301-34-Tong-Compartment Syndrome-Executive Summary

Acute Compartment Syndrome Quantification Device

Background:

Acute compartment syndrome (ACS) is characterized by an increase in pressure and resulting decrease in blood flow in a muscle compartment arising from local trauma. The reduction of blood flow into the muscle cavity leads to a depletion in oxygen delivered by hemoglobin, resulting in ischemia and irreversible muscle tissue damage. Direct pressure measurement of the muscle compartment has shown to result in a 35% false positive rate. A device that measures a metabolic factor, such as pH, of a muscle compartment *in vivo* would improve the accuracy of clinical diagnosis.

One metabolic factor that has been successful in ACS diagnosis is oxygen content. Oxygen content can be measured by a competing device, the OxyLite™ sensor, developed by Oxford Optronix. It is a fluorescence-based sensor that is able to measure dissolved oxygen *in vivo*. OxyLite™ uses a platinum-based fluorophore bonded to the sensor tip which allows for accurate readings within ± 0.7 mmHg. The platinum used in the sensor tip makes the price of sensors too expensive for clinical applications.

Acute Compartment Syndrome Probe Design:

The design proposed to better quantify ACS consists of an enveloping glass tube, three optical fibers, a 16 gauge needle, a spectroscope and a programmed system that displays pH of the muscle compartment *in vivo*. The primary portion of the device is a three optical fiber probe through which a laser of two varying wavelengths of light is transmitted through two of the optical fibers. The wavelengths are determined through a series of filters. At the end of the tip the beams of light reflect off of a glass surface with immobilized chlorophenol red dye. Chlorophenol red is sensitive to the pH range of 4.8-6.7, a range indicative of ACS. The immobilized dye will react with local hydrogen ions and the ratio of protonated and deprotonated dye molecules will change based on the acidity of the solution. The wavelength of the reflected light will vary depending on this ratio of the dye molecules and reflect back toward the processing unit via a recording optical fiber. The difference in signal output from the two different wavelengths of light will be compared to determine the relative acidity of the solution. By calibrating with a buffer solution before use, the probe will be able to quantify the specific pH of the solution in which it is submerged.

Specifications:

The design meets the operation requirements of the ACS quantification device due to its size and ease of calibration. The main requirement of this device is that it fit inside a 16 gauge needle. It would not be reasonable to have a larger affected area for the diagnostic medical setting. The diameter of the final design is 0.32mm, so it would easily fit into the 16 gauge needle which has an inner diameter of 1.194 mm. The second requirement of the client was that the device have a fast and easy calibration process. As the calibration of a classic pH probe is quick and established, medical professionals should not have difficulty adapting to this new device.

Commercialization and Marketability:

This device would have the potential to be commercialized globally in both medical and military settings. While compartment syndrome is not frequent in the civilian population, it is a common occupational hazard of the military, as gunshot and explosion wounds are leading conditions that result in ACS. Because there is not yet a non-invasive, inexpensive, and reliable way to diagnose compartment syndrome, this device would have the ability to be commercialized for use in clinical environments as well as in the military. If commercialized, this design would have the ability to reduce the current false diagnosis rate as well as the total time to diagnose. This would prevent unnecessary emergency fasciotomies and decrease wait time for patients before treatment, reducing the chances of long-term muscle damage or death. The overall goal of this device is to decrease the variability in ACS diagnosis and to improve the outlook for patients with this condition.