Design of Surgical Device to Create Capsulorhexis during Cataract Surgery

Lisle Blackbourn (Team Leader), Molly Krohn (Communicator)
Sean Heyrman (BWIG), Kate Howell (BSAC)

University of Wisconsin-Madison- Biomedical Engineering
Client: Dr. Jon Gunther
Advisor: Dr. Paul Thompson

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Abstract

Approximately 1.5 million cataract surgeries are performed each year in the United States and millions more throughout the world. There is a need for a precise mechanical device that will be significantly more cost effective than the laser technique, thus allowing for much broader access than is currently available with the laser technique. The purpose of this project is to design an instrument that is able to safely enter the human eye through a 2.0 mm incision in the cornea, unfold inside the eye into a circular device that is then able to create a 6 mm circular opening in the capsular tissue of a human lens. The instrument will then need to fold back up and be removed through the same 2 mm incision. The final design utilizes the ultrasound machine. An attachment for the ultrasound machine will be fabricated that uses the suction setting. This semester, the focus was placed on constructing a mechanism to deploy and retract the device at a larger scale. In the future, the mechanism will be made to scale and will be further investigated with the settings on the phaco-tool to perform the capsulorhexis.

Background

1.6 million cataract surgeries are performed every year in the United States alone [1]. Cataracts occur when the lens in the eye becomes opaque. The lens is a hard protein object in the eyeball located behind the pupil which focuses the light waves traveling through the pupil onto the back of the retina. The retina contains rods and cones which transduce light waves into electrical signals that the brain can interpret as the images people see. As people age, the proteins in the lens begin to deteriorate. The lens is held in a lens capsule with no circulation. As the lens breaks down, the proteins are encased in the capsule causing the liquid surround the lens to become cloudy. The opaqueness of the lens capsule affects how the light is reflected onto the retina as seen in Fig. 1. The more cloudiness, the more dispersed the light rays are on the retina resulting in blurry vision. [2]

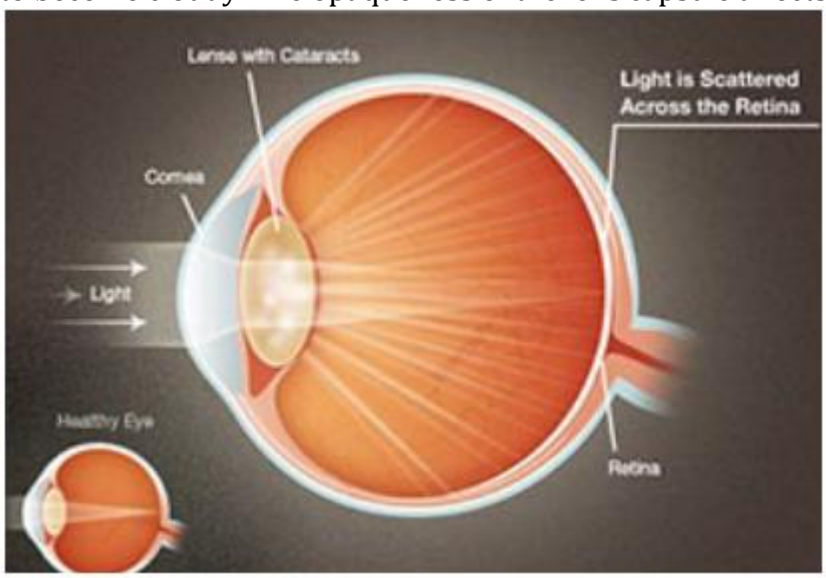

Figure 1. In the lower corner is how a healthy lens focuses light rays onto the retina, and in the center is how cataracts disperse light resulting in blurry vision. [2]

To correct cataracts, surgery is performed to replace the original lens with an artificial lens, also known as an intraocular lens. The most common procedure involves making one to three incisions ranging from 1.8 mm to 2.8 mm on the cornea perpendicular to the lateral edge of the region above the lens capsule. Incisions less than 3 mm are self-sealing incisions requiring no sutures. Viscoelastic is injected into the space above the capsule. Then a device is inserted through the incision and an anterior capsulotomy is made; a centered 6 mm diameter circle is cut into the capsule containing the lens. Then a small amount of saline solution is injected into the capsule to aid in the emulsification of the lens. The phaco-tool is inserted and uses ultrasound to emulsify the lens. The same phaco-tool then aspirates the broken up lens out of the capsule. More viscoelastic is injected into the capsular bag to expand it for the intraocular lens. The intraocular lens is implanted using an injector tool. A hook device is used to place the lens, and lastly the viscoelastic is aspirated. The entire surgery takes less than 10 minutes. [3]

Current Methods

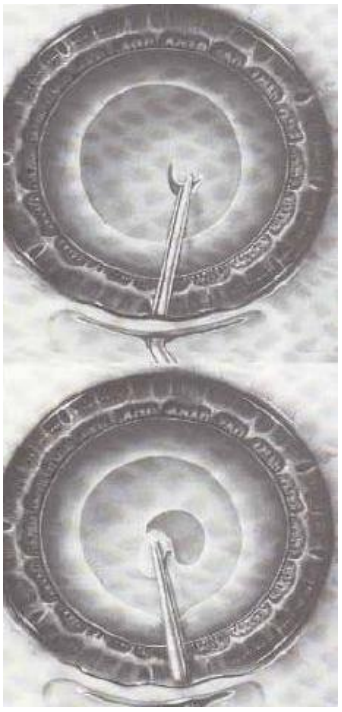

Figure 2. The initial tear and the continuous pulling of the capsule is the basic technique of the CCC.

The focus of this project is the capsulorhexis to access the lens for emulsification and aspiration. The most common method currently is the technique called continuous curvilinear capsulorhexis (CCC). A forceps or a cystotome (a 27 gauge needle bent to conform to the convexity of crystalline lens) is used to make a tear on center of the capsule as seen in Fig. 2. From the center, a 3 mm line is torn outward. At the end of the radial incision, the surgeon tears the circle with a combination of pulling and folding of the torn capsule in a continuous manner. [4] The capsulorhexis is then removed from the eye using forceps. This method leads to various capsulorhexis sizes. It also requires a perfected technique from the surgeon. The edges of the capsulorhexis tend to be jagged. [5]

Recently, femtosecond lasers more commonly used in LASIK eye correction surgery have been utilized to make the capsulorhexis. This method is done externally with computer software. The surgeon positions the laser, and the program is able to cut a precise circle in the capsule. Studies are also being done to test how efficient the lasers are in emulsifying the lens as well. Unfortunately, not all facilities can afford to have a femtosecond laser and using one during surgery can add at least a $1,500 to the medical bill. [1]

Another emerging technology is the Fugo Plasma Blade. It was approved for anterior capulotomies by the USFDA in 2000. The cut is still manually performed by the surgeon, but instead of tearing the cut is made by plasma ablation. The tips are similar in shape to the cystotome. The reusable system costs $23,000 and each tip averages around $60. [6] The edges were found to be more jagged than the continuous curvilinear capsulorhexis. [5]

Problem Statement

A precise mechanical device is to be developed to perform a capsulorhexis that will be significantly more cost effective than the laser technique thus allowing for much broader access than the femtosecond laser. The instrument must safely enter the human eye through a 2.0 mm incision, make a 6 mm diameter circular cut into the anterior capsule, and be removed through the previously mention incision.

Product Design Specifications

The client requirements include the following: device must not create any microtears during surgery, must cut a precise 6 mm circle within 0.5-1 mm accuracy, must be sterilized before use and must not change the current protocol of the surgery. See Appendix 8.1 for more detail on the design requirements.

Design Alternatives

Initially three designs were created to make the capsulorhexis: an ultrasonic ring, suction cut, and "ice-cream scoop" design. They are described in the following sections.

Ultrasonic Ring

The first design alternative is an ultrasonic ring. This is simply a ring with a blade on it that would be able to cut a circular hole in the capsule. The ring would deploy into the eye, where it would form a perfect circle. The configurations of the ring both inside the instrument and inside the eye are shown below in Fig. 3. The ring would then be placed onto the location intended to be cut, and either pressed down to cut the tissue or ultrasound transmitted from the Phaco-tool down a rod connected to the ring would assist in cutting the tissue. [7]

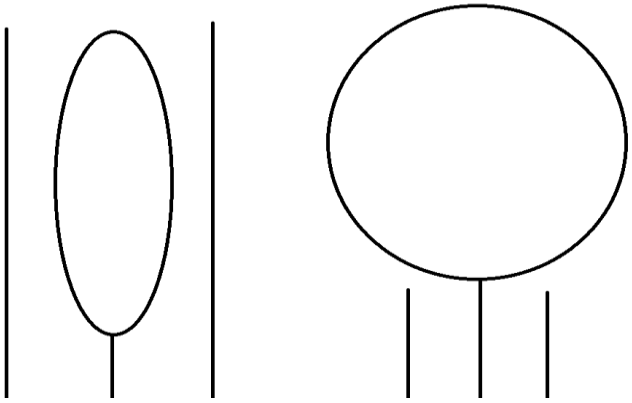

Figure 3. (Left) The configuration of the ultrasonic ring while inside of the instrument, which allows easy access into the eye. (Right) The configuration of the ring once inside the eye allows for a perfectly circular cut.

Because of the unique shape this alternative needs to become during use, a flexible material seems best. Some possible materials are Teflon, a flexible metal, or a shape memory alloy (SMA). [8] These would allow the blade to change shape to fit into the insertion instrument and also allow deployment once in the eye. Because the nature of the materials while utilizing ultrasound is unknown, more testing needs to be conducted to ensure the cut is precise.

Suction Cut

The next design alternative also uses the Phaco-tool; however, this design utilizes the suction aspect of the tool. Again this design consists of an attachment to the Phaco-tool that contains a blade at the end. This "party hat" type attachment would stay in the tool during insertion into the eye. After in the eye, the cone would unfurl extending its diameter to the 6mm necessary for the cut. This process would likely be caused by releasing a torsional spring, causing the attachment to go from a cylindrical shape to a cone shape. At this point the blade would be set upon the capsule and the suction turned on effectively bringing the capsule up to the blade to make the cut. As the cut is not made until the suction is turned on, the tool can be adjusted while in the eye. A rough sketch of this design can be seen below in Fig. 4. Since suction is a key component to this design, airtight materials will need to be used. Materials like rubber may be useful in keeping suction within the attachment.

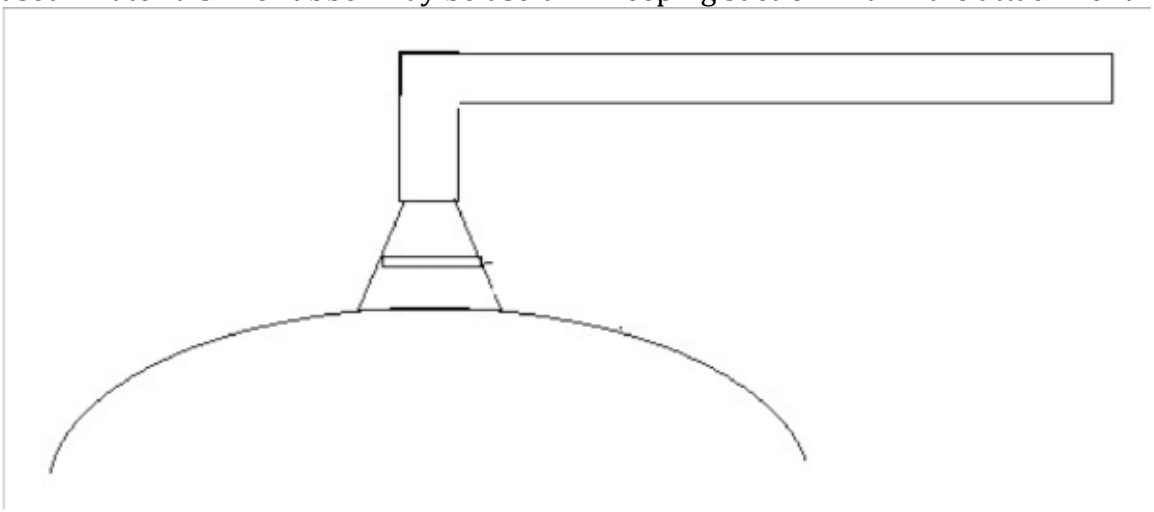

Figure 4. A rough sketch of the suction cut design alternative. As the cone uncurls, the diameter increases to 6mm. The cone can then be placed on the capsule, where suction causes the blade to cut the capsule.

"Ice-cream Scoop" Design

The last design is a device that would use a similar mechanism to an ice cream scoop (see Fig. 5). This mechanism would consist of the lever and the motion "blade" part of an ice cream scooper.

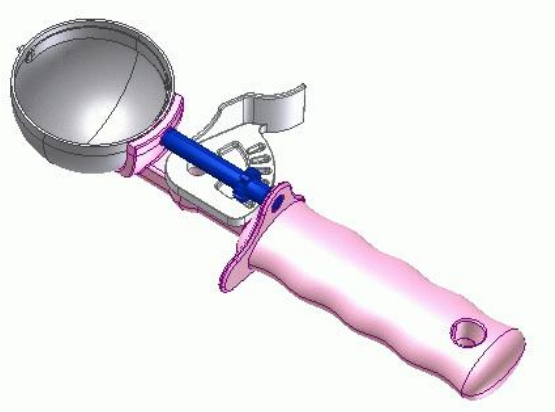

Figure 5. A picture of an ice cream scooper to which the design was based off.

The device would enter and exit the eye with the blade safely located in the device to avoid cutting any part of the eye. By either sliding the lever down or pushing on a "pen-like" button, the blade would appear. The blade would be a semicircle with a radius of 3 mm. When the lever is pressed against the side of the device, the blade would perform the cut, making a hemisphere motion area by rotating 180 degrees. To perform this cut, the blade would be placed on the capsule and then would puncture the capsule by rotating underneath it. While creating this hemisphere, the blade would create the 6 mm diameter circle cut into the lens capsule. Upon the release of the lever, the blade would retreat to its original position. It then could be retracted, and the device could be removed from the eye. A depiction of the device can be seen in Fig. 6.

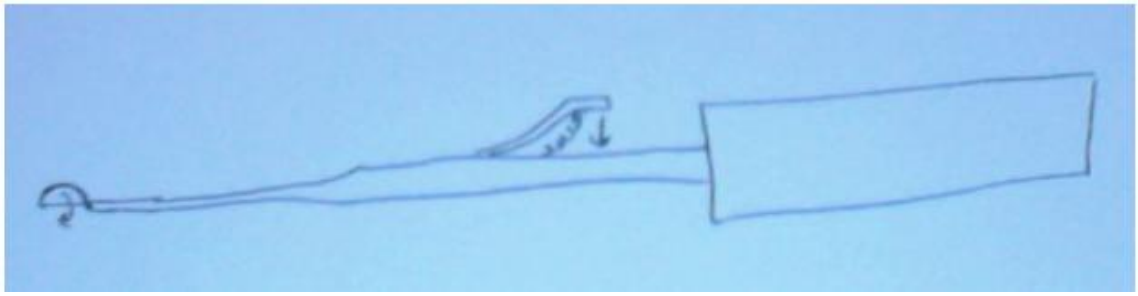

Figure 6. A drawing of the proposed ice cream scooper design. The blade would rotate 180 degrees with the pressing of a lever.

Design Matrix

During the design process, a design matrix was used to evaluate the design alternatives (see Table 1). There are six subcategories within the matrix. A category's significance is made apparent by its multiplication weight within the matrix. The weights were given by Dr. Jon Gunther, the project client. His preferences and opinions account for the degrees of importance assigned to different categories. The total score is out of 100.

The categories are, in order of importance to the client, as follows: precision, safety, size, fabrication, ease of use, and cost. Precision is defined as the device creating a complete and continuous circle, in the correct spot, with no misshapen circle. It also includes creating a 6 mm diameter circle in one try. Safety means that there are no cuts to the eye besides in the lens capsule as well as the material of the device being biocompatible with no adverse effects. The ability of the group to create a prototype is the definition of fabrication and ease of use is in terms of the ease to the surgeon using the device. The cost category is defined as the overall cost to build a prototype.

	Ultrasonic Ring	Suction	Ice Cream Scoop
Precision (x 6)	3	4	2
Safety (x 5)	3.5	2.5	4
Size (x 3)	4	3	2
Fabrication (x 3)	1	3	4
Ease of Use (x 2)	3	4	2
Cost (x 1)	4	4	5
Total (100)	60.5	66.5	59

Table 1. A design matrix used to determine the optimal design according to our client's preferences. Each category was given a weight by our client and each design had a 1 to 5 score for each category. The total score was made by adding up the scores multiplied.

After completing the design matrix, the suction design had the highest score. It scored fairly similar to the other devices in almost all of the categories. It had the highest score in the most weighted category, precision. This helped it have the highest overall score. Some disadvantages of the other designs that contributed to the suction being the best design are described next. The ice cream scoop would require special technique and depends on the surgeons' ability to cut the circle; this may vary from surgery to surgery. Ultrasound is a technique that would need to be investigated more to see how it behaves with a ring and if the vibration would cause microtears.

Final Design

The final design is a tip that will be added to the end of the phaco-tool and use the appropriate power, vacuum level, and aspiration rate to make the capsulorhexis. The geometry of the tip is a cone and is depicted in Figure 7. There are two rings, 2mm and 6mm. The conical surface area connecting the rings is a sheet of flexible material. This material is complaint enough to allow it to be folded up when the tip is retracted. The smaller ring is the top of the truncated cone. It remains in the tip at all times. Attached to the smaller ring are two bars which raise and lower the position of the ring in the tip. The bars are bent 90 degrees towards the end near the small ring to be able to move the ring as seen in Figure 8. The larger ring is also made out of a flexible material but is able to keep the shape of the

circle when deployed. This ring is the part of the tip that would come in contact with the capsule. In addition to the the ring attached to the sheet of material, four strings are attached onto the inner rim of the ring. They are equally spaced along the ring. The other ends of the string go up through the smaller ring into and out of the tip through the other face. Theoretically these ends of the strings would be attached to motors which would be activated creating enough force on the strings to pull up the bottom ring.

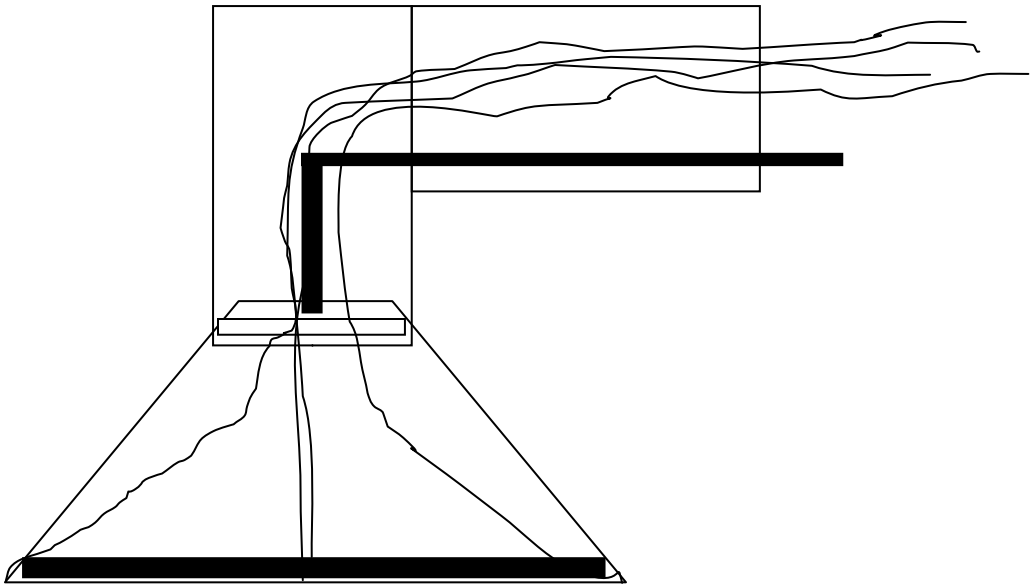

Figure 7. The tip with the cone deployed.

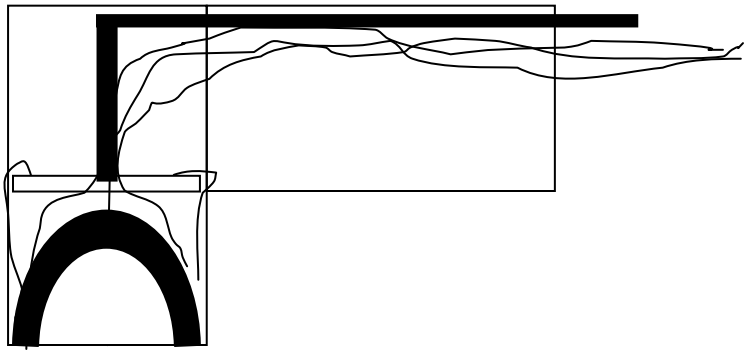

Figure 8. The tip with the cone retracted.

The steps to retract the deployed tip would be as follows: raise the bars to raise the smaller ring farther up into the tip, and then engage the motors which add

enough tension to pull the bottom ring up into the tip and it stores folded up. To deploy the retract ring, the motors release the tension on the strings and unravel enough to allow the strings have slack while the cone is deployed. To push the bottom ring out, the top ring is lower by the bars. The top ring is more like a platform with a circle cut out of the center.

The prototype was made at a scale 19 times larger than the actual device. The tip was modeled using an elbow piece of PVC piping. The smaller top ring was a 5 cm diameter circle cut out of plastic with a inner circle with a diameter of 2.5 cm. The bottom larger ring was an o-ring with a diameter of 15.3 cm and 5 mm thick. The strings were shoelaces, and hot glue was used to adhere the strings to the ring. The plastic used was a plastic drop cloth 50.8 μm thick. The overall height of the cone at rest was 1.5 cm. To attach the plastic to the bottom ring, needle and thread was used to stitch it over the edge of the ring. To attach it to the top ring, hot glue was used once again. The rods were 3 mm in diameter and made out of zinc. To connect the rods and the top ring, two additional 3 mm diameter circles were made into the ring to allow the bars to fit tightly in the holes. Hot super was used to bond the two materials.

Testing

To investigate the application of the phaco-tool to perform the capsulorhexis, a capsule obtained with the 1.1 mm diameter tip of the phaco-tool was compared to the CCC method. Dr. Thliveris at the VA Hospital performed the capsulorhexis with the phaco-tool and CCC method on cadaver eyeballs. Four cadaver eyeballs were utilized in the testing, although only one sample of each method was collected. Table __ shows the testing information using the phaco-tool. This testing illustrates that a high vacuum and power level is needed to perform the capsulorhexis. A scanning electron microscope was utilized to analyze the edge of the capsules to determine if the phaco-tool, with a 1.1 mm tip, has the capability to make a capsulorhexis with uniform edges.

Power	Vacuum Level	Aspiration Rate	Result
55	444	43	No hole
55	50	20	No hole
90	10	20	No hole
100	100	20	No hole
100	120	20	No hole
100	200	20	No hole
100	300	20	Maybe made a hole
100	300	20	Hole obtained

Table 2. Settings and Results from various capsulorhexis attempts.

Several steps were taken to prepare the capsule samples for the scanning electron microscope. The samples were fixed with 1.5% glutaraldehyde in 0.1M Sodium Phosphate Buffer for 16 hours at 4°C. The fixed samples were washed twice with 0.1M Sodium Phosphate Buffer for 10 minutes each. Next, the samples were soaked in an ethanol series (10 minute soak each): 30, 50, 70, 75, 80, 90, 95, 100% (twice), 100% sieve-dried. Then the samples were Critical Point Dried, 10 min soaks (four times) and sputter coated with 30 nm of gold-palladium. The images obtained are shown in Figure 9.

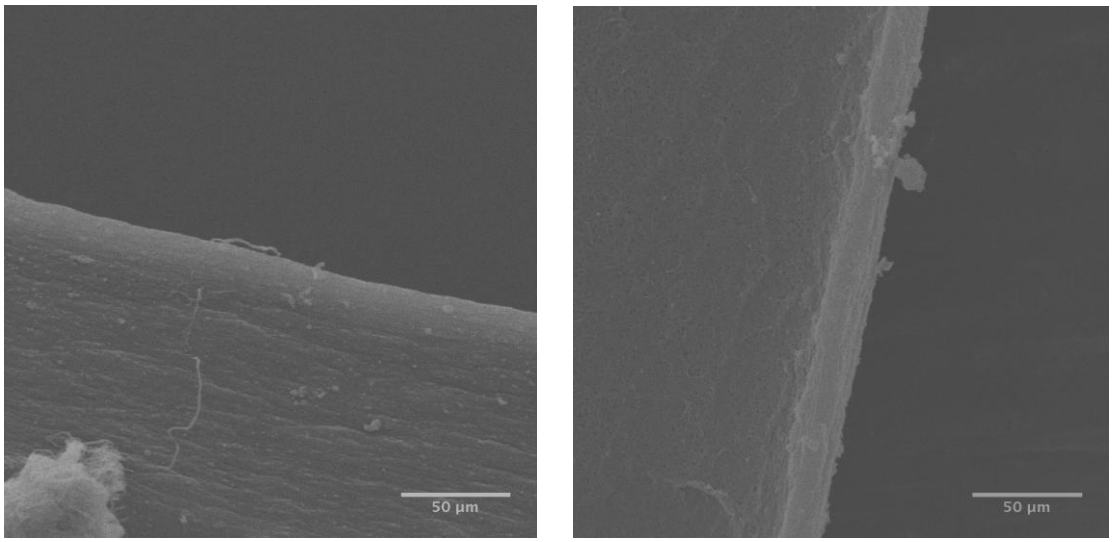

Figure 9. Edge of the capsule performed by (Left) the phaco-tool and (Right) the CCC method.

As shown in Figure 9 (Left), the edge of the capsule of the capsulorhexis performed by the phaco-tool is very straight compared to the edge of the CCC

capsulorhexis as shown in Figure 9 (Right). This qualitative data from the images displays that the caspulorhexis performed by the phaco-tool is better than the CCC method. However, it is important to note that the capsulorhexis performed by the phaco-tool is a 1.1 mm diameter. Our design will increase this diameter by a factor of approximately 6, to 6 mm. Therefore, it will be important to perform more testing in the future to validate the design at this increase of diameter. Also, of note, this is just one image of the edge of the capsule comparing the two methods. The purpose behind this test was to demonstrate the proof of principle; the phaco-method can indeed perform a precise, circular cut. Now, further investigation and focus can be placed on utilizing this technique to create the capsulorhexis.

Estimated Budget

The client has given a very flexible budget with a range of $200 to $500. The cost of the prototype was $16.29 .The price breakdown was: $2.98 for the plastic drop cloth, $1.50 for the PVC elbow, $2.94 for the zinc rod, and $8.87 for the o-ring. The analysis of the scanning electron microscope included a fee of $150 for preparation of the samples and $150 for a two-hour session of imaging the capsules. Based on the Phaco-tool for the ultrasound, it is believed that this is an executable budget and the cost of the device will be on the low end of the budget range. The Phaco-tool costs around $200.

Market

Currently is the US, there are 24,000 ophthalmologists. By talking with our client and others, 85% of these would be willing to buy such a device. This accounts for those that use the laser and those not willing to switch over. This gives a clientele of 20,000 total. After the slow initial phase and the rapid switch to a new technology when everyone knows about the device, we believe we could sell about 1000 a year, selling replacements and to new customers. Expanding to a worldwide market would increase these numbers. After looking at other surgical tools and attachments to these tools, we could sell it at about $150.

Future Work

The first focus for future work is determining which materials will mimic the current properties of the prototype. Some possible materials that could replace the o-ring are shape-memory alloys or thin flexible metals, such as those in collapsible items, such as frisbees. The current plastic membrane may be replaced by a similar plastic or a type of rubber that is fully airtight.

In order to manufacture such a small piece accurate enough to attach to the phaco-tool, a company specializing in manufacturing small parts will be contacted to create the tip. After the tip is manufactured, the suction technique will need to be tested. This will be similar to the technique used in the testing done this semester to determine at what settings the suction will cut the capsule. After the

settings are determined, the holes punctured by the tool will be analyzed using scanning electron microscopy. The resulting images will show the edges, which may or may not have microtears. If there are few microtears and the hole is very circular, then the phaco-tool attachment will advance to further animal testing.

Conclusion

Compared to current manual techniques, the design of this surgical device to create a capsulorhexis during cataract surgery will enable the procedure to be performed in a precise, controlled manner to prevent any microtears that may occur otherwise. Furthermore, it is a cheaper alternative to utilizing a laser to perform the surgery. The final design utilizes suction and will create a 6 mm circular opening in the capsular tissue of a human lens. The device will be easy to deploy and remove from the eye after use. Creation of this device will allow much broader access to a precise instrument to perform the capsulorhexis. A prototype of the mechanism was constructed this semester. In the future, a smaller scaled version will be constructed and further investigation will be placed on the settings of the suction to cut the capsule.

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Appendix A - Design Specifications

1. Physical and Operational Characteristics

a. *Performance requirements*: The device must safely enter the human eye through a 2.0 mm incision in the cornea, unfold inside the eye into a circular device that is then able to create a 6 mm circular opening in the capsular tissue of a human lens within 0.5-1 mm accuracy. Must then fold back up and be removed through same 2 mm incision. Device must be sterilized between uses or may be disposable. The design project will be constructed at a larger scale to show the mechanism in detail.

b. *Safety*: Device must be biocompatible with the eye. It cannot damage, harm or put the eye at greater risk during surgery. Must be sterilized to prevent infection during surgery. The design project will be constructed at a larger scale, therefore safety considerations can be implemented when the device is scaled back down and constructed.

c. *Accuracy and Reliability*: Device must cut varying eye tissues of 15 micron in thickness. It must fit through an incision of 1.9-2.8 mm. No microtears are to be created during surgery. The opening must be within 0.5-1 mm. The design project will fit these requirements at a larger scale.

d. *Life in Service*: The design project will show the mechanism for multiple uses at a larger scale.

e. Ergonomics: Device must be easy to use during surgery. There is only one chance for the circular opening to be made; device must be easy to use with confidence that it will make the opening and not create any microtears.

f. Size: Device must operate in a space of 3-5mm (the vertical distance of the cornea to the lens). Must fit through an incision of 1.8-2.8 mm. The larger scale device will meet these requirements at a larger scale.

g. Materials: Device must be biocompatible. If reusable, must withstand autoclave.

2. Production Characteristics

a. *Quantity*: 1 device.

b*. Target Product Cost*: $200-$500.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval required before use in surgery.

b. *Customer*: Client liked the blade design of cylindrical shape with a lever that deploys a circular blade and then retracts after use.

c. *Patient-related concerns*: If device is reusable, must be sterilized between uses. Materials must be hypoallergenic.

d. Competition: Femtosecond Laser, Nottingham Cataract Device, Fugo Plasma Cutter.