Articles, cases & experience reports

Product line: FEMTO LDV
Title: Improving Presbyopia
Author: Daniel S. Durrie, MD
Publication: Eurotimes, 2013; Volume 17/18 (6)

Purpose:
D. Durrie is an investigator in the prospective, int. study evaluating “Pocket Emmetropia Kamra (PEK)”. He reported results from follow-up to 2 years in the study that enrolled 507 patients at 24 sites in the US, Europe and Asia. All patients received the most recent version of the small aperture inlay. Depth of the pocket for inlay placement was approx. 200 microns, and all of the procedures were done prior to the availability of technology for intraoperative centration guidance (AcuTarget, SMI). The inlay was positioned based on marking the first Purkinje reflex on the epithelium pre-op.

Results:
Dr Durrie noted that with its large patient population and some diversity in patient characteristics and equipment used, the PEK study allowed for subgroup analyses to investigate factors predicting outcome. Differences emerged comparing groups of eyes having pocket creation done using different femtosecond lasers. Three platforms were used across the study sites – the IL FS60, iFS and FEMTO LDV. Vision results were best in eyes where the pocket was made with one of the more advanced lasers that use a tighter spot/line separation, either the iFS or FEMTO LDV, and there was also a benefit for faster vision recovery. The outcomes analyses indicated that the optimal spot/line setting was 6x6 or less.

- Results with settings larger than 6x6 spot/line separation: Mean near UCVA in the inlay eye was about 20/63 at baseline, improved by an average for 3.2 lines to about 20/32 (J2) at one month and remained unchanged over time
- Results with settings 6x6 or smaller: the mean near UCVA improved from 20/63 at baseline to 20/25 at 12 months.

Conclusion:
According to Dr. Durrie the smoother surface obtained by using the newer generation lasers with the tighter spot/line separation provides better optics that explains the better vision results. This technology also results in less of a wound healing response, which accounts for the faster rehabilitation. A drawback of placing the small aperture corneal inlay into a lamellar pocket instead of underneath a flap is that the pocket procedure does not allow for simultaneous laser vision correction of refractive error.

How to use in your sales discussions:
The FEMTO LDV’s small spot size technology shows various advantages. The very low energy of the LDV allows the proprietary high speed scanning system to overlap the laser spots without damaging the cornea. So there is no spot or line separation with this technique, what speaks certainly in favor of our technology vs. other femtosecond lasers. Furthermore, the FEMTO LDV is able to address the mentioned drawback. Thanks to the low energy (leading to less gas creation) precise pockets can be placed underneath a flap without risk of breakthrough. This opens the possibility of a combined two-steps procedure: a std. Z-LASIK surgery for the myopia/hyperopia treatment, followed by a pocket resection¹, for the inlay for presbyopia treatment – which supports a precise surgical outcome.

¹ Please follow the instructions of the inlay manufacturer regarding the surgical technique.
Purpose:
The aim of this paper is to present the accuracy, predictability, and safety outcomes of LASIK enhancements performed with the FEMTO LDV femtosecond laser (Ziemer Ophthalmic Systems, Port, Switzerland) and the Allegretto Wave Concerto 500 Hz excimer laser.

Methods:
FEMTO LDV was used for flap creation in 85 previously LASIK-treated eyes of 62 patients. The intended flap thickness was 90 µm in 81 eyes and 140 µm in 4 eyes. The size of the suction ring was 9.0 mm in 72 eyes and 9.5 mm in 13 eyes. Flap dimensions were measured and correlated to preoperative characteristics.

Results:
With the intended flap thickness of 90 µm in previously LASIK-treated eyes, the actual flap thickness was 90.2±6.6 µm and the flap thickness was 9.2±0.2 mm. The mean hinge length was 4.0±0.2 mm. Flap thickness correlated positively with patient age and hinge length.

For LASIK reoperations, flap lifting of the old flap is the first choice for retreatment. FEMTO LDV enhancement / reoperation are valid options only in rare cases. In general, the need for re-cutting has been small with both microkeratome-based and femtosecond laser-based technologies. LASIK reoperations after previous LASIK treatments pose more risks, and corneal tissue is likely to behave in a different way than in the original LASIK procedure. In LASIK reoperations, when the flap is still readily noticeable and not too tightly adhered, flap relifting remains the recommended procedure. However, if the original flap has a small diameter or is tightly adhered, flap recutting is the method of choice. Femtosecond laser technology with improved predictability in flap thickness is better for LASIK recutting than the traditional microkeratome-based LASIK.

Vertical gas breakthrough can be a problem for the femtosecond lasers that use a high-energy pulse. Problems such as adhesion or uneven cut can occur when the flap cuts across an old corneal incision, such as a radial keratotomy scar. However, FEMTO LDV uses lower pulse energy, and thus vertical gas breakthrough does not seem to be a problem for this femtosecond laser type.

How to use in your sales discussions:
The unique design of the FEMTO LDV laser delivery system features a hand-piece with highly sophisticated optical system. These custom made microscope lenses with high numerical aperture assure a perfect focus and ensure high precision in cutting depth, leading to very precise and reliable flaps.
This precision optics, the custom made laser sources, and a proprietary high speed scanning system generate tightly focused low-energy laser pulses in an overlapped pulse raster. This results in a complete and smooth resection with no interstitial un-dissected spaces and minimal complications – including the risk of breakthrough.
Purpose:
To compare two different femtosecond lasers used for flap creation during laser-assisted in situ keratomileusis (LASIK) surgery in terms of their effects on the corneal endothelium.

Methods:
We performed LASIK surgeries on 254 eyes of 131 patients using IntraLase FS60 (Abbott Medical Optics, Inc, Irvine, CA) and 254 eyes of 136 patients using FEMTO LDV (Ziemer Group AG, Port, Switzerland) for corneal flap creation. The mean cell density, coefficient of variation, and hexagonality of the corneal endothelial cells were determined and the results were statistically compared.

Results:
When compared to manual microkeratomes, femtosecond lasers create flaps with more planar architectures and also improve the precision of flap thickness. To our knowledge, the effects of using FEMTO LDV on corneal endothelial cells have not been reported elsewhere. In this study, we compared corneal endothelial cell density (ECD), coefficient of variation (CV), and endothelial cell hexagonality changes after LASIK surgery using both IntraLase FS60 and Femto LDV. There were no statistically significant differences in the corneal morphology between pre and post LASIK results in each group, nor were there significant differences between the results of both groups at 3 months post LASIK.

Corneal endothelial analysis: No statistically significant differences were found in ECD, CV, and hexagonality between the LDV and IntraLase groups. In addition, no significant difference was observed in pre and postoperative values within the groups.

Conclusions:
Both IntraLase FS60 and Ziemer Femto LDV are able to create flaps without significant adverse effects on the corneal endothelial morphology through 3 months after LASIK surgery.

How to use in your sales discussions:
Although there were no statistically significant differences were found between both systems, this study is a good proof (especially for still skeptic Intralase users) that the FEMTO LDV is at least as safe as the IntraLase systems.

This publication also opens a very interesting discussion: the energy of IntraLase FS60 is higher than that of FEMTO LDV, so that the cutting process is driven by mechanical forces which disrupt an area of tissue is larger than the spot size; however, the cutting process of the FEMTO LDV differs given that the disruption is confined to the focal spot size of the laser pulse. This means, that the mechanical forces produced by IntraLase FS60 could break through Bowman’s layer when it disrupts sections with corneal opacity, while FEMTO LDV is able to disrupt opacity without a problem.

1 For more details on this topic please see „Evaluation of LASIK treatment with the FEMTO LDV in patients with corneal opacity”; Minoru Tomita; JRS2012;28(1)
Purpose:
To assess and compare the dimensions of LASIK flaps created by the Ziemer FEMTO LDV femtosecond (FS) laser and Moria M2 mechanical microkeratome, with 110µm head and -20 blade.

Methods:
720 eyes from 360 consecutive patients were enrolled in this study and divided into two groups of equal size for flap creation with the Ziemer FEMTO LDV and Moria M2 mechanical microkeratome. Nominal flap thickness was 110 µm for all patients and for both devices.

Results:
The flaps in the FS laser group were more regular and uniform showing an almost planar configuration whereas flaps in the microkeratome group had a meniscus shape and were significantly thicker near the flap edge.

Nasal and temporal flap thickness did not differ significantly in the FS laser group, whereas in the microkeratome group, characteristic differences in temporal versus nasal flap thickness were noticed. The femtosecond laser flap and microkeratome flap differ in dimensions, especially in the periphery, as a result of the different manner in which the flap is created. The femtosecond laser flap is formed by laser photodisruption of tissue, and the microkeratome flap is created by a single continuous mechanical cut. Flap dimensions are a new and important parameter in recent LASIK surgery, because a precise and steady corneal flap thickness is vital for accurately correcting refraction, particularly in eyes with high myopia or a thin cornea. With the progressive understanding of corneal biomechanics, the pursuit of thinner and more predictable flaps has led to the development of microkeratomes and to a bladeless method using a femtosecond laser.

In our study, we found the average flap thickness values in the central zone, 1.0 mm and 2.0 mm to the vertex, and peripheral zone were not significantly different with the FEMTO LDV. In the microkeratome the central flap thickness was significantly thinner than the points located off-center. The FEMTO LDV flap maximum deviation from the nominal 110 µm of 14 measurements was 8 µm, whereas the microkeratome flap thickness deviated by 28 µm.

Conclusion:
The Ziemer FEMTO LDV flap thickness was significantly more accurate than the Moria M2 flap thickness.

How to use in your sales discussion:
This publication can be really useful for those microkeratome users who may still be a bit skeptical about moving to the FEMTO LDV system. The accuracy of the FEMTO LDV in regard to flap thickness is significantly higher than with a microkeratome. This allows for thinner flaps (SBK-LASIK) without the risk of getting too thin flaps or other complications as button holes. Increase the safety.
Purpose:
To investigate the speed of visual recovery following myopic thin-flap LASIK with a femtosecond laser.

Methods:
This pilot study prospectively evaluated eyes from 10 patients who underwent bilateral simultaneous LASIK with the FEMTO LDV Crystal Line femtosecond laser. Used to create a circular flap of 9.0 mm diameter and 110 µm thickness followed by photoablation with the Allegretto Wave Eye-Q excimer laser. Binocular and monocular uncorrected distance visual acuity (UDVA), monocular contrast sensitivity, and a patient questionnaire were evaluated during the first hours, 1 day, and 1 month postoperatively.

One of the distinctive features of modern thin-flap LASIK is the speed with which patients recover their vision following surgery. The refractive literature has established that excellent visual outcomes by 1 month and even 1 week following LASIK have become the rule rather than the exception, a fact that stands in contrast to the immediate postoperative results of refractive techniques such as surface ablation.

Results:
In the present study, excellent monocular and binocular visual acuities were obtained within hours following myopic thin-flap LASIK with a femtosecond laser. Visual acuity data from postoperative day 1 compare favorably with previously published prospective data at the same postoperative day.

Twenty eyes from 10 consecutive patients were analyzed. All eyes in the study underwent uneventful LASIK. For binocular UDVA all patients achieved 20/32 by 30 minutes and 20/20 by 4 hours. Low frequency contrast sensitivity returned to preoperative baseline by 1 hour and showed a statistically significant improvement over baseline by 4 hours. But high frequency monocular contrast sensitivity returned to preoperative baseline by 4 hours. This could be the reason why although 100% of patients were legal to drive after 30 minutes, only 1 patient felt comfortable driving, however after 4 hours all patients were legal to drive and felt comfortable driving.

Conclusions:
Visual recovery after thin-flap femtosecond LASIK is rapid, occurring within the first few hours after surgery.

How to use in your sales discussions:
Ziemer’s proprietary FEMTO LDV systems are based on a radically different technology. They operate with very low pulse energy (µJ) and very short pulse width but very high pulse frequencies (MHz). This extremely low energy delivery has turned out to be the most relevant factor for a gentle tissue resection – which leads to a very fast visual recovery.

In 2012, Dr. Durrie performed the same study1 with the FS200 femtosecond laser (Alcon Laboratories, Inc.). The publication shows now that the visual recovery is faster with the FEMTO LDV system.

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1 "Rapid Recovery Beyond 20/20"; Daniel S. Durrie; CRST Supplement; Nov/Dec 2012
Corneal opacity or scars can affect femtosecond laser operation for patients with corneal opacity; flaps typically are created using higher energy and are thicker than normal based on the residual corneal bed thickness. This is to prevent the occurrence of gas breakthrough. Gas breakthrough is one of the most common intraoperative complications with femtosecond lasers. The Femto LDV also appears to have a lower incidence of opaque bubble layer.

Methods:
Patients with corneal opacity were retrospectively selected between March and July 2009. For this study, 205 eyes with 90 μm corneal flaps created using the FEMTO LDV and 200 eyes with corneal flaps created using the IntraLase FS 60. Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), and manifest refraction spherical equivalent (MRSE) were measured pre-and postoperatively and were statistically evaluated using.

Results:
It is widely believed that thinner flaps have advantages for patients such as saving tissue for future operations, lessening the risk of ectasia, and better contrast sensitivity. Regardless of the levels of opacity, eyes in the FEMTO LDV group experienced uneventful procedures with no complications. Eyes in the IntraLase group had uneventful procedures but gas breakthrough was observed in 27 eyes. Of all eyes, 117 eyes from the LDV group and 109 eyes from the IntraLase group were available for 3 month follow-up. No statistically significant differences were noted in UDVA, CDVA, or MRSE between groups.

Conclusions:
Laser in situ keratomileusis with the FEMTO LDV created thin flaps regardless of level of opacity and induced no complications as compared to the Intralase FS 60, where gas breakthrough was significantly more common. Gas breakthrough did not occur in the FEMTO LDV group. Using the FEMTO LDV, no complications such as gas breakthrough, buttonholes, or tearing occurred. Flaps in the FEMTO LDV Group were created and lifted without difficulty even in eyes with heavy corneal opacity. The incidence of opaque bubble layer occurring with the FEMTO LDV is lower than that of the IntraLase. FEMTO LDV is effective in treating patients with corneal opacity.

How to use in your sales discussion/Conclusions:
The IntraLase FS60 has a much higher laser pulse energy (µJoules range) than the FEMTO LDV (nJoules range). For this reason, the laser pulses must be positioned separately (> 6 μm distance); otherwise a too high energy would be applied to the eye. This leads to a cutting process driven by mechanical forces, in order to disrupt an area of tissue larger than the spot size. And these mechanical forces could break through Bowman's layer when it disrupts sections with corneal opacity as we have seen in this study (25% of the eyes!).
The cutting process of the FEMTO LDV is very different. Thanks to the precision optics, the custom made laser sources, and a proprietary high speed scanning, tightly focused low-energy laser pulses are placed in an overlapped pulse raster – so that the disruption is confined to the focal spot size of the laser pulse. Therefore the FEMTO LDV created thin flaps regardless of level of opacity and induced no complications.
Product line: FEMTO LDV  
Title: Efficacy, safety, and flap dimensions of a new femtosecond laser for laser in situ keratomileusis  
Author: Jérôme C.Vryghem, MD; Pavel Stodulka, MD, PhD  
Publication: Journal of Cataract and Refractive Surgery Volume 36, March 2010

Purpose:  
To evaluate the clinical results of a pre-production femtosecond laser for flap creation in laser in situ keratomileusis (LASIK).

Methods:  
This study comprised myopic eyes with a plano target refraction and a target flap thickness of 110 µm. The LASIK flap was created with a Ziemer FEMTO LDV femtosecond laser. Prospective evaluation included flap dimensions, intraoperative and postoperative complications, and visual outcomes. All corneal flaps were created with a preproduction FEMTO LDV femtosecond laser (Ziemer Group). The laser delivers single femtosecond laser pulses with a repetition rate greater than 1 MHz.

Results:  
Sixty-three patients (111 eyes; mean age 37.2 years) were evaluated. Preoperatively, the mean corrected distance visual acuity (CDVA) was 1.34 (Snellen) and the mean manifest refraction spherical equivalent (MRSE), -4.91 diopeters (D) ± 2.45 (SD). Six months postoperatively, the mean CDVA was 1.33; the mean MRSE, -0.05±0.3 D; and the mean uncorrected distance visual acuity (UDVA), 1.27. The UDVA was 20/25 or better in 98.2% of eyes and 20/20 or better in 94.6% of eyes. The MRSE was within ±0.50 D in 95.5% of eyes and within ±1.00 D in 99.1% of eyes. The cylinder was 0.50 D or less in 99.1% of eyes. The mean flap thickness was 106.6±12.6 µm.

Conclusions:  
Flap creation is probably the most important step during laser in situ keratomileusis (LASIK), and complications during it can affect the rest of the procedure and cause permanent visual loss. Overall, LASIK performed using the pre-production femtosecond laser yielded predictable flap dimensions and refractive results and an acceptable complication rate. The mean spherical equivalent and mean residual astigmatism at 6 months compare favorably with results in earlier femtosecond laser studies.

How to use in your sales discussions:  
The FEMTO LDV creates very reliable and accurate flaps. Thanks to the very high numerical aperture and short focal depth, the laser spots can be precisely positioned. Additionally, the FEMTO LDV is the only femtosecond laser that operates with a repetition rate in the MHz range, which allows for a completely different way of running the system: extremely short and focused laser pulses are placed in a unique overlapping technique. Therefore, no tissue bridges will be induced leading on flaps very easy to be lifted as well as an excellent stroma bed quality. This laser scanning method, together with the very low energy of the FEMTO LDV systems, have shown that the visual recovery after Z-LASIK surgery is extremely fast!

1 See „Evaluating the speed of visual recovery following thin-flap LASIK with a femtosecond laser“; Daniel S. Durrie, MD; Journal of Refractive Surgery, 2012; 28(9)