



# Comparison of Manual, Femtosecond Laser, and Precision Pulse Capsulotomy Edge Tear Strength in Paired Human Cadaver Eyes

Vance M. Thompson, MD,<sup>1</sup> John P. Berdahl, MD,<sup>1</sup> Joel M. Solano, MD,<sup>1</sup> David F. Chang, MD<sup>2</sup>

**Purpose:** To compare the anterior lens capsulotomy edge tear strength created by manual continuous curvilinear capsulorhexis (CCC), femtosecond laser capsulotomy (FSLC), and a new automated precision pulse capsulotomy (PPC) device.

**Design:** A 3-arm study in paired human cadaver eyes.

**Participants:** A total of 44 eye specimens from 22 donors in the United States.

**Methods:** Capsulotomy was performed in all eye specimens using manual CCC, a femtosecond laser (LenSx, Alcon, Fort Worth, TX), or an automated PPC device (Zepto, Mynosys Inc., Fremont, CA). The first study arm consisted of 8 pairs of eyes in which 1 eye received PPC and the fellow eye received FSLC. The second study arm consisted of 8 pairs of eyes, with 1 eye receiving PPC and the fellow eye receiving manual CCC. The third study arm consisted of 6 pairs of eyes, with 1 eye receiving a manual CCC and the fellow eye receiving FSLC. After phacoemulsification, 2 capsulotomy edge retractors attached to force transducers were used to stretch the capsulotomy edge of each eye and to measure the resisting force until the capsulotomy edge was torn.

**Main Outcome Measures:** Capsulotomy edge tear strength in millinewtons.

**Results:** The PPC edge tear strength was greater than that of FSLC for all 8 pairs of eyes by an average factor of 3.1-fold (PPC mean  $73.3 \pm 24.9$  mN vs. femtosecond laser mean  $26.1 \pm 6.8$  mN;  $P = 0.012$ , Wilcoxon matched-pairs, signed-ranks test). The PPC tear strength was greater than that of manual CCC for all 8 pairs of eyes by an average factor of 4.1-fold (PPC mean  $95 \pm 35.2$  mN vs. manual CCC mean  $29.1 \pm 23.1$  mN;  $P = 0.012$ , Wilcoxon matched-pairs signed-ranks test). There was no significant difference in the tear strength of capsulotomies produced by manual CCC (mean  $21.3 \pm 4.9$  mN) and FSLC (mean  $24.5 \pm 11.4$  mN) ( $P = 0.75$ , Wilcoxon matched-pairs signed-ranks test).

**Conclusions:** The strength of the PPC capsulotomy edge was significantly stronger than that produced by femtosecond laser or manual CCC. *Ophthalmology* 2016;123:265-274 © 2016 by the American Academy of Ophthalmology.

The introduction of continuous curvilinear capsulorhexis (CCC) in 1991 by Gimbel and Neuhann<sup>1</sup> greatly facilitated the advent of cataract surgery using lens phacoemulsification. As the current gold standard, the manual capsulorhexis edge is strong and ensures the safe performance of the subsequent steps of cataract surgery. However, manual CCC involves a significant learning curve, and the consistent production of a perfectly round, well-centered capsulorhexis of the specific desired size is difficult to master. The size, circularity, and placement (centration) of the capsulotomy along with its edge strength affect refractive outcomes, the development of posterior capsular opacification, and anterior capsular tear resistance.<sup>2-8</sup> This is also an area of particular importance for multifocal and toric intraocular lenses, where a perfectly centered and circular capsulotomy with circumferential overlap of the optic edge is thought to provide optimal visual outcomes.<sup>9</sup>

Femtosecond lasers can produce dimensionally superior capsulotomy openings compared with CCC in terms of circularity and consistent sizing.<sup>7,10-13</sup> Drawbacks in the

use of femtosecond lasers for lens capsulotomy include capital equipment cost, associated maintenance and per case fees, added procedural time, and an extra step in patient workflow. In addition, there are some patient exclusions, including corneal opacities and small pupils. An area of continued concern comes from large clinical series that have shown an increase in the incidence of anterior capsule tears compared with manual CCC.<sup>14-16</sup> A potential explanation for a greater propensity to anterior capsule tears might be mis-aimed laser shots resulting from minute patient eye movements during the capsulotomy step.<sup>17-19</sup> Such aberrant laser shots might create focal areas of weakness in the capsular edge.<sup>14,20,21</sup>

A novel automated method called “precision pulse capsulotomy” (PPC) takes a different approach in providing surgeons with quick and consistently shaped and sized anterior capsulotomies. Precision pulse capsulotomy is performed using a disposable handpiece (Zepto, Mynosys Inc., Fremont, CA.) that has a capsulotomy tip consisting of a soft, clear silicone suction cup housing a compressible

shape memory alloy nitinol capsulotomy ring. The capsulotomy tip collapses to enter the primary corneal incision and reexpands within the anterior chamber back to a circular shape of a predetermined size. Suction is then used to appose the nitinol ring against the capsule, and a low-energy multipulse algorithm is used to instantaneously create a PPC in milliseconds. Instead of a sequential circular capsulotomy path, all 360 degrees of the PPC are created instantaneously and simultaneously.<sup>22</sup> In addition to reproducibly creating consistently sized, circular, and centered capsulotomies, a strong and tear-resistant capsulotomy edge is paramount to surgical safety.

In this study, we quantitatively compared the capsule edge tear strength of capsulotomies produced by the automated PPC device, femtosecond laser, and manual CCC. Previous studies of femtosecond laser capsule edge strength have used porcine eyes,<sup>10,23–26</sup> which have anterior lens capsules that are 2 to 3 times thicker than human capsules.<sup>27,28</sup> Furthermore, porcine anterior capsules are highly elastic, because porcine eyes supplied for research typically come from young animals 6 to 12 months of age rather than from older pigs that can live 10 or more years. The current study specifically tested paired human cadaver eyes from donors in the sixth to eighth decade of age, which is a typical age range for patients undergoing cataract surgery. The comparison of edge strength produced by 2 different capsulotomy methods in paired fellow eyes from the same donor eliminates variables such as age, sex, and time interval from death, and minimizes any other donor factors that might affect lens capsule biomechanics. This systematic 3-way comparison testing in paired cadaver eyes of the capsule edge strength created by the 3 different methods was undertaken to predict their relative resistance to tearing during surgery.

## Methods

### Study Design

The study consisted of 3 experimental arms, with each arm using paired human cadaver eyes. Arm 1 compared the tear strength of the PPC with that produced by a femtosecond laser in which 1 eye of the pair underwent PPC, whereas the fellow eye from the same donor underwent femtosecond laser capsulotomy (FSLC). Arm 2 compared the tear strength of PPC with that produced by manual CCC, and arm 3 compared the tear strength of manual CCC with that produced by FSLC. Each pair of cadaver eyes was randomly assigned to an experimental arm by a study assistant. All surgical procedures, capsulotomies, and tear strength testing were performed by study personnel who were masked to all donor information, including sex, age, and interval from death. Each eye was labeled with a unique identifier for tracking during the various stages of surgical preparation and tear strength analysis. The order of tear strength study was randomized such that fellow eyes were not necessarily studied consecutively, and eyes that received PPC, FSLC, and manual CCC were tested in random order.

### Cadaver Eyes

Paired human cadaver eyes were obtained from 14 eye banks in the United States. All eye specimens underwent tear strength testing within 72 hours of death. Eyes included for study had no history of

ocular surgeries and were from donors at least 50 years of age. Data on the 44 cadaver eyes from 22 donors used in the study are listed in Table 1.

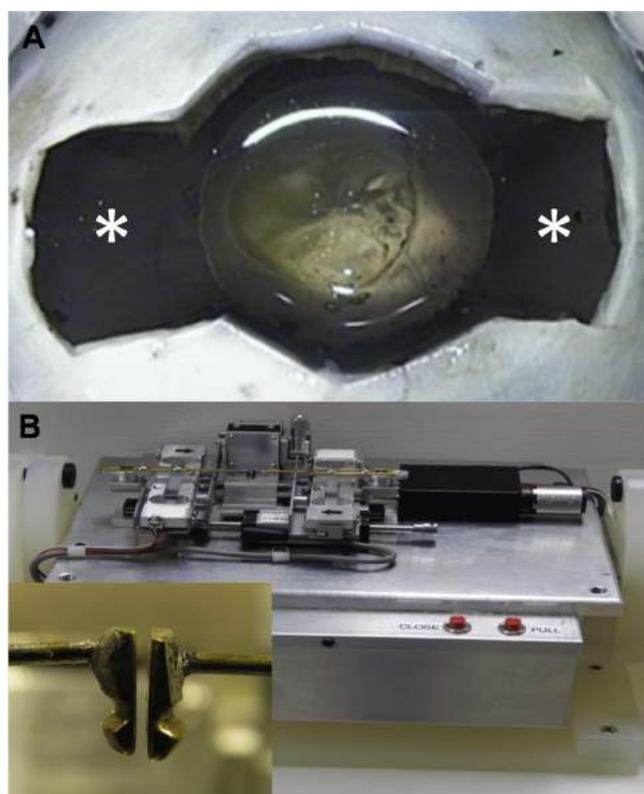
## Capsulotomy and Eye Preparation

Manual CCC and PPC were performed in open sky preparations after removal of the cornea to provide direct instrument access to the capsule edge for tear strength testing. Trypan blue staining (0.06%) was used in all eyes directly onto the capsule to facilitate

Table 1. Eye Specimen Data

Capsulotomy Type	Age (yrs)	Sex	OD/OS	Death to Test (hrs)
PPC N=16	77	M	OD	48–72
	68	M	OS	48–72
	55	M	OD	24–48
	76	M	OD	24–48
	52	M	OS	24–48
	66	M	OS	24–48
	78	M	OD	48–72
	71	F	OD	24–48
	77	M	OD	24–48
	64	M	OS	0–24
	76	M	OD	48–72
	67	M	OS	48–72
	60	M	OD	24–48
	65	M	OD	0–24
	51	M	OS	48–72
	61	M	OD	24–48
	Mean = 66.5±8.7	94% M		
CCC N=14	77	M	OS	48–72
	68	M	OD	48–72
	55	M	OS	24–48
	76	M	OS	24–48
	52	M	OD	24–48
	66	M	OD	24–48
	66	M	OD	48–72
	50	F	OD	24–48
	51	M	OD	24–48
	56	M	OD	48–72
	58	M	OD	24–48
	74	F	OD	0–24
	51	M	OD	48–72
	61	M	OS	24–48
	Mean = 61.5±9.3	86% M		
Femtosecond laser N=14	78	M	OS	48–72
	71	F	OS	24–48
	77	M	OS	24–48
	64	M	OD	0–24
	76	M	OS	48–72
	67	M	OD	48–72
	60	M	OS	24–48
	65	M	OS	0–24
	66	M	OS	24–48
	50	F	OS	24–48
	51	M	OS	24–48
	56	M	OS	48–72
	58	M	OS	24–48
	74	F	OS	0–24
	Mean = 65.2±9.0	79% M		

CCC = continuous curvilinear capsulorhexis; F = female; M = male; OD = right eye; OS = left eye; PPC = precision pulse capsulotomy.



**Figure 1.** Capsulotomy edge strength testing. **A**, An example of a dissected human cadaver eye specimen prepared for capsule edge strength testing. Asterisks indicate the scleral and uveal windows placed 180 degrees apart to create a clear path for the lateral movement of the retractors in the force test instrument. Removal of all scleral and uveal tissues at these locations ensured that the retractors only pulled on the capsule edge to assess its tear strength and that no other ocular tissues contributed any confounding forces. **B**, Photograph of the force-testing instrument showing location for placement of the eye specimen, the retractor arms, and location of the force gauges. The inset shows the retractor tips at higher magnification.

visualization of the capsule and its edge during subsequent tear strength testing.

Manual CCC was performed using capsulorhexis forceps, targeting a diameter of 5 to 5.25 mm, which was confirmed with calipers. Precision pulse capsulotomy was performed by applying the ophthalmic viscosurgical device (OVD) (Viscoat, Alcon, Fort Worth, TX) onto the capsule to mimic the presence of the OVD in the anterior chamber during device use. After placing the PPC device onto the capsule surface, the surgeon instructed the assistant to depress the first button on the control console to generate suction automatically. The surgeon next instructed the assistant to depress the second button on the control console, which generated a multipulse algorithm to produce a complete circular capsulotomy within milliseconds. Suction reversal was automatically delivered by the control console after the capsulotomy, allowing the surgeon to remove the PPC device. Eyes undergoing FSLC were used with the cornea intact for docking and capsulotomy (detailed description follows), after which the cornea was removed, and the capsule was stained with trypan blue (0.06%).

After anterior capsulotomies, eye specimens from all 3 groups (PPC, FSLC, and manual CCC) underwent hydrodissection, phacoemulsification, and cortical aspiration using the Centurion phaco system (Alcon) to achieve an empty but intact capsular bag.

Table 2. Comparison Group Data

Comparison Group	Age (yrs)	Sex	Death to Test (hrs)
PPC vs. femtosecond laser 8 pairs	78	M	48–72
	71	F	24–48
	77	M	24–48
	64	M	0–24
	76	M	48–72
	67	M	48–72
	60	M	24–48
	65	M	0–24
	Mean = 69.8±6.8	87.5% M	
PPC vs. CCC 8 pairs	77	M	48–72
	68	M	48–72
	55	M	24–48
	76	M	24–48
	52	M	24–48
	66	M	24–48
	51	M	48–72
61	M	24–48	
	Mean = 63.3±10.2	100% M	
CCC vs. femtosecond laser 6 pairs	66	M	48–72
	50	F	24–48
	51	M	24–48
	56	M	48–72
	58	M	24–48
	74	F	0–24
	Mean = 59.2±9.3	66.7% M	
	Kruskal–Wallis test		Kruskal–Wallis test
	P = 0.1		P = 0.81

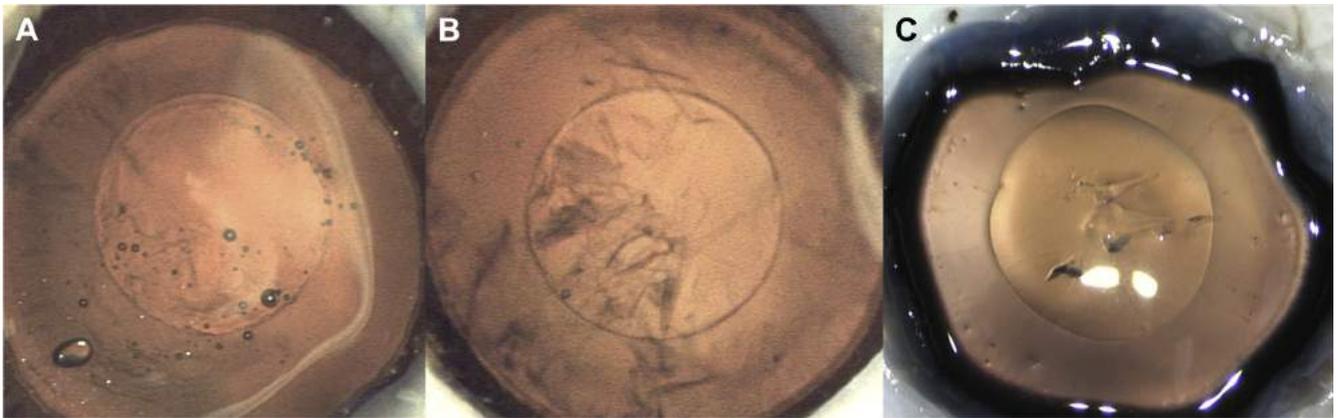
CCC = continuous curvilinear capsulorhexis; F = female; M = male; PPC = precision pulse capsulotomy.

Statistical analysis of the time interval from death to test among the 3 comparison groups was conducted using the Kruskal–Wallis test with intervals of 0–24 hours ranked as 1, 24–48 hours ranked as 2, and 48–72 hours ranked as 3. The Null hypothesis is not rejected, and there is no significant difference in the interval from death to test among the 3 comparison groups.

These steps were performed while the dissected open sky eye preparations were submerged in saline. Two square scleral windows measuring approximately 6×6 mm in size and located 180 degrees opposite each other were made contiguous with the corneoscleral junction (Fig 1A). All uveal tissue under the scleral windows, including the pars plicata, zonular structures, and pars plana, was removed with careful dissection. This provided 2 open pathways with unimpeded access to the capsular bag for the 2 opposing arms of the tear strength testing apparatus. These 2 open pathways prevented adjacent corneal, scleral, or uveal tissue from interfering with the testing apparatus during stretching of the capsulotomy edge.

### Femtosecond Laser Capsulotomy

Femtosecond laser capsulotomy was performed with the LenSx femtosecond laser (Alcon) with the SoftFit patient interface and using software version 2.23. Eyes were placed cornea side down in glycerin (99.5%) for 15 minutes at room temperature to improve corneal clarity. After the eyes were placed in a custom eye holder, a 2.4-mm corneal incision was made. The iris tissue was removed by first circumferentially disinserting the iris root and then gently extracting the iris from the anterior chamber with forceps. The corneal epithelium was removed by mechanical scraping, and Descemet's membrane was stripped to eliminate any corneal folds.



**Figure 2.** Examples of capsulotomies in cadaver eye preparations before use in edge strength testing. **A**, Precision pulse capsulotomy (PPC). **B**, Femtosecond laser capsulotomy (FSLC). **C**, Continuous curvilinear capsulorhexis (CCC). All pictures show capsulotomies in open sky preparations before lens phacoemulsification.

After injecting viscoelastic into the anterior chamber, the eyes were docked to the SoftFit patient interface according to the manufacturer's instructions. No difficulty in docking due to the presence of the corneal incision was noted, and the anterior chamber was well maintained. After ocular coherence tomography image acquisition and acceptance by the laser, the following anterior capsulotomy parameters were entered: capsulotomy diameter of 5.0 mm, 7.5  $\mu$ J, spot separation of 5  $\mu$ m, and a layer separation of 7  $\mu$ m, capsule delta up of 250  $\mu$ m, and capsule delta down of 350  $\mu$ m. After FSLC, the corneas were removed and the open sky eye specimens were prepared in the identical method described for manual CCC and PPC.

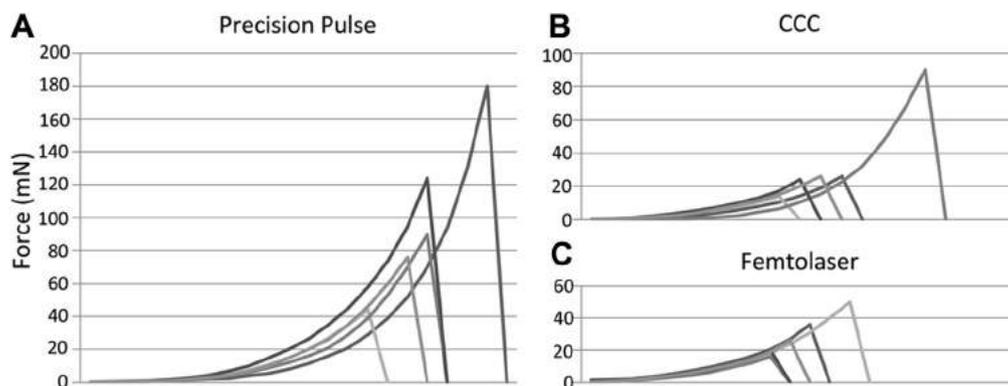
### Capsule Edge Tear Strength Testing

Capsule edge tear strength was quantified using a tensile force tester developed by Mynosys Inc. (Fremont, CA.). The tester consisted of a pair of metal arms (Fig 1B), with each terminal end shaped into a miniature capsule edge retractor (Fig 1B, inset). The retractor tip was designed with a groove to engage only the lens capsule, with a semicircular region of contact approximately 1 mm in radius of curvature. The 2 arms were mechanically attached to force transducers, which recorded the force exerted by the capsule edge resisting the lateral movement of the retractors.

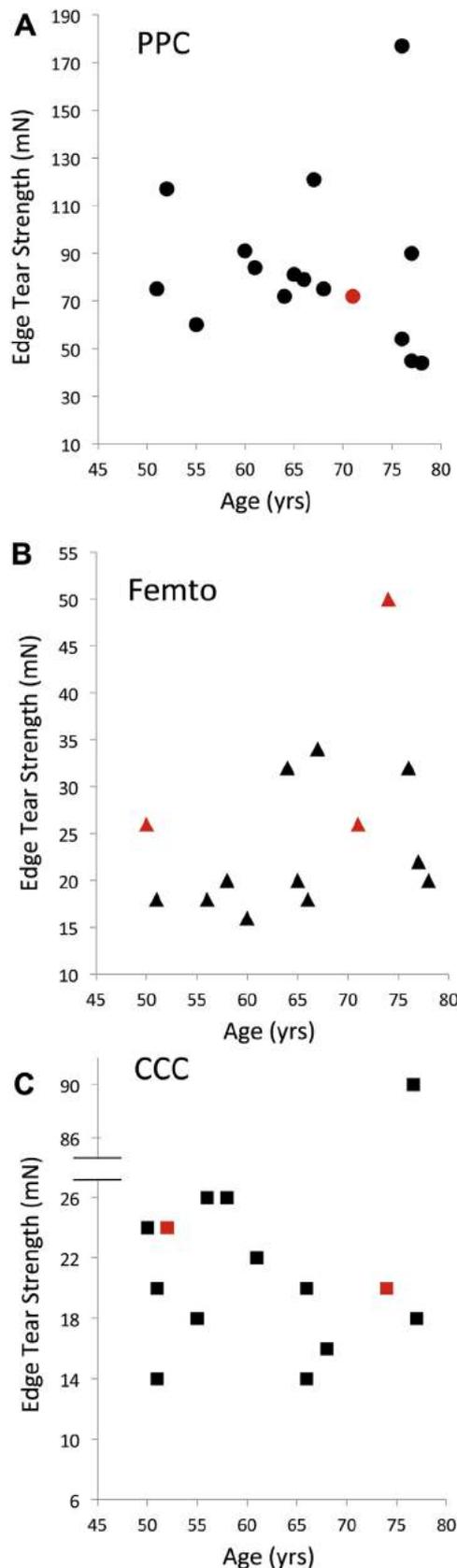
All study eyes (PPC, FSLC, manual CCC) were subjected to capsule edge tear strength testing in the same manner. The OVD (AmVisc Plus, Bausch & Lomb, Rochester, NY) was injected into the empty bag to reinflate the bag and assist in positioning the retractors against the capsulotomy edge under direct microscopic visualization. The 2 retractors were pulled away from each other at a constant velocity of 25 mm/minute. The force exerted by the capsulotomy edge against the lateral pulling retractors was continually measured 4 times per second until a capsular tear eventually occurred. The maximum force recorded just before the capsular tear was considered to be the maximum tear strength.

### Results

A total of 16 eyes received PPC, 14 eyes received manual CCC, and 14 eyes received FSLC. The human cadaver eye donors ranged from 50 to 78 years of age with no differences in average donor age among the 3 test arms (Table 1). The eye banks supplied cadaver eyes predominantly from male donors. The time interval between death of the donor and testing varied from 0 to 24 hours, 24 to 48 hours, or 48 to 72 hours. No eyes were tested at more than 72 hours after donor death.



**Figure 3.** Examples of capsule edge strength (force) versus displacement of the edge retractors in eyes that received (A) precision pulse capsulotomy (PPC), (B) continuous curvilinear capsulorhexis (CCC), and (C) femtosecond laser capsulotomy (FSLC). Each tracing represents data from 1 eye. In each case, the recorded force increases as the capsulotomy edge is pulled laterally by the edge retractors. The force reaches a maximum just before capsule tear, with the recorded force immediately decreasing thereafter. The traces in A–C are given different shadings to facilitate viewing.



**Figure 4.** Graph showing the relationship between capsule edge tear strength and donor age for eyes receiving (A) precision pulse capsulotomy

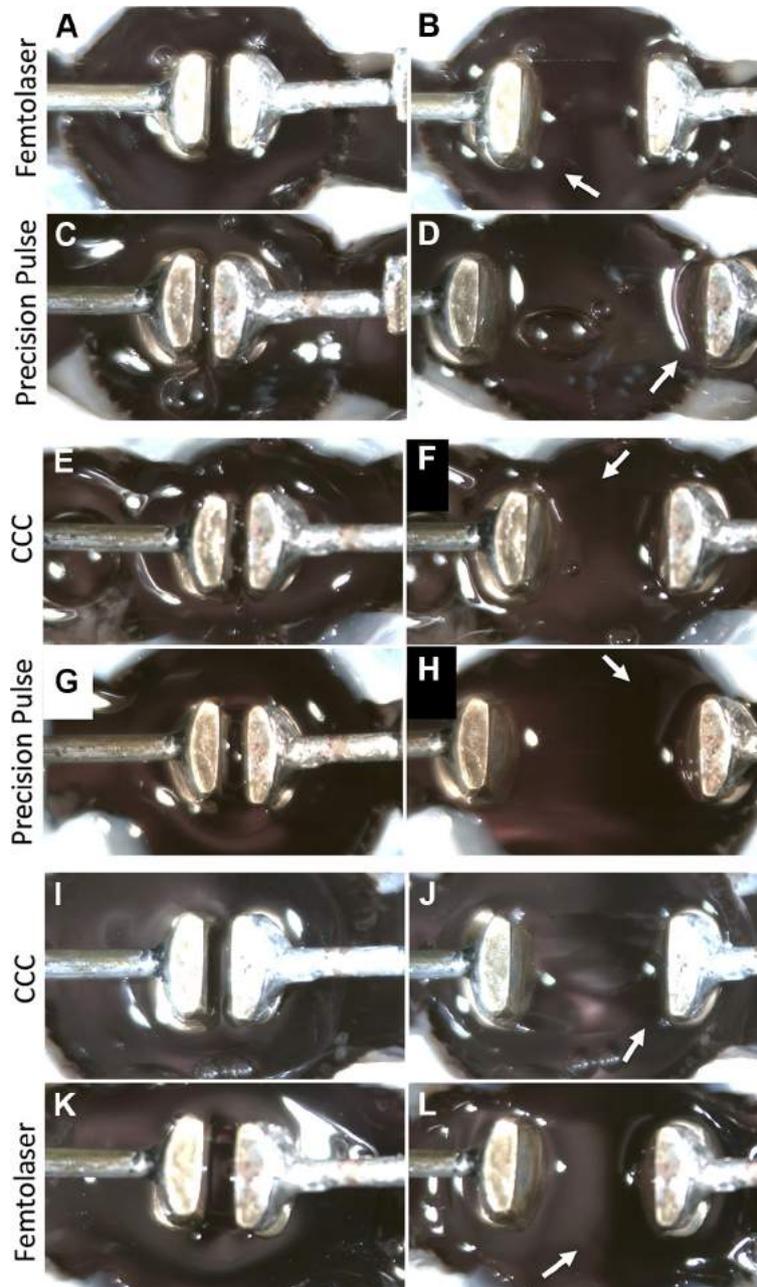
Table 2 lists the age, sex, and time interval since death for each of the 3 study arms. Nonparametric statistical analysis using Table 2 data showed insignificant differences in age ( $P = 0.1$ , Kruskal–Wallis test) and time interval since death ( $P = 0.81$ , Kruskal–Wallis test) for each of the 3 study arms. This is important when validating the accuracy of our cross-comparison of tear strength between each arm of the study.

Examples of a PPC, FSLC, and manual CCC specimen immediately before capsulotomy edge strength testing are shown in Figure 2. The PPC device used in this study was designed to create a 5.0- to 5.5-mm-diameter capsulotomy depending on the biomechanical capsule properties of the individual eye. The actual diameters achieved were all within this range. The FSLC size was programmed to be 5.0 mm in diameter and resulted in actual capsulotomies measuring 5.0 to 5.5 mm in diameter with calipers. Compared with our clinical FSLC experience, we noted more frequent skip areas in the cadaver eyes, which required manual completion. This might have been due to a different lens hydration status in cadaver eyes. A 5.2-mm-diameter capsulotomy was targeted in the manual CCC group. The actual capsulorhexes achieved showed deviations from perfect circularity, with a short axis ranging from 4.8 to 5.5 mm and a long axis ranging from 4.8 to 6.0 mm. After capsulotomy, all study eyes underwent successful hydrodissection, phacoemulsification, and cortical aspiration to create an empty capsular bag for tear strength testing.

Sample graphs illustrating the capsule edge tensile strength measurements versus displacement of the edge retractors for each of the 3 capsulotomy methods are shown in Figure 3. The plots are derived from data recorded by the force transducers. In each case, a maximal tensile force for each capsulotomy edge can be determined just before edge tearing, which is characterized by an immediate decrease in force. The graphs in Figure 4 show the relationship between the capsule tear strength and the donor age for each type of capsulotomy performed. There was substantial variation in capsule tear strength within each age group receiving the same capsulotomy method. The 16 eyes that received a PPC had a mean capsule tear strength of 84.1 mN with a standard deviation of  $\pm 32.3$  mN. The 14 eyes that received a manual CCC had a mean capsule tear strength of  $25.8 \pm 18.2$  mN, and the 14 eyes that received a FSLC had a mean capsule tear strength of  $25.4 \pm 9.1$  mN. The individual variation in capsule edge strength within each capsulotomy group was unrelated to donor age, because substantial differences in edge strength were measured within every age group studied. Our data show that random human eyes of the same approximate age can have significant differences in the biomechanical properties of the anterior capsule. Such individual variability underscores the importance of using paired fellow cadaver eyes to make valid comparisons.

The difference in capsule edge tear strength between PPC and the other 2 capsulotomy methods was also apparent when

(PPC), (B) femtosecond laser capsulotomy (FSLC), and (C) curvilinear capsulorhexis (CCC). Black symbols represent male donor eyes, and red symbols represent female donor eyes. Within all 3 capsulotomy groups, there was substantial variation in capsule edge tear strength at all ages, consistent with significant interindividual differences in intrinsic lens capsule biomechanical properties.



**Figure 5.** Photographs from capsule edge strength testing in paired cadaver eyes. **A–D**, femtosecond laser capsulotomy (FSLC) (**A**, **B**) versus precision pulse capsulotomy (PPC) (**C**, **D**). **A**, Retractors at starting position before lateral pulling on FSLC edge. **B**, Photograph immediately after capsule tear was initiated. **C**, Retractors at starting position before lateral pulling on the PPC edge in the fellow eye. **D**, Photograph immediately after capsule tear was initiated. In this pair of eyes, the distance separating the capsule edge retractors in **D** was greater than in **B**, consistent with greater extensibility of the PPC edge. The tear strength for the FSLC in **B** was 27 mN, and the tear strength for the PPC in **D** was 76 mN. **E–H**, curvilinear capsulorhexis (CCC) (**E**, **F**) versus PPC (**G**, **H**). **E**, Retractors at starting position before lateral pulling on the CCC edge. **F**, Photograph immediately after capsule tear was initiated. **G**, Retractors at starting position before lateral pulling on the PPC edge in the fellow eye. **H**, Photograph immediately after capsule tear was initiated. In this pair of eyes, the distance separating the capsule edge retractors in **H** was greater than in **F**, consistent with greater extensibility of the PPC edge. The tear strength for the CCC in **F** was 19 mN, and the tear strength for the PPC in **H** was 59 mN. **I–L**, FSLC (**I**, **J**) versus CCC (**K**, **L**). **I**, Retractors at starting position before lateral pulling on the FSLC edge. **J**, Photograph immediately after capsule tear was initiated. **K**, Retractors at starting position before lateral pulling on the CCC edge in the fellow eye. **L**, Photograph immediately after capsule tear was initiated. In this pair of eyes, the distance separating the capsule edge retractors in **L** was slightly greater than in **J**. The tear strength for the FSLC in **J** was 19 mN, and the tear strength for the CCC in **L** was 27 mN. All pictures were from video recordings of capsule edge strength testing in paired eyes. The moment of each capsule tear was determined from the review of video recordings of each test and from the recorded force versus displacement data that showed a decrease in resisting force exerted by the lens capsule corresponding to the development of a tear.

comparing the displacement distance between the 2 diverging retractors at the moment of capsule tear (Fig 5). A wider displacement of the 2 retractor tips occurred with PPC compared with both manual CCC or FSLC. This greater capsulotomy extensibility is another indication of the increased strength of the PPC edge.

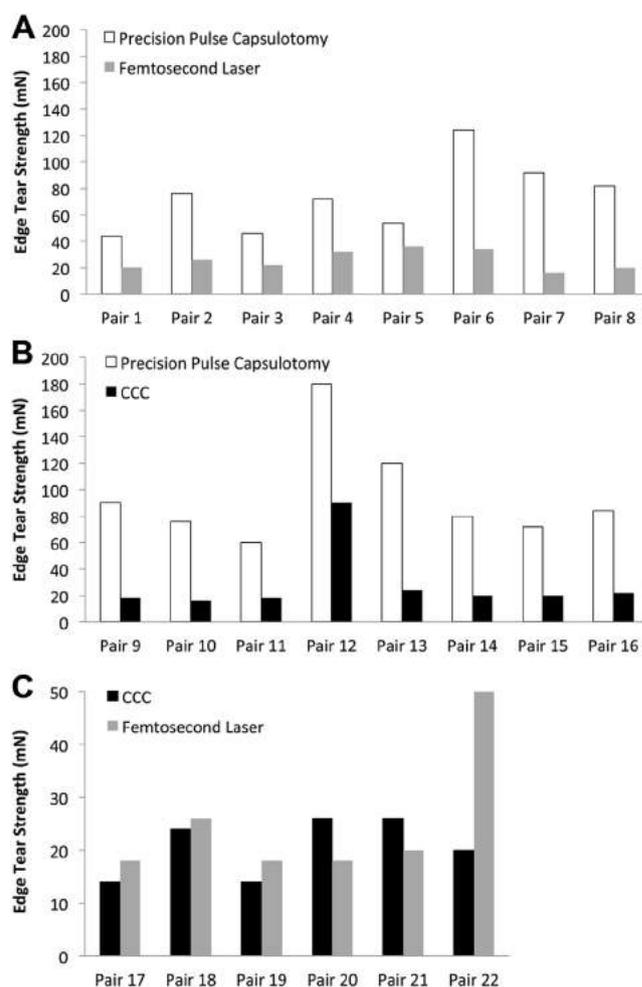
The paired donor eye comparison of tear strength for all 3 study arms is shown in Figure 6. The PPC edge was noticeably stronger in each of the 8 pairs of eyes comparing PPC and FSLC (Fig 6A) and in each of the 8 pairs comparing PPC with manual CCC (Fig 6B). In each of the 6 pairs of eyes comparing manual CCC with FSLC, the latter was stronger in 4 of the pairs (Fig 6C). In the other 2 pairs, the manual CCC edge was slightly stronger than the FSLC.

The paired donor eye comparison data are tabulated along with statistical analysis in Table 3. In the first study, arm PPC capsulotomies were substantially stronger than FSLC in the fellow eye by an average of 3.1-fold. The PPC capsulotomies were also consistently and substantially stronger than manual CCC on average by 4.1-fold. No significant difference was found between the tear strength of manual CCC and FSLC. Specifically, FSLC was stronger in 4 pairs and weaker in 2 pairs.

## Discussion

The current study was designed to quantify the tear strength of the anterior capsulotomy edge created by 3 different methods: manual CCC, femtosecond laser, and a new PPC device. The results from 44 paired human cadaver eyes indicated that the PPC edge was consistently and significantly stronger than that produced manually or by the femtosecond laser.

To our knowledge, the current study represents the first direct comparison of capsule edge tear strength from different capsulotomy methods in paired human cadaver eyes. Three previous published studies compared the tear strength of the capsulotomy edge produced by manual CCC versus the Catalys (Abbott, Abbott Park, IL) femtosecond laser<sup>10,26</sup> or the Victus (Bausch & Lomb) femtosecond laser<sup>23</sup> in porcine eyes. A fourth tear strength study in porcine eyes comparing manual CCC with the LENSAR (Orlando, FL) femtosecond laser has been reported in a published review.<sup>25</sup> A fifth porcine eyes study compared the capsulotomy extensibility between manual CCC and the LenSx FSLC.<sup>24</sup> The tear strength values reported for both manual CCC and FSLC in these porcine eye studies were several times greater than what we measured in our study using human cadaver eyes. The porcine anterior lens capsule is 2 to 3 times thicker than its human counterpart<sup>27</sup> and therefore should be substantially stronger. Furthermore, porcine eyes obtained for research are typically harvested from younger 6- to 12-month-old animals. The greater lens capsule elasticity of younger pigs might mask differences in capsular tear strength associated with different capsulotomy methods. Our study used human cadaver eyes from 50- to 78-year-old donors to provide a more accurate biomechanical model of the lens capsule in a patient population with cataract.



**Figure 6.** Charts showing the capsule edge tear strengths in fellow eyes of the same pair in (A) the precision pulse capsulotomy (PPC) versus femtosecond laser capsulotomy (FSLC) comparison group (pairs 1–8), (B) the PPC versus continuous curvilinear capsulorhexis (CCC) comparison group (pairs 9–16), and (C) the CCC versus FSLC comparison group (pairs 17–22).

Another important difference is that prior porcine studies (with the exception of 1 study<sup>23</sup>) tested the tear strength of capsules from intact undissected eyes.<sup>10,24,26</sup> Mechanical forces from surrounding scleral tissue might artefactually impede lateral movement of the test arms. In our study, scleral window pathways were created to prevent such potential artifacts.

The use of paired cadaver eyes for comparison testing eliminated potential confounding variables such as age, sex, time interval since death, and any other individual factors that might affect capsule biomechanics. The importance of this was underscored by the surprising interindividual variation in capsular tear strength that we found, regardless of the capsulotomy method used. For example, 1 manual CCC specimen exhibited a tear strength of 90 mN, which was stronger than all but 3 PPC specimens. However, its paired fellow PPC eye had an even greater tear strength of 178 mN. By assuming that this individual donor had

Table 3. Tear Strength Comparisons (mN)

Cadaver Eye Pair	PPC	Femtosecond	Fold Difference
1	43	21	2.2
2	76	27	2.9
3	46	22	2.1
4	72	31	2.3
5	53	36	1.5
6	123	35	3.6
7	91	17	5.8
8	82	20	4.1
	Median (range) 72 (43–123)	Median (range) 22 (17–36)	Mean = 3.1
$P = 0.012$			
Cadaver Eye Pair	PPC	CCC	Fold Difference
9	89	18	6.0
10	76	17	4.8
11	59	19	3.3
12	178	90	2.0
13	119	25	5.0
14	80	20	4.0
15	75	21	3.8
16	84	23	3.8
	Median (range) 80 (59–178)	Median (range) 20 (17–90)	Mean = 4.1
$P = 0.0012$			
Cadaver Eye Pair	CCC	Femtosecond	Fold Difference
17	15	18	0.8
18	24	26	0.9
19	15	18	0.8
20	26	17	1.4
21	27	19	1.3
22	21	49	0.4
	Median (range) 21 (15–27)	Median (range) 18 (17–49)	Mean = 0.9
$P = 0.75$			

CCC = continuous curvilinear capsulorhexis; PPC = precision pulse capsulotomy.

Statistical analysis: The tear strength comparison between the 2 types of capsulotomies within each comparison group was conducted using the Wilcoxon matched-pairs signed-ranks test.

unusually thick anterior capsules, testing paired fellow eyes seemed to provide an accurate comparison.

For each capsulotomy method, approximately 2-fold differences in tear strength were found within each of the age groupings (Fig 4). This suggests significant individual variability in lens capsule biomechanical properties that is unrelated to age. Previous studies of porcine capsule tear strength<sup>27</sup> reported similar individual variability of capsular strength. This would also explain the large standard deviations reported in recent porcine studies comparing FSLC and manual CCC capsulotomy strength.<sup>10,23,26</sup> Such significant individual variability of capsular biomechanics might produce misleading results if paired fellow eyes are not used for tear strength comparisons, especially if small sample sizes are involved.

Several clinical studies have reported a higher rate of anterior capsule tears with femtosecond laser cataract surgery compared with phacoemulsification with a manual CCC.<sup>14,15</sup> Other smaller studies did not observe a difference.<sup>16,28</sup> Our study using paired cadaver eyes did not find a statistically significant difference in capsulotomy edge tear strength between manual CCC and FSLC. Although our small sample size might have been a factor, differences in

performing FSLC in cadaver versus living eyes might have been important. Minute eye movements that could hypothetically cause aberrant femtosecond laser shots in patients<sup>29,30</sup> could not have occurred with cadaver eyes.

We also encountered a higher incidence of skipped regions in cadaver eye FSLC compared with our clinical experience using the same laser. Although these capsulotomies were all completed manually, one might question whether these specimens were representative of capsulotomy edges clinically produced by femtosecond lasers. However, similar skipped regions requiring manual completion occasionally occur clinically, and we believe the results from our study are relevant in this context.

The human anterior lens capsule becomes progressively thicker as a function of radial distance away from the geometric center. It is thickest in the mid-peripheral region,<sup>31</sup> corresponding to the general location of a 5.0-mm-diameter capsulotomy centered on the lens.<sup>3</sup> Theoretically, a smaller diameter capsulotomy would have a thinner and weaker edge compared with one with a larger 5- to 5.5-mm diameter. This relationship between capsulotomy diameter and edge strength has been experimentally confirmed in porcine eyes for capsulotomy diameters between 4 and 5.5 mm.<sup>3</sup> In

our study, all PPC and FSLC were between 5 and 5.5 mm in diameter, and all but 2 manual capsulorhexes were between 5 and 6 mm in diameter. According to the results from porcine capsules in Packer et al,<sup>3</sup> capsulotomy sizes within these ranges should result in only a difference of 10% to 20% in tear strength. Instead, we observed differences of 3- to 4-fold in tear strengths that can only be due to different capsulotomy methods, because all other factors were controlled in fellow eyes. Therefore, the main finding of the present study is quantitatively larger than what is solely due to a possible capsulotomy size effect. We did not find significant differences in capsule tear strength between male and female donors (Fig 4). Although serendipitous, the fact that the eye bank specimens were predominantly from male donors minimizes any influence of gender on capsular biomechanics.

The strength of the PPC capsulotomy edge is likely due to its unique morphology that is unlike that observed after CCC and FSLC. Precision pulse capsulotomy results in a capsulotomy edge that is microscopically everted to present the underside of the capsule as a rounded functional edge that circumferentially lines the capsulotomy opening during surgery.<sup>22</sup> This PPC functional capsulotomy edge is formed by the smooth, intact, defect-free capsule undersurface, and thus can be expected to be stronger than the capsule edge formed by CCC and FSLC.

In conclusion, the 3 arms of comparison testing in paired fellow human cadaver eyes showed that PPC consistently produced a stronger capsulotomy edge than the FSLC or manual CCC methods. Although the femtosecond laser also automates the creation of a precisely sized and perfectly circular capsulotomy, several clinical studies have reported a higher rate of anterior capsule tears with FSLC. The stronger PPC edge suggested by our study ultimately may confer a greater margin of surgical safety, particularly in eyes with intrinsically weaker capsule biomechanics.

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## Footnotes and Financial Disclosures

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<sup>1</sup> Vance Thompson Vision, Sioux Falls, South Dakota.

<sup>2</sup> Altos Eye Physicians, Los Altos, California.

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Abbreviations and Acronyms:

**CCC** = continuous curvilinear capsulorhexis; **FSLC** = femtosecond laser capsulotomy; **OVD** = ophthalmic viscosurgical device; **PPC** = precision pulse capsulotomy.

Correspondence:

Vance M. Thompson, MD, Vance Thompson Vision, 3101 W. 57th Street, Sioux Falls, SD 57108. E-mail: [vance.thompson@vancethompsonvision.com](mailto:vance.thompson@vancethompsonvision.com).