Liver Allograft Viability Sensor

Thomas Donnelly¹, Zachariah Noble¹, Ashley Ranere¹, Kyle Smith¹, Andy Wong¹, Rabia Baig², Ben Chu², Carrie Forman², Kishan Ghodasara², Rohan Joshi², JP Loftus², Kambiz Pourrezaei, PhD¹, Meera Harhay, MD²,³

¹School of Biomedical Engineering, Science and Health Systems ²Drexel University College of Medicine ³University of Pennsylvania Medicine, Penn Kidney Transplant Clinic

Background
- 4.5 million US Citizens have Liver Disease (LD)¹
- Liver transplantation is the only treatment for patients with end-stage liver disease (ESLD),¹
- 13,000 new additions are added to the waitlist yearly ²
- 9,500 livers are donated annually ²
- 10% of donated livers are discarded ²
- Normothermic Machine Perfusion (NMP) can improve organ preservation and utilization by replicating physiological conditions. ²
- No quantitative measure to assess viability or improvements to allograft health during NMP.

Existing Solutions
- Oxygenation Saturation: Non-invasive hand-held device that can monitor organ viability and through hypoxemia. It is restricted to user/surgeon interaction and can only obtain point in time measurements as opposed to constant monitoring.³
- Physician assessment of allograft: Quick but subjective assessment of organ viability without quantitative metrics. It can also vary across centers and the lack of standardization may lead to higher discard rates.

Objective
Provide a continuous, quantitative metric to assess liver allograft tissue viability during Normothermic Machine Perfusion.

Solution
- Solution: Functional near-infrared spectroscopy (NIRs)³
- Measurement: Quantify intrahepatic oxygenated and deoxygenated hemoglobin near the organ surface.
- Implemented during normothermic machine perfusion (NMP) of the tissue to help physicians determine real time viability of transplant organs.

Verification & Validation
1. Blood Pressure Cuff
   a. Modulate blood occlusion
   b. Reqs 1, 3, 4
2. Mock Tissue compartment
   a. Mimics photo-absorbance
   b. Reqs 2.3, 4
3. Mock Hematologic Compartment
   a. Working solution of Sheep blood
   b. Reqs 1, 3, 4

Societal Impact
Provide a standardized method with quantitative data for Liver Transplant Surgeons and NMP technicians to better predict the success of tissue transplantation.

Conclude
This sensor provides a novel change to liver allograft transplantation assessment and can be used to reduce medical waste and save lives.

Requirements
- 1. Read relative blood oxygen % change
- 2. Collect data in tissue 6-15mm deep.
- 3. Uninterrupted 30-minute reading intervals.
- 4. Collect data at multiple locations on organ.

Working Models & Prototype

Constraints
1. Time: 9 months
2. Budget: $300
3. Functional Near-Infrared Spectroscopy (NIRs)
4. No interference with NMP device
5. Secure attachment to liver
6. Sterilizable sleeve to cover
7. Testing must use phantom instead of transplant livers

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References: