2023

Development of a Portable Device for Quantifying Internal-External Rotational Laxity of the Knee in Vivo

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DEVELOPMENT OF A PORTABLE DEVICE FOR QUANTIFYING INTERNAL-EXTERNAL ROTATIONAL LAXITY OF THE KNEE IN VIVO

A Thesis Presented

by

Haley Kuralt

to

The Faculty of the Graduate College

of

The University of Vermont

In Partial Fulfillment of the Requirements
for the Degree of Master of Science
Specializing in Biomedical Engineering

August, 2023

Defense Date: July 21, 2023
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ABSTRACT

Osteoarthritis (OA) is the leading cause of mobility-related disability. Post-traumatic osteoarthritis (PTOA) is a form of OA that occurs after an acute injury to the affected joint. In the case of the knee, rupture of the anterior cruciate ligament (ACL) is the most common acute injury. ACL injury occurs in sports that involve cutting and pivoting motions, such as soccer, football, and skiing. Many patients opt to undergo ACL reconstructive surgery (ACLR) so that they may return to their sport with restored knee stability and function. Unfortunately, ACLR does not completely restore the knee to its original state, resulting in altered joint mechanics and abnormal loading on the articular cartilage of the tibia and femur. As a result, the majority of patients develop radiographic signs of PTOA within 10 years of their original injury. An important risk factor for knee PTOA is increased joint laxity, or how much the joint moves given an applied force or torque. While standardized devices exist that measure anterior-posterior (i.e., forward-back) laxity in the knee, no such standardized device exists to measure internal-external rotational laxity in the knee. The purpose of this project was to develop a new, portable, user-friendly device to accurately and reliably measure rotational laxity in the knee.

We developed a device that measures rotation of the knee joint in response to an applied torque along the axis of the tibia. Measurements from inertial measurement units (IMUs) and a torque sensor were combined to quantify rotational laxity of the knee joint, which were defined based on analysis of the resulting torque-rotation curve. Two Arduino IMU sensors were placed on the anterior tibia and lateral femoral epicondyle along the axes of the tibia and femur, respectively, to measure the internal-external rotation of the knee. A custom Python script found the sensor-to-sensor relative orientation, from which internal-external rotation of the joint was calculated. To verify the accuracy of the joint angle measurement, a custom test jig was built with known angle measurements marked on a rotating flange. After verifying the validity of the rotational measurement, the device was tested on a healthy individual with no history of knee joint injury. Multiple tests were performed to measure test-retest reliability. Determining the accuracy and reliably of the internal-external rotational laxity device presented in this thesis is a critical step prior to employing in population-based studies. Future studies will compare side-to-side variability of laxity measurements in healthy individuals, followed by a study comparing laxity measurements in ACLR patients' injured knee to their contralateral one. This device will allow researchers and physicians to better understand altered joint mechanics after ACL injury and/or reconstruction, resulting in a better understanding of mechanisms that lead to knee PTOA and ultimately reducing its incidence.

ACKNOWLEDGEMENTS

I would like to acknowledge continuous support from my thesis advisor, Dr. Niccolo Fiorentino, whose input and guidance played a significant role in the success of this project. I would also like to acknowledge the members of my thesis committee, whose valuable feedback pushed me to greatly improve upon the outcome of this project. Additionally, I acknowledge the support from Dr. James Kay, whose expertise in electrical engineering provided me with a more thorough understanding of the pieces of this project that I had little to no background in. I also acknowledge the support from the members of my lab who assisted me through each stage of the project, from planning to collecting data. Finally, I want to thank my family and friends for providing emotional support throughout this long and difficult process and for listening to me talk about it non-stop from beginning to end.

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CHAPTER 1: INTRODUCTION

1.1. ACL Injury and Post-Traumatic Osteoarthritis

Anterior Cruciate Ligament (ACL) injuries are an increasingly common type of knee injury in the United States. The population most affected by ACL ruptures are adolescent athletes who play high-risk competitive sports such as soccer, football, and skiing, due to the involvement of cutting and pivoting motions which put the athletes at high risk of ligamentous knee injury. It is estimated that up to 250,000 ACL injuries occur annually, with the majority of cases occurring in patients under the age of 30 (Carbone & Rodeo, 2017). Most patients who tear their ACL opt to undergo ACL reconstruction (ACL-R) surgery to replace the damaged ligament. ACL-R surgery involves the replacement of the damaged ACL with a graft either from a tendon in the patient's body, known as an autograft, or from a tendon or ligament in a cadaver, called an allograft. Independent of where it comes from, a graft never behaves mechanically the same as a native ACL, introducing altered joint mechanics to the knee.

It is well known that the ACL plays a primary role in stabilizing the knee in the anterior-posterior direction, but the ligament also plays an important secondary role in internal-external rotational stability of the joint (Wiggins et al., 2016). Injury and reconstruction of the ACL introduces altered joint mechanics to the knee, causing abnormal, increased loading on the articular cartilage of the tibia and femur. One of the main factors that causes this abnormal loading on the knee is increased laxity of the ACL. The increase in laxity of the knee is apparent in both the anterior-posterior and internal-external rotational directions.

Decreased stability in the knee is one of the greatest risk factors for the development of post-traumatic osteoarthritis (PTOA) (Dare & Rodeo, 2014). Osteoarthritis is a debilitating disease which effects about half of the world's adult population, making it the most common form of arthritis, and the leading cause of mobility-related disability (Thomas et al., 2017; Wang et al., 2020). Osteoarthritis is characterized by the degradation of articular cartilage of a joint, causing pain, stiffness, and inflammation. PTOA is a form of osteoarthritis that results after a traumatic joint injury. As 25% of all traumatic knee injuries involve the ACL, these injuries are one of the most prominent risk factors for the development of PTOA in the knee. Progression of PTOA is often faster and more severe than idiopathic OA because patients suffering from PTOA tend to be more active and often return to playing sports after their primary injury. While the development of PTOA is not very well understood, it is thought to be caused by a combination of biological, mechanical, and structural changes that occur after joint injury with patients presenting signs of PTOA in as little as 10 years after the primary injury. Because ACL injury and the resulting increase in joint laxity are some of the most prominent risk factors for the development of PTOA, it is crucial that we are able to measure the knee's laxity to improve our understanding of the disease and how it arises.

Early detection of PTOA is crucial because the onset of the disease is irreversible. Because of cartilage's avascular nature, the tissue has no way to regenerate or heal after the damage has occurred. Therefore, the only way to prevent severe progression of PTOA is to detect it before too much damage has occurred and perform corrective measures. In the later stages of the disease, total knee arthroplasty (TKA) may be the only way to treat the pain and inflammation of the joint.

1.2. Knee Laxity Measurement

So far, no method has been established to detect PTOA in its early stages. With increased joint laxity being one of the main risk factors for PTOA, measurement of this parameter may be the key to early detection of this disease following ACL injury and replacement. The current clinical gold standard for assessing ACL laxity is a series of diagnostic examinations performed by a physical therapist. Although the Lachman test, anterior drawer test, and pivot-shift test are used to assess knee mechanics in a clinical setting, they do not produce any quantitative measurements, and rely heavily on the experience of the physical therapist performing the tests.

Additionally, laxity measurements may be used to inform orthopedic surgeons about the efficacy of their methods for reconstructing the ACL. Studies have shown that ACL reconstruction with anterolateral ligament (ALL) augmentation may improve the rotational stability of the joint, resulting in decreased laxity compared to if the ALL had not been surgically augmented (Abdelrazek et al., 2019; Ferguson et al., 2020). Measuring rotational laxity of the knee may be useful in selecting which patients could be good candidates for ALL augmentation prior to ACL reconstruction surgery. To accomplish this, a device that could quantitatively measure rotational laxity of the knee would be necessary.

CHAPTER 2: PRIOR WORK

The literature was reviewed before beginning work on this device, and prior work in the field of knee laxity measurements was considered in the design of the device described herein. Literature papers will be summarized and reviewed below, followed by a description of the prior work on the rotational laxity device at UVM, which was further developed in this master's thesis project.

2.1 A non-invasive biomechanical device to quantify knee rotational laxity: Verification of the device in human cadaveric specimens (Lee et al., 2019)

2.1.1 Article Summary

Lee et al. developed a knee rotational laxity meter which they tested on human cadaveric specimens. Their device consisted of an ankle orthosis, a torque sensor with a handlebar, and one motion sensor at the bottom of the device. An examiner manually applies a torque to the handlebar which is measured by a torque sensor mounted at the bottom of the orthosis. The resulting rotation is measured with a single electromagnetic motion sensor which was attached to the other side of the torque sensor. The torque sensor and electromagnetic motion sensor were located along the axis of rotation of the tibia so that the measurement was based on the rotation of the tibia.

For each of the cadaveric specimens, the femur was sawed at 15 cm above the joint line and clamped on an autopsy table via two 30 cm long bone pins which were drilled into the femur from the medial to lateral side. To validate the rotational measurement, an intra-operative navigation system was employed. Trackers for the navigation system were mounted on 4.5 mm bone pins drilled into the distal femur and proximal tibia.

Two individual examiners were included in the experiment to calculate inter-rater variability. The cadaver leg was secured at 30° of knee flexion, and each test began at a neutral position with no applied torque. Each tester applied an external torque of 10 Nm followed by an internal torque of 10 Nm for a total of 3 trials per tester.

The results from this study showed an increase in variation between the proposed meter and the gold standard as torque values increased. At 10 Nm of torque, the rotation values measured by the knee rotational laxity meter were about 8° higher than that of the gold standard navigational system. Statistical analysis showed that the system has 'good' correlation to the gold standard with an ICC of 0.78, and inter-rater reliability was excellent with an ICC of 0.99. Overall, this device did a moderately good job at measuring rotational laxity with the best-case scenario but would not work for testing on human subjects.

2.1.2 Study Limitations

While this study had relatively good results, it did not replicate the procedure for real patient testing. This study was done on the absolute best-case scenario, using invasive techniques like bone pins and clamps to measure the torque-rotation response of the knee. The biggest limitation I see for this device is the use of only a single motion sensor to measure rotation of the joint. In a clinical scenario, it won't be possible to clamp the femur in place, therefor some motion of the femur is expected to occur when applying a torque to the tibia. This would mean that the motion sensor is not only measuring the rotation of the knee, but also some of the rotation about the hip as it travels up the femur. However, even with the femur secured in place, the results from this study showed a variation of 8 degrees from the gold standard, which suggests that the measurement is not accurate enough to use in a clinical setting.

2.2 Development of a simple device for measurement of rotational knee laxity (Musahl et al., 2007)

2.2.1 Article Summary

Musahl et al. developed a custom device to measure rotational laxity of the knee which they used to perform a reliability study using human cadaver knees. This device was made up of an Aircast Foam WalkerTM boot, a universal force moment sensor (UFS) to measure applied torques, a handlebar mounted to the sole of the boot and through the UFS, a bubble level to standardize a neutral starting position, and a magnetic tracking system with two electromagnetic sensors. The Aircast boot allowed the team to inflate the individual air cells to 40 mmHg so that the leg and ankle were held secure. A custom Matlab program was developed to record and display the forces and torques during testing, and the position and orientation data from the electromagnetic sensors was output to the computer through a RS232 interface. In the study, 4 fresh frozen cadaveric legs were used which had no history of severe arthritis, fractures, malalignment, or ligamentous laxity. The femur of each specimen was cut and fixed in a custom jig which allowed the researchers to adjust the knee's flexion angle of the knee to 0°, 30°, 60°, and 90°.

For this study, the researchers decided to rigidly fix the electromagnetic sensors to the femur and tibia using bone pins to minimize soft tissue artifact. Two individual testers held the leg at a neutral starting position, then applied 6 Nm of torque in the external direction, then 6 Nm of torque in the internal direction. Each trial was repeated 5 times for each flexion angle. The analysis of the results included means and standard deviations of internal and external rotation angles, intra-class correlation coefficients (ICC), and standard error of measurement (SEM).

Intra-testers ICC values were high (0.94-0.99), proving the measurements from the device are reliable when the same examiner is performing the test. SEM values were low (0.01°-0.94°) which was deemed a negligible amount of error for the results to be clinically relevant. Inter-tester ICC values were also high, ranging from 0.95-0.99, proving that the inter-tester results are also reliable.

2.2.2 Study Limitations

While this study yielded excellent results, there were many limitations which prevent the device from being usable in a clinical setting as it is set up now. First, the use of bone pins to mount the electromagnetic motion sensors and clamp the femur in place are invasive practices which would not be practical in in vivo clinical testing. Another study would need to be done which attached the sensors without the use of bone pins, possibly yielding different results. Another limitation of this study is the use of electromagnetic sensors for measuring the knee's internal-external rotation. Nearby metal and electronic devices may cause artifacts in the sensor data which would impair the reliability of the results.

2.3 Measurement of Varus–Valgus and Internal–External Rotational Knee Laxities In Vivo—Part I: Assessment of Measurement Reliability and Bilateral Asymmetry (Shultz et al., 2007)

2.3.1 Article Summary

Shultz et al. developed a device named the Vermont Knee Laxity Device (VKLD) to measure varus-valgus and internal-external rotational laxities of the knee in vivo. The complex device is made up of several components including an exam table for the subjects to lay on, a padded Plexiglas clamp to secure the thigh in place while torque is applied to the knee, a foot cradle to hold the foot, a torque transducer with a handle to measure applied VR-VL and INT-EXT torques, and an ankle brace to prevent unwanted motion of the foot relative to the tibia. Counterweights were used to simulate non-weight bearing and weight bearing conditions on the knee during experiments. To measure knee rotation angles, two electromagnetic sensors were placed on the subjects' lateral thigh proximal to the thigh clamp, and on the tibial shaft. Study participants consisted of 20 college students (10 female, 10 male) ages 18 to 30, who had no history of knee ligament injury or surgery and had no lower extremity injury or chronic pain within the as 6 months.

In order to verify the consistence of the laxity measurements, 10 subjects (5 female, 5 male) were tested a second time 24 to 48 hours later. The testing setup involved the participant laying in a supine position with their foot strapped into the foot cradle, and their thigh secured in the thigh clamp. The VKLD was adjusted so that its mechanical axes lined up with that of the participant with their knee flexed at 20°. The counterweights were adjusted to offset the effect of gravity on the lower limb, allowing for non-weightbearing measurements. The device was constructed of materials that would minimize the effect on the electromagnetic sensors used to measure knee rotation. Segmental coordinate systems were obtained by digitizing the locations of the hip, knee, and ankle joint centers prior to laxity measurements. For the purpose of this thesis, only the INT-EXT laxity measurements will be discussed. Once the neutral limb position was defined with the knee at 20° of flexion, INT-EXT laxity measurements were taken my applying torques in the internal and external rotational directions about the tibia to a maximum torque of 5 Nm.

For the weight bearing measurements, 40% body weight was applied before measuring INT-EXT laxity, requiring the subject to actively hold their knee at 20° of flexion. For both weight bearing and non-weight bearing measurements, three cycles of INT-EXT rotations were applied following three familiarization cycles. Data from the electromagnetic sensors and the torque sensor were recorded simultaneously at a frequency of 100 Hz and low-pass filtered at 10 Hz and 20 Hz respectively using a 4^{th} order Butterworth filter. INT and EXT values were defined as the angular displacement between 0 and 5 Nm of applied torque and measurements were analyzed to examine day-to-day consistency of measurement as well as to examine side-to-side differences.

The primary findings form this study were that the VKLD could be used to measure knee laxity consistently from one day to the next, with errors less than 7°, and although side-to-side differences were found, the difference was less than that of the observed error. Measurement consistency was found to be good to excellent with the exception of the INT weight bearing measurement, which was much lower. Results show that the VKLD has sufficient measurement precision to identify INT-EXT laxity differences of about 2-3° in 68% of cases, suggesting that findings from VKLD measurements will be clinically relevant.

2.3.2 Study Limitations

Although results from this study showed that the VKLD would be able to measure clinically relevant differences in knee INT-EXT laxity, the device has some limitations which should be discussed. One limitation addressed in the paper was the possibility that some motion of the femur may have occurred during testing even though care was taken to immobilize it with the thigh clamp. In order to fix this issue without rigidly clamping the bones themselves, another stabilizing clamp might be added to the knee to help stabilize it during testing. Another limitation addressed in this paper was the small sample size used when examining day-to-day consistency of the VKLD measurements. An additional study should be conducted on a larger sample size to confirm that the findings in this study are consistent with a larger population. Another limitation to this device is that it is very large and complex. Testing requires at least two examiners, which would limit its ability to be used in a setting outside of a research laboratory. This observation is also supported by the fact that the device itself is very large, making it very difficult to move from one place to another. It is important for a clinical tool to be both user friendly and portable to make accessible to both physicians and patients.

2.4 Reliability of a Robotic Knee Testing Tool to Assess Rotational Stability of the Knee Joint in Healthy Female and Male Volunteers (Beckley et al., 2020)

2.4.1 Article Summary

Beckley et al. developed a device named the robotic knee testing device (RKT) that could measure tibial rotation while collecting data from all 6 degrees of freedom. This device consisted of an exam table, foot plates to hold the feet in place, knee and thigh clamps, to stabilize the upper leg and prevent rotation about the femur, a single electromagnetic sensor placed on each tibia, and a servomoter to automate the application of internal and external torques to the knee. Ninety-one participants between the ages of 20 and 48 were recruited for the study. Participants were all moderately active and were required to have no chronic or current spinal cord injuries as well as at least one healthy knee with no history of ACL injury. A reliability study was conducted with 25 of the participants involving rotational knee laxity measurements completed daily for 5 days at a similar time of day.

All testing was carried out by the same examiner. The test setup involved participants laying on their backs of the exam table with their legs both strapped into the RKT device and their knees at 30° of flexion. Feet began in the upright position and strapped tightly to the foot plates, and the knee and thigh clamps were tightened, securing the femur. The electromagnetic sensors were placed medially of the tibial tubercle on both legs. The servomotor, which was responsible for rotating the foot plates and applying torques up to 6Nm before changing direction, were programmed to rotate. Externally then internally for a total of three cycles per trial. Load deformation curves were created by fitting a third order polynomial to the data from the third cycle of each trial and were used to simplify further analysis. The curve was divided into three sections which were separated by the two turning points of the curve. The turning points were defined by the points in the curve where the rate of change of torque becomes faster or slower than the rate of change of rotation. External and internal laxity were then defined as the amount of rotation that occurred between the turning point and the corresponding maximum rotation value. The rotational deformation that occurred in the middle region of the curve between the two turning points was defined as slack. In this study, mechanical propertied of the knee were examined by focusing on the internal laxity, external laxity, and slack measurements. Pointwise mean, SEM and ICC were calculated to analyze the entire load-deformation curve. Statistical analysis was performed using R statistical software.

ICC values for axial rotation of the tibia demonstrated good reliability with values ranging from 0.83 to 0.89, while the SEM ranged from 0.14° to 0.18°. The three features of the curve resulted in moderate to good ICC values of 0.61 to 0.76 and SEM values of 0° to 0.6°. Most measurements were not found to be significantly different when comparing males to females. Results showed that measurements taken at increased torque values had better specificity, sensitivity, and accuracy than those taken closer to 0 Nm of torque. In this study the RKT device was found to demonstrate good reliability in measuring rotational laxity of the knee.

2.4.2 Study Limitations

While this study yielded good results, demonstrating that the RKT had good reliability of measurements, limitations in the test setup should be addressed. First, the device did not involve any ankle support to immobilize the subject's ankle. This would mean that the torque applied at the foot would not result in isolated rotation of the knee but would also involve rotation of the ankle which is not measured. An ankle brace should be used to immobilize the ankle joint, ensuring that the measured rotation is due to the knee alone. Additionally, only one motion sensor was used to measure the rotation of the tibia. Without a second sensor on the femur, it is impossible to know how much the femur might have moved within the stabilizing clamps. In future studies, a second motion sensor should be applied to the femur to measure the tibias rotation in relation to the femur. The authors of the paper also reported a limitation of the study, noting the difference in setup of the right leg compared to the left leg. This limitation makes it difficult to trust the evaluation of side-to-side variation in laxity measurements from the RKT device.

2.5 The Rotational Laxity Device

The Rotational Laxity Device (Figure 1) was initially developed as part of a Senior Experience in Engineering Design (SEED) project at the University of Vermont in the 2018-2019 academic year. The device consists of a rigid ankle brace boot with adjustable straps to stabilize the patient's ankle. Attached to the bottom of the boot is a flange-to-flange mounted reaction torque cell with a T-handle that can measure applied torques up to 45 Nm (Omega TQ301-400). The torque sensor was originally wired to a LORD Microstrain SG-Link-200-OEM which wirelessly transmitted data to a serial port on a computer. Using the LORD Microstrain SensorConnect software, the SEED team was able to visualize the torque data in real time. While the device was able to measure applied torques to the lower leg, the team was unable to incorporate a method to measure and calculate the internal-external rotation of the knee, though they suggested the use of IMU sensors for future work on the device. The design they created was intended to be simple, portable, and user friendly which was accomplished in the year that the team had to design it. By and adding rotation measurement and improving upon their design, the device will be able to measure the internal-external rotational laxity of the knee in vivo accurately and reliably.

Figure 1: The rotational laxity device

As an honors college undergraduate thesis, a method for measuring the internal-external rotation of the knee joint was developed using wearable sensors. The chosen wearable sensors were two Arduino Nano 33 BLE inertial measurement unit (IMU) sensors. These sensors were intended to be secured to the skin of the patient with double sided tape, located on the anterior tibial shaft aligned with the axis of the tibia, and on the lateral femoral epicondyle aligned with the axis of the femur. Motion data was then recorded using the Arduino IDE software in conjunction with Python code (Appendix I). Before data recording was to begin, the two rotation sensors needed to be initialized using the Arduino IDE. Code written in this software instructed the sensors to continuously read tri-axial accelerometer, gyroscope, and magnetometer data at 30 Hz. Once the sensors were initialized, Python code instructed them to record these three parameters for a set period before saving the data in a file. Next, the saved file would be entered into another section of Python code which extracts the x, y, and z accelerations, angular velocities, and magnetic field strength. These readings are filtered using a second order lowpass Butterworth filter with a cutoff frequency of 20 Hz, and entered into a sensor to sensor relative orientation (SSRO) function (Adamowicz et al., 2019) which calculated the relative locations of the two IMU sensors at each sample point with a method using quaternions which were then converted to rotation matrices. From the rotation matrices, three-dimensional cardan joint angles were calculated using the math.atan2() function in Python. The measured rotation angles were then plotted over time.

Upon receiving the Rotational Laxity Device to finish developing as a master's thesis project, a number of limitations of the device needed to be addressed. First, while the device was able to measure both torque and rotation of the knee, the two measurements were in no way synced up, and therefore no torque vs. rotation relationships could be found without manually syncing the data during post-processing. Second, the rotational measurement was not found to be reliable and needed adjustments to be made in the Python script. Therefore, the overall aim of this master's thesis was to adjust the rotational measurement and verify that it is accurate and reliable as well as sync the rotation and torque measurements so that correlations could be assessed, and rotational laxity could be measured automatically.

CHAPTER 3: MATERIALS AND METHODS

3.1 Aim 1: Validation of Rotation Angle Measurement

The first aim of this master's thesis was to validate the rotation angle measurement of the Rotational Laxity Device. To accomplish this, a test jig was built out of PVC pipes and a rotating flange to mimic the shape of a leg in which the knee is constrained to only rotate in the internal-external direction (Figure 2). Two 3 by 24-inch PVC pipes were cut to mimic the approximate lengths of the upper and lower leg segments. A 45° fixed flange joint was fitted to the PVC pipe representing the upper leg segment using a 3-inch coupling to mimic a knee fixed at 45° of flexion. A rotating Flange of the same size was attached to the fixed flange to simulate the knee's internal-external rotation. The PVC segment representing the lower leg was fitted into the rotating flange, and a 90° elbow fitting was applied to the other end to mimic the foot with the ankle fixed at a 90° angle. All parts of the test jig were glued together using liquid cement. On the rotating flange, known angles were measured and marked in sharpie at 0°, +30°, and −30° (Figure 3). The two Arduino Nano 33 BLE sensors were mounted on the test jig with one on the upper leg segment and one on the lower leg segment. The first sensor taped to the anterior "tibia" along its long axis, and the second sensor was taped to the lateral portion of the rotating flange joint aligned with the "thigh" axis.

Figure 2: PVC pipe validation jig in the rotational laxity device.

Figure 3: Marked angle values on the rotating flange of the validation jig.

To test the accuracy of the rotational measurements, the device needed to be rotated at a series of known angles to verify that the sensor-measured angles were accurate. After initializing the sensors in the Arduino IDE and starting the recording in Python, an examiner held the handle at the base of the device, starting at a neutral position of 0°, and externally rotated the test jig to 30° followed by rotating it internally 30°. This action was repeated three times before the test jig was rotated back to the starting position of 0° for a total of five trials. The two datasets (one for each sensor), which contained values for acceleration, angular velocity, and magnetic field strength in the x, y, and z directions, were then filtered using a second order lowpass Butterworth filter with a cutoff frequency of 20 Hz. The data was then entered into the SSRO code in Python and angle values were calculated from the series of resulting rotation matrices. These angles were then plotted with time on the x-axis to show how the calculated angle values change over time.

To quantify the validity and reliability of the angle measurements calculated by the Rotational Laxity Device, a series of statistical analyses were performed. To examine consistency and accuracy of the measurements, means and standard deviations of the positive and negative peak angles were calculated, and standard error of measurements (SEM) were also calculated. The peak angle measurements were found using the numpy.min() and numpy.max() functions in python for the three rotations of all five trials.

3.2 Aim 2: Reliability of Laxity Measurement on a Healthy Control Subject

3.2.1 Sensor Communications and Calculations

The second aim of this master's thesis was to sync the data collection of the rotation and applied torque measurements so that they may be correlated to assess knee laxity. To accomplish this, the measured applies torque from the Omega TQ301-400 torque reaction cell needed to be rewired to a microcontroller that would run on the same IDE as the sensors used for the rotational measurement. Therefore, rather than using the LORD Microstrain SG-Link-200-OEM to transmit the data to the computer, another Arduino microcontroller was used instead. Throughout the timeline of this project different microcontrollers were used to communicate the applied torque to the Arduino IDE. First, the torque sensor was wired to an Arduino Micro, which received voltages from the torque sensor via analog pins. This method did not however allow the two parts of the data collection to be recorded in sync. The next attempt involved replacing the Arduino Micro with a third Arduino Nano 33 BLE, in hopes that using the same microcontroller for the two measurements would enable the data to be time synced. When this method did not work, it was decided to wire the torque sensor to the open analog pins on the Arduino Nano 33 BLE that was being used as the IMU sensor for measuring the position of the lower leg segment. This method was successful in syncing the data collection for the applied torque and internal-external rotation measurements.

In order for the Arduino to receive the output from the torque sensor, an operational amplifier (op amp) needed to be constructed to amplify the torque signal to a range that the microcontroller could read. The op amp circuit, built with the assistance of UVM Electrical Engineering Lecturer James Kay, took outputs from the torque sensor, and amplified and filtered them before sending them to the analog pins of the Arduino microcontroller (Appendix II). Since the Arduino Nano 33 BLE could only read positive voltages, the op amp added an offset proportional to the amount of input voltage provided by battery packs. The offset ensured that all voltages received by the Arduino would be positive. The output voltages from the torque sensor were used to calculate the applied torque to the system using the following equation:

$$T_{Nm} = \frac{(A_1 - A_3)(FS)}{(D)(A_3)(\alpha)(G)}$$

Where T_{Nm} is the applied torque in newton meters, A_1 and A_3 are the analog to digital converter counts for the sensor and offset reference inputs respectively, FS is the sensor FS range in newton meters which is equal to 45.19Nm, D is the voltage divider ratio of the reference circuit which is 4.713, G is the amplifier gain which is equal to 498, and alpha is the sensor sensitivity which is equal to 1.771×10^{-3}. This equation was entered into the Arduino IDE so that the serial output from the Arduino would simply be the torque value in newton meters.

The two Arduino Nano 33 BLE sensors used in this device were initialized using Arduino code. Both sensor 1, which was used to measure the position of the upper leg segment, and sensor 2, which was used to measure the position of the lower leg segment were programmed to record triaxial IMU measurements at a sampling frequency of 50 Hz. Sensor 2 was additionally programmed to record the applied torque at 50 Hz, and all of the data was sent through serial connection to a laptop. The IMU data for both sensors was organized in 9 columns with the first three columns containing x, y, and z accelerations, the second three columns containing x, y, and z angular velocities, and the last three columns containing x, y, and z magnetic field measurements. Sensor two has an additional column at the end containing the applied torque measurement.

With the Arduino code organizing and sending the IMU and torque data through the serial connection with the laptop, a Python script was needed to calculate the internal-external rotation of the knee as well as filter and analyze the laxity data. The first section of the python script initialized a ray framework for communicating with the Arduino sensors through the serial ports (*Productionizing and Scaling Python ML Workloads Simply*). Within the ray framework, custom functions read and recorded the serial data, organizing it into a 2-dimensional array for each sensor. The ray framework recorded data from the serial ports for a set amount of time and saved the data to a NumPy file to an output folder in the current working directory. During the data collection period, the torque values were printed to the Python console for the examiner to reference. The next section of Python code loaded the data back into python and saved it as two NumPy arrays. This section also filtered the data using a lowpass 4th order Butterworth filter with a cutoff frequency of 5Hz to remove unwanted noise from the dataset. The next section of code calculated the sensor-to-sensor relative orientation, returning a rotation matrix for each sample point describing the position of sensor 2 in relation to sensor 1. This array of rotation matrices was then converted to 3-dimensional cardan joint angles using the math.atan2() function, resulting in 3 angles describing the orientation of the knee joint. To calculate the internal-external rotation of the knee, the alpha angle was subtracted from the beta angle to describe rotation about the tibia. After internal-external rotation of the knee was calculated, it could be compared to the applied torque values which was done graphically by creating a torque vs. rotation curve, the slope of which would describe the rotational laxity of the knee.

3.2.2 Experimental Procedure for Measuring the Rotational Laxity of a Healthy Control Subject

To prove that the device was able to measure internal-external knee joint laxity, tests were performed on a single healthy control subject who had no history of ligamental knee injury or surgery. Before testing began, the participant's knee health was assessed and manipulated by a licensed physical therapist to precondition the ligaments. One the physical therapist was confident in the health of the subject's knees, the height of an adjustable treatment table was set so that the participant's knee was bent at 45° of flexion. Next, the participant was secured in the Rotational Laxity Device by tightening the straps on the boot and the chair to a tight, comfortable pressure. Once the participant was positioned correctly, the Arduino Nano 33 BLE IMU sensors were taped to their skin. To find the correct location, the examiner palpated the approximate locations to find the anterior tibia and the lateral femoral epicondyle and aligned the sensors with the tibia and femur, respectively. To ensure that the thigh sensor was aligned with the femur, the greater trochanter was palpated, and the sensor was aligned such that its long axis was pointed towards the anatomical landmark. These sensor locations would allow the sensors to approximate the locations and positions of the tibia and femur noninvasively. After the IMUs were in place, they were connected to a computer via serial ports and the custom Arduino IDE scripts were uploaded onto the two Arduino Sensors, and the Python data collection code was run for a set time of 30 seconds. The experimental setup is shown below in Figure 4.

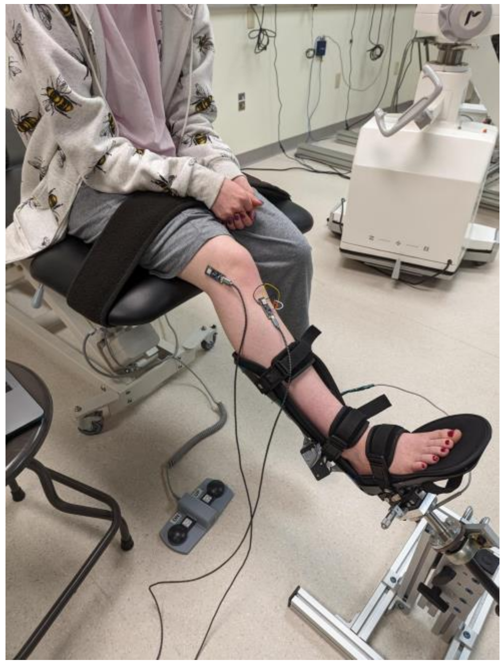


Figure 4: Experimental setup for assessing the reliability of the Rotational Laxity Device on a healthy control subject.

During the data collection period, the examiner, a licensed physical therapist, used the handle at the base of the Rotational Laxity Device to apply a torque to the tibia in the external direction. After the examiner reached a maximum applied torque of 6Nm, the knee was unloaded, and torque was applied in the internal direction up to a maximum torque of 6Nm. This cycle was repeated for a total of three times within the data collection period. To ensure the examiner reached the maximum torque without going past it, another researcher read out the live torque values printed in the Python console. This process was completed for both the right and left legs to verify that the device could be used on either side.

3.2.3 Analysis of Laxity Data Collected

To verify the measurement reliability of the Rotational Laxity Device, a statistical analysis was performed on the collected data from the single healthy control subject. The means and standard deviations were compared for several parameters including peak rotation and torque measurements as well as laxity calculations for each knee. Knee laxity was calculated using the method described by Beckley et al. (Beckley et al., 2020). Using the graph with rotational displacement on the x-axis, and applied torque on the y-axis, a third order polynomial was fitted to the shape of the torque-rotation data. Features of this curve could then be analyzed to determine the mechanical properties of the subject's knee. To calculate the internal and external stiffness of the knee, the curve was split into three sections divided by the turning points of the curve. The turning points were found by visually determining the point where the torque was changing at a greater rate than the rotation. The stiffness in the internal and external directions were defined as the slope of the line connecting each turning point to its corresponding maximum rotation value on the torque-rotation curve. The slack is defined by the amount of rotation in the region between the two turning points.

CHAPTER 4: RESULTS

4.1 Aim 1 Results: Validation of Rotation Angle Measurement

Figure 5 shows a graph of IMU measured internal-external knee joint angles over time for one of the study 1 trials. In this graph, the measured angles clearly start at 0°, then oscillate between 30° and −30° three times before finally returning to 0° as described above in the methods.

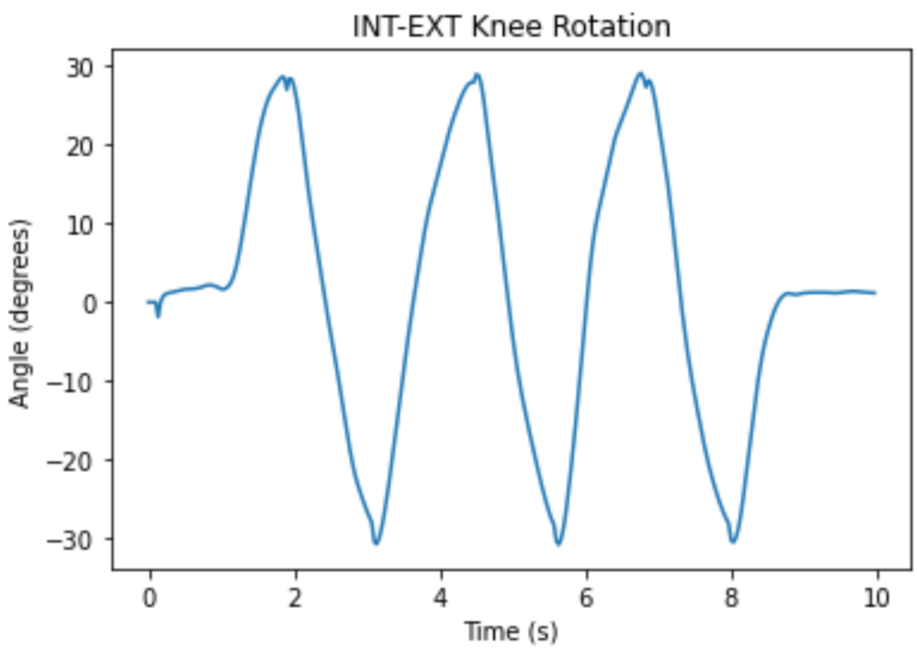


Figure 5: Graph of measured internal-external joint angle values over time for trial 2.

The local minima and maxima for all the 5 trials were recorded and means and standard deviations were calculated for each trial by averaging the three external rotation peaks and the three internal rotation peaks (Table 1). By averaging the mean values from all five trials, the mean external rotation angle was found to be 29.49° ± 0.30° and the mean internal rotation angle was found to be 29.84° ± 0.25°. Standard error of measurement

(SEM) is displayed in Table 2 below remaining relatively low at 0.13 standard deviations for the internal rotation measurement and 0.11° for the external rotation measurement. The values in Table 1 are presented in degrees and the values in Table 2 are presented in standard deviations.

Table 1: Means and standard deviations of internal-external rotation values from study 1.

Trial #	Mean EXT Rotation	Mean INT Rotation	SD EXT Rotation	SD INT Rotation
1	29.68	-29.21	0.59	0.19
2	29.43	-30.39	0.31	0.15
3	28.88	-30.65	0.20	0.12
4	29.17	-30.07	0.23	0.45
5	30.27	-28.87	0.16	0.32
Averages:	**29.49**	**-29.84**	**0.29**	**0.25**

Table 2: Standard Error of Measurement values across all 5 trials for internal and external rotation

Trial #	SEM EXT Rotation	SEM INT Rotation
1	0.26	0.08
2	0.14	0.07
3	0.09	0.05
4	0.10	0.20
5	0.07	0.14
Averages:	**0.13**	**0.11**

4.2 Aim 2 Results: Reliability of Laxity Measurements in a Healthy Control Subject

Table 3 and Table 4 present the peak rotations and corresponding torques for the left and right knees, respectively. In these tables are also the means and standard deviations for each of the parameters. From the tables, it is clear that the data collection for the left knee was more consist with standard deviations of 0.65° and 1.04° for internal and external rotations, respectively. The external rotation measurement for the right knee was consistent with a standard deviation of 1.13°, but the internal rotation measurement had a much higher standard deviation of 9.30°. Following the collection and calculation of laxity data, three graphs were created for each knee measured using the rotational laxity device.

The first set of graphs generated for visual analysis (Figure 6, 7, 10, and 11) were graphs of the internal-external rotation of the knee over time and the applied torque over time. The final graph generated for visual analysis was the comparison of applied torques to internal-external rotation shown in Figure 8 and Figure 12. These graphs were fitted with third order polynomials to simplify feature analysis of the torque-rotation curve.

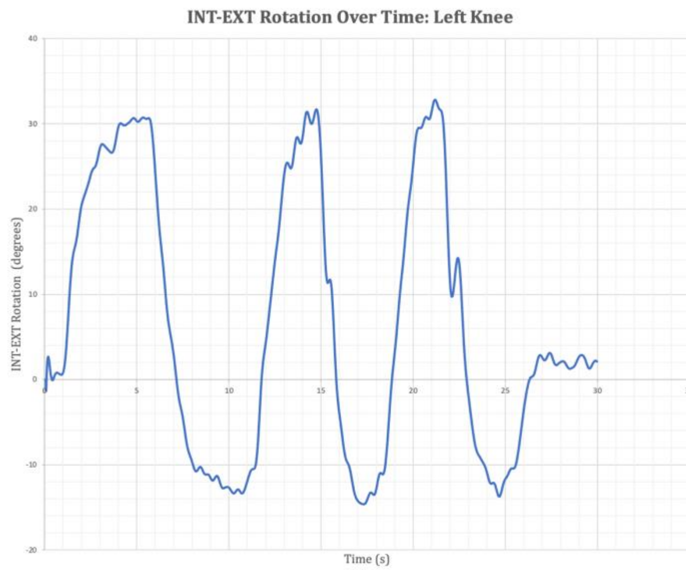


Figure 6: Internal-external rotation over time for the left knee of the control subject measured by the rotational laxity device.

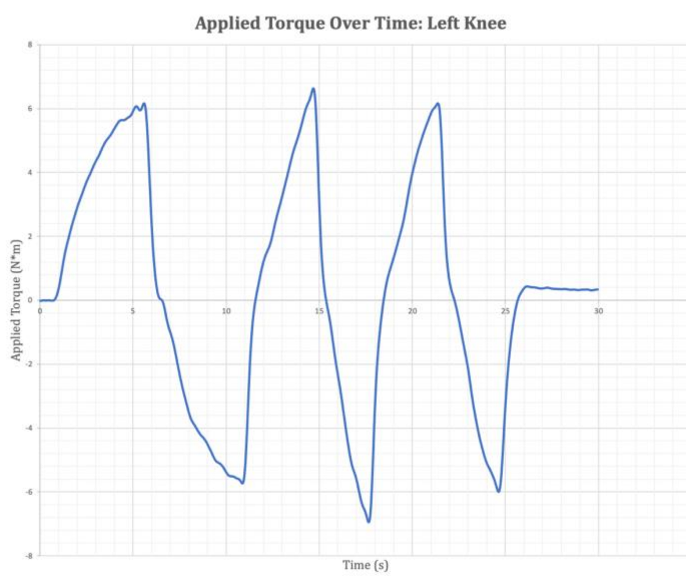


Figure 7: Applied torque over time for the left knee of the control subject measured by the rotational laxity device.

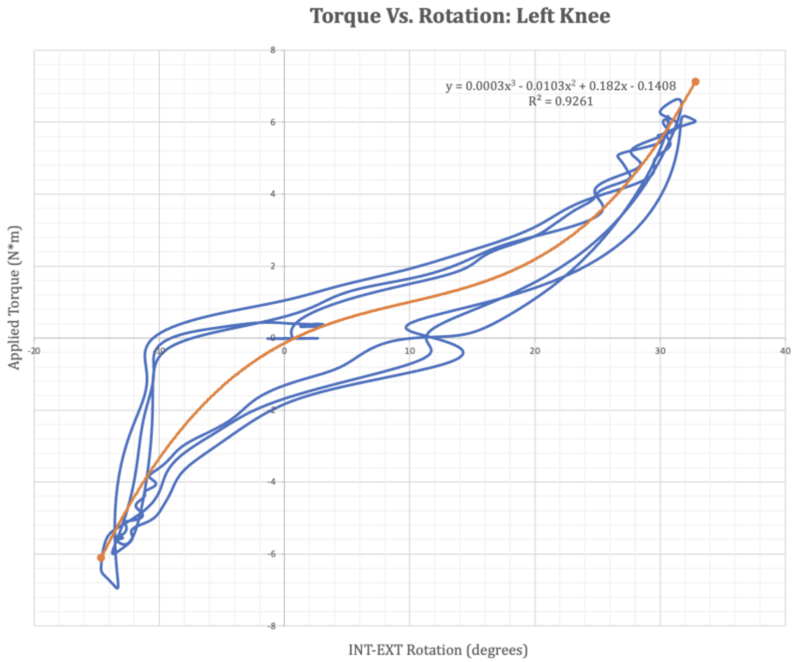


Figure 8: Graph of torque vs. rotation for the left knee of the control subject fitted with a third order polynomial torque-rotation curve.

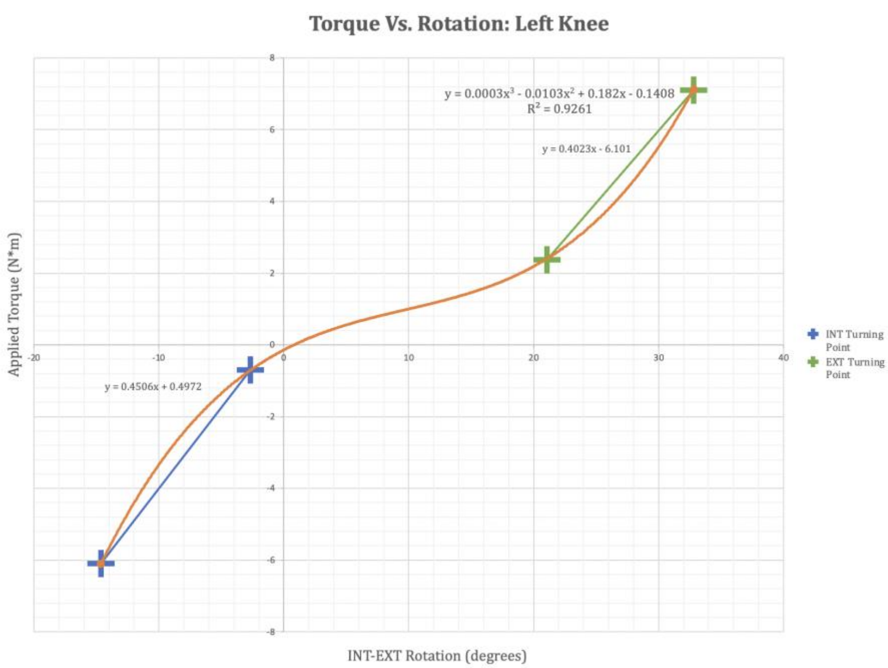


Figure 9: Torque-rotation curve with labeled turning points used to calculate the stiffness of the knee in internal and external rotation.

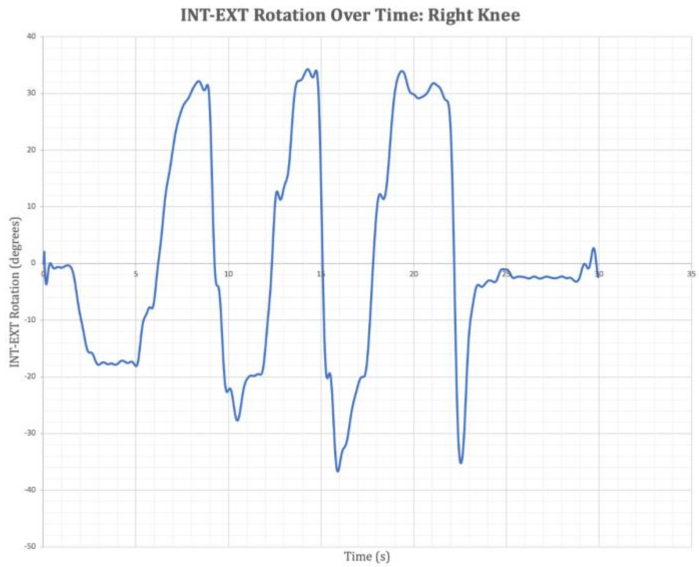


Figure 10: Internal-external rotation over time for the right leg of the control subject measured by the rotational laxity device.

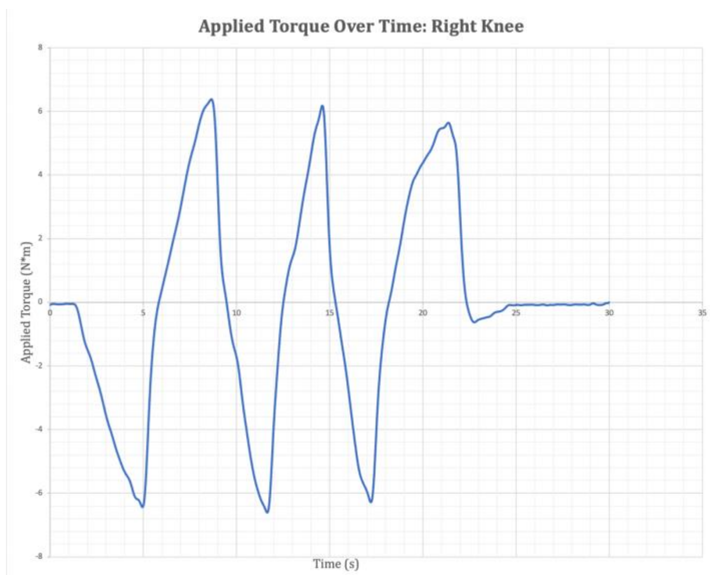


Figure 11: Applied torque over time for the right leg of the control subject measured by the rotational laxity device.

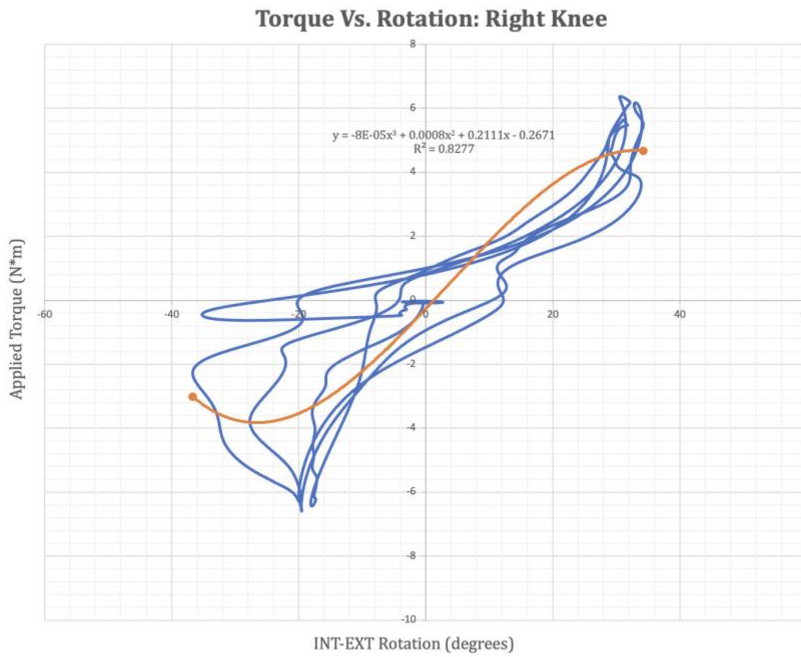


Figure 12: Graph of torque vs. rotation for the right knee of the control subject measured by the rotational laxity device.

The two graphs with torque and rotation plotted over time provide a clear visualization of the cyclic loading and deformation of the knee throughout the data collection. The third order polynomial curve was a good fit for the torque-rotation data collected from the left knee, with an R^2 value of 0.93. This made assessing the features of the curve possible, as it was a good representation of the data. From the torque-rotation curve, internal and external rotational stiffnesses were calculated by finding the slope of the curve between the turning point and the end point in each direction. In regards to the left knee, external stiffness was 0.40Nm/° and internal stiffness was 0.45Nm/° with 23.73° of slack in between. The fitted third order polynomial curve for the right knee was less of a good fit for the collected. While the curve generated had an R^2 value of 0.83, the curve was flipped on the x-axis, and did not line up with the general curve of the data which can be seen in Figure 12. Because the torque-rotation curve generated from the data collected from the right knee did not match up well with the data, the stiffness values from this curve would not be accurate, and this data was left out of further analyses.

Table 3: Maximum internal and external rotations and applied torques for the left knee of the control subject.

Left knee	INT Rotation	EXT Rotation	INT Torques	EXT Torques
Cycle 1	13.38	30.73	5.73	6.16
Cycle 2	14.64	31.69	6.95	6.63
Cycle 3	13.74	32.82	5.99	6.16
Mean	13.92	31.75	6.22	6.32
SD	0.65	1.04	0.64	0.27

Table 4: Maximum internal and external rotations and applied torques for the right knee of the control subject.

Right Knee	EXT Rotation	INT Rotation	INT Torques	EXT Torques
Cycle 1	32.19	18.13	6.38	6.44
Cycle 2	34.29	27.72	6.18	6.61
Cycle 3	33.96	36.72	5.64	6.28
Mean	33.48	27.52	6.07	6.44
SD	1.13	9.30	0.38	0.16

CHAPTER 5: DISCUSSION

5.1 Discussion of Results from Aim 1: Validation of Rotation Angle Measurement

In the current study, the internal-external knee rotational measurement was determined to be accurate and reliable. The use of two IMU sensors, one representing the position of the tibia and the other representing the position of the femur, was proven to be an acceptable method for estimating the tibia's rotation in respect to the femur with the use of a validation jig constructed from PVC pipes and a rotating flange. Figure 5 shows an example graph from one of the validation trials in which the validation rig was rotated in the Rotational Laxity Device between 30° of external rotation and 30° of internal rotation. This graph clearly shows the accuracy and reliability of the rotational measurement.

In addition to the graph, statistical analyses were performed on the rotation data to provide quantitative validation of its accuracy and reliability. The results of these statistical analyses are reported in Table 1 and Table 2. The largest error found during this study was found to be an error of only 1.13° for the internal rotation of trial 5. This produced a standard error of 0.14 standard deviations. The standard deviations presented in Table 1 are all very low, proving that the rotation measurement for the Rotational Laxity Device is reliable. As the measurements across all 5 trials had a mean standard deviation of 0.30° for external rotation and 0.25° for internal rotation, it was determined that the measurements were repeatable across multiple trials. These values are very good compared to those of Shultz et al. and Lee et al. whose standard deviations ranged from 0.9° to 8.3°.

5.2 Discussion of Results from Aim 2: Reliability of Laxity Measurements in a Healthy Control Subject

The primary aim of the second study was to demonstrate that the rotational laxity device can measure the internal-external rotational laxity of the knee in vivo. The results from this study support the idea that the rotational laxity device may be an excellent device for the noninvasive measurement of knee rotational laxity while also being portable and user friendly. The combination of the IMU sensors to measure rotation of the knee and the torque cell attached to an ankle boot to measure applied torque produce results comparable to those seen in the current literature. The rotation over time and torque over time graphs are a clear depiction of the individual measurements being taken by the device throughout the data collection period and are a good indication of the accuracy of the measurements. The torque vs. rotation graph clearly shows the correlation between the applied torque to the device and the resulting rotation of the tibia. The shapes of these graphs are comparable to those seen in the literature from studies by Beckley et al., Branch et al., and Lee et al (Beckley et al., 2020; Branch et al., 2010; Lee et al., 2019).

From the torque vs. rotation graphs, third order polynomial "torque-rotation" curves were fitted to represent the data in a simpler form. These curves simplified the process of assessing features of the torque vs. rotation data such as the ends of the curve used to calculate stiffness of the knee and the center region of the curve used to calculate slack. The data presented in Figure 9 is a good example of this process. While the fitting of a third order polynomial was successful for the data collected from the left knee, the data from the right knee did not produce a torque-rotation curve that matched the trend seen in the data. This discrepancy was likely due to insufficient preconditioning of the ligament prior to testing. This would have caused the ligament to be stretching out as the test was going on, resulting in increasing rotation values at maximum torque for each cycle. This problem could be solved by performing a warm-up trial with the same procedure to condition the knee to the applied torque.

5.3 Study Limitations

Several possible limitations were identified during the current study. One of the most prominent limitations that could affect the accuracy of the rotational laxity measurement is the existence of soft tissue artifact which is present in most cases of using sensors affixed to the skin. While the decision to use IMU sensors was made with the knowledge that soft tissue artifact would be a factor, it means that rotation measurements from the rotational laxity device may not be comparable to findings from other methods with a more precise approach to measuring rotation. Additionally, another limitation to this device is the ineffective method for restraining the thigh. While there is second IMU sensor on the thigh specifically for the purpose of accounting for thigh translation, this sensor would not be able to pick up minute rotations of the femur leading to a rotation at the hip rather than isolating the rotation to the knee. This would result in higher rotation measurements than what the knee actually experiences because the hip rotation is also included in the measurement. A solution to this problem would be to restrict the thigh just above the knee using a similar method to Branch et al. which would isolate the internal external rotation to the knee, preventing it from rotating at the hip as well. As mentioned earlier in the discussion, the rate at which torque is applied to the knee may be a clinically important factor to consider. Completely solving this issue would involve automating the device to apply torque at a constant rate up to a maximum of 6Nm, but this solution was not within the scope of this project and may be unsafe to automate torque application. Another possible solution to this problem would be to choose the optimal velocity for torque application and set a metronome for the examiner to follow throughout the test. The final limitation identified for this project is the inadequate immobilization of the ankle. Although the ankle boot has adjustable straps to secure the patient's ankle, the straps do not provide sufficient stability to the ankle to hold it perfectly in place. One possible solution to this problem would be to include an adjustable air cast that could provide custom support to the ankle, therefore ensuring that the ankle is fully restrained, and the torque is applied directly to the knee without any effect from the ankle.

CHAPTER 6: FUTURE WORK

Within the scope of the current project, the rotational laxity device was proven to be useful for the noninvasive measurement of internal external rotational laxity of the knee in vivo. Following the completion of this stage of the project, a study will be conducted to assess the repeatability of rotational laxity measurements across a larger sample size of participants with no history of knee injury. While the data collected during the present study provided some evidence that the device's measurements are relatively reliable, a study must be conducted with a large enough sample size to prove this with statistical significance. An additional aspect of this study will be measuring the average side-to-side differences in knee rotational laxity for patients with two healthy knees and no history of ligamental injuries. This will provide useful information for other studies investigating the effect of ACL injury and reconstruction on rotational laxity of the knee by assessing the difference in stability of a person's knee compared to what would be considered healthy for that individual.

In future studies, additional analyses might prove to be clinically relevant to the health of a patient's knee. Future studies should investigate the area of the hysteresis for each cycle of applied internal and external torque. This would provide information about how much energy is lost in the ligament when a load of 6Nm is applied and released. A larger hysteresis would indicate greater energy loss, possibly caused by an unhealthy and/or reconstructed ligament. In this study, the 3rd order polynomial torque-rotation curve was fitted to all three cycles in the test trial, but future studies should also investigate the repeatability of measurements by fitting a torque-rotation curve to each cycle in a trial and assess the variability of measurements. Further breaking down the data collected in each trial, future studies using the rotational laxity device might also want to assess the difference in stiffness values when looking at the portion of the data collected when loading compared to unloading of the applied torque. This would also provide information about the energy loss in the system which would be important when assessing the health of the knee. As mentioned earlier, the timing and velocity of the applied torque may have a significant effect on the laxity measurements, and therefore, a study should be conducted to examine the most clinically informative velocity for the knee to be rotated at. If velocities are too high, the patient/subject may engage their leg muscles, changing the measurement, but if velocities are too low, the viscoelasticity of the ligaments in the knee will allow them to stretch, changing the stiffness so that it is not representative of the knee's natural response in the case of injury. Finally, another study should be done to investigate the amount of soft tissue artifact experienced by the IMU sensors. This study could be done using a dual fluoroscopy system to measure the true position of the bones in the leg and compare the data to the values collected from the IMUs. This would result in a better understanding of how well the IMU sensors measure knee rotation as well as provide a potential offset value to the IMU data to make it more representative of what the femur and tibia are really doing.

CHAPTER 7: CONCLUSION

A new device for measuring the internal external rotational laxity of the knee in vivo was presented in this thesis. The device's rotational accuracy and reliability were verified using a verification jig, showing very low amounts of error. The reliability of the device was proven through the study with a healthy human participant, which showed a high degree of repeatability. The present study suggests that the Rotational Laxity Device may be an excellent tool for the measurement of internal external rotational laxity of the knee. Further studies involving the Rotational Laxity Device will further verify its reliability and assess the side-to-side differences in knee rotational laxity in healthy controls. After the completion of this study, the device might be used to document differences in knee rotational laxity for purposes like following ACL injury and reconstruction and assessing possible progression of PTOA following injury.

REFERENCES

Abdelrazek, B. H., Gad, A. M., & Abdel-Aziz, A. (2019). Rotational stability after ACL reconstruction using anatomic double bundle technique versus anatomic single bundle technique plus anterolateral ligament augmentation. *Journal of Arthroscopy and Joint Surgery*, *6*(2), 108–113. https://doi.org/10.1016/j.jajs.2019.01.006

Adamowicz, L., Gurchiek, R. D., Ferri, J., Ursiny, A. T., Fiorentino, N., & McGinnis, R. S. (2019). Validation of Novel Relative Orientation and Inertial Sensor-to-Segment Alignment Algorithms for Estimating 3D Hip Joint Angles. *Sensors*, *19*(23), Article 23. https://doi.org/10.3390/s19235143

Beckley, S., Stinton, S., Lesosky, M., September, A., Collins, M., Branch, T., & Posthumus, M. (2020). Reliability of a Robotic Knee Testing Tool to Assess Rotational Stability of the Knee Joint in Healthy Female and Male Volunteers. *Sports Medicine - Open*, *6*(1), 33. https://doi.org/10.1186/s40798-020-00266-7

Branch, T. P., Browne, J. E., Campbell, J. D., Siebold, R., Freedberg, H. I., Arendt, E. A., Lavoie, F., Neyret, P., & Jacobs, C. A. (2010). Rotational laxity greater in patients with contralateral anterior cruciate ligament injury than healthy volunteers. *Knee Surgery, Sports Traumatology, Arthroscopy*, *18*(10), 1379–1384. https://doi.org/10.1007/s00167-009-1010-y

Carbone, A., & Rodeo, S. (2017). Review of current understanding of post-traumatic osteoarthritis resulting from sports injuries. *Journal of Orthopaedic Research*, *35*(3), 397–405. https://doi.org/10.1002/jor.23341

Dare, D., & Rodeo, S. (2014). Mechanisms of Post-traumatic Osteoarthritis After ACL Injury. *Current Rheumatology Reports*, *16*(10), 448. https://doi.org/10.1007/s11926-014-0448-1

Ferguson, D., Cuthbert, R., & Tibrewal, S. (2020). The role of anterolateral augmentation in primary ACL reconstruction. *Journal of Clinical Orthopaedics and Trauma*, *11*(Suppl 3), S389–S395. https://doi.org/10.1016/j.jcot.2019.09.026

Lee, J. C.-Y., Yung, P. S.-H., Lam, M.-H., Hung, A. S.-L., Fong, D. T.-P., Chan, W. Y., & Chan, K.-M. (2019). A non-invasive biomechanical device to quantify knee rotational laxity: Verification of the device in human cadaveric specimens. *Asia-Pacific Journal of Sports Medicine, Arthroscopy, Rehabilitation and Technology*, *16*, 19–23. https://doi.org/10.1016/j.asmart.2018.11.005

Musahl, V., Bell, K. M., Tsai, A. G., Costic, R. S., Allaire, R., Zantop, T., Irrgang, J. J., & Fu, F. H. (2007). Development of a simple device for measurement of rotational knee laxity. *Knee Surgery, Sports Traumatology, Arthroscopy*, *15*(8), 1009–1012. https://doi.org/10.1007/s00167-007-0317-9

Productionizing and scaling Python ML workloads simply. (n.d.). Ray. Retrieved August 9, 2023, from https://www.ray.io/

Shultz, S. J., Shimokochi, Y., Nguyen, A.-D., Schmitz, R. J., Beynnon, B. D., & Perrin, D. H. (2007). Measurement of varus–valgus and internal–external rotational knee laxities in vivo—part i: Assessment of measurement reliability and bilateral asymmetry. *Journal of Orthopaedic Research*, *25*(8), 981–988. https://doi.org/10.1002/jor.20397

Thomas, A. C., Hubbard-Turner, T., Wikstrom, E. A., & Palmieri-Smith, R. M. (2017). Epidemiology of Posttraumatic Osteoarthritis. *Journal of Athletic Training*, *52*(6), 491–496. https://doi.org/10.4085/1062-6050-51.5.08

Wang, L.-J., Zeng, N., Yan, Z.-P., Li, J.-T., & Ni, G.-X. (2020). Post-traumatic osteoarthritis following ACL injury. *Arthritis Research & Therapy*, *22*, 57. https://doi.org/10.1186/s13075-020-02156-5

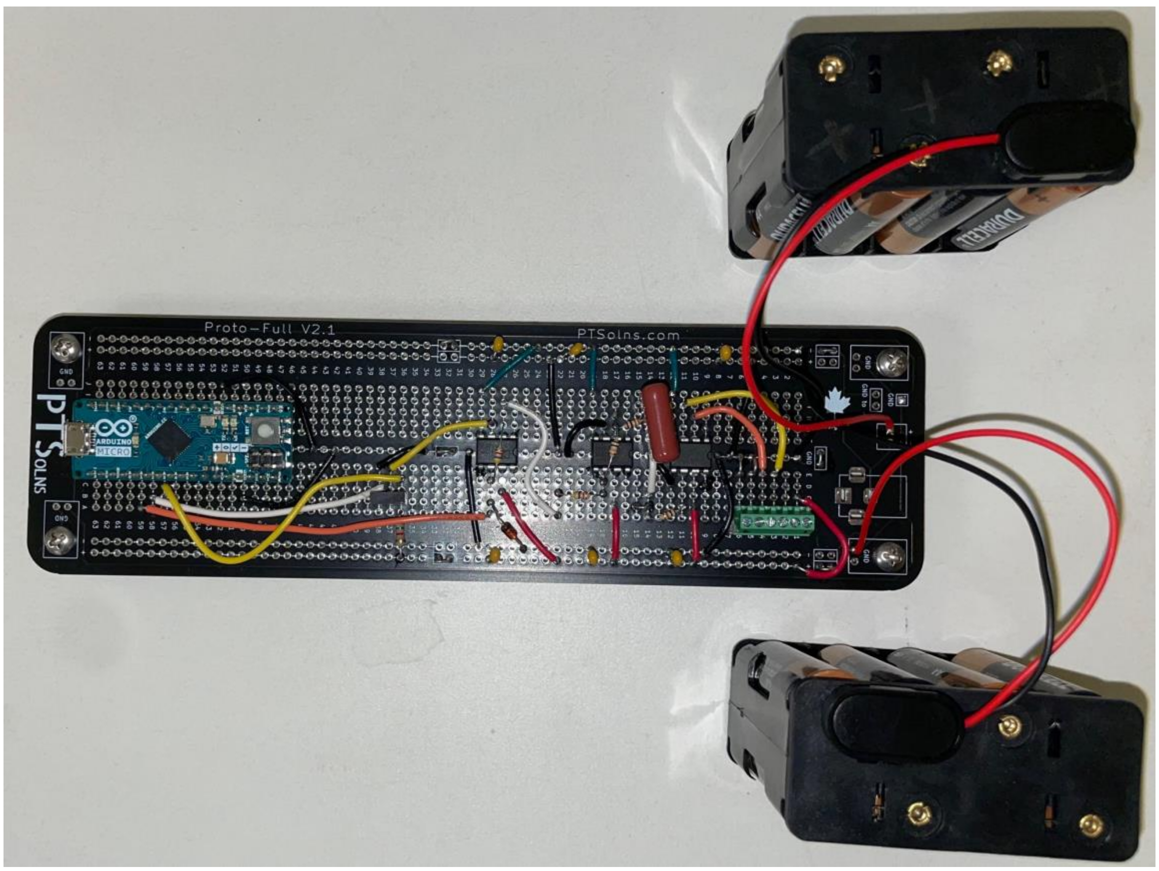
Wiggins, A. J., Grandhi, R. K., Schneider, D. K., Stanfield, D., Webster, K. E., & Myer, G. D. (2016). Risk of Secondary Injury in Younger Athletes After Anterior Cruciate Ligament Reconstruction: A Systematic Review and Meta-analysis. *The American Journal of Sports Medicine*, *44*(7), 1861–1876. https://doi.org/10.1177/0363546515621554

APPENDIX I – Arduino and Python Code

Code used for the data collection for the rotational laxity device can be found on this public GitHub page: https://github.com/Hkuralt/RLD-Data-Collection/tree/main.

APPENDIX II – Torque Sensor Operational Amplifier Circuit

Supplemental Figure 1: Operational Amplifier Circuit for amplifying and adding a reference offset to outputs from the torque reaction cell



Arduino Inputs for Rotational Laxity Torque Sensor

The following inputs will be provided from the interface circuit to the Arduino. These will be soldered connections in the prototype.

Output -> Tie to Arduino analog input 1 on pin 5. Once converted by the A/D this signal becomes A_1.

Gnd -> Tie to Arduino GND on pin 14.

HalfRef -> Tie to Arduino analog input 2 on pin 6. Once converted by the A/D this signal becomes A_2.

Ref -> Tie to Arduino analog input 3d on pin 7. Once converted by the A/D this signal becomes A_3.

Torque Sensor Connections
The torque sensor will have 4 connections to the interface circuit. These will be made via screw terminals on the prototype board. These signals can be connected or disconnected from the interface circuit using a small screwdriver.
V_E = Excitation voltage. The nominal value is 12V. At 12 V the circuit is balanced so that the positive and negative torque ranges are the same. If the value is not 12V the range of the positive and negative torques will be different. However, the Data Acquisition Equations given below are still valid. This signal will be on pin 1 of the screw terminal connection on the prototype board. The color of this wire is Red.
V_+ = Sensor positive output. This signal is the positive side of the sensor output. This signal will be connected to pin 3 of the screw terminal connection on the prototype board. The color of this wire is Green.
V- = Sensor negative output. This signal is the negative side of the sensor output. This signal will be connected to pin 4 of the screw terminal connection on the prototype board. The color of this wire is White.
V_G = Sensor excitation return. This signal is the return path for the sensor excitation. This signal will be connected to pin 6 of the screw terminal connection on the prototype board. The color of this wire is Black.

Battery Connections
The circuit is powered by two battery packs each consisting of 8 AA batteries for a nominal voltage of both positive 12V and negative 12V. These are connected to polarized battery clips that are soldered to the prototype board.

Rotational Laxity Torque Sensor Data Acquisition Equation
The equation relating the analog to digital convertor counts to torque is:

T_{NM}= torque in Newton meters =

$$[(A1-A3)(FS)]/[(D)(A3)(\alpha)(G)]$$

Where:
A_1 = Analog to digital convertor counts of sensor input (Channel 1 of A/D)
A_3 = Analog to digital convertor counts of reference input (Channel 3 of A/D)
FS = Sensor FS range in Nm = 45.19 Nm
D = Voltage divider ratio of reference circuit = 4.713 for the current prototype.
G = Amplifier gain. The current prototype has a value of 498.0.
α = sensor sensitivity = 1.771×10^{-3} (On the calibration report this is given as 1.771 mV/V. Here we take out the prefix milli and convert to a unitless number).

Example calculation (final circuit values used). Say the A/D count or A_1 = 1023 which is full scale and that A_3 is at half scale at 512 counts (which is the nominal value by design for a 12V supply voltage). Then:

T_{NM} = (1023-512)(45.19)/(4.713*512*1.771e-3*498.0) = 10.87 Nm

The measured offset of the signal conditioning circuit was -16.4mV at the output. Each bit of the Arduino A/D is 4.9mV so this error is about 3.3 counts. Correcting for this offset is not recommend. If correction is desired, add 3.3 counts to both A1 and A3 prior to using them in the equation above.