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Blinking Orbital Prosthesis

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Abstract

Prosthetic eyes are a common solution to physical deformity. An orbital prosthesis is an artificial eye that closely mimics a natural eye. Although current prosthetics improve natural appearance, they are still noticeable because they do not blink. We will create a mechanism that allows an orbital prosthesis to blink. Our team considered technical and physiological feasibility, as well as client input, to develop a prototype that exemplifies a pneumatic solution to this problem.

Fabrication of the design has resulted in a prototype 54% larger than an actual prosthesis. This prototype demonstrates successful operation of the mechanism. Continued work will decrease the scale of the prototype to a realistic size, offering a blinking alternative to the current, static orbital prosthetics.

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Background

Motivation

The purpose of an orbital prosthetic is to create the illusion of a real, functioning eye. The act of blinking is important to maintaining natural appearance of the eye; the average person blinks between 17,000 and 22,000 times daily. That is about one blink every four to five seconds. Currently, no blinking orbital prostheses are commercially available, and unblinking prosthetic eyes are easily recognizable. Each year in the United States, 11,000 incidents occur that leave patients with a large facial gap where their eye had previously been (Lee, 1998). These people are candidates for prosthetic eyes, and would benefit emotionally and socially from a less detectable prosthetic (Adkisson, Jay 2006).

Prostheses

A prosthetic is an artificial extension that replaces a missing body part. The term prosthetic is more commonly referred to when discussing limbs, such as legs or arms, but can be applied to any part of the body. An orbital prosthesis is one that replaces an eye and the surrounding facial tissue. Most static orbital prostheses are custom made of silicone or PVC. The materials can be skillfully molded into exceptionally life-like, individualized ocular replicas *(Figure 1).*

Figure 1. An orbital prosthesis created by Greg Gion, *Medical Art Prosthetics Clinic, Inc*, using silicone. Note the level of realism achieved (Gion and Vest).

Client Information

Our team's client is Greg Gion. He established The Medical Art Prosthetics Clinic, Inc. in 1985. His company produces prosthetic eyes, noses, ears, hands, and fingers. Their goal is to create the most life-like restorations possible while still producing durable, comfortable, and manageable prostheses.

Problem Statement

Dr. Greg Gion has requested a design for an orbital prosthesis that blinks on command. Blinking orbital prosthesis prototypes created for Dr. Gion in the past have been bulky, unreliable, and appear unnatural. The next prototype will blink reliably in a natural fashion when prompted by the user and be primarily self-contained, aside from an exterior controller.

Competition

Our team's blinking orbital prosthesis must compete with a few existing designs. The most prevalent source of competition is from the scientists M. Honda, A. Niimi, and M. Ueda, who developed an eyelid that blinked poorly. Their work is found is the Journal of Oral and Maxillofacial Surgery (Honda et al 1999). The schematic diagram *(Figure 2)* shows the mechanism for their design. An electromagnetic activator causes a rotating arm to move the eyelid in front of the eyepiece. Then, a retractable spring is used to pull the eye lid back into the open position.

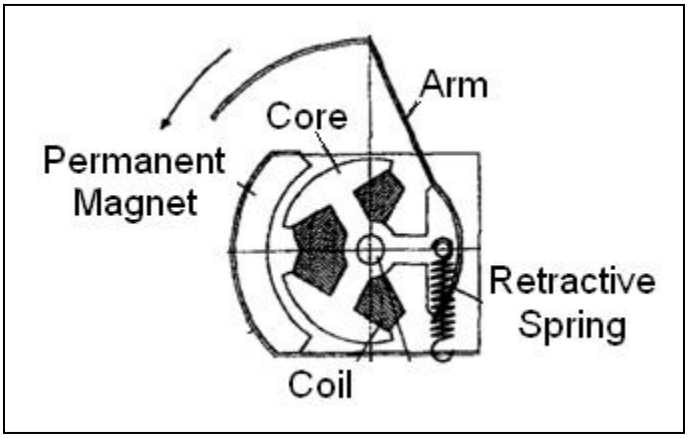

Figure 2. Schematic diagram of the electromagnetic- activated blinking orbital prosthesis (Honda et al 1999).

This design is also able to detect blinks in synchrony with the healthy eye through a circuit that monitors changes in the orbicularis oculi muscle. This muscle would be used to blink the eye were it present. Despite the development of this design, it never became commercially available. The eyelid was not life-like since it was made from rigid silicone. Also, the blinking prosthesis was about twice as heavy as a conventional orbital prosthesis. Another problem with the device was the slow rate of blink detection.

Further competition is found in a blinking doll-eye design. This device is US patent number 20020049023 (Simeray 2001). It also incorporates an electromagnetic mechanism (*Figure 3*). The eyelid can remain closed or open for extended periods of time, using only current to change between open and closed conformations. The eyepiece is made of plastic.

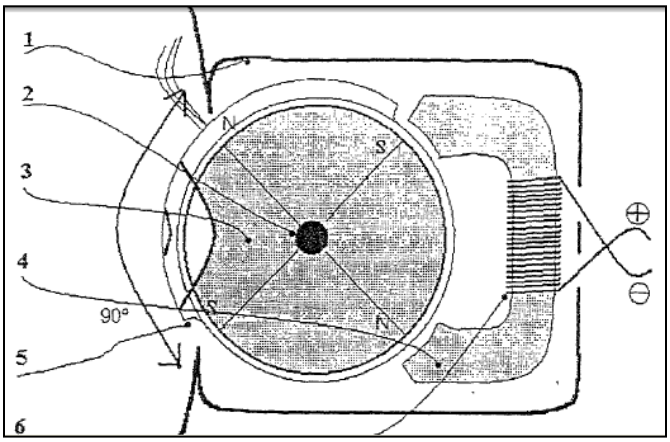

Figure 3. Diagram of doll's eye lid patent design (Simeray 2001).

Our team's blinking prosthesis will also compete with traditional non-blinking prostheses *(Figure 1),* which have been tried and perfected over the years. The new blinking prosthesis must be comparable in size, comfort, and convenience to these traditional counterparts.

Design Specifications

Consultation with Greg Gion allowed our team to develop design specifications for the blinking orbital prosthesis prototype. It will function as a natural, blinking ocular replacement. Machinery will be contained within the prosthesis, which will fit into the ocular cavity behind the acrylic eyepiece. This eyepiece will be held in place by a silicone mold which will gently interface with the skin. Most importantly, it must blink reliably on command. The possibility to blink in coordination with the healthy eye was addressed, however the client, Greg Gion, decided that this aspect was beyond the scope of one semester. To achieve the most reliable blink, the mechanism must be as simple as possible. This decreases the risk of failure and therefore increases the consistency of the blink.

In addition to these functional specifications, the actual blinking orbital prosthesis device will be primarily constrained to less that 5.5 cm^3 in volume and 45 g in weight. These values correspond to the average volume of a human eye and a typical weight of a non-blinking prosthesis. These size limitations restrict only the portion of the device that will be placed within the ocular cavity. In order to give the user timed control of the blink, the design will also incorporate a blink controller that will exit the ocular portion in a discrete manner, perhaps hidden by eye glasses, and would terminate at the user's side or in a pocket.

Traditional non-blinking prostheses are used daily for an average of three to four years. Therefore, to compete with these prostheses, the team's blinking orbital prosthetic should have a lifespan of at least three years, even with daily use. It will be operated in contact with the user's skin and therefore must be resistant to moisture and other biological residue. These constraints restrict the materials from which the blinking orbital prosthesis can be made. No latex can be used to avoid allergic reactions from the user. The client recommended the material polymethylmethacrylate (PMMA), because of its ease of use and low cost. The material selection must also allow a natural appearance.

Finally, the device must not cause any detrimental physiological effects. Potential areas of risk include chemicals that may irritate the user's skin and damaging electromagnetic effects. If electricity is used to power the mechanism, the circuit must be enclosed and harmless to the user. For a complete, condensed description of the design specifications, see *Appendix A.*

Design Alternatives

Considering the design specifications, the team brainstormed many potential solutions. These were then narrowed to the three most feasible ideas. Each of these three design alternatives is powered by a different source. The first that will be presented is the mechanical wind- up prototype idea, which uses mechanical energy. The next design is the solenoid design, followed by the pneumatic design, which is powered by the movement of air. All three alternatives have a common external blink controller, which would travel discreetly from the ocular portion of the prosthesis to an area easily accessible to the user.

Mechanical Wind-Up

The mechanical wind-up concept utilizes stored energy that is input from the user in the form of a wind-up mechanism *(Figure 4)*. Before each insertion into the ocular cavity, the user would wind the gear-based mechanism to create stored potential energy. The blink controlling device would release one gear section at a time when prompted by the user. Rotating the gear by one section would allow the eyelid to fall in front of the eyepiece, causing the appearance of a blink. A spring of the proper constant would be attached to the eyelid, and when the eyelid fully covers the eyepiece this spring would be at the correct tension to pull the eye lid back into the open conformation. The eyelid would quickly rotate up and come to rest in the gear once again.

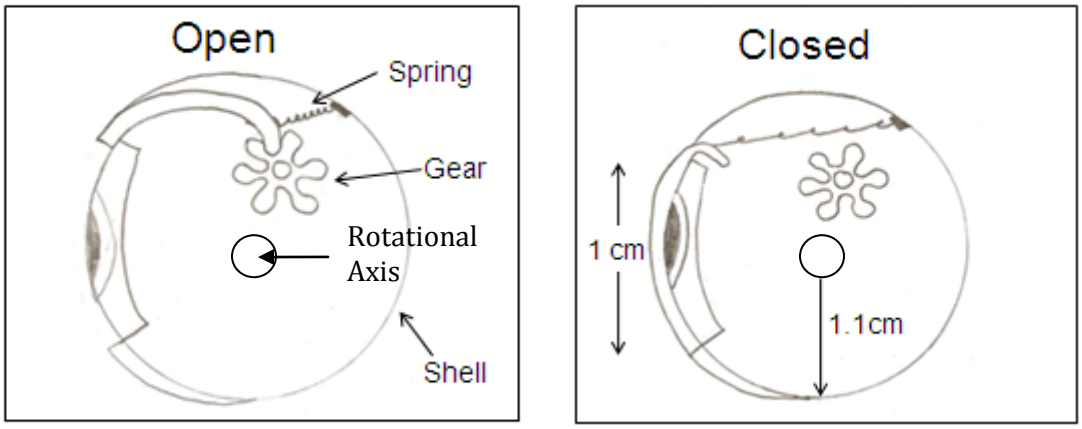

Figure 4. Diagram of the mechanical wind-up design alternative, which utilizes stored potential energy to execute blink. Rotational axis extends behind page. External blink controlling device not shown.

In order to prevent rubbing against the user's skin, the components of the prosthesis would be contained in a spherical shell. This shell would also provide a place to anchor the retractable spring, as well as the axis for the gear mechanism.

This design alternative effectively uses stored energy to power the blink mechanism. Since the energy is input by the user, there would be no potential for battery failure. The negative aspect associated with this stored energy is that the user would have a limited number of blinks with each insertion of the device into the ocular cavity. Furthermore, this device has a large risk of failure due to the complex mechanism involved. Coordinating the gear and the spring would require precise placement of the gear as well as exact calculation of the spring constant. This device is also limited to quick blinks. There is no option for the user to produce an extended blink which leaves the eye lid in front of the eyepiece for a longer period of time.

Push Solenoid

The push- solenoid prototype design is based around a tubular, push type solenoid *(Figure 5).* When an electrical current passes through the solenoid, a pin protrudes from the center of the electromagnet. The motion of the eyelid will be actuated by this dynamic pin.

The eyelid rotates on a centrally positioned, lateral axis. An extension opposite the eyelid across the lateral axis is also contained within the ocular cavity. When current passes through the solenoid, its pin extends and contacts this extension of the eyelid, which pivots the eyelid on its axis. Only momentary current through the solenoid is needed to close the eyelid. When the solenoid receives no

current, the pin retracts. This allows a properly balanced counterweight to rotate the eyelid in the opposite direction, restoring the eye to the open position.

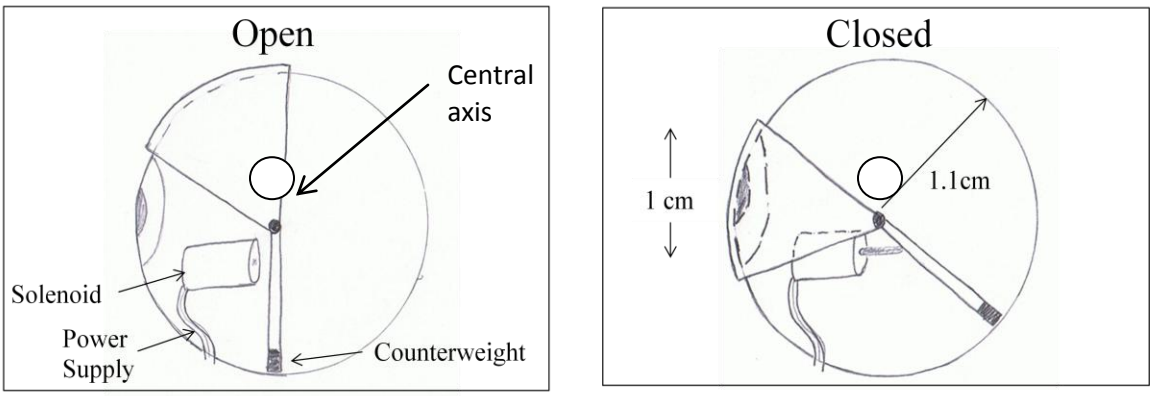

Figure 5. Diagram of the push solenoid design alternative. Mechanism utilizes protruding pin and counterweight to execute blink. External controlling device not shown.

The solenoid will be anchored to the ocular plate within the orbital cavity to maintain proper relative position to the lower extension of the eyelid. This system will be powered by two 9 V batteries which will be mounted in a remote actuator and connected to the solenoid via wires. This circuit will include a switch on the actuator that enables the current to be turned on and off. This remote/battery system could be concealed discreetly in the user's pocket. Furthermore, the wire which runs from the eye to the actuator may be concealed with eye glasses or by other case specific means. In this system, every click of the remote translates to one blink of the eye.

This design requires spacing between the eyelid and upper eye moldings of the prosthetic. This may be achieved by enclosing the system in a thin, light-weight casing which can be incorporated into the prosthetic. The push solenoid design alternative would have fewer moving parts than the mechanical wind up design. This added simplicity affords a more reliable mechanism. The major negative aspect of this design is the potential for battery failure. The user would be required to change batteries at unknown intervals depending on battery life. However, this design allows the eye to remain open in case of failure which gives the user more confidence in their appearance. Finally, this design allows the user to reproduce various types of expressive blinks, as the duration of eyelid closure can be directly controlled by the user.

Pneumatic

The distinguishing characteristic of the pneumatic design is a balloon catheter, which has an inflatable balloon at the end of extended synthetic tubing. This balloon will be the main actuator of the system. The eyelid, as in the solenoid design, will rotate on a central, lateral axis *(Figure 6)*.

Figure 6. Diagram of the pneumatic design alternative, which utilizes air pressure stored in a closed system to inflate a catheter, and trigger a blink. External controlling device not shown.

When air is delivered to the balloon, it inflates and contacts the hindmost portion of the eyelid. This interaction rotates the lid to the closed position. Upon rotation, the lid will contact the lower eyelid, ending its motion in the closed position. As air is released from the balloon, it loses contact with the hind portion of the eyelid. This releases tension on the eyelid, allowing the eye to reopen. As in the solenoid design, a properly balanced counterweight (not shown in *Figure 6*) will provide the energy needed to reopen the eyelid. However, further testing will give more insight as to the practicality of the counterweight mechanism. The team is still considering magnetic, spring, and material mechanisms to reopen the eyelid.

The major benefit of the pneumatic design is its lack of dependence on battery life. For air to be delivered to the balloon, only a simple air bulb is necessary. The air bulb will connect to the ballon via the synthetic tubing. This design successfully utilizes manual energy from the user. As the air bulb is compressed, the balloon inflates initiating a blink of the eyelid. However, for the blink to appear natural, the eyelid must reopen with enough speed to mimic an actual blink. The duration of the blink should be 300-400 milliseconds. This requires the air bulb to deflate with sufficient relative speed. Further testing of materials will determine the realism of the blink.

One downside of the pneumatic design is the concealment of the air tube that runs from the air bulb to the eye. It may be possible to disguise the tube with eye glasses worn by the user. Furthermore,

a major goal of material testing will be to minimize the diameter of the tubing. However, the diameter must be properly proportioned to still allow the flow of the necessary amount of air in the required time.

Design Evaluation

A set of design criteria, weighted according to importance, was used to evaluate the mechanical, pneumatic, and solenoid prototype concepts *(Table 1)*. Each was scored on a scale of 0 to 5; 0 indicated no satisfaction of the criteria by the prototype and 5 indicated complete satisfaction. High totals therefore indicate more complete satisfaction.

Criteria	Weight	Pneumatic	Wind-Up	Push Solenoid
Feasibility	1	4	2	3
Size	1	3	4	4
Reproducible	0.3	3	3	3
Safety	0.7	4	4	3
Cost	0.3	4	3	2
Risk of Failure	0.6	3	1	2
Appearance	0.3	3	3	3
Totals		**14.30**	**11.90**	**12.45**

Table 1. Design Matrix. Shows list of design criteria weighted according to importance. Wind-up, pneumatic, and solenoid prototype concepts each assessed on a scale of 0-5; 0 indicating no satisfaction of criterion, 5 indicating complete satisfaction. Totals indicate that pneumatic solution is most promising concept.

Feasibility and size weigh most heavily in final design determination. Because a variety of technological advancements have been made in the bio-prosthetics (University of Pittsburgh, 2007), and direct incorporation of physiological signals as triggers for blinking would require extensive installation techniques and expertise, it is important to maintain a level of simplicity and feasibility in the final design concept. Ocular exonerations are also variable in depth and shape, depending on the patient's circumstance; (Adkisson Publishing, Inc., 2008) minimizing the size and number of integrated components within the final design concept is therefore important for reliable, more universally applicable operation.

Safety and risk of failure also weigh heavily in final design determination. The blinking orbital prosthesis will be designed for use in a human system, and presumably this human will be interacting

regularly with environmental, chemical, and physical stresses of daily life. It is important that any final design is able operate without harm to the biological systems of the user and without risk of harm to those who interact with the user. Production of a prosthesis involves a considerable time commitment by the medical artist as well as a considerable monetary commitment by the user. The primary function of our team's prosthesis is to increase the naturalism of current, static prosthetics through the addition of a blinking feature. Any final design must have a low risk of failure so that use of the blinking orbital prosthesis will not significantly increase the instance of malfunction, and therefore social discomfort, for the user.

At this level of development, cost, reproducibility, and appearance carry the least weight in final design selection. The project is operating under an ample budget of $500, creation of orbital prosthetics is a highly individualized practice, and framing of the mechanism in order to blend with the face can be perfected by the medical artist in the lab.

The pneumatic prototype satisfies these criteria most completely. Our team will therefore pursue it as the final design concept.

Final Design

The pneumatic prototype concept most thoroughly satisfies criterion set forth by this team and Greg Gion, and has therefore been selected as the final design. Outstanding aspects of the solenoid and wind-up designs have been incorporated for maximum functionality. Blinking motion of the rotating lid will be initiated by compression of a bulb actuator, which will trigger the expansion of a balloon catheter through a closed-pressure system. Displacement of a counterweight upon lid closure will initiate the retraction phase; the process will take place over the course of 300-400ms.

The large scale prototype of the blinking orbital prosthetic is shown from the front (*Figure* 7). A cross sectional sketch of the mechanism and the rear view of the mechanism are shown, (*Figures* 8 and 9, respectively).

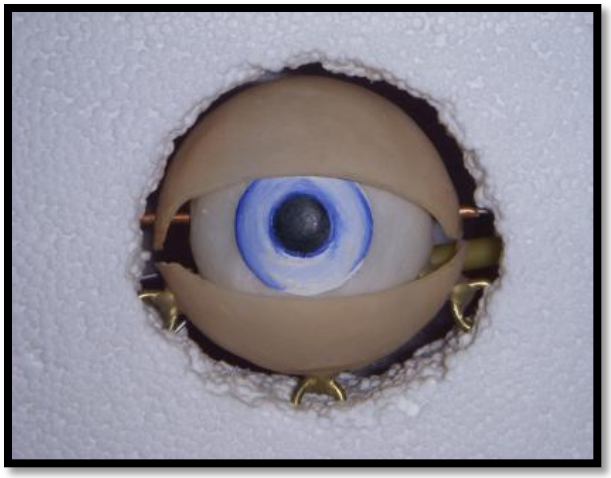

Figure 7. Front view of the large scale blinking orbital prosthetic prototype.

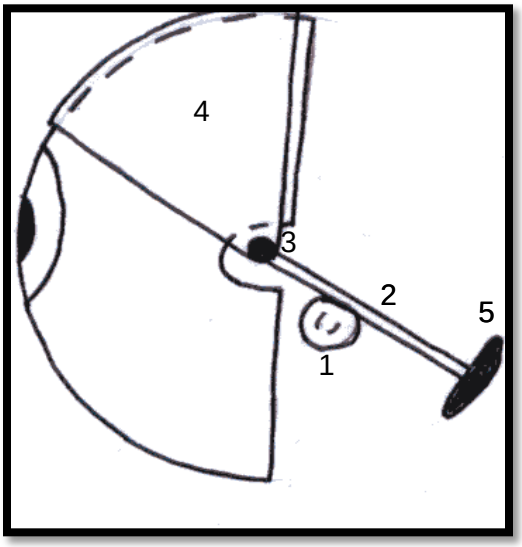

Figure 8. Cross sectional view of the mechanism in the open position. Numbers mark key elements of the mechanism. 1) balloon in the deflated position; 2) lever arm; 3) central axis; 4) upper eyelid; 5) counterweight.

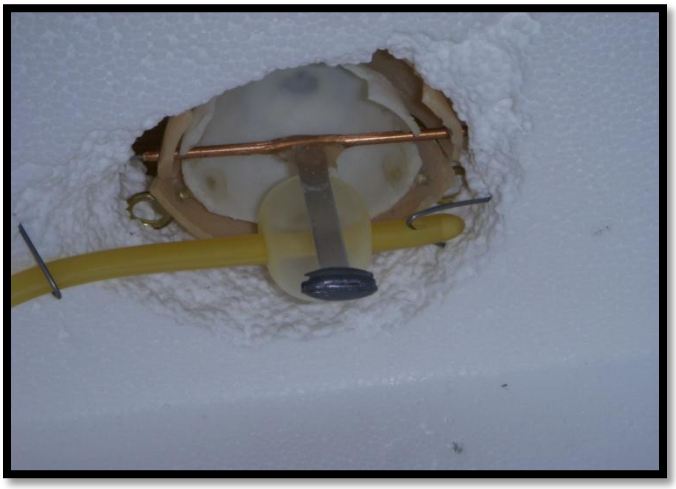

Figure 9. Rear view of the prototype in the closed position. Note the inflated balloon.

A large scale- proof of concept was created during this semester due to budget limitations. The catheter necessary to create the ideal life-size prototype was outside of the available budget (LacriCATH, 2009). Also, investing in such expensive materials would be unwise without first evaluating the success of the mechanism.

When a blink is desired, the user triggers an air bulb from a discrete location, such as the user's pocket. Deflation of the air bulb causes inflation of the catheter balloon, which is positioned underneath a lever arm. Upon inflation of the balloon, the lever arm is forced upward. The lever arm is attached to the central axis which is connected to the upper eyelid. When the lever arm is moved upward, both the central axis and the upper eyelid rotate forward, closing the eyelid. The user can choose the duration of the blink by varying the length of compression of the air bulb. When the air bulb is released, the balloon will deflate. This allows the lever arm to return to the initial position. A counterweight located at the distal end of the lever arm aids the return of the eyelid to the open position.

The rubber catheter and aluminum lever arm create a bouncing motion of the eyelid when the lever arm contacts the deflated balloon. In the future, different material choices may eliminate this negative quality. For the large scale prototype, however, a small amount of foam was placed underneath the counterweight to dampen the eyelid oscillation. This foam is not shown in the figures.

Fabrication

The fabrication of our prototype began with a simple large scale acrylic eye model created by Greg Gion. This eye model consisted of an upper eyelid that was mounted to the eyepiece with two loop screws. The eyelid was able to rotate on the two pivot points provided by the screws. However, the first step of fabrication was to install a centrally rotating axis which required the removal of the two loop screws. In order to do so, a portion of the acrylic eyepiece was removed. A thin copper tube was then fastened to the central points of the upper eyelid using Krazy glue. Next, a thin steel wire was threaded through the thin copper tube. This wire serves as the central axis upon which the eyelid rotates.

Initially the design was mounted in moldable putty but it was relocated to a Styrofoam casing to achieve a more realistic casing. A circular hole was cut in a Styrofoam box to emulate an ocular cavity. The eye was installed by mounting the securing the lower lid and connected eyepiece to the underside of the Styrofoam cavity. The central steel axis was then threaded through and secured in the Styrofoam and the copper tubing of the upper lid was slid into place over the wire.

At this point, the rotating eyelid was fully functional, but the counterweight and catheter were still absent. Through trial and error, it was decided that a thin aluminum lever arm 4.6 cm in length could be used for placement of the counterweight. This arm was initially attached to the central copper tubing with Krazy glue at an angle slightly below horizontal in the open state of the eyelid. This angle enables the counterweight to hold the lid in the open position. However, after further testing, this form of attachment was decidedly insufficient to handle the force exerted by the catheter. To better secure the lever arm, PMMA (polymethyl methacrylate) was added to the connection point and allowed to harden. Next, the counterweight was attached to the end of the lever arm. We experimentally determined the necessary counterweight to be 1.906 grams. This weight was sufficient to hold the eyelid open and yet light enough to allow the catheter balloon to close the lid.

With the counterweight attached, the Kenguard, Silicon- Coated Latex Straight Foley Catheter was then mounted to the Styrofoam casing. It was secured underneath the lever arm, close to the central axis using two U-shaped steel pins. The pins fit around the catheter tubing and were secured in the Styrofoam. At first, a syringe was used to inflate the catheter balloon but the deflation time of this method was too slow. In order to fix this problem, an air bulb was interfaced with the distal end of the catheter tubing. The balloon deflation time of this method was much more realistic. Finally, the elasticity of the catheter balloon caused the lever arm and consequently the eyelid to bounce upon reopening the eyelid. As a solution, a small piece of foam was placed underneath the counterweight to dampen the oscillations. With the foam in place, the lever arm no longer directly contacted the catheter in the open eye position; however, the blinking function of the eye remained effective.

Materials and Cost Analysis

Total expenses this semester (*Table 2*):

Item	**Cost**
Silicone Foley Balloon Catheter	13.52
Solenoid, Tubular Push Type	32.30
Axis Materials, Plating	1.62
Catheters	38.67
Air Bulb	7.99
Total	$94.10

Table 2. Total expenses: $94.10. Materials purchased September to December 2009.

Initially, one silicone Foley balloon catheter and one solenoid were purchased to evaluate which prototype design would be the most feasible. After making the decision to pursue a pneumatic prototype, the team purchased more balloon catheters, materials for the axis, counterweight, and lever arm, and an air bulb for a total of $94.10.

Total cost for a single, large scale prototype (*Table 3*):

Item	**Price**
Silicon-Coated Latex Straight Foley Catheter- 16 Fr/ 5cc	$1.71
Acrylic eye piece and eyelid	$5.00
Loop Screws (3)	$2.00
Copper Tube	$0.40
Steel Wire	$0.20
Aluminum Lever Arm	$0.10
Air Bulb	$7.99
Polymethyl Methacrylate $3.57/ oz	$0.71
Total Cost	**$18.11**

Table 3. Total cost of materials in single, large scale prototype: $18.11. Labor for fabrication not included.

In order to create a single prototype, the team used the materials listed (*Table 3*). The main element of our design is the Kenguard, Silicon- Coated Latex Straight Foley Catheter- 16 Fr/ 5cc that was purchased from www.iMED.com. The catheter used is a urinary catheter that has a tubing of 16 Fr. The tubing is connected to a balloon that expands to 5 cc. The air bulb actuator is from an earwax removal kit purchased from Walgreens. The capacity of the air bulb is 25 mL. The copper tubing, steel wire, aluminum plate, and lead counterweight were all purchased from Dorn Hardware and cut to the appropriate size. The total cost of a single prototype was calculated to be $18.11.

Testing

In order to ensure that the blinking orbital prosthetic prototype follows design specifications, multiple aspects of the prototype were tested. These aspects include user safety, force quantities, and blink duration.

A potential health concern associated with the use of this orbital prosthetic is that the balloon may rupture forcefully, therefore harming the user. This potential problem was evaluated by finding the maximum capacity of the balloon before failure from overload. A syringe was used to inflate the balloon. Since the capacity of the syringe was only 35mL, the syringe was repeatedly emptied into the catheter balloon. This was possible because the catheter has a mechanism that allows air to be trapped inside of the balloon even upon removal of the syringe. The results of this test were that the balloon can be inflated with approximately 420mL of air before rupturing (n=1). In the final design, the air trapping mechanism was removed from the catheter to allow deflation of the balloon in sync with the release of the air bulb. The air bulb regularly used to inflate the balloon only contains 25 mL of air; therefore, the air bulb volume is insufficient to overload the balloon. Ideally the same testing procedure would have been performed multiple times; however, the lack of catheters limited this testing to only one repetition. Future testing may repeatedly determine the required air pressure to overload the balloon, such that critical pressures can be evaluated with respect to different combinations of temperature and volume.

A second test was performed to find the force used to close the eyelid using a force transducer. The force transducer was positioned so that the eyelid would fall upon it during closure. Initially a small force transducer was used that had a maximum measurement capacity of 150g. The eyelid exceeded this capacity multiple times. A second force transducer was obtained with a greater capacity, but this transducer had less accuracy. The experimentally determined force of closure of the eyelid was approximately 200g (n=7), which corresponds to 1.962N. It should be noted that the force of closure of the eyelid measured by this method is different than the minimum force necessary. It is believed that the minimum force necessary to close the eyelid is less than 1.962N.

Finally, video analysis was used to find the blink duration of the large scale prototype. The eye was blinked 19 times in succession. Using video software, these blinks were observed in slow motion to find the precise length of the blink from the open position, through the closed position, and back to the open position. The bouncing motion associated with the eye opening was not included in the blink duration. Figure 10 shows the frequency of each blink duration. Of 19 total blinks, 73.4% were 300 or 400ms in duration. The remaining 26.6% did not deviate more than 100ms from the optimal range. The

average blink duration was .374 s, SE ± .02 s. This follows the design criteria of creating a realistic blink, since the average human blink is between 300 and 400ms. Also, there was no deterioration of blink quality when multiple blinks were performed. It should be noted that this testing was performed to find the minimal blink duration. If the user desires a longer blink for added emotion, this is possible through continued compression of the air bulb.

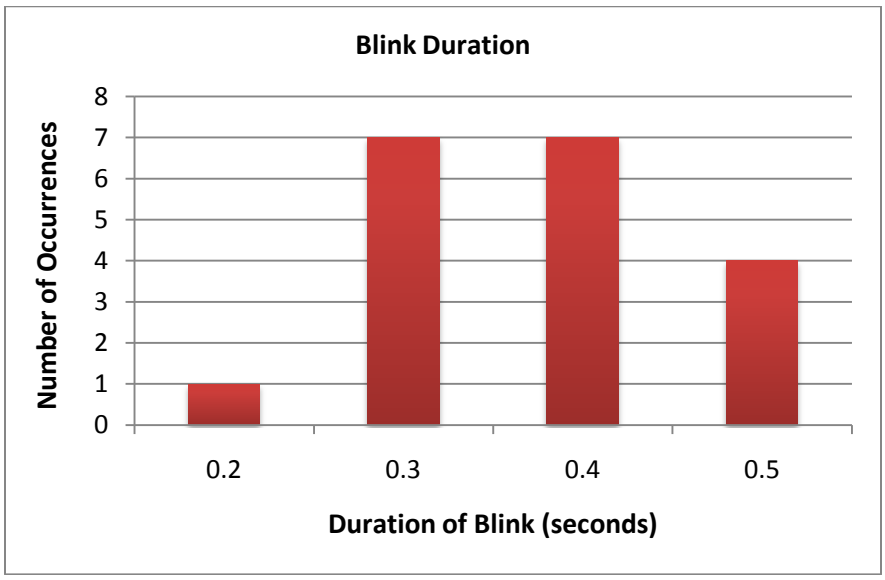

Figure 10. Number of blinks at a given blink duration (seconds). Duration of blink represents time for closure and reopening. Average blink duration = .374 s, SE ± .02 s. Precision of measurements limited to nearest tenth of a second by available software. n=19.

Ergonomic Considerations

Attention to human comfort and safety are essential for implementation of a successful blinking orbital prosthesis. Maintenance and operation by the user must be minimal in order to ensure satisfaction and improve quality of life for the user. The final blinking orbital prosthesis must also be implemented with minimal irritation to the living tissue it contacts. Ideally, the prosthetic would never need to be removed from the ocular cavity for maintenance, cleaning, or charging. The creation of a reliable design that requires minimal technical proficiency or alteration to the daily routine of the user is of utmost importance. Also, satisfaction of the user can be enhanced by the open-failure mode of the orbital prosthetic. This means that if the mechanism should fail, it will fail in the open position due to the position of the counterweight. This spares the user from potential embarrassment.

Ethical Considerations

The blinking orbital prosthesis is designed for incorporation into a living system. Our team aimed to create a device that holds user-safety above maximum functionality. Our team also considered and made known risks associated with repeated use of the device and potential failure of the device.

Currently, the counterweight in the orbital prosthesis mechanism is made of lead. While convenient for a proof of concept, because it is relatively inexpensive and dense, lead has been shown to cause harm to physiological systems (Nemours Foundation, 2009) and therefore would be unacceptable in a design intended for human use. Further developed pneumatic mechanisms would most likely utilize tungsten instead, which has been proven safe in physiological systems (Peuster, 2003).

Small-scale balloon catheters add significant cost to the fabrication of a pneumatic orbital prosthetic because they have been approved as specialized, "medical-grade" materials. This team has considered fabrication of a customized balloon and actuator system. If completed, special care will be taken to fulfill "medical grade" requirements, and hold the safety of biological interaction with the device paramount (Encyclopedia Brittanica, 2009).

Eventually, a refined pneumatic orbital prosthesis mechanism will need to be clinically tested in human subjects. Such experimentation will be done with full consent of the participant and with particular attention to participant health and safety.

Future Work

Though the large-scale prototype functions well to prove our design concept, several further steps need to be taken in order to make the pneumatic orbital prosthesis functional in a realistic environment.

Scale-Down

The first challenge will be to scale down the prototype to approximately 54% of its current size (*Table 4*). This will satisfy the design specification that restricts total prosthetic volume to 5.5cm^3. Currently, the device weighs approximately 20 g; therefore the scaled down model should easily satisfy the maximum weight specification of 45 g.

Component	Current	Ideal
Diameter (cm)	5.5	3.0
Lever Length (cm)	4.6	2.5
Tube Diameter (Fr)	16.0	9.0
Balloon Volume (cc)	5.0	3.0
Closure Force (N)	1.96	1.06

Figure 4. Reducing the size of the blinking orbital prosthesis will make it workable in a realistic setting. Ideal measurements are conservatively scaled to 54% of the current prototype.

size. Experimentation, material changes in the counterweight, and diameter of the small-scale balloon will dictate the shortened length. Minimizing the length of the counterweight lever will make the prosthetic a viable solution for patients with relatively shallow ocular cavities.

Design Refinements

After the prototype has been reduced to a realistic size, some refinements can be made to the design to enhance reliability. First, tubing length will be extended between the balloon and actuator bulb. This extended tubing, in conjunction with eyeglasses, can be used to make actuation by the user as discreet as possible; tubing exiting the prosthesis can be buried in the eyeglass frame, run behind the ear and into a pocket, from which the user could actuate blinks.

Besides extended tubing, the pneumatic system in the scaled-down prototype could be improved further by making the balloon, extended tubing, and actuator bulb one continuous unit. Not only would this reduce production cost and effort, it would minimize chances of air leak within the system, and therefore minimize the potential for design failure.

Finally, construction of an enclosure for the prosthetic device can be considered. Completion of a complementary orb or frame would allow correct, reliable placement of each component of the device with respect to other components, reduce risk of irritation to tissue by individual design components, and offer secure placement of the enclosure and prosthetic in the orbital cavity.

Material Changes

During design refinement, some material changes can be made to enhance the function and the naturalism of the prosthetic. Thin, naturally sculpted layers of silicone can be molded for the upper and lower lids of the prosthetic eye, and placed over the lightweight acrylic that currently serves as the upper and lower lids. The addition of this layer will provide the prosthetic with a natural appearance comparable to that observed in the current static prosthetics (*Figure 1*) while still maintaining a low lid weight. This translates to a lighter counterweight, greater ease of actuation, and therefore realistic functionality of the device. Also, coating of the hard acrylic lids in the current prototype with softer, dampening silicone will reduce the noise currently associated with lid closure, and reduce rebound oscillation observed upon re-opening of the upper lid. The eyepiece will also be changed from the current acrylic and rendered realistically.

Currently, the proposed pneumatic design for an orbital prosthesis uses a medical grade catheter balloon to displace the counterweight, causing a blink. Small-scale, similar grade catheters are nearly impossible to procure at a reasonable price; any scaled-down prosthetic may instead utilize a prefabricated balloon made continuous with the extended tubing and actuator bulb. This also could be made of 9 Fr medical grade silicone, specifically for the prosthetic. It would therefore not include 2-way or 3-way drainage pathways designed into urinary or tear duct balloon catheters, which would reduce unnecessary material and cost.

Finally, the current, large-scale prototype utilizes a dense, lead counterweight. Since lead has the potential to cause physiological harm, future prototypes will more likely utilize a tungsten counterweight; tungsten has a high density (19.3 /gmL) (THP, 2009), and elevated levels do not harm human cells (Peuster, 2003).

Testing

Besides blink duration, force of closure, and maximum balloon capacity testing on the small-scale prototype, it would be beneficial to perform long-term testing on the device, primarily to determine how many actuations can occur before blink failure.

Future work incorporates the addition of extended tubing, therefore it must be determined if the extension of the closed-air system significantly slows blink response time or blink duration.

Testing should also be performed to determine the viability of the prosthesis in a realistic setting. Evaluation of functionality in various environmental conditions such as slight moisture or excessive cold and in orientations besides the upright position will help to determine usability.

Conclusion

The creation of an operational blinking orbital prosthesis could provide social and mental relief to over 11,000 people currently living with ocular exonerations. The design, fabrication, and testing of a large-scale, pneumatic blinking orbital prosthetic shows promise in providing this relief. Though the design must be scaled to a realistic size, and further testing must be performed to ensure safe, effective operation in a realistic setting, further development of the pneumatic design has great potential to improve the quality of life for those affected by eye loss.

References

Adkisson, Jay. April, 2006. Coping with Monocular Vision after Enucleation or Eye Loss from Cancer, Accident, or Disease. ISBN: 9780595392643

Adkisson Publishing, Inc. 2008. Lost Eye Support and Information. http://www.losteye.com/enucleat.htm September 15, 2009.

Gion, Gregory, Allison Vest. Medical Art Prosthetics Clinic. http://www.medicalartprosthetics.com/content.php?page=galleries&gallery=orbital

Honda M., A.Niimi, M.Ueda"New Orbital Prosthesis With a Blinking Eyelid: Report of a Case" *Journal of Oral and Maxillofacial Surgery*, Volume 57, Issue 6, Pages 730-733

LacriCATH: Quest Medial, 2009. Lacrimal Duct Catheter: *Product List.* http://www.lacricath.com/products/ November 6, 2009

Lee, P., Wang, C. C., & Adamis, A. P. (1998). Ocular neovascularization: An epidemiologic review. Survey of Ophthalmology, 43(3), 245-269

Materials Science, 2009. Encyclopædia Britannica Online: *General Requirements of Biomaterials* http://www.britannica.com/EBchecked/topic/369081/materials-science December 07, 2009

Nemours Foundation, 2009. *Lead Poisoning* http://kidshealth.org/parent/medical/brain/lead_poisoning.html December 5, 2009

Peuster, M., Fink, C., von Schnakenburg, C., 2003. Biocompatibility of corroding tungsten coils: in vitro assessment of degradation kinetics and cytotoxicity on human cells. *Biomaterials.* Oct;24(22):4057-61.

Simeray, Janick . December 2001. http://www.freepatentsonline.com/20020049023.pdf

Tungsten Heavy Powder, Inc. (THP) 2009. General Information: *Maximum Density, 20˚C* http://www.tungstenheavypowder.com/Tungsten_Heavy_Powder/About_Tungsten/about_tungsten.html December 1, 2009

Appendix A

Project Design Specifications—Blinking Orbital Prosthesis
September 16, 2009
Team: Carmen Coddington, Bryan Jepson, Elise Larson, Michelle Tutkowski
Client: Greg Gion, Medical Art Prosthetics
Advisor: Willis Tompkins, Biomedical Engineering

Function:
The Orbital Prosthesis will function as a natural, blinking ocular replacement. Machinery will be contained within the prosthesis, which will fit into the ocular cavity behind the acrylic eyepiece. This eyepiece will be held in place by a silicone mold which will gently interface with the skin. The prosthesis should weigh less than 45 g, have a minimum lifespan of three years, and should not cause detrimental physiological effects.

Client Requirements:

- Cost Effective
- Natural Appearance
- Simple Mechanism
- Reliable Blinking Function

Design Requirements:

1) Physical and Operational Characteristics

a) *Performance requirements* – Must blink on command.

b) *Safety* – No negative biological effects: no harmful electromagnetic, chemical, or physical components

c) *Accuracy and Reliability* – Must consistently blink on command.

d) *Life in Service* – Used daily for 3-4 years.

e) *Shelf Life* – Not applicable; prostheses are custom made for immediate use.

f) *Operating Environment* – In contact with skin and adhesive, close proximity to brain may require magnetic connections. Must operate from -40^{o} to 45^{o} C.

g) *Ergonomics* – Comfortable for extended use, easily maintained, convenient blinking control device.

h) *Size* – Mechanism contained in 5.5 cm^3 spherical volume.

i) *Weight* – Less than 45g.

j) *Materials* – Cost-efficient, no latex, polymethylmethacrylate (PMMA) recommended.

k) *Aesthetics* – Must maintain natural appearance of eye and surrounding tissue.

2) Production Characteristics

a) *Quantity* – One prototype device.

b) *Target Product Cost* – $2000. This includes acrylic eye and blinking mechanism.

3) Miscellaneous

a) *Standards and Specifications* – FDA approval is not required. The device will be considered a "custom device" by the FDA; therefore, FDA review and approval for the use of the device are unnecessary.

b) *Customer* – Individuals in need of an ocular prosthetic.

c) *Patient-related concerns* – Should look realistic to an outside observer, and give the patient confidence in their appearance.

d) *Competition* – Traditional orbital prosthetics, self-lubricating orbital prosthetics (U.S. Patent 5171265.)