

Blinking Orbital Prosthesis

Final Design Report

BME 200/300

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Abstract

While current orbital prostheses have the visual appearance of a normal eye, they are static and do not move. This makes a prosthesis quite noticeable, especially when a person blinks their normal eye – giving them an appearance of constant winking. We have designed and constructed a blinking orbital prosthesis that closely mimics the blink of a normal eye. This design can help disguise the prosthesis and boost the user's confidence in their appearance, which can increase their quality of life. The design can be further advanced by miniaturizing it to fit inside the orbital cavity and by coordinating the prosthesis's blink with that of the normal eye.

Background and Motivation

Every year 11,000 people in the United States have an orbital exenteration – a complete removal of an eye and the tissues surrounding the eye. This can occur due to an injury or disease, such as squamous or sebaceous cell carcinoma. While sight in that eye is permanently lost, it is possible to replace the eye with a realistic prosthesis to give the user their original appearance.



Figure 1: Acrylic eye prostheses

An orbital prosthesis is made using an acrylic eye made of polymethyl methacrylate, also known as PMMA, as seen in Figure 1. The acrylic eye is set in a static silicone restoration of the soft tissues. These soft tissues include the eyelid and all of the skin surrounding the orbital cavity lost during the exenteration. This unit can then be inserted and removed on a day-to-day basis. Currently the orbital prosthesis gives the appearance of a natural eye, mimicking the skin and the glassy orbital, as seen in Figure

2. However, the prosthetic eye is noticeable because it is not animated; it does not blink.

Patients of orbital exenterations with a prosthetic eye are more likely to feel self-

conscious of their

disability because of the

prosthesis's inability to

mimic the animation of a

blink. Many patients wear

dark glasses to cover up

the prosthesis for this

reason. If the prosthetic

eye could blink, this

would raise self confidence in prosthetic patients.



Figure 2: An example of using an orbital prosthesis

This project is a continuation of a previous semester. The previous team was able to fabricate a prototype that produced a blink using a mechanism driven by a motor, as seen in Figure 3. Two prongs were attached to the back of the prosthetic eyelid. A motor powered by a battery spun an arm that made contact with the two prongs. When prong B was hit, the lid would be forced down in the motion of a blink. The arm would continue to rotate and make contact with prong A, which would force the eyelid up, completing a blink. While this design does create a blink, there are several design specifications which it does not meet. First, the prongs that facilitate the movement of the eyelid stick out from

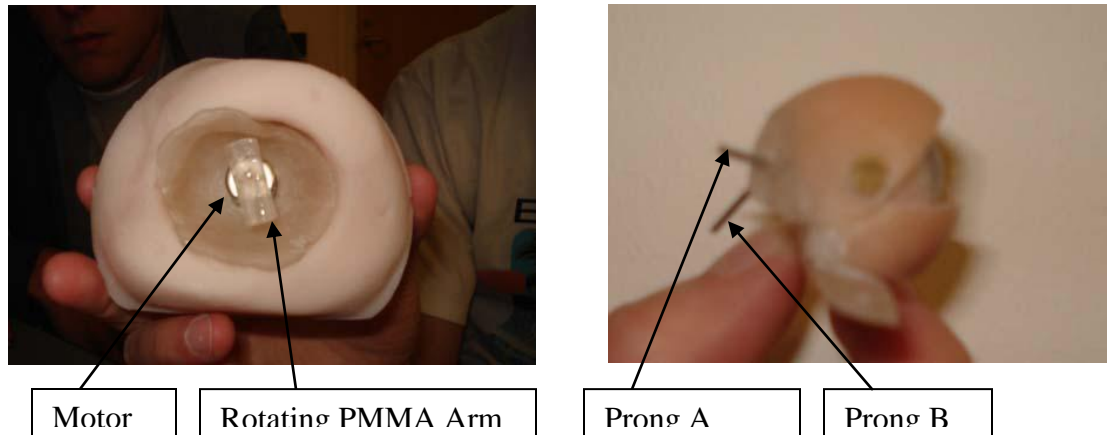


Figure 3: Prototype of previous semester's team

the back of the prosthesis, creating a potential hazard to the patient. This also means that the mechanism is not entirely contained within the cavity – including the rotating arm and motor. Second, while the blink occurs, it does not mimic a single spontaneous blink of a normal eye. The motor cannot be controlled, and the arm continuously rotates, produced a rapid succession of blinks. Third, the mechanism requires contact between the arm and the prongs behind the eye, which causes a lot of noise to be made each time the prosthesis blinks. The amount of noise produced by the prosthesis causes it to be noticed by the outside observer – which is counteractive to the purpose of this project. The primary goal of our design is to solve the second and third problems: the ability to control the blinking of the prosthesis and to eliminate any noise produced.

Problem Statement

When a patient has an orbital exenteration the large cavity is restored with an acrylic eye surrounded by a detailed but static silicone rubber restoration of the soft tissues (lids, etc). The PMMA eye is incorporated into the silicone part and the patient places the entire unit in each day. It is retained with adhesive, osseointegrated

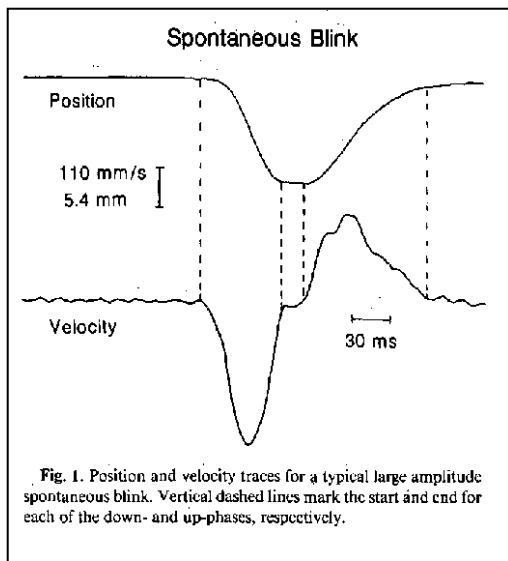


Figure 4: Graph showing velocity and position of an eyelid during

investigative ophthalmology and visual sciences that tracked upper eyelid movements that were measured with a search coil. The graph shows velocity and position versus time of a spontaneous blink. The device needs to mimic the motion of a blink; this graph shows that the motion of the upper eyelid is about the same in each direction which helped us to choose a mechanism for the prosthesis. The graph also shows that the velocity of a blink is approximately 110 millimeters per second (1700 degrees per second). The device should be able to achieve this velocity so that it correctly mimics the blink and speed of the natural eye.

Design Specifications

Several requirements for the design were proposed by the client, influenced by the previous design. First, and most importantly, the device should have the ability to be controlled, with a blink occurring on command or in controlled intervals. The actuator

percutaneous (adhered onto the bone via needle puncture through the skin) fixtures or by gentle anatomical fit. Most patients' cavities have an adequate volume to house a mechanism that produces animation. The goal is to fabricate a patient simulator model with a prosthesis that blinks, and in the future have the mechanism be synchronized with the blinking of the working eye.

Figure 4 is from a paper about

mechanism should not produce a noticeably audible noise, since this project aims to disguise the prosthesis. The device creating the actuation should also have the ability to be self-contained within the orbital cavity. Since most people wear glasses to help disguise the prosthesis, it is acceptable to have an external power source (i.e. a battery) contained within the glasses frame. The device should also have the ability to match the velocity of a blink of a normal eye – approximately 1700 degrees per second. Finally, the device should be safe to use within the orbital cavity. The client provided an adequate budget for this project.

Alternative Designs

Design 1: Electromagnet

The first design that our group formulated is based on a coil wrapped around a ferromagnetic core located behind the eyelid, creating an electromagnet, as shown in figures 5 and 6. When a current is applied to the coil, it creates a magnetic field directed upwards that is amplified by the core. The magnetic field that is produced acts on an external permanent magnet that is attached to the eyelid via an elastic or hinged connection. When the current is turned on, the external magnet is repelled upwards causing the eyelid to pivot on its hinge and close. When the current is turned off gravity will cause the eyelid to fall back down to its initial open position. A spring could also be incorporated into the design to pull the lid to its initial position.

This design has many advantages. In this configuration, the only times current need to be applied would be when the eyelid closes. This is power conservative, and would mean that for a majority of the time, no power would need to be used. This design

is also space efficient and can be scaled up or down in size based on the current requirements and the size of the magnetic field that is required while still maintaining the size requirements of the project specifications.

The design does have a few drawbacks. Problems related to the size of our current and magnetic fields could arise, based on a number of factors – such as the strength of the magnet, the number of loops in the electromagnet of the type of battery used. Voltage and current should be kept low so as not to violate the safety portion of our design requirements. The size of this design is also an issue, as the mechanism is on a small scale and needs to fit inside the cavity.

“Open”

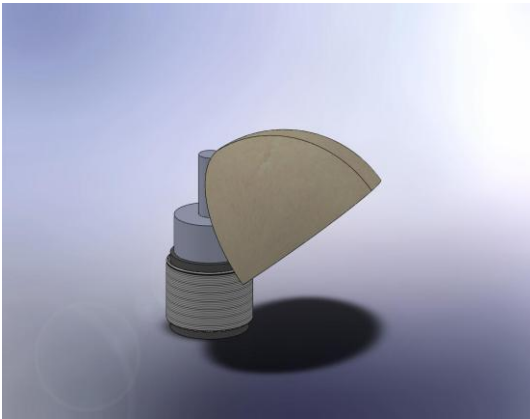


Figure 5: Solenoid open eyelid position

“Closed”

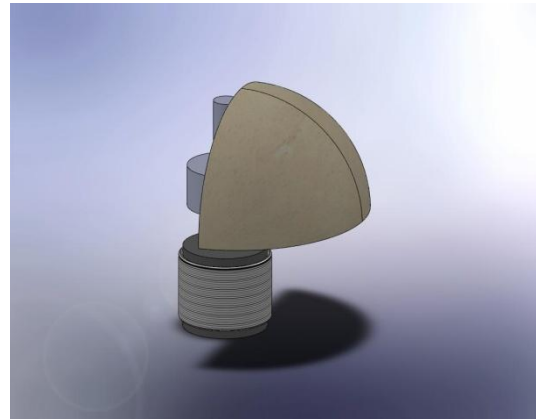


Figure 6: Solenoid closed eyelid position

Design 2: Linear Actuator

This design operates around a linear actuator located behind the eyelid. A linear actuator functions very similarly to a piston in a car engine. When a current is applied to the actuator, its piston moves rapidly up and down. This piston would be attached via an elastic or hinged connection to the rear of the eyelid much like the electromagnet design.

When the piston of the linear actuator is extended, the rear of the eyelid will be forced up, pivoting the eyelid on its hinge causing it to close. When the piston is retracted, the eyelid will be pulled with it and it will return to its open position.

This design has a few advantages, including the construction and circuitry aspects of the design. For this design, our group would simply have to order the actuator and connect it to the eyelid; all of the circuitry that regulates the piston movement is contained in the actuator.

However, this design has several disadvantages. Since our group is not capable of constructing this kind of actuator within a semester, it would need to be purchased, which would cost almost \$600. This price is also for the smallest model we could find, which still isn't small enough to fit in the orbital cavity. These drawbacks aside, if we were able to purchase a linear actuator at a reasonable price that was dimensioned to fit in the orbital cavity, we would still have to determine exactly how much current to apply to make the eyelid open and close at normal blinking speeds in a single iteration.

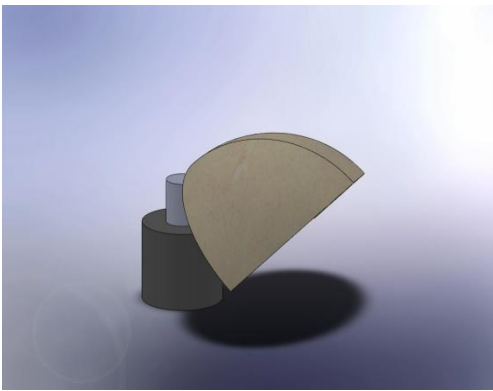


Figure 7: Linear Actuator open position

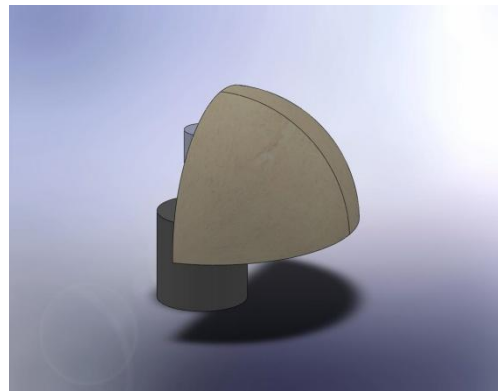


Figure 8: Linear Actuator closed position

Design 3: Belt/Motor

In our belt/motor design, the driving mechanism for movement is the motor located in the center of the base (shown in black in Figures 9 and 10 below). The base also includes four rollers (shown in green). When the motor is engaged in a clockwise direction, the belt that is wrapped around the motor and the rollers moves in a counterclockwise direction. When the motor is engaged in the counterclockwise direction, the belt moves in a clockwise direction. The movement of the belt in both cases is what causes the movement of the eyelid. When the belt moves in a clockwise direction, the elastic connection that is attached to both the belt and the eyelid moves with it, causing the eyelid to pivot and close. When the belt moves in a counterclockwise direction, the elastic connection moves with it and the eyelid pivots back to its initial open position.

Perhaps the greatest advantage to this design is that we would not be limited to only two positions of the eyelid. Rather than only having an open and closed position, we could half-close the eyelid, or keep it in a half closed position to simulate exhaustion. Another advantage to this design would be the ability to control the speed of the motor more easily than we would be able to control the speed of the actuators. By controlling the speed at which the motor revolves, we can control the speed at which the eye blinks. This would allow us to accurately simulate the speed of a normal blink as well as incorporate a fast or slow blink if we want to simulate excitement or exhaustion.

Despite the advantages this design offers in controllability, this model would be extremely hard to construct. The small scale of the project makes it extremely difficult to construct a base with rollers and a belt small enough to make this design feasible. There

would also need to be significant circuitry to attain the level of controllability that this design calls for, such as changing the direction and speed at which the motor operates.

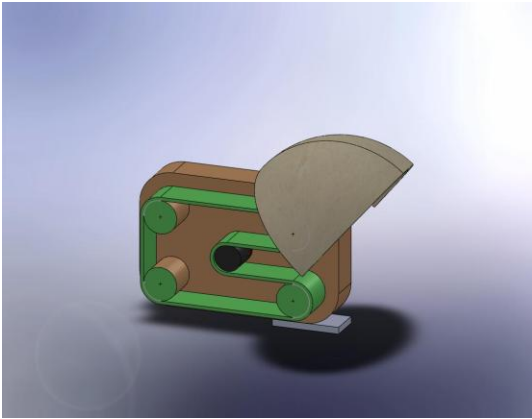


Figure 9: Belt/Motor open eyelid position

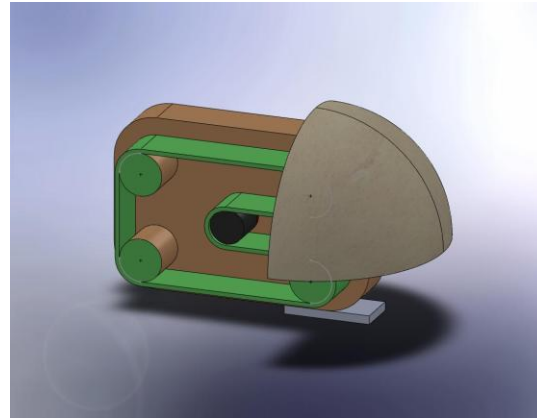


Figure 10: Belt/Motor closed eyelid position

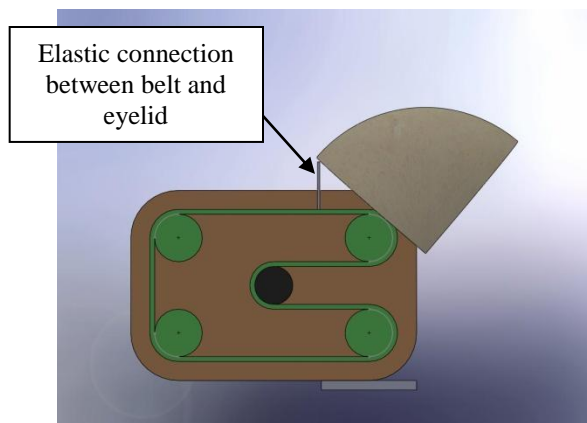


Figure 11: Belt/Motor side view. Open eyelid position shown.

Design Matrix

A design matrix was used to determine which design would be integrated into the design. Based on the client requirements and team goals, each design was rated in six categories. Categories were weighted, with more important criteria having a higher possible score. As seen in Table 1, the designs were rated on the level of noise produced,

extent of current control, size, safety, ease of manufacturing, and cost. Noise and cost, while important considerations, were not as much of a concern as the other criteria. These were each weighted as 10, with the remaining categories each worth 20, making the highest possible score 100. The electromagnet was rated highest in the noise category because it does not use a motor, which would create noise, and it also involves the least amount of contact between parts. For control of current, the linear and electromagnets were rated highly since current would only need to be in one direction and turned on and off, as opposed to the belt/motor design which would require an alternating current. Preliminary research showed that an electromagnet could be entirely self-contained within the orbital cavity, whereas the linear actuator and belt/motor would be much more bulky and require more space, which is why the electromagnet was rated higher in this category. Each design is safe – there would be no exposed wires or sharp points to pose a danger to the user of the prosthetic, so each design received the same score of 15. Since there is a limited amount of time for a prototype to be built, ease of manufacturing was weighted heavily. The simplicity of the designs was considered, resulting in the linear actuator being more highly rated than the other two designs. The belt/motor design is tremendously complex, with extensive circuitry involved, which is why it did not receive a high rating in this category. While cost is a factor, we have an adequate budget, so it was not weighted very heavily. Preliminary research on costs of design parts found that the linear actuator would be quite expensive, whereas the other two not nearly as much so. The electromagnet received the highest total rating of the three designs, so the design was progressed from this proposed design.

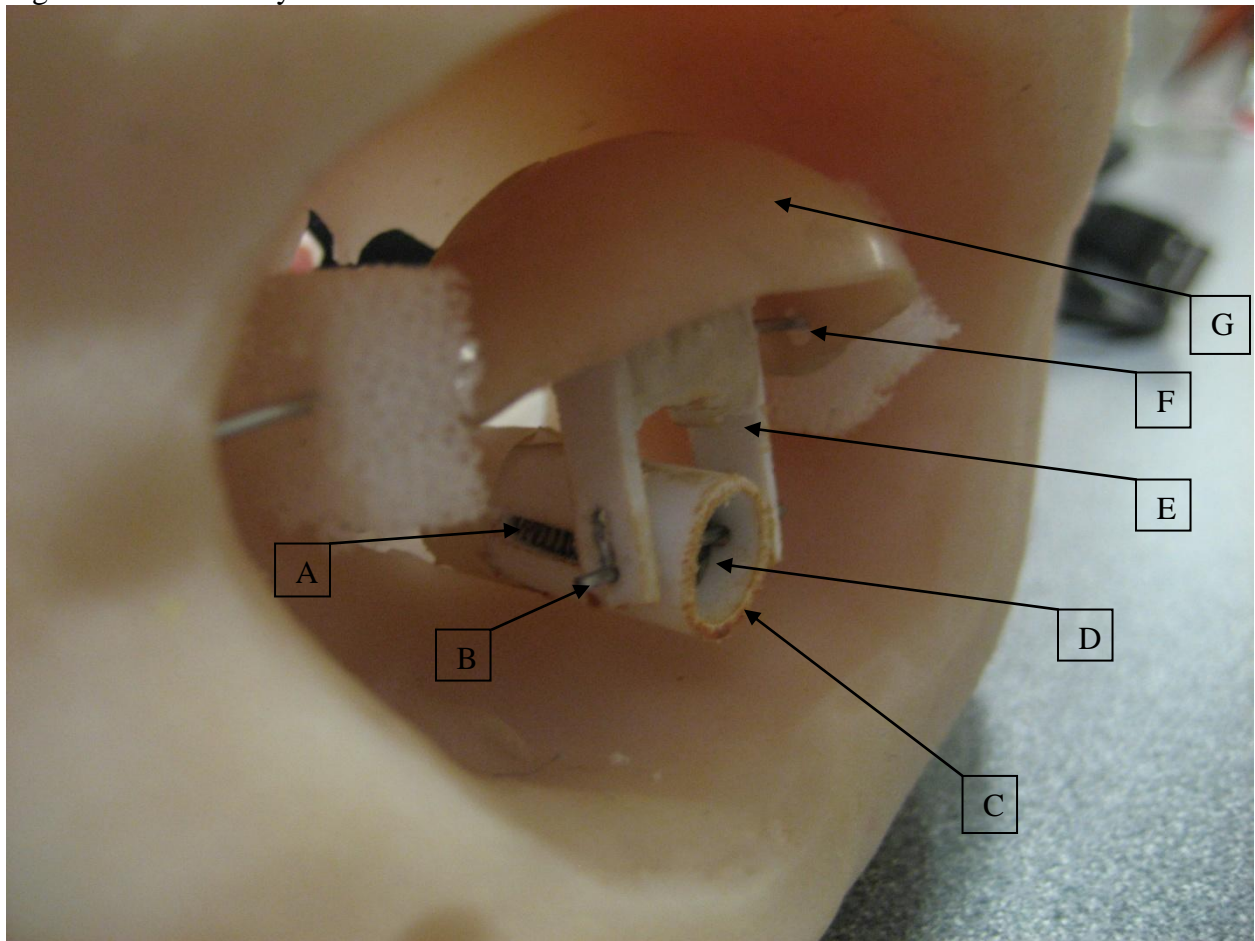
| Design | Noise (10) | Control of Current (20) | Size (20) | Safety (20) | Ease of Manufacturing (20) | Cost (10) | Totals |
|------------------------------|-----------------------|--|----------------------|------------------------|---|----------------------|---------------|
| Solenoid Actuator | 9 | 17 | 16 | 15 | 12 | 8 | 77 |
| Linear Actuator | 7 | 19 | 10 | 15 | 19 | 2 | 72 |
| Belt/Motor | 5 | 10 | 10 | 15 | 8 | 8 | 56 |

Table 1: Design Matrix

Final Design

The electromagnet was rated as the best design, and was integrated into the device. As a simple mechanism with several benefits, it was clearly the optimum design to use. The final prototype uses a solenoid – also correctly labeled as an electromagnet – to produce the blinking actuation. However, several changes were made to the proposed design. Initial testing of electromagnets revealed that a design in which the electromagnet attracted the magnet – as opposed to repelling it – would be preferred due to the magnet’s natural response of aligning its own magnetic field so as to be attracted to the electromagnet. To minimize the amount of space required for the mechanism, a lever system was employed to produce a mechanical amplifier. This means a small movement of the magnets due to the electromagnet creates a large movement of the eyelid. This was done using the design shown in figure 12.

Figure 12. Labeled Eye Mechanism



A: Slot of the magnet track. The spring can be seen through the slot.

B: Pin connecting the lever and the magnet track.

C: Magnet track

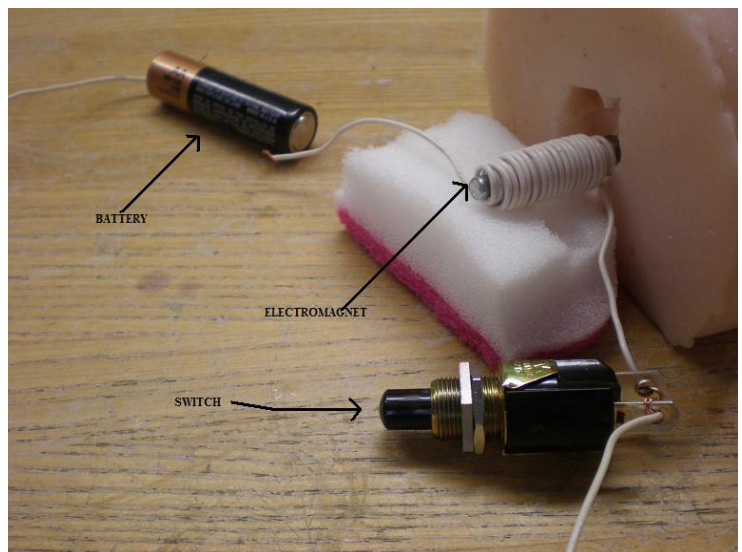
D: Magnet connected to the pin (not well visible)

E: Bar permanently connected to eyelid

F: Pivot around eyelid rotates to blink

G: Eyelid

First, the solenoid was rotated horizontally with its long axis pointing through the middle of the cavity. A plastic tube placed in front of the solenoid provided a track for the magnets to move through. A plastic bar



acting as the lever was attached to the tube via a small metal rod inserted through a slot cut into the tube. This rod is magnetically attached to the magnet and moves along with it. The lever runs from the front of the tube and extends to and connects with the back of the eyelid. A bar running through the sides of the eyelid and the lever acts as the pivot point about which the eyelid rotates.

Wire wrapped in a coil around an iron core makes up the electromagnet. The wire is connected in series to a battery and a standard switch. When the switch is pushed, current is turned on, creating the magnetic field in the electromagnet. This draws the magnet through the tube towards the electromagnet. The rod moves along the track with the magnet, which cause the lever to rotate about the pin acting as the pivot point. This causes the eyelid to close. When the switch is released, the magnetic field disappears, and a spring located between the solenoid and magnet cause the magnet to return to its original position, which opens the eyelid.

Conclusions and Future Work

There is still much work to be done before synchronized actuation with the patient's working eye can be achieved. The first improvement upon the current prototype that could be made would be to miniaturize the existing actuating mechanisms so that all of the components could fit within the cavity of the eye: a design specification. The current prototype has the electromagnet protruding from the back end of the silicone. Ideally, the electromagnet would be located in the posterior part of the cavity. To accomplish this, however, miniaturization of the electromagnet would have to occur while maintaining the magnetic field strength β of the electromagnet. This could be done

in several ways. According to Ampere's Law $\beta = \frac{k \times \mu_0 \times N \times I}{L}$, the strength of the magnetic field ' β ' produced by the electromagnet is proportional to the number of loops ' N ' the wire makes around the ferromagnetic core, the strength of the electric current ' I ' and the relative permeability, ' k ' of the ferromagnetic material being used. The relative permeability is the quantitative measurement of how conductive a material is to propagating a magnetic field and can range from the order of 100 to many hundreds of thousands for some of the most modernly created alloys. The magnetic field also inversely proportional to the length of the electromagnetic ' L .' μ_0 is a constant called the magnetic constant and is equal to $4\pi \times 10^{-7}$ T m/A. So, merely by changing any one of these parameters the magnetic field could be increased as the physical size of the electromagnet is decreased.

Alternatively, the force which the electromagnet exerts on the neodymium magnets can be changed apart from simply manipulating Ampere's Law and the magnetic field. As is apparent in the equation, $F = \frac{\beta^2 \times A}{2\mu_0}$, the force exerted by an electromagnet F can be manipulated by changing yet another parameter besides the strength of the magnetic field β . The cross-sectional area A of the electromagnet can be increased to increase force exerted. So, one could shorten the length of the electromagnet yet increase its cross-sectional area to fit it in the orbital cavity while still maintaining its ability to accelerate the neodymium magnets.

Further miniaturization of the internal actuating mechanisms could be done to provide even more space for the electromagnet. This group had difficulty reducing the size of the components used but is sure that miniaturization could occur via manufacturing processes.

After miniaturization, further work could be done on testing the angular velocity at which the prototype's eyelid actuates. This should be done in order to determine whether the velocity of the prototype's blink should be increased or decreased relative the data representing the actual velocity of a normal, spontaneous blink, or roughly $1700^\circ/\text{s}$. The blinking velocity of the prototype could then be increased or decreased accordingly by changing the parameters of the magnetic field as described above.

Finally, work could be done on synchronization of the blink of the prototype to that of the working eye. To accomplish synchronization of the blinks, one solution has been proposed by our client; an infrared signaler and infrared sensor would be placed on a pair of glasses. The patient would wear these glasses as well as a reflective contact lens in his/her functional eye. When the patient blinks, this infrared signal would be interrupted and this interruption would effectively act as the new "switch." This switch would then prompt the prosthetic insert to blink simultaneously with the patient's working eye.

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Appendix A: Product Design Specifications

Blinking Orbital Prosthesis

Client: Greg Gion

Advisor: Mitch Tyler

Team Members:

Andrew Bremer (BSAC)

Padraic Casserly (Team Leader)

Becca Clayman (Communicator)

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Problem Statement: When a patient has an orbital exenteration the large cavity is restored with an acrylic eye surrounded by a detailed but static silicone rubber restoration of the soft tissues (lids, etc). The PMMA eye is incorporated into the silicone part and the patient just places the entire unit in each day. It is retained with adhesive, osseointegrated percutaneous fixtures or by gentle anatomical fit. There seems to be adequate volume in a well lined cavity to house the needed mechanism for animation. The goal is to fabricate a patient simulator model with prosthesis that blinks, and a mechanism developed that would synchronize blinking with the working eye.

Client Requirements:

- Actuating mechanism is self – contained
- Contained sagittally between the lacrimal and the zygomatic bone and transversely between the maxilla and frontal bone1
- Mimics a typical spontaneous blink
- Not noticeably audible (less than 15 dB)
- Safe for use within orbital cavity
- Adequate budget available

Design Requirements:

A. Physical and Operational Characteristics

1. *Performance Requirements:* Mimic a typical spontaneous blink, where a “typical spontaneous blink” is defined by a change in amplitude of the eyelid of 10-mm at a velocity between 150 mm/sec and 350 mm/sec (1700°/sec)²

2. *Safety:* Must be safely contained in orbital cavity with no exposed wires or other materials that would interfere with existing human processes and a magnetic field strength of less than 3 mG³

3. *Accuracy and Reliability*: Produce a blinking motion that is 0.16-0.4 seconds in duration when prompted
4. *Life in Service*: Functional with single power supply for a full 15-hour day
5. *Shelf life*: The device should have a shelf life of 1 year
6. *Operating Environment*: Should be able to operate within orbital cavity while exposed to fluctuating conditions within and around the human body, including temperatures between -29° and 49°C
7. *Ergonomics*: The device should be manufactured to fit comfortably within the orbital cavity.
8. *Size*: Volume of orbital cavity varies between patients so device should be as small as possible in order to fit in a range of cavities, but should be no more than 3 cm in diameter.
9. *Mass*: The device should be no more than 60 grams, but additional weight may be added if external components are included (i.e. eyeglasses).
10. *Materials*: The portion of the device in contact with the skin is primarily composed of silicone and should not cause irritation, as shouldn't the other materials comprising the device.
11. *Aesthetics, Appearance and Finish*: The device should mimic as closely as possible a normal human eye.

B. Product Characteristics

1. *Quantity*: Only one prototype required, but should have the ability to be included in custom made orbital prostheses.
2. *Target Product Cost*: Less than \$2,000.

C. Miscellaneous

1. *Standards and Specifications*: FDA approval is required
2. *Customer*: Customer would like a comfortable, non-invasive device
3. *Competition*: There is little to no competition, as no current patents exist and no attempts are being made for non-invasive methods

Appendix B: Calculations

Solenoid Magnetic Field Strength

$\beta = \frac{5000\mu_0 \times N \times I}{L}$ where β is magnetic field (measured in Tesla, T), μ_0 is the magnetic constant (measured in $\frac{N}{m^2}$), 5000 is relative permeability of magnetic iron which can be assumed to be of the same relative permeability as the steel rod, N is the number of coils, L is the length of the steel rod around which the coil wraps (measured in meters), and I is the current running through the wire (measured in Amperes).

$$\beta = \frac{(5000)4\pi \times 10^{-7} \left[\frac{N}{m^2} \right] \times 55 \times 0.01 [A]}{.0325 [m]} = 0.1063 \text{ T}$$

Force Exerted by Magnetic Field

$F = \frac{\beta^2 \times A}{2\mu_0}$ where β is magnetic field, A is the cross-sectional area of the rod, and μ_0 is the magnetic constant

$$F = \frac{0.1063^2 \left[\frac{kg^2}{A^2} \right] \times 1.59 \times 10^{-5} [m^2]}{(2)4\pi \times 10^{-7} \left[\frac{N}{m^2} \right]} = 0.0715 \text{ N}$$