

Blinking orbital prosthesis

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Abstract

The goal of this project is to create a mechanism which allows an orbital prosthesis to blink. Currently, orbital prostheses do not blink. Although the prosthesis allows the patient to look more like themselves again, it never looks completely normal because it does not blink. Through this project, we hope to create an orbital prosthesis that would improve the quality of life of the patient and develop more interest in the topic. We want to make something that other students or researchers can use as a basis for more development. Two parts of this project include the use of a sensor for an automated system and the mechanism for movement of the eyelid. Due to the brevity of the semester, we will focus on the eyelid mechanism. We will, however, continue to research the sensor because we feel it is key to the future success of this product.

Problem Statement

When someone's eye is enucleated, it usually occurs unexpectedly. This can for obvious reasons be a traumatizing experience. Anything that can be done to help that person feel whole again is desirable. The proposed blinking orbital prosthesis will be designed to display a natural looking blink in sync with the functional orbital. The design must be small enough to fit inside the orbital as well as not too heavy as to cause discomfort to the user. In addition, the eyelid must blink at the same speed as the other functional eye and ideally produce no noise. None of the materials used can be harmful to a human being especially because their positions will be so near to the brain. Lastly, the design should require no manual work from the user. Combined, all of these specifications should create a product that operates smoothly and effectively.

Background Information

Problem motivation

Every day in the world, accidents occur that leave patients with a gap in their skull instead of an eye. Some resort to old-fashioned methods such as eye patches; however, many others prefer a much more functional option. Orbital prostheses provide an option for a more realistic look. Although these prosthetics look very life-like, their inability to blink hinders the overall effect. Many patients resort to wearing dark-tinted glasses in order to cover this up. The final design for this project should allow for a blinking orbital prosthesis that will use motion sensors in order to detect the natural blinking motions of the real eye. This will make the prosthetic more realistic and less detectable. Each mechanism created would have to be customized for each individual situation. With more life-like function, patients will be able to have a nearly untraceable prosthesis.

Prostheses

A prosthesis is a device that artificially replaces a missing body part or organ in an attempt to impart a more natural look. Prostheses (the plural of prosthesis) are usually employed when a person has lost body parts as a result of injury or due to a congenital defect. Most prostheses are made from silicone or PVC because of the life-like qualities that these materials impart (Figure 1). In particular, orbital prostheses are used when a person has lost an eyeball due to tragic circumstances. It should be noted that orbital prostheses do not serve the same function as an eye and in no way is the patient able to see through the prosthesis as if it were an eye.



Figure 1: An orbital prosthesis made from medical silicone. The incredible realism of the prosthesis can clearly be seen.

Design constraints

The amount of space to work within the orbital cavity will be very limited: almost 1 inch³. Hence, the mechanism controlling the motion of the eyelids will have to be contained in this space. The device must also operate properly at 98.6°F and standard pressure. In addition, the motion sensor unit will have to be small enough to fit onto a pair of standard glasses in order to preserve the life-like effect.

Previous/Current device

According to our client Greg Gion, several devices of this nature have been attempted in the past using a wire running from the contralateral eye muscle of the working eye into the orbital prosthesis. This is a very invasive and complex approach to the problem. Our client would like to see a non-invasive solution using motion sensors. He currently does not use an orbital prosthesis capable of blinking.

Team Goals

Our goal is to design and create an actual size working, blinking orbital prosthesis. This design must accurately and reliably provide a blink that is realistic and believable. In addition, the overall cost must be under \$1000.

Competition

There is little to no competition for the device being developed. Most of the progress being made in the field of orbital prosthetics involves making the orbital move on a 2-dimensional axis (up-down, left-right), and as such blinking is not high on the list of priorities. Nonetheless, our design may be patented at a future date.

Alternative Design Descriptions

While brainstorming potential design ideas there were two major factors taken into account: the client's requirements and the amount of usable space located in the eye cavity. Though the client's requirements were flexible and easy to work around, the small dimensions of the cavity proved to be a major stumbling stone. The initial brainstorming sessions allowed produced several conclusions, most notably the fact that some sort of electrical impulse would be needed to make the eyelid blink. From this basic train of thought four designs were developed including closing the eyelid using actuator an actuator, generating a repelling magnetic field to close the eyelid, producing an attracting magnetic field to keep the eyelid open, and using a memory metal circuit to close the eyelid.

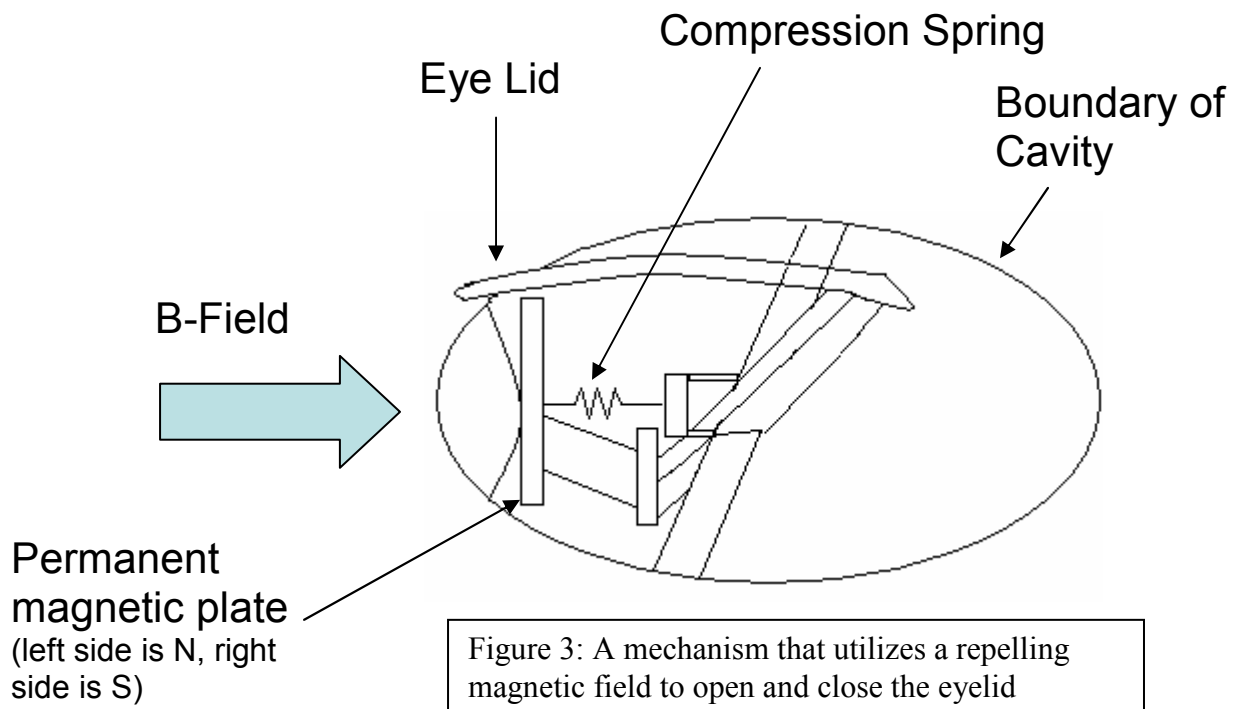
Actuator movement

The first solution presented is an actuator connected to an op amp that would drive the eyelid up and down, causing a blink to occur. The op amp's input will be received from two electrodes connected to the contralateral eye muscle, with an addition electrode used as a reference, effectively creating a differential amplifier. This design has several advantages, the most notable being the fact that that it will work regardless of the environment outside the eye (i.e. in front of the face). This is important in situations like poor weather, or under certain research conditions. This design is also very durable and will continue to work when under significant stress. This solution does have several major flaws, however. First and foremost, this design is highly invasive, needing the electrodes to be surgically implanted into the patient's nerve, which will also necessitate that the device be permanently implanted. Finally, the components take up

large quantities of space the largest of which is the power source, which must be located in the cavity to power the op amp.

Repelling magnetic field

The second idea offered utilizes a repelling magnetic field to close the eyelid (Figure 3). The magnetic field (often referred to as a B-field) is generated by the glasses frame in front of the prosthetic eye, located outside the cavity. The glasses use several coils of wire to effectually create a solenoid, whose magnetic field is used to repel a permanent magnetic plate. The magnetic plate is located behind the globe, connected to a compression spring that will return the plate to its initial position after the magnetic field has been turned off. The initial motion of the plate will cause the eyelid to close, while the returning motion will cause the eyelid to open back up. This design is extremely non-intrusive, and the power source is located outside the eye cavity, allowing more space to be used by the mechanism. In addition, power is only required when the eye blinks, which makes the device more economical and reliable.



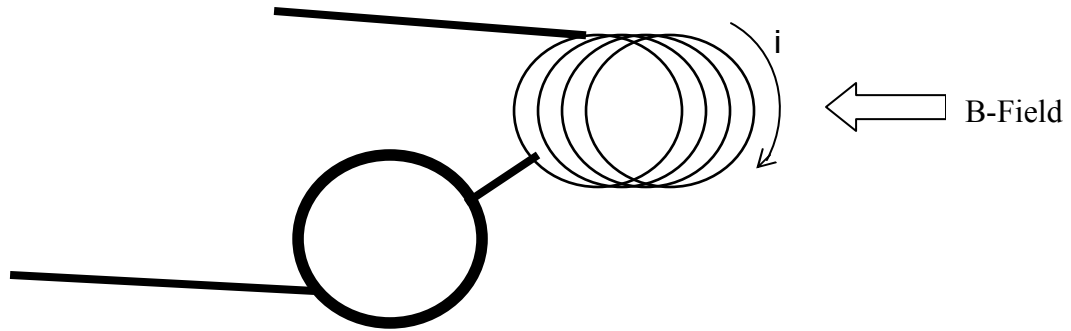


Figure 4: The glasses that produce the magnetic field as indicated. The left smaller circles represent the coils of the solenoid, with i representing the current.

Attracting magnetic field

The third idea offered is very similar to the second design, but instead uses an attractive magnetic field to keep the eyelid open (Figure 5). This design also uses the glasses to generate a magnetic field, whose direction is identical to the repelling magnetic field (Figure 4). In this design, the magnetic plate polarity is opposite that of the second design, and is connected to a tensile spring that keeps the eyelid closed. The magnetic field attracts the plate, opening the eyelid. The nature of this design necessitates that the magnetic fields default state be turned on and turned off when a blink occurs. Turning of the magnetic field causes the tensile spring to return to its unstretched length, opening the eyelid. This design has all the advantages of the previous design, and even generates a faster blink, but it has one major disadvantage. Power is being constantly consumed, necessitating that the power source be frequently changed.

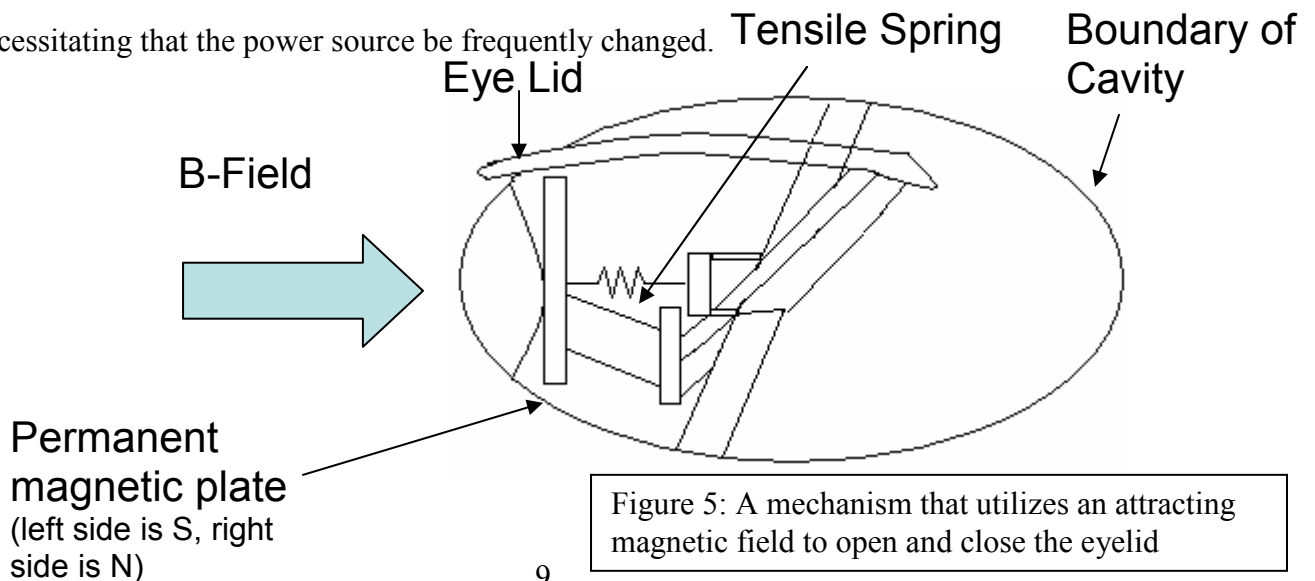


Figure 5: A mechanism that utilizes an attracting magnetic field to open and close the eyelid

Memory Metal Circuit

Initial research procured an additional design idea that involved using a memory metal circuit to initiate a blink in the eyelid. The basic concept behind memory metal, the fact that it reforms to an initial shape after heat is applied, is used in conjunction with current supplied from a power source. The memory metal's heated shape would connect to other parts of the circuit, allowing current to travel to previously inaccessible areas. Eventually, the memory metal could even be used to physically push the eyelid closed and then relaxed to open it back up again. This design has one major advantage over all the others in that it could be designed to be very space efficient, because the memory metal can be easily collapsed into many different shapes. However, heating the wire to the point where it would cause the memory metal to return to its initial state would require a large current. The memory metal circuit would need to be entirely self-contained within the eye cavity, and as such a large current would be very dangerous. Finally, extensive circuit engineering would be required, and the time frame of the project does not allow for such a design to be developed.

Design Matrix

The design matrix included all four designs to make the orbital prosthesis blink (Table 1). These ideas include the actuator, repelling magnetic field, attracting magnetic field, and a memory metal circuit. The designs were evaluated using five criteria: “feasibility”, “durability”, “reliability”, “cost effectiveness”, and “safety”. These were weighted 33%, 25%, 25%, 15%, and 5%, respectively. The “safety” category was given only 5% because of the inherent nature of our project; either it will be deadly or it will not. In addition, the client does not want to test the prototype on humans. The design decided upon, the repelling magnetic field, was rated highest in feasibility, reliability, cost effectiveness and safety. The repelling magnetic field was rated higher than the attracting magnetic field under reliability because it draws power only when a blink is occurring. The attracting magnetic field was rated high under durability because it uses a tensile spring, which is inherently more durable than a compression spring.

	Feasibility (1-30)	Durability(1-25)	Reliability (1-25)	Cost Effectiveness (1-15)	Safety (1-5)	Total (100)
Actuator movement	15	20	22	3	3	63
Repelling B-field	25	18	20	12	3	78
Attracting B-field	25	19	18	12	3	77
Memory Metal circuit	5	10	12	8	1	35

Table 1: Design matrix that indicates the scoring of the possible designs. The highlighted design achieved the highest score, and is the final design.

Proposed Design

After completing the design matrix, the repelling magnetic field was determined to be the best design. This design uses a magnetic field produced from a solenoid-like electromagnet located in the glasses from in front of the prosthesis. The glasses frame, and hence the solenoid turns, are approximately 2.5 cm from the back of the globe (the part of the prosthesis mimicking the front of the eyeball). A magnetically permanent plate (i.e. clearly defined North and South poles that cannot change) will be located at this position in a grooved tract. This plate will be attached in 3 places to two separate components. The first attachment is a compression spring, which is in turn connected to a static platform. The magnetic plate is also attached to plastic rods, which are at a -45° angle from the horizontal, and attached to a paddle (Figure 6). This paddle is connected to the eyelid via a different plastic rod roughly 2 cm in length. This rod is free to rotate around a cross bar spanning the length of the cavity.

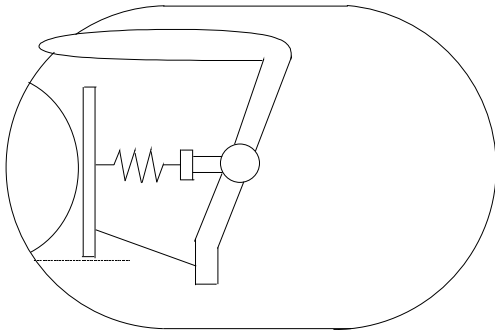


Figure 6: A side view of the mechanism allowing a blink to occur

When the magnetic field is turned on (by allowing current to flow through the wire) the magnetic plate will be forced back by a repulsive magnetic force. This motion will cause the plastic rods to push the paddle back, which will in turn rotate the rod causing the eyelid to drop down. This is the first part of the blink; the eyelid is now down. Once the

magnetic field is turned off the compression spring will force the magnetic plate to its former position, initiating the reverse process. The rods will be pulled back, forcing the eyelid up and completing the second part of the blink.

This design uses the maximum amount of space located in the eye cavity without overcrowding the usable space. One of its greatest advantages is that the power source is located outside the cavity, which is both safe for the patient and makes changing a full power source for a depleted one easy. This design also produces a very realistic blink, with a casual observer being completely unable to necessary process behind it. This design does have several possible problems, however.

The relatively large distance between the solenoid and the magnetic plate necessitates that a large magnetic field be produced in order to supply a sufficient magnetic force to push the magnetic plate back. Generating a larger magnetic field means that a higher current must be supplied to the coils, and the higher the current the more deadly it becomes. Another possible flaw is that the device will not work without the glasses. If for whatever reason the patient does not have the glasses on, the magnetic force will not reach the orbital and the blink will not occur.

Future Work and Conclusions

For the rest of the semester we will be focusing on fabricating a working prototype of our blinking orbital prosthesis. Also, we will be contacting professors and researchers for their input during the manufacturing process. By doing so, we hope to gain further insight on possible improvement that we will incorporate into the mechanism. We have adequate resources and budget to incorporate all of the parts into

the orbital prosthesis. After the semester is over, we hope that future teams will continue working on a blinking orbital prosthesis. However, for now we will concentrate on gathering all of our needed materials and calculations we will need before we can start fabrication. With our finished product, the next step along the design process would be to incorporate infrared sensors to detect a blink from the functioning eye and relay that information to the circuit controlling the magnetic field.

Appendix A: Product Design Specifications

Product Design Specification for BME 201 Group 19: Blinking Orbital Prosthesis

(As of March 11, 2008)

Group Members: Hallie Kreitlow, Joel Gaston, Allison McArton, and Ryan Kimmel

Function

The focus of this project is to design an animated orbital prosthesis. Currently, few attempts have been made to create a mechanism that allows the prosthesis to blink. The method previously used was running a wire from the contralateral eye muscle into the orbital prosthesis, causing the eye to blink with the contralateral impulse. Our team is to design and fabricate a model simulator with a prosthesis that blinks. The device used for animation must be small enough to fit inside the eye cavity, as well as contain all parts needed for operation.

Client Requirements

- Impart life-like quality to a variety of materials
- Thin materials to save weight and space
- Motion sensor housed in glasses to detect a blink
- Synchronization could and should be considered later
- We are provided with an “adequate” budget

Design Requirements

According to the client, the cavity has about 20 to 30 cubic centimeters, which is adequate volume in a well-lined cavity to house the needed mechanism for animation. An acrylic

eye surrounded by a detailed but static silicone rubber restoration of the soft tissues must still be able to fit inside the eye cavity. The prosthesis will be retained with adhesive, osseointegrated percutaneous fixtures or by gentle anatomical fit. The typical orbital prosthesis is a softer medical silicone rubber about 1 to 5 Shore A hardness so as not to harm delicate thin skin lining the exenteration cavity, so we must maintain similar properties.

Patient application is not required, for the sole purpose of this project is to develop ideas that could evolve into a fully functional product. Therefore, it does not need to be aesthetically pleasing. The prosthesis must be light enough to avoid cumbersome properties. It must be able to function for an entire day, but it will be removed at night.

1. Physical and Operational Characteristics

a. Performance Requirements

The prosthesis is meant to resemble a naturally blinking eye.

b. Safety

The prosthesis must be able to be easily removed at night. The prosthesis might need to be housed in polyurethane or a similar material to protect the patient from air, rain, and other elements. Also, we need to make certain that the materials don't interfere with normal brain and organ functions.

c. Accuracy and Reliability

This device will be used daily by the patient, so it must be easily removed. It must be able to withstand normal wear and tear. It also must be removed for cleaning and comfort reasons. Finally, it must be accurate enough to resemble a naturally blinking eye.

d. Life in Service

The main factor limiting the life of this prosthesis is the battery. However, this can easily be replaced. Also, the main components related to animation will be outside of the eye cavity, so they could also be repaired.

e. Shelf Life

The client expects the product to last for 2-5 years.

f. Operating Environment

The device must be able to operate at body temperature, which is normally 98.6 degrees Fahrenheit. It must also operate at atmospheric pressure.

g. Ergonomics

This device does not promote enhanced efficiency. Instead, it is merely to add realistic features to a prosthetic eye.

h. Size

The diameter of the globe will be about 25mm. The eyeglasses will be of standard size.

i. Weight

A normal globe weighs 30 grams, but the weight of this globe should exceed 60 grams. Also, with the implementation of eyeglasses with its added components should add at most 200 grams. Weight should be kept down, be if it is too heavy, it will be uncomfortable.

j. Materials

The orbital prosthesis will be made out of softer medical silicone rubber. PMMA will be used to mold the eyelid.

k. Aesthetics, Appearance, and Finish

The client does not request for the device to be aesthetically pleasing.

2. Production Characteristics

a. Quantity

Since there has never been a blinking orbital prosthesis in production, there will not be a considerable demand for them. However, if this product were to gain FDA approval, people would gain an interest in it.

b. Target Product Cost

The cost of all of the materials will total between \$500 and \$1000. Insurance wouldn't fully cover this type of product, so the price could be up \$3000 over a basic orbital prosthesis. Therefore, the price could range from \$4000 to \$7000.

3. Miscellaneous

a. Standards and Specifications

A blinking orbital prosthesis has never gained FDA approval. Therefore, we will be working with a prototype while keeping aware of possible approval qualities.

b. Customer

The purpose of this device is to conceal any human imperfections. The customer base would include people seeking a more realistic appearance, even though this device has no major advantages over a basic non-blinking orbital prosthesis.

c. Patient-Related Concerns

Lowering material costs will make this device more affordable. Also, it must be able to withstand daily wear and tear.

d. Competition

Currently, few methods are being used to manufacture a blinking orbital prosthesis. Some companies have an interest in making robotic eyes involving infrared sensors.

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