Bioreactor for Laryngeal Tissue Engineering

Product Design Specifications, v1

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Client: Dr. Nathan Welham

Problem Statement: The larynx has three major functions physiologically. It separates the windpipe from the esophagus, is important in swallowing, and has a major function in sound production. When a problem occurs in the larynx, all three functions can be disrupted. Our purpose is to design a laryngeal bioreactor that can decellularize a larynx to make a scaffold and recellularize it with patient-specific cells. A previous team designed a device that adequately decellularized the tissue, but recellularization had not been thoroughly tested. The client would like an iteration of the design that keeps the larynx horizontal during the experiment and allows easy access to the catheters supplying fluids through the vasculature. This semester, the team should focus on building a design that allows cells to be exposed to both air and media during cellular growth while allowing researchers to view the experiment taking place. Additionally, this semester, the team should seek to incorporate and build upon the automation system that the previous team began constructing.

Function: The device will serve to perfuse and support laryngeal tissue to aid in the decellularization of existing cells and recellularization with patient-specific cells.

Client requirements:

- The bioreactor must be able to decellularize and recellularize the larynx
- The bioreactor must be able to function continuously up to three weeks in time
- The bioreactor must be sterile and capable of interfacing with the previous group's pumps

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The bioreactor needs to be able to create an acellular scaffold by decellularizing a larynx. After decellularization, the bioreactor needs to be capable of housing the larynx and repopulating the scaffold with new cells.

b. *Safety*: The device will be used in conjunction with chemicals; therefore chemical exposure must be prevented. The device needs to be sterile to prevent future contamination/inflammatory responses, or functional loss after implantation.

c. *Accuracy and Reliability*: The device must be able to provide and/or facilitate consistent decellularization and recellularization over multiple larynges. The bioreactor needs to function for up to three weeks in time without functional loss.

d. *Life in Service*: Our client intends to use the device for several months over the course of the current research study. The device must function accurately and reliably over that time in segments of continual use for several days (for decellularization) to three weeks (for recellularization). The bioreactor must be reusable.

e. *Shelf Life*: The device should maintain its functionality for as long as possible so the client can use it in multiple similar studies.

f. *Operating Environment*: The device is intended to be used atop a standard lab bench by the researcher.

g. *Ergonomics*: The device must not place unnecessary strain on the user. It needs to be reasonably movable and provide easy access to the tissue specimen.

h. *Size*: Overall size of the device must be limited to prevent crowding on the bench top, but large enough to house a human or large animal model larynx.

i. *Materials*: All materials used in the device must be biocompatible with fresh tissue and support cell viability. None of the materials should degrade in the media used during decellularization or recellularization.

j. *Aesthetics*, *Appearance, and Finish*: Although the client expressed no preferences as to aesthetic quality, the design should appear finished and professional.

2. Production Characteristics

a. *Quantity*: One prototype serving as the second iteration of the design, with the assumption of future modifications.

b. *Target Product Cost*: $1,000-3,000

3. Miscellaneous

a. *Standards and Specifications*: None aware of at this time

b. *Customer*: Dr. Nathan Welham and his fellow researchers

c. *Patient-related concerns*: None

d. *Competition*: None specifically for the larynx.