Development of an electronic platform to quantify human knee function

IJ Thomson

orcid.org/0000-0003-3134-8758

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Supervisor:	Prof MJ Grobler
Co-supervisor:	Dr M Kramer

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Student number:	26047152

Declaration

I hereby declare that the work presented in this dissertation has not been submitted for any other degree or professional qualification, and that it is the result of my own independent work.

Ian James Thomson

Full Name Goes Here (Candidate)

26/10/2022

Date

Abstract

The purpose of the presented study is to determine whether wearable motion analyzers are suitable for monitoring and measuring human knee function. This study focuses on the selection and placement of sensors that can provide data on knee function during daily living activities at home, such as Activity 3: Standing and sitting, putting on shoes, and climbing and descending hills and stairs. Once the biomechanics of the knee and the types of measurements needed to monitor knee function were introduced, it was decided that we needed to measure knee joint angle, knee joint angular velocity, and ground reaction force. A sensor platform was developed to collect data for wearable motion analysis. Accelerometers were used to measure knee joint angle, gyroscopes were used to measure knee joint angular velocity, and Velostat force sensors were used to measure heel and forefoot ground reaction forces. Fifteen participants were recruited for this study, but only thirteen of them were available for knee angle and knee angular velocity data and eight for ground reaction force data. Knee joint angles, knee joint angular velocities, and ground reaction force data were collected for everyday activities like tying shoelaces, standing/sitting, climbing/descending slopes, climbing/descending stairs, and walking. Knee joint angle and knee joint angular velocity results were compared with the Qualysis motion capture system for validation. For validation, the ground reaction force was compared with force plates. The results obtained for knee joint angle and knee joint angular velocity are very similar to those of the Qualyisis motion capture system, which may be useful for everyday motion capture, but based on our analysis of the effectiveness of the sensor platform, it is not ready yet for clinical application while the device is in early stages development and thus requires adjustments. Ground reaction force data obtained from the sensor platform varies greatly. Some areas of the force curve have similar mean values as that of the force plates, but the force readings from the sensor platform vary too much to be reliable for everyday use.

Keywords: wearable; motion analysis; sensor platform; knee function; kinematic analysis; accelerometer; gyroscope; Velostat; ground reaction force

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List of Abbreviations

ADL: Activity of Daily Living

ACL: Anterior Cruciate Ligament

EMG: Electromyography

ADC: Analog to Digital Converter

IMU: Inertial Measurement Unit

HREC :Health Research Ethics Committee

Chapter 1: Introduction

1.1 Introduction

This chapter provides background on the study, which explains why additional research in the field is necessary. The problem statement and proposed research provide information on how the issue can be addressed. The objectives and dissertation structure are also provided.

1.2 Background

Serious injuries to the ligamentous structures of the knee, such as the anterior cruciate ligament (ACL), often require surgery followed by a prolonged (e.g., 9-12 months) rehabilitation process [1]. Patients that have undergone knee joint surgery are required to wear a restrictive knee brace to constrain movement in order to protect key soft tissue structures to allow for more effective rehabilitation as well as progressive tissue adaptation [2]. As the rehabilitation process tends to involve, the knee joint is gradually stressed to a greater extent and the functional range of motion of the knee tends to increase. There is presently a lack of objective knowledge and data on the functionality of the knee joint during various activities of daily living (ADL) while a patient is outside of a clinical setting.

It is fairly common for patients to follow their knee rehabilitation protocol for a limited time after the operation or injury [3]. Additionally, there tends to be a lack of rehabilitation adherence which is usually a response to how the patient perceives the symptoms they have, how they assess the effectiveness of the intervention, and their ability to incorporate the rehabilitation protocol into their everyday life [4]. Unfortunately, besides the apparent detrimental effect on the patient's long-term recovery, physical therapists also have very little information on the patient's compliance with the rehabilitation protocol and whether a given rehabilitation protocol allows for more optimal completion of everyday functional abilities outside of a clinical setting. Furthermore, despite all of the different methods currently incorporated for knee rehabilitation, there remains a lack of consensus involving the duration, intensity, and delivery of rehabilitation [5]. There are insufficient studies that include an adequate number of patients to provide conclusive evidence on rehabilitation methods, which raises the question, what rehabilitation method is the most effective? Current methods for monitoring rehabilitation include motion capture systems, force plate sensors, electromyography devices, questionnaires and visits to clinicians. Extensive studies are required to evaluate the clinical effectiveness of home-based rehabilitation compared to clinically-based exercise sessions [6]. It, therefore, stands to reason that more extensive studies are needed to evaluate the effectiveness of more economical, real-time knee rehabilitation monitoring tools in a real-world setting.

1.3 Problem statement

The kinematics of the knee joint during various ADL's (Activities of Daily Living) are usually evaluated in laboratory-based settings using highly sophisticated and costly technology. There is a need to evaluate knee joint function during various ADL's in a real-world setting using low-cost, yet valid and reliable technology in both healthy and compromised knee joints such that practitioners and rehabilitation specialists would be able to enhance their clinical decision-making processes. From an engineering perspective, it is important to determine whether a wearable motion analysis device is appropriate to monitor and measure human knee function.

1.4 Proposed Research

The present research study focuses specifically on the selection and placement of sensors that provide data to monitor knee function from home, which mainly involves the measurement of ADLs of a healthy individual. Activities of daily living include walking, sitting, standing, tying a shoe, and walking up stairs.[7]

Data from such varied activities would provide a good indication of the status of a person's knee function and would therefore provide clinicians with a better overview of the functional demand on the knee.

An activity such as walking is comprised of a gait cycle which is defined as the time interval between two consecutive occurrences of heel strike of the same leg. [8] (See Figure 1-1 [9]) The gait cycle starts with the initial contact of the foot and moves clockwise around to the loading response, mid-stance, terminal stance, pre-swing, initial swing, mid-swing and ends at terminal swing.

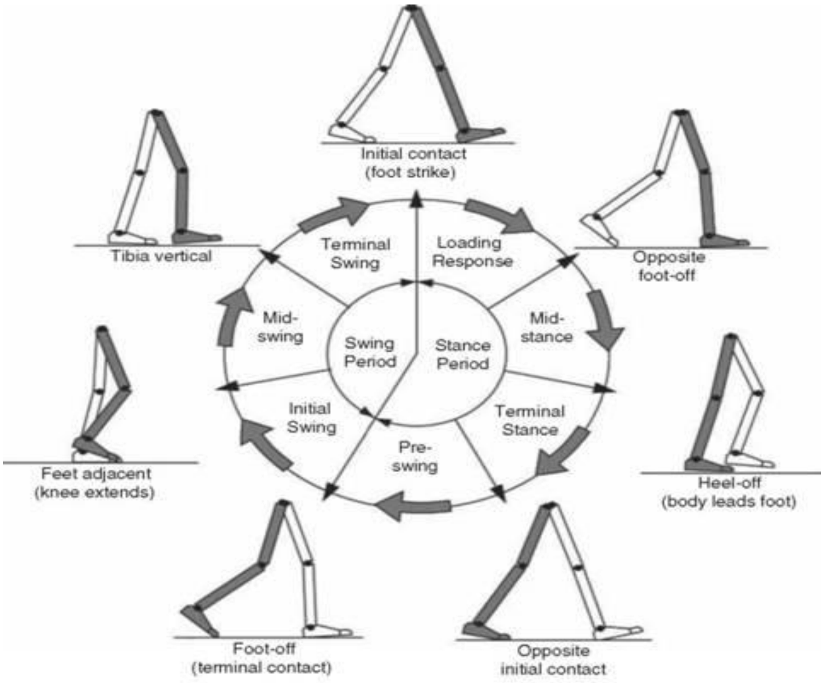


Figure 1-1: Phases of the gait cycle [9]

Monitoring specific gait cycle data would involve measuring gait cycle duration and frequency, terminal contact of the gait, ground reaction forces, and knee joint angle. [10] These measurements are also taken during other activities of daily living, including sitting and standing, tying a shoe, walking up and down slopes and stairs etc.

The following objectives were identified for the present study:

Objective 1: Design and build a sensor platform (brace) with multiple sensors to evaluate knee function

- Research knee joint biomechanics.
- Research applicable existing knee function monitoring devices.
- Research the type of measurements required to monitor knee function.
- Research the types of sensors that can provide lower extremity kinematic data on human knee function.
- Design sensor platform.

Objective 2: To evaluate the validity of the electronic platform for providing kinematic and kinetic data of the knee during activities of daily living.

- Use the sensor platform to collect data on participants completing activities of daily living.
- Analyze the results.
- Complete validation of the experiment results with existing measurement methods, including optical motion capture and force plates.
- Determine if the sensors provide reliable data to monitor human knee function.

1.5 Dissertation structure

The literature study documented in chapter 2 is performed on human knee function using an electronic platform to gain more knowledge on human knee function and possible sensor technologies. The sensor platform design in chapter 3, which attaches to the user's leg shall collect and store time-stamped data points for all the acquired measurements. The experimental strategy in chapter 4 is designed to generate data on human knee function with the sensor platform. The sensor data will be transmitted to and displayed on a terminal to view data as it is captured, for the test operator to ensure that valid data is collected while the experiments are conducted. A number of predefined activities associated with everyday life will be carried out by the participant. The average of all repetitions done per activity will be calculated and the average data will be plotted for each of the steps given above on the graphs. The graphs will be used to analyze the data in chapter 5 and validated using current methods of knee function monitoring. Recommendations are then provided, and a conclusion is given in chapter 6. See Figure 1-2 for an overview of the methodology.

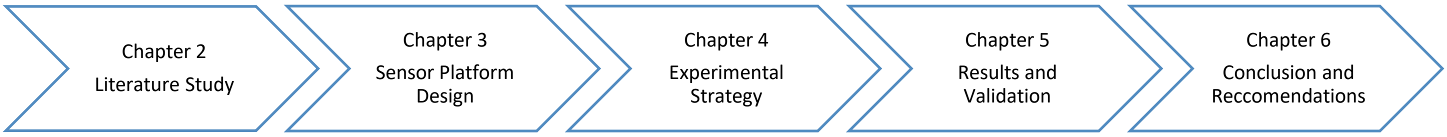


Figure 1-2: Methodology Overview

Chapter 2: Literature review

2.1 Introduction

In the previous chapter, the background was provided on the problem, a problem statement was given with the proposed research, and the dissertation structure was explained. This chapter provides an overview of the literature to gain the knowledge required on knee biomechanics and to gain a better understanding of the requirements when choosing specific sensors from an engineering design perspective. The required measurements are then researched to provide an overview of the types of measurements required for the study. Research will then be done on different types of sensors that would be able to provide data on those measurements.

2.2 Similar Research on Wearable Sensors

Assessments of ADL's in real-world settings using cost-effective wearable sensors that are portable and easy to use from home for both research and rehabilitation purposes are severely limited. Most of the existing literature has focused on motion analysis systems that require a laboratory and considerable expertise [11]. Movement analysis using wearable sensors is expected to play an increasingly vital role in clinical applications due to them being cost-effective and easy to use in everyday settings.

One article discusses a systematic review conducted to determine the validity and reliability of inertial measurement sensors (M/IMU) for joint angle calculation. The review found that M/IMU can be a valid alternative to laboratory-based motion capture systems, but the reported validity varies with the complexity of the task and the joint evaluated. The review also highlights the need for further studies on the reliability of M/IMU to make stronger conclusions, and to standardize technical procedures to obtain more accurate data. Overall, M/IMU can be a useful tool to assess whole body range of motion, but further research is needed to optimize its use [12].

Another article discusses the importance of measuring joint range of motion (ROM) in clinical evaluations and how wearable systems such as exoskeletons and orthoses can aid in this measurement. The article presents a novel methodology to assess the performance of various angle sensors used in wearable joint angle measurement, particularly for articulated ankle-foot orthoses (AFOs). The study compares off-the-shelf and custom-built sensors in terms of dynamic and static errors, accuracy, precision, and cost. The optical encoder was found to have the highest accuracy and precision, while the anisotropic magnetoresistive (AMR) sensor had the highest performance-to-cost ratio. All sensors tested had angular errors below 5° [13].

Another article describes a study that tested a wireless wearable sensor system consisting of inertial sensors for use in rehabilitation. The system was evaluated by measuring hip, knee, and ankle joint angles with healthy subjects and comparing the results to a 3D motion measurement system. The study found that the sensor system produced accurate measurements with a small margin of error. The system was also used to measure joint angles of elderly subjects during gait on a level floor, and it was found to show differences in joint angles between paralyzed and non-paralyzed sides [14].

Past studies on measuring gait with wearable sensors compared to motion capture systems have shown that wearable sensors are able to capture motion data with relatively small margins of error [15]. Studies have also shown that using sensors that do not drift (sensor data that does not have to be integrated) reduces these errors even further [16]. Another study showed that re-positioning of the sensors during data collection has shown a greater deviation in the minimum and maximum angle data but showed acceptable repeatability in capturing motion analysis data when not re-positioned, which is an important note to make looking at how the sensors would be placed on a person [17].

A range of potentiometers, accelerometers and gyroscopes were used to capture motion analysis data in previous studies. Most of the data collected were on maximum sagittal knee flexion angle and comparisons between wearable sensors and motion analysis systems were done by means of a walking trial. [15]–[20] It would thus be interesting to see how wearable sensors would compare to motion capture systems while completing other activities of daily living, like ascending and descending slopes and stairs, tying a shoe and sitting and standing etc.

2.3 Biomechanics of the Knee

The knee joint is exposed to some of the highest impact loads partly due to the fact that it is comprised of two of the longest bones in the human body, namely the femur and the tibia [21]. The acting load is a function of factors such as human body weight, ground type, and contact interface between floor and foot. The force acting on the knee joint is classified into external force and internal force [22]. External forces are human activity and how it interacts with soil, and internal forces are due to ligament and tissue restrictions [23]. These forces are illustrated in Figure 2-1.

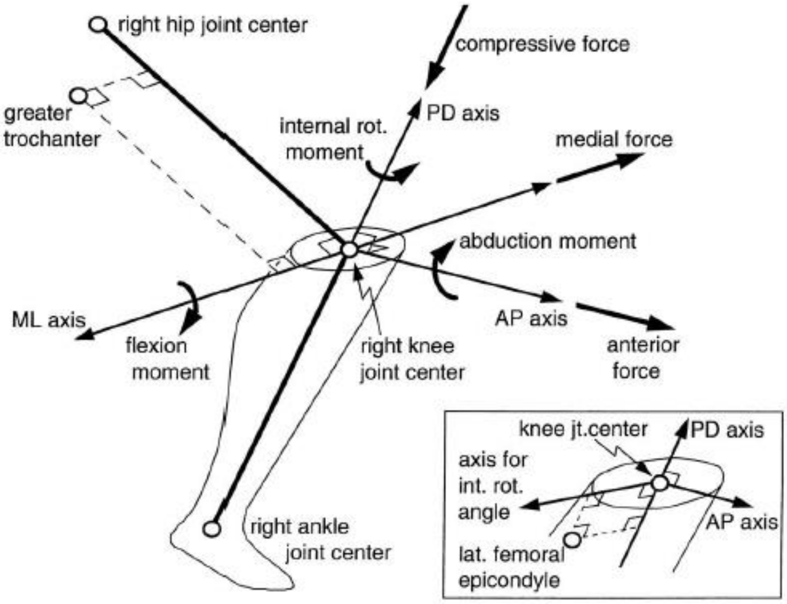


Figure 2-1: Kinematic axes of the Knee joint [23]

Actions such as walking, running, climbing stairs, and standing are very common actions in human daily life. In all movements, the knee joint's primary functions include supporting body weight, absorbing shock during heel strike, and assisting in swinging the lower extremity [24]. Previous studies have shown that passive knee flexion can reach 160 degrees in the sagittal plane, but functional ranges tend to vary substantially depending on the type of activity. Similarly, the typical loads experienced by the knee joint are activity-dependent: walking: two to three times body weight, squatting: two to five times body weight, stair climbing: four to six times body weight, and running: seven to twelve times body weight[25].

2.4 Current Knee Function Monitoring Methods

Current knee function monitoring methods require the patient to visit the clinic. These methods include:

- Questionnaires

  Questionnaires involve asking patients specific questions and having them return an answer. These questions include but are not limited to [26]:
    - How would you describe your overall pain?
    - How long can you walk before experiencing severe knee pain?
    - What level of pain do you experience when standing from a seated position?
    - Does the knee pain interfere with your sleep?

This method requires a high level of expertise from clinicians that know how to interpret the answers to each question. The clinicians can then devise a strategy to rehabilitate the knee or modify the rehabilitation protocol currently in use.

- Electromyography (EMG)

  Electromyography measures the electrical activity in response to a nerve's stimulation of the muscle [27]. For example, electrodes are placed on the leg muscles, and the electrical activity is displayed, as seen in Figure 2-2[28].

Figure 2-2: Electromyography (EMG) [28]

The muscle activation sequencing between knee extensors and knee flexors are then determined. The correct interpretation of EMG signals requires a high level of expertise and there are considerable costs involved. Typically an EMG system could cost anywhere between R80 000 to R1 000 000 depending on the make, model, and number of sensors.

- Isokinetic dynamometry

  Isokinetic dynamometry is a device that works against an applied force and controls the speed of an exercise at a predetermined rate. Therefore, the device measures the force applied through the joint range of motion and is considered the gold standard for evaluating concentric and eccentric muscle strength in various clinical and athletic populations[29]. Figure 2-3 displays an image of an isokinetic dynamometry device [30].

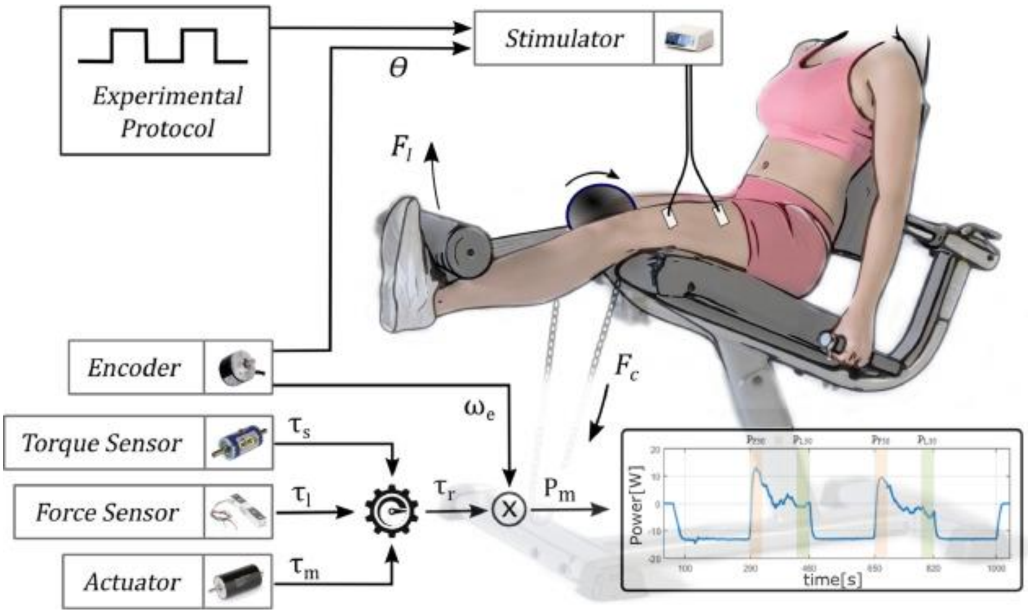


Figure 2-3: Isokinetic dynamometry [30]

An isokinetic dynamometer device is typically used to measure the strength and the ratio between the extensors and flexors [31]. However, isokinetic dynamometry requires a high level of expertise and costs anywhere in the region of R500 000 up to R2 000 000. Furthermore, the equipment is limited to evaluating a single joint in a non-weight-bearing position and therefore has limited application for evaluating functional movements in a real-world setting.

- Force plates

  Force plates use several different sensors to measure the single-axis force or multi-axis force applied to a plate. Force plates measure ground reaction forces and determine deficits and asymmetries between injured and non-injured legs. The force plate typically measures force in Newtons [32]. Figure 2-4 displays what a typical force plate would look like [33].

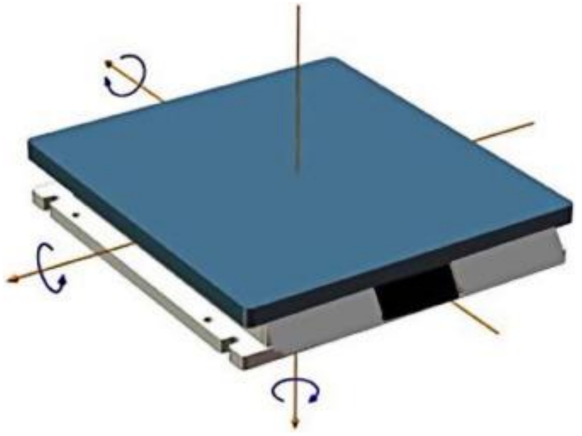


Figure 2-4: Force plates [33]

This method requires expertise and costs anywhere in the region of R200 000 up to R400 000 per plate. Such plates are typically mounted within flooring in a laboratory setting which again limits portability and applicability to real-world settings.

- Clinicians

  A patient starts by visiting a clinic once they observe symptoms of injury (including but not limited to): a popping noise/feeling, crunching noises, swelling, redness, warmth to the touch, stiffness, inability to straighten the knee, weakness or instability [34]. The clinicians then investigate and diagnose the extent of the injury and may send the patient for a scan depending on the type and severity of the injury. The clinician would then follow the knee rehabilitation phases (as mentioned above) depending on the type and extent of injury. After that, the patient would regularly (as advised by the clinician depending on the injury) visit the clinic for monitoring, and the clinician would decide on the rate that the rehabilitation shall take place. The potential disadvantage to this method is the cost and effort associated with visiting the clinician as well as not being able to provide objective data related to ADLs. There is likely to be a disconnect between the expected functional capacity of the knee and the observed capability since the patient would be predisposed to a variety of stresses in the real world compared to the clinical setting.

- Optical motion tracking

  Optical motion capture involves converting movement in real-life to digital data through the use of reflective markers placed on key anatomical landmarks on a patient, which are then tracked by multiple near-infrared cameras at different angles. Specialised software then reconstructs the movement of these markers in a three-dimensional (3D) space, and applies these movements to a computer model to recreate a virtual avatar of the patient [35]. Spatio-temporal parameters (having spatial and temporal qualities) from optical motion tracking technology provide clinicians with more insight into the movement dynamics of the patient. Figure 2-5 displays an example of such a setup [36]. Patients need to attend specialized clinics that accommodate optical motion capture and require expertise. Currently, there are only 9 such facilities in South Africa, implying that a need exists to obtain valid and reliable data related to knee joint kinematics beyond purely academic environments.

Figure 2-5: Optical motion capture [36]

In order to understand the quantitative value of exercise protocols, an alternative constant measurement method is needed. A wearable device housing appropriate sensors capable of capturing real-time movement data could be the answer. If such a device could be worn during all active hours of the day, the user's activity levels outside the exercise period could shed further light on patient recovery. A sensor is an input device that gives an output depending on a physical quantity [37]. Sensors should, however, be small enough to be worn and can monitor the leg's movement without impairing the user's movement. These sensors can include force-sensitive resistors, load cells, accelerometers, and gyroscopes. Important parameters that are required to monitor knee function involve the initial contact of the gait, gait cycle duration, and frequency, terminal contact of the gate, knee load, knee joint angle, and leg sway [38]. These parameters mentioned above are measured while walking, sitting, exercising, and doing other daily activities. These measurements provide biofeedback to clinicians, allowing them to obtain data/information/feedback while completing specific tasks or day-to-day activities.

2.5 Required Measurements

The required measurements to collect and analyze leg-movement data are comprised of above-knee movement data, below-knee movement data, ground reaction forces, and the knee joint angle data [39]

Above-knee and below-knee movement data would involve measuring the multi-axis angular velocity and single-axis angle, which also provides a means to measure the gait. This includes measuring the initial contact of the gait, the terminal contact of the gait, the gait cycle duration, and the gait cycle frequency. The sensor-derived gait data is graphically portrayed, allowing both the visualization and analysis of the measurements mentioned above. The angular velocity will also enable the gathering of data on horizontal sway on both the above-knee and below-knee data, which can indicate unnatural gate movement. The angular data measured above and below the knee provides a knee joint angle by finding the difference in angle between the above-knee sensor and the below-knee sensor. A single-axis (vertical force) force sensor placed under the foot will measure the ground reaction forces. Figure 2-6 illustrates possible sensor positions.

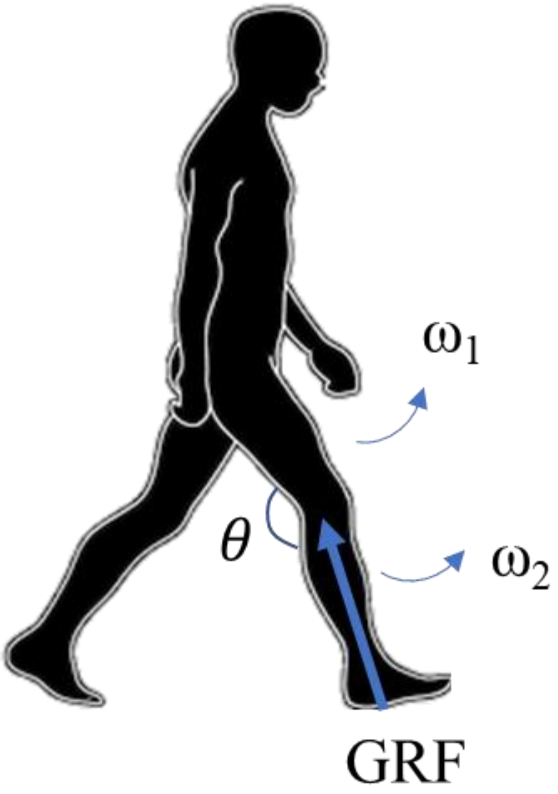


Figure 2-6: Sensor placement and readings. Note: ω_1 = angular velocity of above-knee segment; ω_2 = angular velocity of below-knee segment; Θ = sagittal knee angle; GRF = ground reaction force

Figure 2-7 [40], Figure 2-8 [40], and Figure 2-9 [41] display expected graphical outcomes on knee angle, knee angular velocity, and force plate data, respectively while walking.

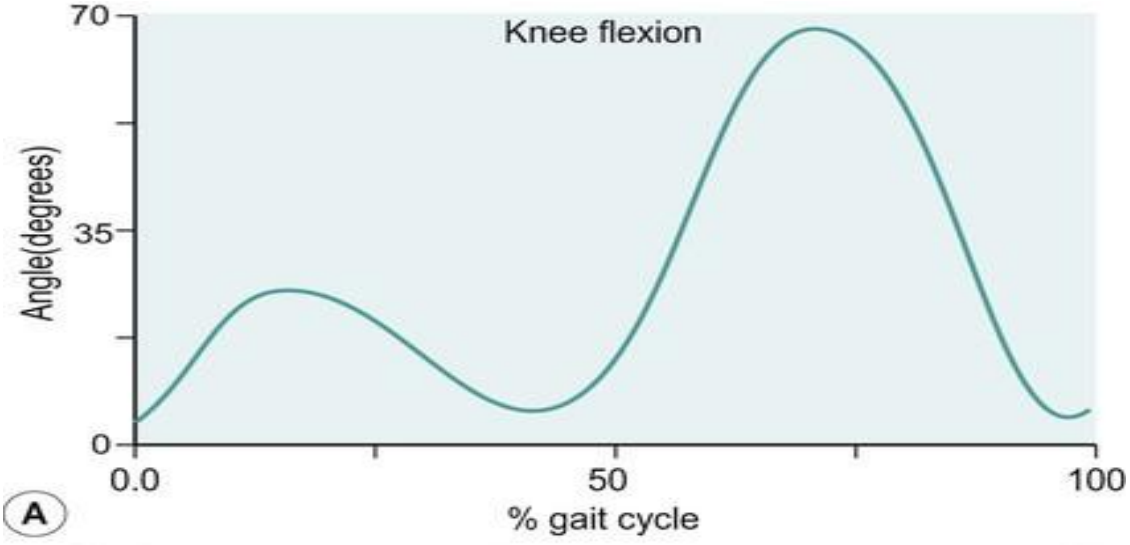


Figure 2-7: Knee Angle during a typical gait cycle [40]

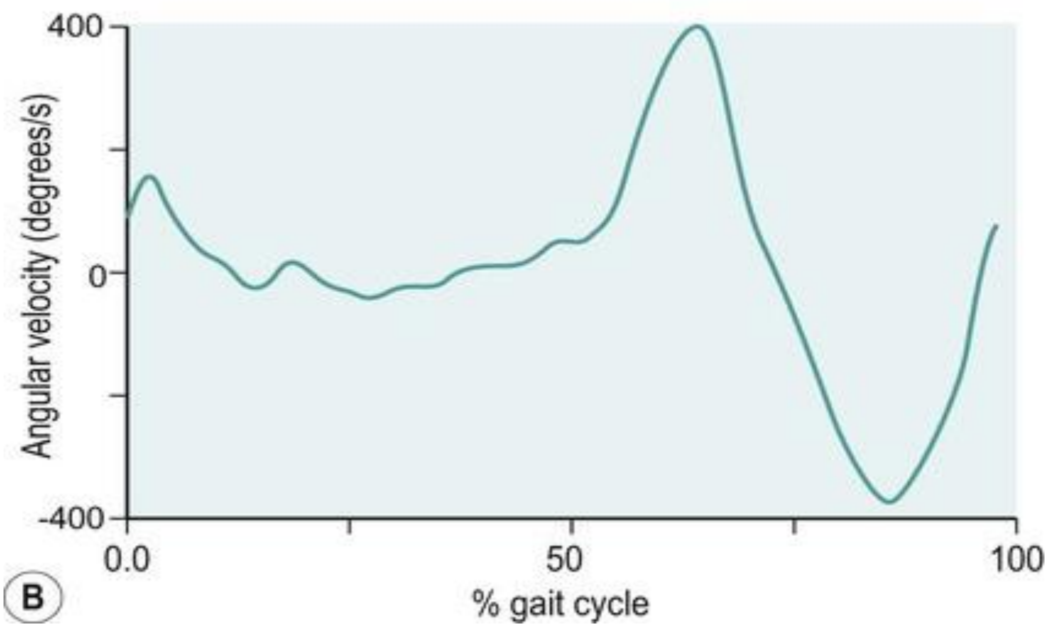


Figure 2-8: Knee Angular velocity during a typical gait cycle [40]

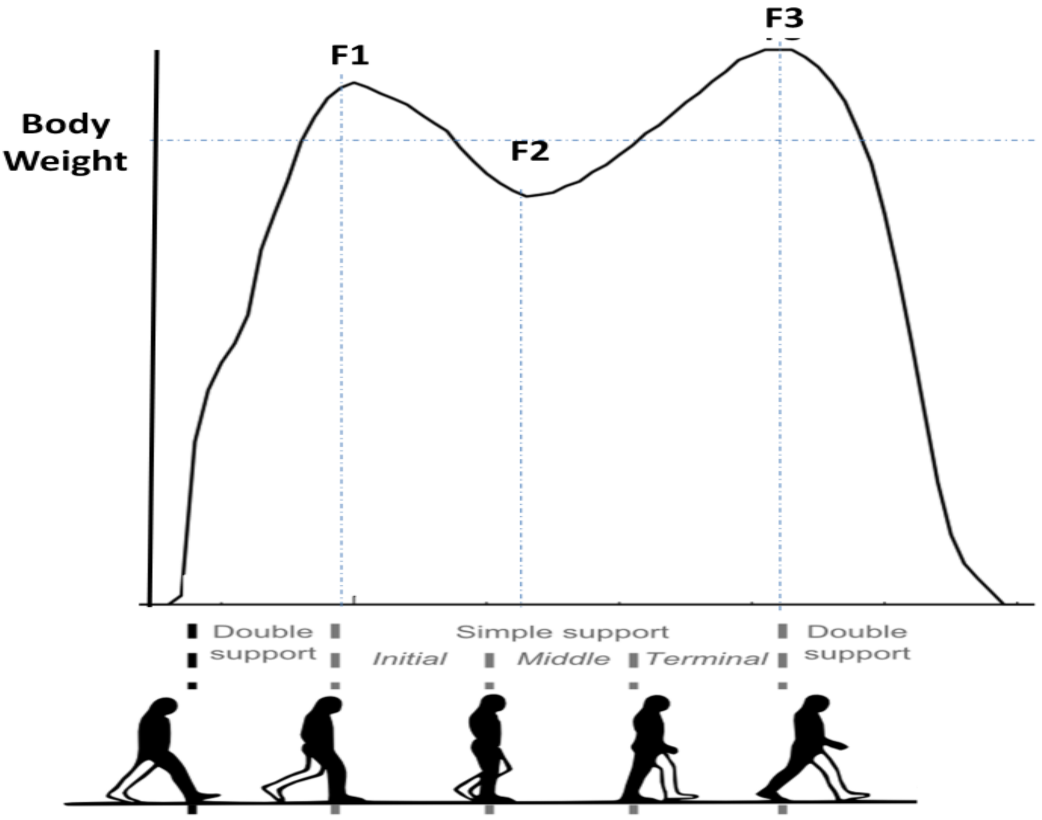


Figure 2-9: Ground reaction force during a typical gait cycle [41]

2.6 Knee Joint Angle

The knee joint angle can be measured using a combination of accelerometers, gyroscopes, or potentiometers. The details of each are highlighted in the text below.

2.6.1 Accelerometers

An accelerometer is an electromechanical device used to measure acceleration forces. Such forces can be static, such as continuous gravity, or dynamic, such as sensing motion or vibration, as is the case with many mobile devices. Accelerometer look like simple circuits in larger electronic devices. Despite its modest appearance, the accelerometer consists of many different parts and works in many ways. Two of them are piezoelectric and capacitive sensors. The piezoelectric effect, the most common form of accelerometer, uses a microscopic crystalline structure that is stressed by a g-force. These crystals generate voltage from stress, and accelerometers interpret the voltage to determine velocity and direction.[42]

To measure the angle of the knee joint, the tilt must be calculated using the accelerometer data. Figure 2-10 [43] illustrates the tilt of an object.

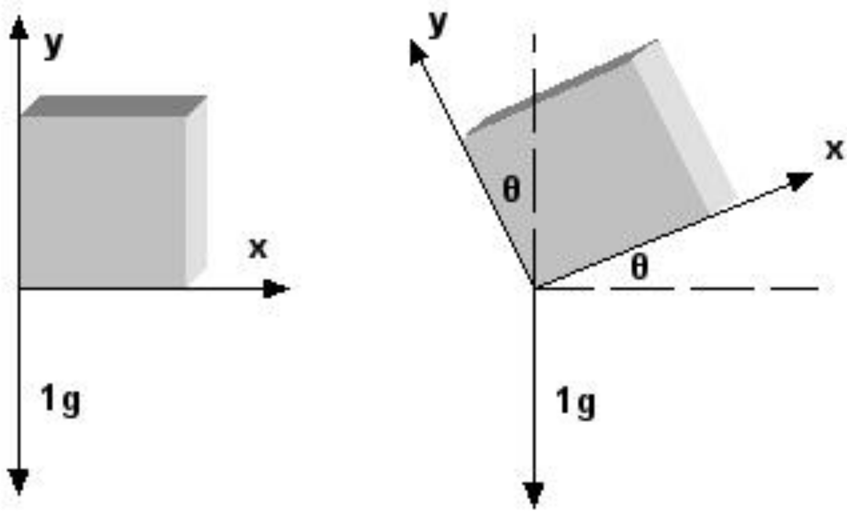


Figure 2-10: Accelerometer Tilt

The knee joint angular data is only 1 axis, thus we use two axes of the accelerometer to calculate the tilt. The tilt can be calculated using Equation 1. [44]

$$Tilt = \arctan\left(\frac{Ax}{Ay}\right) \qquad (1)$$

Figure 2-11 illustrates the quadrant orientation for the accelerometer tilt.

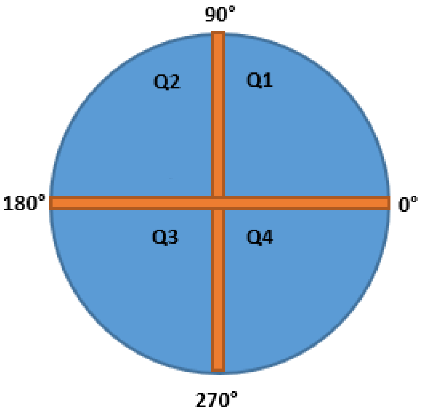


Figure 2-11: Accelerometer Tilt Quadrants

It is important to note that since the outputs in quadrants 1 and 3 are the same, and the outputs in quadrants 2 and 4 are the same, we need to know the signs of the X and Y accelerations to determine the applicable tilt quadrant. For example, tan(45°) = 1 and tan(225°) = 1. If arctan is positive, the tilt angle is in the first or third quadrant. If the arc tangent is negative, the tilt angle is in the 2nd or 4th quadrant. By knowing the signs of AX and AY, we can determine exactly which quadrant the accelerometer is tilting in. [45]

If the accelerometer is tilting in quadrant 1, then

$$Tilt = \arctan\,(\frac{Ax}{Ay}) \tag{2}$$

If the accelerometer is tilting in quadrant 2, then

$$Tilt = \arctan\left(\frac{Ax}{Ay}\right) + 180° \tag{3}$$

If the accelerometer is tilting in quadrant 3, then

$$Tilt = \arctan\left(\frac{Ax}{Ay}\right) + 180° \tag{4}$$

If the accelerometer is tilting in quadrant 4, then

$$Tilt = \arctan\left(\frac{Ax}{Ay}\right) + 360° \tag{5}$$

2.6.2 Gyroscopes

A gyroscope is a frame-mounted device that can detect angular velocity as the frame rotates. Gyroscopes come in many classes, depending on their physical principle of operation and the technology involved. Gyroscopes can be used alone or integrated into more complex systems such as gyrocompasses, inertial measurement units, inertial navigation systems, and altitude and heading reference systems.[46] A 3-axis gyroscope orientation illustration of the angular velocity is displayed in Figure 2-12.

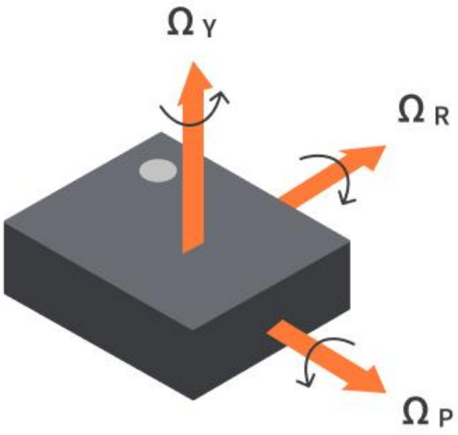


Figure 2-12: Gyroscope Orientation [46]

To be able to calculate the tilt angle using a gyroscope, the angular velocity data must be integrated, as shown in the equations below

$$\Omega = d\theta / dt \quad (6)$$

$$\theta = \int \Omega \, dt \quad (7)$$

One problem with this integration process is that when you integrate the gyro data, the noise is also integrated with it. Additionally, the gyro has the limitation that the output does not have a constant offset at rest. In fact, this value is constantly changing, especially when the temperature changes. This condition is called drift. Drift is very small, but even the smallest offset makes the integrated data grow infinitely when dealing with integration.[47]

2.6.3 Potentiometers

The potentiometer is a manually adjustable three-terminal variable resistor. Two terminals are connected across the resistive element and the third terminal is connected to a sliding contact called a wiper that moves across the resistive element. A potentiometer basically works as a variable resistor voltage divider. A resistive element can be thought of as two resistors in series (the total resistance of the potentiometer), and the position of the wiper determines the resistance ratio between the first resistor and the second resistor. When a reference voltage is applied across the terminals, the position of the wiper determines the output voltage of the potentiometer. [48] See Figure 2-13 for an illustration of a potentiometer.

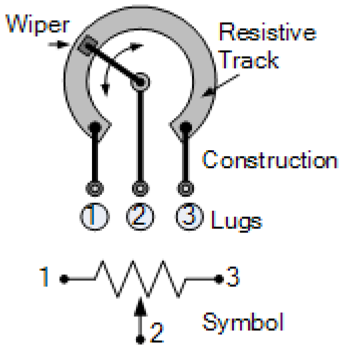


Figure 2-13: Potentiometer [48]

An important characteristic of most potentiometer designs is linearity, usually defined as the proportional difference between the actual output voltage and the position-based calculated voltage (nominal output). [49] This can be seen in Figure 2-14.

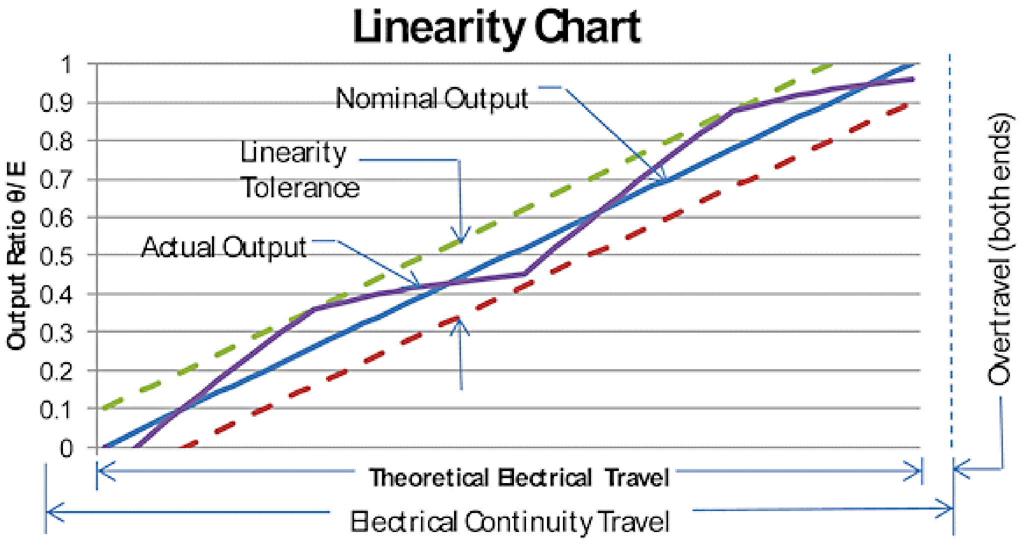


Figure 2-14: Potentiometer Linearity [49]

An ADC is required to be able to measure the output of the potentiometer, which is displayed in Figure 2-15.

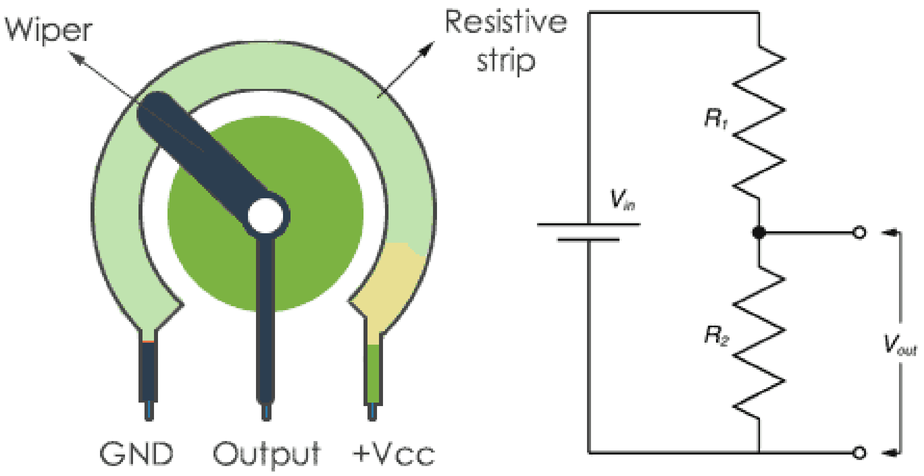


Figure 2-15: Potentiometer Voltage Divider [50]

The output voltage drop across R2 can be calculated using the equation below.

$$V_{out} = \left(\frac{R_2}{R_1 + R_2}\right) V_{in} \tag{8}$$

The output voltage is measured incrementally against the angle of rotation of the potentiometer. The relationship between the output voltage and the angle of rotation of the potentiometer is then plotted and can be fitted linearly in the form of the equation below.[51]

$$y = mx + c \tag{9}$$

Where x and y are the variables, m is the slope of the curve, and c is the y-intercept.[52] We can rewrite the equation to calculate the angle.

$$V_{out} = m\theta + c \tag{10}$$

$$\theta = \frac{V_{out} - c}{m} \tag{11}$$

2.7 Knee Joint Angular Velocity

Similarly, knee joint angular velocity can also be measured using accelerometers, gyroscopes, or potentiometers.

2.7.1 Gyroscopes

The most commonly used arrangement for angular rate sensors is the 3aω array, where all six sensor elements are typically mounted at the centroid The main advantage of this measurement method is that fewer channels are required, reducing the cost and complexity of data acquisition. In addition, the reduced assembly complexity facilitates sensor packaging in the low mass and small volume form factors that are desirable for wearable sensor applications.[53]

As mentioned above (2.6.2) Gyroscopes measure the angular velocity of an object and is thus a sensor that should be considered for the sensor platform.

2.7.2 Potentiometers

Following the same method used above (2.6.3), one can calculate the angle of the knee joint using the potentiometer. Derivative of the captured angular data is performed on the angular data captured by the potentiometer with respect to time to determine the angular velocity of the joint. The derivative of the angular data can be determined using the equations below, where ω is the angular velocity, θ is the angle of rotation, and t is the time.[54]

$$\omega = \frac{\Delta\theta}{\Delta t} \tag{12}$$

$$\omega = \frac{\theta_2 - \theta_1}{t_2 - t_1} \tag{13}$$

2.8 Ground Reaction Forces

The ground reaction forces can be measured using load cells, force sensitive resistors, or a Velostat.

2.8.1 Load Cells

A load cell is a transducer used to generate an electrical signal whose magnitude is directly proportional to the applied force. [55] The different types of load cells are explained below.

Strain Gauge Load Cell

A strain gauge (Figure 2-16) is an electrical conductor rigidly attached in a zigzag pattern to a foil. When you pull on this foil, it stretches causing the ladder to also extend. When you squeeze it, it shrinks and becomes shorter. This change in shape also changes the resistance of the conductor. Since the resistance of a strain gauge increases with applied strain and decreases with contraction, the strain applied to a load cell can be determined using this principle.

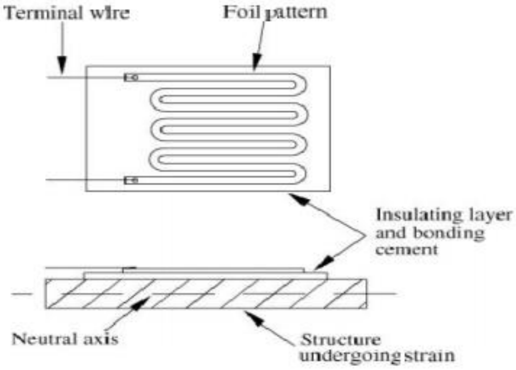


Figure 2-16: Strain Guage [56]

When a force is applied, a metal body deforms slightly like a "spring" and returns to its original shape if not overloaded. As the metal body deforms, the strain gauge also changes shape, resulting in a change in electrical resistance and a change in differential voltage through the Wheatstone bridge circuit. The change in voltage is therefore proportional to the physical force applied to the deflection and can be calculated from the voltage output of the load cell circuit.[57]

Piezoelectric Load Cell

These sensors work based on the piezoelectric effect. This effect occurs when polarized crystal materials are subjected to stress or strain. Strain, in turn, causes a shift in the molecular structure of the material, creating (natural crystals) or changing (manufactured) its polarity. This is analogous to the dielectric effect, which occur when charges are created by the movement of electrons in insulators. Decreasing the polarity will generate current in the direction of the crystal polarity, increasing it will generate current in the opposite direction. [58]

Hydraulic Load Cell

Hydraulic load cells (Figure 2-17 [59]) consist of two plates welded around a closed cell filled with vent oil. The cell is directly connected to the pressure gauge. A load on the cell causes a hydraulic pressure fluctuation that is recorded by a pressure gauge.

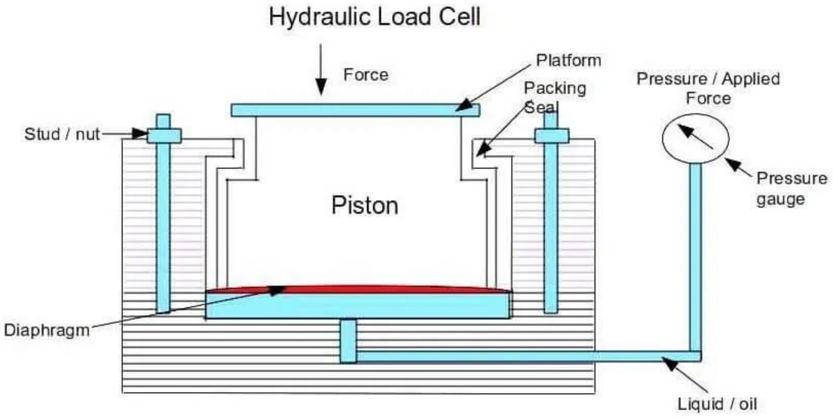


Figure 2-17: Hydraulic Load Cell [59]

Pneumatic Load Cell

Pneumatic load cells (Figure 2-18 [60]) work in a similar manner to hydraulic load cells by transforming fluid pressure into a load measurement, but instead of using liquid, they employ a gas such as air. The load to be measured is exerted on a loading platform on one side of a diaphragm, while a pressure supply regulator introduces pressurized gas to a chamber on the other side of the diaphragm to counteract the force. A pressure gauge is connected to a nozzle, allowing a portion of the pressurized gas to escape from the chamber, with the pressure of the gas flowing through the nozzle being measured. The applied force is directly proportional to the measured pressure.[60]

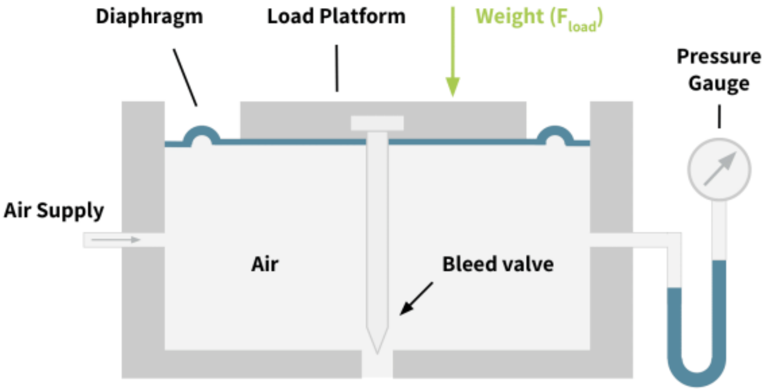


Figure 2-18: Pneumatic Load Cell [60]

Capacitive Load Cell

A capacitive load cell (Figure 2-19 [61]) uses a series of capacitors to measure the weight of the entire load cell. Inside each capacitor are two charged metal plates sandwiching an uncharged dielectric. This simple construction allows the capacitor to measure weight. When a capacitor is loaded, the plates move closer to each other, first creating a current. The equation below is a simple mathematical expression that describes the capacitance of a parallel plate capacitor. Capacitance is a measure of how much electrical charge a capacitor can store for a given voltage. The equation shows that capacitance is directly proportional to the surface area of one of the plates (A) and inversely proportional to the distance between the plates (d). This means that as the distance between the plates increases, the capacitance decreases, and as the surface area of one of the plates increases, the capacitance increases. The electric constant, $\mathcal{E}_0$, is a physical constant that describes the electric field in a vacuum. Its value is approximately 8.85 x 10^-12 F/m. The electric constant is used in the equation to convert the ratio of charge to voltage into capacitance.

$$\mathrm{C} = \mathcal{E}_0 \frac{A}{d}$$

This is converted to an electrical signal and can be reinterpreted as weight. [61]

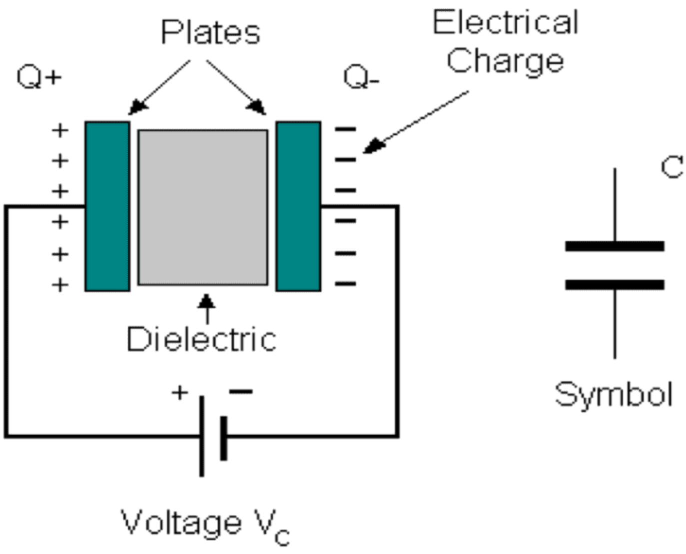


Figure 2-19: Capacitive Load Cell [61]

2.8.2 Force Sensing Resistors (FSR)

Force Sensing Resistors (Figure 2-20 [62]) sensors are devices that allow the measurement of static and dynamic forces on contact surfaces. Its response range depends on the change in electrical resistance. Research shows that FSR sensors are commonly used in robotic grippers and biomechanics. [63]

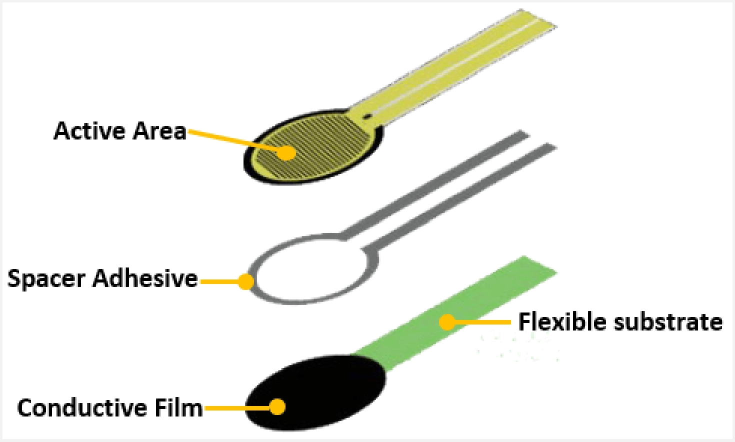


Figure 2-20: Force Sensing Resistor [62]

Force-sensing resistors alone are not pre-calibrated to relate force readings to known engineering units. However, the force measurement output sensed by the force-sensing resistor can be related to the force applied by a calibration procedure. A force-sensing resistor is a piezoresistive sensing technology. This means that it is a passive element that acts as a variable resistor in the circuit. Considering the inverse of resistance (conductance), the response of conductance as a function of force is linear within the specified force range of the sensor. [64]

2.8.3 Velostat

Velostat is a low-cost flat electrical packaging material with piezoresistive properties making it an attractive option for measuring outlet pressure. [65] When sandwiched between two conductors (Figure 2-21 [66]) and pressure is applied, the resistance of the Velostat decreases.[67] The Velostat can be used in the same way as the force sensitive resistor to calculate the force applied.

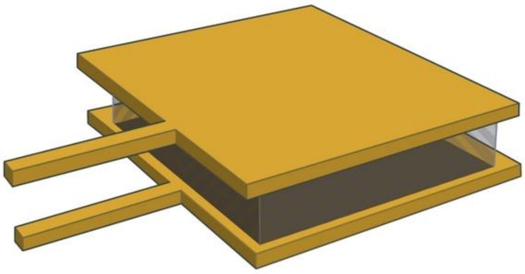


Figure 2-21: Velostat Force Sensor [66]

Some of the most affordable solutions to measure force during a gait cycle includes the use of mats and force plates, but even these prove to be quite expensive. These force sensors are restricted to a certain lab or clinic, where testing is undergone. Even though the Velostat is less accurate, with a ranging error value of 7.3% to 68.8% [68], it is affordable and can be used in everyday settings to get a decent estimation of forces placed on the foot during the gait cycle (Figure 2-22).

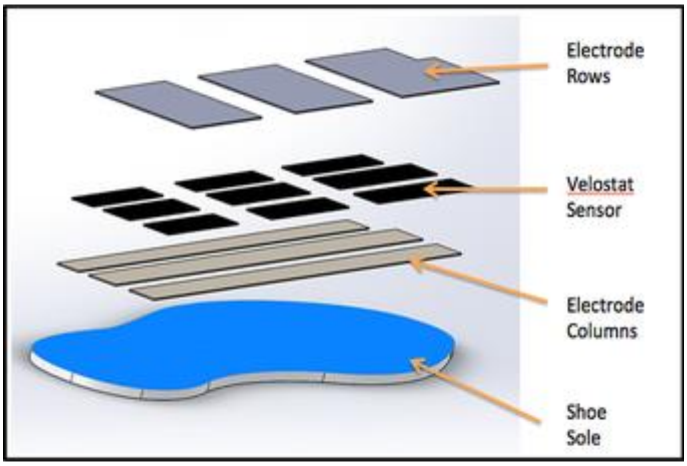


Figure 2-22: Velostat as a Force Sensor in a Shoe [69]

2.9 Conclusion

Gaining a better understanding of knee biomechanics and the types of measurements required for monitoring knee function led to three required measurements, which include, knee joint angle, knee joint angular velocity, and ground reaction forces. Sensors were then researched that could provide data for each individual measurement. The following Chapter will go into detail on the design of the sensor platform.

Chapter 3: Sensor Platform Design

3.1 Introduction

The previous chapter provided details on the literature study done regarding the types of measurements and sensors required to design a sensor platform capable of measuring knee function. This chapter provides thorough motivation for the design choices made during the design of the sensor platform and a list of all required components are given.. The design behind the force sensor, circuit, sensor platform base and data collection application is then discussed.

3.2 Components

The sensor platform will require different components to be able to measure various parameters like knee joint angle, knee joint angular velocity and knee load. The research done on the different methods of collecting data showed that three types of sensors are required. This includes the knee joint angle sensor, knee joint angular velocity sensor, and the ground reaction forces sensor.

3.2.1 Knee Joint Angle Sensor

Using a potentiometer to calculate the angle would require the sensor platform base to be a solid, non-flexible material, in order not to inhibit natural gait movement. Even though the potentiometer is the most affordable of all the sensors that can measure knee angle, it will not be used due to the potentiometer inhibiting natural gait movement An alternative is to make use of a gyroscope which provides the angular velocity. By integrating the angular velocity, the knee joint angle can be calculated. This will however introduce drift and to ensure integrity of the data, the drift must be eliminated. This results in very high accuracy for short-time measurements, but the drift that occurs causes measurements over a long period to be less reliable.

Using accelerometer data to calculate angle is less accurate over short periods due to vibration, which causes oscillation in the measured waveforms. The accelerometer readings are however more reliable at calculating error over longer periods than the gyroscopes. Thus, an accelerometer shall be used to calculate the knee joint angle.

3.2.2 Knee Joint Angular Velocity Sensor

Using a potentiometer to calculate the knee joint angular velocity cause the same problem as calculating the knee joint angle, the sensor platform base would inhibit natural gait movement. Accelerometer data can be used to calculate the angular velocity by finding the derivative of the angle. The oscillations caused by the vibrations on the accelerometer could however cause less reliable data than that of the gyroscope. It would make more sense to use a gyroscope, seeing that it is a sensor designed to measure angular velocity, thus no further calculations are required.

3.2.3 Ground Reaction Forces Sensor

In the literature review, a few options were considered to measure the ground reaction force. This includes the load cell, force sensitive resistor, and Velostat. Load cells are quite large and difficult to place under a foot to measure knee load. Smaller load cells are available, but are costly and are still not small enough that the load cell would not inhibit natural gait movement. Force-sensing resistors are small enough to not inhibit natural gait movement, but force sensitive resistors that are rated for the weight of a person are hard to come by. Force sensing resistors are also a fixed size and would require multiple of them to create the force sensor. Velostat can be made according to the size requirement. Velostat is not as accurate as load cells, but the aim is to design an affordable sensor platform that can be used in everyday settings. The Velostat should be able to provide a reasonable estimation of force applied to the knee. Thus, Velostat shall be used for the ground reaction force sensor.

3.2.4 Sensor Platform Base

The sensor platform base houses the sensors, microcontroller, and power supply that would be required to measure the knee joint angle, angular velocity and knee load. When considering materials for a brace with sensors, there are a few key trade-offs to consider. Some of the most important factors to take into account include durability, breathability, comfort, and cost.

One option for the brace material is plastic, which is highly durable and can withstand a lot of wear and tear. However, plastic can be uncomfortable to wear, especially if it is not breathable. Additionally, plastic can be quite expensive compared to other materials.

Another option is metal, which is also highly durable and can be relatively inexpensive. However, metal braces can be heavy and uncomfortable to wear for long periods of time. Additionally, metal can cause skin irritation and other allergic reactions in some people.

A third option is cloth, which has several advantages. Cloth is highly breathable, which can help prevent sweat build-up and reduce skin irritation. It is also lightweight and comfortable to wear for long periods of time. Additionally, cloth is relatively inexpensive compared to other materials. However, cloth braces may not be as durable as those made from plastic or metal and may need to be replaced more frequently.

Overall, the choice of material for a brace with sensors will depend on the specific needs of the user. However, given the trade-offs between different materials, cloth may be the most suitable option for many people, especially those who value comfort and breathability over durability and cost.

3.2.5 Microcontroller

A microcontroller is required to process the sensor measurements. The integrated sensor's, namely the accelerometers and gyroscopes use I2C communication, while the force sensors are measured using ADC pins. By streaming the real-time data to a computer, a microSD card is not required, saving on costs. Thus, the microcontroller reads the data from the sensors and sends the data to a user interface on a computer using Bluetooth. A microcontroller will thus be used that has two I2C ports and two ADC pins, the microcontroller must also have Bluetooth capabilities.

3.2.6 Power Supply

A portable power supply is required to power the sensor platform, due to the sensor platform being attached to a person, as the person is completing certain activities of daily living. Thus a 18650 Battery shall be used to power the sensor platform. A 18650 battery is a popular choice for powering sensor platforms like the one described due to its high energy density, compact size, and rechargeability. Here are some specific reasons why a 18650 battery might be chosen to power a platform with an ESP32, 2 MPU 6050s, and 2 Velostat force sensors:

- High energy density: A 18650 battery can pack a lot of energy into a relatively small package, which is important for portable devices like sensor platforms. This means that the platform can run for longer periods of time without needing to be recharged or replaced.
- Rechargeability: 18650 batteries are rechargeable, which means they can be used over and over again. This is not only more convenient, but also more environmentally friendly than using disposable batteries.
- Compact size: The 18650 battery is relatively small and can fit easily into the platform without taking up too much space. This is important for portable devices where size and weight are key factors.
- Compatibility with ESP32: The ESP32, which is a popular microcontroller used in many sensor platforms, is designed to work with a range of different battery types, including 18650 batteries. This means that it is easy to integrate the battery into the platform and ensure that it can be charged and discharged safely.

- Adequate power for multiple sensors: The ESP32, 2 MPU 6050s, and 2 Velostat force sensors all require power to operate. A 18650 battery can provide enough power to run all of these components without needing to be recharged frequently.

Overall, a 18650 battery is a reliable and efficient choice for powering a sensor platform with an ESP32, 2 MPU 6050s, and 2 Velostat force sensors. Its high energy density, rechargeability, compact size, and compatibility with the ESP32 make it an ideal choice for portable devices that require a long-lasting power source.

3.2.7 Electronics Housing

The electronics housing acts as a mounting point for the sensors, power supply, and microcontroller to the knee brace. The housings shall be 3d printed specifically for the electronics that are used in the sensor platform. 3D printing is a popular choice for making housings for sensor platforms due to its flexibility, precision, and speed. Here are some specific reasons why 3D printing might be chosen to make a housing for a sensor platform:

- Flexibility: 3D printing allows for a high degree of customization and flexibility in the design of the housing. This means that the housing can be tailored specifically to the dimensions and requirements of the sensor components, as well as any additional features or components that may need to be included.
- Precision: 3D printing technology has advanced significantly in recent years, allowing for very precise and accurate designs to be produced. This is important for sensor housings, which need to fit tightly and securely around the components to protect them and ensure accurate readings.
- Speed: 3D printing can be a relatively quick and efficient process, especially compared to traditional manufacturing methods like injection molding. This means that the housing can be produced relatively quickly, which is important for prototyping and testing.
- Cost-effectiveness: 3D printing can be a cost-effective option for producing small quantities of custom parts, which is often the case with sensor housings. This can help to keep costs low and reduce the overall development time.

Overall, 3D printing is a flexible, precise, and cost-effective choice for making a housing for a sensor platform. Its ability to produce custom designs quickly and accurately makes it an ideal choice for prototyping and testing, as well as for producing small quantities of custom parts.

3.2.8 Interface

An application is essential to interface with a wearable motion sensing system on a leg because it allows for real-time monitoring of movement patterns, tracking of progress over time, and customization of training programs. This can provide invaluable insights and motivation for athletes, physical therapy patients, and individuals looking to improve their overall fitness and health.

3.2.9 IMU Sensor Trade-off

Table 3-1 below illustrates the trade-off between different IMU devices.

Table 3-1: IMU Sensor Trade-off

Sensor	**MPU6050**	**MPU9250**	**LSM9DS1**
Manufacturer	InvenSense	InvenSense	STMicro
Axes	6	9	9
Accelerometer	16-bit	16-bit	16-bit
Gyroscope	16-bit	16-bit	16-bit
Magnetometer	No	14-bit	16-bit
Temperature	Yes	Yes	Yes
Price	Low	Medium	Medium
Power	Low	Medium	Medium

Overall, while the MPU9250 and LSM9DS1 offer additional features such as a magnetometer, the MPU6050 is the most cost-effective and power-efficient option, making it a popular choice for many applications.

3.2.10 Controller Trade-off

Table 3-2 below illustrates the trade-off done for the controller.

Table 3-2: Controller Trade-off

Feature	ESP32	Arduino Uno	Raspberry Pi Zero W
Manufacturer	Espressif Systems	Arduino	Raspberry Pi
CPU	Dual-core 32-bit LX6	8-bit AVR	ARM11
Clock Speed	Up to 240 MHz	16 MHz	1 GHz
Wi-Fi	802.11 b/g/n	No	802.11 b/g/n
Bluetooth	Bluetooth 4.2 and BLE	No	No

GPIO	Up to 34	20	40
ADC	12-bit SAR ADC	10-bit	12-bit
DAC	8-bit DAC	No	No
Memory	520KB SRAM, 4MB flash	2KB SRAM	512MB
Operating Temp.	-40°C to +125°C	0°C to +70°C	0°C to +50°C
Price	Low	Low	Low

The ESP32 would be an ideal microcontroller for a sensor platform that measures motion analysis of a person's leg because of its powerful dual-core 32-bit LX6 CPU, which is capable of processing large amounts of data quickly and accurately. Additionally, the ESP32 has a 12-bit SAR ADC, which provides higher resolution measurements than the 10-bit ADC on the Arduino Uno. The ESP32 also has built-in Wi-Fi and Bluetooth capabilities, which would allow for real-time data transmission and remote monitoring of the sensor platform. Moreover, the ESP32 has a wide range of GPIO pins (up to 34), making it possible to connect multiple sensors to the platform. The larger memory size of the ESP32 would allow for storing of larger datasets, which could be useful for machine learning or other advanced data analysis techniques. Finally, the ESP32's operating temperature range is wider than both the Arduino Uno and Raspberry Pi Zero W, making it suitable for use in harsh environments. In conclusion, the ESP32's powerful CPU, high-resolution ADC, Wi-Fi and Bluetooth capabilities, versatile GPIO pins, larger memory, and wider operating temperature range make it the best choice for a sensor platform measuring motion analysis of a person's leg.

3.2.11 List of Components

Table 3-3: Required Components Table 3-3 illustrates the chosen required components to be able to complete the sensor platform.

Table 3-3: Required Components

Item Number	Item	Details	Quantity
1	MPU-6050 6DOF Module	Triple-axis accelerometer and gyro	2
2	ESP32 development board	Controller	1
3	SA Filament PLA	3D printing PLA filament	1
4	ESP32 18650 battery charge shield	Battery charger	1
5	18650 Battery	Power supply	1
6	Sensor Platform Base Material	Cloth	1

7	Velostat	Force sensitive material	2
8	Adhesive Copper Tape	Conductor	1
9	Conductive Wire	Conductor	1
10	Veroboard	Electronics base	1
11	Resistors	Resistive load	2

3.3 Force Sensor Design

The force sensor (**Error! Reference source not found.**) is comprised of Velostat, sandwiched between two conductors. Using a voltage divider, where R_v is the variable resistance from the Velostat as force is applied, and R_1 is the reference resistance. The reference resistance size is determined by measuring the resistance of the Velostat as the desired pressure range is applied, and choosing a resistor size as close as possible to that desired range [70]. In this case, the reference resistance R_1 is chosen as 10Ω. The value of the reference resistor is crucial for accurate measurements. A resistor with too high of a value would result in a voltage drop that is too large, making it difficult to distinguish small changes in the resistance of the Velostat. On the other hand, a resistor with too low of a value would result in a voltage drop that is too small, making it difficult to measure larger changes in resistance. A commonly used value for the reference resistor in Velostat circuits is 10 ohms. This value provides a good balance between sensitivity and range. A 10-ohm resistor will produce a voltage drop of 100 millivolts for a 10-ohm change in the Velostat resistance. This voltage range is within the range of most microcontrollers' analog-to-digital converters (ADCs), allowing for accurate and precise measurements. Furthermore, a 10-ohm resistor has a low enough value to minimize the effects of self-heating on the resistor, which can be an issue with higher resistance values. Self-heating can cause a change in resistance in the reference resistor, which would result in inaccurate measurements. This analog voltage is an input to the microcontroller.

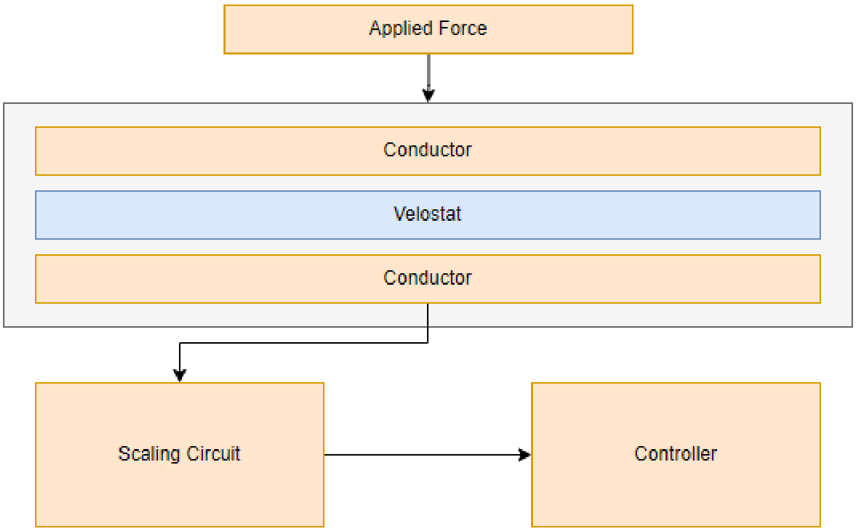


Figure 3-1: Force Sensor Design

Two of these force sensors are made, one for the heel and one for the forefoot (front of the foot). These two force sensors are then placed between two 1mm PVC Sheets, cut in the shape of an inner sole of a shoe (Figure 3-2), which allows it to be placed inside a shoe. The height of these force sensors is under 2 mm, ensuring that the sensors do not inhibit a natural gait.

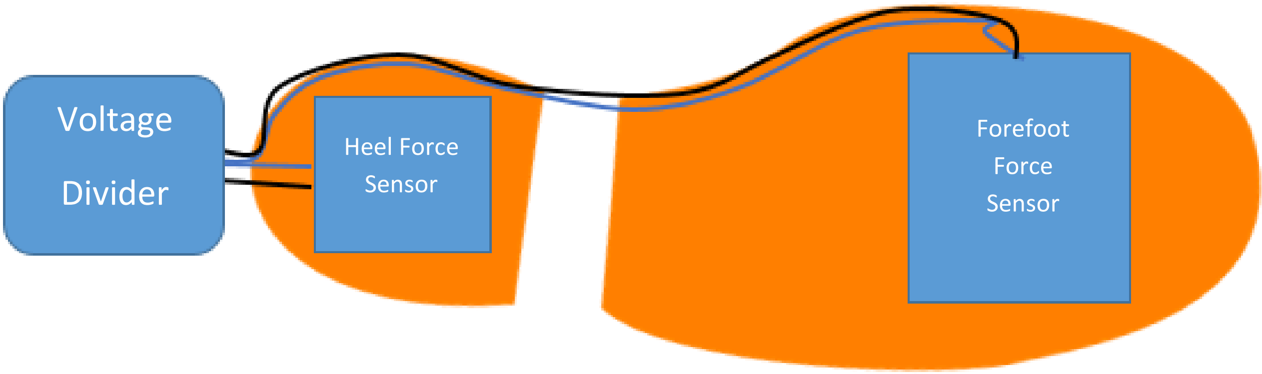


Figure 3-2: Force Sensor Inner Sole

The heel and forefoot sensors are then calibrated individually. The sensor output is measured as an ADC reading. This is done by incrementally adding 5 kg weight to the force sensor while reading the sensor output, and plotting them. A trendline is then added to find the equation required to determine the force applied to the knee. For the Heel sensor (Figure 3-3), the equation is

$$Weight = 92307(Sensor\ Output)^{-1.289} \tag{14}$$

With an R-Squared of 0.987

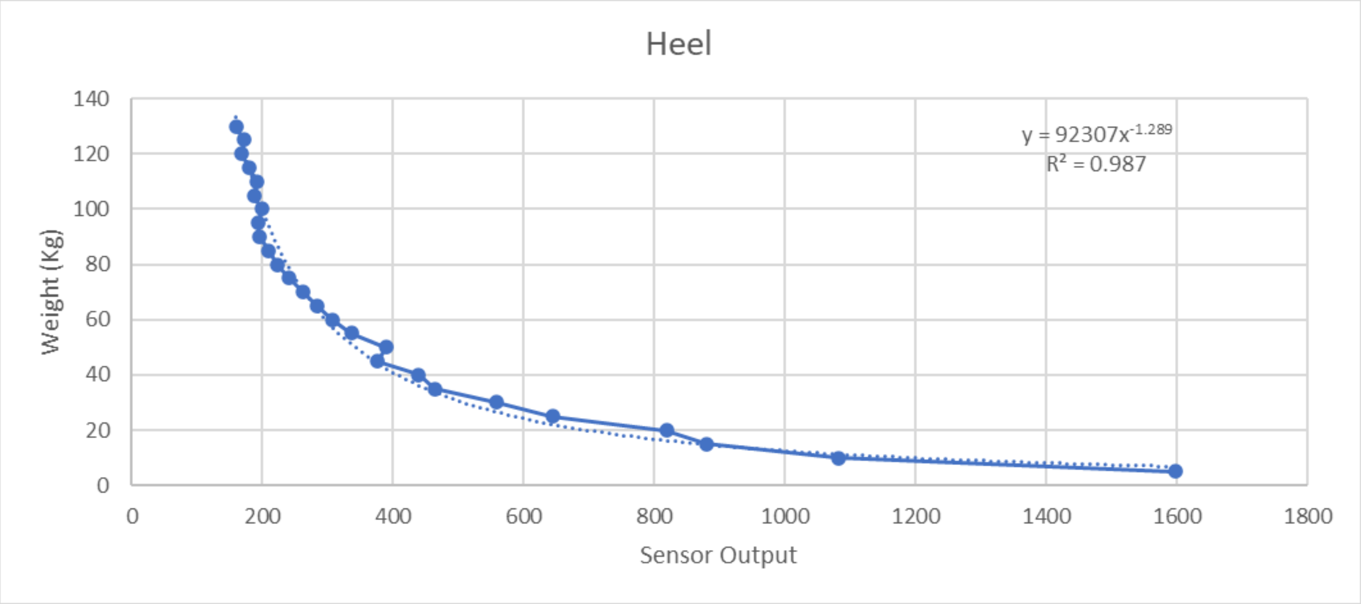


Figure 3-3: Heel Force Sensor Calibration

For the forefoot sensor (Figure 3-4), the equation is

$$Weight = 3E + 06(Sensor\ Output)^{-1.719} \quad (15)$$

With an R-Squared of 0.967

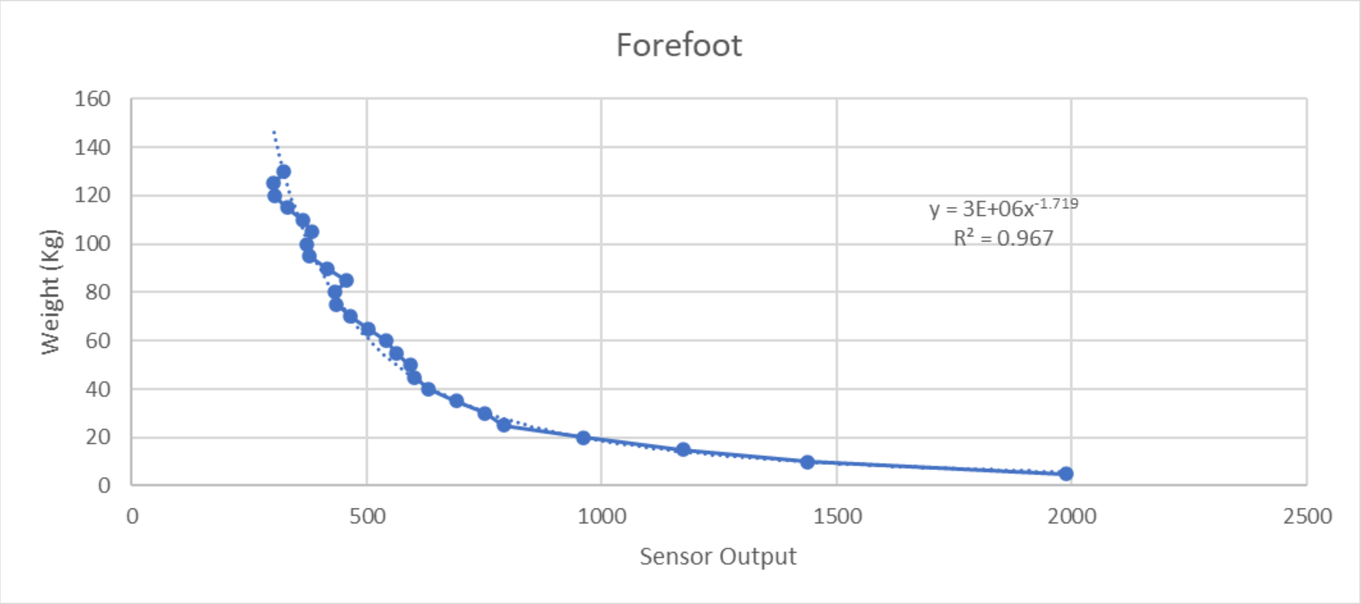


Figure 3-4: Forefoot Force Sensor Calibration

We can see that as the amount of weight applied increases, the sensor output decreases. These equations can be used to calculate the force applied to both force sensors, using the sensor output data. The completed inner sole force sensor can be seen in Figure 3-5.

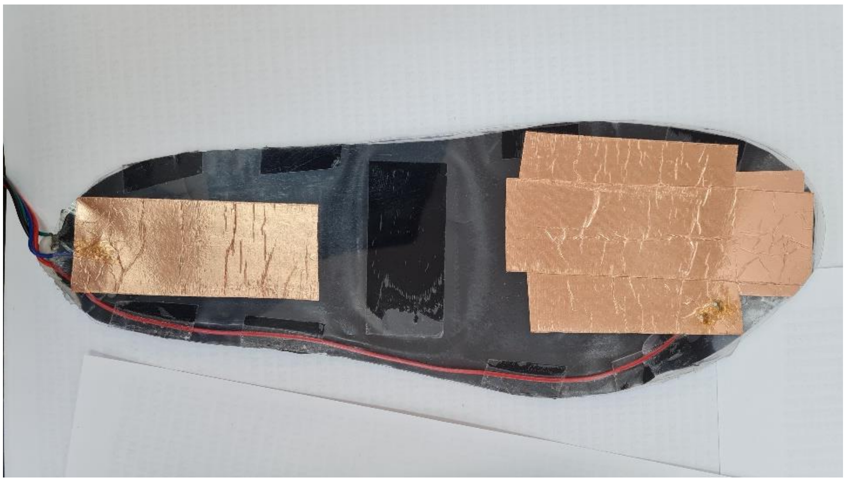


Figure 3-5: Inner Sole Force Sensor

3.4 Knee Joint Angle

The accelerometer is used to calculate both the above-knee angle (thigh angle) and below-knee angle (shank angle) This is done using Equation 1 below

$$Tilt = \arctan\left(\frac{A_x}{A_y}\right) \tag{1}$$

As explained in Figure 2-11 in chapter 2.6.1, This equation changes depending on the quadrant the accelerometer is tilting through. The accelerometers are set up on a joint similar to a knee, one above the joint, and one below the joint (Figure 3-6).

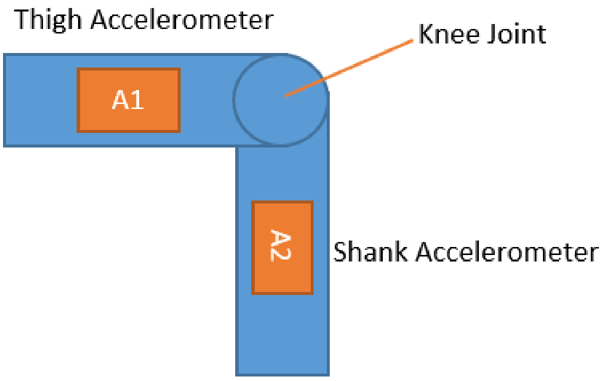


Figure 3-6: Accelerometer set up

The accelerometers are set up at a full-scale range of ± 2 g and a sensitivity scale factor of 16384 LSB/g (See MPU6050 datasheet for more info). We start by using the accelerometer data captured by having the joint in an extended position as if the leg was straight. The joint is then flexed, held for a few seconds, and then returned to its extended position. The thigh accelerometer and shank accelerometer are then used to calculate the thigh angle and shank angle using Equation 1 above. The above-knee angular velocity is displayed in blue and the below-knee angular velocity is displayed in orange. It is important to note that a change in temperature can cause IMU devices like accelerometers and gyroscopes to drift. One way to keep the temperature constant is to use a temperature-controlled environment. This can be achieved by using a climate-controlled room. Note that no filters were applied to the data in the graphs below. Only raw data was used.

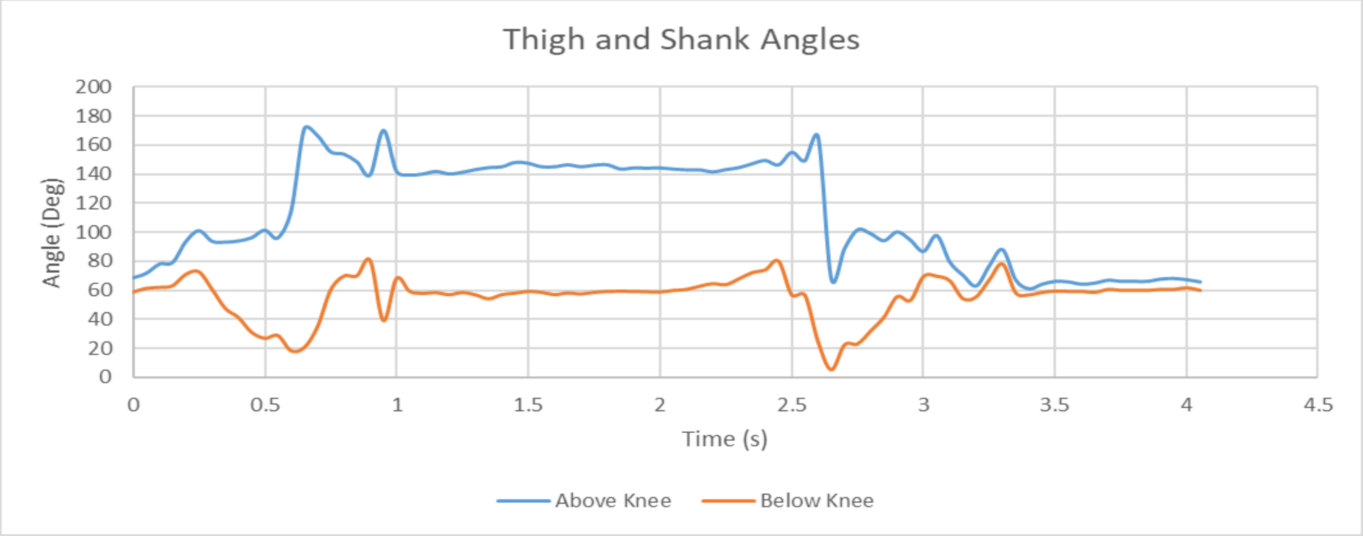


Figure 3-7: Thigh and Shank Angles

The joint angle can then be calculated by using the equation below.

$$\alpha = \alpha_{Thigh} - \alpha_{Shank} \tag{16}$$

The joint angle is illustrated in Figure 3-8.

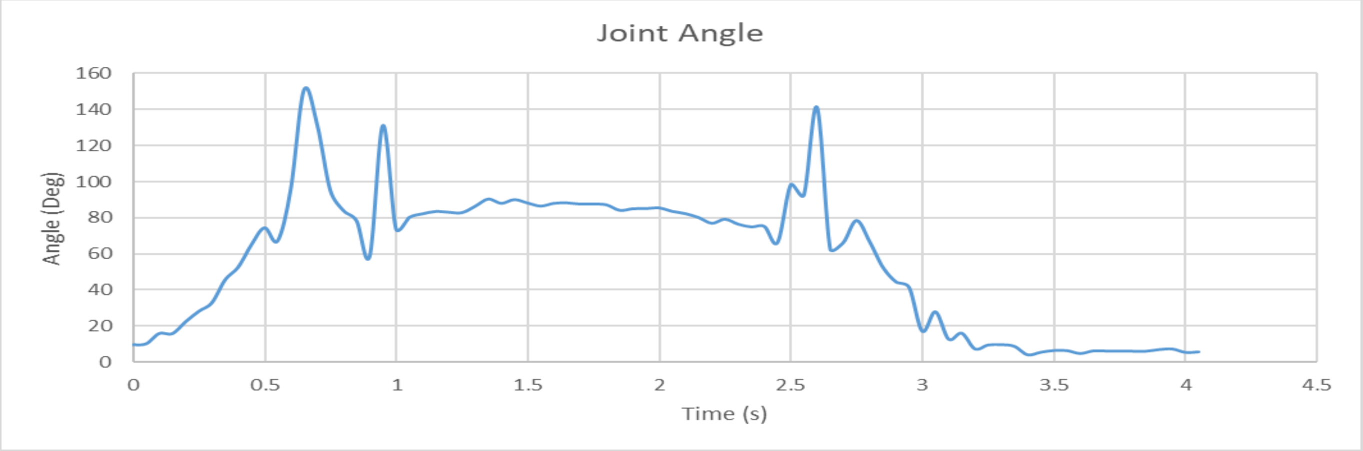


Figure 3-8: Joint Angle

3.5 Knee Joint Angular Velocity

The knee joint angular velocity is captured using the gyroscopes set up in the same way as the accelerometers in Figure 3-6. The gyroscopes are set up at a full-scale range of +- 250 °/s and a sensitivity scale factor of 131 LSB/(Deg/s) (See MPU6050 datasheet for more info). The thigh angular velocity and shank angular velocity captured by the gyroscopes are illustrated in Figure 3-9. The above-knee angular velocity is displayed in blue and the below-knee angular velocity is displayed in orange. During the first phase the angular velocity increases up to point 1 whereafter it decreases to zero at point 2. This is followed by an increase in the opposite direction (negative value) until it comes to rest at point 3.

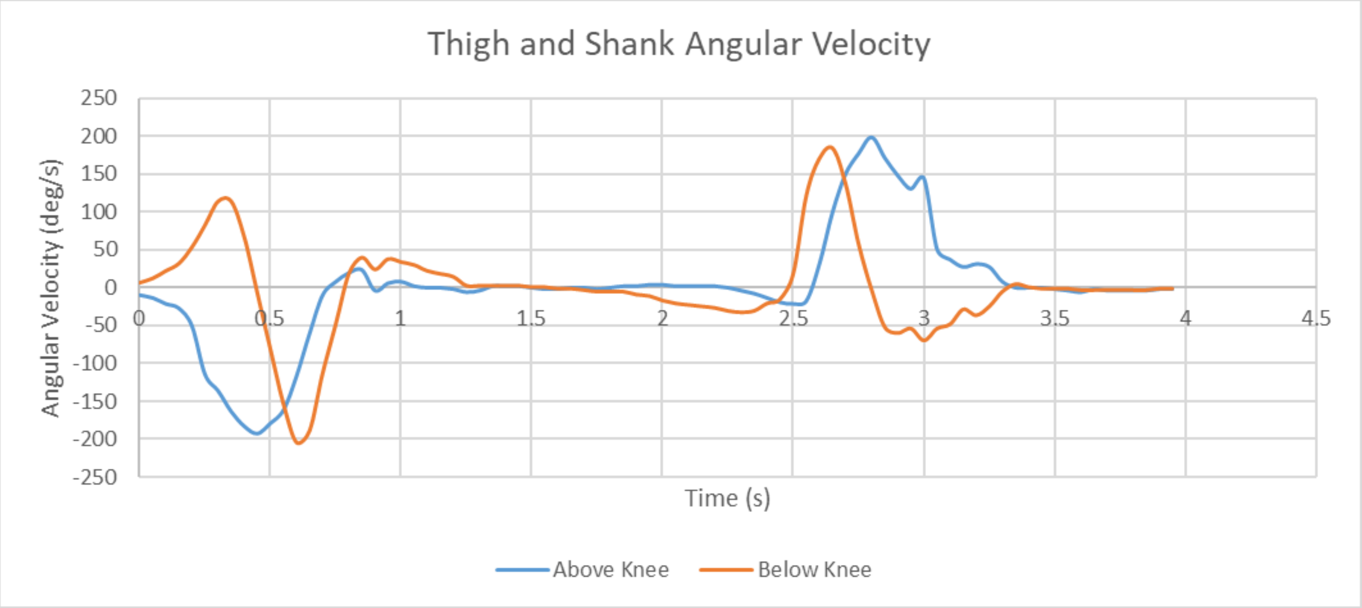


Figure 3-9: Thigh and Shank Angular Velocity

The Joint Angular velocity can then be calculated using the equation below.

$$Joint\ Angular\ Velocity = \text{Thigh Angular Velocity} - \text{Shank Angular Velocity} \qquad (17)$$

The joint angular velocity is illustrated in Figure 3-10.

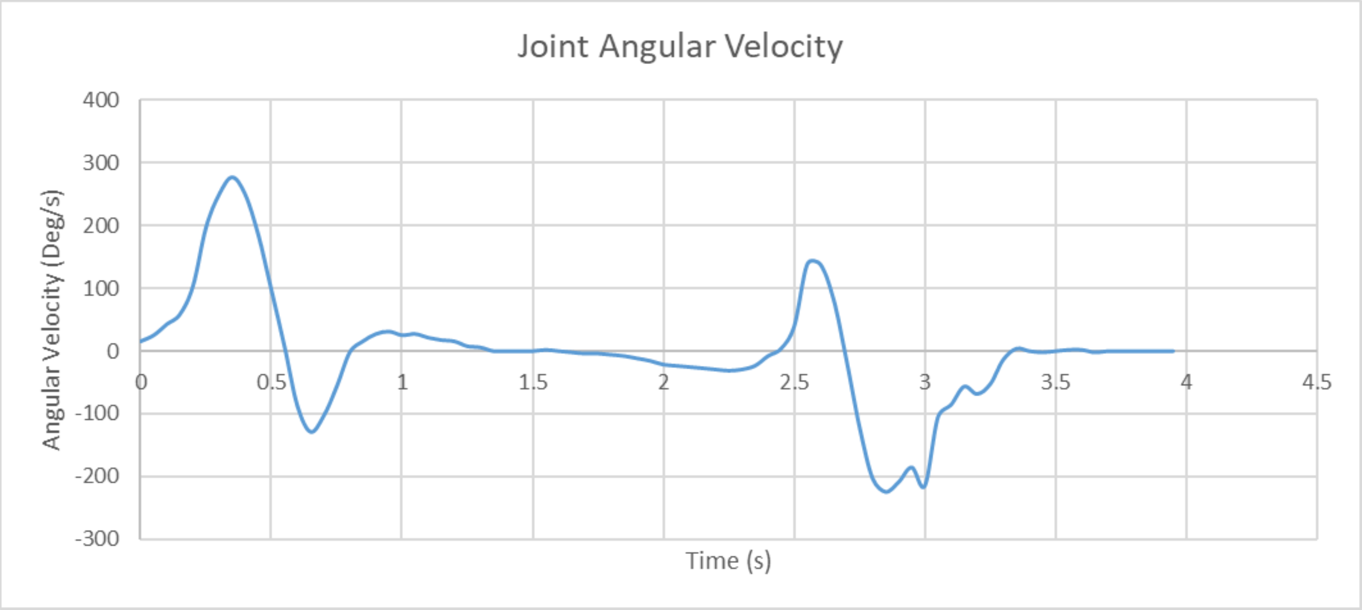


Figure 3-10: Joint Angular Velocity

3.6 Circuit

The electronic component connection is shown in Table 3-4 and **Error! Reference source not found.**.

Table 3-4: Component Connections

Microcontroller (ESP32)	**Power Supply**
Micro-USB	USB
Microcontroller (ESP32)	**Above Knee MPU6050**
3V3	AD0
Gnd	Gnd
D21	SDA
D22	SCL
Microcontroller (ESP32)	**Below Knee MPU6050**
3V3	VCC
Gnd	Gnd
D21	SDA
D22	SCL
Microcontroller (ESP32)	**Forefoot Force Sensor**
3V3	3V3
Gnd	Gnd
D34	SEN

Microcontroller (ESP32)	Heel Force Sensor
3V3	3V3
Gnd	Gnd
D35	SEN

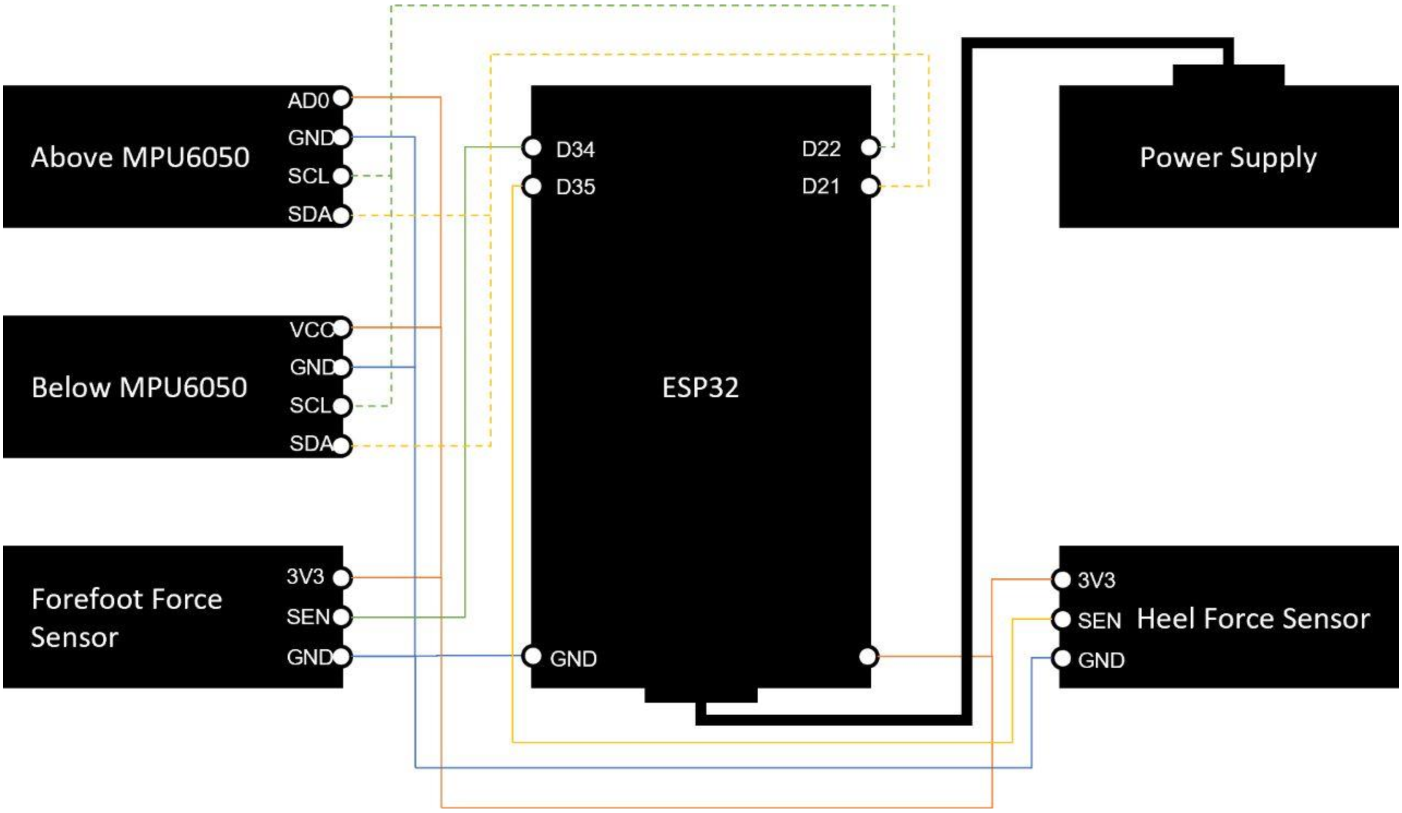


Figure 3-11: Sensor Platform Wiring Diagram

3.7 Sensor Platform Base and Electronics Housing Design

The sensor platform base is a knee brace designed specifically for the sensor platform (Figure 3-12). The knee brace acts as a base for the electronics housings to enable the electronics to be attached to a leg. The brace is made from a flexible material to ensure that the brace does not inhibit natural gait movement. The brace consists of 3 tightening straps above the knee and two tightening straps below the knee. These straps are adjustable and attach to the brace with Velcro.

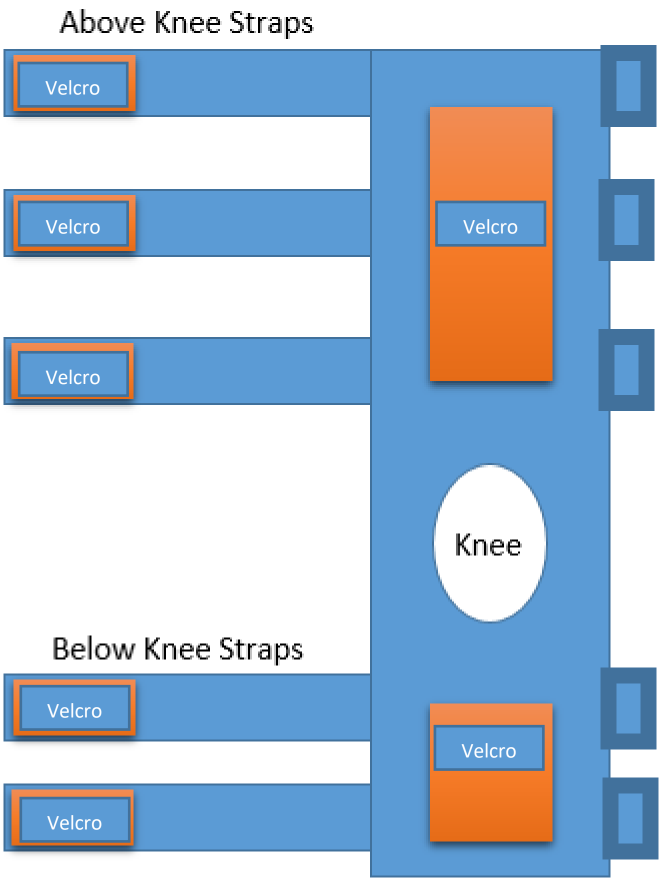


Figure 3-12: Sensor Platform Base Design

The bottom housing (**Error! Reference source not found.**), attaches to the Velcro below the knee and houses the accelerometer and gyroscope for capturing below-knee movement data. It also houses the voltage dividers for the forefoot and heel force sensors.

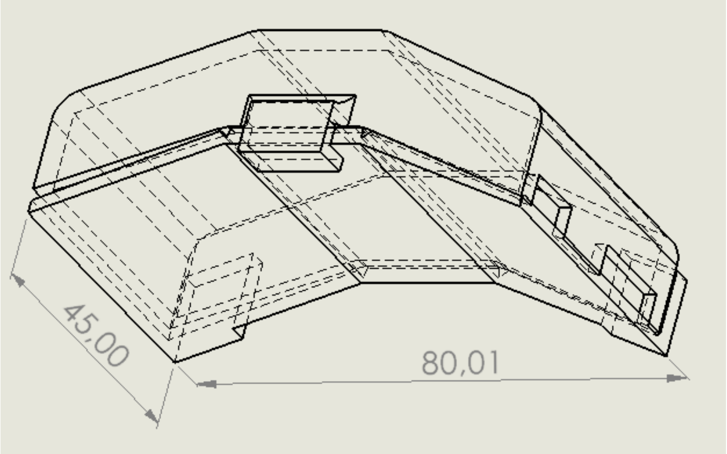


Figure 3-13:Bottom Housing

The top housing (**Error! Reference source not found.**), attaches to the Velcro above the knee and houses the gyroscope and accelerometer for above-knee movement data. It also houses the microcontroller and power supply.

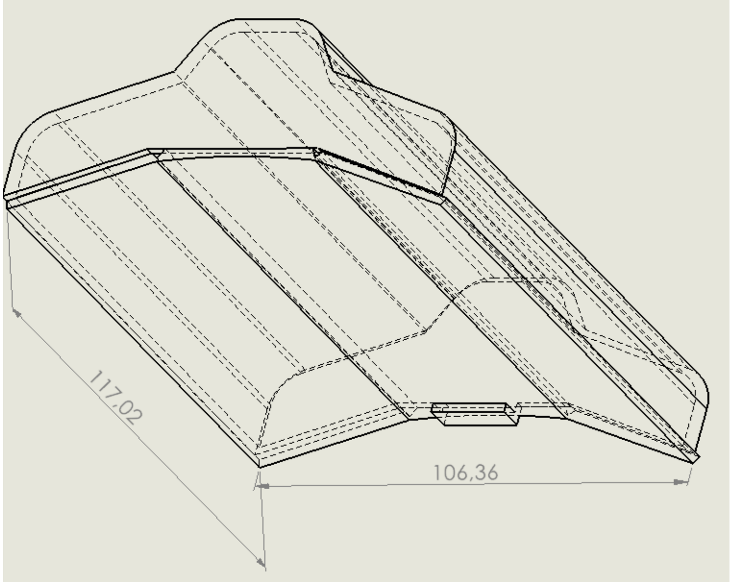


Figure 3-14: Top Housing

The completed sensor platform base with attached electronics housing can be seen in Figure 3-15.

Figure 3-15: Sensor Platform Base and Housing

3.8 Data Collection Application

A type of user interface was required to manage data collection throughout the experimental procedure. Bluetooth was chosen as a communication method between the sensor platform and the user interface. The microcontroller sends real-time data to a user interface. The user interface was designed on MatLab as a standalone application on a computer that can manage the data being sent by the sensor platform. This involves initiating and ending data generation, and storing the data so that it could be analyzed. The application (Figure 3-16) collects data from the sensor platform, using Bluetooth, and plots the data directly after an activity of daily living has been completed.

The application works by entering an activity name. When the start button is pressed, the red indicator light will turn green and the real-time knee angle data will be displayed. When the activity is completed, the stop button is pressed, and the raw data is saved to a TXT file. Pressing the plot button will plot all of the raw data collected, to ensure the captured data is correct. A new activity name can then be entered and the procedure can be repeated for different activities.

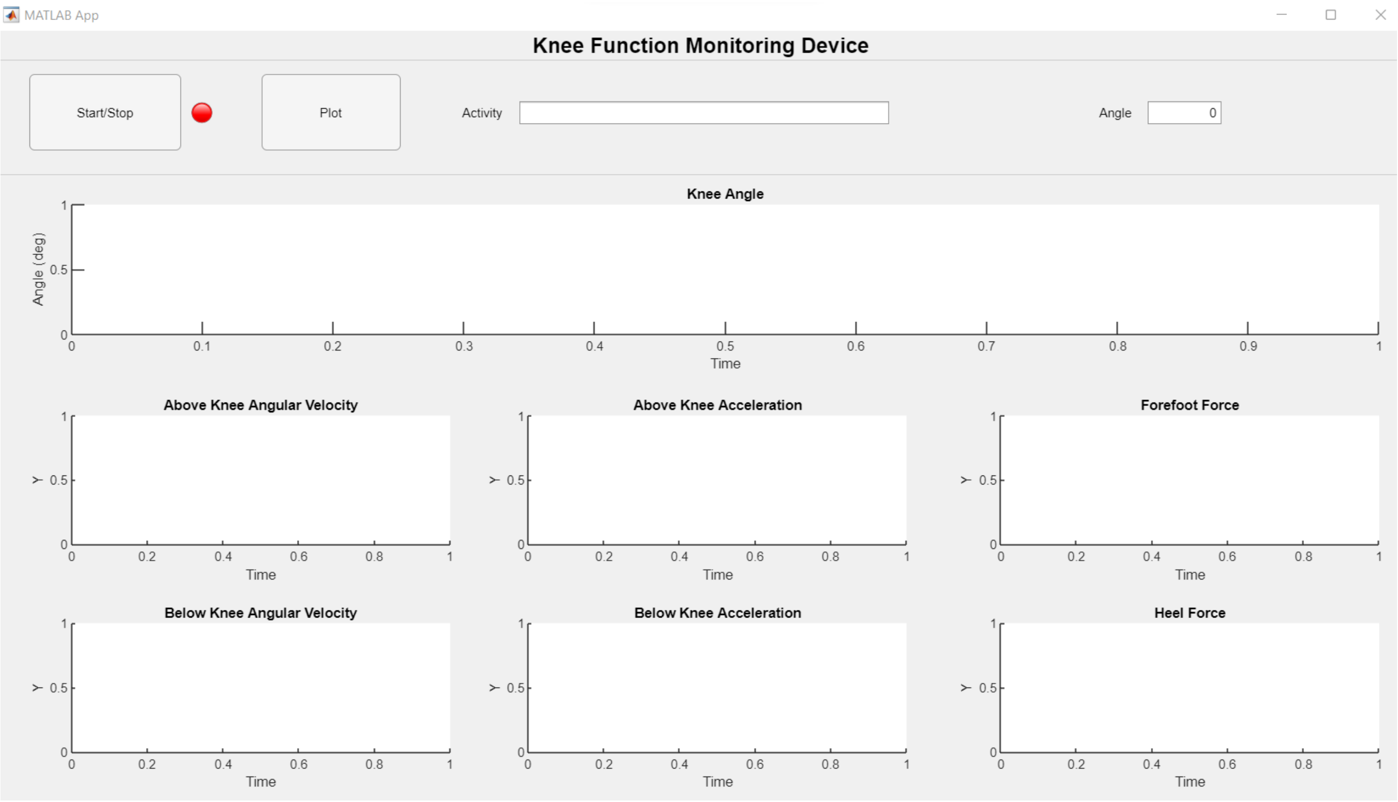


Figure 3-16: Data Collection Application

3.9 Conclusion

The sensor platform (Knee brace) shall use accelerometers to determine knee joint angle, gyroscopes to measure knee joint angular velocity, and Velostat to measure ground reaction forces. The design behind each component has been discussed, including the chosen components, force sensors, electronic circuit, sensor platform base, sensor housings, and the data collection application. The next chapter discusses the experimental method followed to gather data from the participants.

Chapter 4: Experimental Strategy

4.1 Introduction

In the previous chapter, the test platform was discussed. The sensor platform will be used to gather the required data from the participants. This chapter discusses the details of how the sensor platform was used to generate data and discusses the sample size, recruitment criteria, risks and benefits, experiment overview, recruitment process, monitoring of research, experiment process, statistical analysis, and verification and validation steps that shall be taken through the study process. This chapter also forms part of the process that was assessed by the ethics committee to gain ethical clearance on a study that involves human participants. The data measured by the knee brace was used as the reference method and data generated by the Qualysis motion analysis system was used as the criterion method.

4.2 Sample size

A sample size of 15 was determined *a priori* based on the kinetic and kinematic data acquisition requirements for the present study [71]. Since participant-specific data (e.g. knee joint range of motion) measured by the knee brace and generated by the Qualyisis motion analysis system was compared (criterion standard), a paired analysis [72] was conducted, thereby further increasing the statistical power. The type II error rate was set at 20%, with the statistical power, therefore, being set at 80%. In terms of measurements related to foot contact time, loading rate, peak vertical force, peak braking force, running speed, and foot contact angle, it is recommended that 15-20 steps be taken per participant utilizing 15-20 participants [73]. As mentioned above, 15 participants were required for the present study, with each participant being measured for 20-25 steps per experimental condition thereby ensuring adequate statistical power.

4.3 Criteria

Inclusion criteria were specified in terms of gender, ago, medical condition, location, language proficiency...

4.3.1 Male or female between the ages of 18 and 45.

Only activities of daily living shall be measured (e.g. walking, stair climbing, etc) [74]. The participant does not have to be physically fit or young, as long as they have a normal gait. Ages lower than 18 are not used due to the sensor mounts being designed to fit a fully grown adult. Ages over 45 will not be used as muscular strength tends to be affected in those who are not physically active (e.g. sarcopenia), which may inadvertently affect activities of daily living and skew the results of the study.

4.3.2 Participants must be free of any injuries or recent surgery (< 6 months) that might impair gait or activities of daily living.

All participants should exhibit normal gait and be able to complete activities of daily living unhindered. Injuries to soft tissue structures (e.g. tendons, ligaments, and muscles) take time to heal and are dependent on the extent of injury. Thus, only those who are free of recent injuries and/or surgeries that might impair gait will be considered for inclusion.

4.3.3 Participants must live within the Potchefstroom area.

Convenience sampling will be utilized. Since sophisticated, laboratory-bound equipment will be used for data collection it is not possible or feasible to evaluate participants beyond the Potchefstroom area. Therefore, to minimize costs on all fronts, only local participants will be eligible for inclusion.

4.3.4 Must be competent in English language (e.g. reading and writing).

Instructions, information sessions, and informed consent forms will be provided in English.

4.3.5 Participants must weigh less than 150 kg.

The load cell that shall be used in the study can measure a maximum of 200 kg but is more accurate when measuring below the threshold maximal threshold. Most people over the weight of 150kg would also likely have a compromised gait pattern.

Exclusion criteria are:

4.3.6 Individuals suffering from diseases and/or disorders that impair gait or activities of daily living (e.g. osteoarthritis, rickets, etc.).

The device needs to be tested on persons that have a normal gait, a disorder like osteoarthritis or rickets might impair the gait of the participant.

Note: Participants with pacemakers could take part in the study. The knee monitoring device makes use of Bluetooth to transmit data to a computer interface. The Bluetooth transmitter is worn on the leg, and will therefore not interfere with the pacemaker since it is located further than six inches from the pacemaker.

4.4 Risks and Benefits

The possible risks of the study are:

- Covid-19 infection

  Participants would be in close proximity to the biokineticist and researcher. To minimize this risk, all Covid-19 regulations shall be followed at all times during the study.
- Ascending and descending stairs

  Since measurements are required while participants ascend and descend stairs, only indoor stairs that meet all safety standards (e.g. anti-slip material, presence of railings, standard step height [<20 cm]) will be used in the current study. Furthermore, the study shall be conducted in the presence of a qualified biokineticist to mitigate any potential risk of falling.
- Ascending and descending slopes

  Manoeuvring across variable terrain (e.g. slopes) also forms part of activities of daily living. Given that measurements are required while participants ascend and descend a sloped terrain ($<15^{o}$ of incline), the present study shall be completed in the presence of a qualified biokineticist to minimize any potential risk for injury while navigating such sloped terrains.
- Participants will be required to wear the electronic sensor platform (i.e. knee brace), however, the device is a low-voltage device and would not pose any risk to the participant. (i.e. there is no risk of electric shock). Furthermore, the electronic monitors (i.e. accelerometers) fitted on the brace are not in direct contact with the participant, further posing no safety risk to the participant.

The benefits of the study are:

- Direct benefits

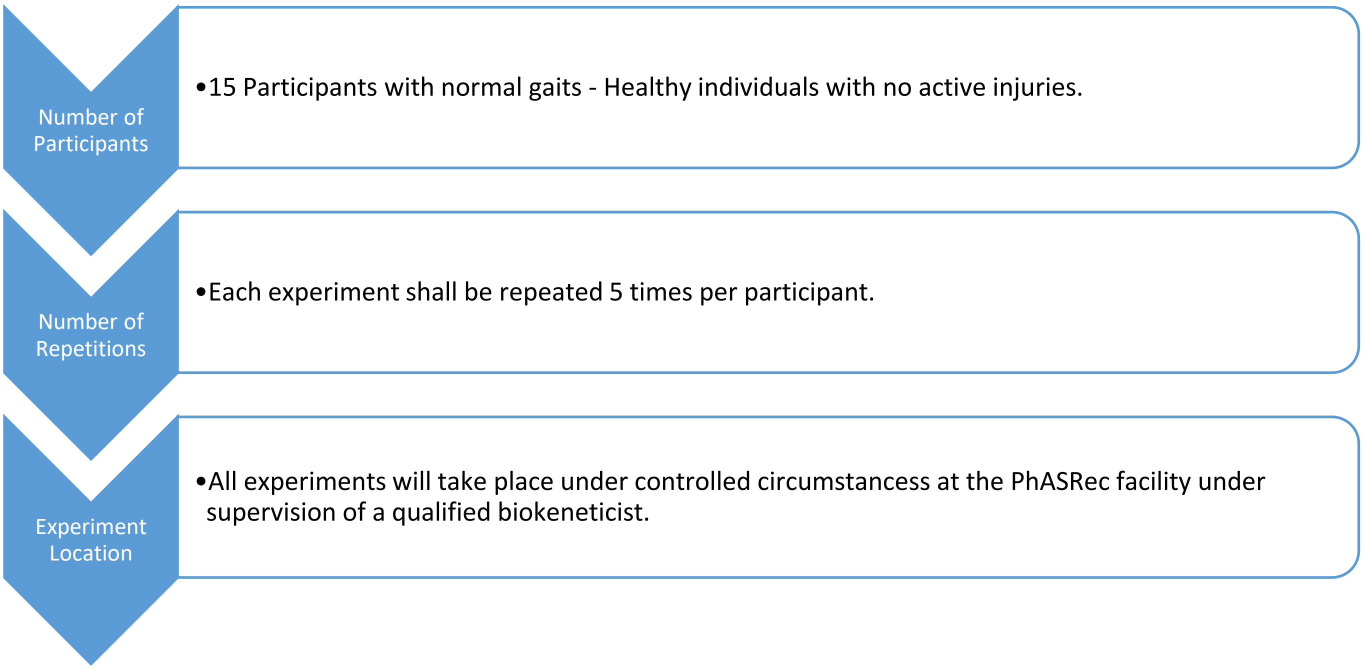
  A gait report will be provided to the participant and will offer an overview of kinetic and kinematic data related to activities of daily living. This report shall be sent to the participants by means of email.
- Indirect benefits

  Information from the study will provide valuable information related to the development of an affordable and easy-to-use knee monitoring system may add to rehabilitation monitoring and further studies concerning leg movement.

In summary, the minor risks identified can be mitigated and participants will only be exposed to activities of daily living to ensure that the benefits substantially outweigh the risks.

4.5 Overview

Figure 4-1 displays the experimental strategy that shall be implemented. The experimental strategy describes the number of participants, the number of repetitions of each experiment, and the location where the experiments will occur. The experiment will be conducted at the PhASRec (what does it stand for) facilities under the controlled supervision of a qualified biokineticist.



Number of Participants

- 15 Participants with normal gaits - Healthy individuals with no active injuries.

Number of Repetitions

- Each experiment shall be repeated 5 times per participant.

Experiment Location

- All experiments will take place under controlled circumstancess at the PhASRec facility under supervision of a qualified biokeneticist.

Figure 4-1: Experimental strategy

In Figure 4-2 the data to be measured is summarised. This includes measuring knee joint angle, knee joint angular velocity, and knee load. Figure 4-2 also provides a short description of each measurement.

Knee Joint Angle	How much (in angular terms) the knee is bent while performing activities of daily living
Knee Joint Angular Velocity	What the angular velocity of the knee joint is while performing activities of daily living
Knee Load	The force applied to the knee as weight is applied to it while performing activities of daily living

Figure 4-2: Required measurements

4.6 Recruitment

The targeted sample involved the selection of persons within the Potchefstroom area. An advertisement was placed on social media and posters were placed at strategic areas within Potchefstroom (e.g. Cachet park). An advertisement was placed in the local newspaper (Potchefstroom Herald) to recruit participants. The social media platforms that were used for participant recruitment included Instagram, Twitter, and Facebook. Participants were reimbursed using the time-inconvenience-expenses principle. Given that only local participants were recruited for the study, as well as the relative simplicity of the data collection procedures, participants were provided with a refreshment in the form of bottled water, due to the short time period of the study. Further recruitment took place via email. For convenience, a QR code was generated for possible participants to contact the researchers if they showed interest. The QR code was placed on the recruitment poster. Each participant was given a reference number replacing their name and stored in a password-secured folder on a cloud drive to ensure privacy. The scheduled study was set for one month after the advertisement has been placed. The study was completed in a time frame of one week.

4.7 Monitoring of Research

The project leader has compiled an annual monitoring report of the research which has been submitted to HREC (Health Research Ethics Committee). Should any incident occur during the data collection process, an incident report will be drafted and submitted to HREC immediately.

4.7.1 Autonomy, privacy, confidentiality, non-harmfulness, and justice

4.7.1.1 Autonomy

The autonomy of the participants was guaranteed by respectfully treating each participant and by abstaining from being biased toward the participant’s race, background, values, beliefs, or views. Participants were given appropriate written and verbal information about this study and what can be expected from them as participants. Participants were also informed about their rights and will not be pressured into any situation in which they are not completely comfortable. The purpose of the research was explained thoroughly during the information session, and participants were assured that their results will be kept anonymous and confidential. Participants were under no obligation to take part in the study, and they were free to withdraw from the study at any time during the study. The informed consent form thoroughly described the risks, benefits, and requirements associated with the study.

4.7.1.2 Non-harmfulness

The research will be carried out in a safe environment at the Physical Activity, Sport, and Recreation (PhASRec) entity on a day and at a time agreed upon by all stakeholders concerned. No severe physical, psychological, social stress or other negative consequences beyond the risk encountered in normal life and everyday living are anticipated for this project. No negative influence due to the presence of other participants is anticipated since only one participant will be tested at a time. In case of illness or other injury, participants will immediately be withdrawn from the project and will be allowed to leave at any time should they choose to do so. During all testing, all personnel did wear protective disposable gloves and face masks. All testing and training sessions during this study were led by the investigators of this project.

4.7.1.3 Privacy and confidentiality

The anonymity of participants was ensured in that only the principal investigator had access to the data. No form of identity appeared in the published articles upon completion of the study. Each participant was allocated a reference number, which bound the identity of the participant to the researcher and any potential graduate assistants collecting the data. All hard copies of the data, including the completed forms, will be scanned electronically and kept safe and secure by storing electronic copies of the data on a desktop computer and a password-protected external hard drive in the study/project leader’s office at the North-West University (NWU), Potchefstroom Campus, for seven years where-after it will be destroyed. Furthermore, the data will be backed up on RedCap, a cloud-based system, at the North-West University. This ensures the participants’ right to privacy, anonymity, and confidentiality.

4.7.1.4 Justice

The processes of data collection were explained to all participants prior to obtaining their consent. Full cooperation and honesty were requested from participants. None of the participants’ names will be linked to the content of the data, except through an anonymous reference number that is known only to the researchers. All data, including the completed forms, are kept safe and secure in a filing cabinet, and electronic data was stored on a computer and an external hard drive under password protection only known by the principal investigator of the study.

4.8 Data Management Plan

The data management plan is aligned with the data management plan stipulated by PhASRec in Appendix B.

4.9 Experimental Process

An informed consent form was sent via email to potential participants that are interested in taking part in the present study. These were persons that have made contact via the contact details provided on the advertisements on social media and printing services. The informed consent (Appendix A) provided information to possible participants regarding the location of data collection, the specific requirements information on where data collection was done, what the specific requirements are, who captured the data during data collection, what data was gathered, and what was done to the data once it is obtained. The informed consent documentation was provided in English. Participants took part in the experiments one participant at a time, whereby scheduled slots were allocated separately to each participant. Participants were asked to wear long pants for the experiments which prevented the device from moving out of position. All persons taking part in the experiments were treated professionally and with respect. As the experiments took place, the participant was submitted to a low-risk environment under the supervision of a qualified biokineticist.

Before the data collections took place, an explanation on Covid-19 protocols was given and strictly adhered to throughout the course of data collection to keep participants and researchers safe and protected. Once the participant arrived at the location the door was closed to prevent unintended entry to the laboratory while data collection takes place. The biokiniteticist then ensured that all criteria are adhered to by examining the gait pattern of the potential participant. If the participant did not adhere to the criteria, a detailed explanation was provided why the recruit could not take part in the study. Prior to data collection, the researcher verbally explained the experimental processes and went through the informed consent document with the participant.

After that, the participant was granted the chance to ask any questions. An independent person (Ms Bridget Grobler) was used to obtain informed consent and the participant was asked to sign the informed consent document (hard copy) if they wished to participate. The participant was clearly informed that they should not feel pressured into taking part in the experiment. Signing of the informed consent took place at the location of data collection in an access-controlled office in the PhASRec laboratory. Once the participant had signed the informed consent form, the researcher could proceed with the experimental steps.

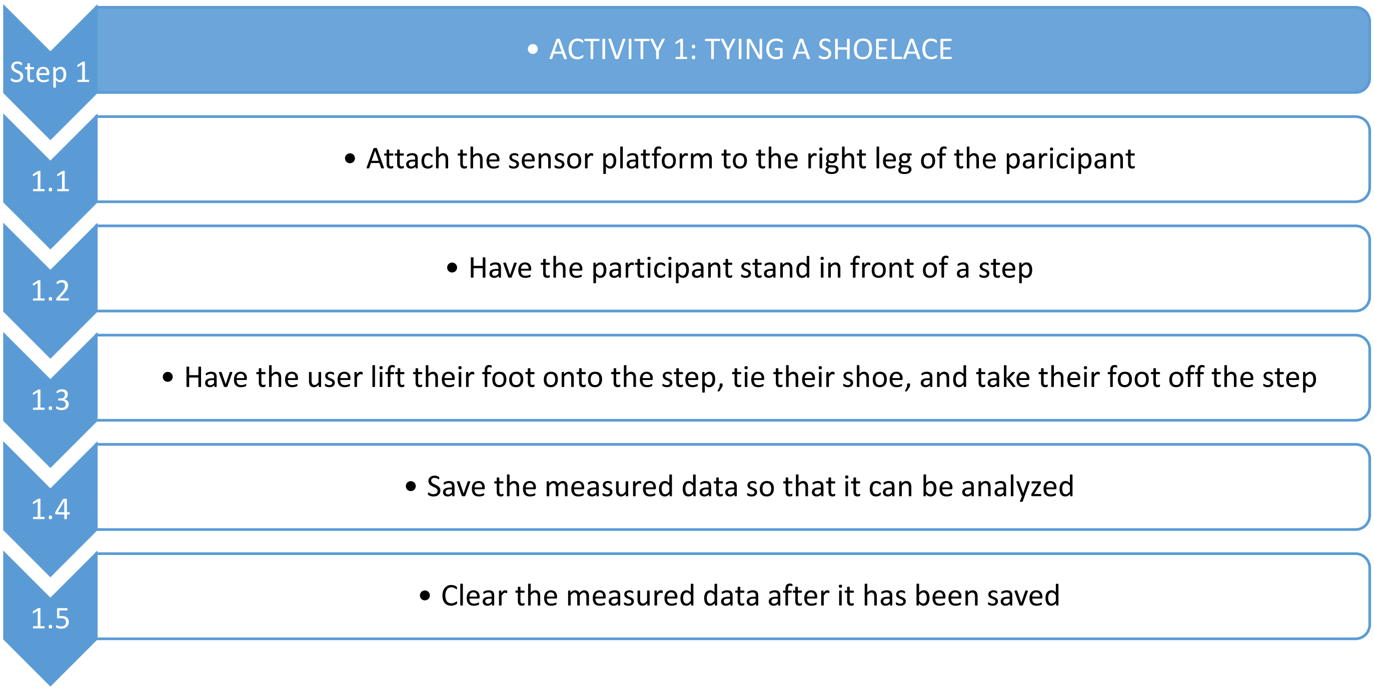
Following data collection, the informed consent document was then scanned and stored as a password-protected PDF document, which was also done by the independent person. On completion of data collection, the participant then received their refreshment (e.g. bottled water). The bottle was sanitized prior to distribution to prevent risk of Covid-19 transmission.

4.10 Experimental Steps

Figure 4-3 to Figure 4-7 describe the five experimental steps that took place. These steps involve measuring the data defined in Figure 4-2 while completing ADL's (Activities of Daily Living). These ADLs include:

- Activity 1: Tying a shoelace
- Activity 2: Ascending and descending a step
- Activity 3: Standing and sitting
- Activity 4: Ascending and descending a slope
- Activity 5: Walking

4.10.1 Activity 1: Tying a shoelace



Step 1 • ACTIVITY 1: TYING A SHOELACE

1.1 • Attach the sensor platform to the right leg of the paricipant

1.2 • Have the participant stand in front of a step

1.3 • Have the user lift their foot onto the step, tie their shoe, and take their foot off the step

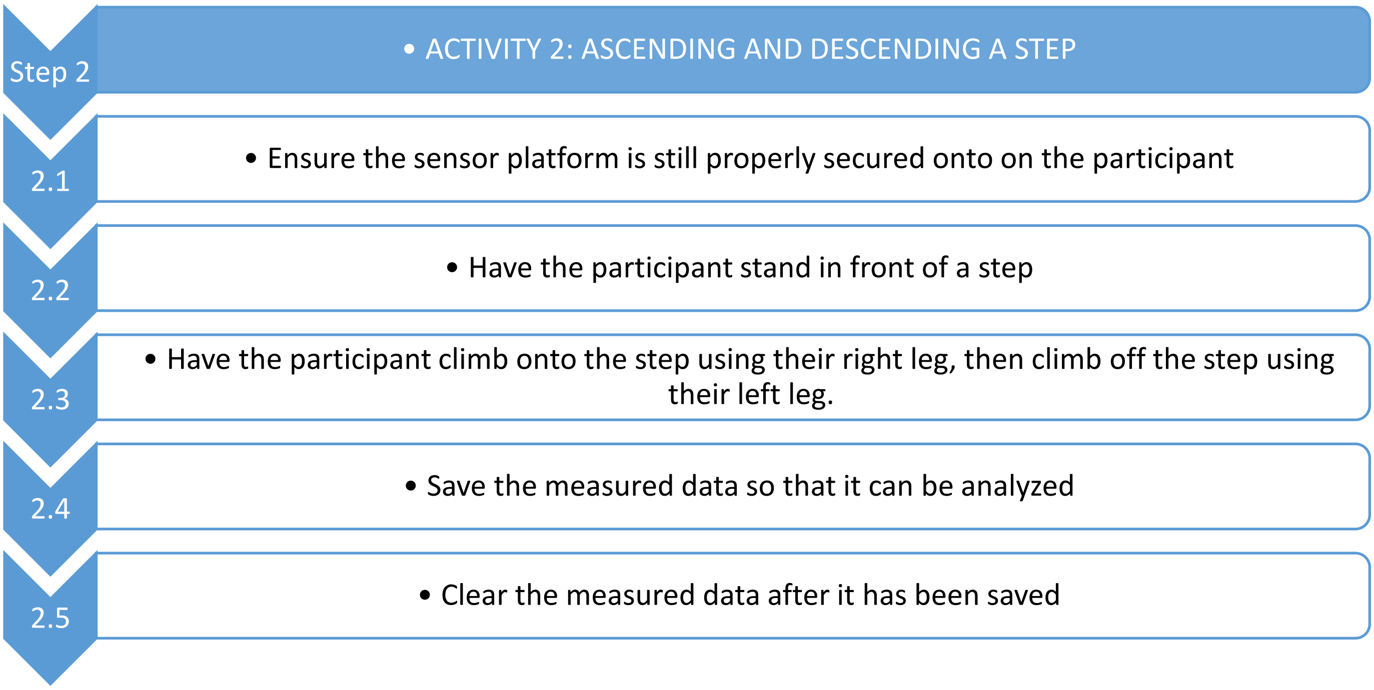
1.4 • Save the measured data so that it can be analyzed

1.5 • Clear the measured data after it has been saved

Figure 4-3: Tying a shoe

For this experimental setup, the participant was required to stand in front of a chair. The sensor platform and motion tracking cameras are activated, and the participant was asked to lift their foot onto the step and tie their shoelace. The data is streamed to a laptop and plotted after the activity to monitor the quality and integrity of the data being collected. Thereafter, the participant was asked to stand still while the measured data is saved to a password-secure folder under the participant's reference number provided in the recruitment process so that it could be analyzed. For adequate kinematic data quality control, the experimental condition was repeated another four times. The measured data was then cleared from the measuring devices, and the data was saved on a cloud drive in a password-secured folder. The participant was then asked to move to the location of the next experimental step.

4.10.2 Activity 2: Ascending and descending a step



Step 2 • ACTIVITY 2: ASCENDING AND DESCENDING A STEP

2.1 • Ensure the sensor platform is still properly secured onto on the participant

2.2 • Have the participant stand in front of a step

2.3 • Have the participant climb onto the step using their right leg, then climb off the step using their left leg.

2.4 • Save the measured data so that it can be analyzed

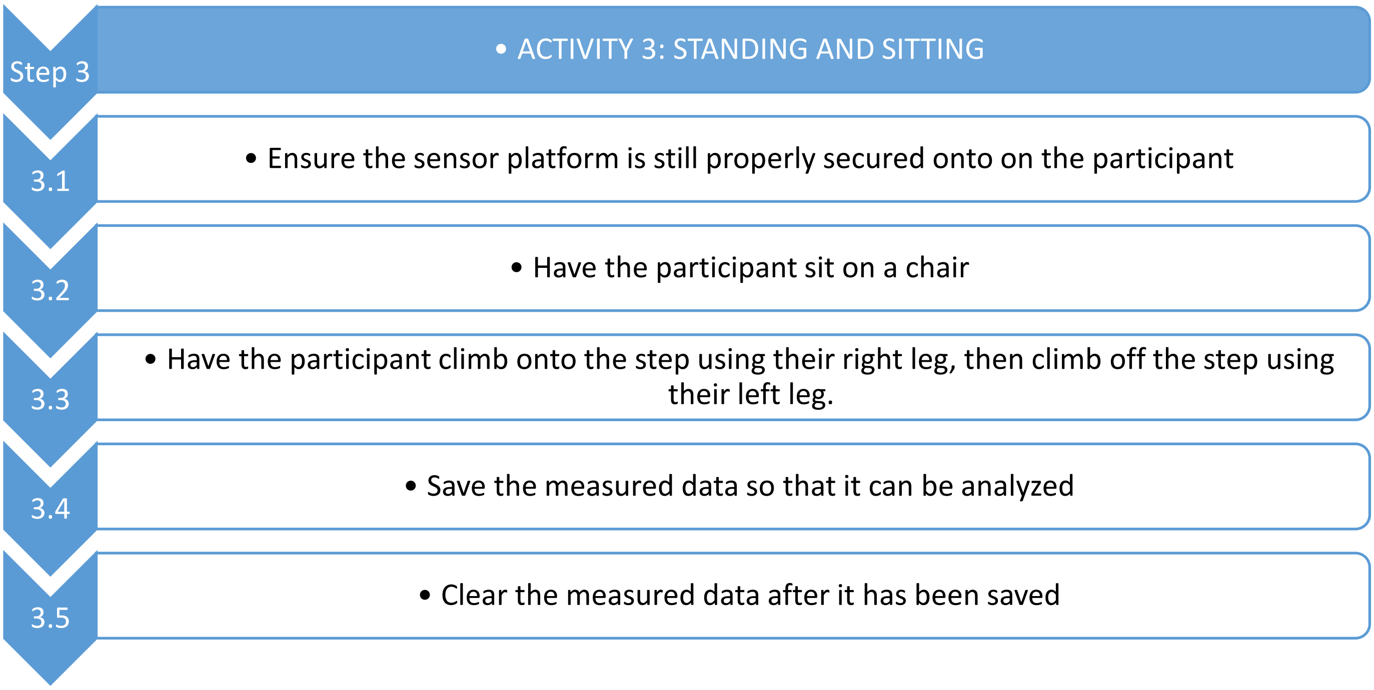
2.5 • Clear the measured data after it has been saved

Figure 4-4: Activity 2: Ascending and descending a step

Before the experimental step starts, the participant was asked to stand still to ensure the sensor platform and motion-tracking reflectors are still in the correct position. The participant was asked to stand in front of the step with their feet shoulder-width apart. The sensor platform and motion tracking cameras are activated, and the participant was asked to climb onto the step using their right leg, and then climb off the step using their left leg.

The data was streamed to a laptop and plotted after the activity to monitor the quality and integrity of the data being collected. After that, the participant stood still while the measured data is saved to a password-secure folder under the participant's reference number provided in the recruitment process so that it could be analyzed. For adequate kinematic data quality control, the experimental condition was repeated another four times. The measured data was then cleared from the measuring devices, and the data was saved on a cloud drive in a password-secured folder. The participant was then asked to move to the location of the next experimental step.

4.10.3 Activity 3: Standing and sitting



Step 3 • ACTIVITY 3: STANDING AND SITTING

3.1 • Ensure the sensor platform is still properly secured onto on the participant

3.2 • Have the participant sit on a chair

3.3 • Have the participant climb onto the step using their right leg, then climb off the step using their left leg.

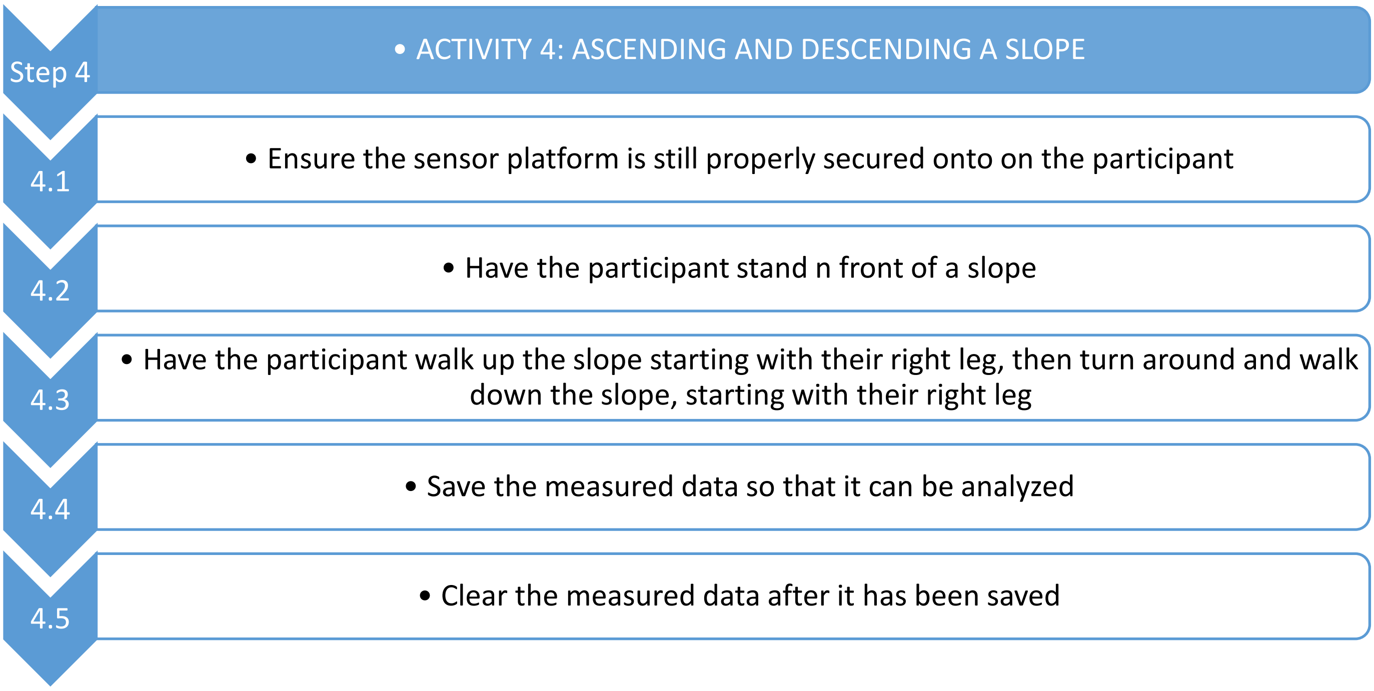
3.4 • Save the measured data so that it can be analyzed

3.5 • Clear the measured data after it has been saved

Figure 4-5: Activity 3: Standing and sitting

Prior to data collection, a step was set up in the capture volume, facing optical motion tracking cameras. The participant was asked to stand still to ensure the sensor platform and motion-tracking reflectors are still in the correct position. The participant was asked to stand in front of the step with their feet shoulder-width apart. The sensor platform and motion tracking cameras were activated, and the participant was asked to climb onto the step using their right leg, and then climb off the step using their left leg. The data was streamed to a laptop and plotted after the activity to monitor the quality and integrity of the data being collected. After that, the participant was asked to stand still while the measured data is saved to a password-secure folder under the participant's reference number provided in the recruitment process so that it could be analyzed. The procedure was repeated four times to obtain adequate kinematic data. The measured data was again cleared from the measuring devices; thus, the data was saved on a cloud drive in a password-secured folder. The participant was then asked to move to the location of the following experimental step.

4.10.4 Activity 4: Ascending and descending a slope



Step 4
- ACTIVITY 4: ASCENDING AND DESCENDING A SLOPE

4.1
- Ensure the sensor platform is still properly secured onto on the participant

4.2
- Have the participant stand n front of a slope

4.3
- Have the participant walk up the slope starting with their right leg, then turn around and walk down the slope, starting with their right leg

4.4
- Save the measured data so that it can be analyzed

4.5
- Clear the measured data after it has been saved

Figure 4-6: Activity 4: Ascending and descending a slope

Prior to data collection, a sloped platform (13° angle) was set up in the capture volume facing the optical motion tracking cameras. The participant shall be asked to stand still to make sure the sensor platform and motion-tracking reflectors were still in the correct position. The participant was asked to stand in front of the sloped platform with their feet shoulder-width apart. The sensor platform and motion tracking cameras were activated, and the participant was asked to ascend a slope, starting with their right foot, turn around, and walk down the slope starting with their right foot. The data was streamed to a laptop and plotted after the activity to monitor the quality and integrity of the data being collected. Thereafter, the participant was asked to stand still while the measured data is saved to a password-secure folder under the participant's reference number provided in the recruitment process so that it could be analyzed. Again, the procedure was repeated four times to obtain adequate fidelity with regards to the kinematic data. The measured data was then cleared from the measuring devices; thus the data was saved on a cloud drive in a password-secured folder. The participant was then asked to move to the location of the next experimental step.

4.10.5 Activity 5: Walking

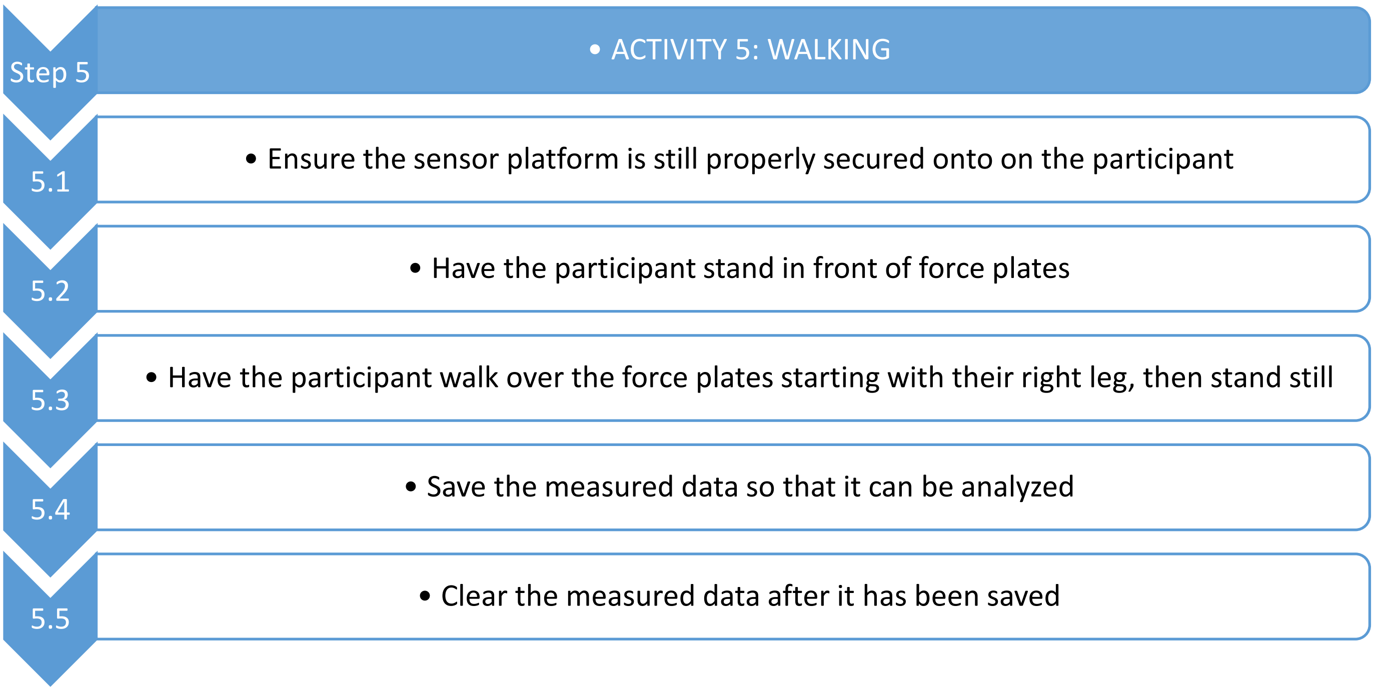


Figure 4-7: Walking

For the final experimental condition that forms part of the ADL processes, the participant was required to stand in front of the force plate. The participant was asked to stand still to ensure the sensor platform and motion-tracking reflectors are still in the correct position. The sensor platform, force plate, and motion tracking cameras are activated, and the participant was asked to walk over the force plate, starting with their right foot, and then stand still. The data was streamed to a laptop and plotted after the activity to monitor the quality and integrity of the data being collected. After that, the participant stood still while the measured data was saved to a password-secure folder under the participant's reference number provided in the recruitment process so that it could be analyzed. The measured data was then cleared from the measuring devices; thus the data was saved on a cloud drive in a password-secured folder. This was repeated another four times. The sensor platform and motion tracking reflectors were then removed from the participant, which marked an end to the experimental process.

4.11 Statistical Analyses

All data are presented as means ± standard deviation (SD) unless otherwise stated. Data were evaluated for normality using the Shapiro-Wilk [75] test whereby deviations from normality were accepted at an alpha level of less than 0.05.

With regards to the first objective, data from the sensors were generated at a baud rate of 115 200 bps. Data generated from the sensors were stored as a XLS file. MATLAB$^{(R)}$ (R2021a Update 3 (9.10.0.1684407) 64-bit, The MathWorks, Massachusetts, USA) was used to remove outliers and then the average of each experiment was evaluated and retained for analysis. All kinematic data for each activity was ensemble averaged and plotted on a line graph resembling that of Figure 3-3. The kinematic data are evaluated as a function of time and were time-normalized to facilitate comparisons across all participants. A smoothing filter was applied to each experimental dataset.

With regards to the second objective, once the smoothing filter was applied, the triaxial data from the knee brace was compared to the data from the 3D motion capture system and force plates. Differences in the angular data generated by the knee brace and the Qualisys system. were evaluated using the paired t-test from the statistical parametric mapping (SPM{t}) package (Matlab, SPM1d, v. M.0.4.7). The SPM{t} analysis is based on random field theory which describes the probabilistic behaviour of random curves and accounts for the smoothness of the data, which was used to set a critical threshold (α = 0.05) [76], [77]. If the SPM{t} curve exceeded this critical threshold, angular data was deemed to be significantly different at these specific time nodes. [78] Furthermore, validity was assessed using a Bland-Altman analysis [79] to evaluate the level of agreement of peak kinetic and kinematic data derived from the knee brace (reference method) and the Qualysis motion analysis system (criterion method). A level of agreement within 5% will be accepted as valid.

All statistical tests were completed using the Statistical Package of Social Software (SPSS) (IBM Corporation 2019, Version 26.0.0), and Matlab (R2021a Update 3 [9.10.0.1684407] 64-bit, The MathWorks, Massachusetts, USA) that can be accessed through the North-West University's network.

4.12 Verification and Validation

The validity of the sensor-derived measurements was assessed by comparing criterion methods such as 3D Motion Analysis and force plate technologies. The technology available for use at NWU Potchefstroom includes:

- Qualisys Motion Analysis System with 8 Oqus 300+ cameras (Qualisys, Sweden) for collecting 3D motion data at a sampling frequency of 200 Hz
- Three AMTI force plates (AMTI BP400600, Watertown, MA, USA) for collecting triaxial force data during various tasks at a sampling frequency of 2 kHz

4.13 Conclusion

A total of 15 participants were recruited to take part in a study that involves measuring knee joint angle, knee joint angular velocity, and ground reaction forces. These measurements were taken while the participants perform activities of daily living like Activity 1: Tying a shoelace, Activity 2: Ascending and descending a step, sitting and standing, Activity 4: Ascending and descending a slope, and walking. The next chapter provides the results and the validation and discussion thereof.

Chapter 5: Results, Validation, and Discussion

5.1 Introduction

In this Chapter, we discuss the data generated by the Knee brace. The results are obtained from the trials described in the experimental method. The results are validated against existing methods of knee function monitoring and are discussed in detail.

5.2 Data Generation

The Knee brace generates data at 20 Hz. The choice of sampling rate depended on the characteristics of the motion being analyzed. For example, the motion is relatively slow or simple, a higher sampling rate did not provide much additional benefit. In this case, was a sufficient sampling rate for capturing the necessary data. For the purpose of this study, 15 participants were recruited for data collection. Only 13 of the 15 participants' data could be used for the knee joint angle and knee joint angular velocity due to a loss of data from two participants. Which results in a total of 65 iterations per activity. Only 8 of the 15 participants' data could be used for the knee load data, due to a connection error on the force sensor while data was being gathered. Which results in 40 iterations of the activity.

5.3 Sensor Platform Knee Joint Angle Results

The results of the tying a shoe activity shall be discussed in detail, the same method is applied to the other activities. We start with the tying a shoe activity by obtaining the above knee (Thigh) angle and below knee (Shank) angle as discussed in Chapter 3. There are five iterations done per participant per activity. The data collected from the activity is synchronized so that it can be analyzed. Each dataset was synchronized manually to ensure that each participant's data starts at the same instance so that the data can be analyzed. We can see that the deviation of the data increases as time increases, which is due to each person taking different amounts of time to complete a given activity. Figure 5-1 illustrates the above knee angle of five iterations of a single participant completing the Activity 1: Tying a shoelace activity. The angular value displayed is the value captured in the quadrant that the accelerometer is tilting in as explained in chapter 2.6.1.

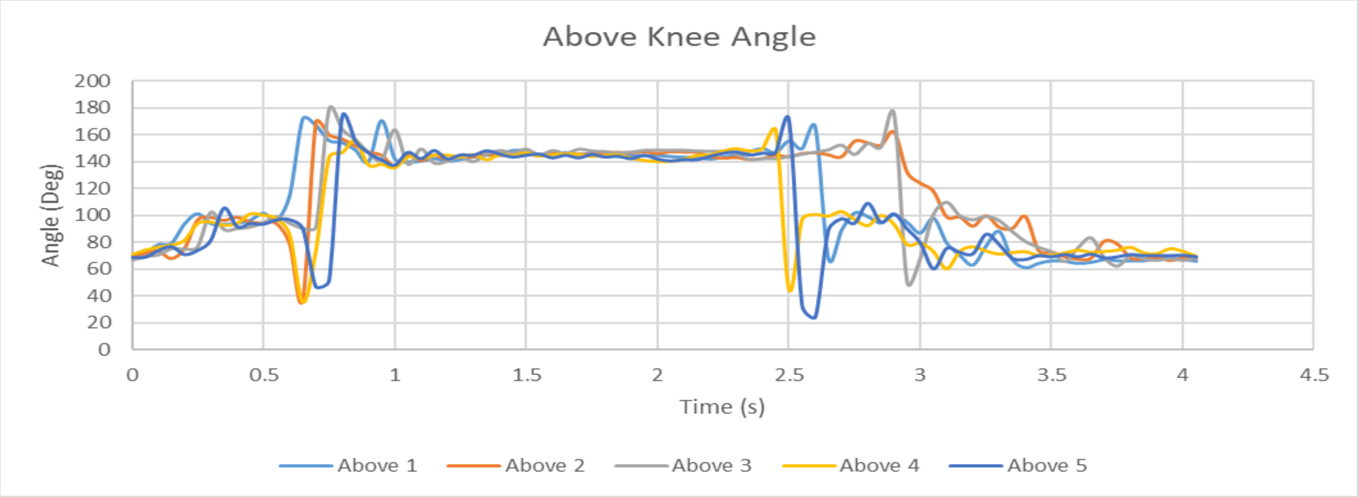


Figure 5-1: Individual Participant: Above Knee Angle

Figure 5-2 illustrates the above knee angle of five iterations of a single participant completing the tying a shoe activity.

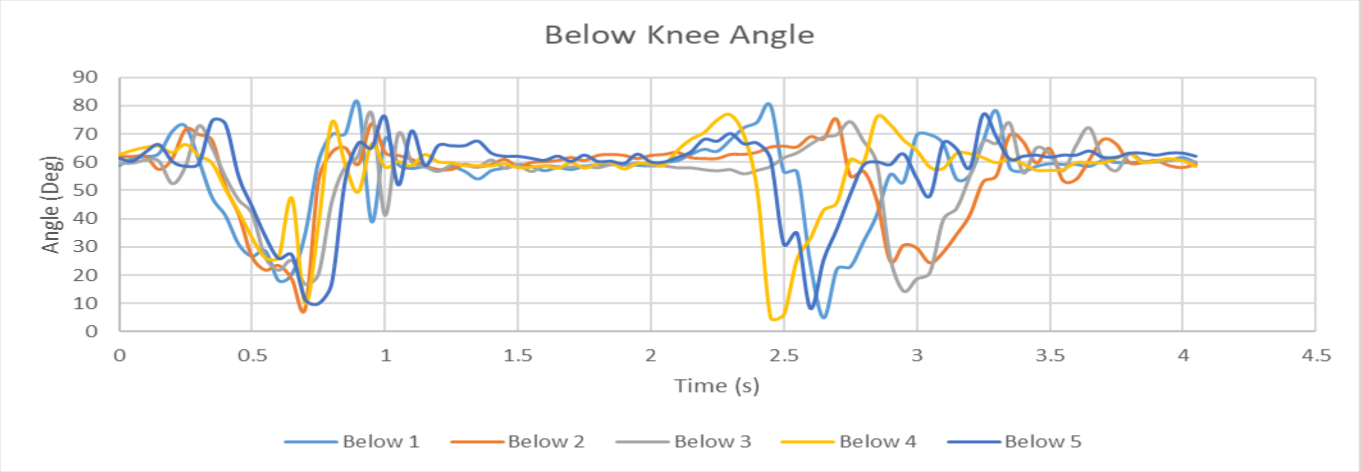


Figure 5-2: Individual Participant: Below Knee Angle

The above knee angle and below knee angle from the five iterations of the participant are subtracted from each other as explained in chapter 3.4 to calculate the knee joint angle (Figure 5-3). We can see there is a lot of noise caused by the accelerometer data. Here the knee joint angle is 0° when the leg is fully extended, and increases as the joint begin to flex. Thus, the knee joint angle is the number of degrees the knee is flexed, which can be seen in Figure 2-6. Form Figure 5-3, the participant is standing still in front of the step at 0.0 s, between 0.0-0.1 s the participant lifts there foot onto the step, between 1.0-2.4 s the participant ties their shoelace, between 2.4-3.5 s the participant returns there leg to its original position in front of the step. We can see that every time the foot makes contact with the ground, the vibrations detected by the accelerometer cause oscillations in the waveform. This can be seen between 0.5-1.0 s and 2.4-3.0 s

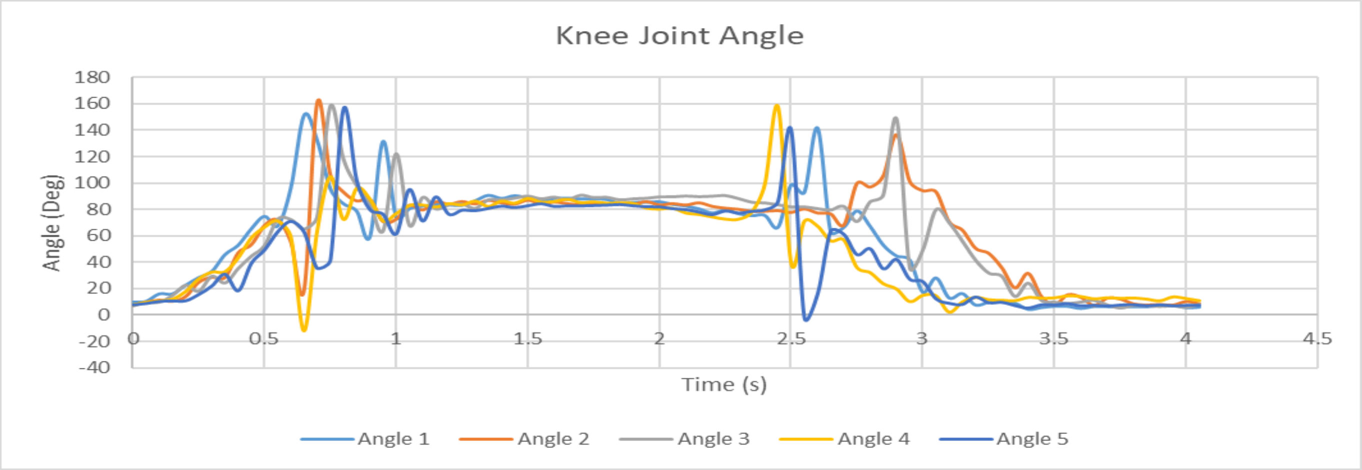


Figure 5-3: Individual Participant: Knee Joint Angle

An exponential smoothing filter is used to filter out some of the oscillation caused by vibration on the accelerometers as the foot makes contact with the ground. (Figure 5-4).

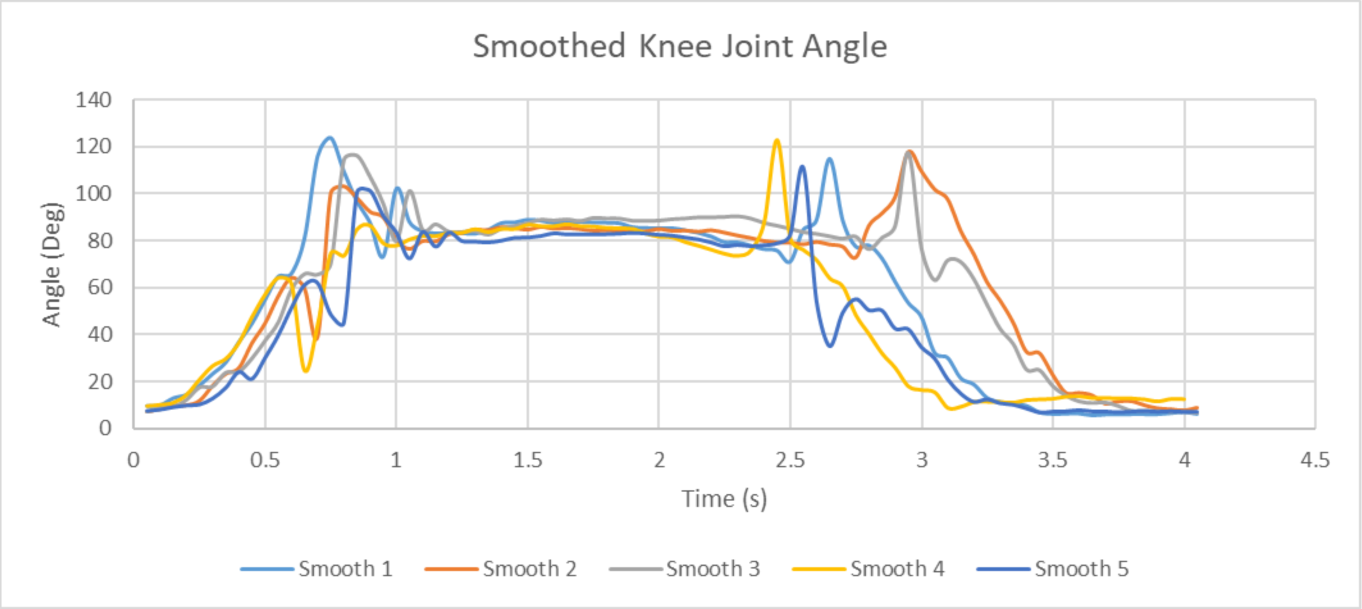


Figure 5-4: Smoothing Filter on Knee Joint Angle

The mean is then calculated from the five iterations completed by the participant completing the Activity 1: Tying a shoelace activity and the offset is removed (Figure 5-5).

Figure 5-5: Individual Participant: Tying a Shoe Mean

This process is repeated for each of the other activities completed by the participant. The mean data of each of the other completed activities for the individual participant are illustrated in Figure 5-6.

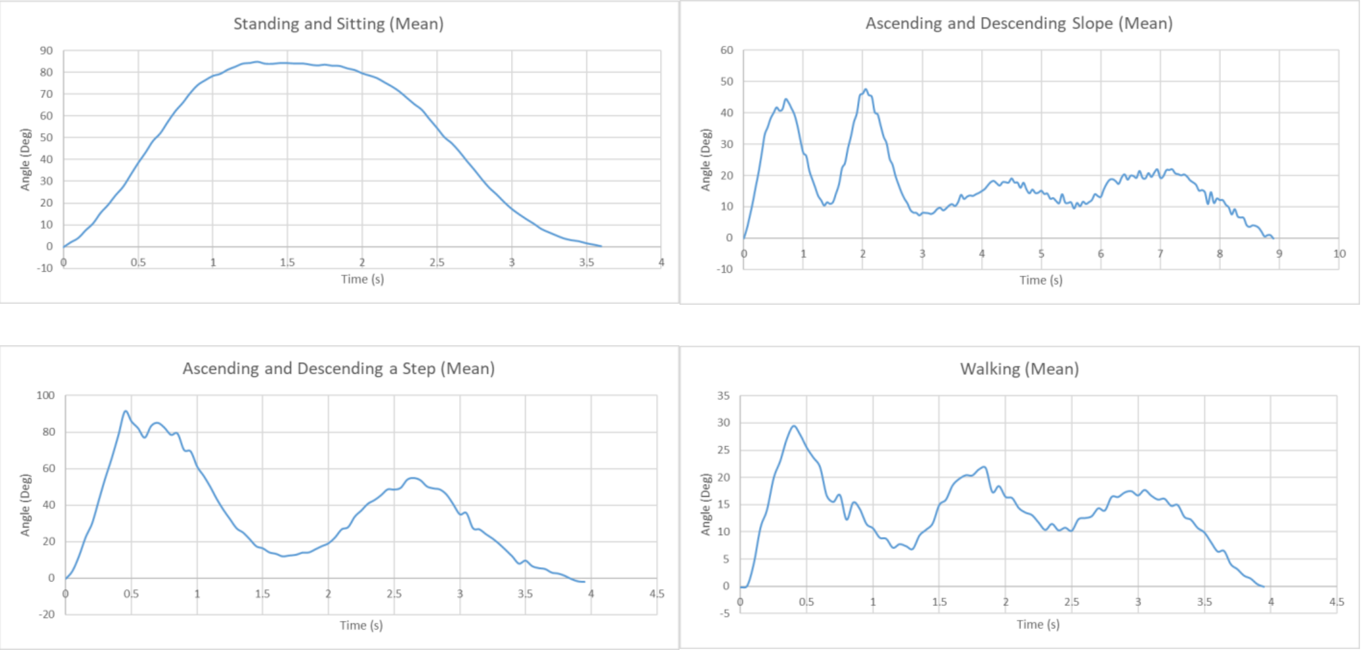


Figure 5-6: Individual Participant: Daily Activity Means

This same process is followed for each of the 13 participants. The mean data of all the participants completing a certain activity are then plotted in Figure 5-7. The time is converted to a normalized unit to simplify the validation process. The normalized unit is the time converted to a percentage of the time taken to complete a given activity.

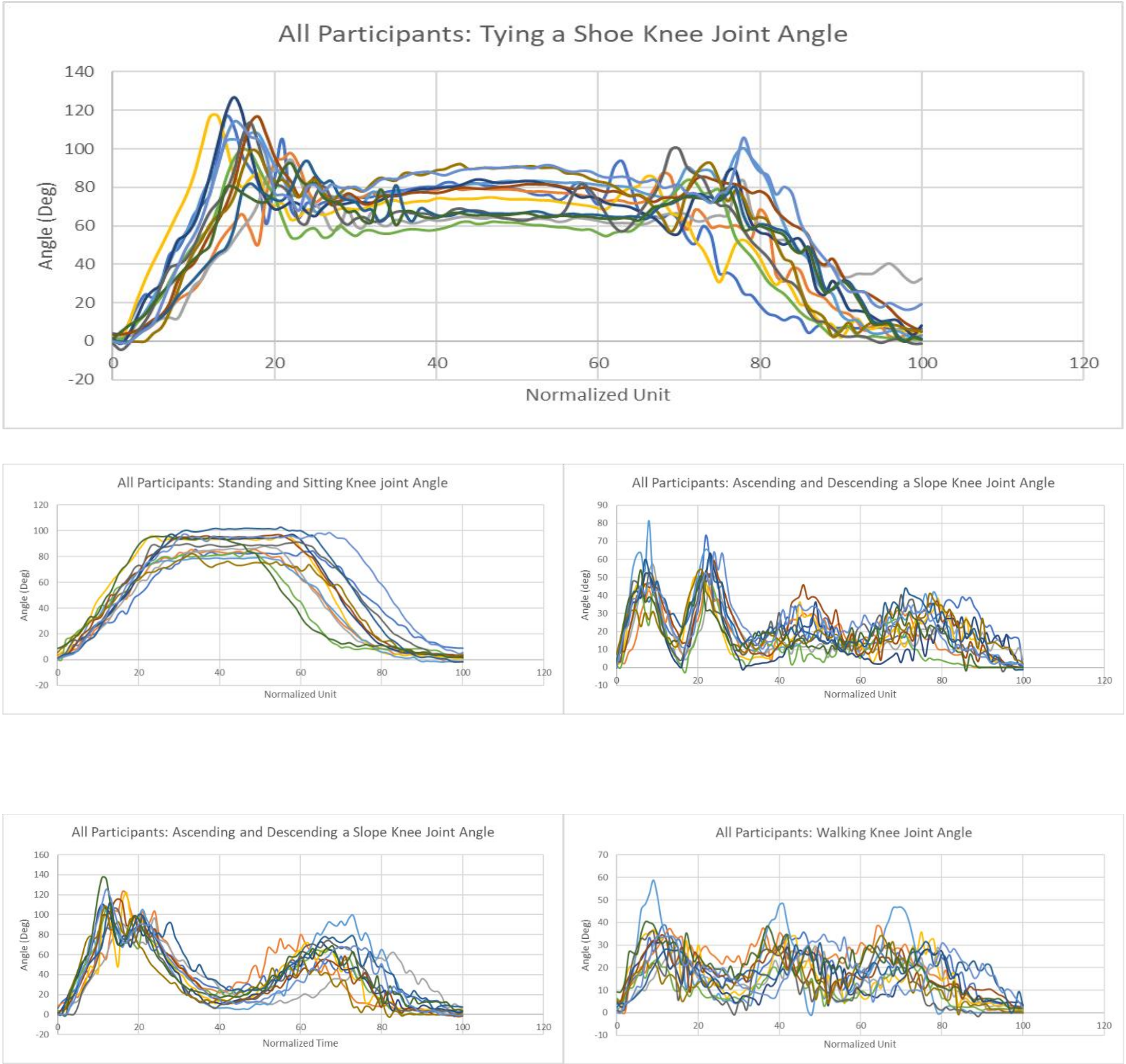


Figure 5-7: All Participants: Activity Means

The data is now ready to be validated, which involves comparing the data from the sensor platform to that of existing motion analysis devices.

5.4 Sensor Platform Knee Joint Angular Velocity Results

The Activity 1: Tying a shoelace activity results shall be described in detail. The other activities completed by the participants shall be done similarly to the tying a shoe activity. The above-knee angular velocity and below-knee angular velocity are used to determine the knee joint angular velocity, as discussed in Chapter 3.5. Each participant completed five iterations per activity, The iterations completed by an individual participant for the tying a shoe activity are illustrated in Figure 5-8.

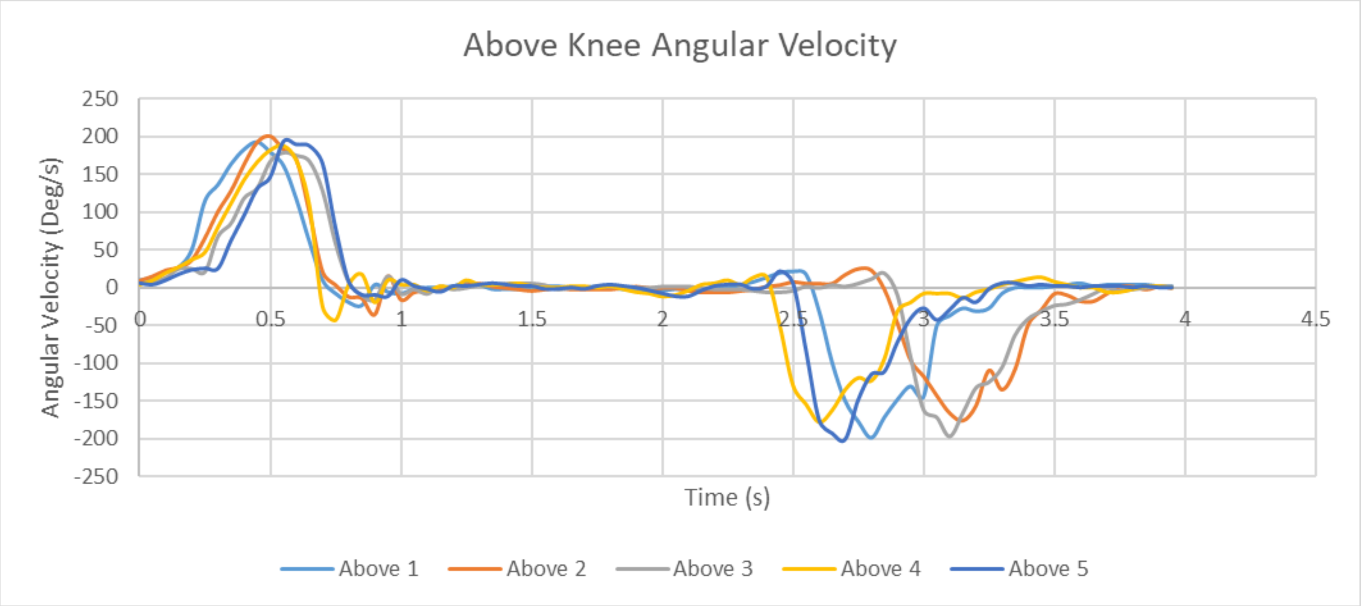


Figure 5-8: Above Knee Angular Velocity

The mean is calculated from the five iterations and is illustrated in Figure 5-9.

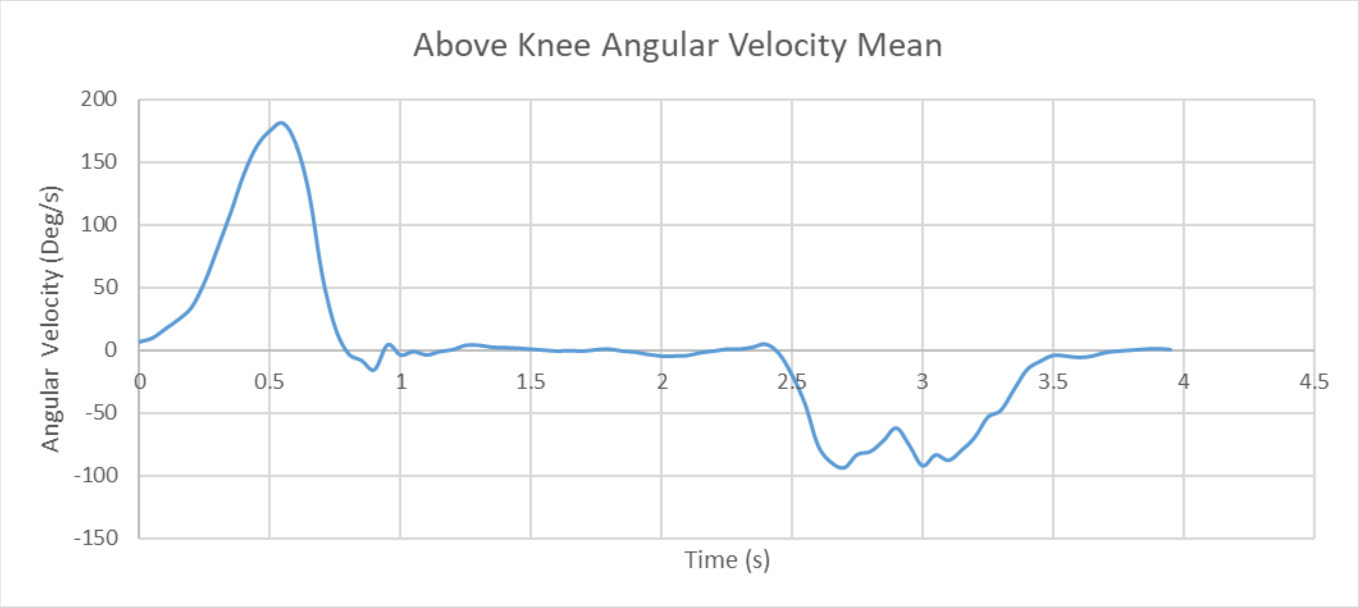


Figure 5-9: Above Knee Angular Velocity Mean

The same is done with the below-knee angular velocity. The five iterations of the tying as shoe activity are plotted (Figure 5-10) and the mean is calculated.

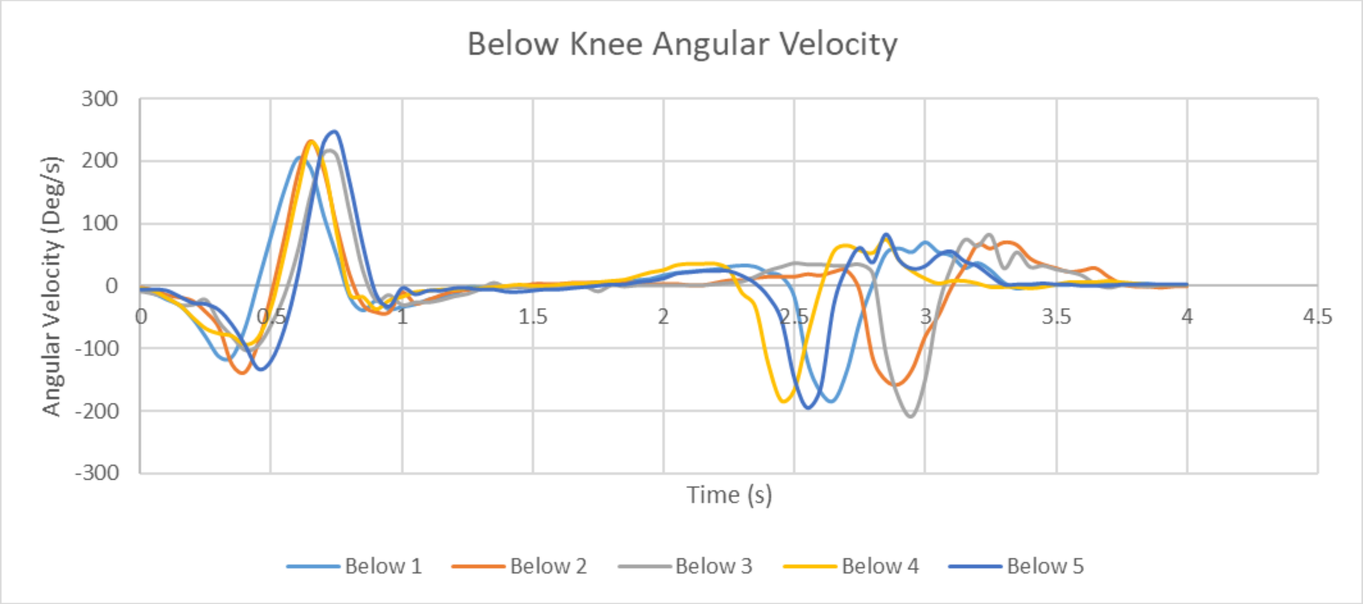


Figure 5-10: Below Knee Angular Velocity

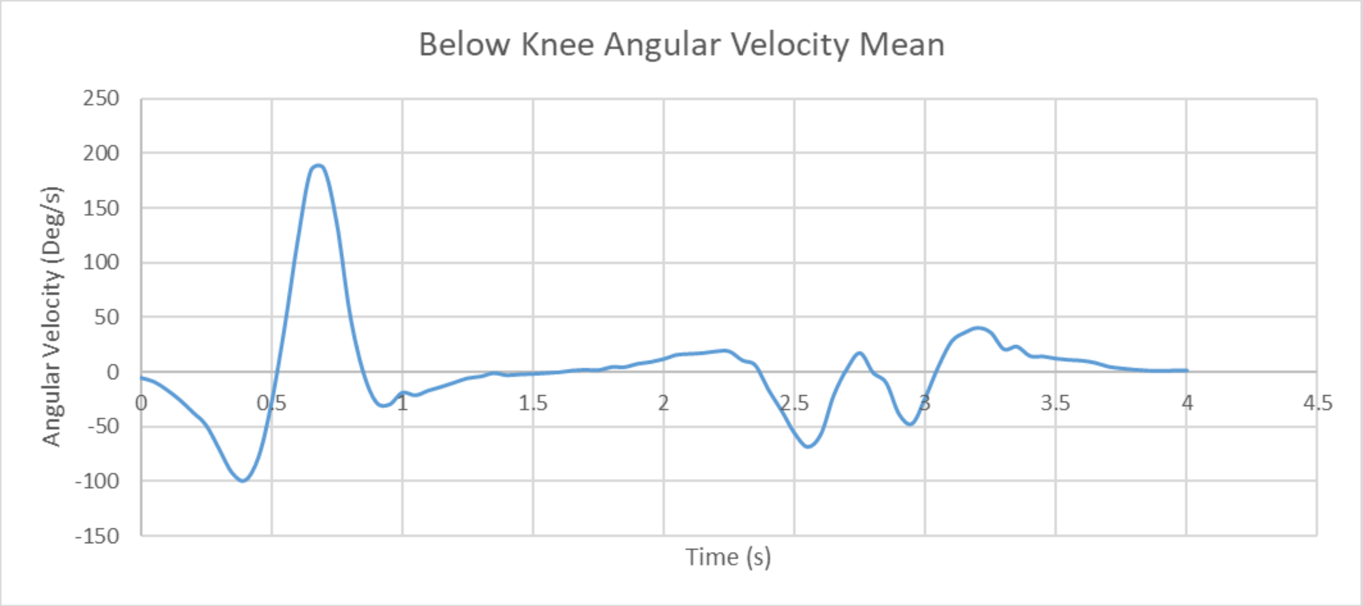


Figure 5-11: Below Knee Angular Velocity Mean

The knee joint angular velocity can now be calculated using the above-knee angular velocity and below-knee angular velocity which is illustrated in Figure 5-12. We can see that the participant is standing still in front of the step at 0.0 s, between 0.0-1.0 s the participant lifts their foot onto the step, between 1.0-2.4 s the participant ties their shoe, between 2.4-3.5 s the participant returns their leg to its original position in front of the step.

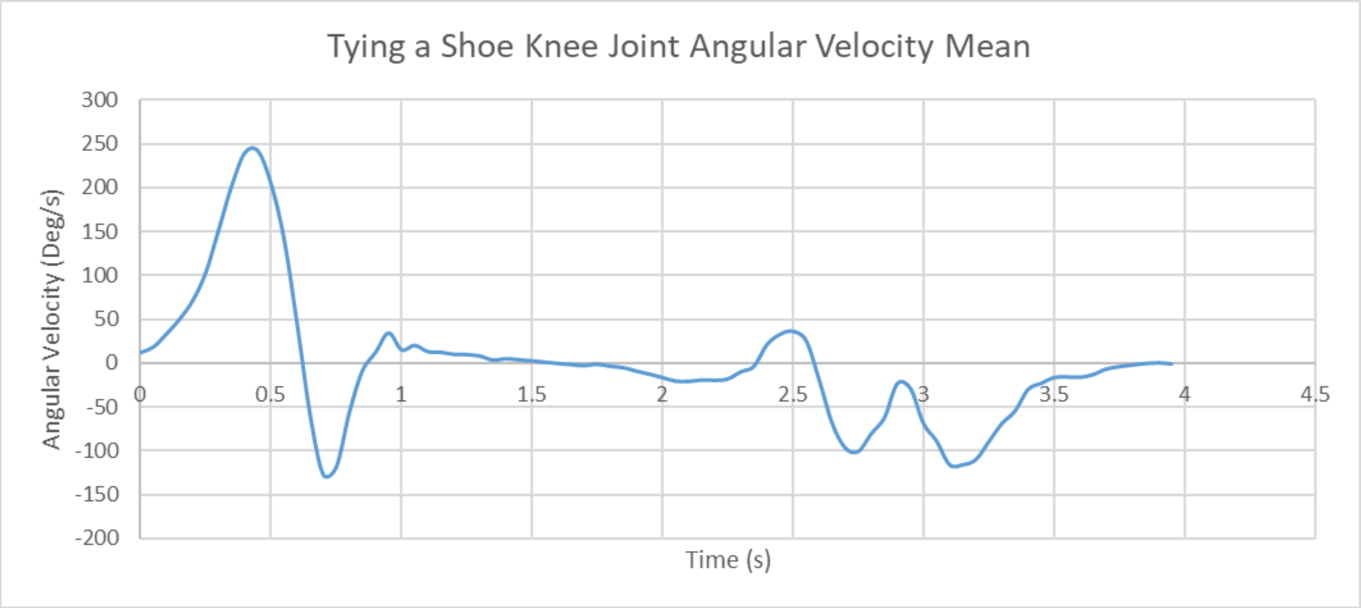


Figure 5-12: Tying a Shoe Knee Joint Angular Velocity Mean

The whole process is then repeated for the other activities of daily living. The mean data for each of these activities for the individual participant is illustrated in Figure 5-13.

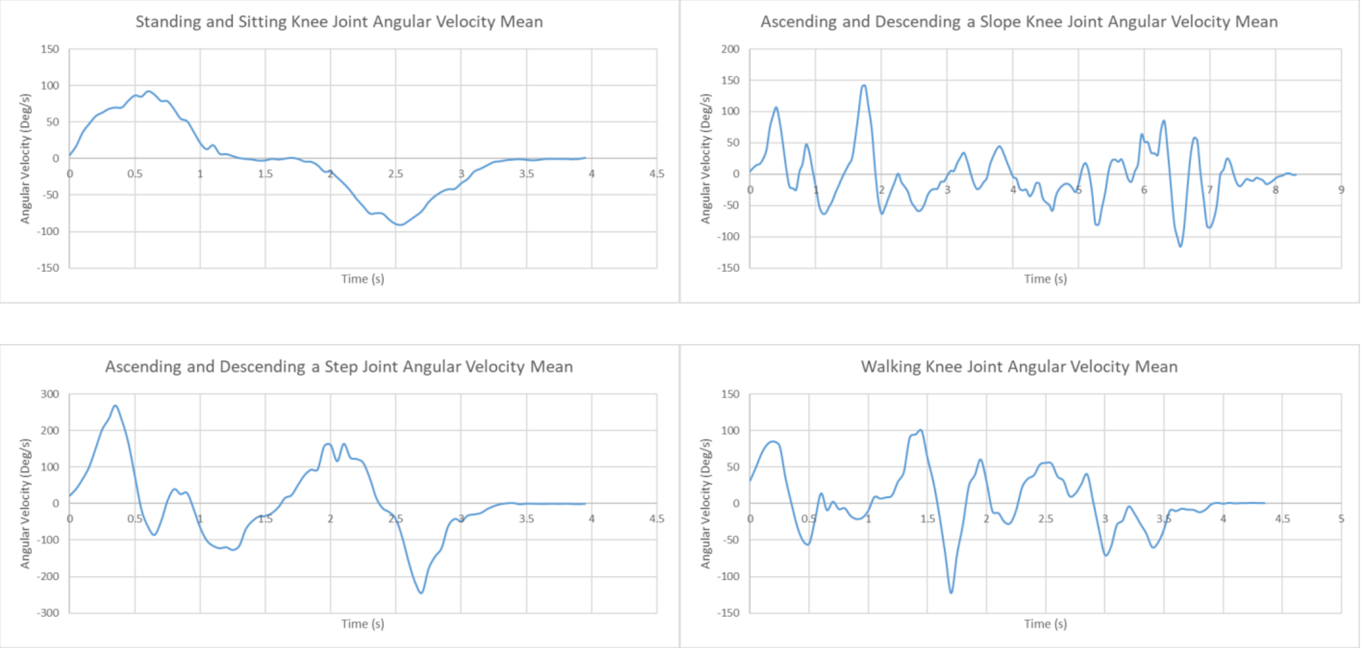


Figure 5-13: Individual participant: Activity Means

This process is repeated for each of the 13 participants and is plotted on graphs in Figure 5-14. The time is converted to a normalized unit for validation purposes. The normalized unit is the time converted to a percentage.

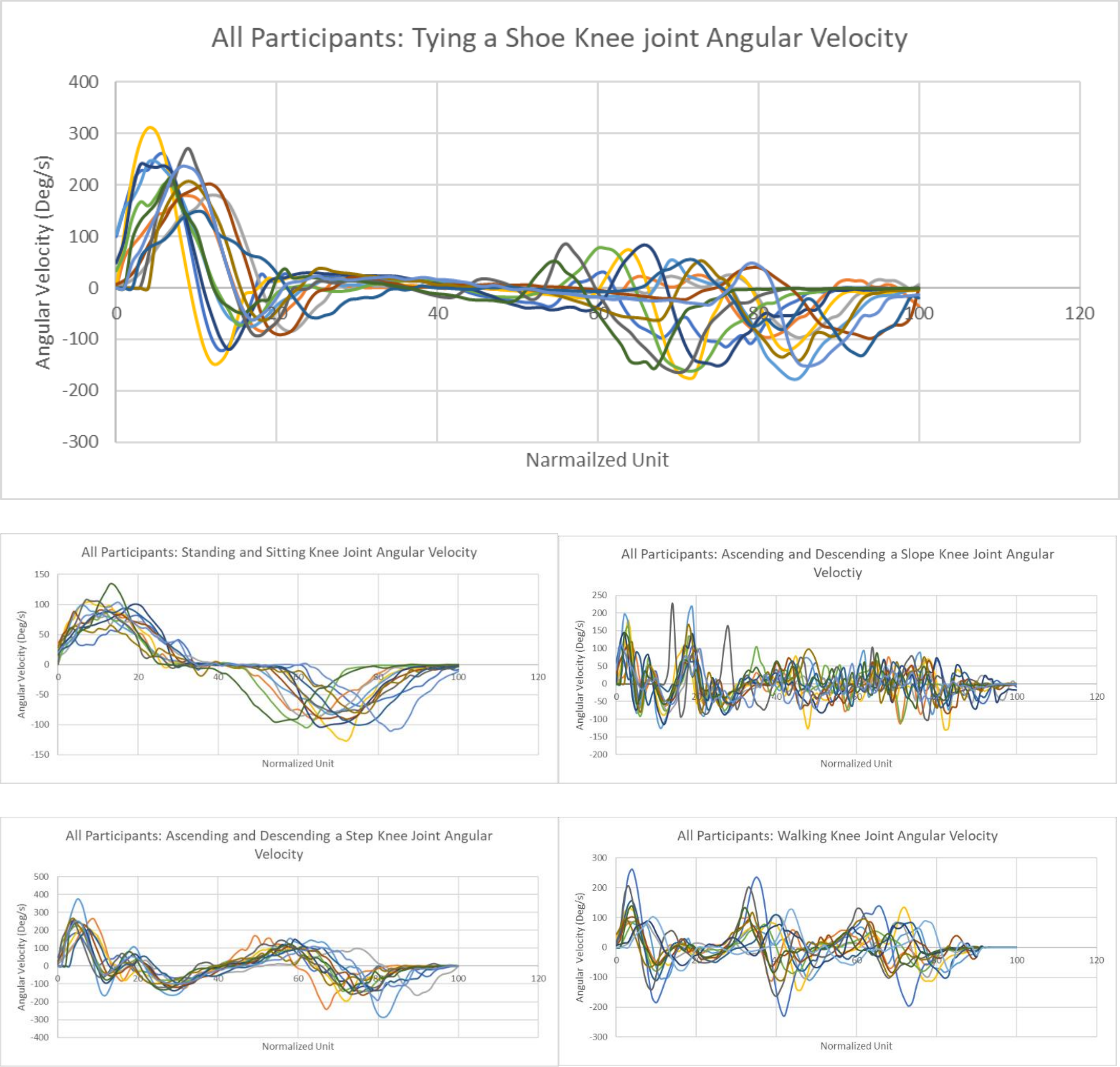


Figure 5-14: All Participants: Activity Means

The angular velocity data from the activities is now ready to be used for validation.

5.5 Sensor Platform Ground Reaction Force Results

The heel sensor results shall be explained in detail. A similar method is followed with the forefoot sensor. We start by plotting the five iterations done by an individual participant in the walking activity. The raw sensor output data from the heel sensor can be seen in Figure 5-15. We can see that as force is applied to the sensor during the gait cycle, the heel sensor output decreases. Thus, the more weight applied to the sensor, the smaller the sensor reading. We can also see that saturation occurs as force is applied, meaning that the heel sensor can only handle a certain amount of weight. This could result in less accurate readings.

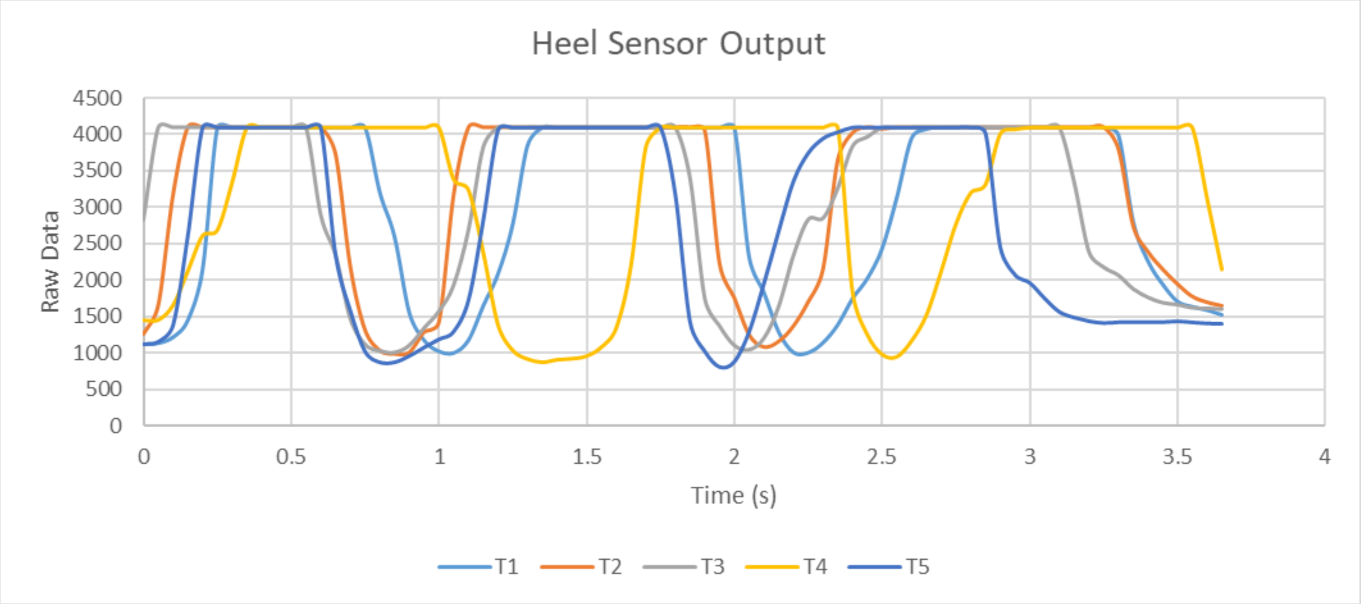


Figure 5-15: Heel Sensor Output

The mean is calculated using the five iterations of the participant and is displayed in Figure 5-16.

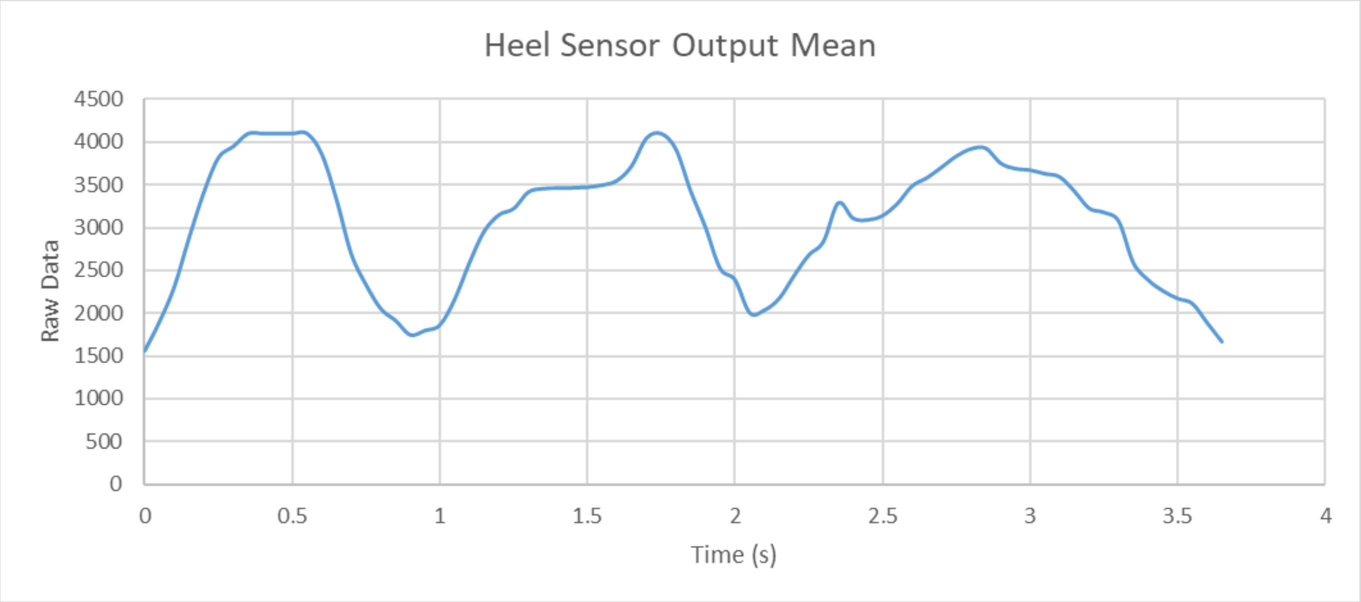


Figure 5-16: Heel Sensor Output Mean

The mean is used to calculate the weight applied to the force sensor (Figure 5-17), as described in the calibration process in Chapter 3.

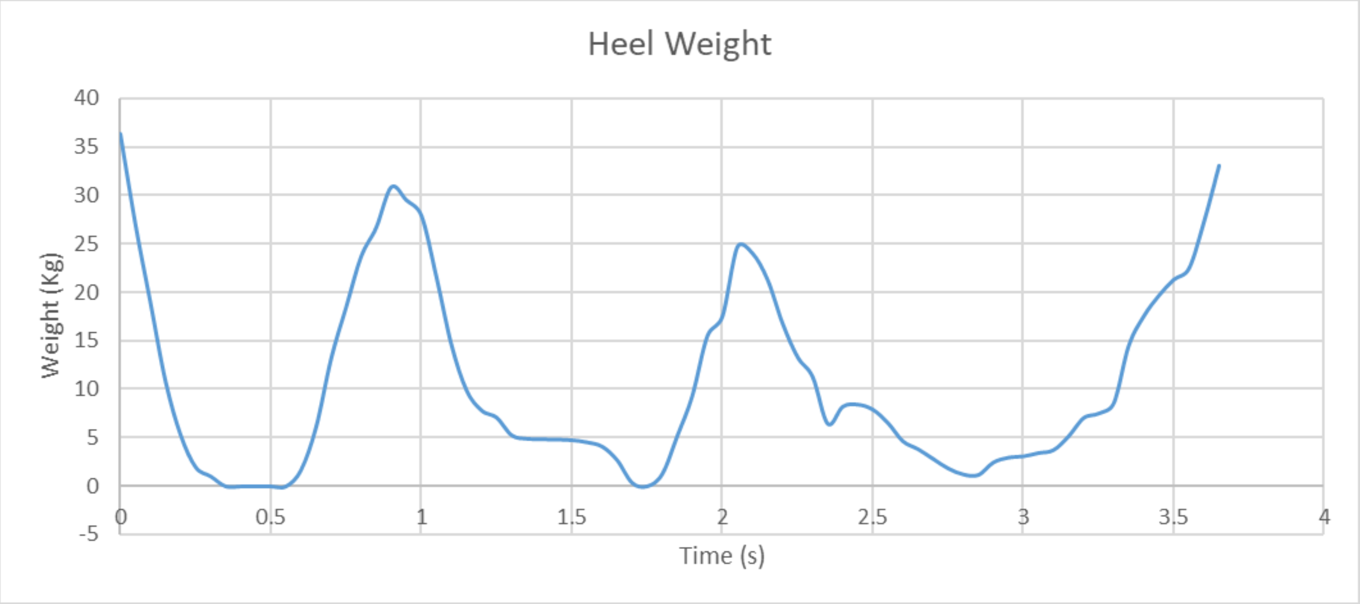


Figure 5-17: Heel weight

We can now convert the weight to a force reading (Figure 5-18). We can see that there are two steps taken, which are illustrated by the two peaks. The first is at 0.8 s, and the second is at 2.1 s. The first step, from toe strike to heel strike, is between 0.5-1.5 s and the second step is between 1.5-2.5 s.

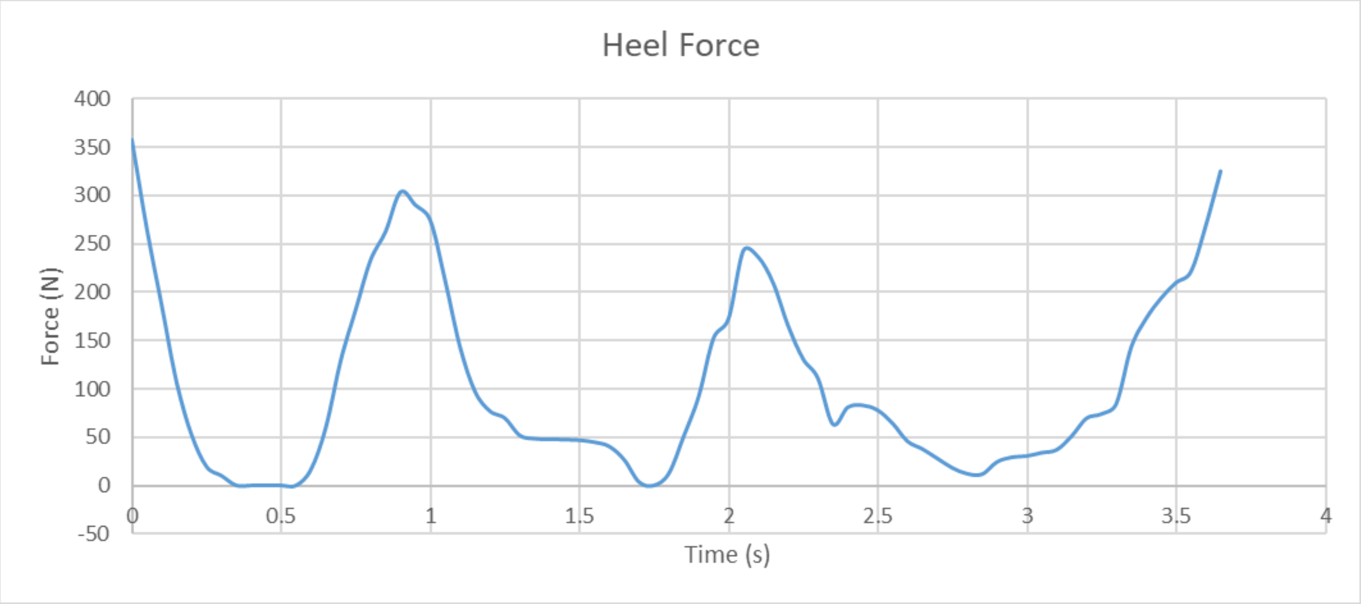


Figure 5-18: Heel Force

The same method is used for the forefoot force. The forefoot force can be seen in Figure 5-19.

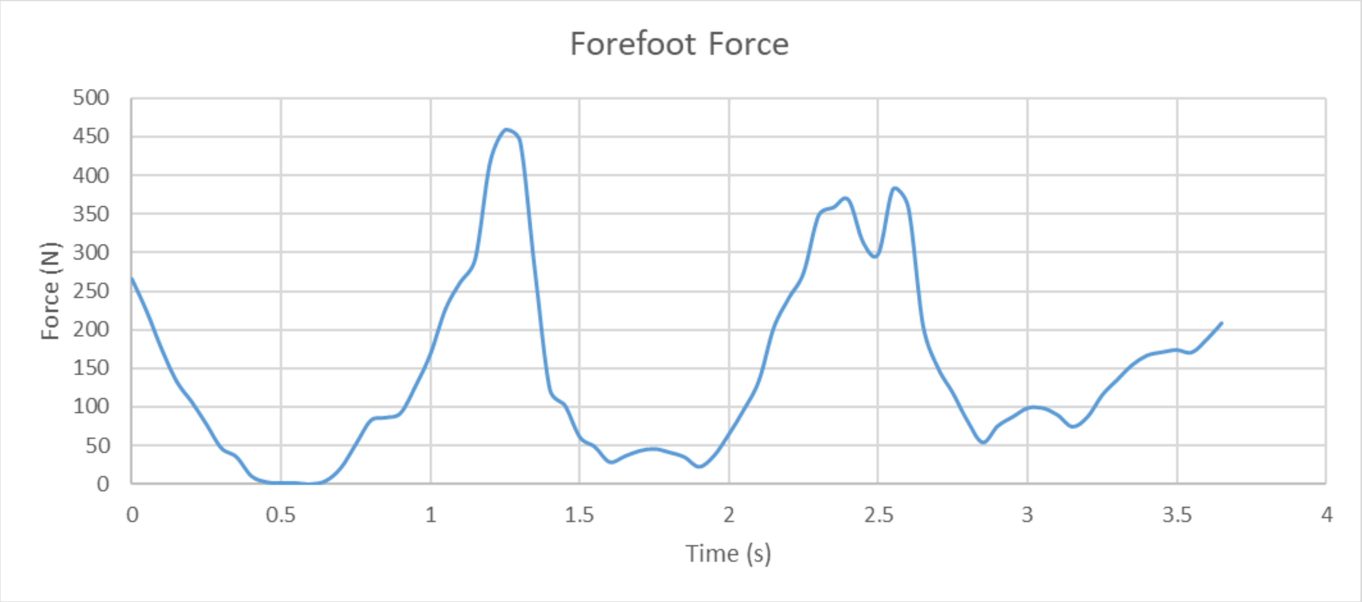


Figure 5-19: Forefoot Force

The entire process is repeated for all 8 participants. A single step is extracted from the force graph and the mean heel force and mean forefoot force for each participant are then plotted and can be seen in Figure 5-20 and Figure 5-21. From Figure 5-20, we see that there is one dataset that is higher than the rest (Green). This is the type of measurement received from the sensor platform with a connection fault, there was a loose connection on the conductor at the heel sensor.

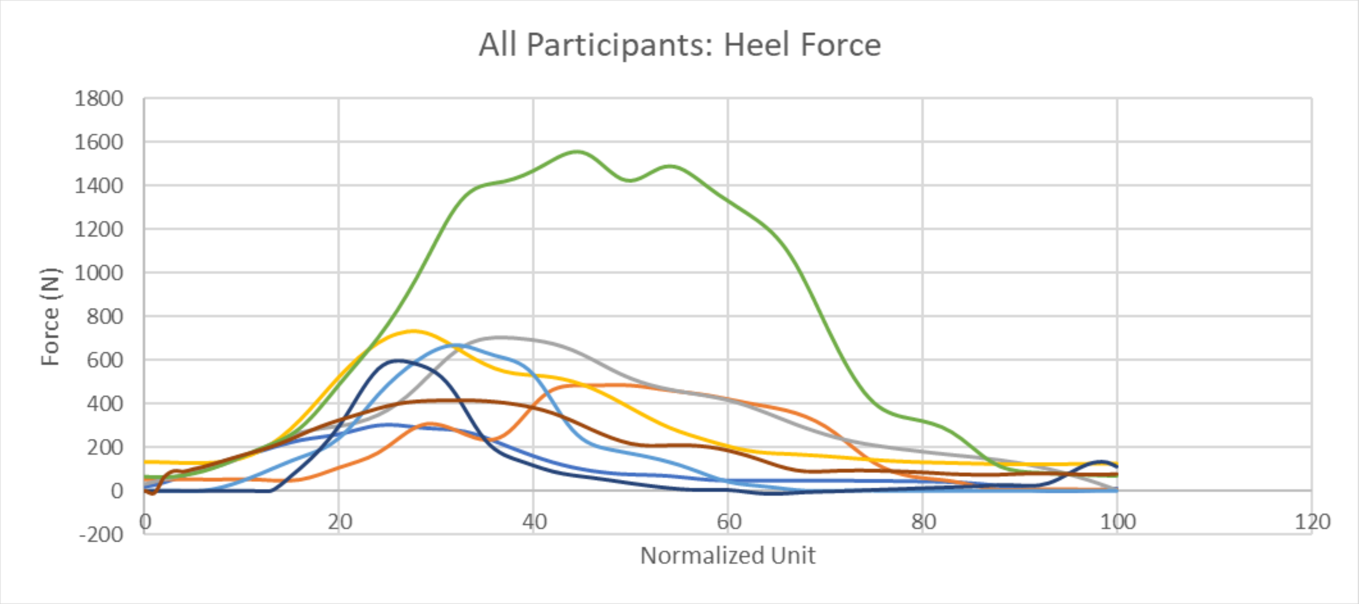


Figure 5-20: All Participants: Heel Force

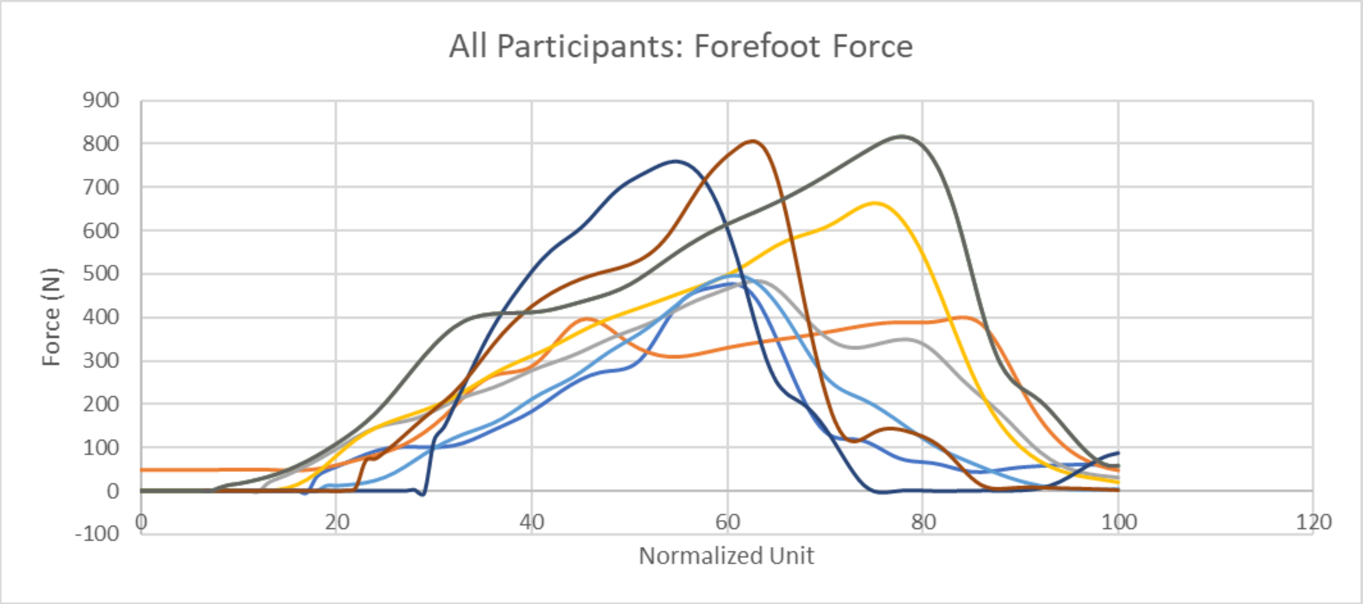


Figure 5-21: All Participants: Forefoot Force

We can now validate the data.

5.6 Validation

The data processing for the Qaulysis system and force plates were done similarly to that of the sensor platform. The mean data for each participant per activity was obtained and plotted on the same graph. The time was also normalized to a percentage to validate the data. The validation for the knee joint angles and knee joint angular velocities was done using a Qualisys Motion Analysis System with 8 Oqus 300+ cameras sampling at a frequency of 200 Hz. The knee joint angles and knee joint angular velocities were evaluated and validated for each activity separately. Each of the validation graphs displays the mean and standard deviation of both the sensor platform (Brace) and the Qualisys. The brace is indicated as a black line, with the standard deviation indicated in grey. The validation device is indicated as the red line for angular data (with the standard deviation as light red) and the blue line for angular velocity (with the standard deviation as light blue). The light purple areas in the graph indicate an area where there is a high probability of the data being significantly different at those specific time nodes. Figure 5-22 and Figure 5-23 illustrate the tying a shoe trial, which consists of lifting the foot to the step and then bringing it back to its original position. It is observable that both the knee angle and knee angular velocity are very similar. The knee angle graphs are less similar near the beginning and end of the movement, with an average error of -17.46^{o} (95% CI [-25.52^{o}, -9.38^{o}]) (brace data > Qualisys data). The angular velocity graphs are the least similar at the end of the movement, with an average error of -1.18$^{o/sec}$ (95% CI [-2.71, -0.34]). We can also see that the standard deviation increases as time goes on, with the Qualisys system being slightly higher at the end of the knee angle graph.

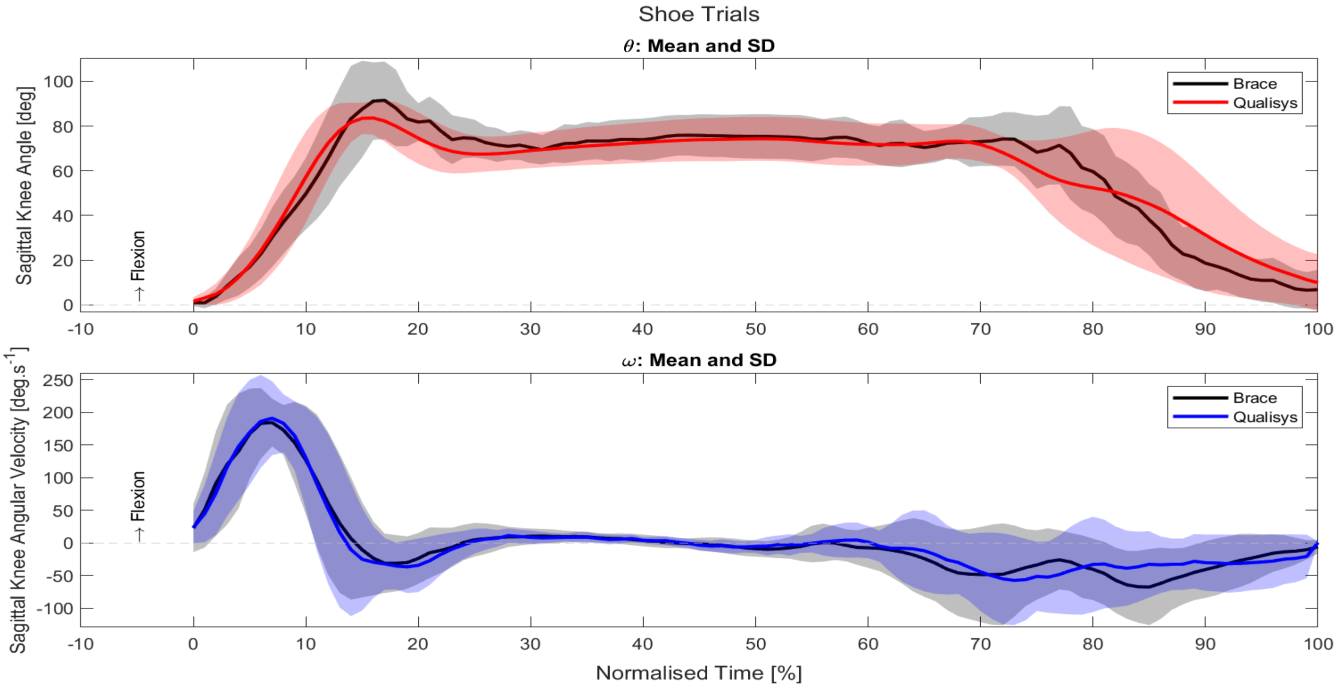


Figure 5-22: Shoe Trials

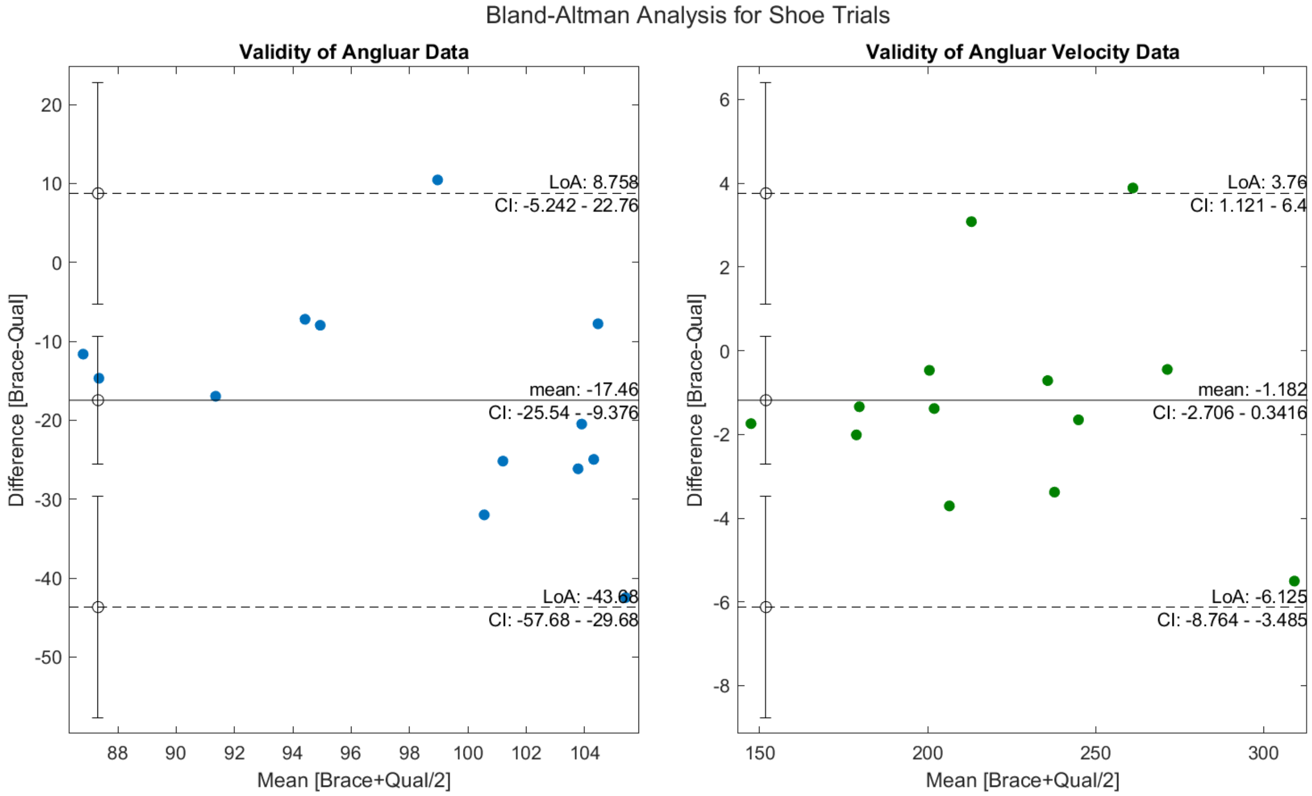


Figure 5-23: Bland-Altman results for the Shoe Trials

Figure 5-24 and Figure 5-25 display the Activity 3: Standing and sitting trials. Like the tying a shoe trial, it is a simple movement that requires participants to sit and stand from a regular chair. The most significant differences from both the knee angle and knee angular velocity graphs are again at the beginning and end of the movement. We can see that there are significant differences indicated on the knee angle graph with a mean error of -1.72° (95% CI [-3.56°, 0.12°]), first as $p<0.001$ between 0-10%, second as $p=0.026$ between 10-20%, and third as $p<0.001$ between 60-95%. There is also a significant difference on the angular velocity graph with a mean error of $-0.59^{o/sec}$ (95% CI [-1.04, -0.14]), as $p<0.001$ between 0-7%.

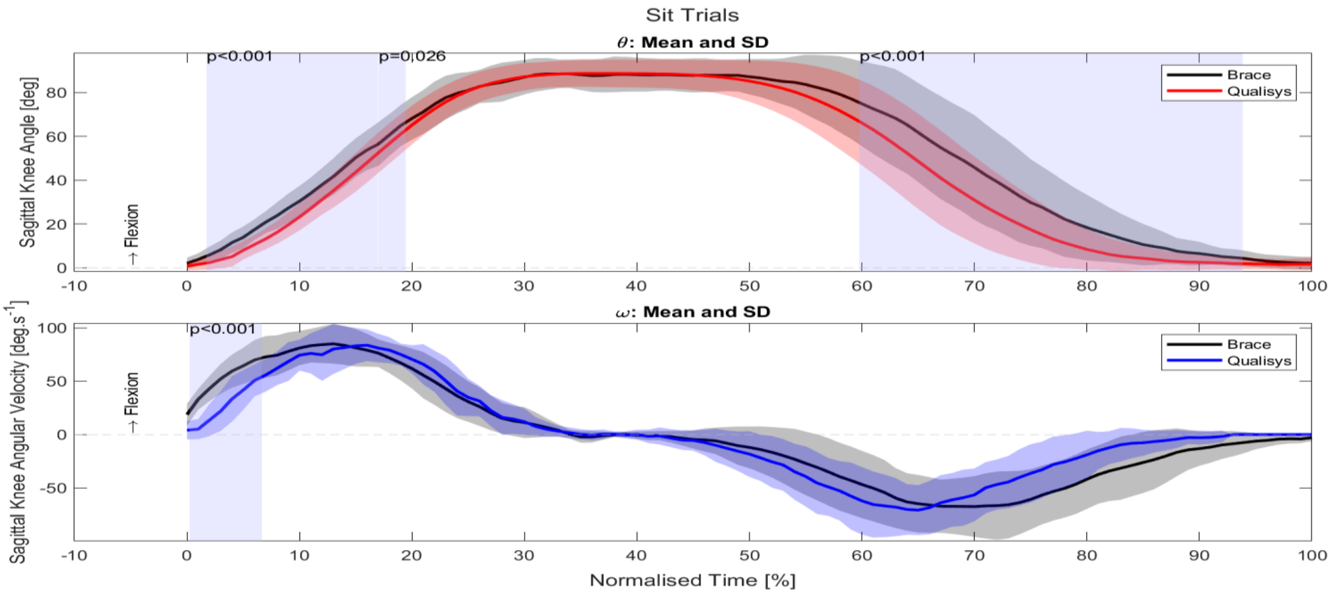


Figure 5-24: Sit Trials

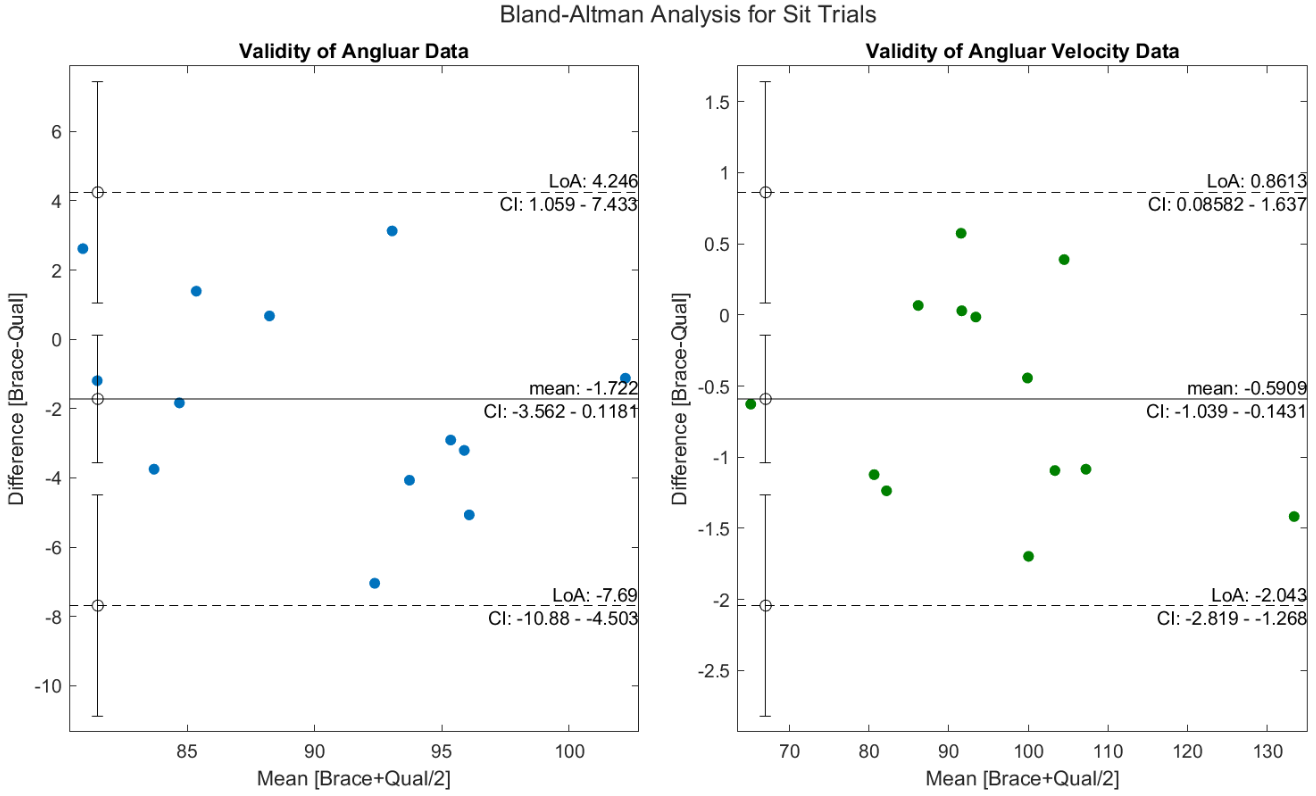


Figure 5-25: Bland-Altman Results for Sit Trials

Figure 5-26 and Figure 5-27 show the ascending and descending slope trials. This trial is more complex than the last two, with substantially more steps. This includes two steps up the slope with the right leg, turning around, and two steps back down the slope with the right leg. Similar to the other trials, the most significant differences are at the beginning and end of the movement. The knee angle graph has a mean error of -4.50° (95% CI [-9.91°, 0.91°]) and the knee angular velocity graph has a mean error of -3.98°/sec (95% CI [-11.28, 3.33]). A statistically significant difference is indicated for the knee angular velocity graph as $p<0.001$ between 0-4%.

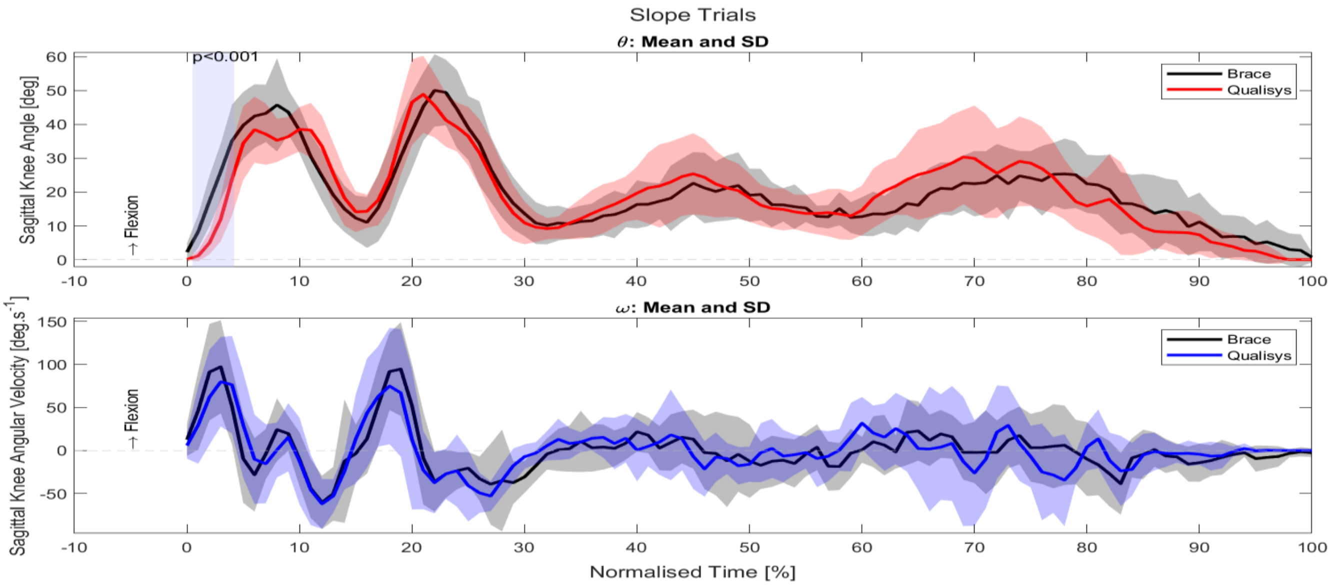


Figure 5-26: Slope Trials

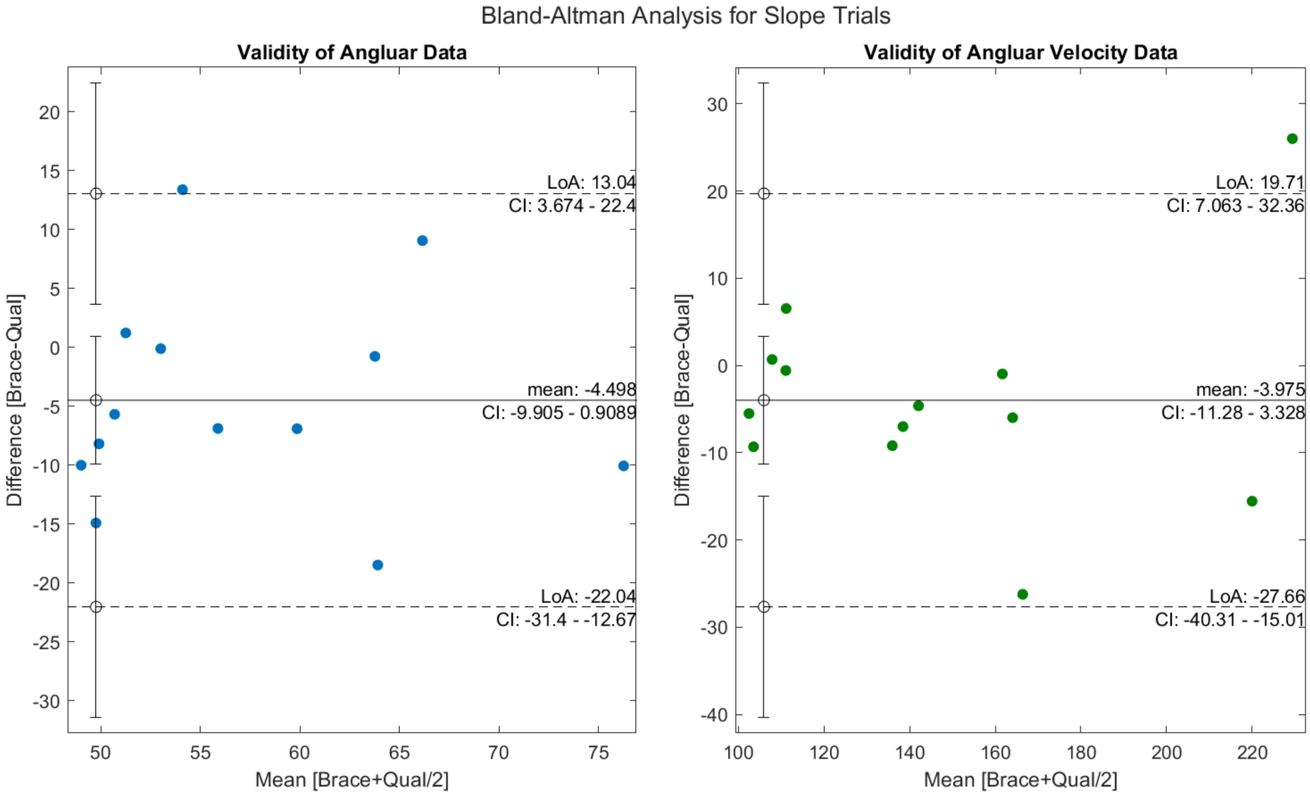


Figure 5-27: Bland-Altman Results for Slope Trials

The validation results for the Activity 2: Ascending and descending a step trial can be seen in Figure 5-28 and Figure 5-29. The trial involves climbing onto a step and then climbing off of the step. There are significant differences in the angle of the two peaks in the knee angle graph, with a mean error of -18.18° (95% CI [-26.55°, -9.83°]). There is also a flag indicated as $p<0.001$ between 18-21%. The angular velocity graphs are quite similar, with a mean error of -1.92°/sec (95% CI [-3.16, -0.67]), with two regions indicated as being statistically different. The first region is $p<0.001$ between 3-5% and another is $p<0.001$ between 15-16%.

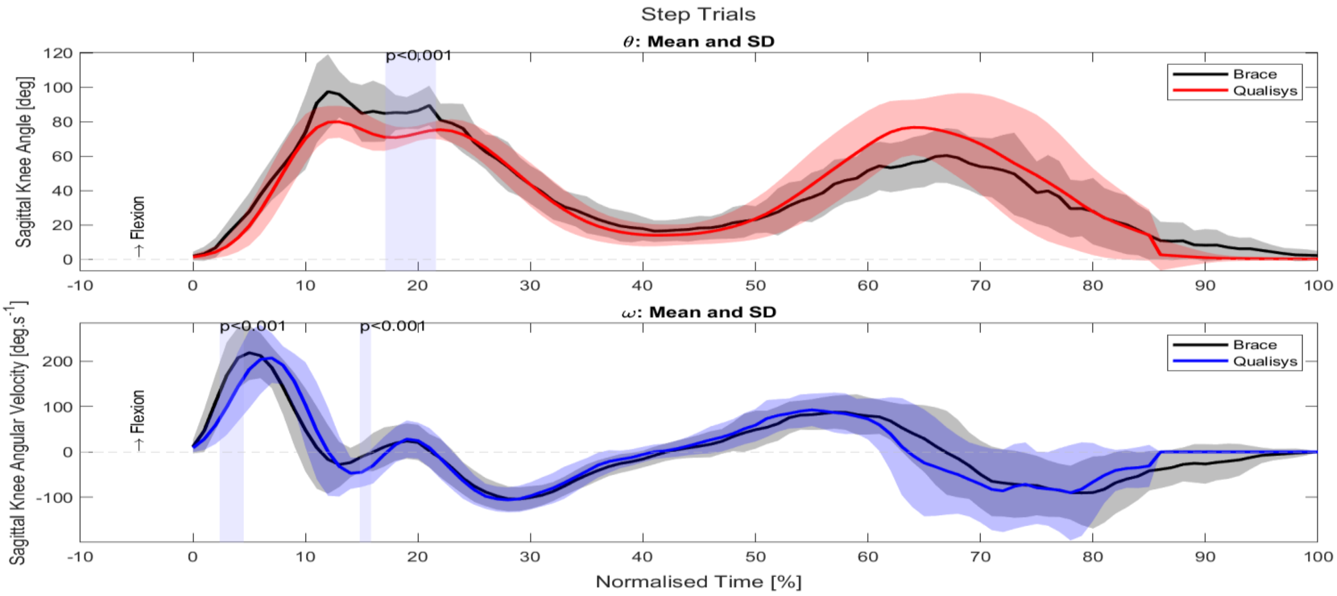


Figure 5-28: Step Trials

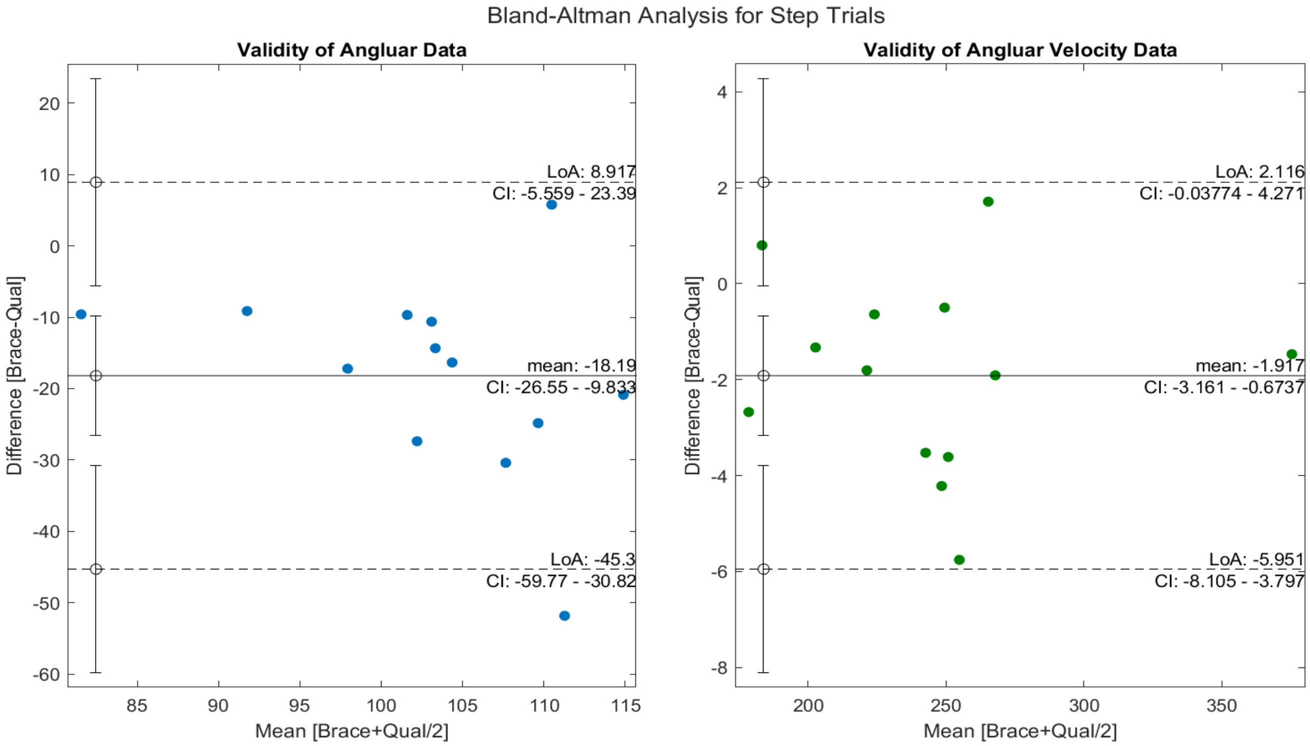


Figure 5-29: Bland-Altman Results for Step Trials

Figure 5-30 and Figure 5-31 display the walking trials, like the slope trial, the walking trial has more steps that are taken. Looking at the knee angle graph, we can see a decrease in the accuracy of the brace as time goes on. We can also see that the most significant differences are again at the beginning and end of the trial, with a mean error of 8.36° (95% CI [2.90°, 13.82°]) for the knee angle and a mean error of -4.53°/sec (95% CI [-9.31, 0.25]) for the knee angular velocity. We can see that flags are indicated on the knee angle graph as p<0.001 between 2-7% and as p<0.031 between 20-21%. There is also a significant difference indicated on the angular velocity graph as p<0.001 between 3-4%.

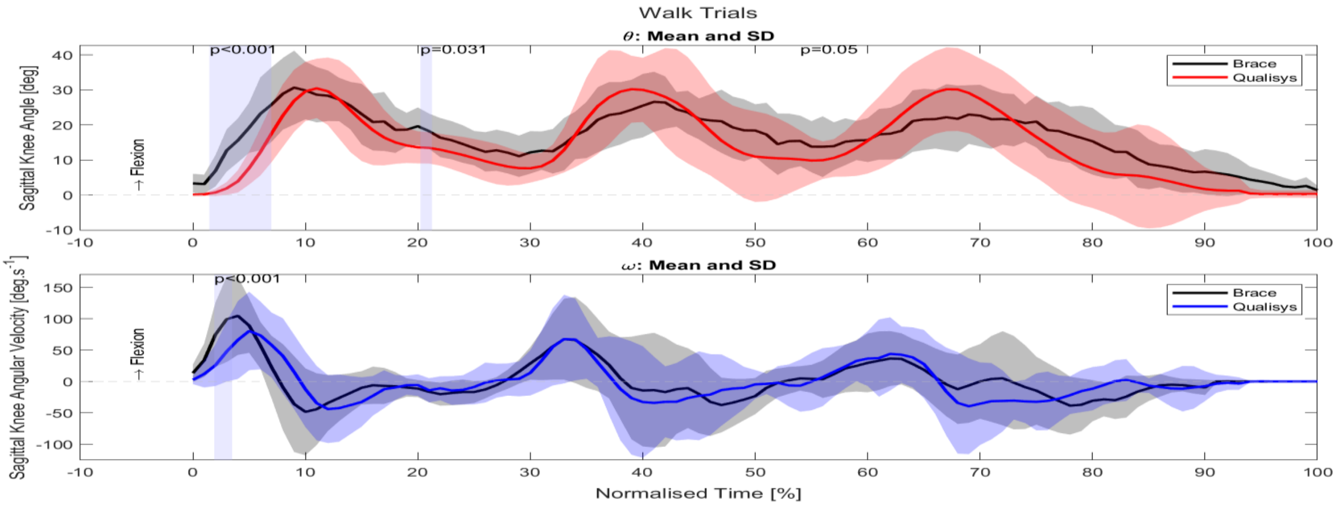


Figure 5-30: Walk Trials

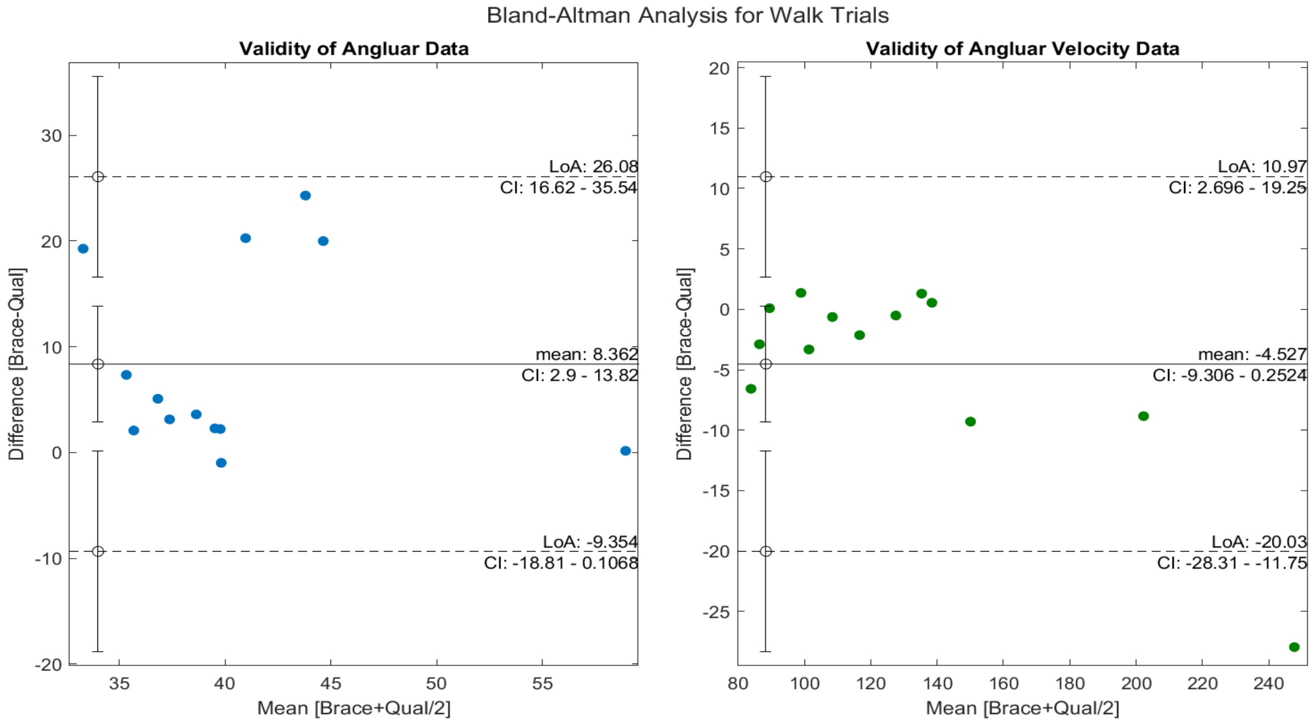


Figure 5-31: Bland-Altman Results for Walk Trials

The validation of the force was completed using three AMTI force plates at a frequency of 2 kHz. The sensor platform (Brace) is indicated as a black line (with standard deviation in grey). The force plate data is indicated as a red line (with standard deviation in light red) on the heel. The force plate data is indicated as a blue line (with standard deviation in light blue) on the forefoot. The validation graphs for the force sensors are displayed in Figure 5-32 and Figure 5-33. We can see that the mean values for the heel force are quite similar with a mean error of -205.60 N (95% CI [-449.50, -38.24]), but the standard deviation from the Brace is significantly larger than that of the force plates. The force on the forefoot, however, is only similar up to 60% of the trial with a mean error of 132.70 N (95% CI [-30.83, 296.20]), with the standard deviation also being significantly larger than that of the force plates. An important caveat within this latter analysis is the lack of statistically significant differences which may largely be attributed to the small sample size rather than the actual lack of differences within the data. Although clear differences are observable in the forefoot data, there is insufficient statistical power to flag these differences as being statistically different.

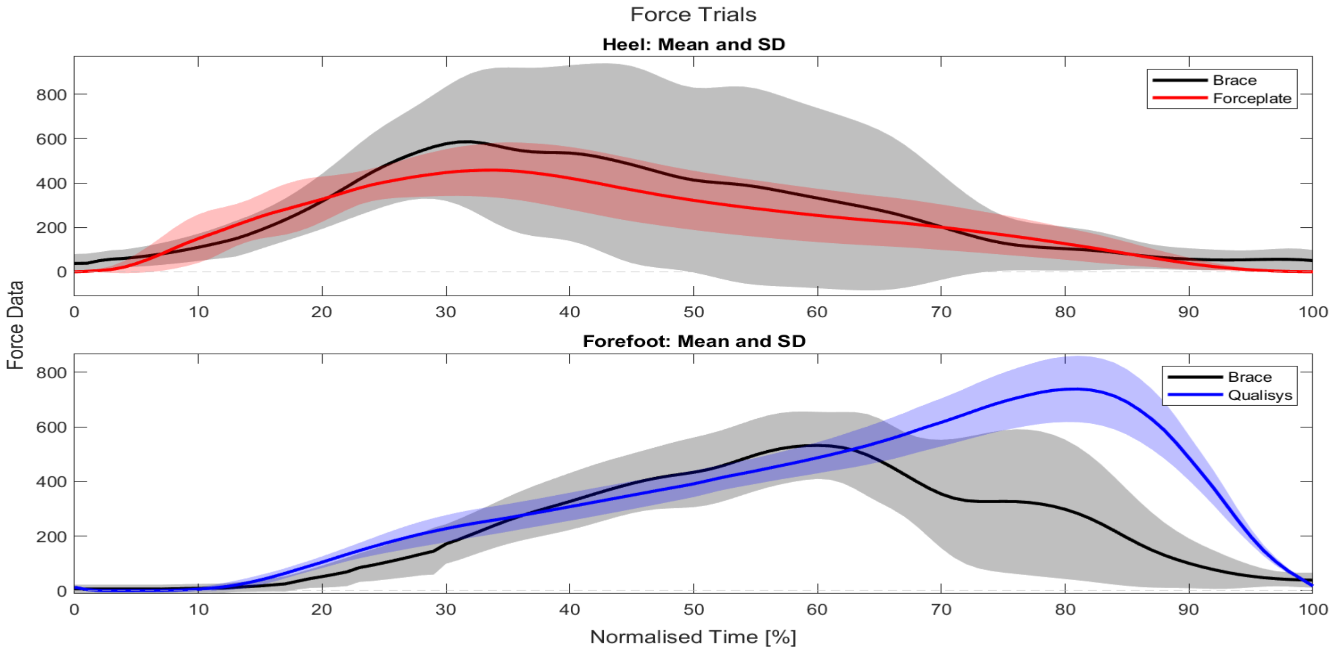


Figure 5-32: Force Trials

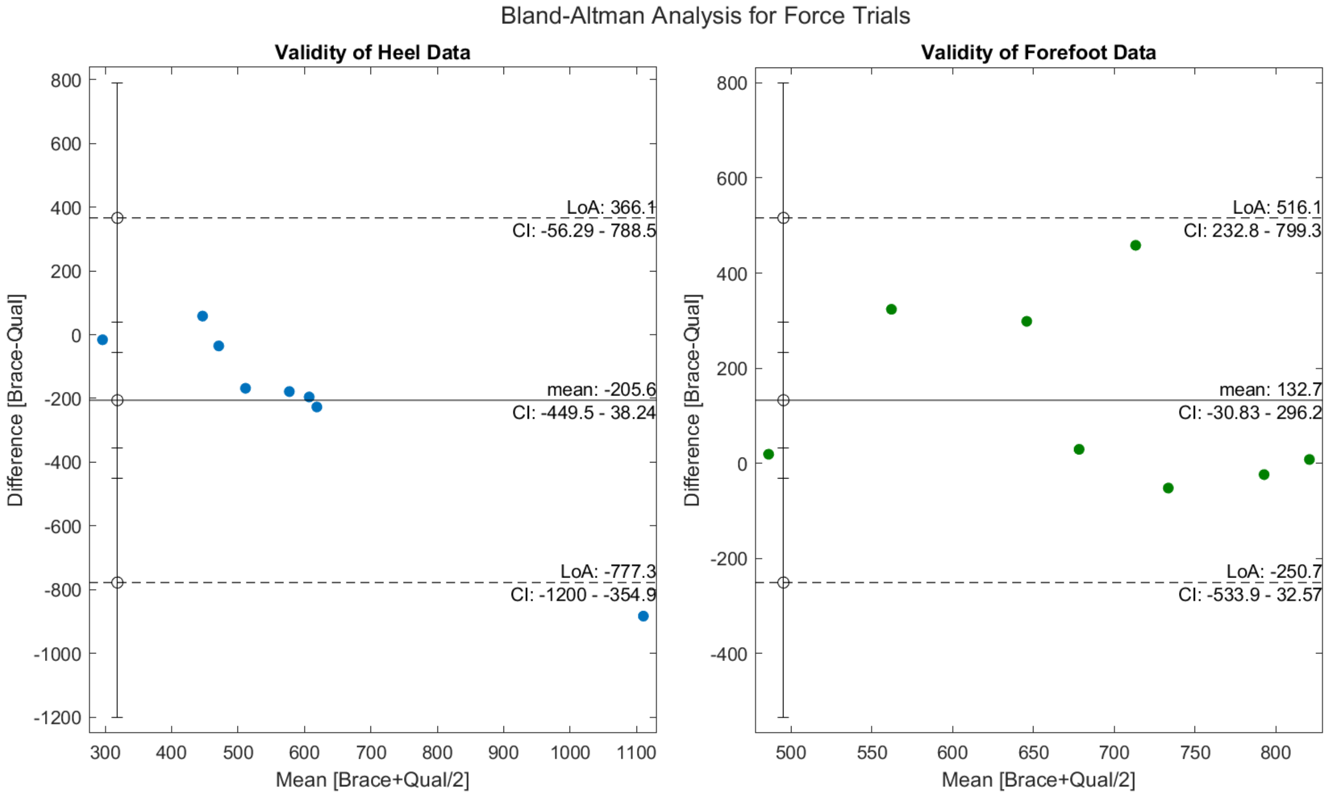


Figure 5-33: Bland-Altman Results for Force Trials

5.7 Discussion

For the most part, the knee angle and knee angular velocity of the Brace and Qualysis system are similar. The most significant differences tend to be at the beginning and end of each trial. It seems that the values derived from the Brace are, on average, higher than those derived from the Qualysis system. Furthermore, the differences tend to vary as a function of time. It is plausible that these differences could be attributed to a scaling issue on the brace (sensor platform). The brace is set to send data to the data-gathering application using Bluetooth at a frequency of 20 Hz. The amount of time it takes to process the data was not taken into consideration, which may increase the sampling period slightly and cause scaling calculations to be slightly off. Another possible reason that the beginning and end of the trials have more significant differences, could be due to sudden start and halt movements. The sudden movement could cause additional oscillation in the accelerometer readings, which could in turn account for a difference in data readings. This is particularly noticeable in tying a shoe trail (Figure 5-22) where the two peaks of the Brace knee angle are higher than that of the Qualysis system.

Another important difference to note is the more significant differences in the knee angle at certain trials, namely, the Activity 4: Ascending and descending a slope trial, Activity 2: Ascending and descending a step trial, and walking trial. For some reason, these trials were less accurate as time increased than the tying a shoe trial and Activity 3: Standing and sitting trial. If we look at the differences in the type of movements made in those trials compared to the two that were accurate, we see that these trails also include movements where the leg is extended behind the body, for example, at terminal contact in the walking trail. It is my opinion that as the leg is extended behind the body, it causes the Brace to slip, in turn causing the distance between the sensor and the joint to decrease. We can see this in Figure 5-26, Figure 5-28, and Figure 5-30, where the decrease in accuracy occurs directly after the leg is extended behind the body. For the slope trial, this happens when descending the slope, for the step trial, this happens when descending the step, and for the walking trial, this happens after terminal contact occurs during the gait cycle.

It is my opinion that the device applies to measuring knee angle and angular velocity for everyday applications. Based on the analysis of the validity of the device, it is clear that the device is not yet ready to be used in clinical applications and requires modifications to increase accuracy. At this stage, the mean differences and limits of agreement are too wide for clinical application. For everyday applications of the device, it is recommended that a reliability analysis should be conducted. Although the device may lack validity at this early stage of development, it may be sufficient reliability to provide feedback on various movement parameters related to activities of daily living.

Finally, the differences in the force data were significant. The force sensors from the brace are not accurate enough, and the standard deviation is too high. The differences could be due to the Velostat properties changing as it is used for multiple trials. The forefoot sensor discrepancies might be attributed to the location of the sensor. The sensor might be placed too far to the back, causing the sensor to read more midfoot force than forefoot force, as evident when considering Figure 2-9, where the force reading is lower at the midfoot area.

5.8 Conclusion

The data generation and method of validation were discussed in this chapter. The results were obtained, analyzed and validated with existing methods of knee function monitoring. The results were discussed, and it was concluded that the knee angle and knee angular velocity data is applicable to use for everyday settings, but is not yet accurate enough for clinical settings.

Chapter 6: Conclusion and Recommendations

6.1 Conclusion

The aim of the research presented is to determine whether a wearable motion analysis device is appropriate to monitor and measure human knee function. The research focuses on the selection and placement of sensors that can provide data when performing knee function on activities of daily living from home, which include Activity 3: Standing and sitting, tying a shoe and ascending and descending slopes and stairs etc.

After a better understanding of knee biomechanics and the types of measurements required to monitor knee function was gained, it was decided that knee joint angle, knee joint angular velocity and ground reaction forces had to be measured. A sensor platform was designed to gather the data on wearable motion analysis. Accelerometers were used to measure the knee joint angle, gyroscopes were used to measure knee joint angular velocity, and a force sensor comprising of Velostat was used to measure ground reaction forces on the heel and forefoot.

There were 15 participants recruited for the study, where only 13 could be used for the knee angle and knee angular velocity data, and eight could be used for the ground reaction force data. Data on knee joint angle, knee joint angular velocity and ground reaction forces were collected while each participant did five iterations of the following activities of daily living:

- Tying a shoe
- Activity 3: Standing and sitting
- Activity 4: Ascending and descending a slope
- Activity 2: Ascending and descending a step
- Walking

The knee joint angle and knee joint angular velocity results were compared to a Qualysis motion capture system for validation. The ground reaction forces were compared to force plates for validation. The results obtained for the knee joint angle and knee joint angular velocity were quite similar to that of the Qualyisis motion capture system and might be valid for everyday motion capture, but based on the analysis of the validity of the sensor platform, it is not yet ready for clinical application in its early stages of development. The ground reaction force data obtained by the brace is significantly different to that of the force plates. Even though the means are similar in some areas throughout the force curves, the deviation of the sensor platforms' force readings is too wide. Figure 6-1 displays the completed sensor platform combined with the reflectors from the Qualysis motion capture system.

Figure 6-1: Sensor Platform (Brace) set up with motion Qualysis motion analysis reflectors

6.2 Recommendations

6.2.1 Acceleration and Angular Velocity

It is recommended to investigate the accuracy of knee joint angle and angular velocity measurements of the sensor platform. The primary source of discrepancy between the sensor platform and validation devices is the slipping of the sensor platform base (brace). To overcome this issue, a mounting device for the sensors that attaches directly to the participant's skin should be designed, eliminating the slipping factor and resulting in more precise sensor readings. Furthermore, the accuracy of the sensors can be improved by incorporating a calibration procedure for each participant. Another approach to improve the accuracy and reliability of the sensors is to minimize the drift caused by temperature deviation. This can be achieved by adjusting the sensor readings based on temperature data to correct for temperature-related errors, either in real-time or in post-processing of the data. These recommendations can contribute to the development of improved sensor technology for more accurate knee joint angle and angular velocity measurements. Another point to note is The Tilt equation used to calculate the angle of the knee. The equation assumes that the device is moving at a constant velocity and not experiencing any acceleration. However, in real-world scenarios, it is highly unlikely that a device will always move at a constant velocity, and some form of acceleration will always be present. An approach that can be used is to use a more advanced algorithm that can take into account the acceleration of the device and compensate for it. For example, a Kalman filter can be used to estimate the tilt angle by combining the measurements from both the accelerometer and gyroscope sensors, taking into account the expected acceleration of the device..

6.2.2 Force Sensors

It is recommended to address the significant deviation observed in the data from force sensors compared to the force plates. A potential solution is to develop a new force sensor for each participant, which would minimize deviations caused by wear on the Velostat material when using the same sensor on multiple trials. In addition, conducting reliability tests for wearable sensors during activities of daily living can provide insights into long-term usage of such sensors in motion analysis. To enhance the reliability and accuracy of force sensors, linearization techniques should be incorporated during the calibration process. These recommendations can lead to improved force sensor technology and contribute to the development of more accurate and reliable motion analysis.

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Appendix A: Informed Consent

Private Bag X1290, Potchefstroom
South Africa 2520
Tel: +2718 299-1111/2222
Fax: +2718 299-4910
Web: http://www.nwu.ac.za

NWU-HREC Stamp

INFORMED CONSENT DOCUMENTATION FOR HUMAN KNEE FUNCTION MEASURING METHOD PARTICIPANT

TITLE OF THE RESEARCH STUDY: Development of an electronic platform to quantify knee function

ETHICS REFERENCE NUMBERS:

PRINCIPAL INVESTIGATOR: Prof. MJ Grobler

POST GRADUATE STUDENT: IJ Thomson

ADDRESS:Office 204, Building N1, NWU Engineering Campus 18 Calderbank Ave, Potchefstroom, 2520

CONTACT NUMBER: 082 878 5894

You are being invited to take part in a **research study** that forms part of a Master's study. Please take some time to read the information presented here, which will explain the details of this study. Please ask the researcher or person explaining the research to you any questions about any part of this study that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research is about and how you might be involved. Also, your participation is **entirely voluntary** and you are free to say no to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part now.

This study has been approved by the NWU-Health Research Ethics Committee of the Faculty of Health Sciences of the North-West University (**NWU-00334-21-S1**) and will be conducted according to the ethical guidelines and principles of Ethics in Health Research: Principles, Processes and Structures (DoH, 2015) and other international ethical guidelines applicable to this study. It might be necessary for the research ethics committee members or other relevant people to inspect the research records.

What is this research study all about?

- *We plan to measure knee function while doing everyday activities with the use of sensors attached to the leg. The study will determine if using sensors to measure knee function is a valid cost-effective method compared to more expensive methods like optical motion tracking cameras and force plate sensors. This will allow more clinics to make use of knee monitoring devices around the world.*
- *This study will be conducted* at the PhASRec facilities *and will be done by experienced health researchers trained in engineering and biokinetics. 15 participants will be included in this study.*

Why have you been invited to participate?

- To be included in the present study the following criteria have to be met:
  - Male or female between the ages of 18 and 45.
    - Only activities of daily living shall be measured (e.g. walking, stair climbing etc).
  - Must be free of any injuries or recent surgery (< 6 months) that might impair gait or activities of daily living.
  - Must live within the Potchefstroom area.

- Must be competent in English language (e.g. reading and writing).
- Must weigh less than 150 kg.
  - The load cell that shall be used can measure a maximum of 200kg, but is more accurate when measuring below the threshold.

- *You have been invited to be part of this research because you meet all relevant inclusion criteria, and are asked to please assist in the evaluation of our cost-effective knee function monitoring device by allowing us to use your data (after it has been completely anonymised).*
- *You will unfortunately not be able to take part in this research if you are:*
  - Suffering from diseases and/or disorders that impair gait or activities of daily living (e.g. osteoarthritis, rickets etc.).

What will be expected of you?

- *Data collection will take place at the PhASRec facilities on NWU Potchefstroom Campus. The data collection processes will last for approximately 90 minutes. You will be expected to complete 4-5 trials across nine activities of daily living, which include knee extension, walking, ascending 5 stairs, descending 5 stairs, walking up a slope, walking down a slope, sitting and standing, tying a shoe, and lifting an object. All these activities will be completed while wearing a knee function monitoring device on your right leg as well as being fitted with reflective markers that will track your motion across all tasks. Please note that none of the movement tracking is invasive; all markers are externally fitted onto your clothes and/or skin using double-sided taping, and the brace will be fitted around the knee using Velcro strapping.*

Will you gain anything from taking part in this research?

- *Direct gains from this study will include a functional report that will provide an overview of kinetic and kinematic data related to activities of daily living.*
- *The other gains of the study relate to the development of an affordable and easy to use knee monitoring system may add to rehabilitation monitoring and further studies concerning leg movement.*

Are there risks involved in you taking part in this research and what will be done to prevent them?

Please note that all precautions have been taken to minimise any potential risks of injury to you and/or the research staff. All testing will be facilitated by a qualified Engineer and Biokineticist to ensure maximum participant safety throughout the data collection processes.

- *Possible Covid-19 infection*
  The risk of Covid-19 infection would not exceed that of going to a shop/mall. All precautions have been taken to mitigate any potential risk of exposure by ensuring that (i) all equipment is adequately sanitised prior to use, (ii) researchers will wear a face mask, sanitise hands,

and wear neoprene gloves, and (iii) participants will be required to wear a face mask and sanitise their hands on entry to the testing venue.. Thus all Covid-19 regulations shall be followed at all times during the study.

- *Ascending and descending stairs*
  Measurements are required while you, as the participant, ascend and descend stairs as you would in every day life. The activity shall be done in the presence of a qualified biokineticist, and the stairs shall conform to all safety regulations (e.g. railings will be present to prevent a risk of falling, and step heights will not exceed 20cm).
- *Ascending and descending slopes*
  Measurements are required while participants ascend and descend a sloped surface (<20°). The activity shall be done in the presence of a qualified biokineticist, and the slope shall meet all safety regulations to prevent any potential for falling (e.g. anti-slip surfacing will be used).

How will we protect your confidentiality and who will see your findings?

Anonymity of your findings will be protected by only working with one participant at a time and any identifying information will be coded such that no one except the primary researcher and study supervisor shall know your identity or that you are taking part in the study. Your privacy will be respected by not forcing you to reveal any information you do not want to reveal. Your results will be kept confidential by keeping all findings in password protected files and USB drives. Only the researchers and study supervisors will be able to look at your findings. Findings will be kept safe by locking hard copies in locked cupboards in the researcher's office and for electronic data it will be password protected. All hard copies of the data, including the completed questionnaires, will be scanned electronically and kept safe and secure by storing electronic copies of the data on a desktop computer and a password-protected external hard drive in the study/project leader's office at the North-West University (NWU), Potchefstroom Campus, for 20 years where-after it will be destroyed.

Furthermore, the data will be backed up on RedCap, a cloud-based system, at the North-West University. This will ensure the participants' right to privacy, anonymity, and confidentiality. All hard copies of the data will only be kept for a period of 7 years after which they will be destroyed, and only the electronic copies will be retained for future analyses.

The data will be retained for a period of 20 years to allow for longitudinal comparisons of the data collected (e.g., cybex, force plate, motion data). Since participant characteristics are important in classifying the other data collected, the demographic and anthropometric data will also need to be retained.

What will happen with the findings or samples?

- *The findings of this study will only be used to evaluate the effectiveness of an electronic knee brace for measuring knee motion during activities of daily living. Any personal identifying information obtained during data collection will be coded such that your anonymity will be* *retained. The results of the study will be published in a peer-reviewed journal such that the findings can be made public to facilitate further research and aid practitioners involved with evaluating knee function. No personal information will be made public and will not be made available to anyone outside of the study; therefore your privacy, anonymity, and confidentiality will be retained at all times.*

How will you know about the results of this research?

- *We will provide you with your own results as well as the results of this research when the study has been completed by emailing the completed study to you.*
- *You will also be informed of any new relevant findings by email.*

Will you be paid to take part in this study and are there any costs for you?

You shall be reimbursed using the time-inconvenience-expenses principle by providing you with refreshments during data collection.

Is there anything else that you should know or do?

- *If you have any questions and/or queries, you can contact Mr Ian Thomson at ianjt1995@gmail.com if you have any further questions or have any problems.*
- *You can also contact the NWU-Health Research Ethics Committee via Mrs Carolien van Zyl at 018 299 1206 or carolien.vanzyl@nwu.ac.za if you have any concerns that were not answered about the research or if you have complaints about the research.*
- *You will receive a copy of this information and consent form for your own purposes.*

Declaration by participant

By signing below, I ……………………………….…………. agree to take part in the research study titled: Development of an electronic platform to quantify knee function

I declare that:

- I have read this information/it was explained to me by a trusted person in a language with which I am fluent and comfortable.
- The research was clearly explained to me.

- I have had a chance to ask questions to both the person getting the consent from me, as well as the researcher and all my questions have been answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be handled in a negative way if I do so.
- I may be asked to leave the study before it has finished, if the researcher feels it is in the best interest, or if I do not follow the study plan, as agreed to.

Signed at (*place*) ....…......……………... on (*date*) …………....……….. 20....

....

Signature of participant **Signature of witness**

Declaration by person obtaining consent

I *(name)* ……………………………………………..……… declare that:

- I clearly and in detail explained the information in this document to

  ……………………………………………………

- I did/did not use an interpreter.
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I gave him/her time to discuss it with others if he/she wished to do so.

Signed at (*place*) ....…......……………... on (*date*) …………....……….. 20....

....

Signature of person obtaining consent

Declaration by researcher

I *(name)* …………………………………………….……… declare that:

- I explained the information in this document to ensure that everything is understood by the participant.
- I did not use an interpreter
- I encouraged him/her to ask questions and took adequate time to answer them.
- The informed consent was obtained by an independent person.
- I am satisfied that he/she adequately understands all aspects of the research, as described above.
- I am satisfied that he/she had time to discuss it with others if he/she wished to do so.

Signed at (*place*) ....…........…………….. on (*date*) …………..……….. 20....

....

Signature of researcher

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7 February 2019

➢ **File reference: 9.1.5.6NWU-00334-2**

Appendix B: Data Management Plan Overview

Title: Development of an electronic platform to quantify human knee function
Creator: Ian Thomson
Affiliation: North-West University (nwu.ac.za)

Executive summary

Current human knee function monitoring methods are costly and require substantial expertise, thereby limiting their applicability for daily or even weekly implementation. In order to understand the quantitative value of exercise protocols, an alternative constant measurement method is needed. A wearable device housing appropriate sensors (sensor platform) capable of capturing real-time movement data could be the answer. Important data required when monitoring the leg for knee function would include initial contact of the gait, gait cycle duration and frequency, terminal contact of the gate, knee load, knee joint angle and leg sway. This experimental data shall be captured while doing activities of daily living like knee extension, walking, ascending stairs, descending stairs, ascending slope, descending slope, standing and sitting, tying a shoe and lifting an object. The data shall be sent to a user interface, where it is analysed with the use of graphs. The reliability and validity of the sensor-derived measurements will be assessed by comparison to criterion methods such as 3D Motion Analysis and force plate technologies.

Start date: 02-01-2022
End date: 11-30-2023
Last modified: 09-08-2021

PROJECT: DEVELOPMENT OF AN ELECTRONIC PLATFORM TO QUANTIFY HUMAN KNEE FUNCTION

DATA COLLECTION

What data will you collect or create?

The details related to the data stage, data description, data type and data format for the present study are highlighted in Table 1.

Table 1: Data collection

Data Stage	Dataset Description	Type of Data	Format
Raw Data	IMU	Numerical	.csv; .xlsx
	Force Sensors	Numerical	.csv; .xlsx
Processed Data	Data spreadsheet	SPSS files	.sav
		CSV files	.csv
		Excel Files	.xlsx
Analysed Data		JASP; Jamovi; R	.jasp; .omv
		SPSS; Statistica	.sav
		Matlab	.mat
Other	Poster presentation	PowerPoint	.ppt
	Project website	HTML	.htm

DOCUMENTATION AND METADATA

What documentation and metadata will accompany the data?

There are several documents that will accompany the data:

1. Executive summary of the research study (e.g., study design, data collection methods, sampling methods, inclusion/exclusion criteria, ethics, statistical procedures)
2. Details of the researchers
3. Raw data stored in an online repository (with link to access the data)
4. Statistical procedures used for each of the research objectives (where possible the actual code will be provided e.g., JASP and/or Jamovi files)

How will you manage copyright and Intellectual Property Rights (IP/IPR) issues?

The data and intellectual property rights (IR/IPR) will be owned by the Physical Activity, Sport, and Recreation (PhASRec) Research Focus Area and the North-West University (NWU).

For instances where data will be shared across different universities (i.e., multi-partner project), a consortium agreement will be created whereby the anonymised data can be shared between universities. Data sharing will be restricted only to those directly involved in the project; the details of which may be adjusted by the PI who collected the data.

STORAGE AND BACKUP

How will the data be stored and backed up during the research?

All hard copies will be stored in a locked cabinet at PhASRec. An electronic copy of the hard copies will be made to allow for electronic backups to be performed. All other data will be captured and stored electronically on RedCap which is a cloud-based system.

Data will be backed up bi-monthly by both the PI and the Data Manager (e.g., Dr. Mark Kramer) at PhASRec. Since RedCap is a university-wide database and cloud-based management system, storage of data on RedCap occurs automatically and daily. Therefore, data retrieval can occur at any stage.

How will you manage access and security?

Only the PI and the Data Manager will have access to the anonimised data, with only the PI knowing the original participant codes. Furthermore, only the PI will have the password for direct access to the data. All datasets will be password protected to ensure that access is limited only to those with the password.

All data will be saved and backed up on RedCap, which is a University-wide cloud-based data management system. All data is behind a highly secure firewall thus ensuring that no other entities could access the data.

All hardcopies will be kept in a secure filing cabinet in the PI's office, and only the PI will have access to the secured cabinet. Electronic copies of the documents will be made which will be uploaded to the PI's RedCap account for digital security and backup.

SELECTION AND PRESERVATION

Which data are of long-term value and should be retained, shared, and/or preserved?

All hard copies of the data, including the completed questionnaires, will be scanned electronically and kept safe and secure by storing electronic copies of the data on a desktop computer and a password-protected external hard drive in the study/project leader’s office at the North-West University (NWU), Potchefstroom Campus, for 20 years where-after it will be destroyed.

Furthermore, the data will be backed up on RedCap, a cloud-based system, at the North-West University. This will ensure the participants’ right to privacy, anonymity, and confidentiality. All hard copies of the data will only be kept for a period of 7 years after which they will be destroyed, and only the electronic copies will be retained for future analyses.

The data will be retained for a period of 20 years to allow for longitudinal comparisons of the data collected (e.g., cybex, force plate, motion data). Since participant characteristics are important in classifying the other data collected, the demographic and anthropometric data will also need to be retained.

To allow for longitudinal comparisons, the formatting of the data (i.e., which parameters, parameter calculations, data storage format [e.g. .csv file] will be clearly stipulated in the methodology section). This will ensure that data are collected in the same manner by all researchers involved in similar projects.

What is the long-term preservation plan for the dataset?

Each project should have 3 datasets, (i) raw, unprocessed data, (ii) cleaned and processed data, and (iii) analysed data. This will ensure that future researchers can access the original datasets and re-run analyses where necessary.

All data will be back-up as follows:

1. Hard copies: stored in a filing cabinet to which only the PI has controlled access
2. RedCap: copies of all datafiles (electronic copies of the hard copies, .csv files etc).

Both the data manager and the PI will have access to the RedCap database such that data can be access only by these individuals. Each project will have its own folder within the RedCap system, which is password protected, and only the data manager and PI will know the password for the relevant project folder. The data manager therefore acts as the gatekeeper for all projects thereby ensuring that only the PI for a specific project has access to their own datasets and not those of other projects.

The RedCap database system is a university-wide system and therefore imposes no additional costs to researchers.

DATA SHARING

How will you share the data?

Data sharing will be at the prerogative of the PI, and depending on the agreement, the data manager as well. It is imperative that a consortium agreement be set up between institutions to ensure clarity in terms of what data may be accessed and shared between institutions. Based on the agreement, a request may be filed with the data manager and PI, with clear stipulations as to what data is required and in what format it should be.

Data will only be made available on request and would need to be driven by the PI. If the PI is no longer available, the request would need to be filed through the data manager as per the original consortium agreement.

Data associated with a publication should be made freely available via a public data repository (e.g., Harvard Dataverse). Data stored on such a repository must be anonymised. Keeping a dataset that is associated with a publication on an accessible data repository will ensure openness and transparency and will allow for data replication where necessary. Such datasets will be accompanied by a persistent identifier (e.g., DOI). Such data may be re-used but only with the permission of the PI and/or data manager, depending on the original agreement of the associated project.

Are any restrictions on data sharing required?

A memorandum of understanding (MoU) between the PI and data manager will be created that clearly outlines data sharing policies and restrictions. For the current project, the dataset will be exclusive to the PI under the following conditions:

1. The duration of the study of the PI, after which the dataset will belong to PhASRec subject to a non-disclosure agreement to provide protection for confidential data.
2. The duration of employment of the PI, after which the dataset will belong to PhASRec. Should publications emanate from the dataset, the original PI should be approached for co-authorship. A non-disclosure agreement will be followed to ensure sufficient protection for confidential data.
3. Unless otherwise stated, the dataset associated with a project will be exlusive to that project and associated researchers for a period of 3 years, after which the dataset will belong to PhASRec subject to a non-disclosure agreement between the PI and PhASRec.

RESPONSIBILITIES AND RESOURCES

Who will be responsible for data management?

At the departmental scale, the responsible person for the over-arching data management plan (DMP) is Dr Mark Kramer. At the project level, the responsible person for the DMP is the PI. The PI should liaise with the departmental DMP to ensure that data is sufficiently backed up on a regular basis (e.g., bi-monthly).

In the case of inter- and intra-institutional research, it is imperative that a DMP coordinator be established at the inter- or intra-institutional level to ensure that all data management policies can be standardised and adhered to. It will be the role of the PI to ensure that a suitable DMP coordinator is established, and the details thereof should be clearly stipulated in the project proposal.

The project PI should ensure that data is accurately and appropriately captured, ensure data quality, storage and backup as well as data archiving. These datasets should then be sent in electronic format to the departmental DMP coordinator who would have ensured that the project PI will have access to the password-protected RedCap system so that all data associated with the project can be electronically archived.

What resources will you require to deliver your plan?

At the project level it will be the responsibility of the project PI to ensure that data can be adequately backed up (e.g., hard drive space). However, at the departmental level, all data will be archived on RedCap which imposes to costs to the PI. It is imperative that data associated with a project is regularly backed up in electronic format (e.g., bi-monthly) to minimise any risk of loss or data corruption.