PROTOTYPE DEVELOPMENT AND PERFORMANCE EVALUATION FOR A POSTOPERATIVE KNEE BRACE MONITORING SYSTEM

AN ABSTRACT

SUBMITTED ON THE 4TH DAY OF MAY 2020

TO THE DEPARTMENT OF BIOMEDICAL ENGINEERING IN THE

SCHOOL OF

SCIENCE AND ENGINEERING

OF TULANE UNIVERSITY

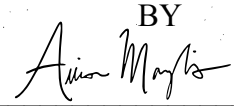
IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREES OF

MASTERS OF SCIENCE
AND
BACHELOR OF SCIENCE IN ENGINEERING

IN BIOMEDICAL ENGINEERING

BY



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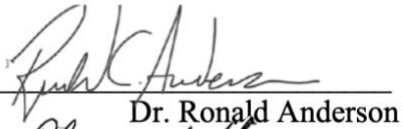
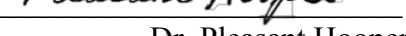
APPROVED:



Dr. Ronald Anderson



Dr. Pleasant Hooper

Dr. Michael Dancisak

ABSTRACT

Medical devices are needed in order to provide optimal care for patients and the most accurate and beneficial information for medical professionals. There are many important factors to consider throughout the conception and development of a medical device. There must be a thorough understanding of the problem, followed by an iterative design progression before the product is tested and validated. This paper will explore these processes through the creation and verification of a wearable medical device. The subject device is an attachment to a postoperative knee brace for patients who have undergone total knee replacement surgery and it is intended to measure the range of motion (ROM) and total knee cycles (TKC) of the knee during the patient's recovery process.

The purpose of this paper is to understand the different steps and processes that are necessary in order to create an effective and therapeutically beneficial medical device. Although the discovery of problems and the conception and development of successful devices will be different for each medical device that is created, the general progression is standard. The process starts with traditional research in order to gain a complete understanding of the problem and identify any existing competitive devices. This is followed by a brainstorming process to determine various ways to solve the problem, accompanied by theoretical device designs that can be created and tested through computer software. After the initial design of the device is created, prototypes are made and thoroughly tested. Following pre-clinical testing, redesigns and post clinical testing, the device must be approved by the FDA. Once the device design is finalized, the tests are successful, and the device is approved, it can be commercialized. These steps are all essential in ensuring that the device is most beneficial for the patients and their medical professionals.

The knee brace attachment that is the subject of this paper is presently going through design adjustments and testing and is expected to fulfill all of its original goals of providing medical professionals with ROM measurements and additional information to better enhance their patients' postoperative outcomes.

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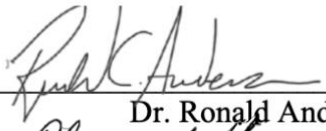

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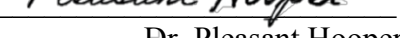
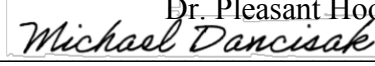


Dr. Pleasant Hooper



Dr. Michael Dancisak

ACKNOWLEDGEMENTS

First and foremost, I thank Dr. Pleasant Hooper for giving me the opportunity to work on this project. You have supported each and every decision, triumph and failure. Your guidance is truly appreciated. Further, I would like to thank Ted Brown, Josh Talbot and the Smart Brace team for all of your contributions and help. This device would not be what it is today without all of your insights and hard work.

Thank you to Dr. Anderson for your guidance and for always assuring me that everything will be okay. This project would not have been possible if you did not believe in me, and I am so grateful that you gave me the freedom to pursue my passions. Thank you to Dr. Dancisak for advising and supporting me in all of my studies and projects. I am so appreciative of all that both of you have done as my professors and mentors. I would not be the student or person I am today without the support, encouragement and guidance from you, and all of my other devoted professors.

Lastly, I thank my friends and family. Thank you to all of my friends, especially Marissa, Milli and Ellie. I cannot thank you enough for all of the study sessions, late nights, and laughs that have made my Tulane engineering experience so much better. Even during this last year without you at Tulane, you have been such an unbelievable support system. Most importantly, thank you to my parents. Thank you for always supporting me, no matter what, for cheering me on and for lending an ear when I need to cry, complain or vent. I would not have made it through these last five years without your support and guidance; I am so lucky. I love you.

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1. INTRODUCTION

There is an increasing need for medical devices to treat and monitor patients before, during and after treatment. This is especially so since so many medical procedures are increasingly being performed on an outpatient basis. When developing a medical device, there must be thorough understanding of the problem, followed by an iterative design process to create a device that safely and effectively solves the problem. The aim of this paper is to understand the process of creating and commercializing a medical device through the development of an electronic attachment for a knee brace that will allow a medical provider to remotely monitor patients after full knee replacement surgery.

There are many available devices that provide some of the services that this device would offer. None of them, however, encompass all aspects of this device. There are postoperative knee braces, compression sleeves and manual devices, such as goniometers, which can help medical providers and therapists facilitate a patient's recovery from injuries. These devices, though, do not accurately or continuously monitor a patient's mobility during the rehabilitation process or provide instant data for physical therapists and doctors, which can be used to evaluate the patient's progress. The knee brace attachment is being designed to do this. Further, this device will provide an interface allowing clinicians to observe their patients' postoperative physical therapy effectiveness in real time. One of the goals of this device is to reduce the number of physical therapy and postoperative check-up appointments patients need to attend, therefore freeing up clinicians' schedules for other patients.

The device's components use new and current technology to provide medical professionals with accurate and continuous information of their patients at all stages of their rehabilitation. With this device, medical professionals will have an opportunity to get more

information from a single device. The knee brace attachment uses a combination of an accelerometer, rotary sensor, timer, code and other components to measure the knee joint movements of the patient wearing the device in order to monitor their range of motion (ROM) and total knee cycles (TKC). Range of motion is a critical marker in determining patient recovery because it examines the physical functionality of the knee following surgery. Therefore, the data that the device collects and displays is essential in showing the progress of a patient's rehabilitation.

The purpose of this project is to understand the conception and creation of a medical device at every preclinical step of the process, specifically in terms of the creation of a particular medical device- a knee brace attachment device that monitors range of motion and total knee cycles. The discovery and development will always be unique for each new product, but the general procedure of creating a new device is standard. Traditional research methods are used to determine, understand and analyze the problem as well as to understand the market and identify competitive devices. It is essential to brainstorm multiple ways to solve the problem and create various theoretical device designs that can be tested through online software or physical tests. Once these initial tests are complete, and the best device design chosen, a prototype is created to test the success of a device. Device design is an iterative process that includes multiple prototypes as the design is modified based on testing results. The processes of data collection, brainstorming, prototyping and testing are all key aspects of developing a successful device. For both the circuitry component and the outer casing of the device, multiple redesigns and testing phases were completed. These steps were taken to explore the effectiveness of the monitoring and recording of ROM and TKC by the device.

2. BACKGROUND

2.1 Creating a Medical Device

2.1.A What is a medical device? What is a wearable medical device?

As defined by the United States Food and Drug Administration (FDA), a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article [...] intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease" (Center for Devices and Radiological Health [CDRH], How to Determine if Your Product is a Medical Device 2019). A medical device does not require or depend on chemical action to perform its intended function (CDRH, 2019). The FDA has set up guidelines for classifying medical devices. They are grouped into three classes - Class I, II or III - based on their intended use and indications for use (CDRH, Classify Your Medical Device, 2020). The risk associated with the use of the device is also a factor in the device's classification, and the larger class number denotes increased risk (Kramer et al., 2012).

A wearable medical device is a noninvasive device that performs its function with the human body as its support system (Fotiadis et al., 2006). For the purpose of this project, wearable devices, or wearables, refer to medical devices that monitor patient data and provide immediate and continuous feedback. Wearable devices collect information through sensors, accelerometers, and other data processing technology which can store and relay data (Fotiadis et al., 2006). Wearable devices can be utilized throughout patient treatment as well as rehabilitation, as shown through the devices which are the focus of this paper.

Although wearable devices can be expensive, they are beneficial to the healthcare system because their cost is offset through their extended use by patients. Care is more efficiently and effectively provided when patients are continuously monitored. With wearable devices, patients can be sent home earlier, thus freeing up hospital space and reducing the patient need for larger, more expensive equipment. Further, at-home wearables can lead to fewer trips to the hospital after the initial stay, leading to the clinicians being able to see more patients (Fotiadis et al., 2006).

2.1.B Types of Medical Devices

2.1.B.I FDA Approval Requirements

The FDA has outlined four steps to follow in order to bring a medical device to market:

> " Step One: Classify Your Device and understand Applicable Regulatory Controls
> Step Two: Select and Prepare the Correct Premarket Submission
> Step Three: Send Your Premarket Submission to the FDA and Interact with FDA Staff During Review
> Step Four: Comply with Applicable Regulatory Controls Including the Establishment Registration and Device Listing" (CDRH, How to Study and Market Your Device, 2019).

The first step is discussed in section 2.1.B.II Classification. Following the device's classification, proper premarket

submissions must be chosen and prepared. These consist of 510(k), or Premarket Notification, Premarket Approval (PMA), De Novo Classification Request or Humanitarian Device Exemption (HDE). While some Class I and II devices are exempt from 510(k) submission, most Class II devices and some Class I devices require it. A 510(k) submission proves substantial equivalence to a device already on the market.

Class III devices do not qualify for 510(k) submission; they require PMA, which mandates scientific proof that the device is both safe and effective according to the device's intended use. Devices require De Novo Classification when they are automatically classified as Class III- no predicate device is substantially equivalent and there is proof of safety and effectiveness. Lastly, devices that follow the HDE regulatory pathway are devices intended for use for specific conditions of diseases. Premarket submission, no matter which regulatory pathway is followed, is dependent on design controls and testing. Once the proper premarket submission is selected and prepared, the submission must be sent to the FDA. The FDA assesses the submission to qualify for substantive review. During the assessment period, FDA staff interacts with submission applicants. If and when the device receives FDA clearance, it can be registered and listed, and thus brought to market (CDRH, How to Study and Market Your Device, 2019).

2.1.B.II Classification

Approved medical devices are divided into categories based on classification. Device classification is determined by the FDA and is dependent "on the intended use of the device" (CDRH, Classify Your Medical Device, 2020). Further, indications for use and risk factors are considered when determining the classification of a device (CDRH, 2020). There are three regulatory classes: Class I General Controls, Class II General Controls and Special Controls and Class III General Control and Premarket Approval. Devices with the lowest risk fall into Class I, and risk increases with the class. Both Class I

and Class II categories have subsets depending on whether the device is exempt or not.

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption
I	Lowest	Present minimal potential for harm	General	510(k) 510(k) Exempt
II	Moderate	Higher risk than class I devices	General and Special (if available)	510(k) 510(k) Exempt
III	Highest	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury	General and PMA	PMA

Figure 1. Medical Device Classification Breakdown
Note: Adapted from Health, C. for D. and R. (2020, January 28). *How to Study and Market Your Device*. FDA; FDA. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device

Exemptions are based on requirements for premarket notification, or 510(k), as determined by the requirements of the Federal Food, Drug and Cosmetic Act. Devices that are exempt do not require the same testing and proof of safety and effectiveness as non-exempt devices (Van Norman, 2016). For every device in any regulatory class that is not exempt, and is "intended for human use," and does not require a Premarket Approval application (PMA), a 510(k) must be submitted. A 510(k) submission is intended to show that the device is both safe and effective. Safety and effectiveness of a device is determined by substantial equivalence to another device that is already on the market (CDRH, Premarket Notification 510(k), 2020).

Class III devices require PMA unless they are exempt, in which case, a 510(k) submission is necessary. Premarket Approval is the process most Class III

medical devices undergo by the FDA to prove safety and effectiveness. It is both a scientific and regulatory review of the device (CDRH, Premarket Approval (PMA), 2019). Certain devices which are "intended to support, supplement, and/or augment the performance of one or more parent devices" can be categorized as accessories. These devices are classified based on their intended use and risk factors and must have an Accessory Classification Request approval to be marketed (CDRH, Medical Device Accessories, 2019).

2.1.B.III Market for Medical Devices

Globally, the medical device market was worth $425.5 billion in 2018, and by 2025 is projected to reach $612.7 billion (Fortune Business Insights, 2019). The United Stated medical device market is the largest market, valued at $156 billion in 2017, with a projected value of $208 billion by 2023 (Select USA, n.d.). Wearables account for a smaller, but growing, portion of the medical device market, with a global value of $24.6 billion in 2018 and a projected value of $139 billion by 2026. Further, in 2018, diagnostic and monitoring wearable devices accounted for more than 50% of all wearable devices (Fortune Business Insights, 2019).

The medical device market is growing as the number of surgeries globally significantly increases. The number of Total Knee Arthroplasties (TKA) performed in the United States alone is expected to reach 3.5 million procedures by 2030 (Inacio et al., 2017). The average cost of a TKA without complications was $30,249 per procedure in 2017 (Blue Cross Blue Shield, 2019). The weeks of required therapy following a TKA costs over $1,000, the average cost for 10 visits

(PT Central, 2019). The number of procedures, as well as cost for the procedure and required rehabilitation continue to grow, showing a need for a device that can create a more cost effective and productive model.

2.1.C Design and Development Process

The process of creating a medical device is long, arduous and expensive. This is due to the ideating, researching, designing, prototyping, and testing that goes into the device before it can be approved for market (Kaplan et al., 2004). The first step in the process of creating a medical device is identifying a problem. After identifying a problem, the brainstorming phase begins which results in different designs of a product. This phase can be extensive because it includes researching the problem, currently available devices and potential new technologies that can be implemented.

When a single design of the device is finalized, the prototyping and testing phase begins. It is common that the device undergoes multiple rounds of prototyping and testing in order to ensure that the device meets all of the design criteria and is effective. Assessment begins with bench testing. It continues in laboratory settings, before receiving approval for clinical trials. Once the device is approved for human clinical trials, testing can be completed to gather data in order to reach FDA approval for market. This process is shown in the diagram below.

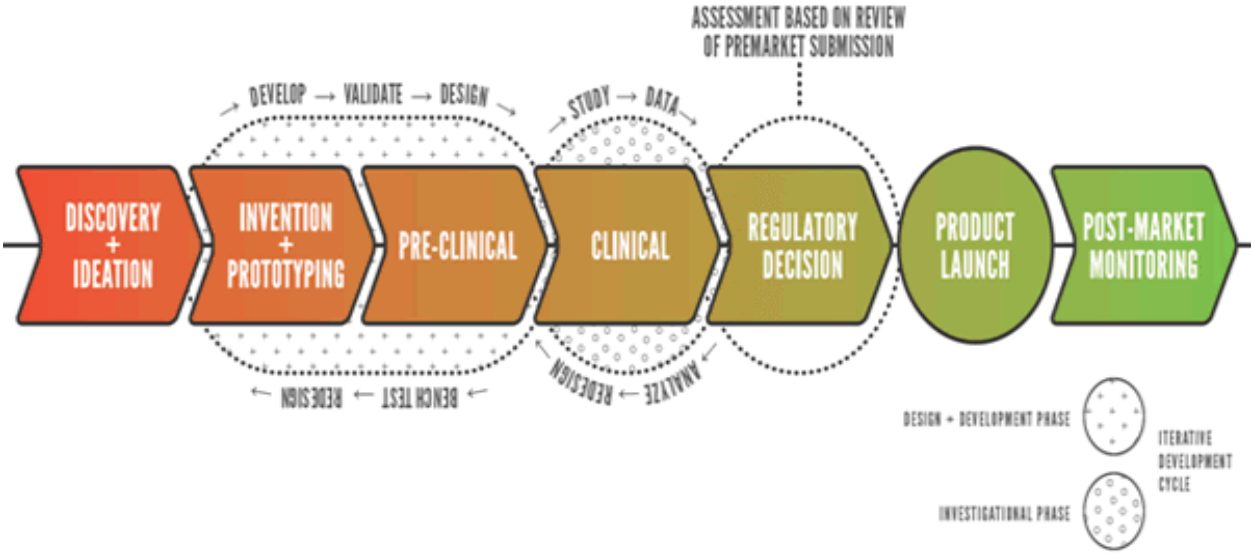

Figure 2: Medical Device Development Process
Note: Adapted from CDRH Innovation Initiative, by Health, C. for D. and R. (n.d.-a). CDRH Innovation - Medical Device Innovation Initiative White Paper [WebContent].

The process of creating a wearable medical device follows the same steps as other medical devices. There are, however, some different components that must be accounted for. Various outside conditions and patient use are two of the major differentiating factors of process and play a dominant role in their design process of wearable medical devices (Fotiadis et al., 2006). The conditions that wearables must endure must be taken into consideration when utilizing various technology, in order to ensure that the device works in any situation. Patient use requires device comfort, ease of use and acceptance, which are essential factors (Fotiadis et al., 2006). If the device is functional but the patient refuses to wear it because it is uncomfortable or difficult to use, for example, the device does not serve its intended purpose.

Once the device has been designed, the prototyping stage begins. Prototyping is an essential step in the design and development process. It allows designers to identify design benefits or issues in order to produce subsequent iterations that better meet

engineering requirements, user needs and design goals. While prototyping encompasses the entire process of fabricating a physical model of an idea (Deininger et al., 2017), in terms of this project, it refers to the prototyping of the encasement for the circuit of the device.

For this project, prototyping relies on the use of computer-aided design (CAD) software and 3D printing of the case. With CAD software and 3D printing especially, prototypes can be developed rapidly and inexpensively and still serve as sufficient design models (Deininger et al., 2017). The use of CAD in the prototype stage is beneficial not only because of lower costs but also because it allows for faster, virtual understanding of a product. It is a cost reducing process because it allows users to effectively design a product without having to incur the costs of manufacturing processes. Additionally, through the use of dynamic CAD software, the virtual prototype can be analyzed and tested in a similar fashion to physical models (Lukaszewicz, 2017).

Models and devices of varying complexity can be 3D printed. Prototypes are printed from 3D renderings by 3D printers which deposit a specific material layer by layer. This process is more cost effective and less wasteful - the printer only deposits the requisite material (Department of Energy, How 3D Printers Work, 2014). The models can range from general objects used for teaching to patient specific anatomy to prepare for surgery (Garcia et al., 2020), and devices can also range from general concepts to complex structures (CDRH, 3D Printing of Medical Devices, 2020). For this project, SolidWorks was the CAD software of choice. Multiple iterations of the case were designed and altered easily and rapidly with the CAD software. This project utilized Cura Software to prepare the SolidWorks rendering for printing on an Ultimaker 3 3D printer.

Once the prototyping phase is complete, the device must undergo preclinical testing, which usually begins with benchtop testing. The entire testing process can take two or more years and cost more than $10 million because the testing cycle usually results in redesigning and retesting the device (Van Norman, 2016). Benchtop testing for this project began with ensuring that the circuit worked and then continued with the setting of the circuit within the case.

Once the case was 3D printed, the circuit was installed and the case was attached to the hinge system of the knee brace. The testing of the case ensured that it would securely hold the circuit board and that it would withstand the forces applied to it from the brace. Redesigning the case was necessary as the circuit board changed and subsequent testing was necessary. Testing failed when the 3D printed top or bottom of the case had an error or if the tolerancing of the case was not precise enough to hold the circuit board in place and/or connect with the adjoining piece. Testing was considered a success when the case held the circuit board, accurately connected and attached to the brace. There were many successful tests of the case for each design of the device. Testing of the system as a whole, with the circuit in the case attached to the hinge of the knee brace, was the last step in the testing process of this project. Testing was considered a success when accurate and useful data was collected, and a failure if no data, or flawed data was collected.

2.2 Total Knee Replacement

2.2.A Total Knee Replacement Surgery

In the United States, more than 600,000 total knee replacement, or total knee arthroplasty (TKA) surgeries, are performed every year (Foran, 2015). Between 2000 and

2010, the mean age of patients undergoing TKA surgery decreased for both men and women, from 69.3 to 66.5 and from 68.7 to 66.0, respectively. Further, during this 11-year study, it was found that patients aged 45 and over comprised 98.1% of the population undergoing TKA surgeries (Williams, 2015). TKA surgery is a viable option to reduce knee pain that can be caused by a variety of medical issues. Most commonly, TKA patients suffer from osteoarthritis, rheumatoid arthritis or post-traumatic arthritis, or other issues that cause debilitating pain that limits an individual's daily activities or does not diminish through other means of treatment (Foran, 2015). It is estimated that by the year 2030, over 3 million TKA surgeries will be performed, costing hospitals approximately $28.5 billion (Masaracchio et al., 2017).

A TKA surgery requires damaged tissue to be removed from the body and artificial components to be implanted into the body, forming a new knee joint. In order to do this, cartilage and a portion of bone at the ends of both the femur and tibia are removed. Metal pieces replace the removed tissue, creating a new surface for articulation. These pieces are anchored into the femur and tibia bones. A plastic spacer is placed between the metal pieces, and in some cases the patella is resurfaced (Foran, 2015). While total knee arthroplasties are performed for different disease states, the goal of a TKA is to reduce, and ideally, eliminate pain and improve physical functionality of the joint (Weinstein et al., 2013).

2.2.B Postoperative Recovery

Rehabilitation begins soon after the surgery is complete. Patients begin to use their knee the day of, or the day after, their surgery with the assistance of physical therapists and they typically resume their normal daily activities three to six weeks after

the operation (Foran, 2015). Although preoperative measures can be taken, there is no conclusion as to what exercises, or types of exercises are more beneficial to postoperative recovery. Preoperative exercises can "enhance the recovery of knee-extension strength and functional performance after TKA" (Bandholm et al., 2018). Postoperative rehabilitation, either at-home care or in a facility, however, is the most crucial part of patient recovery (Bandholm et al., 2018). In 2009 alone, physical therapy following TKA costs totaled $648 million (Ong et al., 2015), with this amount continuing to rise each year with the increase in total number of TKA performed.

Typical rehabilitation programs following surgery include at home regimens, some of which are accompanied by outpatient care with a physical therapist. There is no difference in the short-term success of these programs for enhancing physical function and reducing pain (Artz et al., 2015). Basic rehabilitation programs include exercises that strengthen and stretch the muscles in the entire leg, which should be continued for four to six weeks after surgery, in addition to follow-up examinations with the orthopedic surgeon (American Academy of Orthopedic Surgeons [AAOS], 2017). Additional exercises are performed to improve range of motion (ROM), gait, and overall knee mechanics. As a patient progresses through his/her rehabilitation, more advanced exercises are continuously added to their program until normal knee functionality is restored (Lahey Hospital & Medical Center, 2017).

Patients, though, rarely adhere to a recommended at-home regimen due to limited time, failure to remember or inability to understand the exercises and how the rehabilitation program will aid in their recovery (Bahadori et al., 2018). Clearly, this can be detrimental to a patient's recovery. If the patient does not complete the exercises that

will strengthen and mobilize the knee, he/she will not be able to return to normal functionality and, thus, not recover fully.

Throughout a patient's rehabilitation program, mobilization belts, goniometers and mechanical devices, such as devices that produce sustained pressure to a patient, are used by therapists to increase and measure a patient's ROM (Shah, 2008). Bracing is also utilized to limit knee instability (Rodriguez-Merchan, 2011). There are a number of wearable devices currently available on the market to monitor and record patient data following TKA. Individually, these devices can perform the actions of goniometers, or measure ROM, sit-to-stand transitions, and movement through the use of accelerometers or other sensors (Bahadori et al., 2018). There is no device that collects all of the essential data to understand the progression of a patient's rehabilitation and recovery.

2.2.C Postoperative Rehabilitation Progression

Knee functionality is dependent on knee flexion and extension (Shah, 2008), which is why range of motion (ROM) is a critical aspect of postoperative rehabilitation. Further, postoperative rehabilitation is essential in reducing pain, stiffness and swelling of the knee joint following surgery (Bell et al., 2019). While different surgeons may have specific goals and timelines they want their patients to follow, the first stage of postoperative rehabilitation is increasing ROM and decreasing pain, stiffness and swelling (Berthelot, personal communication, 2020).

Flexion and extension of the knee is measured with a goniometer. The center axis of the device is aligned at the lateral epicondyle of the femur, the stationary arm is positioned along the femur in line with the greater trochanter and the moving arm is

positioned along the fibula in line with the lateral malleolus (Schache et al., 2016) as seen in Figure 3.

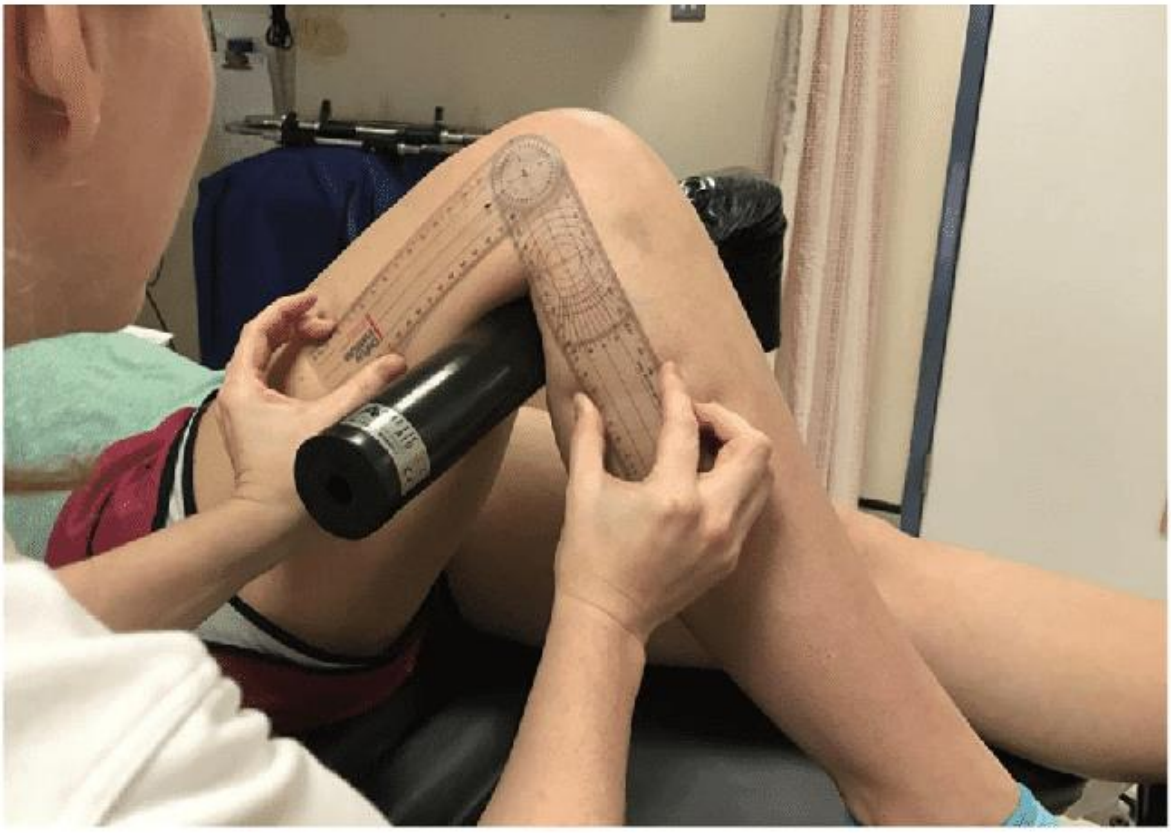

Figure 3: Use of Goniometer to Measure Knee Flexion
Note: Adapted from Hancock, Graeme & Hepworth, Tracey & Wembridge, Kevin. (2018). Accuracy and reliability of knee goniometry methods. Journal of Experimental Orthopaedics. 5. 10.1186/s40634-018-0161-5.

Preoperative knee extension and flexion are the best indicators for a patient's postoperative ROM (Pua et al., 2019). The more extension and flexion a patient has before the TKA, the more likely a patient recovers full ROM following the surgery. While preoperative physical therapy can be beneficial for patients, there is no conclusive evidence that it is essential for regaining full knee flexion and extension (Ontario H.Q, 2005).

Typically, during the first phase of rehabilitation, benchmark flexion and extension angles are 90 degrees and 0 degrees, respectively. The next standard benchmark is 120 degrees of flexion (UW Health Orthopedics and Rehabilitation, 2019). Different protocols have different timelines of phases. So, these benchmark measurements are used in conjunction with the patient's ability to perform certain activities, movements, and/or exercises to determine when a patient can move onto the next phase and, ultimately, be discharged from therapy.

Physical function following TKA is dependent on muscle strength, specifically hamstring and quadricep strength (Moon et al., 2016). While range of motion is a metric used to determine the types of activities a patient can perform, these activities are dependent on overall knee stability and leg strength, which is why strengthening exercises are crucial to postoperative rehabilitation and long-term recovery. Physical therapy regimens begin with more simple range of motion and strengthening exercises and gradually build up to strengthening and more active exercises as patients progress through their rehabilitation (Berthelot, 2020). Initial phases include exercises such as sit-to-stand squats, straight leg raises and muscle isometrics, in conjunction with stretching exercises. As patients progress, exercises such as leg presses, single leg balance, multiple direction step-ups and more weight bearing activities are introduced into their rehabilitation protocol (UW Health Orthopedics and Rehabilitation, 2019). Since patients progress at different rates, their timing of rehabilitation discharge varies and is dependent on different criteria, such as independent gait, proper balance and proprioception (Brigham and Women's Hospital, 2012).

2.3 Data Collection and Use

2.3.A Data Collection Using Sensors

Wearables utilize sensors to automatically collect data. While there is a wide range of available sensors, this device uses an accelerometer and a rotary sensor coupled to the hinge axis of the support brace to measure ROM and total knee cycles of motion (TKC). These simple analog sensors are combined with complex digital micro controller circuitry to collect and record patient data.

2.3.A.I How the Sensors Work

Sensors are devices that respond to stimuli with an electrical output. There are both analog and digital sensors. An analog sensor continuously measures a stimulus and outputs a signal. Digital sensors measure stimulus and responds in either an “on” or “off” state. This means that they are unlike analog sensors in that they do not continuously measure and respond to varying stimuli. There are analog to digital converters that can be implemented into the circuit in order for a microcontroller system to read the signals (Electronics Hub, 2019). The use of analog sensors in this device ensures continuous response to the stimuli, allowing the device to provide constant data. The accelerometer is used to measure the acceleration at which TKC occur. It also allows for special custom utilization depending on patient and clinician needs. The rotary sensor measures the angle of flexion as the hinge of the knee brace is bent. The collected data from these sensors is recorded and displayed.

2.3.B Data Use

The data collected by the device will be stored on a solid state disc chip and, upon connection to a software program, it will be transferred to a user interface. The data will be represented in a graphic display of angle of flexion over time. The raw data is stored as a comma separate value (csv) set, as seen in Figure 4. The data is in the format of date: year-month-day, time: hour: minute: second.millisecond, angle in degrees, and acceleration in the x, y and z directions.

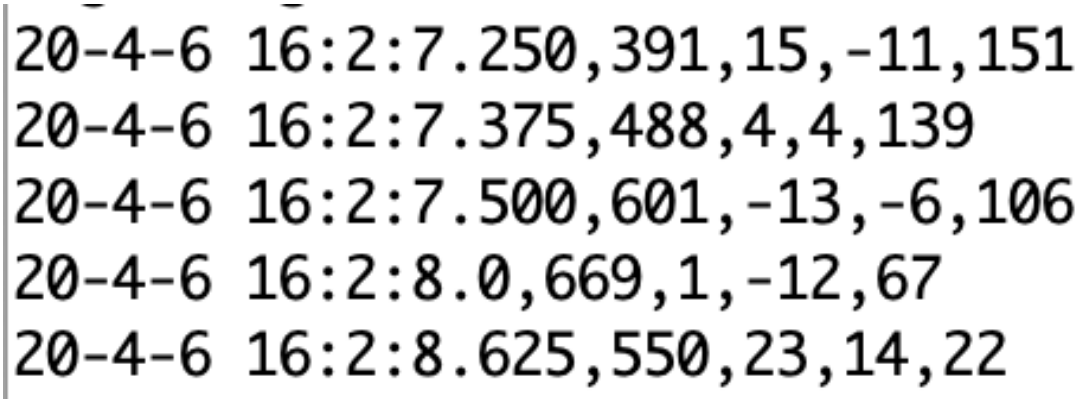

Figure 4. Device Data displayed as CSV Set as date, time, angle, x-, y-, z-direction accelerations

This will allow for easy analysis and clinical interpretation and review. By presenting the data this way, patients and clinicians will be able to see and understand progress. Patients will see their progress through the interface, while clinicians have the ability to see the interface and analyze the data on a deeper level to monitor postoperative physical therapy effectiveness. Further, since this device will provide a single, comprehensive database for all physical therapists and surgeons, the data they collect and analyze will be the same. This is essential because orthopedic surgeons and physical therapists often utilize different assessments to measure postoperative progress (Imada et

al., 2017). This device will provide a platform for consistency between the clinicians and the care they provide their patients.

2.4 Success of Wearable Devices

With regard to this project, the device's success will be determined by accurate data collection and storage. Data is classified as accurate data if it appropriately measures the angle flexion over time, meaning that it is comparable to data collected by using a goniometer, and records the correct number of TKC. This will be examined in the testing phase of this project.

Information collected from the devices, and the way it improves communication between medical professionals and their patients, are important considerations. This will be measured by data collected from the knee brace attachment that is both meaningful and useful to the orthopedic surgeon and physical therapist during patient rehabilitation. A user-centered design and development process ensures patient satisfaction and compliance to achieve the ultimate goal of the devices: to provide beneficial care to the patient (Abras et al., 2004).

3. DESIGN CRITERIA AND PROTOTYPE DEVELOPMENT

3.1 Design Criteria and Specifications

3.1.A Purpose of the Device

The goal of this device is to provide a more comprehensive assessment of home-based physical therapy programs following Total Knee Replacement (TKR). This device records the range of motion and total knee cycles during home-based rehabilitation in order to effectively document and monitor patient rehabilitation effectiveness and progress. This is done through the use of simple analog sensors in collaboration with a digital microcontroller circuit, which records angular displacement. The device consists of a circuit board in a 3D printed encasement. There is a micro USB rechargeable battery that powers the device, with one full charge lasting weeks. This micro USB port also acts as a connection point between the device and the software in order to transfer the collected data. The accumulated data is stored on solid state disc chips as comma separated values (csv) that are then displayed graphically, through the use of biostatistical evaluation methods. The data storage as csv allows for easy uploading to Microsoft Excel or other programs for more in depth analysis, which can be completed on an individual basis if desired.

3.1.B Design Constraints

The device's design is confined by the knee brace to which it is attached. Since the device is compatible with any hinged knee brace, it was designed to be small and lightweight so that it can easily be attached to any brace, not impede any motion or add any unnecessary weight to the brace. The circuit measures 86.25 mm x 32.1 mm x 19.85 mm. The device encasement measures 120 mm x 36.5 mm x 23.5 mm. This version of

the device is the testing version to accommodate the more robust circuitry. The final design of the encasement will be 14 mm tall instead of 23.5 mm tall, when the circuit is mass produced instead of pieced together by hand. Further, the piece that is directly attached to the hinge of the knee brace is moveable. It is a circular part with a post that is inserted through the case into the accelerometer which translates the movement of the hinge of the brace to the accelerometer, thus measuring the ROM and TKC.

3.2 Device Design

3.2.A Design of the Circuit

3.2.A.I Circuit Design

The design of the circuit, which was created by Theodore Brown, a student at Tulane University Medical School, is from the latest iteration of the device, which was developed for testing purposes. It was designed to fit the Qduino Mini from Sparkfun. This piece is an Arduino compatible component that consists of many of the necessary components, including most resistors and capacitors, for the device to function. Including this piece into the circuit bypassed the need to assemble the smaller components that were causing errors in the earlier iterations. Further, this component allows for the use of the imbedded profile for the board in the Arduino software, simplifying the associated code. The most notable components on this board are the USB port, power switch, SRAM, battery charger, fuel gauge and LED lights. There are two embedded LED lights. One shows the device's charge status and one is programmable. In the case of the subject device, the second LED light indicates when it is it operable. The battery charger connects to a lithium ion battery, which allows the device to be used for

an extended period of time while the battery gauge monitors the amount of battery left on the device. The SRAM, or static RAM, component allows for on-board memory. The power switch is responsible for turning the device on and off. The USB port is one of the most notable components of this project's board. In the older iterations of the circuit board, the USB port would constantly break off partially or completely, causing a disconnect between the board and the software, so data could not be uploaded (Sparkfun, Qduino Mini, n.d.).

The other significant components of the circuit board that are not included in the Sparkfun piece are the SD card, integrated clock, battery coin cell and associated battery, accelerometer and rotary sensor. The rotary sensor is essential in measuring the angle of the range of motion of knee flexion. The piece used is Bourns rotary position sensor. The rotor shaft sits in the D-shaped hole and rotates the movable portion of the sensor as the knee flexes or extends. The accelerometer, which is manufactured by STMicroelectronics, measures the acceleration in the x-,y-, and z-directions. This data is integrated into the associated code. The battery cell holder is manufactured by MPD and houses a battery cell that provides power for the device when it is not connected to a power source. The incorporated clock, which is from Maxim Integrated, allows the device to keep track of time, which is utilized in the code in order to monitor progression over a specific amount of time. Lastly, the SD card holder, manufactured by Molex, holds an SD card which is the on-board memory source for the acquired data. The Kicad diagram and schematic of the testing iteration of the circuit board can be seen in the schematic included in Appendix B.

3.2.A.II Constructing the Circuit

Each iteration of the circuit was built in a similar fashion. The circuit board itself was fabricated by OSHPark. As seen in Figure 5, the circuit board has pin holes and pads in order to solder each component of the circuit to the board.

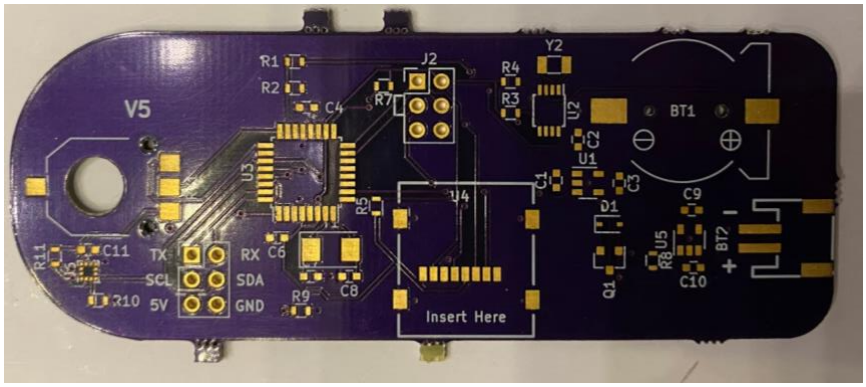

Figure 5. Older iteration of the circuit board fabricated by OSH Park, before applying any of the components

For the first two iterations of the circuit board, each individual component was soldered onto the board separately. This was completed with the help of a stencil from OSH Stencils (Figure 6).

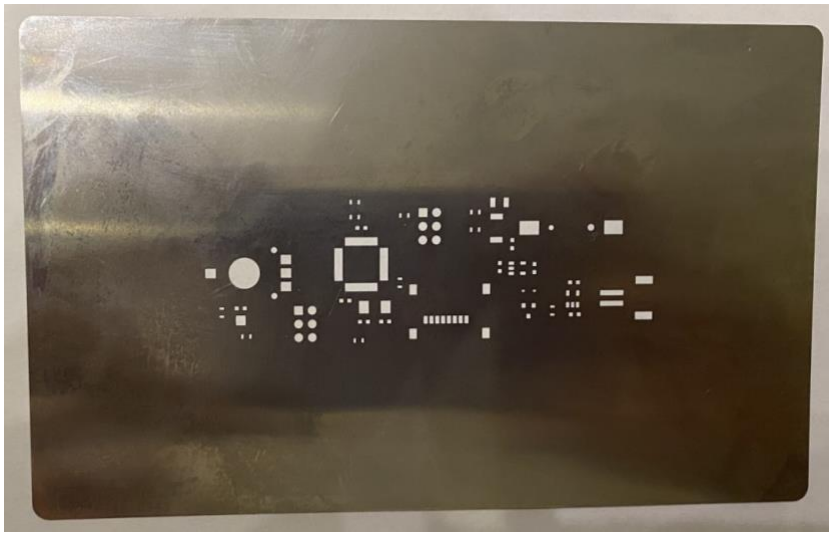

Figure 6. OSH Stencil of the older iteration of the circuit board

The circuit design was uploaded to the program, and the result is a thin metal sheet that has cutouts of the pads where solder is needed. This metal sheet is laid over the circuit board, as seen in Figure 7. Solder paste is applied over the stencil and spread into a thin layer using the solder paste spreader, as seen in Figure 8.

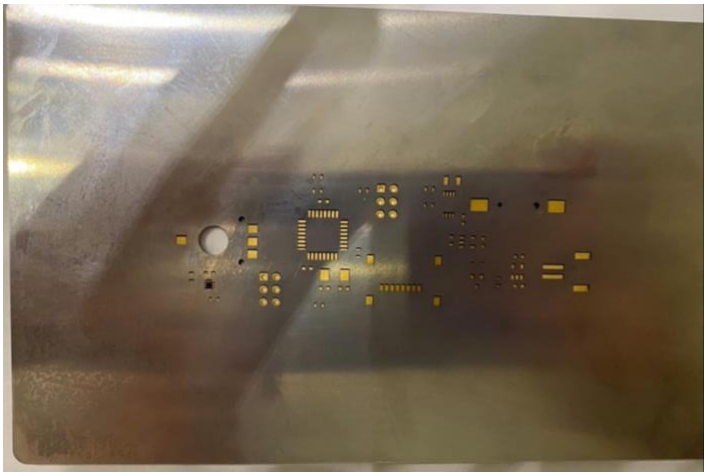

Figure 7. OSH Stencil overlaid on the circuit board, revealing the gold pads that require solder paste

Figure 8 Stencil on top of the circuit board with the solder past in the syringe with the accompanying solder paste spread that was utilized to evenly spread the solder paste across the stencil

Once the solder paste was applied, the stencil was removed and each component was placed onto the board using tweezers. The solder paste was activated by the use of a heat gun, and each component was soldered to the board. This was a very tedious process not only because the components are so small, but also because there is no simple way of ensuring that each component is properly soldered to the board and, therefore, working as a part of the circuit. Each component was checked with the use of a voltage meter. If there was no voltage running through the component, it was replaced or resoldered. There were multiple builds of the first two iterations of the circuit board since so many of the components broke. So, using the voltage meter became an impractical process whenever the circuit board stopped working. There were so many components to check and it was never fully clear if the component itself did not work or if it was not properly connected to the board. Due to this, the third iteration of the board was designed.

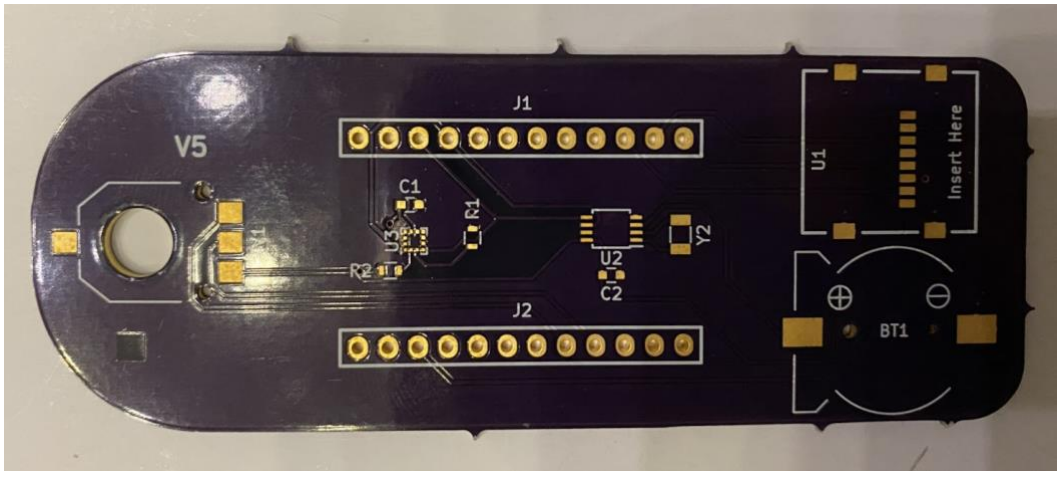

Figure 9. Circuit board for the third iteration before any components were attached.

This iteration utilizes a bulk piece in the center of the board that contains most of the small components- capacitors, resistors as well as the micro USB and power switch. The same procedure that was used to build the previous circuit boards was implemented for building the testing iteration. It was a less complicated process, however, because fewer components needed to be individually soldered onto the board.

3.2.B Design of the Encasement

I designed the medical device's encasement around the circuit. It is composed of both a top and bottom piece. The bottom piece is connected to the knee brace. The outer side of the case (Figure 10) has a strong velcro strap (see Figure 25) to attach it to the knee brace. The inner side of the bottom piece (Figure 11) has three projections which are for simple flat head screws that connect the top and bottom pieces of the case. This side also has a smaller projection in the middle, which serves as an anchor point for the circuit board.

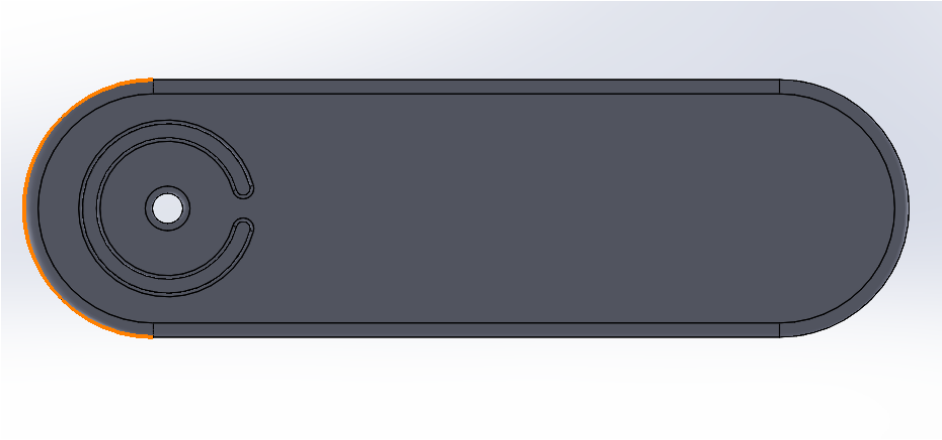

Figure 10. The Outer Side of the Bottom Piece of the Encasement

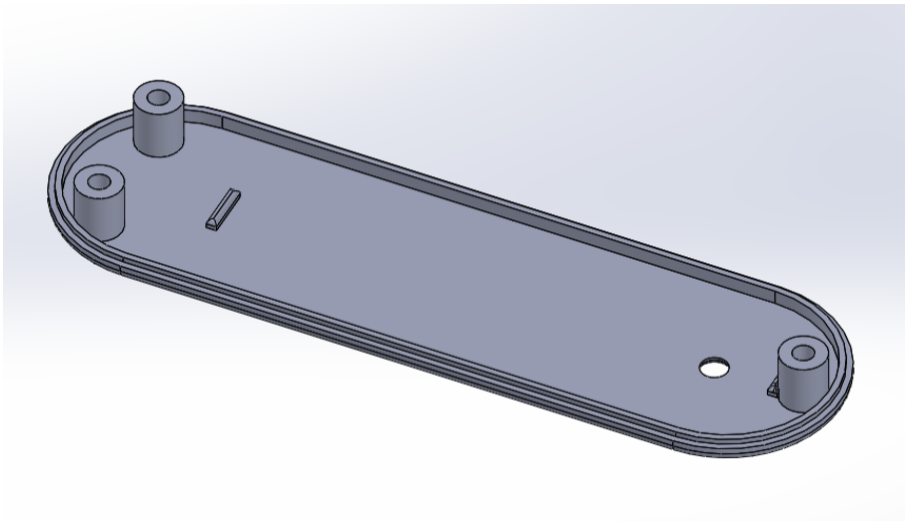

Figure 11. The Inner Side of the Bottom Piece of the Encasement

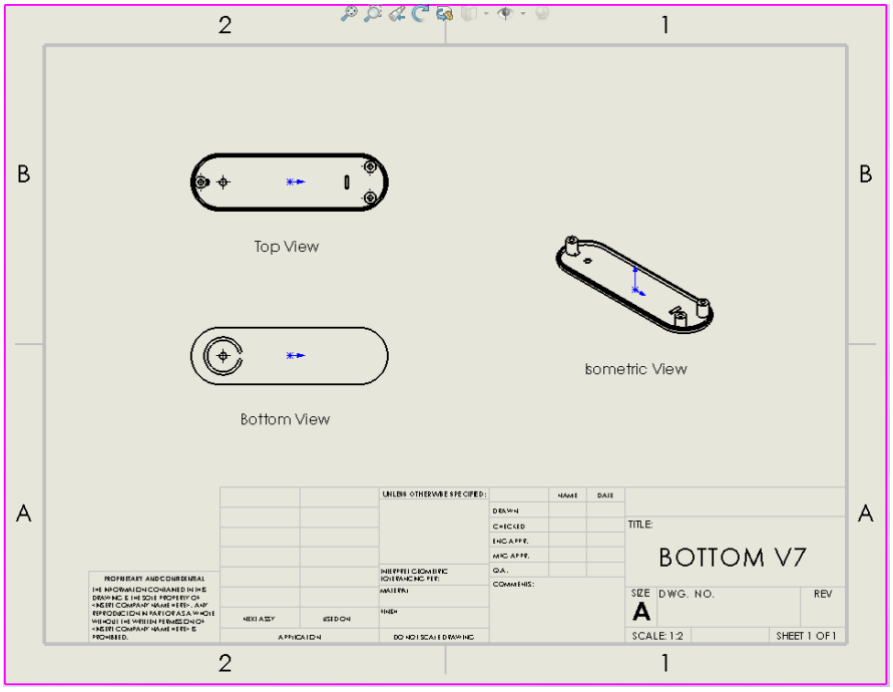

Figure 12. Drawing of The Bottom of the Encasement

A rotor shaft (Figure 13) lies on the outer side of the bottom piece and connects to the hinge of the brace. The shaft of this piece lies in the hole in the bottom piece of the encasement and continues through the D-shaped hole in the accelerometer on the circuit board of the device.

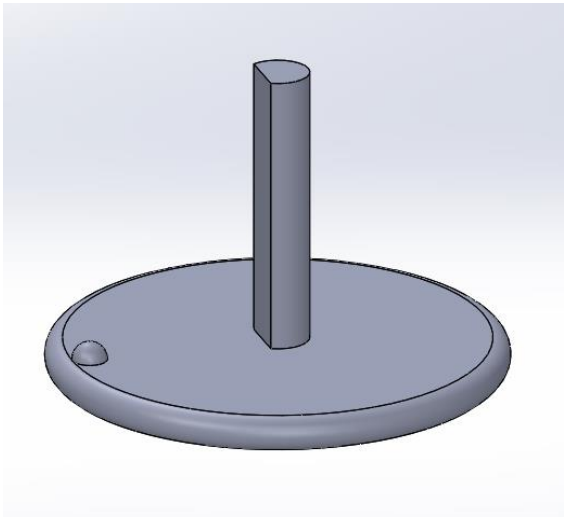

Figure 13. Underside of the Rotor Shaft

This rotor shaft follows the circular path (seen in Figure 10). There is a small projection (see Figure 13) on the underside of the moveable piece that sits in the indentation on the bottom of the case. This path is not 360°. This is because there is a "dead zone" in the accelerometer. If the accelerometer completes a full 360° rotation the data becomes skewed. The incomplete circle path that the rotor shaft follows inhibits the moveable piece which allows for accurate data. The measurements of the case are 120 mm x 36.5 mm x 23.5 mm. The current version of the top of the case is version ten (Figures 14 and 15). The holes on the top of the case are the insertion points for the screws.

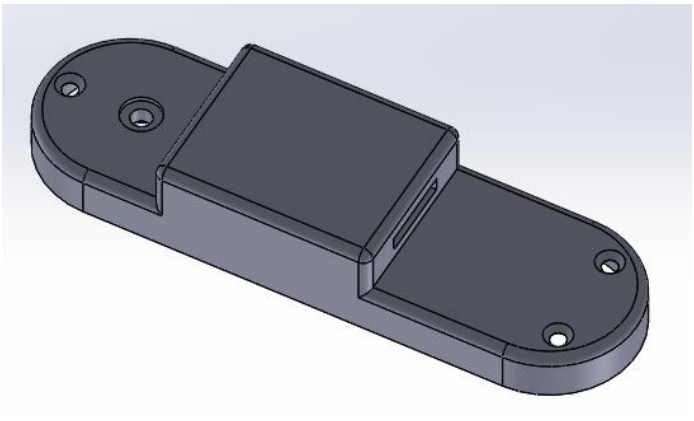

Figure 14. The Outer Side of the Top of the Case

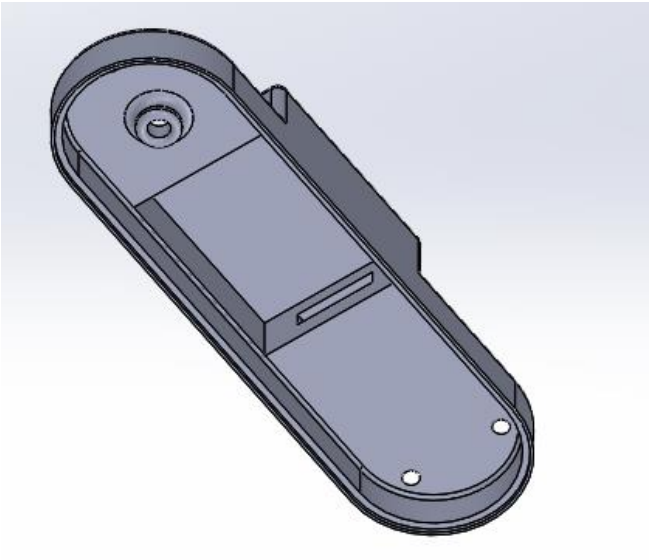

Figure 15. The Inner Side of the Top of the Encasement

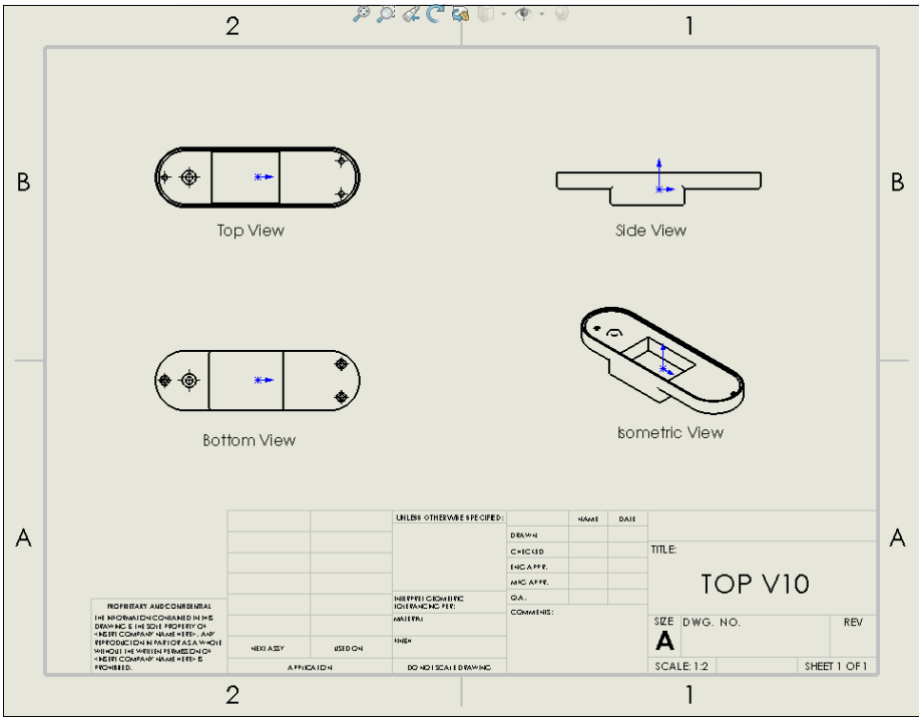

Figure 16. Drawing of the Top of the Encasement

Iterations six through ten of the top of the case account for the testing version of the circuit. Since this version of the circuit has an attachment that has a greater height than the rest of the circuit board, the encasement has a large protrusion in the middle to accommodate this piece of the circuit board. This projection has a slit in it to provide access to the power switch and USB port. The original iterations of the top of the case had a flat top and had the USB port on the side, so there was an opening on the side, as seen in Figure 17.

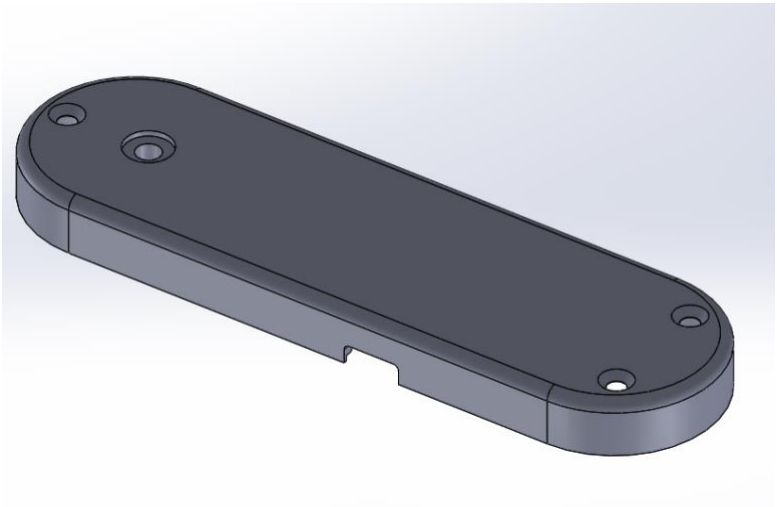

Figure 17. Outer Sider of Top of the Encasement- Old Iteration

3.2.C Prototype Development

The circuit board was designed on Kicad, an open source software used to design circuits. Each component was laid on and soldered to the board by hand. The first iteration of the circuit was comprised of individual components. This resulted in a tedious fabrication process. Further, since each piece was individually connected to the circuit board, when an error was encountered, each piece had to be separately tested for performance and accuracy. This was not only time consuming, but also not always successful. This resulted in deconstructing the board and reconstructing it with new pieces. Additionally, during the fabrication process and testing of the first iteration of the board, many pieces broke completely. As a result, the second iteration of the circuit includes a factory-made bulk piece which consists of most of the pieces of the board and also includes the power switch and USB connection port. The bulk piece is a more durable component since it includes all of the necessary pieces for the device to perform accurately and effectively. While this piece makes the circuit somewhat bulkier, it makes it far more reliable for the testing process and easier to apply to the board. In addition to

the bulk piece, the SD card, battery and accelerometer need to be soldered by hand individually. Ideally, when the testing is complete and verified, the circuit will not be manufactured by hand, which should allow for a more compact version.

I designed the encasement using SolidWorks, a three-dimensional computer-aided design software. The top and bottom pieces were designed separately, with the same design constraints, based on the size of the circuit board. These two pieces are designed to snap together. While the tolerancing of the design ensures that the top and bottom pieces of the case stay together, they are completely secured using three simple flat head machine screws. The SolidWorks design was exported and then uploaded to Ultimaker Cura which allowed each iteration of the case to be 3D printed using the Ultimaker 3 3D printer. The different iterations of the encasement were constructed to be toleranced more reliably, fit the hardware better, or accommodate updates to the circuit board.

During the printing process, there were multiple printed encasements that failed due to printer error. One print had a failed wall (Figure 18), numerous prints had uneven printing on the outside (Figure 19) and, due to different printing setting, some of the encasements had different infills. This resulted in cases with different strengths, some of which are unsuitable for the durability of the device.

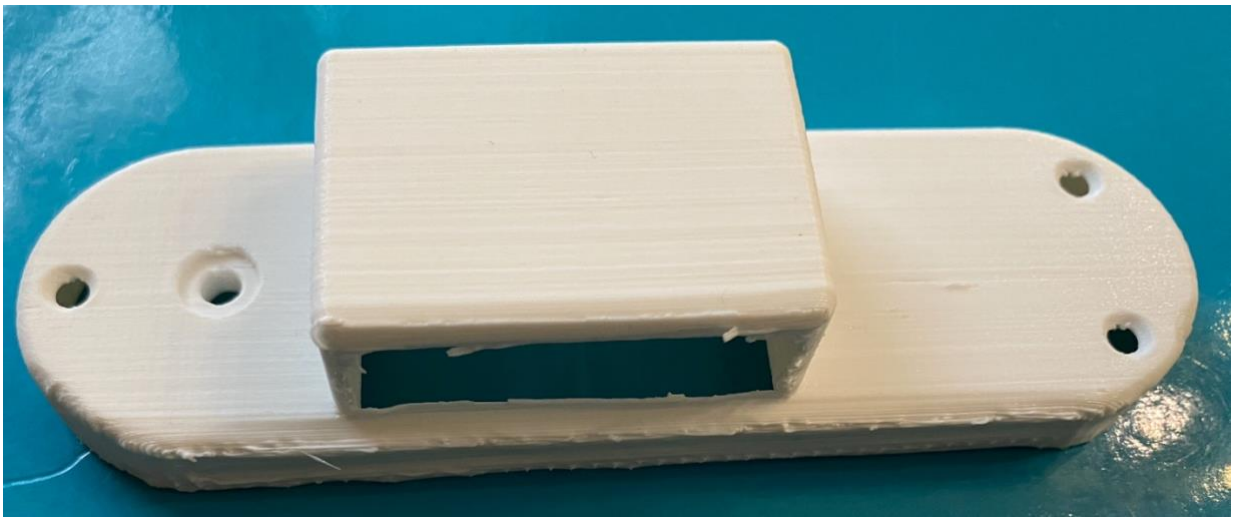

Figure 18. Printed Encasement with Failed Wall

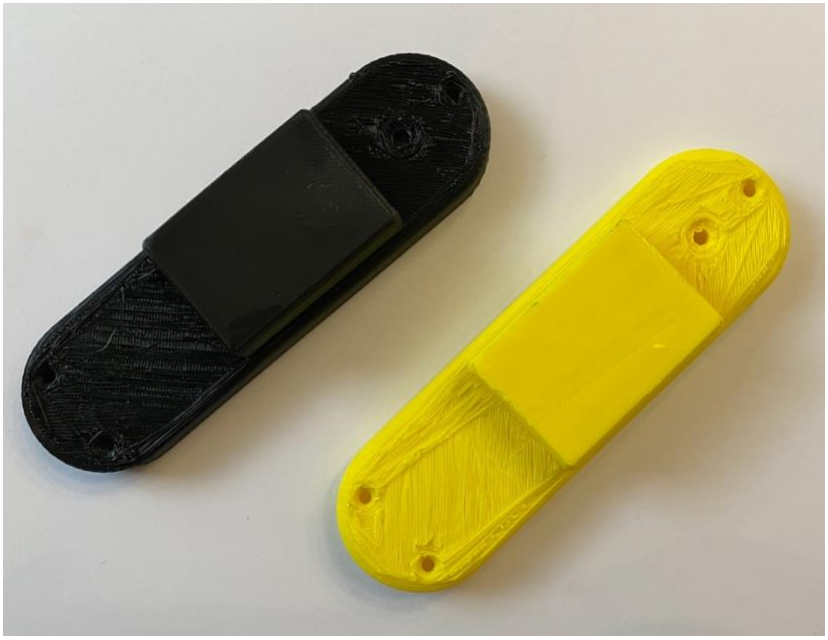

Figure 19. Printed Encasements with Uneven Print Job

3. 3 Data Collection

The data that is collected is the angular displacement of the hinge of the knee brace, which measures the range of motion. This collected data is stored on solid-state disc chips and stored as comma separated values (csv). A solid-state storage disc is a chip data storage mechanism. This storage mechanism requires less power and is faster than its hard disk drive

counterpart (Micheloni et al., 2012). The stored csv data contains date, time and angular displacement. This data is transferred to the computer program through the USB port connection. The device is connected to both an Arduino code and a Python code. The Arduino code has a user interface that allows one to check the battery of the device, see the stored data, and wipe the data if and when desired. The Arduino code is written into the Python code, so the Python code is able to retrieve the uploaded data. The output of the Python code is a graphical representation of the angular displacement of the knee over time. This graph allows clinicians to see the effectiveness of patient rehabilitation by tracking the progress of angular displacement. This angular displacement corresponds to knee flexion, which is an important metric measured following TKA. Additionally, the uploaded data can be analyzed on other platforms to review and evaluate certain timeframes or specific events of angular displacement.

4. PROTOCOL AND PERFORMANCE EVALUATION

4.1 Device Accuracy: Manual Testing

4.1.A Manual Testing Configuration

The purpose of this device is to measure the range of motion (ROM) and total knee cycles (TKC) of a patient during at-home rehabilitation following a total knee arthroplasty. It is essential that the device accurately measures ROM and TKC to ensure that reliable data about the patient's progress is provided to clinicians. The initial step in performance evaluation of the device is to determine that the data recorded by the device is accurate.

A rotor shaft incrementally rotates around a unit circle to measure the accuracy of the device. The unit circle covers the surface of the bottom piece of the case, with a cutout in the center of the circle so the case lays flat. This is executed by manually rotating the rotor shaft along the path on the outer side of the bottom piece of the case. A unit circle will cover the surface of the bottom piece of the case, with a cutout in the center for the rotor shaft to lie. The unit circle is lined up according to the path on the case- zero degrees is at the beginning of the path. The rotor shaft is then manually rotated along the path of the circle. The designated angles are 45°, 90°, 120°, 180°, 240°, 270° and 300°. At each increment, as indicated by the placement of the arrow on the rotor shaft piece, the rotor shaft will pause for a moment and then continue.

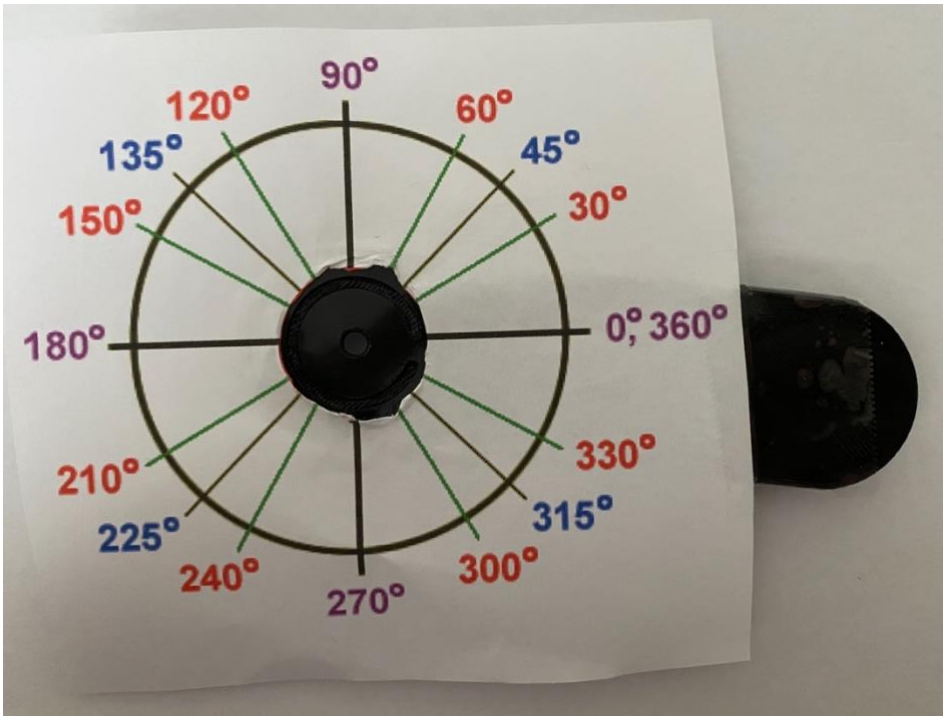

Figure 20. Unit circle overlaid on the case with zero degrees at the beginning of the path

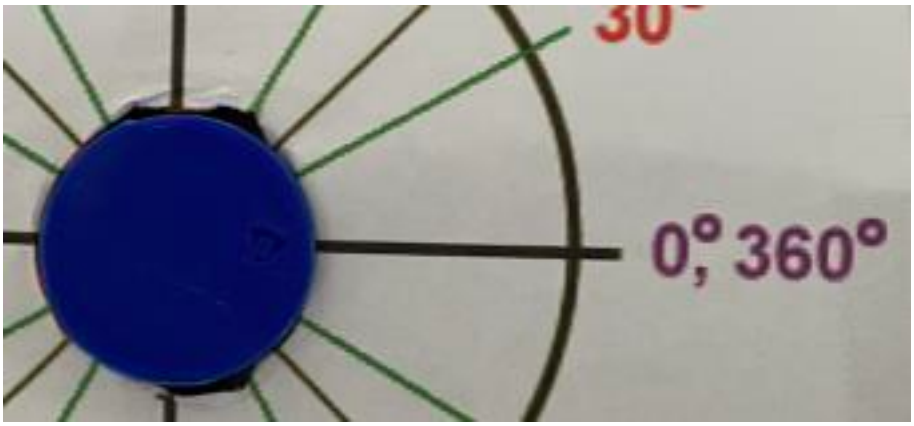

Figure 21. Close up of the unit circle overlaid on the case with the rotor shaft in place with the arrow at zero degrees.

4.1.B Manual Testing Protocol and Evaluation

To measure the accuracy of the device, the rotor shaft is incrementally rotated according to the unit circle. The rotor shaft returned to zero at the beginning of every trial. Data points were collected from each graph. The specified area was selected using

the zoom tool, and the data point that represented the determined angle was identified and recorded. The results are recorded by the device and displayed graphically, as seen in Figure 22.

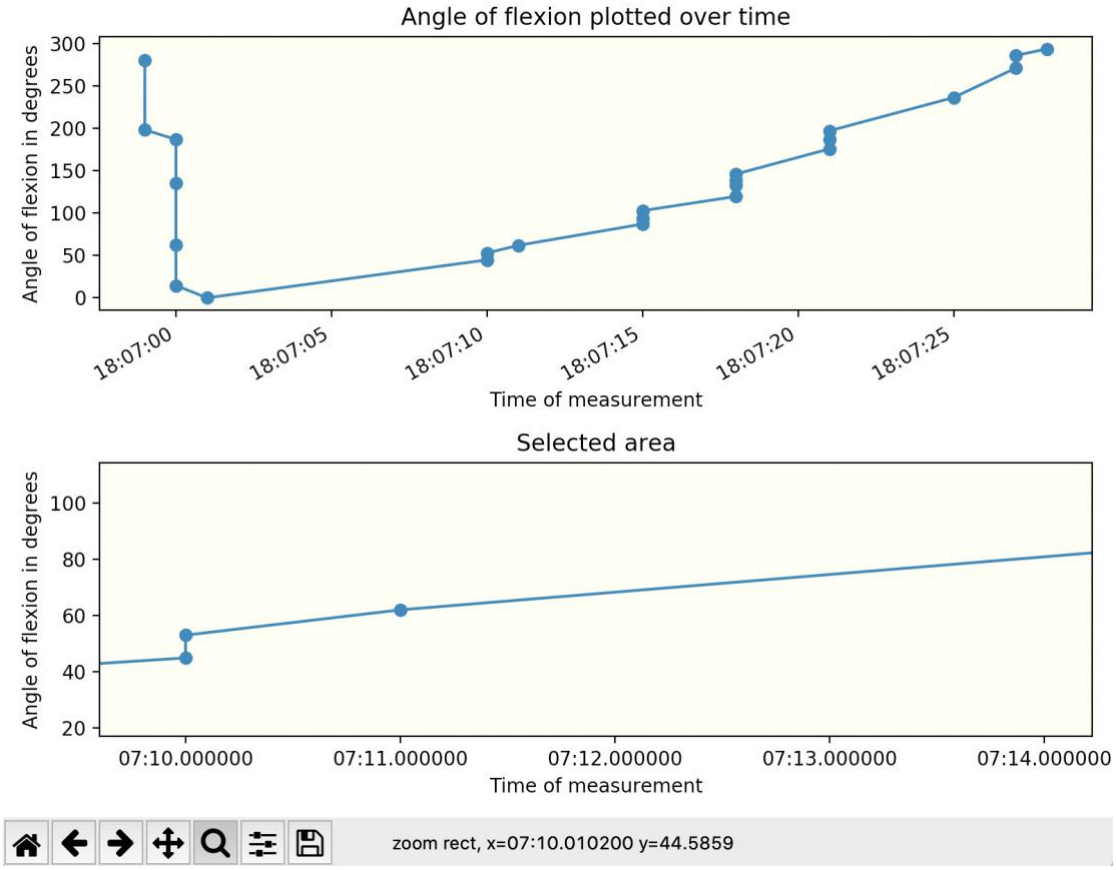

Figure 22. The graphical representation of a manual trial of device accuracy

This procedure was followed 75 times.

- 30 trials produced accurate, usable data
- 29 trials produced flawed data
- 16 trials resulted in errors in the Python code.

Accurate, usable data is defined by data that represents the actions performed in the procedure, with results as seen in Figure 22. Trials that produced improper graphical

representation of the procedure were classified as flawed data trials. These trials resulted in graphs that either showed only one collected data point (Figure 23) over years, instead of as a function of seconds, or multiple data points that do not accurately depict the range of motion of the device (Figure 24).

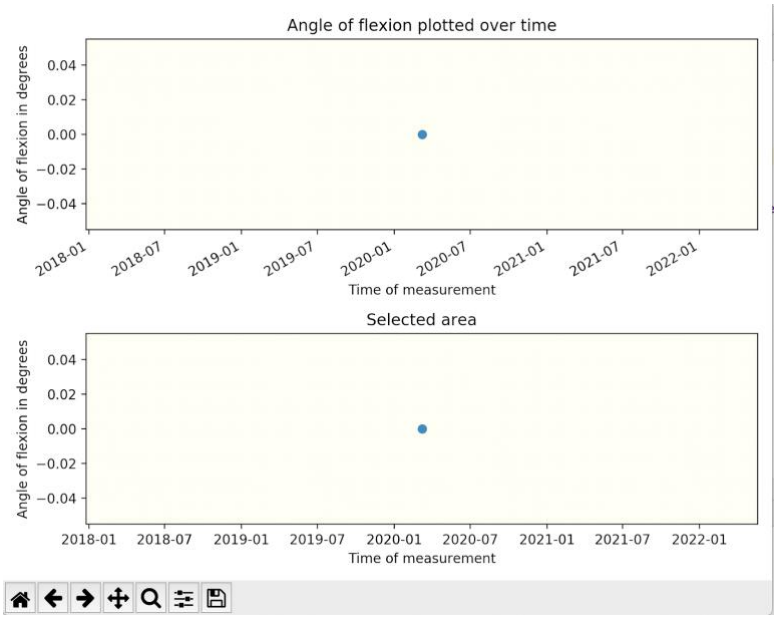

Figure 23. Singular data point collected from a flawed data trial

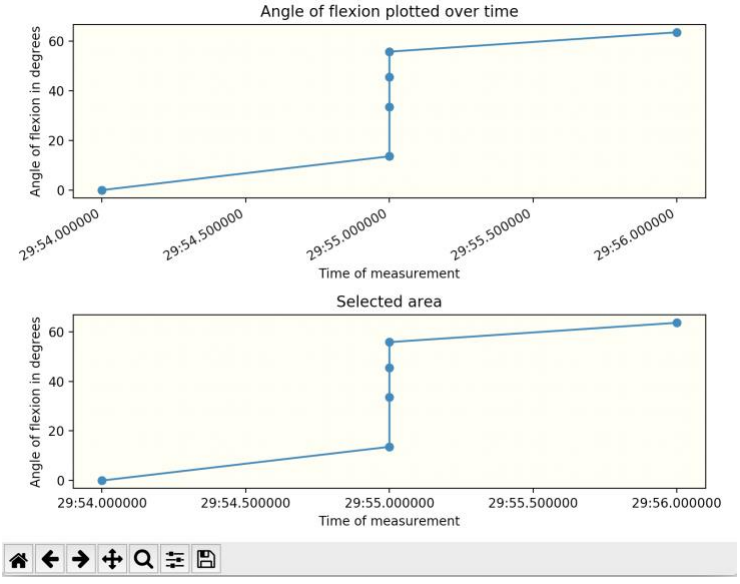

Figure 24. Graphical representation of a flawed data trial

These errors that caused the graphs in Figure 23 and 24 are due to errors in the Python code. Currently there is no restriction on the scope of the graph to a desired time, which is a flaw in the code and a possible reason for the improper time scale. Further, since multiple measurements taken on the same day are close to one another and distant from measurements taken another day, the data is condensed to one point or line. This is something that needs to be fixed in order to monitor data over a longer period of time.

When it was manually rotated, accuracy of the device was calculated based on the 30 successful trials. There was an average of 1.68% error for all of the collected data points, a sample of which can be seen in Table 1, with the full data in Chart 1 in Appendix A.

		Expected Value (°)							
		0	45	90	120	180	240	270	300
Trial #	1	0.416	44.6	93.3	119	187	236	276	294
	2	0.019	29.2	86.1	120	187	228	275	303
	3	0.169	38.4	94.5	117	182	237	269	296
	4	0.060	51.0	84.8	118	174	230	262	N/A
	5	0.125	45.0	78.9	119	174	231	270	309
	6	0.0863	40.6	106	122	168	243	267	301
	7	0.0313	29.2	83.3	118	175	236	275	N/A
	8	0.00151	40.7	89.8	121	184	226	263	297
	9	0.0881	44.7	76.8	122	182	251	267	302
	10	0.0211	44.2	88.1	121	183	232	274	307

Table 1. Acquired data from 10 trials of the accuracy testing of the device.

The sources of error are due to the device design and human error. Because of the projection on the underside of the rotor shaft, it is difficult to precisely rotate the shaft for every trial. This is due to the fact that the manufacturing of the rotor shaft, and the small piece of the projection, is unreliable. It is a small piece, so the projection does not fit into and slide along the path as smoothly as needed. Also, the ambiguity of the arrow on the top of the rotor shaft causes error because it is not detailed enough to precisely point to the desired angle. These two factors can cause inconsistencies in the angle that is recorded by the device.

Human error also factored into the placement of the unit circle diagram overlaid on the device. If it was not perfectly placed, with zero degrees at the start of the path, each incremental rotation would be incorrect and produce a faulty reading. Additionally, according to Bourns, the manufacturer of the piece, the rotary position sensor on the device has a +/-2% linear specificity, which accounts for potential manufacturing errors. The velcro that is used to attach the device to the hinge system also presents a source of error, mostly because of the connection between the rotor shaft and the hinge. This is because the velcro limits the freedom of the rotor shaft, causing inconsistent rotation. The hook and loop laxity of the velcro allows the rotor shaft to lift, enabling it to move outside of its path and into the dead zone of the rotary sensor. The flaws in the recorded trials, the collected data showed promising consistency.

4.2 System Testing

4.2.A Pre-Clinical Application Testing

The next step in testing is to apply the device to the hinge of a knee brace and record its accuracy by the measurements of a goniometer. The hinge of the brace will not

be attached to the knee brace, and instead, will be manipulated manually. This is because the way in which the knee brace is worn each time can introduce a source of error, as application of the brace to the leg can differ with each use which could then result in incorrect measurements by the device (Berthelot, personal communication, 2020).

The device is attached to the rigid support of the knee brace with velcro, as seen in Figure 25. A small piece of velcro is attached to the rotor shaft (Figure 25a), which aligns with a piece of velcro on the hinge, while a larger piece of velcro is on the case of the device, which aligns to a piece of velcro on the rigid support of the hinge piece, as seen in Figures 25 and 26.

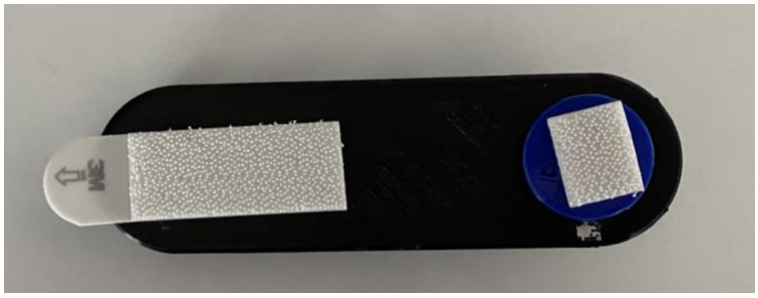

Figure 25. Velcro on the bottom of the case that connects to the velcro on the hinge

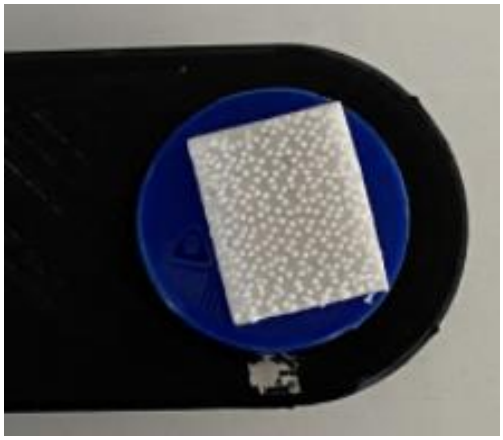

Figure 25a. Velcro on the rotor shaft that connects to the velcro piece on the axis of the hinge system (Figure 7a)

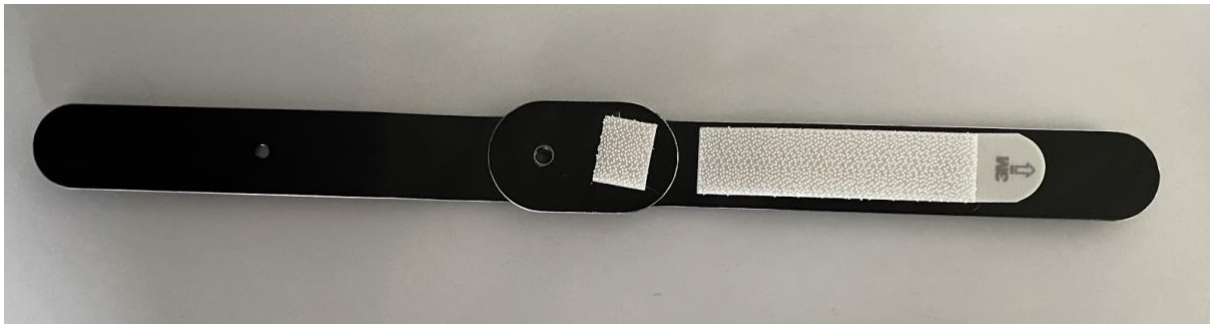

Figure 26. Velcro on the hinge system that connects to the velcro on the encasement

Figure 26a. The velcro on the axis of the hinge system that connects to the velcro on the rotor shaft

4.2.B Testing Using the Goniometer- 90° and 120°

In order to test the device in a pre-clinical method, the case is secured to the rigid hinge system from a postoperative knee brace. The bottom of the case is attached by the velcro straps to the portion of the hinge system which would align with the patient's femur when the knee brace is donned and the rotor piece is connected to the hinge (Figure 27).

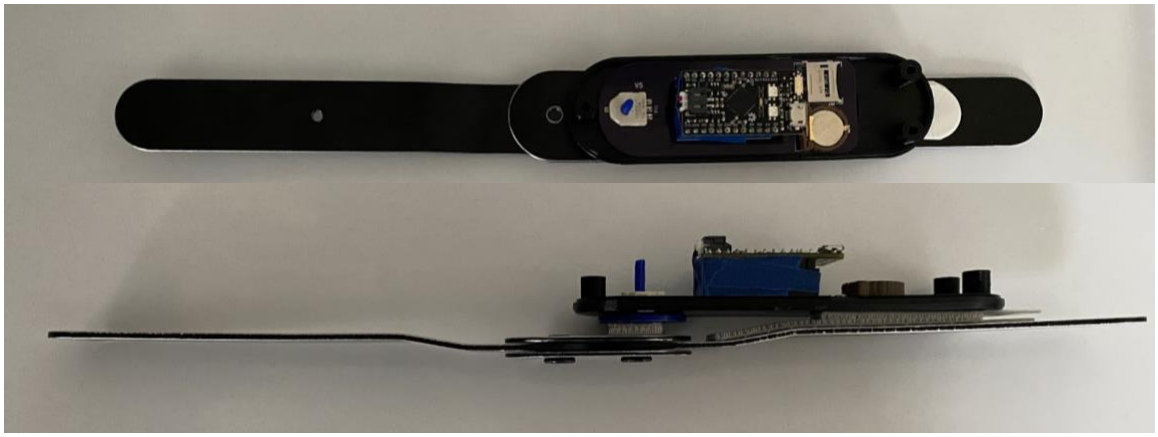

Figure 27. Top and side views of the device attached to the hinge system

Figure 27a. Device attached to the hinge system, which sits in the knee brace

Figure 27b. The device (with the top and bottom of the casing employed) attached to the hinge system, which sits in the knee brace which is worn on a subject's leg

The goniometer is the industry standard device used by physical therapists and clinicians to measure ROM. The device trials are completed as the hinge system is overlaid on a goniometer. Full extension of the hinge system is zero degrees. The goniometer was positioned at a specified angle for the first and second rounds of testing, 90° and 120°, respectively. The angle was maintained throughout each round of testing. The body and stationary arm of the goniometer aligned with the femoral side plate of the hinge system at zero degrees (full extension), while the moving arm was rotated to the desired angle, as indicated by the center axis lines on the moving arm. The hinge system starts at full extension, as seen in Figure 28. The fibular component is then manually

rotated until the centerline aligns with the centerline of the moving arm of the goniometer as seen in Figures 29 and 30.

Figure 28. Starting position of the brace and device at zero degrees while the goniometer is angled at 90°

Figure 29. Device overlaid on goniometer bent at 90°

Figure 30. Device overlaid on goniometer bent at 120°

This protocol was followed first with the goniometer at a 90° angle of flexion and then repeated at 120°. These angles were used because patients must be able to bend their knee to 90° in order to be discharged following their surgery (Hancock et al., 2018) and 120° is a benchmark measurement during rehabilitation (Berthelot, personal communication, 2020). For each trial, the hinge system was angled to the specified angle (either 90 or 120°) five times. After each trial, the device was connected to a computer, the data was uploaded and displayed graphically.

4.2.B.I Testing at 90°

The procedure was completed in three sets while the goniometer was measuring 90°. The first set consisted of 42 trials; 59.5% of the trials produced improper data, while the other 40.5% of the trails resulted in an error message from the code, with no acquired data. The 25 trials that produced flawed data

were labeled as improper because the data displayed either as one point (similar to Figure 23), had an incorrect number of peaks or inconsistent height of peaks (Figure 31).

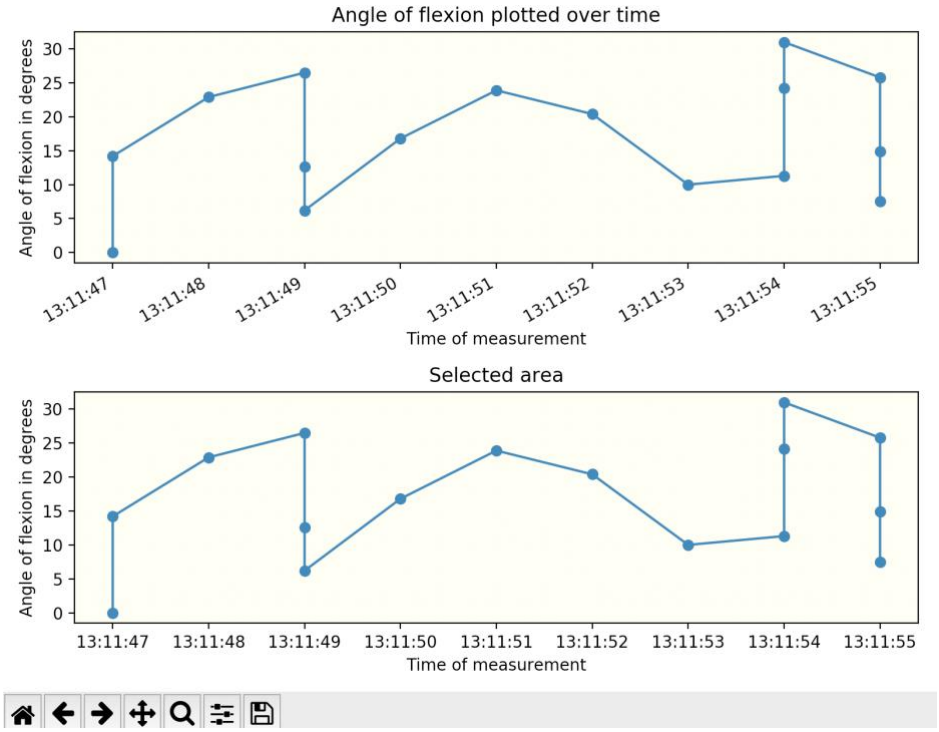

Figure 31. Flawed data from a trial with the goniometer at 90°

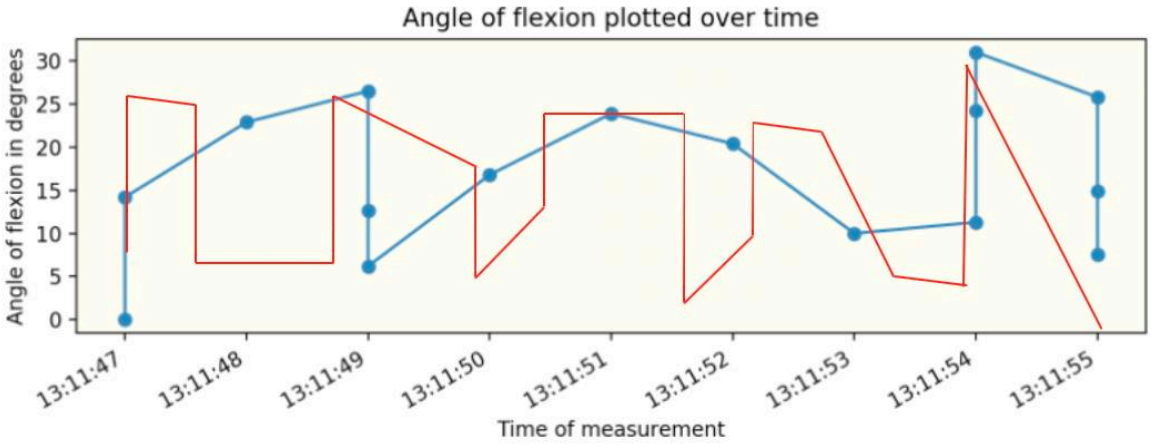

Figure 31a. Flawed data (blue) from a trial with the goniometer at 90° with usable data (red) superimposed

Each graph should have displayed five peaks, as depicted by the red line in Figure 31a, with one peak per rotation of the hinge. This was not shown in the improper data trials; thus, they were labeled as improper data.

While the second set of trials was completed in the same manner, the device was turned off and then back on after the data was collected and the log was cleared. The apparatus was not turned off after an error message was displayed. This set consisted of 30 trials: 10 produced usable data (Figure 31), 10 produced error messages and 10 produced flawed data. The flawed data trials typically followed the trials in which an error message was displayed. Usable data is defined as data collected from a trial that produces a proper graphical representation of the procedure, a sample of which is shown in Table 2.

		Peak #				
		1	2	3	4	5
Trial #	1	19.1	21.6	21.7	20.4	19.1
	2	27.2	31.4	27.0	26.9	30.0
	3	32.5	19.2	21.0	26.0	27.1
	4	21.2	24.3	20.2	20.2	18.0
	5	19.4	14.5	11.2	21.5	12.4
	6	12.1	11.9	17.4	9.53	16.6
	7	19.9	23.1	19.8	21.0	19.9
	8	22.3	21.0	19.5	20.2	9.35
	9	17.0	16.2	18.4	22.3	25.8
	10	21.8	21.4	19.6	19.3	24.4

Table 2. Sample data from the testing of 90° flexion

This led to the third set of testing at 90°, in which the device was turned off and on, and the data log was wiped, after every single trial. This set consisted of 16 trials: 10 produced usable data, 4 produced error messages and 2 produced flawed data. Although this set provided the greatest percentage of usable data, one of the intended functions of this device is to record data over time. Therefore, having to clear the data log in between data collections is inefficient and problematic. This is because every time the data log is cleared, the stored data is lost and can no longer be evaluated, separately or in comparison to newly collected data.

Overall, 88 trials were completed through the three sets with the goniometer bent at 90° and only 20 produced usable data, seen in Chart 2 in Appendix A. Usable data is defined by the trials which produced consistent data for each peak, with the proper number of peaks represented graphically, as seen in Figure 32.

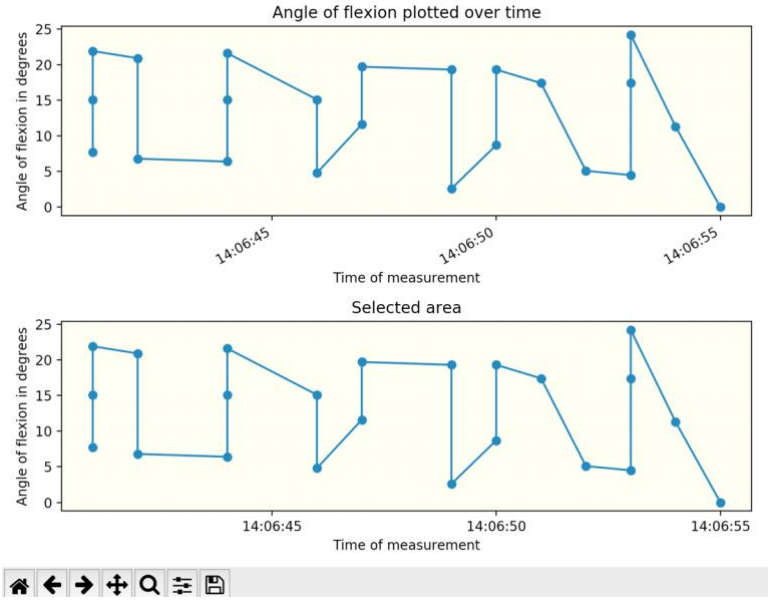

Figure 32. Usable data from a trial with the goniometer bent at 90°

This graphical representation of one trial shows five consistent peaks, one for every manipulation of the hinge as it was bent to 90°. The differing shapes of the peaks represent the varying time each manipulation took. The usable data was analyzed collectively. The average recorded angle from the 20 trials, with 5 cycles each, is 20.3°.

4.2.B.II Testing at 120°

The goal of testing with the goniometer at 120° is to measure and record accuracy and consistency. The procedure was completed in two sets. Both sets followed the protocol of the third round of testing at 90°. The device was shut off and turned back on after the data was collected and wiped from the previous round.

The first set consisted of 14 trials: 10 usable data trials (seen in Table 3), 2 that produced error messages and 2 that produced flawed data. Again, the flawed

data trials typically followed the trials that produced the error messages. The second set consisted of 12 trials: 10 that produced usable data and 2 that produced error messages. The number of trials in each round was determined by the amount of trials it took to collect usable data from 10 trials in order to match the 20 trials of usable data from the 90° testing. As with the 90° testing, the 20 trials of usable data were analyzed collectively. The average recorded angle was 28.9°, with the full data set shown in Chart C in Appendix A.

	Peak #					
		1	2	3	4	5
Trial #	1	29.6	28.9	20.3	14.2	20.9
	2	27.5	28.6	29.6	29.6	28.6
	3	24.6	22.4	20.4	17.0	22.1
	4	27.1	27.2	28.3	24.4	21.3
	5	24.0	29.6	29.5	28.7	29.1
	6	29.2	30.8	27.2	30.3	31.1
	7	34.5	37.9	40.9	32.1	37.7
	8	26.6	27.3	37.0	40.6	37.0
	9	33.9	30.8	31.6	29.1	28.0
	10	34.6	35.1	36.4	32.4	33.8

Table 3. Sample data of 10 usable data trials from the testing of 120° flexion

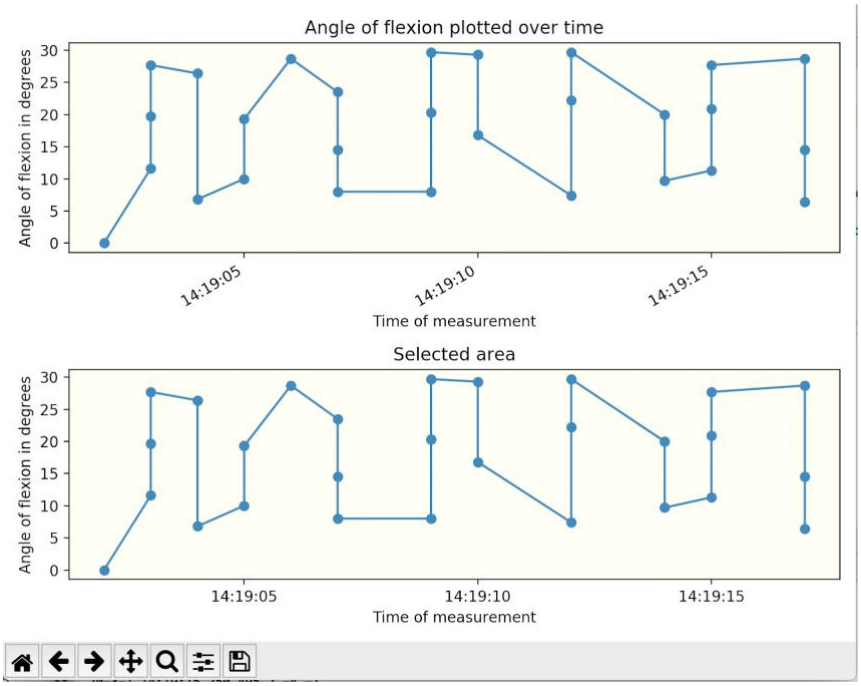

Figure 33. Usable data from a trial at 120°

4.2.B.III Results and Analysis

The average angles from the 100 data points collected for both the 90° and 120° trials showed that the device does not measure the full angle of the bent hinge. This is because there are actually two hinges. There is a hinge axis where the femoral portion of the brace meets the hinge piece and a hinge axis point where the fibular portion of the system meets the hinge piece (Figure 26). Due to the placement of the rotor shaft on the device, as seen in Figure 8, the rotary sensor only measured the angle of rotation of the femoral hinge portion. This is sufficient to measure clinical activity. The two hinge brace is used because the separate axis points can be adjusted with the use of pins to restrict ROM for different knee surgeries. This device is designed around this knee brace system,

rather than designing a completely new single hinge brace to accompany the device.

An additional goal of the trials performed at 120° was to determine the accuracy and consistency of the multiplication factor determined from the trials performed at 90°. The average recorded angle of the 90° trials: 20.3°. That produces a multiplication factor of 4.43. The average angle from the 120° trials is 28.9, which results in a multiplication factor of 4.16. The difference in the multiplication factor between the 120° trials and 90° trials is .27. Thus, the multiplication factor is not consistent enough between the two angles to show that the device itself is reliable when it comes to measuring and recording ROM on the brace. The other goal of the brace, however, is to measure TKC, which it does properly in usable data trials. This is displayed by the correct number of peaks in each graph of a usable data trial, as each peak represents a single cycle of the knee.

5. DISCUSSION

This project examined the design and development process of creating a wearable medical device through the creation of an attachment for a postoperative knee brace following total knee arthroplasty. Through the design and testing phases of the device, the intended uses of the device were evaluated. The goals of this device that were assessed include accurately recording patient range of motion (ROM) and total knee cycles (TKC) to monitor patient rehabilitation progress. Based on the circuitry and associated encasement design, this device should have correctly, continuously and consistently monitored these elements. However, through the testing completed to date, this was not the case.

In total, the device went through 189 testing trials- 75 for rotation accuracy and 114 for simulated knee flexion accuracy. Of these 189 trials, only 70 produced usable data. That is a 37% overall success rate, which shows a lack of consistency. The usable data from the rotation accuracy trials confirmed the accuracy of the device components, with a 1.68% error across 210 data points. While the device was not reliable in collecting usable data across all trials, the usable data was accurate and consistent. Conversely, the usable data collected from the simulated knee flexion trials was not the expected angle values. For both the 90° and 120° rounds, the average measured angles were in the 20° range. This shows that when the device is applied to the hinge of a knee brace, external influences cause error in the collected data. Although the usable data was not consistent with the reading of the goniometer, it was consistent between sets. Therefore, it can be useful in measuring progress by monitoring change in over time. This progress would not be quantitative, as the angle of flexion is incorrect, but the TKC and changes in peaks over time could provide clinicians with a sense of progress patients are making.

The device was most consistent and accurate when the data log was cleared in between trials and the device was turned off and back on. This shows that while the device is meant to be a continuous monitoring system, it performs best when it is reset before collecting new data. This would be problematic in a clinical setting, because the goal of the device is to show patient progress. If the device is incapable of collecting correct data over an extended period of time, progress cannot be monitored.

Both device design and human error are sources of inaccurate data. The design of the rotor shaft introduced potential errors during data collection because the projection on the underside of the piece does not reliably sit in the path on the bottom of the case. This is due to manufacturing error. Since the small piece was 3D printed, it does not fit into the path as precisely as it should. This causes a data acquisition error when the projection moves outside of the path and causes the rotary sensory to move into the "dead zone," which produces an error in the code. Human error also factors into inaccurate data caused by the rotor shaft. The rotor shaft is attached to the hinge of the knee brace by a separate piece of velcro, and thus requires extreme precision when it is attached. If the projection is not at zero degrees on the brace when it is attached, the calibration of the device will be incorrect, and all data collected will be skewed. Additionally, if the placement of the rotor shaft is incorrect, the projection could start in the "dead zone" so no data will be recorded. The velcro also introduces a force pulling the rotor shaft away from the case, which can also cause the projection to enter the "dead zone."

Human error was most present during testing. During the first testing protocol, human error existed in the placement of the unit circle as well as in the manual manipulation of the rotor shaft, because of the inaccuracy of the arrow on the rotor shaft. The original idea for testing was to perform the protocol with a physical therapist, but due to extenuating circumstances caused by

the Covid-19 pandemic, testing was performed alone. In the second testing protocol, when the device was attached to the hinge of the brace, device placement was a source of error. Device placement consists of the velcro strips on the brace hinge, device case and rotor shaft. As stated above, if the rotor shaft was placed incorrectly, it caused flawed data trials. Further, the placement of the device on the hinge is what led to the incorrect angle readings. Since the hinge brace is a two-point axis system, the placement of the device on the proximal axis caused it to only read the change in the angle of this axis, not the hinge system as a whole.

Lastly, there are sources of error in the comprehensive analysis of the device. The accuracy of the device is based on usable data trials tests which are only a fraction of all tests performed. This shows that while the usable data is consistent, the reliability of the device is not. Further, the data acquisition is meant to be continuous. However, trials were only conducted for a set number of repetitions, with data cleared after each trial. This creates an inability to analyze the device's ability to monitor progress over time.

The next steps for the device first begin with redesigning components of the case. All of the tests were completed with only the bottom of the case present. The latest iteration of the top of the case fits the device, but the opening for the USB port and power switch is not large enough for the USB cord to connect to the device while the top is on. Therefore, the opening for the USB port and power switch needs to be updated to accommodate so that the top of the case can remain on while the device is in use and when it is plugged in. The rotor shaft also needs to be redesigned or updated. The redesign of the rotary shaft needs to produce a component that results in a better and more consistent reading. This means that the projection needs to be redesigned or manufactured in a way that is more reliable, or the entire piece and path portion of the bottom of the case need to be redesigned.

Further, one of the considerations that needs to be taken into account during the redesign phase is that most postoperative knee braces have a dual axis hinge system. So, since the device does not record the rotation of both hinges, the device must be altered to accommodate for the dual point hinge system. This means that the code must be updated to account for both axes, and/or the design of the device must be changed in order to measure the ROM of both axes.

After the redesign phase, additional testing must occur. More extensive testing - testing with the knee brace on, different physical therapy movements, etc. is needed in order to analyze how the device works in various conditions. These tests will be a more accurate representation of how the device will be used in a clinical setting. Additionally, testing over a longer period of time, without clearing the data log, is needed to evaluate the effectiveness of the device in accurately monitoring patient progress over time. These alterations to the device design and future testing steps will allow the device to be utilized in a clinical manner that will provide reliable information to patients and clinicians.

6. CONCLUSION

The design and development of this device followed the basic steps of creating a medical device. Multiple iterations of the device's design were implemented and tested. During the testing phase, issues with the reliability of the device occurred. The device produced usable data only 37% of the time. This means that the device does not continuously and consistently monitor data. Therefore, in clinical use, this would cause severe problems for clinicians because they would not have accurate or comprehensive data to analyze and monitor patient progression. Further, most of the usable data came from trials that occurred after the data log was cleared and the device was turned off and on. Not only would this require more patient interaction with the device, but also this would cause issues in proper data acquisition. The device is intended to continuously monitor patient progress so, if the log needs to be cleared and the device reset after every set of data is collected, progress cannot be monitored effectively.

These findings show that updates need to be made to the device in order to accurately and consistently collect data that is useful for clinicians to monitor patient recovery. While the device properly measures total knee cycles, the range of motion is the more critical metric for monitoring patient recovery and, thus, it is essential that the device accurately measures it. In addition to design improvements, more testing needs to be completed to ensure both the accuracy and consistency of the device. The findings of this study show promising results for the use of this device in a clinical setting. Updates, however, are required for the device to be implemented as it is intended in order to provide useful information to clinicians, and better care for patients.

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APPENDIX A
Data Charts

		Expected Value (°)							
		0	45	90	120	180	240	270	300
Trial #	1	0.416	44.5859	93.3262	119.706	187.031	236.351	276.305	294.34
	2	0.019	29.19	86.06	120.45	187.007	227.93	274.513	302.606
	3	0.169	38.3895	94.5112	116.657	181.689	236.858	268.92	296.487
	4	0.0602	51.0195	84.8482	116.817	174.064	230.334	262.234	N/A
	5	0.12485	45.002	78.9326	119.226	174.102	230.601	270.355	308.891
	6	0.0863	40.6282	106.182	122	168.203	243.439	267.262	300.61
	7	0.0313	29.212	83.3139	118.465	174.553	235.867	275.476	N/A
	8	0.00151	40.6787	89.7536	120.987	184.012	225.592	263.467	296.813
	9	0.08814	44.7042	76.8184	122.469	182.265	250.593	266.76	301.746
	10	0.0211	44.1938	88.1036	120.991	183.267	231.994	274.364	307.318
	11	0.1565	45.7532	84.0697	118.745	176.836	227.216	262.257	287.7
	12	0.0356	45.4945	84.7335	119.961	177.454	227.292	260.907	278.515
	13	0.000035	57.1627	101.24	120.475	185.339	215.146	280.848	307.131
	14	0.0678	39.6314	86.0205	117.799	178.157	216.234	264.976	296.881
	15	0.1265	43.8951	88.7982	120.249	186.121	233.68	272.581	298.001
	16	0.1038	39.3026	96.8586	121.07	182.736	240.715	276.231	285.403
	17	0.1339	49.6607	82.9772	121.075	180.616	244.5	277.714	298.292
	18	0.2914	44.4817	92.095	126.519	178.317	221.287	N/A	N/A
	19	0.0982	54.4056	96.5326	123.886	186.786	237.64	265.983	305.265
	20	0.08447	47.0521	93.9444	126.338	183.569	242.606	273.33	300.834
	21	0.00106	28.7527	93.079	110.839	171.368	225.238	253.956	N/A
	22	0.00247	51.34	78.6311	138.709	176.831	246.157	269.435	295.87
	23	0.4936	36.9245	97.3695	126.369	185.683	254.647	284.731	297.094
	24	0.09195	33.1397	85.9764	124.936	177.37	236.825	269.754	303.939
	25	0.0196	30.3869	78.7423	124.637	180.579	230.536	273.456	298.205
	26	0.08789	37.2294	93.3338	122.803	181.513	235.998	276.859	293.781
	27	N/A	38.3295	85.8399	118.784	171.556	219.013	277.08	303.971
	28	0.012	50.5077	79.4764	120.458	177.286	216.151	278.279	295.462
	29	0.0409	48.276	91.3129	118.54	188.309	254.236	279.148	295.559
	30	0.415063	48.8296	82.0175	118.065	180.961	240.757	264.149	294.936
	Average	0.1131082	42.605313	88.496607	121.2675	180.11933	233.84777	271.08034	297.90962
	% Error		-5.321526	-1.670437	1.05625	0.0662963	-2.563431	0.4001277	-0.696795
	ABS %Error		5.3215259	1.670437	1.05625	0.0662963	2.5634306	0.4001277	0.6967949
	AVG % Error								1.6821232

Chart 1. The full data and analysis of the data collected over the 30 trials of device accuracy testing

		Peak #				
		1	2	3	4	5
Trial #	1	19.0861	21.6268	21.6873	20.4169	19.065
	2	27.1814	31.415	27.0052	26.9171	30.0008
	3	32.4846	19.2184	20.9948	25.9754	27.1326
	4	21.2002	24.3409	20.2443	20.176	17.9912
	5	19.3529	14.4771	11.2266	21.5199	12.3703
	6	12.147	11.9046	17.384	9.52853	16.5597
	7	19.9493	23.1179	19.82	20.9839	19.9493
	8	22.2795	21.0366	19.5451	20.2287	9.35314
	9	17.058	16.1579	18.4425	22.2532	25.7763
	10	21.821	21.4163	19.5951	19.3253	24.4112
	11	17.6872	20.6301	18.3796	20.6301	19.5115
	12	14.7295	19.2077	24.4552	17.3884	25.0853
	13	15.5253	19.9292	15.8041	16.4334	14.1874
	14	13.0546	15.0389	18.6828	14.1489	14.2011
	15	12.0968	12.2373	11.5701	11.2443	12.5884
	16	24.2283	16.6938	24.7112	17.1086	21.8781
	17	23.8525	28.3024	28.7582	30.9399	32.5754
	18	26.8124	24.5894	31.8813	28.7688	27.7017
	19	23.9264	23.4054	19.4612	21.2473	18.717
	20	17.2946	22.5237	19.4366	21.0747	16.0345
				Average Angle		20.29521
				Multiplication Factor		4.434543

Chart 2. The full data and analysis of the data collected over the 20 usable data trials of device for 90° flexion.

		Peak #				
		1	2	3	4	5
Trial #	1	29.5998	28.9374	20.3268	14.2	20.9063
	2	27.5354	28.611	29.6047	29.6047	28.611
	3	24.6431	22.4311	20.4265	16.9703	22.085
	4	27.1076	27.1876	28.2947	24.4455	21.2508
	5	24.0485	29.5949	29.5121	28.6843	29.0892
	6	29.1826	30.753	27.2378	30.3168	31.1019
	7	34.4553	37.8836	40.8548	32.0555	37.6551
	8	26.6026	27.2833	37.0392	40.5559	37.0392
	9	33.8734	30.765	31.613	29.1632	28.0325
	10	34.577	35.0716	36.3965	32.4005	33.7855
	11	32.3711	26.0681	26.7884	29.3997	29.6698
	12	25.641	21.6853	25.0565	21.5414	21.4813
	13	33.481	29.1731	29.9858	30.4828	31.0461
	14	21.4733	22.8388	19.9029	24.3409	20.1078
	15	29.8888	26.043	23.0333	27.6434	20.4931
	16	25.1604	25.6949	24.3205	27.4512	23.786
	17	37.2447	37.7715	32.5036	27.9723	29.5536
	18	37.7004	41.1538	38.0475	39.5422	39.1969
	19	28.2995	27.3426	27.4287	26.1622	27.9037
	20	33.3967	33.1257	29.5034	29.5764	28.0735
				Average Angle		28.86952
				Multiplication Factor		4.156633

Chart 3. The full data and analysis of the data collected over the 20 usable data trials of device for 120° flexion.

APPENDIX B
Circuit Diagrams

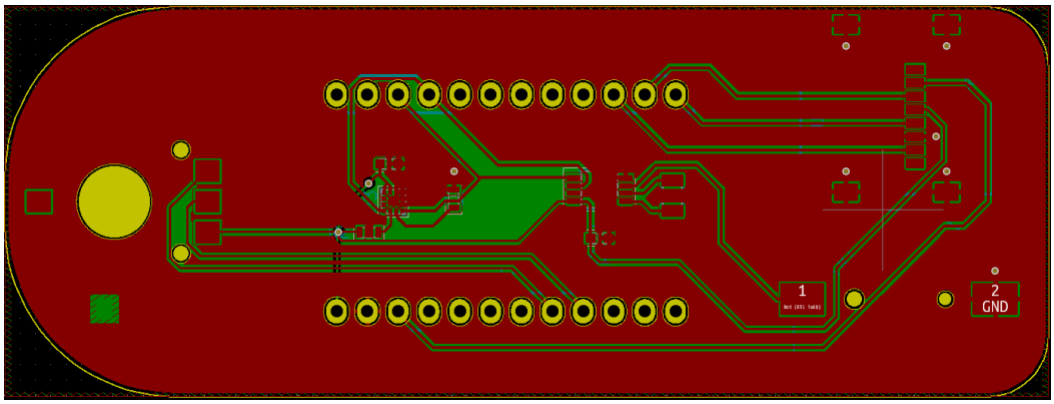

Diagram 1. KiCad Schematic of the testing iteration of the circuit

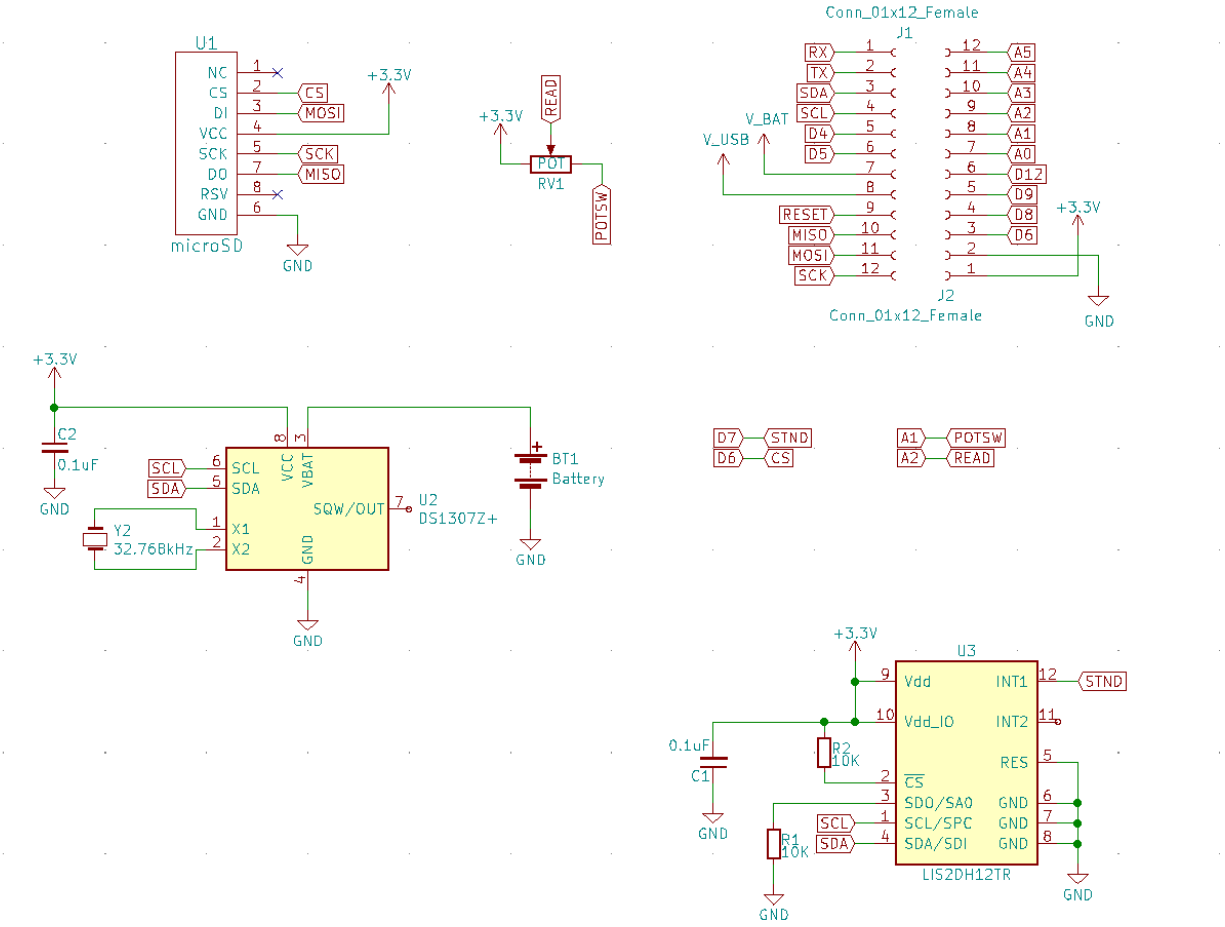

Diagram 2. Schematic of the testing iteration of the circuit

BIOGRAPHY

Allison Margulies is in her fifth year at Tulane University pursuing her Bachelor of Science in Engineering and Master's Degrees in Biomedical Engineering, with a minor in Mathematics. Allison is passionate about medical device design. She has spent the last two years as a prosthetic intern at the New Orleans VA Hospital. There, she works with clinicians and patients to help design new products. Allison's passion for medical devices led her to work with Dr. Pleasant Hooper on the device that is the subject of this project. Following graduation in May, Allison will move to Minneapolis to begin her career as a Research and Development Engineer at Teleflex Incorporated

Outside of academics, Allison enjoys traveling, cooking and spending time with friends and family. One day, she hopes to return to London, where she studied abroad. Allison has absolutely loved exploring all that New Orleans has to offer over the last five years. In her free time, she has enjoyed listening to live music, trying all of the delicious food and discovering new places in and around the city. Also, she loves to explore her creativity by painting and applying creative makeup designs. Most of all, Allison loves to learn. She has treasured every opportunity that she has had as a student at Tulane.