10/21/2009

Blinking Orbital Prosthesis

Carmen Coddington, Bryan Jepson, Elise Larson, Michelle Tutkowski

Greg Gion, Medical Art Prosthetics Clinic, Inc.
Willis Tompkins, University of Wisconsin-Madison

Abstract

Incidents occur each year that leave people with a large facial gap where their eye had previously been. Prosthetic eyes are a common solution to this 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, while developing three main design alternatives to accomplish this goal. These alternatives were evaluated, and a pneumatic solution will be pursued as the final design concept. Successful fabrication of the design will increase the patient's social comfort and confidence in their new orbital prosthesis.

Table of Contents

Background Information

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.

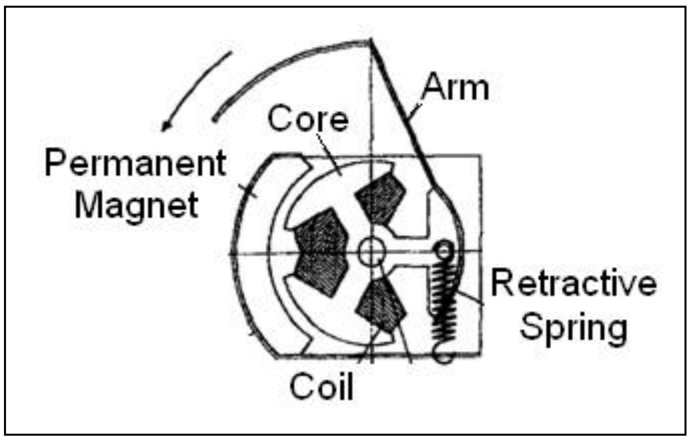

Figure 2. Schematic diagram of the electromagnetic-activated blinking orbital prosthesis (Honda et al 1999).

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.

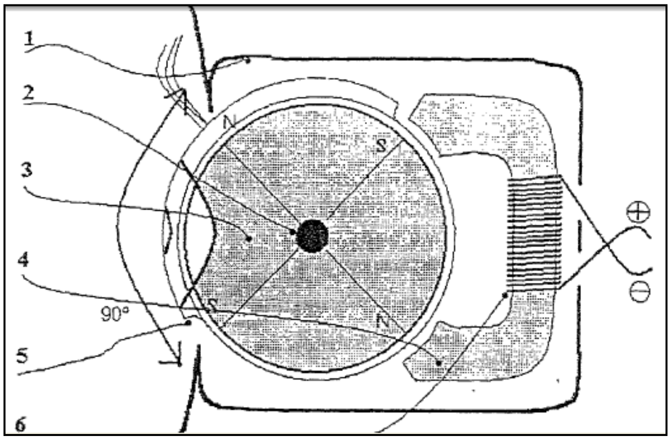

Figure 3: Diagram of doll's eye lid patent design. (Simeray 2001).

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.

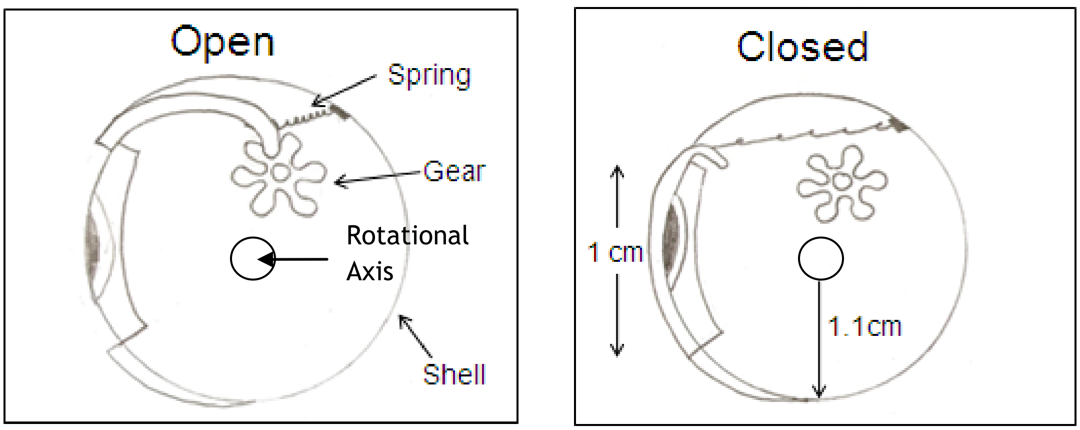

Figure 4. Diagram of the mechanical wind-up design alternative, which utilizes stored potential energy to execute blink. Rotational axis extends behind page. External blink controlling device not shown.

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.

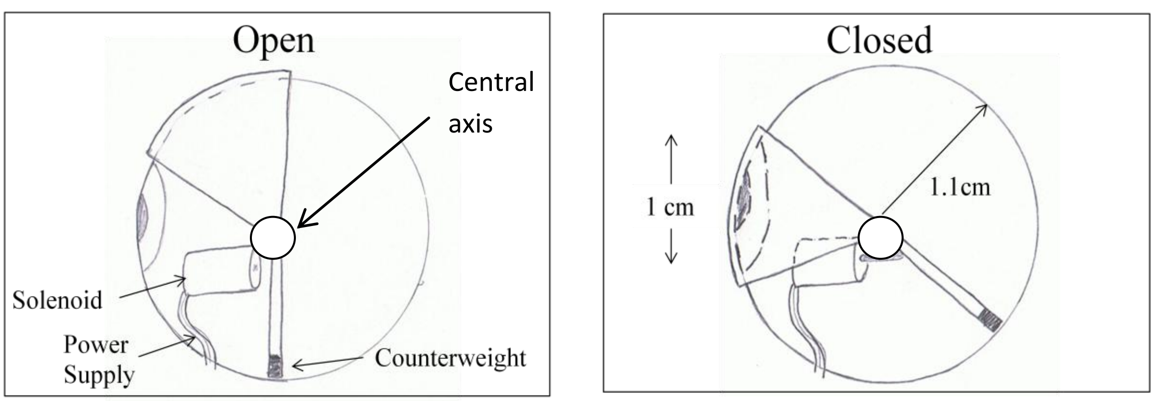

Figure 5. Diagram of the push solenoid design alternative. Mechanism utilizes protruding pin and counterweight to execute blink. External controlling device not shown.

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)*.

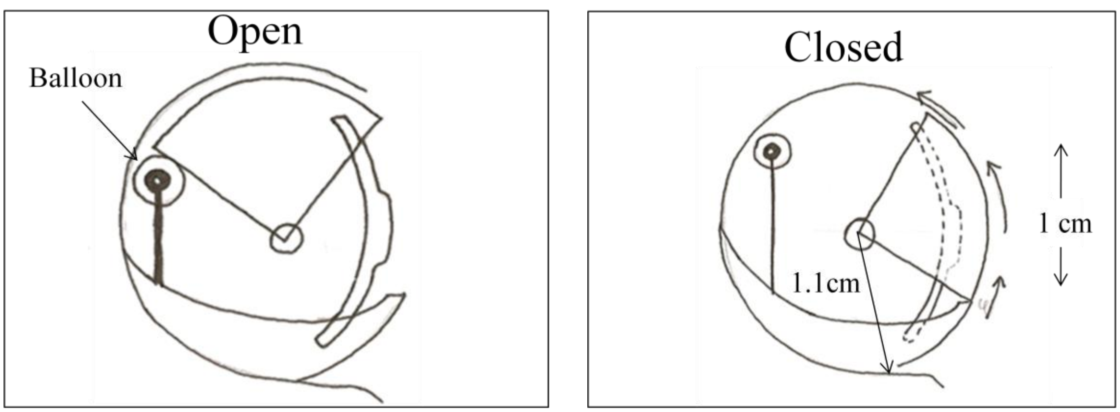

Figure 6. Diagram of the pneumatic design alternative, which utilizes air pressure stored in a closed system to inflate a catheter, and trigger a blink. External controlling device not shown.

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 basis for 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 *(Figure 7).*

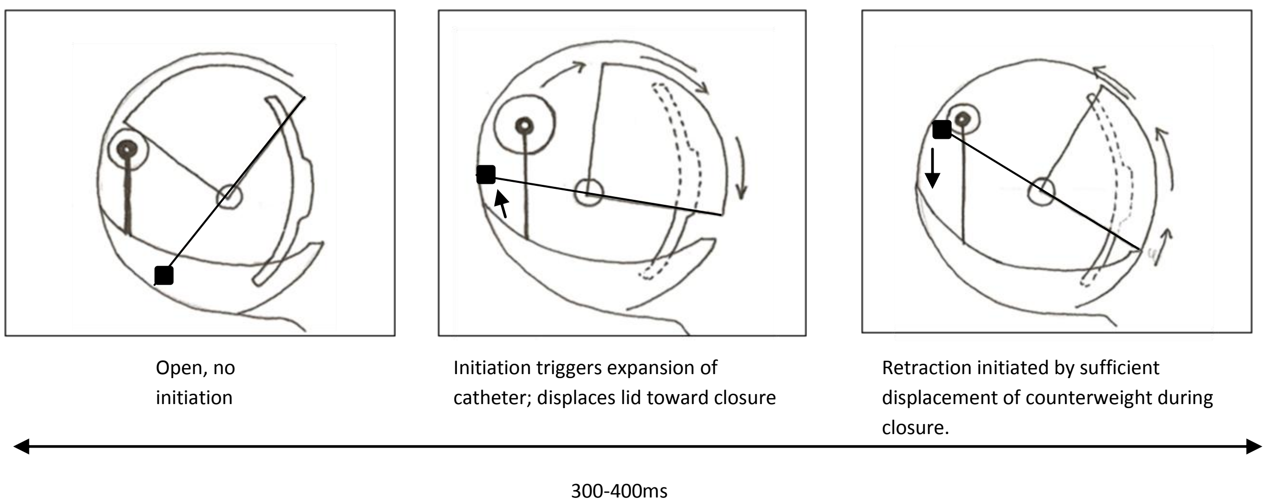

Figure 7. Mechanism of final, pneumatic solution. Blinking motion will be triggered by expansion of the balloon catheter; upon deflation and displacement of a counterweight, lid will retract into open, resting position. Completion of sequence will take place in 300-400ms.

Potential Obstacles

The implementation of the pneumatic solution as a final concept offers interesting challenges. The first is the effective, aesthetically natural incorporation of an air pressure tube necessary for actuation. Our team is investigating the use of glasses to disguise a small airway. Also, complete retraction of the lid depends heavily on rapid, consistently reliable deflation of the balloon catheter after inflation. The team is considering the use of fluid in place of air within the catheter system in order to facilitate more rapid deflation.

The final design utilizes a counterweight to guarantee retraction of the lid. Alternative mechanisms of retraction including the implementation of a repelling magnetic field between upper and lower lid, incorporation of elastic materials to facilitate recoil, and spring tension, have been considered and will be evaluated further as alternative forms of retraction throughout the testing process.

Ergonomics

Attention to human comfort and safety will be 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.

Though aesthetic differences between the natural eye and current static prosthetic solutions are nearly imperceptible, the user may still feel conspicuous during extended conversation or interaction, because the absence of a regular blink is distracting to colleagues or acquaintances. The final blinking orbital prosthesis device must offer natural movement to disguise the artificial nature of the prosthetic. Furthermore, the design must inherently contain the most natural-looking failure mode to avoid embarrassment should the design malfunction.

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 also of utmost importance.

Ethical Considerations

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

Future Work

Though prototype designs are promising, there is still much work to be done before an operational blinking orbital prosthesis can be completed. First is the creation of a large-scale, proof-of-concept model that can be used for preliminary testing. The team can determine whether deflation can occur rapidly enough to facilitate a 300-400ms blink, whether a counterweight retraction mechanism is the most efficient option, and if media besides air will lead to a more reliable design. The most efficient use of internal space can be determined, as can the most failsafe arrangement of components.

The team will then scale down the mechanism, and determine operational rotating lid arc length, catheter diameter, internal media pressure, tube length, and the necessary counterweight. The team will order materials and fabricate a blinking orbital prosthesis that operates reliably in or under a 5 cm^3 volume. A few materials have already been purchased. These expenditures are shown in table 2 and include an experimental balloon catheter and a push solenoid which were used to evaluate the feasibility of the pneumatic and push solenoid design alternatives.

Date	Item	Cost
10.9.2009	Silicone Foley Balloon Catheter	13.52
10.9.2009	Solenoid, Tubular Push Type	32.30

Table 2. Current team expenditures.

Meanwhile, our team plans to visit the Medical Arts Laboratory of Greg Gion to observe his working methods. Incorporating his talent will benefit the user of the blinking orbital prosthesis greatly; he will be able to create a flawless aesthetic interface between the mechanism and user's living tissue.

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. Though testing and fabrication are sure to offer challenges, 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

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

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

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.)