VisuMax Femtosecond Laser Offers an All-in-One Refractive Procedure

A well-designed femtosecond laser is a breakthrough for corneal microsurgery.

BY JOHN F. DOANE, MD

Lamellar corneal surgery for the correction of refractive errors has been evolving for more than 60 years.[1-5] As we enter the second decade of the third millennium, it is surprising when something "new" is actually a paradigm changer in laser vision correction. The principals in the refractive division of Carl Zeiss Meditec, Inc. (Dublin, CA), I believe, have created a device and concept that could be the next major advance in lamellar corneal refractive surgery. It is unlikely that José I. Barraquer, MD, foresaw this latest advance. Dr. Barraquer began developing lamellar corneal surgery in 1948. It is only through his sheer genius, persistence, and ingenuity that the field of lamellar corneal refractive surgery in the form of LASIK is with us today. Many of his concepts remain the foundation of this aspect of ophthalmic surgery.

Fundamentally, refractive lamellar corneal surgery attempts to remove, add, or modify the corneal stroma so that the radius of curvature of the tear film-anterior corneal interface is altered as desired. Dr. Barraquer's quintessential contribution was the microkeratome, which functions like a carpenter's plane not only to access the corneal stroma but also to perform a planar lamellar resection of stromal tissue to induce refractive changes. The success of Dr. Barraquer's lamellar refractive approach approach did not pan out until the 193-nm excimer laser was married to the procedure as the tool to precisely effect the refractive correction instead of the cryolathe.[6-9] The precision by which an excimer laser can remove tissue—0.25 µm per pulse—revolutionized the refractive surgical landscape and allowed for commercialization of refractive surgery across the globe.

The femtosecond laser allows surgeons to change the curvature of the stroma with the excimer laser.[10] Through the groundbreaking work of Ron Kurz, Tibor Juhanzs, and Eric Weinberg, the Intralase Corporation (now Abbott Medical Optics Inc., Santa Clara, CA) was able to bring to market a device that made the flap's creation easier, safer, and more predictable.[10] Additional work by Intralase/Abbott Medical Optics Inc., Carl Zeiss Meditec, Inc., and other companies has enabled femtosecond lasers to be designed and utilized for therapeutic corneal surgery. The most recent advance by Carl Zeiss Meditec, Inc., goes beyond the flap's creation with a curved ocular interface (Figure 1) to therapeutic techniques that use the femtosecond laser for an all-in-one refractive procedure called *ReLEx* (for refractive lenticule extraction) with the Carl Zeiss Meditec, Inc.'s VisuMax femtosecond laser (Figure 2). No 193-nm excimer laser is needed.

Figure 1. Disposable curved ocular interface.

CONCEPT

The ReLEx technique can correct any refractive error—simple myopia and hyperopia, compound myopic and hyperopic astigmatism, mixed astigmatism, and more. ReLEx encompasses two different approaches. The first is the femtosecond lenticule extraction or FLEx procedure. The femtosecond laser

Figure 2. VisuMax femtosecond laser.

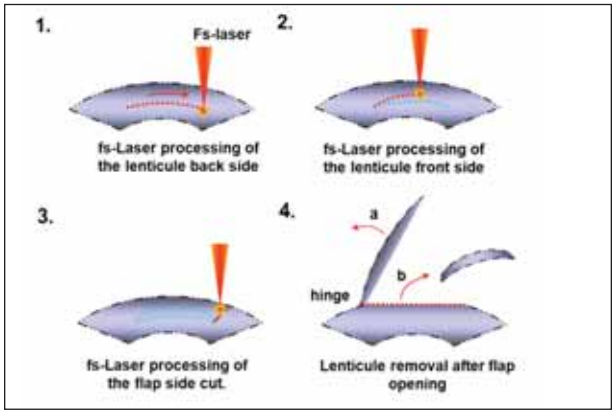

Figure 3. Animation of the FLEx procedure.

makes essentially two passes. The first or posterior pass of the femtosecond laser creates the posterior surface of the lenticule that will be extracted. The second or anterior pass of the laser accomplishes three goals: the flap's side cuts, the side cut to lenticule edge pass effectively creating the peripheral stromal bed, and the anterior surface of the lenticule that will be extracted. After the laser passes, the surgeon lifts the peripheral edge of the flap, dissects the flap from the anterior surface of the lenticule, and then takes hold of the peripheral edge of the lenticule to lift the lenticule from the stromal bed (Figure 3). The flap is then positioned in the normal fashion.

The FLEx procedure diverges from traditional LASIK in that, instead of the excimer laser's being used for the "refractive step," the femtosecond laser creates a lenticule of corneal tissue for removal to cause the refractive change (Figure 4). In this setting, the procedure is reminiscent of automated lamellar keratoplasty. The major difference is that the refractive predictability is on par with excimer-based corneal refractive procedures (discussed later).

The second approach to ReLEx is the small-incision lenticule extraction or SMILE technique. Rather than create and lift a hinged flap, the surgeon performs two passes of the femtosecond laser. As in the FLEx procedure, the first pass of the laser creates the posterior aspect of the lenticule and a peripheral stromal bed. The second pass of the femtosecond laser creates the anterior surface of the lenticule and one or two small access incisions. The surgeon can then dissect the remaining corneal attachments of the anterior and posterior surfaces and remove the lenticule through a small incision. The advantages of the SMILE concept are that it is less invasive, there is no chance for flap dislocation, the cornea inherently maintains a greater biomechanical structure, and there should theoretically be a shorter healing cycle.

FDA SUBMISSION FOR US CASES UNDERWAY

To date, no ReLEx procedures have been performed in the United States, but FDA submission for these studies is underway and expected to start domestically in the second half of 2010. Outside the United States, ReLEx procedural development under the guidance of Carl Zeiss Meditec, Inc., is occurring at six sites on three continents. Investigations at all of these sites have shown exquisite refractive results that meet or exceed the best LASIK results to date. Data from the international sites (R. Shah, Vadodara, India; W. Sekundo, Mainz, Germany; M. Blum Erfurt, Germany; O. Ibrahim, Alexandria, Egypt; I. Solomatin, Riga, Latvia; R. Wiltfang, Munich, Germany) mirror current LASIK results, although the visual recovery with ReLEx in general has not been as quick. Refractive predictability with ReLEx is equivalent or superior to current LASIK results; with the former, 95% of the eyes are ±0.50 D from refractive target. Interestingly, the predictability has been just as good for patients with low myopia as it has for those with high myopia. Efficacy rates have shown that 95% of the eyes achieve at least 20/30 uncorrected distance visual acuity at 3 months for even moderate-to-high myopic levels. Importantly, the safety results have been excellent, with only 1% to 2% of eyes losing two or more lines of BSCVA (N = 777 eyes). Refractive stability is essentially achieved at 1 week, and little-to-no change is seen between this interval and the 1- and 3-month data sets (data on file at Carl Zeiss Meditec, Inc.).

Are there unknowns? Yes, long-term data are lacking. Like all surgeons, I would like to see the results in my own hands. It is also currently unclear if very small refractive errors (≤1.00 D) can be treated with the ReLEx procedure. Furthermore, investigators have yet to determine what surgeons can achieve for the typical enhancement cases that are less than 1.00 D spherical equivalent

(Courtesy of Walter Sedundo, M.D.)

Figure 4. Still photograph of the FLEx procedure. Note the reflected flap at the bottom (superior patient position) of the photograph. An 8-mm cord length flap has been created. The side cut is clearly evident. A 6-mm–diameter lenticule is being lifted from the corneal bed.

refraction. Can these be addressed with a ReLEx enhancement? As this technique evolves and if other manufacturers want to follow Carl Zeiss Meditec, Inc., new systems must have low energy (approximately 200 nJ per photodisruptive spot), have a high hertz rate (500), not applanate the cornea, and have the ability to scan with incredible accuracy in three dimensions.

From a clinician's standpoint, it is quite clear that, if designed properly, a femtosecond laser is a breakthrough for corneal microsurgery. Very soon, it should be apparent what impact a femtosecond laser can achieve as a stand-alone refractive surgical device. ■

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"Presby-LASIK provides patients with adequate functional near vision while maintaining good distance visual acuity through the creation of an optically superior corneal shape."

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My colleagues and I have now treated 500 patients, and surgeons at other centers around the country have operated on another 200 or so patients. The results have been excellent, and patients' satisfaction has been very high and consistent between centers. At our facility, no patients have lost BSCVA. Other concerns such as night vision problems and glare have not been an issue and certainly no different than for our nonpresbyopic laser patients, according to data obtained from our postoperative questionnaire. Our enhancement rate is higher, in the range of 8% to 10%, but we feel this will decrease as we fine-tune our nomograms. As indicated in Figures 2 and 3, uncorrected binocular distance visual acuity is 20/25 in 95% of patients at 6 months and is very stable at that point. Uncorrected binocular near vision is J3 in 95% of patients, which again seems to be stable by 3 to 6 months. We achieve these results by creating a prolate shape with a negative spherical aberration and a negative Q-value (Figure 4).

CONCLUSION

Presby-LASIK provides patients' with adequate functional near vision while maintaining good distance visual acuity through the creation of an optically superior corneal shape. Is the procedure the perfect solution to presbyopia? Of course not. Nothing short of restoring patients' full accommodative amplitude will be optimal. Fortunately, surgeons are working with a physiologic optical system that is pliable and adaptable and allows for compromises.

For my colleagues and me, presby-LASIK has been a valuable addition to our laser practice. The procedure now accounts for about 35% of our laser surgeries and permits our patients a wider range of presbyopia-correcting solutions. ■

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