Sealability of ultrashort-pulse laser and manually generated full-thickness clear corneal incisions

E. Valas Teuma, PhD, Steven Bott, PhD, Henry F. Edelhauser, PhD

PURPOSE: To compare the sealability and geometry of full-thickness clear corneal incisions (CCIs) created manually or with an ultrashort-pulse laser.

SETTING: Lensar, Inc., Orlando, Florida, USA.

DESIGN: Experimental study.

METHODS: Ex vivo human donor globes were randomly assigned to groups for the manual or laser-generated full-thickness CCIs. Standard 3-plane manual or laser incisions were made in 22 globes. Incision geometry was measured using an optical coherence tomographer. Sealability was assessed by inflating globes to physiologic intraocular pressure (IOP) and pressing a mechanical plunger into the globe to deform the globe and increase IOP until leakage was detected using the Seidel test. The test of sealability at lowered IOP was performed similarly; the anterior chamber was monitored for signs of ingress of a povidone–iodine 10% solution placed externally.

RESULTS: The mean IOP elevation at which leakage occurred was higher for the laser than for manually generated full-thickness CCIs, indicating that the mean sealability was better for the laser. However, *t* tests showed that there was no statistically significant difference in the mean IOP elevation at which full-thickness incision leakage occurred between manual and laser full-thickness CCIs. Thus, the sealability of the manual and laser full-thickness CCIs were equivalent for the incision geometry tested. The laser full-thickness CCIs were statistically closer to target geometry and showed less variability than the manual full-thickness CCIs.

CONCLUSIONS: The sealability of laser and manual full-thickness CCIs were statistically equivalent. The laser full-thickness CCIs were more consistent in geometry and closer to the target incision geometry.

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For the past decade, starting in the early 2000s with their increasing commercial availability, femtosecond lasers have been used in lieu of diamond blades to create precisely positioned incisions in the optically transparent tissues of the eye.[1–5] To make an incision, the point of focus of a femtosecond laser is scanned across a planar or curved surface within the target tissue to form the incision. The beam intensity at focus is chosen to substantially exceed the laser-induced optical breakdown threshold of the tissue. As each pulse is delivered, plasma-mediated photodisruption occurs, vaporizing a miniscule volume of tissue at and near the point of focus. A cavitation bubble subsequently forms near the point of focus, which helps cleave the damaged region to form the incision.[6,7] Using a scanning laser guidance system, laser pulses are placed contiguously in 3 dimensions across the desired planar or curved surfaces to form the overall incision.

The human cornea has the ability to self-seal after penetrating incision wounds.[8] This ability is essential for the eye to be able to reestablish and maintain a physiologic intraocular pressure (IOP) after accidental injuries or after any surgery that involves a full-thickness corneal incision. One concern with any such surgical procedure is that the corneal seal integrity be such that no leak occurs even when the IOP in the eye is substantially elevated, for example by a patient rubbing the eye postoperatively. Any leak of fluid into the eye can substantially increase the risk

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for endophthalmitis with an associated risk to eye health.[9,10]

Three-plane full-thickness clear corneal incisions (CCIs) are frequently used to provide access to the anterior chamber and crystalline lens in cataract surgery. Studies of optimum incision geometry have shown that full-thickness CCIs with a square or nearly square geometry are more stable with respect to sealing and maintaining IOP.[11–14] In a square incision, the total length of the tunnel is approximately equal to the width of the incision (Figure 1).

In this study, the sealability of the cornea was assessed using an ex vivo human donor globe model. The sealability of manually and laser-generated 3-plane full-thickness CCIs was assessed by pressing a purpose-built mechanical plunger designed to emulate a Bailliart ophthalmodynameter[15] against a human donor globe and measuring the IOP rise in the globe using a pressure transducer connected to the anterior chamber. The IOP at which leakage occurred was measured using a standard Seidel test, which is based on using the change in the color of fluorescence of 10% fluorescein applied externally to the cornea to detect the presence of aqueous leaking from the anterior chamber.[16] Ingress of fluid into the anterior chamber through full-thickness CCIs in eyes with an IOP below the physiologic value is generally assessed using India ink applied externally at the external wound and then examining the anterior chamber under a microscope after washing off extraneous external dye.[17,18] An ex vivo model was chosen so the IOP could be easily and accurately measured up to the 500 mm Hg IOP limit used in these experiments. The mechanical plunger was designed to simulate pressure applied to the eye by a patient rubbing the eye postoperatively.

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Brock Magruder, MD, Laservue, Orlando, Florida, USA, performed the manual full-thickness clear corneal incisions used in the study. Aissatou Barry, Lensar Biolab assistant, helped with the testing and optical coherence tomography measurements.

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The Lensar Laser System[A] (Lensar, Inc.) was used for the laser full-thickness incisions. The same nearly square, 3-plane architecture was used for the manual and laser-generated full-thickness CCIs. Because sealability likely depends on corneal thickness and detailed biomechanical cornea parameters such as the Young modulus of the stroma, human donor globes were used instead of other animal eyes because corneal thickness and other corneal properties vary considerably across the range of potential animal models. Ex vivo eyes were used so leakage could be tested at high IOPs without exposing human subjects to potential safety risks.

Sealability was assessed by inflating human donor globes to physiological IOP (15 to 20 mm Hg) and then applying pressure with a mechanical plunger (see Materials and Methods) to increase IOP. The IOP was increased until a Seidel test showed leakage or an IOP of 500 mm Hg (above atmospheric pressure) was reached. The mechanical plunger, similar to a Bailliart ophthalmodynamometer, not only increases the eye's IOP but also slightly deforms the eye, distorting the geometry of the 3-plane incision and increasing the probability of leakage. For this reason, the plunger is a more realistic test of the integrity of the wound in real-world circumstances (such as a patient rubbing the eye) compared with other methods of IOP elevation, such as pumping excess fluid into the globe through a cannula or needle. Preliminary testing showed that due to the distortion of the incision during the compression test, the position at which the mechanical plunger pushes on the globe relative to the position of the full-thickness incision had an effect on the IOP at which leakage occurred. For this reason, readings at 2 representative positions of the plunger were chosen for the leak assessment.

Although the elevated IOP testing was the primary quantitative means of assessing manual versus laser generated full-thickness incision sealability, a smaller number of lowered IOP tests were performed to confirm wound integrity under those conditions. A solution of povidone–iodine 10% (Triadine) with dye miscibility property similar to the India ink dye was used for the ingress tests.[19]

MATERIALS AND METHODS

This study used human donor eyes obtained from the Lions Eye Institute, Tampa, Florida, USA. Globes were harvested and stored at room temperature in plastic cuvettes (moist chamber) designed for the purpose. Twenty-two human donor globes were used for the tests. Eight globes from 4 donors were used for the manual full-thickness CCIs; 14 globes from 7 donors were used for the laser full-thickness CCIs. The mean age of the subjects was 62 years (range 47 to 74 years). The donor globes were treated an average of 31 hours postmortem (range 16 to 48 hours).

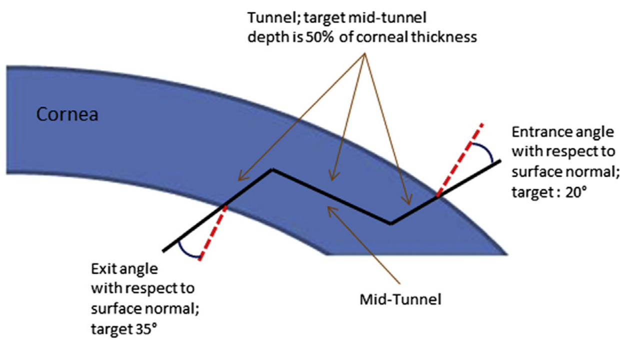

Figure 1. Full-thickness corneal incision wound geometry.

Creation of the Corneal Incisions

For the laser full-thickness CCIs, the globe was placed and secured into a purpose-designed eyecup; the suction ring was attached to the limbus exactly as would occur for an actual laser procedure. Next, the globe and eyecup were placed on a platform and moved to a position just under the laser's patient interface device ring arm. The index matching chamber of the patient interface device was filled with phosphate-buffered saline (PBS) (Dulbecco D8662, Sigma-Aldrich Co.), a laboratory substitute for balanced salt solution, and then the laser platform was lowered until the laser software indicated that the patient interface device ring arm was in the correct position. Locations of the corneal surfaces were determined by the built-in biometric system of the laser. The laser cutting parameters for full-thickness CCIs were entered into the system. The laser treatment was performed, and the globe was undocked and removed from the suction device, again in a manner analogous to that used for an actual laser procedure. The laser was set to use a pulse energy of 4 μJ and the spacing between pulses in the cornea was set to 3 μm vertically and horizontally.

Three of the 14 laser full-thickness CCIs were rejected because the incision entrance was not completed due to the incision pattern being placed too close to the limbus, causing the laser beam to be partially or completely blocked by opacities (limbal spur, fatty deposits [arcus senilis]) often found near the limbus. The laser incisions are restricted to regions of the cornea in which the cornea is clear, according to the laser's user's manual. For these 3 eyes, the full-thickness CCIs could not be easily opened with the Weinstock wound dissector or Slade limbal relaxing incision dissector, which was used to open the laser full-thickness CCIs.

The method of creating the manual incisions has been described.[20] For both the manual and laser full-thickness CCIs, a roughly 50:50 mixture of 2.20 mm and 2.85 mm wide incisions were created. For the manual incision, a blade of that thickness was used and in the case of the laser, the value was entered into the laser software. In all cases, an entrance angle of 20 degrees and an exit angle of 35 degrees were targeted (Figure 1). The approximate 20-degree entrance angle makes it easier to transition between the upper tunnel and mid-tunnel for the manual incisions, and the approximate 35- to 45-degree exit angle allows the breakout of the lower tunnel into the anterior chamber to be accomplished with less risk for nicking the crystalline lens capsule. The target mid-tunnel depth was 50% of the corneal thickness.

The length of the mid-stromal tunnel planar segment was targeted so the length of the 3 planar incisions totaled approximately 2.2 mm; that is, the width of the narrower of the 2 blades used for the incisions. For the 2.2 mm wide incision, this results in the square geometry preferable for stable incisions. For the wider 2.85 mm full-thickness incisions, the geometry was slightly off square; however, the same mid-tunnel length (from 0.8 mm to 1.0 mm) was targeted to provide a comparison of 2 incision geometries with the same overall tunnel length and because a longer tunnel length in a real procedure would increase the probability of the incision encroaching onto the optical zone of the patient. Because the total length of the 3-planar tunnel is dependent on corneal thickness, the entry and exit incision angles, and the length of the mid-tunnel, the selection of the length of the mid-tunnel is not an exact science; results are based on the judgment and experience of the surgeon.

The geometry of the laser full-thickness CCIs was chosen to mirror, as closely as possible, those used in the manual part of the comparison test so that the sealability measurements for the laser and manual methods would be as comparable as possible. The incision width (2.20 or 2.85 mm) and the entrance and exit angles (20 degrees and 35 degrees, respectively) were entered into the laser software. The laser automatically targets a mid-tunnel depth of 50% of the thickness of the cornea at the place of the incision. The remaining parameter, the mid-tunnel length, was adjusted to values between 0.8 mm and 1.0 mm to achieve the 2.2 mm total 3-planar tunnel length targeted with the manual full-thickness CCIs. Also, the 2.2 mm tunnel length target gave the tunnel incision the appearance of a square architecture, which has been shown to be more resistant to external deformation than the rectangular counterparts.[13,14]

A high resolution Fourier-domain optical coherence tomography (OCT) system (RTVue, Optovue, Inc.) was used to measure the incision geometry. After a full-thickness CCI was created with the laser, the globe was undocked and placed on another purpose-designed eyecup in front of the OCT system with the corneal axis oriented parallel to the OCT beam. The incision geometry was measured, using software included in the OCT system (Figures 2 and 3).

Measurements of the Sealability of Incisions

After the OCT measurements, the sealability of the manual and laser full-thickness incisions were measured. A cannula was inserted through the optic nerve into the anterior chamber. The optic nerve was then tied off around the cannula to ensure a seal. Tubing attached to the cannula was routed through a "T" connection with 1 branch of the "T" connected through a stopcock valve to a syringe filled with PBS. The other branch was attached to a digital pressure gauge (DPGW-05, 0-15 PSIG, Dwyer Instruments, Inc.). At the beginning of the measurement, the syringe and all tubing were filled with PBS. The syringe was used to inject PBS into the globe to reach physiologic IOP, taken to be between 17 mm Hg and 20 mm Hg, using the pressure gauge to indicate IOP. The stopcock valve was then turned off to isolate the syringe from the globe.

Figure 4 shows the apparatus used to apply pressure to the globe with a mechanical plunger. The globe was oriented with the full-thickness incision located immediately adjacent to the plunger (0 degree) or clocked 90 degrees to the plunger (Figure 5). A fluorescein sodium ophthalmic strip (Ful-Glo, Akorn, Inc.) was moistened with a drop of PBS. The

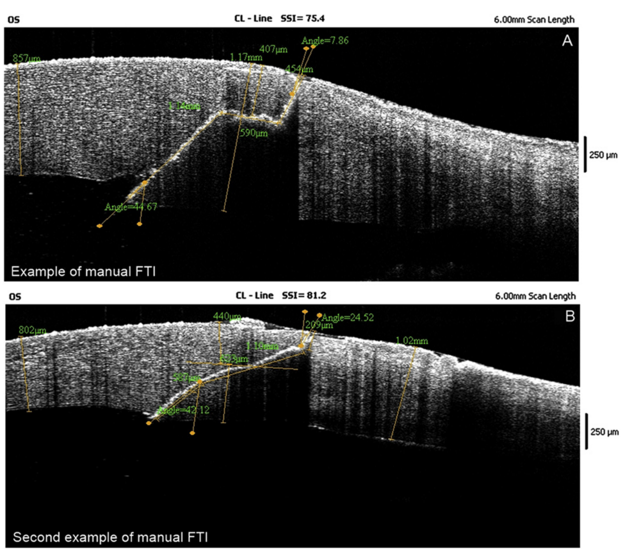

Figure 2. Two typical examples of OCT images of manual full-thickness incisions showing incision geometry. *A*: Entrance incision angle 8 degrees, exit angle 67 degrees (targets 20 degrees and 35 degrees); mid-stromal tunnel location 35% (target 50%) of corneal thickness. *B*: Entrance incision angle 25 degrees, exit angle 42 degrees; mid-stromal tunnel location 43% of corneal thickness. Manual full-thickness incisions often have less distinct slope changes between the 3 incision planes, as seen here (FTI = full-thickness incision).

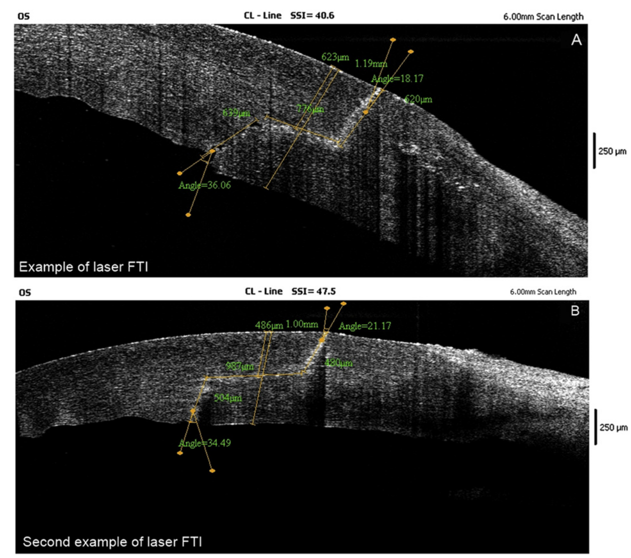

Figure 3. Two typical example OCT images of laser full-thickness incisions showing incision geometry. *A*: Entrance incision angle 19 degrees, exit angle 36 degrees (targets 20 degrees and 35 degrees); mid-stromal tunnel location 52% (target 50%) of corneal thickness. *B*: Entrance incision angle 21 degrees, exit angle 34 degrees; mid-stromal tunnel location 49% of corneal thickness (FTI = full-thickness incision).

fluorescein dye on the strip tip was spread on the full-thickness incision anterior wound. It stains the cornea wound orange under white-light illumination and stains the sclera yellow. A computer-controlled stepper motor was used to push the plunger into the eye (0.5 mm step and 2 seconds between consecutive steps). At frequent intervals, the globe in the vicinity of the full-thickness incision was examined for a change in the color of the fluorescein from orange to bright green, indicating leakage of the aqueous through the full-thickness incision (Seidel test). The IOP reported by the pressure gauge was recorded at the first sign of leakage. If the IOP reached 500 mm Hg without leakage, the test was considered complete.

The test of sealability at lowered IOP (ingress) was done before the high-IOP tests for each eye for the laser-treated eyes. (For the manual full thickness CCIs, which were performed earlier before the need for the lowered IOP ingress assessments was identified, the measurements were performed in only the final 2 eyes in the series.) For these tests, the IOP was adjusted to physiologic IOP using the stopcock valve and PBS syringe. A drop of solution of povidone–iodine 10.0% solution was placed on the globe at the full-thickness CCI. The IOP was then lowered to between 2 mm Hg and 5 mm Hg. The eye was examined under a

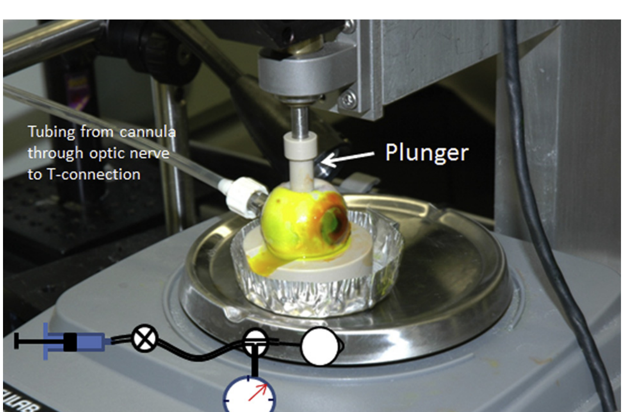

Figure 4. Plunger apparatus used for measuring sealability. Schematic drawing of test setup used to set and measure IOP shown in left corner.

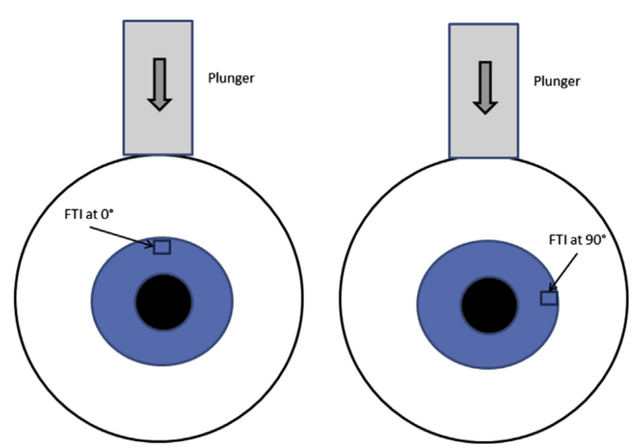

Figure 5. Sealability measurement geometry (FTI = full-thickness incision).

Table 1. Manual full-thickness CCIs.

Globe ID	Age (Y)	Blade Width (mm)	Mid-Tunnel Depth Location (%)	Length			
				Lower Plane (mm)	Middle Plane (mm)	Upper Plane (mm)	Total Tunnel (mm)
Manual 1	69	2.2	35	1.05	1.24	0.265	2.555
Manual 2	69	2.2	43	0.587	1.1	0.209	1.896
Manual 3	64	2.2	24	1.18	0.402	0.221	1.803
Manual 4	64	2.2	18	1.49	0.679	0.234	2.403
Manual 5	74	2.85	41	0.86	0.36	0.44	1.66
Manual 6	74	2.85	35	1.14	0.59	0.454	2.184
Manual 7	65	2.85	44	0.63	0.468	0.706	1.804
Manual 8	65	2.85	27	0.915	0.377	0.29	1.582
Mean	68	2.53	33	0.98	0.65	0.35	1.99
SD	4	0.35	10	0.30	0.34	0.17	0.35

CCI = clear corneal incision; IOP = intraocular pressure; NA = test not performed

Table 2. Laser full-thickness CCIs.

Globe ID	Age (Y)	Blade Width (mm)	Mid-Tunnel Depth Location (%)	Length			
				Lower Plane (mm)	Middle Plane (mm)	Upper Plane (mm)	Total Tunnel (mm)
Laser 1	61	2.2	34	1.05	0.80	0.46	2.31
Laser 2	66	2.85	42	0.98	0.81	0.56	2.36
Laser 3	66	2.85	42	0.76	0.81	0.50	2.07
Laser 4	67	2.85	65	0.42	0.81	0.70	1.93
Laser 5	47	2.2	52	0.64	0.78	0.62	2.04
Laser 6	47	2.85	54	0.68	0.80	0.71	2.18
Laser 7	50	2.2	45	0.99	0.84	0.40	2.22
Laser 8	52	2.85	49	0.50	0.99	0.48	1.97
Laser 9	52	2.2	50	0.66	1.00	0.39	2.05
Laser 10	59	2.85	60	0.59	1.05	0.77	2.41
Laser 11	59	2.2	52	0.59	1.03	0.55	2.18
Mean	57	2.55	49	0.72	0.88	0.56	2.16
SD	8	0.34	9	0.21	0.11	0.13	0.16

CCI = clear corneal incision; IOP = intraocular pressure

surgical microscope for signs of the coloration inside the anterior chamber. A binary assessment (yes or no) was made as to leakage at the lowered IOP. Povidone–iodine was used instead of the often-used India ink for the ingress testing because the same globes were used for the ingress tests (performed first) and the elevated-pressure leakage tests. The India ink tended to stain the corneas, making the initial onset of the color change of the fluorescein in the subsequent pressure test more difficult to discern. In preliminary testing, the povidone–iodine showed up as well as the India ink for the ingress testing but had the advantage that it could be washed off with PBS before the application of the fluorescein for the elevated-pressure test.

RESULTS

Table 1 and Table 2 show OCT measurements of incision geometry and the sealability assessment for the manual and laser full-thickness CCIs.

Figure 6 shows the results of the manual versus laser full-thickness CCI sealability at elevated IOPs. Variance of the laser full-thickness CCIs at 0 degree and 90 degrees was significantly less than that of the manual full-thickness CCIs (standard deviation 28 mm Hg versus 94 mm Hg at 0 degree and 43 mm Hg versus 100 mm Hg at 90 degrees). F tests of variance at a significance level of $\alpha = 0.05$ were performed for the 0-degree and 90-degree full-thickness incision orientation for the manual versus laser full-thickness CCIs. The null hypothesis (variance of the IOP at leakage for manual and laser full-thickness CCIs are the same) was rejected in both cases, with P values of $< .001$. However, as seen in the tables, the values of IOP at which leaks were detected were not distributed normally because of the 500 mm Hg cap used in the protocol. Therefore Levene

Table 1. (Cont.)

Exit Angle (°)		Ingress Test: IOP Lowered to 2–5 mm Hg	Plunger Position 0°		Plunger Position 90°	
Target: ∼35°	Target: ∼20°		Initial IOP (mm Hg)	IOP at Leak (mm Hg)	Initial IOP (mm Hg)	IOP at Leak (mm Hg)
45	29	NA	20	450	18	250
42	25	NA	18	500	17	500
38	14	NA	16	500	18	500
38	13	NA	19	500	19	500
38	9	NA	20	350	18	320
45	8	NA	16	500	20	500
19	31	No	18	250	18	350
18	13	No	20	500	17	420
35.4	17.7	—	18.4	444	18.1	418
11.1	9.2	—	1.7	94	1.0	100

Table 2. (Cont.)

Exit Angle (°)		Ingress Test: IOP Lowered to 2–5 mm Hg	Plunger Position 0°		Plunger Position 90°	
Target: ∼35°	Target: ∼20°		Initial IOP (mm Hg)	IOP atLeak (mm Hg)	Initial IOP (mm Hg)	IOP atLeak (mm Hg)
34	22	No	18	500	17	500
35	20	No	19	470	19	375
35	20	No	18	460	19	500
36	21	No	19	500	17	500
36	18	No	20	500	19	500
36	21	No	17	500	20	500
36	21	No	18	420	19	420
34	21	No	18	500	19	500
36	20	No	20	450	19	500
35	20	No	19	500	20	500
36	21	No	19	500	20	500
35.3	20.6	—	18.6	482	18.9	481
0.6	1.0	—	0.9	28	1.0	43

tests were performed on the same data using the same significance level. The results showed that the null hypothesis was accepted for the 0-degree full-thickness incision orientation ($P = .219$) and rejected for the 90-degree orientation ($P = .019$).

One-tailed t tests of the 0-degree and 90-degree full-thickness incision orientation sealability tests for the manual versus laser full-thickness CCIs, assuming unequal variance for the 90-degree and equal variance for the 0-degree full-thickness incision orientation, with the significance level $\alpha = 0.05$ resulted in acceptance of the null hypothesis (mean IOP at which leakage occurred for the manual versus laser full-thickness CCIs were the same) in both cases, with P values of 0.22 for the 0-degree orientation and 0.061 at 90 degrees. The t tests also showed no statistically significant differences between the sealability of the 2.2 mm incisions and the 2.85 mm incisions for either manual or laser full-thickness CCIs oriented at 0 degree or 90 degrees.

Regarding the OCT-measured incision geometries, the variances of the mid-tunnel depth location, the individual lengths of each planar segment, and total length of the 3-plane incisions and the entry and exit angles for the manual versus laser full-thickness CCIs were subjected to F tests of variance for the manual versus laser incisions. Table 3 shows the results of F tests for each parameter. In several cases, noted with asterisks, the laser incisions resulted in more consistent results. In no case did the manual

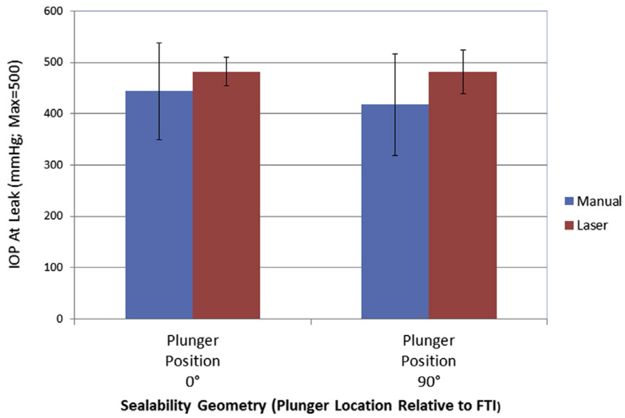

Figure 6. Comparison of mean IOP at leakage for manual and laser full-thickness CCIs. Error bars show 1 standard deviation (FTI = full-thickness incision; IOP = intraocular pressure).

Table 3. F tests of various incision geometry parameters comparing manual and laser full-thickness CCIs.

Parameter	α Value	*P* Value†
Mid-tunnel depth location (%)	0.05	<.38
Length lower plane (μm)	0.05	<.14
Length middle plane (μm)*	0.05	<.001
Length upper plane (μm)	0.05	<.20
Total tunnel length (μm)*	0.05	<.01
Exit angle (°) (target ∼35°)*	0.05	<.001
Entry angle (°) (target ∼20°)*	0.05	<.001

*Geometric parameter in which the laser incisions were statistically significantly less variable than the manual incisions
†One tailed

incisions result in measurements with a lower variance than that of the equivalent laser incision.

A 2-tailed *t* test of the mid-tunnel depth location versus target (50%) at a significance level of $\alpha = 0.05$, assuming equal variances resulted in a rejection of the null hypothesis (the mean deviation from target 50% depth of mid-tunnel incision for the manual versus laser CCIs were the same), showing that the laser CCI was statistically significantly closer to the target value of 50% than the manual CCIs. The *P* value was 0.00546 for the test.

Ingress tests for leakage for fluid through the incision into the anterior chamber performed following established methods showed that in no case did the lowered IOP cause leakage of the full-thickness CCI into the anterior chamber.

DISCUSSION

Three-plane full-thickness CCIs created manually using an ultra-sharp blade were compared with similar incisions generated automatically with the Lensar Laser System. The geometries of the manual and laser incisions were measured using OCT, and the sealability of the incisions under conditions of elevated IOP were measured using a mechanically driven plunger and the Seidel test for corneal leakage. The plunger test, which simulates the effect of a patient rubbing his or her eye postoperatively, has been used to test the seal of full-thickness CCIs generated by femtosecond lasers.[14]

Although the mean IOP elevation at which leakage occurred was higher for the laser full-thickness CCIs than for the manual full-thickness CCIs (indicating that the mean sealability was better for the laser), 1-tailed *t* tests of the mean manual versus laser sealability measurements showed that there was no statistically significant difference in the mean IOP elevation at which full-thickness incision leakage occurred in tests with the full-thickness incision oriented immediately inferior to the plunger ($P = .22$) or when the full-thickness incision was oriented temporally with respect to the position of the plunger ($P = .061$). Thus, the sealability of the manual full-thickness CCIs and the laser full-thickness CCIs were equivalent for the range of tunnel lengths considered in this study.

A Levene test[B] of the variance of the IOP elevation at which leakage occurred showed that the manual method produced incisions with statistically higher variance than those of the laser incisions for the second geometry discussed above ($P = .019$) but not for the first geometry ($P = .219$). (The Levene test was used in place of an F test because of the non-Gaussian distribution of the parameters.)

The foregoing tests were performed under conditions of high IOP. In tests of leakage of the manual and laser full-thickness CCIs under conditions lower than normal IOP (ingress of fluid through the full-thickness incision into the anterior chamber), there was no difference in susceptibility to fluid influx between the 2 types of incisions.

In addition to the sealability tests, the incision geometries of the manual and laser full-thickness CCIs were compared by taking OCT measurements across a cross-section through the center of the full-thickness CCI. The measurements of manual and laser full-thickness incision geometry showed that the mean value of the location of the mid-plane of the 3-plane full-thickness CCI was placed significantly closer to the target placement (50% of the corneal thickness) for the laser full-thickness CCIs than for the manual full-thickness CCIs ($P = .00546$). In addition, F tests of the variance of the angles of the entrance and exit planar incisions relative to the corneal surface showed

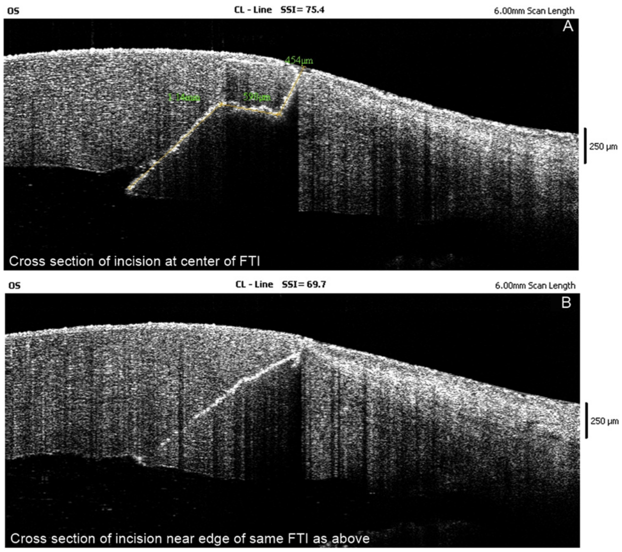

Figure 7. An OCT image of the incision geometry at the center and edge of a manual full-thickness CCI. *A*: Incision geometry in center of full-thickness CCI distinctly shows the desired 3-plane geometry. *B*: Incision geometry in an OCT cross-section approximately 0.5 mm from edge of the same full-thickness CCI in *A* shows degradation in the desired sharp angular break between the entrance, middle, and exit incision planes (FTI = full-thickness incision).

that the laser incisions had statistically significantly lower variance for these geometric parameters than the manual incisions ($P < .001$ for exit angle and $P < .001$ for entrance angle). In no case did the variability of the laser full-thickness CCIs exceed that of the manual full-thickness CCIs.

In addition to the OCT measurements through a cross-section through the center of the full-thickness CCI, additional OCT measurements were taken at each edge of the full-thickness CCI to check whether the geometry of the incision was consistent across the width of the wound. For the laser full-thickness CCIs, the incision geometry was almost identical at the edges versus center of the incision. However, for the manual full-thickness CCIs, the incision geometry at the edges of the incision tended to exhibit much less distinct changes in the slope between the 3 planes composing the full-thickness CCI; that is, the 3-plane incision often appeared more like a single-plane incision, as shown in Figure 7. This effect was probably due to the angled shape of the surgical blade. Because the center point of the blade is angled from the plane of the entry incision to create the middle plane of the incision, the edges of the blade trail the center and cannot follow the same trajectory through the corneal tissue as the center. A similar incision progression occurs in creating the angle between the plane of the middle incision and the exit incision.

As noted above, the net effect of the less ideal incision geometry at the edge of the manual full-thickness CCIs versus that of laser full-thickness CCIs was not manifest in a statistically significantly poorer seal for the manual incisions, although it may have contributed to the lower mean IOP values at leakage for the manual full-thickness CCIs than for the laser full-thickness CCIs. For incision geometries that are less square than those tested here, the seal is less secure and more prone to leakage[11,12,21] and the effect of the less ideal geometry at the edge of the manual full-thickness CCI may be more deleterious. This will be the subject of a later study.

Overall, the sealability testing showed that for the range of tunnel length considered, the manual and laser methods were statistically equivalent in sealability but that the laser method produced more consistent wound geometry that was more predictable and would potentially induce less astigmatism postoperatively. These tests compared the quality of the full-thickness CCI seal resulting from a skilled experienced surgeon creating 3-plane full-thickness CCIs manually using a blade versus those that can be routinely created using the laser. Not all surgeons possess the skill level to manually generate accurate 3-plane CCIs, and the quality of the manual full-thickness CCI seal will vary depending on the tunnel length and surgeon's skill. Because laser full-thickness CCI do not rely on the surgeon's manual dexterity level, the results obtained here for laser-generated full-thickness CCIs should be realized by any surgeon using the laser to create full-thickness CCIs.

WHAT WAS KNOWN

- The scientific literature contains studies that quantify the sealability of conventional manual full-thickness CCIs for cataract surgery in in vivo and ex vivo human eyes and other references to sealability of laser full-thickness CCIs in ex vivo human eyes and in clinical practice without quantification of the IOP at which leakage occurs.

WHAT THIS PAPER ADDS

- This study, based on ex vivo human donor globes, found no statistically significant difference in the IOP level at which leakage occurs for manual versus laser full-thickness CCIs intended for cataract surgery, as measured by a standard assessment method. However, for key measures of intended versus actual incision geometry, the laser full-thickness CCIs were closer than the manual CCIs to the target geometry ($P < .001$).

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