FIBREEZE: LEAK-PROOF HOLLOW FIBERS for ARTIFICIAL LUNGS

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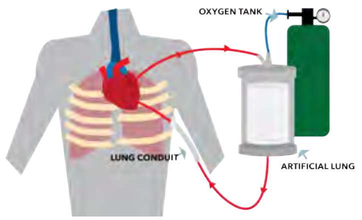
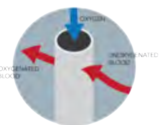
Artificial Lung Basics





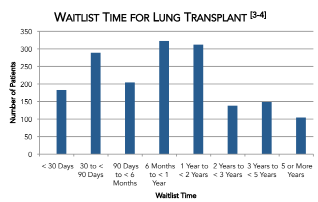
← FIGURE 1: Artificial lung circuit through the heart
↑ FIGURE 2: Gas exchange through one porous fiber to oxygenate blood

Clinical Need & Problem

- Lung disease is one of the leading causes of death in the United States, killing 4 million Americans a year. [1-2]
- Demand for lung transplants exceeds supply of healthy lungs donated and lung transplantations had a low success rate so patients are often on the waitlist for a long period of time
- Artificial lungs replace repeated lung transplants or provide a temporary solution until a lung can be successfully transplanted
- Often patients need repeated lung transplants, which means higher costs, increased use of resources and greater risk of infection and other health complications
- Devices fail due to plasma and air leakage, which can cause pulmonary embolisms and therefore death. [1-2]
- Re-engineered artificial lung with proper material coating and efficient coating method would solve these problems

Description of Market

- As of May 2, 2014, there are 1,666 people on the waitlist for a lung transplant – this is the target audience. [3-4]
- Since many patients have such long waits and may often die while on the waitlist, artificial lungs are necessary to bridge the gap to a healthy lung transplant



Novelty & Innovation

Old Methods [5]
- Flat Sheet membranes vs. hollow fiber membranes
- Materials like PMP, Tygon, PTFE, PDMS, Silicone
- Coatings like Nitric Oxide, Heparin, Carbonic Anhydrase
- Coating methods like plasma deposition and spin coating

Retained Methods
- Using hollow polypropylene fiber membranes
- Use of PDMS
- Polyurethane potting material

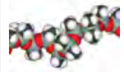
New, Adapted Methods
- PDMS as a coating for the PP fibers
- Airbrush coating method to form PDMS thin film
- Adapted Dip coating method to coat bundles of fiber

Description of Design

MATERIAL COATING CHOICE:

Material Selection Criteria:

- Biocompatibilty
- Gas exchange
- Thin film capabilities
- Compatibility with Polypropylene and Polyurethane
- Material Cost
- Curing temperature



Polydimethyl Siloxane (PDMS) – silicone based organic polymer used in many medical and scientific applications; properties of stability, chemical resistance, and biocompatibility make it appealing

Young's Modulus	Shear Modulus	O2 Permeability	Cost
360-870 kPa	4.35×10^{-5} – 2900 psi	1.29×10^{-4} – 3.01×10^{-4} $cm^3.m/m^2.day.atm$	\$4.77 - \$5.67/lb

[6]

AIRBRUSH SPRAY COATING:

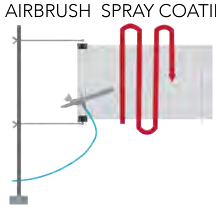


Figure 3: Airbrush spray coating schematic

The airbrush spray coating uses a standardized amount of PDMS solution per side with a consistent spray method to coat each side of the fiber sheet with a thin film of polymer

DIP COATING:

Figure 4: Dip coating method schematic

The dip coating method utilized a fiber bundle dipped with both ends in PDMS solution and air dried between dip coats.

SCANNING ELECTRON MICROSCOPY:

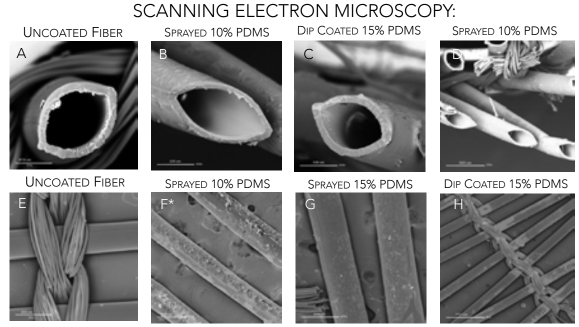


Figure 5: Scanning electron microscope pictures of the uncoated and coated fibers coated in 10% or 15% PDMS solution in hexane solvent showing varying coating surfaces. * Image F shows a coated that was scraped to show a contrast in the image

FURTHER RESEARCH

- The fibers were potted into artificial lung prototypes, however the potting process requires further optimization
- Gas exchange testing of these potted artificial devices through a circuit shown in Figure 6 would allow for blood gas analysis with samples taken to assess the effectiveness of the lung fibers and coating.

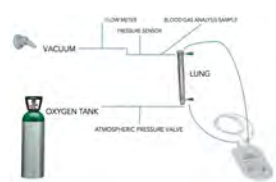


Figure 6: Gas exchange circuit schematic

PRODUCT COSTS

Part Description	Amount/Unit	Bulk Cost ($)	Cost/Unit ($)
PP fibers	2.4 m^2	\$150/m^2	\$360
Potting Material	300 mL	\$150/1L	\$45
Biospan, for Housing	750g	\$200/1kg	\$150
PDMS	300g	\$60/2kg	\$10.50
Hexane	38.7 mL	\$70/4L	\$0.68
Centrifuge tubing	1/100 units	\$6.32	\$0.63
Mold	1/100 units	\$150	\$1.50
Tubing	1	\$1.50/line	\$1.50
Connectors	2	\$13.12/50	\$0.52
Spraying kit	1/100 units	\$15.46	\$0.15
Airbrush hose	1/100 units	\$8.86	\$0.08
Cleaning brushes	1/100 units	\$6.96	\$0.69
TOTAL			\$571

REGULATORY PATHWAY [7-9]

- Class III medical device: new product, sustains human life, high risk of illness/injury
- FDA approval requires:
  - Premarket approval (PMA), includes reliable data from pre-clinical and clinical studies to establish safety and effectiveness
  - Center for Biologic Evaluation Research approval because of blood collection and processing procedures
- Extracorporeal Membrane Oxygenator : similar purpose, different in process so cannot mandate 510(k) clearance and PMA
- Need to conduct pre-clinical trials in compliance with Good Laboratory practice for Non-clinical Laboratory studies

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