Retractor for Sensing Muscle Ischemia during Spinal Fusion Surgery

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Abstract

During spinal fusion surgery, sturdy metal retractors are used to separate the tissue for long periods of time. This subsequently results in hypoxia within surrounding muscle tissue, leading to cell death. The SensIschemia Retractor uses a force sensor and a thermistor to detect when the forces placed on the tissues and muscles are too high and/or the body's temperature has dropped too low, respectively. It signals when ischemia is nearing, at which point surgeons can release the retractor. The device itself is integrated into a retractor similar in design and dimensions to those currently used in spinal fusion surgeries, with the added quality that the retractor is hollow, thus providing a placement position for the wiring from the metabolic and force sensors, away from the surgical field. The SensIschemia Retractor is revolutionary, eliminating the harmful possibility of muscle tissue death and potential years of pain for the patient post-surgery. The SensIschemia Retractor is versatile and could be used in other surgeries in the future, forever replacing the current version.

Introduction

Need:

An intraoperative tool to monitor the onset of ischemia in muscles and other tissues during spinal fusion surgery

Background:

- Over 400,000 people in the United States alone undergo spinal fusion surgery each year
  - Surgery takes approximately 5 hours
- Retractor is used to splay tissue and muscles open, away from spinal column
  - Creates pressure gradient that exceeds normal capillary pressures, causing ischemia
  - Weitlaner retractor is commonly used

Figure 1: Weitlaner retractor commonly used in spinal fusion surgeries.

Problems with Current Surgical Retractors:

- In addition to causing ischemia of tissues and muscles, current designs have no quantitative way of determining when ischemia is occurring
  - Lack of sensors
  - Lack of real-time feedback

Needs & Specifications:

- Retractor must have force and temperature sensors
- Retractor must be easy to open and close
- Retractor must have ratcheting mechanism
- Retractor must display real-time results via LEDs

SensIschemia Retractor

Design & Function of Device:

- Modeled after existing Weitlaner retractor with ratcheting mechanism
  - Scaled up in size
- Solid blades for sensor placement at retractor-tissue interface
- Sensor wiring secured within hollow retractor arms and connected to Arduino
- Arduino and battery contained in display box for real-time feedback via LEDs

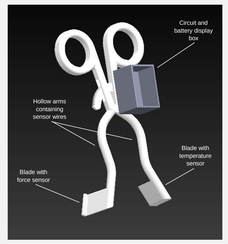

Figure 2: SolidWorks rendering of SensIschemia Retractor, illustrating Weitlaner-based design and key features.

Sensors:

- Force: FlexiForce A301
  - Load cell measures amount of force applied to tissue → force converted into electrical signal
  - Detects forces ranging from 0 to 25 pounds
- Temperature: 10K Precision Epoxy Thermistor
  - Measures resistance as a function of temperature (resistance decreases as temperature increases)
  - Temperature range of -67 to 257 degrees Fahrenheit

Figure 3: FlexiForce A301 sensor used in SensIschemia Retractor.

Figure 4: 10K Precision Epoxy Thermistor used in SensIschemia Retractor.

Electronics:

The temperature of the muscles in contact with the retractor and forces on these muscles are displayed in an easy-to-interpret LED display, where green indicates normal physiology and red indicates likely muscle death.

- 9-Volt battery powers the Arduino
- Force and temperature values are collected every 100 milliseconds.
- For research purposes, these values can also be displayed in a serial port monitor if the Arduino is attached to a computer, though for normal intra-operative use, this would not be necessary.

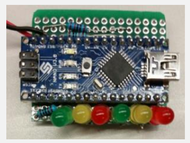

Figure 5: Circuit setup with LEDs for the force and temperature sensors shown.

Final Prototype:

- Printed using Acrylonitrile Butadiene Styrene (ABS)
  - Final product will be made with 316L stainless steel
- Force and temperature sensors
  - Final device will have both sensors on each blade
- Hollow arms allow wires to run internally

Figure 6: Final prototype, with wires running from the sensors to the box containing the Arduino and battery.

Testing

Retractor Opening and Closing:

- The retractor was measured to open to a maximum angle of 67 degrees. This equates to a 6.5 inch opening of the incision site. The retractor blades are separated 1.5 inches when fully closed.

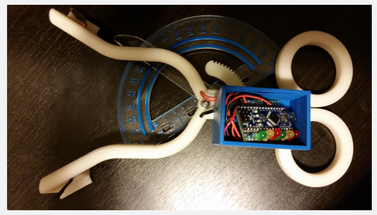

Figure 7: Measuring the angles formed by the retractor when opened and closed.

Force Sensor Calibration:

- Calibration of the force sensor was performed by placing a series of known weights on the sensor and recording the associated output voltages. A small dowel was used to focus the weight onto the sensor's small surface area. Included is the resulting calibration curve.

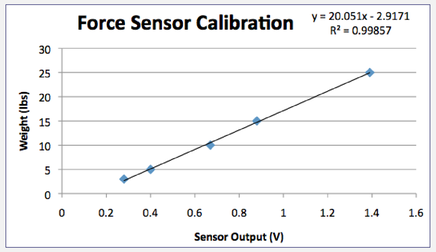

Figure 8: Calibration of the FlexiForce A301 sensor using a series of known weights.

Thermistor Calibration:

- Calibration of the thermistor was performed by placing the sensor in water of a known temperature and measuring the resulting output. Calibration focused on a physiologically relevant range of temperatures (75-115 degrees Fahrenheit).

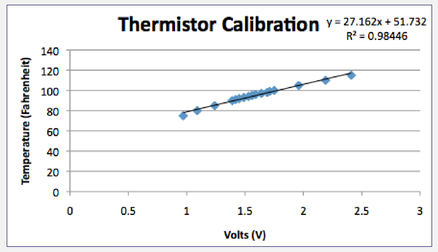

Figure 9: Calibration of the 10K Precision Epoxy Thermistor using known temperatures of water.

Conclusion

The SensIschemia Retractor expands and improves upon current technologies and tools that are used during spinal fusion surgery. Force and temperature sensors will allow surgeons to detect when ischemia levels are nearing, providing the opportunity for the surgeon to react in real time and prevent injury to the patient. It was shown through testing that the force sensor can accurately measure forces of up to 25 pounds, and the thermistor can accurately measure changes in temperature. Having all of this information displayed on the LED lights of the retractor display box allows the surgeon to monitor for ischemia without the inconvenience of extra wires or equipment.

This novel idea will change the face of spinal fusion surgery and improve the lives of patients that would otherwise suffer from muscle ischemia. The monitoring and detecting applications of this device could also be useful for other types of surgery, thus expanding its clinical impact beyond spinal surgery alone.

Next Steps

- Incorporate multiple sensors on each retractor blade in order to obtain measurements at various locations
  - Increase the accuracy of detecting ischemia onset
  - Finely-tune measurement levels associated with ischemia
- Integrate an oxygen sensor (NIRS oximeter) to measure tissue oxygen saturation
- Create the final device with 316L stainless steel in order to incorporate the ratcheting mechanism and improve the tool's overall strength
- Reduce the size and bulkiness of the circuit/display box
- Conduct further testing in preclinical and clinical models.

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