1) Background and Problem Statement

Injury of the ankle or foot often requires orthopedic surgery for treatment. Following surgery, patients will put on a large walking boot which provides structural protection and support of the healing tissues. In such instances, these walking boots are worn passively with no reassurance nor knowledge of how the user's injured ankle/foot region is healing. Walking boots are also worn by patients with chronic inflammation of the connective tissue of their feet - a condition known as Charcot foot - or peripheral neuropathy which is a common issue for diabetics. These conditions bring along reduced sensory perception and pain of the foot. In such cases, orthopedic boots are worn for months to years to help alleviate pain. The combination of very long periods of wearing the boot combined with reduced sensory perception creates high risk of pressure ulcer development.

The Smart AFO is an improved, novel redesign of the typical orthopedic walking boot, that provides useful diagnostic data regarding the state of health of the wearer's ankle/foot. The key components of the device are a simple partial weight off-loading mechanism, pressure sensors strategically placed at the standard points of contact of the foot, and electronically controlled air bladders which adjust the distribution of pressure across the sole of the user's foot. By changing the pressure distribution pattern, the boot can automatically adjust partial weight bearing conditions and simultaneously offer a mechanism to vary areas of continuous contact between the foot and boot, reducing risk of pressure ulcer formation. Sensor data is wirelessly sent to the user's smartphone or computer for processing and tracking of the user's walking activity and to identify regions of concern for ulcer development, or risk of post-surgery complication. Physicians and patients can make use of the information collected over the period the boot is worn to modify and verify successful treatment.

2) Design Approach and Concepts

The challenge of altering the pressure distribution across the foot of a person wearing an orthopedic boot was first approached by considering how a person's weight could be offloaded using supports constrained to the calf or knee. Designs were taken from standard patellar-tendon bearing (PTB) prosthetic devices. However, it was found that PTB prosthetics are only able to offer 100% offloading because of the gap resulting from amputation. Typically orthotic devices are designed to minimize foot to ground offsets. Thus the design shown in figure 1 composed of a strap to fully support the wearers weight, and external actuators changing the height of the band relative to the foot was discarded. Another variable causing rejection of the external actuator design are customer interviews which revealed discomfort when too much offset was accompanied with wearing a standard orthopedic boot.

The first concept for the weight bearing adjustment mechanism are simple actuators external to the boot, arranged in rod structures. The boot will have straps which wrap around the shin will support the user’s weight, and the actuators adjust the height of the boot to change the effective distance between the foot and the sole of the boot.

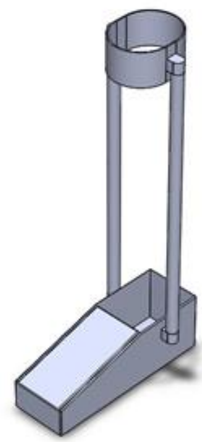

Figure 1. External actuators concept

The second design concept is an internal actuator mechanism. Scissor linkages expand and contract, as controlled by internal motors or other sort of actuator. When the linkages are expanded, the sole of the boot will be at minimum height with respect to the ground. The linkages will be compressed, causing the internal sole of the boot to rise away from the ground, and apply pressure on the sole of the foot. A similar weight bearing strap mechanism would be used similar to the first concept design.

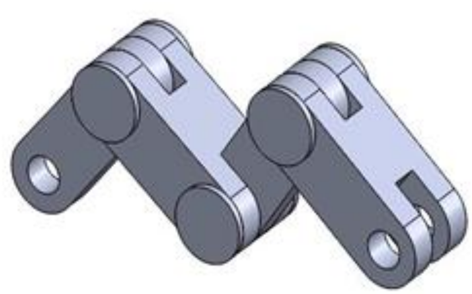

Figure 2. Internal adjustment mechanism concept

During the design process customer interviews indicated perhaps the need was not off-loading, but simply pressure redistribution across the foot’s may be sufficient for a successful device. Thus the design process was changed to consider how pressure can be adjusted across the user’s foot. The final concept design conceived is composed of a system of inflatable air bladders controlled by a miniature air pump. Each section of the bladders are individually adjustable in order to modify the pressure distribution pattern across the foot.

3) Final Approach and Design

Taking into consideration the three design concepts and customer requirements, a decision matrix was constructed as shown in table 2, to identify which design ought to be chosen. Each design parameter was given a weight from 1-5 with 1 being the least important. Then each design concept was given a score of how well the design fulfills the design parameter. Multiplying the score by the weight, and then summing the products provided a metric by which to choose the design to move forward with. In this case the air bladder system was the winning design and was taken forward.

Table 2. Adjustment Mechanism Decision Matrix

		External Actuators		Internal Actuators		Air Bladders	
Design Parameter	***Weight***	***Score***	***Weighted Score***	***Score***	***Weighted Score***	***Score***	***Weighted Score***
Low Cost	4	3	12	2	8	8	32
Low weight	5	2	10	3	15	10	50
Low noise	4	5	20	3	12	7	28
Pleasing Aesthetics	2	5	10	9	18	9	18
Properly supports weight range	3	10	30	7	21	8	24
Structurally stable	5	10	50	6	30	7	35
Manufacturing complexity	3	7	14	1	3	8	24
Weighted Score Total			**146**		**107**		**197**

The rationale behind the third concept design is that by using air bladders the weight will be minimized, and the complexity of manufacturing remains relatively simple as compared to manufacturing external or internal actuators.

Figure 3. Chosen concept: internal Air bladder system

4) Outcome

Following the completion of prototyping of the device, validation of the partial weight bearing adjustment mechanism will be needed. A local retired physical therapist has offered to assist in clinical validation of the Smart AFO. The pressure mapping functionality of the boot, as well as the pressure redistribution functionality, will both be validated against the Tekscan F-scan pressure sensing system. This experiment will be the deciding, “killer experiment” which will determine if the Smart AFO design is successful, or requires redesign of some, or all components. Additional studies to be included in clinical trials will be motion capture studies. Tracking the sway and gait of a person walking with the boot compared to people without the boot would yield any possible negative effects of long term use.

It is anticipated that that when the user uses the Smart AFO, they will be relieved of a portion of their pain while also having full mobility in being able to walk. This result would be both for diabetics and the relief of pressure ulcers in their feet, and for people recovering from foot and ankle injuries and the ability to continue to live out their traditional daily lives. These improvements in life for two large demographics in the world today are what powers the production of the Smart AFO and the hope is that it will exceed expectations in the realm of making people’s lives easier.

5) Production Cost and Pricing

The potential customers of the Smart AFO include diabetics who have a higher risk of developing pressure ulcers, patients who have developed foot and ankle injuries. From the interviews conducted, the Smart AFO would be of a huge benefit to athletes as it would enable them to have monitor the amount of load applied on their healing which could return result to faster recovery. As shown in Figure 4 below, the number of people who have had trouble with ankle injury in the United States is increasing every year. Data from the years 2011, 2012, 2014 and 2016 regarding incidents of annual ankle and foot fractures were found through literature review. In 2011, there were 8.67 million people have an ankle injury; 12.5 million in 2012; 17.4 million in 2014 and 18.83 million people in 2016. These increasing numbers of foot and ankle injuries from accidents and about 29.1 million people diagnosed with diabetes every year signifies that we have a huge market to provide for. Table 3 shows the materials needed to create the Smart AFO and the cost of producing the boot.

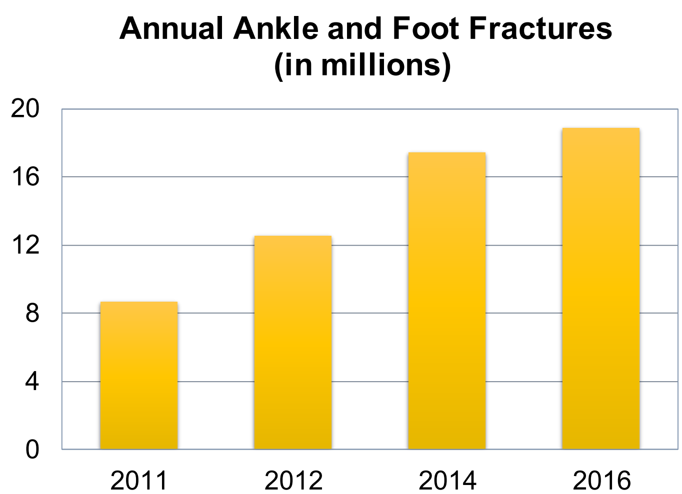

Figure 4: Foot and ankle fractures for the years 2011-2016

Table 3:Materials and cost of production of the Smart AFO

Materials	Cost
FlexiForce A502 pressure sensors from Tekscan	$ 102.00
Air bladder system	$ 34.20
Walking boot from Amazon	$ 90.00
Arduino UNO	$ 25.00
Bluetooth Module	$ 6.00
Air Pump	$ 9.00
Battery	$ 40.00
OpAmps	$ 10.00
Total	**$ 317.00**

6) Significance

The recovery period following orthopedic surgery on the ankle or foot is accompanied by a lengthy period (typically 8 weeks) of wearing an orthopedic walking boot. While a patient wears the walking boot, they are required to place a certain percentage of their entire weight on the healing foot, however the non-compliance of the patients either intentionally or unintentionally usually leads to post-surgery complications. Presently, no orthopedic walking boots on the market offer feedback mechanisms that detect the pressure distribution across a patient's foot which is important for diabetic patients who are prone to developing pressure ulcers. Additionally no device is capable of automatically changing the pressure distribution pattern or amount of partial weight bearing on the foot. The objective of this project is developing a smart ankle foot orthosis capable of measuring the pressure distribution across the foot of the patient, communicating this data to a smartphone for patient knowledge, as well as automatically adjusting the partial weight bearing percentages without user input.

The unique market advantage of the smart AFO is the value it provides in reducing the incidences of post surgery complications, reducing costs to physicians and clinics, and saving time for the patient. Below are the design features in the Smart AFO:

- **Pressure Sensors**: these measure the pressure on the injured/fractured foot
- **Bluetooth**: via the bluetooth which would be connected to the patient's smartphone, patients and physicians would be able to keep track on the amount of load applied on the healing foot. This is the feedback mechanism.
- **Air Bladders**: adjusts the pressure on the foot.

7) Acknowledgements

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