Parameters affecting anterior capsulotomy tear strength and distension

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Purpose: To study the effects of anterior capsulotomy diameter and discontinuity on tear threshold load and distension for the technique of continuous curvilinear capsulorhexis (CCC).

Setting: Singapore National Eye Centre, Singapore, and CapsuLaser Inc., Livermore, California, USA.

Design: Two separate randomized pairwise cadaver eye preclinical studies.

Methods: Capsulotomies were performed in 40 cadaver eyes of 20 donors using CCC. The pairwise comparisons were divided into 2 study groups: Study A: Continuous versus discontinuous capsulotomies; Study B: Capsulotomy diameter of 5.0 mm and smaller versus diameters of 5.2 mm and larger. A shoe-tree method was used to apply load to the capsulotomy rim, and the Instron tensile stress instrument measured threshold load and distension to initiate a capsular tear. Wilcoxon matched-pairs signed-rank tests were performed to assess statistical superiority.

Results: In Study Group A, all pairs demonstrated that continuous capsulotomies were better than discontinuous capsulotomies for both the anterior tear threshold load and distension (P < .01). In Study Group B, 80% of the pairs demonstrated that diameters of 5.2 mm and larger were better than those of 5.0 mm and smaller diameter (P < .05).

Conclusions: Anterior capsulotomies behave as nonlinear elastic (elastomeric) systems when exposed to an external load and distension. This study demonstrated that continuous circular capsulotomies were more resistant to anterior tears than discontinuous capsulotomies. A point of irregularity or a defect in a capsulotomy rim has a high probability of being the tear initiation point. Furthermore, larger diameter capsulotomies were more resistant to anterior tears than smaller capsulotomies.


Anterior capsulotomy has been a fundamental component of cataract surgery since Jacques Daviel first performed extracapsular cataract surgery in 1747.1 At present, the standard technique for creating an anterior capsulotomy is a continuous curvilinear capsulorhexis (CCC),2,3 and alternative automated capsulotomy techniques are now available.4–6,A,B The incidence of anterior tear rates range from 0.2 to 5.3%,7–10 whereas posterior extension after an anterior tear has been reported to be between 24%11 and 49%.12 Clinically, it is recognized that correctly sized, circular, and centered capsulotomies increase the likelihood for complete intraocular lens (IOL) coverage by the capsulotomy rim.13 Conversely, a lack of precision in sizing or centration of the capsulotomy or an anterior tear will result in incomplete coverage of the IOL, yielding an increased likelihood of IOL tilt, malposition, and the early onset of posterior capsular opacification (PCO).14–17 Several pairwise studies have investigated anterior capsulotomy load distension between differing capsulotomy techniques.6,18–20,A Many of these studies might not have controlled for CCC continuity and diameter, and some also used porcine eyes. This study evaluated parameters affecting capsulotomy strength, specifically diameter and discontinuity of the anterior capsulotomy using the technique of CCC on human cadaver eyes.

MATERIALS AND METHODS

Two preclinical pairwise studies of ex vivo human cadaver eyes were performed to determine the effects of capsulotomy continuity and diameter on anterior tear threshold load and distension. Specifically, the pairwise comparisons were divided into 2 groups as follows:

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Study Group A: Continuous circular versus discontinuous capsulorhexis.

Study Group B: Capsulorhexis diameters of 5.0 mm and smaller versus diameters of 5.2 mm and larger.

In both studies, the left and right cadaver eyes were randomly allocated to the respective arms of the study. Pairs of phakic cadaver eyes from a donor in the specified age range of 38 to 70 years old were obtained within 72 hours postmortem from either the SightLife Eye Bank (Seattle, Washington, USA) or Singapore Eye Bank (Singapore National Eye Centre, Singapore).

For all eyes, the cornea and iris were removed to allow access, improve visibility, and permit direct optical measurement of the capsulotomy size. The anterior capsules were rinsed and coated with 2% sodium hyaluronate acid (CapsulVisc 2%, Excel-Lens, Inc.) cohesive ophthalmic viscosurgical device (OVD). The CapsuLaser (Excel-Lens, Inc.) device was used to project a red laser circular reticule of a user-defined size and location onto the anterior capsule as a guide for the size, circularity, and centration of the CCC. The CCCs were formed with capsulorhexis forceps (Micro-surgical Technology). All nuclei were hydroexpressed using a balanced salt solution and the resultant capsular bags were filled with 3% sodium hyaluronate acid (CapsulVisc 3%, Excel-Lens, Inc.) dispersive OVD. If cortex was observed, it was removed via an irrigation and aspiration device (Stellaris, Bausch & Lomb, Inc.). Capsules that ruptured during manipulation and hydroexpression were excluded from the studies and additional pairs of eyes were used.

In both studies, the diameter and continuity of the capsulotomies were controlled with respect to their objectives. In Study Group A, discontinuity was the manipulated variable and the average diameter of the capsulotomy was maintained in a tight range at 5.0 mm. Conversely in Study Group B, the diameter of the capsulotomy was the variable and continuity was maintained. The diameter and circularity were measured for all study eyes using image processing software (provided by Excel-Lens, Inc.). A microscope mounted camera captured images of the capsulotomy with an intraocular ruler placed in the plane of the anterior capsule. The intraocular ruler was used to calibrate the dimensional scale. The capsulotomy rim edge was defined by the reviewer identifying at least 40 points. The least-square method was used to determine the best-fit circle for these identification points: yielding the circle diameter and center. To remain consistent with previous studies,13,21 capsulorhexis circularity was calculated via 2 methods. First, circularity calculated as the ratio of 

\[ \text{area of best-fit-circle} / \text{perimeter distance from point to point} \]

Second, the least-square approach was used to determine the best-fit for an ellipse to the identification points, with the reported circularity value being the ratio of minor to major axes. In both methods, circularity of 100% represented a perfect circle.

In Study A, in both arms, all capsulotomy diameters were within 5.0 mm ± 0.2 (SD). In the continuous control arm, all eyes had a capsulotomy of circularity greater than 95% as calculated by both methods. The discontinuous arm had circularity less than 95% and a defined point of irregularity on the capsular rim. To achieve this, the capsulotomy was deliberately made with an irregularity in the rim shape. The start of the capsulotomy traced an approximately 4.5 mm circle for approximately 120 degrees and was purposefully enlarged to a diameter of approximately 5.5 mm. When the capsulotomy was within 10 degrees of the start point, the capsulotomy was diverted in an inward radial direction to join the starting point. Figure 1 shows the shape and dimensions of the capsulotomies in the 2 arms.

In Study B, all capsulotomies were continuous and had a capsulotomy of circularity of greater than 95% as above for the continuous arm. The 5.0 mm and smaller arm had a range of 4.7 to 5.0 mm, and the larger diameters arm had a range of 5.2 to 5.6 mm for capsulotomy diameter. If any of the eyes failed the aforementioned criteria, the pair of eyes were excluded from the study.

An Instron 3343 mechanical tester (Instron Corp.) was used to determine the capsulotomy load–distension curves. The system was calibrated by the manufacturer before these measurements were taken. Figure 2 shows the dimensions of the load–distension probe. Before insertion, the probes were cleaned and dipped in molten paraffin wax (approximately 90°C), and then removed and allowed to drip dry. The purpose of the wax was to reduce any possibility of trauma from the metal surface on the capsule edge. The load–distension probe was then inserted into the capsular bag through the capsulotomy, with the rim located on the waist of the probe. The capsular bag supported by the probe was dissected from the globe with scissors cutting the zonular fibers similar to the method described by Werner et al.17 The probes were then connected to the mechanical tester. The system was reset to zero, and the test started under computer control and video monitoring. One arm of the fixture remained fixed in position while the other was translated at 0.1 mm/sec, stretching the CCC to its tear point. The external surface of the capsular bag was frequently irrigated with the balanced salt solution during the load–distension to prevent dehydration. The maximum load at the peak of the load–distension curve was the threshold load for initiation of the anterior tear, and the corresponding distension was the threshold distension. The formula for the perimeter of the capsulotomy was:

\[ \pi \times \text{D} + 2 \times \text{L} \]

Figure 1. The form of the capsulotomies for the 2 arms of Study A. The continuous capsulotomies are defined to be circular with mean diameter of 5.0 ± 0.2 mm, the limits are highlighted with the dotted lines. The irregular capsulotomies are defined to have a point of irregularity and start with a diameter of 4.5 mm, spiral out to a diameter of 5.5 mm, and then abruptly transition to the point of initiation. The diameter limits of 4.5 mm and 5.5 mm are represented with the dashed lines.

Figure 2. Load–distension probe in side and cross-section profiles (D = 4.5 mm diameter of the probe; L = distension length; mN = millinewton).
where \( L \) is the distension length and 4.5 mm is the diameter of the probe, (Figure 2).

The datasets were analyzed to test superiority between the 2 arms for each pairwise study using the Wilcoxon signed-rank test. The null hypothesis for each of the 2 pairwise studies was that the mean difference including confidence interval between pairs was zero, with the alternative hypothesis being that the mean averages are different to the extent that one arm is proven to be superior and the other arm is proven to be inferior (2-sided).

**RESULTS**

The donor eyes for the 2 pairwise studies were similar in age and sex distributions with no meaningful differences (Table 1). To facilitate the Wilcoxon signed-rank tests, results for pairwise comparisons were organized in ascending order of absolute differences in threshold load and perimeter.

For the pairwise Study A, which compared the continuous with the discontinuous capsulotomy arms, the threshold loads for anterior tears in all 10 pairs of the continuous arm exceeded that of the discontinuous arm (Figure 3). Using the Wilcoxon signed-rank statistical analysis, continuous capsulotomies were statistically superior (being more resistant to tearing) than the discontinuous capsulotomies \( (P < .01) \). In 9 (90%) of 10 cases with discontinuous capsulotomies, the tear initiated at the point of irregularity. The exception was the A5 pair where the capsule with the discontinuity stretched further than the circular capsulotomy.

For the pairwise Study B, which compared 5.0 mm and smaller to 5.2 mm and larger capsulotomies, the threshold loads for anterior tears are shown in Figure 4. The larger capsulotomy arm exceeded that of the smaller capsulotomy arm in 8 (80%) of 10 pairs, with Pairs B1 and B2 being the exceptions. The Wilcoxon signed-rank statistical analysis showed a statistically significant difference with larger capsulotomies being better than smaller capsulotomies at tear resistance \( (P < .05) \).

Threshold perimeters for anterior tearing were also investigated for pairwise Studies A and B. The perimeters followed the same trend as the load results. In Study Group A, all 10 pairs (100%) of the continuous capsulotomies were statistically superior to the irregular capsulotomies, with the

<p>| Table 1. Human cadaver eye donor age and sex distributions for the 2 pairwise studies. |
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<table>
<thead>
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<th>Parameter</th>
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<th>Sex (M/F)</th>
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<td>50% M</td>
<td>Mean ± SD</td>
<td>54 ± 9</td>
<td>60% M</td>
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![Figure 3. Study Group A threshold load pairwise comparison of continuous capsulotomies (solid black bars) to discontinuous capsulotomies (horizontal line patterned bars) (mN = millinewton).](image-url)
continuous capsulotomies being more extensible \( (P < .01) \) (Figure 5). In Study Group B, 8 (80%) of 10 pairs with larger capsulotomies were statistically superior in being more distensible than the smaller capsulotomies \( (P < .05) \) (Figure 6).

**DISCUSSION**

Anterior capsulotomies behave as nonlinear elastic (elascomeric) systems when an external load and distension are applied. As observed in cataract surgery, once an anterior capsule tear is initiated, it can rapidly propagate radially.\(^1\)\(^2\) From a material science perspective, in a continuous circular capsulotomy, the load is distributed over the whole perimeter, with a tear being initiated at a naturally occurring microscopic defect in the collagen membrane rim.\(^2\)\(^3\) The defect concentrates tensile forces and if the load exceeds a threshold, this leads to tear initiation (dissociation of intramolecular bonds). Once there is a tear, it propagates in an orthogonal direction to the applied forces for as long as adequate force is applied.\(^2\)\(^3\)

All discontinuous capsulotomies, by definition, had a surgically induced sharp radius at the point of irregularity. From a material science aspect, the stress concentration factor is inversely proportional to the square root of the radius at the tip of the tear or irregularity.\(^2\)\(^3\) For comparison, this stress factor at the point of irregularity (assuming a radius of 0.2 mm or less) is at least 4 times larger than at a general point along the perimeter of the capsulotomy, thereby providing an explanation of the observation that the majority of discontinuous capsulotomies tore at the point of irregularity. Moreover, this also provides a rationale for the demonstrated superiority of the continuous circle to discontinuous capsulotomies, with continuous capsulotomies being more tear resistant with respect to external load and distension.
In Study Group B, the small diameter arm had a mean of 4.9 mm and a range of 4.7 to 5.0 mm and the large diameter arm had a mean of 5.4 mm and a range of 5.2 to 5.7 mm. The threshold loads associated with anterior tears were 193 millinewton (mN) for the smaller diameter and 242 mN for the larger diameter. The difference was statistically significant, indicating larger capsulotomies were stronger in terms of resistance to tear and highlighting the nonlinear elastic behavior of a capsulotomy. With larger diameter capsulotomies, a prolapsing lens is less likely to tear on distention than a smaller capsulotomy, and this is consistent with Young’s modulus of elasticity, where a material’s extension under external load is proportional to the original length, that is, a larger diameter capsulotomy is more distensible. Packer et al. demonstrated similar findings in porcine eyes. The human anterior capsule has also been shown by Barraquer et al. to increase in thickness with age (11 to 15 μm) at the anterior pole and also in the midperiphery (13.5 to 15 μm). This indicates that the anterior capsule is thickest in the midperiphery, representing the diameters from 4.9 to 5.5 mm peaking at 5.25 mm. This midperipheral increase in thickness might also provide a further contributory factor to the observed increased strength of larger capsules in this study.

Surgeon discretion is required when selecting the appropriate capsulotomy diameter. There is a need to balance the risk for anterior tear attributable to, for example, a prolapsing nucleus as in the case of a large hard nucleus, with the benefit of achieving complete 360-degree coverage of the IOL with the associated benefits of hindering early onset PCO and reducing tilt. This pairwise study of human cadaver eyes was performed to determine the effects of capsulotomy continuity and diameter on anterior tear threshold load and distention. Continuous circular capsulotomies are statistically more resistant to anterior tears than discontinuous capsulotomies. Furthermore, larger diameter capsulotomies are statistically more resistant to anterior tears than smaller capsulotomies. In light of these findings, future comparative capsulotomy studies should control for continuity and diameter. With these observations, the conclusions of previous past studies might need to be reevaluated. Finally, in selecting capsulotomy size, the surgeon should balance the benefit of a larger and stronger capsulotomy with that of complete IOL coverage.

**WHAT WAS KNOWN**
- Previous literature has reported differences in threshold loads for anterior tears associated with a variety of capsulotomy techniques; however, the basic parameters of capsulotomy irregularity and diameter have not previously been studied in detail.
- A previous porcine study showed larger diameter capsulotomies are stronger.

**WHAT THIS STUDY ADDS**
- This human cadaver eye study showed larger diameter continuous circular capsulotomies were more resistant to tears from external load and distention than smaller capsulotomies.
- Continuous capsulotomies were significantly more resistant to tears than discontinuous capsulotomies. A point of irregularity in a capsulotomy had a high probability of being the tear point.
- Future pairwise comparative studies involving CCC should control for both continuity and diameter.
REFERENCES


OTHER CITED MATERIAL


Disclosures: Dr. Daya is a consultant to Bausch & Lomb, Inc. and a consultant to and equity owner in Excel-Lens, Inc. Dr. Chee is a speaker for Bausch & Lomb Technolas. Dr. Packard is an equity owner in Excel-Lens, Inc. Dr. Mordaunt is an equity owner in Excel-Lens, Inc. None of the other authors has a financial or proprietary interest in any material or methods mentioned.

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