



SENSEI

“The Cast Master”

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Abstract

Acute compartment syndrome (ACS) occurs in 26,500 people in the US each year and is a result of capillary blood flow becoming compromised when tissue pressure exceeds 30 mmHg. The consequences of ACS are extremely severe if it is not immediately diagnosed. ACS can result in permanent muscle damage, nerve damage and/or amputation, and 70% of cases can be traced back to fractures. The current diagnostic method requires invasive pressure measurements if a patient's primary symptom assessment is inconclusive. Thus, we have designed SENSEI, a non-invasive device that constantly monitors pressure and can diagnose ACS underneath a cast post-fracture. The device interacts with an Android application via bluetooth to let the user know if they are at risk in real time. SENSEI currently measures compartmental pressure of the forearm within a range of 20-40 mmHg with 91% accuracy. In the future, we plan on improving our pressure sensors so that SENSEI can diagnose ACS with 100% confidence. Other potential additions to SENSEI include designing a sleeve for the lower leg and developing an iOS application to capture more market share.

Introduction

Acute Compartment Syndrome

Acute compartment syndrome (ACS) is a true orthopedic emergency, and is a result of an acute increase in intracompartmental pressure, causing tissue ischemia. This occurs when capillary blood flow becomes compromised and intracompartmental tissue pressure increases to 25 mmHg - 30 mmHg, exceeding arterial pressure. When this occurs, arterial flow becomes constricted leading to tissue ischemia. This results in irreversible muscle, nerve, blood vessel, and skin damage, and in some scenarios may lead to amputation or can even be life threatening.¹ 70% of ACS cases can be traced back to fractures as both closed and open fracture treatment can cause increases in compartment pressure from altering the configuration of tissue compartments.² Additionally, overly constrictive casts and significant swelling from trauma may also lead to ACS; thus, it is vital for clinicians to be monitoring a patient for signs of ACS as delayed or missed diagnosis have significant ramifications for the patient and surgeon performing the limb-saving operation called a fasciotomy.

Diagnosis

The current diagnostic procedure for ACS is imperfect and largely subjective as it relies heavily on patient-reported symptoms. Patients initially seek treatment for compartment syndrome on their own accord and go to the doctor complaining of pain or numbness in their casted limb. If the doctor thinks that compartment syndrome is the cause, the doctor uses the 5 P's assessment: pain, paresthesia (tingling), paralysis, pallor (paleness), and pulselessness, to

¹ Torlincasi, Allison M, and Muhammad Waseem. "Acute Compartment Syndrome." *StatPearls*, 18 Nov. 2018.

² Via, Alessio Giai. "Acute Compartment Syndrome." *Muscles, Ligaments and Tendons Journal*, 2015.

clinically diagnose ACS before prescribing a fasciotomy.³ If this assessment is inconclusive, an invasive compartment measurement using the golden standard, a Stryker Handheld Manometer Device, is performed to diagnose ACS. The device injects a small amount of saline into the closed compartment to measure the resistance from tissue pressure, and a pressure reading above 30 mmHg indicates the patient has ACS.⁴ If the pressure reading is below 30 mmHg, the doctor will keep performing this invasive measurement for about 4 hours or until he or she is confident that the patient is not at risk of having ACS.⁵ Refer to **figure 1** for a flow chart of the current diagnosis process. This diagnostic process is particularly problematic as the 5 P's assessment is frequently inconclusive due to its subjectivity and difficulty. For example, pain can be nonspecific and it is very difficult for a patient to distinguish pain from the fracture from pain stemming from ACS. Communicating with doctors becomes even more complicated when patients are children, critically ill, or just emerged from general anesthesia or received a nerve block during surgery. Furthermore, paresthesia can also be particularly confusing because peripheral nerve injury may result directly from trauma, not ACS.⁶ In a study conducted by Bae and colleagues, they reported that the 5 Ps were relatively unreliable.⁷ Thus, due to the high subjectivity of the 5 P's assessment there are three main problems: **1)** painful, invasive compartment pressure measurements are administered more often than necessary to diagnose

³ Pechar, Joanne, and M. Melanie Lyons. "Acute Compartment Syndrome of the Lower Leg: A Review." *The Journal for Nurse Practitioners*, vol. 12, no. 4, 2016, pp. 265–270.

⁴ Boody AR, Wongworawat MD. Accuracy in the measurement of compartment pressures: a comparison of three commonly used devices. *J Bone Joint Surg Am* 2005;87(11):2415-22.

⁵ Taylor, Ryan M., et al. "Acute Compartment Syndrome: Obtaining Diagnosis, Providing Treatment, and Minimizing Medicolegal Risk." *Current Reviews in Musculoskeletal Medicine*, vol. 5, no. 3, 2012, pp. 206–213.

⁶ Stracciolini, A., & Hammerberg, M. E. (2019). Acute Compartment Syndrome of the Extremities. Retrieved from <https://www.uptodate.com/contents/acute-compartment-syndrome-of-the-extremities>.

⁷ Bae DS, Kadiyala RK, Waters PM. Acute compartment syndrome in children: contemporary diagnosis, treatment, and outcome. *J Pediatr Orthop* 2001;21(5):680–8.

ACS 2) ACS may be misdiagnosed and the patient undergoes an unnecessary fasciotomy and 3) ACS diagnosis is delayed or missed, leading to serious complications for the patient.

Thus, our group designed SENSEI, a real-time, objective, non-invasive compartment syndrome measurement device to redefine how ACS is diagnosed in fractures.

Our Solution: SENSEI

SENSEI streamlines the fracture-induced compartment syndrome diagnosis process for the patient and the clinician. Instead of being a reactive measurement to symptoms, SENSEI is proactive and measures compartmental pressures continuously throughout the fracture recovery process, when ACS can develop. It uses feedback from eight sensors on a sleeve worn underneath a cast. An alert is triggered to the user when the threshold pressure is exceeded, telling the patient to see a physician in order to be clinically examined and have the doctor review the pressure reading history to prescribe a fasciotomy.

SENSEI eliminates the communication barrier between the patient and physician by providing quantitative assessments, thus eliminating the need for painful, invasive compartment pressure measurements. Additionally, because it is continuously monitoring pressure readings for signs of ACS, it reduces the chances of a patient being misdiagnosed and the doctor missing a diagnosis.

SENSEI also has a broader impact on society. By only alerting the patient if they are at risk of having ACS, SENSEI also reduces the number of unnecessary visits to physician offices and hospital emergency rooms. This is a social and economic burden to society as unnecessary visits take time and resources away from patients who actually require immediate care.

Objectives and Approach Overview

Major Objective

To build a device that non-invasively measures compartmental pressures underneath an orthopaedic cast for any fracture patient during the recovery period due to the risk of developing ACS. The device should be proactively monitoring for signs of ACS, and in the event that intracompartmental pressure exceeds 30 mmHg, the device becomes a diagnostic, eliminating the need for invasive pressure measurements before the fasciotomy.

Approach Overview

In order to redefine how ACS is diagnosed, our device needed to be able to accurately measure compartment pressure underneath an orthopedic cast. With this in mind, we knew our pressure reading range had to read pressure values between 20 to 40 mmHg as this is the critical pressure range where ACS develops. In addition, pressure readings have to be collected at least every 5 cm on the ventral and dorsal sides of the arm. This is because pressure can change significantly every 5 cm.⁸

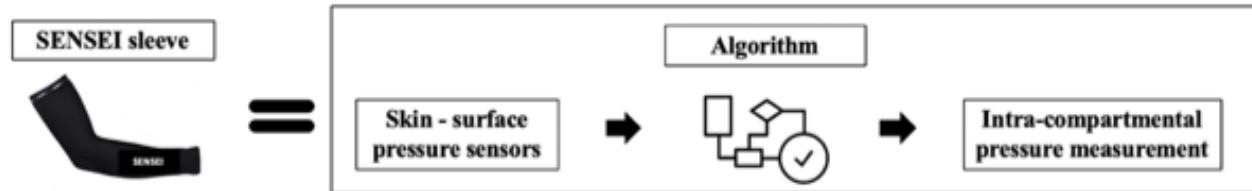
Our Solution to Solve the Problem

Our solution replaces the invasive manometer measurements with non-invasive pressure measurements, thereby eliminating the problem of the patient having to endure painful, and sometimes unnecessary, invasive compartment pressure measurements. Additionally, by incorporating SENSEI into the fracture treatment process, there is no longer a need for physicians to use the extremely subjective 5 P's assessment as the primary tool to diagnose ACS. This will significantly reduce misdiagnosis or missed diagnosis cases.

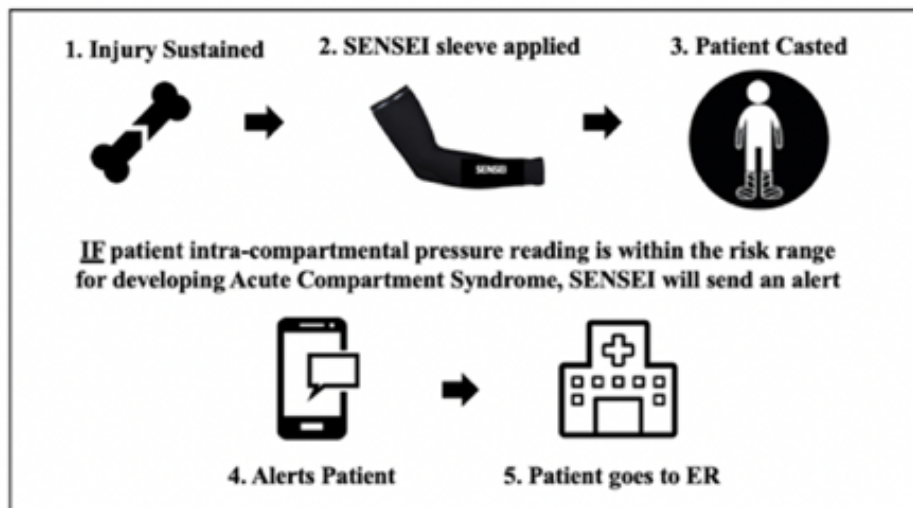
⁸ Heckman MM, Whitesides TE Jr, Grewe SR, et al. Compartment pressure in association with closed tibial fractures. The relationship between tissue pressure, compartment, and the distance from the site of the fracture. J Bone Joint Surg Am 1994;76(9):1285–92.

Our concept is innovative as it completely replaces how ACS is diagnosed and monitored after a fracture. It does not build on current approaches, but it is similar to current ACS diagnosis methods in that it measures the intracompartmental pressure to confirm or rule out ACS.

Project Illustration



DIAGNOSTIC DEVICE



Specifications and Design Goals

We identified three groups of specifications to be used to guide our design process. These are technical specifications, specifications regarding the dimensions of our device, and miscellaneous specifications. The technical specifications cover pressure range, pressure accuracy, and spatial resolution of the sleeve; the specifications relevant for setting dimensionality are length of the sleeve, weight of the sleeve+device, and thickness of the sleeve; the miscellaneous specifications include other relevant but less fundamental factors such as biocompatibility, application time, and cost. In this section, we will explain each of them and provide their clinical justification.

Key Technical Specifications



1. *Pressure Range: 20 mmHg - 40 mmHg.*

Achieving this pressure range is key for our device because acute compartment syndrome occurs within this range⁹. This pressure range changed throughout the year because we were previously trying to encompass both baseline or normal pressure and very high pressures. After reevaluating this specification and focusing on the overall goal of SENSEI, we realized that our device must be very good at measuring the pressures in the range critical for acute compartment syndrome.

2. *Accuracy of Pressure Readings: 100%*

One of our biggest setbacks from last semester was not having considered the accuracy of our pressure readings. This is one of the most relevant specifications because we are trying to objectively diagnose people who are at risk of developing acute compartment syndrome. If we

⁹ Reneman, R. S., Slaaf, D. W., Lindbom, L., Tangelder, G. J., & Arfors, K. (1980). Muscle blood flow disturbances produced by simultaneously elevated venous and total muscle tissue pressure. *Microvascular Research*, 20(3), 307-318.

were to have an accuracy of 50%, it would mean that if the device measures a pressure of 20 mmHg, then the actual pressure could be anywhere from 10 mmHg to 30 mmHg. This would be extremely problematic since 10 mmHg is a normal pressure, but at compartment pressure of 30 mmHg¹⁰, it is likely that the patient would already be experiencing muscle and nerve damage¹¹. Ultimately, we decided to set an unrealistic target of 100% accuracy, hoping we would be as close as possible to it. We knew a 100% accuracy was unrealistic given that current devices do not even have these accuracy. However, we were not able to find the accuracy values of competing devices, so we also couldn't choose a comparable accuracy value.

3. *Spatial Resolution: $\leq 5\text{cm}$*

This is also a specification that was set during second semester. It is crucial for our design process that we understand the spatial resolution required to accurately and exhaustively detect compartment pressures, as this would determine the spacing of the pressure sensors in our device. This specification also allowed us to determine the number of pressures our sleeve required both on the dorsal and ventral side of the forearm. After performing an exhaustive literature review, we found that changes in compartment pressure are significant every 5 cm¹². Because of this, the spatial resolution of our device had to be less than or equal to 5 cm.

¹⁰ Reneman, R. S., Slaaf, D. W., Lindbom, L., Tangelde, G. J., & Arfors, K. (1980). Muscle blood flow disturbances produced by simultaneously elevated venous and total muscle tissue pressure. *Microvascular Research*, 20(3), 307-318.

¹¹ Mubarak, S. J., Owen, C. A., Hargens, A. R., Garetto, L. P., & Akeson, W. H. (1978). Acute compartment syndromes. *The Journal of Bone & Joint Surgery*, 60(8), 1091-1095.

¹² Heckman MM, Whitesides TE Jr, Grewe SR, et al. Compartment pressure in association with closed tibial fractures. The relationship between tissue pressure, compartment, and the distance from the site of the fracture. *J Bone Joint Surg Am* 1994;76(9):1285-92.



Dimension Specifications

1. *Length: $\geq 250\text{mm}$*

Because the sleeve goes under the cast, it was important for us to use the average forearm length as the minimum length required for the SENSEI sleeve. Originally, we had used the average length of the entire arm as the quantitative value for this specification, but after learning that forearm fractures require casts that reach until the elbow, we changed it to the average length of the forearm, which is roughly 250mm¹³.

2. *Weight: As lightweight as possible*

After evaluating the future of the cast manufacturing industry, we realized that a lot of efforts are being made towards creating casts that are lighter to provide more comfort for the patient and thus increase compliance¹⁴. Casts need to be as lightweight as possible so that the patient feels the most comfortable, as he/she has to wear the cast for on average 6 weeks¹⁵. Since our device is an add-on to a cast, we thought it was relevant to apply the same design principles that are pertinent for casts. Instead of setting an arbitrary value as we had done in the past for the weight, we decided to leave it open ended which allowed us to consider weight when making all of our decisions (but prioritizing the technical specifications).

3. *Thickness: As thin as possible*

This specification was also set based on the trend to make casts as comfortable as possible for the patient¹⁶. Again, since the sleeve goes under the cast, SENSEI had to be as thin as possible so that its presence would be almost negligible for the user. Instead of setting an

¹³ Zarzycka, N, and S Zaluska. "Measurements of the Forearm in Inhabitants of the Lublin Region." *Annales Universitatis Mariae Curie Skłodowska*, vol. 44, 1989, pp. 85–92.

¹⁴ Smith, G. D., Hart, R. G., & Tsai, T. (2005). Fiberglass cast application. *The American Journal of Emergency Medicine*, 23(3), 347-350.

¹⁵ Thompson, S. R., & Zlotolow, D. A. (2012). Basic Principles of Analgesia. *Handbook of Splinting and Casting*, 3-6. doi:10.1016/b978-0-323-07802-3.00112-4

¹⁶ Smith, G. D., Hart, R. G., & Tsai, T. (2005). Fiberglass cast application. *The American Journal of Emergency Medicine*, 23(3), 347-350.

arbitrary value as we had done in the past, we decided to leave it open ended which allowed us to consider thickness when taking our decisions (but prioritizing the technical specifications).



Miscellaneous Specifications

1. Biocompatibility: Not cytotoxic, won't sensitize skin or cause irritation

Since the sleeve would be in contact with the skin of the user and infections are already problematic in casts, an important specification was for our device to be biocompatible with the skin. Following ISO guidelines for biocompatibility, we want a material that is not cytotoxic, that won't sensitize the skin, and that does not induce irritation or intracutaneous reactivity¹⁷.

2. Application Time:

Regular fiberglass casts take from 10 to 30 minutes to apply¹⁸. Because we want to decrease the burdens of orthopedic injuries as much as possible, we believe our solution should add no more than 5 minutes to the total application procedure. This limit was set in accordance with our discussions with Dr. Benjamin Chang.

3. Costs: <\$1641

Because our device would be replacing the golden standard to diagnose acute compartment syndrome, we decided to benchmark ourselves against the price of this Stryker device, which is \$1641¹⁹.

¹⁷ Federal Drug Administration (2016). Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

¹⁸ "Casting and Splinting." *American Family Physician*, vol. 79, no. 1, 1 Jan. 2009, pp. 23–24.

¹⁹ Cook, S., & Bruce, G. (2002). Fasciotomy for chronic compartment syndrome in the lower limb. *ANZ Journal of Surgery*, 72(10), 720-723. doi:10.1046/j.1445-2197.2002.02526.x

Professional and Government Standards

Because SENSEI is a diagnostic device, it would normally be approved by the FDA as a Class II device, and we would have to go through the 510(k) pathway²⁰. That said, if we use a different language and initially brand our device as a cast enhancement, it could be considered a Class I device, and no FDA approval would be required²¹.

A relevant engineering standard would be ISO 22523:2006 for “External limb prosthesis and external orthoses”, published in October 2016, last reviewed and confirmed in 2017. Our device falls under this category because under the Code of Federal Regulations Title 21 (CFR) a prosthetic or orthotic accessory classifies any device intended for medical purposes that support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis²². Within the ISO standard, it covers design specification requirements in regard to strength, materials, restrictions on use, assemblies of components, etc. However, in order to access the document, the International Organization for Standardization requires a payment of \$200 to download²³.

²⁰ Center for Devices and Radiological Health. “Overview of Device Regulation.” *FDA*, www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation.

²¹ BMP Medical. “What’s the Difference between a Class I Medical Device and a Class II?” *BMP Medical*, 25 Sept. 2018, www.bmpmedical.com/blog/whats-difference-fda-medical-device-classes-2/.

²² Federal Drug Administration. Code of Federal Regulations Title 21. Sec. 890.3025 Prosthetic and orthotic accessory.

²³ International Organization for Standardization. ISO 22523: 2006. External limb prostheses and external orthoses. Requirements and test methods.

Design and Testing

Design Process

Our goal for senior design was to create a non-invasive and proactive compartment pressure measuring device that did not require the removal of a cast to take the measurement. In order to arrive at such a device, we took the following steps:

- 1. Selecting pressure sensors that would measure skin surface pressure to relate it to compartment pressure*

When deciding which pressure sensors to use, we initially had not established our specifications regarding pressure accuracy and pressure range, which was probably our biggest mistake because these proved to be the most important technical specifications. Given this and an increasing demand for smart textiles in various medical applications, we made the decision to manufacture our own sensors with micro-structured polymeric materials. We were hopeful about these sensors because according to the protocol in a Stanford paper, they were capable of detecting pressure changes as small as 0.0225 mmHg. It is important to mention that these sensors correlate changes in pressure to changes in capacitance, in contrast with most commercially available force sensing resistors which correlate changes in pressure to changes in resistance.

In the end, we decided to pivot from building our sensors to using commercially available ones with a slight modification. Different factors were taken into account in order to make this decision. First, technical complexity was considered. For capacitive sensors such as the polymeric sensors we created, capacitance is measured indirectly by using it to control the frequency of an oscillator or to vary the degree of coupling (or attenuation) of an AC signal. That

sensor system would require the use of AC supply adapters and AC sources, which would have increased the complexity of our circuit significantly, thus defeating the purpose of creating a portable device. On the other hand, resistive sensors can be easily used with Arduino to detect changes in voltage using DC current.

Second, the time available was key. While the idea of creating sensors with remarkable sensitivity and resolution was enticing, a few months of work did not seem to be enough to create the sensors and then put together the entire device.

Additionally, the cost of creating these sensors was uncertain, yet seemed to be high if we intended to create high-quality sensors (e.g. getting high-quality wafers to fabricate the PDMS sensors was very costly and exceeded our budget).

Finally we decided to take time and set the specifications for pressure range and accuracy described in the previous section. After doing so, we realized that the well-understood and commercially available sensors (**Figure 2**) were going to be sufficient for our purposes.

2. Determining the number and location of sensors used to detect compartment pressures

No tradeoffs had to be made in this step because our chosen pressure sensor had the appropriate dimensions to satisfy the placement of sensors every 5 cm or less, which was required based on our spatial resolution specification. Given this and the average length of the forearm, the number of sensors was determined to be 4 on each side (dorsal and ventral).

3. Incorporating the pressure sensors into a sleeve or sleeves to be worn inside casts

When building our sleeve of sensors, we decided to sew our 8 pressure sensors into a single sleeve. Because the space was very constrained, we had to figure out how to make them fit. We ended up cutting the tail of the sensors and attaching FlexiForce™ male berg connectors

to the trimmed ends so that we could also easily connect the conductive thread to the sensors. Purchasing the FlexiForce™ sensors increased the cost of our sleeve and the trimming of the sensors slightly lowers the accuracy in the pressure readings. As such, a competent person could have decided not to cut them.

However, had we decided not to cut them, we would have had to place four sensors in one sleeve, then four sensors in another one, and lastly attach those two sleeves to each other to have a “single device”. By using two different sleeves the patient arm is more compressed inside the cast, which could increase risks of developing ACS. Additionally, without the male berg connectors it was extremely difficult to keep the two ends of the sensors from touching each other.

Lastly, we needed a single ground for the 8 sensors, which would have been very challenging to do had the sensors been on two separate sleeves. Since all of our wiring in the sleeve was done with conductive thread, it was extremely important to find the best way to guarantee that the grounds and 5 V ends of all sensors were not touching each other. With two sleeves, achieving this manufacturing goal would have been very difficult and time consuming.

In conclusion, we prioritized patient comfort, achieving manufacturing goals, and avoiding an increased risk of ACS.

4. Designing the hardware device (Arduino + battery power) and how it would be attached to the sleeve of sensors

Two trade offs were made in this step. First, we made the decision to battery power our device rather than having it connect to a power port. We decided to battery power our device so

that it could be portable and so a patient could get continuous readings. However, in doing so, we sacrificed some portability due to the bulkiness of the batteries.

Second, we decided to have the hardware device separated from the sleeve. In doing so, the hardware device can be recycled by the physicians and costs for the patients can be reduced. Once we made this decision, we were forced to spend extra time figuring out a way to easily and seamlessly enable patients and physicians to connect the hardware device to the sleeve. Ultimately, this was achieved, and will be demonstrated further below.

5. Developing the algorithm to detect acute compartment syndrome

Our algorithm to detect acute compartment syndrome works in the following way: it takes skin-to-surface pressure readings and using our standard curve, (to be described below) converts them to compartment pressure readings in mmHg. Therefore, at each location where we have a sensor, we have a compartment pressure reading. Then, the algorithm makes an ACS diagnosis by taking the highest reading out of all the sensors and comparing it to our threshold. If the reading is greater than 20 mmHg, then the user is at risk of developing ACS and is sent to the hospital. We could have established more controls once a pressure reading exceeds 20 mmHg, such as also analyzing the neighboring pressures and considering the site of fracture (some studies have shown that pressure readings directly at the site of fracture show inaccurate elevated readings²⁴); however, given that we prioritized the elimination of false negatives, we instead decided to just take the highest reading out of all sensors to determine ACS.

²⁴ Heckman MM, Whitesides TE Jr, Grewe SR, et al. Compartment pressure in association with closed tibial fractures. The relationship between tissue pressure, compartment, and the distance from the site of the fracture. J Bone Joint Surg Am 1994;76(9):1285–92.

6. *Relaying the information to the patient*

We incorporated a bluetooth module into our device to relay the readings and the warnings to the patient's phone and used the MIT app inventor to code the mobile app. However, because the MIT app inventor is only compatible with Android, our product as of now would only be available for Android users. We sacrificed the initial penetration of our device to iOS users because we can launch our product with Android users and use it as a pilot to identify flaws and areas we can improve. Once these are identified, we would employ more time and resources into the iOS app development to expand our reach to more customers.

Design Solutions - Evaluation Process, Results and Conclusions

Design iterations

During the course of this project we went through four main design iterations. These iterations are mainly defined by the type of sensor we studied and tested. The other components of our design, namely having a sleeve of sensors that relays readings to a microcontroller device which calculates compartment pressure and produces a response depending on this pressure value, did not change over the course of the development process. The four pressure sensors we assessed were a force-sensing resistor made of conductive fabric, a force-sensing resistor made of a polyolefin and carbon black called Velostat® , a force-sensing capacitor made of microstructured silicon and metal plates, and a commercial force-sensing resistor called FlexiForce™.

1. Our first iteration utilized sensors made of commercially available conductive fabric purchased from Adafruit. The fabric consists of copper-nickel plated nylon with a resistivity of less than 1 Ohm per foot in any direction across the textile (**Figure 3**). The

material proved to be comfortable and elastic which was ideal for our design. For these sensors, resistance varied significantly in response to longitudinal loading, the resistance change response to perpendicular pressure was poor and barely detectable by multimeters. Further testing with Arduino confirmed a very limited range of voltage out change and resolution in the measurements.

2. The second material we explored was Velostat® , a polymeric foil (polyolefins) impregnated with carbon black to make it electrically conductive (**Figure 4**). It was selected because its resistance changes with either flexing or pressure^{25 26}. We cut off sensors of different sizes from a Velostat sheet and tested resistance change with a multimeter and an Arduino (analog readings) in response to normal loading. Observations revealed a satisfactory range and resolution in readings. Then we proceeded to model a cast as described in the evaluation section using a pressure bag to model swelling. We again observed a good range and resolution in response to the pressure applied by the pressure bag inside the cast. Thus, we proceeded to define a circular standard sensor (diameter of 2 cm) to convert analog readings to pressure readings. We observed a measurement range of around 17 to 400 mmHg (analog readings for pressures below 17 mmHg or above approximately 400 mmHg were indistinguishable). As the sensor size decreased, the measurement resolution and range increased, and that the material is somewhat fragile. We also used these sensors to create a proof-of-concept prototype. It included two standardized sensors sewn into a fabric arm sleeve using conductive thread

²⁵ Adafruit. Pressure-Sensitive Conductive Sheet (Velostat/Linqstat). <https://www.adafruit.com/product/1361>.

²⁶ Drake, N. (1996). Polymeric Materials for Electrostatic Applications. Rapra Technology. p. 131. ISBN 978-1-85957-076-0.

and connected to an Arduino Uno. An alert system code that sent an email upon reaching 30 mmHg was coded into the Arduino.

3. A force-sensing capacitor made of microstructured silicon and metal plates. These sensors were based on research conducted by Bao et al. and suggested by Dr. Shu Yang²⁷. Our desire to explore these sensor stemmed from their extremely low pressure sensitivity which was not achieved with sensors using conductive thread and Velostat®. In order to fabricate these sensors, we used mold release spray and duct tape to remove the coating from a series of CDs. CDs served as a mold because of their inherent 3-D-microstructured topography. We then poured Dragonskin 30 silicone to replicate the microstructures on the CD coating on silicone. After letting the silicone harden, we placed it between two aluminum foil sheets to create a capacitor. Microstructures provide space in which air acts as a dielectric. Normal forces compress these microstructures and change the capacitance of the sensors by changing the amount of air trapped between the plates. We observed that perpendicular pressure applied to the foil resulted in temporary voltage increase as expected from a capacitor sensor.
4. Our last iteration consisted of FlexiForce™ force sensitive resistors. Force-sensing resistors consist of a conductive polymer sheet or ink that can be applied by screen printing. The sensing film consists of both electrically conducting and non-conducting particles suspended in matrix. Force applied to the surface of the sensing film causes particles to touch the conducting electrodes, changing the resistance of the film²⁸. Evaluation of this iteration will be explored in detail in the following section, yet we were

²⁷ Mannsfeld, S. C., Tee, B. C., Stoltenberg, R. M., Chen, C. V. H., Barman, S., Muir, B. V., ... & Bao, Z. (2010). Highly sensitive flexible pressure sensors with microstructured rubber dielectric layers. *Nature materials*, 9(10), 859.

²⁸ Wikipedia. Force-sensing resistor. https://en.wikipedia.org/wiki/Force-sensing_resistor#cite_note-5.

able to prove that the sensors had a detection range that included the target 20-40 mmHg range, and had sufficient resolution and accuracy. Sensors were sewn onto a polyester sleeve side by side on both the ventral and dorsal sides of the sleeve, providing a spatial resolution of 4 cm. We trimmed sensor tails and used FlexiForce™. Male berg connectors were used to connect to the conductive thread, which was sewn through the sleeve to provide appropriate wiring to the microcontroller. We used an Arduino Nano powered by two CR2032 batteries and voltage divider circuits using 1,000 Ohm resistors. A Bluetooth module was used to send pressure readings to an Android smartphone.

Evaluation of experimental design

In order to evaluate these iterations, we designed two experimental setups: one used digital scales and calibration weights and the second was a full model of a cast that incorporated an IV pressure bag that sat between the skin and the sleeve of sensors. We only calculated standard curves and evaluated the second and fourth sensors.

1. The experimental model for pressure measurement was applied to standardized sensors (Velostat® and FlexiForce™) for consistency. We used calibration weights or containers that could be filled with increasing volumes of water to measure ‘true pressure values.’ The contact area of these objects matched the area of the sensors in order to apply uniform pressure on the sensors and to calculate pressure from the known weights. Analog readings were collected at different pressure values from 0 to 400 mmHg.
2. This experimental model shown in **Figure 5** was a complete model of a soft cast. It incorporated an IV pressure bag that sat

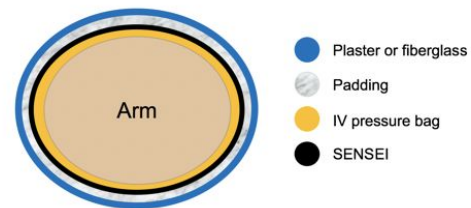


Figure 5: Full model of cast incorporating the pressure bag

between the skin and the sensors. Padding and soft cast material were applied on top. ‘True pressure readings’ in the compartment (IV pressure bag) were measured using sphygmomanometers. Analog readings were collected at ‘real pressure values’ from 0 to 120 mmHg by inflating the IV pressure bag.

Evaluation results

While we evaluated our final design extensively, we only performed very limited evaluation of the second design using Velostat® sensors. For Velostat® sensors we only calculated a standard curve using the scale and weights experiment to prove feasibility (**Figure 6**) and were able to define some specifications:

- Detection range was defined as the range over which the sensor could resolve pressure. It was estimated to be from 17 to around 400 mmHg. Above or below these limits pressures could no be resolved.
- The resolution was approximately 1.25 mmHg/step in the 20-40 mmHg range, which was too low for our purposes.

We extensively evaluated our final design. **Table 1** summarizes our proposed and achieved specifications and how these were evaluated:

Table 1: Summary of evaluated specifications.

Specification	Promised	Delivered	Evaluation Method
Length (sleeve)	260-280 mm	360 mm	Using a ruler
Dimensions (device)	5 cm x 5 cm x 0.5 cm	6.5 cm x 6.2 cm x 2.3 cm	Using an analog caliper
Weight	As light as possible	0.06 kg	Using laboratory digital scale
Thickness (sleeve)	As thin as possible	1.02 mm	Using an analog caliper
Confidence range	20-40 mmHg	20-40 mmHg	Maximum deviation from best fit curve (linear) below 10%

Resolution	1 mmHg	0.08 mmHg	Dividing the pressure range (20-40 mmHg) by analog read steps over the range
Accuracy	1% error	9% error	Sensors were used to measure pressure at multiple pressure levels to determine error. Measurements were compared to ‘true values’ measure with a gold standard (sphygmomanometer)
Biocompatibility	Compatible with skin	Compatible with skin	Contact with the skin for 1-3 hour periods , non-invasive. Compliant with ISO biocompatibility guidelines. Materials used were investigated through published literature
Application time	<5 minutes	28 ± 8 seconds	Timed the application of the sleeve 10 times and calculated an average
Sensitivity	>90%	95.4%	Study using model of cast with IV pressure bag. Blinded person determines if patient has ACS to calculate true positive, true negative, false positive and false negative
Specificity	>90%	56.2%	Study using model of cast with IV pressure bag. Blinded person determines if patient has ACS to calculate true positive, true negative, false positive and false negative

Going back to our goal of creating a device that provides real-time, objective, non-invasive compartment syndrome measurement, we can put our evaluation results into perspective. In general, the device can provide moderately accurate pressure measurements over the 20-40 mmHg range (**Figure 7B**), which is where critical changes in pressure related to ACS take place. The sensitivity study (**Table 2**) was particularly exciting and proved that even when our accuracy is not close enough to 100%, we still have a very high sensitivity (very low rate of false negatives). This was achieved by adjusting the algorithm and lowering our threshold for ACS to account for the error rate. This way we keep sensitivity high which is most

Table 2: Results of blinded study for sensitivity and specificity (P = 38).

Result	Frequency
True positive	21
True negative	9
False positive	7
False negative	1

important, because ACS must be treated promptly to avoid adverse results. Negative diagnoses that are close to a threshold we have concluded is appropriate (25 mmHg), can be confirmed using Stryker compartment pressure manometers to confirm if it is a true negative.

In general our evaluation confirms that SENSEI can be used to assess the onset of ACS with great sensitivity in a real-time, non-invasive manner. Also, SENSEI's accuracy is comparable to the widely used Stryker straight needle measurement which is the golden standard (Figure 7C and Figure 8): R^2 (Stryker) = 0.9358 vs. R^2 (SENSEI) = 0.9318.

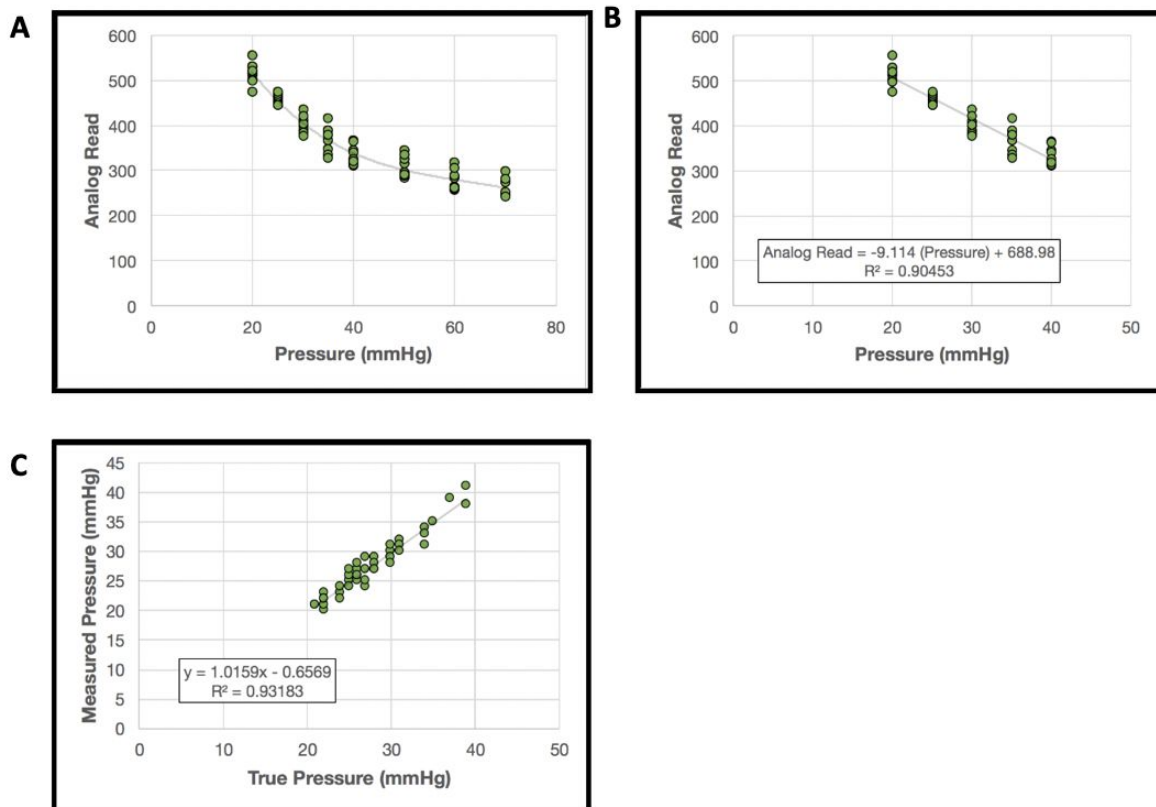


Figure 7: (A) Standard curve (polynomial) of FlexiForce™ sensors. (B) Standard curve using reduced range to obtain linearity and decrease error. (C) Regression of true vs. measured pressure values for SENSEI sensors.

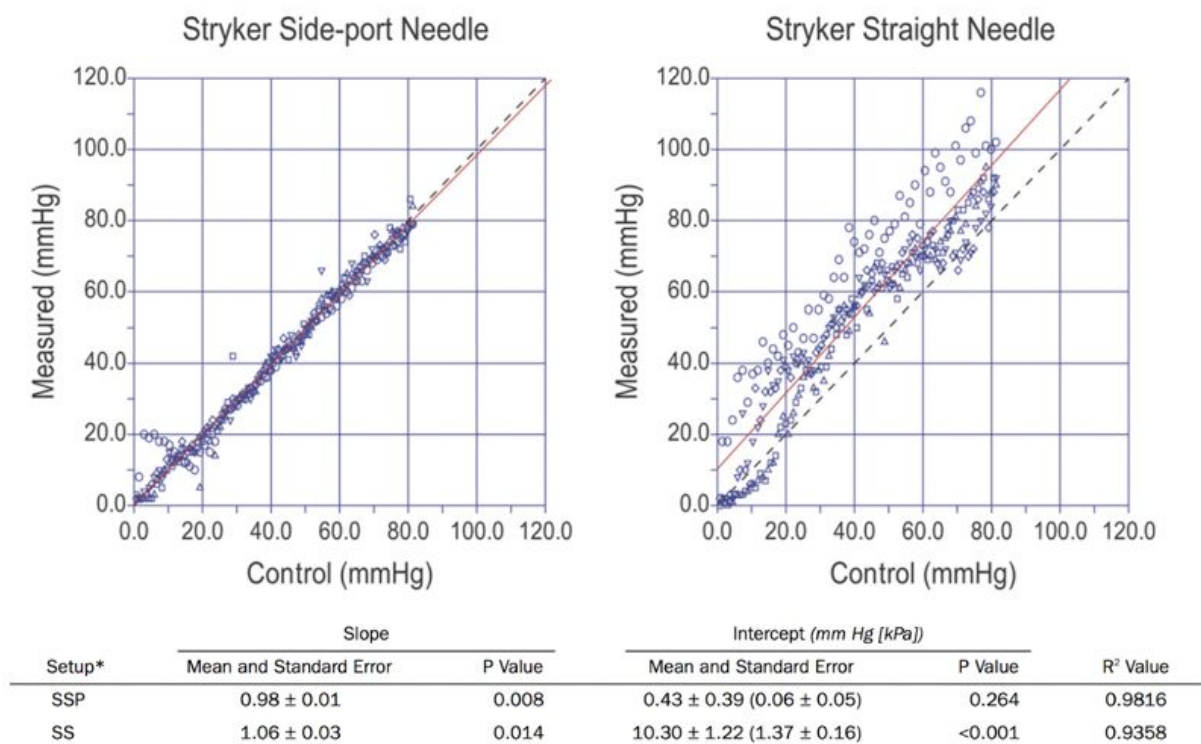


Figure 8: Regression of true vs. measured pressure values for Stryker device using two needle configurations.

Optimal Design Performance

Three specifications were considered fundamental to achieving the performance level we targeted: range, spatial resolution, and accuracy. A fourth specification that we recently explored after the final presentation was sensitivity. **Figure 7B** demonstrates great linearity and resolution over the range of confidence ($R^2 = 0.9045$). Our goal was to be at a maximum deviation of less than 10% over the 20-40 mmHg range, which we achieved. This is crucial because this curve is used by the microcontroller to produce pressure readings in mmHg. The range is within the area of interest for ACS. The accuracy that we targeted was as close to 100% as possible. We achieved a 91% accuracy or 9% error. While this is moderately positive, by adjusting our algorithm as described before, we are able to make up for reduced accuracy to guarantee our sensitivity stays high. Finally, the spatial resolution needed to be less than or equal to 5 cm. We achieved a resolution of 4 cm on both the ventral and dorsal side which allows for excellent spatial tracking of changes in pressure.

Project Impact

Based on the fact that we hit all of our design specifications except for the 100% accuracy (SENSEI accuracy = 91%), we are still confident that our device can be used as an ACS diagnostic.

SENSEI meets the clinical need of various stakeholders by providing real-time pressure measurements underneath a cast to monitor the development of ACS. If adopted by the market, SENSEI is able to replace the current diagnosis protocol of the subjective 5 P's assessment and the painful, invasive compartmental measurements with a pressure sensing sleeve worn underneath a cast that non-invasively and proactively monitors for signs of ACS.

For patients who are wearing our device for long periods of time, SENSEI provides reassurance that pressures under the cast are in control. Patients are usually told to check for the 5 P's but they have little or no experience doing so, or these metrics are too subjective. With SENSEI, pressures are checked continuously in real time. If there ever is a risk of developing ACS, the patient is notified immediately and thus is saved from developing the permanent nerve and muscle damage associated with a late detection of ACS. With our accuracy and sensitivity, we are confident that SENSEI can catch most false negatives and thus send people to the ER to seek treatment. This also means that patients developing ACS will not have to go through the painful compartment measurement process using the Stryker device. Having achieved all of our dimension specifications, patients barely feel the presence of SENSEI under their casts which is ideal to keep the patient as comfortable as possible.

For the physician, SENSEI provides value by streamlining the current diagnosis standard of care. The physician no longer needs to rely on the subjective 5 P's assessment to make a diagnosis or use an invasive pressure measurement device to confirm or rule out ACS. With SENSEI, the physician no longer needs to worry about the consequences of a missed diagnosis or a misdiagnosis of ACS.

Lastly, for the cast technicians SENSEI is convenient because right now they solely rely on their training and communication with the patient to determine if a cast is too tight. Thus having a quantitative pressure measurement underneath a cast would greatly inform technicians during the casting process to ensure appropriate casting before the patient is discharged. Additionally, the simplicity of the SENSEI application protocol is ideal because it adds less than 30 seconds to the total casting procedure. It requires minimal training to ensure the sensors are

located in the correct locations and does not change the regular casting procedure once SENSEI is applied.

Again, by using SENSEI, we are able to solve most problems we outlined with the current diagnostic process effectively by:

1) Problem: painful, invasive compartment pressure measurements are administered more often than necessary to confirm ACS diagnosis due to the subjective 5 P's measurement.

How SENSEI meets the need: With SENSEI, the Stryker device will only be used to confirm or rule out ACS as a backup diagnosis for when SENSEI detects pressures close to the threshold for diagnosing ACS. In general, our evaluation confirms that SENSEI can be used to assess the onset of ACS with great sensitivity in a real-time, non-invasive manner.

2) Problem: ACS may be misdiagnosed and the patient undergoes an unnecessary fasciotomy

How SENSEI meets the need: Given that SENSEI's accuracy is not perfect, we had to compromise and choose which of these first two problems to target. We concluded that eliminating false negatives was more important than eliminating false positives, because the consequences of the former are way worse than those of the latter. As such, our specificity value of ~56% is not ideal for preventing patients from getting an unnecessary fasciotomy.

3) Problem: ACS diagnosis is delayed or missed, resulting in severe complications

How SENSEI meets the need: Since SENSEI gathers compartment pressures real-time and continuously, the diagnosis for ACS is done in a timely manner. More importantly, with a sensitivity of 95%, we can almost get rid of all false negative cases (this ended up becoming the main goal of our device).

Final Display of Product

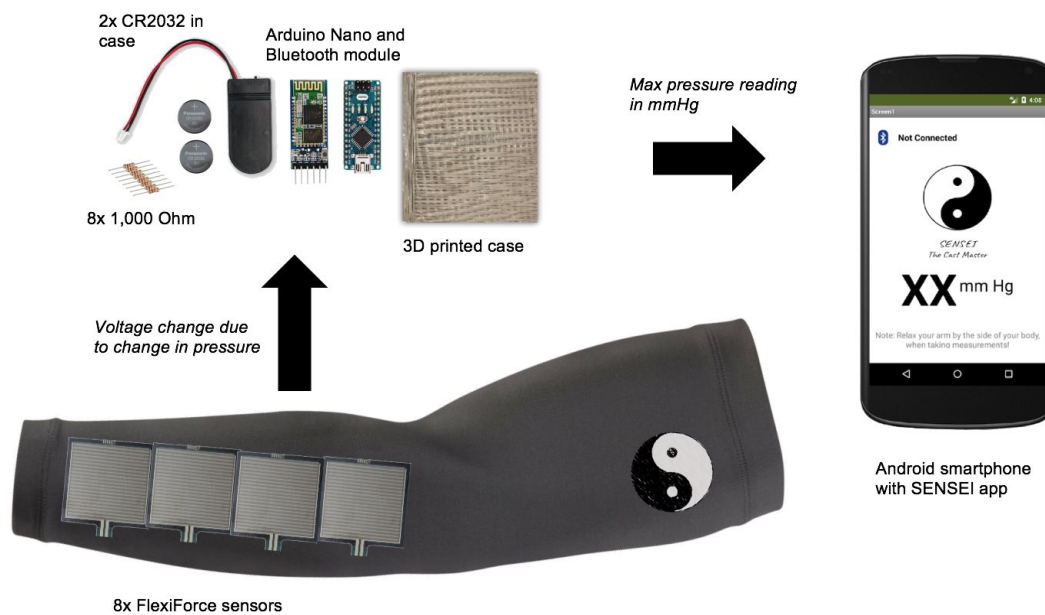


Figure 9: Diagram of main components of SENSEI

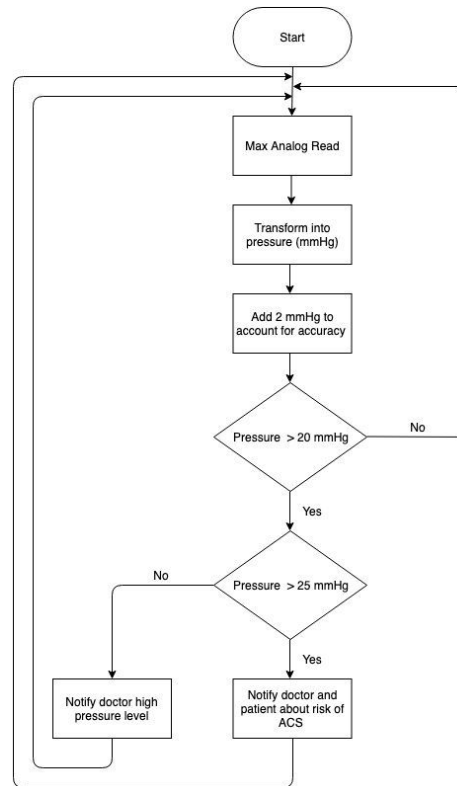


Figure 10: Flowchart explaining the algorithm SENSEI uses to interpret pressure readings

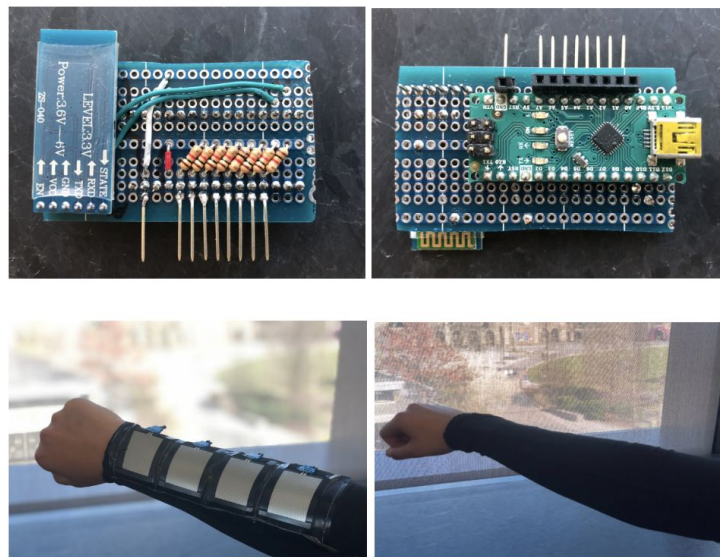


Figure 11: Circuitry for the device and the interior components and exterior of the sleeve

Budget

R&D Expenses:

In total, our group incurred expenses of \$477.34. \$423.84 (88.8%) of the total expenses were paid for using the class budget, which is funded by Penn Engineering, and \$53.50 (11.2%) of the total expenses were paid for by our group out of pocket. A full list of the items included in our budget and the justification for the items purchased can be found in **Appendix 1**.

Cost of Prototype:

The total cost of our prototype is \$144.31. The device that is plugged into the sleeve is comprised of the Arduino Nano, the Arduino Bluetooth module, and the battery, and the sleeve is comprised of the eight pressure sensors, the sleeve fabric, and conductive wiring. The bulk of the cost can be attributed to the eight pressure sensors (66.5%), and we believe that further cost savings can be realized due to economies of scale during production.

Conclusion

Our goal with SENSEI was to make the fracture-based ACS diagnostic process as easy and as effective as possible. We wanted to minimize the number of fasciotomies and amputations that occur by letting patients know the second their compartment pressure enters the at-risk range, so that they can seek medical attention immediately. We also wanted to minimize the number of times the Stryker manometer needs to be used, as it is expensive for the hospital and painful for the patient. We did this by giving patients and physicians a quantitative way to measure the main driver of ACS, allowing the disease to be ruled out or confirmed without the

use of the Stryker device. With a 91% accuracy, we were able to solidify a strong proof of concept and show that our vision of a more painless ACS diagnostic process is achievable.

Specifications Met

We were able to meet most of our specifications, which bodes well for a potential launch of the product in the future. We were able to read pressure within the target range of 20-40 mm Hg. Because the threshold range for ACS is within this range, this means that SENSEI will be able to detect when the threshold is reached, and therefore when the patient is at risk for ACS.

Another crucial spec we were able to meet was spatial resolution. Because our device has a spatial resolution of <5cm, we are able to catch ACS wherever it occurs in the arm. If our device had the sensors more spread out, we might miss a reading in a location where the syndrome had begun to develop. Although both of these specs were met, we were not able to hit our target of 100% accuracy. However, with our 91% accuracy, and setting the threshold to 23 mmHg or adding 2 mmHg to readings we are able to get rid of false negatives as we would be able to detect 100% of true readings above 25 mmHg. We believe that improved accuracy can be achieved with further device and sensor refinement, perhaps going back to the very sensitive sensors used in the Bao et al. paper.

We were able to hit all three of our size-related specs. Our device is extremely thin (~1mm) and lightweight (0.06kg). This will allow the Sensei user to move their arm around comfortably, not adding any perceived negativity to the fracture-healing process. It is also long enough to cover the entire forearm and a little bit further, for easy connection of the hardware device to the sleeve. Regardless of the location of the fracture in the forearm, the patient can be assured that Sensei will be able to detect ACS.

Lastly, the biocompatibility will allow us to progress through the regulatory process with ease, while the negligible increase in application time and low cost will allow the device to easily be adopted into the market. SENSEI aims not only to improve fracture outcomes, but to make the patient's overall experience easier.

Future Steps

In the future, we hope to extend the use of the device to the leg-fracture market, as these patients are at an even higher risk of developing ACS. We will create a more robust standard curve by investing in more sensitive and accurate pressure sensors, so that our device yields more accurate pressure readings. These modifications will hopefully allow us to hit our 100% accuracy goal. We will make an iOS application so that the device is not only available to Android users. Once all of this is done we will reach out to physicians who see the same opportunity in this device that we do, and unleash SENSEI onto the world.

Attributions and Acknowledgments

We would like to take the time to thank Dr. Shu Yang for all her help when we tried to fabricate our own pressure sensors, Dr. Benjamin Chang for his valuable feedback to helping us build an innovative device that fulfills a need, and Dr. Sangeeta Vohra and Dr. Ari Brooks for providing their valuable input during the brainstorming sessions about our business strategy and market opportunity for our device. Additionally, we want to thank the BE Lab staff for their help, and for providing us with the space to carry out our senior design project. Lastly, we want to thank Seville, Dr. Meaney and Dr. Rizk for their advice and support.

SUPPLEMENTAL BUSINESS PLAN

Overview

Acute Compartment Syndrome (ACS) occurs when tissue pressure exceeds perfusion pressure. ACS occurs in 26,500 people in the US each year and about 70% of these cases can be traced back to a fracture.²⁹ It requires emergency surgery, a fasciotomy, to relieve the build up of pressure to avoid permanent nerve and muscle damage and even amputation.

ACS remains an obscure, complex and difficult-to-assess condition that has to be handled in a timely manner to avoid serious complications. There is a need in the medical field to revolutionize how ACS is diagnosed because the current standard of care is problematic. Due to the high subjectivity of the 5 P's assessment there result in three main issues: **1)** painful, invasive compartment pressure measurements are administered unnecessary to confirm or rule out ACS **2)** ACS may be misdiagnosed and the patient undergoes an unnecessary fasciotomy and **3)** ACS diagnosis is delayed or missed leading to serious complications for the patient.

SENSEI fills a need by revolutionizing the diagnosis process with a non-invasive, real-time, continuous, and proactive compartment pressure measuring device that is worn underneath an orthopaedic cast to monitor for signs of ACS throughout fracture recovery.

Target Customer Segment

Although ACS is rare, affecting only 26,500 people in the US each year, the consequences can be devastating if a diagnosis is missed or delayed. Thus, we believe all fracture patients will want to use our device to proactively monitor for signs of ACS, given that patients are at an increased risk to developing ACS after a fracture.

²⁹ Via, Alessio Giai. "Acute Compartment Syndrome." *Muscles, Ligaments and Tendons Journal*, 2015.

Market Opportunity

Fractures are the most common orthopedic problem in the US as over 6 million people break their bones each year. Although our current product is only intended for use in wrist and lower arm fracture patients, the same technology with a slightly different sleeve design can easily be translated to include ankle, tibia, and fibula fracture patients.

The current market opportunity for SENSEI is approximately \$84 M with the potential to expand to \$122 M when SENSEI becomes a diagnostic device for the lower leg. This number is derived from the total number of wrist and lower arm fractures that occur each year for the current market opportunity, and the additional number of ankle, tibia, and fibula fractures that occur each year for the potential market opportunity. The price of the device (\$188.40) was derived using a cost-plus strategy, applying a 25% margin, which is the healthcare devices industry average for profit margins.³⁰ Detailed calculations for the market size and total potential revenue can be found in **Appendix 2**.

Our product comes with a wave of at home diagnostics. The at home diagnostic market is expected to increase 30% in the next 7 years.³¹ This is largely due to an increase in smartphone usage, which has nearly doubled in the past six years,³² and allows for applications like Sensei's to work in tandem with devices to bridge the information gap and put patients in control of their own health.

³⁰ MedPac

³¹ "Home Diagnostics Market Forecast, Trend Analysis & Competition Tracking - Global Market Insights 2018 to 2026." Fact Mr., Sept. 2018, www.factmr.com/report/1892/home-diagnostics-market.

³² "Slowing Growth Ahead for Worldwide Internet Audience." *EMarketer*, 7 June 2016, www.emarketer.com/Article/Slowing-Growth-Ahead-Worldwide-Internet-Audience/1014045.

Value Proposition:

We identified three key stakeholders: patients, physicians, and orthopaedic cast technicians that we see would benefit from adopting SENSEI.

The Patient: Fracture patients are the ultimate users of our device and are the people who interact with SENSEI on a day-to-day basis. In this case, the patient is an adult or a child, and this stakeholder not only interacts with the device, but also with the physician and the orthopedic cast technician.

- As a patient with a fracture, you are casted and informed of potential risks such as developing ACS. As such, you are told to monitor for symptoms such as extreme pain and tingling. However, gauging pain can be difficult, especially in children, as you cannot see underneath a cast or know how much a fracture is supposed to hurt. To help give patients peace of mind, a proactive, non-invasive, continuous and real time compartment pressure measurement device such as SENSEI is ideal to monitor for a limb-threatening condition.
- SENSEI also integrates seamlessly with the casting procedure as it is just a sleeve that goes under a cast plus an electronic device plugged on top. Most importantly, it does not restrict a patient in any way to perform their daily activities.

Within this patient stakeholder population, we also view a child's parent as an important stakeholder. This is because 40% of girls and 50% of boys experience a fracture during childhood, and thus parents are extremely involved in the treatment process and are the ones who

communicate with the doctor, ask questions, and make decisions for their children.³³ To a parent of a child who just fractured their arm, our device offers additional value.

- SENSEI eliminates the need for invasive pressure measurements and offers value to the parent because children are frequently afraid of needles, so parents no longer have to manage a child's stress/emotions by using SENSEI. Moreover, SENSEI's accuracy is comparable to the gold standard—Stryker's handheld manometer device—in measuring compartment pressure, so it does not provide any disadvantages against what is currently available on the market
- The proactive component is especially valuable to parents, as children often have a hard time communicating exactly what is wrong or what hurts, so allowing the parent to check consistently is another way they can monitor their child's recovery. This also gives parents peace-of-mind so they can constantly monitor for signs of ACS, as opposed to after their child feels pain/symptoms, which may already be too late.

The Physician: This stakeholder is relevant because the physician will be the one recommending our device to the user and will be the one using our device to review pressure reading history to diagnose ACS. SENSEI is valuable to the physician because it streamlines the ACS diagnosis process.

- The physician no longer needs to rely solely on the subjective 5 P's assessment to make a diagnosis or use an invasive pressure measurement device to confirm or rule out ACS. With SENSEI, the physician does not need to worry about the consequences of a missed diagnosis or a misdiagnosis of ACS.

³³ Bone Fractures in Children: When Should Parents Be Concerned? (n.d.). Retrieved from <https://www.nationwidechildrens.org/family-resources=education/700childrens/2018/04/bone-fractures-in-children-when-should-parents-be-concerned>

- In the event that a patient comes in complaining of pain, the physician can check the readings from SENSEI to confirm or rule out pain stemming from ACS. This saves the doctor time by eliminating one factor that could be causing the pain.

The Orthopedic Cast Technician: This stakeholder is relevant because cast technicians are the ones in charge of applying casts to fracture patients. They need to make sure casts are appropriately applied to ensure healing of fractures without causing harm to the patients. Because overly restrictive casts can increase the risk of a patient getting ACS, SENSEI provides value to the cast technician as well.

- Cast technicians currently have no objective way to determine if a cast is too tight or too loose. They rely solely on their training and communication with the patient, thus having a quantitative pressure measurement underneath a cast would greatly inform technicians during the casting process to ensure appropriate casting before the patient is discharged.
- Additionally, the simplicity of the SENSEI application protocol is ideal because it adds less than 30 seconds to the total casting procedure. It requires minimal training to ensure the sensors are located in the correct locations and does not change the regular casting procedure once SENSEI is applied.

Go-To-Market Strategy

Before entering the market, we will need to register our Class I medical device with the FDA. Our device falls under the sub-category of cast components within the orthopedic device category and is not required by the FDA to submit a premarket notification, 510(k), or premarket application (PMA).³⁴ After successfully registering our device, we will first market SENSEI to

³⁴ U.S. Food and Drug Administration

hospitals and orthopaedic clinics, will a focus in pediatric care facilities because of the additional value our device provides to these stakeholders.

Competition

As mentioned in the main paper, our concept is innovative as it completely replaces how ACS is diagnosed and monitored for after a fracture. It does not build on current approaches, but is similar to the current gold standard ACS diagnosis method, the Stryker manometer, in that it measures the intracompartmental pressure to confirm or rule out ACS. Our main competition is the Stryker manometer handheld device. It involves injecting small amounts of saline into a closed compartment to measure the resistance from tissue pressure and costs \$1641.³⁵ Our device also measures the pressure of a closed compartment, but does so non-invasively at less than an eighth of the cost for only \$188.40 from a diagnostic point of view. While there is a non-invasive diagnostic device called the EBI (non-invasive Compartment Evaluator), this device is not recommended for clinical use due to poor measurement accuracy.³⁶

SENSEI is the only device that can monitor for signs of ACS underneath a cast that is able to detect ACS symptoms by monitoring pressure in order to diagnose ACS in a timely manner. This differentiates us from the reactive diagnostics already available on the market because with SENSEI, a physician can diagnose and treat ACS as symptoms rise, thus reducing the risk of patients suffering from the severe consequences of ACS.

Intellectual Property: After conducting a prior art search, we can file a design patent for the sleeve and hardware of SENSEI and a utility patent for the software of SENSEI in the US.

³⁵ Cook, S., & Bruce, G. (2002). Fasciotomy for chronic compartment syndrome in the lower limb. *ANZ Journal of Surgery*, 72(10), 720-723. doi:10.1046/j.1445-2197.2002.02526.x

³⁶ Cook, S., & Bruce, G. (2002). Fasciotomy for chronic compartment syndrome in the lower limb. *ANZ Journal of Surgery*, 72(10), 720-723. doi:10.1046/j.1445-2197.2002.02526.x

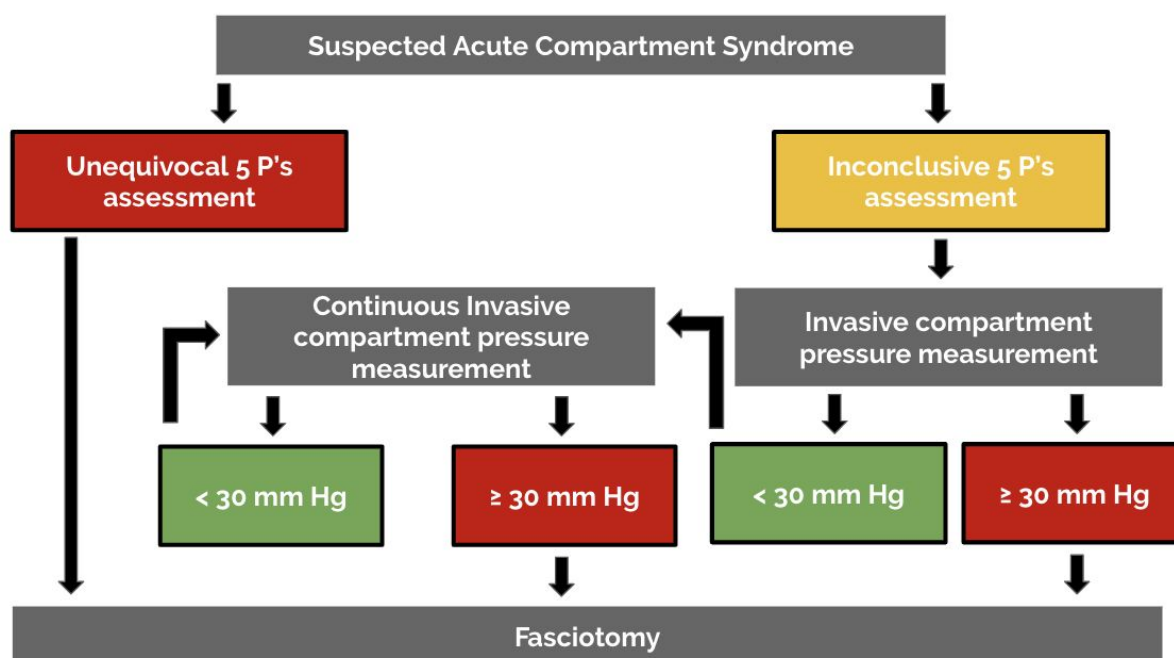
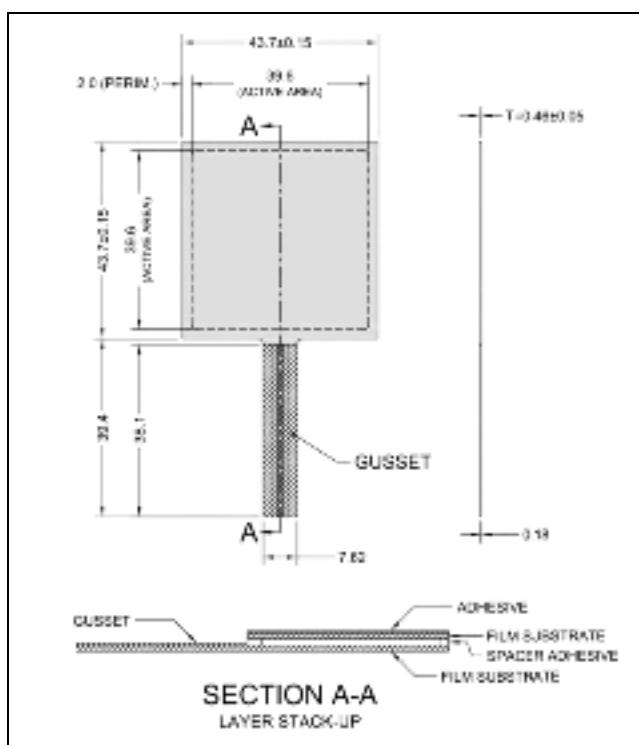
FIGURE 1: Current ACS Diagnosis Process**FIGURE 2:** Final Sensors incorporated into SENSEI

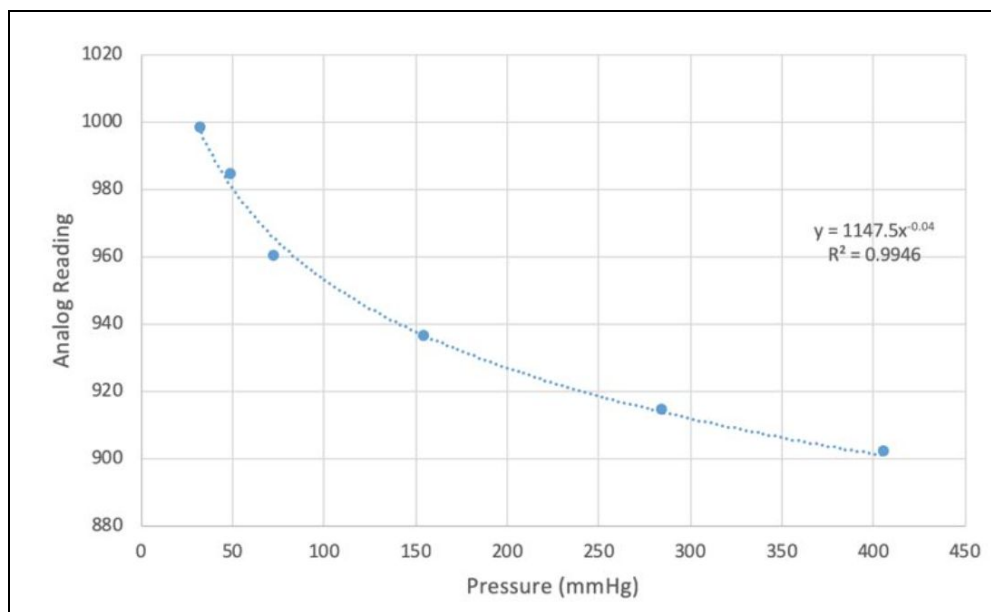
FIGURE 3: Iteration 1 using the Conductive Fabric



FIGURE 4: Iteration 2 using the Velostat Sensor



FIGURE 6: Standard Curve for Velostat Sensors



APPENDIX 1: Total Expenses Incurred

Items Purchased	Unit Price	Quantity Ordered	Total Price	
Coin Cell Battery Holder	\$ 1.95	2	\$ 3.90	
Stainless Thin Conductive Thread	\$ 5.95	2	\$ 11.90	Class Budget
Arduino Nano Board	\$ 23.50	2	\$ 47.00	Out-of-pocket
Arduino Bluetooth Module	\$ 8.49	2	\$ 16.98	
Samsung Galaxy S5 Android Smartphone	\$ 99.99	1	\$ 99.99	Items used in SENSEI
FlexiForce Male Berg Connector	\$ 24.50	4	\$ 98.00	Items essential for the Design Testing Process
Disposable Pressure Infuser Bag	\$ 12.99	1	\$ 12.99	
Pressure-Sensitive Conductive Sheet (Velostat/Linqstat)	\$ 3.95	2	\$ 7.90	
Cables and Sensors Reusable Pressure Infusion Bag	\$ 65.00	1	\$ 65.00	
3M Scotchcast Synthetic Cast Padding	\$ 16.74	1	\$ 16.74	
3M Scotchcast Soft Casting Tape	\$ 28.45	1	\$ 28.45	
Bememo Unisex UV Protection Sleeves	\$ 14.99	1	\$ 14.99	
Knit Jersey Conductive Fabric	\$ 15.67	1	\$ 15.67	
Sewing Needles	\$ 2.95	1	\$ 2.95	
Sewing Thread	\$ 4.50	1	\$ 4.50	
CD-Rx 50 pack	\$ 15.99	1	\$ 15.99	
Mann Ease-Release 200	\$ 14.39	1	\$ 14.39	
Total			\$ 477.34	

Justification of Items Purchased: Items highlighted in orange were incorporated into the final prototype of SENSEI, the cost of the pressure sensors used in our final prototype is not reflected in the budget because they were supplied by the Bioengineering Labs. Items highlighted in green were essential for the testing and evaluation process of SENSEI. The Pressure-sensitive conductive sheet, knit jersey conductive fabric, CDs, and Mann Ease-Release 200 were all necessary during the exploration process of figuring out what kinds of sensors would be the best for our sleeve. Item quantities that exceeded 1 were ordered as back-up, except for the Male Berg Connectors in which many were incorporated into the sleeve design.

APPENDIX 2: Detailed Market Sizing and Market Opportunity Calculations

Table 1: Fracture Statistics in the US

Bone	Number of Cases per Year
Wrist Fracture	72 per 100,000 persons per year ³⁷
Lower Arm Fracture	64 per 100,000 persons per year ³⁸
Ankle Fractures	101,944 in 1998 ³⁹
Tibia and Fibula Fractures	67,600 in 1998 ⁴⁰

1998 US Population: 276.1 M⁴¹

2018 US Population: 327.2 M⁴²

Current Market Size for injuries: 444,992

Wrist Fractures: $72 * (327,200,000/100,000) = 235,584$

Lower Arm Fractures: $64 * (327,200,000/100,000) = 209,408$

Potential Market Size: 645,914

Wrist Fractures: 235,584

Lower Arm Fractures: 209,408

Ankle fractures: 120,811 (adjusted for 2018 population)

Tibia and Fibula fractures: 80,111 (adjusted for 2018 population)

Price: \$180.40 (Cost +25% margin)

Total Cost for Device: \$144.31

Healthcare devices profit margin (industry standard): 25%⁴³

Total Potential Revenue = Number of injuries * price

Current market = $444,992 * \$188.40 = \$83,836,293$

Potential market = $645,914 * \$188.40 = \$121,690,198$

³⁷ National Ambulatory Medical Care Survey & American Academy of Orthopaedic

³⁸ Ibid

³⁹ Ibid

⁴⁰ Ibid

⁴¹ United States Census Bureau

⁴² Ibid

⁴³ MedPac