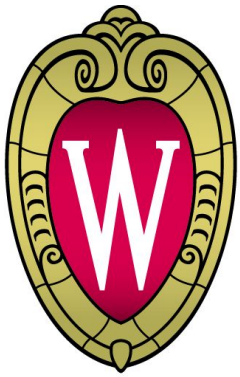

WISCONSIN

UNIVERSITY OF WISCONSIN–MADISON

Improving Diagnostic Technology of Acute Compartment Syndrome

Biomedical Engineering Design: 200/300

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Client: Christopher Doro, MD

Advisor: Walter Block, P.h.D.

Abstract

Acute compartment syndrome (ACS) is a condition in which the pressure of the muscle compartment is increased significantly due to a traumatic event, most commonly a bone fracture. The consequences are a decrease in the pressure gradient of blood flow which essentially causes arterial blood to bypass the injured muscle, leading to cell anoxia, muscle ischemia and muscle death. Diagnosing ACS is problematic as current methods rely on the subjective assessments of clinical examinations and/or inaccurate intracompartmental pressure readings. These deliver unusually high false-positive diagnoses in trauma patients which often lead to unnecessary and invasive surgical treatment of a fasciotomy. Recently however, it has been shown that alternative biochemical markers, such as glucose and pH, may lead to more a more accurate and concrete quantification of this ailment. While current technology exists to detect these markers in a canine model, these models are unfit for human patients, but there exists potential to translate these tools to a clinical setting. The aim of this paper is to explore possible routes - pH, glucose, and conductivity - to diagnose ACS in humans. Afterwards, we will describe the fabrication of the augmented glucose detection technology, experimental testing, and our observed findings. We aim to create a glucose probe that is biocompatible, accurate (40 - 160 mg/dL glucose concentration range), invasive (2 - 8 centimeters into tissue), and able to continuously (1 sample/ 10 minutes) measure a biochemical marker associated with ACS. In creating a comprehensive diagnostic technology, we hope to eschew trauma patients from undergoing harmful and unnecessary surgery.

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Introduction

A. Motivation

Diagnosing acute compartment syndrome (ACS) traditionally utilizes subjective clinical examinations of trauma patients [1]. In recent years, an effort has been made to replace such qualitative measures with a method that's both accurate and reproducible. Intercompartmental pressure readings have shown some promise; however, quantifications may vary within the patients' compartments and a pressure threshold that defines ACS is not well defined [2,3]. Most alarmingly, these readings may falsely diagnose patients 35% of the times, thus a number of patients will undergo a fasciotomy to treat their perceived ailment [4]. It is clear that a more accurate and definitive diagnosis for ACS must be explored to prevent unnecessary and intensely invasive surgeries.

A. Current Methods

Currently, clinical examinations in combination with a pressure reading taken from the compartment are the standard for diagnosing patient with compartment syndrome. This method is flawed as it has an unclear threshold and is ultimately a subjective assessment performed by the medical professional. Experimental methods are also being tested in the areas of near infrared oximetry, pH, glucose, and partial oxygen pressure measurement, some with more success than others [5]. A promising alternative route for ACS diagnosis is the interstitial pH quantification [5]. The Orian™ 8133BNWP ROSS™ Combination Spear Tip pH Electrode, a Fisher Scientific product, has been utilized to diagnose adult beagles with intentionally onset compartment syndrome. The probe's tip is 3 mm wide, 40 mm long, and detects pH 0 - 14 ∓ 0.01, and is therefore not directly applicable in the human medicine setting. Furthermore, Dr. Doro has shown that continuous glucose monitoring may unveil compartment syndrome in adult beagles [6]. A REAL-Time Guardian Continuous Glucose Monitoring System, Medtronic, (U.S. Patent No. 6,809,653) in conjunction with an Enlite™ Sensor, Medtronic, showed a significant difference in glucose levels between control and injured compartments. The sensor was 10 mm in length and must be calibrated for 90 minutes prior to use.

B. Problem Statement

Acute Compartment Syndrome (ACS) impacts many trauma patients and presents medical providers with perplexing dilemmas regarding the diagnosis and treatment of this condition. ACS diagnosis is most frequently based on clinical examinations and traditional measurements of intracompartmental (IC) pressure, but these techniques prove unreliable, and therefore, commonly lead to misdiagnosis and unnecessarily invasive procedures. While alternative biochemical markers, such as glucose and pH, have been linked to ACS in a canine model, the diagnostic technology has not been readily translated to the clinical setting. The goal of this project is to create a tool that accurately, continuously, and easily quantifies a chosen biochemical marker indicative of ACS in human subjects. An accurate detection of these markers may expedite ACS diagnosis and prevent patients from undergoing unnecessary treatment.

Background

A. Preliminary Research

A compartment is a section within the body that includes a group of muscles and their nerves surrounded by a layer of inelastic fascia. These compartments are found all over the body, and there are multiple in each extremity. Capillary beds across the compartment create a perfusion gradient, allowing blood to flow from high pressure to low pressure. This blood flow provides the muscles in the compartment with the nutrients they need to remain functioning. ACS is created when a serious injury, commonly a bone fracture or deep bruising, causes the inside of the nearby muscle compartment to swell. Since the fascia is unable to stretch, the pressure inside of the compartment rises, which eliminates the perfusion gradient. Blood is no longer able to flow into the muscle because the pressure inside the compartment is no longer lower than the arterial pressure. This syndrome leads to cell anoxia, muscle ischemia, and eventually muscle death if not treated. A fasciotomy is performed to decompress the compartment, and if this is not performed in time, the patient will have permanent damage from Volkmann's Muscle Ischemia, which is death of the muscles within the compartment [12].

B. Design Research

Our client, Dr. Doro, has done previous studies showing pH and glucose are effective biochemical markers that will accurately diagnose ACS. In Dr. Doro's studies, a crude meat and cheese probe measured the intercompartmental pH in anesthetized beagles with compartment syndrome. This method measured the change of pH in a dying compartment. In his research, he found that the pH in an injured muscle can drop well below 7.1, a pH that would be fatal to a human [5]. In a separate experiment, he used a Medtronic Enlite™ Sensor to measure the glucose of the canines. He concluded that the glucose level in the compartment essentially goes to zero [6]. Therefore, he highly encouraged that we try to build our probe measuring one of these biochemical markers. However, beyond Dr. Doro's initial research, he later informed us that potassium ions are a strong indicator of an increase in conductivity in the compartment. This is because in all dying muscle cells, potassium ions are released from the cells in mass quantities, which causes a major increase in conductivity. Therefore, potassium ions are also a strong biomarker to diagnose compartment syndrome.

The bulk of our background research that we used to formulate our preliminary designs came from studying current devices that measure pH and glucose. There are no devices designed for the purpose we would be using them for, so they all would require some degree of modification. As stated earlier, the Orian™ 8133BNWP ROSS™ Combination Spear Tip pH Electrode is a Fisher Scientific product commonly used to measure the pH in meat and cheese. In order for this technology to fit our requirements, we would have to create a prototype that was thinner and deeper. The continuous glucose sensor we have researched is one made by Medtronic used to monitor the blood glucose levels of diabetics. This sensor, the Medtronic Enlite™ Sensor, works by creating a redox reaction in the surrounding fluid of the wire that is inserted into the body. This redox reaction allows for an electrical signal to be transmitted to the sensor outside of the body, giving a glucose reading [8]. This device, however, is not long enough to satisfy our requirements, and it requires calibration. From this research, we concluded

that in order for this technology to be compatible with our problem statement and design specifications, we would have to create a probe that uses this technology but is longer, more rigid, and does not require calibration.

C. Client Information

Our client, Dr. Christopher Doro, is an Orthopedic Surgeon at the UW Hospital. He has conducted his own research on compartment syndrome, mainly including the experimentation on dogs to test the effectiveness of biochemical markers, pH and glucose, as standards to diagnose compartment syndrome. He has concluded that these biochemical markers work well and has asked us to create a probe that effectively measures them in humans.

D. Design Specifications

The most important requirement for our design is that our probe is able to improve the current false positive rate of 35% for compartment syndrome by monitoring a chosen biomarker continuously and directly with readings being taken at least once every 10 minutes. Additionally, the probe must be long and rigid enough to reach the muscle tissue (~1-5 cm) within a compartment. The probe should also not create more discomfort for the patient nor a greater risk of infection, therefore the probe should be no larger than a 16 gauge needle. Medical staff must be able to use this device quickly, easily, and safely while in the chaotic environment of an emergency room. Finally, the device should ideally consist of two different parts; a disposable part that is cheap and readily available, and a reusable analyzation component that is reasonably affordable. The total budget for this project is $10,000. Additional and more specific design requirements can be found under the Product Design Specifications in Appendix A.

Preliminary Designs

The following designs will be used to puncture the muscle compartment. These designs will be applicable to any given compartment. Depending on the compartment in question, the probe, electrode, or wire will penetrate directly into the muscle compartment where the black lines in Fig. 1 are drawn.

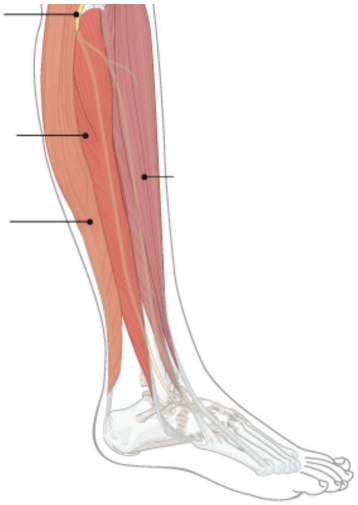

Figure 1: Surgical reference of where the prototypes will be inserted into the patient. [7]

A. pH Probe:

Our pH probe design was based on our client's previous research with measuring pH in the muscle compartments of beagles. Since even a slight drop in pH is associated with a dying compartment, pH can be used to effectively diagnose ACS in a trauma patient. The rudimentary probe used in our client's research was extremely large, 3 times the width of the ideal needle referenced in the design specifications. A pH probe works by securing two silver alloy electrodes into the glass bulb (tip) of the probe, one to directly measure the hydrogen ion concentration of the compartment and the other for reference of a hydrogen ion concentration equal to a neutral pH of 7. The hydrogen ions in compartment will perfuse through the glass bulb due to a concentration gradient across the working electrode, thus generating current between the working and reference electrode. A processor takes into account the generated current and may relate this to pH after calibration.

For our design, since there are two electrodes in the glass bulb, the probe will remain at an unchangeable 3mm. The probe length will be extended to 8 cm to reach into any compartment in the patient. The probe will rely on a stylet entry system for insertion into the body. This stylet will be non conductive and rigid to ensure there is no contamination before entering the compartment and help with the insertion of the probe. A rigid needle and a surrounding case, comprising the stylet system, will puncture the body into the muscle compartment. The inner needle will be removed, making a gap in the hollow case. The probe will be inserted into the imbedded portion. By using this technique (Fig. 2), although the probe is still an unpleasant 3mm wide, the fragile probe will be at a lower risk of breaking apart.

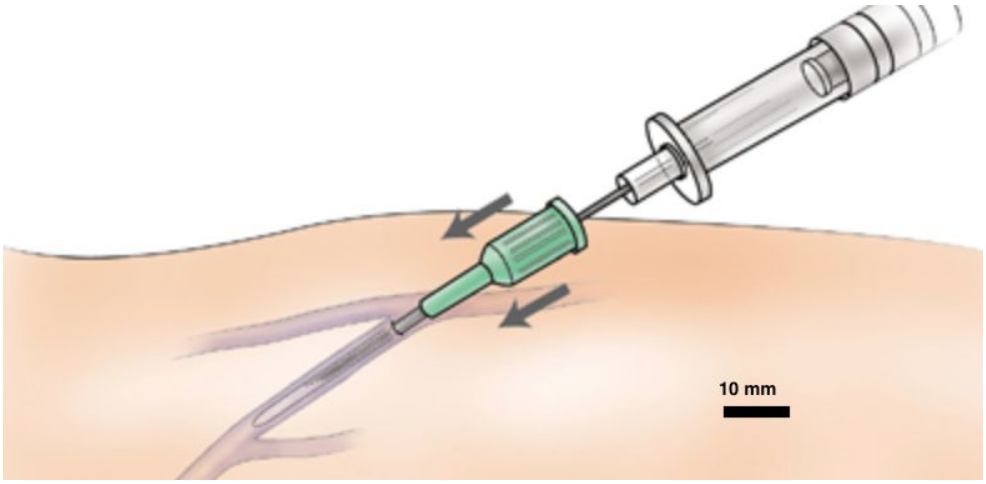

Figure 2: This figure represents a stylet entry system that would be utilized with the pH probe. The green portion is the case, and the device above would be the rigid needle that would be removed to make room for the probe. Instead of being inserted into a vein, as pictured, the stylet would puncture the muscle compartment. [10]

Muscle can survive at a pH significantly lower than the systemic pH level, and an injured muscle drops to a pH around 6.27 [9]. A pH reading significantly below this would be indicative of compartment syndrome.

B. Conductivity Electrode:

Our second design is utilizing the conductivity in the compartment based on the increase of potassium ions. Because we know that there is a positive correlation between conductivity and potassium levels, this strategy can be used to diagnose ACS. Currently, conductivity probes calculate how well ions conduct electricity in a compartment based on their concentration.

The electrode consists of an anode (negative end) and a cathode (positive end) that interact together to measure that rate of flow of ions between them. The particular electrode that we are basing our design off of [11], consists of two electrodes that are 5mm apart and 1 mm below the housing unit of the electrode housing unit. The electron housing unit is 155mm long and has a diameter of 12mm. The housing unit is then connected to the analyzer via cable. It can measure conductivity from 10 microsiemens/cm to 1 siemon (concentration of ions per cm space). For our modified design, we are going to separate the anode and cathode so the diameter of insertion is smaller. We will insert them into the body using two 18 gauge (1.02 mm), pull away needles, so when the electrodes are inserted into the body, the needles can be removed from the body by pulling the tabs and having the needles rip down the side via a perforated line. The needles will be connected exactly 2.96mm apart, so the 5 mm electrode distance is maintained in the compartment, and and 9.5 mm from the tip of the electrode to ensure the connection point is above the skin. The electrodes will be left in the compartment for continuous monitoring and connected to an analyzer outside of the body.

C. Continuous Glucose Monitor

The continuous glucose monitoring design is based off of the technology currently in use for diabetic patients. This monitor is made up of three components: the wireless monitor, the transmitter and the sensor. A perforated 18 gauge needle (1.02mm in diameter) will house the thin flexible wire during insertion to the muscle compartment, similar to the conductivity electrode design. Once at the target location inside the muscle compartment, the tabs at the top of the needle will tear apart and be removed from the body, leaving only the coated transmitting wire in the body to maximize patient comfort. Two needles and two wires are required per patient. One needle will be positioned in the injured compartment, and another in the healthy compartment on the opposing limb.

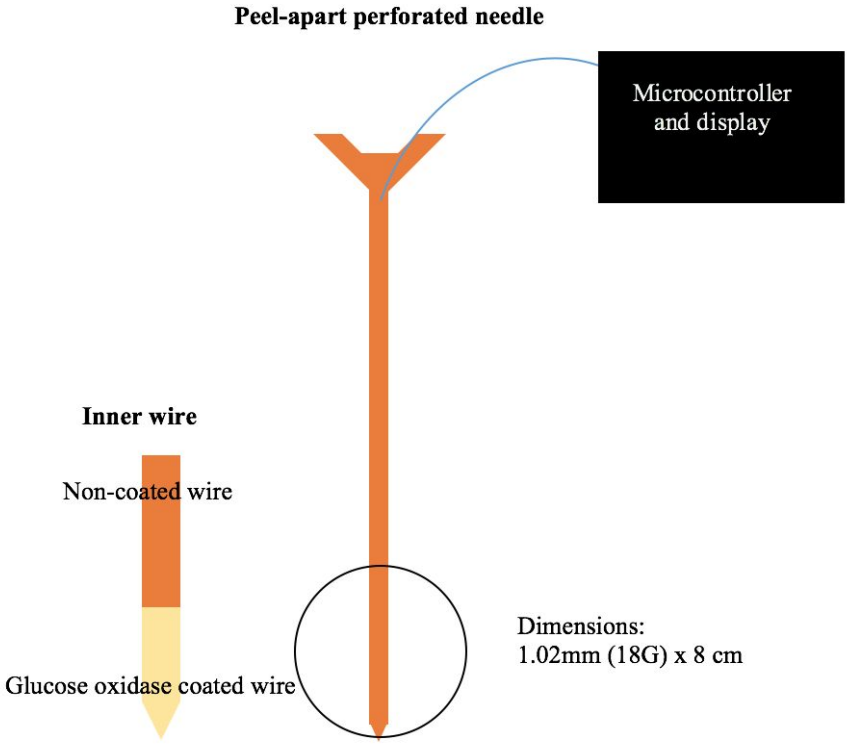

Figure 3: Schematic of components of continuous glucose monitor design. A working prototype requires two needles/wires.

The platinum-iridium (Pt/Ir) alloy wire will be coated with glucose oxidase in the innermost 2 centimeters of the wire. This will ensure that the following reaction will take place only in the muscle compartment. Glucose oxidase spurs a reaction with the surrounding tissue and fluid, converting glucose into hydroxide, which will react with the wire and generate an electrical signal to transmit to the sensor above the skin [8]. The readings from both compartments will be read and the difference between the healthy and unhealthy glucose levels will indicate compartment syndrome. Since a muscle undergoing muscle ischemia will not be receiving nutrients from the blood, glucose levels essentially drop to zero in a limb with compartment syndrome. We expect the two electrode system will negate a need for a threshold

value that could lead to problems with false positives and misdiagnosis. Also, since glucose is so variable depending on diabetes status of the patient, diet, time since meals, etc., the reference value will eliminate patient variability.

Preliminary Design Evaluation

A. Design Matrix Criteria

Seven categories were created to rank the potential compartment syndrome detector designs. Each category was given a certain weight to signify its importance in determining the final preliminary design. These categories were then inputted into a design matrix (*Table 1*) and evaluated to determine the best design.

Accuracy and Precision: (25/100)

This ranking carries the most weight considering the current limitations of compartment syndrome diagnosis include generating false-positives via oxygen pressure measurements. We are first and foremost concerned with whether or not our technology will work. Our new device must replace the current standard of diagnosis by quantifying a novel biochemical marker. Because various biomarkers may correlate differently with acute compartment syndrome, it's crucial we select a biomarker consistent across patient populations, easy to detect, and is homogenous within a compartment. The pH and potassium conductivity probes scored highest in this category. Both pH and potassium levels are very consistent throughout the population making systemic, reference values easily identifiable. For instance, pH ranges from 7.35 to 7.45 [9] and extracellular [K^+] ranges from 3.5 to 5 mM [11]. During muscle ischemia pH drops down as low as 6.29 [9] while [K^+] rises up to 16 mM [11]. These large changes in biomarker levels combined with low margins of error on their respective probes give both these probes the maximum score in this category.

Ease of Analysis: (20/100)

Refers to how easily this device is able to read and report data as well as ease of calibration and continuous use. The nurse or doctor should ideally be able to continuously monitor the chosen biomarker level without performing additional, time-consuming steps. The glucose probe received the highest score in this category because there are pre-existing glucose monitors that are capable of providing continuous, digital read-outs of glucose levels within the body. They are also already capable of tracking glucose over time, and displaying the results both graphically and numerically. There are also many options to calibrate a glucose probe such as using a finger-prick test or having it factory calibrated.

Safety: (20/100)

Refers to the current standard of care and how comfortable the patient will be during the use of the probe, as well as the safety of the nurse. In current method for determining if a patient has compartment syndrome the nurse uses an eighteen gauge needle. It is required our new probe is up to or exceeding the current standards. The new probe should also be comfortable for the patient to have inserted into their compartment. Lastly, the nurse needs to be able to safely insert the probe into the patient without causing harm to their own body. The glucose probe received the highest score because of the ability to use a small needle, however there were concerns with using two needles and possible entanglement. The conductivity technology was given a slightly score because it also requires two entry points like the glucose probe, but both entry points would need to be significantly larger than glucose (18 gauge needle vs 22 gauge needle). The pH probe was immediately counted out at this stage in the matrix. Since safety is a category with high importance, the 16G max requirement was a strict guideline that we were not comfortable overlooking. The 3mm probe would have been too large to insert into the patient and would lead to an unnecessary amount of pain and increased risk of infection which would compromise the safety of the patient.

Ergonomics: (15/100)

Refers to the ease and efficiency of use of the device. The doctor should be able to make this reading quickly and insert the needle with one hand so that the patient can be secured with the other. The device should be small and be able to be operated by one trained professional in the ER. The glucose probe and the conductivity electrodes received the same score, they both require two needle insertions but they are relatively small needles and the operator should already have experience.

Ease of Fabrication: (10/100)

Refers to how easily our design team will be able to fabricate the sensor. The sensor will likely be composed of a probe that will be inserted into the patient and an analyzer that will read the measurements from the probe. Our team must be able to either buy or fabricate these two components using our current skill set. We will have access to the student shop. The potassium conductivity sensor received the highest score because we would be able to purchase all materials necessary for the sensor making fabrication as simple as connecting the parts together. The glucose probe would require us manufacturing the electrode portion, since there are no currently existing electrodes that are long enough.

Reusability: (5/100)

Refers to the device having a main analyzation system that is able to be used repeatedly while the sterile sensing probes are disposable. The glucose probe was awarded the highest value

in the reusability category because the computing boxes can be reused, and the needles will be relatively cheap and disposable.

Cost: (5/100)

Refers to the ability of the device to be tested and fabricated under the restrictions of a reasonable budget. The disposable piece should be very cheap to buy, and the reusable part of the design should be of reasonable price. The glucose probe received the highest score since continuous glucose probes can be found for under $100. The disposable needles to be used with such a probe would also be quite cheap.

Criteria (Weight)	**pH Probe**		**Glucose Probe**		**Potassium Conductivity Technology**	
Accuracy and Precision (25)	5	25	4	20	5	25
Ease of Analysis (20)	4	16	5	20	2	8
Safety (20)	0	0	4	16	3	12
Ergonomics (15)	3	9	4	12	4	12
Ease of Fabrication (10)	4	8	4	8	3	6
Reusability (5)	4	4	4	4	4	4
Cost (5)	3	3	4	4	3	3
Total	65/100		84/100		70/100	

Table 1: Design matrix comparing potential devices including pH probe, glucose probe, and sodium conductivity technology. The total numbers are out of 100, and the highest number represents the most feasible option with regards to the criteria.

A. Proposed Final Design

After evaluating the final design matrix, we concluded that the relative measurements from the glucose probe would be the best option. It excelled in almost all of the categories and will offer the operator freedom with individual patient reading and continuous monitoring. It

involves an easy application of two 18G needles, and similar technologies already exist in medicine. Calibration should be negligible because the difference in the readings should offer all of the needed information to diagnose compartment syndrome. A downfall of this device could include if a patient came in with bilateral injuries where a reference measurement is not possible.

Fabrication

A. Materials
    a. FreeStyle Libre™ Continuous Glucose Monitor: Utilize for analysis of electrode readings and for displaying data.
    b. Arduino Uno: To take the two readings from the body and convert that into a relative difference to be read in by the analyzer.
    c. Platinum/Iridium Electrode (x2): To measure current from glucose redox reaction
    d. Glucose Oxidase: Catalyzes glucose redox reaction
    e. Osmium Mediator: Increases kinetic favorability of redox reaction
    f. Cellulose Acetate (Selectively permeable membrane): Makes sure that only glucose is reacting with glucose oxidase
    g. Electrode Connective Wires: Connect electrodes to Arduino Uno
    h. 22 Gauge pull-away introducer: To get electrode into the compartment
B. Methods

To build our continuous glucose monitor we will start with a base building block of a FreeStyle Libre™ Continuous Glucose Monitor. This glucose monitor already has a functioning display and electrode current analyzer that we can modify. We will connect this to the Arduino Uno, which will take the raw current from the electrodes and convert it, so that it is compatible with the glucose monitor. Connected to the Arduino Uno via connective wires will be the Platinum/Iridium Electrodes. The conductive portions of these electrodes will be coated with glucose oxidase and an osmium mediator. Then the electrode will be covered with a selectively permeable membrane. Finally this whole electrode setup can be inserted into the intracompartmental space using a 22 gauge pull-away introducer.

C. Final Prototype
N/A

D. Testing

One of the tests we will run is on chicken meat with a wetsuit exterior to imitate the structure, consistency, and low glucose levels of a compartment. This test will help us know if our device is rigid enough to enter the compartment and accurate enough to measure the glucose concentration.

1. Obtain continuous glucose monitor used for diabetic patients
2. Buy 2 chicken breasts and 2 thighs (to imitate a muscle compartment), and obtain neoprene (to act as the fascia for the compartment)
3. Soak 1 of the chickens in a solution of a low concentration of glucose, and one into a “normal” concentration solution, as the reference point, for 4 hours each.

4. Secure the neoprene to the meat.
5. Insert one side of the probe into the reference piece of meat and the other into the "ACS" meat.
6. Secure the probes and turn on probes
7. Make sure there is an accurate reading of glucose level in the low glucose chicken.

Future Work

Upon meeting with our client, we have since discovered that this idea of using comparable compartment measurements is flawed. Bilateral injury is more common than originally thought, making this proposed idea invalid among a portion of the patients, and our client specifically wants a piece of technology that is reliable and universal in all compartment syndrome cases. Furthermore, continuous glucose monitors (CGM) requires a baseline to calibrate the sensor, usually done with paper test strips and manual readings among diabetic patients. We have been informed that the reading from the manual method used within the CGM adjusts the glucose range within the microcontroller. If we were to calibrate it to systemic level, this would equate the starting muscle glucose level to the systemic level which isn't necessarily accurate, especially if the patient already has compartment syndrome at the time of the first reading. It would lead to a skewed range. A differential between the two limbs, assuming one was healthy, would not be useful either, as glucose readings may vary depending on immediate surroundings. Whether bone or fascia or excess interstitial fluid is near the probe, the readings can be vastly different. Also, calibrating with interstitial fluid from the muscle compartment is promising, it poses new challenges since samples are very difficult to draw from the vacuum environment in a compartment.

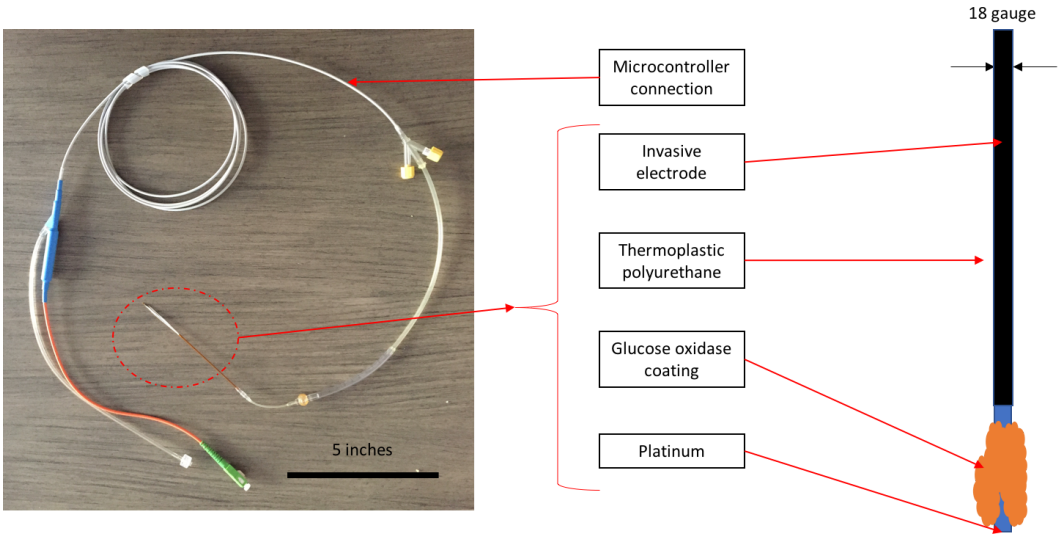

Figure 5: This shows the ultrafiltrate probe and a breakdown of its components.

We have begun to look into the idea of an ultrafiltrate probe, (Fig. 5). This incorporates a way to draw fluid from the muscle. We could incorporate this into our design to draw interstitial fluid from the muscle to test with the manual paper strips for an initial calibration of the CGM. This would allow the continuous glucose monitor to give a definitive value for glucose level and negate the need for a reference electrode in the bilateral compartment. The device would be calibrated to the correct level and the diagnosis wouldn't have to be reliant on a glucose difference. Drawing the fluid would also solve the problem of diagnosing pre-existing compartment syndrome, if a patient were to come in with the condition, instead of developing it while in the hospital.

Our next areas of focus are on ordering and fabricating a prototype. Once developed, testing can begin, to review the accuracy of the sensor and assess the technology's promise with diagnosing compartment syndrome to eliminate false positives.

Results

N/A

Discussion

N/A

Conclusions

N/A

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Appendix

A. Product Design Specifications

Function:

Acute compartment syndrome (ACS) impacts many trauma patients and presents medical providers with perplexing dilemmas regarding the diagnosis and treatment of this condition. ACS diagnosis is most frequently based on clinical examination findings, but, traditional measurements of intracompartmental (IC) pressure are unreliable and therefore commonly lead to misdiagnosis and unnecessarily invasive procedures. The goal of this project is to create a diagnostic tool that accurately, continuously, and easily quantifies biochemical marker associated with ACS. These markers – pH, glucose, or pyruvate – may expedite ACS diagnosis and prevent patients from misdiagnosis or the trauma of compartment syndrome.

Client Requirements:

- Design a probe to that can continuously measure and quantify specific biomarkers associated with acute compartment syndrome.
- The probe must be long enough to invade various muscular depths (1 cm - 5 cm)
- Probe must be cheap and autoclavable before use
- The probe should be continuously analyzed by a main analyzer
- The probe must be ergonomic for clinicians to operate

Physical and Operational Characteristics:

a. Performance Requirements:

- The probe must be able to measure a chosen biomarker that directly relates to the presence of compartment syndrome in a patient
- The probe must be able to continuously monitor the biomarker
- The probe must be precise, so that there is a lower incidence of false positives (<34%) than the currently used pressure gauge detector.

b. Safety:

- In order for the probe to be up to the current standard of care for detecting compartment syndrome, the probe, if being inserted to the patient, must be smaller than an eighteen gauge needle.
- Cannot cause an increase in discomfort for the patient.
- Cannot increase the risk of infection in the already wounded limb of the patient.

c. Accuracy and Reliability:

- *The detector must accurately measure the specified biomarker/signal to avoid falsely diagnosing the patient.*

d. Life in Service:

- The disposable probe should be used once per patient. This means from the time the patient enters the hospital until the patient is discharged.
- The main analyzer should be able to be reused for many patients, lasting six months.

e. Shelf Life:

- The main analyzer should have a shelf life of approximately 3 years
- The disposable probe should have a shelf life of 1 year.

f. Operating Environment:

- The probe should be continually monitoring the compartment in all situations.
    - The ER immediately following the patient's arrival into the hospital.
    - The second is the patient' hospital room.
    - Another possibility is into an operating room for possible surgery.

g. Ergonomics:

- Physicians must easily probe the patient with one hand while securing their limb with the other. Will be similar to administering a shot.

h. Size:

- The probe to detect compartment syndrome has to be small enough so a nurse can bring it into the ER and collect a reading efficiently within a crowded area surrounding a patient.
- Also, our client does not want it to "scare" the patient as the probe is getting data.
- There are no specific specifications for the size.

i. Power Source:

- The main analyzer will utilize standard wall outlets as a power source.

j. Weight:

- The probe will be roughly 5 ounces. The main analyzer will be roughly 1 pound, subject to change.

k. Materials:

- Invasive probe, spectrometer/pH meter, glucose monitor, plastic box to house analyzer equipment

l. Aesthetics, Appearance, and Finish:

- The overall finish of the probe should not include any abrasive edges or jagged surfaces, which could injure the patient or doctor.
- The probe color will likely consist of neutral colors such as white, black, or grey.

Product Characteristics:

a. Quantity:

- One main analyzer compartment and many (20) reproducible probes to test on various subjects.

b. Target Product Cost:

- We have not been given a strict budget, the technology will be paid for through grants from the client.

Miscellaneous:

Standards and Specification:

- The probe will be no bigger than an 18 gauge needle and able to penetrate roughly 5 cm into muscular tissue.
- The main analyzer should withstand small drops and falls

Patient-Related Concerns:

- The patient does not want a large needle or series of tubes coming from their injured limb.
- The probe itself should also not be large or complex enough to frighten the injured patient.
- The patient is not under anesthesia so the insertion of the probe should not be lengthy.

Competition:

- Currently the only way to detect compartment syndrome is by pressure. This is very inaccurate and has led to a lot of false fasciotomies.
- There is also a new market using infrared detection to detect oxygen levels. This is also quite inaccurate.

Customer:

- Dr. Doro is an orthopedic surgeon at the UW Health Orthopedics and Rehabilitation center in Madison, Wisconsin. His research primarily focuses on diagnosing trauma patients with acute compartment syndrome.