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Z-LASIK in Practice

Two years of clinical experience with the FEMTO LDV Surgical Laser.

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Z-LASIK in Practice

A new kind of femtosecond laser technology is impressing surgeons with its ease of use, tissue preservation, reliability, utility, and myriad other attributes. In this monograph, respected surgeons from Europe and the United States share their experience regarding the FEMTO LDV femtosecond surgical laser (Ziemer Group AG, Port, Switzerland). Those interested in more information about the laser can find it at http://www.ziemergroup.com.

I adopted femtosecond laser technology early in its development, beginning with the 15-Hz IntraLase FS laser (Advanced Medical Optics, Inc., Santa Ana, CA). I have helped advance this modality since those early days by actively working with the IntraLase user group to help other surgeons reduce the negative effects of their devices. We found that we could overcome most of the laser's problems by reducing the energy it delivered per spot. When the IntraLase was perfectly tuned, we could lower its energy to approximately 1 µJ. At this level, the other surgeons and I saw a significant improvement in the consistency of our refractive results without the inflammation that the high-energy spots induced.

OBSTACLES TO ADVANCEMENT

Unfortunately, continued efforts to advance this device's utility as a flap maker and beyond seem to be limited by the complexity of its optics and amplifiers as well as ongoing issues with reliability. The IntraLase has two prominent, irresolvable problems. First, its long focal distance from the eye creates an elliptical plasma and large cavitation bubbles that sometimes inject gas into the deep stroma. Because the laser's dissecting effect depends on lamellar expansion in the same plane as the center of the plasma, this gas interferes with the surgeons' ability to lift the flap in the area affected by this phenomenon, which has been termed *opaque bubble layer* or *OBL*. The IntraLase's high-energy spots cannot be overlapped without overheating ("cooking") the stroma and causing interstitial keratitis (Figure 1), which again complicates dissections. The act of lifting places large amounts of stress on the flap, and the OBL in the stromal bed blocks the excimer laser's tracker and tissue ablation. In fact, further experience has shown that, if an OBL occurs centrally, it increases the probability of an undercorrection. An OBL in the superior zone most commonly causes superior coma.

The IntraLase's second biggest problem is that its high-energy infrared laser can produce a light-sensitivity syndrome in approximately 10% of patients. Lowering the device's energy output to 1 µJ reduces but does not eliminate the symptom. Also, the same number of patients report seeing a chromatic halo effect, although many of them do not mention this phenomenon unless they are asked about it. Ronald Krueger, MD, from the Cleveland Clinic in Ohio reported that the incidence of chromatic halos seemed to be related to alignment issues inherent in the IntraLase.[1]

In July of 2007, I replaced my IntraLase FS laser with the newest system from Ziemer Group AG (Port, Switzerland), called the FEMTO LDV femtosecond surgical laser. Let me explain my decision and describe my early experience with the LDV.

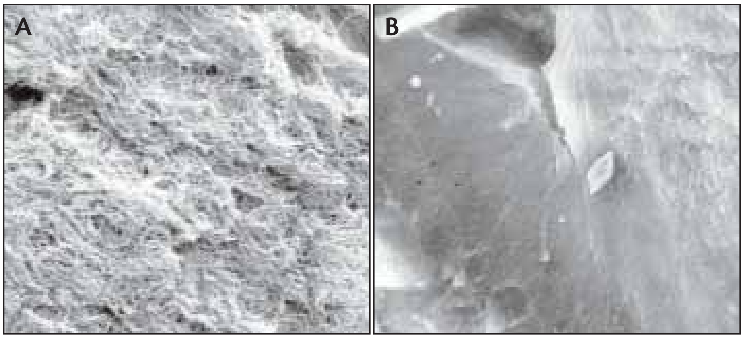

Figure 1. Compared with the FEMTO LDV (A), the IntraLase's high-energy, large-spot laser beam "cooks" the stroma (B), causing inflammation.

HISTORY

Professor Holger Lubatschowski (featured on page 4), was investigating femtosecond laser technology at the Hannover Laser Center (Laser Zentrum Hannover e.V.), a think tank at the University of Hannover, in Germany. Professor Lubatschowski's research focused on the use of nonamplified cavitational energy in the nanojoule range by positioning the laser's optic 2 mm above the eye. The high numerical aperture of his optical design (which Ziemer Group AG adopted to create the FEMTO LDV) focuses the laser beam to approximately 2x2x2 µm. This range delivers short pulses of energy at a rate of several megahertz and generates small cavitation bubbles in the water at the plane of dissection. The energy would be too low to dissect the tissue with single spots, so the system overlaps the spots several times as it progresses in a so-called *fast phase*. Because the laser does not leave "tissue bridges" between the spots, it dissects the cornea deeply and smoothly at any depth. Watch my video on Eyetube.net of the LDV cutting at 500 µm deep, and note the smooth stromal surface (http://www.eyetube.net/videos/default.asp?rumevo).

The FEMTO LDV was cleared for clinical use in the United States in 2006 and became commercially available in the spring of 2007. Because I believed in the physics of this device, I purchased my first LDV in August 2007. Due to my extensive experience in helping to develop the IntraLase, Ziemer Group asked me to become a medical monitor for the LDV in North America.

EXPERIENCING A DIFFERENT KIND OF LASER

My experience with the FEMTO LDV and Ziemer Group AG has been very gratifying. The company's representatives have used surgeons' recommendations to proactively modify the laser. If we had published a similar report about the IntraLase FS 2 years after its introduction, we would have been discussing severe problems and how we were managing them. In comparison, the LDV's learning curve has primarily involved minor issues such as centration and increasing the laser's energy and pass speed.

MEASURABLE IMPROVEMENTS

The LDV's unique method of overlapping low-energy spots means easy flap lifts, less manipulation, and no OBL. These factors should translate into quicker recovery and less skew in surgeons' results. In the current FEMTO LDV user group, the improvement in visual outcomes is immediately evident in better 1-day acuities, to which the authors in this monograph will attest. In fact, approximately 70% of my patients who undergo flap formation with the LDV have 1-day UCVAs of 20/50, and 30% of them achieve 20/12.5. These data represent a marked improvement over my outcomes with the IntraLase, which tended to take longer to stabilize.

FLAP CONFIGURATION AND THICKNESS

The LDV shines in its ability to make thin, yet safe and reproducible LASIK flaps. It can create sub–100-µm cuts without risking buttonholes and gas breakthroughs. I personally prefer creating 110-µm flaps using the laser's 110-µm InterShield spacer. My average flap thickness (as calculated with intraoperative subtraction pachymetry) is 104 µm. However, I have made a number of flaps of 90 µm and thinner without complications using the LDV's 90-µm spacer.

LOOKING AHEAD

In my second year of experience with the FEMTO LDV, I anticipate the development of a new laser head that can be focused up and down inside the cornea to cut customized shapes and edges. This upgrade should negate the only remaining perceived reason to own a high-energy femtosecond platform. Furthermore, other surgeons continue work to expand the LDV's utility beyond creating perfect flaps. For example, Theo Seiler, MD, PhD, and his team in Zurich, Switzerland, are seeing promising results with creating corneal tunnels for the insertion of rings and segments (see page 6). Soon, we may even have the capacity to remove lenticles through small laser incisions. In the meantime, I believe there is no better refractive surgical advancement than the stromal bed surface that the LDV creates. Quite simply, it does not interfere with the excimer laser's intended correction, thereby enabling more consistent refractive results.

Thanks to Professor Lubatschowski and Ziemer's engineering excellence, the FEMTO LDV's worldwide installations are currently exceeding the company's expectations, and the laser seems well on the way to establishing itself as a universal tool for precision microsurgery. I see refractive and corneal surgery's future in full dissections created by minimal-energy, overlapping spots delivered at megahertz speeds. No inflammation, and no OBLs. Only the LDV can achieve these goals, and its future looks bright!

—Richard B. Foulkes, MD

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1. Krueger RR, Thornton IL, et al. Rainbow glare as an optical side effect of IntraLASIK. *Ophthalmology.* 2008;115(&):1187-1195.

State-of-the-Art Technology

What makes the FEMTO LDV different from other femtolasers.

BY HOLGER LUBATSCHOWSKI, PHD

The first commercially available femtosecond lasers for tissue processing were *oscillator-amplifier* systems, a term that denotes a two-step process. These lasers begin the cutting process by generating short femtosecond pulses. However, their energy expenditure is too low to achieve photodisruption or photoablation, so an amplifier strengthens the pulses to the desired degree of pulse energy, in the range of microjoules. This amplification step enables the cupping of the corneal tissue. These two-step systems had two primary disadvantages: they were expensive and complicated to operate. Their calibrations were very sensitive to the environment, such as changes in temperature and humidity and to any physical movement of the machine. This is why the original oscillator-amplified lasers were not usable out of the box; each one purchased by a physician had to be set up and calibrated by an engineer. Today's oscillator-amplified femtosecond lasers have undergone many iterations of development and now are what designers refer to as *plug-and-play*. They are designed as so-called industrial laser systems and do not have the same sensitivities as their predecessors.

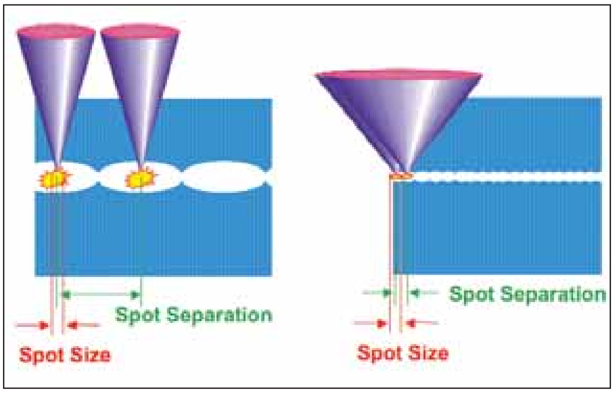

Figure 1. Femtosecond laser tissue interaction can be classified into two groups. In the high-pulse energy group (left), the cutting process is driven by mechanical forces, which are applied by the expanding bubbles and disrupt the tissue. This cutting process is efficient but less precise, because the radius of disrupted tissue is larger than the laser spot size. Hence, the spot separation of the scanned laser pulses can be larger than the spot diameter. Using low-pulse energies (right), the cutting process is confined by the focal spot size of the laser pulse. As a consequence, more pulses are needed to cut the same area. To keep the total operation time the same, higher pulse repetition rates are required.

NEW FEMTOSECOND TECHNOLOGY

Today's femtosecond laser's oscillator technology has advanced beyond the point of needing an amplifier. Engineers of the FEMTO LDV femtosecond surgical laser (Ziemer Group AG, Port, Switzerland), for example, have strengthened the focus of the optics and increased the laser's repetition rate in order to decrease the threshold for photodisruption. In simpler terms, the laser uses less energy per pulse to cut the tissue, in the range of tens of nanojoules. These advancements eliminated the need for an amplifier, thus reducing the number of components of the original FEMTO laser and making this newest version simpler to operate as well as more compact, affordable, and reliable. Furthermore, because it delivers lower pulses of energy, the FEMTO LDV laser is much more gentle on the corneal tissue that surrounds the ablation site. The acoustic transients the laser creates quickly dissipate into sound-waves, unlike the residual stress transients generated by

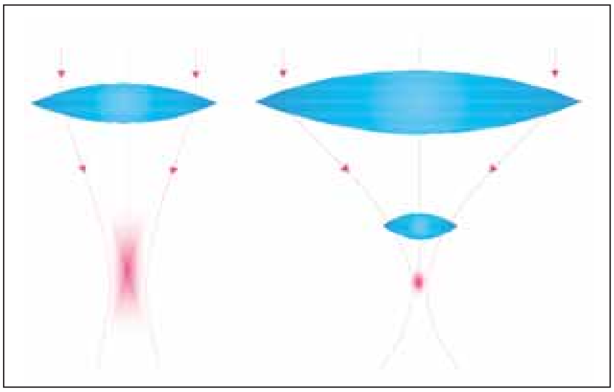

Figure 2. The focal spot size depends on the optic's focal length and the diameter of the original laser beam or the focusing lens, respectively. The relationship of the lens' diameter to the beam's focal length is the numerical aperture (NA) of the optical system. Small focal spot sizes can be achieved by either large lenses and long working distances or by smaller lenses with shorter working distances.

Nd:YAG and excimer lasers, which are high enough to cause possible mechanical stress, even at a larger distance from the eye. The amount of tissue disruption correlates with the strength of each laser's pulse energies. Thus, the oscillator systems that use less energy cause less tissue disruption and are a little more precise than other types of lasers, but they also use a smaller focal point and therefore must deliver many more treatment pulses to photoablate the same sized area (Figure 1). Consequently, lasers with small focal points require longer ablation times or else higher rates of repetition. Thus, oscillation femtosecond lasers have repetition rates in the megahertz regime, whereas amplifier systems have repetition rates in the range of kilohertz.

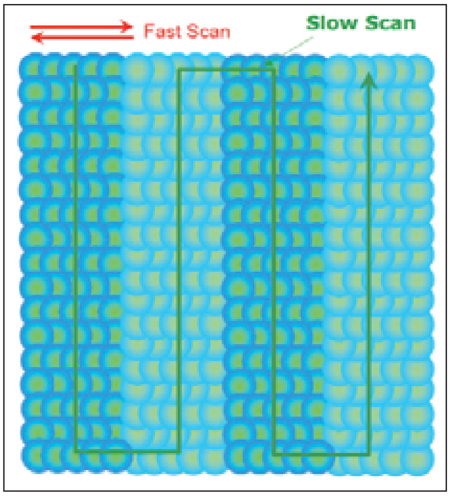

Figure 3. The LDV system uses a single internal unit to generate a line of multiple pulses in a process called *fast scan*. This line has a length of less than 1 mm and a diameter of a single laser spot, which is less than 1 µm. In contrast to the amplified lasers, where the ablation zone is scanned spot by spot, the LDV's scanning delivers the ablation zone line by line, in a process called *slow scan*.

High Numerical Aperture

The focal spot size of a laser's beam depends on two factors: the optic's focal length (the shorter the focal length, the smaller the focus) and the diameter of the original laser beam or the focusing lens, respectively (the larger the original beam's diameter, the smaller the focal spot size). The relationship of the lens' diameter to the beam's focal length is the numerical aperture (NA) of the optical system (Figure 2). A high NA denotes a large-diameter lens and/or a short focal length. If you want the beam's focus to be very small, you have to use a very short focal length, which necessitates a short working distance from the eye. A larger, more comfortable focal length requires a large-diameter lens. All femtosecond lasers that work with an amplified system have relatively low NA, in the range of 0.3 (the diameter of the lens over the focal length), but they have a working distance of several centimeters. The FEMTO LDV laser has a very large NA and a very small focal volume. Its focal length is about 1 mm, which is very close to the eye. For this reason, all of the laser's optics have to be contained in the headpiece that delivers the laser pulses to the patient's eye.

Scanning Time

The typical amplified lasers deliver their pulses line by line in either a horizontal or a spiral pattern, each within a circular ablation zone. This pattern is achieved by two moveable mirrors that are controlled by a motor. The state-of-the-art approach for controlling the ablation pattern is with pulses delivered with a 10- to 200-kHz repetition rate. The system delivers one pulse every 5 to 100 microseconds, which allows it time to control every single pulse. A megahertz repetition rate leaves only nanoseconds between each pulse, and no scanner technology is fully able to handle such a high repetition rate. The LDV system uses a single internal unit to generate a line of multiple pulses. They are delivered so quickly that the naked eye cannot distinguish individual pulses; the operator sees only a line of ablation inside the cornea. Ziemer calls this technology of generating a line so quickly *fast scan*. This line has a length of less than 1 mm and a diameter of a single laser spot, which is less than 1 µm. In contrast to the amplified lasers, where the ablation zone is scanned spot by spot, the LDV delivers the ablation zone line by line. This process is called *slow scan* (Figure 3).

CONCLUSION

The pure oscillator concept of the LDV offers a small, compact, and robust laser device and makes it the only femtosecond laser that is truly mobile. Another important feature of the oscillator concept is its low-pulse energy, which reduces the size of the cavitation bubbles formed during the cutting process. The smaller bubbles allow surgeons to position the cut more precisely. Thus, the LDV seems to be the most suitable system for creating ultrathin flaps.

On the other hand, the downside to the use of low-pulse energy and precise cutting characteristics is the limited cutting geometry. Cutting only in one layer restricts the LDV to cutting flaps as well as pockets for corneal implants. It remains to be seen if Ziemer Group advances the LDV's handpiece with the freedom to perform full three-dimensional cutting patterns for keratoplastic applications or even to make full lenticule extractions, as shown with the Visumax system (Carl Zeiss Meditec AG, Jena, Germany). ■

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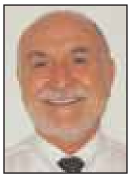
Z-LASIK With the FEMTO LDV

Two-year experience with this state-of-the-art femtosecond laser technology.

BY THEO SEILER, MD, PHD, AND TOBIAS KOLLER, MD




Through the years, we have tried nearly every type of microkeratome for making corneal flaps. Now that we have femtosecond laser technology in the form of the FEMTO LDV surgical laser (Ziemer Group AG, Port, Switzerland) at our disposal, we like to say that we use it in every surgery in which flap thickness matters. We have had this laser for approximately 2 years and have performed hundreds of procedures with it. We find the LDV adept at cutting consistent, well-formed flaps in all kinds of eyes, including those with irregular corneas. The following is a review of our experience with this laser in comparison to other keratome devices we have used.

RELIABILITY

One of the worst obstacles a refractive surgeon can encounter is a device's technical failure that forces him to reschedule a patient's surgery. Aside from the inconvenience to the patient and the potential detriment to the practice's reputation, having to reschedule a patient's surgery costs the surgeon and his staff a considerable amount of time and money. The IntraLase FS laser (Advanced Medical Optics, Inc., Santa Ana, CA) has a history of requiring frequent servicing and adjustments. We wanted a femtosecond laser that operates like a Volkswagon: easy to use and extremely reliable. Since we have installed the FEMTO LDV laser, it has not experienced any downtime, and it is so easy to use that our technicians actually prefer it to a mechanical microkeratome, which was not the case with the IntraLase FS.

FLAP THICKNESS

In general, femtosecond lasers produce a much more reliable flap thickness compared with mechanical microkeratomes. We have experienced cases with these microkeratomes in which we could not proceed with the excimer ablation because the resulting stromal bed was too thin. This issue never occurs with the FEMTO LDV, because its distribution is so tight. Our standard flap thickness is 110 µm, and we have never cut beyond ±10 µm of a flap's target (Figure 1). Our standard of deviation is ±8 µm, and Bojan Pajic, MD, of Olten, Switzerland, reports that his is ±3 µm with the LDV. No other keratome device today has a tighter range.

We do not like to make flaps thinner than 100 µm (so-called *sub-Bowman's cuts*), because we feel they are less safe. These ultra-thin flaps develop small striae too easily, sometimes just by the patient squeezing his eyelid shut too tightly. The striae do not compromise the patient's visual acuity, but having to smooth them out at the slit lamp the next day detracts from the patient's satisfaction with the procedure. Ultra-thin flaps are also subject to tearing during relifts, as Jerome Vryghem, MD, of Belgium has reported.[1] Remember that the epithelium is approximately 60 to 65 µm. So, if a flap is 90 µm, the residual stroma will be only 30 µm.

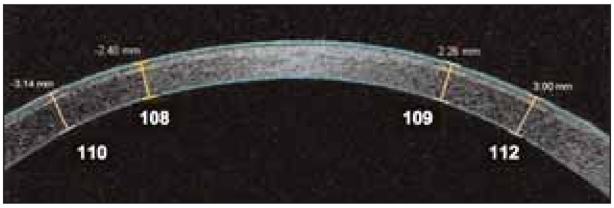


Figure 1. At 1 month after LASIK, the thickness of a flap (as measured by OCT) was 109 ±3.7 µm (range, 101 to 116 µm).

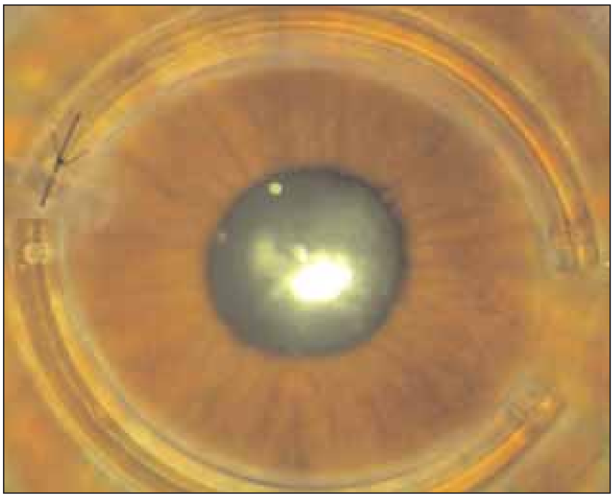


Figure 2. The postoperative view of intrastromal rings implanted in channels created with the FEMTO LDV laser.

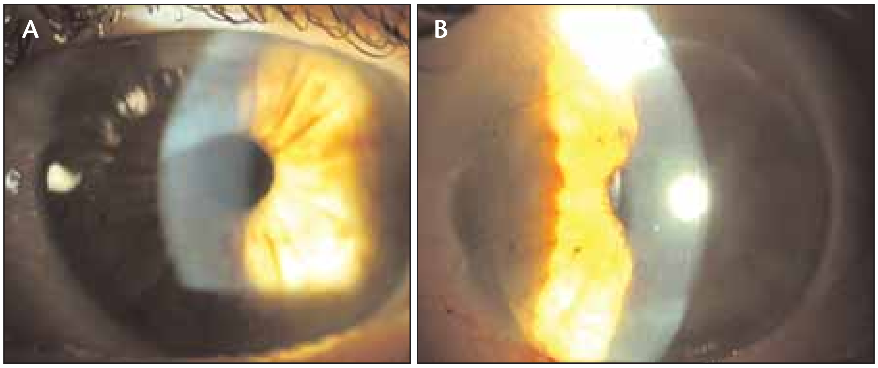


Figure 3. Lamellar rotation keratoplasty in one eye with herpes keratopathy (A and B). The cut with the LDV was 250 µm deep.

PATIENT RECOVERY

Although some surgeons place a lot of importance on the strength of the laser's energy delivery, we believe the truer measure of a laser's efficacy is how violently it disrupts corneal tissue. Therefore, it is clear that a laser with a low energy expenditure per pulse (such as the LDV) creates less mechanical trauma to the cornea compared with a laser with a high output of energy per pulse (such as the IntraLase). Thus, flap healing and visual acuities after FEMTO LDV cuts are quite comparable to what we have seen with the latest mechanical microkeratomes. All of our patients achieve UCVAs of between 20/20 and 20/25 on postoperative day 1. We have not seen any incidence of transient light sensitivity, as some of our IntraLase patients have experienced, and LDV eyes have much less redness and bleeding in the conjunctiva. We attribute these superior outcomes to the LDV's oscillator technology and smaller cavitation bubbles, which seem to preserve corneal tissue better than other devices.

CHALLENGING CASES

We are especially pleased with how well the LDV's femtosecond technology treats challenging eyes compared with a mechanical microkeratome. Eyes with very high or very low keratometric readings and those that have undergone previous keratoplasties, radial keratotomy, or astigmatic cuts are at greater risk for buttonholes and other flap complications with mechanical microkeratomes. An applanating laser system cuts these types of corneas easily and consistently. Our only caveat is that scar tissue (from radial keratotomy, for example) is slightly more challenging for the LDV to cut through, so we lift the flaps in these eyes a little more carefully. Overall, however, the LDV allows us to approach these cases with much more confidence.

EXPLORING OTHER INDICATIONS

The FEMTO LDV is much more than just a flap maker. We were the first surgeons to perform lamellar keratoplasties with this machine, and we have had good success with this application so far. We use the LDV's standard equipment. For deep lamellar keratoplasties, we make the surface parallel cuts as deep as 450 µm.

Additionally, 6 months ago, we began using the LDV to cut channels for intrastromal rings. We are still fine-tuning this technique, but it seems very promising (Figure 2). The procedure requires a special program on the laser, but we do not alter the laser's head in any way. We are currently making incisions at 350 to 450 µm, and Ziemer Group is now developing optimized hardware and software for these kinds of lamellar corneal surgery applications.

CONCLUSIONS

What we like best about using the FEMTO LDV laser, particularly in challenging cases, is the peace of mind it gives us. Since we began using it, our complication rate with this laser has been low and minor (ie, flaps that are too small). Most problems with this laser are issues with applanation and manipulating the flap, but they do not include the disadvantages associated with other femtosecond lasers such as transient light syndrome or diffuse lamellar keratitis. Furthermore, although certain eyes (deep-set eyes and hyperopic eyes with very small lid fissures) can be difficult to capture with the suction ring, the LDV will not let you proceed without adequate suction, which is a nice safety feature. Finally, we appreciate the ability to do things with thin flaps that were not previously possible due to the limits of corneal thickness as well as abnormal corneal curvatures. ■

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1. Vryghem J, Assoiuline M, Cummings AB, et al. Complications in LASIK: Prevention and Management. Paper presented at: The XXVI Congress of the ESCRS; September 13, 2008; Berlin, Germany.

Properties of Flaps Created With the FEMTO LDV

A review of an extensive clinical series.

BY JUHANI PIETILÄ, MD

I have had the FEMTO LDV femtosecond surgical laser (Ziemer Group AG, Port, Switzerland) since July 2007—one in both of my practice locations, Tampere and Helsinki, Finland. In addition to these two clinical locations, my staff operate a mobile LASIK surgical unit, in which they travel to surgery centers all along the eastern coast of Finland.

To date, I have performed 1,020 flap procedures in Tampere with this laser, and I have taken careful and extensive measurements in all of these surgeries. This article discusses my experience and data with the FEMTO LDV.

A MOBILE LASER

The FEMTO LDV is the only portable femtosecond laser, and this “plug-and-play” capability allows us to treat patients remotely. We transport the FEMTO LDV and our excimer laser (the WaveLight Concerto; Alcon Laboratories, Inc., Fort Worth, TX) in a van that has a lift. Transporting the LDV does not damage it or interfere with its performance in any way. It rests on a soft, fixed bed inside the van, and we can wheel this bed into any building (provided that there is an elevator if the surgical suite is not on the first floor). One of our technicians is trained in using the laser’s calibration instruments, which includes a stereoscope that can readjust the optics of the machine, if necessary. Once the laser is inside the surgery center, our technician can get it set up and operational in 15 to 25 minutes. The process is very easy.

STANDARD PROCEDURE

My standard LASIK procedure with the FEMTO LDV begins with a preoperative examination with the Allegro Oculyzer topographer and the Allegro Analyzer wavefront aberrometer (both manufactured by Alcon Laboratories, Inc.). With the FEMTO laser, my standard flap parameters include a superior hinge, a thickness of 90.0 µm (± 5.1 µm), and a diameter of 9.12 mm (Table 1).

> “The FEMTO LDV produces flaps with a very small deviation in thickness compared with different types of microkeratomes.”

Then, I perform the excimer ablation with the Concerto laser at an energy delivery rate of 500 Hz. Even with these thin flaps, patients’ recovery time is fast. Most patients see at 20/25 to 20/20 UCVA within 2 hours postoperatively.

I have conducted flap-thickness measurements in every corneal refractive surgery since January 2001. I take at least three measurements in each case, so I now have compiled more than 10,000 measurements. I try to take these measurements at exactly the same time in each case, unless there is a complication that causes the cornea to dry out, which affects the measurement. Otherwise, I open the eye with the speculum, which takes exactly 10 seconds. Then, using the Tomey SB 3000 (Tomey Corporation, Nagoya, Japan), I measure the cornea three or four times. Approximately 2 to 3 seconds after making the cut and lifting the flap, I take three to four measurements of the bed. I try to use very careful methodology. Following are the early results of my most extensive clinical series.

CLINICAL LASIK SERIES

As of September 6, 2008, I have used the FEMTO LDV to make 90.0-µm flaps in 1,020 eyes undergoing primary LASIK surgery. I have experienced no major complications and only a small number of minor ones, and importantly, I have been able to fully complete each surgery. I have 1-month results for 777 of these eyes (701 myopes and 76 hyperopes).

According to pachymetry with the Tomey SP 3000, the flap thickness in the right eyes was 90.0 ±5.5 µm, and in the left eyes, it was 90.1 ±4.6 µm. Sixteen flaps were

TABLE 1. ZIEMER FEMTO LDV FLAP RESULTS
• Average flap diameter: 9.12 mm
• Standard deviation: 0.20 mm
• Range: 8.0 to 10.0 mm
• Average hinge length: 4.0 mm
• Standard deviation: 0.40 mm
• Range: 2.0 to 5.2 mm

thicker than 100 µm (the thickest was 107 µm), 32 flaps were between 71 and 80 µm, and one flap was thinner than 70 µm (67 µm). (I was able to lift and reposition the extremely thin flap without tearing or even wrinkling it, and I consider this a testimony to the machine's efficacy.) The average flap diameter was 9.12 mm (range, 8.0 to 10.0 mm), with a standard deviation of 0.20 mm. The length of the flaps' hinges was 4.0 mm on average (range, 2.0 to 5.2 mm), and the standard deviation was 0.40 mm.

REFRACTIONS

In the myopic surgeries, the mean refraction was -4.65 ±2.50 D (-0.25 to -17.00 D). The mean preoperative astigmatism was 0.60 D (0 to 4.25 D). The deviation from the target was as follows: ±0.25 D in 561 eyes (80%); ±0.50 D in 670 eyes (96%); and ±0.75 D in 692 eyes (99%). The average postoperative astigmatism was 0.12 ±0.23 D (0 to 1.50 D, and more than 1.00 D in only two eyes).

In the hyperopic eyes, the mean refraction was +2.61 ±1.60 D (+0.25 to +7.00 D), and the mean preoperative astigmatism was 0.70 D (0 to 3.50 D). The deviation from the target was as follows: ±0.25 D in 52 eyes (68%); ±0.50 D in 67 eyes (88%); and ±0.75 D in 72 eyes (95%). The average postoperative astigmatism was 0.23 ±0.31 D (0 to 1.50 D, and more than 1.00 D only in one eye).

Lines of Acuity

Nearly all the myopic patients experienced the same change in Snellen lines postoperatively. At 1 month, there were no lines lost; patients either had no change (417 eyes) or they gained one or two lines (150 and two eyes, respectively) (Figure 1). The hyperopic eyes (65 total) performed similarly; there were no lines of acuity lost, but six eyes gained one line and two eyes gained two lines (Figure 2). As many surgeons know, it is more common to gain lines of acuity in hyperopic LASIK corrections.

Flap Complications

Lifting normal flaps requires three steps in a fluid motion. The surgeon inserts the spatula at 11 o'clock and makes sure that it exits at 1 o'clock. The instrument must extend beyond the pupillary area so that the entire flap is lifted. Then, the surgeon sweeps the spatula forward, toward its periphery, to separate the tissue. Finally, using the same instrument, he pushes down at the 6-o'clock position and folds the flap back at 12 o'clock.

I noted complications in 166 of 787 eyes (21.1%). Most of these complications were bleedings (100 eyes, 12.7%). Smaller flap diameters can sometimes control bleeding, but eyes that have neovascularization due to contact lens wear will inevitably bleed. However, it is a minor complication that always clears up.

In the last 250 eyes, I have had only one incidence of epithelial defect, and since this series, my rate of decentered flaps has decreased to one in 200 cases. These statistics indicate a learning curve with the LDV. With this laser, a decentered cap with a small diameter (8.0 mm) is considered a true free cap. However, these free caps can be preserved if the surgeon does not lift them completely off the eye for the ablation. If he inserts a spatula or other instrument underneath the flap at 11 o'clock so that it emerges at 1 o'clock and then folds the cap back as if it were hinged, then it will stay in place while

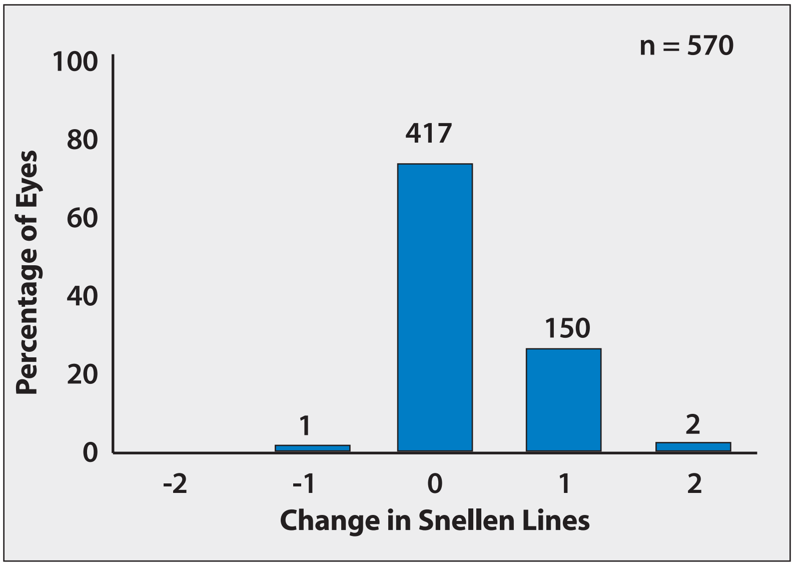

Figure 1. This graph shows the lines of acuity gained or lost by myopic eyes that underwent Z-LASIK with the LDV.

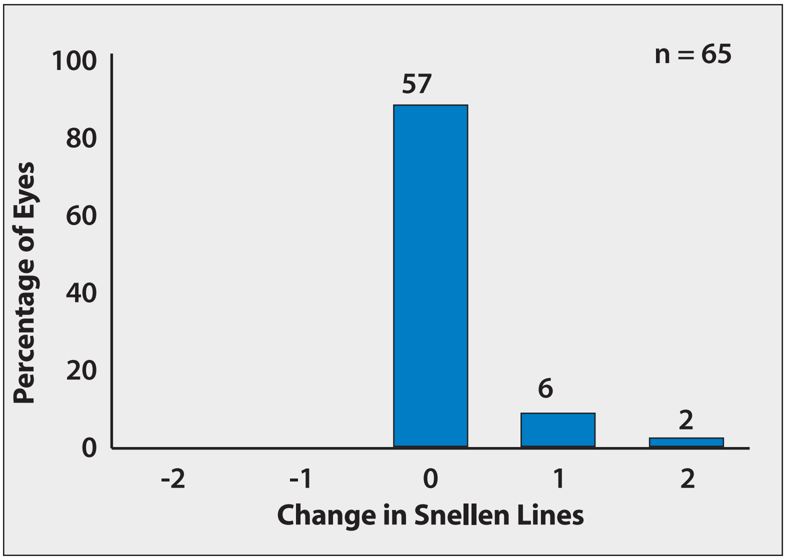

Figure 2. This graph shows the lines of acuity gained or lost by hyperopic eyes that underwent Z-LASIK with the LDV.

he performs the ablation, and he can reposition it fully afterward.

Buttonholes and pseudobuttonholes can occur if the LDV's energy level is not 100% during the application. This is why the energy must be checked prior to each surgery. Most pseudobuttonholes occur on the nasal side of right eyes and on the temporal side of left eyes; in other words, toward the endpoint of the laser's cut.

The only problem I encountered under the epithelium was an opaque bubble layer at 12 o'clock. I cannot explain why it happens, although I have also experienced it with the IntraLase FS laser (Advanced Medical Optics, Inc., Santa Ana, CA). With the FEMTO LDV, however, my total incidence is only three cases in 1,020 eyes.

I experienced three flap displacements with the LDV, which occurred during the immediate postoperative period between the time that I removed the patients' postsurgical contact lenses at the slit lamp and sent them downstairs to the pharmacy. I did not have to take the patients back to the OR to fix their flaps, however. My corneal marks were still visible, so I easily repositioned the flaps at the slit lamp, and they did not move again. Flap displacement is much more rare with the femtosecond laser than with a mechanical microkeratome because of the angle of the cut. Mechanical microkeratomes approach the cornea at approximately a 26° angle, but a femtosecond laser cuts at 90°. Moreover, flap displacements always occurs in eyes that are very dry.

Again, none of these complications prevented me from proceeding with the planned corneal ablation.

SECONDARY OPERATIONS

I have found the FEMTO LDV to be ideal for creating flaps in postsurgical eyes, because its low energy delivery and small cavitation bubbles do not interfere with the initial surgical results. I have amassed a small series of these cases (49 eyes [38 myopes and 11 hyperopes]) that is composed of 28 post-LASIK eyes, 16 post-PRK eyes, three post-PKP, two post-CK, and two post-LASEK eyes. All these operations took place at least 6 years after the initial surgeries. The average flap thickness was 92.0 ±8.3 µm, and flap healing was excellent. The deviation from the target refraction was ±0.75, or 96%. The hyperopic eyes had a mean refraction of +2.66 ±1.60 D (+0.25 to +5.25 D) and a mean astigmatism of 1.80 D (0 to 7.50 D).

For all the myopic eyes, the mean refraction was -1.35 ±1.10 D (-0.25 to -5.25 D), and the mean astigmatism was 0.60 D (0 to 2.25 D). The deviation from the target was ±0.25 D in 32 eyes (65%), ±0.50 D in 40 eyes (90%), and ±0.75 D in 47 eyes (96%). The average induced postoperative astigmatism was 0.27 ±0.48 D (0 to 2.50 D, and more than 1.00 D in only two eyes).

CONCLUSIONS

The FEMTO LDV produces flaps with a very small deviation in thickness compared with different types of microkeratomes. My best standard deviation with mechanical microkeratomes has been ±11 µm. Also, the FEMTO LDV creates flaps of the same thickness between the right and left eyes, whereas mechanical microkeratomes always create 7- to 10-µm thinner flaps in the left eye.

I want to stress that the FEMTO LDV has a quick learning curve. Recently, I was teaching two surgeons how to use it. One physician had mastered the laser after six eyes. The other surgeon had never cut a LASIK flap, not even on a pig's eye. He cut his first two flaps with the LDV perfectly. Of course, new adoptees should begin with easy eyes and develop their skill and experience for more challenging cases. ■

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Visual Outcomes With the Femto LDV

How my clinic benefited by adopting the Ziemer femtosecond laser.

BY CHARLES MOORE, MD

I purchased the FEMTO LDV femtosecond surgical laser (Ziemer Group AG, Port, Switzerland) in January 2008. The solid-state technology appealed to me because it fit my workflow like a traditional microkeratome. The cavitation bubbles disappear as soon as the flap is lifted, so I do not have to wait to do the ablation. Therefore, the total treatment time per patient is only a few minutes more than with a microkeratome, and it is all executed under the microscope of the Allegretto Wave Custom LASIK laser system (Alcon Laboratories, Inc., Fort Worth, TX). This article discusses factors that influence visual outcomes with Z-LASIK (the term for LASIK performed with the FEMTO LDV).

"This more targeted form of flap creation greatly improves our patients' 1-hour and 1-day UCVAs."

TABLE 1. DAY-1 UCVAs

Myopia and Hyperopia	
20/15	40.9%
20/20	41.8%
20/25	6.4%
20/30	3.6%
20/40	7.3%

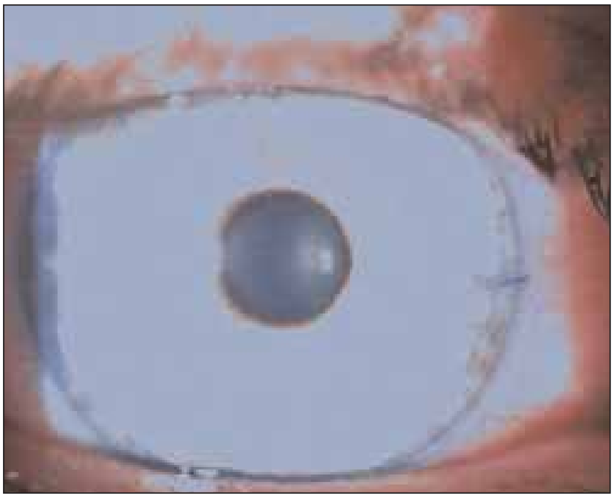

Figure 1. An eye 5 minutes after receiving an excimer ablation under a Z-LASIK flap.

MAKING THE FLAP

Centration

Technically speaking, I found flap centration to be the most difficult part of learning to use the FEMTO LDV, although it is simply a matter of becoming familiar with the technique. The user must manually center the laser's handpiece over the pupil. Once you get the hang of it, however, centration is quite easy.

Creation

Compared to the IntraLase FS laser (Advanced Medical Optics, Inc., Santa Ana, CA), which is the other approved femtosecond laser in the United States, the FEMTO LDV has a faster pulse rate and a narrower beam. My clinical impression is that this more targeted form of flap creation greatly improves our patients' 1-hour and 1-day UCVAs (Table 1). From a usability standpoint, the FEMTO LDV has the smallest footprint on the market.

Size

I create 9.5-mm flaps for all my patients, because the 400-Hz Allegretto Wave Custom LASIK laser system that we use ablates out to 9 mm. The 9.5-µm flap prevents me from ablating the hinge or outside of the flap. The LDV's flaps are very thin; I use the 90-µm InterShield spacer on the laser's head to cut most flaps.

Another feature of the FEMTO LDV that I like is the ability to position the hinge away from the cylinder ablation axis. My data show that this orientation produces better 1-hour, 1-day, and 1-month visual acuities.

Lifting

Lifting an LDV-created flap is quite simple. As soon as the laser finishes the flap, the cavitation bubbles are small enough that the patient can fixate on the laser's fixation light without being moved, and I can lift the flap and treat the eye immediately. The underlying beds are quite smooth and dry (Figure 1), and their thickness ranges from 85 to 100 µm. After the ablation, the repositioned flaps adhere to the corneal bed quite well, and my patients have not had any flap dislocations, postoperative striae, or epithelial ingrowth.

POSTOPERATIVE OBSERVATIONS

My impression is that the FEMTO LDV's technology produces excellent visual outcomes. I have seen no issues of transient light sensitivity, opaque bubble layers, or other postoperative symptoms that can occur with other lasers. In fact, our patients' healing response is rapid, and their postoperative vision is excellent (Figure 2). My staff and I assess our surgical outcomes by using the Refractive Surgery Consultant software (SurgiVision, Inc., Phoenix, AZ). This is an outcomes analysis program into which we enter all our pre- and postoperative data to determine what percentage of our patients are achieving 20/20 or better outcomes.

A particularly significant benefit of the FEMTO LDV laser that my staff and I have noticed is an increase in our patients' BSCVAs by one line or more (36% at 1 month postoperatively) (Figure 3).

Moreover, we see fewer problems related to dry eye and ocular surface disease, which has made our postoperative management of these patients much less time consuming.

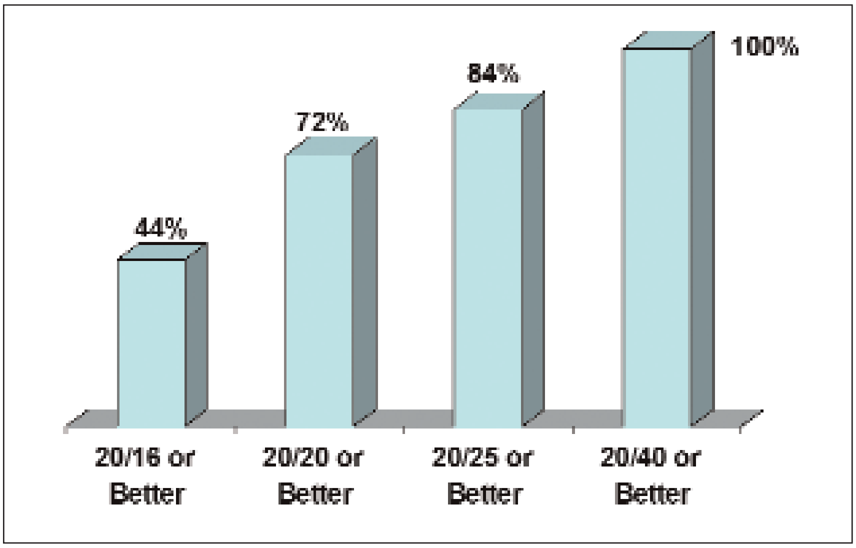

Figure 2. This graph shows 1-month UCVAs for the author's first 100 myopic and hyperopic Z-LASIK patients.

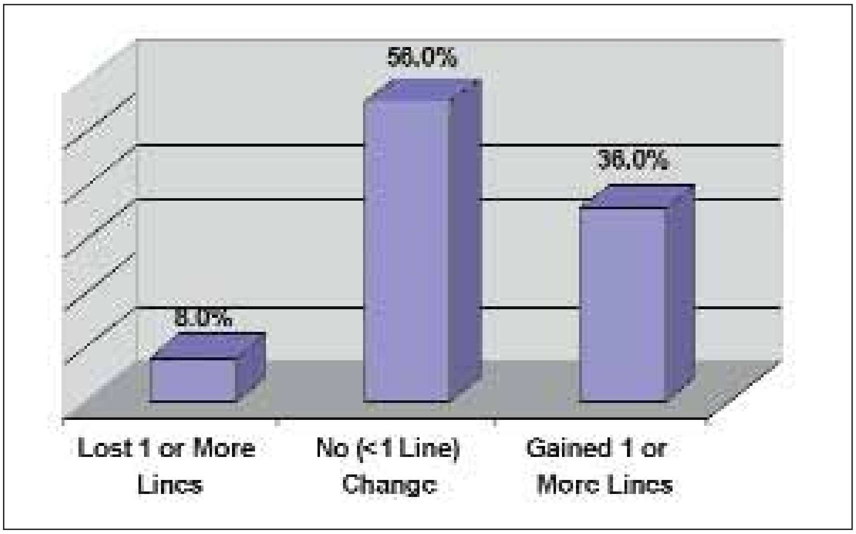

Figure 3. This graph shows lines of acuity gained or lost in the author's first 100 myopic and hyperopic Z-LASIK surgeries.

SUMMARY

In conclusion, the FEMTO LDV has been a worthwhile addition to my practice. Its reliability has been excellent, and our only service call was completed online and overnight to avoid downtime in our clinic. ■

Charles Moore, MD, is the Founder and Medical Director of International EyeCare in Houston, Texas. He is the National Medical Monitor for Alcon/WaveLight. Dr. Moore may be reached at (713) 984-9777; crm@texaslasik.com.

Avoiding and Managing Complications With the LDV

Tips to shorten the learning curve and increase the reproducibility of results.

BY JÉRÔME C. VRYGHEM, MD

The FEMTO LDV Femtosecond Surgical Laser (Ziemer Group AG, Port, Switzerland) is a fantastic tool that creates thin LASIK flaps safely and reproducibly. I have had the laser for 2 years, and I have participated in several of its clinical studies. Because most of the complications that occur with the laser result from the operator's error, increased use and familiarity are the surgeon's best defense. This article suggests strategies for avoiding and managing complications with the FEMTO LDV laser.

Since its initial development, the FEMTO LDV has undergone fine-tuning that has improved its performance and lowered its rate of complications. For example, the strength of suction on the eyepiece has been increased from 500 to 700 millibars, and the eyepiece now incorporates a mechanism that compensates for a loss of suction. The FEMTO LDV's energy level has also been enhanced, which has lowered its rate of adherent flaps dramatically.

PEARLS FOR AVOIDING COMPLICATIONS

Examining the Device

The very first thing the surgeon or technician must do before creating a flap with the FEMTO LDV is examine the laser's head for cleanliness. Dust particles or air bubbles trapped in between the InterShield spacer (a plastic foil placed over the laser that controls the flap's thickness) and the mirror can interfere with the cut and cause corneal adhesion (Figure 1). If any debris or air bubbles are visible, the user must remove the shield and clean the window before proceeding.

The surgeon must also make sure that only one InterShield spacer is attached to the window of the laser's head and that it is not the one for the previous patient. The laser emits a warning signal to prevent surgeons from reusing a shield, but they would be wise to double-check that the shield is new before proceeding. Likewise, operating the laser with two shields attached to the head may cause a superficial cut (a mini-flap), and the cut will have to be repeated.

Energy Levels

Before applying suction, the surgeon should consult the monitor to check the laser's energy levels, which have the potential to decrease gradually. The FEMTO LDV operates best at 100% power; otherwise, it cuts less efficiently and increases the risk of flaps adhering to the corneal bed. If the laser's energy drops, the surgeon or a technician may increase it by adjusting the mirrors of the laser's head, thus enhancing its performance.

The Cornea

Before beginning a FEMTO LDV cut, the surgeon must make sure that the epithelium is perfectly smooth. The tissue must not be allowed to dry out due to exposure. Applying too many anesthetic drops or obtrusively measuring the eye's pachymetry before performing the cut can cause epithelial damage. The resulting surface irregularity will interfere with the laser's cut, causing adhesions, an uneven bed, and perhaps even a pseudobuttonhole.

I think it is essential to calculate the thickness of the flap

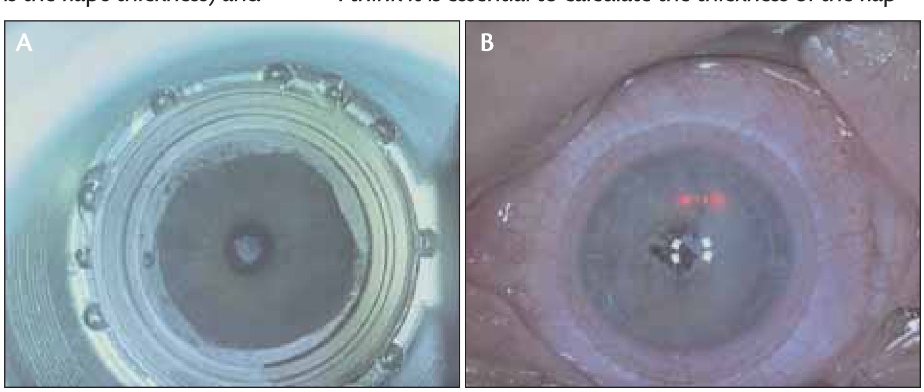

Figure 1. An air bubble trapped underneath the FEMTO LDV's foil (A) causes an area of the cornea to remain uncut after the laser's pass (B).

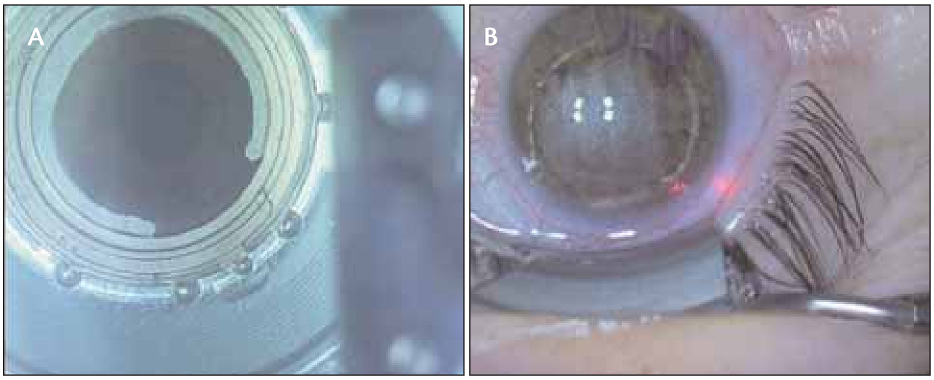

Figure 2. If the surface of applanation does not cover 70% of the laser head's window (A), the resulting flap can be decentered and/or too small (B).

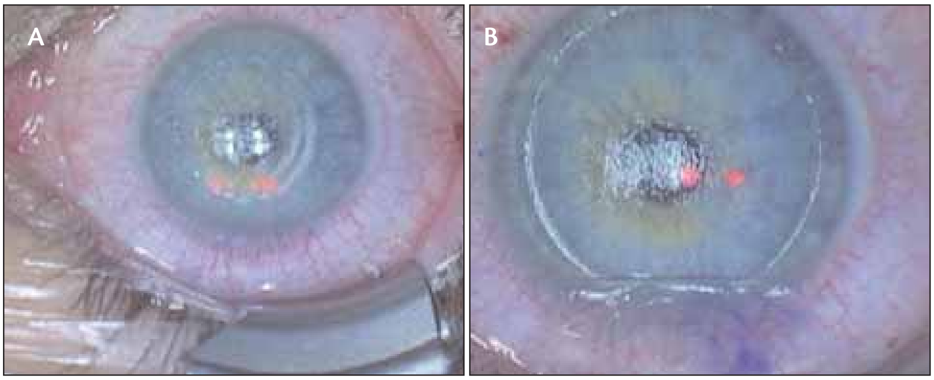

Figure 3. A mini-flap (A) was recut immediately and lifted without complication (B).

before starting any excimer laser treatment. I calculate the flap's intraoperative thickness using a subtraction method, in which the thickness of the cornea or bed is considered to be the lowest of at least five consecutive central corneal measurements made with a pachymeter. I favor the Corneo-Gage pachymeter (Sonogage, Inc., Cleveland, OH). I measure the corneal thickness before making the flap and determine the thickness of the stromal bed immediately after making the flap (before performing the ablation). The difference between the two measurements is the flap's thickness.

Suction

The laser's vacuum suction ring comes in four diameters: 8.5; 9.0; 9.5; and 10.0 mm. I prefer the 9.5-mm ring for most eyes. Coating the epithelium with a viscosurgical device helps to ensure appropriate suction between the eye and the laser's head. Most FEMTO LDV users outside the United States choose Laservis viscoelastic (0.25% hyaluronate; TRB Chemedica International SA, Geneva, Switzerland [not available in the US]), because its particular viscosity promotes suction. The surgeon must apply enough of the viscoelastic to eliminate any air bubbles trapped beneath the suction ring. If large enough, these air bubbles can block the laser beam and interrupt the cut, potentially resulting in uncut margins of the flap.

Obtaining sufficient applanation and maintaining strong suction between the handpiece and the eye are critical to achieving a successfully cut flap. Users of the FEMTO LDV can verify that the suction is complete by making sure that the surface of applanation fills at least 70% of the window on the laser's head (Figure 2). Suction is difficult to achieve in certain eyes. Because the LDV's handpiece is asymmetrical, positioning it over left eyes and deep-set eyes can be challenging, and the surgeon may have to tilt the patient's head to the right (this positioning is called the *temporal canvas*).

Once suction has been established, the surgeon does not need to lift the eye with the laser's handpiece to verify the suction, as ophthalmologists sometimes do with manual microkeratomes. Because the strength of the LDV's suction is slightly lower than that of a mechanical microkeratome (700 millibars for the former compared with 800 to 850 millibars for the latter), lifting the eye in this manner may disengage the suction.

Centration

There are a few steps that surgeons may follow to maximize the flap's centration with the FEMTO LDV. Primarily, I use minimal magnification on the excimer laser's microscope when positioning the laser's head over the eye. I find that setting the microscope to 1.0 magnification gives me a better view of the entire field.

Second, the surgeon must make sure the eye is positioned correctly before he applies the suction ring. There should be an equal amount of space between the eyelid and the limbus superiorly and inferiorly. Lifting the patient's chin can help achieve the desired position. With deep-set eyes, the surgeon may need to ask the patient to look in a specific direction to aid centration.

EXPERIMENTING WITH THE FLAP'S THICKNESS

The FEMTO LDV femtosecond surgical laser (Ziemer Group AG, Port, Switzerland) has the ability to create flaps of 140, 110, 100, 90, and even 80 µm with a very low standard of deviation (approximately 10 µm). Although my standard flap is 100 µm when I use the 110-µm InterShield spacer, I have conducted several clinical studies in which I created ultra-thin flaps (90 and 80 µm) with the LDV laser. The 90-µm InterShield spacer is very useful for thin corneas and eyes with high ametropia in patients who desire LASIK. I have cut 90-µm flaps in 110 eyes since the beginning of this year, and the only complication I experienced was a flap's tearing in its periphery due to corneal adhesion, which I attributed to low energy levels. Still, I recommend using 90-µm flaps only when necessary.

Based on my clinical study in 33 eyes, I think 80-µm flaps are too thin to work with safely. They wrinkle too easily when moved. I had to use bandage contact lenses over these eyes in the early post-LASIK period to make sure the flaps did not develop folds. Also, I found that the stromal bed appeared rough, almost like cobblestones, due to the higher density of the superficial stroma (the effect has no visual impact, however). In one eye, air bubbles developed within the flap and caused underlying adhesions. One eye developed a pseudobuttonhole due to a dry spot on the epithelium. Moderate haze developed in the interface of four eyes and resulted in a slight loss of BCVA.

Third, to assist the surgeon in obtaining centration, the manufacturer has engraved a black ring within the laser's head. However, I do not feel that this ring works effectively, because it is quite defocused when viewed through a microscope. I have asked the company to improve this feature or else find another way to ensure good centration.

Size of the Flap

I find that the best parameters for most eyes are flaps of 9.5 mm in diameter with a hinge that is 0.4 mm wide. Ten-millimeter flaps are too large; they run the risk of cutting the blood vessels of the peripheral cornea and causing bleeding. Also, the laser cannot cut through the limbus if a flap's diameter happens to traverse it, and the laser will leave an uncut margin. In hyperopic or astigmatic eyes, I find that a 9.5-mm optical zone leaves plenty of corneal tissue for the ablation.

Alignment

Although it is necessary to apply corneal markings before making a flap with a microkeratome, the dye will absorb the FEMTO LDV's laser beam and may interfere with the laser's cut. Therefore, LDV users must mark the cornea after performing the ablation. Marking the cornea after the cut allows a better realignment of the flap after the ablation, particularly in the rare cases in which a free flap occurs. I use a hockey stick (Moria, Antony, France) for corneal marking.

Adhesions

Occasionally, the FEMTO LDV will make flaps that adhere to the corneal bed and do not lift easily. Moderate adhesions are detached fairly easily by any variety of spatula (for example, the Vryghem spatula 19087 (Moria) or the Storz Manipulator E 9071 (Bausch & Lomb, Rochester, NY). Stronger adhesions may require a small hook with a sharp point to separate the tissue. If an adhesion is too strong to lift, the surgeon must recut the flap. The LDV's software permits recuts within 5 minutes of the initial cut (Figure 3). The surgeon may use the same flap parameters, but he must apply the excimer laser treatment within a smaller optical zone. Also, surgeons need to remember to change the laser's trajectory if they are recutting only a portion of the flap, and they must eliminate the flap's margins to accommodate the smaller optical zone. Otherwise, there will be a flap within a flap.

SUMMARY

Compared with the flap-cutting outcomes of available mechanical microkeratomes, the FEMTO LDV laser produces thinner flaps and a flap thickness that is more predictable. Other parameters, such as the width of the flap's hinge, are also more predictable, thus allowing the surgeon more control of the cut. Like any surgical device, the FEMTO LDV involves a learning curve. Surgeons quickly learn to operate it with minimal problems, however, and most complications are easily corrected, as I have described. In cutting thinner flaps, the surgeon preserves more corneal tissue, farther away from the 250-µm ectasia barrier. This makes the flap procedure safer and enables surgeons to treat higher degrees of ametropia. ■

Jérôme C. Vryghem, MD, is with the Brussels Eye Doctors in Belgium, and he is a member of the Cataract & Refractive Surgery Today Europe *Editorial Board. He acknowledged no financial interest in the products or companies mentioned herein. Dr. Vryghem may be reached at +32 2 741 69 99; j.c.vryghem@vryghem.be.*