with other sensors	-limitation: accuracy	-outside price range	-limitation: adjustable

Table 4.3 Sensors Measuring Acceleration

	WitMotion Accelerometer	Xsens MTi-G-710	Arduino with Acceleration Module
Wearable & compact	1	0	1
Portable	1	0	1
Ease of use	0	0	1
Adjustable	0	0	0
Durable	1	0	0
Accuracy	0	0	0
Data collection - sampling frequency	1	0	1
Data Storage capacity	1	0	1
Battery Life	0	0	1
Cost	0	-1	1
Total:	**5**	**-1**	**7**
Additional notes:	-limitation: accuracy -does low price substitute quality and accuracy?	-outside price range	-within price range -coding needed

These design matrices and scoring allowed for final decisions to be made regarding the sensor that would be chosen for each measurement component of the sensor system. Based on the scoring criteria, the following sensors best met the needs and requirements set for the sensor system:

- o Measurement of ground reaction force: Orpyx® LogR
- o Measurement of joint angles: Potentiometer from Adafruit
- o Measurement of acceleration: Arduino with Acceleration Module

The use of these sensors would allow for measurements to be made that the sensor system requires in order to calculate joint reaction forces and further estimate tibia bone loading. However, there were several considerations that need to be made and further construction and integration needed in order for the sensors to meet the requirements for this system.

4.6 Design Conclusions

4.6.1 Conceptual Design
After the components of the wearable sensor system were finalized an overall conceptual design was created of the sensor system. This system would be attached to

a single leg of the test subject to improve the feasibility of the project the focus was on one leg. However, the system components can be interchanged between legs. The ground reaction component of the system is the Orpyx LogR insole pressure sensors given to use by Doctor Karen Troy's lab. These sensors measure the ground reaction force acting on the sensor and the center of pressure, which is where on the foot the force is acting at. This data is saved to a cloud in a .csv file. The next component of the system is the flexion angle component. This sensor measures the flexion angles of the knee and ankle joint over the course of one gait cycle. A team built electric goniometer is the sensor used to collect this data for our system. The final component of our wearable sensor system is the acceleration component and for this our sensor system employs three inertial measurement units built by the team. The devices are attached to each body segment using athletic tape and measure the acceleration of each segment. In Figure 4.5 shows the sensor system attached to a test subject's right leg with each component outlined. Additionally this figure shows a free body diagram depicting what data each sensor collects for calculating JRF and JRM.
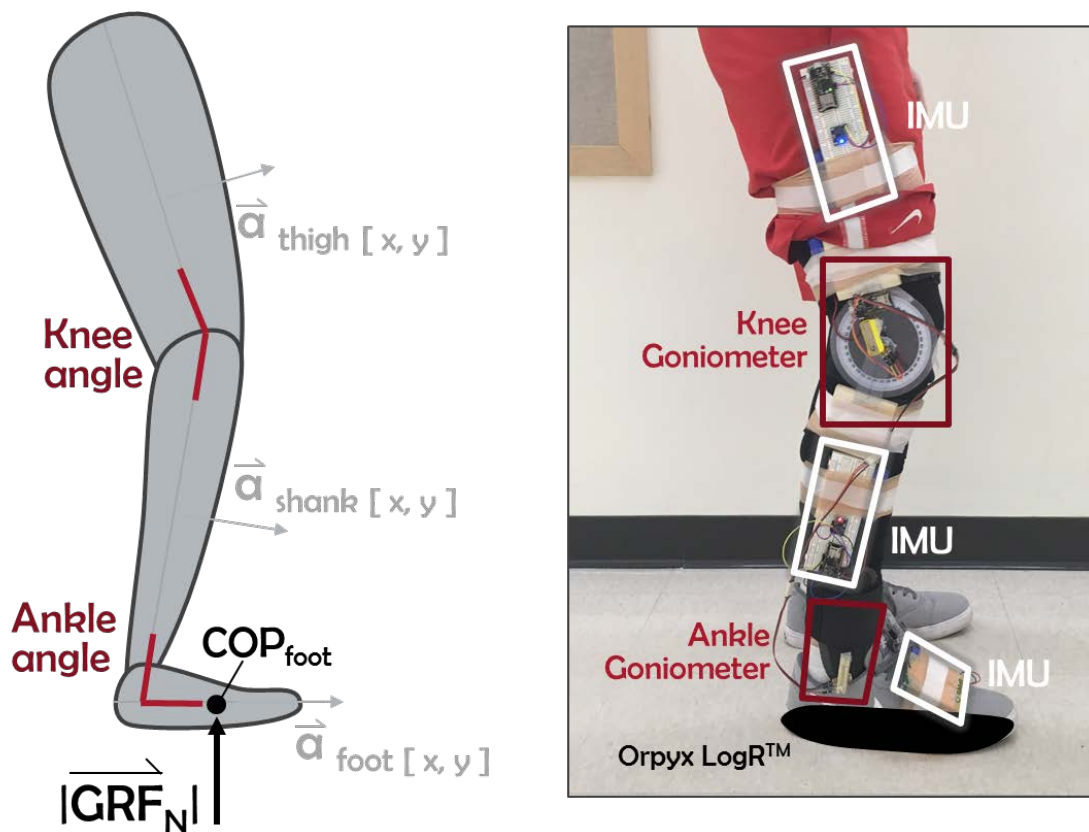
Figure 4.4. Conceptual Design of Wearable Sensor System

4.6.2 Use of Orpyx LogR

Orpyx LogR consists of two insoles that each have 8 pressure sensors integrated into the sole material. The insoles are placed into the subjects shoe under the sole. The wireless module is then attached to the laces of the shoe so it doesn't impede the test subject's gait. The shoes are then controlled by a mobile app which shoes you real time measurements which can be stored in .csv files onto a cloud storage space. The data is collected in both pounds and force for each data point and the data is collected at 100 Hz. A new .csv file can be created with every trial in the experiment.

4.6.3 Potentiometer Construction and Usage

The potentiometer, typically used for audio control, measures voltage. The sensor system will utilize the capabilities of this potentiometer to determine changes in joint angle by measuring voltage during movement.

- o Paired with an Arduino (processor) that has an SD card reader, joint angle can be measured over the duration of walking
- o Data can be collected at desired frequency (100Hz) and then stored on the SD card that can be analyzed later
- o One Arduino and two potentiometers can measure the joint angle of both the knee and ankle at the same time during walking

In order to use the potentiometer on the body, a knee brace and an ankle brace will be altered in order to measure the angle about the knee and ankle, respectively.

Construction of knee device
- o Silicon knee brace with adjustment and tightening straps on top and bottom of the brace can be placed on test subject for alignment of device
- o Knee brace had metal supports on both sides of knee joint to help with stabilization. Supports were removed and replaced with plastic goniometer
- o Then measuring device can be placed on subject
    - • Plastic 12inch goniometer with a potentiometer fixated in the center where the device rotates about

- "Plywood Arm" is attached to the potentiometer and the plastic goniometer to each other so as the goniometer moves so does the dial on the potentiometer thus allowing the Arduino to measure the joint angle
  o The measuring device would be attached to the brace with the potentiometer is aligned with the knee joint center

Construction of the ankle brace
  o Plastic ankle stabilization brace with hinge joint at the ankle joint center
  o Potentiometer is fixated onto the metal hinge joint then another "plywood arm" is placed on the potentiometer dial and the brace so as the top portion of the brace which is attached to the subjects lower shank moves the dial will move
  o Arduino can then measure the ankle joint flexion angle during walking because it reads the potentiometers change in voltage

4.6.4 Accelerometer
Accelerometers created using an Arduino Microprocessor with SD Card Reader and an Arduino acceleration module. The components are placed and soldered to a breadboard making the breadboard an IMU. The breadboard is then placed onto the object of interest to measure the acceleration of the object during the activity. Data is collected at 9.6kHz and stored onto SD card in .csv file.

  o Thigh - Thigh Band and Athletic Tape to place sensor over COM of thigh
  o Shank - Thigh Band and Athletic Tape to place sensor over COM of Shank
  o Foot – Athletic tap to the subjects show over the COM of the foot

Chapter 5. Final Design Verification

Concurrent validation tests between the wearable sensor system and the in laboratory system provided data to assess if there is a statistically significant difference between the two systems. Verification of the system components along with the whole system was conducted and compared against trial data from the in lab system to ensure the sensor system provided expected results and were calibrated as necessary. The devices' precision was tested through different trials and its accuracy to the in lab sensors and literature during the same motion. The code was verified during the trials to ensure both sensor systems provided estimated bone loading. Qualitative assessments were made to test how well the system stood up to design objectives laid out at the beginning of this project.

5.1 Component Verification

Static and dynamic tests were conducted to demonstrate each individual component functioned as intended. The subject for all verification tests were a male and female member of the group. For force verification, the Orpyx LogR system was concurrently tested against the in laboratory force plates to assess if the peak force data from both systems were statistically equivalent. For angle verification, the self-designed angle measurement device was concurrently tested against the calculated joint angle Polhemus motion tracking system. For acceleration verification, the self-designed acceleration device with the calculated acceleration from the second derivative of joint displacement from Polhemus motion tracking system. After preliminary testing each device was calibrated as necessary and retested to ensure the data from each component of the wearable sensor system collected the expected values.

5.1.1 Force Verification

The purpose for each force verification test was to determine if the Orpyx LogR system measures the same force as the laboratory force plates when tested concurrently. Standing, walking, and jumping tests were conducted. To evaluate this, ten trials were conducted for each gender and the peak force of both systems were assessed for each trial. The peak force data for all three tests were analyzed using a 2 tailed paired t-test of the following form:

H_0: $x_1 = x_2$; both peak forces are equal
H_a: $x_1 \neq x_2$; peak forces are not equal

Where, x_1 is Orpyx data and x_2 is laboratory force plate data and if $p > 0.05$ there is not sufficient evidence to reject the null hypothesis and accept that there was no peak difference between the two sensors.

Static test protocol: Subjects stood on the force plate with the Orpyx insole sensors in their shoes. Group members started collecting data on both sensors simultaneously and stopped after 10 seconds.

Walking test protocol: Force plates were set-up and the subject wore the provided shoes with the Orpyx insole sensor. The subject started on a wooden platform the same size as the in laboratory force plates. They stepped forward first landing on a second wooden platform followed by 2 force plates and ended with another wooden platform. Group members started collecting data on both sensors simultaneously and told the subject when to start moving. When the subject was stationary on the last wooden platform group members stopped data collection.

Jumping test protocol: A force plate was setup and the subject wore the provided shoes with the Orpyx insole sensor. The subject started by standing with one foot on each force plate. Group members started collecting data on both sensors simultaneously and told the subject when to begin the trial. The subject bent their knees naturally and jump vertically extending their legs entirely and landed back on the force plate (bending knees slightly to alleviate impact as needed). When the subject was stationary, group members stopped data collection.

5.1.2 Angle Verification

The purpose of the static testing of the self-designed goniometer was to calibrate the sensor using known angles. From the static testing a linear correlation was created to calibrate the sensor. The purpose of the dynamic walking testing was to compare the data concurrently with laboratory sensors to ensure the self-designed goniometer was measuring accurately to within 10% of the laboratory sensors. The angle measurement data output from the goniometer was compared to the angle calculated from the Polhemus position data using trigonometry equations.

Static test protocol: The Polhemus motion tracking device was set-up and sensors were attached to the subject's phalanges, lateral malleolus, lateral condyle of tibia, and greater trochanter. The subject stood in the positive quadrant with respect to the Polhemus motion tracking origin box and all the sensors were turned on. The goniometers were attached to knee and ankle braces and were placed and secured at the joint center of the knee and ankle. The subject stood still in 3 positions, legs extended vertically (180 degrees), legs bent to 135 degrees, and 90 degrees with respect to the ground. A digital angle output was placed on the knee using an analog goniometer and group members checked to ensure the subject was standing at the correct angles. Data was collected on both sensors simultaneously for 5 seconds during each static position. Additional static testing was conducted with an analog goniometer. The self-designed goniometer was attached to the analog goniometer and held at 90 degrees. Once the self-designed goniometer was collecting data, the analog goniometer was moved 10 degrees in the positive direction every five seconds until 270 degrees was reached.

Walking test protocol: The Polhemus motion tracking device was set-up and sensors were attached to the subject's phalanges, lateral malleolus, lateral condyle of tibia, and greater trochanter. The goniometers were attached to knee and ankle braces and were placed and secured at the joint center of the knee and ankle. The subject started on a wooden platform, and walked forward taking 5 steps, first landing on a second wooden platform then alternating between force plate and wooden platform and landing on a wooden platform on the last step. Group members started collecting data on both sensors simultaneously and told the subject when to begin the trial. When the subject was stationary, group members stopped data collection.

5.1.3 Acceleration Verification

The purpose of the acceleration verification tests was to ensure the accelerometers output expected values compared to literature data and the second derivative of the Polhemus motion tracking data. For static testing, the accelerometer was held stationary and dropped. The data collected was compared to the known gravitational

acceleration. If the device was stationary, the axis in the direction of the gravitational acceleration would output 9.8 m/s$_2$. The other two axes would output 0 m/s$_2$. When the accelerometer was dropped an output of 0 m/s$_2$ was expected since the accelerometer was moving in the direction of gravity. For walking data, the accelerometer collected acceleration data and the Polhemus collected position data. In order to compare the two data sets, the second derivative of the Polhemus data was taken to provide acceleration.

Static test protocol: The accelerometer was held stationary such that the x-axis was in the direction of gravity and the y and z-axis felt no acceleration. After three seconds, the device was turned such that the y-axis was in the direction of gravity and the x and z-axis felt no acceleration. After another three seconds, the z-axis was turned in the direction of gravity and the x and y-axis felt no acceleration. Additional tests were conducted by dropping the accelerometer to ensure constant acceleration of 0 m/s$_2$ in the x, y, and z-axis.

Walking test protocol: The Polhemus motion tracking device was set-up and sensors were attached to the subject's phalanges, lateral malleolus, lateral condyle of tibia, and greater trochanter. The laboratory force plates were setup according to their protocol. The accelerometer was mounted on the subject, at the center of mass of the femur, shank, and foot. To find the center of mass, the subject was asked to stand on a scale, and the mass was recorded. From this literature data provided us the expected location of the center of mass. Starting on a wooden platform, the subject walked forward taking 5 steps, first landing on a second wooden platform then alternating between force plate and wooden platform landing on a wooden platform on the last step. Group members started collecting data on both sensors simultaneously and told the subject when to begin the trial. When the subject was stationary, group members stopped data collection.

5.1.4 Wearable Sensor System Verification Assessment

Table 5.1 shows the assessments of the components of the wearable sensor device after component verification. Each category was given "neutral", "yes", or "no" based on whether they met, exceeded, or fell short of the design requirement respectively.

Table 5.1. Assessment of device components

Design Requirement	Force	Acceleration	Angle
Durable	Yes	Neutral	Neutral
Collect 1 hr of Data	Yes	Yes	Yes
Portable	Yes	Yes	Yes
User Friendly	Yes	No	Neutral
Comfortable	Yes	No	No
Sufficient Data Storage	Yes	Yes	Yes
Battery Life of 2 hours	Yes	Yes	Yes
Resizable/Adjustable	No	Yes	Yes

5.2 Overall Design Verification

After component verification, the integrated wearable sensor system was tested through initial male and female trails on the group. This was used to verify the usability of the system and ensure the sensors collected the required data and the code provided estimated bone loading. The purpose of this testing was to ensure the sensor system data and the protocol for using the sensor system and testing were all repeatable and consistent. This ensured subject testing was efficient and the data collected was valid. The testing protocol followed that of the subject testing protocol. Four trials of walking were conducted for each per gender to calculate joint reaction forces and joint reaction moments and estimate bone loading. The tests included five meters of walking. The data collected was put through the code which estimated bone loading. The entire system was assessed against the original design requirements to determine if the device met the design goal. Table 5.2 shows the assessment of the integrated wearable sensors system against the design requirements using the same criteria as Table 5.1.

Table 5.2: Assessment of wearable sensor system

Design Requirement	Integrated Wearable Sensor System
Durable	Neutral
Collect 1 hr of Data	Yes
Portable	Yes
User Friendly	Neutral
Comfortable	No
Sufficient Data Storage	Yes
Battery Life of 2 hours	Yes
Resizable/Adjustable	Neutral

5.3 Subject Testing

Beta testing of the integrated wearable sensor system was conducted through initial testing on group members. The estimated bone loading was compared to the in laboratory system and literature data. Additional assessments of the usability of the system was conducted with additional comments and concerns. The wearable sensor system was assessed against the design requirements to evaluate if the system met the design goal.

5.4 Data Collection Results

5.4.1 Force Verification Data

All data was collected concurrently between the Orpyx insole sensors and the laboratory force plates. Figure 4.1-4.3 show example graphs of standing, walking, and jumping tests respectively. These tests were conducted to understand the limitations and accuracy of the system compared to the laboratory force plates.
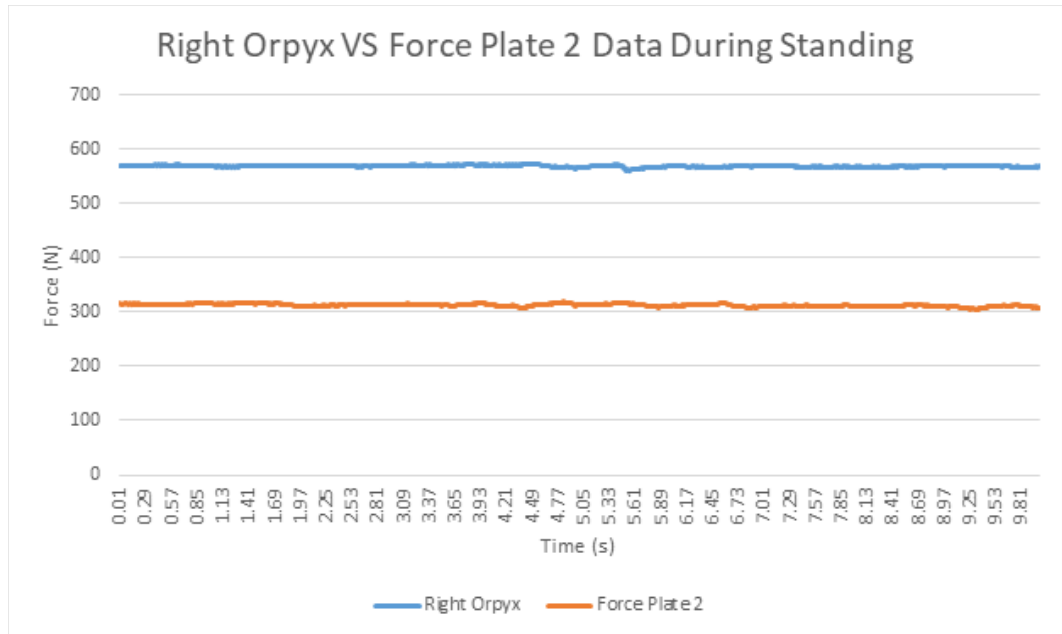
Figure 5.1. Comparison of right Orpyx insole against Force Plate
during standing over time.
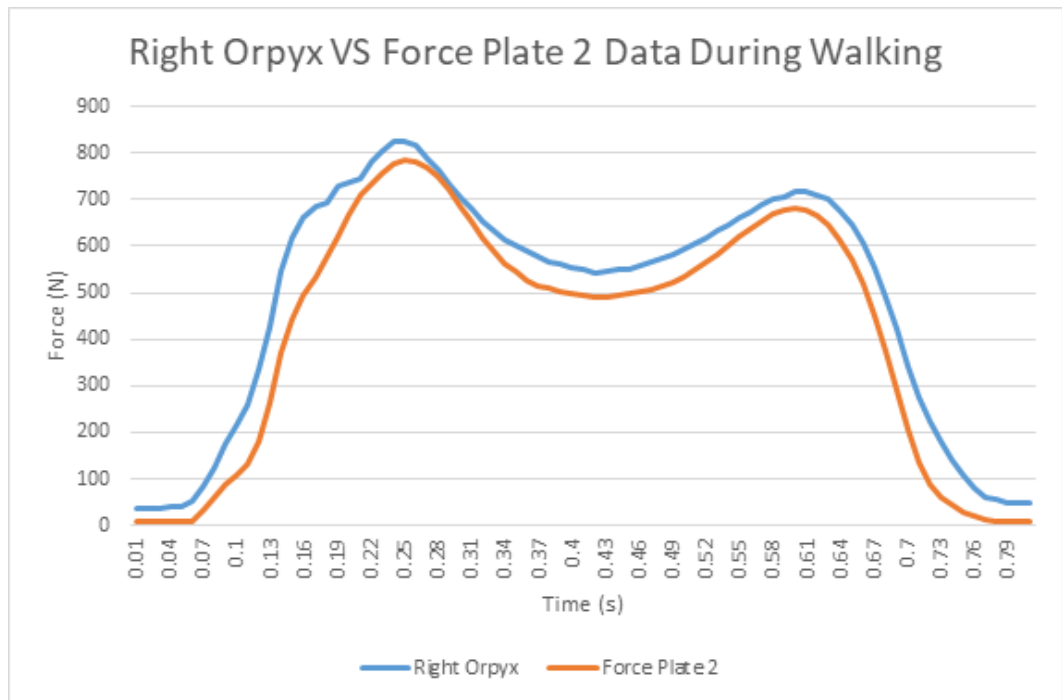
Figure 5.2. Comparison of right Orpyx insole against Force Plate
during foot strike to toe-off over time.
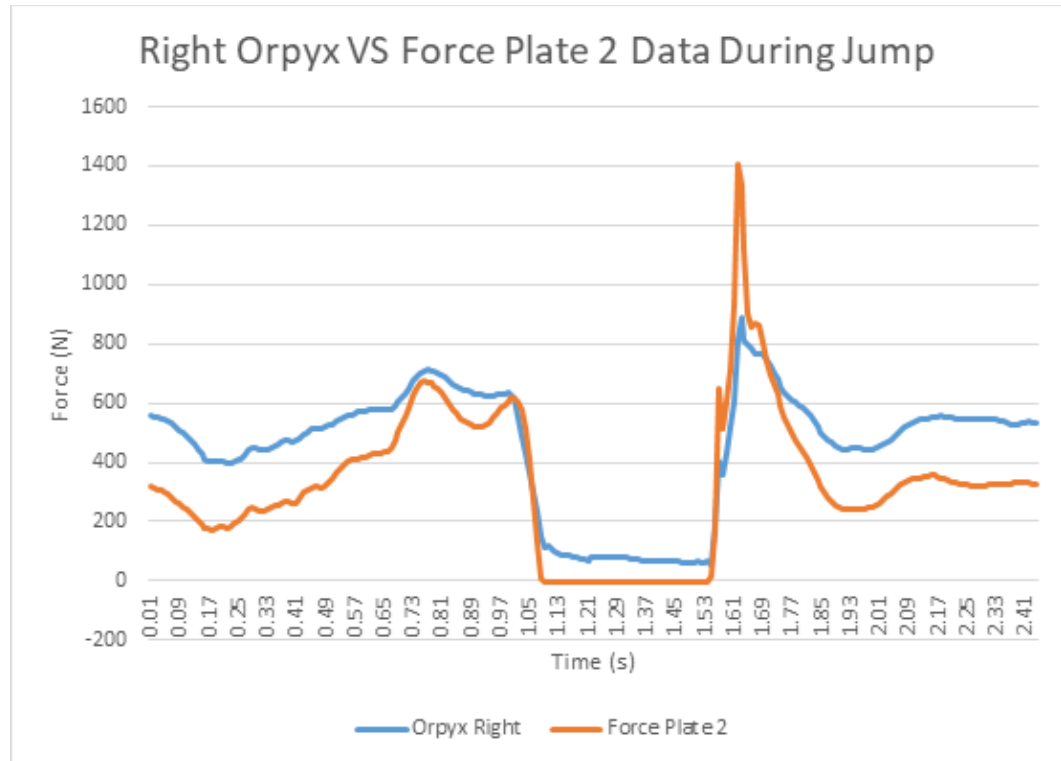
Figure 5.3. Comparison of right Orpyx insole against Force Plate
during jumping over time.

5.4.2 Angle Verification Data

Static testing was conducted to ensure the goniometer output the same angle as an analog goniometer. The goniometer was secured onto the analog angle output, calibrated so that both devices output 180 degrees. The analog goniometer was brought to 90 degrees and moved in 10 degree increments until it reached 270 degrees. Figure 5.4 shows the graph of analog goniometer vs digital goniometer output from the static testing. The purpose of the static testing was to assess if the goniometer output the expected angle and to calibrate the device as necessary. For the walking test, goniometer data was collected concurrently with the laboratory Polhemus system to verify the goniometer output produced the same data as the Polhemus system during walking. Using trigonometric equations, knee and ankle flexion angle was calculated from the Polhemus data. The Polhemus data showed a significant amount of noise and was incomparable to literature and goniometer data. For this reason, Figure 5.5 and 5.6 shows ankle and knee flexion angles compared to literature data respectively. Additional goniometer data can be found in Appendix G.
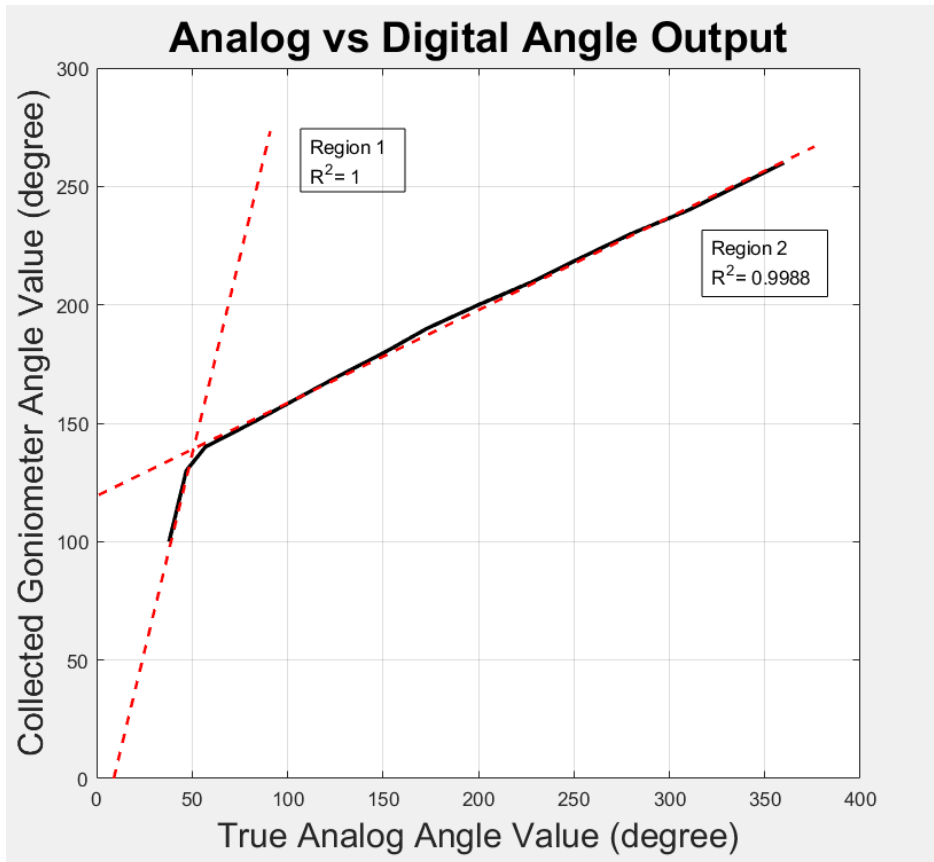
Figure 5.4. Comparison of self-designed digital goniometer against known angle values from analog goniometer.
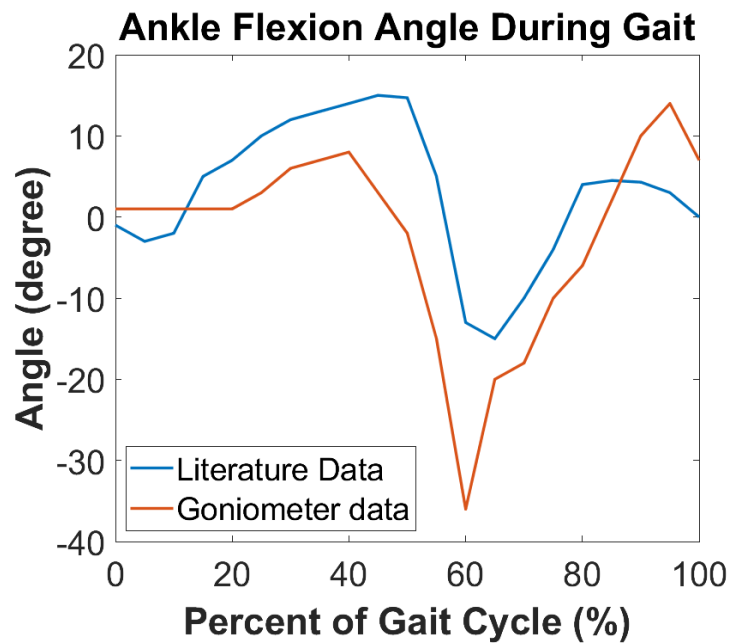
Figure 5.5. Comparison of self-designed goniometer on ankle against ankle flexion literature data during one gait cycle [31].
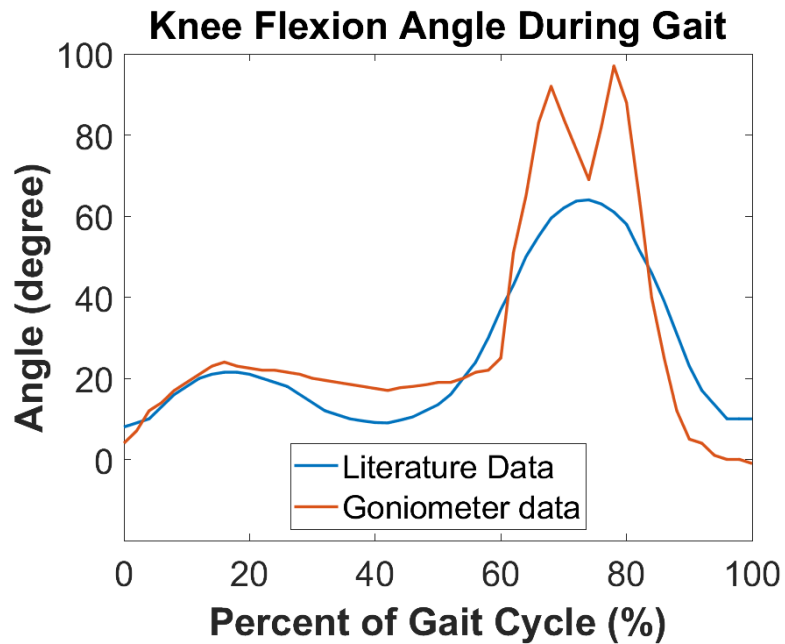
Figure 5.6. Comparison of self-designed goniometer on
knee against knee flexion literature data during one gait cycle [32].

5.4.3 Acceleration Verification Data

Each three axis of the IMU (X ,Y, and Z) were exposed to the gravitational force. The values collected were compared to the known value of gravity ($9.81 \mathrm{m/s^2}$) to determine the accuracy of the IMU. Figure 5.7 shows the static test performed on the shank IMU.
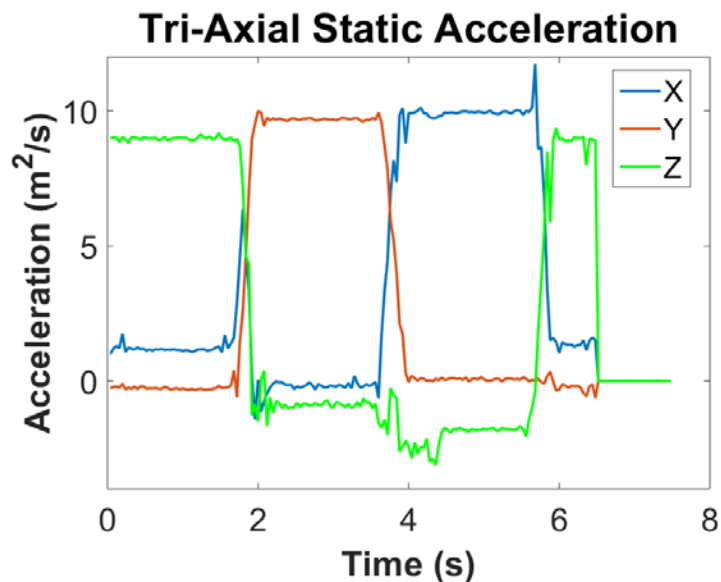
Figure 5.7 Gravitational acceleration measurement of each
axial component on the designed accelerometer.

Similarly to the static test, a drop test was conducted on each IMU to ensure when each axis was dropped, its initial reading was 9.81 m/s² and dropped to zero as it accelerated toward the ground. Figure 5.8 shows the results of the drop test done to the shank IMU.
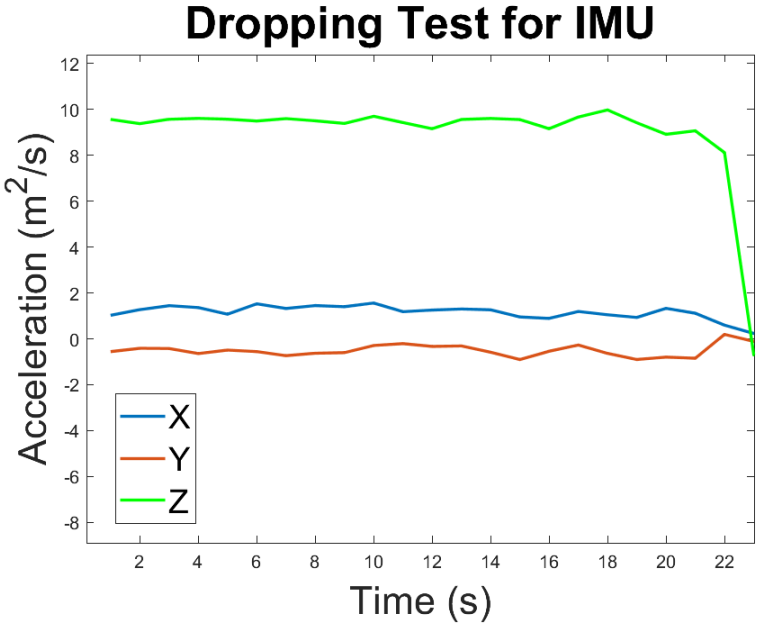
Figure 5.8 Drop test of the self-designed accelerometer.

5.4.4 Configured Wearable Sensor Verification Data

The raw data collected from the goniometers and the IMUs were placed into the equations of motion for each body segment via a MATLAB script to determine the JRF and JRM of the knee and the ankle. These values were then compared to literature data to analyze the trends, peaks, and troughs for accuracy. Figure 5.7 shows the JRF of the ankle compared to literature data and Figure 5.8 shows the JRM of the ankle compared to literature data.
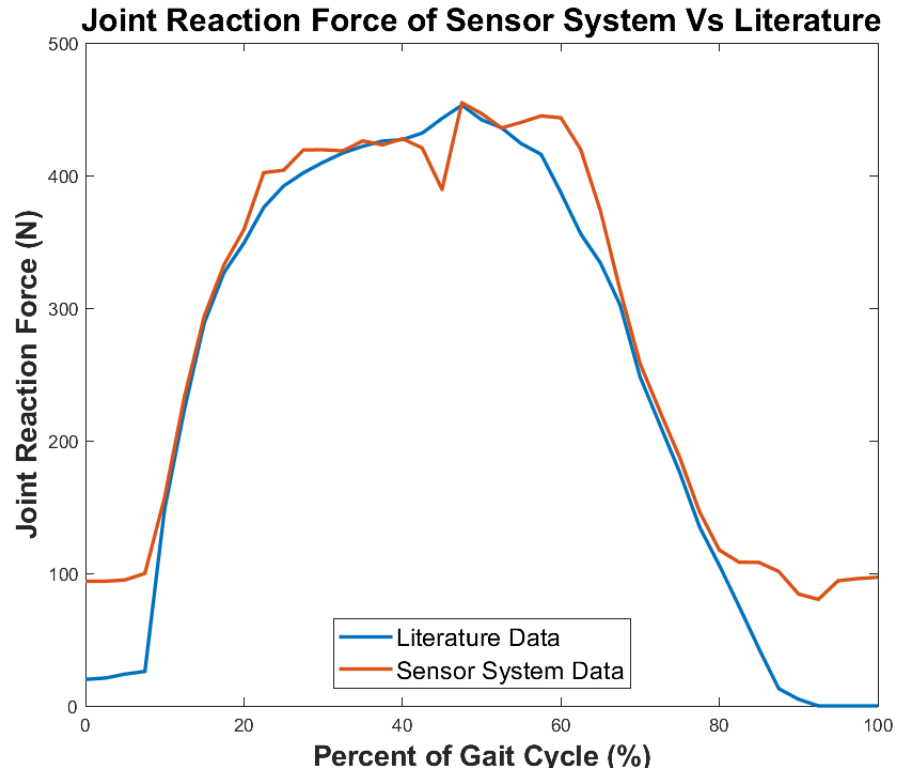
Figure 5.9 Comparison of joint reaction force between calculated from the wearable sensor system and literature data [33].
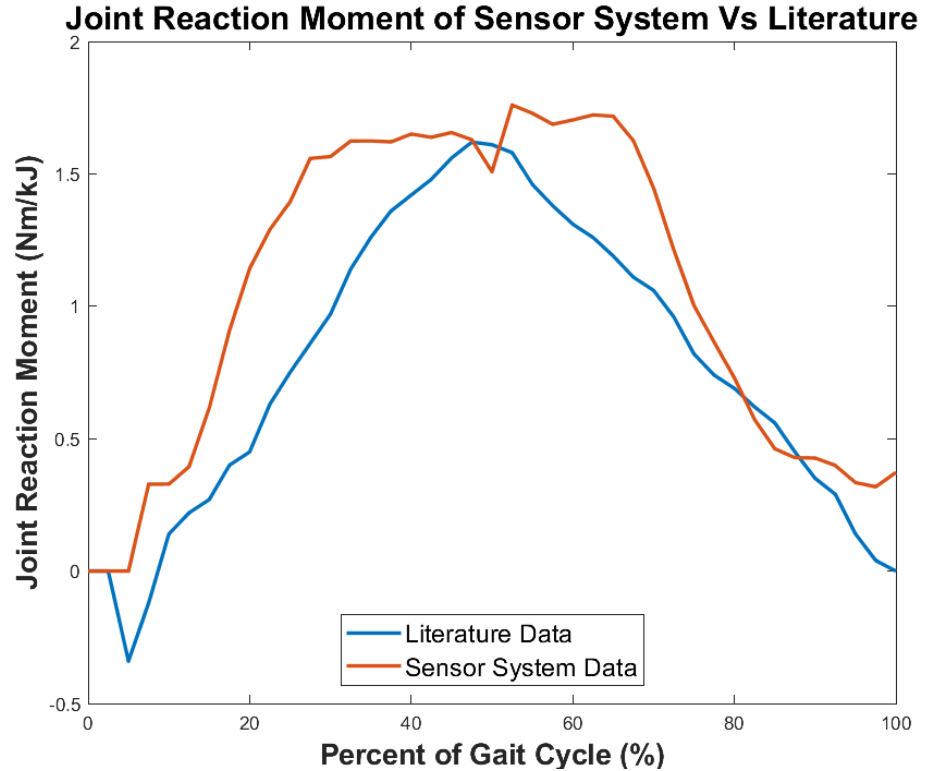
Figure 5.10 Comparison of joint reaction moment between calculated from the wearable sensor system and literature data [34].

5.5 Data Analysis

5.5.1 Force Data Analysis

Concurrent force data during standing, walking, and jumping was collected using the Orpyx LogR system and in laboratory force plates. The Orpyx insole sensors collected pressure data on the eight sensor locations embedded in the insole. The program provided by the Orpyx insole sensors derived the estimated force from the pressure data through the estimation of area the foot contacted the ground. Due to these assumptions it poorly estimated static forces and overestimated standing force. For walking and jumping data, the Orpyx insole sensors followed similar trends as that of the forces plates as well as literature data. The Orpyx insole sensors over tended towards the over estimation of force and consistently missed the peak jumping force. Since the Orpyx insole sensors were placed inside the shoes secured to the foot, there were forces on the foot even when the subject was not exerting forces, as shown during the aerial phase of a jump seen from 1.1-1.55 seconds in Figure 4.3.

5.5.2 Angle Data Analysis

Concurrent testing of the Polhemus sensor system and goniometer device showed that the Polhemus sensors were affected by hardware malfunctions and the collected data was additionally affected by the noise created by metal in the surrounding laboratory space. Due to these limitations, the collected goniometer data was collected and compared to knee and ankle flexion data from literature data collected from gait studies. These data showed that the goniometer followed similar tends compared to literature. The knee angle data showed closer similarities to the literature data than the ankle angle data. A more secure ankle brace would provide less error in the data collected. Both knee and ankle goniometers overestimated or missed peaks during data collection. A higher sampling frequency would improve data collection.

5.5.3 Acceleration Data Analysis

Figure 5.7 shows the values collected from the static testing of the shank IMU. The peak value of the X-axis when it was exposed to the gravitational force was 8.97m/s^2, the peak value of the y-axis was 9.68m/s^2, and the peak value of the z-axis was 9.82m/s^2. The difference in the axis peak values and the known gravitational force of

9.81m/s^2 is most likely due to the fact that the IMU was not completely level with the breadboard causing each value to be a bit lower or higher than the known value.

Figure 5.8 shows the results of the dynamic drop test of the IMU. The X and Y axis values were 1.36m/s^2 and -0.64 m/s^2 respectively. The Z axis, which was the axis that was exposed to the gravitational force, started at 9.60 m/s^2 and ended at -0.67 m/s^2 after dropped. The deviation from the known values of 9.81m/s^2 and 0m/s^2 are most likely due to the IMU not being completely level with the breadboard leading to a difference in starting values.

5.5.4 Configured Wearable Sensor Data Analysis

Figure 5.9 shows the values of JRF calculated from the collected raw data of the sensor system compared to the literature values found for a similar biomechanical study. The overall trend of the curves are almost identical, but the sensor system missed the peak value. This is most likely due to a sampling rate that was too low to detect the peak value.

Figure 5.10 shows the values of JRM calculated from the collected raw data and the equations of motion for each body segment. These values were then compared to the values found from a similar biomechanical study. The overall trends of the two curves are very similar, but, much like the JRF calculations, the sensor system misses two peaks which results in the sensor system continuously overestimating the JRM of the ankle during the gait cycle.

5.6 Statistical Analysis

5.6.1 Force Data Statistical Analysis

Analysis of the data from concurrent force verification tests was conducted by using a 2 tailed paired t-test of the peak force of both devices. This analysis showed that there was a difference between the peak forces of the Orpyx LogR system and the laboratory force plates during standing, walking, and jumping. The focus of the tests were on walking data, which the sensors most accurately collect. The data showed the Orpyx

LogR system overestimated by 9.4% for the male subject, and 5.7% for the female subject when compared to the force plates.

5.6.2 Angle Data Statistical Analysis

Concurrent angle data collection during standing showed that the goniometer needed to be calibrated in order to produce the expected angle. The data showed two linear regions and a linear fit curve was used to determine the linear calibration for the device. The first region ranged from 90-140° and the linear equation was y=3.33x-26.67. The second region ranged from 140-270° and the linear equation was y=0.39x+119.69. The linear fit equations had R_2=1 and R_2=.9988 respectively. The linear equations were used in MATLAB code to calibrate the device post data collection. Due to limitations of the laboratory Polhemus sensors, concurrent validation of the goniometer could not be assessed.

5.6.3 Acceleration Data Statistical Analysis

Data collected from the IMU during the gait cycle was to be compared to the Polhemus data collected in lab to verify accuracy. However, due to the Polhemus not functioning properly this data could not be obtained. Due to this no statistical test could be run to determine the accuracy of the IMU.

5.6.4 Configured Wearable Sensors Data Statistical Analysis

The calculated data was to be compared to the data calculated from the raw data obtained from the Polhemus. Similar to the IMU, due to the fact that the Polhemus did not function properly the raw data could not be collected and no statistical test could be done to verify the accuracy of the system.

Chapter 6. Design Verification: Discussion

6.1 Economics

While the current prototype of this project's wearable sensor system does not directly affect the economics of everyday living there exists the potential for it to one day. With improvements to sensor system the device could be not only used in a research setting but also in a commercial setting. In research the device can be used to further knowledge in the field of biomechanics and further improve our understanding of bone loading and the bone remodeling cycle. Additionally the system would overcome the limitations of the current laboratory system and allow for more testable activities to collect more data to be analyzed. In the commercial setting this system if further developed and enhanced could be sold as a consumer product. This device could then help impact the way people perform their daily activities to improve bone health. Additionally it could be used as a tool to help prevent low BMD so that the risk of fracture decreases as a person ages.

6.2 Environmental Impacts

The use and creation of this product will have no direct effect on the environment. The environmental impact of the product will be tied to the manufacturers of the individual sensors of the system. This means that any increase/decrease in environmental impact associated with the sensor system will be the cause of any measures adopted by the manufacturers of the sensors that comprise the system.

6.3 Societal Influence

This product is designed to measure the loading experienced by the tibia over time to show any difference in bone density. In doing this the product could bring the problem of osteoporosis to the forefront of medical discussion. This would in turn increase both awareness of the disease and efforts to prevent it from developing. The system can help people modify their behaviors in ways they do physical activities or activities they do on a daily basis. By modifying their behavior this will lead to performing tasks in manners that will help decrease the chance of developing osteoporosis as a person ages. If this occurs the number of people, the severity and the number of injuries associated with osteoporosis could drop significantly due to this product.

6.4 Political Ramifications

As mentioned previously this product is designed to address the problem of osteoporosis. If successful, this product could bring a change in the way that people look at exercise and low bone density prevention. This could potentially change the culture of the entire world by putting more emphasis on living a healthier life in order to prevent the effects of low bone density and improve the lives of everyone.

6.5 Ethical Concerns

The current prototype of the wearable sensor system developed in this project is not a marketable product. Due to this, there are no significant ethical concerns related to the device designed or the testing performed in this study. Therefore the ethical concerns of this study are not applicable.

6.6 Health and Safety Issues

As mentioned earlier Osteoporosis effects a lot of individuals and causes numerous injuries every year. With this product, the possibility of modifying activities to help promote healthier bone loading can help decrease the likelihood of developing osteoporosis as a person ages.

6.7 Manufacturability

This wearable sensor system was produced using off the shelf sensors already on the market coupled with a MATLAB script written in the C format. Along with the code and the sensors, the use of athletic tape and prewrap were used in order to securely attach the sensors to the body segments. With an appropriate budget and experience in both mechanics and computer science a team of individuals would have little problem reproducing the end product. With a larger budget and individuals with a bit more experience in the required fields the product could even be improved from its current state.

6.8 Sustainability

The wearable sensor system utilizes an onboard battery that needs to be changed or charged in order for continued use. Due to this factor, any issues with regards to sustainability associated with the use and disposal of batteries would apply to this system. With further development of this system, given more time and a larger budget, this system could potentially

use a renewable energy generator to either charge the battery or power the system in order to decrease or eliminate this sustainability impact.

Chapter 7. Final Design and Validation

7.1 Overview of Final System Design

The wearable sensor system design consisted of three components to configure the whole system. Each of these components had a specific value to measure. The system needs to be able to measure the following during a one gait cycle, the ground reaction forces acting on the foot, the flexion angle of the knee and ankle, and finally the acceleration of the foot, shank, and thigh of the person. With these measurements, MATLAB code would then be used to calculate the Joint Reaction Force (JRF) and Moments (JRM) acting on the tibia during gait. The MATLAB code was created using biomechanical calculations with equations of motion. The values collected by the componentry of the system are then used in each of the equations to calculate the JRF and JRM at each data point. From there a graph can be produced showing the JRF and JRM acting on the tibia changing during the entire duration of the exercise.

The first component of the system is the ground reaction force (GRF) component. This component of the system measures the GRF that acts on the subject's foot during one gait cycle. In the laboratory method this is accomplished using force plates configured in a manner that suits the activity being tested. This limits the number of activities and real-world exercises that can be tested due to the force plates being so large and not being portable. To overcome this our system utilizes in-sole pressure sensors created by a company called Orpyx. The inserts are wireless thanks to a Bluetooth module attached to the insoles and the measurements the shoes make can be transmitted via Bluetooth to an app on a phone showing the real time pressure readings. Once done using the insoles the data is then saved into an excel file and stored on the Orpyx cloud drive which can be accessed using the insoles identification credentials. The excel file can then be used in our MATLAB script to be used to calculate the necessary values.

The inserts have eight pressure sensors placed at location on the insole. The pressure sensors have a pressure transducer in them which has a sensing element of a constant area. The element responds to the force applied to the area by fluid pressure. The force applied will deflect the diaphragm inside the transducer and this is then measured and converted into an electrical output. The electrical output can then be calibrated to correspond with the correct

pressure being applied and the time. This creates a sensor that can measure the pressure applied to it and then convert it to psi or Newtons using a microprocessor or computer. The sensors created by Orpyx can be placed in either size 7.5 women's shoes or size 10.5 men's shoes under the shoes regular insole. The sensors embedded in the insoles can measure 0-75 psi and the sampling frequency is 100 Hertz. With the measurement range and the frequency of the device these sensors are acceptable to be used as our GRF component of our sensor system to measure JRF and JRM during gait. An image of the insole pressure sensors can be seen in Figure 7.1.
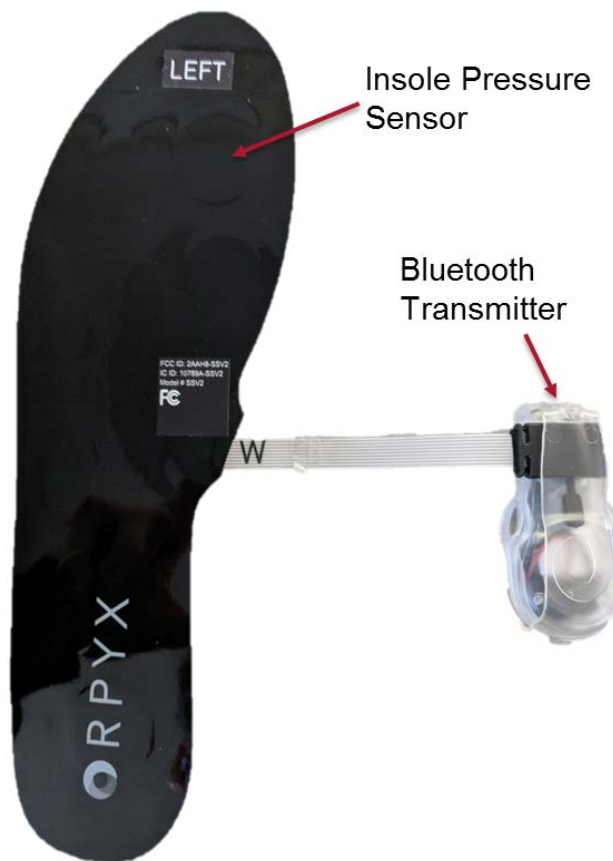
Figure 7.1. Orpyx® LogR insole sensor.

The second component of the system would be the flexion angle component. This component of the device will measure the flexion angle of the knee and ankle during one gait cycle. The flexion angle of the joints influences the magnitude of the forces acting on the joint and body segment. Making it crucial to calculating JRF and JRM during gait. In the laboratory method this is accomplished using a motion capture system or fiducial markers. The vectors of the

relative body segments are measured, and the flexion angle is calculated using trigonometry. Portability becomes an issue and limitation of this method because it means you must measure flexion angle in a lab thus restricting the number of activates that can be tested. A wireless goniometer can be used to measure the flexion angle of each joint but due to budgetary restrictions impossible to purchase any goniometers. Our system employs a student built attachable and wireless "goniometer." Our device can measure flexion angle due to a Potentiometer, which is a manually dial adjustable variable resistor with 3 terminals. Two terminals are connected to both ends of a resistive element, and the third terminal connects to a sliding contact, called a wiper, moving over the resistive element. The position of the wiper determines the output voltage of the potentiometer. Using a microprocessor and code the voltage can be used to measure the angle of the dial which can correspond to the angle of the joint of interest. For our device 2 potentiometers were connected to microprocessor datalogger with an SD card slot. A schematic of the connection between the potentiometer and the datalogger can be seen in Figure 7.2.
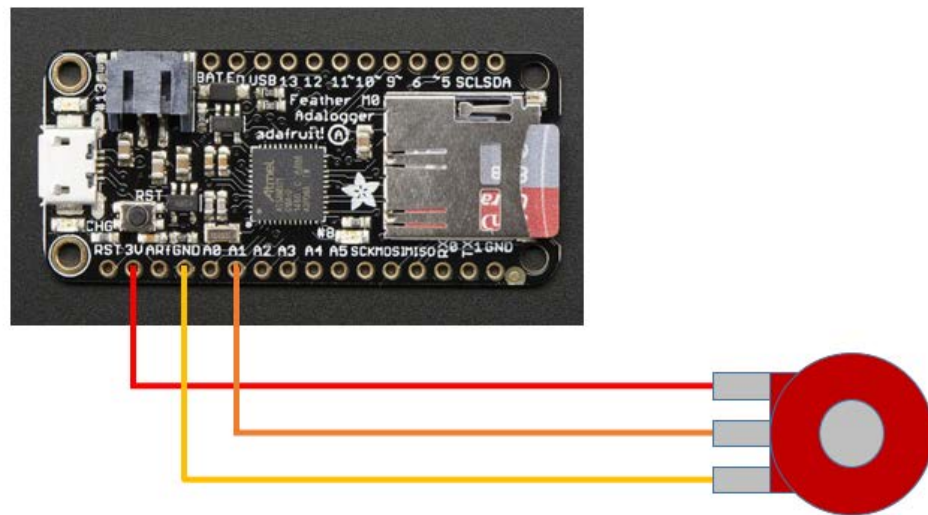
Figure 7.2. Wiring schematic of potentiometer component of the electric goniometer connecting to datalogger.

One potentiometer was attached to a plastic ankle brace with a hinge joint located over the ankle joint center. The other potentiometer was attached to a plastic goniometer, the potentiometer was placed at the center of the goniometer over the hinge joint. Two "Arms" were created using plywood and attached to the dial of the potentiometer with the moving arm on the goniometer and the top portion of the ankle brace. With this set up a

microprocessor datalogger with an SD card slot and working code can calibrate the dial of the potentiometer with the corresponding angle. Figure 7.3 and 7.4 show the knee and ankle components of the goniometers.
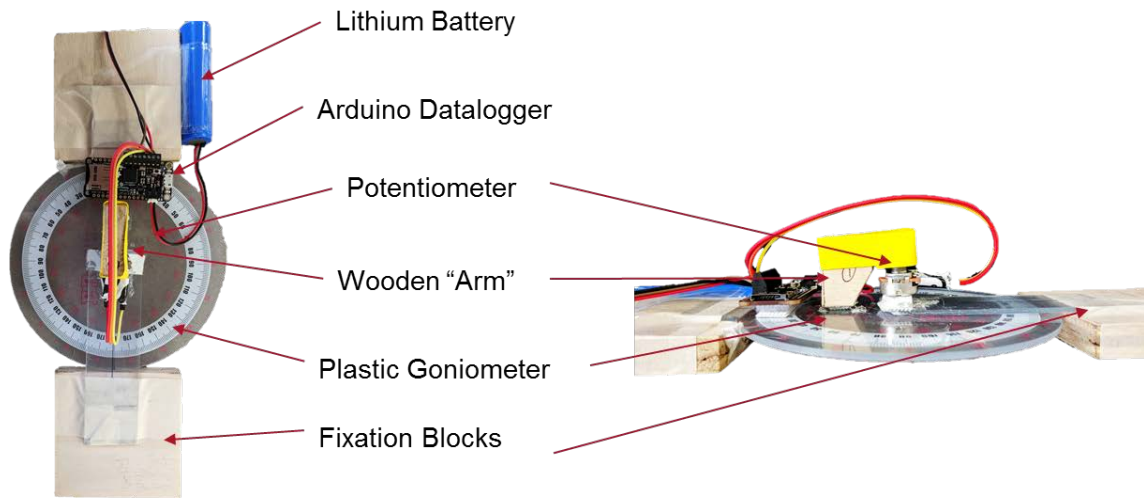
Figure 7.3. Front (left) and side (right) view of digital goniometer for knee joint.
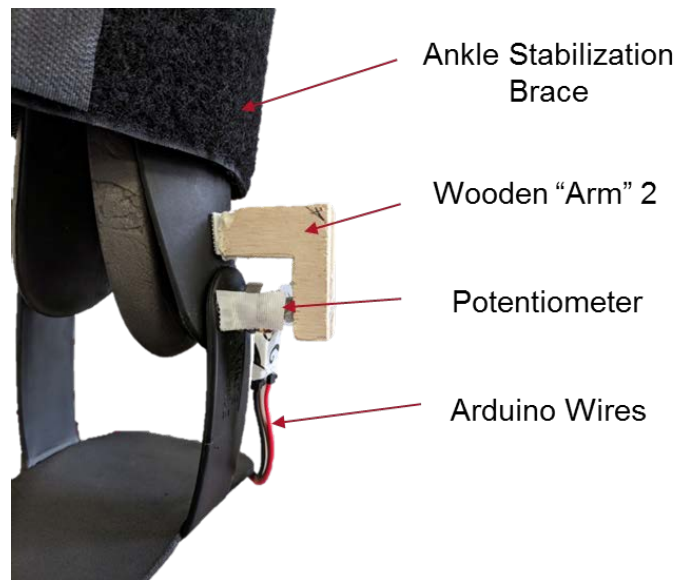
Figure 7.4. Digital goniometer attached to ankle brace for ankle joint.

When attached to the test subject, these components measure the flexion angle of the knee and ankle during the duration of the walk. This data is then saved as a .csv file onto a SD card, which can later be used in our main MATLAB code to calculate the JRM and JRF of the tibia

during gait. Figure 7.5 shows the flexion angle components attached to a test subjects right leg.

Figure 7.5. Knee and ankle goniometer devices on test subject

The third and final component of the systems is the acceleration component. These measure the acceleration of the foot, shank, and thigh of the test subject during gait. In the laboratory method this is accomplished wither using a motion capture system or an Inertial Measurement Unit (IMU). Both systems can measure the acceleration of the body segment of interest. Using a motion capture system once again limits tests to laboratory facilities and limits the amount of activities one can test. IMUs help overcome this with since they are wireless, but they usually cost over $1,000 a sensor. Three wireless IMUs would be needed in our system and with our budgets restricted to $1,000 it was impossible to purchase even one IMU. Our system employs three student built wireless IMUs using an accelerometer/gyroscope module in combination with a microprocessor with an SD card slot. An accelerometer is an electromechanical device that measures an object acceleration forces. A schematic of the IMU can be seen in Figure 7.6.
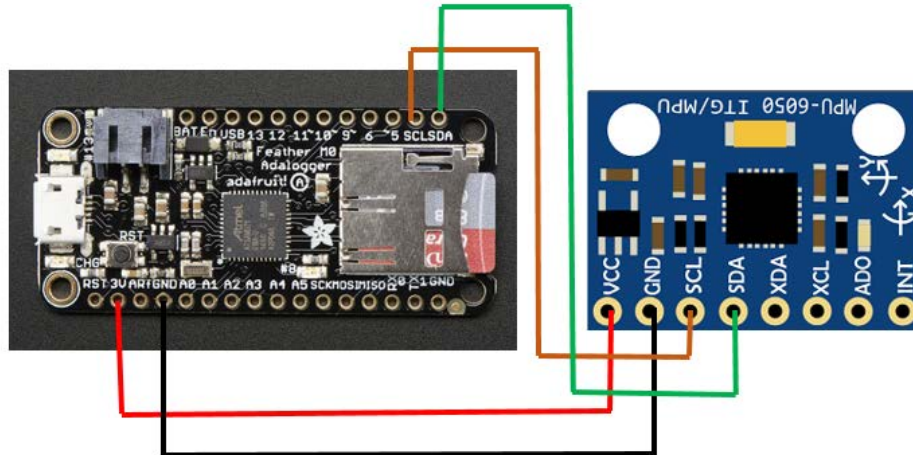
Figure 7.6. Wiring schematic of IMU to datalogger.

The module and microprocessor were fixated to a breadboard which can then be fixated over the center of mass of body segment of interest to measure the acceleration of the segment during one gait cycle. The data measured is then saved in a CSV file onto a SD Card which can be used later in our main MATLAB code to calculate the JRM and JRF of the tibia during gait. Figure 7.7. shows all three IMUs fixated to a test subjects right leg.

Figure 7.7. Three accelerometers attached to subject's lower limb
at the center of mass of the thigh, shank, and foot.

7.2 System Manufacturing

Manufacturing the sensor system consisted of building the three components one at a time starting with the GRF component, followed by the flexion angle component, and the acceleration component was built last. The components were built using off the shelf sensors and componentry which is an objective of the project. The GRF component of the sensor system consisted of a pair of Orpyx Wireless In-Sole Pressure Sensors. The sensors were purchased by the WPI Biomedical Engineering Department and were provided for us to use for our sensor system.

The Flexion angle component was the most challenging sensor built since it required integrating electronic components with mechanical ones. First step was purchasing the necessary componentry which included a plastic 12-inch goniometer, one plastic ankle stability brace, one silicon knee stability brace with metal supports, 4 pieces of plywood (3inx3inx0.5in), two pieces of industrial strength Velcro, 2 potentiometers, a cylinder lithium battery, a microprocessor board with a SD card slot, 8GB SD card, gorilla glue, male and female ended breadboard wiring. The first step of the manufacturing the device was fixating the potentiometers to the ankle brace and goniometer. This was done using gorilla glue, on the ankle brace the potentiometer was glued onto the circular metal hinge joint on the brace. On the goniometer the potentiometer was glued to the center hinge joint of the goniometer so that the potentiometer moved with the moving arm of the goniometer. Once fixated properly the next step was to fabricate the "arms" that will allow the dial to spin and change the voltage in the potentiometer to correspond with the flexion of the knee and ankle. Measurements were taken using a caliper so that the proper dimensions could be used to build the "arms." Once the measurements were taken sketched of the two "arms" were placed onto a piece of plywood each so that the cuts could be made using a vertical band saw. A drill with a 0.25-inch drill bit head was then used to drill the holes into each "arm" so the dial of the potentiometer could be fixated to the "arm."

Once the "arms" were cut then then were fixated to each device, one to the ankle brace and one to the goniometer. On the ankle brace the device was situated to the right lower support of the brace using gorilla glue and then once the arm was fixated to the brace the dial of the potentiometer was glued to the "arm" within the hole drilled into it. This then allowed the dial

to spin with the flexion of the tibia once properly attached to the test subject. A visual representation of the "arm" on knee component of electronic goniometer can be seen in Figure 7.8.

Figure 7.8. Side view of wooden "arm" for potentiometer fixation on electric goniometer.

For the goniometer the "arm" was attached to the non-moving portion of the goniometer using gorilla glue, then the dial was fixated to the "arm" in the hole drilled. This then allowed the dial to move with the flexion of the knee once properly attached to test subject. The remaining two blocks of plywood were then fixated to the arms of the goniometer using tape, this was done so that the device could be attached and aligned to a test subject both properly and with relative ease. The microprocessor was attached to the goniometer using Velcro with an adhesive side so that board could be secure on the goniometer during. The lithium battery that powers the processor was fixated to the side of the bottom plywood block, so it could be in a spot that wouldn't impede the test subject when worn. The device was then placed onto a test subject following the attachment protocol which can be found in Appendix I. These measurements were taken to determine the length of wiring needed to connect both potentiometers to the port. The wires were then fixated to the board via a terminal block and could be attached to the potentiometers when needed. The wire schematic seen in Figure 7.2 was used to wire both potentiometers to the microprocessor datalogger fixated to the plastic goniometer.

The acceleration component of the system was all-electronic componentry. The schematics for wired the microprocessor were found online on the Arduino Library. The datalogger microprocessor and accelerometer/gyroscope module had pins soldered to them so that each

component could be integrated to the breadboard. On a breadboard the microprocessor was attached to terminals 1 to 18. The acceleration module was then attached to the breadboard in terminals 26 to 34. We then followed the wiring schematic seen above in Figure 7.6. This process was repeated two more times and a total of three accelerometers were made in the same procedure. Figure 7.10 below shows a completed IMUs.
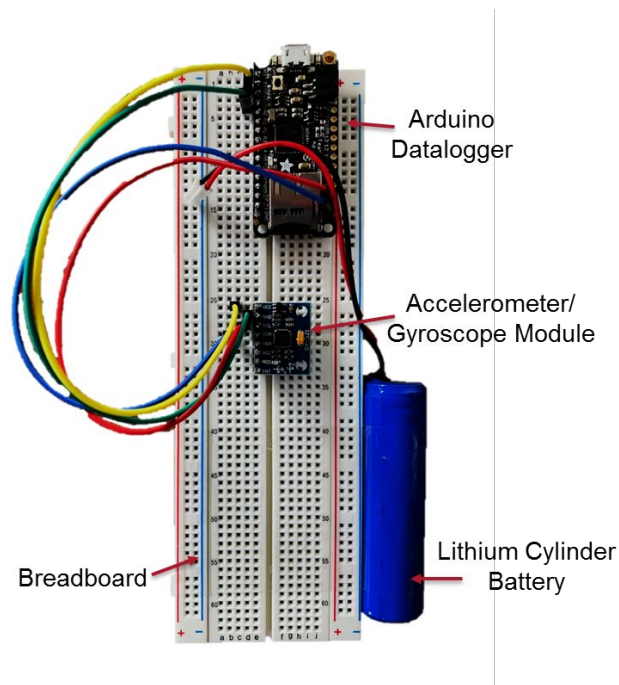
Figure 7.9. The designed IMU fixated to a breadboard featuring the datalogger, accelerometer/gyroscope module, and lithium battery.

7.3 System Operation

Operation of the sensor system involves two phases, the first phase is attachment and then data collection. The first step involves attaching all the system components to the test subject. This process involves attaching the angle measurement device, the three inertial measurement units (IMU) and the Orpyx In-Sole Pressure Sensors. The Orpyx sensors are placed into the test shoes provided by the team. The angle measurement device is attached next, this starts by having the test subject will place on a silicon knee brace onto their right knew. This is done so that the knee flexion component of the angle measurement device can be aligned and secured properly for testing. Next the test subject will place then ankle flexion component onto their right ankle. Once that is done the test subject will stand up and remain standing for the knee flexion component to be attached. This is done by aligning the wooden blocks of the component with the straps on the knee brace above and below the joint center. The

component is then secured using athletic tape and taping the plywood blocks to the knee brace. If done correctly the potentiometer at the center of the component will be aligned with the knee joint center. Then plug the wires running from both potentiometers to the microprocessor terminal block. Any slack in the wiring would then be addressed with athletic tape to eliminate the threat of tripping the test subject during gait. Finally, the accelerometers are attached, one to each of the three body segments of interest. Using the values take from literature and the height of the test subject the distance from the bony landmarks to the segment center of mass. Table 7.1 shows the specific values of literature which were used taken from Winters "Biomechanics and Motor Control"

Table 7.1. Literature Values for Estimation of Bone Loading

Body Segment	Segment Weight	CoM (Proximal)	CoM (Distal)	Radius of Gyration (CoG)
Foot	0.0145(Mass)	0.50 (Segment Length)	0.50 (Segment Length)	0.475 (Segment Length)
Leg/Shank	0.0465(Mass)	0.433 (Segment Length)	0.567 (Segment Length)	0.302 (Segment Length)
Thigh	0.100(Mass)	0.433 (Segment Length)	0.567 (Segment Length)	0.323 (Segment Length)

Using athletic tape the accelerometers will be attached to the body segment over the center of mass. This allows us to measure the acceleration of the body segment during gait.

The final phase of operating the sensor system is data collection. Once properly attached and calibrated all that is needed is to start and stop the data collection on each component. For the Orpyx sensors the data collection is controlled via a phone application that starts and stops each session. The rest of the components are designed to be controlled by a button located on each microprocessor. Each microprocessor can be coded so it starts recording on an initial push and then stops recording on the second push. The next time the button is pushed it will then start the process over with a new data file for data collection, each time a new CSV file is created and saved with the data for each trial. So, to operate the system, the test subject will stand on the end of the wooden platform to perform one gait cycle. The buttons on all the system components are then pressed to begin the data collection of the trial. While this is happening, the Orpyx are also recording data through a phone and the data is being stored onto the cloud while the other components store their data to an SD card. After the recording

has been initiated on all components the test subject performs one gait cycle. Once completed the buttons on each component are then pressed to stop data collection. Each SD card is then taken from each microprocessor and all the CSV files containing the raw data are saved to a computer along with the CSV file of the data collected by the Orpyx. The data is then ready to be put through a MATLAB code that will calculate the joint reaction forces and moments acting on the tibia during gait. The SD cards are returned to the microprocessors and the Orpyx are recalibrated to collect new data. From there the process repeated again for each trial and variation of the experiment until all the necessary data is collected to be analyzed. Once finished the system is taken off the test subject by the team and this concluded the operation of the sensor system.

7.4 Experimental Methods and Data Analysis

To validate the wearable sensor system, first static testing was conducted to calibrate the components of the system. Static testing included constant force on the Orpyx insole sensors and maintaining the goniometer and accelerometer at known angles and accelerations. After component calibration, dynamic testing was conducted to assess the accuracy and precision of the components during walking. The system was integrated to collect data to estimate bone loading from joint reaction forces and moments. This was conducted by mounting the wearable sensor system on the subjects' lower right limb. The team assisted in the attachment of all sensors to confirm they were correctly located on the joint centers and segment centers of mass. The subjects took five steps forward starting with their left leg. This ensured that data were consistent between all trials.

Repeatability of the data was produced from the male and female subject during static and dynamic testing. The Orpyx insole force data followed similar trends with the laboratory force plates but had a tendency to overestimate force. This was due to the assumptions the Orpyx LogR program used to estimate force from the collected pressure data. Knee and ankle angle data during walking similarly showed trends with literature data. A higher sampling frequency would have provided more accurate peak angle data during gait. The knee angle showed a closer trend to literature compared to ankle data. This was due to the loose fit and high restriction of the ankle brace. Having a tighter and lower friction ankle brace would have provided better ankle data. Acceleration data was collected in the x, y, and

z directions and compared to the known value of gravitational acceleration. Using inverse dynamics, MATLAB code was created to calculate joint reaction force and joint reaction moment. These data were compared to literature values from gait studies and showed similar trends. Due to limitations and malfunctions of the laboratory sensors, concurrent validation of the wearable sensor system against the laboratory sensor system was inconclusive. Future validation of the device through subject testing would confirm the reproducibility and accuracy of the wearable sensor system.

7.5 Design Validation

In the beginning of the project design objectives were created in order to set the path of our project. These objectives would help determine if at the end of the year we were able to accomplish what was asked in the revised client statement. 7 Design Objectives were created and they can be seen in Table 7.2 with the measurable values assigned to each one to determine if the objective was met.

Table 7.2 Ranked Design Criteria for Wearable Sensor System

Rank	Criterion	Description
1	Wearable and compact	<2 lbs.
2	Accurate data	20% accuracy
3	Device durability	no catastrophic failure during testing and use
4	Battery capacity	2 hrs. of testing
5	Portable	use during everyday activities i.e. walking, running
6	Ease of Use	simple setup (<10 min.) to limit user error
7	Adjustable	fits wide range of subjects

Of the seven design objectives identified for this project, six were able to be met at the end of the project.

Objective 1 (Wearable and Compact)

The total weight of all the components of the system was at 1.5 pounds, meaning Objective 1 was accomplished because it was under the 2 pound maximum.

Objective 3 (Device Durability)

Objective 3 was met because over the course of the academic year, no component of the system had catastrophic failure during testing or use. Catastrophic failure was defined as breaking to the point where repair was not possible and a new part was needed.

Objective 4 (Battery Capacity)

The 4th Objective was met because each component of the system had a battery capacity that exceeded 2 hours, meaning the whole system could run for over 2 hours on its own power.

Objective 5 (Portable)

Objective 5 was met because the system could be worn for multiple everyday activities. This was tested when the system was worn during activities like walking, running, and jumping.

Objective 6 (Ease of Use)

Objective 6 was met because in all the trials of testing the fixation of the system to the test subject leg was timed and not a single trial exceeded 10 minutes. These trials consisted of assisted and unassisted fixation following the user manual.

Objective 7 (Adjustable)

Objective 7 was met but with restriction, the IMU's of the system can be attached with athletic tape and pre wrap. The goniometer components are attached via braces that can be adjusted to the user's size. The main limitations is the pressure sensors utilized by the system are restricted to 7.5 Women's and 10.5 Men's shoe sizes which limit the number of people that can use the system.

Objective 2 (Accurate Data)

Only Objective 2 was not met in our project in the academic year. Accuracy between data collected by our sensor system and that of the data collected by the laboratory method with equipment available to us was not determined. This was due to limitations with our prototype and also not being able to concurrently test our system with the laboratory equipment. Limitations with our prototype due to our team's limited coding capabilities

restricted the system components to function when plugged into a laptop making data collection tedious. Additionally, with the metal parts of the sensor system it was impossible to test the system concurrently with laboratory equipment available to use without corrupting the data collected by the Polhemus System. Going forward with the project concurrent testing of the system will further validate the data collected by the system and allow for better estimations of bone loading.

Engineering Standards stated in Chapter 3.3 of the report were all adhered to and followed throughout the design process. Resulting in meeting all the standards we needed to meet. Based on this and the design objective met by the team we have determined we have met the goals of our revised client statement and have produced a wearable sensor system that collects the relative data for estimating bone loading.

Chapter 8. Conclusions and Recommendations

8.1 Conclusions

Currently, 54 million Americans have low BMD or osteoporosis. Those with low BMD are at great risk of fragility fractures but changing factors that affect your BMD earlier in life could help reduce these incidences. Physical activity remains a modifiable factor affecting BMD, but the relationship between the two must be refined to determine optimal bone loading activities. Currently the best method of estimating bone loading is calculating Joint Reaction Forces (JRF) and Moments (JRM) using the combination of force plates and 3D motion capture systems in a laboratory space. However, this method has limitations ranging from extensive set up time, expensive laboratory equipment, and a limited amount of testable real word activates due to wiring and limited space. The goal of this project was to overcome these limitations with a wearable sensor system and create a system that could estimate the lower limb joint loading.

Our group utilized research and off the shelf sensors to design a wearable sensor system that could measure the necessary data to calculate the JRF and JRM acting on the lower limb during gait. The data collected by each of the three components of our sensor system were then validated by it to data collected from laboratory equipment available to use or using literature data from similar biomechanical studies. Once the data was validated we then were able to use MATLAB to calculate the JRF and JRM acting at the ankle and knee joints during the process of one gait cycle. These values were validated using the literature values to show that our system can estimate the bone loading acting on the lower limb during gait.

With this wearable sensor system, the limitations of the laboratory system can be overcome. This can then lead to more real world activates that data can be collected on and then studied to estimate the bone loading acting on the knee and ankle joints during that activity. This information can then be used to modify or improve the way a physical activity can be done in order for it to more beneficial to the person's health. From there prevention plans can be developed and put into place to help prevent low BMD or osteoporosis from every developing in adults.

8.2 Future Recommendations

This project accomplished our primary design objectives and fulfilled our client statement, however there were areas for growth these include:

- **Increase angle sensor size.** By increasing the size of the potentiometer which was used to measure the flexion angle of the knee and ankle joints the data collected will be more accurate and have less error.

- **Improvement in wireless capabilities.** The current prototype of the system can only operate when connected to a computer due to our limited Arduino coding capabilities as a team. By making all the sensors wireless more activates can be tested and the system can become more portable.

- **Increase the sampling frequency.** The current porotype of the system operates at 100Hz. By increasing the sampling frequency more data can be collected and more accurate calculations can be made for estimating bone loading.

- **Integrate the system into one functioning unit.** Each component of the system operates on its own and collects its own relative data. Integrating all the sensors into one function unit can be done with additional coding and wiring.

- **Implement less restrictive braces.** Stabilization knee and ankle braces are used to align the flexion angle components properly on the test subject and for safety purposes. Implementing less restrictive braces will allow for better biomechanical analysis and not impact the test subjects gait.

- **Further simplification of system setup process.** To further improve the ease of use and set up process of the system future work should be done to find a simpler way to align the IMUs over the body segment center of mass without using literature.

- **Limit data storage to one SD Card.** The current version of our prototype sensor system uses a total of 4 SD cards and external cloud storage to save all the necessary data to estimate bone loading. Limiting all the data storage to a single SD card can be done with additional coding and wiring to further improve the testing capabilities of the system.

- **Validation with more accurate laboratory data.** Due to limitations with our sensor system and not being able to concurrently test it with the laboratory system available to us we cannot validate our data to that from the laboratory method. Future work should be done to be able to concurrently test our system with laboratory equipment to compare data.

- **Increase number of test subjects.** More tests subjects are needed to collect more data to validate the sensor system and further evaluate the durability of the device as well. By increasing the number of test subjects can bring more statistical significance to the estimates calculated by the system.

Future work could utilize the foundation this project created in its wearable sensor system and MATLAB code to help produce a sensor system that can be used in both a research and consumer setting to help prevent the development of low BMD and osteoporosis in adults.

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Appendix A: Bill of Materials for Electric Goniometer

Bill of Materials showing the products used to to create the Electric Goniometer used in the Wearable Sensor System to measure flexion angle. Total Cost of manufacturing the sensor was $68.24.

Homemade Electronic Goniometer Bill of Materials

Item	Quantity	Method of Acquisition	Cost (Total for quantity)
Ever Ready Plastic 12" Goniometer 360 Degree ISOM- Top Quality	1	Amazon	$6.95
SanDisk 8GB MicroSD	1	Amazon	$9.98
Adafruit Feather M0 Adalogger	1	Adafruit	$19.95
Panel Munt 10K Log Potentiometer (Breadboard Friendly)	2	Adafruit	$1.90
2.54mm/0.1" Pitch Terminal Block (8-Pin)	1	Adafruit	$2.75
Lithium Ion Cylinrical Battery - 3.7v 2200mAh	1	Adafruit	$9.95
Breadboard Jumper Cables (Male to Female End)	12	Amazon	$1.20
Silicon Knee Brace (Provided to Team)	1	Team	$0
Mueller Lite Ankle Brace	1	Amazon	$15.56
			$68.24

Appendix B: Bill of Materials for Inertial Measurement Unit (Thigh and Shank)

Bill of Materials showing the products used to create the two IMUs for the thigh and shank body segments used in the Wearable Sensor System to measure body segment acceleration of the thigh and shank. Total Cost of manufacturing the two sensor was $96.06.

Homemade Inertial Measrument Device (Thigh & Shank)

Item	Quantity	Method of Acquisition	Cost (Total for quantity)
Elegoo EL-CP-003 MB-102 Breadboard 830 Point	2	Amazon	$6.66
Adafruit Feather M0 Adalogger	2	Adafruit	$39.90
Lithium Ion Cylinrical Battery - 3.7v 2200mAh	2	Adafruit	$19.90
Breadboard Jumper Cables (Male to Male End)	8	Amazon	$0.80
3 Axis Gyroscope + Accelerometer Module	2	Amazon	$9.04
SanDisk Ultra 8GB MicroSD Card	2	Amazon	$19.76
			$96.06

Appendix C: Bill of Materials for Inertial Measurement Unit (Foot)

Bill of Materials showing the products used to create the IMU for the foot body segment used in the Wearable Sensor System to measure acceleration of the foot body segment. Total Cost of manufacturing the sensor was $51.66.

Homemade Inertial Measurment Device (Foot)

Item	Quantity	Method of Acquisition	Cost (Total for quantity)
Elegoo 400 tie-points breadboard	1	Amazon	$6.86
SanDisk 8GB MicroSD	1	Amazon	$9.98
Adafruit Feather M0 Adalogger	1	Adafruit	$19.95
Lithium Ion Cylinrical Battery - 3.7v 2200mAh	1	Adafruit	$9.95
Crayola Chalk Box	1	Team	$0
Breadboard Jumper Cables (Male to Male End)	4	Amazon	$0.40
3 Axis Gyroscope + Accelerometer Module	1	Amazon	$4.52
			$51.66

Appendix D: MATLAB script

The raw data collected from the sensors were run through the MATLAB script (shown below). This script allowed the raw data to be converted into all of the needed values in order to calculate the JRF and JRM of the knee and ankle. The script is also able to calculate the JRF and JRM while also being able to compare these values to literature values from similar biomechanical studies.

Sensor System Code

clear; clc; close all; %Clears the workspace

Accelerometer Verification

```
fileName='Verification_Data.csv'; %Sets the file name for the acceleration data
Data=csvread(fileName); %Reads acceleration data from 3 sensors
n=6;

%Creates X, Y, and Z axis acceleration, in vector form, from raw data for the thigh IMU
thighAccelerationV=Data(:,1);
thighAccelerationVx=thighAccelerationV(1:n:end);
thighAccelerationVy=thighAccelerationV(2:n:end);
thighAccelerationVz=thighAccelerationV(3:n:end);

%Creates X, Y, and Z axis acceleration, in vector form, from raw data for the shank IMU
shankAccelerationV=Data(:,2);
shankAccelerationVx=shankAccelerationV(1:n:end);
shankAccelerationVy=shankAccelerationV(2:n:end);
shankAccelerationVz=shankAccelerationV(3:n:end);

%Creates X, Y, and Z axis acceleration, in vector form, from raw data for the toe IMU
toeAccelerationV=Data(:,3);
toeAccelerationVx=toeAccelerationV(1:n:end);
toeAccelerationVy=toeAccelerationV(2:n:end);
toeAccelerationVz=toeAccelerationV(3:n:end);

%Converts the raw data in bits into acceleration readings using equation
%(Q/16384)*9.81
thighAccelerationx=(thighAccelerationVx/16384).*9.81;
thighAccelerationy=(thighAccelerationVy/16384).*9.81;
thighAccelerationz=(thighAccelerationVz/16384).*9.81;
```

```matlab
shankAccelerationx=(shankAccelerationVx/16384).*9.81;
shankAccelerationy=(shankAccelerationVy/16384).*9.81;
shankAccelerationz=(shankAccelerationVz/16384).*9.81;

toeAccelerationx=(toeAccelerationVx/16384).*9.81;
toeAccelerationy=(toeAccelerationVy/16384).*9.81;
toeAccelerationz=(toeAccelerationVz/16384).*9.81;

%Plots the acceleration of the X, Y, and Z axis during static testing for
%each accelerometer
hold all;
plot(thighAccelerationx);
plot(thighAccelerationy);
plot(thighAccelerationz);

hold all;
plot(shankAccelerationx);
plot(shankAccelerationy);
plot(shankAccelerationz);

hold all;
plot(toeAccelerationx);
plot(toeAccelerationy);
plot(toeAccelerationz);
```

Drop Test

```matlab
droppingDataFile='Drop_Test.csv'; %Sets the file name for the drop test
droppingData=csvread(droppingDataFile); %Reads the file into a CSV format

%Creates one vector of the raw data collected by the IMU
droppingData1=droppingData(:,1);

%Seperates raw data into acceleration vectors of the X, Y, and Z axes
droppingDataRX=droppingData1(1:n:end);
droppingDataRY=droppingData1(2:n:end);
droppingDataRZ=droppingData1(3:n:end);

% Converts raw data in bits to acceleration values using the equation
% (Q/16384)*9.81
droppingDataX=(droppingDataRX/16384).*9.81;
droppingDataY=(droppingDataRY/16384).*9.81;
droppingDataZ=(droppingDataRZ/16384).*9.81;
```

```matlab
%Plots the acceleration in the X, Y, and Z during the drop test
hold all;
plot(droppingDataX);
plot(droppingDataY);
plot(droppingDataZ);
```

Angle Verification - Static testing and linear correlation

```matlab
Kfile1='Knee_Verification_L.xlsx'; %Sets verification data for the knee flexion
Kdata1=xlsread(Kfile1); %Reads the knee verification data file into a CSV format

n2=2;
kneeAngle=Kdata1(3:n2:end); %Seperates the relevant knee angle data from the read raw data
plot(kneeAngle)

ankleAngle=Kdata1(2:n2:end); %Seperates the relevant ankle angle data from the read raw data
plot(ankleAngle)

a=(100:10:260); %analog output
e=[38;41;44;47;57;81;104;127;151;173;200;229;254;280;310;335;360]; % digital output

%Linear fit equations
x = (0:1:375);
y = (0:1:90);
L1 = 3.3333*y - 26.667;
L2 = 0.3924*x + 119.69;

%Graph of analog vs digital angle output values
graph1=plot(e,a,'k');xlabel('True Analog Angle Value (degree)','fontsize',18);
ylabel('Collected Goniometer Angle Value (degree)','fontsize',18);
title('Analog vs Digital Angle Output','fontsize',22)
set(graph1,'linewidth',2);
hold on;

Line1=plot(L1,'r--'); set(Line1,'linewidth',1.5);
hold on;

Line2=plot(L2,'r--'); set(Line2,'linewidth',1.5);

xlim([0,400]);
ylim([0,300]);
grid on;
hold off;
```

Walking Angle Verification

```matlab
file2 = 'Angle_Example_Data.xlsx'; %Sets file name to raw data of the angle during gait
data2 = xlsread(file2); %Reads angle data file into a XLS format
n2=2;

knee=data2(3:n2:end); %Seperates relevant knee angle data from read raw data
ankle=data2(2:n2:end); %Seperates relevant ankle angle data from read raw data
t2=0:0.5:21;

%Converts knee angle data to knee flexion angle data
kneef=180-knee;
anklef=180-ankle;

%Graphs flexion angle of the ankle as a function of time
graph2=plot(t2,anklef,'b');
```

Gait analysis with linear correlation

```matlab
hold off;
t3=0:0.5:20.5;

%graphs knee flexion angle as a funtion of time
graph4=plot(t3,knee);
xlabel('time (s)','fontsize',18); ylabel('Flexion Angle (degree)','fontsize',18);
title('Ankle Flexion Angle During Gait','fontsize',22);
set(graph4, 'linewidth',1.5);

%forloop using the linear correltaion equations to calibrate device
for i = 1:length(knee)
    if knee(i)>=140
        knee(i)=knee(i)*3.3333-26.667;
    else
        knee(i) = knee(i)*0.3924+119.69;
    end
end
```

GRF Verification

```matlab
fileName='Walking_Example_Data.xlsx'; %Sets walking data as the file name
data=xlsread(fileName); %Reads set file into an XLS format

orpyx = data(:,1); %Sets orpyx data as the first column of the read file
forcePlate = data(:,2); %Sets force plate data as the second column of the read file
```

```
t1 = 0:0.01:0.8;

%Graph of orpyx and force plate data as functions of time
graph=plot(t1,orpyx,t1,forcePlate);
xlabel('Time (s)', 'fontsize', 18); ylabel('Force (N)', 'fontsize', 18); title('Force Over Time During
Footstrike', 'fontsize', 22);
legend({'Orpyx Sensor','Force Plate Sensor'},'fontsize',16);
set(graph,'Linewidth',2);
hold;
grid;
```

Thigh Walking

```
walkingFileThigh='Thigh_Walking_Data.csv'; %Sets thigh data as the thigh walking data file
walkingDataThigh=csvread(walkingFileThigh); %Reads set file into a CSV format
n=6;

%Pulls out the 4 trials of the walking test into 4 seperate vectors
thighWalkingData1=walkingDataThigh(:,1);
thighWalkingData2=walkingDataThigh(:,2);
thighWalkingData3=walkingDataThigh(:,3);
thighWalkingData4=walkingDataThigh(:,4);

% Separates the 4 trials into X, Y, and Z readings vectors
thighWalkingData1x=thighWalkingData1(1:n:end);
thighWalkingData1y=thighWalkingData1(2:n:end);
thighWalkingData1z=thighWalkingData1(3:n:end);

thighWalkingData2x=thighWalkingData2(1:n:end);
thighWalkingData2y=thighWalkingData2(2:n:end);
thighWalkingData2z=thighWalkingData2(3:n:end);

thighWalkingData3x=thighWalkingData3(1:n:end);
thighWalkingData3y=thighWalkingData3(2:n:end);
thighWalkingData3z=thighWalkingData3(3:n:end);

thighWalkingData4x=thighWalkingData4(1:n:end);
thighWalkingData4y=thighWalkingData4(2:n:end);
thighWalkingData4z=thighWalkingData4(3:n:end);

%Creates vectors of the averages of the walking data in X, Y, Z
thighWalkingDataRawx=walkingDataThigh(:,24);
thighWalkingDataRawy=walkingDataThigh(:,26);
```

```matlab
thighWalkingDataRawz=walkingDataThigh(:,28);

%Converts the raw data of bits into acceleration values
thighWalkingDatax=((thighWalkingDataRawx/16384)*9.81);
thighWalkingDatay=((thighWalkingDataRawy/16384)*9.81);
thighWalkingDataz=((thighWalkingDataRawz/16384)*9.81);

%Graphs the X and Y axis acceleration for the gait cycle
hold all;
plot(thighWalkingDatax);
plot(thighWalkingDatay);
%plot(thighWalkingDataz);
```

Shank Walking

```matlab
walkingFileShank='Shank_Walking_Data.csv'; %Assigns shank walking data as the file name
walkingDataShank=csvread(walkingFileShank); %Reads the assigned file into a CSV format
n=6;

%Pulls out the 4 trials of the walking test into 4 seperate vectors
shankWalkingData1=walkingDataShank(:,1);
shankWalkingData2=walkingDataShank(:,2);
shankWalkingData3=walkingDataShank(:,3);
shankWalkingData4=walkingDataShank(:,4);

% Separates the 4 trials into X, Y, and Z readings vectors
shankWalkingData1x=shankWalkingData1(1:n:end);
shankWalkingData1y=shankWalkingData1(2:n:end);
shankWalkingData1z=shankWalkingData1(3:n:end);

shankWalkingData2x=shankWalkingData2(1:n:end);
shankWalkingData2y=shankWalkingData2(2:n:end);
shankWalkingData2z=shankWalkingData2(3:n:end);

shankWalkingData3x=shankWalkingData3(1:n:end);
shankWalkingData3y=shankWalkingData3(2:n:end);
shankWalkingData3z=shankWalkingData3(3:n:end);

shankWalkingData4x=shankWalkingData4(1:n:end);
shankWalkingData4y=shankWalkingData4(2:n:end);
shankWalkingData4z=shankWalkingData4(3:n:end);

%Creates vectors of the averages of the walking data in X, Y, Z
shankWalkingDataRawx=walkingDataShank(:,21);
```

```matlab
shankWalkingDataRawy=walkingDataShank(:,23);
shankWalkingDataRawz=walkingDataShank(:,25);

%Converts the raw data of bits into acceleration values
shankWalkingDatax=((shankWalkingDataRawx/16384)*9.81);
shankWalkingDatay=((shankWalkingDataRawy/16384)*9.81);
shankWalkingDataz=((shankWalkingDataRawz/16384)*9.81);

%Graphs the X and Y axis acceleration for the gait cycle
hold all;
plot(shankWalkingDatax);
plot(shankWalkingDatay);
%plot(shankWalkingDataz);
```

Toe Walking

```matlab
walkingFiletoe='Toe_Walking_Data.csv'; %Assigns toe walking data as the file name
walkingDataToe=csvread(walkingFiletoe); %Reads the assigned file into a CSV format
n=6;

%Pulls out the 4 trials of the walking test into 4 seperate vectors
toeWalkingData1=walkingDataToe(:,1);
toeWalkingData2=walkingDataToe(:,2);
toeWalkingData3=walkingDataToe(:,3);
toeWalkingData4=walkingDataToe(:,4);

% Separates the 4 trials into X, Y, and Z readings vectors
toeWalkingData1x=toeWalkingData1(1:n:end);
toeWalkingData1y=toeWalkingData1(2:n:end);
toeWalkingData1z=toeWalkingData1(3:n:end);

toeWalkingData2x=toeWalkingData2(1:n:end);
toeWalkingData2y=toeWalkingData2(2:n:end);
toeWalkingData2z=toeWalkingData2(3:n:end);

toeWalkingData3x=toeWalkingData3(1:n:end);
toeWalkingData3y=toeWalkingData3(2:n:end);
toeWalkingData3z=toeWalkingData3(3:n:end);

toeWalkingData4x=toeWalkingData4(1:n:end);
toeWalkingData4y=toeWalkingData4(2:n:end);
toeWalkingData4z=toeWalkingData4(3:n:end);

%Creates vectors of the averages of the walking data in X, Y, Z
```

```
toeWalkingDataRawx=walkingDataToe(:,21);
toeWalkingDataRawy=walkingDataToe(:,23);
toeWalkingDataRawz=walkingDataToe(:,25);

%Converts the raw data of bits into acceleration values
toeWalkingDatax=((toeWalkingDataRawx/16384)*9.81);
toeWalkingDatay=((toeWalkingDataRawy/16384)*9.81);
toeWalkingDataz=((toeWalkingDataRawz/16384)*9.81);

%Graphs the X and Y axis acceleration for the gait cycle
hold all;
plot(toeWalkingDatax);
plot(toeWalkingDatay);
%plot(toeWalkingDataz);
```

Joint Reaction Force (Foot)

```
masterData='Master_Data.csv'; %Assigns master data as the JRF and JRM data file
masterWalkingData=csvread(masterData); %Reads assigned file into a CSV format

weight=135;
massFootKg=weight*2.205;
mf=massFootKg*0.0145;
weightKg=weight*0.453592;
weightNewtons=weightKg*9.81;

%Pulls out and converts raw acceleration data in the X and Y from bits to
%acceleration values
afx=(masterWalkingData(:,27)./16384).*9.81;
afy=(masterWalkingData(:,5)./16384).*9.81;

%Sets the values of the ground reaction force in the X and Y directions
GRFx=0;
GRFy=masterWalkingData(:,2);

% Calculates the Joint Reaction Force of the ankle in the X and Y
% directions
JRFax=mf.*afx-mf.*GRFx-mf.*0;
JRFay=mf.*afy-mf.*GRFy-mf.*9.81;

%Calculates the magnitude of the Joint Reaction Force calculations
JRFa=sqrt(JRFax.^2+JRFay.^2);

%Converts the calcultions from N to % body weight
```

```
JRFaBW=(JRFa./weightNewtons).*100;
```

```
plot(JRFaBW);
```

Joint Reaction Force (Shank)

```
massShankKg=weight*2.205;
ms=massShankKg*0.0465;
```

```
asx=(masterWalkingData(:,26)./16384).*9.81;
asy=(masterWalkingData(:,4)./16384).*9.81;
```

```
JRFsx=JRFax-ms.*0-ms.*asx;
JRFsy=JRFay-ms.*9.81-ms.*asy;
```

```
JRFs=sqrt(JRFsx.^2+JRFsy.^2);
```

```
JRFsBW=(JRFa./weightNewtons).*100;
```

```
plot(JRFsBW);
```

Joint Reaction Moment (Foot)

```
centerOfMass=0.5;
radiusOfGyration=0.475;
r=radiusOfGyration^2;
X1=0.108;
X2=0.216;
```

```
Ax=(mf*r^2).*afx-X2.*JRFax-X1.*GRFx;
Ay=(mf*r^2).*afy-X2.*JRFay-X1.*GRFy;
```

```
A=sqrt(Ax.^2+Ay.^2)./massFootKg;
```

```
%plots the joint reaction moment of the ankle
plot(A);
```

Joint Reaction Moment (Knee)

```
radiusOfGyrationShank=0.302;
r=radiusOfGyrationShank^2;
X1Shank=0.368;
X2Shank=0.159;

%Calculates the joint reaction moment of the knee in the X and Y directions
Kx=(ms*r^2).*asx+X2.*JRFax-X1.*JRFsx;
Ky=(ms*r^2).*asy+X2.*JRFay-X1.*JRFsy;

%Calculates the magnitude of the joint reaction moment calculations
K=sqrt(Kx.^2+Ky.^2)./massShankKg;

%Graphs the joint reaction moment of the knee
plot(K);
```

Compare Knee Flexion Data with Literature

```
Afile = 'Literature_Knee_Angle.xlsx'; %Sets literature knee angle as the file name
dataknee = xlsread(Afile); %Reads the set file into an XLS format

%Pulls out the collected and literature knee flexion data from the read
%file
datam = dataknee(:,2);
datal = dataknee(:,3);

t3=0:2:100;

%Graphs the literature and collected flexion angle values as a function of
%time
graph = plot(t3,datam,t3,datal);
xlabel('Percent of Gait Cycle (%)', 'fontsize',26 , 'fontweight', 'bold');
ylabel('Angle (degree)', 'fontsize',26 , 'fontweight', 'bold');
title('Knee Flexion Angle During Gait', 'fontsize', 30);
a = get(gca,'XTickLabel'); set(gca,'XTickLabel',a,'fontsize',24)
legend({'Literature Data','Goniometer data'},'fontsize',22, 'location', 'south');
set(graph, 'linewidth',2);
```

Compare Ankle Flexion Data with Literature

```matlab
Ankfile = 'Ankle Verification.xlsx'; %Sets ankle verification as the file name
dataAnkle = xlsread(Ankfile); %Reads set file into an XLS format

%Pulls out the literature, precent, and collected ankle flexion data sets
%form the read file
percent= dataAnkle(:,1);
knee5=dataAnkle(:,2);
ankle5=dataAnkle(:,3);

%Graphs the literature and collected flexion angles as a function of
%percent of gait
ankgraph=plot(percent,knee5,percent,ankle5);
xlabel('Percent of Gait Cycle (%)', 'fontsize',26 , 'fontweight', 'bold');
ylabel('Angle (degree)', 'fontsize',26 , 'fontweight', 'bold');
title('Ankle Flexion Angle During Gait', 'fontsize', 30);
a = get(gca,'XTickLabel'); set(gca,'XTickLabel',a,'fontsize',24);
legend({'Literature Data','Goniometer data'},'fontsize',22, 'location', 'southwest');
set(ankgraph, 'linewidth',2);
```

JRF LIterature Graph

```matlab
dataFile='JRF_literature_and_SS_Data.csv';% Sets JRF literature and SS data as the file name
jrfLiterature=csvread(dataFile); %Reads the set file into a CSV format

%Removes the Literature and collected JRF calculations from the read file
jrfDataLit=jrfLiterature(:,1);
jrfDataSS=jrfLiterature(:,2);

t4=0:2.5:100;

%Graphs the JRF values from the sensor system and literature as a function
%of time
graph = plot(t4, jrfDataLit, t4, jrfDataSS);
xlabel('Percent of Gait Cycle (%)', 'fontsize', 26, 'fontweight','bold');
ylabel('Joint Reaction Force (N)', 'fontsize',26,'fontweight','bold');
a = get(gca,'XTickLabel'); set(gca,'XTickLabel',a,'fontsize',24);
title('Joint Reaction Force of Sensor System Vs Literature', 'fontsize', 30);
legend({'Literature Data', 'Sensor System Data'},'fontsize', 22, 'location', 'south');
set(graph, 'linewidth',2);
```

JRM Literature Graph

```matlab
jrmDataFile='JRM_literature_values_graph.csv'; %Sets JRM literature values graph as the file
name
jrmLiterature=csvread(jrmDataFile); %Reads the set file into a CSV format

%Removes literature and sensor system JRM data from the read file
jrmDataSS=jrmLiterature(:,1);
jrmDataLit=jrmLiterature(:,2);

t5=0:2.5:100;

%Graphs the JRM values from literature and the sensor system as a function
%of time
graph = plot(t5, jrmDataLit, t5, jrmDataSS);
xlabel('Percent of Gait Cycle (%)', 'fontsize', 26, 'fontweight','bold');
ylabel('Joint Reaction Moment (Nm/kJ)', 'fontsize',26,'fontweight','bold');
a = get(gca,'XTickLabel'); set(gca,'XTickLabel',a,'fontsize',24);
title('Joint Reaction Moment of Sensor System Vs Literature', 'fontsize', 30);
legend({'Literature Data  ', 'Sensor System Data'},'fontsize', 22, 'location', 'south');
set(graph, 'linewidth',2);
```

Appendix E: Potentiometer Arduino Script

The goniometer code (shown below) takes in the raw data from the goniometer, converts the raw data into angle measurements, and then uploads the data into a microSD card in the form of a txt file.

Goniometer Code:

```
/*
  SD card read/write

 This example shows how to read and write data to and from an SD card file
 The circuit:
 * SD card attached to SPI bus as follows:
 ** MOSI - pin 11
 ** MISO - pin 12
 ** CLK - pin 13
 ** CS - pin 4 (for MKRZero SD: SDCARD_SS_PIN)

 created   Nov 2010
 by David A. Mellis
 modified 9 Apr 2012
 by Tom Igoe

 This example code is in the public domain.

 */

#include <SPI.h>
#include <SD.h>

// sets all the relevant global variables needed to record the goniometer data to the SD
card
File myFile;
int sensorValue1 = 0;
int sensorValue2 = 0;
int angle1 = 0;
int angle2 = 0;

void setup() {
  // Open serial communications and wait for port to open:
   Serial.begin(9600);
  while (!Serial) {
    ; // wait for serial port to connect. Needed for native USB port only
  }

 // Looks to see if there is an SD card in the port and prints failed if not and done if
there is
   Serial.print("Initializing SD card...");

  if (!SD.begin(4)) {
     Serial.println("initialization failed!");
    while (1);
  }
   Serial.println("initialization done.");

  // open the file. note that only one file can be open at a time,
```

```arduino
  // so you have to close this one before opening another.
  myFile = SD.open("test.txt", FILE_WRITE);

  // if the file opened okay, write to it:
  if (myFile) {
    Serial.print("Writing to test.txt...");
    myFile.println("testing 1, 2, 3.");
    // close the file:
    myFile.close();
    Serial.println("done.");
  } else {
    // if the file didn't open, print an error:
    Serial.println("error opening test.txt");
  }

  // re-open the file for reading:
  myFile = SD.open("test.txt");
  if (myFile) {
    Serial.println("test.txt:");

    // read from the file until there's nothing else in it:
    while (myFile.available()) {
      Serial.write(myFile.read());
    }
    // close the file:
    myFile.close();
  } else {
    // if the file didn't open, print an error:
    Serial.println("error opening test.txt");
  }
  //Serial.println("A1");
  //Serial.println("A2");
}

// Runs the readPots function and records the results onto the SD card in the following
format
void loop() {
  // nothing happens after setup
  // re-open the file for reading:
  readPots();
  myFile = SD.open("test.txt", FILE_WRITE);
  if (myFile) {
    myFile.println(angle1);
    myFile.println(angle2);
    Serial.println("Printing");
    myFile.close();
  }
  else {
    Serial.println("nooooooooooooooooooooo");
```

```
  }
   Serial.println(angle1);
   Serial.println(angle2);
  delay(100);
}



// Takes in the raw data from the goniometer and converts it to angle
void  readPots(){
  sensorValue1 = analogRead(A1);
  sensorValue2 = analogRead(A2);
  // Convert the analog reading (which goes from 0 - 1023) to a voltage (0 - 5V):
  angle1 = sensorValue1 * (360.0 / 1023.0);
  angle2 = sensorValue2 * (360.0 / 1023.0);
   Serial.print(angle1);
   Serial.print(angle2);
}
```

Appendix F: IMU Arduino Script

The IMU code (shown below) takes the raw data from the IMU for each of the three body segments and uploads that data into a microSD card in the form of a txt file.

Accelerometer Code:

```
/*
   SD card read/write

 This example shows how to read and write data to and from an SD card file
 The circuit:
 * SD card attached to SPI bus as follows:
 ** MOSI - pin 11
 ** MISO - pin 12
 ** CLK - pin 13
 ** CS - pin 4 (for MKRZero SD: SDCARD_SS_PIN)

 created   Nov 2010
 by David A. Mellis
 modified 9 Apr 2012
 by Tom Igoe

 This example code is in the public domain.

 */

/*
   SD card read/write

 This example shows how to read and write data to and from an SD card file
 The circuit:
 * SD card attached to SPI bus as follows:
 ** MOSI - pin 11
 ** MISO - pin 12
 ** CLK - pin 13
 ** CS - pin 4 (for MKRZero SD: SDCARD_SS_PIN)

 created   Nov 2010
 by David A. Mellis
 modified 9 Apr 2012
 by Tom Igoe

 This example code is in the public domain.

 */

#include <SPI.h>
#include <SD.h>
#include <Wire.h>

// Sets all of the relevant global variables needed for the recording of the accelerati
values

File  myFile;
const  int  MPU6050_addr=0x68;
```

```
int16_t AccX = 0;
int16_t AccY = 0;
int16_t AccZ = 0;
int16_t Temp = 0;
int16_t GyroX = 0;
int16_t GyroY = 0;
int16_t GyroZ = 0;

void setup() {
  // Open serial communications and wait for port to open:
  Wire.begin();
    Wire.beginTransmission(MPU6050_addr);
   Wire.write(0x6B);
   Wire.write(0);
    Wire.endTransmission(true);
   Serial.begin(9600); // Begins the serial monitor

  while (!Serial) {
     ; // wait for serial port to connect. Needed for native USB port only
  }


   Serial.print("Initializing SD card...");

// Checks to see if an SD card is present in the board and prints failed if it is not a
done if it is
  if (!SD.begin(4)) {
      Serial.println("initialization failed!");
    while (1);
  }
   Serial.println("initialization done.");


  // open the file. note that only one file can be open at a time,
  // so you have to close this one before opening another.
  myFile = SD.open("test.txt", FILE_WRITE);

  // if the file opened okay, write to it:
  if (myFile) {
     Serial.print("Writing to test.txt...");
     myFile.println("testing 1, 2, 3.");
    // close the file:
     myFile.close();
      Serial.println("done.");
  } else {
    // if the file didn't open, print an error:
     Serial.println("error opening test.txt");
  }
```

```
    // re-open the file for reading:
    myFile = SD.open("test.txt");
    if (myFile) {
        Serial.println("test.txt:");

        // read from the file until there's nothing else in it:
        while (myFile.available()) {
            Serial.write(myFile.read());
        }
        // close the file:
        myFile.close();
    } else {
        // if the file didn't open, print an error:
        Serial.println("error opening test.txt");
    }
    //Serial.println("A1");
    //Serial.println("A2");
}

void loop() {
    // nothing happens after setup
    // re-open the file for reading:

    // run readPots function and print outputs to SD card in below format
    readPots();
    myFile = SD.open("test.txt", FILE_WRITE);
    if (myFile) {
        myFile.print(" "); myFile.println (int16_t(AccX));
        myFile.print(" "); myFile.println (int16_t(AccY));
        myFile.print(" "); myFile.println (int16_t(AccZ));
        myFile.print(" "); myFile.println (int16_t(GyroX));
        myFile.print(" "); myFile.println (int16_t(GyroY));
        myFile.print(" "); myFile.println (int16_t(GyroZ));
        myFile.close();
    }
    else {
        Serial.println("nooo");
    }
}

// Takes in the inputs of the IMU and records the acceleration in the X, Y, and Z along
with the temperature and the angular acceleration in the X, Y, and Z.
void  readPots(){
    Wire.beginTransmission(MPU6050_addr);
    Wire.write(0x3B);
    Wire.endTransmission(false);
    Wire.requestFrom(MPU6050_addr,14,true);
    AccX=Wire.read()<<8|Wire.read();
    AccY=Wire.read()<<8|Wire.read();
```

```
 AccZ=Wire.read()<<8|Wire.read();
 Temp=Wire.read()<<8|Wire.read();
 GyroX=Wire.read()<<8|Wire.read();
 GyroY=Wire.read()<<8|Wire.read();
 GyroZ=Wire.read()<<8|Wire.read();
Serial.print("  ");  Serial.print(AccX);
Serial.print("  ");  Serial.print(AccY);
Serial.print("  ");  Serial.print(AccZ);
 Serial.print("  ");   Serial.print(Temp/340.00+36.53);
Serial.print("  ");  Serial.print(GyroX);
Serial.print("  ");  Serial.print(GyroY);
Serial.print("  ");  Serial.println(GyroZ);
delay(100);
```

Appendix G: Wearable Sensor System Raw Data Input Files

Example input file with raw data collected by each component of the wearable sensor system. This data is then used in the MATLAB script to calculate JRF and JRM over the course of one gait cycle.

Ground Reaction Component:

These data were saved as .csv files and converted to .xlsx files. Rows 1-9 are test headers and row 10 shows the titles for their respective columns. Key below shows what each column shows data wise.

Column Letter	Information
A	Sample Time (s)
B	Heel(psi)
C	Lat1(psi)
D	Lat2(psi)
E	Meta3(psi)
F	Meta2(psi)
G	Meta1(psi)
H	Small(psi)
I	Big(psi)
J	X
K	Y
L	Weight (kg)
M	Force(N)

	Sample Time (s)	Heel(psi)	Lat1(psi)	Lat2(psi)	Meta3(psi)	Meta2(psi)	Meta1(psi)	Small(psi)	Big(psi)	X	Y	Weight (kg)	Force (N)
1	CSV Version	1.4											
2	CSV Header Length	10											
3	Activity	walking											
4	Description	Jess walking verification 1											
5	Shoepod Number	247											
6	Size	7											
7	Session Start Date (YYYY-MM-DD)	2/2/2018											
8	Session Start Time 24H (HH:MM:SS.FFF)	02:58.9											
9	UTC Offset (Minutes)	-300											
10	Sample Time (s)	Heel(psi)	Lat1(psi)	Lat2(psi)	Meta3(psi)	Meta2(psi)	Meta1(psi)	Small(psi)	Big(psi)	X	Y	Weight (kg)	Force (N)
11	0	9.43	7.81	7.89	5.5	4.47	6.87	1.84	2.19	-16.7	71.7	55.4	543.4
12	0.01	9.44	7.82	7.92	5.5	4.47	6.87	1.85	2.2	-16.7	71.8	55.5	544.4
13	0.02	9.44	7.86	7.92	5.5	4.49	6.89	1.87	2.2	-16.7	71.8	55.6	545.3
14	0.03	9.4	7.81	7.95	5.52	4.47	6.93	1.85	2.2	-16.7	72	55.5	544.8
15	0.04	9.38	7.81	7.95	5.52	4.52	6.95	1.87	2.2	-16.7	72.1	55.6	545.3
16	0.05	9.33	7.81	7.95	5.52	4.52	6.97	1.89	2.2	-16.7	72.3	55.5	544.9
17	0.06	9.31	7.79	7.95	5.52	4.52	7.02	1.89	2.22	-16.7	72.5	55.6	545.6
18	0.07	9.27	7.79	7.95	5.52	4.54	7.04	1.89	2.23	-16.7	72.7	55.6	545.4
19	0.08	9.26	7.79	7.98	5.53	4.54	7.05	1.89	2.24	-16.7	72.8	55.6	545.8
20	0.09	9.23	7.79	7.98	5.57	4.54	7.05	1.89	2.24	-16.8	72.9	55.6	545.7
21	0.1	9.24	7.81	7.98	5.58	4.54	7.07	1.89	2.25	-16.8	72.9	55.7	546.3
22	0.11	9.24	7.79	7.98	5.6	4.54	7.05	1.89	2.26	-16.8	72.9	55.7	546.5
23	0.12	9.25	7.79	8.04	5.6	4.54	7.07	1.9	2.26	-16.8	73	55.8	547.4
24	0.13	9.26	7.79	8.01	5.6	4.54	7.05	1.89	2.26	-16.8	72.9	55.8	546.9
25	0.14	9.27	7.81	8	5.6	4.54	7.01	1.9	2.24	-16.8	72.7	55.7	546.5
26	0.15	9.29	7.82	7.98	5.6	4.54	6.92	1.89	2.23	-16.8	72.5	55.5	544.8
27	0.16	9.32	7.84	7.98	5.6	4.54	6.86	1.87	2.21	-16.8	72.2	55.5	544
28	0.17	9.35	7.86	7.98	5.6	4.54	6.77	1.88	2.2	-16.9	71.9	55.4	543.3
29	0.18	9.39	7.84	8.03	5.6	4.54	6.66	1.85	2.16	-16.9	71.5	55.2	541.5

Flexion Angle Component:

Ankle and knee angles were collected concurrently in the same .txt file and converted into an .xlsx file for every trial. The raw data output both sensor data alternating data points in the first column. The first row shows the initialization of testing and proceeding even numbered rows display knee angles and the odd rows display ankle angles.

	A	B	C	D	E	F	G
1	testing 1, 2, 3.						
2	181						
3	129						
4	181						
5	129						
6	181						
7	129						
8	181						
9	129						
10	181						
11	129						
12	181						
13	129						
14	181						
15	129						
16	181						
17	129						
18	181						
19	129						
20	181						
21	130						
22	181						
23	134						
24	173						
25	143						

Acceleration Component:

- Column A: Thigh IMU
  - Format:
    - Row 1: Raw acceleration in X direction
    - Row 2: Raw acceleration in Y direction
    - Row 3: Raw Acceleration in Z direction
    - Row 4: Raw angular acceleration in X direction
    - Row 5: Raw angular acceleration in Y direction
    - Row 6: Raw angular acceleration in Z direction
    - Every 6 data points the pattern repeats until the end of the data set
- Column B: Shank IMU
  - Format: Same as Thigh IMU
- Column C: Toe IMU
  - Format: Same as Thigh IMU

	A	B	C
1	1204	1672	2292
2	-412	-456	-528
3	15932	15012	17576
4	281	-636	-390
5	109	-1262	141
6	70	247	-98
7	1188	1996	2256
8	-324	-368	-560
9	15860	15056	17592
10	285	-1279	-377
11	105	185	122
12	60	149	-116
13	1124	2164	2240
14	-340	-344	-636
15	15788	15064	17700
16	301	-1317	-377
17	119	215	144
18	67	175	-137
19	1148	2040	2208
20	-324	-416	-588
21	15880	14780	17748

Drop Test:

Column A contains raw acceleration data in the same format as the verification data set above. This data was collected when the shank IMU went through a drop test.

	A	B	C	D	E	F	G	H	I	J	K
1	1712										
2	-928										
3	15968										
4	1251										
5	-107										
6	-1										
7	2124										
8	-688										
9	15660										
10	-124										
11	-525										
12	300										
13	2416										
14	-704										
15	15980										
16	735										
17	-652										
18	-1296										
19	2276										
20	-1072										

Thigh/ Shank/ Toe Walking:

This is the raw walking data set for the shank IMU. the first column (U) is the average raw data of acceleration numbers for the X direction and the third column (W) is the average raw data of acceleration numbers in the Y direction. Even though the Z direction (Y) was recorded, these were the only two directions used for calculations. Each IMU data set had the same format as the shank IMU.

	U	V	W	X	Y	Z	AA	AB	AC	AD	AE
1	970		15890		4169						
2	632		15939		4329						
3	626		15882		4520						
4	1177		15850		4383						
5	994		15858		4619						
6	857		15792		4529						
7	890		15768		4464						
8	722		15938		4569						
9	520		15653		4404						
10	759		15608		4511						
11	1376		15576		4528						
12	3792		15659		5233						
13	2040		15438		6945						
14	1599		15166		6302						
15	3999		15674		6460						
16	2262		18468		5616						
17	2419		19737		6103						
18	7478		12027		5199						
19	5078		9506		4055						
20	3466		16850		3496						
21	360		17454		2550						
22	-511		17205		5236						
23	6785		15849		6381						
24	-1441		16208		6759						
25	373		15766		6491						
26	-1109		17185		5823						
27	-1942		22405		6967						
28	5001		14149		5408						
29	8201		9463		5473						
30	6464		16669		6667						
31	8009		17210		9534						
32	3720		15879		4428						
33	-760		16028		6316						
34	3036		16731		5655						

Joint Reaction Force/ Moment Foot/ Shank:

The calculated JRF values of the shank that were calculated using the equations of motion are in column AD. These numbers were also used to calculate the JRM values of the foot and shank. The data set for the JRF values of the foot have the same format

	AC	AD	AE	AF	AG	AH	AI	AJ	AK	AL	AM	AN	AO	AP
1	1	531.55												
2	2	531.38												
3	3	529.58												
4	4	527.4												
5	5	522.76												
6	6	519.4												
7	7	515.06												
8	8	508.86												
9	9	501.75												
10	10	494.9												
11	11	486.32												
12	12	478.01												
13	13	465.67												
14	14	450.23												
15	15	437.78												
16	16	424.14												
17	17	408.99												
18	18	395												
19	19	382.38												
20	20	372.13												
21	21	362.94												
22	22	353.53												
23	23	339.03												
24	24	323.92												
25	25	305.49												
26	26	287.14												
27	27	271.65												
28	28	255.19												

JRF Literature Graph:

Column A contains the estimated JRF values of the biomechanical study from literature in terms of percent body weight and column B contains the calculated JRF values of the sensor system in terms of percent body weight during one gait cycle. These two data sets were graphed on the same graph to compare the two results.

|	A	B	C	D	E	F	G	H	I	J	K
1	20	94									
2	21	94									
3	24	95									
4	26	99.90835									
5	149	157.5217									
6	224	233.4939									
7	289	294.0829									
8	327	332.8031									
9	349	359.3385									
10	376	402.1096									
11	392	403.9093									
12	402	419.2373									
13	410	419.3681									
14	417	418.5483									
15	422	426.0955									
16	426	423.0328									
17	427	427.7082									
18	432	420.7272									
19	443	389.4579									
20	453	454.8303									
21	442	446.682									
22	436	435.8426									
23	424	440.0627									
24	416	444.9148									
25	387	443.4919									
26	356	419.6327									
27	334	373.1619									
28	302	312.8603									
29	248	258.1295									

JRM Literature Graph:

Column A contains the calculated JRM values of the sensor system in terms of Nm/Kg and column B contains the estimated JRM values of a similar biomechanical study in terms of Nm/Kg. Both data sets were graphed on the same graph to evaluate the accuracy of the calculated data.

	A	B	C	D	E	F	G	H	I	J	K
1	0	0									
2	0	0									
3	0	-0.34									
4	0.328135	-0.12									
5	0.328359	0.14									
6	0.3943	0.22									
7	0.616119	0.27									
8	0.908162	0.4									
9	1.142364	0.45									
10	1.289828	0.63									
11	1.393747	0.75									
12	1.558328	0.86									
13	1.5653	0.97									
14	1.624043	1.14									
15	1.624201	1.26									
16	1.620674	1.36									
17	1.650397	1.42									
18	1.638182	1.48									
19	1.655988	1.56									
20	1.628992	1.62									
21	1.508277	1.61									
22	1.760168	1.58									
23	1.728772	1.46									
24	1.687191	1.38									
25	1.703462	1.31									
26	1.72254	1.26									
27	1.717855	1.19									
28	1.625285	1.11									

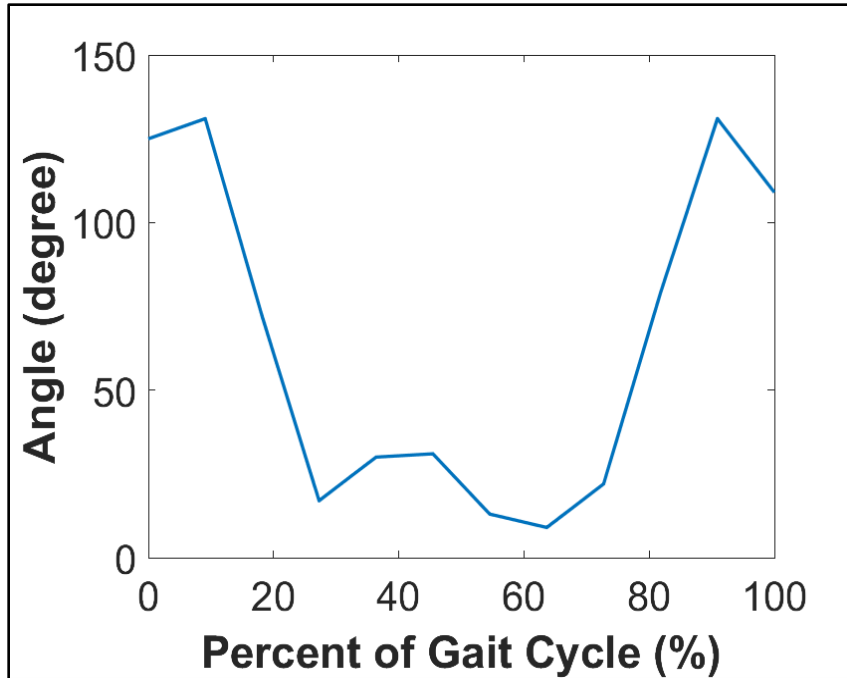## Appendix H: Knee and Ankle Flexion Angle Graphs during One Gait Cycle

The below graphs show three additional trials of knee and ankle flexion angle during one cycle of gait during walking.
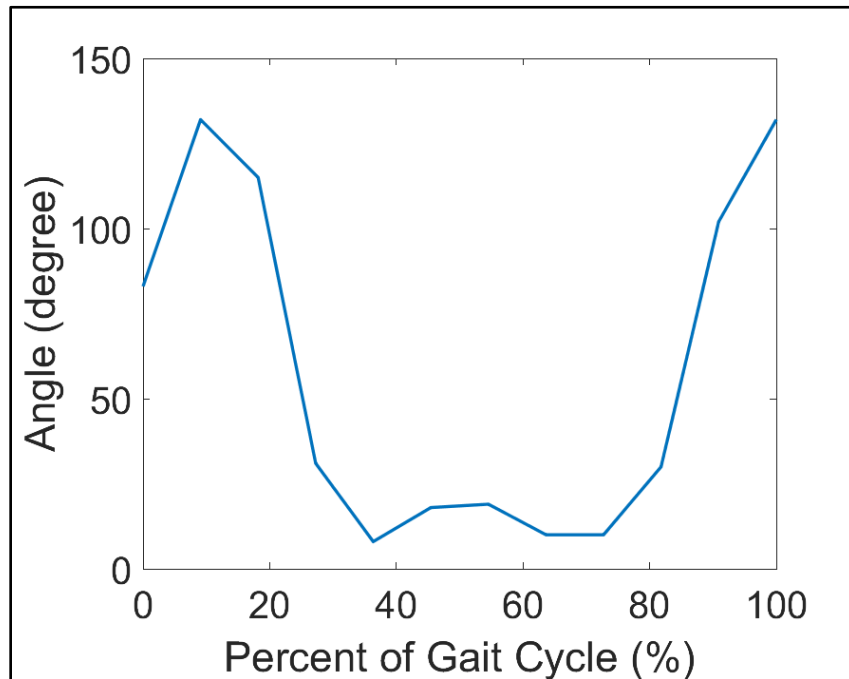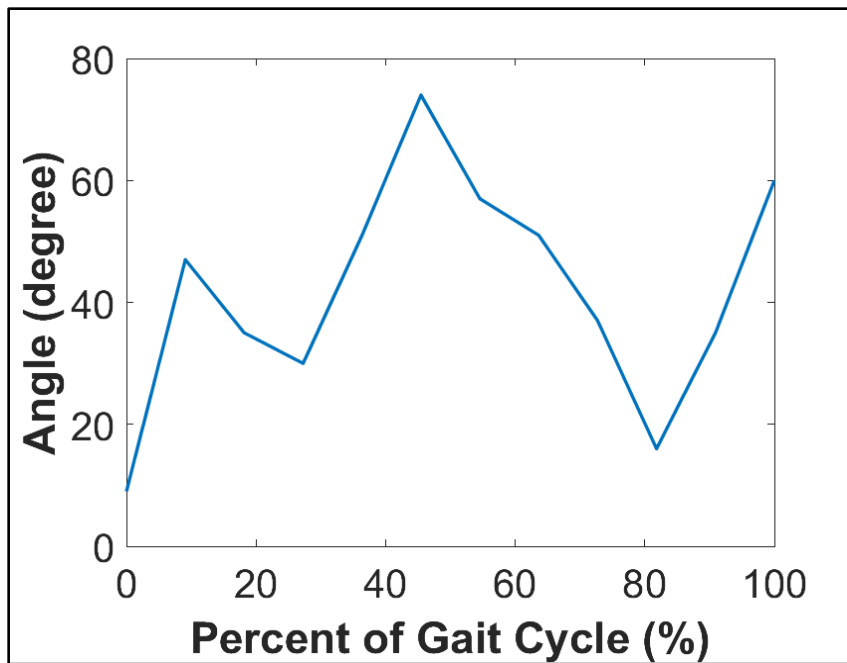

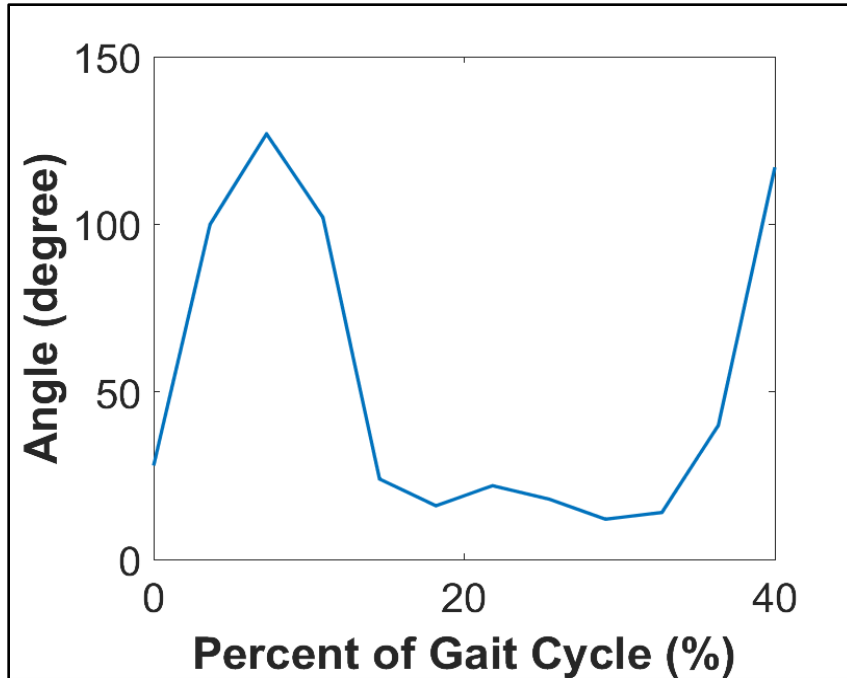Trial 2: Ankle flexion angle during one gait cycle
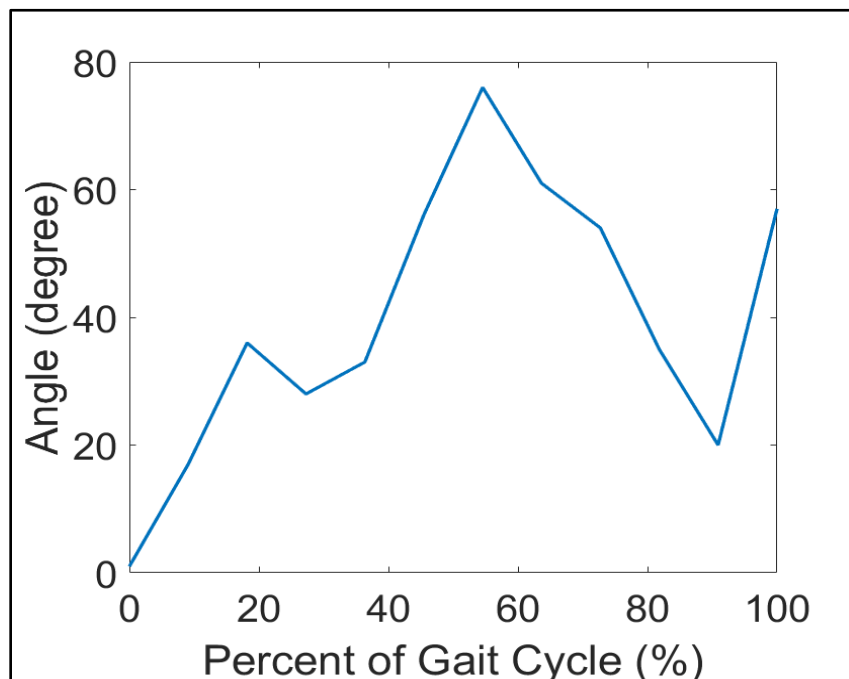
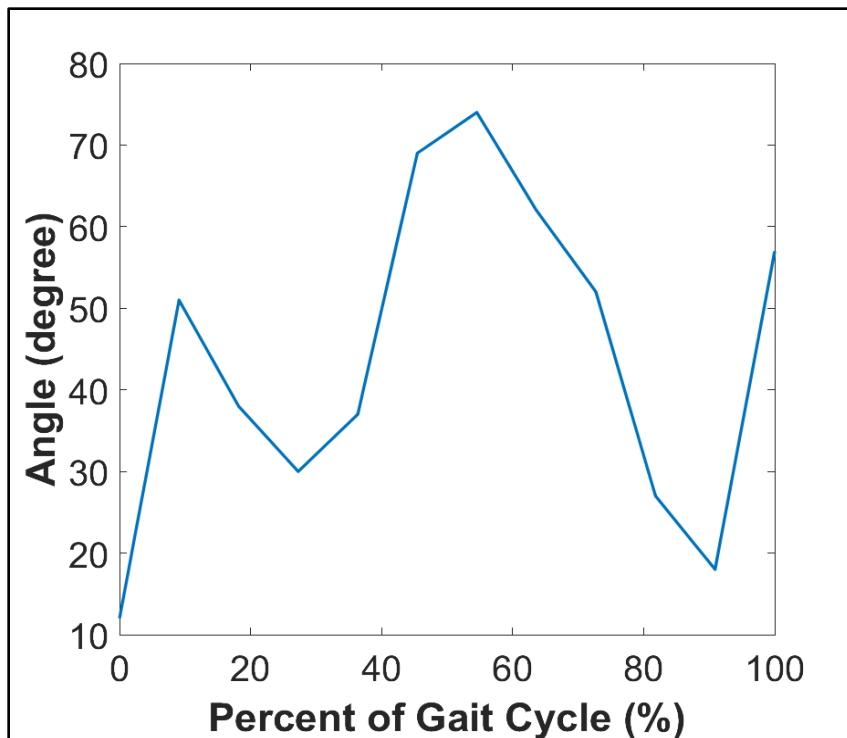Trial 2: Knee flexion angle during one gait cycle

Trial 3: Ankle flexion angle during one gait cycle

Trial 3: Knee flexion angle during one gait cycle

Trial 4: Ankle flexion angle during one gait cycle

Trial 4: Knee flexion angle during one gait cycle

Appendix I: IRB Material

Below is the IRB form approving our human testing and the consent form to be used for test subjects to consent to testing our system.

WORCESTER POLYTECHNIC INSTITUTE

Worcester Polytechnic Institute IRB# 1
HHS IRB # 00007374

5 January 2018
File: 18-0192

Re: IRB Expedited Review Approval: File 18-0192
    "Development of a wearable sensor system to measure
    tibia bone loading during physical activity."
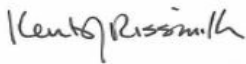
Dear Prof. Troy,

The WPI Institutional Review Committee (IRB) approves the above-referenced research activity, having conducted an expedited review according to the Code of Federal Regulations 45 (CFR46).

Consistent with 45 CFR 46.116 regarding the general requirements for informed consent, we remind you to only use the **attached stamped approved consent forms** and to give a copy of the signed consent form to your subjects. You are also required to store the signed consent forms in a secure location and retain them for a period of at least three years following the conclusion of your study. You may also convert the completed consent forms into electronic documents (.pdf format) and forward them to the IRB Secretary for electronic storage.

The period covered by this approval is 5 January 2018 until 4 January 2019, unless terminated sooner (in writing) by yourself or the WPI IRB. Amendments or changes to the research that might alter this specific approval must be submitted to the WPI IRB for review and may require a full IRB application in order for the research to continue.

Please contact the undersigned if you have any questions about the terms of this approval.

Sincerely,

Kent Rissmiller
WPI IRB Chair

100 INSTITUTE ROAD, WORCESTER MA 01609 USA

Informed Consent Agreement for Participation in a Research Study

Student Investigators: Jessica Cheu (BME), Robert Kirch (BME), Stephanie Silvestris (BME), Rhaine Sziy (BME)

Faculty Advisor: Karen L. Troy, PhD

Contact Information: Department of Biomedical Engineering
                      60 Prescott St
                      Worcester, MA 01605
                      Tel: 508-831-6093
                      Email: ktroy@wpi.edu

Title of Research Study: *Development of a wearable sensor system to measure tibia bone loading during physical activity.*

Sponsor: None

Introduction
You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study: Currently the "Gold Standard" of measuring bone loading is within a laboratory setting. Using a combination of force plates and human motion capture software bone loading can be calculated in order to estimate the force bones undertake during various activities. The objective of this project is to develop a wearable sensor system to calculate bone loading outside the lab using off the shelf sensors. We are recruiting able-bodied subjects to walk to validate our device and compare calculations from the "Gold Standard" and our sensor system.

Procedures to be followed: You will participate in 3 tests that will last approximately 60 minutes total. You will be asked to wear athletic shorts clothing you typically wear during physical activity. You do not need to bring your own athletic shoes; shoes for the testing will be provided.

Before testing your height and weight will be measured and recorded for calculation purposes. Your body weight will be measured and used to calculated testing loads as a function of body weight.

You will be asked to perform three iterations of a 5 meter walk across a level surface at a self-selected pace. On your right leg you will wear the MQP sensor system and on your left will be the sensors of the laboratory method. The first iteration will be done with no load carriage and just be a normal walk. The 2nd and 3rd iterations will involve load carriage, you will have to carry a backpack filled with weights at 10% your body weight and then again at 20% body weight.

After each iteration you will be allowed up to 5 minutes to rest. Water and snacks will be available for you if you desired.

Risks to study participants: The risk for participating in the study is minimal. Athletic tape and pre-wrap will be used to fixate all wireless sensors, this may lead to discomfort in application, testing, and removal. You will be required to walk for no more than 1 minute at a time and no more than 20 minutes total through all tests. You may experience delayed onset muscle soreness in which the muscles are sore for a day or two after the exercise. However, these conditions are normal for any person who is accustomed to regular physical activity, and you will be allowed to take sufficient break between iterations, and you will be able to end the test at any time if you feel uncomfortable.

Benefits to research participants and others: There are no immediate benefits for your participation here, however the knowledge gained through this study will help improve the field of Biomechanics and Biomedical Engineering.

Record keeping and confidentiality: Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or it's designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you.

Compensation or treatment in the event of injury: If you are injured during your participation in this study you may seek medical treatment through your regular care provider. No compensation will be provided. You do not give up any of your legal rights by signing this statement

Cost/Payment: There will be no compensation for participating in this study.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact: Karen Troy (information on the first page). You may also contact the chair of the WPI Institutional Review Board (Prof. Kent Rissmiller, Tel. 508-831-5019, Email: kjr@wpi.edu) or WPI's University Compliance Officer (Jon Bartelson, Tel. 508-831-5725, Email: jonb@wpi.edu).

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____   Date: _____
Study Participant Signature

_____

APPROVED
WPI IRB 1
1/5/18 to 1/4/19

Study Participant Name (Please print)
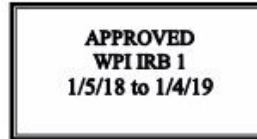
_____   Date: _____
Signature of Person who explained this study

Appendix J: Testing Protocol

Below is the testing protocol to be used to test our wearable sensor system concurrently with laboratory equipment in order to further validate our system.

<u>**STUDY PROTOCOL**</u>

Title: Development of wearable sensor system to measure tibia bone loading during physical activity

Purpose: The current "Gold Standard" for estimating bone loading and calculating the forces and moments that act on bones during any activity is conducted within a laboratory setting. Using a combination of force plates and human motion capture software, forces acting on bones during various activities can be calculated and utilized to further estimate bone loading. This method of estimating bone loading, though valid, has several limitations. These limitations result in a gap between physical activities that can be performed and tested in the laboratory versus "real world", everyday activities. The objective of this project is to design and develop a working prototype of a wearable sensor system that will measure ground reaction force and lower leg joint angles to be used to estimate bone loading. Through concurrent human testing we will be able to compare the results from our sensor system and the laboratory method in order to validate our device estimates bone loading.

Test Subjects: 20 Healthy and able bodied individuals between the ages of 18-23. We will look to test our system out on 10 men and 10 women. This number of subjects was determined using a power analysis and this number will allow us to get data with significance for validation.

We define healthy and able bodied individuals as people who have
- No lower extremity injuries within the past 12 months requiring medical care
- No metal hardware (fracture fixation plate or screws) in their lower extremities

Additionally we will only ask for males with shoe size of 10 and for females with shoe size of 7. This is the because the available insole pressure sensors only fit in those two shoe sizes.

Activities: For testing subjects will perform a 5 meter walk along a level surface while wearing shoes provided by the MQP team. Additionally they will then have to complete 3 iterations of this task by performing it with no load carriage, 10% body weight load carriage and finally 20% body weight load carriage. The load carriage will be done using a backpack because it is a safe method of holding the weights and will not affect the person's gait significantly. Between each iteration the subject will have up to 5 minutes to rest in order to avoid any fatigue and minimize the likelihood of injury.

Procedure for Laboratory Method:
1. Consent form

1. Have test subject read and sign consent form

2. Set up force plates and 3D motion capture for "Level Walking"
    1. Polhemus System
        1. Attach sensors and to the relevant landmarks (using athletic tape)
            1. Toe
            2. Ankle Joint
            3. Knee Joint

3. Attach fiducial markers on test subject at relative bony landmarks (using athletic tape)
    1. Toe
    2. Ankle Joint
    3. Knee Joint

4. Perform Level Surface Walk
    1. Iteration #1
        1. Subject will walk 5 meters along level surface at a self-selected speed
        2. Raw data collected and transferred to software to calculate forces and moments acting on tibia
    2. Iteration #2
        1. Wearing a backpack holding 10% body weight load subject will walk 5 meters along level surface at a self-selected speed
        2. Raw data collected and transferred to software to calculate forces and moments acting on tibia
    3. Iteration #3
        1. Wearing a backpack holding 10% body weight load subject will walk 5 meters along level surface at a self-selected speed
        2. Raw data collected and transferred to software to calculate forces and moments acting on tibia

Procedure for Sensor System:
1. Consent form
    1. Have test subject read and sign consent form

2. Attach device to human subject
    1. Subject will wear special shoe provided by the team
        1. Inside the shoe will be a sole with force sensors placed under the sole of the shoe
    2. Goniometers will be place at the subject's ankle joint and knee joints
        1. Ankle goniometer will be attached by athletic tape and pre wrap
        2. Knee goniometer will be placed on a knee sleeve for proper alignment

3. Accelerometers will be placed on the shoe of the subject and on the subject's shank and on the subject's thigh.
    1. Accelerometers will be attached via athletic tape and pre-wrap or they will be attached to elastic workout bands the subject will wear
    2. Accelerometers will be placed over the mass segment center of the segment based on literature and measurements taken before testing

3. Level Surface Walk
    1. Iteration #1
        1. Subject will walk 5 meters along level surface at a self-selected speed
        2. Raw data collected and transferred to software to calculate forces and moments acting on tibia
    2. Iteration #2
        1. Wearing a backpack holding 10% body weight load subject will walk 5 meters along level surface at a self-selected speed
        2. Raw data collected and transferred to software to calculate forces and moments acting on tibia
    3. Iteration #3
        1. Wearing a backpack holding 20% body weight load subject will walk 5 meters along level surface at a self-selected speed
        2. Raw data collected and transferred to software to calculate forces and moments acting on tibia

Appendix K: Standard Operating Procedure for Wearable Sensor System

Below is the user manual to be followed for attaching the wearable sensor system to the test subject and then running the system to collect the relative data to be used to calculate the JRM and JRF using the MATLAB code provided.

WEARABLE SENSOR SYSTEM USER MANUAL

Materials Required:
- Silicon Knee Brace (1x)
- Athletic Tape (2x)
- Pre-Wrap (2x)
- Homemade Large IMU (2x)
- Homemade Small IMU (1x)
- Homemade Electronic Goniometer
  - Ankle Brace Component
  - Knee Brace
  - Attachable Knee Brace Component
- Orpyx Insole Pressure Sensors (2x [2 sets of soles for each set of shoes])
- Sneakers Provided by MQP Team (2x [Size 7.5 Women and Size 10.5 Men's)

Process (Attachment)
1. First take the test subjects weight and height which will be used to properly attach the IMUs to their body segments and in the biomechanical calculations
2. Provide the test subject with the appropriate sneakers based on their shoe size
3. Remove the insoles of the sneakers and place the Orpyx Sensors into the appropriate shoe and then place the insoles back into the sneakers over the sensors
4. Have the test subject slide on the knee brace onto the knee the feel most comfortable with it on and secure it using the Velcro straps to their desire
5. Have the subject attach the ankle brace component onto the ankle the knee brace is on and secure it using the Velcro straps to their desire
6. Have the test subject place he sneakers on and tie the shoes and then stand up for the rest of the system to be attached.
7. Then using the table found below, attach one of the large IMUs over the center of mass (COM) on the thigh by taking the length of the subjects thigh and then multiplying that measurement by the value found in the table. Then to adhere the IMU first use pre-wrap and then athletic tape in order to properly secure the IMU. Keep the sensor on the outside part of the thigh in order to not inflict with the subjects gait.

8. Repeat Step 7 again with the final large IMU but attach this one over the center of mass (COM) of the leg or shank of the test subject.
9. Using the table again attach the small IMU over the center of mass of the foot by using the pre-wrap and athletic tape to secure the IMU onto the shoe.
10. If followed correctly the sensor system should be attached to a test subject's leg like the image below.
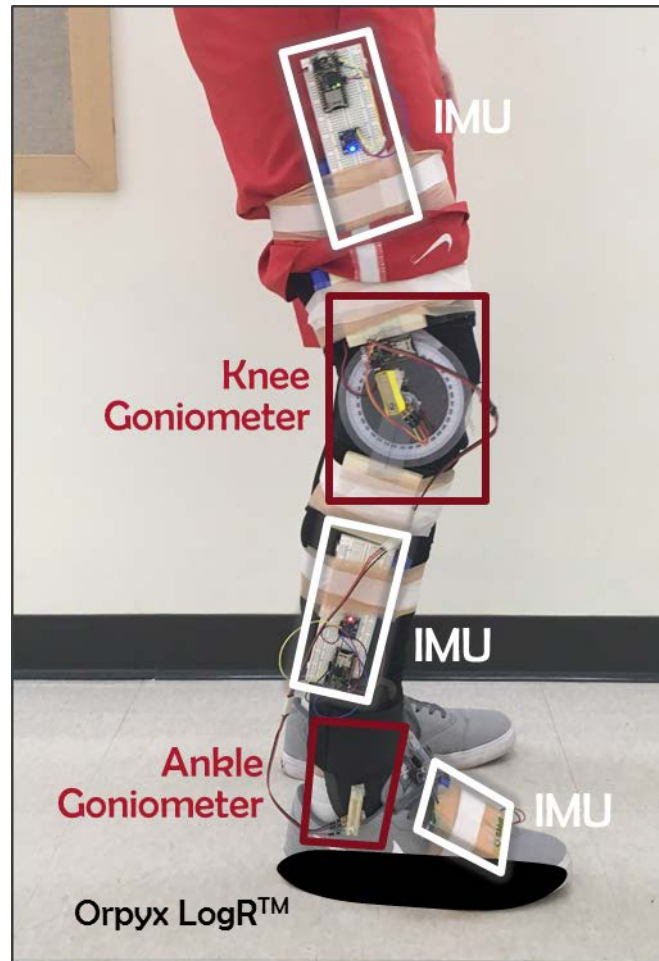
Process (Data Collection)

Orpyx:
1. Calibrate the Orpyx sensor
   a. Lift both shoes into the air so no forces are acting on the sensors
   b. Double tap each foot in the application and wait 3sec. to ensure calibration completes
2. Hit "START" to initiate data collection
3. Wait 2sec. before walking in order to ensure that data collection begins.
4. Once gait is complete hit "STOP" to end data collection

5. Save CSV file to be uploaded to MATLAB script

Goniometer:
1. Place microSD card into the port of the datalogger
2. Plug datalogger into the computer via a USB to micro-USB cable
3. Verify arduino code "PotentiometerCode" to ensure that there are no syntax or logic errors within the coding
4. Upload arduino code "PotentiometerCode" to the board and open the Serial Monitor to make sure the data is being collected
5. Wait 3sec. To ensure that the goniometer starts collecting real data
6. Once gait is complete remove microSD from datalogger
7. Place microSD into the SD adaptor and plug into computer
8. Save file as a CSV file to be uploaded to MATLAB script

IMU:

For each sensor:
1. Place microSD into port of datalogger
2. Plug datalogger into the computer via a USB to micro-USB cable
3. Verify arduino code "AccelerometerCode" to ensure that there are no syntax or logic errors within the coding
4. Upload arduino code "AccelerometerCode" to the board and open the Serial Monitor to make sure the data is being collected
5. Wait 3sec. To ensure that the IMU starts collecting real data
6. Once gait is complete remove microSD from datalogger
7. Place microSD into the SD adaptor and plug into computer
8. Save file as a CSV file to be uploaded to MATLAB script

Table for COM locations

Body Segment	Segment Weight	CoM (Proximal)	CoM (Distal)	Radius of Gyration (CoG)
Foot	0.0145(Mass)	0.50 (Segment Length)	0.50 (Segment Length)	0.475 (Segment Length)
Leg/Shank	0.0465(Mass)	0.433 (Segment Length)	0.567 (Segment Length)	0.302 (Segment Length)
Thigh	0.100(Mass)	0.433 (Segment Length)	0.567 (Segment Length)	0.323 (Segment Length)