

Refractive Laser Lenticular Extraction: a New Paradigm

ReLEx smile provides advantages over LASIK and PRK with a minimal risk of complications.

BY SVEN ASP, MD, DMScI

ReLEx is a recently developed laser corneal refractive procedure based on extraction of an intrastromal lenticule. ReLEx can be performed only with the VisuMax femtosecond laser (Carl Zeiss Meditec AG), which is capable of intrastromal cutting in three dimensions from the corneal surface. In this procedure, a lenticule—a disc of corneal stromal tissue—is cut with micron-scale precision by the laser, and the refractive error is corrected when the surgeon dissects the remaining bridges of corneal tissue and removes the lenticule. Lenticular shape and size are based on mathematical calculations for correcting a specific refractive error.

It is my privilege to be one of the first high-volume ReLEx surgeons. ReLEx can be performed in one of two ways: femtosecond lenticular extraction (flex) and small-incision lenticular extraction (smile). Having performed approximately 700 ReLEx flex procedures and more than 1,600 ReLEx smile procedures, I have gained profound experience with this refractive procedure.

THE LASER

The VisuMax is a solid-state laser source, and tissue interaction is virtually independent of ambient humidity, ventilation, and corneal hydration. All these parameters affect treatment results in different excimer (gas)-based treatment modalities, including LASIK. The VisuMax applies ultra-short, high-intensity, tightly focused laser pulses into the cornea, creating plasma bubbles in the focal center. Cutting is completed when the bubbles fuse and the surgeon manually dissects the remaining bridges of tissue. Laser pulse duration is ultra-short and delivers



Figure 1. Applicator and suction ring used for VisuMax laser treatment.

relatively low absolute energy into the cornea, whereas energy intensity per pulse is of a very high magnitude. Laser cutting is precise and localized, leading to minimal collateral tissue damage. The VisuMax uses a low-pressure corneolimbus-based suction system in which a concave suction applicator ensures well-defined corneal contact, a tight fit, and a minimal increase in IOP (Figure 1).

TREATMENT OPTIONS

With ReLEx flex, the access cut to the corneal stroma is similar to a standard LASIK flap but is shorter because the diameter of the flap is smaller. The main difference between ReLEx flex and LASIK is that, in ReLEx flex, the surgeon manually

removes the stromal lenticular tissue, whereas in LASIK, the tissue is removed by excimer laser ablation. In the minimally invasive ReLEx smile procedure, the lenticule is removed through a superior corneal tunnel as small as 2 mm in width (Figure 2).

ADVANTAGES

ReLEx offers several advantages over LASIK and PRK. Patients' comfort is excellent during and after ReLEx, the procedure is performed without noise or smell, and the procedural time is shorter than LASIK. Suction pressure is minimal during the treatment, and patients are able to follow the fixation light because their vision is maintained (although not in the optical zone toward the end of the treatment due to a layer of bubbles produced by the femtosecond laser). The epithelial incision is approximately one-eighth the size of the incision made during LASIK, and subsequent foreign body sensation is minimal and transient.

In our practice, patient flow in the clinic has been better with ReLEx compared with other refractive procedures, as only one laser is used for the entire procedure, and treatment time is practically independent from the amount of refractive error being corrected. Furthermore, the surgeon can sterilize his or her hands in close proximity to the VisuMax laser because ethanol-chlorhexidine and other aerosols do not affect the laser. Aerosols, humidity, and ventilation are known factors affecting evaporation of tissue by the excimer laser in LASIK and PRK. Also, because the femtosecond laser is a solid-state laser, it requires minimal maintenance, whereas excimer lasers continually need gases refilled and cleaning.

Many studies have demonstrated that ReLEx is precise and accurate in treating refractive errors. The procedure is highly predictable, especially in eyes with high myopia, which are the cases we most often treat with ReLEx. The most recent results from our department show that, in 275 eyes targeted for emmetropia with an average pre-treatment myopia of greater than -7.00 D, the average refraction 3 months after ReLEx was -0.20 ± 0.46 D (average \pm standard error of the mean).¹ Furthermore, 5-year follow-up of ReLEx flex in 35 highly myopic eyes (mean, approximately -6.50 D) revealed insignificant treatment regression (0.10 D), and these results are better than those seen with LASIK. Preliminary results from our department reveal fewer induced aberrations postoperatively after ReLEx smile compared with LASIK.¹

Common side effects after refractive surgery—which include corneal haze; a reduction in tear production or dry eye, corneal sensitivity, and contrast sensitivity; impaired night vision; and foreign body sensation—are expected to occur less frequently after ReLEx smile. Considering the length and location of the incision, it is also expected that corneal stability will be better after ReLEx smile compared with LASIK.

The flap remains the weak link in LASIK; because it can easily be lifted, it consequently compromises corneal stability for decades (probably for life) after treatment. My colleagues and I have seen cases that confirm that the cornea is stable shortly after ReLEx smile, and elite athletes, pilots, and combat soldiers will probably benefit from this treatment in the near future. Further investigation of these topics is necessary.

Flap-related complications such as loose flaps and buttonholes have not been seen in connection with ReLEx smile, but we have experienced a couple of cases of cap perforation. Special caution should be taken when cap thickness is minimal, for

instance when treating eyes with high myopia. The risk of epithelial ingrowth under the cap and flap is expected to be negligible, because the epithelial incision is less than 2.5 mm compared with a LASIK flap, which is approximately 20 mm.

LEARNING CURVE

The surgical learning curve is longer for the ReLEx smile procedure compared with other refractive laser procedures. However, because ReLEx is unique regarding the extraction of intrastromal lenticular tissue, there is not an existing procedure with which it can be fairly compared. Assuming the surgeon has experience cutting flaps, he or she must become familiar with intrastromal corneal tissue manipulation for this new technique. Therefore, it is required that surgeons with flap experience perform a certain number of ReLEx flex cases before learning ReLEx smile. My advice is that surgeons perform 50 ReLEx flex cases to get used to mechanical lenticule removal with an open flap. Subsequently, the surgeon can proceed to not fully open the cut flap but gradually reduce the access to the lenticule until he or she is able to extract the lenticule through a small incision. This approach allows the surgeon to increase the size of the incision in a controlled manner when necessary in problematic cases.

Looked at in another way: using ReLEx, there is no need to spend time understanding complex nomograms, implementing a personal standardized surgical procedure, and getting used to the special needs of the excimer laser (eg, fluence testing, monitoring intraoperative ambient conditions).

PERSONAL OBSERVATIONS

ReLEx smile requires patients' active cooperation. To achieve and maintain the correct centering on the pupil,

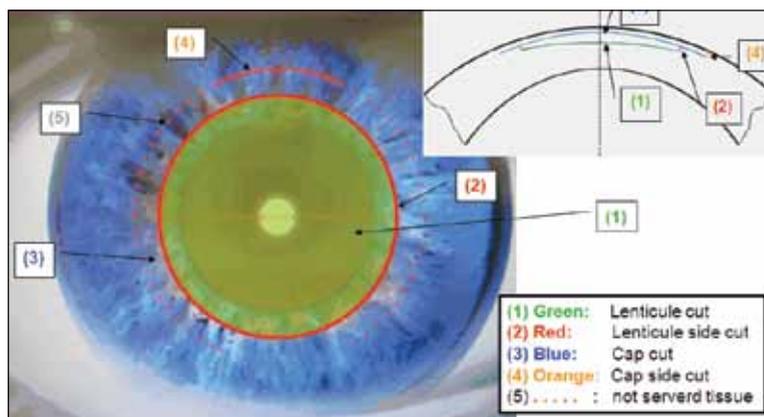


Figure 2. Manual lenticule removal through the superior ReLEx smile incision. Cuts are seen here from front and side perspectives.

US CLINICAL TRIAL OF ReLEx SMILE PROCEDURE UNDERWAY

By John F. Doane, MD

Carl Zeiss Meditec, Inc. announced in April that the FDA had granted the company conditional approval to initiate a clinical trial of the ReLEx small-incision lenticular extraction (smile) procedure for the correction of myopia with its VisuMax Femtosecond Laser. The clinical trial will initially include five sites in the United States. Patients will undergo LASIK in one eye and ReLEx smile in the fellow eye. Initially, my fellow investigators and I will treat spherical myopia in patients with 0.50 D or less of astigmatism and a spherical error of -1.00 to -8.00 D. As the trial advances, we will begin to include bilateral cases and the treatment of astigmatism. To date, nine eyes have been treated in Denver.

Clinical outcomes outside the United States have met or exceeded the results of state-of-the-art LASIK. Data from the international sites mirror current LASIK results with predictability: 95% of the eyes are ± 0.50 D within the refractive target. Interestingly, the predictability has been just as high for patients with low myopia as it has for those with high myopia. In terms of efficacy, 95% of the eyes have achieved an uncorrected distance visual acuity of at least 20/30 at 3 months for even moderate to high levels of myopia. Importantly, safety has been excellent, with only 1% to 2% of eyes losing 2 or more lines of BSCVA. Refractive stability has essentially been achieved at 1 week, and little to no change has been seen between this interval and the 1- and 3-month data sets (data on file with Carl Zeiss Meditec, Inc.).

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the patient must fixate on a green flashing light during the docking procedure and during a maximum of 40 seconds of suction time when the laser is executing the lenticule cut, cap cut, and small incision. During treatment, the cornea becomes increasingly blurred because of the plasma bubbles running from the outside to the center of the pupil. I always tell patients during surgery that this is normal and they should continue looking straight ahead even if the green light becomes blurry. Having the patient concentrate on the green light minimizes the risks of suction loss or patients' moving their eyes. In case of suction loss,

depending on the stage of the procedure, surgeons can immediately start over and finish the surgery or schedule a retreatment for 3 months later.

My colleagues and I found that, especially in early cases, there was a slight delay in visual recovery with ReLEx smile compared with LASIK.¹ Over time, our results have improved due to optimized laser energy settings and our longer experience with ReLEx smile (which for me now includes more than 1,500 cases). For the time being, ReLEx is indicated for treating myopia and astigmatism of up to -10.00 D spherical equivalent. Treatment for hyperopia is under development by the manufacturer.

CONCLUSION

In my opinion, ReLEx smile is the most significant development in corneal refractive surgery since the introduction of LASIK, and this technique has the potential to become the gold standard in the future. In the hands of experienced surgeons, the ReLEx smile technique provides the combined advantages of LASIK and PRK with minimal risk of complications. Early experience suggests it is more precise and accurate than an excimer-laser based ablation, has less treatment regression, and induces fewer aberrations. Patient and clinic flow are smooth and rapid. Visual recovery can match that after LASIK, and corneal trauma is minimal when surgery is performed by an experienced ReLEx surgeon. The corneal epithelium incision is approximately one-eighth the length of a LASIK flap, and the risks of dry eye and epithelial ingrowth are expected to be minimized. Current prospective studies conducted in our department will reveal whether dry eye will be reduced and corneal stability will be better compared with LASIK.

Today, the ReLEx smile procedure is my favorite refractive surgical technique for myopia. Patients with hyperopia and very high astigmatism are still treated with LASIK; however, I anticipate that ReLEx smile will be ready for treating these refractive errors within the next couple of years. For the time being, I am advising this group of patients to consider waiting to undergo treatment until the ReLEx smile procedure is available for them. ■

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1. Vestergaard A, Ivarsen A, Asp S, Hjortdal JO. Small-incision lenticule extraction for moderate to high myopia: predictability, safety, and patient satisfaction [published online ahead of print September 13, 2012]. *J Cataract Refract Surg*. doi:10.1016/j.jcrs.2012.07.021.