

BME 200/300 Design
Developing Implantable Light Source for Optogenetically Modified Mice
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Product Design Specifications

Function:

The discovery of microbial opsin genes, which is a group of genes that enable the neuron to be activated by light, makes it possible to selectively control activation of neuron by light. Optogenetics is the study that combine genes and the emission of light (optics) together. Our client aims to study how tuberculosis could be treated with neurons stimulated by implantable lights near the lung. Our group's product is safe to be implanted in mice and can emit light within certain wavelength requirement. The light source can also be switched on and off easily by operator for research use. The light's intensity is able to trigger all of the neurons inside the lung of mice.

Client requirements:

The goal of our client is to use optogenetic activation or blocking of neurons to alter immune cell functions in mice to understand inflammatory responses in brain and lung diseases. In vivo light delivery is key to this project and our client needs a solution for 470nm and possible 405nm light that can deliver light to a larger area, which is about 1cm in diagonal, and can be switched on and off for hours in the mice. The heat produced by the light should neither be harmful nor kill the cells and tissues near implantation site. The light should be delivered deep enough to stimulate the lung of the mice. The light should also be reusable if it is expensive to develop.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

Light must have a size of approximately 1cm with a broad light source range able to penetrate deep into the organs of the mice. It also needs to have a wavelength of 405nm and/or 480nm without producing UV rays.

Project 1 Additional requirements: Light source must be composed of a flexible biosynthetic material able to operate in conditions within the mice's bodies. It needs to have a wireless system so operator can switch between the 405nm and 480nm wavelengths.

Project 2 Additional requirements: Light source must have an automated way which will allow it to switch on and off for 30 second intervals over 24 hours. Must be flexible and able to stick on the outside of the mice's skull.

b. Safety:

The heat generated by light should be minimal and not be harmful for neighboring cells and tissues. The production of UV rays by the light source would also cause harm to the cells. The material should also be biocompatible so that it could not cause an inflammatory response.

c. Accuracy and Reliability:

The light needs to be durable and biocompatible so that it is able to withstand the environment inside the blood vessels of mice. Also, the light source developed should be broad enough to cover enough areas on the organs of the mice to make sure the light-sensitive genes can be triggered and monitored.

d. Life in Service:

Ideally the device will be disposable and only used once. If our product is expensive then it needs to be reusable. The light source should also work continuously and consistently without unpredicted damage in the hardware.

e. Operating Environment:

Under the rib cage and by the lungs of the mice.

f. Ergonomics:

Make design easy to handle, such as make grooves so tweezers or fingers can pinch it easier and the syringe can take it in and expel it readily.

g. Aesthetics, Appearance, and Finish:

The design needs to be small, compact, and streamlined. Since the design will be used in vivo, wires are acceptable but not preferred. The materials used need to be durable and able to function when in the blood vessels of the mice.

2. Production Characteristics

a. Target Product Cost:

The client did not specify the budget as long as we make reasonable use of the money provided by our client. Our team will try to minimize the amount we might spend and try to make our device reusable and reliable.

3. Miscellaneous

a. Standards and Specifications: FCC Regulation of Wireless Medical Devices

Our device to be built might use a certain type of wireless transmitter. According to Equipment Marketing and Authorization of FCC regulation, every type of wireless transmitters being used must be certified for compliance with the FCC's rules before it can be marketed in the U.S. The certification process involves Testing, Radiation Exposure, and Device Labeling.

b. Customer:

For a preliminary design specification in regard to customer, the device should be user-friendly (easy to handle, will not fall apart easily when mishandled, etc).

c. Patient-related concerns:

Our design will not be applied to patients directly even though the ultimate goal might be to alter immune response of human. For our research subjects, mice, the use of light source must not be detrimental to the research projects and the device should be safe to mice when being implanted in mice.

d. Competition:

1. Biocompatible optical fiber-based nerve cuff can be used for light delivery that wraps around the target neuron. The research mainly considers light delivery to peripheral axons [1].
2. Epidural fiber-optic implants:
Epidural fiber is used in light delivery for spinal cords. The system [2] enables sufficient light intensity and different light wavelength to be delivered.

Reference:

- [1] Towne, C., Montgomery, K. L., Iyer, S. M., Deisseroth, K., & Delp, S. L. (2013). Optogenetic Control of Targeted Peripheral Axons in Freely Moving Animals. *PLoS ONE*, 8(8). doi:10.1371/journal.pone.0072691
- [2] Bonin, R. P., Wang, F., Desrochers-Couture, M., Gassecka, A., Boulanger, M., Côté, D. C., & Koninck, Y. D. (2016). Epidural optogenetics for controlled analgesia. *Molecular Pain*, 12, 174480691662905. doi:10.1177/1744806916629051