Supplement to

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Cataract & Refractive Surgery TODAY

FEMTO LDV Z MODELS

THE POWER OF ONE

The ONE FEMTO PLATFORM for cornea, presbyopia, and cataract*

*The Ziemer FEMTO LDV Z Models are FDA cleared and CE marked and available for immediate delivery. For some countries, availability may be restricted due to local regulatory requirements; please contact Ziemer for details. The creation of a corneal pocket is part of a presbyopia intervention. Availability of related corneal inlays and implants according to policy of the individual manufacturers and regulatory status in the individual countries. Cataract procedures with the FEMTO LDV Z2, Z4 and Z6 models are not cleared in the United States and in all other countries. An upgrade possibility for these devices is planned once cataract options are available and cleared by the responsible regulatory bodies.

ZIEMER IS THE FEMTO-TECHNOLOGY COMPANY OF TODAY, TOMORROW AND THE FUTURE

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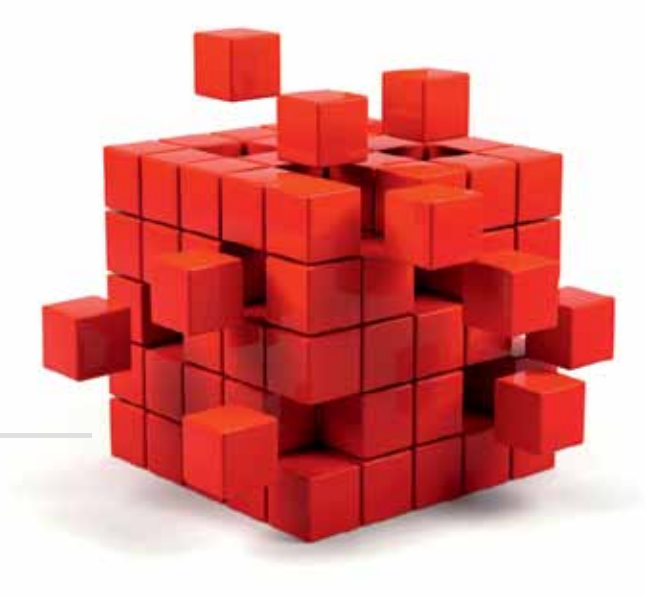

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FEMTO LDV Z MODELS: An Exciting Journey into New Femtosecond Laser Technology

Offering a plethora of tools for refractive and corneal surgery.

BY PETER W. RIECK, MD, PHD

Femtosecond laser applications in ophthalmology have rapidly evolved over the past several years. This technology has been widely used for flap creation in LASIK surgery for quite some time; however, even since the introduction of the femtosecond laser, it has been a constant goal to provide more applications than just cutting a LASIK flap. Very recently, the Ziemer Group has taken a great step forward to achieve this goal. The company's FEMTO LDV Z MODELS are a powerful platform for performing a wide range of procedures in ocular surgery. These new FEMTO LDV Z MODELS, which includes the Z2, Z4, and Z6 femtosecond laser models (Figure 1), released at the end of February 2012, address the demand of ophthalmologists for the most versatile, highly efficient femtosecond platform. With its latest advancements, the FEMTO LDV Z MODELS extend the range of surgical modalities we can offer our patients today.

Figure 1. The FEMTO LDV (A) Z2, (B) Z4, and (C) Z6.

One of the major innovations of the FEMTO LDV Z MODELS is the addition of the z-axis. This means that the Z4 and Z6 models now can move the focused laser beam not just in the x- and y-axis but also in the z-axis. For LASIK surgery, this translates into a new Z-LASIK method, named *Z-LASIK Z*, that enables the resection to be performed three-dimensionally. Thanks to this new system, each flap can be customized to accommodate the desired geometry.

This supplement summarizes the new and exciting surgical tools that are now available with the FEMTO LDV Z MODELS. In the following pages, five surgeons share their experiences with this advanced technology. Holger Lubatschowski, PhD, provides an overview of Ziemer's femtosecond laser technology. He shows that, with the new FEMTO LDV Z MODELS, the spot size remains ultra small and that these spots completely overlap. This is thanks to the laser's architecture, its most precise focus quality, the low energy range, and the highest repetition rate among all femtosecond laser systems.

Next, Scott MacRae, MD, focuses on Z-LASIK using the new FEMTO LDV Z MODELS. Further applications like presbyopia treatment with the Kamra inlay are covered by Minoru Tomita, MD, PhD. Then, lamellar keratoplasty techniques using the FEMTO LDV Z MODELS will be addressed by Francois Majo, MD. Lastly, Richard Foulkes, MD, details his experience and results with the FEMTO LDV Z6.

My colleagues and I hope that you will find these articles informative and also relevant for your daily clinical practice. ■

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The Ultimate Femtosecond Laser Technology

The newest FEMTO LDV Z MODELS have expanded modules for vertical cuts, including one for intrastromal pocket creation.

BY MINORU TOMITA, MD, PHD

At Shinagawa LASIK Center in Tokyo, we have performed more than 1 million LASIK cases since opening in 2004. We are committed to providing the best quality treatments to our patients by using the world's leading refractive technologies. Therefore, we started performing femto-LASIK with the FEMTO LDV femtosecond laser (Ziemer Group) in 2009. In this time, we have come to realize that the FEMTO LDV is the ideal technology for refractive surgeons who desire to complete their LASIK procedures with a high level of safety and patient satisfaction.

The clinical outcomes, surgical quality, and usability of the first and second FEMTO LDV sytems were excellent, and we recently worked together with Ziemer to further improve the laser system in several areas, including the addition of multiple vertical cutting settings. Ziemer has now developed these systems and released its new FEMTO LDV Z MODELS with remarkable features that fulfilled our expectations. Three models, the Z2, Z4, and Z6, are new to the market. We have started using these FEMTO LDV Z MODELS for corneal surgery in our clinic. Below I report the clinical outcomes of LASIK using these new FEMTO LDV Z MODELS and also the outcomes from post-LASIK Kamra corneal inlay (AcuFocus, Inc.) implantation performed with Ziemer pocket-creating technology.

ADVANTAGES OF THE FEMTO LDV Z MODELS

Upon review of our experiences with the FEMTO LDV Z MODELS compared with other femtosecond lasers, we found that this laser excels in LASIK flap creation. The FEMTO LDV Z MODELS offer surgeons and patients many advantages:

High-speed, low-energy scanning system. The FEMTO LDV Z MODELS have a high-speed scanning system that generates low-energy laser pulses at the nanoJoule (nJ) level with high-pulse frequencies exceeding 5 MHz. According to an analysis of the effects of different energy levels on corneal stromal cells, greater inflammatory cell infiltration was observed in the cornea when using lasers with higher energy levels.[1] These higher energy levels also triggered increased cell death. Additionally, typical complications caused by some femtosecond lasers, such as vertical gas breakthrough, rainbow glare, transient light sensitivity syndrome (TLS), opaque bubble layer (OBL) formation, and inflammation, were induced by higher pulse energy femtosecond lasers.[2-5]

Tissue preservation. During flap creation with the FEMTO LDV Z MODELS, small and tightly overlapped dissection spots are produced, resulting in complete resection with no tissue bridges and a smooth stromal bed. It also produces significantly fewer gas bubbles and is free of edema. Besides tissue preservation, the handheld scanning device affords the surgeon a direct view of the cornea and ensures a highly precise cutting depth.

Ergonomic design. Laser energy is deployed from a handpiece that is attached to a maneuverable articulated arm, meaning patients can be treated on the excimer laser bed instead of relocating between the flap creation and ablation procedures. Using the FEMTO LDV Z MODELS, both surgeon and patient can stay in a single position. Therefore, the entire bilateral Z-LASIK procedure can be completed within 6 minutes.

Short procedure time. As the scanning system improved the speed of the operation, the cutting time using FEMTO LDV Z MODELS is now less than 15 seconds. Patients are more comfortable and feel less stress during the procedure.

NEW FEMTO LDV Z MODELS: VARIETY OF FUNCTIONS

In addition to the characteristics and capabilities of the current model, several functions were added to the new FEMTO LDV Z4 and Z6. These FEMTO LDV Z MODELS have a variety of functions, including creation of intrastromal pockets for corneal inlays, keratoconus treatment with tunnel resection for intracorneal ring segments, and corneal keratoplasty. The most outstanding feature of the FEMTO LDV Z MODELS is their ability to resect three-dimensionally.

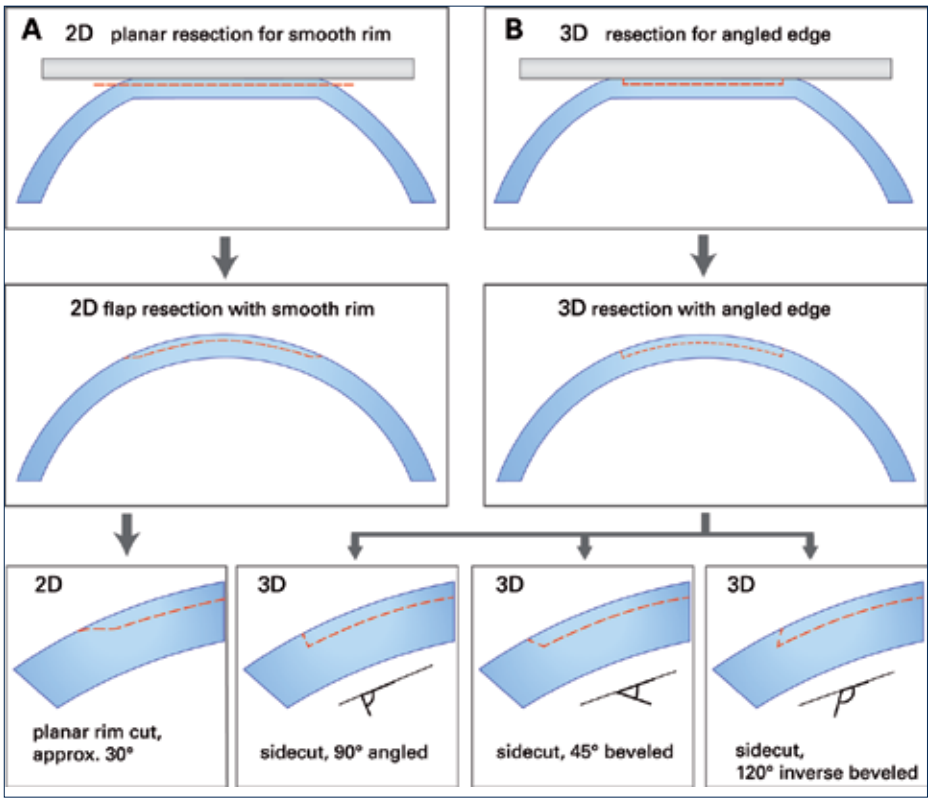

Figure 1. Options (A and B) for creating the flap edge available with the FEMTO LDV Z4 and Z6 Models.

The FEMTO LDV Z MODELS enable users to change flap creation details (Figure 1) such as flap thickness, sidecut angle (30° to 150°), and shape (oval or circular) on the advanced settings screen. Even after applanating the cornea, the surgeon can change settings including flap position and diameter and hinge position.

STUDY OUTCOMES WITH THE FEMTO LDV Z4

In a prospective, noncomparative study conducted at the Shinagawa LASIK Center, 77 eyes (39 patients; mean age, 33 ±8 years) underwent LASIK using the FEMTO LDV Z4 for flap creation and the Amaris excimer laser (Schwind-eye-tech solutions) for myopic correction. The attempted flap thickness was 90 to 100 µm, and visual outcomes (Figure 2) and flap thicknesses were evaluated at 1 day, 1 week, and 3 months after LASIK.

All eyes achieved distance UCVA of 20/20 or better, and 90% of 20/16 or better at 3 months postoperatively. Similarly, at 3 months all eyes achieved distance BCVA of 20/20 or better and 96.7% of 20/16 or better. For postoperative manifest refraction spherical equivalent (MRSE) at 3 months, 86.7% of eyes achieved results within ±0.50 D and 100% within ±1.00 D.

At our clinic, corneal and stromal pachymetry are measured just before and after flap creation with an ultrasound pachymeter (Handy Pachymeter SP100; Tomey Corporation). The mean (±SD) difference from intended flap thickness was 1.0 ±3.9 µm. No intraoperative or postoperative complications were observed in the studied cohort. We concluded that the FEMTO LDV Z MODELS were more predictable than any other femtosecond laser as well as the microkeratome in terms of intended flap thickness.[6]

CORNEAL INLAY SURGERY FOR PRESBYOPIA CORRECTION

As the population of middle-aged and older adults grows, the demand for presbyopia-correcting treatments rapidly increases. One surgical solution that is attracting attention is the Kamra corneal inlay (AcuFocus, Inc.). This intracorneal inlay is designed to create a small aperture effect to increase the depth of focus in the eye. To complete the procedure, a corneal inlay is implanted under a 200-µm LASIK flap or inside a corneal pocket. The inlay controls light transmission, allowing only central rays to reach the retina through a fixed 1.6-mm aperture. This enables the eye to see near and intermediate objects more clearly. We began working with the Kamra inlay in 2009 and since then have performed more than 8,000 procedures.

In that time, I began to explore the possibility of presbyopia correction using the inlay in ametropic and previous LASIK patients. We also evaluated the outcomes of simultaneous LASIK ("SIM-LASIK") and inlay implantation in patients with refractive errors. What we found is that combining the Kamra corneal inlay with LASIK provides excellent visual outcomes and high patient satisfaction.[7]

POST-LASIK PRESBYOPIA CORRECTION USING THE FEMTO LDV Z MODELS

We recently began implanting the Kamra inlay in post-LASIK patients who returned to our clinic for presbyopia correction. The adjustable pocket software of the FEMTO LDV Z MODELS can be used to create an intrastromal pocket for insertion of the corneal inlay. During the procedure, we make a smooth pocket at a depth of 200 to 250 µm, underneath the old flap. The low-energy pulses of the FEMTO LDV Z MODELS create significantly less inflamma-

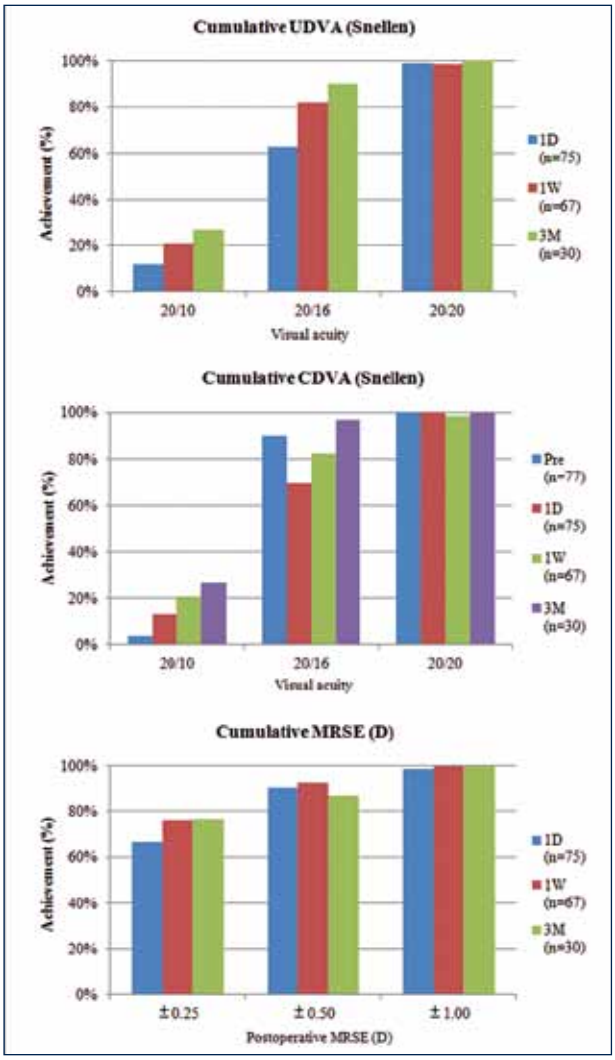

Figure 2. Visual and refractive outcomes of eyes that underwent Z-LASIK with the FEMTO LDV Z4.

tion, and thus far no complications have been observed. Therefore, in our clinic, the FEMTO LDV Z4 is necessary for creating an ideal pocket for post-LASIK Kamra surgery.

We recently evaluated Kamra inlay implantation in 2,193 patients who were treated with LASIK but returned to our clinic for presbyopia correction between November 2010 and February 2012. This group of patients had a mean preoperative spherical equivalent refraction of -0.11 D (range, 2.38 to -2.00 D). All patients had a LASIK flap, so we created the corneal pocket under their prior flap interface. The lamellar pocket was created with the FEMTO LDV Z MODELS adjustable pocket software in patients' nondominant eyes at the depth of 100 µm below their LASIK flap (Figure 3). The new pocket was created at about 200 µm (Tomita Method). In some cases, the previous LASIK flap was lifted and a laser enhancement was performed to achieve a target refraction of plano. In all cases, the inlay was implanted at least 1 month after LASIK.

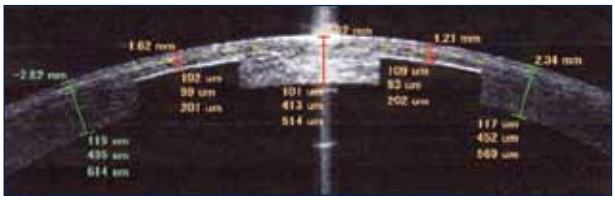

Figure 3. Anterior segment OCT. This Image shows that the previous LASIK flap was made at about 100 µm and the new pocket at 200 µm.

Figure 4 demonstrates the visual outcomes of this study. Follow-up for 484 patients was available at 6 months. Mean distance UCVA had declined 1 line from 20/16 to 20/20; 84% were 20/25 or better, and 74% were 20/20 or better. Near UCVA improved 4 lines, from J8 to J2. Additionally, 82% achieved J3 or better. The 6-month follow-up also showed excellent patient satisfaction, with 94% reporting satisfaction with their UCVA.

Overall, I have been impressed with the results from Kamra inlay surgeries using the Ziemer FEMTO LDV Z MODELS. Like previously reported results for emmetropic presbyopes, our patients experienced gains in near visual acuity while gaining or maintaining good distance UCVA. As a result, we have made the inlay our only choice for presbyopia correction in patients without cataracts. This surgical technique is easy to perform, and patients are pleased with their visual outcomes. The inlay has proven to be a good solution for both ametropic and post-LASIK presbyopes.

FORTHCOMING UPGRADES

The Z6 model is the latest version of the FEMTO LDV Z MODELS femtosecond laser. It keeps the full Z-LASIK capabilities of the FEMTO LDV Z4 and adds capabilities for both lamellar and penetrating keratoplasty. Moreover, the FEMTO LDV Z6 can be upgraded for femtosecond laser-assisted cataract surgery, which will be available in the near future.

Thus, the new FEMTO LDV Z MODELS have improved an already excellent laser by adding the ability to change corneal flap shape, size, and thickness during the operation, while maintaining the characteristic of low tissue damage via low-energy pulses. Accuracy and reproducibility of flap thickness also improved from the previous version, as the new Z modules create precise flaps safely with good postoperative visual outcomes. The fast visual recovery resulting from the FEMTO LDV Z MODELS' gentle treatment enhances patient satisfaction. As refractive surgeons, this is our top priority.

We are working with Ziemer on the next upgrade to the FEMTO LDV Z MODELS. The biggest feature is the addition of an optical coherence tomography (OCT) module. Integrating this advanced multidimensional scanning system will allow the surgeon to perform even safer LASIK surgeries. This technology can be used to

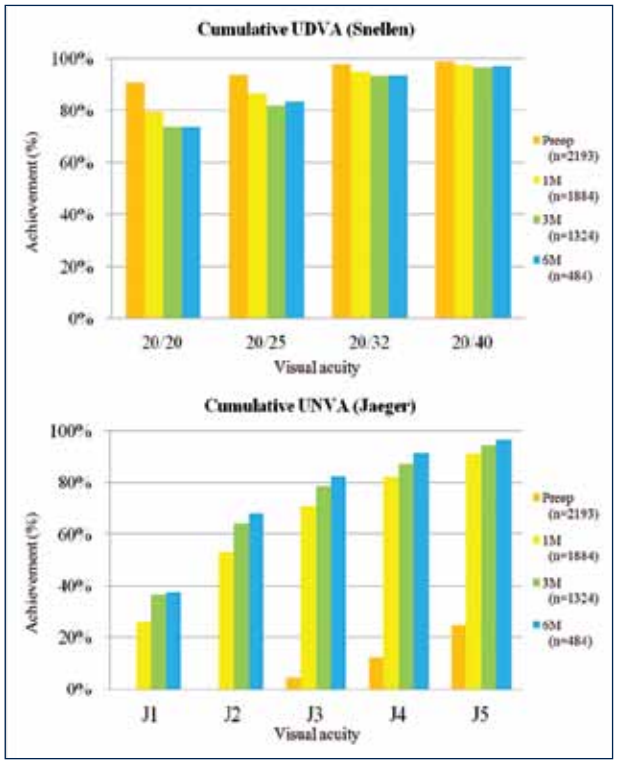

Figure 4. Visual acuity of implanted eyes after post-LASIK Kamra corneal inlay surgery.

ensure enough distance between the Bowman layer and the resection interface, thereby avoiding buttonholes when sub-Bowman LASIK is performed. Furthermore, in cases of ICRS implantation and/or corneal pocket creation for post-LASIK patients, it is crucial to keep a safe distance from the stromal surface or endothelial layer to the ring tunnel or pocket layer. OCT is one of the most important functions for improving the safety of future corneal surgeries.

CONCLUSION

The results of our studies show that the new FEMTO LDV Z MODELS maintains the previous model's excellent characteristics and capabilities, such as the gentle treatment to the eye with low-energy pulses, and add significant improvements, including advanced settings with which the user can change the flap position and settings for the corneal conditions of each patient. In terms of flap creation, flap thicknesses created by the new FEMTO LDV Z MODELS are the most accurate and predictable when compared with other femtosecond lasers.

Visual outcomes after Kamra implantation may differ depending on which femtosecond lasers surgeons use. We need to choose the right laser to create smooth 200-µm pockets for the corneal inlay. As we review our many thousands of experiences creating pockets using the FEMTO LDV Z MODELS and other femtosecond lasers, clearly the FEMTO LDV Z MODELS is one of the best femtosecond lasers for cutting into the deep parts of the corneal stroma. With further developments such as OCT guidance and/or femto-cataract capabilities in the near future, I believe the FEMTO LDV Z MODELS femtosecond lasers will become an indispensable tool for the ophthalmic surgeon desiring the safest and most efficient surgeries. ■

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1. de Medeiros FW, Kaur H, Agrawal V, et al. Effect of femtosecond laser energy level on corneal stromal cell death and inflammation. *J Refract Surg.* 2009;25:869-874.
2. Tomita M, Chiba A, Matsuda J, Nawa Y. Evaluation of LASIK treatment with the FEMTO LDV in patients with corneal opacity. *J Refract Surg.* 2012;28:25-30.
3. Bamba S, Rocha KM, Ramos-Esteban JC, Krueger RR. Incidence of rainbow glare after laser in situ keratomileusis flap creation with a 60 kHz femtosecond laser. *J Cataract Refract Surg.* 2009;35:1082-1086.
4. Stonecipher KG, Dishler JG, Ignacio TS, Binder PS. Transient light sensitivity after femtosecond laser flap creation: clinical findings and management. *J Cataract Refract Surg.* 2006; 32:91-94.
5. Mrochen M, Wullner C, Krause J, et al. Technical aspects of the WaveLight FS200 femtosecond laser. *J Refract Surg.* 2010;26:S833-840.
6. Ahn H, Kim JK, Kim CK, et al. Comparison of laser in situ keratomileusis flaps created by 3 femtosecond lasers and a microkeratome. *J Cataract Refract Surg.* 2011;37:349-357.
7. Tomita M, Kanamori T, Waring GO IV, et al. Simultaneous corneal inlay implantation and laser in situ keratomileusis for presbyopia in patients with hyperopia, myopia, or emmetropia: six-month results. *J Cataract Refract Surg.* 2012;38:495-506.

Laser Technology of the FEMTO LDV Z MODELS

A review of this completely modular laser system.

BY HOLGER LUBATSCHOWSKI, PHD

Today, the FEMTO LDV Z MODELS (Ziemer Group) is one of the most successful refractive corneal laser platforms since these lasers were introduced in ophthalmology in the late 1990s. All of the lasers systems that are available today have evolved from simple LASIK flap-makers to sophisticated workstations capable of many surgical applications, including penetrating and lamellar keratoplasty, endothelial keratoplasty, and preparing pockets and channels for corneal inlays.

Although all of these platforms are femtosecond lasers, the FEMTO LDV Z MODELS are somewhat special. This laser stands out because of its compactness and mobility as well as its unprecedented precision in tissue cutting. To understand this uniqueness, one has to dive a little deeper into the physics of photodisruption.

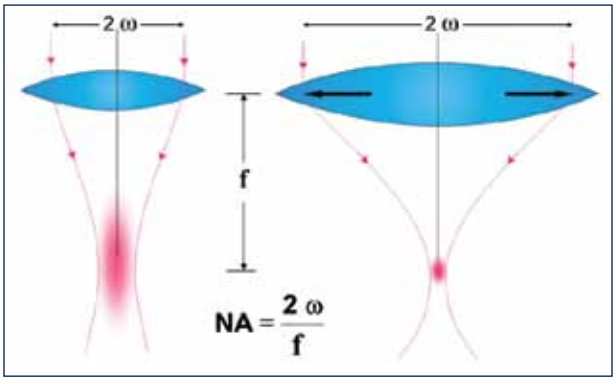

Figure 1. The focal volume of a Gaussian laser beam scales with the NA ∞ ω/f of the focusing lens. The larger the NA, the smaller the focal spot volume and the smaller the energy needed for optical breakdown.

PHOTODISRUPTION: AN OVERVIEW

Photodisruption is a nonlinear process that is, in contrast to photoablation, independent from the wavelength of the laser radiation. With photodisruption, the wavelength is preferably chosen so that the laser beam penetrates the tissue but saves as much as possible for the eye. Ideally, near-infrared radiation combines these two features and enables 3-D processing of several ocular tissues that include the cornea, crystalline lens, vitreous, and sclera. To induce any interaction with these tissues, the laser light must exceed a certain threshold of intensity so that the electrons are stripped from their orbits and the material is locally ionized. This threshold is typically around 1,012 W/cm² and can only be achieved by tightly focusing the laser beam to 10 µm or less in diameter.

A tight focus of the laser beam to create tissue disruption was first used clinically in the 1970s, when ophthalmologists applied nonlinear absorption to the ocular surface to treat open-angle glaucoma with a Q-switched ruby laser.[1] One decade later, surgeons started to apply nonlinear photodisruption with a Q-switched Nd:YAG laser to posterior capsular opacification treatments, using the laser to cut the posterior capsule of the crystalline lens.[2,3] Today, femtosecond lasers are not only used for refractive surgery but for intracellular nano-surgery that cuts with a precision of better than 1 µm.[4] The key point of increasing the precision of photodisruption and minimizing collateral damage is to minimize the laser pulse energy, which is responsible for unwanted side effects such as mechanical rupture due to cavitation and shock wave generation.

LASER INTENSITY

Laser intensity is given by photon energy per time (t) and per focal area at photodisruption per focal volume. Hence, two parameters allow the minimization of pulse energy at a given intensity threshold: the laser pulse duration and the focal spot volume of the laser beam, which is a function of the numerical aperture (NA) of the focusing optics.

Ziemer's femtosecond laser has a pulse duration of approximately 250 fs, which is by far the shortest pulse duration of all clinically used systems. (Other systems have pulse durations that range from 350 to 800 fs.) The focal volume of a Gaussian laser beam is determined by its axial extension z and its lateral extension ω_0: $V \propto z\,\omega_0^2$.

The axial extension z is also known as the Rayleigh range ($z = \pi\omega_0^2 / \lambda$) and its lateral extension is called the beam waist $\omega_0 = f\lambda / \pi\omega_L$, where f is the focal length of the used focusing lens, ω_L is the radius of the beam at the focusing lens, and λ is the wavelength of the laser radiation.

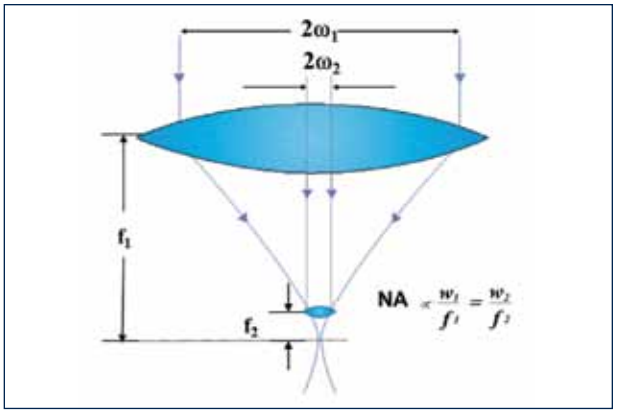

Figure 2. At a constant relationship of focal length and lens diameter, certain focal diameter of the laser beam can be achieved by either large lenses and long working distances or by smaller lenses with shorter working distances.

Having in mind that, for the NA of a focusing system we can write NA ∞ wL/f, we see that the focal volume of the laser beam varies inversely with the fourth power of the numerical aperture (NA). The larger the NA, the extremely smaller the focal spot and finally the smaller is the energy threshold for disruption (Figure 1).

According to its definition, there are two ways to increase the NA. The first way is to increase the beam diameter at the focusing optics, which requires large and expensive optical components. The second way is to decrease the focal length of the focusing objective, which also reduces the working distance of the laser system (Figure 2). The optical system of the FEMTO LDV Z MODELS does both. Ziemer has reduced the focal lengths to a few mm, but by keeping the lens diameter relatively large, the NA remains about 2 to 3 times the NA of other laser systems.

PULSE ENERGY

Subsequently, the Ziemer Femtosecond Laser System requires the lowest pulse energy to achieve optical breakdown inside the corneal tissue. This results in the highest precision of any laser platform. At such low pulse energies, low-density plasma is produced. Additionally, the cutting process is dominated by photochemically induced tissue decomposition and thermoelastic disruption.[5] Only at higher pulse energies is luminescent plasma generated. This plasma-mediated ablation process is due to the explosive expansion of the plasma. Mechanical rupture and transient cavitation as well as remaining gas bubbles are typical side effects for this process, which is applied in all other laser systems.

As a consequence, the FEMTO LDV Z MODELS requires more pulses to cut the same area. To keep the total operation time short, higher pulse repetition rates (MHz) are used. Fortunately, this brings further advantage to the system's design and usability. The system is compact and robust because its ultrashort pulses are generated by a simple laser oscillator and need no further amplification. No other refractive corneal femtosecond laser is as mobile as the FEMTO LDV Z MODELS. Additionally, it fits with every excimer laser.

A MODULAR CONCEPT

The architecture of the laser system is completely modular. It consists of the basic unit containing the laser source, the fast-scan unit, and the controller. The fast-scan unit separates the MHz pulses to a line of overlapping pulses that has a length of less than 1 mm and a width of a single laser spot (less than 1 µm). The line of laser pulses is delivered through an articulated mirror arm to a handpiece that contains a sophisticated optical system that focuses the line of laser pulses and places them into the cornea. The optical and the mechanical engineering of the handpiece is an outstanding example of the Swiss precision engineering best known from watchmaking.

The modular concept of the FEMTO LDV Z MODELS and its clearly defined interfaces permit the development of systems for applications other than corneal surgery just by exchanging modules. For laser refractive cataract surgery, the optic design is somewhat different than for corneal surgery. For lens surgery, the target volume is 7 mm in diameter and 4 mm in depth, which is located significantly deeper inside the eye than the target volume for corneal surgery. The depth required for laser cataract surgery passes through a number of refractive surfaces with different indices of refraction. Moreover, an imaging tool like optical coherence tomography is required to navigate and precisely localize laser pulses.

CONCLUSION

Altogether, the Ziemer FEMTO LDV Z MODELS is well prepared for future applications where highest precision, compact design, and mobility are desired. There are currently several applications for the FEMTO LDV Z MODELS, which are described in the following articles. In the future, undoubtedly more applications will follow. ■

Holger Lubatschowski, PhD, is CEO at Rowiak GmbH, Germany. Professor Lubatschowski states that he has a financial interest in the field of femtosecond laser-assisted surgery, and he is a shareholder in Rowiak GmbH. Dr. Lubatschowski also is a paid consultant to Ziemer Group. He may be reached at e-mail: H.Lubatschowski@Rowiak.de.

1. Krasnov M. Laser puncture of anterior chamber angle in glaucoma (a preliminary report). *Vestn Oftalmol.* 1972;3:27-31.
2. Aron-Rosa D, Aron JJ, Griesemann JC, Thyzel R. Use of the neodymium-YAG laser to open the posterior capsule after lens implant surgery: a preliminary report. *J Am Intraocul Implant Soc.* 1980;6(4):352-354.
3. Fankhauser F, Roussel P, Steffen J, et al. Clinical studies on the efficiency of high power laser radiation upon some structures of the anterior segment of the eye. First experiences of the treatment of some pathological conditions of the anterior segment of the human eye by means of a Q-switched laser. *Int Ophthalmol.* 1981;3(3):129-139.
4. Kuetemeyer K, Rezgui R, Lubatschowski H, Heisterkamp A. Influence of laser parameters and staining on femtosecond laser-based intracellular nanosurgery. *Biomedical Optics Express.* 2010;1(2):587-597.
5. Vogel A, Noack J, Hüttman G, Paltauf G. Mechanisms of femtosecond laser nanosurgery of cells and tissues. *J Appl Phys.* 2005;81:1015-1047.

A Breakthrough in Femtosecond Laser Technology

The FEMTO LDV Z MODELS can perform refractive, presbyopia-correcting, and other corneal surgeries.

BY SCOTT M. MACRAE, MD

Ziemer Group recently released three new versions of the FEMTO LDV Z MODELS: the Z2, Z4, and Z6. This will be one of the few platforms that can perform corneal refractive, presbyopia-correcting, and cataract surgery treatments using the same laser. Not only have most of the system's components been redeveloped to coincide with this new release, such as the Z-handpiece and the new scan units, but the latest software is easier to use and has a modern design. Upgrades to the software on any of the three Z models are possible at any time and occur onsite, along with training and surgery support.

In my 4 years of experience performing femtosecond LASIK, I have always relied on the FEMTO LDV systems. I have been quite happy with this system, because its small-bubble technology minimizes inflammation and produces highly reliable results. Because there is no amplifier for the laser, the platform is very consistent and requires minimal maintenance. This article reviews the latest platform, the FEMTO LDV Z MODELS, and discusses my experience.

OVERVIEW OF THE Z MODELS

The FEMTO LDV Z MODELS features a high pulse repetition rate and a short pulse width, producing minimal tissue reaction and mechanical stress as well as very easy tissue dissection. The optical system is unique since it uses a very high numerical aperture, and extremely short focal width, allowing very precise focusing of superfine cavitation bubbles. Because there is more flexibility with this system than with previous FEMTO LDV systems, it is now easier to customize to individual requirements set by any surgeon.

The compact design of the FEMTO LDV Z MODELS fits into even the smallest operating room layout. Additionally, its small footprint can improve productivity because it is designed to roll easily in and out of different surgical rooms. It can therefore be used with any excimer laser or surgical bed as a universal workstation.

APPLICATIONS

All three of the FEMTO LDV Z MODELS can be used to perform femtosecond Z-LASIK; the FEMTO LDV Z4 and Z6 MODELS are also able to perform Z-LASIK "Z," which can produce 3-D resections and create any flap thickness between 90 and 160 µm and any flap diameter between 6.5 and 10.0 mm with beveled or reverse-beveled edges. Additionally, the Z6 has built-in modules for intrastromal corneal ring segment tunnel creation, SIM-LASIK, and intrastromal pockets creation for presbyopic intrastromal corneal inlays. Modules for lamellar keratoplasty and penetrating keratoplasty can be purchased separately. The options for intrastromal pockets, intracorneal rings, and SIM-LASIK can be purchased separately for the FEMTO LDV Z4, which only comes with the built-in Z-LASIK and Z-LASIK "Z" modules.

In the near future, even newer modules will be available for the Z models, including one for OCT-guided cataract surgery. The Z6 model is already designed to perform arcuate and limbal relaxing incisions, lamellar preparation for treatment of corneal blindness (ie, Keramed, Inc.), and several biomechanically enhanced procedures.

FLAP CREATION

The FEMTO LDV Z6 can be used to create vertical or beveled sidecuts as well as LASIK flap hinges in any meridian, including nasal and temporal hinged flaps. Flaps can be constructed with the high-density pulse raster to simplify flap lift and avoid tissue bridges. The high-density pulse raster also sculpts excellent stromal bed quality for enhanced clinical results.

Another nice feature is that the flap can be adjusted to

any thickness, and the diameter can vary between 6.5 and 10.0 mm depending on the treatment profile. The surgeon can also customize the flap to match the ablation profile, both in terms of depth and shape. I call this *anatomical customization*, and it is extremely beneficial, especially in eyes that require an extremely large or small flap. This is helpful using larger-diameter flaps when more treatment is required in the periphery of the cornea. One can also use smaller flaps with small excimer treatment zones. If a surgeon is worried about the flap thickness, it can be adjusted digitally without mechanically changing the spacer. Additionally, the flap can be centered using newly developed software once suction is established; therefore, the surgeon does not have to lose suction and then reapply it in the middle of surgery.

FLAP QUALITY

The flaps that are created with the FEMTO LDV Z MODELS are beautiful. After flap creation, there is less separation or gap between the edge of the flap and the untouched peripheral tissue, which allows the surgeon to get a tight fit. Additionally, tissue disruption is minimal because the gas bubbles are small, compared with larger bubbles that tend to cause more separation. When there is a nice tight fit, however, patients tend to be more comfortable in the early postoperative period, as healing time is quicker and there is less induced astigmatism.

The benefits outlined above equate to stellar improvements in a platform that is already outstanding in its reliability and sophistication. I have noticed that there is more flexibility with this system than the previous generation, and it is easier to customize procedures and center the treatment.

ENERGY LEVELS AND BUBBLE SIZE

When the FEMTO LDV first came out, IntraLase (now owned by Abbott Medical Optics Inc.) claimed that the smaller bubbles that are unique to the LDV system required more energy than the larger bubbles produced by the IntraLase. Indeed, in comparing the pulse rasters, it can be estimated that a bubble created by the FEMTO LDV Z MODELS is about 1,000th the size of a typical bubble created by conventional femtosecond lasers; however, which bubble size is more beneficial? I worked with a physicist at the University of Rochester to compare the two laser systems and discovered that the pulse energy levels produced with the FEMTO LDV Z MODELS (a few nano-Joules; ie, 10^{-9} Joules) compare favorably with the IntraLase, which operates at a few micro-Joules (10^{-6} Joules).

The LDV uses considerably more pulses that can add up to an emitted total energy that is higher compared to other systems. People wrongly try to compare systems on the basis of the total energy, or fluence (J/cm^2), used to create a flap. The use of the emitted energy in such comparisons is wrong because the emitted energy is not equal to the energy deposited in the tissue. Generally speaking: Low-energy, high-frequency pulses couple less energy into the interaction zone. They are less energy efficient but still gentler to the tissue although using a higher total energy.

In summary, with the FEMTO LDV Z6, I rarely encounter any kind of inflammation. In rare cases of minor inflammation, these corneas respond quickly to steroids.

PEARLS OF WISDOM

I have been using the FEMTO LDV lasers for 4 years. The main reasons I chose this over other platforms are its flexibility and reliability. It is true that the ultimate laser (ie, one that can continuously vary bubble size and energy levels) is not yet available, but I believe the FEMTO LDV Z MODELS is the next-best thing. In my opinion, there are two things that are very innovative about the FEMTO LDV Z MODELS. First, this laser will be capable of performing a wide variety of femtosecond procedures, including corneal, presbyopia-correcting, and cataract surgery. Second, the surgeon can select from three laser platforms the one that best suits the variety of treatments he or she offers.

My advice is that, when purchasing a laser, know how reliable the company is and the level of quality customer service you are going to get. Most companies that manufacture femtosecond lasers are established within the ophthalmic community and have been around for a long time, but it is important to make sure you will receive prompt, reliable service if you encounter any problems. Therefore, you should ask yourself the following questions before deciding on a laser platform:

How good is the service and maintenance?

How reliable has this company been in the past, and will they be around in the future?

Does the company have an established track record of continuously improving their product, investing in next-generation developments, and then delivering those developments to their customers?

CONCLUSION

The Ziemer FEMTO LDV Z MODELS—the Z2, Z4, and Z6—are all very good systems. I am quite happy with the FEMTO LDV Z6. This system provides me with the flexibility to perform various treatments, and it is capable of customization, both for the surgeon and for flap creation for the patient. The FEMTO LDV Z MODELS is user friendly, and the software is easily upgradable, allowing the surgeon to select the functions needed now and in the future. ■

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Further Developments for the FEMTO LDV Z MODELS

With the new FEMTO LDV Z MODELS, performing corneal inlay implantation as well as FLEK is simpler than ever.

BY FRANCOIS MAJO, MD, PHD

It is hard to pick just one topic to focus on when discussing the FEMTO LDV Z MODELS (Ziemer Group) because nearly all of its components have been redeveloped to result in the most precise, easy-to-use, and efficient femtosecond laser platform available today. In addition to the new Z-handpiece, articulating arm, laser cavity, scan units, optics, base station, and monitor, the latest software is easier to use than previous generations and has a modern design that is not only visibly appealing but makes programming treatments extremely user friendly. With this already impressive list of reasons why I consider the FEMTO LDV Z MODELS at the top of its class, the real reason that I use this laser is its large range of Z modules, which allow me to perform a variety of treatments. Of particular note, I use the FEMTO LDV Z MODELS not only for Z-LASIK but also to create intrastromal pockets for corneal inlay implantation and to perform Descemet stripping automated endothelial keratoplasty (DSAEK) with the femtosecond laser, otherwise known as femtosecond laser endothelial keratoplasty (FLEK).

The FEMTO LDV Z MODELS represents a unique femtosecond laser technology, mainly due to the incorporation of a very high numerical aperture, extremely short focal depth, and wavefront-optimized optics. These features combine to ensure that significantly fewer and smaller gas bubbles develop during the treatment, that a significant amount of tissue is preserved, and that the eye is quiet and free of edema after surgery. Additionally, the modular architecture of this platform allows tailored application of treatments that can be adapted to the individual requirements of any procedure or patient.

In my experience, clinical results with the FEMTO LDV Z MODELS are excellent, and patients are generally satisfied with their visual outcomes and the pain-free treatment. Below is a recount of my experience with the FEMTO LDV Z MODELS for three surgical procedures: Z-LASIK, intrastromal pocket creation, and FLEK.

Z-LASIK

More than 1.5 million Z-LASIK procedures (ie, femtosecond LASIK procedures with Ziemer FEMTO LDV systems) have been performed worldwide. Because the FEMTO LDV Z MODELS use a high-density pulse raster, Z-LASIK flaps can be easily lifted, with no tissue bridges and excellent residual stromal bed quality. In my experience with Z-LASIK, the ability to make corneal flaps with a uniform and reproducible flap thickness results in excellent and fast postoperative visual quality. With the Z2, the surgeon can create flap thicknesses of 90, 100, 110, and 140 µm. For more flexibility in flap thickness, the Z4 and Z6 models can create any thickness between 90 and 160 µm. The same pattern holds true for flap diameter. With the Z2, the following diameters are possible: 8.5, 9.0, 9.5, and 10.0 mm. With the Z4 and Z6, the flap diameter can range from 6.5 to 10.0 mm in 0.1-mm steps.

Figure 1. The Artificial Anterior Chamber, developed for use with the FEMTO LDV handpiece, is used to create resections in donor corneas.

One nice thing about this platform is that I am able to perform thin-flap (sub-Bowman) LASIK under computer-controlled suction. The resultant flap edge has a natural curvature that is also smooth and self-sealing. The resection is performed in a planar mode, and the hinge size and position are both fully adjustable.

A new procedure, *Z-LASIK* "Z," is also available. This

Figure 2. Donor cornea mounted on the Artificial Anterior Chamber in preparation for a lamellar resection.

Figure 3. The FEMTO LDV handpiece is applied to the Artificial Anterior Chamber in preparation for lamellar resection.

Figure 4. Performing the resection of the donor cornea.

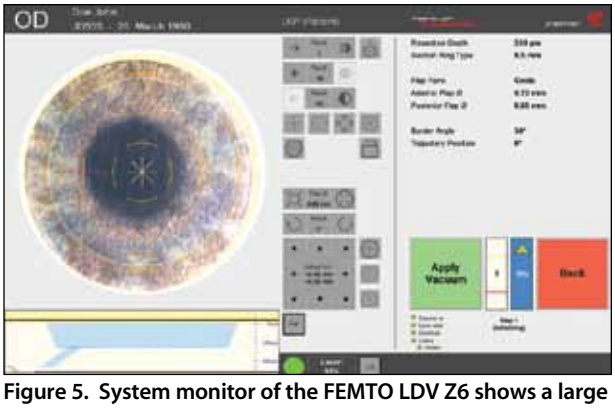

Figure 5. System monitor of the FEMTO LDV Z6 shows a large image of the aspired donor cornea before starting the resection. The position of the resection can be adjusted in 10-µm steps by using the touchscreen.

platform allows resection in 3-D (ie, in the x-, y-, and z-axes compared with only in the x- and y-axes with Z-LASIK). With these Z-LASIK Z procedures, flap thickness can range from 90 to 160 µm and flap diameter from 6.5 to 10.0 mm. Additionally, customizable flaps including round and oval flaps with angled edges (30º to 150º) can be created to accommodate the desired geometry.

INTRASTROMAL POCKETS

The FEMTO LDV Z MODELS Z4 and Z6 include adjustable pocket software that can be used to create intrastromal pockets for corneal inlay insertion. I recently began using the Icolens corneal inlay (Neoptics AG), a bifocal microlens, and noticed a huge benefit when using the FEMTO LDV Z MODELS adjustable pocket module to create the pocket. I typically use the Icolens for patients with -0.50 to 1.00 D of ametropia and less than 1.00 D of cylinder.

During treatment, the laser's low-energy pulses create a smooth pocket approximately 200 to 350 µm into the corneal stroma. I prefer to create my incision temporally, approximately 2 mm from the periphery. The procedure is centered using the visual axis, but the centration can also be adjusted postoperatively if needed. There is very little inflammation after surgery, and patients achieve excellent near visual outcomes without sacrificing distance vision. Visual recovery is very fast due to the gentle tissue resection of the FEMTO LDV Z MODELS, and thus the formation of epithelial ingrowth is avoided.

The adjustable pocket software includes the following: pocket entry and endpoint, pocket depth, and pocket width. These parameters are chosen according to patient data. Additionally, corneal inlay explantation or exchange is possible.

FLEK

In addition to the other modules, the FEMTO LDV Z MODELS is also able to perform both lamellar and penetrating keratoplasty. The FEMTO LDV Z6 laser system is most appropriate for therapeutic procedures because of its PowerPlus profile. As an even more powerful laser source than other FEMTO LDV Z MODELS, the PowerPlus

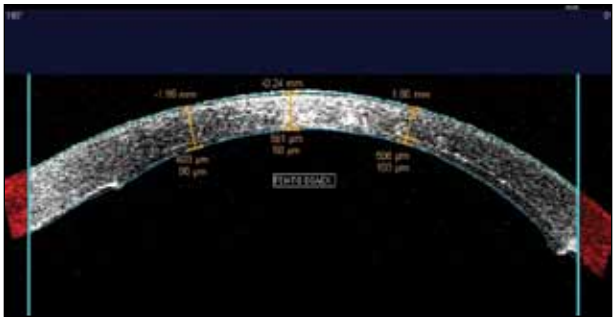

Figure 6. OCT image of a cornea after femtosecond DSAEK, also referred to as femtosecond laser endothelial keratoplasty (FLEK). Image documents the smooth endothelial side of the cornea achieved with FLEK. Thickness of the endothelial graft is approximately 50 µm at the center and 100 µm at the mid-peripheral position (approximately 2 mm from the center).

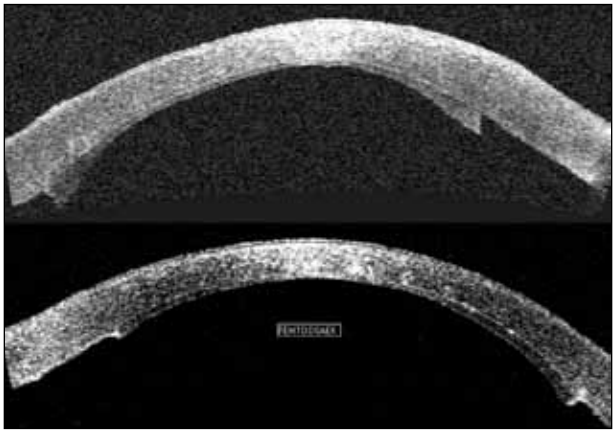

Figure 7. Comparison of endothelial keratoplasty performed with conventional DSAEK (top) and with FLEK (bottom).

profile of the FEMTO LDV Z6 PowerPlus allows higher and adjustable pulse energy, which is truly a breakthrough for femtosecond laser technologies.

For lamellar keratoplasty procedures including FLEK, resection can be performed in two (x- and y-axis) or three (x-, y-, and z-axis) dimensions. The advantage of FLEK is that the resection is customizable according to not only my preference but also to the patient's pathology (Figures 1–5).

My experience with FLEK on the FEMTO LDV Z MODELS laser is limited. In the eight cases that I have done to date, results have been better and more consistent than previous cases I performed with a mechanical microkeratome or the IntraLase femtosecond laser (Abbott Medical Optics Inc.). With the FEMTO LDV Z MODELS, I am able to achieve a thin lamella of approximately 100 µm, which is very beneficial.

OTHER ADVANTAGES

In addition to being able to perform various treatments with the FEMTO LDV Z MODELS, including Z-LASIK, intrastromal pocket creation, and FLEK (Figures 6 and 7), I am also impressed with the customer service from Ziemer Group. The company has always offered educational training for each of its latest technologies. They provide you with the necessary information to optimize results with such technologies as the FEMTO LDV Z MODELS.

> The advantage of FLEK is that the resection is customizable according to not only [the surgeon's] preference but also the patient's pathology.

One of the good things about the FEMTO LDV Z MODELS, specifically, is that it can move from one surgery room to another with ease, and it can also be used with any excimer laser system. Therefore, this compact, robust system is ideal for almost every operating room and also has stable laser sources and optics. It tolerates heat, humidity, and movement, and time loss for moving the laser between locations is minimal.

The FEMTO LDV Z MODELS also has high-definition visual control on a large flatscreen monitor, providing professional high-dynamic range imaging. As a practical detail, a secondary monitor is available. It is placed conveniently before the surgeon, facilitating visual control of the procedure. These features combine to provide easier centration, more precise positioning, and improved usability.

CONCLUSION

The FEMTO LDV Z MODELS represent a unique femtosecond laser technology that offers modular platform solutions for various surgical treatments. I like to refer to it as a Swiss Army knife, simply because it is compact, has so many functions, and is extremely reliable. For a surgeon like myself who performs multiple treatments like refractive surgery, corneal grafts, and cataract surgery, this platform is the best solution. Once the planned cataract surgery module is available, I will use it for almost all of my surgeries.

Paired with the mobility of the unit, the efficiency of the FEMTO LDV Z MODELS is unparalleled. Its low pulse energy, high pulse repetition rate, and short pulse width translate into minimal side effects and mechanical stress, cleavage-free tissue dissection, and excellent clinical results. This platform is not only the best platform today, but it will continue to be the best platform for years to come. ■

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The FEMTO LDV Z MODELS: Representing the Concept of Swiss Precision

A description of this author's experience

BY RICHARD FOULKES, MD

In less than 1 month and no more than 5 surgical days with the new FEMTO LDV Z6 (Ziemer Group), I already knew that this was a winning laser platform. Not only was I impressed with the FEMTO LDV Z MODELS's ability to perform an ever increasing range of different corneal procedures, but I was particularly pleased to see how even routine LASIK procedures achieve better outcomes than before. Below are a few of my early observations in about 50 eyes as well as many explorations with porcine eyes.

There is about 1,000 µm of freedom in terms of moving the location of the flap within the applanation zone without limiting flap size. If the patient has pannus, the flap can be moved or reduced in size to avoid the zone. Hinge placement or ovalization freedom now exists. Of course, the biggest advantage is that we can also move in the z-axis. The device uses its unique servo motor system to maximal advantage. It moves the sweep energy derived directly from the laser cavity (with attenuation now possible) using a prism to guide the layered optics. The sweep can be angled as an example. This cannot be achieved by any other long focal length laser. I am working with the flagship device, the FEMTO LDV Z6, which will soon have OCT and a power boost mode to add to the capability of treating the anterior capsule.

On my first laser day, I made 100-µm flaps. Thanks to the unique design of the suction ring, one is able to get a large applanation zone, with which you can recenter and size the flap. All of my treatments, from suction to release, were only slightly longer than 25 seconds.

The now routine first-day visual acuity of better than 20/20 without inflammation is expected with Ziemer, and there were no surprises. However, the edge variation was a new finding. We cut 60° on all right eyes and 120° on all left eyes. There is no epithelial gap on either cut, as is seen with the larger-spot, higher-energy lasers that "cook" the tissue when overlapped. In my first experience, the reverse cuts at 120° were even more invisible at the slit lamp. We will be following for any refractive differences.

I have a great deal of pent-up desire to work with this device and have created a number of interesting cuts in pig eyes. We have made intrastromal pockets for inlays, tunnels for ring segments, PKPs, angled phaco incisions, side ports, and deep cuts that could be used as LRIs. I even paid homage to Drs. Barraquer and Ruiz with the creation of an ALK lenticule! Our ability to perform lenticule extraction procedures with the FEMTO LDV Z6 is only limited by software, as it cuts perfectly precise, complete dissections deep into the cornea. I cut an endothelial graft with the OCT by using ultrasound to gauge the depth (900 µm of the pig cornea). With a technician's guidance, there seems to be no limit to what you can design and do with the FEMTO LDV Z6!

In conclusion, I believe that the arrival of the FEMTO LDV Z MODELS is a seismic event for surgeons who are open to looking outside the usual billion-dollar companies. All corneal—and in the near future, cataract—procedures can be accomplished with this hearty, mobile system. The procedure fees, maintenance cost, flexibility, and reliability make this system ideal for every surgeon, whether your focus is on laser vision or femtosecond lenticule-based vision correction, cataract surgery, or corneal surgery. The thought of investing $1 million over 3 years on a femtosecond laser cataract system that requires a dedicated room and is limited to one procedure with the enormous risk of being cornered into an unproven platform is absurd in the face of the FEMTO LDV Z6!

I encourage you to take the time to experience the technology yourself at your first opportunity. In the meantime, I will be posting videos online to demonstrate how rapidly we are advancing this device. These are truly exciting times to be an eye surgeon, and I applaud the Ziemer team and its visionary leader for the work they have done to give us this amazing tool! ■

Richard Foulkes, MD, is the Medical Director of Foulkes Vision Research Center, Lombard, Illinois. He is an Adjunct Professor at the University of Illinois. Dr. Foulkes states that he is a medical monitor for Ziemer Group but he does not receive reimbursement. He may be reached at tel: +1 63721400; fax: +1 630 724 1410; e-mail: foulkes52@gmail.com.

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OPHTHALMOLOGY

FEMTO LDV Z MODELS

Modular architecture

With the FEMTO LDV Z Models you have access to a modular femtosecond laser. Strategic flexibility.

Tailored application packages Adapted to your individual requirements	**Z2 Model**	**Z4 Model**	**Z6 Model**	**Z6 Model** PowerPlus
Z-LASIK	●	●	●	●
Z-LASIK Z		●	●	●
Intracorneal Rings (ICR)		○	●	●
Intrastromal Pocket (ISP)		○	●	●
SIM-LASIK		○	●	●
Lamellar Keratoplasty (LKP)			○	○
Penetrating Keratoplasty (PKP)			○	○

● Standard software package
○ To be purchased separately

Arcuate incisions, lamellar preparation for treatment of corneal blindness, biomechanically enhanced procedures…
The corneal applications are constantly being developed as we continue to learn – and your Z6 Model is already designed for these applications.

Ziemer Ophthalmic Systems AG
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