Smart Shoe Design: Adaptable Shoe for Foot Pronation Capstone Nate Appelson^{€±}, Lillian Reape^{€±}, Sean Kane^{¥±}, Dennis Shih^{¥±}

Team

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EXECUTIVE SUMMARY

In the United States, approximately 37% of all adults 60 year or older suffer from knee osteoarthritis. Custom fit orthotics, while helpful, fail to completely alleviate pain caused by this illness. A major weakness of these orthotics is their inability to adapt to changing conditions, either in the patient or the ground. The Smart Shoe solves this issue with the following features:

- Adjustable fit to adapt to changing conditions
- Pressure sensors to collect foot strike pattern
- Algorithm for foot strike analysis and suggestion
- Pneumatic control for stiffness variation

CLINICAL NEED

- \clubsuit Approximately 42% of females and 31% of males over 60 years old have some form of knee arthritis.
- •This manifests as sharp pains in the knee upon moving and is ranked as one of the top 5 leading causes of disability among non-institutionalized adults.
- The recommended treatment options for this condition include surgery, cortisone injections, and foot orthotics [1].
- Foot orthotics usually consist of a "custom fit" insole designed to place the foot in and ideal position for running or walking.
- •While effective, high variations between different orthotics could necessitate multiple orthotics per patient [2].
- Arthritis continues to contribute \$28.5 billion and \$13.7 billion in knee and hip joint replacements respectively per year [1].

MARKET ANALYSIS

• Lower back problems affect 80% of the adult population

- ◆719,000 knee replacements and 332,000 hip replacements occur each year
- ◆ More than 200,000 cases of anterior cruciate ligament (ACL) injures occur each year
- \bullet No variable stiffness orthotic currently in the market
- Price for pressure-sensing insole is approximately \$200

Parts	Amount	Cost	Total Cost
Printed PCB	1	\$60,000 / 20,000 boards	\$3 / board
Sensors	10	\$5.56 (100+)	\$55.60
3D Printed Valves	1	\$55	\$55
tubing	1	\$0.67/foot	\$0.67
Solenoid Valves	2	\$9.95	\$18.90
Air Compress	1	\$13.00	\$13
		Subtotal	\$145.67
Assembly		\$8 / board	\$8
Manufacturing		\$20,000	\$0.10
		TOTAL COST	\$153.77

ESTIMATED COST

DESCRIPTION OF DESIGN

The final design of the "Smart Shoe" can be broken down into two main components: the data collection and processing system, and the control of the shoes variable stiffness. The force distribution of a user's foot will be measured using force-sensing resistor (FSR) sensors, while a Arduino Mega and a custom printed circuit board (PCB) collect and process the force data. Ten FSR sensors are distributed along the insole and communicate with a MATLAB program via Bluetooth. When certain force thresholds are exceeded, the software attempts to vary the stiffness of the insole in order to adjust the forces to an acceptable level. The software does this by triggering solenoid valves and an air compressor to control air-flow inside the shoe that will modify its stiffness. An HC-05 chip is used to transfer the sensor readings via bluetooth to the MATLAB program.

WORK FLOW

The process begins when the user's foot strikes in Figure A. Sensors in Figure B, placed all around the sole of the shoe, pick up the difference in resistance felt in Figure C. This is then translated and interpreted through a Matlab program. The Matlab program then suggests an action in order to correct the pronation or supination involved. This involves signaling the compressor and solenoid valves in Figure D.









FUTURE WORK

There are many avenues of improvement after this proof of concept. For example, a decrease in the size of the design would benefit users of all shoe sizes. The smaller the mechanisms are, the more versatile it can be. Additionally, one can expect a constantly changing algorithm. Rolling out adaptable algorithms that can be catered to the movements and lifestyle of the user would help tremendously. Lastly, if a phone application can be developed, it would be able to sync with the force data gathered through the shoe. A visualization of this data would be helpful to the user, physician, and other stakeholders to better suggest areas of improvements to the user.

Regulatory Pathway

The anticipated regulatory pathway would be a 510(K) Exempt. The team believes that this would be a Class 1 device since it presents minimal harm to the patient. F0scaned, a similar pressure sensor device, filed in 2015 as a 510(K) exempt and the team believes that the company would follow suit and do the same.

NOVELTY

This proof of concept is the first to actively adapt to a user's foot. It is the first product that interprets foot pressure data to undergo shoe adjustments. It is also the first product that utilizes air flow to change the stiffness of the shoe. This is indeed, a very dynamic shoe.

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KEFERENCES

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[1] Centers for Disease Control and Prevention. Osteoarthritis. http://www.cdc.gov/arthritis/basics/osteoarthritis.htm. Accessed

[2] American Academy of Orthopaedic Surgeons. Orthotics. http://orthoinfo.aaos.org/topic.cfm?topic=A00172. Accessed May

