ARTICLE

Intereye comparison of femtosecond laser–assisted cataract surgery capsulotomy and manual capsulorhexis edge strength

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Purpose: To compare the breaking force required to tear the explanted capsule after femtosecond laser–assisted cataract surgery in the worse eye and manual cataract surgery in the contralateral eye.

Setting: Personaleyes, Sydney, Australia.

Design: Prospective nonrandomized case study.

Method: Patients with bilateral cataract had femtosecond laser–assisted cataract surgery with the Lensx laser in the eye with worse vision and manual cataract surgery in the contralateral eye. Each explanted capsule was stretched mechanically, and the breaking force and strain in grams (g) were compared. When a large contralateral difference in capsule strength was found, scanning electron microscopy (SEM) was applied to determine whether morphologic imperfections were present in a case with a weak capsule.

Results: Paired samples of 78 eyes of 39 patients were tested. The mean breaking force was not significantly different between manual capsulorhexes (2.3 g $\pm$ 2.0 [SD]) and femtosecond laser capsulotomies (2.0 $\pm$ 2.2 g, $P = .52$). The breaking strain for the manual samples (33.8% $\pm$ 18.3%) and for the femtosecond laser samples (34.6% $\pm$ 18.6%) were also not significantly different ($P = .81$). In 5 patients, in the femtosecond group, the capsules required considerably less force to break than the capsules in the manual group. However, the SEM images of these samples did not show specific laser imperfections.

Conclusion: In paired human eyes, the capsulotomies created by a femtosecond laser with a contact lens interface were as strong as manual capsulorhexes.

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Femtosecond laser–assisted cataract surgery has been reported to create predictable[1–6] and curvilinear capsulotomies.[1,2–8] This is thought to result in an improved capsule–intraocular lens (IOL) overlap,[3,9] and some studies have found better IOL centration[5,6,9] than with the manual technique.

Creating a strong femtosecond laser capsulotomy is important in preventing anterior capsule tears. There are reports of higher rates of anterior capsule tears with some laser platforms,[10] although these findings have not been reproduced at other centers.[11] The same level of anterior capsule tears have not been reported with other laser platforms.[12]

Several studies have examined the morphology of the edge smoothness of femtosecond capsulotomies, which are created by pulses separated horizontally and vertically. This results in the appearance of postage-stamp perforations at the capsulotomy edge.[7,8,10,13–15] Initially, the perforations showed significant roughness,[7,8,10,13–16] which was attributed to several factors, including the amount of laser energy used to create the capsulotomy.[7,13] Over time, improvements in the software on many laser platforms improved the smoothness of the capsulotomy. The Softfit contact lens in the cornea–laser interface of the Lensx laser (Alcon Laboratories, Inc.) is reported to create capsulotomies that mathematically approach a morphologic smoothness similar to that achieved with manual capsulorhexes.[15,17] Studies have found that, depending on the laser platform, aberrant laser pulses and tags can be seen after femtosecond laser–assisted cataract surgery;

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these might weaken the anterior capsulotomy strength.[18] Morphologic data suggest that the smoothness of the femtosecond laser capsulotomy is approaching that of the manual capsulorhexis, and it could be inferred that the strength achieved with a femtosecond laser capsulotomy would be similar to that achieved with a manual capsulorhexis, if smoothness were a surrogate for strength.

However, some studies[1,2,4,19,20] suggest that the capsule strength achieved with a femtosecond laser capsulotomy exceeds that achieved with a manual capsulorhexis. These results were observed in nonpaired porcine eyes and were consistent across various laser platforms. These results are contrary to the morphologic data mentioned above. There is only 1 paired cadaver human-eye study[21] in which no significant difference was found in capsule strength between the 2 techniques. Cadaver studies are not subject to eye movements and other variables seen in the clinical setting.

A study of eyes of patients[22] concluded that the capsules after femtosecond laser–assisted cataract surgery were weaker than when manual capsulorhexis was performed. This study used a liquid-interface femtosecond laser platform (Victus, Bausch & Lomb, Inc.) and nonpaired samples of cadaver eyes and patients' eyes. In summary, the majority of capsule strength data suggests that rougher capsulotomy edges are stronger than smooth imperfection-free manual capsulorhexis edges.

The present study examined the force required to tear the explanted manual capsulorhexis and femtosecond laser–created capsulotomy in paired eyes of cataract surgery patients.

PATIENTS AND METHODS

Ethics approval was received from the Human Research Ethics Committee, Macquarie University, Sydney, Australia. Patients with a corrected distance visual acuity of 6/12 or worse and who voluntarily consented to participation in the study were recruited sequentially into the 12-week trial. Patients were excluded if they had ocular trauma, pseudoexfoliation syndrome, or a traumatic cataract.

The eye with the lowest acuity had femtosecond laser–assisted cataract surgery and manual cataract surgery in the contralateral eye. Trypan blue was not used during the study.

Surgical Technique

One of 2 surgeons (K.M., C.B.) performed the cataract surgeries. Femtosecond laser–assisted cataract surgery was performed with the femtosecond laser platform (version 2.22, Lensx).

A 4.7 mm femtosecond laser capsulotomy was performed in the middle of the dilated pupil. The capsulotomy settings were 6 μJ energy, 4 μm spot, and 4 μm layer separation. The manual capsulorhexis was started with a needle and completed with a capsulorhexis forceps. The exact dimensions were not controlled. The dimensions were not considered significant because the capsule stretching was performed at the same starting clamp position in all explanted capsules.

The explanted capsules were collected and stored in a balanced salt solution in the refrigerator. Testing was performed within 48 hours after the tissue was thawed at room temperature in a balanced salt solution for 2 hours.

Capsule Stretching

Capsule strength was determined using an SIH muscle tester (World Precision Instruments). This testor consists of a force transducer and a linear motor. A microscope (PZMIII, World Precision Instruments) was used to visualize and load the capsule sample between 2 clamps attached to the force transducer and linear motor. The clamps were initially separated by 1.5 mm. A signal conditioning amplifier system (BAM21-LCB, World Precision Instruments) was used to process the signal from the muscle tester. It powered the force transducer and converted the output of the transducer to an amplified analog voltage that was proportional to the force applied to the transducer. This system also powered the linear motor, which measured the mechanical stretch release property of the tissue sample, and provided an output indicating the actual motor position. This was connected to a digital analog that converted the output of the data to the acquisition system (Lab-trax 8/16 with Microsoft Data Access Components software).

As the sample was stretched using controls from the data acquisition system software, the force transducer converted the force into electrical current, which was proportional to the force applied to the force transducer. The signal controlling amplifier converted the current into a voltage signal that was displayed on the recording device (data acquisition system interface). Before the experiment was initiated, the signal controlling amplifier was adjusted to zero. This set the baseline for the measurements in each sample.

The breaking force and breaking strain required to tear the sample were recorded and compared with those in the contralateral eye (Figure 1).

Scanning Electron Microscopy

Where there was a large difference in the breaking force between the eyes, the capsules were examined by scanning electron microscopy (SEM) for anomalous features that could explain the unilateral weakness, such as aberrant perforation or tags.

For SEM, the torn samples were placed in 10% buffered formalin. The samples were prepared for SEM by rinsing them in a phosphate-buffered solution. They were then dehydrated in a series of ethanol, chemically dried using hexamethyldisilazane, and sputter-coated with gold. Samples were imaged for SEM using a JSM-6480 LA scanning electron microscope (Jeol Ltd.).

Power of Study and Statistical Analysis

The aim was to detect a 5% difference in capsule-breaking strength between femtosecond laser capsulotomy and manual capsulorhexis. The intereye difference in capsule strength in our previous research (unpublished data) was approximately 1.0% with a

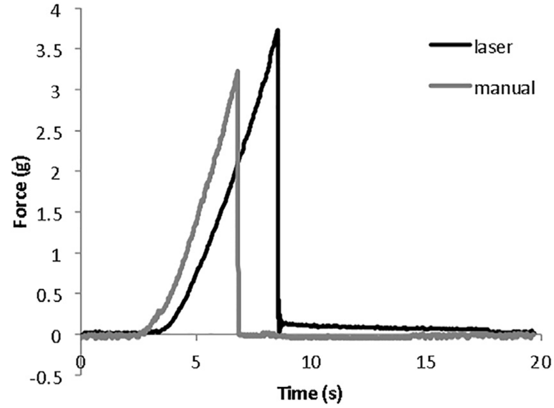

Figure 1. Raw trace of force versus time displaying the breaking point of manual capsulorhexis (*light line*) and femtosecond laser–assisted cataract surgery capsulotomy edge (*dark line*) (g = grams).

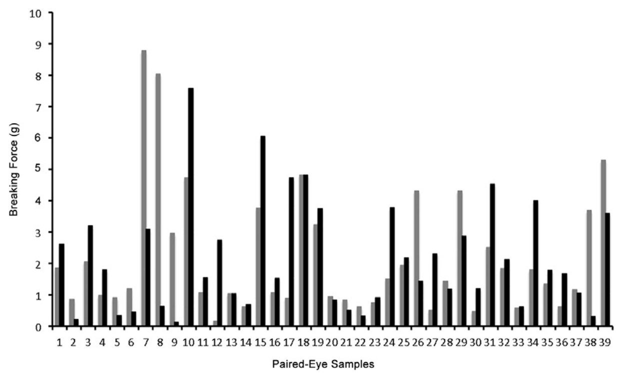

Figure 2. Bar graph representing the breaking force for paired sample of 39 patients. Light and dark bars represent paired-eye samples after manual capsulorhexis and femtosecond laser–assisted cataract surgery capsulotomy, respectively, of each patient. (g = grams).

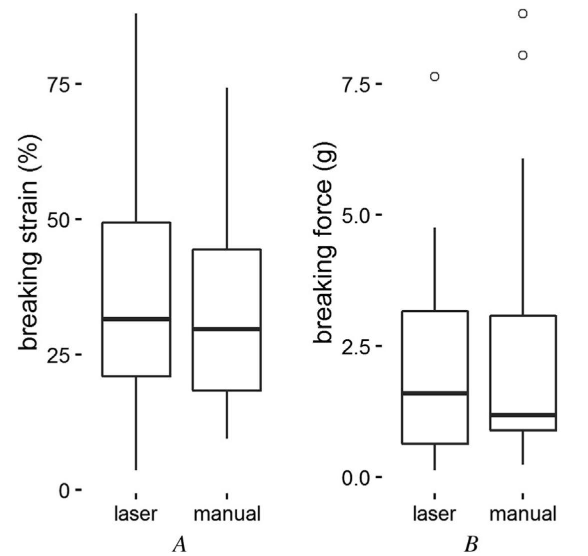

Figure 3. *A* and *B*: Boxplots of average breaking strain and force needed to break laser capsulotomy and manual capsulorhexis from paired eyes (P = .52 and P = .81, respectively).

standard deviation of 4.27%. The variables were normally distributed (Shapiro-Wilk test, W = 0.912; critical value for 5% significance 0.7751; P value 0.485). Based on these assumptions with a 2-sided significance of 0.01 and a power of 0.99, 36 patients would have been needed to test the hypothesis.

A Student paired t test was used to compare the breaking force and strength between the 2 eyes of each patient.

RESULTS

Seventy-eight eyes of 39 patients (mean age 69 years; 16 men, 23 women) were included in this study. No intraoperative or postoperative complications were noted. All patients had in-the-bag implantation of the IOL. All the femtosecond laser capsulotomies were complete. All lens capsules obtained with capsulotomies or capsulorhexes were successfully collected and tested.

The stress–strain graph of the capsules showed a near linear curve, fracturing at their elastic limit, which was the breaking point. Figure 2 shows the breaking force of each patient included in the study. The mean breaking force for the manual capsulotomies was 2.3 g ± 2.0 (SD). The mean femtosecond laser capsule breaking force was 2.0 ± 2.2 g. There was no significant difference in breaking force between the 2 methods (paired Student t test, P = .52) (Figure 3, *A*). The breaking strain was 33.8% ± 18.3% in the manual group and 34.6% ± 18.6% in the femtosecond group. There was no significant difference between the 2 techniques (P = .81, paired Student t test) (Figure 3, *B*).

When the laser capsulotomy was much weaker than the manual capsulorhexis, 5 patients with the greatest intereye difference in breaking force were selected. They were patients 7, 8, 9, 28, and 38 (Figure 2). Their eyes were imaged with SEM. Both ends of the tear caused by the clamp were imaged because the location of the clamp could not be determined; therefore, the location of the start of the tear could not be identified during imaging. The images show the corrugations of the laser pulses abruptly ending at a point where the edge becomes smooth. The latter would represent the edge generated by the tear created by the measurement clamp. No anomalous laser tags or perforations were noted that would explain the difference in breaking force (Figure 4).

DISCUSSION

Femtosecond laser platforms have been increasingly used in recent years to standardize and optimize certain steps of cataract surgery. The most notable of these is the capsulorhexis. As mentioned, the femtosecond laser is reported to produce a more predictable capsulotomy than a manual method in terms of size and shape and independent of variables, such as axial length or pupil size.[9] Together with the better IOL centration and overlap achieved with laser capsulotomy, a more predictable effective lens position as well as decreased IOL tilt and rotation can improve refractive outcomes, in particular when a toric, multifocal, or accommodating IOL is implanted.[23]

The strength of the capsulorhexis is important because the edges must be able to withstand intraoperative maneuvers without tearing. The majority of studies of femtosecond capsule strength after cataract surgery performed on porcine eyes have shown that femtosecond laser capsulotomies were stronger than manual capsulorhexes,[1,2,4,8] with only 1 porcine study stating otherwise.[21] Recently, a study of human eyes versus cadaver eyes[22] examined nonpaired eyes using the Victus platform. The study concluded that based on the aberrant pulses seen with 1 laser platform, all femtosecond laser–created capsules were weaker than manually created continuous curvilinear capsulorhexes. The study, however, did not recognize previous studies that showed the importance of the liquid interface used by some laser platforms and the associated aberrant pulses found with these interfaces.[15] The Softfit contact lens in the

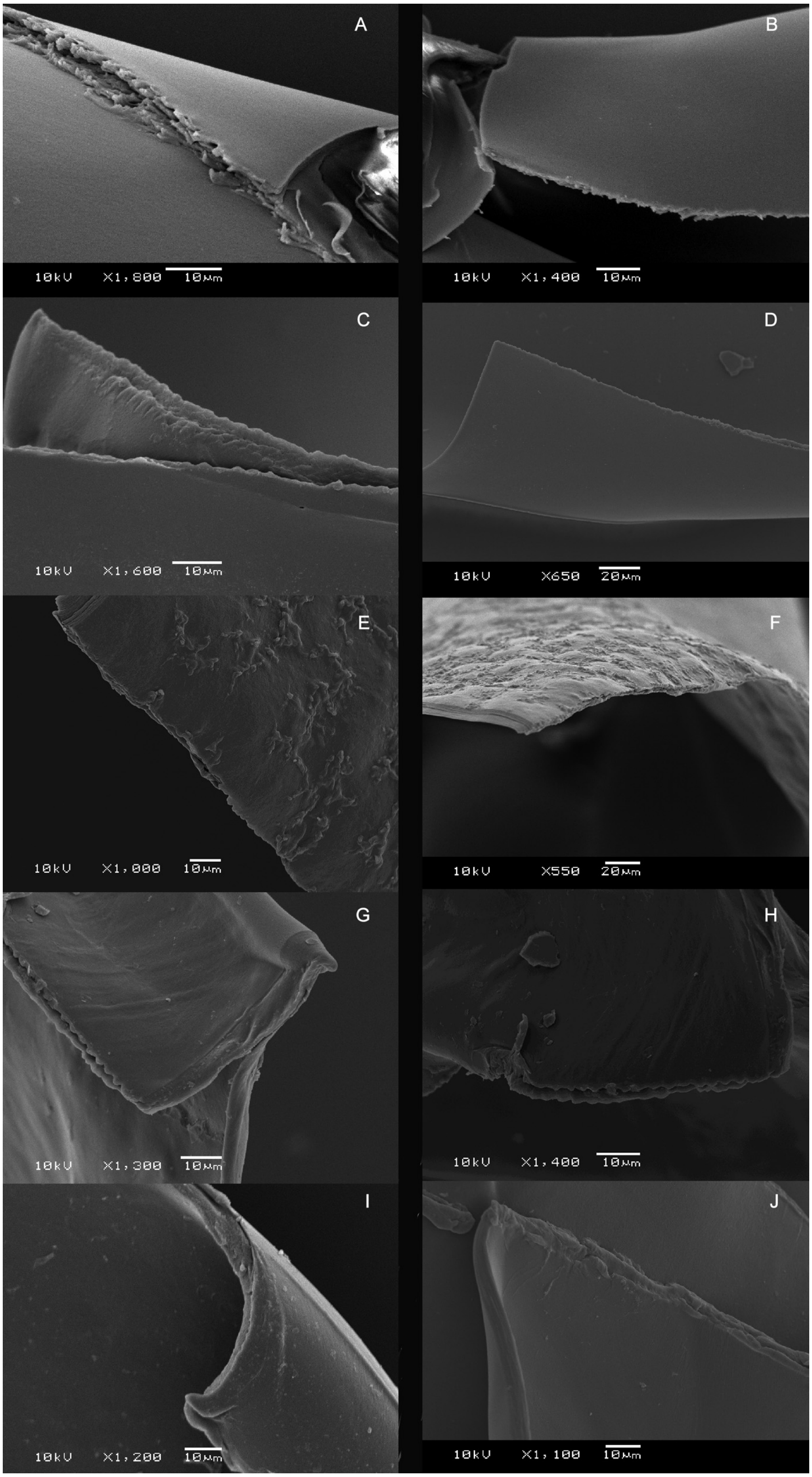

Figure 4. Femtosecond laser–assisted cataract surgery SEM of patients 7 (*A* and *B*), 8 (*C* and *D*), 9 (*E* and *F*), 26 (*G* and *H*), and 38 (*I* and *J*) who had the greatest difference in breaking strength between manual and laser cataract surgery (see Figure 2).

Lensx interface seems to reduce tags and prevent aberrant pulses.[16] Furthermore, the study was not a paired-eye study; therefore, it did not consider the variation in capsule strength between individuals. In paired human cadaver eyes, laser-created capsulotomies were found to be as strong as, but not stronger than, manually created capsulorhexes.[1] Our study confirmed this finding in paired eyes of living patients in a clinical setting.

A major problem with a femtosecond laser-created capsulorhexis is that its edges have a greater number of tags, bridges, and demarcation lines and rougher edges than its manual counterpars.[16,15,16,18] The degree of irregularity in the cut edge varies with the laser platform[16] as well as with the energy settings[7] used. Rougher edges could compromise capsule strength and result in a greater incidence of anterior capsule tears.[11] Femtosecond laser capsule edges have improved over time and are approaching the smoothness of manual capsule edges.[16] Although all the capsules were not examined for aberrant pulses, it is reassuring to know that in the paired eyes with the greatest difference in capsule strength, there were no underlying aberrant pulses to explain the difference.

A major strength of our current study is that it is a prospective study of eyes in living patients. This is a more accurate reflection of actual surgical outcomes than in previous studies that used porcine or cadaver eyes. Our study of 39 patients (78 paired eyes) allowed us to detect a 5% difference in capsule strength with a power of 0.99, which we deemed to be clinically significant. Although these are clinical data, the capsulotomy strength was inferred from the edge strength of the explanted capsule. This is considered acceptable because the explanted capsule edge is a mirror image of the capsule edge left behind in the patient. Furthermore, although the in vivo capsulotomy is subject to circumferential forces from instruments, this can be seen as a longitudinal stretch when small segments are tested, such as between clamps.[22] Last, this is the only ethical manner in which a clinical study of capsule strength can be performed. A cadaver-paired eye study could be performed to test the actual capsulotomy edge strength rather than the explanted capsule edge strength; however, such a study would not emulate real-world factors that could affect laser application, such as eye movements and corneal indentation by the laser interface, which are thought to cause tags and aberrant perforations.[15]

Although the starting distance between the clamps was the same, a limitation of our study was that the location of the clamps could not be targeted to any areas of capsule edge irregularity, such as tags or misdirected laser pulses. Hence, the capsule strength studied in our paper is the average capsule edge strength. Further studies would be required to study the strength of laser capsules at their weakest points, which could have clinical implications. In the patients who had a large difference between the laser and manual technique outcomes, there was no morphologic abnormality at the breaking point. This suggests that the variability in stress and strain measurements arises from the measurement technique. We were unable to accurately measure the thickness of the capsule because it would have been altered by the SEM preparation process. Last, the femtosecond laser and manual samples, although paired, were not randomized. Femtosecond laser–assisted cataract surgery was performed in the worse eye, which could have biased the study against that technique. Denser cataracts could have a stretched capsular bag, potentially increasing the chance of a tear and requiring more manipulation of the crystalline lens and thus exposing the capsule edge to greater forces intraoperatively.

The results in the present study suggest that in a clinical setting, the capsulotomy edge strength after femtosecond laser–assisted cataract surgery is not significantly different from that of a manual capsulorhexis. There is no clear evidence that the femtosecond laser capsulotomy edge strength is greater than that of a manual edge, which would confirm previously published morphologic findings. Also, although the femtosecond laser capsulotomy edges were not as smooth as manual capsulorhexis edges, they had strength equivalent to that of manual capsulorhexis edges.

In conclusion, on average, femtosecond laser capsulotomies created by the Lensx laser platform were as strong as manual capsulotomies in paired living human eyes. Because in general, laser capsulotomies are more predictable than their manual counterparts, femtosecond lasers could have the potential to improve refractive surgical outcomes after cataract surgery.

WHAT WAS KNOWN

- The wound edges achieved with femtosecond laser–assisted cataract surgery systems are morphologically similar to the wound edges achieved with manual capsulorhexis.

WHAT THIS PAPER ADDS

- In paired eyes of living patients, there was no mechanical difference in the strength of the capsulotomies created with a femtosecond laser with a contact lens interface and the capsulorhexes created with manual capsulorhexis.

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