pH Probes for Compartment Syndrome

Jonah Mudge, Hunter Huth, Syafiqah Saidin, Lucas Ratajczyk
Advisor: Dr. Amit Nimunkar
Client: Dr. Christopher Doro

Project Overview

- Acute Compartment Syndrome (ACS) is a difficult-to-diagnose condition that can result in muscle ischemia and death if not properly addressed [1]
    - False-positive treatment (fasciotomy) is debilitating as well
- Our client, Dr. Doro, is an orthopedic surgeon from UW Health who has acquired funding to combat false positive diagnosis through instrumentation-driven diagnostics
- Solution: pH probe

- Must record 48 hrs of pH measurements
- Must be detachable/replaceable
- Must fit through 16 gauge needle

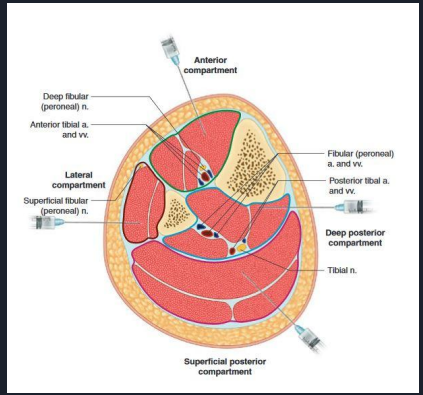


Figure 1: Cross section of leg compartments [2]

Global Impact

- Due to the low frequency of ACS cases (<8 per 100,000 people), no real diagnostic standard [3]
- Existing diagnostic methods inaccurate (35% false positive rate) and expensive ($1000s per unit) [4]
- False-positive diagnosis results in fasciotomy
  - Extremely invasive
  - Debilitating
  - Expensive
  - No point!

Figure 2: Beginning fasciotomy procedure [5]

Final Prototype

- 127 µm Pt-Ir wire coated in IrOx
- 127 µm Ag Wire coated in AgCl
- 2 Carbon Micro Tubes to prevent wires from contacting each other
- 16 gauge steel needle.

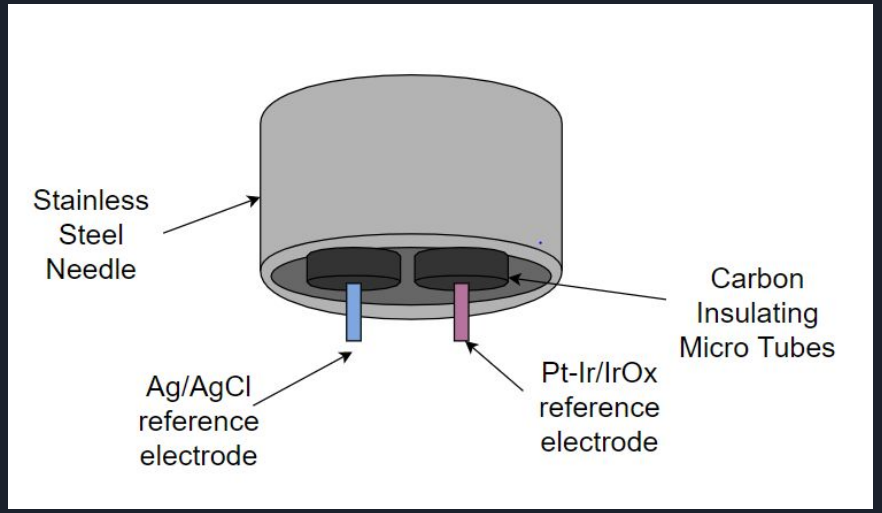


Figure 3: Final Prototype for needle based 2 electrode design

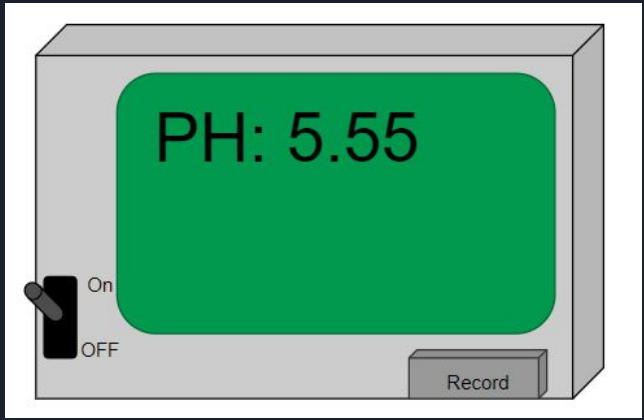


Figure 4: Final device appearance

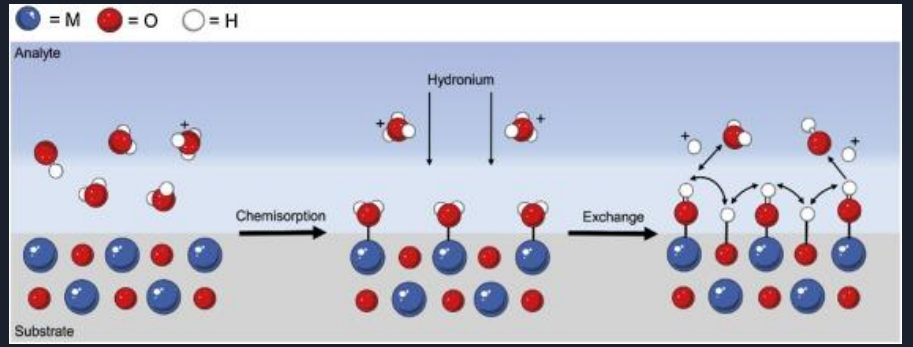


Figure 5: Reaction between Hydronium and IrOx Layer[6]

Testing Results

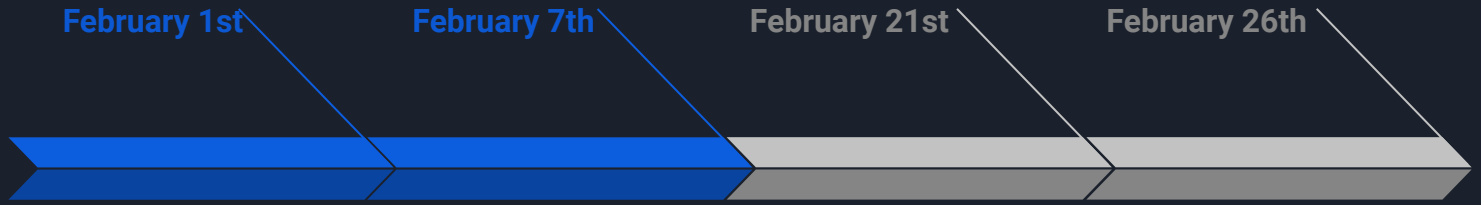
Drift Testing 1-hr:

- Electrode submerged in pH 7 solution with ISFET
- Voltage measured with DMM every 10 minutes
- Drift virtually nonexistent
- Proof of concept

Drift Testing 48-hr:

- Electrode submerged in pH 7 solution with ISFET
- Voltage measured with Arduino every 5 minutes
- Recorded in a text file
- Automation failure prior to full 48-hour testing
- 18-hour full depletion mark $\rightarrow$ 22nd hour in solution

Fabrication Timeline



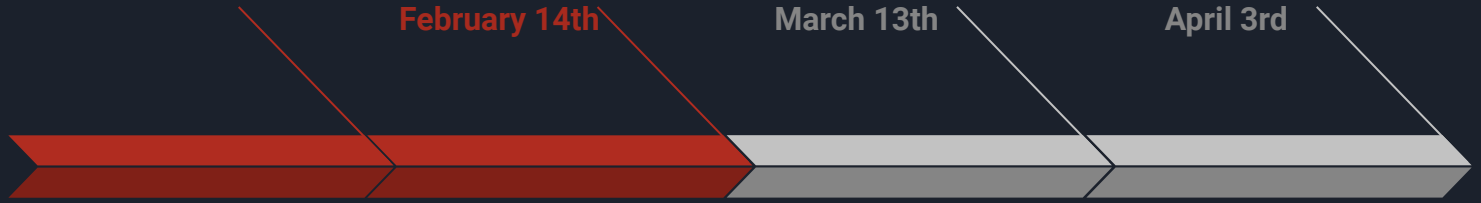
February 1st
IrOx electrodeposition solution mixing

February 7th
Electrodeposition of IrOx electrode

February 21st
Fit the electrodes inside the carbon micro tube

February 26th
Fit the apparatus inside the needle

Evaluation Timeline



Layered Ag/AgCl Testing

Re-do drift test with layered Ag/AgCl reference and determine accuracy over time

IrOx Testing

Drift test to determine accuracy over time

Cadaver testing

Test device in pig cadaver, determine efficacy

Live animal testing

Test device in induced ACS in pigs, determine false positive rate

Preliminary Testing

- 48-hour drift Test
  - Tests the clinical scenario of using for up to 48 hour patient monitoring
  - Compare the following pH sensitive devices
    - Control with glass bulb pH probe
    - ISFET with Ag/AgCl reference electrode
    - IrOx with Ag/AgCl reference electrode
  - Hypothesis: ISFET will maintain voltage for longer due to flaking from IrOx

- Cadaver Testing
  - Preliminary testing for its efficacy in muscle compartments
  - Test in a semi solid substrate

Animal Testing in Porcine Model

- Compare pH readings from pigs with/without compartment syndrome.
  - Test ISFET with Ag/AgCl, and IrOx with Ag/AgCl
  - Test for
    - Significant difference.
    - False-positive
    - False -negative
    - Area under ROC curve
- Hypothesis
  - Significant difference will exist between control and subjects with ACS
  - No significant difference between ISFET with Ag/Agcl and IrOx with Ag/AgCl.

References

[1] Olson, Steven & Glasgow, Robert. “Acute compartment syndrome in lower extremity musculoskeletal trauma*,” J Am Acad Orthop Surg*. 13: 436-444. The Journal of the American Academy of Orthopaedic Surgeons. 13. 436-44, 2005.

[2] C. Doro, private communication, Sep 2019.

[3] D. Purcell, B. A. Terry, and B. R. Sharp, “Acute Compartment Syndrome,” in *Emergency Orthopedics Handbook*, D. Purcell, S. A. Chinai, B. R. Allen, and M. Davenport, Eds. Cham: Springer International Publishing, 2019, pp. 79–85.

[4] M.M. McQueen, P. Gaston and C.M. Court-Brown. “Acute Compartment Syndrome,” *The Journal of Bone and Joint Surgery,* vol. 82, no. 2, 200-203, March 2000.

[5] A. Whitney, R. V. O’Toole, E. Hui, M. F. Sciadini, A. N. Pollak, T. T. Manson, W. A. Eglseder, R. C. Andersen, C. Lebrun, C. Doro, and J. W. Nascone, “Do one-time intracompartmental pressure measurements have a high false-positive rate in diagnosing compartment syndrome?,” *Journal of Trauma and Acute Care Surgery*, vol. 76, no. 2, pp. 479–483, Feb. 2014.

[6] R. H. G. Mingels, S. Kalsi, Y. Cheong, and H. Morgan, “Iridium and Ruthenium oxide miniature pH sensors: Long-term performance,” Sensors and Actuators B: Chemical, vol. 297, p. 126779, Oct. 2019, doi: 10.1016/j.snb.2019.126779.

THANK YOU!