

SOFT ANKLE-FOOT ORTHOTIC

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INTRODUCTION

Foot drop is a neurological disorder which impairs the ability of an individual to dorsiflex the foot (i.e., point the toe upward). This condition is a common side effect of a stroke, ALS, Multiple Sclerosis, or a peroneal nerve injury. Patients who experience foot drop often utilize an assistive device known as an ankle-foot orthotic (AFO) which provides a stable and comfortable support for their foot and ankle and thus mitigates the effects of the condition.

Current AFOs are bulky, rigid, and disrupt the user's natural gait by providing assistance at all times, regardless of need. An active AFO will provide users with assistance only during appropriate times in the gait cycle. This is particularly useful when the active AFO is used on non-level terrain which is difficult to navigate using the current AFOs. Additionally, this active AFO should comfortably fit into a user's existing footwear. The inability to do so is a common user complaint of current AFOs.

The specific goal of the design team is to create an active AFO that uses an infrared-based terrain sensing system [1] to monitor the user's gait and a flexible McKibben muscle actuation system to move the user's foot at the appropriate time. The AFO will have an aesthetically pleasing flexible exoskeleton made from allergy conscious materials and will be integrated with the actuation device, sensing system, and a microcontroller. The AFO will be capable of delivering an entire day's use as an untethered system.

PROBLEM DEFINITION AND TECHNICAL CHALLENGES

Based on input from multiple stakeholders, including researchers, clinicians, and AFO users, a detailed table of requirements was created and is displayed in Table 1. These requirements span disciplines, from mechanical to electrical, but are also largely based on the orthotic as a useable assistive device. Many of the requirements were developed with the specific client base in mind. Based on these requirements, a plan for post-prototype testing has been developed to verify functionality of each requirement. A major part of this testing is assessing the qualitative attributes of the orthotic by surveying a volunteer group for the orthotic's aesthetics and wearability.

P15001: Active Ankle Foot Orthotic - Updated on February 15, 2015							
reqt. #	Importance	Function	Engr. Requirement (metric)	Unit of Measure	Ideal Value	Marginal Value	Direction of improvement
ER1	9	Mechanical	Pressure to leg of AFO	mmHg	20	40	▼
ER2	3		Design failure factor of safety	FOS	1.5	1.5	X
ER3	2		Average skin temperature increase from use	°F	1	3	▼
ER4	9		Torque to lift foot by McKibben air muscle	ft-lbs	3.7	2.2	▲
ER5	3		Dorsiflexion mobility with McKibben air muscle	degrees	90	80	▲
ER6	3	Number of muscle flexes untethered	#		5000	3000	▲
ER7	9	Electrical	Battery in water repellant case	IP Code	54	54	X
ER8	9		Sensors/controls water repellant	IP Code	54	54	X
ER9	9		Immediate max current	mA	100	200	▼
ER10	3		Time between charges	hours	8	6	▲
ER11	3		Response time of Terrain Sensor	ms	100	200	▼
ER12	9	Percentage of time object detected by sensors	percentage	90	80	▲	
ER13	3	Average Time to put on AFO	min	3	5	▼	
ER14	9	Wearability	Weight of AFO on leg	lbs	1	2	▼
ER15	9		Weight of total AFO	lbs	8	13	X
ER16	9		Difference in knee flex	degrees	0	0	X
ER17	1		Aesthetically pleasing	yes/no	yes	yes	▼
ER18	9		Total running noise	dB	<40	<60	X
ER19	9	Added foot width	inches	0.19685	0.295	▼	
ER20	1	Audible Low Battery Alert	dB	70	100	X	
ER21	1	Easy to interface system	yes/no	yes	yes	X	

TABLE 1: ENGINEERING REQUIREMENTS

Research and benchmarking was then conducted on existing AFOs. This included research into the past AFO senior design projects at RIT and professional AFOs in order to address advantages and disadvantages of the AFO technology. This drove an initial design decision to place the McKibben muscle on the front of the leg, where the tibialis anterior is located; the muscle in the leg that provides dorsiflexion. Furthermore, a functional decomposition of the AFO was conducted in order to identify subsystems that required design decisions to be made. The team identified several critical challenges. Namely the size of the air tank, the McKibben muscle design, and the ability to accurately detect heel strike in order to articulate the muscle.

Test data and research indicated that the muscle and air tank would have to provide at least 1,500 steps in a day and move an 8 lb load a distance of one inch, in order to meet the design requirements. A tank life feasibility analysis was conducted in conjunction with a McKibben muscle design optimization to determine the appropriate size of an air tank and McKibben muscle to meet these requirements.

A 90cu.in 4,500psi air tank was found to meet the requirements; however, this tank would cost an additional \$160.95, which would exceed the budget. For prototyping and demonstrating functionality, a smaller tank will be used; however, an air capacity model, validated by test data, was created that proves the larger tank would last for a full day's use. Four muscles were tested with varying widths and lengths. Figure 1 shows the data from the best performing muscle, meeting the defined requirements at three different pressure levels.



Figure 1: MUSCLE OPTIMIZATION

Some of the feasibility testing that was done on the electrical system involved the gait monitoring system. This is a system that will look at heel strike, toe strike, and distance of the leg to the ground. This will then tell the muscle when to articulate as a percentage of the gait cycle and also record the gait information that can be analyzed after use. This was tested for feasibility and the result was that heel strike does lead to muscle articulation and that the data from all sensors was logged. The schematic that was used for this can be seen below. This data shows a person walking on level ground and descending a set of stairs. The system correctly identifies this as stairs and permanently articulates the muscle to provide continuous support.

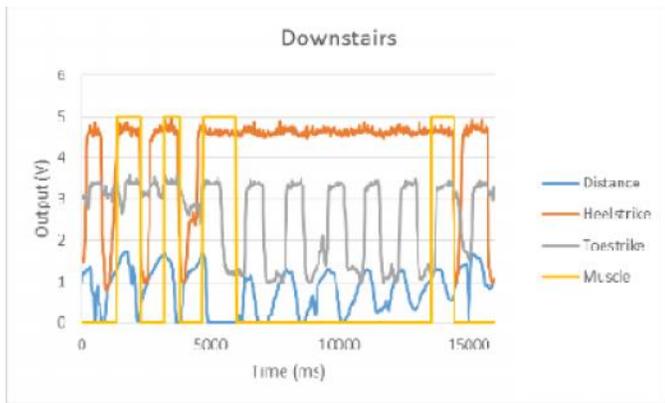


FIGURE 2: ELECTRICAL DATA

PRODUCT DESIGN AND USE

The design of the AFO was split into two pieces, an upper component and a lower component. The upper component consists of a small backpack worn by the user. Housed within the backpack is a compressed air tank with a regulator, a solenoid valve, a printed circuit board (PCB), and batteries. A pressurized air hose, power cable, and signal wiring are tethered together in a mesh sleeve and routed from the backpack to the lower component. The lower component is comprised of the soft orthotic, the McKibben muscle with lower and upper attachments, the lower component housing with the sensor PCB board and IR sensor, the heel sensor, and the toe sensor. Based on the

feasibility outlined above, the team is on track to meet all of the ideal or marginal requirements listed in Table 1.

To use the device, an individual would apply the lower component to their foot, making adjustments as necessary. Once the air hose and power lines are connected, the user will turn on the main power switch in the backpack. To activate the AFO, the user will press a button near their hip on the power supply line. When the device is active it will begin sensing and recording the user's gait data to a micro SD card. Using data from the heel strike sensor, the PCB will articulate the double acting solenoid, which controls the pressurized air flowing into the muscle from the air tank. This in turn, will contract and release the McKibben muscle, lifting the toe during the gait cycle only when needed. When the user is sitting, driving, or anytime they need permanent dorsiflexion support, they can turn the active mode off via the switch near the hip. The device will constrict the McKibben muscle and become a passive orthotic, constantly providing dorsiflexion. Additionally, the user can press a separate button releasing the muscle so the device is not providing any support.

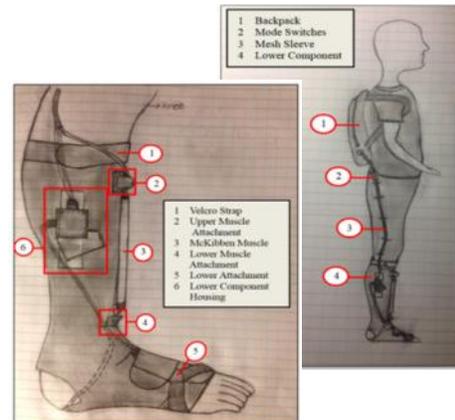


FIGURE 3: INTEGRATED SYSTEM (RIGHT), DETAILED LOWER COMPONENT (LEFT)

MECHANICAL TESTING AND VALIDATION

After the mechanical components were constructed for the final prototype they were tested to ensure they met the specified engineering requirements, seen in Table 1.



FIGURE 4: Dorsiflexion Mobility Test Setup

The first test was a dorsiflexion mobility test. This test measured the total angular displacement of a user's foot, provided by the McKibben muscle. The test setup is seen in Figure 4. A video was taken of a user wearing the orthotic while it operational, which was then analyzed with video tracker software to measure the foot's angular displacement. The best result from the test was 26.56 degrees, which is just under the marginal engineering requirement of 30 degrees. One of the causes of decreased deflection is from slippage in the upper brace, observed with the tracker software. Not only does the brace pull the foot up but it also pulls the upper brace down. Better ways of securing the upper brace to decrease this slippage are being implemented and evaluated in order to improve foot lift. In addition a larger muscle is being constructed which will provide more lift than the current muscle being used.

Next, the orthotic was subjected to an extended use test. This was to determine the performance and reliability of the orthotic for long term use. The setup was very similar to the dorsiflexion mobility test. The orthotic was donned and the muscle was actuated 100 times. A video was taken of the test then analyzed with video tracker software to see if there was any degradation in performance. The test concluded that there was no adverse effects from extended use. There was also worse

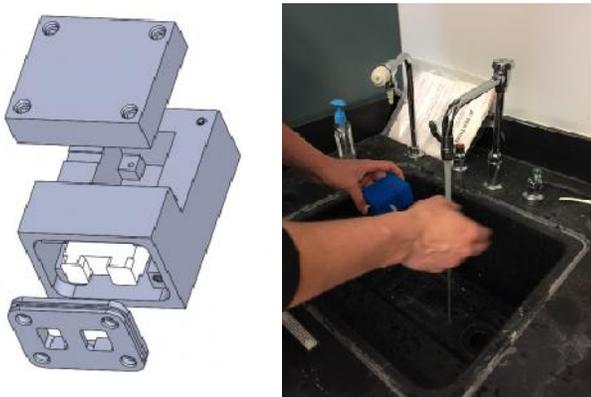


FIGURE 5: LCH and LCH Test Setup

case scenario iteration of the test where the user pressed their toe down as far as they could with the muscle flexed, this lowering the orthotic on their leg. This caused the orthotic to not perform within the desired functional range, therefore requiring the user to readjust the orthotic to restore performance.

To ensure the design met the specified ingress protection rating of IP54, the lower component housing (LCH), seen in figure 5, was subjected to standard testing procedure set forth by the IP Code. In the alphanumeric code IP54, the number 5 means the device is not completely impervious to dust but dust not enter the device to a point that interferes with safe and satisfactory operation. Team members have been continuously observing the amount of dust that has entered the LCH and no observable amount of dust has entered the device to derogate safe and satisfactory operation. 4 means the device can be exposed to splashed of water from any direction and it will not compromise the operation of the device. To test this the LCH housing was filled with paper towels then splashed with water from all directions, in addition the LCH was placed under a stream of water from a faucet. No water was observed to have entered the device, not only meeting but exceeding the engineering requirement. After a final design for an upper component housing (UCH) is selected and

implemented, it will be subjected to the same testing procedure as the LCH.

Lastly for mechanical testing, a tank life test was iterated from the feasibility portion of the project. The reason for the iteration was to gain knowledge about how regulators used in the previous test would leak air. The second test was to see if the tank would have better performance. The muscle was actuated until the tank was exhausted and the number of steps was recorded. Additionally, calculations for the performance of a proposed larger tank, and a proposed larger muscle, to improve dorsiflexion displacement, were done. The results are below in table 2.

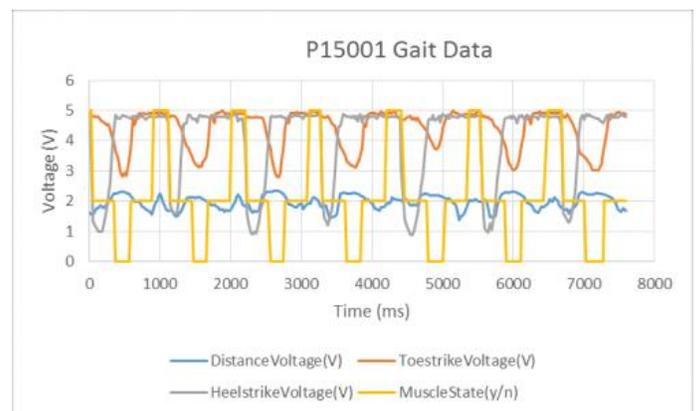
	Current Muscle	Est. from capacity test I	Δ (Outer - Inner) Diameter					
	Proposed Muscle	Est. from capacity test II	0.09375					
Tank #	Tank Vol. cu-in	Tank Press. psig	Reg. Press. psig	Initial Length in	Deflection in	O. dia. (inflated) in	Corrected I steps	Corrected II steps
1	48	3000	60	6.125	1.05	0.52	637	771
2	90	4500	60	6.125	1.05	0.52	1791	2028
1	48	3000	60	6.625	1.15	0.52	590	668
2	90	4500	60	6.625	1.15	0.52	1661	1880

Table 2: Tank Life Test

ELECTRICAL TESTING AND VALIDATION

One of the main focuses on the electrical side was debugging the micro-SD card. The micro-SD card is where the user's gait data is recorded. This is very beneficial information for a clinician to have. An unknown reason was causing the PCB to not recognize that there was a micro-SD card. The issue was resolved when the SD card was examined in the PCB under an X-ray. There was a pool of solder that was causing a short when the SD card was slotted into the PCB. The SD card slot was removed from the PCB and re-soldered resolving the issue.

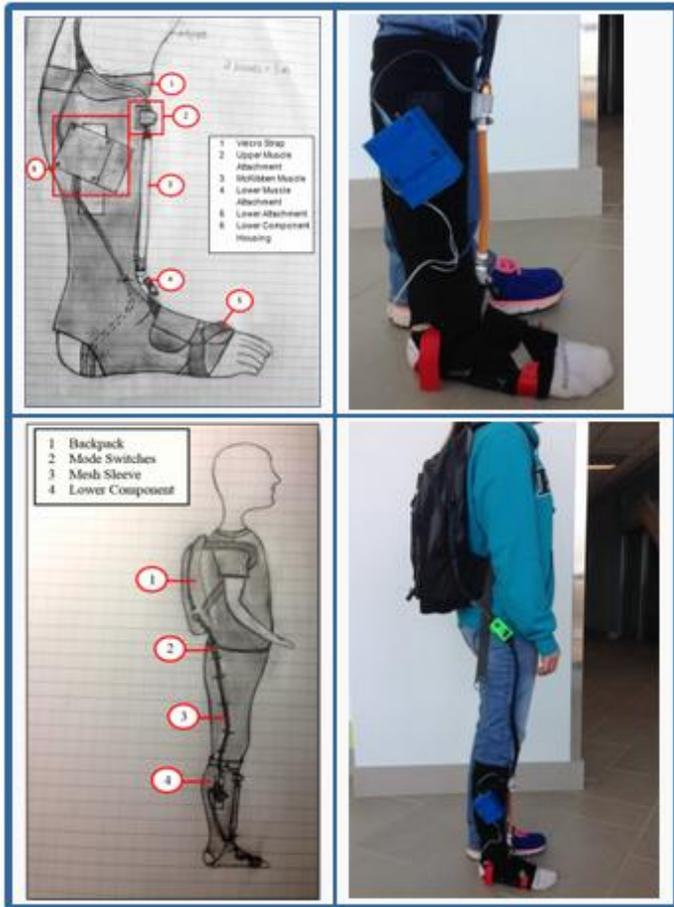
Pressurized air was released into and out of the muscle in small increments, opposed to doing it all at once, this is ramping the solenoid. The purpose of ramping the solenoid was to not jerk the user's foot in a violent manner that felt unnatural. In addition, terrain sensing was no longer used to change how the muscle would function on stairs. A manual switch will be used in its place. However, the terrain data is still being recorded to the micro-SD card since this information is beneficial for a clinician. The data from the micro-SD



manipulated by post processing software can be seen in Figure 6.

FIGURE 6: Gait Data

Below is a comparison between the project design and the final product.



ACKNOWLEDGEMENTS

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REFERENCES

- [1] Christopher Sullivan, Elizabeth DeBartolo, and Kathleen Lamkin-Kennard, "A Wearable Gait Monitor and Terrain Prediction System" Proceedings of the ASME 2013 Summer Bioengineering Conference, Sunriver, Oregon, USA, June 26-29, 2013.
- [2] Kesar, Trisha M., Ramu Perumal, Angela Jancosko, Darcy S. Reisman, Katherine S. Rudolph, Jill S. Higginson, and Stuart A. Binder-Macleod. "Novel Patterns of Functional Electrical Stimulation Have an Immediate Effect on Dorsiflexor Muscle Function During Gait for People Poststroke." *Journal of the American Physical Therapy Association* (2010): 55-66. *US National Library of Medicine National Institutes of Health*. Web. 14 Dec. 2014.

BUDGET & MARKET ANALYSIS

The allotted budget for the project was five hundred dollars. Currently, the projected cost to build and test the prototype is \$456.96, with the largest percentage of the cost attributed to the sensors, printed circuit board, compressed air tank, and batteries.

There is a large market potential for a soft active AFO due to a relatively large foot drop population. Specifically, foot drop is a common side-effect of a stroke, affecting approximately 20% of survivors (~1.3 million people each year) [2]. Foot drop can also occur as a side effect of ALS (Lou Gehrig's Disease), Multiple Sclerosis, radiculopathy, or injury to the peroneal nerve, increasing the number of people affected. Furthermore, there is a drive for a soft orthotic, as many users are unhappy with current rigid AFOs because they are uncomfortable and do not allow for a natural gait cycle.

To introduce the product to the market, research to select a medical distributor that fits the product's needs would need to be done. Given the team estimated manufacturing cost per device without overhead being \$323, the prices for the competitors ranging from \$30-\$700, and the novelty of the device being the only orthotic on the market that provides active dorsiflexion, the price of the device should be set at \$1000. Assuming the device can capture 1%-2% of the annual market, approximately 13,000-26,000 people, the result would be an annual gross profit of \$13-\$26 million.