Intraoperative Complications of LASIK Flaps Using the IntraLase Femtosecond Laser in 3009 Cases

James A. Davison, MD, FACS; Steven C. Johnson, MD

ABSTRACT

PURPOSE: To report the incidence and management of intraoperative complications while using the IntraLase FS femtosecond laser (Abbott Medical Optics) for flap creation during LASIK.

METHODS: A prospective log of intraoperative flap creation complications using the femtosecond laser was maintained over 3009 consecutive LASIK surgeries from August 2002 through July 2009.

RESULTS: Eleven (0.37%) intraoperative complications occurred. Eight suction breaks occurred, seven of which were treated with reapplication of the laser, the other by completing the side-cut with surgical dissection. One case of incomplete flap creation was treated with surgical dissection. Two cases of adherent flap were treated with reapplication of laser energy and surgical dissection. All surgeries were completed successfully during the same operative session.

CONCLUSIONS: Intraoperative complications during flap creation are minor, infrequent, and can be managed effectively within the same surgical session.

Although LASIK is the most commonly used procedure today for treating a variety of ametropia (myopia, astigmatism, and hyperopia), it also is associated with potential complications, which can be divided into three categories: intraoperative, early, and late postoperative. Some of the most challenging intraoperative complications can be experienced during flap creation prior to excimer laser photoablation. Corneal flaps have been created using mechanical microkeratomes with a series of flap-related complications revealed over the years. Complications include epithelial slides and defects (2.6%), thin flaps (0.08%), partially created flaps (0.3% to 1.2%), buttonhole flaps (0.2% to 0.56%), and free caps (0.01% to 1.0%). A buttonhole and near buttonhole classification and management algorithm have been published as part of a recent series, which demonstrated a 0.59% incidence of those problems with the Hansatome (Bausch & Lomb, Rochester, New York) 160- and 180-µm footplates and 0.50% incidence with the Moria M2 (Moria, Antony, France) with the 90-µm footplate.4

The introduction of femtosecond laser technology in corneal flap creation is promising and aims to provide more predictable flap creation and complication-free procedures.5,6 In the present study, we evaluated flap creation complications using the IntraLase FS femtosecond laser (Abbott Medical Optics, Santa Ana, California) in 3009 eyes that underwent LASIK surgery.

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PATIENTS AND METHODS

A prospective list of intraoperative complications including suction break, incomplete flap, and adherent flap cases was recorded from our initial use of IntraLase femtosecond laser technology. These cases came from a consecutive series of 3009 cases performed by one surgeon (J.A.D.) using one laser from August 1, 2002 through July 31, 2009.

Regular periodic preventive maintenance and fine tuning adjustments of pulse energies and spot and line proximities characterized the use of the IntraLase femtosecond laser. With that regimen in place, a raster pattern was used while pulse energy and spot and line separation optimization were incorporated as updates became available.

The most identifiable laser performance improvements were increases in rate of pulse delivery. Initial laser hardware and software created 10,000 laser pulses per second (10 kHz), leading to a total treatment time of approximately 90 seconds for an 8.5-mm diameter flap. Pulse rate delivery was increased three times in 7 years: to 15 kHz on October 16, 2003; to 30 kHz on March 22, 2006; and to 60 kHz on October 18, 2006. Four respective rates of pulse delivery (kHz) defined four groups of eyes operated: 10 kHz, n=309; 15 kHz, n=1030; 30 kHz, n=247, and 60 kHz, n=1423. The increase from 10 kHz to 60 kHz was accompanied by respective decreases in spot and line separation from 10 and 12 µm to 9 and 9 µm, respectively. The closer proximity allowed raster pulse energy to be reduced from 2.4 to 1.5 µJ. Increased side-cut spot density permitted side-cut energy to be reduced from 6.0 to 1.8 µJ per pulse. The combination of all of these improvements decreased treatment time to approximately 25 seconds.

The target flap diameter was 8.5 mm for use with the Technolas 217z (Bausch & Lomb) excimer laser. In August 2008, it was increased to 9.0 mm for use with the ALLEGRETTO WAVE Eye-Q excimer laser (Alcon Laboratories Inc, Ft Worth, Texas). The surgical planning formula for flap and bed thickness included a default flap thickness of 130 µm, which was decreased to 120 or 110 µm as needed to retain a stromal bed thickness of at least 275 µm (with a preference for 300 µm, if possible), consuming ≤43% of

### TABLE

Demographics of 11 Intraoperative Complications of LASIK With the IntraLase Femtosecond Laser (N=3009)

<table>
<thead>
<tr>
<th>Case</th>
<th>Surgery Date</th>
<th>Age/Sex/Eye</th>
<th>Manifest Refraction</th>
<th>Keratometry*</th>
<th>Corneal Thickness (µm)</th>
<th>Flap Thickness (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4/22/2003</td>
<td>43/F/OD</td>
<td>-4.75 -0.25 × 155</td>
<td>44.62/45.87 @ 080</td>
<td>528</td>
<td>130</td>
</tr>
<tr>
<td>2</td>
<td>2/17/2004</td>
<td>45/M/OS</td>
<td>-4.25 -1.50 × 150</td>
<td>44.30/45.00 @ 065</td>
<td>523</td>
<td>110</td>
</tr>
<tr>
<td>3</td>
<td>6/10/2004</td>
<td>19/M/OD</td>
<td>-2.00 sphere</td>
<td>42.10/42.80 @ 092</td>
<td>595</td>
<td>130</td>
</tr>
<tr>
<td>4</td>
<td>10/6/2005</td>
<td>48/F/OD</td>
<td>-6.50 -0.75 × 030</td>
<td>44.40/45.20 @ 093</td>
<td>616</td>
<td>130</td>
</tr>
<tr>
<td>5</td>
<td>10/27/2005</td>
<td>49/M/OS</td>
<td>-9.00 -1.50 × 166</td>
<td>43.60/45.00 @ 091</td>
<td>566</td>
<td>110</td>
</tr>
<tr>
<td>6</td>
<td>10/27/2005</td>
<td>49/M/OD</td>
<td>-9.25 -1.00 × 015</td>
<td>43.30/44.50 @ 106</td>
<td>566</td>
<td>110</td>
</tr>
<tr>
<td>7</td>
<td>12/8/2005</td>
<td>52/M/OS</td>
<td>-5.00 -1.25 × 130</td>
<td>44.60/45.90 @ 037</td>
<td>543</td>
<td>130</td>
</tr>
<tr>
<td>8</td>
<td>11/30/2006</td>
<td>26/M/OD</td>
<td>-2.75 -0.25 × 101</td>
<td>44.00/44.37 @ 090</td>
<td>540</td>
<td>130</td>
</tr>
<tr>
<td>9</td>
<td>12/4/2008</td>
<td>37/F/OS</td>
<td>-2.25 -0.25 × 150</td>
<td>43.87/44.25 @ 080</td>
<td>600</td>
<td>130</td>
</tr>
<tr>
<td>10</td>
<td>2/26/2009</td>
<td>31/M/OD</td>
<td>-5.25 -0.50 × 120</td>
<td>44.30/44.90 @ 014</td>
<td>526</td>
<td>120</td>
</tr>
<tr>
<td>11</td>
<td>7/23/2009</td>
<td>54/M/OD</td>
<td>+0.50 +1.25 × 010</td>
<td>42.12/43.00 @ 024</td>
<td>594</td>
<td>130</td>
</tr>
</tbody>
</table>

UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, OD = right eye, OS = left eye, SB = suction break

*Manual Bausch & Lomb keratometry on cases 1 to 8, Orbscan keratometry on cases 9 to 11.
surgeries were usually bilateral with the left eye operated first. This convention had been carried over from the days of using early mechanical keratomes, which required different assembly for left and right eyes. In the normal case, the flap bed tissue plane was surgically dissected with the spoon end of a Machat flap lifter AE-2830 (ASICO, Westmont, Illinois) 1 to 3 mm inferior to the end of the superior hinge on the right side. A Slade flap elevator (E0622, Bausch & Lomb) was used to accomplish stromal bed dissection in three passes before lifting.

Suction break cases were compared to a sample of 80 non-suction break cases performed on similar dates with respect to average age, keratometry, and corneal thickness.

### RESULTS

Of the 3009 eyes that underwent LASIK flap creation using the IntraLase femtosecond laser, 11 (0.37%) experienced complications during flap creation. Eight cases of suction break, 1 case of incomplete flap, and 2 cases of adherent flap were recorded (Table).

Suction was lost during the raster pass in 6 cases and during side-cut creation in 2 cases. In the raster cases and one side-cut case, a new suction ring was applied and docked with the same cone and the flap was successfully created during the same session. In the other side-cut case (case 7), suction was lost late, therefore, the flap edge was completed by surgical dissection.

<table>
<thead>
<tr>
<th>Laser Speed (kHz)</th>
<th>Event</th>
<th>Treatment</th>
<th>Postoperative UDVA</th>
<th>Postoperative Refraction</th>
<th>Postoperative CDVA</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>SB 7.0 mm into bed creation</td>
<td>Reinitiate and complete</td>
<td>20/20</td>
<td>Plano sphere</td>
<td>20/20</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>SB 1.00 mm into bed creation</td>
<td>Reinitiate and complete</td>
<td>20/20</td>
<td>+1.00 −0.50 × 090</td>
<td>20/20</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>SB early in side-cut creation</td>
<td>Reinitiate side-cut only</td>
<td>20/20</td>
<td>Plano sphere</td>
<td>20/20</td>
<td>Squeezing</td>
</tr>
<tr>
<td>15</td>
<td>SB 13 seconds into procedure</td>
<td>Reinitiate and complete</td>
<td>20/25</td>
<td>Plano sphere</td>
<td>20/25</td>
<td>Squeezing</td>
</tr>
<tr>
<td>15</td>
<td>Adherent flap</td>
<td>Reinitiate and complete</td>
<td>20/25</td>
<td>+0.25 −1.00 × 165</td>
<td>20/20</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Adherent flap</td>
<td>Reinitiate and complete</td>
<td>20/20</td>
<td>Plano −0.50 × 175</td>
<td>20/20</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>SB 5 seconds remaining in side-cut creation</td>
<td>Complete side-cut with 25-gauge needle</td>
<td>20/25</td>
<td>−0.50 −0.50 × 155</td>
<td>20/20</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>False applanation</td>
<td>Tear new flap edge 1.0 mm from intended</td>
<td>20/20</td>
<td>Plano −0.25 × 146</td>
<td>20/20</td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>SB late into bed creation</td>
<td>Reinitiate and complete</td>
<td>20/20</td>
<td>Plano sphere</td>
<td>20/20</td>
<td>Squeezing</td>
</tr>
<tr>
<td>60</td>
<td>SB 1.0 mm into bed creation</td>
<td>Reinitiate and complete</td>
<td>20/20</td>
<td>Plano sphere</td>
<td>20/20</td>
<td>Arching back</td>
</tr>
<tr>
<td>60</td>
<td>SB mid visual axis</td>
<td>Reinitiate and complete</td>
<td>20/20</td>
<td>Plano sphere</td>
<td>20/20</td>
<td>Squeezing</td>
</tr>
</tbody>
</table>

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The ratios of suction break cases to total cases within a given laser speed were: 0/309 for 10 kHz; 5/1030 for 15 kHz; 0/247 for 30 kHz; 3/1423 for 60 kHz; and 8/3009 (0.27%) for the total series. Comparing the 8 suction break cases to a sample of 80 cases operated on similar dates, respective similarities were observed in average age (41 vs 39 years), female/male ratio (3/8 vs 56% female), average keratometry (44.20 vs 44.17 diopters), and mean corneal thickness (566 vs 557 µm).

In all of the laser reapplication cases, the perimeter of the anticipated ablation pattern was identified by realigning the computer-generated centration rings over the partially created flap. The original diameter and total corneal thickness for flap creation and excimer laser treatment.

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depth were used in all laser reapplication cases and the laser restarted from the beginning of treatment except in the case of suction break that occurred early during side-cut creation (case 3). In that case, the laser was re-started at the beginning of the side-cut mode only.

Surgical dissection was used to create part of the flap border in the case of incomplete applanation, which had resulted in a partially created flap (case 8). In the cases of adherent flap (cases 5 and 6), the original cones had been discarded so new cones and suction rings were used for each eye. Blunt dissection was accomplished using the blunt edge of the Machat flap lifter and countertraction with a 0.12-mm forceps.

In all of the cases, normal anticipated postoperative uncorrected and corrected visual acuities were obtained, no postoperative complications were experienced, and no subsequent retreatments were required (Table).

**DISCUSSION**

In addition to the complexities of computer/laser technology and its expense, and the lengthened time of increased intraocular pressure during the procedure, there have been some reports of clinical disadvantages of LASIK performed with the IntraLase femtosecond laser, which include anterior chamber gas bubble that can block the excimer laser tracking camera; a tendency for thinner flaps to be created, which could make them vulnerable to stretching or tearing; increased incidence of postoperative day 1 slipped flaps; increased interface and side-cut inflammation; increased measured corneal backscatter; late transient light sensitivity syndrome; and rainbow glare.

There also have been reports of equivalency between laser-created flaps versus keratome-created flaps: similarity in the perception of intraoperative flashes etc., predictability of thin-flap dimension, uncorrected vision, and general clinical outcomes.

However, more reports have demonstrated the superiority of femtosecond laser-created flaps: decreased incidence of no light perception during the procedure, increased flap bed depth accuracy, greater consistency, the elimination of buttonhole flaps, decreased epithelial injury, and greater flap adhesion strength. The resultant corneal stromal bed created by femtosecond laser technology has been reported to provide qualitative advantages to LASIK outcome, eg, a planar shape and smoother, more uniform surface with implications for improved visual performance. Additionally, functional performance advantages have been reported: faster visual recovery and better uncorrected visual acuity, improved uncorrected visual acuity and contrast sensitivity, better refractive astigmatic neutrality, decreased higher order aberrations after flap creation but before excimer laser treatment, decreased higher order aberrations after excimer laser treatment, and decreased corneal insensitivity and tear function compromises.

An important intraoperative advantage of the femtosecond laser is the opportunity to minimize flap decenteration by using computer-guided electronic adjustment prior to activation of laser energy. The intraoperative advantage cited in the current study is the ability to re-dock and retreat during the same operative session once a problem such as loss of suction has occurred. In an early study of 1000 consecutive IntraLase LASIK cases, 8 cases of suction break were observed. Two cases experienced suction break in which the femtosecond laser was reapplied on the same surgical day whereas 6 cases were reoperated at a later date. Another study of 28 eyes operated with the IntraLase laser reported one suction break, which...
was treated with a second pass in the same operative session without difficulty or adverse consequences.\textsuperscript{26} A subsequent study found a very low rate of suction break over a large series (3/4772 eyes [0.06%]) among 5 surgeons using the 15- and 30-kHz frequency IntraLase femtosecond laser.\textsuperscript{29} All 3 surgeries were completed by reapplication of the laser during the same operative session. The current study features the 10-, 15-, 30-, and 60-kHz IntraLase platforms with an intermediate suction loss rate (0.27%) but with all surgeries completed during the same session.

Our suction loss and same session retreatment experience was limited but successful. When the raster pass was interrupted, we used a different suction ring but the same cone and initiated the procedure again from the start of hinge creation using the same flap dimensions. This was possible because the essential function of the femtosecond laser was to generate pulses of infrared light, which pass through tissue to create a surgical plane by way of an extremely accurate focus at a preset depth. In case 9, although it took 2 seconds to release the foot switch, laser light continued to create the surgical plane 130 µm below the surface, but only in the area of tissue where applanation was present (Figs 1A and 1B). Although suction was lost, light still penetrated the tissue and had its photodisruptive effect where it could pass through applanated cornea. It did not have an effect where air interrupted the liquid continuum where the glass did not touch the cornea. The light effect was either present at its predetermined focused depth or absent so no partial depth plane was created. It was for this reason that same-session retreatment was successful in cases of lost suction during flap creation.

The IntraLase laser training manual recommends three retreatment options in case of suction break during the raster pass.\textsuperscript{30} The first is the immediate reapplication of the suction ring (using a new one if suction break recurs), docking with the same cone, overlapping the computer-generated centration rings on the border of the opaque bubble layer pattern, and retreatment in the same plane. Rapid reapplication is recommended because the transient opaque bubble layer pattern is required to identify the border of the first raster pass. The second is to return a day or more later and create a second plane at least 40 µm away from the original depth, and the third is to consider excimer surface ablation.

Junctional irregularities at first pass–second pass intersections in same plane retreatments were visible with the operating microscope in a laboratory study using porcine eyes.\textsuperscript{31} Because of these, a second raster pass in the plane of the first was not recommended, especially if the junction occurred in the inferior or central cornea. However, the junctions in those porcine eyes were not visible with ocular coherence tomography. And, they appear to have been clinically insignificant in the achievement of good objective and subjective vision in our cases, even when the junction occurred in the inferior (case 9, Fig 1C) and central cornea (case 11, Fig 2). The junctional irregularities in our cases may have only defined the difference in appearance between the portion of the stromal bed experiencing two raster passes and the portion experiencing one.

In our study, suction loss during early side-cut creation was treated by reactivating the side-cut program and using the same diameter as originally programmed (case 3). Although this was successful, it is contrary to the recommendation of the IntraLase training manual, which recommends flap diameter reduction of 0.5 mm.\textsuperscript{30}

Partial applanation demonstrates that a partial depth surgical plane can be created by the laser treating through liquid on the cornea’s surface (case 8, Fig 3). To prevent this, it is especially important to watch as the applanated edge of the slightly moistened corneal surface spreads. Initial central corneal contact should be made and then maintained using X-Y adjustments so that the widening applanation edge continues to be central and circular. It should not be allowed to flatten eccentrically or only appear to flatten because of contact with fluid contained in the conjunctival cul de sac, as it did in this case.

The features of cases 5 and 6 are intriguing. Both of these patients’ corneas experienced an extraordinarily white opaque bubble layer (Fig 4A). With great effort, only two small pockets could be created before flap dis-

![Figure 2. Case 11. A) An increase in opaque bubble layer (arrow) is visible at the junction where the second raster pass went through the border of the interrupted first raster pass. B) A horizontal junction (arrow) exists between the appearance of the twice-treated superior stromal bed and once-treated inferior bed.](image-url)
section was abandoned. A second complete femtosecond treatment was accomplished in each eye with new suction rings and cones (Fig 4B). The flaps were still adherent but dissection was eventually accomplished requiring 11 minutes for the left eye and 4 minutes for the right eye. A normal range of ease exists with mechanical flap dissection (effectiveness of tissue photodisruption) and opaque bubble layer appearance when using the IntraLase femtosecond laser. Normally, the 3-µm spot diameter of infrared laser energy pulsed in 1 quadrillionth of a second units results in a photodisruptive plasma that produces a cavitation bubble of water and carbon dioxide. If pulse energies are too low or line and spot separation distances too great, flaps may be difficult to elevate. If energies are too high, flaps might be easy to elevate, but there may be more opaque bubble layer and postoperative diffuse lamellar keratitis. In cases 5 and 6, a significantly greater than normal amount of opaque bubble layer was generated, which may have interfered with delivery of an effective photodisruptive effect.

Young age, flatter mean keratometric power, and narrow palpebral fissures have been found to be risk factors for insufficient fixation during microkeratome use. On the contrary, our current study demonstrated similarities in average age, keratometry, and corneal thickness for suction break cases versus non-suction break cases operated with the femtosecond laser.

Complications experienced during IntraLase LASIK flap creation are infrequent, relatively minor, and can be managed effectively in the same operative session.

Figure 3. Case 8. A) The right side of the cornea was not completely appplanation because of excess fluid in the cul de sac. Gas bubbles (arrow) can be seen to escape from the right edge of the raster pattern approximately 1.0 mm central to the intended appplanation line. B) A torn flap edge (long arrow) approximately 1.5 mm central to the intended right side-cut flap edge (short arrow) has been created by blunt surgical dissection using the Machat flap lifter and traction with a 0.12-mm forceps.

Figure 4. Case 5. A) Extraordinary white opaque bubble layer has been generated during the first raster pass. B) Opaque bubble layer during the second raster pass is not visible in the two pockets (long arrows), which had been created by blunt dissection during attempted flap lift after the first pass. Some minimal opaque bubble layer from the first raster pass can still be seen in the inferior cornea (short arrow).

AUTHOR CONTRIBUTIONS

Study concept and design (J.A.D.); data collection (J.A.D.); analysis and interpretation of data (S.C.J.); drafting of the manuscript (J.A.D.); critical revision of the manuscript (S.C.J.)

REFERENCES


