Blinking Orbital Prosthesis

Client: Gregory G. Gion, MMS, CCA

Advisor: Professor Pablo Irarrazaval, PhD

Co-Leaders: Justin Cacciatore, Michael Konrath

Communicator: Blake Marzella

BWIG: Michael Musser

BSAC: Jeff Groskopf

Appendices :

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 breaks the illusion of realism every time the patient blinks. Previously, we were able to create the mechanism for a blinking prosthesis. Our goal is now to be able to synchronize that mechanism to blink at the same time as a healthy human eye. This will further increase the realism of the prosthesis, helping Mr. Gion to better achieve his goals. Through our research, we were able to find methods of detecting blinking and incorporate them into our design. From this we have devise a blinking orbital prosthesis which can be synchronized with a healthy eye using an LED/photodiode system due to its safety and easy of use.

Introduction

Prosthetics falls into a field of study called biomechatronics, which is the science of integrating mechanical devices into biological systems [1]. The term prosthetics more specifically refers to 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 [2]. The first use of prosthetics dates back to thousands of years ago when Ancient Egyptians used simple pieces of wood or animal bone to replace injured limbs [3]. Today, prosthetic science is vastly growing as the fields of medicine and engineering continue to push technology to new heights. There are now prosthetic devices available to replace a huge variety of injured or diseased body parts, joints, and even internal organs.

Background

Figure 1: Missing orbital cavity (left); after orbital prosthesis implantation (right) [2].

The type of prosthetic device that pertains to our design this semester is an orbital prosthetic. Orbital prosthetics are prosthetics that are used to replace a missing eye and eye socket, or "orbital" region. This region often extends far beyond the eye itself; it can include the eyelids, eyebrows, nasal tissue, or even parts of the cheek depending on the severity of the patient's situation [2]. Patients that require an orbital prosthesis usually undergo surgery first to remove the affected eye and eye socket. This is the main component that sets orbital prostheses apart from ocular prostheses. Ocular prosthetics are used when only the patient's eye has been removed, in which the prosthetic eye can simply be inserted back into the existing eye socket. These prosthetics require a less extensive surgery called enucleation, where only the eyeball is removed [4].

Figure 2: Artificial eye made of PMMA, with surrounding silicone "skin." [www.eyeconcern.com]

The surrounding tissue region in an orbital prosthesis is most commonly imitated by silicone, or some kind of silicone-based material. Silicone is a popular material in most prosthetic devices because of its durability, flexibility, and biocompatibility. Most importantly, silicone can be easily crafted to look impressively skin-like. The artificial eyepiece itself is most often made out of a material called polymethyl methacrylate (PMMA). PMMA is a semitransparent thermoplastic that can be easily manipulated when heated. The resulting glossy, translucent look of PMMA gives it a striking resemblance of a real human eye (see Figure 2) [5]. The use of these materials to craft an orbital prosthesis is just as much an art form as it is a science. This falls under a term called anaplastology, which refers to the blending of artistry and science to create a prosthetic that is as aesthetically pleasing as possible [2]. Since orbital prostheses are dealing with a patient's facial region, this is an especially essential part in creating such devices. Anaplastologists consider meticulous details such as wrinkles, blood vessels, hair follicles, and even freckles while customizing the prosthetics. Each prosthetic is completely unique to precisely match the appearance of each patient [2]. Patients who receive an orbital prosthesis are recommended to wear eyeglasses. This serves as protection for their one remaining healthy eye as well as helps mask the appearance of the prosthetic.

Problem Statement

Every year people all over the globe of any age or gender experience injuries, genetic defects, and diseases to the eye and its surrounding tissues. These health issues

Figure 3: Current prosthetic eye keeps shape even when squeezed by fingers www.medicalartprosthetics.com

could be severe enough to require the eye cavity to be surgically removed. If this happens, patients will want to have some way to make their face appear to be normal. Orbital prostheses are used to replace the full eye cavity and are made to look exactly like the patients previous eye. The realistic appearance will help the patient gain self-confidence and improve their self-image. However, no matter how realistic and aesthetically pleasing orbital prosthetics are, they still cannot replicate the full functionality of a real human eye. Current orbital prosthetics are static and cannot blink. As illustrated in Figure 3, the eyeball and prosthetic has no moveable parts. This is why last semester we developed a mechanism that allows an orbital prosthetic to have a realistic looking blink. Our group created a working presentation model to help show how the mechanism worked. This semester our client desires for us to expand on our blinking mechanism by synchronizing the blink of our prosthetic eye with that of a healthy human eye. Also, he wants us to reduce the size of our current mechanism. These two further developments will improve our presentation model so that it more closely resembles a fully functioning and implementable prosthetic eye.

Problem Overview

The development of last year's mechanism that creates the realistic blink of the eye in an orbital prosthesis was the first step to providing individuals who have endured the surgical removal of the eye cavity with a fully functioning orbital prosthetic. Our client was pleased with how last year's presentation model turned out, but now we can improve on this model to slowly transition it to becoming an actual orbital device. Our client has emphasized that our main focus should be synchronizing the blink of the prosthetic to the patients' healthy eye. This will create a more realistic appearance for the prosthesis. However, the synchronization needs to be accomplished without removing the realism and aesthetically pleasing appearance of the current presentation model. In order to accomplish this, we will need to research different ways to detect the signal of a healthy eye as it blinks. Finally, our client also wants us to compact the current blinking mechanism in order for it to fit into the eye cavity of a patient.

Problem Motivation

Anaplastolgists create prostheses to look as identical to an actual human eye as possible [10]. They want to make it so that the patient can live their life without the surrounding population knowing that the patient had an orbital prosthesis. However, the static nature of the prosthetic prevents a completely realistic appearance from being obtained. With the mechanism we created, we have allowed the orbital prosthesis to blink. This makes it appear more realistic; but, if the prosthetic blinks at a different time than the normal eye, it will seem even more fake than the non-blinking prosthetic. This gives us a motivation to develop a synchronization system of the healthy eye with the orbital prosthesis to help these patients to gain a feeling of normalcy.

Design Constraints

Our client, Mr. Greg Gion, has set forth a number of specifications for our design this semester. As mentioned above, our goal for the semester is synchronization. With this goal in mind, our client has stressed to us that we are striving towards a *working presentation* *model*. Essentially our model will demonstrate “proof of theory” that synchronization of an orbital prosthetic eye blink is not only possible, but plausible for future medical applications. Our client understands that in order for such a mechanism to be fully implemented into a real-life patient, many more design aspects will have to be considered that are beyond the scope of our immediate project.

Mr. Gion has proposed that we come up with some type of bracket or casing that can encompass both our motor and eye piece into one, compact structural component. This would ensure consistent tension between the cords which would make our mechanism much more accurate and durable for repeated use in the future. He also requests that this bracket have some kind of detachable component so that adjustments and modifications can still be made to the mechanism if need be. As always, we need to keep in mind the materials being used for the safety of the patient and to keep it easily interchangeable in case we run into problems during further development. Lastly, our client has given us a budget of approximately $500 for our semester’s work.

Previous Work: Embedded Cord Tension Mechanism

Last year we worked to develop a mechanism to cause an orbital prosthesis to have the ability to blink. We accomplished this task by studying the surrounding muscular structure of the eye. Two separate pieces of fishing lines are used in our design to replicate two muscles of the real eye, the orbicularis oculi and the levator palpebrae. The fishing line is tightened and allowed to relax by a servo motor. The servo tightens the closing cord (based on the orbicularis oculi) while relaxing the levator cord (based on the levator palpebrae), and viceversa.

We used an actual prosthetic orbital made by our client and incorporated our mechanism. The upper eyelid was removed and a new one was created out of silicone with the fishing line cords embedded within. The placement of the fishing line is diagrammed in Figure 5. The silicone allows for a very realistic appearance.

The servo motor we used was the Feather Hitec HS-56 servo. It was controlled with an Arduino Deumillanove board programmed to rotate the motor 90^o and back at the push of a button. The motor was positioned an appropriate length to pull the cords enough to create a full blink.

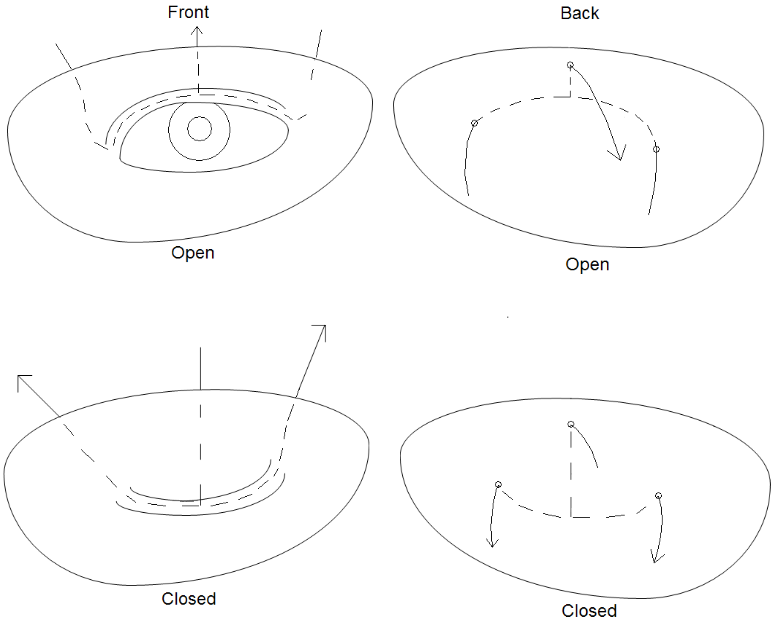


Figure 5: The placement of the cords and how they're pulled; drawn from the front and back.

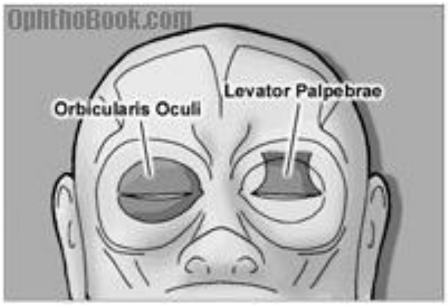


Figure 4: Eyelid muscles with the orbicularis oculi and levator muscles
http://www.ophthobook.com

Improvements to Last Year's Mechanism

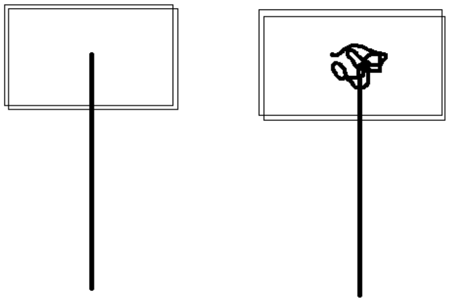


Figure 7 Left: The first semester levator cord design bonded straight between the two sheets of silicone that make up the upper lid. Right: The new levator cord design which has much more surface area for the silicone adhesive to bond to between the two sheets of silicone.

Figure 8. Using a weight set to quantitatively test the strength of the new and old levator cord design.

Several improvements have been made to our current mechanism that do not fall under our main focus of synchronization. The first improvement made on last semester's design, is a newly designed levator cord (Figure 7)., the piece of fishing line that is pulled by the motor arm to reopen the eyelid. Formerly, the levator cord was oriented straight along the vertical axis of the upper lid. This fishing line was bonded between the two sheets of silicone that make up the upper lid of the prosthetic with a silicone adhesive. Because silicone is notoriously difficult to bond to other materials and because the fishing line did not provide much surface area to adhere to the silicone sheets, this bond was not strong. It only last several weeks before breaking in our original presentation model and was able to support only 450g before breaking in a controlled test run (Figure 8.). To increase the strength of the levator cord, one end of the fishing line was melted with an open flame until it began to deform. It was then folded over itself with a small metal spatula and flattened to create a wide flat piece at the end of the line. This was done to increase the surface area of the end of the cord and give the adhesive silicone a greater area to bond to. When this line was bonded into the silicone lid, it was found to hold 750g before breaking, an increase in strength of 66%.

Current Devices/Competition

Currently orbital prostheses are widely used around the world. To this date, however, there has yet to be an orbital prosthetic device in humans that is able to mimic the blink of a real human eye. In regards to our goal for this design, there is extensive research available that suggests a variety of methods for recognizing and detecting blink occurrence. Some of these include obtaining muscle or brain signals that correspond to blink stimuli - different methods for harvesting these signals include electromyography (**EMG**), electrooculography (**EOG**), and electroencephalography (**EEG**) [6]. Eye tracking devices or cameras can also be programmed in ways to detect blinks [7].

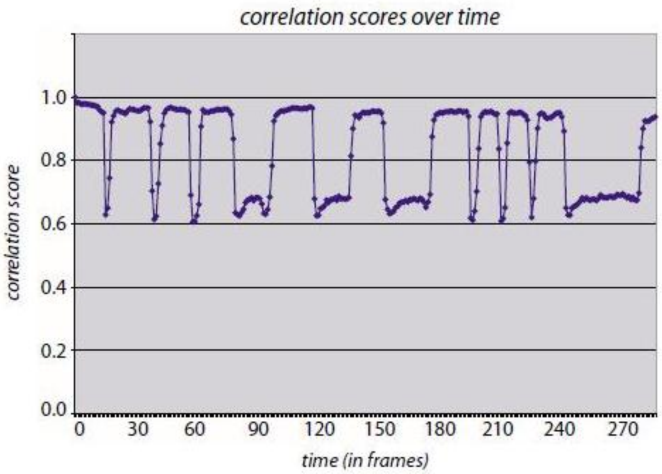


Figure 10: Example of blink detection program [7]

The graph below (Figure 10) is part of a computer science study conducted at Boston University in Massachusetts. Using a simple USB computer camera, the students were able to come up with an algorithm that proved affective at detecting blinks. After recording a few eye blinks, the program creates an "online template" that correlates to an open eye. This template is assigned a correlation score of positive one. A blink causes variation from the open eye template, which thus creates a valley on the graph where the correlation score is lowered. Although this system was relatively simplistic in principle, it still was tested to have nearly 90% accuracy on a sample of 2300 blinks [7]. We researched and brainstormed many possible ways to detect blinks in efforts to fulfill our goal of designing a fully synchronized blinking mechanism. Full details of these methods can be found in the "Potential Designs" section.

Potential Designs

EMG/EOG

Our first design idea uses electrodes to measure the electromyogram (EMG) or the electrooculogram (EOG) generated by blinking. The EMG is the electrical potential generated by muscle cells. For picking up a blink, the EMG is measured for the Orbicularis oculi. The Orbicularis oculi is a sphincter muscle and is responsible for closing the eye as shown in Figure 11. [9].

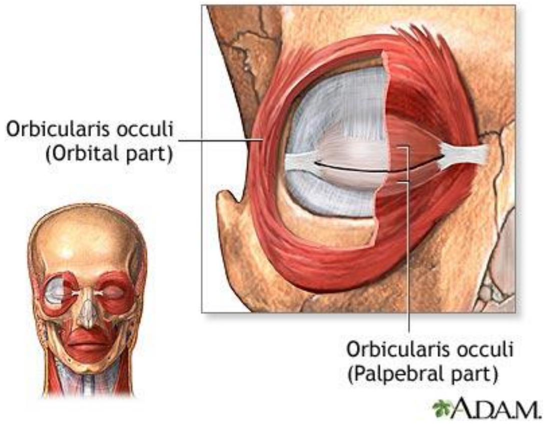


Figure 11. Diagram showing the anatomy of the Orbicularis oculi (http://www.nlm.nih.gov/medlineplus/ency/images/e

For our purposes, the EOG signal would be due to the vertical movement of the eyelid. EOG typically is used to determine eye movement. The anterior end of the eye serves as a positive pole with the posterior end serving as a negative pole. This creates a dipole which affects the potential read by the electrodes. The vertical movement of the eyelid during a blink alters the effects of the dipole on the electrodes, which subsequently makes it possible to use the EOG to detect blinking [8].

Both the EOG and EMG would require the use of three electrodes. It is possible to use two electrodes; however, the signal would not be very accurate. The placement of the electrodes is shown in Figure 12.

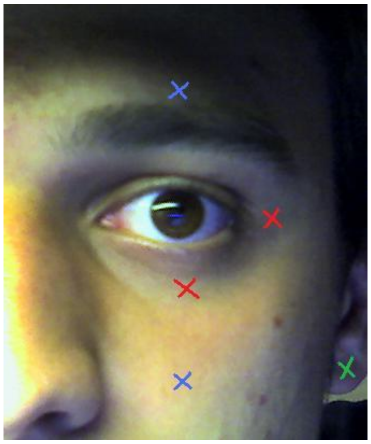


Figure 12: Red x's represent EMG electrode placement, blue x's represent EOG and the green x is a reference electrode used by both the EOG and EMG.

These electrodes would ideally be surgically implanted into the patient to generate the best signal as well as best hide their presence. However, this is impossible for our project, so surface electrodes would need to be used. Since the electrodes would need to be worn by the patients with orbital prostheses for long periods of time, long term electrodes would be needed. Finally, to prevent patients from having to prepare the electrode site by abrading the surface or using any gel, dry electrodes would be used [8].

The voltage generated by the EMG and EOG is very weak, approximately 500 μV [8] (Figure 13.) . To be read and read accurately, this signal would need to be amplified. Also, to eliminate noise from other muscles as well as external sources, the signal would need to be filtered. A passband between .3 and 50 Hz is adequate [8] . A bio-amplifier can do both of these as well as prevent any electrical shock to the patient. An amplified and filtered signal can be between 80%-90% accurate [8]. This signal would be sent to our Arduino board via wires threaded down a pair of glasses. If voltage passed a certain level, the servo motor would be triggered to blink.

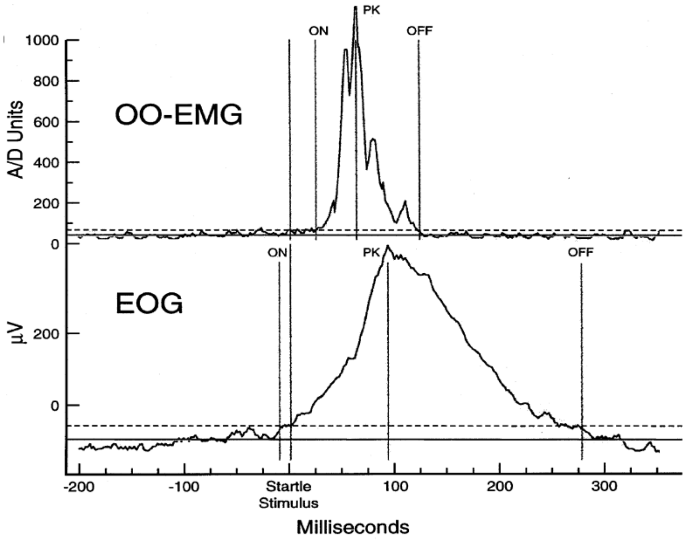


Figure 13: Example EMG and EOG signals [8].

This design has some major disadvantages. Wearing three electrodes would be very inconvenient for the patient. The electrodes would also hinder the realistic appearance of the prosthetic even when disguised. The patient would also have to precisely place the electrodes themselves. The placement needs to be correct in order to generate a signal accurate enough to trigger the servo correctly. While dry, long-term, surface electrodes are pretty inexpensive, about $50 for a pack of 30, they would need to be continuously purchased. This combined with the cost of a bio-amplifier would make this design the most expensive of our three.

Camera

Our second design idea centers around the use of a camera. The first hurdle was making sure we could find cameras small enough for our purposes. We found that the size of the camera would not be a problem for this design. For example, there are cameras that cost $30 that are 5 cm in their longest length and weighing less than 15 g that we could use. More expensive cameras only get smaller and lighter. Either wired or wireless cameras are an option. The camera is attached to pair of glasses (Figure 14.), attached on the arm with a mirror to reflect the image of the eye into the lens of the camera. This creates more distance between the eye and the camera in order to get the whole image of the eye in frame. Figure 4 shows this setup.

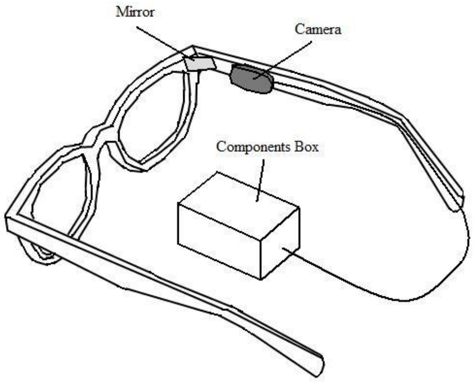


Figure 14: Diagram of glasses design.

The camera would be used with image recognition software. This would be used to create a template of what the open eye looks like. This could be done once since the glasses allow the camera to be positioned in the same spot at every use. However, if this proves inaccurate, template creation can be done at the start of every use. When the user blinks, the image recorded by the camera would differ from the template [7]. A threshold would be set so that when the image differs by an amount greater than the threshold, the servo would be triggered to blink.

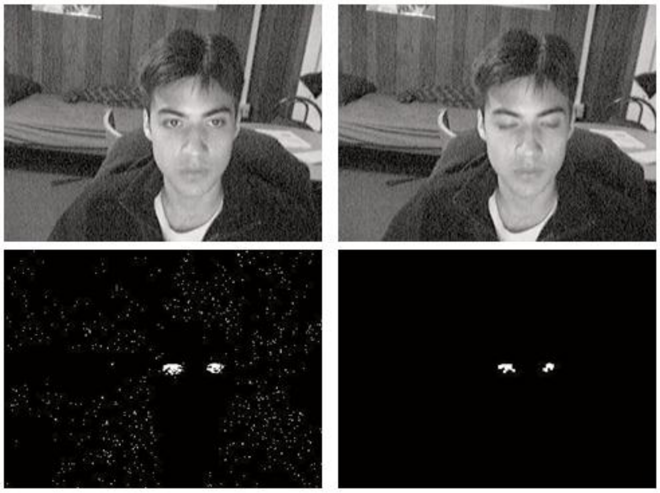


Figure 15: The first picture is the open eye which is used as the template. The second picture is a fully closed blink. The third picture is the difference between the first two with the last eliminating the noise of the third [7].

Using a correlation of .85 as the threshold, one study was able to detect blinks with 95.3% accuracy [7].

This study and multiple others have already written programs to detect blinks. An example of the waveform generated by one of these programs is shown above in Figure 15. These programs require much more powerful hardware than our Arduino board. However, these studies had the camera multiple feet away from the eye, having the whole face as well as background items in the picture of the camera [7]. Since we would only be looking at the eye and some surrounding tissue, we believe we can simplify this programming to not require such powerful hardware. However it would still be unlikely to simplify it enough to use with our Arduino. We could however simplify it for use with an ARM processor instead of a laptop like was used in the studies.

Figure 16: Example of an ARM processor (http://www.embeddedsys.com/subpages/products/images/sbc1625.jpg).

As well as more than likely requiring a more powerful processor, this design would need an image acquisition board in order to work with either an Arduino or ARM processor (Figure 16.). All of these components, including the batteries to power the design, would be contained in a box and kept in the patient's pocket. The added weight of the camera to the glasses would cause minor imbalances in the glasses on the patient's face. While this wouldn't be very substantial, it could be enough to alter the image picked up by the camera. It would be very simple to add a counterweight to the other arm of the glasses to correct this, which is something we would do. Wires for both the camera and blinking mechanism would run along the glasses.

The additional hardware, as well as much more complicated programming, is the main drawback of the camera design. This would make it much harder for us to complete the design by the end of the semester. It would also make it more expensive. However, this design is very accurate and patient friendly.

Infrared LED and Photodiode

Our third design utilizes an infrared light emitting diode (LED) to illuminate the eye's surface and a photodiode to detect the reflection of IR light from the eye. As the LED is constantly emitting light against the eye, the amount of IR reflected back into the photodiode changes the course of a blink. That is, there is a greater reflection of IR light from the eyelid than from the cornea. This increased reflection of IR light from the eyelid causes an increased voltage typically on the order of 500 mV[11]. It is this increased voltage that serves as a signal to detect when an eye blink occurs. This increase in voltage can then be read by our Arduino circuit board, mentioned in our previous work, to stimulate the prosthetic eye to blink. To account for fluctuations in eyelid movement from a normal blink, such as squinting, we could program the Arduino to only stimulate mechanism to blink when the magnitude of the current coming from the photodiode crosses a certain threshold. This would prevent the prosthetic eyelid from completing a full blink if the normal eye only partially blinks or squints. Programming a threshold value would also allow us to customize the design for different user. That is, it is reasonable to assume that the eyelids of different individuals reflect various amounts of IR light. Programming different threshold values would allow us to compensate for these differences and make the device more customizable. The models we are looking at using are an Osram SFH485-2 IR LED and the Osram SFH229 Fa Photodiode as shown in Figure 17, with the LED and photodiode house within one device.

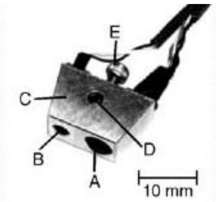


Figure 17: Osram LED and Photodiode[12]

The use of IR light as a detection method makes this design susceptible to interference from sources in the environment that emit IR light, such as fluorescent light bulbs and the sun. The interference from these sources could drastically alter the amount of IR light entering the photodiode, causing the prosthetic eye to blink out of sync with the normal eye. This can be overcome by using either a brighter IR illuminator or by using high frequency, pulsed IR illumination to differentiate the signal from the excess noise. The Osram SFH-485-2 IR LED can pulse light at a frequency of 62.5 kHz to help eliminate this problem[11,12]. Another difficulty to overcome would be relocating the correct orientation of the LED and photodiode with respect to the eye each time the device is used. This could be overcome by fixing the LED and photodiode to a pair of glasses, which would keep a fairly constant distance and orientation of the device to the eye between periods of use. This is illustrated below in Figure 18.

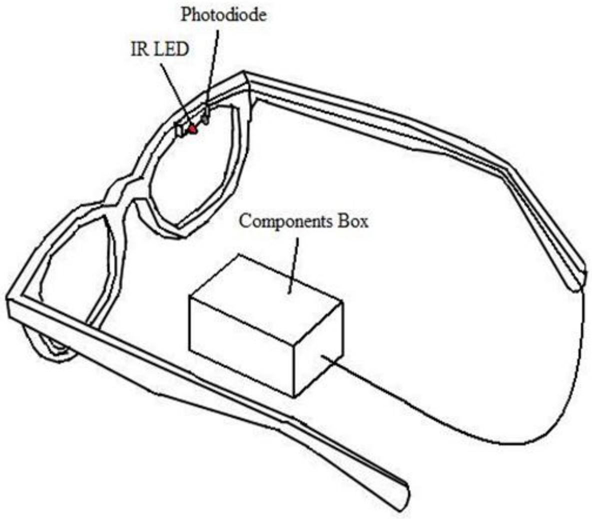


Figure 18: Fixing of LED and photodiode to a pair of glasses for patient use.

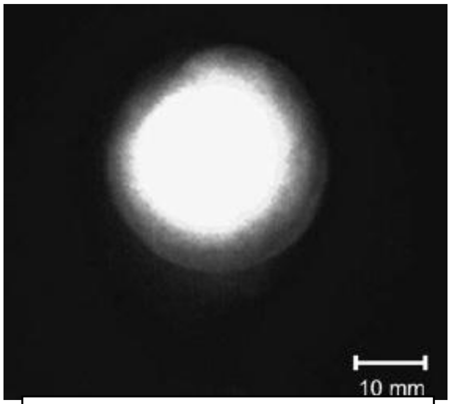


Figure 19: Surface viewing area of photodiode at 20mm

In researching this design, we found a study using the same model LED and photodiode as we propose using to detect eye blinks in laboratory rabbits. It was found that the photodiode was able to detect eyelid movement within 0.3% of a full blink, suggesting that this device can quite easily and accurately detect eyelid movements[11].It has also been found that a wider field-of-view acquired at a distance of 20mm from the eye, which is common distance with glasses, creates a viewing surface area of the photodiode of around 177mm^2, as shown in Figure 19, which is roughly the area of the upper eyelid[11]. This study also found that the LED/Photodiode's power consumption is 150mW and had an intensity of 4.46mW/cm^2 at a distance of 20mm from the eye[11]. The results of this study indicate that this design could be practically implemented for the purposes of synchronization of a prosthetic eye with a normal eye.

Final Design Selection/Design Matrix

Finally, after review the relevant criteria, as displayed in Table X below, with the most important criteria being signal strength, delay, and ease of use our group chose the LED/Photodiode method. The LED/Photodiode design was chosen because of its ability to pick up a strong signal from a blink and its ease of implementing the design with our current mechanism. This design, besides the purchases of the Osram IR LED, doesn't need any other hardware or software requirements. This design is also extremely inexpensive, the Osram IR LED and Photodiode can be purchased for under $20[12]. One of the main concerns for the LED/Photodiode deign we needed to overcome was determining the safety of shining IR light onto an individual's eye. We found two independent studies stating that there are no potential health concerns for emitting IR light into a person's eye at the wavelength of 880 nm, the wavelength of light the Osram SFH-485-2 IR LED emits[13,14]. The EMG/EOG design we ruled out primarily because of its invasive nature and difficulty for long-term use. In the long-term application of this design, the patient would be responsible for correctly placing and concealing the electrodes on his/her skin every day. As such, the EMG/EOG method is not very user friendly. The camera method we decided against due to the additional hardware and software requirements, making it more complicated and less practical to build. The delay between the three methods ended up not being a significant factor in the decision because it was found that all three methods have a similar signal delay of around 100 ms.[11]

Method	Cost	Size	Ease of Use	Safety	Difficulty	Signal Str.	Accuracy	Delay	Weight	Power	Total
Weight	5	5	15	10	10	15	10	15	5	10	100
EOG/EMG	2	2	6	8	5	6	6	12	2	4	53
Camera	4	4	12	10	3	12	8	12	3	5	73
IR-LED	5	5	12	8	9	13	10	12	4	7	85

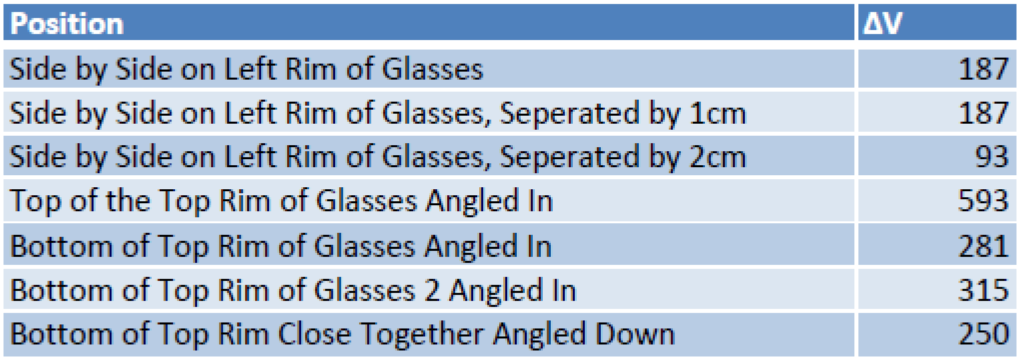
Table 1. Design Matrix: the table indicates the weight of each criterion and the scores for each design possibility

Final Design

The main idea behind our design to synchronize the blink of our prosthetic eye with the blink of a healthy eye is really quite simple in theory. Aside from the necessary circuitry and programming (see Circuitry, Programming), only two mechanical components were needed: an infrared light-emitting diode (LED) and a photodiode (specifications in Appendix B). These two components were used in conjunction with one another to synchronize the blinks. When the LED emits infrared light at the eye (invisible to the human eye), a certain portion of this light is reflected back at the adjacent photodiode. The photodiode then takes the received light energy and converts it into a voltage. Since there is a greater reflection of IR light from the eyelid than the cornea, a blink leads to increased reflection as the lid begins to close. This increase in reflection coincides with an increase in photodiode reception which ultimately leads to an increase in voltage[11].

Although the theory behind this device is rather straightforward on paper, there were many outstanding factors that we had to account for while constructing the LED/photodiode unit. The main problems we had to consider included the positioning and sensitivity of the LED and photodiode. In order for the system to work for our purposes, we needed to focus as much of the IR light emitted from the LED onto the eye as possible. This would thus maximize the amount of light reflected off the eye. We also needed to limit the amount of *excess* light received by the photodiode to ensure that the major cause of the voltage change was from the reflected IR light, not other external light sources. To overcome these issues, we encased the LED and photodiode in electrical tape so that only the tips of the diodes were able to emit or receive light.

Next, the positioning of the LED and photodiode had to be determined. As previously mentioned, we decided to fix the LED and photodiode onto a pair of glasses. This provided a reasonable distance of approximately 20 mm between the diodes and the eye – a distance that produces a viewing area of the photodiode very close to that of an eye, 177 mm^2 .[11] To find the location to mount the sensors on a pair of glasses, the sensors were first hand held at different positions on the glasses (lower rim, side rim, above the top rim, below the top rim etc.) while an individual blinked. During this test, the voltage jump triggered by the blinks was monitored on an oscilloscope to find the orientation that created the largest voltage jump and therefore the clearest blink distinction. After analyzing these values for highest change in voltage and comfort of placement (Table 1) it was found that the lower portion of the upper rim of the glasses was the best place to mount the IR LED and photodiode.



Position	ΔV
Side by Side on Left Rim of Glasses	187
Side by Side on Left Rim of Glasses, Seperated by 1cm	187
Side by Side on Left Rim of Glasses, Seperated by 2cm	93
Top of the Top Rim of Glasses Angled In	593
Bottom of Top Rim of Glasses Angled In	281
Bottom of Top Rim of Glasses 2 Angled In	315
Bottom of Top Rim Close Together Angled Down	250

Table 2: Output voltage change with respect to differing locations of the LED/Photodiode on glasses.

Two major positioning angles then had to be determined in order to maximize the amount of reflected light received by the photodiode. First, the ideal angle between the adjacent LED and photodiode had to be found. Since the surface of the eye is curved, the angle of incidence (incoming light) to the eye wasn't necessarily equal to the angle of reflected light. The easiest way to set this angle was through qualitative testing and analysis. After many trials of simply holding the LED and photodiode at different orientations, it was clear that the blink response was greatly affected by their relative positions. We tried numerous orientations until the response was most accurate, and then traced that angle onto a small slat of wood, with an angle between the LED and photodiode being approximately 10-15 degrees. Now the diodes simply had to be glued onto the slat; additional taping and securing was also used to limit any possible movement between the diodes that would disrupt the correct orientation.

Now that the lateral orientation between the LED and photodiode was set, we had to determine the correct vertical orientation of this LED/photodiode pair with respect to the eye. Since manually changing this positioning directly triggered different blink responses, qualitative testing and visual analysis was used once again. After loosely attaching the LED/photodiode underneath the upper rim of the glasses, we carefully manipulated the vertical angle until the blink response was most accurate. We found that the most accurate response occurred when the

LED/photodiode were pointing slightly upwards towards the very top of the eye (right beneath the upper lid). This resulted in the least amount of delay between blinks since the changes in infrared reflection occurred at the very onset of upper lid movement. The resulting picture in Image 1 shows the final design.

Image 1: Final Design

Circuitry

The LED/Photodiode design makes use of two independent circuits, one for the LED and another for the photodiode circuit. The LED circuit simply contains a 5 volt voltage source in series with a resistor of 1k ohms and the LED, which is then connected to a grounding source. The 5 volt source comes directly from the Arduino microcontroller board. An illustration of this circuit can be seen in Figure 20. The use of the 1 kΩ resistor is used to help control the amount of current reaching the LED within the operating values noted for the LED listed in the appendix.

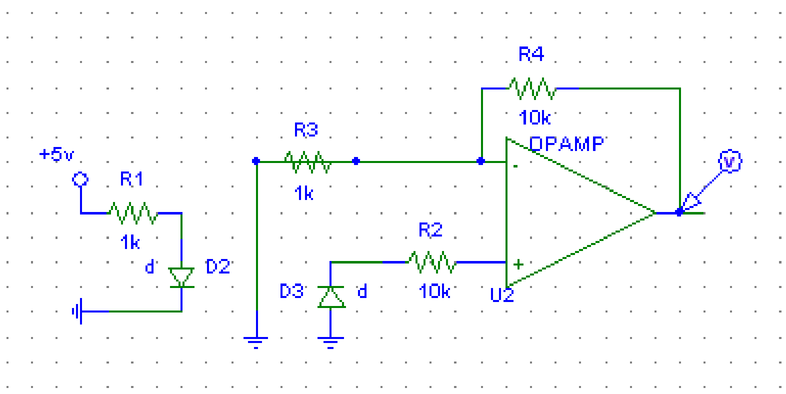


Figure 20. Circuit layouts for LED and Photodiode

The photodiode circuit utilized contains a mcp-6002 op-amp. The resistors and photodiode are positioned as a non-inverting amplifier with a positive gain of 11 V for the voltage generated the IR light entering into the photodiode. This gain is produced by the op-amp and controlled by the 10k ohm (R4) and 1k ohm (R3) resistors by the equation $V_{output} = (1 + 10k/1k)V_{photodiode}$. The mcp-6002 op-amp was used primarily because it only requires one voltage input of 5 volts and a connection to a ground source to operate. This allows the op-amp to be powered by the Arduino microcontroller, eliminating the need for excess batteries or power connections. Upon IR light entering into the photodiode, a voltage is inspired which is then amplified into by the op-amp. This amplified signal is then sent to the input terminal within the Arduino.

Programming

The output voltage from the circuit is connected to an analog pin of the Arduino. The Arduino is programmed to read the voltage at that pin and convert it from an analog value to a digital one. The Arduino we are using has a 10 bit A/D converter and accepts a voltage range of 0-5 V. This means each step size is approximately 5 mV, which gives us plenty of resolution to detect the change in voltage resulting from a blink. The program initially fills an array with the first 10 digital values read. The voltage is sampled every 15 ms. After the array is filled, the voltage is sampled at the same rate, and if the new value is greater than the running average of the values in the array by a certain threshold (20 values), the motor is signaled to blink. Once the threshold is crossed, the motor is told to move to a position of 90°, and then the program waits 250 ms to give the motor enough time to rotate fully and pause slightly at the closed position before rotating back to the 0° spot, this time with a delay of 150 ms. After determining whether or not blinking is taking place, the value read is added to the array of values to be averaged replacing the oldest value in the array.

The process of comparing the output value of the circuit to an average of the previous values, rather than just a fixed threshold, allows us to accommodate for changes in light. External light changes the voltage produced by the photodiode, whether it is from the sun or from artificial light sources. With the dynamic average of previous values produced, increased light will initially cause the prosthesis to blink, but once the array is filled with values from the new condition, normal response will resume. The code can be found in Appendix B.

Bracket

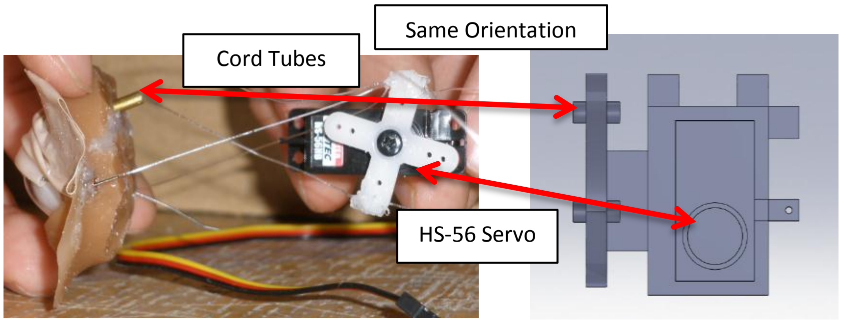


Figure 21. Right: Blinking mechanism w/out motor box. Left: Blinking mechanism motor box w/servo but w/out silicone bonded around front piece.

A major improvement made to last semester's mechanism is the addition of a new motor bracket to attach the prosthesis and the motor by one fixed piece (Figure 21). Formerly, the motor and prosthesis were only attached by the levator and closing cords. To function properly, these cords must be in constant tension. Therefore, the motor and the prosthesis had to be physically separated to put tension on the cords. This presented two problems. The first problem being that when the motor and prosthesis were separated to the point of tension, the mechanism's length was too great to fit in the volume of the eye. The next problem was that the mechanism was physically unstable. In last semester's presentation model, the motor and the prosthesis were both embedded at their base in a piece of Styrofoam to separate them. This method of separation worked for the presentation, but the constant tension on the mechanism led the Styrofoam to eventually give way, allowing the motor to move closer to the prosthesis. This relieved the tension on all cords and the prosthesis was no longer able to blink.

.Both of these problems have contributed to the motivation behind the design of the motor bracket. This new motor bracket was rapidly prototyped and consists of a flat disc like piece with three extruded tubes, two at the bottom for the closing cords and one at the top for the levator cord (Appendix A). For reference, these tubes are located in the same location and orientation as the small metal tubes embedded in the silicone from the first iteration of the Embedded Cord Tension Mechanism. Silicone was molded to the front of this new disc and sculpted to look like the patient's own skin and eye. To make sure the silicone bonded strongly to the bracket, 1mm holes were drilled in the disc allowing silicone to bond all the way through to the back of the disc. The front ends of the three extruded tubes for the levator and closing cords are flush with the silicone at the front of the eye so they are not easily seen from the front. Protruding out from the back of the disc is a square attachment for a motor box. The motor box itself has a square cut 2mm into the front of it (half the depth of the front of the motor bracket) of the same size. The square bracket attachment fits into the front of the motor box square like a puzzle piece, fixing the box in the x and y directions. The motor has been inserted into the motor box with only its motor arm protruding from the box. As seen in Appendix A, two slits have been cut into the back of the motor box. In those slits, two zip ties have been wrapped around the motor box and square bracket protrusion to fix both the motor box securely to the bracket disc and make contact with the motor, fixing it securely within the motor box. Epoxy glue was then used to secure any loose points to the bracket design. Attached to the outside of the motor bracket are several small cubes with one hole drilled in one direction to guide the closing and opening cords to the motor arm. They act essentially as "powerlines" for the closing and opening cords from the eyelid to the motor are. This motor bracket has greatly increased the stability and tension in the mechanism, while also reducing the size of the mechanism to the point where it can fit comfortably within the volume of the eye socket.

Testing

To test our design, one person wore the glasses for 1 minute, blinking normally. The number of true positives (when the actual eye and prosthetic blinked), false positives (when the prosthetic blinked without the real eye blinking) and false negatives (when the actual eye blinked but the prosthesis didn't) were recorded. This was done for 3 trials, then repeated with the wearer moving their head slowly and constantly side to side, and then up and down. These tests also were done for 3 trials each. The sensitivity (percentage of time the motor blinked when the user blinked) and positive predictive value (percentage of time the user blinked when the motor did) was calculated from the totals of each different test. The results of this test are shown below in Table 3.

Actual Eye					
Head Steady					
	Positive	Negative		Sensitivity	PPV
Positive	204	73		0.985507246	0.736462
Negative	3				
Head Moving Side-to-Side					
	Positive	Negative		Sensitivity	PPV
Positive	186	54		0.877358491	0.775
Negative	26				
Head Moving Up and Down					
	Positive	Negative		Sensitivity	PPV
Positive	114	233		0.850746269	0.32853
Negative	20				

Table 3: Values obtained from the totals of three 1 min trials each for different movements of the head.

This data shows that when the user blinks, the prosthesis will also blink nearly consistently. However, the prosthesis blinks too often when the user is not blinking. We believe this is due to a slightly faulty connection in the soldering of the circuit causing spikes in voltage. We were unable to locate any faults in the circuit, and due to time constraints we were unable to correct this problem or solder a new circuit.

Prior to fixing the diodes to the glasses, we also tested different angles between the diodes and the corresponding voltage change resulting from blinking. The results of this testing are shown below in Figure 22. The following shows that an angle of approximately 10-15° gave the greater change in voltage.

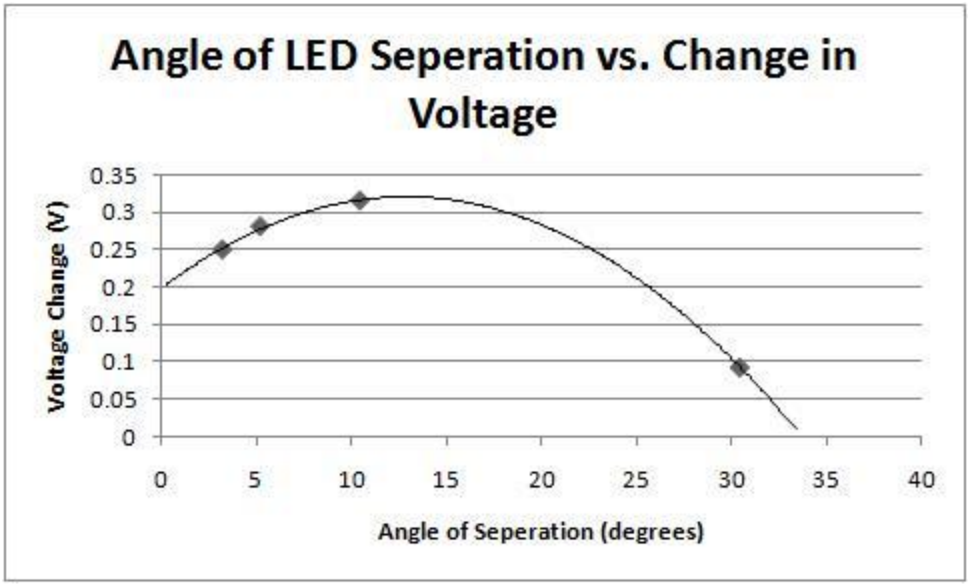


Figure 22 : Voltage change during blinking with respect to changing angle between diodes.

Future Work

Currently, we have created a presentation model that simply serves as a 'proof of theory' that a prosthetic eye can be synchronized with a healthy eye. As stated before, we have developed a bracket to house the motor to reduce the size and allow it to fit in the eye cavity. Also, through using infrared LED and a photodiode, we can detect a blink and use the signal to make last semester's embedded tension cord mechanism to cause the prosthetic eye to blink. However, improvements still need to be made in order for it to be implemented into a real patient. We are still currently using the same servo motor as we did last semester. Therefore, we still have the same problems with the motor creating a significant amount of heat while running and vibrating. Most of the vibrations have been reduced thanks to the bracket, even so, noticeable vibrations are still present. The heat is still a significant issue since it could be hazardous to patient due to it being close to sensitive organs (eg. mouth, brain, ear, etc.). Through our earlier research, we discovered that currently there are no motors that meet our requirements of enough speed and torque to create a blink while still being economically feasible. We believe that with time and as technology improves, motors will become available that would better meet the requirements of this project. Taking this into account, our mechanism has been designed to operate with any kind of rotational motor. Finally, the motor and overall eye piece would need to be encapsulated within a smooth material. This material would need to be able to be cleaned easily. Then the overall eye piece would need to be able to fit into the eye cavity of a patient before it can be implemented for use.

The current infrared LED and photodiode is able to detect a blink but is not as accurate as desired to be used with actual patients. We hope that in the future we can use a smaller size infrared LED and photodiode that can easily be imbedded into the frame of glasses that are specially designed for them. These glasses will also be able to securely hold the LED and photodiode in place at the precise angle that will allow them to receive the greatest voltage difference as an eye blinks. The glasses could also be designed to have the wires of the components run through them to the ear and then have them blend into the skin to allow an overall aesthetically pleasing appearance. In the future, we will design a pair of glasses that does this. Additionally, more testing would need to be done to ensure the safety of this design, as is discussed further in the ethics section.

Finally, we need to develop a battery supply for overall device since right now for our presentation model requires it to be plugged into a power source. This obviously cannot work for a patient going about his/her daily activities. Ideally, the batteries would be rechargeable with the capability of powering the Arduino for approximately twelve hours.

Ethical Considerations

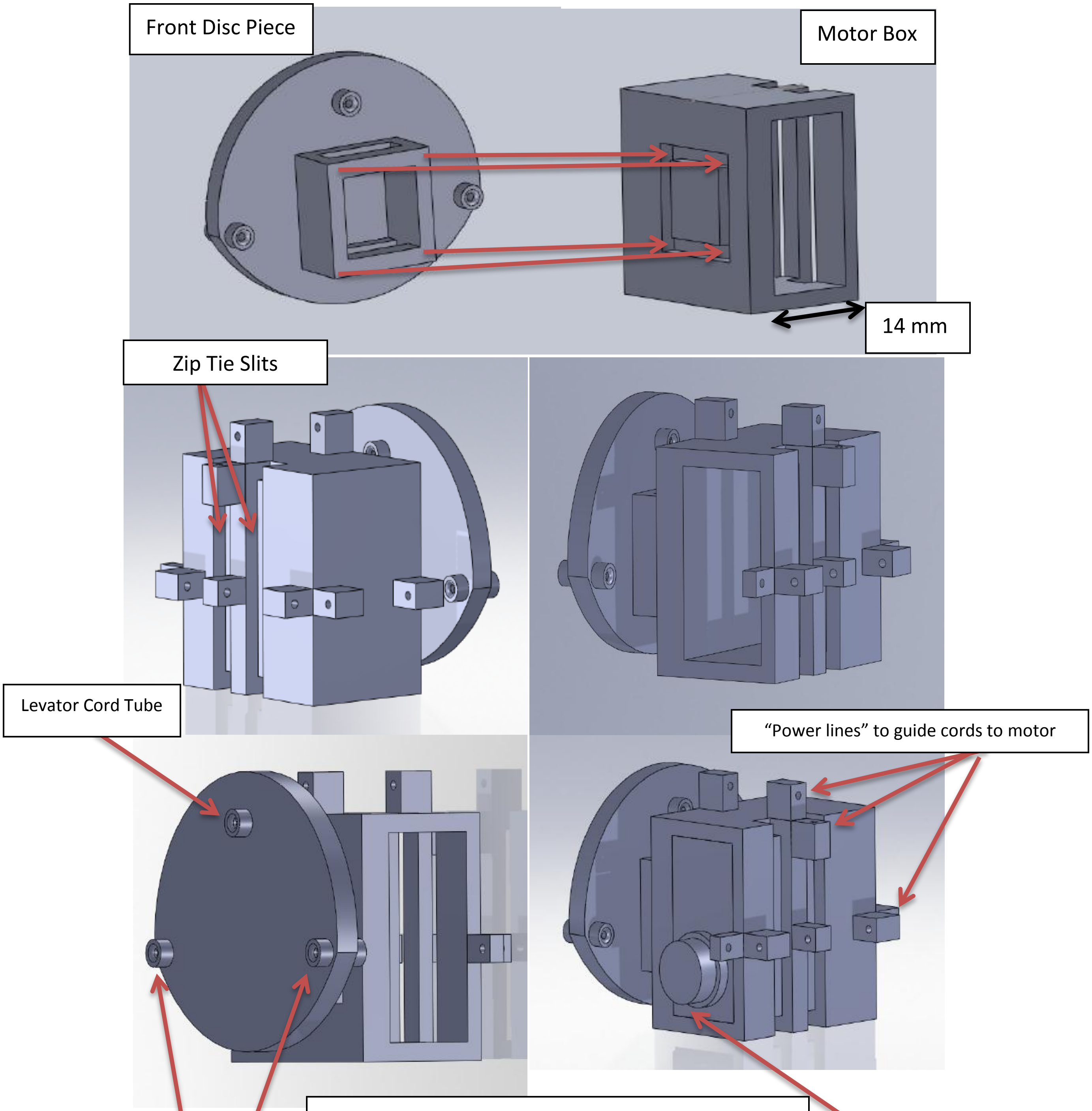
With the implantation of any medical device, whether surgical or not, ethical considerations must be taken into account to make sure the patient is completely safe. In the case of the blinking orbital prosthesis, our main areas of concern come from the use of materials in close, long-term contact with the skin along with the use of potentially hazardous electronic equipment. Concerning the long term contact with the skin of the patient, only materials that are biologically inert were used in the making of the prosthesis, including silicone, acrylic and plastic. These materials have already been in use by the makers of static orbital prostheses for decades and are safe for use.

As for using electronic equipment, the circuit and microcontroller used to power and control this device are housed in a safe plastic circuit box that can fit comfortably in the pocket of the patient. Wires lead from this circuit box to the glasses of the patient, but they are completely housed in wire casing or electrical tape, so there is never contact between the metal of the circuit and the skin of the patient. In the event that the metal of the circuit does contact the skin of the patient, no electric shock will occur due to the low voltage supply of the Arduino microcontroller. Regardless, further work can be done to make sure that there is absolutely no risk of shock to an individual who uses this device.

Our next area of ethical consideration comes from the use of an IR-LED to detect the movement of the eyelid. This IR-LED is pointed directly and the remaining healthy eye of the patient, so it is imperative that it not be the source of any physical harm. It has been found, however, that the use of IR light is not a danger to an individual's eyes [13,14].

Lastly, it should be noted that the microservo used to pull the closing and opening cords of the mechanism does overheat with extended use. This is more a source of malfunction in the mechanism than it is a danger to the patient, but it is still a concern. In the future, either a different motor should be used to avoid this problem or a cooling system should be designed to keep the motor at a safe and functioning temperature for periods of time up to 12 hours.

Appendix A: Motor Bracket Design Details



Top: Illustration of how the front disc piece of the motor bracket fits to the back of the motor box. Below: Illustrations of different views of the motor bracket highlighting the most important elements of the design, including the power lines, zip tie slits, motor box, and cord tubes.

Appendix B – Code

```
#include <Servo.h>

Servo myservo;        // create servo object to control a servo

int sensorPin = 2;    // sets pin to read the output voltage from photodiode
int sensorValues[10];  // stores previous ten readings
unsigned char idx = 0; // current index in sensorValues to overwrite
const int THRESHOLD = 20; // Threshold above which we should blink
const int LOOPDELAY = 15; // delay to wait between loops

void setup() {
  // Fill array with current sensor reading;
  for (int i = 0; i < 10; ++i) {
    sensorValues[i] = analogRead(sensorPin);
    delay(10);
  }
  // attach servo on pin 9
  myservo.attach(9);
}

void loop() {
  int currentReading;
  int avgReading = 0;

  // Get current reading
  currentReading = analogRead(sensorPin);

  // Calculate avg of last 10 readings
  for (int i = 0; i < 10; ++i) {
    avgReading += sensorValues[i];
  }
  avgReading = avgReading/10;

  // Replace oldest entry in past 10 readings (LIFO)
  sensorValues[idx] = currentReading;
  idx = (idx + 1) % 10;

  // Blink if there was sufficient deviation from avg reading
  if ((currentReading - avgReading) > THRESHOLD) {
    myservo.write(90); // Tell servo to head to 90 degrees
    delay(200);       // Give it time to get there, and stay on for a few ms
    myservo.write(0);  // Tell it to go back
    delay(150);       // Give it time to get there
  }

  delay(LOOPDELAY);
}

void loop() {
  int currentReading;
  int avgReading = 0;

  // Get current reading
```

```
  currentReading = analogRead(sensorPin);

  // Calculate avg of last 10 readings
  for (int i = 0; i < 10; ++i) {
    avgReading += sensorValues[i];
  }
  avgReading = avgReading/10;

  // Replace oldest entry in past 10 readings (LIFO)
  sensorValues[idx] = currentReading;
  idx = (idx + 1) % 10;

  // Blink if there was sufficient deviation from avg reading
  if ((currentReading - avgReading) > THRESHOLD) {
    myservo.write(90); // Tell servo to head to 90 degrees
    delay(200);       // Give it time to get there, and stay on for a few ms
    myservo.write(0);  // Tell it to go back
    delay(150);       // Give it time to get there
  }

  delay(LOOPDELAY);
}
```

LED Specs: operation at 940 nm wavelength

Model	276-143
Product Type	4-7 mm lens
Enclosure Color	CLEAR
Body Material	Multi

Photodiode specs:

Model	276-145
Product Type	Phototransistor
Body Material	Multi

Appendix C- References

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Appendix D – 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. Last semester we designed a mechanism to create a realistic looking blink. Our intention this semester is to reduce the size of this mechanism and to synchronize its blink with the blink of a healthy eye.

Client requirements:

- Costs for the project should be under $500.
- The mechanism, not including circuitry, should be contained inside of the cavity of the globe of the eye.
- The mechanism, not including circuitry, must be consolidated into a single piece of hardware
- The prosthetic eye must be detachable from the motor.
- The mechanism must be enclosed in a silicone covering, so as to separate it from the patient's flesh.
- Must be damped in order to minimize sound and vibrations.
- Must be as aesthetically pleasing.
- The blink must be synchronized with the blink of a healthy eye

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.
- Must be synchronized with the blinking of the other functional eye, without noticeable delay.

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 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 Acrylic. 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. It must also not be delayed in its synchronized blink

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.