



Liver Allograft Viability Sensor

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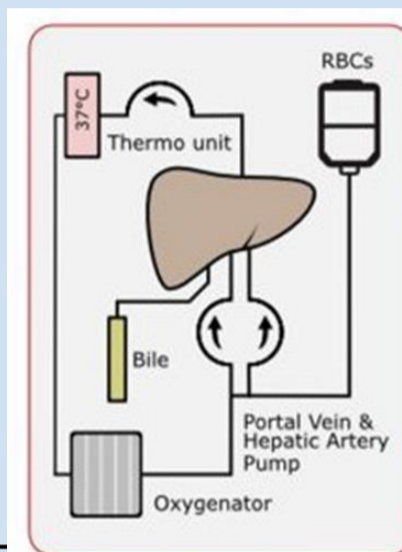


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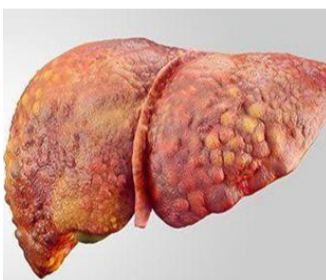
Background

- 4.5 million US Citizens have Liver Disease (LD)^[1]
- Liver transplantation is the only treatment for patients with end-stage liver disease (ESLD),
- 13,000 new additions are added to the waitlist yearly ^[2]
- 9,500 livers are donated annually ^[2]
- 10% of donated livers are discarded
- Normothermic Machine Perfusion (NMP) can improve organ preservation and utilization by replicating physiological conditions
- 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
- Physician assessment of allograft:**
Quick but subjective assessment of organ without quantitative measures. It can also vary across centers and the lack of standardization may lead to higher discard rates

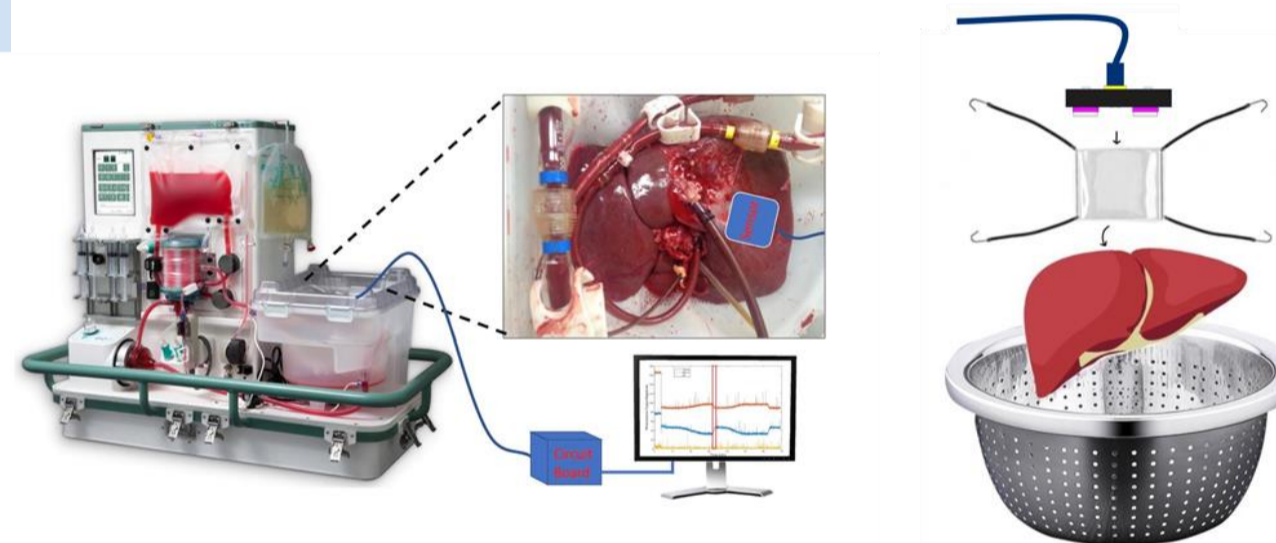


Objective

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

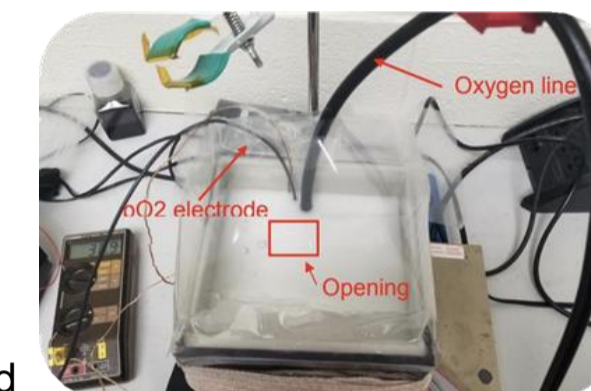
Solution

- **Solution:** Functional near-infrared spectroscopy (fNIRs)^[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.

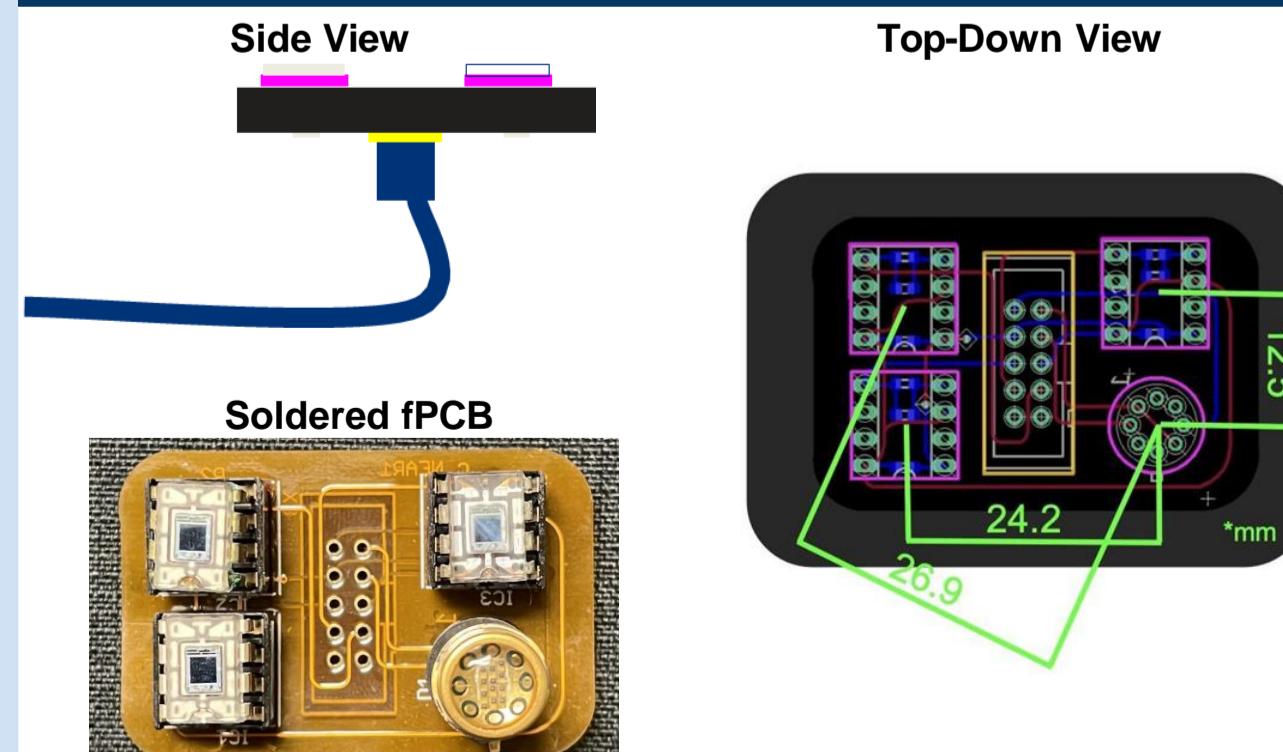
- Provide a Point of Care to:
- Reduce **13,000 people** on waiting list
 - Reduce **~950 livers** we throw away

- Financial Impact
- **\$94,100/liver** spent on procurement with \$700 million total ^[4]
 - **\$812,500/liver = \$6 billion** spent on total procedure costs
 - **\$718,400/ liver** difference could be saved on non-viable liver transfer
 - **\$13.5 million** total in post-op complications reduced

Conclusion

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

Working Models & Prototype



Constraints

1. Time: 9 months
2. Budget: \$300
3. Functional Near-Infrared Spectroscopy (fNIRs)
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

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.

Acknowledgments

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Dr. Harhay, Clinical Advisor Dr. Swoboda, Academic Advisor

References: [1] Centers for Disease Control and Prevention. FASTSTATS - chronic liver disease or cirrhosis. Centers for Disease Control and Prevention. [2] OPTN metrics. (n.d.). Retrieved November 8, 2021, from https://insights.unos.org/OPTN-metrics/. [3] Adams, P. S., et al (2019). Associations of perioperative renal oximetry via near-infrared spectroscopy, urinary biomarkers, and postoperative acute kidney injury in infants after congenital heart surgery. Pediatric Critical Care [4] Cook, M. & Zavala, E. (2019). The finances of a liver transplant program. Current Opinion in Organ Transplantation, 24 (2), 156-160. doi: 10.1097/MOT.0000000000000612. Medicine.