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

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Abstract
Performing capsulorhexis is often considered the most difficult part of cataract surgery. Not only is it difficult to perform, but doing it correctly is important for refractive outcomes (Okada, Hersh, Paul, & Straaten, 2013). Poorly done capsulorhexes are associated with problems including posterior capsulor opacification, capsulor fibrosis, and capsulor phimosis (Raviv, The perfect capsulorhexis: more critical than ever, 2010). This study investigates whether or not a proposed surgical instrument will produce more precise capsulorhexes as measured by the circularity index. 60 capsulorhexes were performed on cigarette paper laid over clay. Half were done using the continuous curvilinear capsulorhexis method, while half were done using the proposed instrument. The precision of the capsulorhexes was then measured using the circularity index. The proposed instrument led to more precise capsulorhexes which would 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 remove the cloudy lens. This step of the procedure is known as capsulorhexis. It is essential that this be done right because if done incorrectly, it can lead to various problems. The focus of this project was to develop a working prototype of an instrument designed to optimize the ease and precision of performing capsulorhexis, ultimately leading to better outcomes for patients. It was expected that the proposed instrument would produce more precise 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. Cataracts are the most common cause of blindness and are conventionally treated with surgery. Visual loss occurs because opacification of the lens obstructs light from passing through and being focused on the back of the eye.
Over time, yellow-brown pigment is deposited within the lens. 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 experience difficulty in appreciating colors and changes in contrast, driving, reading, recognizing faces, and coping with glare from bright lights.

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, or fluid space, just behind the cornea. A gel is injected to maintain this space during surgery to remove the lens. The lens capsule can be opened in a circular fashion on the anterior surface of the lens. This exposes the cloudy substance that will be removed. Making this circular opening is called capsulorhexis and is a very important part of the overall procedure. An accurate opening made during capsulorhexis is important in lens centration and stability.
Capsulorhexis history. In 1754, the first cataract lens was removed from the eye. Previously, surgeons pushed the cataract lens into the interior of the eye, which led to numerous complications. From this time until the mid-19th century, techniques used to cut the lens capsule typically left jagged edges behind (Gimbel, 2007). A common technique used 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. This formed a 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 used as the standard method of lens replacement. The edges of an IOL have two curved extrusions called haptics. These are used to hold the lens in place after implantation.
From the invention of the IOL until the 1980s and 1990s, the can-opener capsulotomy or similar techniques were used to cut the lens capsule. A major problem with this approach was that often the haptics of an IOL would 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 it difficult to achieve an accurate refraction for the patient. The continuous curvilinear capsulorhexis, or CCC, was introduced in the 1980s to address such issues (Apple, 2007).

The CCC was developed largely by Dr. Gimbel from Alberta, Canada, and Dr. Neuhann from Munich, Germany. The technique begins with an initial needle puncture in the lens capsule. Then forceps are used to tear smooth arcs in opposite directions. This leaves a smooth circular shape through which the procedure can follow. Today, this is the standard technique used during cataract surgery. However, it is not without problems.

**Significance of the capsulorhexis.** Obtaining a capsulorhexis with the proper shape is important for several reasons. Ideally, a capsulorhexis will leave an edge of the capsule overlapping slightly with the edge of the implant. One advantage of this overlap is the prevention of posterior capsular opacification, or PCO. PCO 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.

Another benefit of proper overlap is that the implant is prevented from shifting forward should fibers in the lens capsule become rigid and expand. The expansion of the lens fibers is known as capsular fibrosis. This can push the implant forward, causing it to shift. A shifted implant can lead to a change in the patient’s refraction (Raviv, The perfect capsulorhexis: more critical than ever, 2010).
A further benefit of a good overlap is that if the lens shrinks, it will do so symmetrically, which will help prevent the lens from becoming off-centered. The lens might shrink due to what is known as capsular phimosis. This is where fibers expand causing the diameter of the incision to shrink. The lens becoming off-center 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 (Raviv, 2010).

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, an anterior shift of the implant, and decentration. Too small of a capsulorhexis is problematic for other reasons. This will make surgery more difficult to perform and place unnecessary stress on the anterior capsule while removing the cataract. Further, it can cause the lens to shrink too much. It is important to note that some amount of 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 in the patients vision. This can block light from coming in through the periphery of the lens which leads to worse vision (Raviv, The perfectly sized capsulorhexis, 2009).

Studies have been performed that show the effects of a well formed opening from capsulorhexis. For example, 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 (Okada, Hersh, Paul, & Straaten, 2013).
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 was 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 was used as an adhesive to attach the blade to the wire. This completed the prototype assembly.
Once the assembly was complete, modeling clay was obtained and wrapped with cigarette paper. This simulated a human lens capsule (Saraswathy Ramanathan, Andrew Thliveris, Arlene Bagga, 2011). Using the prototype, 30 capsulorhexes were performed on the paper-wrapped clay. Another 30 were performed 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 so measurements could be taken.
Measurements were then taken in order to calculate the circularity index (Banerjee, Edward, Liang, Bouchard, Bryar, Ahuja, Dray, & Bailey, 2012). A program called SmallMeasure was used to measure the length of all eight radii on each outline. These values were then entered into Microsoft Excel where the circularity index was calculated. Finally, a standard t-test was used to determine the significance regarding the precision of the capsulorhexes performed using the prototype.

**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 proved 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

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Discussion

The results indicate that the proposed instrument for performing capsulorhexis will lead to more precise outcomes. This is clinically significant as 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. This was done because the keratome blade used on the prototype was not sharp enough to effectively cut through eyes obtained from pig cadavers, as was originally proposed for the experimental design. Further research could be by performed by replacing the keratome blade with a diamond blade. It is believed that 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

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References


