Compartment Syndrome Diagnostic Probe
Design Matrix

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Introduction

We present three potential methods to precisely diagnose Acute Compartment Syndrome by quantifying intramuscular pH. All three methods rely on an optical fiber light sensor pair with a pH-reactive indicator dye that changes color depending on surrounding protic conditions. By detecting the dye's proportion of light absorbed as it changes color, we may calculate the correlated pH. Because all methods employ a similar optical fiber measurement technique, this report will focus on various configurations of chambers equipped to house the indicator dye. These chambers will be evaluated on the following criteria: Invasiveness, reusability, accuracy and precision, biocompatibility, continuity, cost, and safety.

Hydrogel-Dye Microenvironment

This design utilizes optical fibers that will extend into the compartment in a highly confined space. At the end of the fiber will be a pH-reactive indicator dye that will change color due to surrounding proton concentration. The dye will be encased and immobilized within a hydrogel, and then encased within a rigid hydrogen-permeable membrane that will be exposed to the muscular compartment. By shining a monochromatic light within the compartment, the optical fibers will detect its attenuation due to the dye's specific absorbance. It should be noted there will be a reflective surface at the bottom of the hydrogel well, allowing the recollection of light. Overall, this design allows for the safe and invasive measurement of intramuscular pH.

Reflective pH-reactive tape

Using a congruent theory of optical fiber measurement, this configuration will also measure the attenuation of a light source as it is exposed to a pH-reactive indicator dye. However, instead of a hydrogel-dye microenvironment, the indicator dye will be immobilized on a reflective and adhesive surface that may fasten to the end of our probe. By layering a reflective surface, indicator dye, and adhesive, the small tape-like structure will provide a reusable detector "dot".

Microdialysis chamber

This design will also measure the attenuation of light to detect an indicator dye's color and calculate the corresponding pH. However, rather than building an invasive probe, we plan to use a microdialysis pump to extract intramuscular fluid from the compartment. This may alleviate patient discomfort by inserting a smaller probe than an invasive optical fiber configuration would allow. The fluid would then be stored in a small chamber that would be exposed to our monochromatic light.

Criteria (Weight)	**Hydrogel Microenvironment**		**Reflective pH Tape**		**Microdialysis chamber**	
Accuracy and precision (35)	5	35	4	28	3	21
Biocompatibility (25)	4	20	4	20	5	25
Invasiveness (15)	3	9	3	9	3	9
Ease of Reuse(10)	2	6	4	8	4	8
Measurement Continuity (10)	5	10	5	10	3	6
Cost (5)	3	3	4	4	3	3
Total	83/100		79/100		72/100	

Table 1: Design matrix comparing potential methods of measuring pH including using a hydrogel microenvironment, reflective pH tape, and a microdialysis chamber. The total numbers are out of 100, and the highest number represents the most feasible option with regards to the criteria.

Accuracy and Precision

This ranking carries the most weight because of the current limitations of compartment syndrome diagnosis, which has a 35% false positive rate. Our new device must replace this current standard of diagnosis while still being 100% sensitive to true positives. The Hydrogel Microenvironment scored highest because the hydrogen-permeable barrier would expose the indicator to the pH within the compartment without influencing acidity.

Biocompatibility

Biocompatibility refers to the inertness of the probe inside the body. It is ranked second-highest because the probe should not damage the surrounding tissues beyond the initial insertion. The Microdialysis Chamber scored the highest because the indicator would be outside the body, and it would involve simply removing fluid using an FDA-approved hypodermic needle.

Invasiveness

Invasiveness refers to the degree of interaction between the probe and the inner body. Ideally, invasiveness would be minimized to decrease the amount of damage done to the patient’s tissues. The nature of acute compartment syndrome and its diagnosis require an invasive procedure, so the device with the least invasiveness would score highest. All three probes, however, scored 9/15. Both the Hydrogel Microenvironment and the Reflective pH Tape would involve the insertion of an 18-gauge needle and an indicator container, a substance foreign to the body. The Microdialysis Chamber would not involve the insertion of an indicator, however, this method would require that fluid be removed from the body, which if done over a prolonged period could also injure the patient.

Ease of Reuse

Ease of Reuse refers to how easy it is to get the device ready for reuse. This category encompasses either the ease of sterilization for designs that don't have replaceable parts or the ease of replacement for designs that have replaceable parts. The Reflective pH Tape and Microdialysis Chamber tied for the highest score in this category. The Reflective pH Tape would simply need to be disposed of and then another pre-made piece of tape adhered to the end of the probe. For the Microdialysis Chamber the entire analysis chamber could be reused, and only new dialysate solution and new needles would be needed for reuse.

Measurement Continuity

Measurement continuity refers to how continuously we can receive pH measurements. The Hydrogel Microenvironment and Reflective pH Tape designs both received full marks in this category since they can be altered by the controlling circuit to be as continuous as we need.

Cost

Cost refers to our ability to test and fabricate the probe within a reasonable budget. The disposable piece should be less than $100 to purchase, and the reusable part of the design should be less than $2000. This project is funded by a grant through the surgery department at UW-Health, therefore the budget is large, but does not have an official ceiling. The Reflective pH Tape scored highest because its parts (optical fibers, reflective tape, etc.) would be the cheapest to purchase and assemble.

Final Evaluation

Based on our design matrix, the Hydrogel Microenvironment design will be the design that we move forward with for the remainder of the project. The Hydrogel Microenvironment design really stands out for having superior accuracy and precision over the other designs. Additionally, it scored very well in biocompatibility and measurement continuity. The biggest knock on this design is its reusability, as continuously replacing a dye-filled hydrogel could be cumbersome. Despite this, the Hydrogel Microenvironment design accomplishes all the criteria outlined by our client, thus it should serve as an excellent blueprint.