The IntraLASIK Learning Curve

Personal experience with introducing the IntraLase system into clinical practice.

BY DANIEL B. GOLDBERG, MD, FACS

Most refractive surgeons are watching from the sidelines as early adopters of the INTRALASE FS laser (IntraLase Corp., Irvine, CA) report encouraging results.[1-4] As evidence in support of laser keratomes accumulates, more refractive surgeons and patients are likely to prefer its use over that of mechanical microkeratome blades for refractive procedures. I conducted my own prospective study of my first 100 IntraLASIK cases to help illustrate the learning curve with this system. My findings are based on my surgical diary and clinical records.[5]

BECOMING ACQUAINTED WITH THE SYSTEM

Careful preparation can ease the transition from mechanical to laser keratectomy. Because the FDA does not require surgeons to take a course before operating the INTRALASE FS laser, reviewing existing literature and visiting with an experienced surgeon are invaluable learning tools. This laser requires more space than a mechanical keratome. Practitioners may assemble it separately from the excimer laser for two-step procedures, or alongside it if the excimer laser's patient platform can rotate, as can that of VISX, Inc. (Santa Clara, CA). A clinical specialist from IntraLase assists in training the staff and surgeon, and a preoperative wet lab prepares the surgical team.

STUDY GROUP

My staff and I performed IntraLASIK on our first 100 eyes during December 2002 and January 2003. The study involved 51 patients (20 males, 31 females) between 22 and 71 years of age. Eighty-four eyes were myopic, and 16 were hyperopic; 11 of the myopic patients chose monovision. During the learning period, we performed IntraLASIK in over 95% of our total surgeries (one patient chose mechanical keratectomy due to lower pricing, and another patient required surface ablation due to thin pachymetry readings).

PROCEDURE

Centering the Vacuum Ring

Intraoperatively, the INTRALASE FS laser has the potential for improving flap centration compared with mechanical microkeratomes. Centration begins with the surgeon's careful positioning of the suction ring. Because the excimer laser ablation is centered on the pupil, the surgeon may best place the suction ring by accurately marking the pupil's center under the microscope with a Sinskey hook dipped in gentian violet dye. Then, he should align the 90º notches on the suction ring with the center of the pupil before applying suction. After achieving suction, the surgeon docks the IntraLase Delivery System and calculates computerized centration (Figure 1).

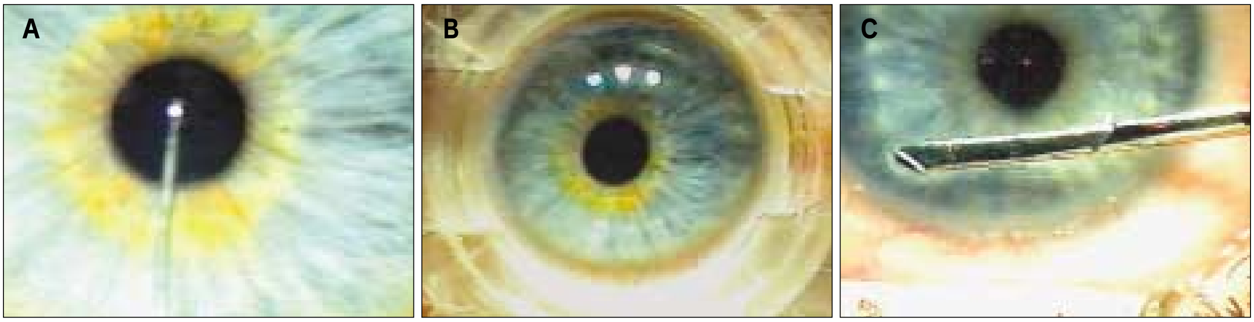

Figure 1. The author marks the center of the pupil (A) and centers the vacuum ring (B). After laser ablation, he separates the flap (C).

Femtosecond laser keratectomy differs significantly from mechanical keratectomy and requires the surgeon to adopt a new set of procedures and skills. Because the suction ring for the INTRALASE FS laser is in place longer than that of a mechanical microkeratome (40 to 60 seconds total time), subconjunctival hemorrhage is more likely to occur. Most laser users recommend reducing this risk by instilling vasoconstrictors preoperatively.

Separating the Flap

Once the laser's computer has confirmed centration, the surgeon administers the femtosecond laser emission and then releases the vacuum. Next, he positions the patient under the excimer laser.

The femtosecond laser emission produces a flap with microadhesions that the surgeon separates from the underlying stromal bed with specially designed instruments (such as a Slade spatula; American Surgical Instruments Corporation, Westmont, IL) prior to performing excimer ablation. Patients may experience slightly more postoperative discomfort with IntraLASIK than with mechanical LASIK procedures due to the different flap and edge anatomy. I have found that applying a bandage contact lens at the conclusion of the procedure and removing it the next day greatly improves patients' comfort and may also prevent early flap slippage.

INTRAOPERATIVE COMPLICATIONS

My staff and I have experienced no major flap complications or epithelial defects with the IntraLASIK procedure. We used minor, infrequent intraoperative difficulties as educational examples. These included a break in suction on the fourth eye, from which we learned that we could reapply the suction ring and proceed with the keratectomy. Also, we had difficulty separating the flap on the 10th eye because the femtosecond energy level was set too low. Our 68th eye experienced a 1-mm flap decentration when the patient strongly squeezed his lids during the application of the suction ring, and this episode reinforced the advantages of accurate centration. Finally, the 90th eye's flap dislocated, but we were able to refloat it into place.

One striking difference we have found between laser and mechanical keratectomy is that the former creates an opaque bubble layer, which results from the cavitation bubbles produced by the interaction between the laser and tissue. These bubbles disappear after 10 to 15 minutes in a two-step procedure, but they can occasionally interfere with excimer laser tracking in sequential treatments. Surgeons can massage away the bubbles with a spatula in order to proceed directly from creating the flap to excimer ablation.

POSTOPERATIVE RESULTS

The eye in which it was difficult to separate the flap developed grade I DLK, but the condition cleared after two hourly doses of topical steroids. The eye that suffered a flap dislocation achieved an excellent visual outcome. Two highly myopic eyes had postoperative microstriae. One eye required refloatation to correct one lost line of BSCVA. Also, four eyes experienced large subconjunctival hemorrhages, and three eyes had interface debris.

We noted a reduced need for punctal plugs (10 eyes) for postoperative dry eye, as well as fewer enhancements (six) compared with mechanical keratectomy (10% to 12%). We did not perform statistical analysis due to the small size of our study, but other studies have also reported reduced postoperative dry eye and enhancement rates with IntraLASIK.[2,4]

Our patients' visual results were excellent. Ten myopic eyes gained one to two lines of BSCVA (Figure 2). One highly myopic eye experienced postoperative microstriae and a one-line loss of BSCVA, but the eye recovered BSCVA after refloatation.

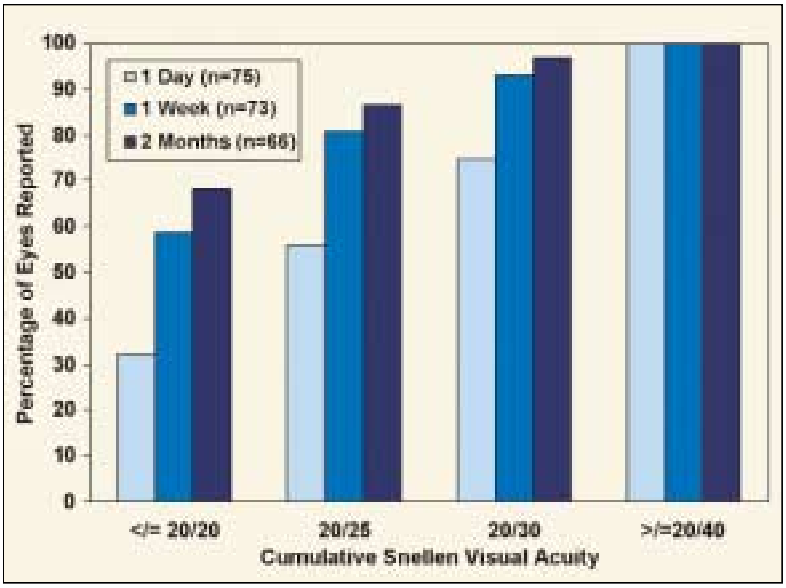

Figure 2. Myopic study eyes achieved these postoperative UCVAs.

TWO-STEP LEARNING CURVE

Based on my surgical diary, I have divided the IntraLASIK learning curve into two steps. Step 1 involves becoming familiar with the equipment in

TABLE 1. FLAP DIAMETER

Attempted Diameter	Achieved Diameter (±SD)
9.00 mm	8.65 mm (±0.25 mm)
9.50 mm	9.26 mm (±0.36 mm)

order to feel confident performing a new procedure. Users of the system will be immediately aware that the overall IntraLASIK procedure takes 3 to 5 minutes longer per eye than conventional ablations. Surgeons may therefore have to adjust the tempo of their surgical procedures and patient flow. New users will easily learn centration, docking, and flap separation with the IntraLase system, and they will likely be impressed by the precision of the flap architecture and the reduced patient discomfort with the IntraLASIK suction ring compared with that of mechanical keratomes.

The second step in the IntraLASIK learning curve is developing new surgical skills. For example, precisely centering the keratectomy facilitates excimer laser centration, contributes to better visual results, and may produce more predictable flap-induced optical aberrations. The applanation cone's 10-mm diameter and the anatomic considerations of the limbus and orbit limit the maximal flap diameter created with the INTRALASE FS laser (Table 1). The system's maximum attainable flap diameter is approximately 9.0 mm including the pocket that collects cavitation bubbles, and approximately 9.5 mm without the pocket. My mean flap diameter is 8.65 mm with the pocket and 9.26 mm without the pocket.

Surgeons must also learn how to recognize and avoid problems such as decentration and loss of suction with the laser. I found that the suction ring was easy to apply and was less likely to move during suction application than a mechanical suction ring. Once the ring is in place, however, the surgeon has a limited ability to maneuver the patient or delivery system. Centration is best accomplished by carefully placing the ring initially and subsequently moving the computer cursor after docking to allow an additional 0.5 mm of centering in 0.1-mm increments.

Finally, the IntraLASIK learning curve requires implementing and optimizing the system's many adjustable parameters. Energy levels must be optimized in each IntraLase unit in order to achieve easy flap separation and smooth ablations. The surgeon is able to adjust the flap diameter and thickness and to create flaps as thin as 80 µm. Also, the hinge location can be moved superiorly, temporally, or nasally (eg, for dry eyes). The flap's width

PERSPECTIVE AFTER 1 YEAR WITH THE INTRALASE FS

I now use the INTRALASE FS laser to create 100% of my LASIK flaps, and I consider the laser to be a more significant advance for LASIK surgery than customized ablations. The laser's enhanced safety profile has been established by more than 100,000 procedures performed nationwide. In nearly 1,000 procedures, I personally have experienced no epithelial defects, buttonholes, or incomplete flaps. Diffuse lamellar keratitis, microstriae, and epithelial ingrowth have been rare. The degree of dry eye symptoms and use of punctal plugs by my patients has decreased, and the number of enhancement procedures I perform has dropped by more than 50%.

Additionally, several recent reports[1-4] have demonstrated that creating flaps with the INTRALASE FS laser results in fewer optical aberrations, better visual results, less dry eye, and greater patient safety when compared with mechanical keratomes. The investigators attributed these advantages to the laser's creation of more precise flap architecture, including planar flap anatomy and dry stromal beds, prior to excimer ablation.

With the INTRALASE FS laser, I am able to place the hinge temporally or nasally, and I can create thinner flaps (which reduce corneal nerve damage) than I can with a mechanical microkeratome. Currently, I use a temporal hinge for dry eye patients and large-diameter (eg, 9.5 mm) flaps for hyperopic patients. My ability with the INTRALASE FS laser to predictably create thin flaps lowers my patients' risk for ectasia and enables me to perform LASIK versus surface ablation more often than in the past in cases of borderline corneal thickness. My preferred flap thickness is now 90 to 100 µm, but I can target 80 µm for thin corneas.

The INTRALASE FS' new 15-kHz engine has reduced my treatment times to between 40 and 60 seconds, and I find it has also facilitated flap separation. Occasionally, mild interface haze associated with photophobia occurs. Karl Stonecipher, MD, of Greensboro, North Carolina, has demonstrated with confocal microscopy the presence of activated keratocytes in these cases and has suggested that therapy with Restasis (Allergan, Inc., Irvine, CA) may be helpful.[5]

I experienced difficulty creating complete stromal separation in two eyes due to air bubbles that escaped through preexisting defects in Bowman's membrane during the flap creation and prior to the side cut. In both cases (one eye had previously undergone PRK, and the other had a previous defect in Bowman's membrane from a prior corneal foreign body), the air bubbles were able to escape through Bowman's membrane, accumulate in the potential space between the applanation lens and the corneal epithelium, and partially block the stromal ablation. I recommend deeper ablation and careful flap separation in such cases.

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and the beveled angle of the flap's edge also adjust for greater flap stability.

CONCLUSION

The advantages of the femtosecond flap include precision with exquisite centration, accurate and thin flap thickness with a planar flap anatomy that results in lower enhancement rates, and more predictable flap-induced optical aberrations, which enable surgeons to treat more eyes with IntraLASIK and possibly improve their results with customized excimer laser ablations. Because the INTRALASE FS laser eliminates incomplete or buttonhole flaps and epithelial defects, both surgeons and patients experience less anxiety. With careful attention to detail, I had a short learning curve with this device. Users of the system can achieve excellent results without significant morbidity. Additionally, I have witnessed a more visible flap edge upon postoperative slit-lamp examination, which may be an advantage in terms of a stronger adhesion of the beveled edge (compared with mechanical keratectomy) that would reduce the potential for subsequent trauma. The disadvantages of the IntraLASIK procedure include increased cost and procedural times. The bottom line, however, is that the INTRALASE FS laser is a better means of creating a LASIK flap. ■

Daniel B. Goldberg, MD, FACS, is Associate Clinical Professor of Ophthalmology at the Drexel University School of Medicine in Philadelphia. He does not hold a financial interest in any of the companies or products mentioned herein. Dr. Goldberg may be reached at (732) 219-9220; dangold@att.net.

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