Design of Surgical Device to Create Capsulorhexis during Cataract Surgery

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1. Abstract

Approximately 1.5 million cataract surgeries are performed each year in the United States and millions more throughout the world. A precise mechanical device is looking to be developed 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 previous 2 mm incision. The final design utilizes the ultrasound machine. An attachment for the ultrasound machine will be fabricated that uses the suction setting.

2. Background

1.6 million cataract surgeries are done every year in the United States alone [1]. Cataracts are when the lens in the eye becomes opaque. The lens is a hard protein object in the eyeball right 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 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 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]

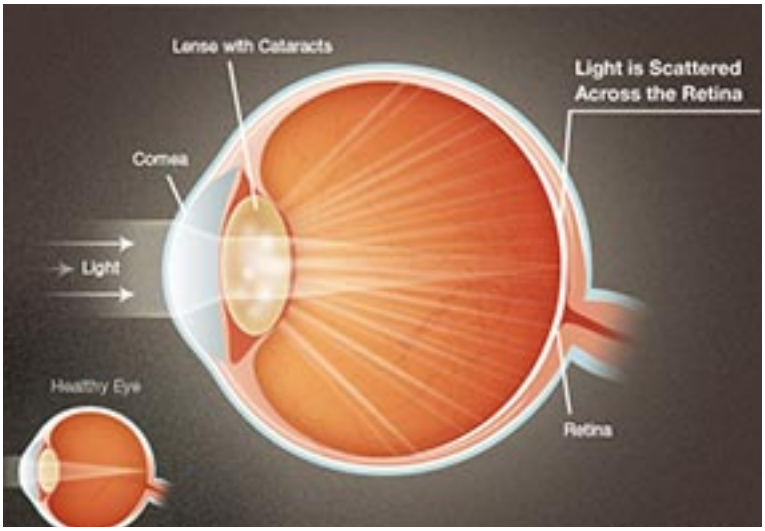

Figure 1: In the lower corner is how a healthy lens focuses light rays onto the retina, and in the center is how cataracts disperse light resulting in blurry vision. [2]

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. When the incisions are less than 3 mm, then they 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]

3. Current Methods

The focus of this project is the capsulorhexis to access the lens for emulsification and aspiration. The most common method is using a 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 there a 3 mm line is torn outward from the center incision. 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]

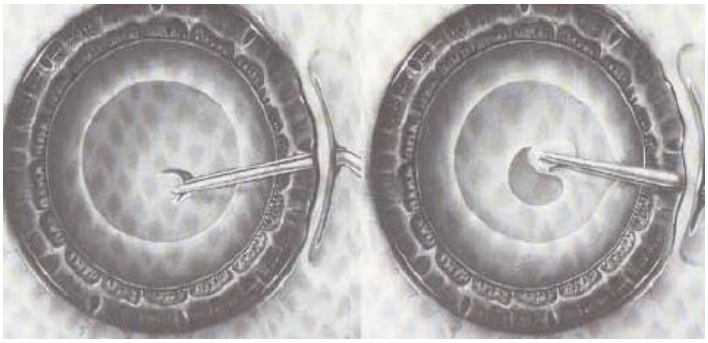

Figure 2: The initial tear and the continuous pulling of the capsule is the basic technique of the CCC.

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]

4. 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.

4.1 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 9.1 for more detail on the design requirements.

4.2 Design Alternatives

4.2.1 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, from the Phaco-tool would assist in cutting the tissue. [7]

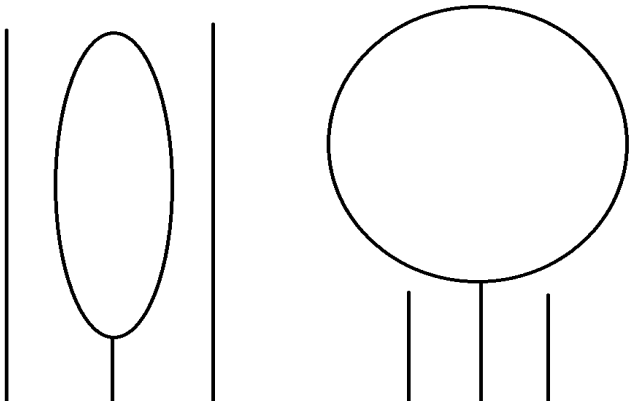

Figure 3: (Left) The configuration of the ultrasonic ring while inside of the instrument, which allows easy access into the eye. (Right) The configuration of the ring once inside the eye allows for a perfectly circular cut.

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.

4.2.2 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.

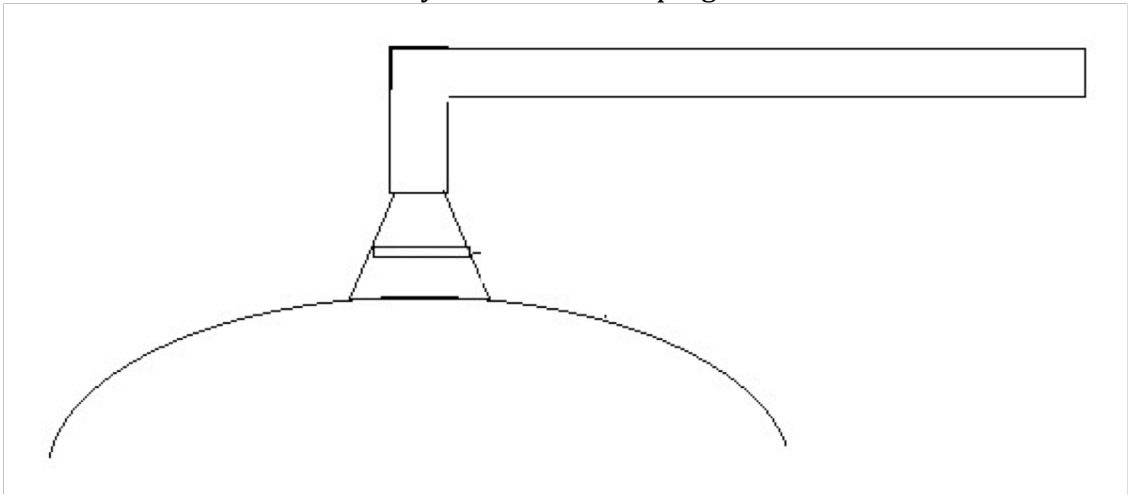

Figure 4: A rough sketch of the suction cut design alternative. As the cone uncurls, the diameter increases to 6mm. The cone can then be placed on the capsule, where suction causes the blade to cut the capsule.

4.2.3 "Ice-cream Scoop" Design

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

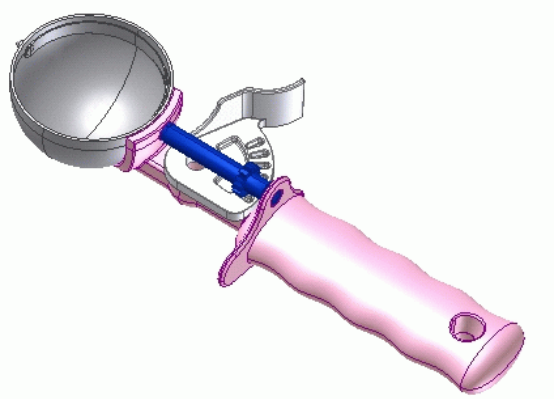

Figure 5: A picture of an ice cream scooper to which the design was based off.

The device would enter and exit the eye with the blade safely located in the device to not adversely cut 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.

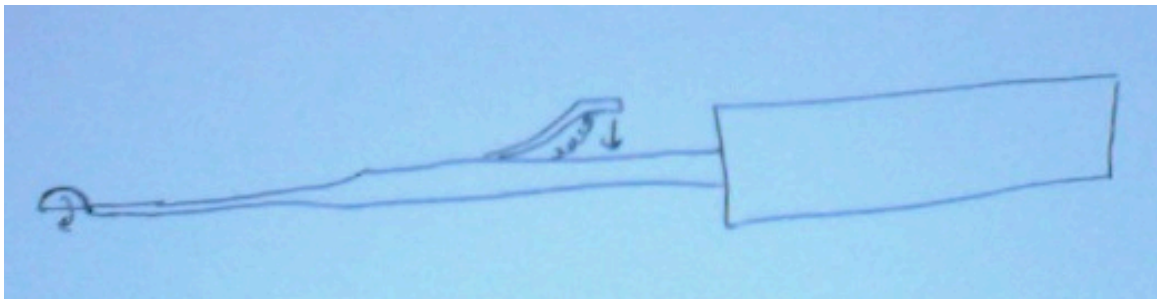

Figure 6: A drawing of the proposed ice cream scooper design. The blade would rotate 180 degrees with the pressing of a lever.

4.3 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 on 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 ovulation of the 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 by the respectable weights.

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.

4.4 Final Design

The final design will be using the ultrasound machine. The team will design and fabricate an attachment for the ultrasound that utilizes the suction setting. The attachment will be a cone shaped device, similar to a "party hat." The sides will be able to move back and forth, sliding against each other to make the cone increase and decrease in diameter as it enters and exits the attachment in the eye. The diameter will be able to increase and decrease with the help of a torsional spring. On the bottom edge of the cone attachment, there will be a sharp edge to act as a blade. This will help cut the capsule as the suction presses the capsule against the attachment.

4.5 Estimated Budget

The client has given a very flexible budget with a range of $200 to $500. If needed, the client has said that he would be willing to give a higher budget. No extensive research into materials has been completed at this point. Therefore, no exact cost analysis can be done. 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.

5. Future Work

After making the decision of the final design, the first major task to accomplish is material selections. The main properties that will determine the selection of each material within the final design will be the weight of the material, biocompatibility, size constraints in the eye, and its' strength. Significant material research will need to be done to find the proper materials for the final design. Selection of the optimal materials that meet these criteria will result in the best possible fabrication of a prototype.

Upon selecting the materials of different components, the team will start fabrication of the device. Fabrication should be done in a timely matter. The original prototype may not be on the correct size scale needed to perform a cataract surgery, but the mechanism of the device will be the same.

After completion of a prototype, testing of the device will be completed. Currently, the client has a contact in Madison with a supply of cadaver eyes and has the ability to perform cataract surgery. Through testing, the team will be able to locate and fix problem areas of the device for the completion and fabrication of a second prototype, on the proper scale needed for human cataract surgery.

6. 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.

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8. Appendix

8.1 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.

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.

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.

d. *Life in Service*: Device must withstand duration of use of 30-60 seconds during surgery.

e. Shelf life: Device must withstand sterile packaging for 6 -12 months if not reusable.

f. Operating Environment: Device must withstand the composition of the eye including saline solution.

g. 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.

h. 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.

i. 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: Laser, Nottingham Cataract Device.