Refractive Surgery Beyond LASIK

... and Other Advancements in Femtosecond and Excimer Laser Treatment

Supported by an educational grant from Carl Zeiss Meditec
Ever since the introduction of intrastromal excimer laser ablations such as PRK and LASIK, refractive surgeons have continually streamlined the technique, developing new strategies and technologies to maximize results and minimize harm. The latest revolution in intrastromal ablation procedures is ReLEx (Carl Zeiss Meditec, Jena, Germany). This is the first femtosecond-only laser vision correction procedure available to patients. Using the VisuMax (Carl Zeiss Meditec), ReLEx simplifies corneal refractive laser surgery because the corrective lenticule and overlying corneal flap are created in one step using one laser.

ReLEx is not just another way of doing LASIK; it is a new procedure. At this time, only the VisuMax femtosecond laser is capable of such controlled intrastromal lenticule formation. In my experience, the technique is really straightforward and easy to perform. Figure 1 depicts the steps of ReLEx.

With the femtosecond lenticule extraction (FLEx) option, the corrective lenticule and overlying corneal flap are created in the intact cornea within one step (Figure 2). Then, the corneal flap is lifted, as in conventional LASIK, thus removing the lenticule (Figure 3). After the refractive correction is complete, the corneal flap is repositioned.

The FLEx strategy creates a full corneal flap for removal of the intrastromal lenticule; now, a minimally invasive option, small incision lenticule extraction (SMILE), has also been developed, with many surgeons converting to its use. In this modification, the lenticule is created as usual, but only part of the anterior flap sidecut is completed to the surface. The lenticule is then removed through a 4- or 5-mm superior corneal tunnel. The possible advantages of this option include less postoperative irritation, due to the small epithelial cut; less affected corneal sensibility and tear production, due to fewer corneal nerves being cut; the possibility for improved biomechanical stability; and a lower risk of corneal ectasia, due to continuous and preserved anterior stromal lamellae across the cornea.

**BENEFITS**

The benefits of using just one laser for refractive correction are obvious. First, there is a lower cost associated with the procedure, because the surgeon does not have to purchase two lasers, one to make the flap cut and one to perform the ablation. With ReLEx, both steps are done with the VisuMax. Second, this setup saves time, because the patient does not have to be moved between two laser stations or two patient beds. Third, patient comfort is heightened, because the procedure is quiet, no smelling debris is produced, and the suction pressure during laser cutting is considerably lower than with
Redefining Cataract Surgery

microkeratome-based LASIK. Fourth, the refractive lenticule is cut with minimal contact with the cornea.

During conventional LASIK, variations in corneal hydration during excimer laser ablation may affect the refractive precision of the procedure. With this new method of ReLEx, after a short learning curve, even refractive surgeons in training can perform high-quality corneal refractive surgery, avoiding the potential complications associated with microkeratome- and femtosecond-laser based LASIK.

50 CASES

Our initial experience included 50 ReLEx procedures for moderate and high myopia, all of which were performed at Aarhus University Hospital in Denmark. Patients' UCVA 1 day after surgery is comparable to or better than UCVA after conventional femtosecond LASIK. Additionally, the precision of the procedure is better than what we have noted after conventional femtosecond LASIK. No surgical complications occurred during these 50 procedures, and no retreatments were necessary.

CONCLUSION

The current ReLEx procedure is just the first step in the evolution to corneal refractive lenticule extraction techniques. Over time, surgeons will develop modifications to the shape of the corrective lenticule in the hopes of refining and reducing the number of surgically induced aberrations that are associated with corneal refractive surgery with high myopia.

ReLEx for the treatment of myopia from 6.00 to 10.00 D is very precise. In our first 50 cases, we did not have to perform one single retreatment; however, if required, retreatments after FLEX should be performed with the excimer laser and preceded by manual lifting of the flap.

After SMILE, retreatment should be performed as a surface ablation procedure. If the patient has a small refractive error postoperatively, another option is the placement of relaxing incisions. Although this option is still today highly unexplored, it is perhaps a good strategy to use for patients who experience small changes in refraction with age.

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Why Introduce ReLEx Into Your Practice?

Beginning surgeons should start with patients with high myopia.

BY YVES GULDENFELS, MD

The use of femtosecond lasers in refractive surgery has become mainstream over the past few years. Its first function was to create the corneal flap during LASIK, but now, with the VisuMax platform from Carl Zeiss Meditec (Jena, Germany), it is possible to complete the entire refractive procedure with the femtosecond laser alone.

The femtosecond-only procedure ReLEx can solely be performed with the Zeiss femtosecond laser platform. This platform allows surgeons to perform complete laser vision correction with the option to choose between two procedures, performing femtosecond lenticule extraction (FLEx) or the microincision ReLEx technique of small incision lenticule extraction (SMILE; Figure 1). I have been using both ReLEx techniques since March. Any time it is possible, I prefer to use SMILE, because it enhances the maintenance of an intact Bowman's layer. Additionally, I prefer SMILE not only because I can use the laser to create a 320º flap but because the entire procedure is completed inside the corneal layers, through only a small opening. Converting to small-incision refractive surgery surely seems to be a major revolution in these treatments.

This technology is interesting for the future, because I see refractive treatments being performed purely as intrastromal procedures.

I think over the long term, SMILE is more stable for our patients; however, this has yet to be shown in clinical trials and is therefore just my opinion.

I decided to incorporate ReLEx into my practice after I attended lectures delivered by Walter Sekundo, MD, of Marburg, Germany, and Marcus Blum, MD, of Erfurt, Germany, at a recent ESCRS meeting. What specifically caught my interest was the fact that, with the VisuMax femtosecond laser, it was now possible to perform an entire refractive procedure with only one laser. Additionally, this technology is interesting for the future, because I see refractive treatments being performed purely as intrastromal procedures. Lastly, I was interested in performing ReLEx because there is no influence from the environment of the operating room, including temperature or atmospheric humidity.

The initial results Drs. Sekundo and Blum had with ReLEx were so promising that I knew I had to incorporate this treatment into my practice as well. I contacted Dr. Sekundo, who shared some surgical pearls with me. I also traveled to India to observe Rupal Shah, MD, as she perhaps has the most experience to date with this technique. Now, after personally performing 60 treatments using ReLEx, I can safely say that it is a revolutionary procedure that is paving the way for small-incision refractive surgery. This shift in technique is much like the shift from extracapsular cataract extraction to phacoemulsification was in cataract surgery.

PERSONAL EXPERIENCE, ADVICE

The procedure is reproducible, and the nomograms from Zeiss are very accurate. Of the patients I have treated, which include those patients with as much as -9.00 to -10.00 D of myopia, there is less regression at 3 months with the all-femtosecond technique compared with excimer laser LASIK using the VisuMax for flap creation only.

From my personal experience, I would advise those surgeons just beginning with ReLEx to initially perform FLEx in their patients. Not only is FLEx an easier tech-
I can safely say that ReLex is a revolutionary procedure that is paving the way for small-incision refractive surgery.

...
Redefining Cataract Surgery

Presbyopia correction is the last frontier in refractive surgery that we have yet to completely conquer. Many proposed techniques and mainstay procedures are performed today; however, most, if not all, fail to truly correct presbyopia over the long term. Nevertheless, in an attempt to obtain a foolproof correction, the number of available surgical presbyopia correction procedures has grown. Although presbyopia correction remains a challenge to surgeons, we have discovered that Laser Blended Vision is the most appropriate solution available today.

Developed by Dan Z. Reinstein, MD, MA(Cantab), FRCSC, DABO, FRCOphth, of London, and Eckhard Schroeder, of Carl Zeiss Meditec (Jena, Germany), Laser Blended Vision is a treatment option for presbyopia correction in patients with emmetropia, myopia, or hyperopia, even in the presence of astigmatism. It can be used to treat refractive errors between 5.75 and -9.00 D. Laser Blended Vision combines nonlinear aspheric ablation profiles with micro-monovision. The beauty of Laser Blended Vision is that it does not compromise contrast sensitivity or night vision and also retains functional stereoacuity. This treatment can be performed using the CRS-Master (Carl Zeiss Meditec).

WELL TOLERATED

In contrast to monovision, Laser Blended Vision increases the depth of field of each eye. In comparison to monovision, both treatments correct the dominant eye for distance and the nondominant eye for near. The nominal target refraction is plano in the dominant eye and -1.50 D in the nondominant; however, if the surgeon chooses, and depending on the patient’s refraction, these targets can be modified manually. What happens is that, as the brain merges the two images, a blend zone is created. This blend zone provides patients with quality UCVA at near intermediate, and far. According to a study conducted by Dr. Reinstein,1 more than 95% of patients tolerated Laser Blended Vision, compared with only 59% to 67% of patients who tolerate contact lens monovision.2 Laser Blended Vision is a relatively short procedure, lasting between 10 to 15 minutes if performed as a bilateral simultaneous LASIK treatment. To program the procedure, the dominant eye is keyed in, followed by the refraction of both eyes. At this point, the surgeon selects to perform either a full or mini Laser Blended Vision treatment; this decision is directly related to the patient’s score on a clinical tolerance test. The surgeon then accepts the automatically programmed nominal targets or alters them, depending on the patient’s refractive error. Additionally, it is possible to upload the registration image from the wavefront analyzer and/or the keratometry values from topography.

MECHANISMS, ABLATION PROFILE

Five mechanisms are responsible for the success of Laser Blended Vision, each relating to how it increases the depth of field: (1) controlled increase in corneal aberrations, (2) pupil constriction during accommodation, which provides a depth of focus increase on the retinal image, (3) retinal and cortical processing, which increases contrast of the retinal image, (4) micro-monovision, which provides continuous distance-to-intermediate-to-near vision between the eyes, and (5) central cortical processing, including neuronal gating and blur suppression.

The optimized ablation profile of Laser Blended

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**My Experience With Laser Blended Vision**

This viable presbyopia treatment is appropriate for patients with emmetropia, myopia, or hyperopia.

**BY ETIENNE HACHET, MD**
Vision relies on the patient’s age, his or her refraction, preoperative spherical aberration, corneal topographical vertex, and tolerance for anisometropia. This profile, in combination with pupil constriction during accommodation, is responsible for increasing the depth of field. The profile also works to maintain good visual quality, contrast sensitivity, and night vision.

PERSONAL EXPERIENCE

In my clinic, we frequently treat patients with the following refractive situations: young patients with hypermetropia and no presbyopia, anisometropic patients with or without binocular vision, patients with relatively average myopia (-2.00 D), patients with significant myopia (~10.00 D), and emmetropic patients. What we have to keep in mind is that, although patients may present with the same conditions, they have very different personalities, which means they have very different demands.

We have often treated such patients with progressive glasses, bifocal implants, multizonal LASIK (ie, presby-LASIK), monovision, and conventional LASIK. However, the increases or decreases in depth of field after these treatments are unreliable. Either the depth of focus is too weak, with two focalization planes, or it is too strong, with a modification of asphericity. But with Laser Blended Vision, it is an aspheric nonlinear ablation, so the depth of focus increases in each eye.

I have treated 38 patients with Laser Blended Vision; all have reported excellent tolerance to this treatment and none have required an enhancement. I use high-definition aberrometry, which measures 1,452 points across the entire eye. I take measurements first with undilated and then dilated pupils, to determine quality of the limbus and iris. After I enter the parameters into the software, I perform the treatment at 80 µm, using an 8-mm diameter flap and a 60º sidecut.

To date, our results have shown that monocular vision is better than what we expected for the non-dominant eye (7/10 at -1.50 D). Even more impressive, binocular vision is better than monocular vision (12/10 vs 10/10, respectively), because both eyes combine to form a blend zone. Additionally, there is a large increase in the depth of field, without intermediate weak vision as we have seen with bifocal implants, and no loss of lines on distance or near vision. All patients have at least 9/10 distance visual acuity and read J3 or better.

CONCLUSION

I have been very satisfied with the laser blended treatment performed with the CRS-Master. Results in all patients have been outstanding, and this treatment has truly proved to be fully reliable and customizable. I will continue to use Laser Blended Vision in my patients as long as the patient can tolerate a microbalance between eyes.

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The VisuMax Femtosecond System is a Standard Tool for Keratoplasty

The femtosecond laser may allow standardization of selective lamellar endothelial replacement.

BY LEONARDO MASTROPASQUA, MD; MARIO NUBILE, MD; AUGUSTO POCOBELLI, MD; AND MANUELA LANZINI, MD

Traditional penetrating keratoplasty (PKP), based on mechanical trephination of a full-thickness corneal button, has been the most exploited corneal transplantation technique for many decades. It historically provides surgical simplicity and good clinical results. During the last decade, however, keratoplasty surgery underwent evolutions that led to the development of new surgical procedures that opened new perspectives for our patients. Based on the concept of lamellar surgery, these techniques target lamellar replacement of the normal cornea, and as a selective approach, rely on replacing either anterior stroma—anterior lamellar keratoplasty (ALK)—or posterior replacement of deep stromal and endothelial layers—endothelial keratoplasty.

Recently, there has been an increase in the number of completed anterior lamellar and endothelial keratoplasty procedures. As a testament, reports from the Eye Bank Association of America confirm a significant increase in the demand for donor corneas for endothelial keratoplasty procedures (13.3% in 2006, 28.2% in 2007, and 33.3% in 2008). Now, another development has surfaced: the use of the femtosecond laser to create precise trephination and lamellar cuts suitable for various keratoplasty procedures. Femtosecond laser devices have potential to produce high-precision microsurgery, particularly in applications involving the transparent tissue of the cornea. The solid-state femtosecond laser uses a wavelength in the infrared range, and the spot size is adjustable to a few microns or less; in contrast to excimer laser photoablation, the cornea is transparent to its laser beam, allowing intrastromal photodisruption.

CUTS IN STROMAL TISSUE

We are currently using the 500 kHz VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany) to perform various keratoplasty procedures. Our experience with this laser platform extends to 2 years. The sequence of adjacent cavitation bubbles precisely focused in the corneal stroma produces cuts in the stromal tissue, which may be created at various depths or shapes, with minimal collateral tissue injury. The femtosecond laser has been used to generate custom corneal trephination profiles in PKP, deep corneal dissection in lamellar keratoplasty, and posterior lamellar discs for Descemet’s stripping endothelial keratoplasty (DSEK). It is also capable of performing corneal trephination with adjustable diameter, size, cut angle, and shape and full-thickness, anterior, and posterior lamellar dissections.

Quality and regularity of femtolaser cuts are key elements for excellent surgical results, particularly when considering the optical quality of deep stromal interfaces obtained by femtosecond dissections in deep anterior and posterior lamellar keratoplasty. Postoperative results strictly depend on the frequency.

Figure 1. Scanning electron microscopy at 500X magnification of the human cornea after VisuMax (500 kHz) dissection and trephination of a donor corneal button. Note the smoothness and regularity of the surfaces and borders obtained by the femtosecond laser cut.
energy, and spacing of the laser pulses—particularly for deep stromal cuts—because of looser fibrillar configuration of the rear stroma and of the laser energy attenuation in deep layers. First-generation femtosecond lasers were characterized by high energy levels and low frequency, producing irregularities in deep stromal cuts (defined as stucco-like texture) and possible tissue bridges. 

By increasing the frequency, reducing single-spot energy, and fine tuning other laser parameters such as spot spacing, new-generation femtosecond lasers now produce smoother deep dissection surfaces useful for both anterior and posterior lamellar keratoplasty.

At 500 kHz, the VisuMax has one of the highest frequency now available on the market, and it is capable of performing PKP, ALK, and endothelial keratoplasty with high cut quality and regularity. This is confirmed by scanning electron microscopy (SEM) investigations (Figure 1).

**PKP**

Use of the VisuMax femtosecond laser for PKP presents several advantages over conventional mechanical trephination of the recipient cornea and blade punch of the donor tissue. In both cases, the laser performs the trephination from the epithelial side; cut angle, size, and borders are more likely to perfectly fit together, therefore reducing the risk for misalignment and induced astigmatism. The VisuMax can perform a full-thickness trephination in any case, and the surgeon can choose and customize the angle of trephination cut with respect to the corneal surface (Figure 2). This represents a great advantage.

Generally, conventional mechanical trephinations produce vertical cuts at approximately 65° with respect to the corneal surface at the periphery (Figure 3); however, punching from the endothelial side of the donor tissue may produce a different configuration of the cut border, leading to an imperfect matching between donor and recipient tissue. Using the femtosecond laser may improve donor-recipient matching, even when using straight trephinations instead of complex configurations such as the mushroom or top hat (Figure 2). We prefer to use a 90° cut for both donor and recipient, as we have found and SEM has confirmed that cut quality is excellent (Figure 2). By using this configuration, we have several advantages: (1) identically angled borders for both recipient and donor tissue, (2) increased surface of contact for better wound healing, (3) reduced risk of leaking, (4) better graft geometry (Figure 3), and (5) less tight sutures are required.
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ALK. The femtosecond laser can also create lamellar cuts for ALK.\(^1,3\) Today, the VisuMax platform offers the greatest potential in this field, thanks to its high frequency. Cuts are sufficiently smooth and easily placed at the desired depth in the posterior stroma, even through corneal opacities (at least within a certain density).

The ideal candidates for femtosecond-assisted ALK are patients with visually debilitating corneal dystrophies, corneal scars, and leucomas. It must be highlighted that, with the femtosecond laser, we can accomplish deep stromal dissection but cannot dissect within Descemet’s plane. Therefore, the big-bubble deep anterior lamellar keratoplasty (DALK) technique remains the gold standard procedure for keratoconic patients and eyes with high visual potential.

The advantages of performing femtoALK in selected patients are based on the rapidity and ease of the procedure, which offers great patient comfort during and after surgery. It can be performed under topical anesthesia (similarly to LASIK), and the dissection phase requires only a few minutes (Figure 4). Because we use angled trephination borders, we prefer to use eight single sutures to anchor the graft, which are generally removed after 6 to 10 months. Surgeons can customize the dissection depth, diameter, and angle of trephination in the recipient and donor cornea. In cases of preoperative postinfectious opacity and thinning of the cornea (Figure 5), the surgeons can program the lamellar dissection at a desired depth, which is generally guided by the Visante OCT (Carl Zeiss Meditec) to calculate the level of stromal involvement and corneal thinning. If needed, the surgeon may use different settings for the donor cut to better restore physiological thickness and geometry of the cornea after the lamellar graft (Figure 5).

Endothelial keratoplasty. Recent developments have also made it possible to perform endothelial keratoplasty with the femtosecond laser. In this procedure, the femtosecond laser creates posterior corneal lenticules, also known as posterior lamellar discs (PLD) for DSEK.\(^12,13\) The gold-standard technique is based on microkeratome dissection of the PLD.

The VisuMax femtosecond laser creates high-quality PLDs of customized size and thickness. The donor cornea is cut onto the artificial anterior chamber (we
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CONCLUSION

Our DSEK procedures with 140 to 160 µm PLD thickness (Figure 6) typically have good results. Ongoing studies are investigating the role of the VisuMax in producing ultra-thin PLDs (below 100 µm) for DSEK. Initial results are promising, and in our opinion, this femtosecond laser may offer the surgeon a real chance to further standardize selective lamellar endothelial replacements, which are the present and will be for sure the future worldwide standard for treatment of endothelial pathologies.

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Figure 6. DSEK assisted by the 500 kHz VisuMax femtosecond laser. (A) Preoperative slit-lamp image of a severe case of bullous keratopathy. (B) Slit-lamp image of the same case after VisuMax DSEK. (C) Visante OCT findings after surgery. The posterior lamellar disc has a central and paracentral thickness of 140 µm approximately with minimal increase of values in the periphery (red arrow). The interface is regular and the recipient cornea has regained normal thickness.

prefer a diameter of 8.5 to 9.0 mm). We use 90° trephination of the border because this vertical peripheral cut, rather than the horizontal cut of the microkeratome blade, reduces classic peripheral thickening of the PLD, which plays a role in postoperative hyperopic refraction shift. Moreover, PLD thickness can be easily customized according to the preoperative pachymetry of the donor cornea. Obtained lenticules present smooth surfaces, minimal increase of peripheral thickness, and great precision in terms of desired thickness.
The innovative combination of precise refractive femtosecond laser technology with lenticule extraction marks the next generation in laser vision correction beyond LASIK.

**Perfect outcomes**
- Precise vision correction cut inside the intact cornea
- Virtually independent of corneal hydration and environmental conditions
- Outcome predictability and small incisions for biomechanical stability of the cornea

**Beneficial to surgeons**
- Least minimally invasive method
- Entire workflow integrated into ONE femtosecond laser workplace for highest efficiency
- Precise refractive corrections, even in cases of high refractive errors

**Satisfied patients**
- Highly precise, safe and gentle laser correction
- Short treatment times
- Maximal patient comfort due to one-step, odor-free, virtually pain- and soundless treatment
- Curved patient interface with corneal suction prevents trauma and temporary blackouts

*For more information about ReLex, please visit: www.meditec.zeiss.com*