Implanted Creatinine Sensor for Cardiopulmonary Bypass Patients

BIOMEDICAL ENGINEERING
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EXECUTIVE SUMMARY

Cardiopulmonary bypass (CPB) is a surgical method that allows the doctor to operate on a patient's heart without it beating. The CPB machine takes over the heart's function of circulating blood, but does so imperfectly. Because the kidney receives 20% of the heart's blood outflow, it is greatly affected by this change. **5% of patients develop acute kidney injury (AKI)**, half of which lead to kidney failure.

Creatinine is a metabolic waste product in blood that is normally excreted from the body by the kidney. When the kidney fails, it is unable to excrete creatinine, and creatinine is, instead, reabsorbed into the blood. Our device **detects this increase in blood creatinine level** and **warns the doctor early** so he/she can make the appropriate changes to the CPB pump.

PROBLEM & CLINICAL NEED

Our device could prevent kidney failure in 25 cardiac and ECMO patients per year in one hospital. There have been a few attempts to address the problem, including an implantable pH sensor for determining kidney failure and a handheld device that returns creatinine level after obtaining a finger-prick blood sample from the patient. These solutions would both return inaccurate results, and the latter is not a real-time monitor. We have chosen to design our device focusing on **accuracy** and **durability**, along with **speed** and **comfort**.

MARKET ANALYSIS

Table 1 shows costs associated with increases in creatinine level. Our device can reduce these costs, and can reduce the need for dialysis treatment, which costs 2.6-fold the cost of treating non-dialysis AKI patients. Hospitals consider kidney failure as one of the five most expensive diseases in terms of research and treatment. Our device will greatly help patients and hospitals financially and in terms of well-being.

Criterion	Mean Adjusted (Marginal) Increase in Total Cost ($)
↑ SCr ≥ 0.3 mg/dl	$ 4,886
↑ SCr ≥ 0.5 mg/dl	$ 7,499
↑ SCr ≥ 1.0 mg/dl	$13,200
↑ SCr ≥ 2.0 mg/dl	$22,023
↑ SCr by 25%	$ 3,721
↑ SCr by 50%	$ 5,510
↑ SCr by 100%	$ 8,999
↑ SCr by 50% to a minimum peak of 2.0 mg/dl	$11,719
↑ SCr ≥ 0.5 mg/dl with baseline SCr < 2.0 mg/dl or ↑ SCr ≥ 1.0 mg/dl with baseline SCr ≥ 2.0 and < 5.0 mg/dl	$ 7,982

Table 1: Costs associated with increases in creatinine level

DESIGN

Components (left to right): microcontroller (A), voltage supply(B), transistor (C), resistor (D), capacitor(E), sensor(F), electrode(G)

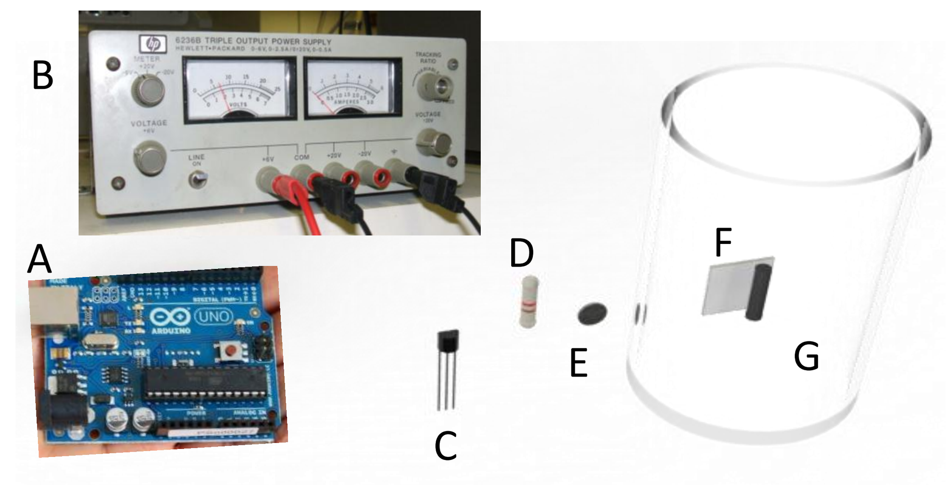


Figure 1: Schematic for the prototype model of our device, which demonstrated proof-of-concept of the function of our device.

Electrode maintains 1.8V voltage in solution → Creatinine binds to sensor, changing conductivity → Microcontroller detects change and converts electric signal into digital output

Implantation: The sensor and their attached wires would be implanted into the region between the cortex and medulla, where newly-filtered blood is abundant. This complex is approximately *0.5mm* x *0.5mm* and coated with anti-biofouling agents such as polyethylene glycol (PEG)

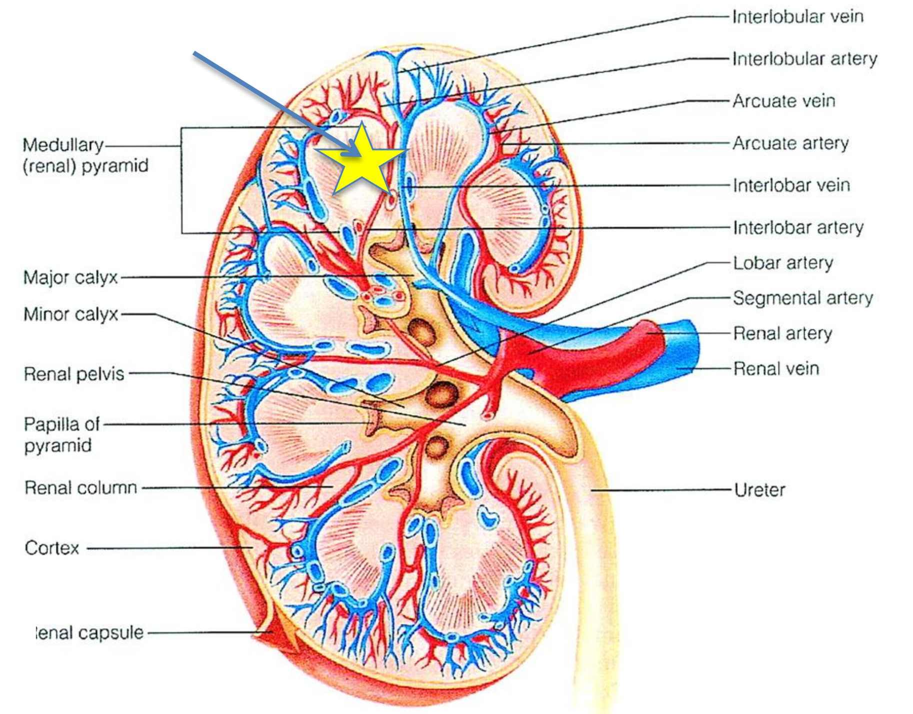
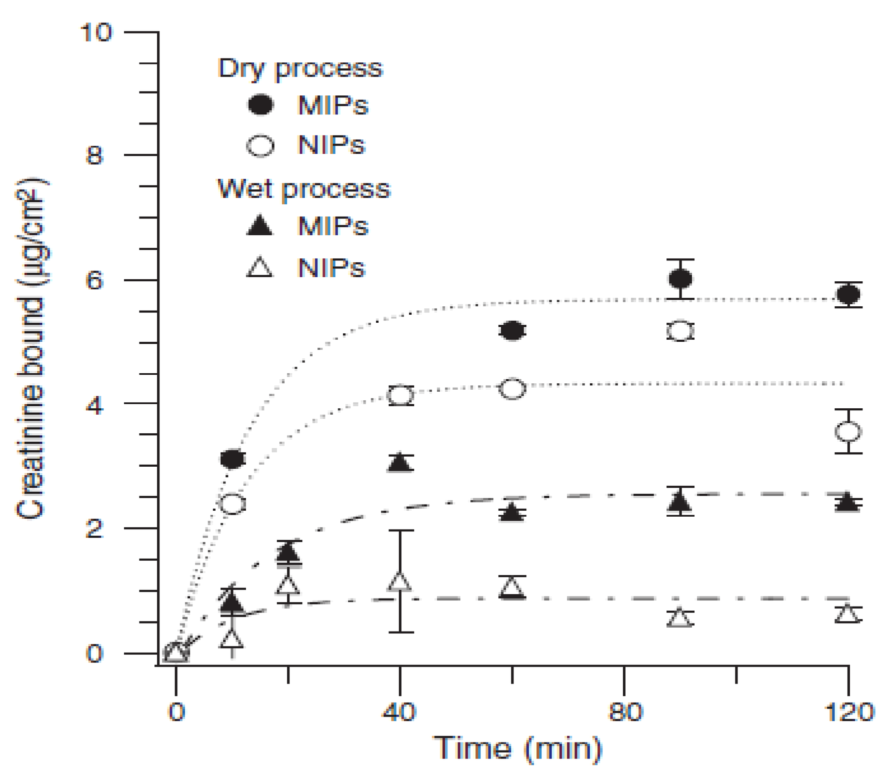


Figure 2: Diagram of the anatomy of the kidney and location of creatinine sensor implantation as marked by the star.



Sensor: The sensor consists of a molecular-imprinted polymer, EVAL, that allows creatinine to bind to it. The results from literary, shown in Figure 3, shows that creatinine binding reaches equilibrium in about 40 minutes. This delay is shorter than any other existing methods for creatinine measurement.

Figure 3: The equilibrium rebinding of creatinine to (imprinted and non-imprinted) EVAL membrane which prepared by either wet or dry process.[1]

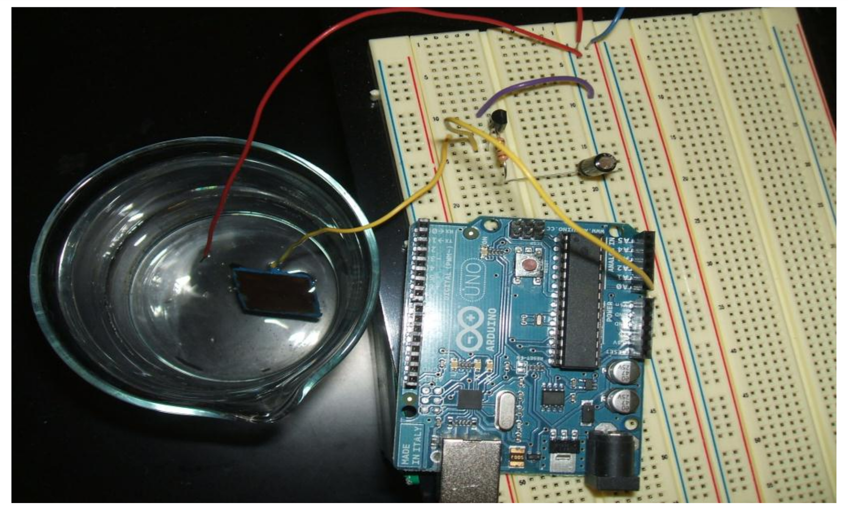


Figure 4: Prototype of the creatinine sensor. Components include: sensor in creatinine solution (left), transistor, capacitor, resister(top right), microcontroller (bottom right)

WHAT IS NOVEL

Our device utilizes this polymer to detect the creatinine level in the patient's body. Also, currently, urine is used to determine the blood levels creatinine and creatinine clearance; however, this method takes about 24 hours. We use implantable BioMEMS to monitor the level of creatinine in real-time. The real-time data enables the doctors to quickly detect an early sign of kidney failure by monitoring the level of creatinine in real-time.

PRODUCT COSTS

The total cost to create one unit of our device is $111.88 Because our material was bought in bulk, this cost-per-unit would decrease if the rest of the purchased material was used to build more.

Off-the-Shelf

- Arduino
- Circuit board
- Polymer

TOTAL: $30.38

In-House

- Resistor
- Capacitor
- Transistor
- Metal plate (Ag)
- Manufacturing Process

TOTAL: $81.50

ANTICIPATED REGULATORY PATHWAY

Class III medical device → Pre-Market Approval (PMA) rather than 501(k) → PMA post-approval requirements: periodical reports to the FDA of the device's safety, effectiveness, and reliability

ACKNOWLEDGEMENT

The authors would like to thank Dr. Zapanta and Dr. Antaki for their guidance throughout this project. We would also like to thank Dr. G. Fedder, Dr. C. Bettinger, Matt Cline, and Lawrence Hayhurst for their expertise and for providing us the necessary equipment and materials to complete this project.

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