Blinking Orbital Prosthesis

Client: Gregory G. Gion, MMS, CCA
Medical Arts Prosthetics

Advisor: Professor Thomas Yen, PhD
University of Wisconsin - Madison

Leader: Bret Olson

Communicator: Justin Cacciatore

BWIG: Michael Konrath

BSAC: Blake Marzella

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Abstract

At the Medical Art Prosthetics Clinic in Madison, Greg Gion and his associates make prosthetics for those who have lost their eyes due to an accident, disease, or genetic disorder. Mr. Gion's goal is to help the thousands of people who have an absence of facial tissue by restoring their appearance and giving them greater self confidence. The problem with the current prosthetics is that they are completely static, which makes them quite noticeable to the casual observer. Our goal for this project is to create a prosthetic eye that has the ability to blink, and therefore enhances the realism of the prosthesis as a whole. Through our research, we were able to incorporate the function of the actual human eye muscles and a few existing designs to develop an effective prototype.

Introduction

A prosthetic is a medically fabricated device that serves as an extension or replacement of a damaged body part in order to restore functionality and provide the user with a more natural appearance [1]. In the event where an individual experiences the loss or surgical removal of an eye due to an injury, genetic defect, or disease, the use of an orbital prosthesis restores the individual's natural appearance (Figure 1). However, while the current orbital prosthetics promote an overall sense of restoration and realism, the prosthetics lack the ability to simulate a human blink. It is this static nature which prevents an orbital device from completely restoring an individual's appearance. We intend to design a mechanism that will allow for an orbital prosthetic to blink in order to provide the appearance of functionality of a natural eye in conjunction with the already realistic static appearance.

Figure 1: Actual Medical Arts Prosthetics Clinic Patient
http://www.medicalartprosthetics.com

Background

The development of an orbital prosthesis is regarded as both an art and a science, referred to as anaplastology[2]. Each prosthesis must be custom made in order to provide the most realistic and life-like appearance. As such, variances such as the individual's skin tone, direction of skin folds, skin texture, facial proportions and anatomical landmarks must all be taken into consideration[2]. The overall surface area of the prosthesis must also be taken into consideration. For example, some individuals may experience the surgical removal of larger regions than just the eye; regions such as the eyebrow, portions of the nose as well as parts of one's cheek[1]. As a result, an orbital prosthesis may include extensions to satisfy these areas, affecting the aesthetic appearance. Great artistic skill is required in order to provide a prosthesis that smoothly transitions from the organic tissue to the prosthetic material. These skills also aid in the development of the prosthetic eye which must match its real equivalent in size, shape, shading, and coloration. In order to satisfy the need for a natural prosthesis, these devices are commonly made out of PMMA, or poly methyl methacrylate, and silicone[1]. The silicone composes the fleshy portions of the prosthesis while the eye is composed of PMMA. A prosthesis typically lasts an individual for upwards of two years and commonly needs to be replaced due to color degradation and user wear and tear. Consistent cleaning and maintenance as well as the use of sunglasses to slow the color degradation from UV radiation exposure can extend the life of an orbital prosthesis [2].

The making of an individual prosthesis commonly begins by taking molded impressions of the empty orbital cavity. This is done in order to accurately record the anatomical features of the cavity which provide the basis for the development of the prosthesis [2]. From this mold, a wax prototype is created and sculpted. This is done in the presence of the patient in order to integrate the patient's opinion into the prosthetic's development[1]. Once a wax prototype is accurately made which satisfies the client's needs, pictures are taken of the client's skin surrounding the orbital cavity in order to assist in the development of prosthesis' color tone. At this point, a prosthesis is made out of PMMA and silicone and placed on the client. Here, meticulous details such as freckles, blood vessels in the eye, hair, and the skin folds are made by hand to help provide a more natural transition from the surrounding tissue to the prosthetic material [1] (Figure 2). From this, the final prosthesis is made and delivered to the client.

Figure 2: Development of realistic prosthetic eye
http://www.medicalartprosthetics.com

Problem Statement

People of any age or gender may experience the surgical removal of an eye due to an injury, genetic defect, or disease. The use of an orbital prosthetic allows these individuals to gain a sense of self-confidence and a more positive self-image. However, while prosthetics have been developed to create an incredibly realistic and aesthetically pleasing orbital device, they have failed to provide the appearance of functionality of a real eye. That is, the prosthetics are static and cannot blink. This is illustrated in Figure 3 as the eyelids of the prosthetic remain in the same position even when the eye is removed. Our client desires for us to devise a mechanism which would allow for a prosthetic eye to blink. This mechanism will be used as a model in presentations to illustrate the blinking mechanism's effectiveness and potential for further development. As such, our design does not have to meet the requirements for direct use for a client. However, we intend to expand upon our client's original goal and look forward toward the implementation of our mechanism into an actual orbital device. That is, we aim to meet some of the basic requirements for function in an actual orbital prosthesis through the development of our blinking mechanism. It is our hope that by doing so, our blinking mechanism can easily transform from a working theory to the actual implementation of our design for an individual's use in a prosthetic. Only by developing a mechanism through which an orbital prosthesis can blink can the steps toward developing a complete orbital prosthesis, one that includes both a natural appearance and the appearance of functionality, be undertaken.

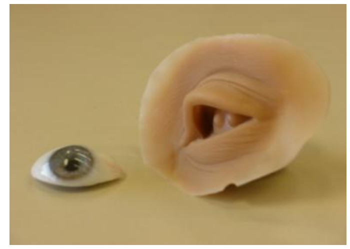


Figure 3: Current prosthetic eye, showing the acrylic eyepiece and PMMA material separately.

Problem Overview

In order to provide individuals who have undergone the total surgical removal of an eye a complete orbital prosthesis, we intend to develop a mechanism which would allow a prosthetic eye to blink. Our client's main focus is to develop a mechanism that can be used in presentations to demonstrate our design's potential for further development. However, we are taking into consideration the constraints and environment our mechanism would be exposed to should it be developed into an actual prosthesis. We hope that by doing so, we can facilitate a smoother transition from a presentation model to an implantable blinking prosthetic eye. In order to create such a mechanism, it is imperative that we research the blinking mechanism of a normal human eye. Our mechanism must be able to successfully recreate both the normal blink of a human eye and its consistent performance throughout the day. We must also consider how our mechanism is to be powered and how this power option could the affect the development of a later prosthetic prototype.

Problem Motivation

People who experience damage to an eye due to trauma, birth defect or disease have two options considering an orbital prosthesis. If only the eye is damaged, an ocular prosthesis is used. However, if there is damage to the surrounding area, such as the eye lids or orbit, an orbital prosthesis must be used. Patients who receive an orbital prosthesis do so to retain a normal appearance. Ideally, these patients could live their lives and the people they encounter on a daily basis would never know they had a prosthetic orbital device [1]. Anaplastolgists are able to create a prosthesis that looks nearly identical to a human eye. However, there are factors that limit the realism of their creations. One of those limitations is the prosthetic's static nature. No matter how realistic a prosthesis looks, it may become noticeable when the prosthetic eye fails to blink. Our motivation for this project is to give back a sense of normalcy to these patients.

Design Constraints

There are essentially two sets of constraints for our design project. The first set of constraints concerns our final goal of creating an implantable blinking orbital prosthesis. Though this is not our primary goal, we are designing our device with these final constraints in mind. Most obviously, the eye must be able to blink. It must also be able to do so at a speed as close as possible to the actual speed of a blink, a rate of 200-300 milliseconds per blink. Since this would actually be implanted into a person, there are size constraints. Each prosthesis is a different size depending on the patient, so this design would need to fit in about the size of the human eyeball, which has a diameter of about 25-29mm in order to accommodate all of them. The prosthesis would have to be comfortable for the patients to wear on a nearly daily basis. This means the design would have to be silent, not produce vibrations and relatively lightweight, all of which would be bothersome for the patient. Most importantly, the design would have to be safe. There would have to be no chance of electrical shock. Materials used would have to be bio-compatible and non-allergenic and the prosthesis would need to be easily sanitized to avoid complications such as infection. Current orbital prostheses already need to be replaced occasionally due to growth of the patient or wear [1]. Ideally this design would last as long as the rest of the prosthesis. We decided that a lifetime of a year, with only minor maintenance, would be reasonable. To achieve maximum realism, the prosthesis would need to blink synchronized with the real eye. It would also need to do so reliably without failure.

Our primary set of constraints concerns the creation of a model to be used for demonstrations. Therefore, these constraints focus only on the mechanical aspects of our blinking mechanism. Our model will have to be able to blink upon request. If the demonstration fails even once or breaks, the quality of the design will be questioned. Our design must also be safe for the demonstrator to use. We will also be trying to keep our design as small and fast as possible.

Current Devices

Currently, there are no blinking orbital prostheses on the market due to the fact that current orbital prostheses are completely static. There are many different ways that the current static prostheses can be attached. Osseointegration is one such attachment process where the prosthesis is surgically attached to the bone of the patient. Another is the use of a pair of magnets that can be attached to the bone as well as the prosthesis. Finally, the prosthesis can just be attached using adhesives[1].

Our group took inspiration from current devices which aid in the blinking function of patients with intact eyes. These devices are used to help patients with muscle paralysis, a condition that prevents these individuals from blinking normally. This is done for cosmetic, but more importantly, functional purposes as well. Since the patients still has a working eye, they still need to blink in order to lubricate the eye. Our blinking orbital prosthesis would only need to blink for cosmetic reasons as an artificial eye would have no need for lubrication. The technique that is most similar to our project is research being done using EPAM (electroactive polymer artificial muscle). Researchers in California have been working on using EPAM to close the eyelid and the use of sling to open the eyelid. At least one patient has had this EPAM technology successfully implanted [3],[4]. Another device called the Arion sling has been used in the past to treat ptosis, a condition occurring when the eyelid sags lower than it should [5]. Other methods, which are used to treat paralytic lagophthalmos, include the use of implantable gold weights and palpebral springs. Gold weights, which are used much more commonly, are gold implants that weigh the eyelid down due to gravity, but are light enough where the patient can still open their eyelid using their own muscles. Palpebral springs work in a similar fashion, only instead of relying on gravity, the force of a torsion spring closes the eye. The palpebral spring is rarely used as it is more invasive than the gold weight implant, but is favored by some since it doesn't depend on gravity [6]. While these designs aren't used in orbital prostheses, there is some potential for the incorporation of these concepts into the development of our blinking mechanism.

Our group also considered the designs of three previous BME design groups who worked on this project. The group in the fall 2009 semester created a prototype with a pneumatic mechanism. The upper eyelid, made out of PMMA, was hinged to a rod and held in the open position due to a counterweight. The user would then squeeze an air bulb which was attached to a catheter which led to the eye. When the bulb was squeezed, a balloon at the end of the catheter would inflate and lift the counterweight caused the eyelid to drop to the closed position. When the bulb was released, the balloon would deflate allowing the counterweight to reopen the eye. We close to not continue with their design for a couple of reasons. First of all, since the goal of an orbital prosthesis is realism, we wanted the blinking and eyelids to look as realistic as possible. The rigidness of the PMMA coupled with the mechanical look of the blink made the prosthesis look less realistic than we desired. The speed of the blink was slower than we wanted, again causing the prosthesis to be unrealistic. Also, we found their prototype to be a little too delicate and unreliable. Some additional tinkering may have fixed these issues, but we wanted to avoid the additional complications if possible. Finally, since the ideal blinking orbital prosthesis would blink synchronized with the real eye, we wanted a design that could accommodate this in the future. Since this design needed the user to actuate it, there would be no way to automatically synchronize blinks with the other eye.

The fall 2008 group's design relied on magnetism. An electromagnet would attract neodymium magnets which were contained in a slotted tube when you applied current. When attracted to the electromagnet, the neodymium magnets would pull two rods connected to the upper eyelid through the slots in the tube. This would cause the hinged eyelid to move down to the closed position. When the current was turned off, the electromagnet would no longer attract the neodymium magnets and a spring between them would force the neodymium magnets back down the tube again moving the rods and this time lifting the eyelid to the open position. We also chose not to continue this design for various reasons. First and foremost, the prototype is no longer intact so we were unable to gauge its performance. When researching electromagnets in the early stages of our design process we found both their attractive and repelling forces to be disappointing. This design also uses PMMA lids giving it the same rigid and mechanical look.

The spring 2008 group's design was powered by a motor. Blades on the motor would strike rods on the back of the eyelid as the rotor of the motor turned. The rods were positioned so that one would be forced upward when struck causing the eyelid to rotate on a hinge and close and the other forced downward causing the eye to open. While our final design also uses a motor, we did not continue with this groups design. Again, the prototype was no longer intact so we were unable to gauge its performance. This design also uses PMMA lids and would have a more mechanical look than we would like. All three designs had this in common and we really wanted our design to blink more fluidly like the real eye. We also want our design to be highly adaptable to future technological improvements, something we didn't see in these designs.

Competition

While there are is no current blinking orbital prosthesis, there is still competition for our design. That competition is the current non-blinking orbital prosthesis. Even though the patients who use an orbital prosthesis do so for realism, they may not always want a more realistic blinking prosthesis for a few reasons. The biggest reason would be cost. A blinking orbital prosthesis will always be more expensive than a non-blinking orbital prosthesis since the blinking prosthesis would contain all of the same parts as the non-blinking prosthesis as well as the parts of the additional blinking apparatus. Therefore, it is important for us to keep costs low enough to where it would be reasonable for a significant portion of the candidates to choose a blinking prosthesis over the static one.

The comfort constraint plays an important role here, as any noise, vibration or weight problems would give the patient a reason to not want a blinking prosthesis. Also, our design would potentially require additional maintenance, such as routine battery changes and mechanics servicing. We must always consider the balance of the added benefits of a blinking orbital prosthesis with any extra hassle it may bring to the user.

Potential Designs

The first two of our three preliminary designs (*servo & memory shape*), and possibly the third (*EPAM*) use the same machinery to force the prosthetic eye to blink. The designs differ only in the way that they are powered. We call this shared method the *embedded cord tension mechanism.*

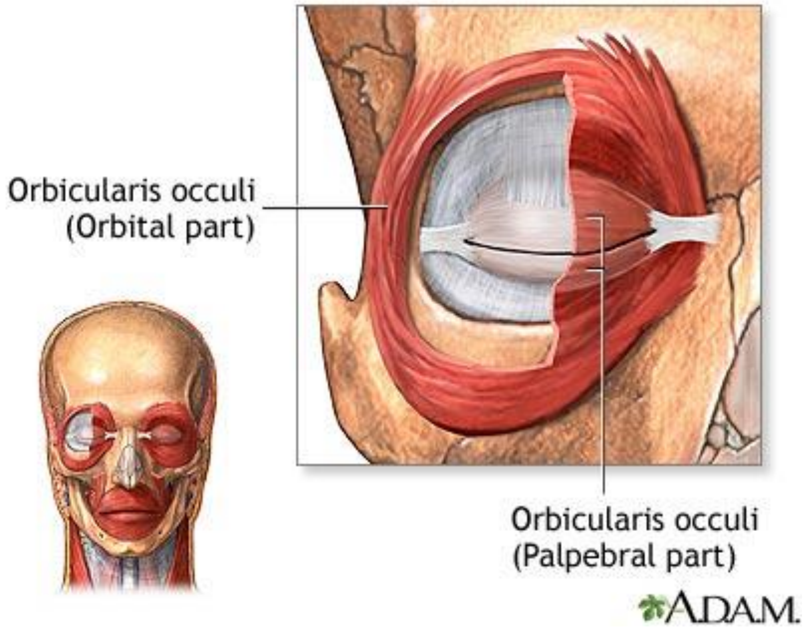
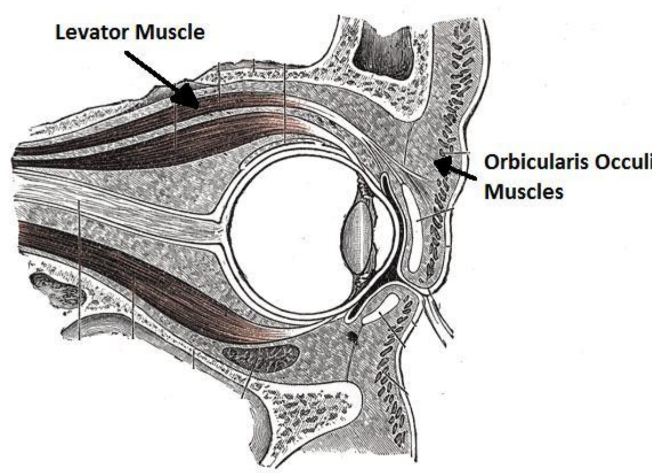


Figure 4: Eye muscle anatomy; highlighting the Orbicularis occuli muscles
http://lomalindahealth.org

Embedded Cord Tension Mechanism



We tried to incorporate our study of the anatomy and function of the actual human eye muscles as inspiration for this mechanism. The orbicularis occuli is the sphincter muscle that surrounds each eye and causes it to blink, both voluntarily and involuntarily[7]. The orbicularis occuli is the system of donut-shaped muscles, the innermost of which extends from a fixed point at the corner of eye, continues through the eyelid, and connects to a fixed point at the other corner (Figure 4). When these muscles contract, they want to span the shortest possible distance between the fixed points and due to the geometry of the eyeball the shortest distance is the closed position. In other words, when you want to close your eyes a message is sent via electrical impulses from your brain to these orbicularis occuli muscles which, in turn shorten, causing the upper eyelid to come down upon the lower one. The orbicularis occuli muscles act in direct opposition to the levator muscle (Figure 5) which pulls the eye back open after a blink has been completed[7].

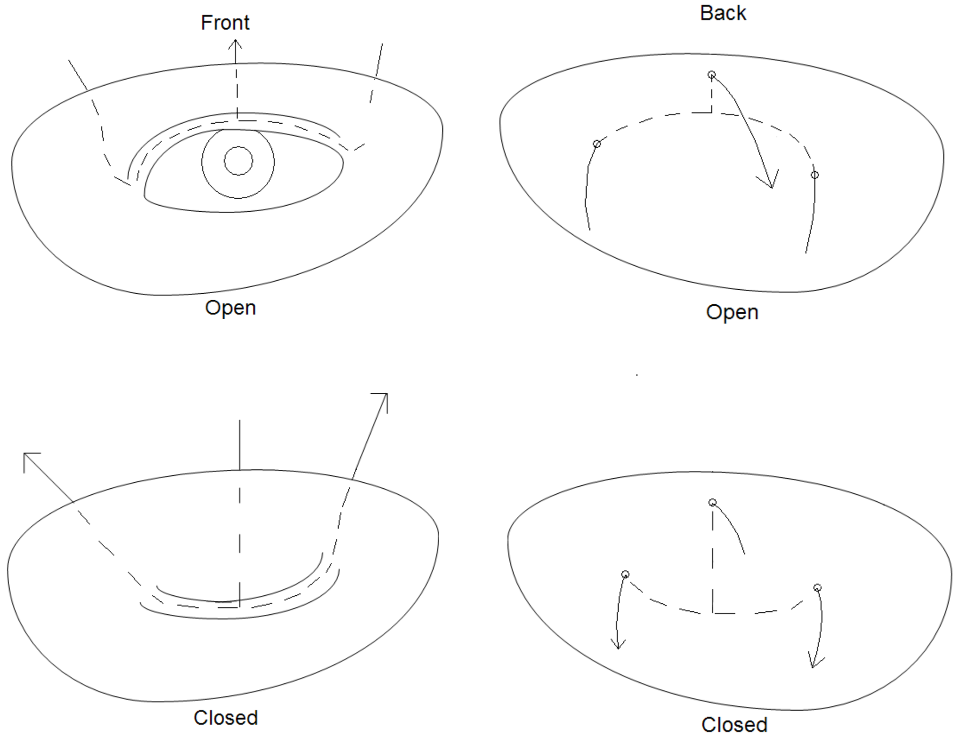


Figure 6: Embedded cord tension mechanism; viewed from both the front and the back. Drawn by Blake Marzella

Our mechanism imitates these companion muscles using a thin plastic string, the silicone of the current prosthetics, and a simple coil spring. We intend to form a piece of the silicone material into the shape of the opening of the eye; the piece will have both an upper and lower lid. We would then bore a tiny hole into the upper lid and run a thin plastic cord through it. The lids would then be placed over the acrylic, prosthetic eyeball and fixed at the corners of the eye as shown in Figure 6. The thin string embedded in the silicone is fixed by an inflexible, stabilizing strap. The positions of the straps are crucial. They must be placed in such a position so that when the strings are pulled at the sides the upper eyelid will be forced to come down upon the lower one. This position will be slightly below the level of the lower eyelid and also located on the same hemisphere as the model eyeball. The action created by pulling the strings mimics movement of the orbicularis occuli in the actual eye. The levator muscle action is reproduced by the spring. The spring will be attached to the upper eyelid at the midpoint between the stabilizing straps. It is positioned here so that after the strings do work to bring the eye the down the spring force will immediately bring the upper eyelid back to its initial position, thus completing the blink. Now, our focus turns to how to get tension on the cord in order to initiate the blink.

Micro Servo Motor

Our first design alternative incorporates a micro servo motor (Figure 7). A servo is an automatic device that uses error-sensing feedback to correct its own performance[8]. We intend to use a miniature servo motor (on the order of 50x50x50mm) to create tension on the aforementioned cords. The micro servo motor would be located on the side opposite the eyelids in the cavity of the eyeball. Here, it would be fixed by metal supports so that it remained stationary while it worked. The cords would then be attached to the mechanical arm of the servo, so that when the arm is spun, the cords are pulled, and the eye blinks (Figure 8). The ability of the servo to control and sense its own position is very important because it allows us to program the motor to pull the cords just far enough to create a realistic blink and then stop without delay. This feature prevents any damage to the *embedded cord tension mechanism* that could be caused by excessive pulling. Some more advantages of the micro servo include that it has proven to be quick, and strong relative to its small size. For example, a specific Futaba servo rotates a speed of 60 degrees per 0.19 seconds and generates a torque of 4.1 kg*cm[9]. Another positive feature of the servo motor

Figure 7: Micro Servo Motor. Model: GWS Naro+D Micro Digital Servo Motor http://www.robotshop.ca

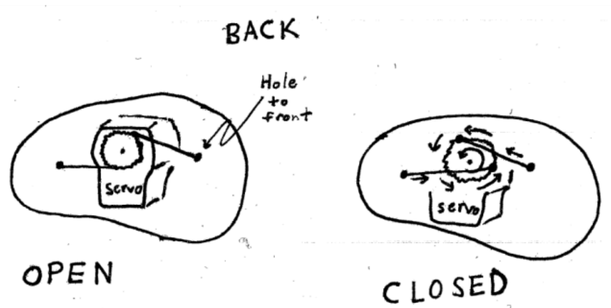


Figure 8: Drawing of the embedded cord tension mechanism powered by a micro servo. Drawn by Michael Konrath.

is that it can be easily controlled by a remote, which is essential to our model design because the presenter will not be able to gain access to the cavity of the eye while presenting. The final, but maybe the most important benefit of using a micro servo motor to power our mechanism is that servo motors have a long history and are part of a highly developed market. This makes them easily obtainable, affordable, and guarantees that there will be plenty of individuals with servo expertise to help us should we run into problems during assembly or testing. Some concerns facing this design are noise and bulkiness. Both of these problems have the possibility of causing the patient discomfort while using our device.

Memory Shape Alloy

Our second design incorporates a memory shape alloy actuator (Figure 9). The memory shape material is a copper-based, Nickel-Titanium alloy. The alloy is able to change shape when an electric current is applied to it. The unique property of this alloy is that it is able to transform into pre-memorized shapes when a specific current is applied to it[10]. We would fix this actuator in the cavity of the eyeball and then attach the cords to both ends. Thus, when the motor contracts, the strings are pulled and the eye closes (Figure 10). The benefits of using a motor that incorporates this memory shape alloy is that it is silent, small (less than 7cm long),weighs just over a gram and can be run from a remote-control. These properties fit into our project well because we are working in such a small place and we also want to minimize any discomfort that weight or noise could cause the user. Some problems with this design include that the memory shape alloy motor has a relatively short life cycle of only about 1,000,000 contractions which would only allow the patient to use it for about a month, before it would need to be replaced[11]. It also remains to be seen, if the motor will have enough power to pull the strings far enough to simulate a blink.

Figure 9: Shape memory alloy actuator. http://www.sparkfun.com

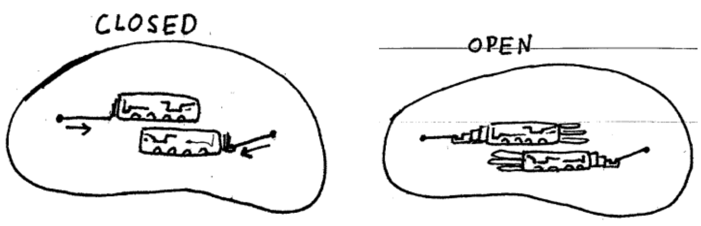


Figure 10: Memory shape alloy actuator drawing. Drawn by Michael Konrath.

Artificial Muscles (EPAM)

The focus of our third design centers on a new technology called artificial muscles or EPAM, which stands for electroactive polymer artificial muscle. Artificial muscles consist of a thin layer of dielectric polymer film between two conductive, compliant electrodes.

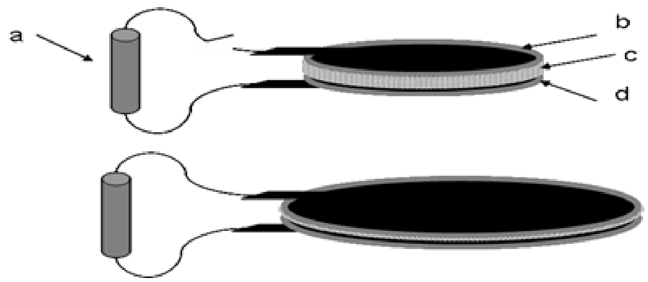


Figure 11: Basic function of EPAM device
http://www.artificalmuscles.com

When a voltage is applied to these electrodes, the positive and negative charges of the electrodes attract each other. This causes the polymer to contract in thickness and expand in area because the polymer as a whole is incompressible. By attaching materials to direct this motion into the desired axis, an EPAM actuator is created that can effectively mimic the muscle movements of living organisms.[12]

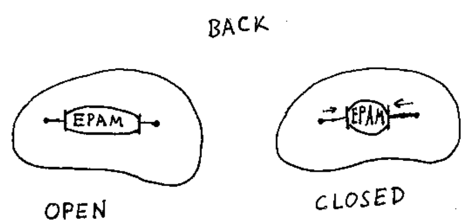


Figure 12: Drawing of *embedded EPAM lid Mechanism. Drawn by Michael Konrath.*

Benefits of artificial muscle include that it is fast, completely silent, strong, achieving actuation pressures up to 1.9 MPa, and able to contract a large distance relative to its length, having strain values greater than 30%.[13] Artificial muscles can also be very small, "allowing designs that may achieve the size and forms of geckos, hummingbirds and cockroaches." [14] All of these attributes make them ideal as a power source for our *embedded cord tension mechanism.* In this case, a small EPAM actuator would be fixed behind the acrylic artificial eye piece, each end attached to one of the strings of the *embedded cord tension mechanism*. When the EPAM actuator would contract, it would pull both strings and activate the blinking mechanism.

Artificial muscle also lend itself to a unique design of ours called the *embedded EPAM lid*. This mechanism would consist of a band of artificial muscle running through the lower edge of the top silicone eyelid of the prosthesis. This artificial muscle would be fixed at the corners of the eye so that when it contracted, the shortening of the muscle would force the eyelid downward. This design borrows heavily from the function of the human orbicularis occuli muscle as mentioned earlier.

The largest drawback of EPAM technology comes from its low level of availability. Currently only one company (Artificial Muscles Inc.) is in charge of commercializing the product, selling only to other companies or large research groups with large amounts of funding. EPAM cannot be found in a hobby store and there is no sample kit. Being that so few people work with this technology nationwide (for example, no one on the UW Madison Campus works with this technology), it may also prove difficult to get help with our design should we run into any technical problems.

Design Matrix

Table 1: Design Matrix; the table indicates the weight of each criterion and the scores for each design possibility

Table 1: Design Matrix								
	Speed	Noise	Size	Power	Cost	Availability	Endurance	**Total**
Weight	20	16	20	20	4	12	8	**100**
Shape Memory Alloy	3	16	18	4	4	12	2	**59**
Micro Servo	18	10	13	18	3	12	7	**81**
Artificial Muscles (EPAM)	16	14	19	16	0	0	7	**72**

Final Design

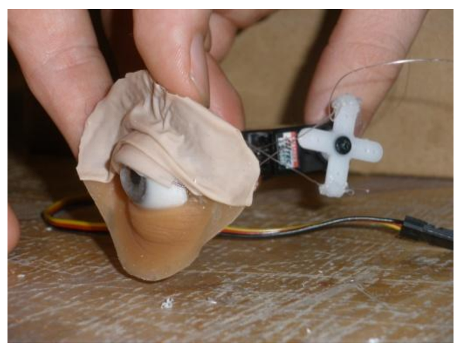


Figure 13: Picture of final mechanism

Our final design employs the original concept of the *embedded cord tension* mechanism. It uses the force of a cord (fishing line), fixed at the corners of the prosthetic eye and running through the lower edge of the silicone eyelid being pulled at both ends, to drive the top eyelid down onto the lower eyelid. However, after working with the materials and the static prosthetic eye that we used for a base to create our blinking prosthetic eye, our group has made several considerable adjustments and improvements to the mechanism.

The first major improvement we made was the use of lubrication and other tools to remove as much friction resisting the blink as possible. The lubrication used to make the lid slide easily on the acrylic eyepiece is simple vegetable oil. This lubricant does not warp or deform the silicone lid and remains on the eyepiece for a considerable amount of time before it must be reapplied. While working with the silicone area surrounding the acrylic eyepiece, we found that it puts large amounts of pressure and friction on any object sticking into or through it (e.g. our fishing line cord). For this reason, our group implanted tiny metal tubes about 1.5mm in diameter into the silicone area surrounding the eye where the cords from the eyelid would go through to the back of the mechanism. This, combined with the use of an oil lubricant for the eyelid, cuts down the friction in the mechanism to the point where our small servo motor has no problem creating enough torque to activate a blink.

Another large improvement to the original mechanism concerns the how the eyelid reopens after it is pulled shut. Our original idea was to run a thin spring through the lower edge of the silicone eyelid and embed the ends of the spring in such a way that the relaxed position of the spring would keep the eyelid in the open position. We did run into some trouble with this strategy. If we embedded the two ends of the spring so that the lid looked fully open in its relaxed position, it created an "overbite" with the lower lid once closed. If we embedded the spring ends so that this overbite was eliminated, the lid only returned to an open position that could be described as a "sleepy" eye (it did not go high enough).

To fix this problem, we added a "levator cord" or opening cord to our mechanism. It should be noted that the spring was left in the lower eyelid because it was observed to help maintain the eyelids natural curved form. This levator cord is attached to the back of the lid by a layer of silicone, and runs through the back of the silicone at the top of the eye. When this cord is pulled, it brings the eyelid to a fully open position. This cord is attached to the servo motor in such a way that when it is pulled, slack is given to the two ends of the closing cord. When tension is put on the closing cord, slack is given to the levator cord. In this way neither action, opening nor closing, opposes the other when creating a blink.

The final improvement or refinement to the original *embedded cord tension mechanism* concerns the attachment of the skin of the lid to the silicone area surrounding the eyepiece. It was originally thought that when the eyelid closes, it stretches the skin over the eye. After further research it was discovered that the lid actually folds in such a way that it stays taut when open, but gives slack to the lid when closed. This is how we have attempted to fold our silicone eyelid.

As with our original design we have used a servo, the Hitec HS-56, to power our device. We have programmed this servo to rotate 90° and immediately return to its original position at the click of a button. When this button is pushed, the servo rotates first in the direction to give slack to the levator cord and put tension on the closing cords; this closes the eye. As soon as the eye closes, the servo begins to rotate the opposite direction, putting tension on the levator cord and giving slack to the closing cords; this reopens the eye.

Testing

Positioning

In order for the embedded cord tension mechanism to work properly, initial tests were performed to determine the appropriate distance between the servo motor and the blinking eye. This was accomplished by tying the three strings involved in the mechanism to their respective places on the micro servo motor arms. The micro servo motor was programmed to provide an angular displacement of 90 degrees in a clockwise motion when stimulated. As the motor rotated, we experimented with various lengths of string seeking the correct combination that would provide the appearance of a natural blink. Due the qualitative nature of observations gathered when trying to recreate a natural blink, we found the most efficient means of determining the string length was to use our measurements merely as guidelines and instead to adjust the lengths of each string upon visual inspection. The measurements used were the respective displacements of the strings in relation the eyeball during the course of a blink. That is, during a blink, the upper cord is pulled approximately 1.1 cm toward the center of eye and the two lower cords are pulled down 1.1 cm.

Reliability

To determine the reliability and durability of our design, we stimulated the prosthetic eye to blink 50 times and recorded the following data: longest continuous blinks without error, lubrication requirement, average time to complete one blink, and percentage of complete blinks. The recorded data is summarized in the following table:

Blinks	Longest continuous blinks	Lubrication	Average blink time	Percentage complete blinks
50	15	1	.33 seconds	84%

Lubrication was originally applied to the eyepiece by spreading less than one mL of vegetable oil onto the acrylic eye and under the upper lid. Additional lubrication was only added upon the visual observation of stuttered eyelid movements as a result of increasing friction. The blink time was recorded from the instant the mechanism was provided with the stimulus until the upper eyelid returned to its open position at the end of the blink. Completed blinks were recorded when the upper eyelid closed to cover the eye entirely and returned fully to the open and relaxed position.

Assumptions and Inherent Limitations

Much of the testing for this design involved qualitative analysis and visual observation and adjustments. As such, our methodology does not allow for exact replication of our results or testing. However, taking into consideration the knowledge that each prosthetic eye must be individually made and that anaplastology is considered both an art and a science, we feel it is appropriate and necessary that this mechanism does not provide the ability for exact replication. That is, since each eyepiece must be custom made it order to create a natural appearance, the positioning of the blinking mechanism and its components must also be individually adjusted for each eyepiece in a way which presents an aesthetically pleasing and natural looking blink. This can only be accomplished through qualitative analysis and thus cannot provide a standard method of implanting the mechanism within a prosthetic eye.

Future Work

As previously stated, the prototype that we built is meant only to be used as a presentation device. Moreover, our main goal for this project was to find an adequate and reliable mechanism to make the prosthetic eye blink. With this goal, our project is by definition a step toward the real possibility of implanting a blinking orbital prosthesis in an actual patient.

Building a Patient-Ready Model

The first step in constructing a device that would be available for patient use is minimizing its size. The main components of our device, the eye itself and the servo motor are relatively small and would be easily housed in the patient’s eye cavity. However, at the present time the servo motor requires an Arduino USB board for control and an AC adapter for power. The size of these components is not a problem when the device is being used for presentations, but it would be unacceptable for patient use. The next step would be to find a motor that can be controlled without the use of the Arduino board and powered by a battery. During our research, we were unable to find a motor that would both meet these requirements and produce the torque and speed necessary to generate a blink. We believe that with time, technology will develop and smaller, more suitable motor could replace our micro-servo.

An additional problem with the current servo motor is that it vibrates and creates a significant amount of heat while working. The vibrations could be a serious problem for a patient that must wear the prosthesis for an entire day. And the heat would also be hazardous, considering the sensitivity of the face and its proximity to vital organs (e.g. brain, ears, and mouth). To solve these problems the type of motor used might need to be changed, but perhaps vibrations will occur with any motor. In that case, a buffer system might need to be created. The buffer would hopefully minimize vibrations and cool the motor to prevent harm to the patient. And as with any electrical device being used on a human patient, any electrical circuit and/or moving parts must be properly fastened and protected.

Beyond just making the prosthetic eye blink, an effort to synchronize the artificial blink with the blink of a remaining natural eye must be made. Most, if not all of the realism and aesthetic appeal gained by wearing a prosthetic eye that can blink, would be lost if blink was not coordinated with the other eye. This is a completely new problem that can only be solved once a reliable blinking orbital prosthesis has been made.

Integration & Production

After making the necessary improvements (above) and thorough testing, our client Mr. Gion would need to approve our device for use at the Medical Arts Prosthetics Clinic. Once approved, this product would be an available to anyone who has lost an eye. Mr. Gion could complement his artistic skill with the mechanics of the blink and offer an exciting alternative to his clients. The prosthetics that incorporated our design would be made on a case by case basis. Every individual’s situation is unique. Although the fundaments of the design would remain the same, each device would be slightly different, varying in size, shape, and color.

Summary of Ethical Considerations

Since our goal for this project was to make a model orbital prosthesis for presentation use, we did not have to take safety into much consideration. Our design would need to undergo rigorous safety testing before it could be implanted into patients. Safety is the main ethical concern for our device. As engineers we are responsible for what we create and would be responsible for putting the patient into dangerous situations and potentially causing them harm if our device was to have safety flaws. Various organizations such as the US Food and drug

Administration (FDA), the American Society for Testing and Materials International (ASTM) and the International Organization for Standardization (ISO) have strict regulations regarding medical devices implanted into patients.[15] Each individual component as well as our design as a whole would need to be proven to be safe. We noticed that the servo motor gets quite hot when used for extended periods of time. This especially would need to be rigorously tested to show that it could maintain a safe temperature even when used constantly for an entire day. Until testing is done to meet any organization's standards, as well as our own, we would not be comfortable implanting our device into a patient. With proper approval, we would also need to test our device in clinical trials. Physicians and possibly engineers would need to be present in case of any complications to ensure patient safety. When our device meets and exceeds all the safety requirements, our client Mr. Gion, would need to be familiar with all the components so that when he creates the silicone and acrylic portions of the prosthesis he could properly implement our mechanics. The patient should also be taught about our device so they can avoid any improper use.

It is ethically our responsibility to have our device be reliable. If our device failed, it could put the patient into potentially embarrassing situations. We would not be able to proudly distribute our design is it were to cause any emotional harm either. Therefore, we would also like to test the accuracy and durability of our design more thoroughly. Finally, the patient would have to be informed that they have a choice between our blinking prosthesis, a traditional prosthesis or even no prosthesis at all.

Appendix A

Consideration of Electromagnets

During our brainstorming process, the idea of using small electromagnets to either attract or repel a permanent magnet in a prosthetic eyelid to create a blink did arise. The magnets are small enough, the smallest having a height and width of about .5 inches. They are also completely silent, which made them a hopeful candidate for one of our designs. Though, when further research was conducted while attempting to purchase an electromagnet to test, it was found that these magnets had no magnetic field at only .5 inches away, let alone any power to attract. The maximum distance of attraction was actually at 1/8 inches. It was also discovered that these magnets were not made to repel objects. They could be modified to do so, but this power to repel would amount to approximately 1/25 of the power of the magnet to attract. For these reasons, electromagnets were ruled out as a possible design element for the blinking orbital prosthesis.

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Management Planning

Time Management	
Task	***Estimated Hours***
Brainstorming	25
Research (including opthalmology seminar)	19
Material purchase (including travel)	2
Styrofoam head construction	3
Servo Motor Configuration	9
Blinking mechanism construction	13
Poster/Papers	8
Client Meetings	2.5
Advisor Meetings	7
Total	***88.5***

Cost Management	
Item	***Price***
Arduino USB board	$29.95
Momentary push button switch	$0.50
1CB86 PC board	$1.99
Detector plug	$3.29
HS-56HB Servo motor	$30.94
Styrofoam display head	$13.34
Fishing line	$2.84
Total	***$82.85***

Appendix B – Product Design Specifications

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. We intend to accomplish this by designing a device that enables the prosthetic eye to blink. Our design will focus on developing a model that portrays this blinking mechanism.

Client requirements:

- Costs for the project should be under $500.

- Create a mechanism to cause the prosthetic eye to blink.
- The mechanism should be contained inside of the cavity of the globe of the eye.
- Must be damped in order to minimize sound and vibrations.
- Must be as aesthetically pleasing.
- Blink time must be realistic.

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.
- Fully Functional: Must be synchronized with the blinking of the other functional eye.

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 or 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 device will be used in an open environment and as such will not be as limited by the size requirements of an eye socket.
- Fully Functional: 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 silicone. 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.

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.