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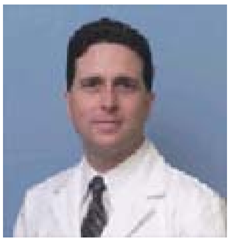
INTERNATIONAL

Scientific rationale for why femtosecond laser intrastromal keratomileusis is the future of corneal refractive surgery

by Dan Z. Reinstein, M.D.



We are in the age of the femtosecond laser. Having first found utility in creating a flap for LASIK procedures, it became clear that the potential for other uses in eye surgery was significant. Most recently, cataract surgery femtosecond applications have been the focus of development for laser companies. Now with the clinical trial of the VisuMax laser under way, a true refractive platform may be possible with only the use of a femtosecond laser. As with all new technology, there will no doubt be continued improvement, and we can expect that the results will improve. Is intrastromal keratomileusis the future of corneal refractive surgery? Dan Reinstein, M.D., makes a

Ever since femtosecond lasers were first introduced into refractive surgery, the ultimate goal has been to create an intrastromal lenticule that can be manually removed in one piece, thereby circumventing the need for incremental photoablation by an excimer laser. Following the introduction of the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany) in 2007, the intrastromal lenticule method was introduced in a procedure called femtosecond lenticule extraction (FLEx) in which a flap was created and lifted to allow the lenticule to be removed.

Following the successful implementation of FLEx, a new procedure called small incision lenticule extraction (SMILE) was developed. This procedure involves passing a dissector through a small 2-3 mm incision to separate the lenticular interfaces and allow the lenticule to be removed, thus eliminating the need to create a flap. The results of the first prospective trials of SMILE have been reported,[1, 2] and there are now more than 50 surgeons routinely performing this procedure worldwide.

A number of femtosecond lasers are commercially available, but the VisuMax is the only one being used for an intrastromal lenticular cut. There are six distinct design elements of the VisuMax that represent how the device was conceived from the ground up as a high precision intracorneal lenticular cutting tool. Central to the VisuMax mode of operation is the extremely light-touch coupling system that minimizes corneal distortion and a rapid, high precision femtosecond pulse placement to achieve sufficient 3D geometric cutting precision such that refractive lenticules can be created accurately within the body of the stroma. The main elements are (1) the curved coupling contact glass, which

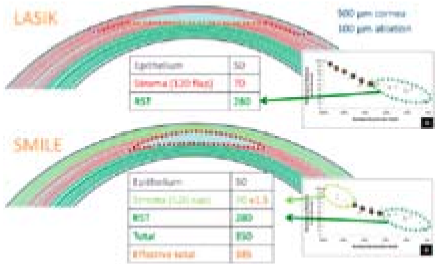


Figure 1: Diagrams of the intact stromal lamellae after LASIK (top) and SMILE (bottom) highlighting the anterior lamellae that remain intact after SMILE. The RST calculations are shown for a 500 µm cornea with a 100 µm ablation/lenticule and 120 µm flap/cap thickness. The LASIK RST of 280 µm consists only of posterior stroma. The SMILE RST has the same 280 µm of posterior stroma, but also has 70 µm of anterior stroma, for a total of 350 µm of stroma. However, since the anterior stroma is 50% stronger than posterior stroma, a further 35 µm can be added to make an effective total of 385 µm

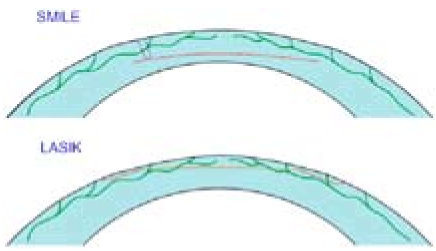


Figure 2: Diagrams demonstrating the difference between SMILE (top) and LASIK (bottom) in how the two procedures affect the anterior corneal nerve plexus

compelling case in this month's "International outlook" column. One thing is certain: Refractive surgeons around the world will be watching this carefully. Read for yourself and form your own opinion.

John Vukich, M.D.,
international editor

results in minimal corneal distortion, (2) coupling suction applied to the peripheral cornea (not the conjunctiva/sclera) allowing for a low suction force to immobilize the cornea, again reducing tissue distortion, (3) individual calibration of each contact glass based on confocal detection of radiation, (4) the combination of an optical beam path that is suspended on a fulcrum with force-feedback servo control of the height of the patient bed and headrest in order to maintain a consistent contact glass force onto the cornea (again minimizing tissue distortion), (5) a high numerical aperture of the beam designed to deliver a tight concentration of femtosecond energy with low per-pulse energy load, and (6) a high pulse repetition rate of 500 kHz in order to minimize treatment time.

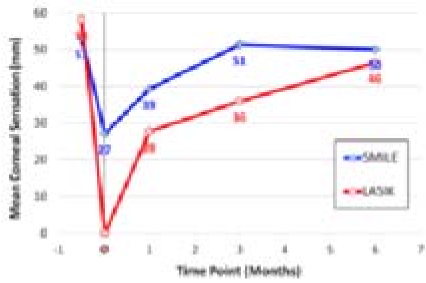


Figure 3: Mean corneal sensation for 39 eyes after SMILE compared with the corneal sensation after LASIK averaged over nine published studies

Source (all): Dan Z. Reinstein, M.D.

Advantages of ReLEx SMILE over LASIK

These new femtosecond intrastromal lenticule procedures offer a number of potential advantages.
1. More accurate and repeatable tissue removal: Intrastromal lenticule procedures may have
advantages over LASIK as all of the potential errors associated with excimer laser ablation are avoided, such as stromal hydration, laser fluence projection and reflection losses, and other environmental factors. In ReLEx, the tissue removal is defined only by the accuracy of the optomechanics of the femtosecond laser, none of which is affected by environmental conditions. Therefore, it is likely that there will be less need for personalized nomograms to be used for different machines, locations, or surgeons. In addition, the accuracy remains similar for low and high corrections as the only variable is the distance between the upper and lower lenticular cuts.
2. Increased biomechanical stability and reduced biomechanical variability: Potential benefits of SMILE are the relatively higher biomechanical strength of the remaining cornea as well as a reduction in the variability of the biomechanical effects produced by refractive tissue removal.
Randleman et al[3] published a study in 2008 in which they measured the tensile strength of strips of stromal lamellae cut from different depths within the cornea. They found a strong negative correlation between stromal depth and tensile strength. The anterior 40% of the central corneal stroma was found to be the strongest region of the cornea, whereas the posterior 60% of the stroma was at least 50% weaker.
We are accustomed to calculating the residual stromal thickness in LASIK as the amount of stromal tissue left under the flap, so the first instinct is to apply this rule to SMILE. However, because there is no flap created in SMILE, the anterior stromal lamellae remain intact everywhere except for the small 2-3 mm incision. Therefore, the actual residual stromal thickness in SMILE is calculated as the stromal thickness below the posterior lenticule interface plus the stromal component of the overlying cap—between the anterior lenticule interface and the epithelium. Moreover, because anterior stroma is 50% stronger than posterior stroma, a further 50% of the untouched

anterior stromal thickness can be added to get a residual stromal thickness value that can be compared to a LASIK residual stromal thickness.

If this concept is applied to an example case (Figure 1), the significant improvement in biomechanics can be appreciated. Consider an eye with a spherical equivalent refraction of –8.00 D and a central corneal pachymetry of 500 µm. We will assume that the epithelial thickness is 50 µm, that the LASIK excimer laser ablation depth and SMILE lenticule thickness are 100 µm, and that both procedures were performed under a 120 µm LASIK flap and with a 120 µm SMILE cap (depth of the anterior lenticule interface). The LASIK RST would be 280 µm, but the SMILE RST would be 385 µm after adding 1.5 times the 70 µm of intact anterior stroma.

Recently, Knox Cartwright et al[4] performed a study on human cadaver eyes and found that creating a sidecut only resulted in a similar increase in strain to that found after creating a whole flap, with a significantly greater increase when the depth was increased from 90 to 160 µm. On the other hand, the increase in strain was the same at both depths when a delamination cut only was performed.

Applying this finding to SMILE, since no anterior corneal sidecut is created, there will be slightly less increase in corneal strain in SMILE compared to thin flap LASIK and a significant difference in corneal strain compared to LASIK with a thicker flap.

Also, given the finding that the increase in corneal strain with a delamination cut only is independent of depth, this means that the SMILE lenticule can be created at any depth within the stroma. Therefore, putting this finding together in context of the varying tensile strength of stroma at different depths as described above, the effective post-op corneal biomechanical strength will increase as the lenticule is moved deeper. Therefore, it is possible that SMILE might be used to extend the range of myopia that can be corrected by corneal excimer laser surgery.

3. Reduction in post-op dry eye: The other major potential advantage of the flapless ReLEx SMILE procedure is the reduction in post-op dry eye compared with that observed after PRK and LASIK.

The cornea is one of the most densely innervated peripheral tissues in humans. Nerve bundles within the anterior stroma grow radially in from the periphery toward the central cornea. The nerves then penetrate Bowman's layer and create a network of nerve fibers, known as the sub-basal nerve plexus, by branching both vertically and horizontally between Bowman's layer and basal epithelial cells.

In LASIK (as shown in Figure 2), sub-basal nerve bundles and superficial stromal nerve bundles in the flap interface are cut by the microkeratome or femtosecond laser, with only nerves entering the flap through the hinge region being spared. Subsequent excimer laser ablation severs stromal nerve fiber bundles. Post-op, this means that the patient may have dry eye symptoms and decreased corneal sensitivity while the nerves regenerate. A number of studies have reported the recovery of corneal sensation after LASIK and show that recovery to normal levels takes on average 6 months. Figure 3 shows the average corneal sensation across these nine studies.

In SMILE on the other hand, the anterior corneal anatomy is preserved and the anterior stromal nerve plexus is disrupted significantly less since there are no sidecuts created—no flap is created; this should result in fewer dry eye symptoms and a faster recovery of post-op patient comfort. Early results seem to support this hypothesis. We have measured corneal sensation in 39 eyes after SMILE and the results compare favorably with the average data taken from similar published LASIK studies. Corneal sensation had recovered to the baseline level by 3 months after SMILE compared with 6-12 months after LASIK. Also, corneal sensation was only slightly depressed in the majority of eyes after SMILE at the day 1 post-op visit, whereas corneal sensation was found to be generally 0 in published LASIK studies reporting 1-day data.

In summary, with the introduction of the VisuMax femtosecond laser technology it has become clinically feasible to now create refractive lenticules of proper regularity with sufficient accuracy to meet and possibly exceed the accuracy of excimer laser tissue ablation for corneal refractive corrections. This enables Jose Ignacio Barraquer's original concept of keratomileusis to be effectuated through a minimally invasive pocket incision with maximal retention of anterior corneal innervational and structural integrity. It is the final frontier in the realization of the perfect refractive surgical technique for both patients and surgeons.

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