Journal of Interdisciplinary Undergraduate Research

Volume 8 *Journal of Interdisciplinary Undergraduate Research* | Article 6

2016

Development of a Surgical Instrument Prototype to Perform a More Precise Capsulorhexis

Kirk Haugen
kirkhaugen@southern.edu

DEVELOPMENT OF A SURGICAL INSTRUMENT PROTOTYPE TO PERFORM A MORE PRECISE CAPSULORHEXIS

Kirk J. Haugen

Southern Adventist University

Abstract

Performing capsulorhexis is often considered the most difficult part of cataract surgery. Not only is it difficult, but performing it correctly is important for refractive outcomes.[4] Inaccurate capsulorhexes are associated with complications including posterior capsular opacification, capsular fibrosis, and capsular phimosis.[6] This study investigates the possibility of a proposed surgical instrument producing more precise capsulorhexes as determined by the circularity index. 60 capsulorhexes were performed on cigarette paper laid over clay - half using the continuous curvilinear capsulorhexis (CCC) method, and half using the proposed instrument. The precision of the capsulorhexis was then measured using the circularity index. The capsulorhexes cut with the proposed instrument were more precise than the current method, suggesting the adoption of the instrument may lead to better refractive outcomes in patients.

Development of a Surgical Instrument to Perform a More Precise Capsulorhexis

Cataract surgery is a procedure that removes a cloudy lens from the eye and replaces it with a clear implant. Part of the procedure involves making a circular tear in the lens capsule in order to allow access to the cloudy lens. This step of the procedure is known as capsulorhexis. It is essential that this be performed correctly because mistakes can lead to various complications. The focus of this project was to develop a working prototype of an instrument designed to optimize the ease and accuracy of performing capsulorhexis, ultimately leading to better outcomes for patients. It was expected that the proposed instrument would produce more accurate capsulorhexes as measured by the circularity index.

Background information. The crystalline lens is located just behind the iris. Its purpose is to focus light onto the retina. The nucleus, the innermost part of the lens, is surrounded by softer material called the cortex. The lens is encased in a membrane-like bag called the lens capsule and suspended within the eye by tiny "guy wires" called zonules. A cloudy lens is called a cataract. Over time, yellow-brown pigment is deposited within the lens causing a cataract. This, together with disruption of the normal architecture of the lens fibers, leads to reduced transmission of light, causing visual problems. Those with cataracts commonly

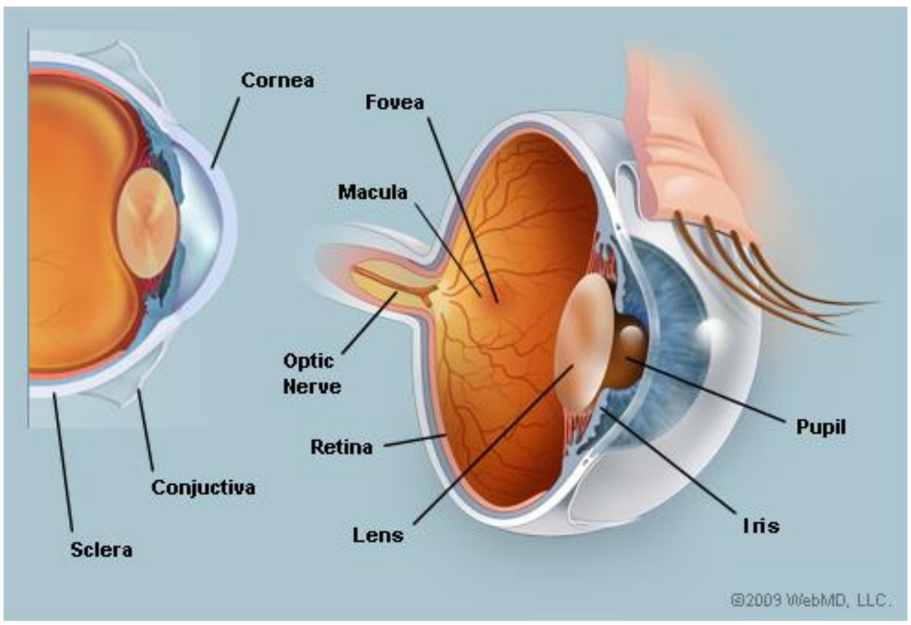


Figure 1. Basic anatomy of the human eye.

experience difficulty in appreciating colors, noticing changes in contrast, driving, reading, recognizing faces, and coping with glare from bright lights. Cataracts are the most common cause of blindness and are conventionally treated with surgery.

Cataract surgery is performed from the front of the eye with the iris fully dilated. An entry is made at the edge of the cornea to access the anterior chamber, the fluid space in front of the iris. A gel is injected to maintain this space during surgery. A circular opening is then made on the anterior surface of the lens capsule, exposing the cloudy substance that will be removed. Making this circular opening is called capsulorhexis. An accurate opening in the lens capsule is important for lens centration and stability.

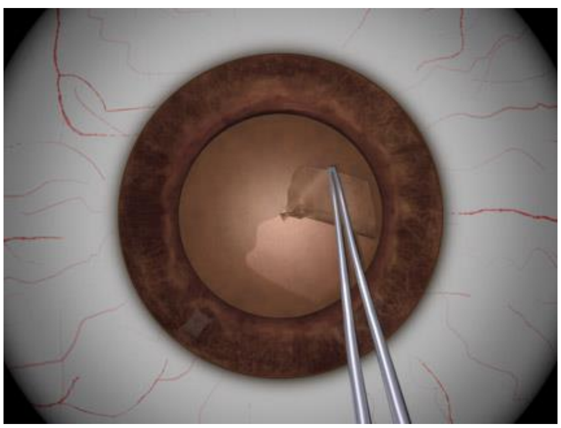


Figure 2. Performing capsulorhexis.

Figure 3. The lens capsule to the right has been stained with blue dye to increase contrast against a totally white lens. Once the capsule is opened, the lens can be removed using the appropriate instruments. The resulting empty space is filled with the implant.

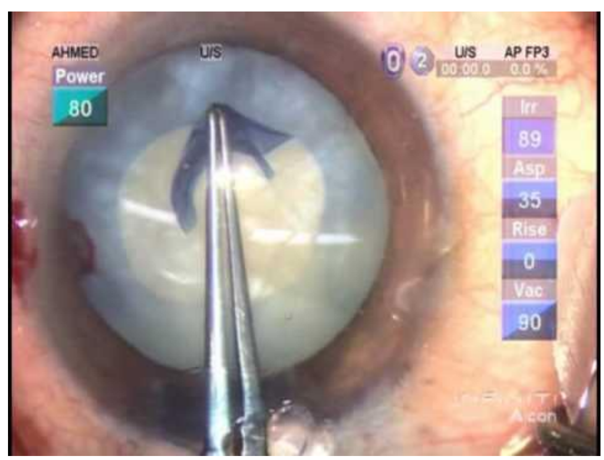


Figure 4. The implant as seen within the capsular bag. The edges of the capsular opening are visible overlying the edges of the implant.

Capsulorhexis history. In 1754 the first cataract lens was removed from the eye. From this time until the mid-19th century, the techniques used to cut the lens capsule typically left jagged edges.[3] A common technique was known as the can-opener capsulotomy. This approach involved using a small bent needle to make little incisions around the anterior surface of the lens. For this approach, a small bent needle was used to make little incisions around the anterior surface of the lens. This formed a jagged hole through which the lens could be removed.

In the 1940s, Sir Harold Ridley invented the intraocular lens, or IOL. Since its original production the IOL has been the standard lens replacement. The edges of an IOL have two curved extrusions called haptics. These are used to hold the lens in place after implantation.

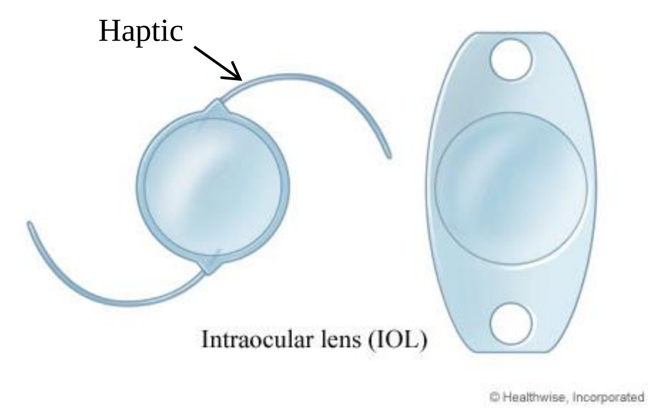


Figure 5. Basic design of an intraocular lens, or IOL.

A major problem with the can-opener capsulotomy was that the haptics of an IOL would often slip through one of the jagged v-shapes left on the periphery of the lens capsule. This would lead to lens decentration, and other problems, that made achieving an accurate refraction difficult. The continuous curvilinear capsulorhexis (CCC) method was introduced in the 1980s to address such issues.[1]

The CCC method was largely developed by Dr. Gimbel from Alberta, Canada, and Dr. Neuhann from Munich, Germany. The technique begins with an initial needle puncture in the lens capsule. Forceps are then used to tear smooth arcs in opposite directions, leaving a smooth circular opening. Today, this is the standard technique for cataract surgery. However, it is not without problems.

Significance of the capsulorhexis. A capsulorhexis of the proper shape is important for several reasons. Ideally, the edge of the capsule will slightly overlap with the edge of the implant. One advantage of this overlap is the prevention of posterior capsular opacification (PCO). This occurs when leftover cataract cells within the lens capsule proliferate on the backside of the capsule, causing the vision of the patient to become cloudy. A proper overlap of the lens capsule and the implant acts as a barrier to prevent the spread of these leftover cataract cells.

Proper overlap also prevents the implant from shifting forward should fibers in the lens capsule become rigid and expand. The expansion of the lens fibers is known as capsular fibrosis. A shifted implant can change the patient's refraction.[6]

Additionally, the symmetry of good overlap helps prevent the lens from becoming off-centered if the lens shrinks. The lens might shrink due to a process called capsular phimosis. This occurs when the fibers expand and cause the diameter of the incision to shrink. When this causes the lens to become off-center it is known as late in-the-bag decentration. If there is not proper overlap with the capsule and the implant, then phimosis could push unevenly on the implant causing it to become decentered, leading to a poor refraction.[6]

The size of the opening created during capsulorhexis is also important. If it is too large problems such as those mentioned above can occur – namely PCO. Too small of an opening is problematic for other reasons. It makes surgery more difficult to perform and places unnecessary stress on the anterior capsule while removing the cataract. It can also cause the lens to shrink too much – though it is important to note that some fibrosis and shrinkage of the capsule occur after nearly every surgery. If the opening is too small then the capsule will shrink to a size that can cause problems with the patients vision by blocking light from coming in through the periphery of the lens.[5]

Studies have shown the effects of a well formed opening from capsulorhexis. One study compared the outcomes of patients with accurate versus inaccurate openings. For patients who received better procedures, there was no significant change in refraction after one month or one year. However, over half of the patients who received inferior procedures had significant changes in refractions after both one month and one year. [4]

Methods and Materials. A 1 cc tuberculin syringe was used as a handle for the device. A 20 gauge needle was then cut to approximately 5/8 of an inch, and bent at a 45 degree angle near the hub. The distal 2 mm were bent at 90 degrees. A 4 mm length of 26 gauge wire was bent at 90 degrees directly in the middle. This was inserted into the short post at the end of the needle creating a rotating horizontal wire. A small portion of a 3.2 mm keratome blade was cut in a triangular fashion. Maximum bond cyanoacrylate served as an adhesive to attach the blade to the wire. This completed the prototype assembly.

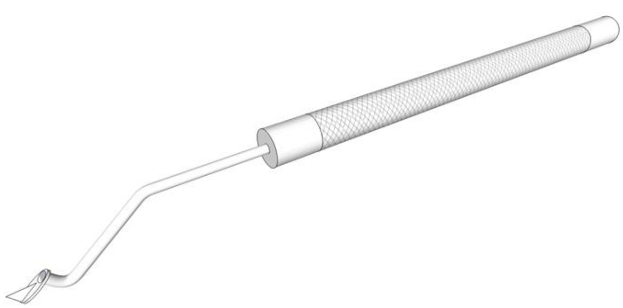


Figure 6. AutoCAD drawing of the proposed instrument.

Figure 7. Swiveling plate with attached blade.

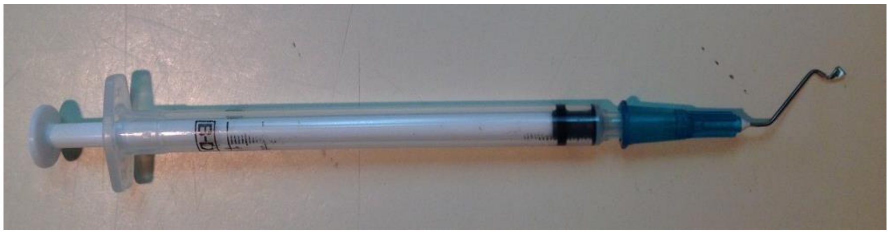


Figure 8. Prototype made with tuberculin syringe and keratome blade.

Once the assembly was complete, modeling clay was obtained and wrapped with cigarette paper. This simulated a human lens capsule.[7] Using the prototype, 30 openings were cut into the paper-wrapped clay. Another 30 were cut using a standard surgical capsulorhexis forceps and a cystotome. A picture was then taken of all the circular cuts.

Adobe Photoshop was used to capture the outline of the cuts. Each outline was then transferred to Microsoft Word and expanded. A picture of lines intersecting at 45 degree angles was then overlaid on top of each outline.

Measurements were then taken in order to calculate the circularity index.[2] A program called *SmallMeasure* was used measure the length of all eight radii on each outline. These values were then entered into Microsoft Excel and the circularity index was calculated. A standard t-test was then used to determine if the prototype produced significantly more accurate openings.

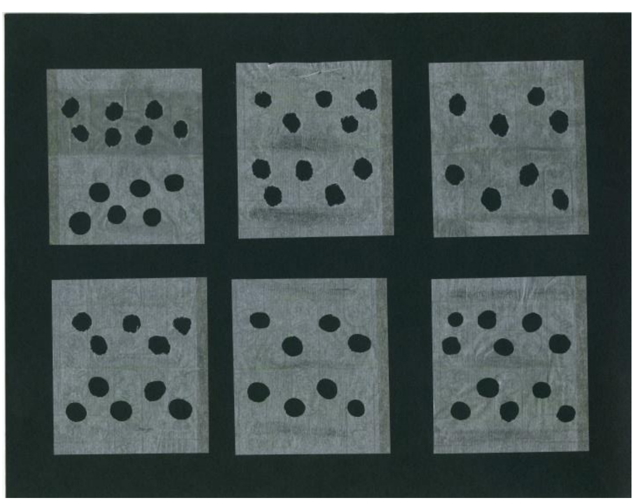
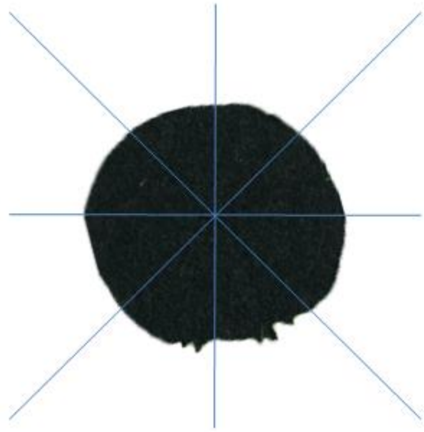


Figure 9. Thirty capsulorhexes were performed on cigarette paper using both the CCC method and the new method.

Figure 10. Intersecting lines were overlaid on the outlines formed by the capsulorhexes in order to measure the circularity index .



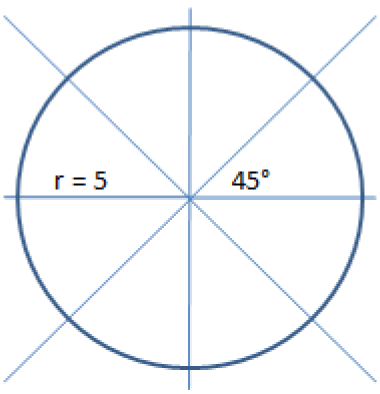


Figure 11. The circularity index is defined as the average radius divided by the maximal radius in the capsulorhexis trajectory measured at 45 degree intervals. In this perfect circle with a radius of 5 units, the circularity index is 1.

Results. The proposed method for performing a capsulorhexis provided more precise openings (M = 0.885032, SD = 0.046886) than the current CCC method (M = 0.830547, SD = 0.0486). A one tailed t-test showed the significance of these results with a p-value of 0.000022. The results are summarized in table 1.

Table 1

Statistically significant results from both the CCC method and the new method

	CCC method	*New method*
Mean	0.830547389	0.88503229
Variance	0.002361939	0.00219827
SD	0.048599785	0.04688576
Observations	30	30
df	58	
t Stat	-4.41920565	
P(T<=t) one-tail	2.19895E-05	
t Critical one-tail	1.671552762	

Discussion. The results indicate that the proposed instrument will lead to more precise outcomes. This is clinically significant because more precise capsulorhexes will likely reduce complications for patients, as well as improve refractions. One limitation of this study was the use of cigarette paper and clay as a substitute for cadaver eyes. The keratome blade used on the prototype was not sharp enough to effectively cut through pig cadaver eyes, as was originally proposed for the experimental design. Further research could be performed by replacing the keratome blade with a diamond blade. A diamond blade would be sharp enough to perform capsulorhexis on human cadaver eyes. The results of this study provide evidence regarding the effectiveness of the proposed instrument, as its development and use would likely lead to better outcomes.

Acknowledgments. I would like to extend special thanks to Dr. Norskov for his supervision and input regarding this project. I would also like to thank Dr. Haugen for help in developing the prototype, and for performing the experimental capsulorhexes.

References

1. Apple D.J. Why Did We Abandon the Can-Opener Capsulotomy? *CRST*. 2007;7(10):43-45.
2. Banerjee P, Edward D, Liang S, Bouchard C, Bryar P, Ahuja, Dray P, Bailey D. *Medicine Meets Virtual Reality 19.* Amsterdam: IOS Press; 2012.
3. Gimbel H.V. History of the Capsulorhexis Technique. *CRST*. 2007;7(10):39-41.
4. Okada M, Hesh D, Paul E. Straaten D.V. Effect of Centration and Circularity of Manuel Capsulorhexis on Cataract Surgery Refractive Outcomes. *Ophthalmology*. 2013;121:763-770.
5. Raviv T. The Perfectly Sized Capsulorhexis. CRST. 2009;9(6):37-41.
6. Raviv T. The Perfect Capsulorhexis: More Critical than Ever. *Adv. Ocular Care*. 2010;1(2):23-24.
7. Saraswathy R, Andrew T, Arlene B. Cataract tips from teachers: what is the best way to practice a continuous curvilinear capsulorhexis? *ASCRS EyeWorld*. 2011; November. http://www.eyeworld.org/article-what-is-the-best-way-to-practice-a-continuous-curvilinear-capsulorhexis. Accessed March 10, 2014.