Ambulatory Extracorporeal Blood Oxygenation Assist Device

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Executive Summary

Chronic obstructive pulmonary disease (COPD) causes approximately 125,000 deaths annually in the United States. For many patients, the only real solution to their loss of lung function is a complete lung transplant. This often means that patients need artificial lung function while they wait for a transplant. Current extracorporeal membrane oxygenation (ECMO) methods confine patients to bed due to bulky machines and cumbersome catheter connections. In order to keep patients in the best possible condition for a transplant, an artificial lung device allowing patient ambulation would be ideal. The goal of our project is to design a dual lumen catheter to replace the current two-catheter setup as well as create a portable blood oxygenation system. This catheter will take in deoxygenated blood from the right atrium and deliver oxygenated blood to the left atrium. By still utilizing the partial function of damaged lungs, this catheter could permit the use of a smaller external gas exchanger that could be more mobile than typical ECMO devices. Because a smaller gas exchanger can be used, it can be contained in a backpack to allow the patient to be mobile while awaiting transplant. This offers a vast improvement over current lung assist devices that force a patient to remain bedridden while also increasing the risk for infection by maintaining two openings in the skin.

Description of the Problem and Clinical Need

- **Problem:** Patients undergoing ECMO are confined to a bed because machines are too large to move and they require two cannula insertion points.
- **Intended Patients:** Patients currently receiving ECMO who have maintained at least partial lung function
- **Advantages:**
  - Reduces infection by using one cannula entry point
  - Allows patient mobility with small oxygenator and single insertion point
  - Uses partial lung function to reduce oxygen requirements

Description of Market

- The primary group of customers that the product would appeal to is health care providers treating patients with COPD and payers would be patients who are in need for a lung transplant or those who are undergoing acute lung failure.
- ~125,000 patients have COPD. Only 1500 lung transplants are performed, showing a need for alternative solutions which our product can provide.
- Our dual-lumen catheter design proposes a lower risk of infection and increased patient mobility over leading two-catheter systems. Similar dual lumen designs on the market, although none of them are functional as oxygenation catheters.
- Manufacturing through extrusion costly due to lack of available companies
- Increasing mobility through catheter design promotes product. However, patients face greater risk due to risky atrial wall puncture procedure
- Difference in costs of current catheters and our design is negligible. Greater mobility allows for less in-patient care and reduces healthcare costs.

Description of Design

Cannula Design:

- A single dual lumen tube inserted through the jugular vein
- One lumen terminates in the right atrium and removes deoxygenated blood
- Second lumen passes through a transseptal puncture to deliver oxygenated blood directly to right atrium

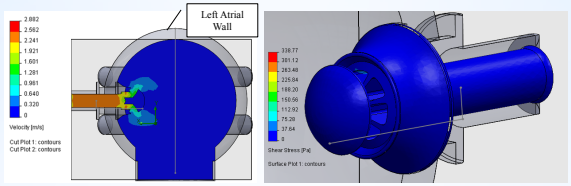


Figure 1: Flow analysis in transseptal puncture catheter tip. Velocity distribution (left) shows that the . Wall shear stress distribution (right) shows that the wall shear stress is less than 400 Pa, so hemolysis should not be a problem.

Oxygenator Design:

- Reverse engineer a Baxter Oxygenator
  - Exceed total surface area of oxygen fibers
  - Exceed total residence time of blood in contact with fibers
- Flat design to incorporate into a backpack carrier
- Prototype limited by manufacturing processes
  - Sharp corners and boxy shape
- Prototype demonstrates functionality and concept

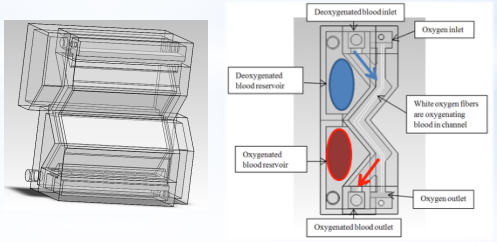
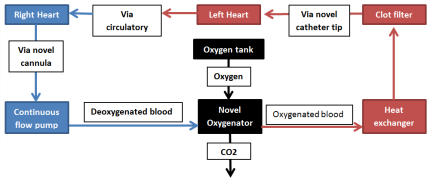


Figure 2: Oxygenator model (left) and oxygenation schematic (right)

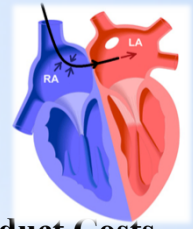
Overall Oxygenation Circuit:



What is Novel?

Novel Cannula:

- Current ECMO methods use two catheters
  - one inserted into the femoral vein to remove deoxygenated blood and another inserted into the jugular vein to replace oxygenated blood
  - Cumbersome connection
- Transseptal puncture allows partially functioning lungs to keep oxygenating blood in a limited capacity
  - Reduces oxygenator requirements



Estimation of Product Costs

System Component	Part	Manufacturing Method	Estimated Cost ($)
Cannula	Tubing	Extrude	10**^^
	Tip	Injection Mold	6*
Oxygenator	Casing	Injection Mold	45*
	Fibers	Buy	50^
	Resin	Buy	20^
	Labor	$50/Hr x 5	250
Heat Exchanger	Tubing	Injection Mold	55*^^
	Heater	Buy	975**^
	Labor	$50/Hr x 7	350
Pump	N/A	Buy	250^
Filter	N/A	Buy	25^
Tubing/Connectors	N/A	Buy	20**
Backpack	N/A	Buy	75**^
	Labor	$50/Hr x 1	50
		Total Cost	2181.00

*Custompart.net estimate
**McMaster-Carr Estimate
^Adjusted from retail price to wholesale price
^^Excluding extrusion machine fixed cost

Anticipated Regulatory Pathway

- Our device is similar to existing products: ECMO machine and cardiovascular cannulas
- Class III device because the patient's life depends on its function
- Because of this high risk, PMA is anticipated regulatory pathway
  - Requires thorough testing to prove safety and effectiveness of device (biocompatibility tests, risk analysis, ex-vivo tests, in vivo animal tests, clinical tests)