

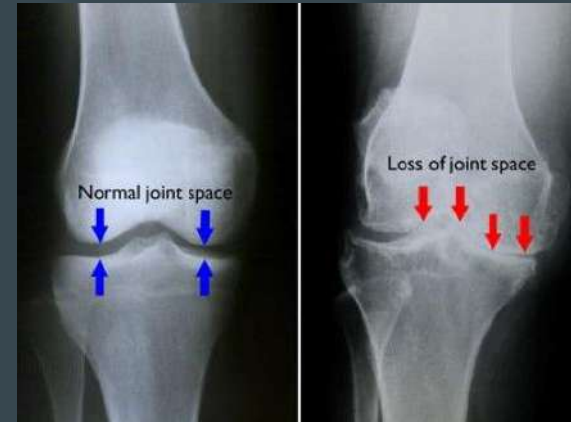
The Adaptive Knee Brace: Final Presentation



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Advisors: Dr. Alvandi (BME) & Dr. Katz (ECE)

Background - Knee Osteoarthritis

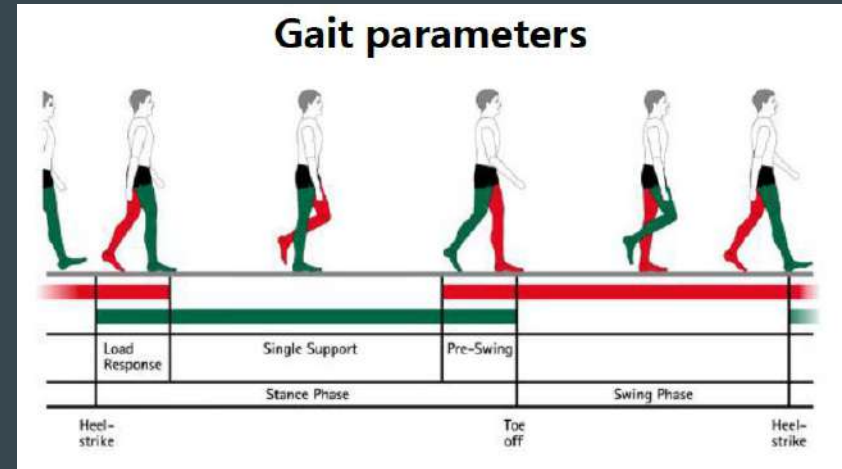
- *Knee Osteoarthritis (OA)* is the degeneration of the articular cartilage in the knee joint
 - Two types: *Primary* and *Secondary*
 - *Primary OA* occurs with no clear underlying reason
 - *Secondary OA* occurs due to an abnormal concentration of force across the joint, injury, or due to abnormal articular cartilage
- Common treatments include:
 - Conservative methods
 - Medication, physical therapy (PT), knee bracing, and corticosteroid injections
 - Surgery is typically required if the conservative treatments fail
 - Rehabilitation methods can also be used to treat more severe side effects from knee OA, such as losing the ability to walk



<https://orthoinfo.aaos.org/en/diseases--conditions/arthritis-of-the-knee/>

Background - What is Gait

- *Gait rehabilitation* is generalized as the process of learning how to walk again after sustaining an injury or disability and is meant to help strengthen muscles and/or improve stability
- Assistive devices, such as knee braces, are often used to assist these types of patients
- Some gait rehabilitation exercises that can improve muscle strength include:
 - Walking on a treadmill
 - Performing a “marching” like motion in place



Phases of the gait cycle when walking and the associated loads during each phase

Introduction

Goals of The Adaptive Knee Brace:

- To design an assistive knee brace for elderly patients between the age of 65-90 years old with severe Osteoarthritis in the knee joint
- The assistive brace will be designed with the motions of gate rehabilitation in mind, since gate rehabilitation is a common rehabilitation method used for patients with severe knee osteoarthritis
- In order to accomplish the above, the brace will reduce the varying loads on the knee, based on the angle of the knee through the gate cycle
 - Results in long term pain reduction in the knee
 - Allows for improved knee motion due to less muscular strength required to bear the varying loads on the patient's knee joint

This will allow the patient to perform gate rehabilitation easier with less pain and better motion.

Problem Statement

A way to alleviate symptoms caused by knee osteoarthritis for elderly patients, aged 65-90 years old, by reducing contact forces in the knee in order to assist in gait rehabilitation.

Design Inputs: Requirements & Specifications

Design Input - Requirements & Specifications

Requirement	Specification	Verification/Validation	Verification/Validation Protocol Name
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of $48.0 \pm 5.6 \text{ cm}^2$ 1.2 The device must be wearable to by men and women with an average calf circumference $32 \pm 3.2 \text{ cm}^2$	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.	Knee Brace Size / Fit Verification Protocol
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability	Knee Brace Load Capacity Verification Protocol
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below $0 \pm 3^\circ$	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation	Knee Brace Hyperextension Prevention Verification Protocol
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above $60 \pm 5^\circ$ (between initial and pre-swing)	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation	
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	The device will go through a series of physical tests to measure and record the displacement and range of angles for the brace.	Hinge Motion Verification Protocol

Design Input - Requirements & Specifications

6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to sampling rate of 300Hz	Calculations based on microcontroller processing speed and sensor sampling rate	Microcontroller Verification Protocol
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	Ammeter to probe system to test amperage of circuit	Current Withdraw Verification Protocol
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: - Flexion/Extension/Rotation - Angles/Speed/Steps per minute	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.	Data Recording Verification Protocol
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage	External Moisture Shielding Verification Protocol
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour	Battery Verification Protocol
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards	Knee Brace Biocompatibility Verification Protocol

Design Input - Requirements & Specifications

1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.	Knee Brace Fit and Range of Motion Validation Protocol
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device		
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys		

Design Input - Requirements & Specifications

Justifications:

1. The device must be able to fit users with different body shapes / sizes within the target population of elderly patients, aged 65-90 years old. Within this population the average thigh circumference was found to deviate by 5.6 cm and the average calf circumference was found to deviate by 3.2 cm. So, the brace must be able to fit the minimum and maximum circumference for both the calf and thigh.
2. The device must be able to support the weight of the user with additional factors of safety designed into the device to allow the brace to support the user's weight during various activities. Since men have a higher average weight compared to women, only the weight for men will be verified since it is the maximum spec.
3. The device must be able to measure angles of the knee or else the device may put the user at risk of potential harm during gait assistance
4. The device must be able to measure angles of the knee or else the device may put the user at risk of potential harm during gait assistance
5. Vertical movement of the joints during sudden high forces is important for avoiding increased strain on the knee joint. Rotational motion allows for proper joint motion and allows for the patient to better perform gait rehabilitation.
6. For any feedback of the actuator the sensor and latency are limited to allow response time. The device must operate at 10mA to avoid potential electrical problems while having a significantly lower risk of injury in reference to shock hazards (at worst a minor shock may be perceived).
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8. Data collection during sessions with the patient is necessary for analyzing forces, knee angles, and other aspects of gait rehabilitation.
9. During sessions and exposure to elements, the hazards can be mitigated by shielding the electrical components. The battery for the device should last one charge per session to reduce injury risk and ensure data collection throughout the entire session.
10. During sessions and exposure to elements, the hazards can be mitigated by shielding the electrical components. The battery for the device should last one charge per session to reduce injury risk and ensure data collection throughout the entire session.
11. It is necessary for the device to be comfortable and biocompatible so that the user is not uncomfortable or gets further injury using the device.

Design Solutions

- Brace was designed to fit our intended user with an average thigh circumference of 48 ± 5.6 cm and a calf circumference of 32 ± 3.2 cm
- A sizing chart from other knee braces was used. A thigh circumference of 48 cm and a calf circumference of 39 cm was ideal for our intended user
- Adjustable velcro straps were also used to allow for adjustability in the fitting of the brace for slightly smaller or larger users

Z-12 Size Chart				
Size #	Size	Thigh Circumference	Standard Calf Circumference	Athletic Calf Circumference
XX = 01	XS	13.5" - 16" (34 - 41 cm)	12.5" - 14" (32 - 36 cm)	11" - 12.5" (28 - 32 cm)
XX = 03	S	16" - 18.75" (41 - 48 cm)	14" - 15.5" (36 - 39 cm)	12.5" - 14" (32 - 36 cm)
XX = 05	M	18.75" - 21.5" (48 - 55 cm)	15.5" - 17" (39 - 43 cm)	14" - 15.5" (36 - 39 cm)
XX = 07	L	21.5" - 24.25" (55 - 62 cm)	17" - 18.5" (43 - 47 cm)	15.5" - 17" (39 - 43 cm)
XX = 09	XL	24.25" - 27" (62 - 69 cm)	18.5" - 20" (47 - 51 cm)	17" - 18.5" (43 - 47 cm)
XX = 11	XXL	27" - 29.5" (69 - 75 cm)	20" - 21" (51 - 53 cm)	18.5" - 20" (47 - 51 cm)

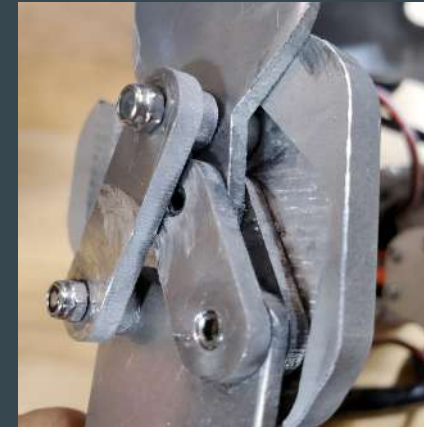
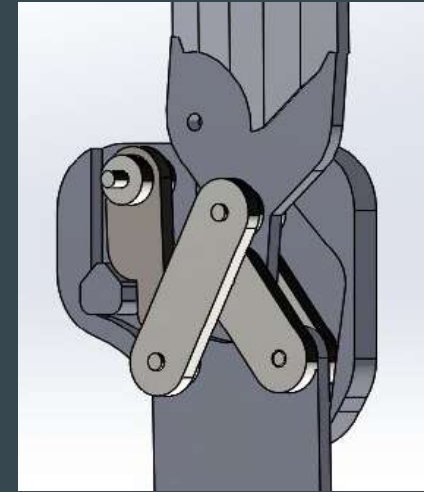
*Thigh circumference measure 6" (15 cm) above mid-patella. Calf circumference measure 6" (15 cm) below mid-patella.
Brace length: Standard 13" (33 cm), Extended 15" (38.1 cm).*

<https://www.breg.com/products/knee-bracing/functional-oa/duo-knee-brace/>



Design Solutions

- Double Hinge Mechanism
 - Double hinge provides vertical and rotational motion during knee bending
 - The double hinge mechanism consists of:
 - A backplate to protect the user from injury and to provide a solid base to mount the other components to
 - Three 2.5 mm 316 stainless steel machine bolts to hold the components together
 - Two shorter plates connect the thigh portion to the calf portion directly while bypassing the mounting bolts creating the “first” hinge
 - A final plate connecting the top mounting bolt to the bottom mounting bolt completing the “second” hinge mechanism
 - The final bolt is used to attach the flapper which is used to restrict the angle
 - The novel hinge mechanism is loosely based on TM+5 joint mechanism. The TM+5 brace differs in that it does not allow the restriction of angles.

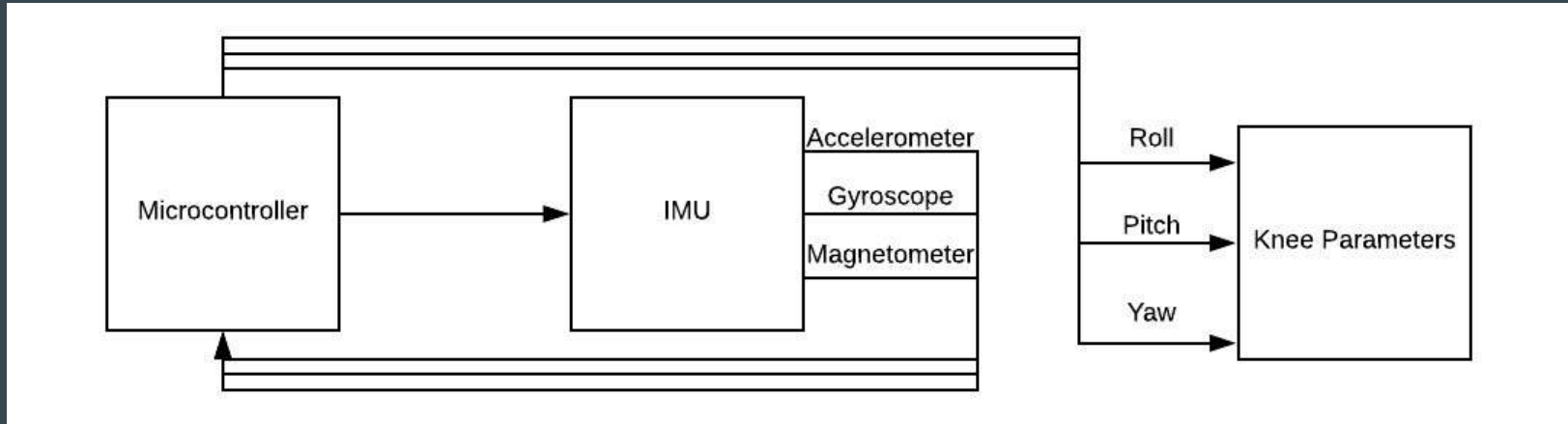


Design Solutions

- Final material chosen and verified by using FEA
 - $\frac{1}{8}$ " 6061 T6 Aluminum was used for the manufacturing of the calf and thigh portions of the brace
 - $\frac{1}{8}$ " 6061 T6 Aluminum was also used for the plates and spacers in the hinge
 - $\frac{1}{4}$ " 6061 T6 Aluminum was used for the back plate of the hinge mechanism, the angle restricting slider, and the servo mount
 - Cheaper and more manufacturable than Steel 321 (Stainless)
 - Machined through water jet, bent through rolling press



Design Solutions - Electronics Block Diagram



- The inertial mass unit provide reading on the knees angle, orientation, and acceleration
- Data is fed back to the microcontroller
- Microcontroller handles gait analysis computations based on sensor data

Design Solutions - Microcontroller

Arduino Nano BLE 33 vs Raspberry PI 4 Technical Specifications

Microcontroller	Dimensions (mm)	Clock Rate	Onboard IMU	Current Draw	Pins	Communication Interface
Arduino Nano BLE 33 ¹ 	45 × 18	64MHz	Yes	< 20 mA	16 Digital 9 Analog	IC2 SPI
Raspberry PI 4 ² 	85.6 × 56.5	1.5 GHz	No	< 500mA	40 GPIO	IC2 SPI

1. *Arduino Nano 33 BLE*. Arduino Nano 33 BLE | Arduino Official Store. <https://store.arduino.cc/usa/nano-33-ble>.

2. *Raspberry Pi. Raspberry Pi 4 Model B specifications*. Raspberry Pi. <https://www.raspberrypi.org/products/raspberry-pi-4-model-b/specifications/?resellerType=home>.

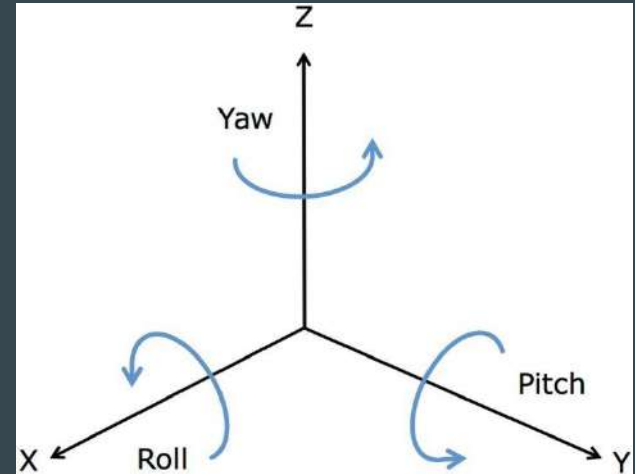
Design Solutions - Battery Pack

- Requirements
 - The battery lasts the period of gait analysis and still be active for gait rehabilitation.
 - Output voltage greater than 3.3V supply required by microcontroller
 - Rechargeable
- Battery Pack - Lithium Ion Battery Pack - 3.7V 6600mAh
 - With estimated 10mA from IMUs device operation lasts 27.5 days

$$Battery\ Life = \left(\frac{6600mAh}{10mA} \right) \left(\frac{1\ day}{24\ h} \right) = 27.5\ days$$

Design Solutions - Inertial Mass Units

- The IMU consists of an accelerometer, gyroscope, and magnetometer which can measure, angle, orientation, and acceleration.
- The IMU is able to measure the calf and thigh angular displacement, orientation of the knee and angular velocity of the knee.
- Calculations were used to convert data into measures in term of roll, pitch, and yaw
- Sensor was placed on the side of the brace in such a way that the yaw position corresponds to the knee angle during the gait cycle

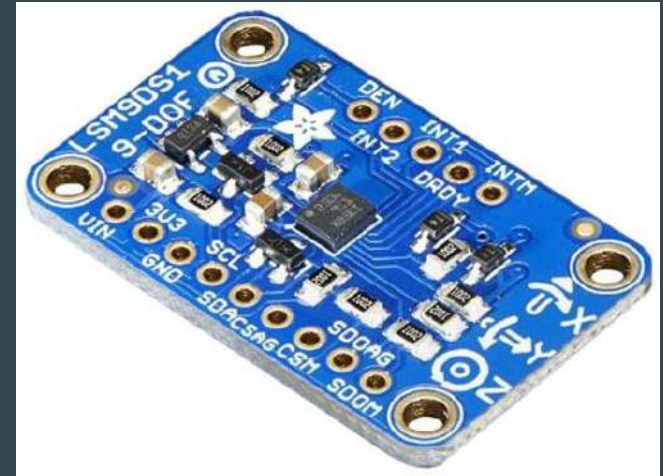


Design Solutions - Inertial Mass Units

- The Arduino Nano 33 BLE with an onboard IMU reduced the cost of the project since only one other IMU was required with it
- The onboard IMU is a LSM9DS1 which has the following technical specifications*:

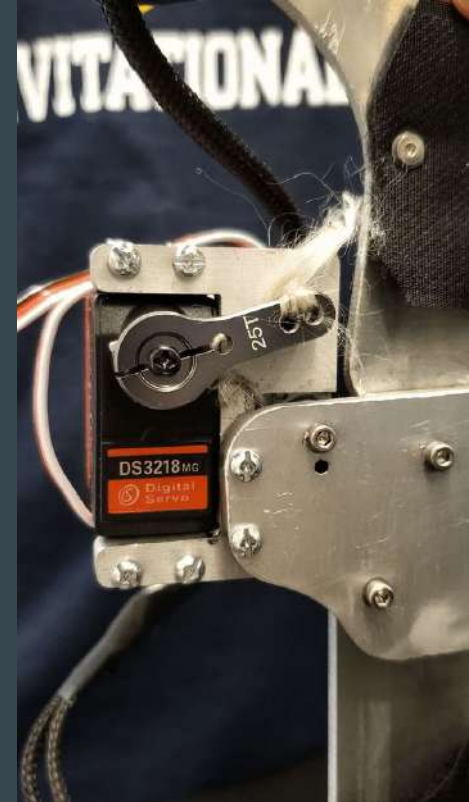
Accelerometer	Gyroscope	Magnetometer
The LSM9DS1 has $\pm 2/\pm 4/\pm 8/\pm 16$ g ranges	LSM9DS1 gyro has $\pm 245/\pm 500/\pm 2000$ dps ranges	The LSM9DS1 has $\pm 4/\pm 8/\pm 12/\pm 16$ gauss ranges.

*Industries, A. Adafruit 9-DOF Accel/Mag/Gyro+Temp Breakout Board - LSM9DS1.
https://www.adafruit.com/product/3387?gclid=Cj0KCQiAzZL-BRDnARIsAPCJs7lKkbGxPcDF5ybQfBTvmbq8yrXhDnddTSZ23kYIgebTRG201-_dvYaAuBEALw_wcB.



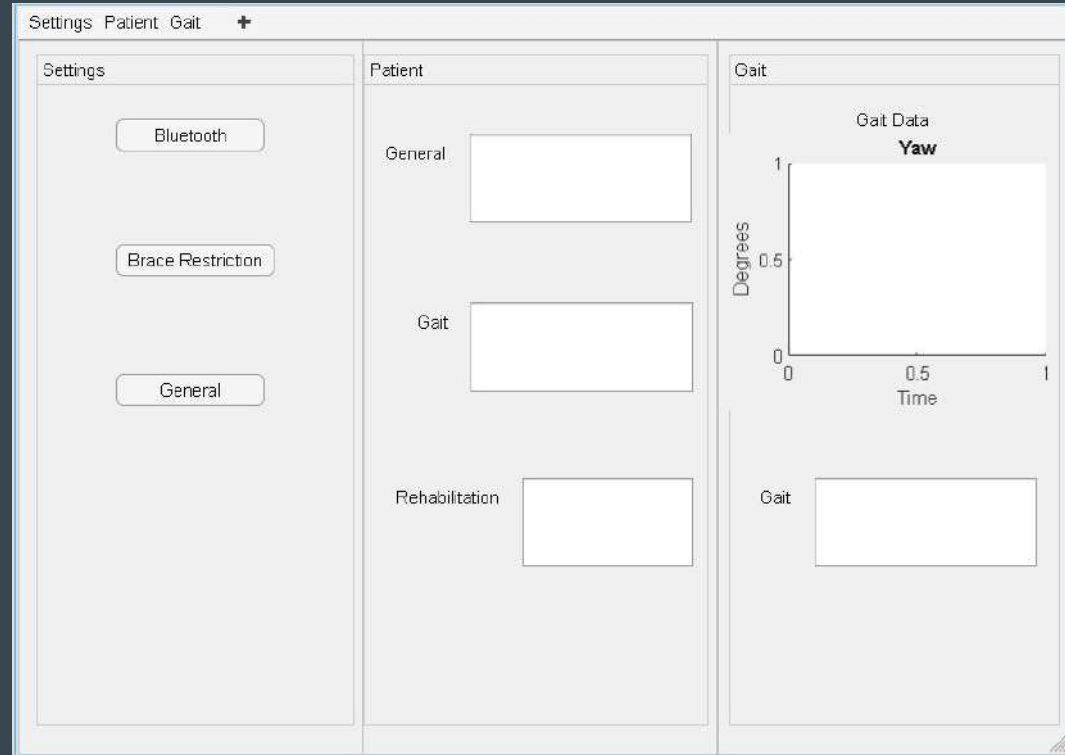
Design Solution Servo Motor

- The brace was also restricted at different angles using the high torque servo motor which is controlled through the Arduino BLE microcontroller.
- The arm of the servo is programmed to reach 3 different points of rotations which causes a different angle restriction of the knee.
 - 2° - 30°
 - 2° - 50°
 - 2° - 88°
- Programmable knee restrictions allow us to see the changes in the gait cycle when the brace is restricted at different angles.



Design Solution - Graphical User Interface (GUI)

- General GUI for software application
- Create a seamless experience for the user to connect to the device without having to perform any manual setup
- Easily access gait information for rehabilitation



Design Solution - Prototype



Verification Testing

Requirement 1: Size and Fit

- As per requirement 1 the brace was designed to fit our intended user with an average thigh circumference of 48 ± 5.6 cm and a calf circumference of 32 ± 3.2 cm
- Using this requirement and a sizing chart from other knee braces, a thigh circumference of 48 cm and a calf circumference of 39 cm was ideal for our intended user



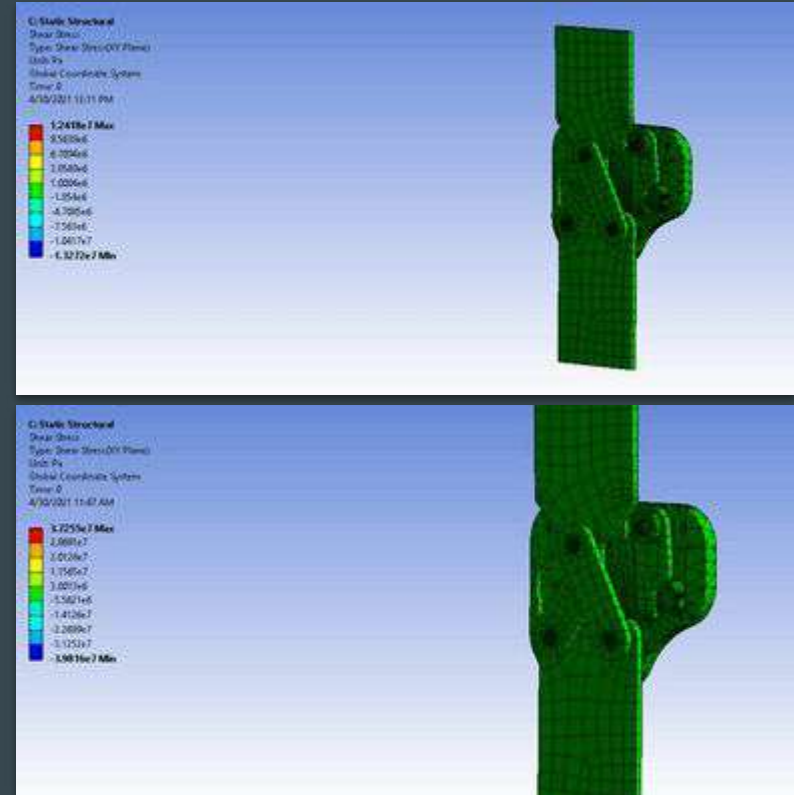
Verification Testing

Requirement 2: Load Capacity

- For the FEA analysis we used Ansys Workbench
- In Ansys a Rigid dynamics system report was run for Deformation, Shear stress, and Normal stress for the brace design
- The forces put on the brace were both that of an average intended user and three times that of an average intended user to show both the normal case and an extreme case
- The resulting maximum normal and shear forces on the brace were compared to the material properties

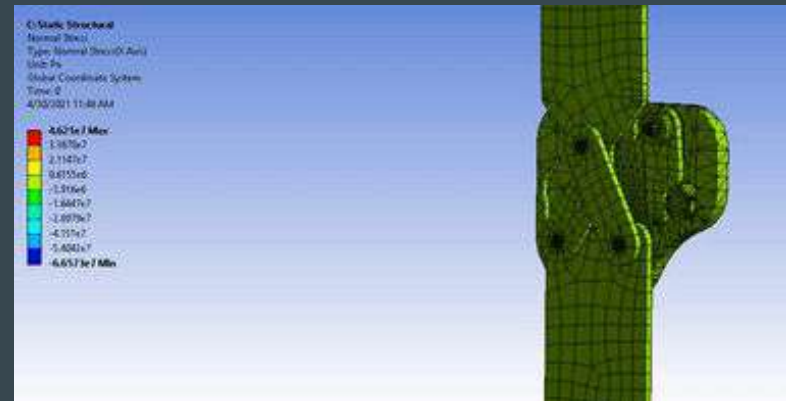
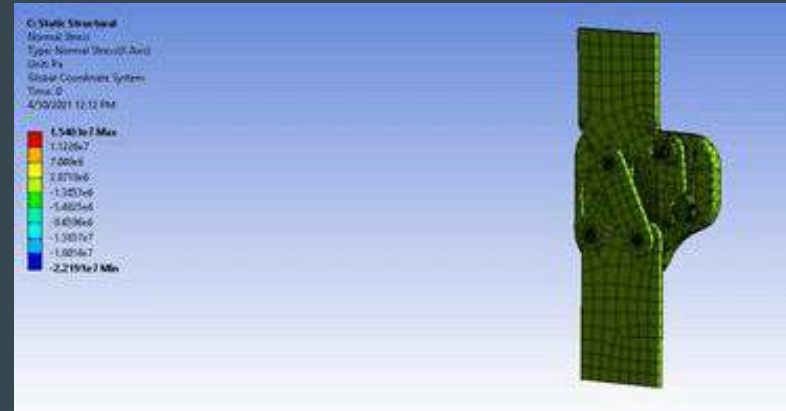
Verification Testing

- To simulate normal use a load of 705.6N in both directions was used
- The maximum shear force was 1.24 MPa and the maximum normal force was 1.54 MPa
- The Elastic modulus for both the 304 steel (193 MPa) and the 6061-T6 aluminum (68.9 MPa) are both well above the maximum forces in this simulation



Verification Testing

- To simulate an extreme load a force of three times the intended average (2116.8N) force was applied to the brace
- The maximum shear force was 3.27 MPa and the maximum normal force was 4.62 MPa
- The Elastic modulus for both the 304 steel (193 MPa) and the 6061-T6 aluminum (68.9 MPa) are both well above the maximum forces in this simulation



Verification Testing

Requirement 3: Hyperextension Prevention

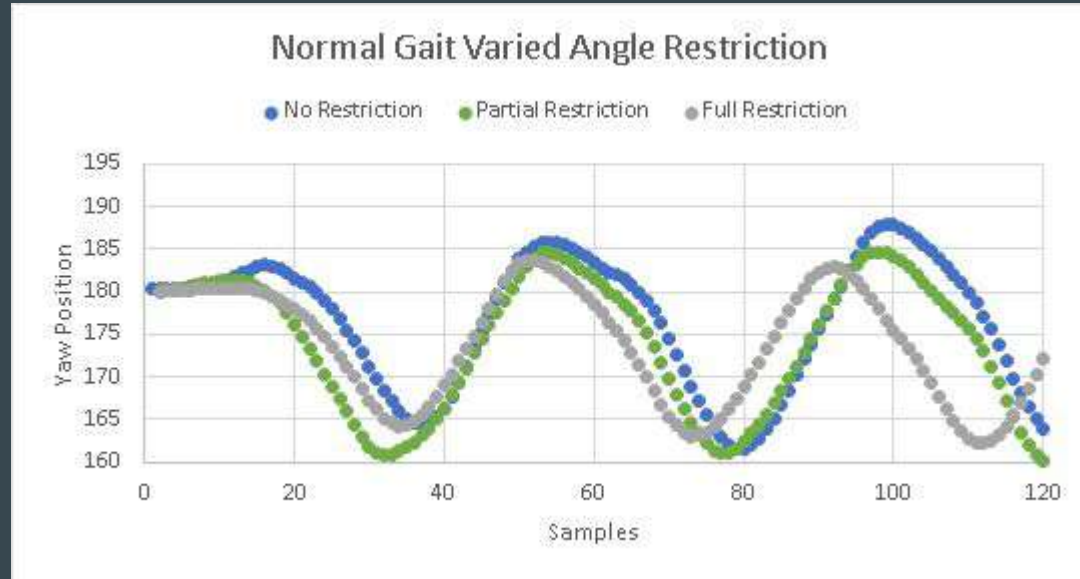
- Brace was bent mechanically and angles were measured by protractor.
- Mounting plate made of $\frac{1}{4}$ " 6061 Aluminum mechanically restricted hyperextension of brace at about 2° .
- A paired t-test was performed for hyperextension bending trials ($p > 0.05$)



Verification Testing

Requirement 4: Applied Resistance Throughout Gait Cycle

- Gait was tested during these different settings:
 - 2° - 30°
 - 2° - 50°
 - 2° - 88°
- Peaks show significant differences in angles achieved during gait.

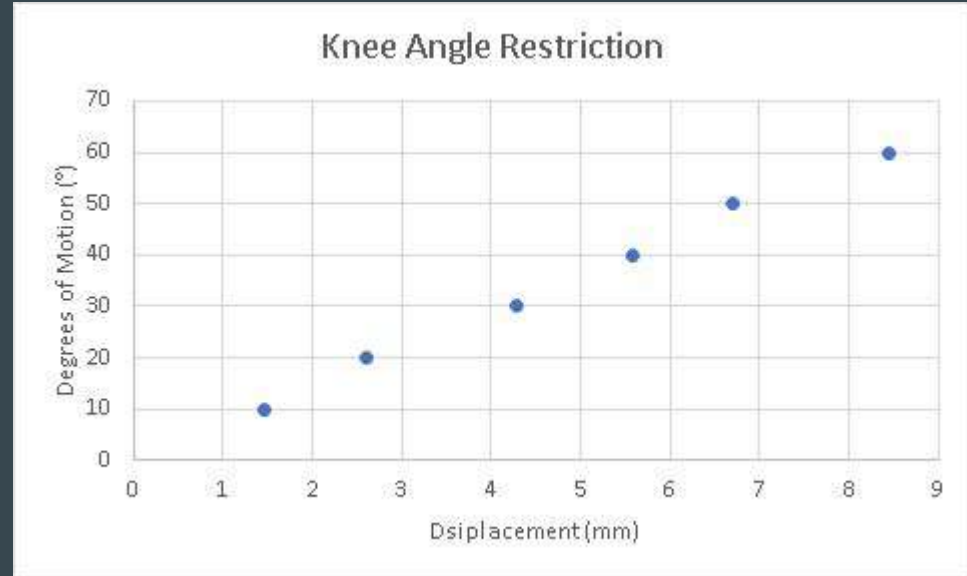


*Repeated Swing phase due to an accelerometer limitations

Verification Testing

Requirement 5: Hinge Motion

- The brace mechanically restricts the motion to 2° - 88° during knee flexion
- Additionally the servo can restrict the range of motion further by moving the slider up and down to predetermined positions



Verification Testing

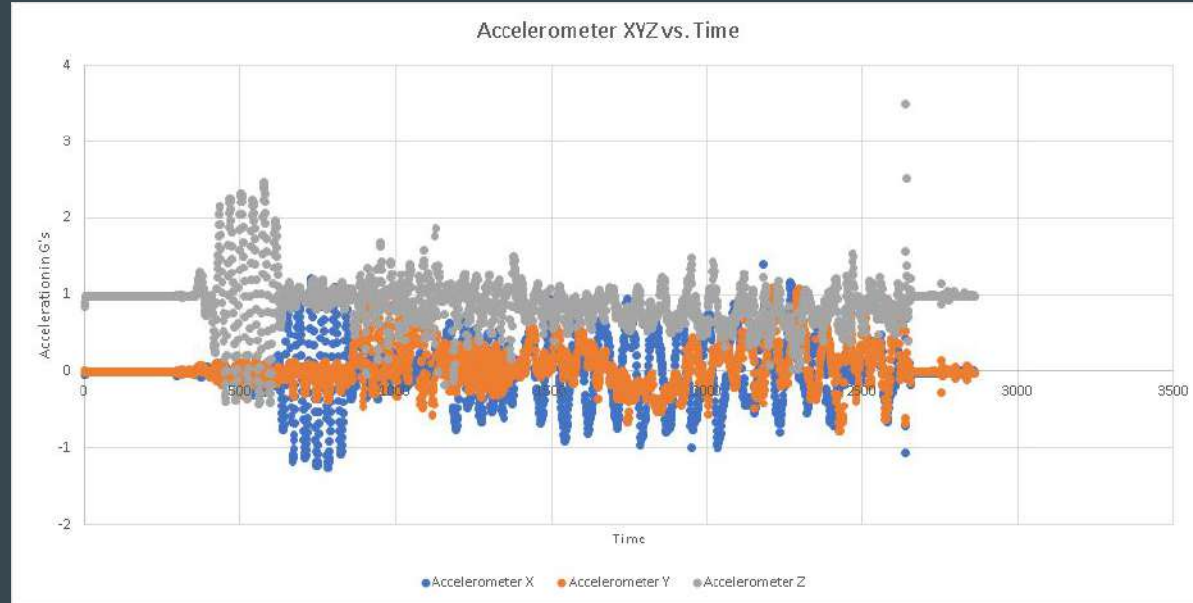
Requirement 6: Low Latency

- The LSM9DS1 sensors in our design have sampling rate modes that range from 14.9Hz to 952Hz for the accelerometer and gyroscope and 0.625Hz to 400Hz for the magnetometer
- The requirement defined was to have a sampling rate greater than 300Hz
- The accelerometer and gyroscope were tested at a sampling rate of 476 Hz
- The magnetometer was tested with a sampling rate of 400Hz
- This resulted in the average sampling rates:
 - Accelerometer: 463.04Hz
 - Gyroscope: 462.94
 - Magnetometer: 420.81
- For our data sampling we ended up with a sampling rate of only 104Hz, which was sufficient for data collection, and could be improved based on the sensors capabilities

Verification Testing

Requirement 8: Data Recording

- Arduino code was compiled to output Accelerometer X, Y, and Z data
- That data was printed to the serial monitor in the Arduino IDE and copied to excel



Verification Testing

Requirement 9: Moisture Shielding

- Moisture Shielding was tested using the spray bottles onto the plastic coverings of the electronics
- No damage was caused to the device and data was collected without additional latency ($p > 0.05$)

Requirement 7 & 10: Battery Capacity & Low Current Withdraw

- Battery was tested
- The maximum current drawn from the battery was 11.8mA

Validation Testing

Fitting and Range of Motion validation:

- Comfort levels while wearing and putting on were indicated and accessed based on user feedback

Data Collection, Accessibility, and Security validation:

- Data is accessible by the PT on any device with the Arduino software and the data is saved to a local drive.

Electronic Component validation:

- Data was collected on Arduino and IMU with an overlap in functions to confirm

Validation Testing

Device Integrity and simulated testing validation:

- Electronics secured on brace with insulation and protection to allow long term use for any kind of motion using the brace,

Device Intervention validation:

- Device was tested and constantly measured to prevent improper lateral movement and hyperextension of the knee

Budget - \$400

	\$368.35
Remaining	\$31.65

Item	Company	Quantity	Part Number	Cost Per Unit	Shipping Cost	Special Handling (Hazards)	Total Cost
Arduino Nano 33 BLE	Amazon	1	ABX00030	\$23.00	\$0.00	None	\$23.00
IMU (BNO055 or BNO085)	Adafruit	1	4754	\$19.95	\$3.95	None	\$23.90
Lithium Ion Battery Pack - 3.7V 6600mAh	Adafruit	1	353	\$7.95	\$0.00	Battery	\$7.95
Wires and Connectors		1		\$29.50	\$0.00	-	\$29.50
Springs		1		\$30.00	\$0.00	-	\$30.00
Support Materials		1		\$45.00	\$0.00	-	\$45.00
Straps		1		\$30.00	\$0.00	-	\$30.00
Fabric + Cushion		1		\$30.00	\$0.00	-	\$30.00
Double Jointed Hinge		1		\$20.00	\$0.00	-	\$20.00
Electric Linear Actuator		1		\$129.00	\$0.00	-	\$129.00
						Total Cost:	\$368.35

Actual Spending

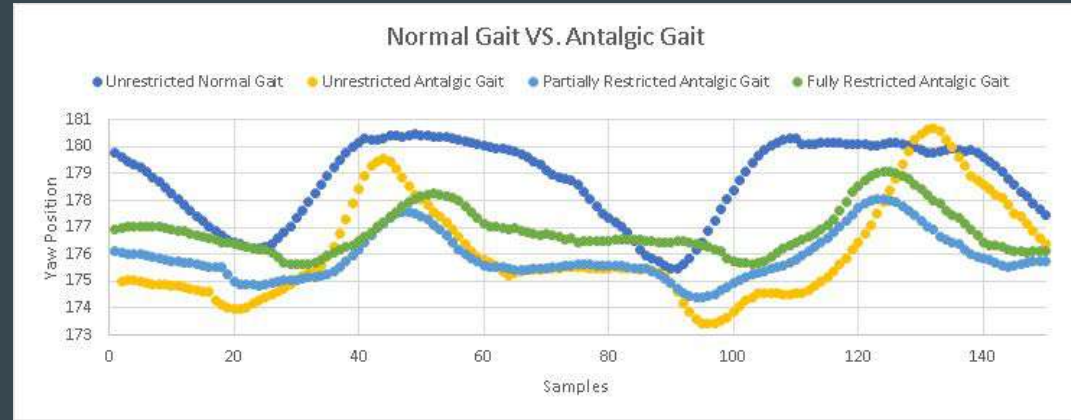
Item	Company	Quantity	Part Number	Cost Per Unit	Shipping Cost	Special Handling (Hazards)	Total Cost
Arduino Nano 33 BLE	Amazon	1	358-6010602	\$22.50	\$0.00	None	\$22.50
LSM9DS1 IMU sensor	Amazon	1	2129	\$14.95	\$0.00	None	\$14.95
Lithium Ion Battery Pack - 3.7V 6600mAh	Adafruit	1	353	\$29.50	\$0.00	Battery	\$29.50
Wires and Connectors	Amazon	1	N/A	\$1.00	\$0.00	None	\$1.00
Aluminum 6061 1/8" Size: 12"x20"	Metals Depot	2	S318T6	\$42.57	\$16.13	None	\$101.27
Aluminum 6061 1/4" Size: 5"x12"	Metals Depot	1	F4145	\$14.37	\$10.48	None	\$24.85
Straps	Amazon	1	N/A	\$15.07	\$0.00	None	\$15.07
Neoprene Sleeve	Donjoy	1	N/A	\$22.88	\$0.00	None	\$22.88
Bolts, Washers, and Nuts	Bolt Depot	12	22462	\$0.37	\$17.25	None	\$33.09
		6	22907	\$0.28			
		12	24838	\$0.25			
		24	24849	\$0.14			
		48	23037	\$0.07			
High Torque Servo	Amazon	1	N/A	\$16.99	\$0.00	None	\$16.99
Twine	Lowes	1	1289800	\$3.93	\$0.00	None	\$3.93
Washers	Lowes	1	18846	\$1.28	\$0.00	None	\$1.28
Heat Shrink	Lowes	1	757551	\$2.28	\$0.00	None	\$2.28
Mounting tape	Scotch	1	394734	\$3.93	\$0.00	None	\$3.93
Bolts	Lowes	1	62054	\$1.28	\$0.50	None	\$1.78
				Shipping Cost:	\$44.36	Total Cost:	\$295.30

Cost Analysis

- Material costs were higher than anticipated due to the trial and error that was expected in the manufacturing process of the brace
 - The supportive material of the brace had to be rolled in order to be manufactured, which is a process with high variability and typically requires multiple attempts to achieve the correct brace shape
 - 4x the required material was purchased to allow for flexibility during the manufacturing process
 - Material costs were about \$61.12 more than initially planned
- An arduino nano, IMU, and high torque servo motor were purchased to replace the raspberry pi, electric linear actuator, and the gyro voltage regulator which resulted in a savings of about \$119.51
 - Achieved a more cost effective prototype so additional components of the brace could be purchased without maxing out the allotted budget.
- Future steps of the manufacturing process will allow for bulk orders of parts and materials, greatly reducing the price per device by about 20-30% per device
 - This allows marketing of the device at a low cost while still maintaining a high return value

Major Outcomes

- Antalgic Gait was simulated with the subjects and with reduced restrictions, the gait peaks/ angles of knee motion showed no statistical difference to normal gait.



- The servo allows for continuous uninterrupted angle adjustments while the patient is moving
 - Advantage over current mechanical adjusting knee braces in market.
 - High torque servo allows for more specificity than current mechanically restrictive plastic inserts.

Future Direction

- In the future, provided additional time and resources, a true adaptive component would be added to allow for the brace to be programmed with a restrictive angle to start with and then the brace would adapt to the patient's specific needs based on sensor readouts instead of the operator having to change the angle of restriction manually in the program.
- Given more time along with working experts in the field of gait rehabilitation an app can be made to allow for patients to work on bettering their gait at home on their own as well

References

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Questions?