Contact Lens Assistive Device

A Major Qualifying Project Report
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Abstract

The process of inserting contact lenses can be arduous for a person with an upper-limb amputation, limited mobility in their arms, or sensitive reflexes. Our project team pursued three designs for a device to hold open the eyelids so that contact lenses can be inserted with one hand. We developed working prototypes of each design and with approval from the Institutional Review Board we were able to test our devices on WPI community members to get feedback for future improvements.

Acknowledgments

This project could not have been completed without the support and guidance from Professor John Sullivan. Special recognition goes out to WPI's Laura Hanlan, Erica Stults, Kevin Arruda, Matt DePinto, David Planchard, and Todd Keiller for their contributions to the success of the project. We also would like to thank our test participants for their feedback on our designs.

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Executive Summary

Many people prefer contact lenses over glasses because of the freedom and convenience they offer—they allow a person to be more independent and are barely noticeable when worn. A device that holds the eye lids open comfortably would be a great help to the 100,000 individuals in the United States with upper body amputation, and those with limited dexterity [3]. Our goal for this project was to design such a device to assist recent amputees in inserting a contact lens or eye drops.

Our research examined existing optometric procedures and devices to see if they contained information or mechanisms that would be translatable in our design search. By analyzing the advantages and disadvantages of other devices we have determined the type of device to design that will be new and innovative. This investigation has allowed us to develop research questions that shape the focus of our project. According to the Amputee Coalition and the John Hopkins Bloomberg School of Public Health, there are nearly new 30,000 upper-limb amputations each year.

Based upon our initial research on both existing patents and upper-limb amputees, we created a number of design constraints on which to evaluate our device. These design constraints are based around three main categories: Adjustability, Portability, and Safety.

In the initial stages of design, five preliminary solutions were investigated: the Glasses design, the Finger Insertion design, the Table-top design, the Moving Arm design, and the Biomimetic design. The Glasses design, Finger Insertion design, and the Table-top design were not explored to past the brainstorming phase as they were found to have too many limitations early on. The Moving

Arm design and the Biomimetic design were explored to the prototype phase, as well as the Finger Grip prototype modified from the initial Finger insertion design. Each of these prototypes was created using either the Objet260 Connex 3D printer and/or the Haas ToolRoom Mill at Worcester Polytechnic Institute.

Evaluations were performed on each of the three prototypes to gauge the effectiveness of each prototype in terms of meeting our design constraints and project objectives. Human testing was then conducted with only the Biomimetic prototype and the Finger Grip prototype, with approval of the Institutional Review Board (IRB) and the help of WPI community members.

While our prototypes assisted in keeping the eye open, there were some limitations due to unfamiliarity with the device. With more time to become acquainted with the prototypes they could become easier to use. We realize that some individuals can insert contact lenses with one hand, and we propose that our device be used as an acclimation tool to transition from wearing glasses to inserting contact lenses with one hand.

In order to improve on the design with the feedback from our tests, we recommend completing more testing with the same test participants to increase familiarity. We also recommend that future models be made of a commercially available plastic and that the padding be extended to cover the entire arm. This will protect the face and eye from being irritated by the device. We also suggest that an easily adjustable nosepiece be developed as test subjects felt the nose piece could be more user-friendly. With these recommendations we believe these devices could be commercially viable.

Introduction

Many people prefer contact lenses over glasses because of the freedom and convenience they offer—they allow a person to be more independent and are barely noticeable when worn. Many different types of contact lenses (such as long term or dailies) are available for users based on their needs and preferences. However, the biggest reason why people choose glasses over contacts is the process of putting in contact lenses. Inserting contact lenses requires holding the eyelids open wide enough and long enough to place a contact lens in the center of the eye so that it adheres to the surface of the eye. This process can be difficult for a person with sensitive reflexes, limited mobility in their arms, or an upper-limb amputee.

In the United States there are more than 100,000 people with upper-limb amputations [3]. Amputees frequently encounter difficulty completing daily activities due to the absence of a limb. There are a large number of amputees that could be wearing contacts if there were a mechanism that could hold their eye lids open while they place the contact lens on the eye.

A device that holds the eye lids open comfortably would greatly increase the opportunities available to individuals with upper body amputation or limited dexterity. There are devices that will help a person insert a contact lens by directly placing the lens on the cornea. There are also devices such as a wire speculum that will hold the eye lids open. However, this type of product is mainly used in surgery and is more intrusive to the eye and is painful if not used with anesthesia. There is a need for a less intrusive device to help a person hold their eye lids open so that they may insert a contact lens or eye drops.

Our goal for this project was to design a device to help a person hold their eye lids open to insert a contact lens or eye drops. The main objectives were to analyze the problems with similar devices, develop a design that would address those problems, and produce and test the developed prototype for functionality. Applying our research, we developed and refined a design for a device which we then prototyped. People with an upper limb amputation or limited mobility in their arms and hands will be able to use contacts and conduct their eye care quickly and easily.

Background

Existing Devices

Our research examined existing optometric procedures and devices to see if they contained information or mechanisms that would be translatable in our design search. An optometric device we studied was the wire speculum. The wire speculum is a device used in surgery to hold an eye open. The speculum can also be used when performing laser eye operations, cataract removal, and some eye examinations. Typically, a speculum has a set of jaws that are flexible within a certain opening range, or can be set to a specific opening width. The jaws slide between the eyelid and eye to pull the eyelid and expose the entire eye. The design of the jaws can vary and some examples of wire speculums are shown below in Figure 1.

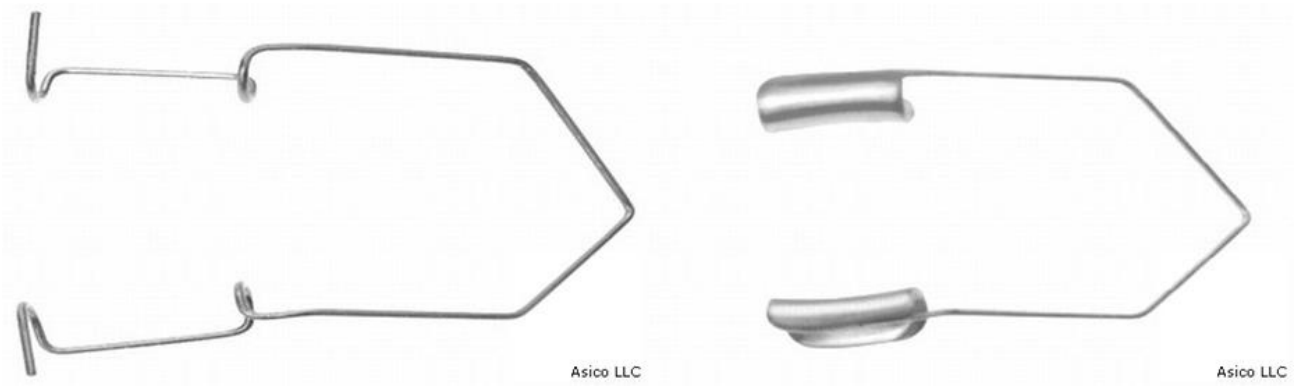

Figure 1-Speculums used in surgery: Barraquer Wire Speculum and Solid Blade Wire Speculum (Asico, LLC)

Another optometric device examined was the non-contact tonometer test. This procedure is commonly known as the "air puff" test. The air puff test gives an eye pressure reading, known as intraocular pressure (IOP) to help detect glaucoma by blowing a puff of air directly onto the cornea. The average peak air puff pressure from five continuous measurements was 11323.7 ±

869.5 Pa or 1.64 PSI [9]. This data is useful as a relatively stable control on which to base our maximum allowable pressures.

There are patented devices that have similar functions to the design we hoped to create. We examined these designs in order to determine what gaps exist in the market. The first similar device is U.S Patent 5474349 A 'Contact Lens Insertion Tool' [13], shown in Figure 2. The device functions as follows:

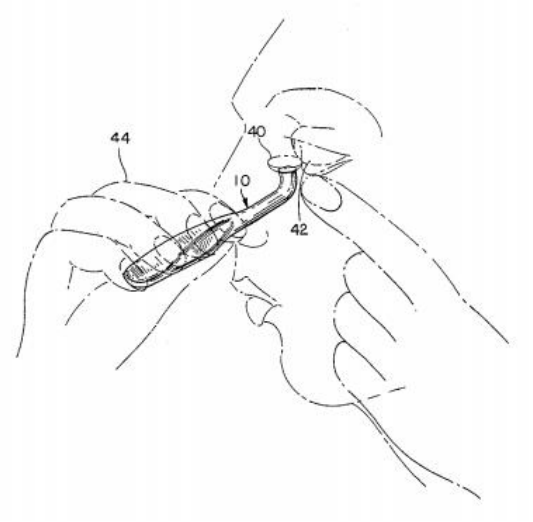

Figure 2-U.S Patent 5474349 A 'Contact Lens Insertion Tool'

> *"The insertion tool is first grasped by a user who will then manipulate the tool to adhere the contact lens to the land area. Next, the user will bring the contact lens edge first to the bottom central area of the sclera of the eye into which insertion is desired, and will secure contact between the lens edge and the eye at an angle ranging from approximately 20° to not greater than 90°. Finally, the user will rotate the tool upward until a point where the adhesion between the contact lens and the eye exceeds the adhesion between the contact lens and the land area of the contact lens insertion tool, thus disposing the contact lens in the user's eye."*

The second similar device is U.S Patent 5941583 A 'Contact Lens Insertion and Manipulation Assembly and Method' [12], shown in Figure 3. The design works as follows:

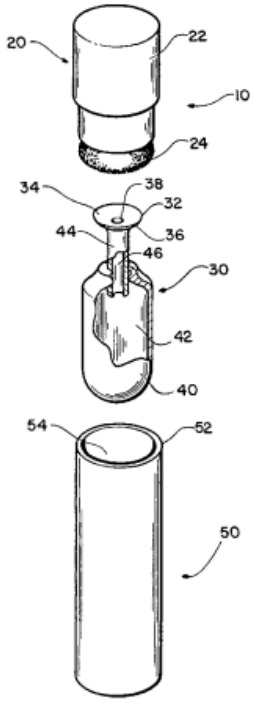

Figure 3-U.S Patent 5941583 A 'Contact Lens Insertion and Manipulation Assembly and Method'

"A contact lens insertion and manipulation assembly has a manipulation device, an insertion device, and an enclosure cap. The manipulation device includes a manipulator bulb made of a material to which the inside concave surface of the contact lens will lightly adhere. The manipulator device allows the user to remove the contact lens from the storage container without the user touching the contact lens. The manipulator bulb is shaped to support the contact lens in its proper shape, facilitating transfer of the lens to the insertion device. The insertion device includes a suction cup capable of removably engaging the outside convex surface of the contact lens and transferring the contact lens from the manipulator bulb to the user's eye. The insertion device and the manipulation device fit within the enclosure cap for compact and protected storage to prevent contamination. The assembly can then be used according to the described method of use to insert the contact lens into a user's eye without the user touching the contact lens with his fingers."

The third device is U.S Patent 7163245 'Contact Lens Insertion Tool' [15] shown in Figure 4. This device is designed for use by functionally blind individuals. It operates as follows:

"The insertion tool includes a housing shaped to accommodate a generated light source and a power source. The generated light source is electrically connected to the

power source and projects a beam of light along an axis toward a distal end of the housing. The insertion tool also includes a lens holder attached to the distal end of the housing. The lens holder has an opening that allows the beam of light to pass through the housing and lens holder. The beam of light is visible to a wearer when the lens holder is aligned with the wearer's eye. The invention uses the strategy of focusing on a target that can be clearly seen by the user to insert a lens that otherwise can't be seen by the user."

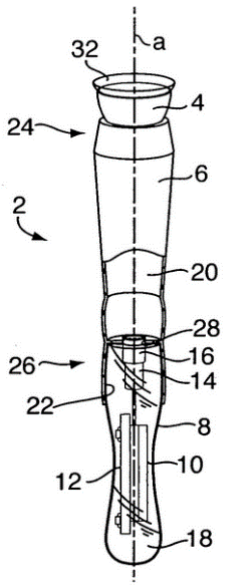

Figure 4- U.S Patent 7163245 'Contact Lens Insertion Tool'

The fourth patent we examined was U.S Patent 7175594 'Ophthalmic Sulcus Speculum' [7] seen in Figure 5. This device functions as follows:

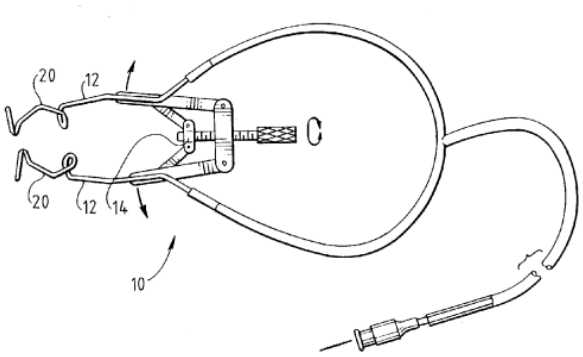

Figure 5- U.S Patent 7175594 'Ophthalmic Sulcus Speculum'

> *"Devices in accordance with certain embodiments of the present sulcus speculum are designed to be placed into the sulcus of an eye to perform one or more of the following functions: evacuation of fluid, opening of the lids, and application of drugs such as anesthetic or antibiotics. The present devices can include a sponge positioned around (a) an aspiration tube for withdrawing fluid and (b) an arm of a speculum. Other variations of the present devices include those with an aspiration tube for withdrawing fluid, the tube being positioned in a trough defined by an arm of a speculum. Alternatively, the speculum arm can define a passage for holding the aspiration tube. In that alternate embodiment, the portion of the speculum arm defining the passage has openings for passing fluid into the passage so that the aspiration tube in the passage can then remove fluid."*

The fifth and final similar patent we investigated was U.S Patent 8231156 'Contact Lens Application Device and Method' [1] shown in Figure 6. It functions as follows:

Figure 6- U.S Patent 8231156 'Contact Lens Application Device and Method'

> *"A pressure application and removal device is provided for the purpose of assisting insertion of contact lenses. The device comprises a frame portion, two contact lens holders, a pressurizing assembly, and a liquid delivery assembly. The frame portion has the structure of standard eyeglasses frames and rests on a user's ears and nose. The contact lens holders are formed of wash cups that retain contact lenses along the inside of their concave surface. Fluid conduits extend from an apex of the wash cups to a flexible ball in the center of the device. When said ball is depressed, a positive pressure or vacuum is generated to facilitate insertion and removal of contact lenses to or from a user's eye. A second flexible ball may be filled with liquid. When the ball is compressed liquid flows through a second set of conduits into the eye of a user."*

By analyzing the advantages and disadvantages of other devices we have determined the type of device to design that will be something new and innovative. This investigation has allowed us to develop research questions that shape the focus of our project.

Marketability

According to the Amputee Coalition and the John Hopkins Bloomberg School of Public Health, there are approximately 1.9 million people missing a limb in the United States, and more than 100,000 of them are upper-limb amputees. The study states that there are about 185,000 amputations each year. Nearly 15% of the amputations each year are upper-limb amputations.

The major causes of upper-limb amputation in North America are accidents, infections or burns, tumors or disease, and congenital disorders such as amelia and phocomelia [3].

In America, around 225 million people wear some form of corrective lenses [6]. The popularity of contact lenses has grown considerably since the 1970s. Approximately 38 million people, or 11% of corrective lens wearers in the US, use contact lenses. The average age of a contact user is thirty-one years and 50% of users are between the ages of 25-44 [2]. The Amputee Coalition estimates that 70% of upper-extremity amputees are younger than sixty-four years of age, which places them in the demographic of contact wearers [3]. The market for a device to hold the eyelids open can extend beyond contact lens users to daily tasks like assistance with the insertion of eye drops. People with glaucoma need to administer medicinal eye drops every day. These drops are an expensive treatment and without assistance may not end up in the eye due to sensitivity with being near the eye and potential mobility limitations that may come with increased age. Having a device to help them keep the eye open could be beneficial [10].

Design Methodology

The objective of our design was to create a simple device that would aid a disabled person in keeping their eye lids open to insert a contact lens or use eye drops. We wanted to create a device that was easy to operate. We wanted the device to be durable enough for daily use, but inexpensive to produce and therefore disposable. We wanted the device to be used by any person that might have trouble keeping their eye lids open to put in contact lenses or eye drops, and specifically people that might be upper limb amputees or have limited mobility in their arms.

When first considering ideas for our design, we brainstormed a list of design constraints. These basic design constraints are to help form an idea of what the device needs.

- Must be operable with either hand
- Must be usable by all ages 13+
- Must be portable
- Must weigh less than 50 grams
- Must be collapsible to the size of an eyeglasses case
- Must be safe for user:
    - Must have rounded edges
    - Must be easy to clean with disinfectant
    - Must be unreactive to chemicals used with contact lenses
    - Must have a soft, smooth material on parts that touch the face of the user
- Must be adjustable for different size facial features

These constraints helped form the different components of the device. The potential designs were refined and altered based on our discussions and debates on how the device could be best used. The original target for this device was for use by single-limb amputees. From an examination of the previously mentioned patents we have identified that the most common functions of the devices currently developed include manipulation of the contact lens and/or interaction directly with the surface of the eye. We have determined that it is not necessary to interact with the

contact lens, but to merely hold the eyelids open in a non-invasive fashion. Our hypothesis was confirmed through an interview with Dr. Gayle Kornman, a local optometrist. In her experience she has found that the most common problem that patients encounter is holding the eyelids open to insert the contact lens or medical eye drops, which could expand the potential market [10]. The following sections outline the tools and processes used to develop our designs.

Design and Fabrication

Preliminary Solutions

Glasses Design

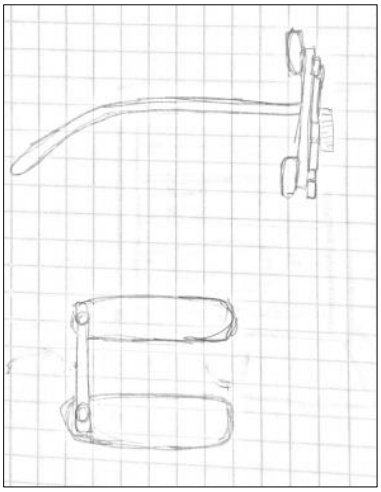

Figure 7-Preliminary Glasses Design Sketch

A glasses type frame was explored due to its proven stability on the face. We envisioned a turning knob with a rack and pinion to open and close the padding that would grip the face. This design was re-explored in conjunction with the Moving Arm design to attempt to solve the issues of attachment to the head. The Moving arm design was to be attached using C-clips.

Finger Insertion Design

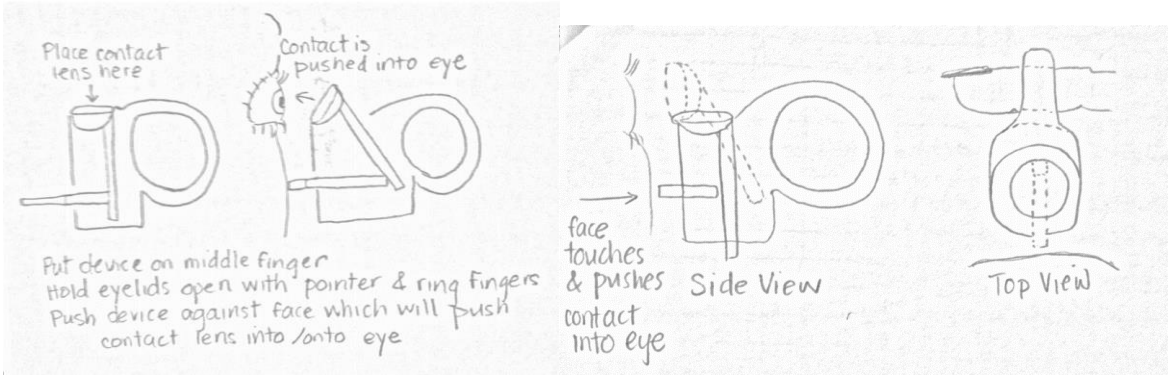

Figure 8-Preliminary idea to help insert a contact lens

This was a device that would also assist in the actual insertion of the contact lens. The device sat on the middle finger and the contact lens sat in the bowl at the top. The pointer and ring fingers then push the eyelids open and hold them there. The middle finger moves the contact lens receptacle towards the face which causes the bowl with the lens to flip up and push the contact lens onto the eye. However, after much discussion, we decided that there was no way to safeguard this design to keep users from poking themselves in the eye and potentially harming themselves. Instead, we decided to pursue a design that would merely hold the eyelids open rather than place the contact lens on the eye.

Table-top Design

Similar to the table top design of devices used for eye exams by optometrists, the device is weighted and sits on top of a table. It includes chin and forehead supports, and the pads for opening the eye move on a track that adjusts in the Y and Z directions. This design was discarded due to its weight and cumbersome nature.

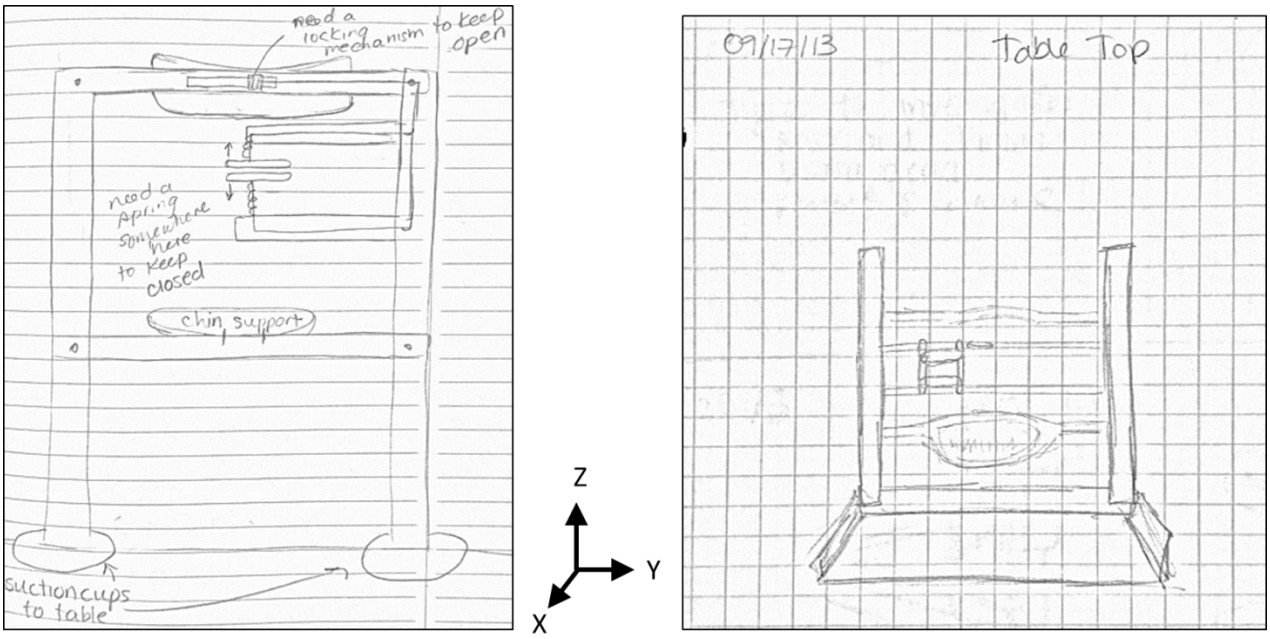

Figure 9- Preliminary Table-Top Designs

Moving Arm Design

The moving arm idea was the original design that we fully explored. The idea stemmed from investigating lobster and nut crackers, but it acts in an inverse direction to open as opposed to close. This design went through multiple iterations as we remodeled the different components. We needed to determine the range of sizes of facial features so that the device was adjustable to suit both males and females. The device needed to be reversible, so that it could be used on either eye, so it was designed to be symmetrical top to bottom.

In order to keep with the theme of simplicity, we developed a set of connected flat arms that would sit in the same plane and would open and close as displayed in Figure 10 and would stay on the head with an elastic headband. We developed three sets of different sized small arms that snap on and off the long arms and offer some adjustability for the user to find a size that works with

their facial features. The device would “lock” open by having a stop or a wedge on the small arms to keep them from opening much further than 185 degrees.

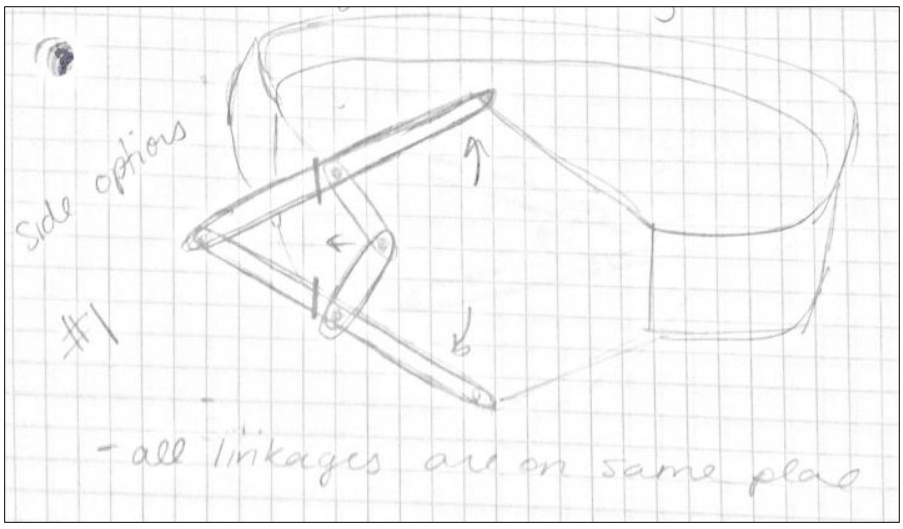

Figure 10-Preliminary Design-Parallel to Face

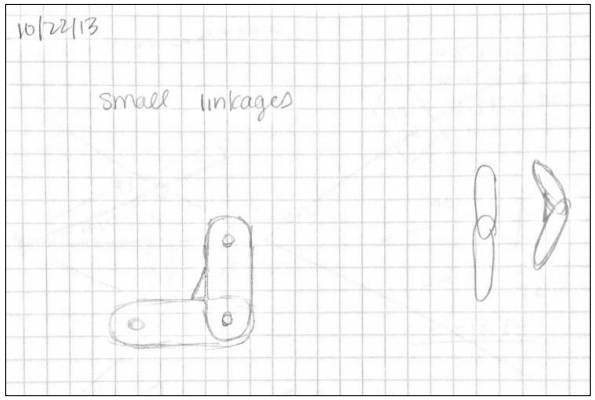

Figure 11-Preliminary Idea-Wedge Stop

We built a stopper into the small arms to prevent the arms from opening more than 185 degrees. Instead of having a protrusion from one arm as seen in Figure 11, we changed one arm to have a straight edge to stop further rotation, shown in Figure 12.

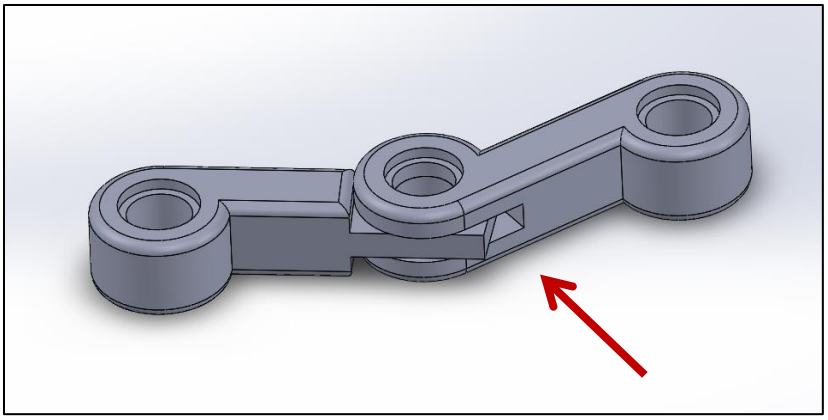

Figure 12-Preliminary Design-Locking Edge on Small Arms

Instead of using screws to attach the small arms to the long arms we found a type of pin that we felt would work for attaching individual pieces together. These pins are more durable than those that we can make in the rapid prototyping machines.

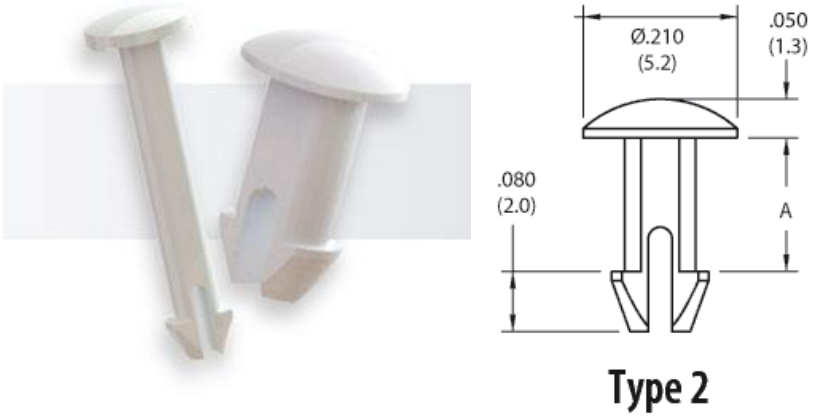

Figure 13-Snap Lock Pin and Type 2 Dimensions

We chose these pins, shown in Figure 13, because they are durable and can be removed easily, if necessary. The dimensions of the pin used in the device are as follows in Table 1:

Table 1-Dimensions of Snap Lock Pin

Part SLP-1-413-01, Type 2 Dimensions [mm]				
Hole Diameter	Length A	Head Diameter	Head Thickness	Snap Length
2.4	10.5	5.3	1.3	2.0

When analyzing the movement of the long arms, we noted that the pads only touch at one point and that the device does not close flat as illustrated in Figure 14.

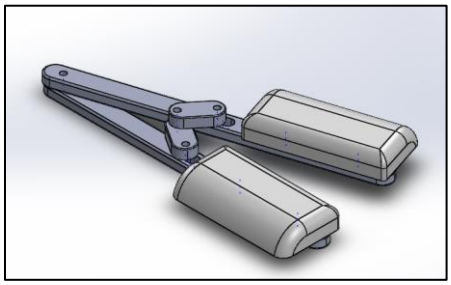

Figure 14-Straight Long Arms

We changed the shape of the long arms to mimic that of a lobster cracker where the ends are curved to allow the arms to fold flat next to each other. We changed the connection at the end of the long arm to look like Figure 15.

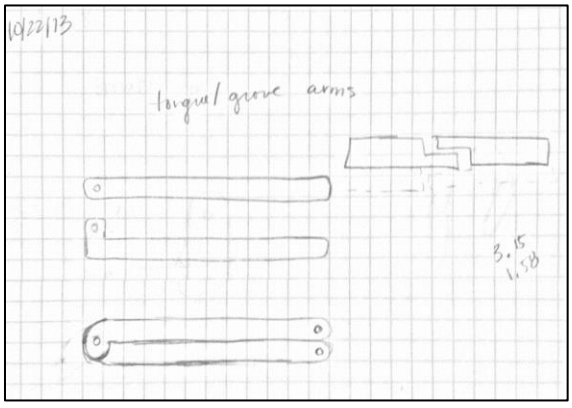

Figure 15-Long Arm Curved Design Change

The next step was to refine how to attach the ear hooks to the eye bars. We explored using plastic T-bars, however, they lacked the necessary durability and could not apply enough pressure. After

reevaluating that idea, our research suggested that using a spring and elastic combination would be the best approach, as a spring supplies an easy way to calculate tensional force. After considering design requirements for an adjustable spring system, we came up with the design shown in Figure 16.

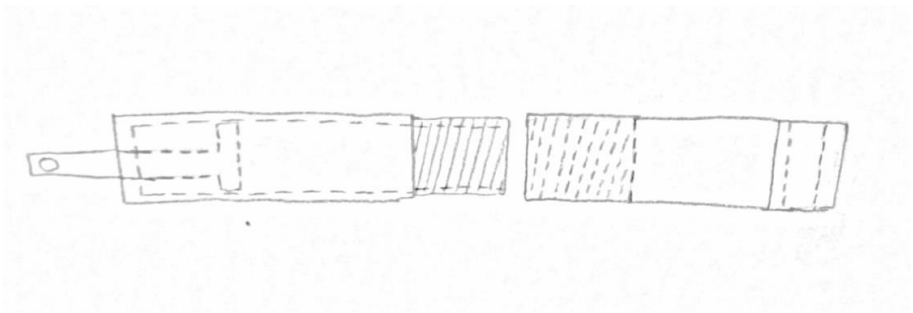

Figure 16-Revised Ear Post Configuration

The element on the right is a solid tube with ten millimeters of internal threads that screws onto the ear post sleeve with external threading on one end of the tube. The sleeve would hold the expander and a spring. The expander and spring cannot fall out the end of the ear post sleeve, as it is closed to a radius that allows the smaller diameter of the expander to protrude. In the two piece system, the expander and spring can be inserted on the threaded side of the end piece. Then, the end piece is screwed into the solid body, preventing the spring and expander from falling any furthur than the threading. In the resting state, the spring is fully extended, and the expander is flush with the threading. As the user puts the ear attachment on, it pulls on the expander and the spring compresses, providing normal force and tension which helps hold the device onto the face.

As we tested this new configuration, we found that the sport ear hooks that we used were not strong enough to apply the necessary pressure to the face to keep the device on the face and the eye lids open. It was also difficult to get the ear hooks around larger sized ears when they were

tied with elastic. To replace them, we took hollow copper tubing and bent it in a C-shape and ran the elastic band through them and tied it to the ear post and locking arms. These ear hooks were much more stable, easy to put on, and fit all sized ears without falling off.

The last component in the device is the eye pads. When designing the pads, we came up with two hatching patterns to increase surface area on the pad. More surface area offers more grip and adhesion to the face, eyelashes, and eyelids. The first design used a diamond knurl pattern, and the second design used a square pattern, illustrated in Figure 17 and Figure 18. After discussion, we decided that the square pattern would be easier and more accurate to design and have manufactured.

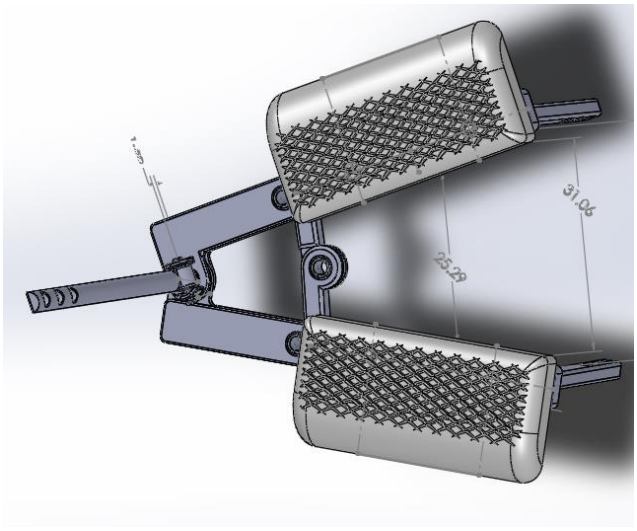

Figure 17-Prototype Version 1 with original pad design

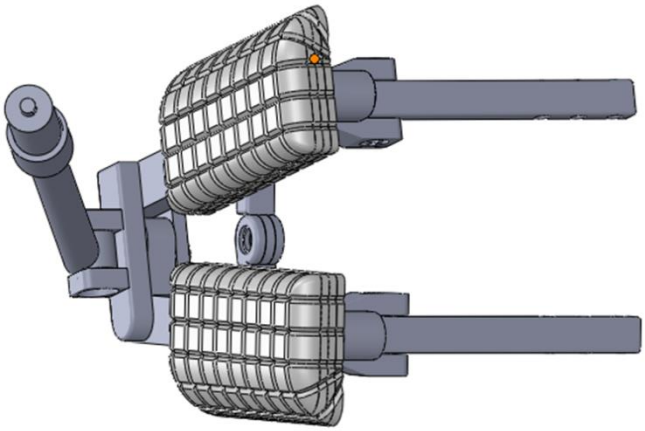

Figure 18-Prototype Version 2 with 2nd version of pad design

Throughout the design process, we tested the device using the following conditions:

1) Device's linkage system opens and closes smoothly without risk of pinching

2) Device can apply enough normal force to hold the eye lids open

3) Manner in which the device is secured to the head is simple and easy to attach and remove from device

4) Different linkage sizes can be easily installed and removed from the device

5) Padding is of ideal shape, softness, and grip to catch the eyelids

This testing phase did not involve outside participants. Instead, this phase of testing was used to check the device's design functionality and safety. The first thing we tested for was safety, as it is a key priority when designing a product. To ensure the device was safe for the user, the device had to fulfill the following criteria: no sharp edges on the outside surfaces, use of bio-safe materials that can be easily cleaned, minimal opportunity or no components that could pinch the user, and little to no possibility of the device poking the user's eye. The Moving Arm prototype fit all of these criteria: all outer edges were filleted, the materials used to produce the prototypes are made from non-reactive materials that can easily be cleaned with a sanitizing wipe or spray, and the only component that poses a pinching hazard is the linkage, the risk of which was minimized almost completely. We tested these criteria ourselves, to verify that the device met these standards. Next, we looked at the device in terms of functionality. In a CAD model it is very difficult to tell if the design will work properly, so flexing the printed prototype was necessary to confirm that it worked the way it was designed to in the CAD model.

Biomimetic Design

This device was created as a solution to the potential problem posed by the angle of the opening linkages in the Moving Arm design. The point of connection between the linkages creates an angle between the pads, as a result they are not parallel to the natural opening of the eye, and therefore have less gripping surface. The user will place the device over the head and secure the elastic band comfortably. Using their hand, the user will then apply downward pressure on the skin below the

cheek bone to allow the pad to grip the lower lid, then apply a similar pressure upward to adjust the upper lid. The contact is then inserted. The other eye is able to function freely and normally to allow the user full visibility of the mirror to insert the contact accurately. This design mimics the natural movement made by the fingers to hold the eyelids open.

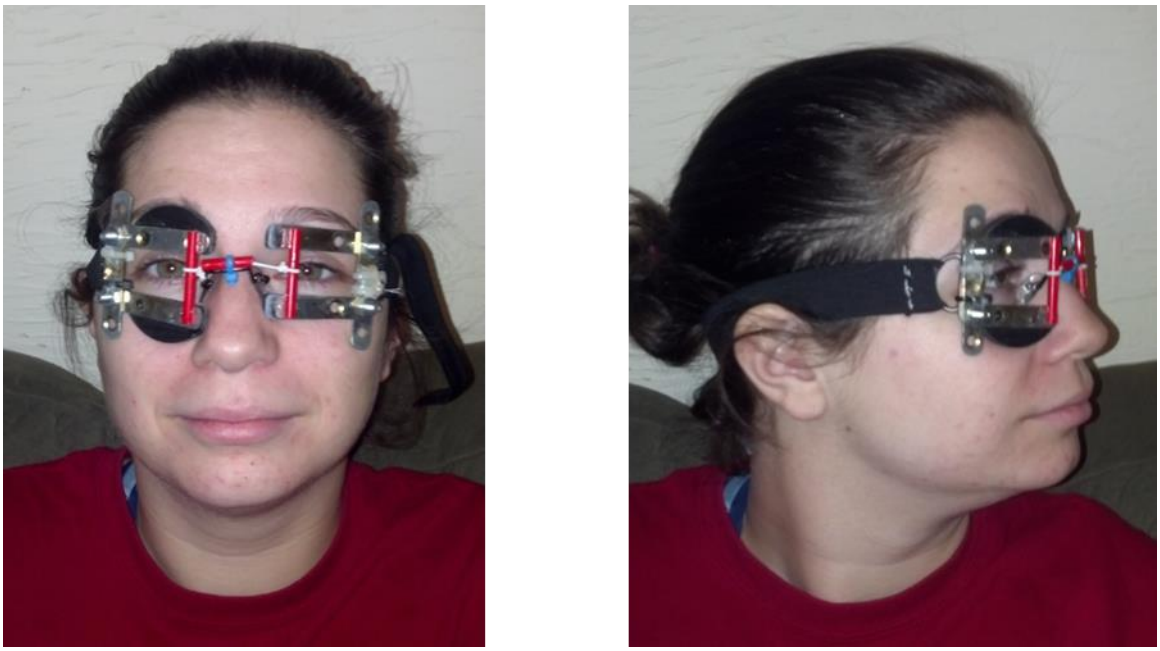

Figure 19-Front and side views of preliminary design of Biomimetic Prototype

Padding Design

Our first padding design was a rectangular block with shallow square crosshatching. The dimensions of this pad are 38mm x 19mm x 6mm. Padding iteration two improved on the original design with deeper and larger, crosshatch squares. This pad kept the same dimensions as the original. Padding iteration three was made using a curved shape to attempt to limit interference from the brow bone. The cross hatching was made smaller, but kept at the same depth. Padding iteration four is 1/3 the length of the first three versions, and 1/2 the width. It also has a glossy finish to increase grip. The pad was made smaller because iteration three still caused interference

with the brow bone when attempting to open the lids. Padding iteration five was designed specifically for use with our curved, biomimetic design. It is half the width of iteration 4, but still the same length. The pad design progression is seen in Figure 20.

Figure 20-Progression of eye pad designs

Construction

3D Printers

In order to choose between the two available 3-D printing machines, the Objet260 Connex and the Dimension P430 ABSplus, we met several times with Erica Stults, the staff person in charge of the Rapid Prototyping machines in the Mechanical Engineering Department. We discussed the capabilities of the two machines, and the differences in materials used in order to decide which would best fit our needs. The Objet printer has smaller tolerances with print layers of 1/1000" thick and is able to combine two polymers of different densities to create one part and emulate the properties of a number of other materials, including engineering grade ABS plastics and rubber-like materials. The Dimension ABS Plus prints in much thicker print layers of 7/1000" and uses only one material at a time. We choose the Objet machine for all of our test pieces and the first two full prototypes, because of its ability to print composite materials. However, one drawback to the Objet 260 Connex machine is that the support material used in a print must be removed manually with a power washer, which can damage smaller parts, while the P430 ABSplus uses support material that is removed through an acid bath.

Table 2- Material Properties of Objet Tango Black Plus & TangoPlus Full Cure 930

Objet TangoBlackPlus FullCure980 and TangoPlus FullCure930					
Property	**ASTM**	**Units**	**Metric**	**Units**	**Imperial**
Tensile Strength	D-412	Mpa	0.8-1.5	psi	115-120
Elongation at Break	D-412	%	170-220	%	170-220
Compressive Set	D-395	%	41734.00	%	41734.00
Shore Hardness (A)	D-2240	Scale A	26-28	Scale A	26-28
Tensile Tear Resistance	D-624	Kg/cm	41674.00	Lb/in	18-22
Polymerized density	ASTM D792	g/cm^3	1.12-1.13		

Table 3-Material Properties of Object VeroClear Full Cure 810

Objet VeroClear FullCure810					
Property	**ASTM**	**Units**	**Metric**	**Units**	**Imperial**
Tensile Strength	D-638-03	MPa	50-65	psi	7250-9450
Elongation at Break	D-638-05	%	41937.00	%	15-25
Modulus of Elasticity	D-638-04	MPa	2000-3000	psi	290,000-435,000
Flexural Strength	D-790-03	MPa	75-110	psi	12,000-16,000
Flexural Modulus	D-790-04	MPa	2200-3200	psi	390,000-480,000
HDT, °C @ 0.45 MPa	D-648-06	°C	45-50	°F	113-122
HDT, °C @ 1.82 MPa	D-648-07	°C	45-50	°F	113-122
Izod Notched Impact	D-256-06	J/m	20-30	ft lb/inch	0.375-0.562
Water Absorption	D-570-98 24hr	%	1.1-1.5	%	1.5-2.2
Tg	DMA, E»	°C	52.54	°F	118-122
Shore Hardness (D)	Scale D	Scale D	83-86	Scale D	83-86
Rockwell Hardness	Scale M	Scale M	73-76	Scale M	73-76
Polymerized density	ASTM D792	g/cm^3	1.04-1.05		
Ash Density	USP281	%	0.02-0.06	%	0.02-0.06

Machine Shop Tools

We used several machine shop tools in order to construct our prototypes. The tools we used were: a HAAS ToolRoom Mill as well as a laser cutter. The ToolRoom Mill is a TM-2 model that possesses the following specifications: A cutting feed rate of .1-100 IPM (Inches per Minute), an RPM range from 0-4000 RPM, and a spindle motor peak rating of 7.5 HP. Our prototypes were constructed of 16 gauge weld-able steel sheets that were adhered to an aluminum cutting block with Mitee Grip

for milling, as seen in Figure 21. We could not cut such thin sheets without adhering it to a support block due to the torsional forces produced by the milling process.

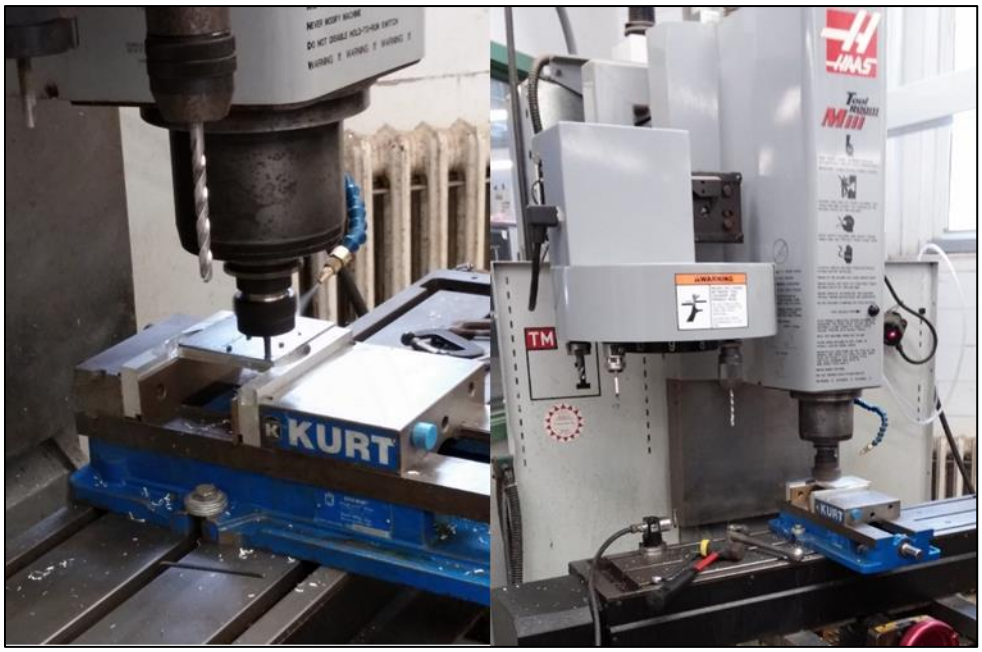

Figure 21- HAAS ToolRoom Mill

Final Prototype Design Solutions

Moving Arm Prototype

Our current prototype combines all of the best components we were able to identify throughout the design process.

Some issues arose with the first 3D print of our prototype. The nature of the printer, which spreads layer upon layer of composite material to create the part, resulted in a weakening of the thinner aspects of our design. These thinner pieces were damaged through the power washing cleaning process, which is meant to remove any support material used during the printing of the device.

In its damaged state, we were unable to conduct any full tests with the first prototype, but we were able to identify a number of issues in the design. We addressed the following issues in the next version of the model:

- ear post was too long for attachment to the ear pieces
- the spring compartment was too short to allow for the range of motion we intended
- pads were quite bulky and not well shaped to the face structure
- opening between the pads was not sufficient for insertion of contact lenses
- there was too much play between the small linkages and the large arms
- the pin meant to be used in the attachment of the long arms did not fit properly
- some edges of the linkages and long arms could look more aesthetically pleasing

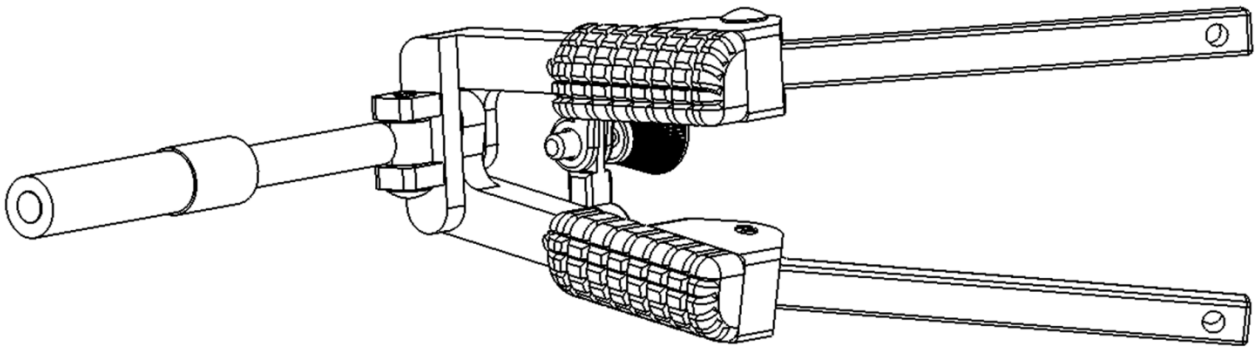

Figure 22-Fully assembled Moving Arm Prototype

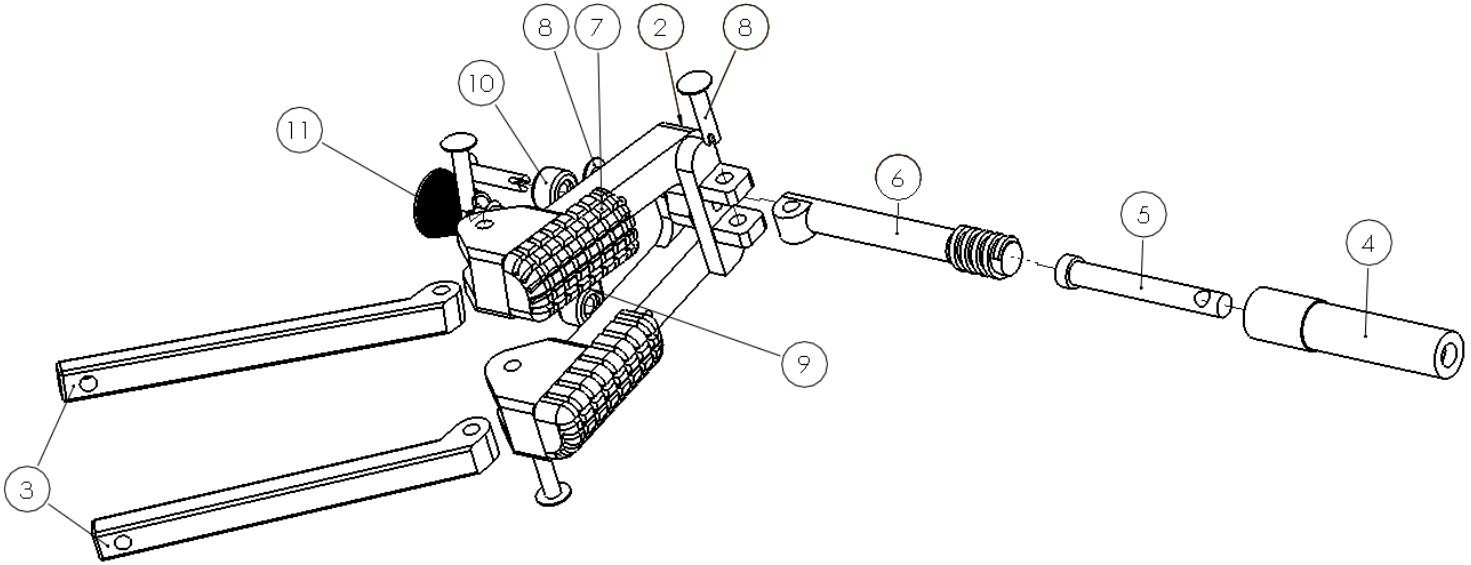

Figure 23- Exploded view of Moving Arm prototype

Table 4-Description of Moving Arm design components

Part Number	Part Name	Material	Description
1	Long Arm Groove	VeroClear	Large interlocking arm that the Eye Pad, Locking Arm, Small Arm Linkage, and Ear Post attach to
2	Long Arm Tongue	VeroClear	Large interlocking arm that the Eye Pad, Locking Arm, and Small Arm Linkage attach to
3	Locking Arm	VeroClear	Arms that lock at 135^{o} to prevent the elastic attaching the ear pieces from interfering with vision of the wearer
4	Ear Post Sleeve	VeroClear	Outer sleeve of the ear post assembly; encases spring that allows for adjustability for different temple lengths
5	Expander	VeroClear	Inner component of the ear post assembly for adjustability; the spring sits around the Expander
6	Ear Post	VeroClear	Base of the ear post assembly; compression fit to the Snap Lock Pin; threaded to fit the Ear Post Sleeve
7	Eye Pad	2/3 TangoPlus; 1/3 VeroClear	Gripping surface that also pads the face for comfort and function; the body in contact with the face is printed in TangoPlus, a rubber like material, and is backed with a more rigid composite of TangoPlus and VeroClear
8	Snap Lock Pin		Pins together the small linkages and used to spread and collapse the device
9	Small Arm Groove	VeroClear	Small interlocking arm that attaches to the Long Arm Groove; connected to the Small Arm Tongue with a removable thumb pin
10	Small Arm Tongue	VeroClear	Small interlocking arm that attaches to the Long Arm Tongue; connected to the Small Arm Groove with a removable thumb pin

Biomimetic Prototype

Upon the second printing of our prototype we made a number of adjustments to refine the design to begin testing.

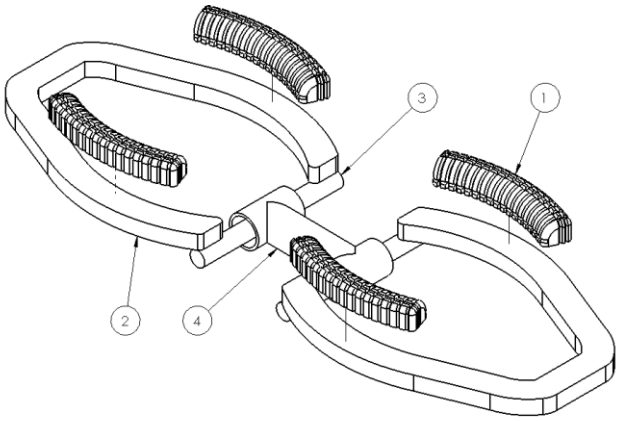

Figure 24-Exploded view of Biomimetic Design

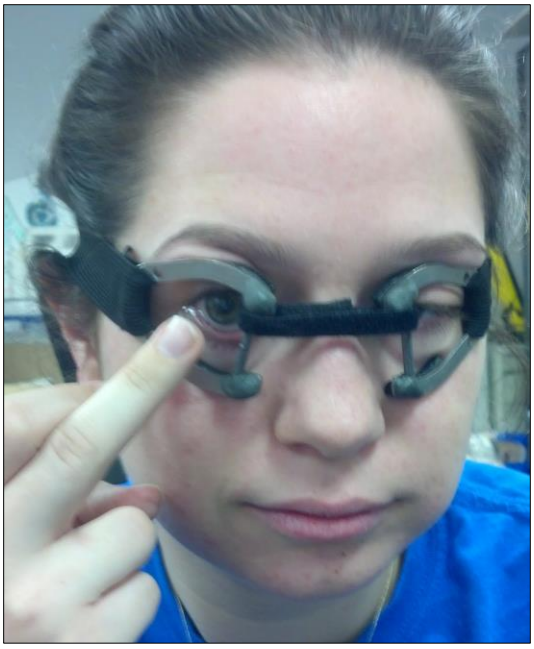

Figure 25-Active device

Table 5-Biomimetic Design component descriptions

Part Number	Part Name	Material	Description
1	Curved Eye Pad	2/3 Tango Plus 1/3VeroClear	Gripping surface that also pads the face for comfort and function; the body in contact with the face is printed in TangoPlus, a rubber like material, and is backed with a more rigid composite of TangoPlus and VeroClear
2	Curved Arms	16 Gauge Steel Sheet Metal (potentially nylon in final form)	Elongated U brackets designed to fit the curvature of the face, and allow for space between bracket arms for insertion of contact lenses
3	Nose Bridge Support Rods	.125" steel dowel	Circular dowels of 1/8" diameter act as support for the nose bridge
4	Adjustable Nose Bridge	VeroClear	Bridge has hollow components which slide over the support rods, allowing the device to adjust to different nose sizes

Using these prototypes and the preliminary tests conducted, we will machine a final generation prototype out of nylon to use for testing and our final recommendations.

Finger Grip Prototype

Figure 26-Finger Grip technology

Figure 27-Use of Finger Grips on One or Two Fingers

Figure 26 shows a standard rubber fingertip, used in the banking industry to count money. The fingertip is made of non-reactive rubber. We have repurposed the fingertip to use it as an assistive

device for opening the eyelids. With one hand, it is possible to insert a contact lens; however, it takes practice for a new amputee or eye care patient. The bumpy surface combined with the rubber material maintains grip on the eyelid when holding it open. A holder was designed to allow the user to easily store and put the fingertip on with one hand. When testing the original version, shown in Figure 26, we found that it would be useful to have a lip on the edge of the holder to push off of when removing the finger grip. Figure 28 shows a CAD model of the second version fingertip holder featuring a rubber bottom to aid in gripping.

Figure 28-Hourglass finger grip holder

Figure 29-Hourglass finger grip holder prototype

Discussion and Results

Prototype Evaluation

As the design process came to a close the group felt it was necessary to compare the three final design solutions, the Moving Arm prototype, the Biomimetic Prototype, and the Finger Grip Prototype, based on specific metrics and their importance to the completion of our overall objective, as well as marketability. To do this, we identified eight design constraints to be weighted:

- Portability
- Cost
- Aesthetics
- Ease of use
- Adjustability
- Durability
- Easy to Clean
- Safety

As seen in Table 6, we compared each individual constraint to another. A value of “1.0” in the horizontal row denotes that factor to be of higher importance than the corresponding column’s factor. A value of “0.0” denotes that factor to be of lesser importance, and a value of “0.5” denotes equal importance. We then totaled the values assigned to each design constraint in the horizontal rows.

Table 6- Rank Order Chart

Rank Order Chart									
Design Contraints	*Portability*	*Cost*	*Aesthetics*	*Ease of use*	*Adjustability*	*Durability*	*Easy to clean*	*Safety*	**TOTAL**
Portability	-	1.0	1.0	0.0	0.5	1.0	0.5	0.0	4.0
Cost	0.0	-	0.5	0.0	1.0	0.0	1.0	0.0	2.5
Aesthetics	0.0	0.5	-	0.0	0.0	0.0	1.0	0.0	1.5
Ease of use	1.0	1.0	1.0	-	0.5	0.5	1.0	0.0	5.0
Adjustability	0.5	0.0	1.0	0.5	-	1.0	1.0	0.0	4.0
Durability	0.0	1.0	1.0	0.5	0.0	-	1.0	0.0	3.5
Easy to clean	0.5	0.0	0.0	0.0	0.0	0.0	-	0.0	0.5
Safety	1.0	1.0	1.0	1.0	1.0	1.0	1.0	-	7.0
Weighting Factor	70	55	45	80	70	65	35	100	-

We then began the process of weighting each design constraint between 0 – 30 for "optional", 31 – 70 for "moderate" and 71 – 100 for "important" items. After deciding that none of these design constraints were optional, we weighted each design constraint on a scale of 35 – 100, with a simple equation:

$$WF = \left[\frac{Design\ Contraint\ Total}{10} * 100\right] + 30$$

Once the weighting factors were assigned, each prototype was then ranked from 0 – 10 on how well it met each of the design constraints. A total score was then calculated by multiplying the weighting factors of each design constraint, by the values (1-10) assigned to each prototype, as demonstrated by Table 7.

Table 7-Design Decision Matrix

	Design Contraints								
	Portability	*Cost*	*Aesthetics*	*Ease of use*	*Adjustability*	*Durability*	*Easy to clean*	*Safety*	
	Weighing Factors								
Design Alternatives	70	55	45	80	70	65	35	100	**TOTAL**
Moving Arm Prototype	8	5	2	2	10	5	5	2	2485
Biomimetic Prototype	9	7	7	7	6	9	8	7	3875
Finger Grip Prototype	10	9	8	8	0	9	10	10	4130

Institutional Review Board Approval

The Institutional Review Board (IRB) is a group of WPI staff, WPI faculty, and local community members that works with WPI researchers to ensure that they comply with the ethical guidelines and regulations when using human subjects for investigations. The Board seeks to promote the welfare of the human subjects in research and testing and protect their rights. The Federal government requires that the IRB review and approve all research protocols, questionnaires, and interviews before testing may take place.

In order to begin testing our device on WPI community members, we submitted our testing protocol, the post-testing questionnaire, and the steps we would take to protect the health and safety of our test subjects, seen in Appendix A: Institutional Review Board Application. In order for the Board to completely understand the risks taken by test subjects, they required that a working prototype be presented for evaluation at their monthly meeting and a demonstration given. Once they had reviewed and discussed the testing protocol and the prototypes, they granted approval to test the Biomimetic and the Finger Grip prototypes on human subjects. The Moving Arm prototype was not given approval and further work on this design was terminated. This decision was also supported by the results from our Design Decision Matrix displayed in the previous section.

Human Testing

Human testing is an essential component of the design process. Testing enables the creator to identify errors in the design, and to gather data on the device and users who test it. These steps are critical for the final production of the device, proof of design concept, and

determining market potential. Testing for our devices occurred in two stages. Stage 1 was a test of the devices themselves, to confirm that they had met all design criteria and were operating as expected. Stage 1 involved assessing the manufactured prototypes for any issues that arose from 3D printing. This stage was conducted during the design process and allowed us to refine the designs to meet all of our objectives.

In Stage 2, study participants used our devices to assess them in various categories such as comfort, functionality, and ease of use. Having individuals test the prototype with no prior knowledge of our devices enabled us to assess the viability of our prototypes and to acquire preliminary data on marketability. Multiple processes had to occur before we could bring test participants in to use our device. First, we chose appropriate dates and locations for the testing to take place. Next, we reached out to the student body to find volunteers willing to participate in the testing of our device.

The human testing procedure was as follows:

1. One student investigator will meet with the subject in a private room and explain the purpose of the devices and the goals of the project. The subject will review a list of materials used in the devices and in the eye drops, if they do not wear contacts. Once the subject knows the expectations of the test and confirms they have no allergies to any of the materials, the student investigator will leave the room so the subject can sign a consent form if they choose to participate.

2. If they have signed the form, the test subject will then be escorted to the testing room by the student investigator.

3. The test subject will be told how to use the device by a student investigator, following the Directions for Using Assistive Device found in Appendix B: Directions for Using the Devices.

4. Each participant will be allowed to use both hands to use the device. The test subject will attempt to put the device on their face, and use it to open their right eye. If they wear contacts, they will try to insert their contact lens. If they do not wear contacts, they will try to insert eye drops using a bottle assigned to them to avoid any germ contamination. They will then be asked to remove the device. Next, they will repeat that procedure on the left eye.

5. Following the conclusion of the above steps, the test subject will be given a Test Evaluation and Feedback Form to answer questions and rate the devices on comfort, ergonomics, usability, and to give feedback.

The Test Evaluation and Feedback Form was completed for both the Finger Grip prototype and the Biomimetic prototype. The full data gathered can be found in Appendix D: Biomimetic Evaluation Form Data and Appendix E: Finger Grip Evaluation Form Data. The most significant questions and replies are shown below. The Biomimetic Design garnered the following responses:

Question 3 asked: Was the device easier to use on the left or right side of the face? The results displayed in Figure 30 show that it was easier to use on either side or the right side.

Question 4 asked for a rating of how comfortable and easy to use the device was for the participants, shown in Figure 31. Participants found that the device was fairly comfortable,

however, it was more difficult to use. This is possibly because the users were not exposed to the device prior to testing it and after more practice, they might find it easier to use. For comfort, the mean rating from test participants was 2.6/4 and for ease of use it was 2.44/4.

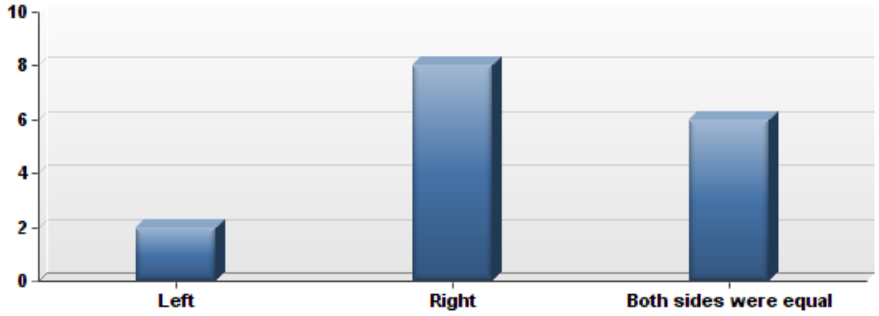

Figure 30- Results from Question 3 for Biomimetic design

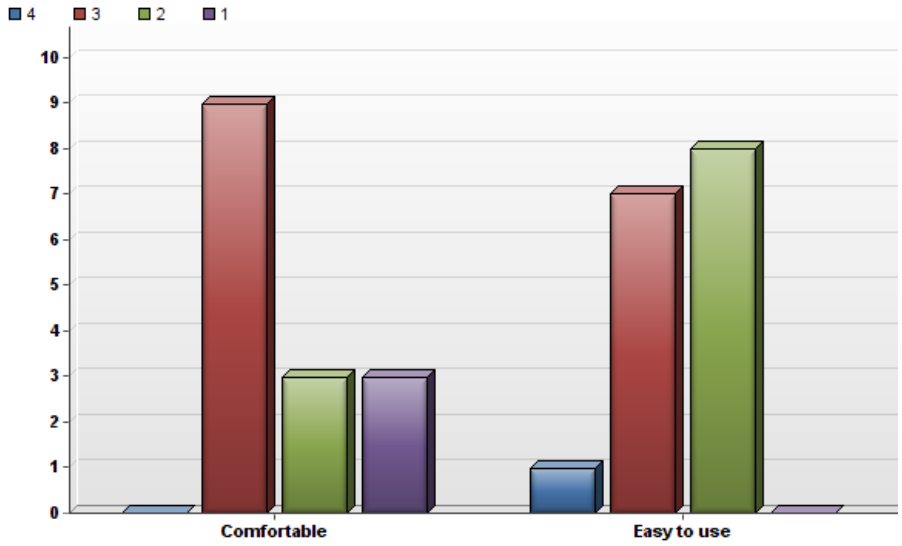

Figure 31-Results from Question 4 for Biomimetic design

Table 8- Statistics on responses to Question 4 for Biomimetic design

Statistic	Comfortable	Easy to use
Min Value	2	1
Max Value	4	3
Mean	2.60	2.44
Variance	0.69	0.40
Standard Deviation	0.83	0.63
Total Responses	15	16

Question 5 asked: What part of the device is most difficult to use? The most prevalent responses to this question were: adjusting the head strap so that the device sat securely on the face, getting the device to initially catch the eyelids, and adjusting the nose bridge to fit correctly so the device was secured on the face and evenly lined up. We attributed this again to a lack of practice and exposure to the device prior to testing. The responses have also told us that we need to design a new type of nose bridge that is easier to adjust.

Question 6 asked: Which part of the device was most uncomfortable to use? The most common answers to this question were: keeping the eye open for an extended period of time without blinking (this dried many participants' eyes out), the metal coming into contact with the brow bone, and wearing the wrong sized device or wearing the device too loose or tight. In order to account for these problems we feel that covering the entire arm with rubber would make users more comfortable with having the device near the eyes. Also by offering three different sized devices, users can determine which size works best for them.

The majority of the test participants felt that the device was stable on their faces and 75% of participants stated they would consider using the biomimetic device if they had only one arm.

The survey questions were repeated for the Finger Grip design. The most significant responses are shown below, but the entirety of the results can be found in Appendix E: Finger Grip Evaluation Form Data.

Question 3 asked: Was the device easier to use on the left or right side of the face?

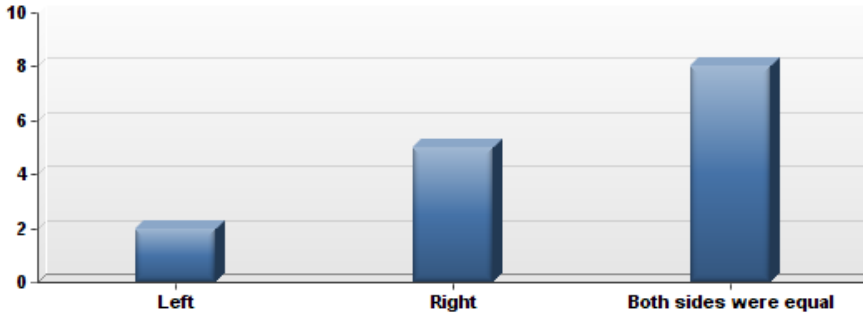

Figure 32-Results from Question 3: Was the device easier to use on the left or right side of the face?

Question 4 asked: Overall would you say the device is: (4 is the highest rating, 1 is the lowest)

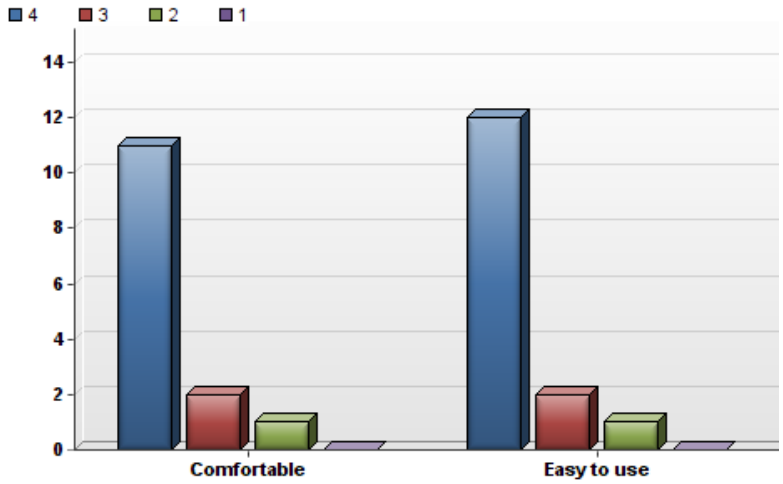

Figure 33-Results from Overall would you say the device is comfortable? Easy to use?

(4 is the highest rating, 1 is the lowest)

Question 5 asked: Which part of the device is most difficult to use? While some participants felt that no part of the device was difficult to use, others felt that putting the gripper on with one hand and wearing the wrong size grippers made use difficult.

Question 6 asked: Which part of the device was most uncomfortable? Most participants found the device was comfortable however some found it uncomfortable if they were wearing the wrong sized grippers.

80% of testers stated that they would be willing to use this device to insert lenses or eye drops if they had only one arm.

Overall, the team was satisfied with the testing results. Seventy-five percent of participants would use the Biomimetic prototype and 80% of participants would use the Finger Grip prototype to put in contacts or eye drops. Eighty-two percent of testers felt the Biomimetic

device felt stable on the face when using it, and 100% of testers felt the Finger Grip design felt stable on the face when using it.

Intellectual Property Process

Our testing results confirmed that our devices could be useful to people if it were commercially available. So to learn more about patenting the intellectual property that is our final design solutions, we attended an informational meeting with WPI's Technology Transfer Officer, Todd Keiller. During this initial meeting we discussed the possibilities of filing a provisional patent for our designs to later be converted to a utility patent. This process includes the filing of an Invention Disclosure form with WPI, detailing research we conducted on prior art, market availability, and potential licensees.

To conduct more extensive prior art research, we met with another expert on patents, WPI Gordon Librarian Laura Hanlan. Our search strategy began with a general search on Google Patents search engine using keywords such as "contact lens assistive device" and "contact insertion device." Using the patent classification numbers for both the US and European Patent Offices found in this search, we then investigated patents in the same grouping to find similar devices. We found some patents that our design(s) improved upon in various ways, and we outlined each of them in the Invention Disclosure form and our report.

The market research we conducted was based around the growing number of contact lens wearers as well as the number of upper-limb amputees. We made a calculated assumption that the percentage of the general population (amputees and fully limbed persons) that use

contact lenses would correlate directly to the percentage of upper-limb amputees that wear contact lenses also.

After submitting our Invention Disclosure form, the Technology Transfer office will then supply our report to an online service, InventionEvaluator.com, which will evaluate our devices for “patentability” and generate a report detailing the strengths, weaknesses, opportunities, and threats to our device. This resource will also generate a list of potential licensees who would have interest in bringing our devices to the commercial market.

The report generated by InventionEvaluator.com will then be reviewed by the Technology Transfer office, and submitted to a local patent lawyer for conversion into a fully-fledged patent application. Once the provisional patent is granted, our team will have one calendar year from the date of filing to apply for a utility patent and secure rights to the claims made in the original patent application, and any further developments.

Conclusions

We found that our designs improved upon the devices that are currently patented, but they still have room for further development. Both prototypes assisted in keeping the eyes open while inserting a lens or eye drops, however, they did not necessarily make the process easier. Much of the limitation of the devices stemmed from participants' lack of experience using devices of this nature – with more time to become acquainted with the prototypes they could become easier to use.

Although we realize it is possible to put a contact in with one hand, new amputees may not have the dexterity and confidence in their movements to do so. In this case, our designs can be used as an acclimation device or a transition from wearing glasses to being able to insert contacts with one hand.

In addition, we believe the device has a large market potential for older individuals and persons with shaky hands who need to insert eye drops. Using the device to hold open the lids allows the individual to use two hands to insert contact lenses or eye drops.

Recommendations

While the designs we developed have met the objectives we originally set for the project, we have a few recommendations for improvements .Another study with multiple rounds should be conducted to eliminate the issue of unfamiliarity with the device among test subjects. In a real life scenario a subject would be using the devices to insert lenses daily, and would quickly become familiar with how to ideally operate the devices. This would help to ensure that the data gathered from each test subject would focus on the function of the devices, as opposed to the difficulties faced in using a new product.

For commercialization, three steps should be taken:

1. Manufacture the devices out of Nylon or another commercially available plastic
2. Extend the padding to cover the entire surface
3. Ensure the nose bridge is easily adjustable

We recommend that a prototype is made with nylon or a bio-safe plastic to replace the metal because it has a lower heat capacity and will be more comfortable for the wearer. Plastics will also be safer for the user and easier to manufacture. In addition to changing the metal frame, we suggest that the padding design be extended to cover the entire arm to further protect the user from the edges of the prototype that might touch the face. Lastly, we propose that a new nose bridge to connect the two c-rings in the Biomimetic design be implemented. The new nose bridge should be easy to adjust and simple to use.

Appendix A: Institutional Review Board Application

WORCESTER POLYTECHNIC INSTITUTE
Institutional Review Board
Application for Approval to Use Human Subjects in Research

WPI IRB use only
IRB #
Date:

This application is for: *(Please check one)* ☐ Expedited Review ☒ Full Review

WPI IRB use only

Principal Investigator (PI) or Project Faculty Advisor: *(NOT a student or fellow; must be a WPI employee)*

Name:	John Sullivan	Tel No:	508-831-5199	E-Mail Address:	Sullivan@wpi.edu
Department:	Mechanical Engineering				

Co-Investigator(s): *(Co-PI(s)/non students)*

Name:		Tel No:		E-Mail Address:	
Name:		Tel No:		E-Mail Address:	

Student Investigator(s):

Name:	Elizabeth Dufresne	Tel No:	508-688-2229	E-Mail Address:	edufresne.wpi.edu
Name:	Emily Miner Kristen Schleier	Tel No:	603-547-7433 518-431-9947	E-Mail Address:	erminer@wpi.edu Kristen.schleier@wpi.edu

Check if: ☒ **Undergraduate project** *(MQP, IQP, Suff., other)* MQP
☐ **Graduate project** *(M.S. Ph.D., other)*

Has an IRB ever suspended or terminated a study of any investigator listed above?
No ☒ Yes ☐ *(Attach a summary of the event and resolution.)*

Vulnerable Populations: The proposed research will involve the following (Check all that apply):
pregnant women ☐ human fetuses ☐ neonates ☐ minors/children ☐ prisoners ☐
students ☐ individuals with mental disabilities ☐ individuals with physical disabilities ☐

Collaborating Institutions: *(Please list all collaborating Institutions.)*
None

Locations of Research: *(If at WPI, please indicate where on campus. If off campus, please give details of locations.)*
WPI Higgins Laboratories

Project Title: Assistive Contact Lens Device

Funding: *(If the research is funded, please enclose one copy of the research proposal or most recent draft with your application.)*

Funding Agency: _____ WPI Fund: _____

Human Subjects Research: *(All study personnel having direct contact with subjects must take and pass a training course on human subjects research. There are links to web-based training courses that can be accessed under the Training link on the IRB web site http://www.wpi.edu/offices/irb/training.html. The IRB requires a copy of the completion certificate from the course or proof of an equivalent program.)*

Anticipated Dates of Research:

WORCESTER POLYTECHNIC INSTITUTE
Institutional Review Board
Application for Approval to Use Human Subjects in Research

WPI IRB use only
IRB #
Date:

Start Date: 11/25/2013 Completion Date: 3/7/2014

Instructions: Answer all questions. If you are asked to provide an explanation, please do so with adequate details. If needed, attach itemized replies. Any incomplete application will be returned.

1.) Purpose of Study: *(Please provide a concise statement of the background, nature and reasons for the proposed study. Insert below using non-technical language that can be understood by non-scientist members of the IRB.)*

The purpose of the study is to test our device for ergonomics and effectiveness. We want to make sure that the device works properly with a variety of different sized facial features.

2.) Study Protocol: *(Please attach sufficient information for effective review by non-scientist members of the IRB. Define all abbreviations and use simple words. Unless justification is provided this part of the application must not exceed 5 pages. Attaching sections of a grant application is not an acceptable substitute.)*

A.) For **biomedical, engineering and related research**, please provide an outline of the actual experiments to be performed. Where applicable, provide a detailed description of the experimental devices or procedures to be used, detailed information on the exact dosages of drugs or chemicals to be used, total quantity of blood samples to be used, and descriptions of special diets.

B.) For applications in the **social sciences, management and other non-biomedical disciplines** please provide a detailed description of your proposed study. Where applicable, include copies of any questionnaires or standardized tests you plan to incorporate into your study. If your study involves interviews please submit an outline indicating the types of questions you will include.

C.) If the study involves **investigational drugs or investigational medical devices**, and the PI is obtaining an Investigational New Drug (IND) number or Investigational Device Exemption (IDE) number from the FDA, please provide details.

D.) Please note if any **hazardous materials** are being used in this study.

E.) Please note if any **special diets** are being used in this study.

3.) Subject Information:

A.) Please provide the exact number of subjects you plan to enroll in this study and describe your subject population. *(eg. WPI students, WPI staff, UMASS Medical patient, other)*

Males: 10 Females: 10 Description: WPI students and faculty

B.) Will subjects who do not understand English be enrolled?
No ☒ Yes ☐ *(Please insert below the language(s) that will be translated on the consent form.)*

C.) Are there any circumstances under which your study population may feel coerced into participating in this study?
No ☒ Yes ☐ *(Please insert below a description of how you will assure your subjects do not feel coerced.)*
We are advertising the study as a volunteer activity so that no one feels pressured the participate. If a volunteer decides that they are not comfortable to participate then they may quit the study at any point.

D.) Are the subjects at risk of harm if their participation in the study becomes known?
No ☒ Yes ☐ *(Please insert below a description of possible effects on your subjects.)*

E.) Are there reasons for excluding possible subjects from this research?
No ☒ Yes ☐ *(If yes, please explain.)*

F.) How will subjects be recruited for participation? *(Check all that apply.)*

☐ Referral: *(By whom)* _____
☐ Other: *(Identify)* _____
☐ Database: *(Describe how database populated)*

☒ Direct subject advertising, including: *(Please provide a copy of the proposed ad. All direct subject advertising must be approved by the WPI IRB prior to use.)*

☐ Newspaper ☐ Bulletin board
☐ Radio ☐ Flyers
☐ Television ☐ Letters
☐ Internet ☒ E-mail

F.) Have the subjects in the database agreed to be contacted for research projects? No ☐ Yes ☐ N/A ☒

G.) Are the subjects being paid for participating? *(Consider all types of reimbursement, ex. stipend, parking, travel.)*
No ☒ Yes ☐ *(Check all that apply.)* ☐ Cash ☐ Check ☐ Gift certificate ☐ Other: _____
Amount of compensation _____

4.) Informed Consent:

A.) Who will discuss the study with and obtain consent of prospective subjects? *(Check all that apply.)*
☐ Principal Investigator ☐ Co-Investigator(s) ☒ Student Investigator(s)

B.) Are you aware that subjects must read and sign an Informed Consent Form prior to conducting any study-related procedures and agree that all subjects will be consented prior to initiating study related procedures? No ☐ Yes ☒

C.) Are you aware that you must consent subjects using only the IRB-approved Informed Consent Form? No ☐ Yes ☒

D.) Will subjects be consented in a private room, not in a public space? No ☐ Yes ☒

E.) Do you agree to spend as much time as needed to thoroughly explain and respond to any subject's questions about the study, and allow them as much time as needed to consider their decision prior to enrolling them as subjects? No ☐ Yes ☒

F.) Do you agree that the person obtaining consent will explain the risks of the study, the subject's right to decide not to participate, and the subject's right to withdraw from the study at any time? No ☐ Yes ☒

G.) Do you agree to either 1.) retain signed copies of all informed consent agreements in a secure location for at least three years or 2.) supply copies of all signed informed consent agreements in .pdf format for retention by the IRB in electronic form? No ☐ Yes ☒

(If you answer No to any of the questions above, please provide an explanation.)

5.) Potential Risks: *(A risk is a potential harm that a reasonable person would consider important in deciding whether to participate in research. Risks can be categorized as physical, psychological, sociological, economic and legal, and include pain, stress, invasion of privacy, embarrassment or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible by using e.g. appropriate monitoring, safety devices and withdrawal of a subject if there is evidence of a specific adverse event.)*

A.) What are the risks / discomforts associated with each intervention or procedure in the study?

-Potentially spread germs between test subjects

B.) What procedures will be in place to prevent / minimize potential risks or discomfort?

-Steps and procedures for using the device and and safety warnings will be presented to the test subjects before using the device.
-Device will be throughly cleaned with disinfectant between each test subject and subjects who have had an eye infection or similar virus will not be allowed to test the device for 2 weeks.

6.) Potential Benefits:

A.) What potential benefits other than payment may subjects receive from participating in the study?

They will have exposure to the project and will be aware that this device will hopefully be available in the future for use

B.) What potential benefits can society expect from the study?

Society can expect a device that will increase the opportunity for disabled persons to wear contacts by helping them to keep their eyes open so they can put in a contact lens.

7.) Data Collection, Storage, and Confidentiality:

A.) How will data be collected?

Data will be collected via an evaluation form that test subjects will fill out after using the device. The evaluation form will ask to rate the device based on the comfort, functionality, usefullness, and will have an open section for comments or suggestions.

B.) Will a subject's voice, face or identifiable body features *(eg. tattoo, scar)* be recorded by audio or videotaping?
No ☒ Yes ☐ *(Explain the recording procedures you plan to follow.)*

C.) Will personal identifying information be recorded? No ☐ Yes ☒ *(If yes, explain how the identifying information will be protected. How will personal identifying information be coded and how will the code key be kept confidential?)*

We will record the length of the nose of each participant, the width of the face and the width of the bridge of the nose. This will allow us to keep track of which participants felt the device worked well and which particpants felt it did not fit their face well. Then we can make revisions to the device based on this data.

D.) Where will the data be stored and how will it be secured?

The data will be stored on a private thumb drive of one of the project group members and will not be shared with anyone outside the group of investigators.

E.) What will happen to the data when the study is completed?
We will present the data in our report and will use the data to further refine the designs based on the comfort ratings of individuals with different sized facial features but we will not include any names.

F.) Can data acquired in the study adversely affect a subject's relationship with other individuals? *(i.e. employee-supervisor, student-teacher, family relationships)*

No

G.) Do you plan to use or disclose identifiable information outside of the investigation personnel?
No ☒ Yes ☐ *(Please explain.)*
We will present the data in our report and will use the data to further refine the designs based on the comfort ratings of individuals with different sized facial features. However, we will not have any identifiable data except nose sizes (ie we will not record a name that corresponds with the nose measurement)

H.) Do you plan to use or disclose identifiable information outside of WPI including non-WPI investigators?
No ☒ Yes ☐ *(Please explain.)*
We will present the data in our report which will be open to the public after completion of the project. However, we will not have any identifiable data except nose sizes (ie we will not record a name that corresponds with the nose measurement)

8.) Incidental findings: *In the conduct of information gathering, is it possible that the investigator will encounter any incidental findings? If so, how will these be handled? (An incidental finding is information discovered about a subject which should be of concern to the subject but is not the focus of the research. For example, a researcher monitoring heart rates during exercise could discover that a subject has an irregular heartbeat.)*

Not possible

9.) Deception: *(Investigators must not exclude information from a subject that a reasonable person would want to know in deciding whether to participate in a study.)*

Will the information about the research purpose and design be withheld from the subjects?
No ☒ Yes ☐ *(Please explain.)*

10.) Adverse effects: *(Serious or unexpected adverse reactions or injuries must be reported to the WPI IRB within 48 hours using the IRB Adverse Event Form found out at http://www.wpi.edu/offices/irb/forms.html. Other adverse events should be reported within 10 working days.)*

What follow-up efforts will be made to detect any harm to subjects and how will the WPI IRB be kept informed?
One week after the particpant tests the device, we will follow up with the participant to check that they have had no adverse injuries from using the device.

11.) Conflict of Interest: *(A conflict of interest occurs when an investigator or other key personnel in a study may enjoy material benefits based on study results. Relationships that give rise to a conflict of interest or the appearance of a conflict of interest must be disclosed in the informed consent statement provided to study subjects. More information, including examples of relationships that require disclosure and those that do not, can be found here.)*

WORCESTER POLYTECHNIC INSTITUTE
Institutional Review Board
Application for Approval to Use Human Subjects in Research

WPI IRB use only
IRB #
Date:

b. Investigator (name) _Emily Miner_ No ☒ Yes ☐
c. Investigator (name) _Kristen Schleier_ No ☒ Yes ☐

B.) If any of the answers to 11A. are "Yes," please attach an explanation of the nature of the conflict to this application and identify appropriate language for use in the consent form. Examples of consent language are found on the IRB website, here.

C.) Does each investigator named above have a current WPI conflict of interest disclosure form on file with the appropriate supervisor/department head? No ☐ Yes ☒

D.) Do any of the investigators' COI forms on file with WPI contain information regarding this research?
No ☒ Yes ☐
a. If "Yes," identify the investigator(s) _____

12.) Informed consent: (*Documented informed consent must be obtained from all participants in studies that involve human subjects. You must use the templates available at http://www.wpi.edu/offices/irb/forms.html to prepare these forms.* ***Informed consent forms must be included with this application.*** *Under certain circumstances the WPI IRB may waive the requirement for informed consent.)*

Investigator's Assurance:

I certify the information provided in this application is complete and correct.

I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the WPI IRB.

I agree to comply with all WPI policies, as well all federal, state and local laws on the protection of human subjects in research, including:

- ensuring the satisfactory completion of human subjects training.
- performing the study in accordance with the WPI IRB approved protocol.
- implementing study changes only after WPI IRB approval.
- obtaining informed consent from subjects using only the WPI IRB approved consent form.
- promptly reporting significant adverse effects to the WPI IRB.

Signature of Principal Investigator [redacted] Date 1-30-2014

Print Full Name and Title John M Sullivan, Jr. Professor

Please return a signed hard copy of this application to the WPI IRB c/o Ruth McKeogh 2nd Floor Project Center
Or email an electronic copy to irb@wpi.edu
If you have any questions, please call (508) 831-6699.

Assistive Contact Lens Device Testing Protocol

E. Dufresne
E. Miner
K. Schleier

The testing of our device will fulfill the following objectives:

- Ensure the device functions correctly and satisfies all design constraints. Even though a CAD model can give you a fairly accurate portrait of a device, there are some mistakes that can only be found once the device is prototyped and tested.
- Ensure the device is ergonomic, comfortable and practical for the user. These criteria will be determined with an evaluation form created by the team that test subjects fill out once they have completed testing the device.

We will accomplish these objectives by using the following testing procedure:

This testing will incorporate test subjects to evaluate how well the device satisfies different qualities and characteristics. They will then fill out a form with their feedback on how effective they believe the device is in terms of our goals. We will collect nose lengths as well as other face measurements of each test subject. We will assign each test subject a number and their name will not be used after this point. Before testing begins, each subject will sit down with a member of the team and learn about the purpose and constraints of the study.

Step-by-Step Procedure:

This procedure will be repeated with each of the 3 devices.

1. One student investigator will meet with subject in a private room and explain the purpose of the devices and the goals of the project. The subject will review a list of materials used in the devices and in the eye drops, if they do not wear contacts. Once the subject knows the expectations of the test and has no allergies to any of the materials, the student investigator will leave the room so the subject can sign a consent form if they choose to participate.
2. If they have signed the form, the student investigator will then measure the width of the test subjects face, the width of the bridge of the nose, and the length of the nose. When finished, the test subject will be escorted to the testing room by the student investigator.
3. The test subject will be told how to use the device by a student investigator, following the *Directions for Using Assistive Device*.
4. Each participant will be allowed to use both hands to use the device.

The test subject will attempt to put the device on their face, and operate/use it to open their right eye. If they wear contacts, they will try to insert their contact lens. If they do not wear contacts, then they will try to insert eye drops using a bottle assigned to them to avoid any germ contamination. They will then be asked to remove the device. Next, they will repeat that procedure on the left eye.

5. Following the conclusion of the above steps, the test subject will be given a *Test Evaluation and Feedback Form* to answer questions and rate the devices on comfort, ergonomics, usability, and to give specific feedback.

View the pictures of the device below, illustrated by Student Investigator Elizabeth Dufresne.

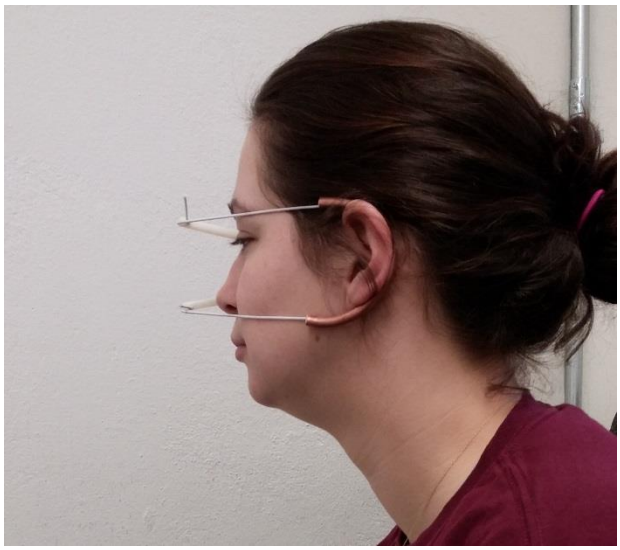

Figure 34-Left View of Device 1 on face

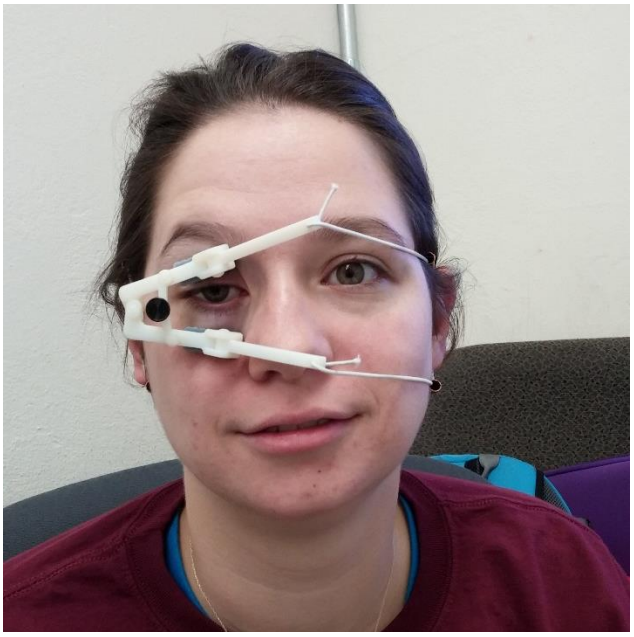

Figure 35-Front View of Device 1 on face

Figure 36-Right View of Device 1 on face

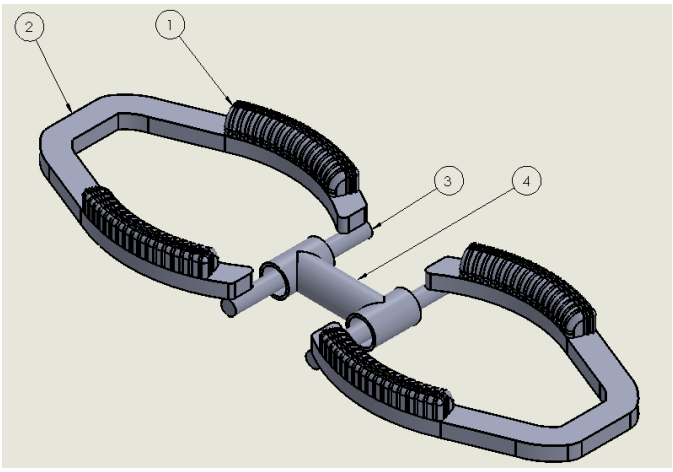

Figure 37-Device 2 (without the head strap attached

This device will be machined as above but the figures below illustrate how the device will sit on the face and attach to the head.

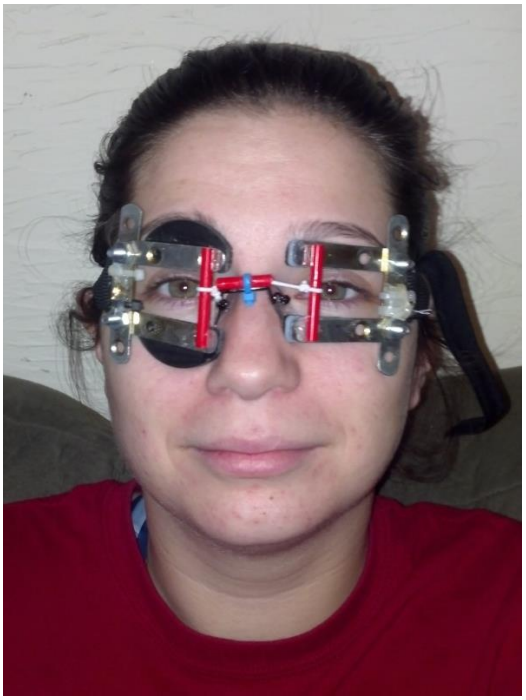

Figure 38-Front view of Device 2

Figure 39-Left Side view of Device 2

Figure 40-Right side view of Device 2

Figure 41-Device 3 Finger Grip (amazon.com)

Figure 42-Device 3 Finger Grip Holder

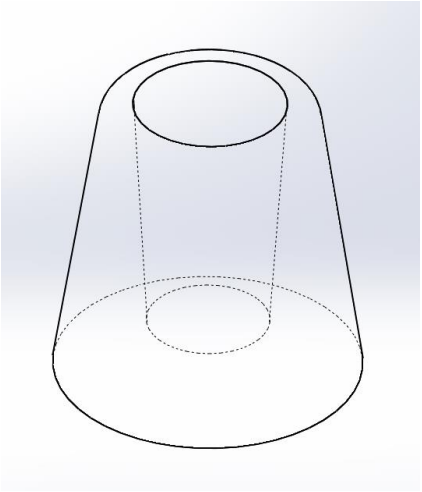

Figure 43-Device 3 Finger Grip Holder inside view

JMS1402 Script to Recruit Test Subjects

This will only be sent to organizations that the Student Investigators are a part of.

Hello [insert organizations name here],

This email is sent on behalf of Liz Dufresne, Emily Miner and Kristen Schleier. We are an MQP group working on a project to design, build and test a device which will assist with the insertion of contact lenses and eye drops for upper limb amputees and individuals with limited mobility in their limbs.

We are seeking individuals to help us test this device. By volunteering to be a part of our testing phase, you will be helping us collect essential data to further refine our MQP. Before any testing begins you will be told the procedures of the test and any risks involved. You will read and sign an Informed Consent Form as well as a Non-disclosure Agreement if you choose to participate, and will be able to opt out of the study at any time.

The time requirement is 1 session lasting 30 minutes.

Anyone can participate in this study, regardless if you wear contacts or not. If you do not wear contacts you should be willing to put in eye drops instead. You do not need to be an amputee or have limited mobility in order to participate.

If you are interested in helping us with our MQP research please contact:
eyes@wpi.edu
or one of the following team members:

Liz Dufresne edufresne@wpi.edu
Emily Miner erminer@wpi.edu
Kristen Schleier kristen.schleier@wpi.edu

Thank you!

Sincerely,
Liz, Emily & Kristen

Informed Consent Agreement for Participation in a Research Study

Investigators: **Elizabeth Dufresne, Student Investigator**
Emily Miner, Student Investigator
Kristen Schleier, Student Investigator
John Sullivan, Project Advisor

Contact Information: **eyes@wpi.edu**

Title of Research Study: The Evaluation of an Assistive Device for the Insertion of Contact Lenses

Sponsor: None

INTRODUCTION
PURPOSE OF THIS STUDY
The purpose of the study is to test our device for ergonomics and to learn about the effectiveness of our device to assist upper limb amputees in the insertion of contact lenses and the administration of other eye care. We want to make sure that the device works properly with a variety of different sized facial features.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

- You do not need to be an amputee to participate in the study
- You should not participate in this study if:
    - you have allergies to the materials on the device (VeroClear/VeroWhite and TangoPlus), the eye drops we have provided, or the cleaning products used to sanitize the device
    - you currently or in the last two weeks (14 days) have had any kind of eye infection or suspect you may be showing signs of one
    - you do not wear contacts AND are not comfortable putting in non-prescription eye drops

PROCEDURES OF THE STUDY
WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?
The research procedures will be conducted at Worcester Polytechnic Institute. The total amount of time you will be asked to volunteer for this study is 90 minutes over the next 1 month.

WHAT WILL YOU BE ASKED TO DO?
You will be asked to use the device as a test for usability, comfort, and functionality. You will be asked to test the device on three different occasions, referred to as Round 1, Round 2, and Round 3. You will test the device on your right eye then your left eye. The rounds of testing will be spread over the next month to allow time for design revision from input gathered in the previous round.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS FOR PARTICIPANTS?
To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?
You will not get any personal benefit from taking part in this study.

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you do not want to be in the study, please tell the student investigator now. At any point during the study you have the option not to continue, and you should inform the student investigator of your decision. There are no repercussions for ending your participation early.

RECORD KEEPING AND CONFIDENTIALITY?
Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or it's designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you.

CAN YOUR TAKING PART IN THE STUDY END EARLY?
If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study are there are no consequences for early withdrawal. In order to withdraw from the study at any point you must inform the student investigators at the contact email listed above, as soon as you have made the decision.

The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you or if they find that your being in the study is more risk than benefit to you.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?
You do not give up any of your legal rights by signing this statement. It is important for you to understand that Worcester Polytechnic Institute does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, Worcester Polytechnic Institute will not pay for any wages you may lose if you are harmed by this study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?
If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT ELSE DO YOU NEED TO KNOW?
There is a possibility that the data collected from you may be shared with other investigators in the future. If that is the case the data will not contain information that can identify you. This study is approved by the Worcester Polytechnic Institute's Institutional Review Board (IRB). The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact: Use the contact information at the beginning of this form. Or contact Professor Kent Rissmiller, Tel. 508-831-5019, Email: kjr@wpi.edu and the University Compliance Officer Michael J. Curley, Tel. 508-831-6919, Email: mjcurley@wpi.edu.

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____ **Date:** _____
Study Participant Signature

_____
Study Participant Name (Please print)

_____ **Date:** _____
Signature of Person who explained this study

We will give you a signed copy of this consent form to take with you.

_____ _____
Signature of person agreeing to take part in the study Date

_____
Printed name of person agreeing to take part in the study

_____ _____
Name of (authorized) person obtaining informed consent Date

Appendix B: Directions for Using the Devices

Moving Arm Prototype

1. Prepare your contact lens or eye drops to be inserted before settling the device on your face.
2. Unfold the arms attached to the elastic bands and ear pieces until they lock. The arms will lock at 135 degrees.
3. Place one ear hook around an ear, keeping the eye pads facing towards the face. Close your eyes and stretch the other elastic and ear hook across the face and around the other ear.
4. Adjust the device to place the pads on the edges of the eyelids, trying to include the eyelashes.
5. Once placed correctly, pull the knob in the middle of the linkage away from the nose until it stops in the vertical position.
6. Insert your contact lens or eye drops.
7. Push the linkage knob towards nose to close the eyelids and remove the device from the face.
8. To store device, fold the fold the posts closed and return to case.

Biomimetic Prototype

1. Prepare your contact lens or eye drops to be inserted before settling the device on your face.
2. Place the elastic strap around your head and tighten or loosen the strap as needed.
3. Adjust the device to place the pads below the eye brow and above the cheekbone.
4. Apply gentle pressure upward on the brow to catch the upper lid on the pad.
5. Apply gentle pressure downward on the cheekbone to catch the lower lid.
6. Insert your contact lens or eye drops.

7. Gently lift the device away from your face to release the grip on your eyelids.
8. Repeat steps 3 through 7 for the other eye.

Finger Grip Prototype

1. Prepare your contact lens or eye drops to be inserted before settling the device on your face.
2. Place the finger gripper into the receptacle.
3. Insert your pointer finger into the finger gripper.
4. Place another finger gripper into the receptacle.
5. Insert your ring finger of the same hand into the finger gripper.
6. Arrange the contact lens on the middle finger of that hand.
7. Apply gentle pressure upward on the brow to catch the upper lid on the pad with one finger gripper.
8. Apply gentle pressure downward on the cheekbone to catch the lower lid with the other.
9. Insert your contact lens or eye drops.
10. Remove your fingers to release the grip on your eyelids.
11. Repeat steps 6 through 10 for the other eye.

Appendix C: Assistive Device Evaluation Form

1. Test Subject #____

2. Are you right or left handed?
    a. Right
    b. Left

3. Is the device easier to use on the left or right side of the face?
    a. Right
    b. Left
    c. Both

4. Overall, would you say the device is:

	Very true	True	Not True	Very untrue
Comfortable				
Easy to use				

5. What part of the device is most difficult to use?

6. Which part of the device do you find most uncomfortable?

7. Was the device stable on your face? (ie It didn't move around on the face)
    a. Yes
    b. No

8. If you only had one arm, would you have reservations about using this device daily?
    a. Yes
    b. No

Please elaborate:

Additional Comments and/or Suggestions:

Appendix D: Biomimetic Evaluation Form Data

2. Are you left or right handed?

#	Answer		Response	%
1	Left		0	0%
2	Right		15	94%
3	Ambidextrous		1	6%
	Total		16	100%

3. Was the device easier to use on the left or right side of the face?

#	Answer		Response	%
1	Left		2	13%
2	Right		8	50%
3	Both sides were equal		6	38%
	Total		16	100%

4. Overall, would you say the device is: (4 is the highest rating, 1 is the lowest)

#	Question	4	3	2	1	Total Responses	Mean
1	Comfortable	0	9	3	3	15	2.60
2	Easy to use	1	7	8	0	16	2.44

5. Which part of device was most difficult to use?

Responses
The nose bridge
Adjusting the headband and nose bridge to fit correctly
Lining up the padding with the eyelids/initially catching the eyelids
The metal arms obstructed vision while putting contacts in
Making the device even across the face
Having the device stay on the eyelids while preparing the contact

6. Which part was most uncomfortable?

Responses
None
Wearing the wrong sized device, which made the metal arms dig into the brow bone/eye socket
The nose bridge
Having the eye open for a long period of time, this dried the eye out
The top padding holding the eye lashes
The tightness of the strap (not sure how tight to make it)

7. Which size fit best?

#	Answer		Response	%
1	Small		3	19%
2	Large		0	0%
3	Medium		13	81%
	Total		16	100%

8. Did the device feel stable on the face?

#	Answer		Response	%
1	Yes		13	81%
2	No		3	19%
	Total		16	100%

9. Would you consider using this device if you only had one arm?

#	Answer		Response	%
1	Yes		12	75%
2	No		4	25%
	Total		16	100%

Appendix E: Finger Grip Evaluation Form Data

2. Are you left or right handed?

#	Answer		Response	%
1	Left		0	0%
2	Right		14	93%
3	Ambidextrous		1	7%
	Total		15	100%

3. Was the device easier to use on the left or right side of the face?

#	Answer		Response	%
1	Left		2	13%
2	Right		5	33%
3	Both sides were equal		8	53%
	Total		15	100%

4. Overall, would you say the device is: (4 is the highest rating, 1 is the lowest)

#	Question	4	3	2	1	Total Responses	Mean
1	Comfortable	11	2	1	0	14	1.29
2	Easy to use	12	2	1	0	15	1.27

5. Which part was most difficult to use?

Responses
None
The rubber fingertip extending past the end of the fingertip, making use awkward
Putting the gripper on the finger with one hand

Not sure which fingers to put the grippers on
Keeping the grippers on the fingers (wearing the wrong size)

6. Which part was most uncomfortable?

Responses
None
The grippers were tight on fingers (wearing the wrong size)
Tip of the gripper coming into contact with eye if used improperly
Holding the lids open

7. Which size fit best?

#	Answer		Response	%
1	Small		1	7%
2	Large		4	27%
3	Medium		10	67%
	Total		15	100%

8. Did the device feel stable on the face?

#	Answer		Response	%
1	Yes		14	100%
2	No		0	0%
	Total		14	100%

9. Would you consider using this device if you only had one arm?

#	Answer		Response	%
1	Yes		12	80%
2	No		3	20%
	Total		15	100%

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