Product Design Specification (PDS)

Use of pH or glucose probes to diagnose compartment syndrome

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Date: 02/07/2018

Function:
The goal of this project is to develop a device to more accurately quantify and detect acute compartment syndrome (ACS). This medical complication often impacts trauma patients and is extremely hard to detect, with a current false positive diagnosis rate of 35% []. The decision whether or not to treat a patient for ACS is highly dependent on clinical diagnosis which becomes an issue in cases where the patient is unresponsive or in extreme pain. The current means to quantify ACS involves measuring the intracompartmental (IC) pressure and comparing it to the current accepted value of delta 30. There are a few logistical reasons why this method is not ideal, the most prominent being the fact that different muscles can maintain extremely different deltas prior to damage. Location and prior strenuous experiences on the muscle are just two potential reasons for these delta variations.

As a result of these diagnostic conflicts, a means to definitively quantify ACS is desired. A key factor in ACS is the decrease of oxygen to the compartment which leads to the ceasing of cellular respiration. As a result, many biochemical markers typically seen in an *in vivo* environment are reduced. Two key markers, glucose and pH, have both been seen to decrease in induced ACS in dog trials []. These, along with other metabolic biochemical markers, are suspected to be effective measurable variables.

The focus of this project is the development of a device that accurately quantifies ACS via a metabolic biomarker while taking into account patient safety.

Client requirements:
- Probe must accurately detect positive ACS
- Must enter the body in an 16 gauge needle or smaller

- Probe must be a length between 4-6 cm

Design requirements:

1. Physical and Operational Characteristics
    a. *Performance Requirements:* The probe of the measuring device should be able to accurately (within 5%) and consistently measure a specific metabolite inside a muscle compartment in vivo. The output of the device should display the measurement of that metabolite that is easily readable by the user. The time needed to calibrate the device should be less than 5 minutes. The device will be used whenever ACS is suspected to be present in a patient.
    b. *Safety:* The probe that measures the metabolite would be a hollow needle. The needle needs to comply with FDA standards. The circuit should be insulated well to prevent electrical shock to both the patient and user.
    c. *Accuracy and Reliability:* This device need to be specific enough to determine the concentration of the biomarker within a hundreth. For particular biomarkers, a change by even a tenth can be damaging to the body. As such, this device would need to accurately measure a biomarker, and be extremely reliable so a patient does not get misdiagnosed.
    d. *Life in Service:* The primary portion of the device is likely going to be one-time use. As it is a needle-based product it will not remain in the body for more than a minute and penetrate about 4-6 cm into the body. The circuitry and interface for the device will be developed for multiple uses, ideally it would function for multiple years. It should be mobile from one examination room to the next.
    e. *Shelf Life:* The circuitry for the device will should not have a shelf life. Any chemicals used in the device, if unopened, should have a shelf life of multiple years.
    f. *Operating Environment:* The device should be able to detect the accurate value in all situations. The device should normally be used in a hospital setting for the diagnosis of ACS.
    g. *Ergonomics:* The device should be easy and quick to use in a trauma setting. It must be able to be set up, used, and diagnose ACS in a timely manner in order for the medical specialist to begin treatment.
    h. *Size:* The device must be able to fit into a 16 gauge needle.
    i. *Weight:* Given the size requirement for the device, the probe must be very light in order to be able to fit through a 16 gauge needle, and the corresponding circuit must be able to held in the user's hand.
    j. *Materials:* Any materials that have the potential to elicit an adverse reaction in the body should not be used for this project.

k. *Aesthetics, Appearance, and Finish:* The device must have a smooth finish in order to prevent excessive tissue damage, promote ease of use, and reduce patient discomfort.

2. Production Characteristics
    a. *Quantity:* There is no specific production requirements at this point. A long-term requirement would be the ability to mass produce the exposable portions of the device. At this moment, a functional prototype is what is necessary for the client, so quantity of the product is not a concern.
    b. *Target Product Cost:* In order to get a working prototype, the target product cost in not a concern at the moment. Later, cost of production will need to be investigated and from there the assessment of the product cost can be made.

3. Miscellaneous
    a. *Standards and Specifications:* As a device that would be used in a clinical setting, IRB approval would be needed if testing ever needed to be done on humans. In addition, FDA approval would be necessary if this product were ever to be used commercially.

    b. *Customer:* The client would like for the device to be as precise as possible, with a small enough probe that can fit through a sixteen gauge needle. In settings where this device may need to be used, the patient will often be unresponsive to any questions and this probe will need to be small enough as not to cause any alarm and small enough where surgery is not required to perform this test.

    c. *Patient-Related Concerns:* The most important concern to address is accuracy. With the current false positive rate of 35% this device should be able to more accurately diagnose compartment syndrome, in order to avoid any needless fasciotomies, a procedure that ultimately would cause unnecessary needs for a patient should they be falsely diagnosed with compartment syndrome.

    d. *Competition:* There are currently no existing probes that are capable of diagnosing compartment syndrome in a human. However, there are many other probes that can detect pH and glucose that can be adapted for this need.