

Blinking Orbital Prosthesis

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Leader: Michael Konrath

Leader: Justin Cacciatore

Communicator: Blake Marzella

BWIG: Mike Musser

BSAC: Jeff Groskopf

Function:

Patients of any gender or age may experience the loss or absence of their eye due to some type of accident, genetic defect, or disease. Prosthetic eyes are made to help these people have a greater sense of confidence and positive self-image. Our goal is to create an improved orbital prosthesis which can restore a truly natural appearance. Last semester we designed a mechanism to create a realistic looking blink. Our intention this semester is to reduce the size of this mechanism and to synchronize its blink with the blink of a healthy eye.

Client requirements:

- Costs for the project should be under \$500.
- The mechanism, not including circuitry, should be contained inside of the cavity of the globe of the eye.
- The mechanism, not including circuitry, must be consolidated into a single piece of hardware
- The prosthetic eye must be detachable from the motor.
- The mechanism must be enclosed in a silicone covering, so as to separate it from the patient's flesh.
- Must be damped in order to minimize sound and vibrations.
- Must be as aesthetically pleasing.
- The blink must be synchronized with the blink of a healthy eye

Design requirements:

The model of the orbital prosthesis will only be used in presentation settings, to demonstrate the blinking mechanism. However, we will still take into consideration the requirements for a fully functional orbital prosthesis.

1. Physical and Operational Characteristics

a. Performance requirements:

- Model: It would be used once a week for 10-20 minutes at a time.
- Fully Functional: Must be equipped for continual daily use, 16-18 hours a day for at least one year.

b. Safety:

- Model: Must have proper electrical wiring, in order to prevent electric shock to the presenter.
- Fully Functional: Must be made of easily sanitized materials that are biocompatible.

c. *Accuracy and Reliability:*

- Model: Must blink when prompted, on every occasion. Must be able to blink at a rate of 300-400 milliseconds per blink.
- Must be synchronized with the blinking of the other functional eye, without noticeable delay.

d. *Life in Service:*

- Model: Reusable; must be usable 300 times a year, ideally for multiple years.
- Fully Functional: Must be operational for daily use for at least a year, with only minor maintenance.

e. *Shelf Life:*

- Model: The shelf life of our design would be the shelf life of the motor that we use.
- Fully Functional: Skin mimicking gelatin may need to be replaced after extended use. Batteries might also need to be replaced at regular intervals.

f. *Operating Environment:*

- Model: The orbital prosthesis will be used within a patient's eye socket. The prosthesis will be limited by the small volume available and also needs withstand the conditions of the human body.

g. *Ergonomics:*

- Model: The device should be easily operated by a single presenter.
- Fully Functional: The device must be easily removable, chargeable, and sterilized.

h. *Size:*

- Model: The maximum size of the prosthesis should be the size of the human eye socket.
- Fully Functional: The fully functional prosthesis should be no bigger than the model.

i. *Weight:*

- Model: Not an issue. Reasonable weight for one person carrying (3-5 lb.)
- Fully Functional: Must be comfortable for patient use.

j. *Materials:*

- Model: Prosthetic eyes now are made out of PMMA, Poly(methyl methacrylate) and Acrylic. Our device will use these materials, a light weight metal and/or plastic for the motor and elastic polymer for the closing mechanism.
- Fully Functional: Any materials that would come in contact with the patient's skin will need to be non-allergenic or coated with a material to prevent any allergic reaction.

k. *Aesthetics, Appearance, and Finish:*

- **Model:** It should be aesthetically pleasing. The mechanism should be completely contained within the globe the prosthesis with the exception of an actuating device (ex. switch or button).
- **Fully Functional:** The goal is to make a more realistic prosthesis, so a human-like appearance is what the product should display.

2. Production Characteristics

a. *Quantity:* 1 deliverable.

b. *Target Product Cost:* Under \$500, additional funding will be available if specialized materials need to be ordered.

3. Miscellaneous

a. *Standards and Specifications:* We must adhere to the medical device regulations established by the U.S. government and the World Health Organization. We must also make a device that satisfies our client's standards.

b. *Customer/Patient related concerns:* None for the model. However, the fully functional prosthesis would need to be small enough to fit comfortably into the patient's eye socket, quiet, capable of performing with minimal vibrations, and easy to disinfect regularly. It must also not be delayed in its synchronized blink

d. *Competition:* There have been multiple attempts and possibly successes at a blinking orbital prosthesis. However, at least here in the Madison area these prosthetics are not available to the general public for use.