The Adaptable Knee Brace:
An Assistive Gait Rehabilitation Device for Severe Osteoarthritis (OA)

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Abstract

Elderly patients with osteoarthritis in the patellofemoral and lateral femoral region in the knee joint develop irregular gait from impairment mobility from pain and weakening of the muscles around the knee. For proper gait rehabilitation of the knee, a patient requires customized rehabilitation training combined with a force-assisted brace. The Adaptive Knee Brace is designed to meet these criteria as an assistive knee brace to successively alter the patient's gait in order to mitigate factors leading to impaired mobility. The device reduces the excess load on the knee based on the angle of the knee through the gate cycle. The electronic components of the brace include an accelerometer, a gyroscope, a magnetometer, and a high torque servo motor to monitor and limit the knee position throughout the gait cycle. These components provide accurate measurements and proper feedback in the knee for the desired gait angles during the rehabilitation process. The year-long project will result in a knee brace that will increase motion in the patient's knee during the swing and stance phases in their gait cycle and an overall reduction in contact forces in the areas most affected by knee OA of the end-user post-rehabilitation.

Introduction

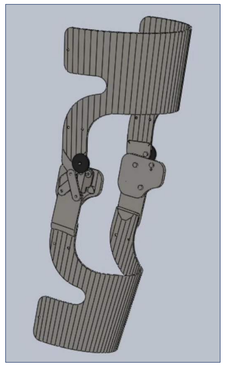
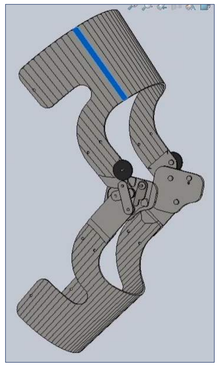
Knee injuries are very common, often resulting in sprains/tears of the soft tissue surrounding the knee. One of the most common knee injuries seen in the elderly community is knee osteoarthritis, which is commonly accompanied with knee pain, and can inhibit the proper walking motions of the knee depending on severity. The goal of The Adaptive Knee Brace is to design an assistive knee brace for elderly patients with severe osteoarthritis in the knee joint. The device will be targeted towards elderly patients between the ages of 60 to 90 years old, as they are a higher risk group for severe knee osteoarthritis. Since gate rehabilitation is a common rehabilitation method for patients with severe knee osteoarthritis, the assistive brace will be designed with the motions of gate rehabilitation in mind. In order to allow this brace to assist in the gate rehabilitation cycle, it will reduce the varying loads and contact forces on the knee (based on the angle of the knee through the gate cycle) which in turn should reduce pain in the knee joint. Additionally, the device will require less strength from the patient's muscles surrounding the knee in order to bear the given load of the user, which will allow the patient to perform gate rehabilitation easier with less pain and better motion.

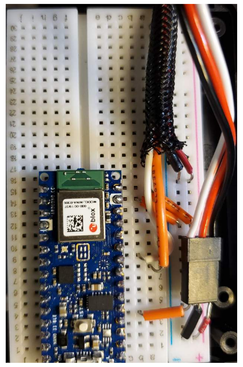
Design Inputs

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 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 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±3°	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 ± 5° (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
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
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 Solution

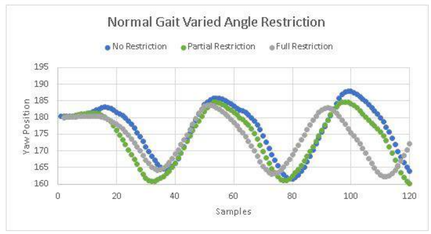
A mechanically restricting knee brace was designed with a modified double hinge to allow for rotational motion, as well as slight vertical motions for impact-type movements. The angle of rotation has been restricted to a range of 0° to 90° to prevent hyperextension of the knee. The supportive brace was manufactured using ⅛ inch 6061-T6 aluminum to allow for proper rolling during the manufacturing process, while also maintaining the capability to meet the load bearing requirements from the design inputs. The compression sleeve was added to provide a layer of protection for better comfort. The electrical components used in the design were the Arduino Nano 33 BLE Microcontroller, LSM9DS1 Inertial Mass Unit Sensor, and a High Torque Servo Motor. The inertial sensor and the onboard inertial sensor of the microcontroller communicate to collect accelerometer, gyroscope, and magnetometer data. An algorithm is used to convert this data into positional data throughout the walking gait cycle. The servo motor was used to restrict the brace at different angles through gait testing.

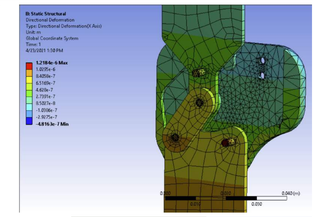



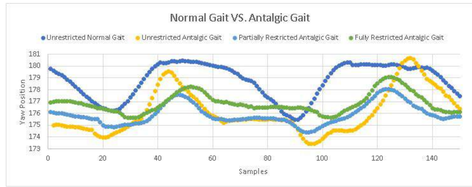




Testing

- FEA simulations were run and confirmed that the brace design can withstand forces more than three times that of the intended average user with a weight of 72kg. Simulations assumed a force equal to that of an average patient jumping from an one meter height and having the force go completely through the brace
- Angles of the knee brace were measured and verified within the range of 0°- 88°
- Hyperextension of the knee was restricted up to 0° ± 3° mechanically by a ¼ inch mounting plate for the servo motor
- Gait testing was performed with the Arduino Nano 33 BLE microcontroller and LSM9DS1 inertial sensor with a sampling rate of 104 Hz
  - Test were performed based on varied angle restrictions of knee motions: No Restriction (0-88°), Partial Restriction (0-50°), and Full Restriction (0-30°)
- Results show that the brace successfully produces controlled restrictions at different angles using a slider and servo motor mechanism against the double hinge mechanism.
- During Antalgic Gait testing, reduced restrictions led to an increase in knee angle magnitude
- The unrestricted Antalgic gait shows no significant difference in the subject knee angles compared to unrestricted normal gait ($p > 0.05$).







Conclusions

Testing of the prototype has shown that the rotation motion can be controlled and restricted to specific angles to help with gait rehabilitation. Programmable active control and restriction of knee angles during rehabilitation provides a distinct advantage over mechanically restricting knee braces. The electrical components can monitor the subjects gait and provide user programmable feedback to the patient in smaller and more specific increments by a trained professional. Restricted antalgic gait at reduced resistances outputs data that indicates a shift to normal gait patterns.

Future clinical trials should be conducted with different types of gait and the programmable restrictions needed for long term gait rehabilitation. Additionally, the algorithm used to determine gait can be designed to provide active feedback to the user for more optimizable rehabilitation.

References

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