pH Probe for Diagnosing Acute Compartment Syndrome: Product Design Specifications

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Function:

Acute compartment syndrome (ACS), a dangerous condition in which the increased intracompartmental pressure (ICP) of a muscle prevents blood flow to the region, 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 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 receiving a false diagnosis and undergoing the trauma of a fasciotomy, the standard treatment for 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 in - 5 in)
- Probe must be cheap and preferably autoclavable before use (<$100 final prototype)
- The probe should be continuously analyzed by a main analyzer (8 hours of readings)
- The probe must be ergonomic for clinicians to operate (setup time 5 minutes)

Physical and Operational Characteristics:

a. Performance Requirements:

- The probe must be able to measure pH that directly relates to the presence of compartment syndrome in a patient (pH 6-7)
- The probe must be able to continuously monitor the biomarker (1 sample/15 minutes, 8 hours in total)
- The probe must be precise, so that there is a lower incidence of false positives (<34% of diagnoses) than the currently used pressure gauge detector while still ensuring that no cases of ACS are missed.

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. (pH 6-7, high sensitivity +/ - .01 pH)

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.
- Must be able to reach at least 4-5 inches into the body
- Must fit within an 18-gauge needle.

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, pH meter, optical fibers, plastic box to house analyzer equipment, hydrogel, chlorophenol red indicator, indicator immobilization substrate

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. Final prototype should be $100.

Miscellaneous:

Standards and Specification:

- The probe will be invasive, and will therefore require FDA approval to be used in the United States.
- Before the device can be tested *in vivo* on animal models, the study will have to be approved by an internal review board (IRB).

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 may not be under anesthesia so the insertion of the probe should be as quick as possible.

Competition:

- Currently the only way to detect compartment syndrome is by pressure. There is little agreement in the literature and amongst surgeons on the proper pressure threshold for diagnosing ACS; therefore, this is very inaccurate and has led to a lot of unneeded fasciotomies.

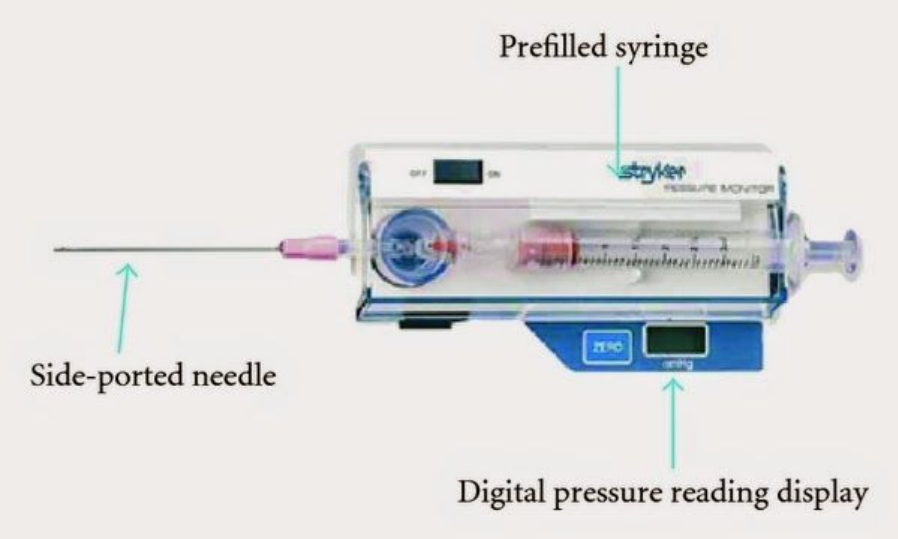

Figure 1: A Stryker Needle, a common instrument for monitoring pressure in a muscle compartment. The side-ported needle is inserted into the affected compartment, leading to a digital pressure reading that the clinician then compares to established threshold values for diagnosis.

- There is also research surrounding the use of near-infrared (NIR) spectroscopy to detect oxygen levels. While accurate in a lab setting, it has been difficult to adapt to a clinical setting.

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.