

Intrastromal Laser Refractive Surgery

Femtosecond lasers are being used to treat myopia, hyperopia, and presbyopia without trauma to the corneal surface.

BY LANCE J. KUGLER, MD, AND MING X. WANG, MD, PhD

Femtosecond lasers in ophthalmology were initially investigated with the hope of reshaping the cornea intrastromally, thus eliminating the risks associated with the LASIK flap's creation or the removal of the epithelium and Bowman's layer during PRK. Although this initial intent did not come to fruition, the femtosecond laser has revolutionized the creation of LASIK flaps as the method of choice for an increasing number of LASIK surgeons. The full potential of femtosecond technology has yet to be achieved,

however, as new applications of this powerful and precise innovation continue to emerge.

Although the current discussion of the future of femtosecond technology has largely focused on augmenting cataract surgery, there are many ongoing advances in the realm of femtosecond keratorefractive surgery as well. Two intrastromal techniques, one primarily for the treatment of myopia and one primarily for the treatment of presbyopia, have demonstrated success in early studies.

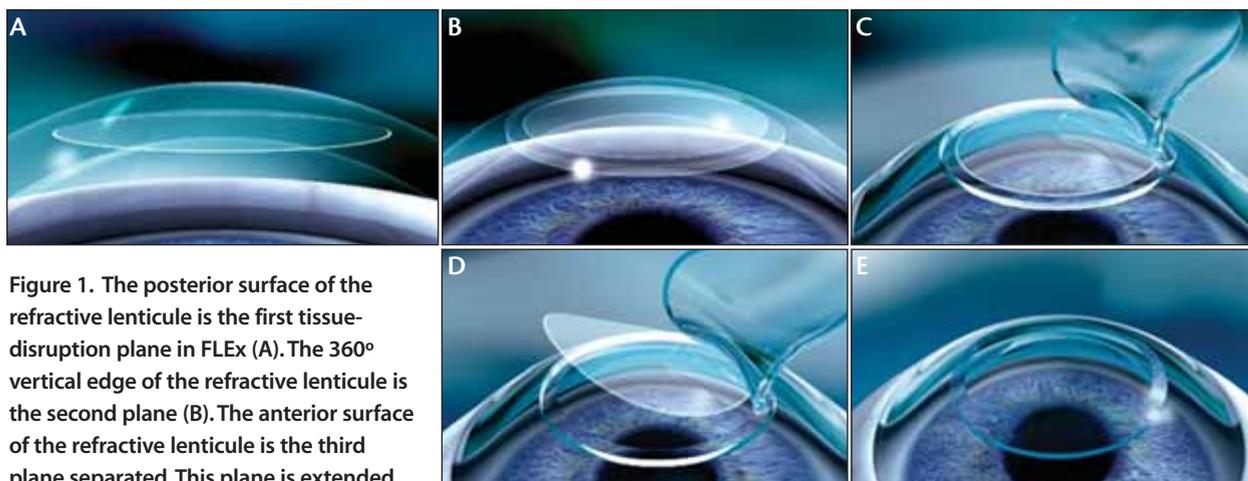


Figure 1. The posterior surface of the refractive lenticule is the first tissue-disruption plane in FLEX (A). The 360° vertical edge of the refractive lenticule is the second plane (B). The anterior surface of the refractive lenticule is the third plane separated. This plane is extended

approximately 0.5 mm beyond the optical zone (C). An incision 250° to 300° in length (FLEX) or 30° to 50° (SMILE) is then made and the lenticule removed (D). The flap is replaced (E). (Images courtesy of the video "Femtosecond lenticule extraction (FLEX) Single Step All-Femtolasar Refractive Procedure" by W. Sekundo, ASCRS 2008.)

(Courtesy of Dr. Luis Antonio Ruiz.)

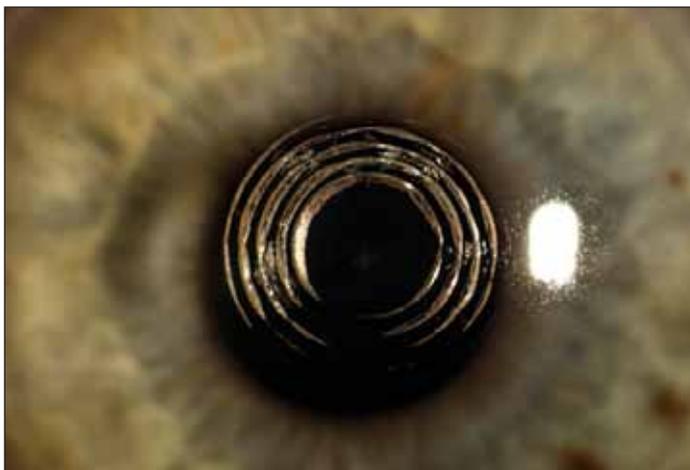


Figure 2. Cornea post-Intracor.

FEMTOSECOND LENTICULE EXTRACTION

A relatively new technique involves the use of a femtosecond laser to remove a lenticule of corneal stroma to correct refractive error. The entire procedure is completed with a single femtosecond laser and does not require the use of an excimer laser. There are two versions of this technique performed with the VisuMax femtosecond laser (Carl Zeiss Meditec AG, Jena, Germany): femtosecond lenticule extraction or FLEx and small-incision lenticule extraction or SMILE. The FDA has approved the VisuMax laser for the creation of LASIK flaps, but the laser is not indicated for lenticule extraction with either of these techniques.

Both FLEx and SMILE involve the creation of four different tissue-disruption planes (Figure 1). The difference between the two techniques is that, in FLEx, the fourth incision extends 250° to 300° (similar to a LASIK flap), which allows excision of the refractive lenticule. In contrast, the fourth incision in SMILE extends only 30° to 50°, through which the lenticule is extracted.

Preliminary clinical results are promising. Sekundo et al published 6-month data on 10 myopic eyes using a prototype of the VisuMax laser. Patients had a mean age of 39 years and a mean spherical equivalent of -4.73 ± 1.48 D (standard deviation) preoperatively and -0.33 ± 0.61 D 6 months postoperatively. Ninety percent of eyes were within ± 1.00 D, and 40% were within ± 0.50 D of the intended correction. No eye lost two or more Snellen lines, and aberrometry showed no significant induction of higher-order aberrations.¹ A second study by Blum et al, initially presented at the 2008 ESCRS meeting, showed 74.8% of 108 eyes within ± 0.50 D and 98.1% within ± 1.00 D of the intended correction. Only 0.9% of eyes lost one Snellen line, 43% gained one Snellen line, and 9.3% gained two Snellen lines of BSCVA.² In a more recent study with

a later-generation VisuMax, Dr. Rupal Shah evaluated 500 eyes after either FLEx or SMILE and found the treatments to be stable and accurate, with 93% of eyes achieving a postoperative refractive error of ± 0.50 D at 6 months (personal communication, January 2010). Dr. Shah used the procedure to correct as much as -10.00 D. Adverse events were minimal and limited to either a loss of suction during femtosecond ablation necessitating a restart of the procedure or the surgeon's difficulty discerning the tissue planes between the lenticule and the surrounding stroma. Both of these obstacles were easily corrected at the time of surgery and did not affect the result of the treatment.

FLEx and SMILE appear to compare favorably to LASIK in terms of efficacy, stability, and safety, with few adverse events. Both of these "all-in-one" techniques hold promise. A one-laser system would decrease the cost of the procedure, reduce the space required in the laser suite, and improve surgical workflow. With SMILE, because the anterior corneal structure remains largely intact, there is a potential for the safer treatment of higher levels of myopia than is currently possible with excimer laser procedures. The corneal nerves are also mostly spared, so there is theoretically less risk of dry eye problems.

Despite these advantages, many factors may limit the adoption of these new all-in-one techniques. Perhaps the most significant obstacle is that current excimer laser techniques are accurate and reproducible, and they have a long-established safety record. Thus, in order to gain market share, any new technique must demonstrate significant advantages over current excimer laser techniques. Experience with LASIK flaps dictates that the more refractive surfaces that are introduced into the visual axis, the more chance there is for misalignment of these surfaces with respect to the visual axis. Such misalignment can cause aberrant light scattering, irregularity, and higher-order aberrations. Lenticular extraction requires the creation of two parallel planes of lamellar dissection that oppose each other after resection of the lenticule, which theoretically increases the risk of misalignment, irregularity, or light scattering. Current data suggest eyes have impressive stability after lenticular extraction, but long-term data are needed.

INTRASTROMAL KERATOTOMY FOR THE TREATMENT OF PRESBYOPIA

Intrastromal ablation for the treatment of myopia, without disruption of the epithelium or Bowman's layer,

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has not been possible due to the need to remove corneal tissue from the central cornea to decrease corneal curvature. Keratorefractive treatment of hyperopia or presbyopia, however, requires steepening the central cornea and thus is not hampered by the same limitations.

The recently introduced Intracor technique uses the Technolas Femtosecond Laser System (Technolas Perfect Vision, Munich, Germany) to create a multifocal, hyperprolate cornea. A series of circular intrastromal keratotomy rings, starting in the posterior stroma and progressing anteriorly (Figure 2), are created to steepen the central cornea and enhance the patient's reading vision and depth of focus. The ring pattern works best in eyes that have a mildly hyperopic refraction preoperatively, and it can be modified with additional pulses for eyes with low myopia, hyperopia, or astigmatism. The laser's computer software and nomogram take into account the eye's keratometry, corneal thickness, and refraction.

Low amounts of myopia may also be treated by intrastromal radial disruptions, and Intracor may be combined with PRK to correct high refractive errors. Eyes with results that regress may be enhanced by the addition of more rings, depending on the magnitude of the residual refractive error.

Early data are encouraging. A recent study by Dr. Luis Ruiz of 245 eyes treated using the Intracor technique demonstrated improved uncorrected near visual acuity in 100% of eyes at 6 months, with minimal or no change in uncorrected distance visual acuity. At 12 months, uncorrected near visual acuity improved to J1 in these eyes, with continued improvement in mean uncorrected distance visual acuity. Dr. Ruiz found that 89.2% of eyes achieved both J2 and 20/25 or better vision. Mean best-corrected distance visual acuity and distance-corrected near visual acuity continued to improve with time, and there were no significant complications.³

Possible limitations to this technique may stem from corneal biomechanics and intrastromal inflammation associated with the laser. The concentric rings are remi-

niscient of hexagonal incisional keratotomy techniques, which also steepened the central cornea to treat hyperopia. These techniques fell out of favor because of the weakening effect on the cornea, which caused visual instability as well as severe denervation from the 360° deep anterior incisions. Intracor is theoretically less likely to weaken and denervate the cornea, because the laser incisions are midstromal and do not disrupt the stronger anterior cornea or the subepithelial nerves. Femtosecond lasers are more likely to induce intrastromal inflammation, however, as evidenced by the higher rate of diffuse lamellar keratitis when LASIK flaps are created with a femtosecond laser versus a mechanical microkeratome.⁴ It is possible that intrastromal inflammation resulting from 360° rings near the visual axis will induce destruction of keratocytes and digestion of tissue. This in turn may contribute to changes in corneal biomechanics and physiology, causing irregular astigmatism, scarring, and general physiologic disturbance. Early data on this technique are encouraging, but further study is needed.

CONCLUSION

The treatment of keratorefractive error with an intrastromal laser, without breaking the corneal surface, remains a primary goal of refractive surgery. Both femtosecond lenticular extraction and intrastromal keratotomy are promising techniques in the continuing evolution of refractive surgery. ■

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