The Adaptive Knee Brace: Final Design Presentation

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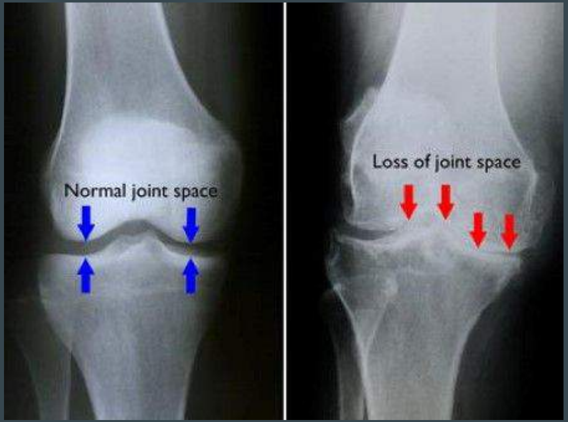
Background - Knee Osteoarthritis

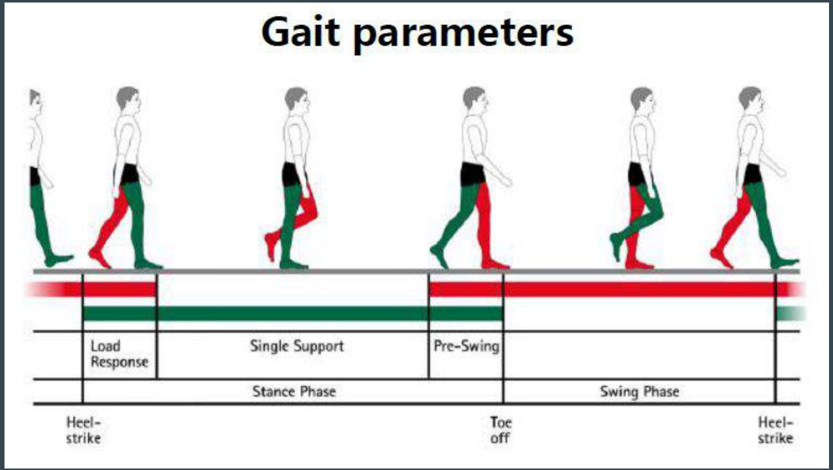
- *Knee Osteoarthritis (OA)* is the degeneration of the articular cartilage in the knee joint
  - Two types: *Primary* and *Secondary*
    - *Primary OA* occurs with no clear underlying reason
    - *Secondary OA* occurs due to an abnormal concentration of force across the joint, injury, or due to abnormal 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

https://biomechanix.com.au/gaitanalysis

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 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 Input - Requirements & Specifications

Requirements	Specification	Verification
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 ± 5.6 cm^2 [1] 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2 [1]	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.

Justification: The device needs to fit users with different body types and shapes in the target population

Design Input - Requirements & Specifications

Requirements	Specification	Verification
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] 2.2 The device must be able to withstand forces of up to 3 times the body weight [2]	2.1.1 The prototype will be simulated in an FEA environment using forces of an average body weight and applied cyclical loading 2.2.1 The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability

Justification: The device must be able to support the weight of the average user without breaking or losing functionality

Design Input - Requirements & Specifications

Requirements	Specification	Verification
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3° [4]	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
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±5° (between initial and pre-swing) [4]	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation

Justification: The device must be able to measure angles of the knee or else cause potential harm to the patient during gait

Design Input - Requirements & Specifications

Requirements	Specification	Verification
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device [2]	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed

Justification: 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.

Design Input - Requirements & Specifications

Requirements	Specification	Verification
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms [3] 6.2 Sensor must be limited to sampling rate of 300Hz [3]	Calculations based on microcontroller processing speed and sensor sampling rate
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA [3]	Ammeter to probe system to test amperage of circuit

Justification: 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)

Design Input - Requirements & Specifications

Requirements	Specification	Verification
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 [4]	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.

Justification: Data collection during sessions with the patient is necessary for analyzing forces, knee angles, and other aspects of gait rehabilitation

Design Input - Requirements & Specifications

Requirements	Specification	Verification
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 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
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 [6]	The devices power consumption will be monitored and will be continuously recording data for an hour

Justification: 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.

Design Input - Requirements & Specifications

Requirements	Specification	Verification
11. The design must be comfortable	This requirement will be measured quantitatively by survey confirmed through validation surveys	---
12. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	Our device is classified Category B Surface Device and has to pass the tests for Cytotoxicity, Sensitization and Irritation [6]	All materials that will make contact with the skin will be in accordance with ISO biocompatible standards

Justification: It is necessary for the device to be comfortable and biocompatible so that the user is not uncomfortable or get further injury using the device.

Validation

Requirement	Category	Validation
1, 5, 11	Fit and Range of Motion	User will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
6, 8	Data Collection, Accessibility, and Security	The data will be accessible, understandable, secure, and accurate
3, 4, 6, 7, 10	Electronic Component Testing	Electronic components will be tested using National Instruments VirtualBench to ensure they are functioning properly.

Validation

Requirement	Category	Validation
2, 5, 9	Device Integrity and Simulated Testing	The electronics will be tested for water resistance. The brace components will be simulated and cyclically tested to show long term integrity
3, 4	Device Intervention	Device provides resistance to stop the user from improper movement and assists the user
12	Biocompatibility	The device must be biocompatible in accordance with ISO 10993

Design Solutions - Brace

Brace & Compression Sleeve:

- Increases stability compared to a brace with no sleeve
- Possibly restricts motion
- More expensive than a brace with no compression sleeve (2 components vs 1 component)

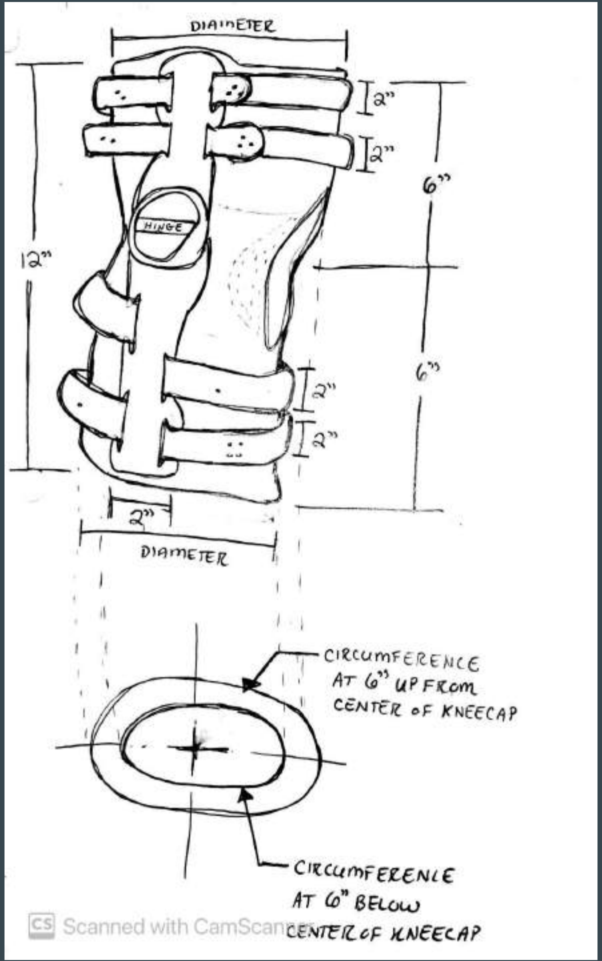
Brace measurements are made by taking the circumference of the leg 6 inches above the mid-patella, and 6 inches below the mid-patella

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/



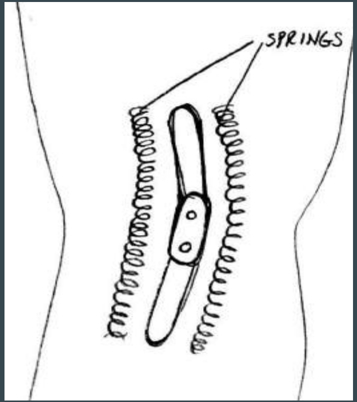
[10]

Note: The dimensions shown are estimates and are subject to change

Design Solutions - Hinge System

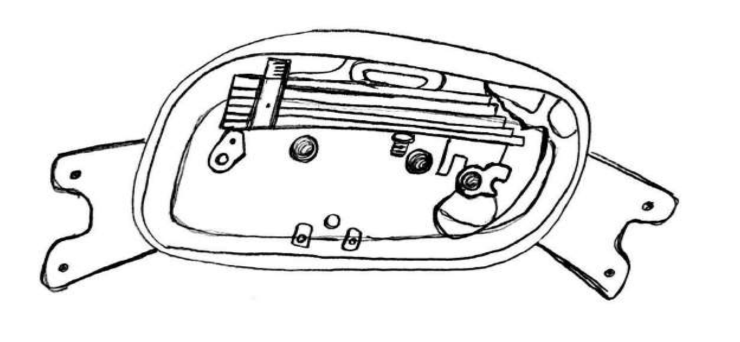
Single Hinge (Free Joint):

- Simple design
- Cheap to manufacture
- Springs create added resistance when the knee bends, limiting range of motion
- Only accounts for rotational motion, is not designed for vertical motion



Single Hinge (Mechanically Restricted Motion):

- Slightly more complicated design
- Mechanical resistance is created when the knee bends and the hinge rotates, contacting the varying length bars, which creates more resistance as pressure against the bars increases
- Only accounts for rotational motion, is not designed for vertical motion

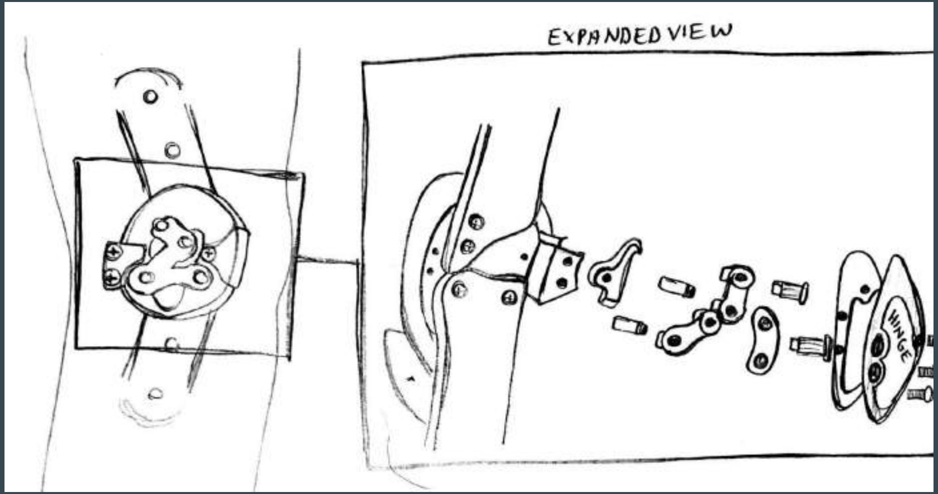


[11]

Design Solutions - Hinge System (Continued)

Double Hinge (TM +5 Hinge):

- Most complicated design
- Hinges are overlapped so that varying directions of motion can be accomodated
- Accounts for both rotational motion and vertical motion (the knee experiences slight vertical motions during impact activities)
- Most expensive design

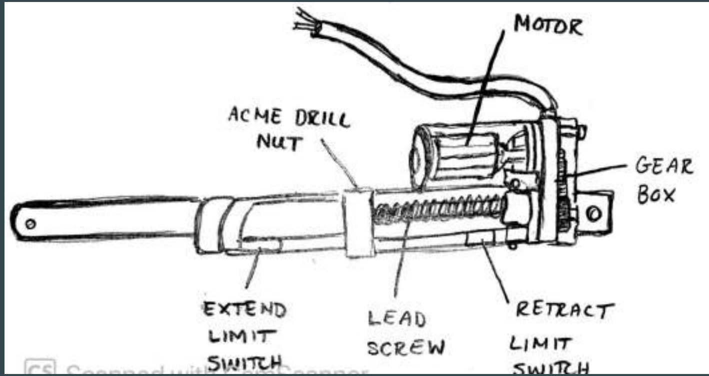


The most important aspect of the hinge systems discussed, independent of which is chosen, is the placement of the hinge system. The hinge must be placed adjacent to the wearer's knee. Misplacement of the hinge can lead to user varying degrees of injury, irritation, etc. [10]

[12]

Design Solutions - Electric Linear Actuator & Cable

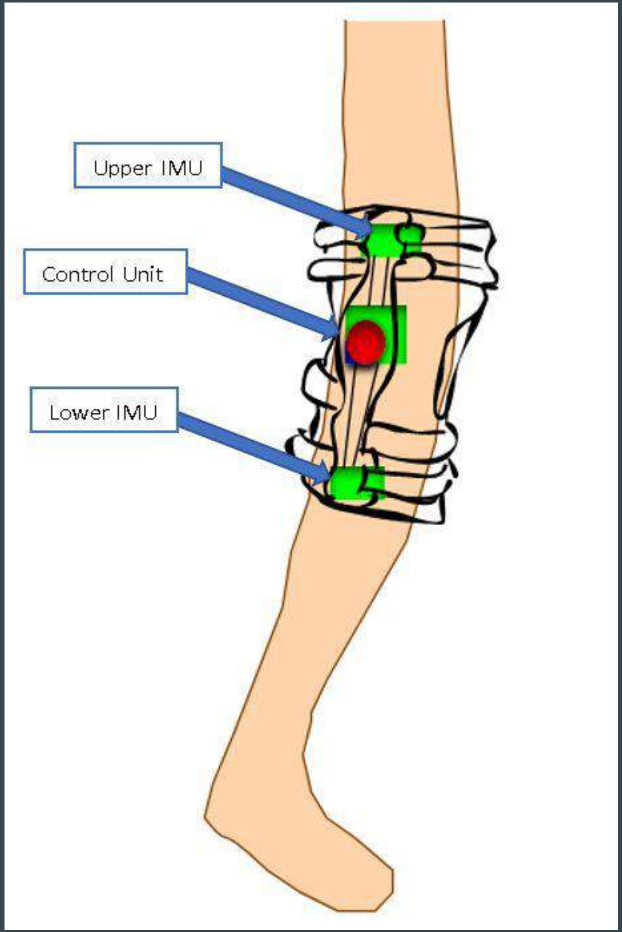
- Electric Linear Actuator will be programmed to act as feedback from accelerometer, gyroscope, and inverse dynamic algorithm (calculate knee joint angle)
- Allows there to be dampening force, or assistive force on hinge during gait. (Adjusted to each individual)
- 33” steel flexible actuator cable allows for the hinge assistance without needing to mount a linear actuator behind the hinge mechanism.



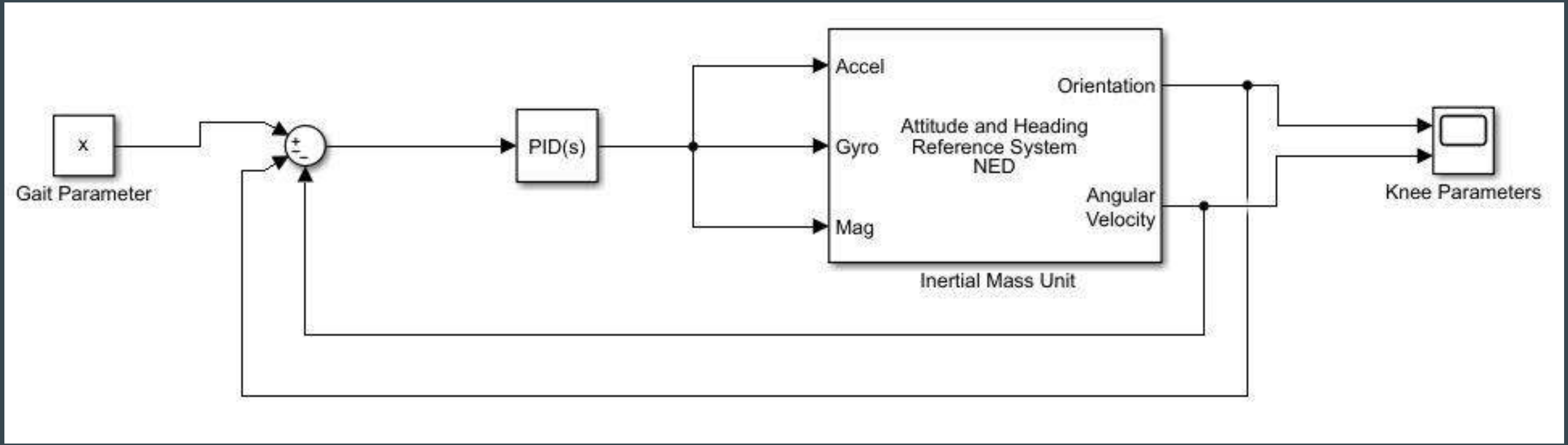
https://www.allelectronics.com/item/fac-1/33-flexible-actuator-cable/1.html

Design Solutions - Electronics

- Microcontroller supplied with a battery pack around the most stable midsection of the brace with two inertial mass units (IMUs) above and below the microcontroller.
- Microcontroller Arduino Nano 33 BLE with onboard inertial sensor acting as the upper IMU. Battery pack still around the most stable midsection of the brace for weight distribution and the second IMU below.
- The upper IMU around the top of the brace approximately mid to lower thigh, the lower IMU around the bottom of the brace, mid to upper calf.



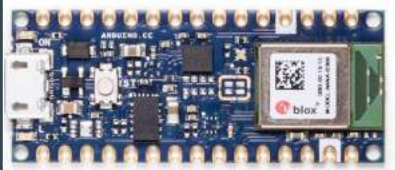
Design Solutions - Electronics Control Unit



- 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

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

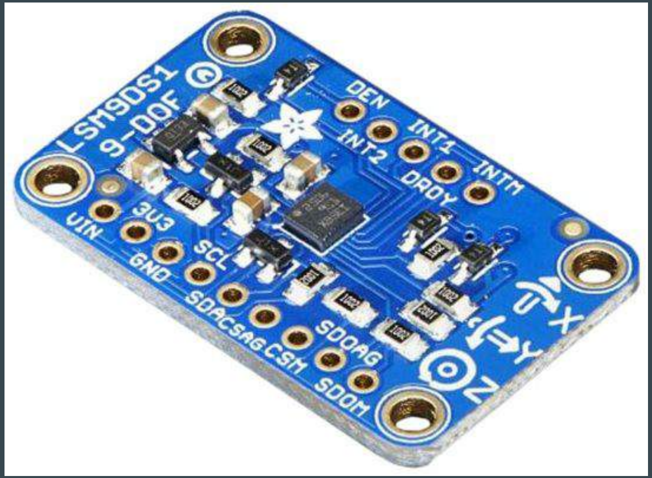
Design Solutions - Inertial Mass Units

- The IMU consists of an accelerometer, gyroscope, and magnetometer which can measure, angle, orientation, and acceleration.
- One design solution would be to use separate sensors and interface them all with the microcontroller, however it would be easier to use one combined inertial mass unit that incorporates all three sensors.
- The IMU will be able to measure the calf and thigh angular displacement, orientation of the knee and angular velocity of the knee.

Design Solutions - Inertial Mass Units

- Using the Arduino Nano 33 BLE with an onboard IMU we would only have to purchase one other IMU which would reduce the cost of the project.
- The onboard IMU is a LSM9DS1 which has the following technical specifications*:

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



*Industries, A. *Adafruit 9-DOF Accel/Mag/Gyro+Temp Breakout Board - LSM9DS1*.https://www.adafruit.com/product/3387?gclid=Cj0KCQiAzZL-BRDnARIsAPCJs71KkbgxPcDF5ybQfBTvvmbq8yrXhDnddTSZ23kYIgebTRG201-_dvYaAuuBEALw_wcB.

Design Solution 1

Simplest and Cheapest:

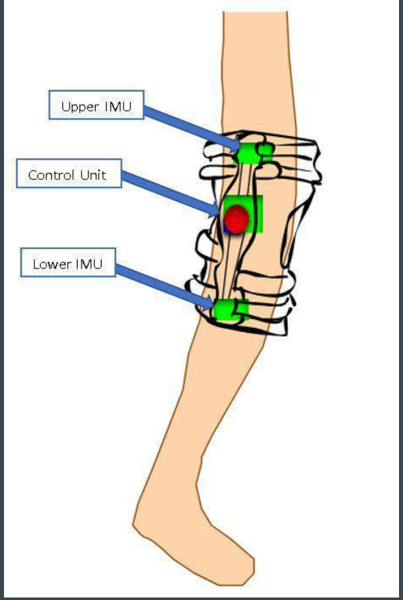
- Brace Only
- Single Hinge System (Free Joint)
- Electronics - Microcontroller and Combined IMU

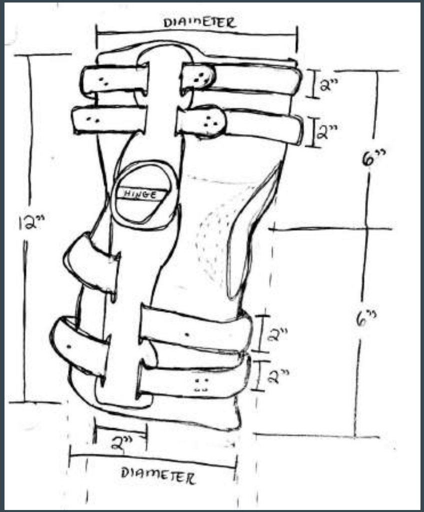
Pros:

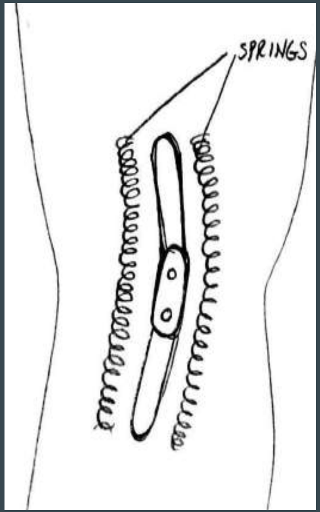
- Increases mobility due to less constriction of the leg
- Least expensive
- Simple design

Cons:

- Reduced stability
- Only accounts for rotational motion, is not designed with vertical motion in mind







Design Solution 2

Simple, Restricted Motion:

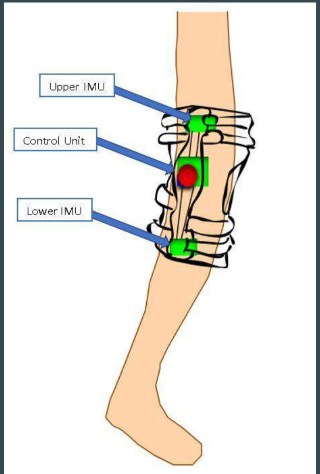
- Brace & Compression Sleeve
- Single Hinge System (Mechanically Restricted Motion) with an added resistor set on the opposite side of the current resistors to ensure hyperextension of the knee does not occur as well as too far of knee flexion
- Electronics - Microcontroller and Combined IMU

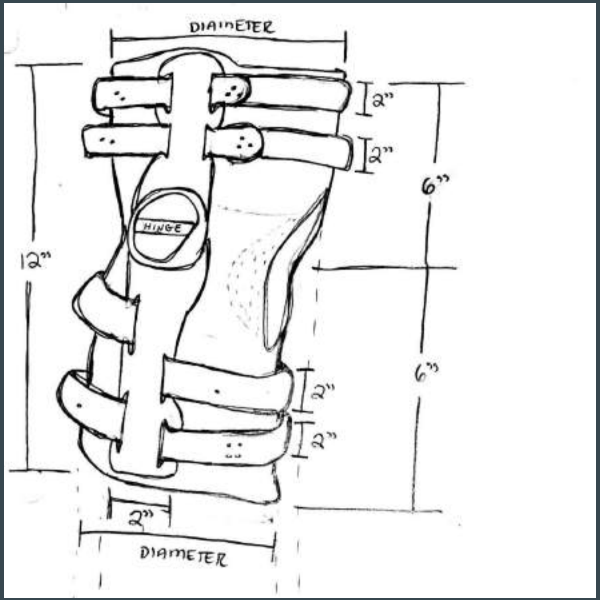
Pros:

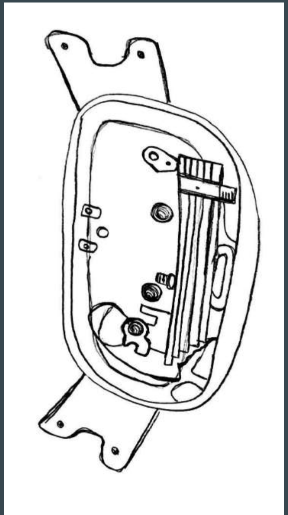
- Simple design
- Prevents user from bending knee too far to the point of difficulty while standing back up

Cons:

- Only accounts for rotational motion, is not designed with vertical motion in mind



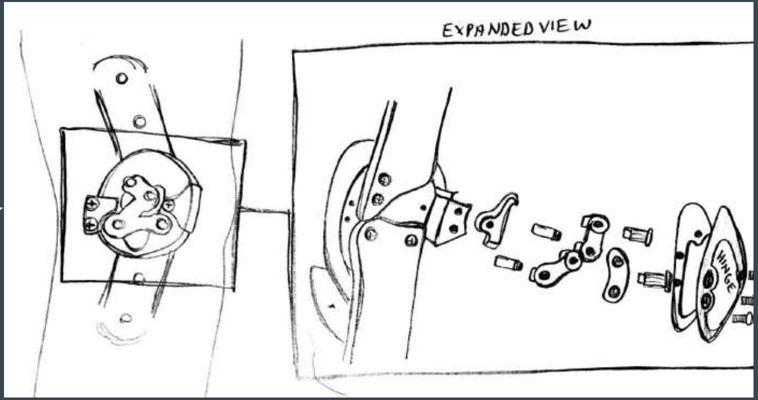




Design Solution 3 - Final Design

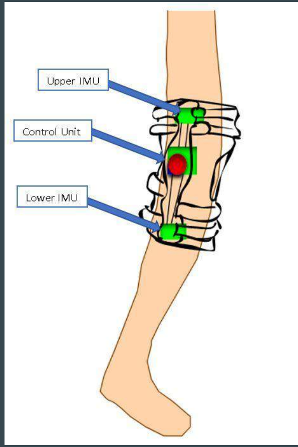
Complex, Accommodates all Motion:

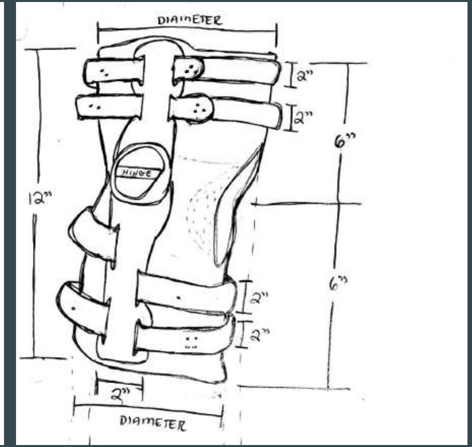
- Brace & Compression Sleeve
- Double Hinge System (TM +5 Hinge) with added mechanically restricted motion resistors to prevent knee hyperextension and to limit the vertical motion allowed to small movements
- Electric Linear Actuator with flexible Steel Cable
- Electronics - Microcontroller and Combined IMU



Pros:

- Accounts for both rotational motion and vertical motion (the knee experiences slight vertical motions during impact activities)
- Restricts vertical motion to minimal movements (impact)
- Provides feedback data from electronics





Cons:

- Most complicated design
- Most expensive design

Design Matrix - Brace Design

	Design Matrix: Brace Design			
	Mobility	**Stability**	**Restriction**	**Expense**
Brace Alone	More mobility due to less constriction on the leg	Reduced stability due to less keeping it on	Less restrictive due to having no compression sleeve	Less expensive due to not needing the sleeve
Brace with compression sleeve	Less mobility due to the sleeve constricting the leg	Increased stability due to having the compressive sleeve helping to keep it in place	Has a possibility to restrict motion	More expensive since it has the cost of the compressive sleeve on top of the cost of the brace

Design Matrix - Hinge Design

	Design Matrix: Hinge Design			
	Complexity	**Restriction**	**Range of Motion**	**Cost**
Single Hinge (Free Joint)	The least complex of our potential designs which consists of a simple hinge and spring system	Springs are used to restrict and assist motions	Limited, only rotational	Cheapest design
Single Hinge (Mechanically Restricted)	Slightly more complex consisting of a hinge with a mechanical resistance system	Mechanical methods such as metallic bars restrict and assist motions	Limited, only rotational	Mid range expense
Double Hinge	The most complex design consisting of two hinges which allow for a great range of motion	Metallic bars and or spring restrict and assist motions	Accounts for both rotational and vertical motion	Most expensive design option

Design Matrix - Microcontroller

	Design Matrix: Microcontroller								
	Price	**Memory**	**Clock Speed**	**Multitasking**	**Voltage**	**Flash**	**USB**	**Operating System**	**Integrated IMU**
Raspberry PI Model B	$35.00	512MB	700 MHz	Yes	5V, This voltage is within a safe range which would not cause harm is something were to go wrong	SD Card (2-16GB)	Two	Linux distributions	None
Arduino UNO	$30.00	2KB	16 MHz, Not the best option since we plan on our device needing a high frequency	No, Not good since we are planning on having multiple inputs running at the same time	7-12V, Neither good nor bad, higher then we would like but low enough not to change anything	32KB,Storage is very low for our device to be ran for any length of time	One	None	None
Arduino Nano 33 BLE	$20.20	256KB	64 MHz	No, Not good since we are planning on having multiple inputs running at the same time	3.3-21V, This voltage is within the safe range which would not cause harm	1MB, Low memory but could be made to work	One	None	LSM9DS1

Design Matrix - Combined IMU

Design Matrix: Combined IMU							
	Absolute Orientation	**Velocity Vector**	**Acceleration Vector**	**Gravity Vector**	**Temperance**	**Power Input**	**Price**
BNO055	3-axis at 100Hz	3-axis (in rad/s) at 100Hz	3-axis (gravity+ linear motion in m/s^2) at 100Hz	3-axis (minus any movement in m/s^2) at 100Hz	Ambient temperature at 1Hz	2.4-3.6V	$19.95
BNO085	3-axis at 100Hz	3-axis (in rad/s) at 100Hz	3-axis (gravity+ linear motion in m/s^2) at 100Hz	3-axis (minus any movement in m/s^2) at 100Hz	Ambient temperature at 1Hz	2.4-3.6V	$19.95
LSM6DS33	3-axis at 104Hz	3-axis at 104Hz	3-axis at 104Hz	3-axis at 104 Hz	None	Max 4.8V	$11.95

Design Matrix - Overall Design

	Design Matrix							
	Cost	**Complexity**	**Practicality**	**Efficiency**	**Weight**	**Battery Life**	**Material**	**Performance**
Design 1: Brace Only, Single Hinge (free joint), Microcontroller and IMU	Least cost overall	Lest complex due to the simple brace and hinge design being used	This device would restrict vertical movement and not provide the proper form of resistance	This design is the least able to fulfill our purpose	Weights the least of designs	Since all designs have the same electronics the battery life for all devices will be the same	This would require the least materials but the spring is the worst of the three resistance systems	This would perform the least effective in providing assistance for gate rehabilitation
Design 2: Brace and Compression Sleeve, Single hinge (mechanically restricted), Microcontroller and IMU	Mid range cost	Slightly more complex since the brace also includes the compressive sleeve and mechanically resistive hinge design	This design would be okay for our purpose but would restrict vertical movement	This design will fulfill our purpose but restrict vertical movement	Weights slightly more then the free joint design due to the mechanically restrictive hinge design		This system is better since it has the mechanical resistance which is better then a spring	This would be adequate for gate rehabilitation but would restrict movement to a degree
Design 3: Brace and Compression Sleeve, Double hinge system, Electric Linear Actuator Microcontroller and IMU	Most expensive	The most complex design since it has both the compressive sleeve and the double hinge system	This design would be the most applicable to what we want to do and allow the user to have the best range of motion	This device would be the most efficient for the user in both resistance and range of motion	The heaviest of the three since it has the double joint system which is heavier then the single joint designs		This would be the best design material wise even though it would take the most materials since it would allow for the most natural gait posture	This would be the best option for gate rehabilitation since it would not provide any vertical range of motion restriction

Risk Assessment

Hazard	Severity	Occurrence	RPN
Hyperextension of the knee	3-5 Could cause anywhere from minor irritation/injuries to cartilage/muscle tears depending on the extremity of hyperextension	2 Added resistive components of the hinge prevent knee from extending past tracked angles	6-10
Resistive force stops the leg too quickly	6 If the leg stops mid swing, the likelihood of falling is high and in elderly patients, falling can cause moderate/possibly permanent damage though bone fractures	6 Added resistive components of the knee increase likelihood of preventing leg extension	36
Over-constriction of compressive straps	2-3 Could irritate the skin and cause bruising/scapes and cuts depending on tightness of the straps	7 For each patient over tightening knee straps is common during proper fitting	14-21
Lithium battery	7 If the lithium battery explodes or catches on fire, third degree burns are common. Acidic burns can also occur	1 Modern day battery technology with a combination of limited current draw	7
Sensor error	1-2 No harm occurs due to sensor error, however it can affect the resistive forces added at incorrect times which can create some discomfort	7 Sensors recalibrations are common, and misreadings are also very common	7-14

Severity Chart

Rank	Criteria: Severity of Effect	Consequence	Treatment
10	Death	-	-
9	Quadriplegia	Lifelong medical care necessary / coma / permanent damage	Hospital stay
8	Amputations, paraplegia, blindness, deafness, traumatic brain injury (severe), fourth-degree burns	Lifelong medical care necessary / coma / permanent damage	Hospital stay
7	Complex fractures, open fractures, inner injuries, traumatic brain injury (severe), third-degree burns	Permanent damage possible	Hospital stay
6	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (moderate), second-degree burns	Permanent damage possible	Hospital stay
5	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (mild), second-degree burns	Reversible injury	Hospital stay or ambulance treatment
4	Severe cuts, severe scratches, severe contusions, strains, first-degree burns	Reversible injury	Ambulance treatment or self-treatment
3	Minor cuts, minor scratches, minor contusions, stiff muscles, tension, blisters, excoriations, sickness, first-degree burns	Discomfort during application up to three days after application	Self-treatment
2	Slight sickness, pressure marks	Discomfort	-
1	No harm	-	-

Occurrence Chart

Rank	Probability of Occurrence
10	Occurs or may occur very likely during every use of the session
9	Occurs or may occur likely during every use of the session
8	Occurs in 1 of 5 sessions (less than once a day)
7	Occurs in 1 of 10 sessions (less than once a day)
6	Occurs 1 in 50 sessions (less than one in half a month)
5	Occurs 1 in 100 sessions (less than once a month)
4	Occurs 1 in 500 sessions (less than once in half a year)
3	Occurs 1 in 1000 sessions (less than once a year)
2	Occurrence very unlikely
1	Occurrence nearly impossible

Severity vs Occurrence Chart

		Occurrence									
		1	2	3	4	5	6	7	8	9	10
Severity	1	1	2	3	4	5	6	7	8	9	10
	2	2	4	6	8	10	12	14	16	18	20
	3	3	6	9	12	15	18	21	24	27	30
	4	4	8	12	16	20	24	28	32	36	40
	5	5	10	15	20	25	30	35	40	45	50
	6	6	12	18	24	30	36	42	48	54	60
	7	7	16	21	28	35	42	49	56	63	70
	8	8	16	24	32	40	48	56	64	72	80
	9	9	18	27	36	45	54	63	72	81	90
	10	10	20	30	40	50	60	70	80	90	100

1-29
30-50
51-100

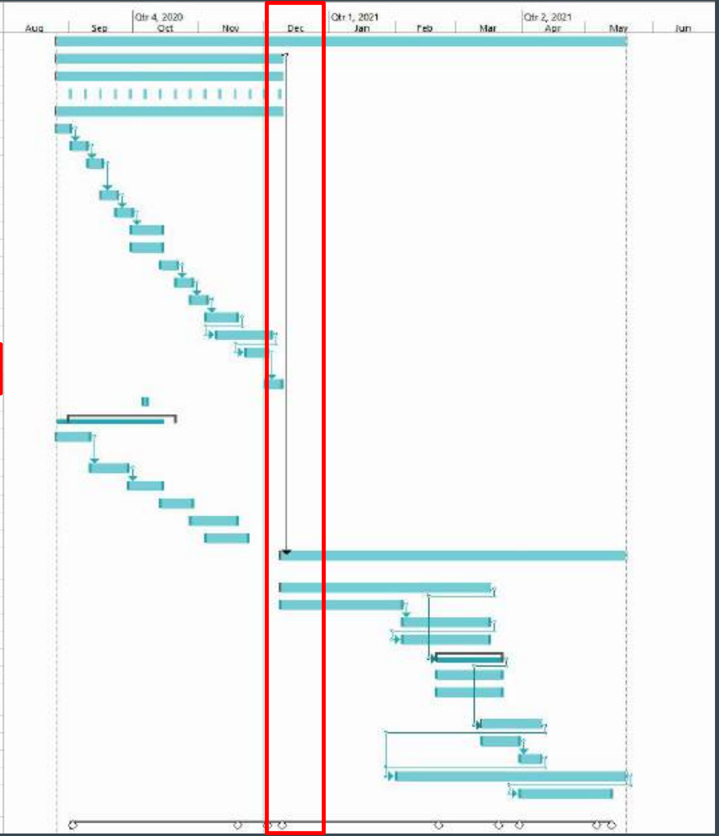
1-29: This range was chosen for the acceptable region since it encompases the very low chance of occurrence but severe and higher chance of occurrence but not severe ends of the spectrum which which are acceptable for our device and keep the patient within a comfortable safety range.
30-50: Was determined to be an acceptable range as long as it is as low as reasonably possible for the specific hazard. If something falls into this range it was determined to not be too dangerous for our project.
51-100: This range was determined to be unacceptable due to the fact that anything in this range because it occurs too often for its severity for our device.

Budget Overview

Item	Company	Quantity	Part Number	Cost Per Unit	Shipping Cost	Special Handling (Hazards)	Total Cost
Arduino Nano 22 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	None	$29.50
Springs		3		$10.00	$0.00	None	$30.00
Support Materials		1		$45.00	$0.00	None	$45.00
Straps		1		$30.00	$0.00	None	$30.00
Fabric + Cushion		1		$30.00	$0.00	None	$30.00
Double Jointed Hinge		1		$20.00	$0.00	None	$20.00
Electric Linear Actuator		1		$129.00	$0.00	None	$129.00
						Total Cost:	$368.35

Gantt Chart

ID		Task Mode	Task Name	Duration	Start	Finish	Predecessors
1			**Senior Project**	**191 days**	**Wed 8/26/20**	**Wed 5/19/21**	
2			**Semester I**	**76 days**	**Wed 8/26/20**	**Wed 12/9/20**	
3			**Semester I Due Dates**	**76 days**	**Wed 8/26/20**	**Wed 12/9/20**	
4			**Advisor Meeting**	**71 days**	**Tue 9/1/20**	**Tue 12/8/20**	
20			**Canvus Due Dates**	**76 days**	**Wed 8/26/20**	**Wed 12/9/20**	
21			Device Requirments	5 days	Wed 8/26/20	Tue 9/1/20	
22			Preliminary Website Design	6 days	Wed 9/2/20	Wed 9/9/20	21
23			Design Requirments Presentation	5 days	Thu 9/10/20	Wed 9/16/20	22
24			Realistic Constraints	6 days	Wed 9/16/20	Wed 9/23/20	23
25			Standards	6 days	Wed 9/23/20	Wed 9/30/20	24
26			Gantt Chart	11 days	Wed 9/30/20	Wed 10/14/20	25
27			Budget Outline	11 days	Wed 9/30/20	Wed 10/14/20	
28			Safety Survey	6 days	Wed 10/14/20	Wed 10/21/20	
29			Interim Design Review	6 days	Wed 10/21/20	Wed 10/28/20	28
30			Hazards Analysis	6 days	Wed 10/28/20	Wed 11/4/20	29
31			Project Abstract	11 days	Wed 11/4/20	Wed 11/18/20	30
32			Final Report - Draft	20 days	Mon 11/9/20	Fri 12/4/20	31
33			Semester I Final Presentations	8 days	Mon 11/23/20	Wed 12/2/20	32
34			Final Report	6 days	Wed 12/2/20	Wed 12/9/20	33
35			Machine Shop Meeting	2 days	Tue 10/6/20	Wed 10/7/20	
36			**Design and Parts Research**	**36 days**	**Tue 9/1/20**	**Tue 10/20/20**	
37			Look up other brace designs for inspiration	12 days	Wed 8/26/20	Thu 9/10/20	
38			Find potential parts and datasheets	12 days	Fri 9/11/20	Mon 9/28/20	37
39			Start creating potential device designs	12 days	Tue 9/29/20	Wed 10/14/20	38
40			Finalizing Design	11 days	Wed 10/14/20	Wed 10/28/20	
41			Writing/Finalizing Abstract	16 days	Wed 10/28/20	Wed 11/18/20	
42			Writing SPI Paper	14 days	Wed 11/4/20	Mon 11/23/20	
43			**Winter Break and Semester II**	**111 days**	**Wed 12/9/20**	**Wed 5/12/21**	**2**
44			**Project Prototyping**	**54 days**	**Wed 12/9/20**	**Sat 2/20/21**	
45			Ordering Parts	41 days	Wed 12/9/20	Wed 2/3/21	
46			Electrical Components	29 days	Thu 2/4/21	Tue 3/16/21	45
47			Brace Construction	29 days	Thu 2/4/21	Tue 3/16/21	46
48			**Prototype Verification/Testing**	**22 days**	**Sat 2/20/21**	**Mon 3/22/21**	**44**
49			Strength test brace by cicular loading	22 days	Sat 2/20/21	Mon 3/22/21	
50			Test electronics during use to ensure accuracy	22 days	Sat 2/20/21	Mon 3/22/21	
51			**Design Adjustments and Validation**	**13 days**	**Sat 3/13/21**	**Tue 3/30/21**	**48**
52			Data Collection	13 days	Sat 3/13/21	Tue 3/30/21	
53			Gate Analysis	8 days	Wed 3/31/21	Fri 4/9/21	52
54			Senior Project Paper	78 days	Mon 2/1/21	Wed 5/19/21	53,51
55			Senior Project Presentation	31 days	Wed 3/31/21	Wed 5/12/21	54
56			**Milestones**	**181 days**	**Wed 9/2/20**	**Wed 5/12/21**	



References

1. Stallard J, Dounis E, Major RE, Rose GK. One leg swing through gait using two crutches. An analysis of the ground reaction forces and gait phases. Acta Orthop Scand. 1980;51(1):71-77.
2. Lee, H., Ha, D., Kang, Y. S., & Park, H. S. (2016). Biomechanical Analysis of the Effects of Bilateral Hinged Knee Bracing. Frontiers in bioengineering and biotechnology, 4, 50.
3. Fast, Flexible Closed-Loop Feedback: Tracking Movement in “Real-Millisecond-Time”, Keisuke Sehara, Viktor Bahr, Ben Mitchinson, Martin J. Pearson, Matthew E. Larkum, Robert N. S. Sachdev, eNeuro 14 October 2019, 6 (6) ENEURO.0147-19.2019
4. Alonge, F., Cucco, E., D'Ippolito, F., & Pulizzotto, A. (2014, May 13). The Use of Accelerometers and Gyroscopes to Estimate Hip and Knee Angles on Gait Analysis. Retrieved September 16, 2020
5. International Organization for Standardization. (2020, January 09). Retrieved September 16, 2020,
6. Paluska, S. A., & McKeag, D. B. (2000). Knee braces: current evidence and clinical recommendations for their use. American family physician, 61(2), 411–424.
7. Kerrigan, D. C., Todd, M. K., Della Croce, U., Lipsitz, L. A., & Collins, J. J. (1998). Biomechanical gait alterations independent of speed in the healthy elderly: evidence for specific limiting impairments. Archives of physical medicine and rehabilitation, 79(3), 317–322.
8. Wagenaar, R. C., & Beek, W. J. (1992). Hemiplegic gait: a kinematic analysis using walking speed as a basis. Journal of biomechanics, 25(9), 1007–1015.

References

9. Trail, J. (n.d.). Biocompatibility Testing for Surface Medical Devices: An Overview. Retrieved September 16, 2020
10. S. Sterling, Anatomically Designed Orthopedic Knee Brace, 2007.
    K. Martin, Knee Brace Hinge, 1984.
11. D. A. Taylor, Post Operative Knee Brace, 1994.
12. Tao, W., Liu, T., Zheng, R., & Feng, H. (2012). Gait analysis using wearable sensors. Sensors (Basel, Switzerland), 12(2), 2255–2283.
13. Takeda R., Tadano S., Todoh M., Yoshinari S. (2009) Human Gait Analysis using Wearable Sensors of Acceleration and Angular Velocity. In: Lim C.T., Goh J.C.H. (eds) 13th International Conference on Biomedical Engineering. IFMBE Proceedings, vol 23. Springer, Berlin, Heidelberg.
14. Stetter, B. J., Ringhof, S., Krafft, F. C., Sell, S., & Stein, T. (2019). Estimation of Knee Joint Forces in Sport Movements Using Wearable Sensors and Machine Learning. Sensors (Basel, Switzerland), 19(17), 3690.
15. Sensors/Accel, Gyro, and Magnetometers. https://www.adafruit.com/category/521

Questions?