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UN-TETHERED, ACTIVE ANKLE-FOOT ORTHOTIC

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INTRODUCTION

Foot drop, or the inability to dorsiflex the foot (i.e., point your toe upward) is a fairly common lasting side-effect of a stroke, affecting approximately 20% of stroke survivors (~1.3 million people each year). The customers have adopted the use of Ankle Foot Orthotics (AFOs) in order to aid in the dorsi-flexion of the foot. These passive devices do not allow users to safely move down inclines or stairs as the user's foot will always be pointed upwards when off the ground.

The goal of this project was to design and develop an active AFO that aids a user in the dorsiflexion of their foot when moving down stairs or ramps. The project utilizes an existing terrain sensor system [1] to detect the upcoming terrain. The sensors are processed by a microcontroller which then will trigger movement of a mechanical locking system to change the angle of the foot according to the angle of the upcoming terrain.

PRODUCT DESIGN

The novel part of the system is the utilization of the sensing system to detect the upcoming terrain and adjust the position of the foot accordingly. This system, processed by the microcontroller and battery and sustained by the mechanical locking system allows the mobility of the patient's foot without being tethered to an outside system.

The team was given an existing AFO featuring two rigid components connected by a tamarack joint and an anti-plantar flexion hard stop located posterior to the heel courtesy of Nazareth College's Physical Therapy Clinic. This device was modified to include a hydraulic locking mechanism, terrain sensing system, and processing and control systems.

The hydraulic locking mechanism was designed in order prevent plantar-flexion of the foot while the user's foot is off the ground during a normal gait cycle on flat ground or up stairs and ramps. The mechanism will disengage and allow for normal plantar or dorsi flexion of the user's foot when descending stairs or ramps. The mechanism consists of a 9/16 inch piston cylinder arrangement with a 3 inch stroke attached to the orthotic via 2 pin joints located posterior to the heel and to the calf. As the foot is plantar and dorsi flexed, the piston will actuate in and out of the cylinder.

The flow of water in and out of the upper portion of the piston will be controlled by a solenoid powered valve. When the valve is open, fluid will be able to travel between the vacuum in the piston and a nearby reservoir. When the valve is closed, the fluid will be stuck in the piston chamber, thus preventing plantar-flexion due to the incompressibility.

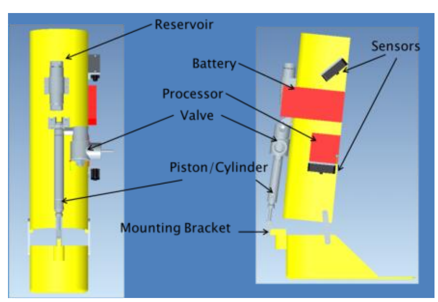

Figure 1: CAD model of design

The purpose of the electrical subsystem on the PCB is threefold: It powers the solenoid, the microcontroller, and the sensors, monitors the battery power level, and routes the sensor signals to the microcontroller to be processed and returned as control to the solenoid. This is accomplished by mounting the microcontroller on top of the 2.9in by 2.2in PCB, which has the added benefit of reducing surface real estate on the AFO casing. Horizontal space on the AFO is very limited. The battery level monitoring is a voltage divider that passes the signal to the microcontroller. When the voltage drops past a certain point, the microcontroller turns on an LED to indicate a failing battery.

The sensor system, which is an adaption of the system described in "Terrain Characterization," [1] operates with two sensors. The vertical sensor determines if the foot is on or off of the ground and the forward sensor is calibrated to determine the upcoming terrain. The forward sensor is calibrated based on the distance between the calf and ground at a standing position. When the forward sensor detects a longer length, the microcontroller can determine if the foot is planted on the ground or mid stride. When the foot is on the downward slope or stairs, the solenoid will release and allow the foot to drop.

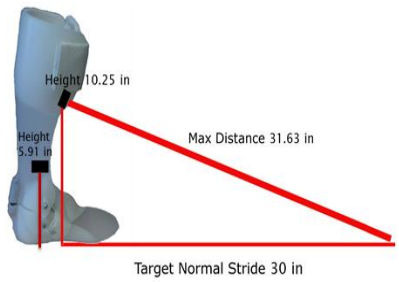

Figure 2: Sensor placement on device with the terrain characterization distances.

The microcontroller ties together the many components of the system. Using analog-to-digital converters the microcontroller takes input from the sensors and determines the type of terrain being traversed. Once the terrain type has been determined the microcontroller will take the necessary actions to trigger the valve response, while determining the next step. Using the information provided by the sensors and their relative position to the ground, it is possible to determine the type of step the user is taking, the quantity of that type of particular stepping motion they are making, and then in turn record this data to an external SD card for future reference by users and health care providers. The last duty of the microcontroller is to determine if the battery level is low and to warn the user that they should charge the device.

Figure 3: Main printed circuit board on top portion of electronics enclosure with the battery in base of enclosure.

Specification testing was completed to validate the system function. The device was tested on flat terrain, on a ramp, and stairs and results displayed the foot to have a range of motion between 70.03° and 147.27° with a response time less than 400ms.

Figure 4: Device components attached to donated orthotic (4) Main printed circuit board with microcontroller inside electronics enclosure.

BUDGET & MARKET ANALYSIS

The budget for the project was provided on behalf of a grant from the National Science Foundation, through the university's senior design office. The team used the budget to purchase the supplies for the system and all the testing equipment was provided by facilities at the Rochester Institute of Technology. The cost to purchase all the materials for the device was $324.

The device would be marketed towards any patients with the lasting side effect of foot drop. Each year, approximately 800,000 people in the US suffer a stroke, which would be the market potential of the portable device [2]. Since not all patients would need the device, it was assumed that 50% would accept the technology after 5 years. If mass producing the system, the materials would cost about $300 per device. The total cost of the device materials, separate from the cost of the orthotic, at a market size of 400,000 units per year would be about $120 million. In addition, the estimated costs to assemble the device, including overhead costs, was estimated to be $100 per device. The suggested sales price of the device, with a 20% markup, would be $460. If 20,000 devices were sold in 2013, the net profit would be $1.2 million whereas if the 400,000 device were sold in 2018, the net profit was estimated to be $24 million.

REFERENCES

[1] Sullivan, Christopher; DeBartolo, Elizabeth; and Lamkin-Kennard, Kathleen; "Terrain Characterization Using Modified RANSAC Analysis of Human Gait Data", *2012 ASME Summer Bioengineering Conference*, Fajardo, Puerto Rico, June 2012

[2] Stroke facts. (2012, Oct 17). Retrieved from http://www.cdc.gov/stroke/facts.htm

