Refractive Laser Lenticular Extraction: A New Paradigm

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

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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), 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. I have performed more than 1,500 ReLEx procedures and 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 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 corneolimbal-based suction system in which a concave suction applicator assures well defined corneal contact, a tight fit, and a minimal increase in intraocular pressure (Figure 1).

TREATMENT OPTIONS

ReLEx can be performed in one of two ways: femtosecond lenticular extraction (flex) and small incision lenticular extraction (smile). 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 2.5 mm in width (Figure 2).

ADVANTAGES

ReLEx offers several advantages over LASIK and PRK. Patient comfort is excellent during and after ReLEx, the procedure is performed without noise or smell, and the procedure 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 (submitted for publication) show that, in 275 eyes targeted for emmetropia with an average pretreatment myopia of greater than -7.00 D, the average refraction 3 months after ReLEx was -0.20 ±0.46 D (average ± standard error of the mean). 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 is seen with LASIK. Preliminary results from our department reveal less induced aberrations postoperatively after ReLEx smile compared with LASIK (in press).

Common side effects after refractive surgery, including 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 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.

Figure 2. Manual lenticule removal through the superior ReLEx smile incision; cuts are seen here from front and side perspectives.
In the hands of experienced surgeons, ReLEx smile provides the combined advantages of LASIK and PRK with minimal risk of complications.

**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. Our advice is that surgeons should 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 for spending 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 active patient cooperation. To achieve and maintain the correct centering on the pupil, 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. 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 up to -10.00 D spherical equivalent. Treatment for hyperopia is under development by the manufacturer, and it is only a matter of time before these refractive errors can also be corrected with ReLEx smile.

**CONCLUSION**

In our 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 excimer-based laser ablation, has less treatment regression, and induces fewer aberrations. Patient and clinic flow are smooth and rapid. Visual recovery can match 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 our favorite refractive surgical technique for myopia. Patients with hyperopia and very high astigmatism are still treated with LASIK; however, we 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 (hyperopes and patients with high astigmatism) to consider waiting to undergo treatment until the ReLEx smile procedure is available for them.

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