SMILE: Exceeds LASIK, two years of clinical data

Kimiya Shimizu, MD

Kimiya Shimizu, MD, Tokyo, started performing LASIK at his clinic in 1997 but stopped in 2008. His reason was most complications from LASIK continued not only immediately after surgery but for a significantly long period of time after. Take, for instance, epithelial ingrowth. Cases can return 14 years after flap-making LASIK with the complication. It is not a very common complication, but it is not so rare. The most common complication following flap-making LASIK is dry eye. At five years after LASIK, tear breakup time shortened to an average of 4.2 seconds from an average of 9.3 seconds in 55 patients. In addition, while 18% of LASIK patients were using some kind of medicine for dry eye preop, the percentage rose to 78% postop.

Flapless refractive surgery – SMILE

Most complications following LASIK are caused by the flap. The next step is therefore flapless surgery through a form of refractive lenticule extraction: SMILE.

Flapless surgery is performed using the Visumax femtosecond system (Carl Zeiss Meditec Inc., Jena, Germany). Femtosecond lasers do not ablate tissue; they remove tissue by photodisruption. For laser vision correction based on the corneal nerve, femtosecond lasers have been considered appropriate because there is no need to remove the flap to perform laser vision correction. SMILE is therefore the less invasive procedure. One year after surgery, fluorescein staining revealed a better corneal surface with SMILE.

Comparison of visual acuity, higher-order aberrations and ocular light scatter, and surgery time.

In a study comparing ReLEx, specifically FLEx, with wavefront-guided LASIK, Dr. Shimizu and his colleagues found that the two procedures were comparable in terms of third-order and total HOAs, but were significantly different in terms of fourth-order aberrations (ReLEx 0.07 microns change in HOAs, LASIK 0.29 microns change in HOAs). With LASIK, the fourth-order aberrations increased according to the amount of spherical equivalent correction (p<0.003); no significant correlation was found between HOAs and spherical equivalent correction in ReLEx (p>0.05). The reason for this has not yet been determined. Because some transient haze forms immediately after surgery, ocular scatter increases with ReLEx in the early postop period, but gradually recovers with time. Finally, in terms of surgery time in Dr. Shimizu’s hands, ReLEx, specifically SMILE, took about half the time to perform wavefront-guided LASIK—SMILE took 4:09 minutes, wavefront-guided LASIK took 10:02 minutes. ReLEx thus produces good results with fewer complications compared with wavefront-guided LASIK. In the past, Dr. Shimizu has performed PK, mini-PK, LASIK, and, most recently, wavefront-guided LASIK. He began performing ReLEx, specifically SMILE, in 2010, and today he considers it the best option for refractive surgery.

Reference


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Innovation: Seeing beyond

SMILE: An intrastromal form of keratomeleusis

History of intrastromal refractive surgery

Ever since femtosecond lasers were first introduced into refractive surgery, the ultimate goal has been to create an intrastromal lenticule that can then be removed in one piece manually, thereby circumventing the need for incremental photodestruction by an excimer laser. Early studies were made using picosecond lasers (1996-1998) and femtosecond lasers (1998-2003), however, these did not culminate in actual clinical trials.

The introduction of the VisuMax femtosecond system (Carl Zeiss Meditec Inc., Jena, Germany) in 2006, the intrastromal lenticule method was reintroduced in a procedure called femtosecond lenticule extraction (FLEx), which involved lifting a LASIK flap to allow the removal of the lenticule. Given the success of FLEx, the procedure evolved into its current flapless form known as SMILE (small incision lenticule extraction). The SMILE procedure involves creating one or two small incisions through which the lenticule interfaces can be separated allowing 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.

VisuMax design elements enabling refractive lenticule surgery

The VisuMax femtosecond laser is currently the only femtosecond laser being used for intrastromal lenticular surgery. In order for accurate 3D intrastromal cutting, a number of technological hurdles have to be overcome; not only does the femtosecond pulse placement 3D accuracy need to be very high and pulse energy very low, but there has to be minimal tissue distortion of the site electro-optically coupling to the femtosecond laser source. 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. First, the coupling contact glass is curved in order to minimize corneal distortion. Tissue distortion is further minimized as coupling suction is applied to the peripheral cornea (not the conjunctiva/sclera) allowing for immobilization of the cornea using a very low suction force. A third mechanism for minimizing tissue distortion is that the optical beam path is suspended on a fulcrum with force-feedback servo control of the height of the patient bed and headrest, thus maintaining a consistent force onto the cornea.

The beam uses a very high numerical aperture, designed to deliver a very tight concentration of femtosecond laser energy with very low per-pulse energy load. Each contact glass is also individually calibrated when attached to the laser device. Finally, the high pulse repetition rate of 500 kHz minimizes treatment time.

Advantages of SMILE over LASIK and PRK

1. More accurate and repeatable tissue removal

Intrastromal lenticule procedures may bring advantages over LASIK and PRK 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 SMILE, the tissue removal is defined only by the accuracy of the femtosecond laser, which is not affected by any changes in environmental conditions. This accuracy is demonstrated by the 4.4 μm reproducibility of cap thickness. Therefore, it is likely that there will be less need for personalized nomograms to be used for different machines, locations, or surgeons.

2. Increased biomechanical integrity

Another potential benefit of SMILE is increased biomechanical stability. The absence of a flap and the fact that the stromal tissue is removed from within the stroma means that the anterior-most stromal lamellae remain intact after the procedure (except for the region of the small incision). This is in contrast to both LASIK, where the anterior stromal lamellae are severed by the creation of the flap and also by the excimer laser ablation, and PRK, where the anterior stromal lamellae are severed by the excimer laser ablation.

Therefore, SMILE must leave the cornea with greater biomechanical stability than both LASIK and PRK as the anterior stroma is known to be the strongest part of the stroma, which has been elegantly demonstrated by Randellman et al. In their 2008 study, they measured the tensile strength of strips of stromal lamellae cut from different depths below the lenticule.

Incision geometry of the ReLEx SMILE procedure. (1) The lenticule cut is performed (the underside of the lenticule), (2) followed by the lenticule side cuts. (3) Next, the cap interface is created (the upper side of the lenticule), and (4) finally a 2-3 mm small incision is created supero-temporally. The lenticule interfaces are separated using a flap separator and the lenticule is extracted manually, all via the small incision.

In summary, with the introduction of the VisuMax femtosecond system it has become clinically feasible to now create refractive lenticules of proper regularity with sufficient accuracy to meet and probably exceed the accuracy of excimer laser tissue ablation for corneal refractive corrections. This enables José Ignacio Barraquer’s original concept of keratomeleusis to be effectuated through...
PREBYOND Laser Blended Vision: My solution of choice for presbyopia in emmetropic, myopic, or hyperopic patients

The ideal solution for presbyopia would be to restore accommodation, however, no procedure up to now has been able to restore the natural dynamic focusing mechanism of the eye. While there is ongoing research on dynamic solutions to achieve this, clinical applications such as the functional accommodating IOLs or lens refilling will probably not be available for quite some time. Current treatments for presbyopia rely on splitting the refractive power for distance and near either within the same eye (multifocality) or between eyes (monovision), or a pinhole corneal inlay solution; however all these treatment modalities require some compromise from the patient. The ideal solution from a patient’s standpoint would be a procedure that achieves good binocular vision at far, intermediate, and near while also maintaining optical quality, contrast sensitivity, night vision, and stereovision. Preferably the procedure should be reversible and repairable if complications arise. This was the goal set when developing our method of modified monovision, now a commercially available software upgrade to the Carl Zeiss Meditec Inc. (Jena, Germany) excimer laser called PREBYOND Laser Blended Vision.

Concept behind PREBYOND Laser Blended Vision

The human visual cortical system is inherently capable of filtering spherical aberration. Spherical aberration occurs naturally in the human eye, increases naturally with age, and in fact increases naturally during accommodation. Introducing spherical aberration disammoniates the retinal image focusing point, meaning that there is a wider range of distances where the focus is equivalent, although slightly reduced. However, while the retinal image may be degraded by the spherical aberration of the optical system of the eye, our brains filter this spherical aberration and produce a sharp, unaberrated image in our minds. Our approach, in essence, was to utilize the range of inherent spherical aberration neural processing capability of the human visual cortex as a dynamic range for preclinical visual processing.

Thus, the spherical aberration of the eye can be modulated on the cornea by LASK or to increase the depth of focus of the visual system by working within the natural processing range of corotic image sharpening so as not to affect the quality of the perceived image in the mind. This increase in depth of field has been demonstrated by the better-than-expected distance vision in the near eye of treated patients targeted for a nominal refraction of 1.50 D in the nondominant eye; the mean visual acuity was about 20/45 whereas 20/80 would be expected for a nascent 1.50 D refraction.

Of course, if there is too much ocular spherical aberration, the visual cortex is no longer able to fully “process” the spherical aberration, and this results in aberration-related quality of vision symptoms. Our research led us to conclude that we could use spherical aberration modulation to increase the depth of field of the eye by approximately 1.50 D; increasing spherical aberration beyond this level results in overloading cortical filters, leading to a loss of contrast sensitivity. Therefore, spherical aberration modulation cannot be used to produce 3 dioptres of accommodation and hence provide full presbyopic correction by itself without compromising safety. The solution is to combine this 1.50 D of increased depth of field with a micromonovision to achieve good near vision, but with a lower degree of anisometropia than in traditional monovision. As with spherical aberration, monovision is also based on a natural process, that of neural binocular rivalry, summation and suppression (interocular rivalry, not intracocular). This strategy creates a blend zone of vision between the two eyes at intermediate distances meaning that much less suppression is required compared to traditional monovision, and there is no dissociation but rather fusion between the images of each eye. In fact, patients retain a functional level of uncorrected stereovision—proving that they have binocular function. Therefore this method provides a solution to the common limitations of traditional monovision including loss of fusion due to anisometropia, poor intermediate vision, poor distance vision in the near eye, reduced binocular contrast sensitivity, and reduced (or even broken) stereovision.

In PREBYOND Laser Blended Vision a number of factors are considered including age, accommodative amplitude, preoperative wavefront, tolerance to anisometropia, and the amount of refractive error. The software then combines these factors to generate an ablation profile with the aim of leaving the patient with an appropriate level of spherical aberration in order to maximize the depth of field without compromising contrast sensitivity, stereovision, or night vision.

At one year after PREBYOND Laser Blended Vision, binocular UDVA was 20/20 or better and continued on page 4
A (r)evolutionary step in multifocality: Introducing the trifocal AT LISA tri 839MP

Surgeons, like all people, will see the glass as either half full or half empty. According to Detlev Breyer, MD, Germany, the surgeons who do not like to implant multifocal IOLs tend to be pessimistic—they are those who see the glass as half empty.

However, this is not to say that there is absolutely no factual basis for their misgivings. In a 2007 survey update, Nick Mamalis, MD, found that while 90% of bifocal multifocal IOL (MIOL) patients were happy, 4% were unhappy and 1% were highly unhappy. They are those who see the glass as either half full or half empty.

The AT LISA trifocal concept

The AT LISA trifocal concept (Carl Zeiss Meditec Inc., Jena, Germany) is a trifocal IOL. Its optic is trifocal by defraction up to a diameter of 4.34 mm, bifocal from 4.34 to 6 mm diameter. The IOL has hydrophobic surface properties around a hydrophilic core and is designed with sharp edges to prevent posterior capsule opacification.

The optic is mounted on four point plate haptics, making the IOL easy to implant while providing excellent rotational stability (demonstrated by Breyer et al. in a four-year follow-up study) and—in worst-case scenarios—ease of explantation even after years.

The AT LISA trifocal concept was J2 or better in 95% of 136 myopic patients (up to –8.50 D with astigmatism), 77% of 111 hyperopic patients (up to +5.75 D with astigmatism), and 95% of 148 emmetropic patients (within ±0.88 D). These outcomes are superior to intraocular and corneal multifocal solutions published to date in the peer-reviewed literature. The safety was the same as for standard LASIK with no eyes losing more than one line CDVA, and contrast sensitivity was either the same or slightly better than preop. The procedure can be safely enhanced if future shifts in refraction occur. The spherical aberration modulation centered on the visual axis provides corneal depth of field, which may be combined with high quality monofocal IOLs in the event that the patient requires cataract surgery in the future.

Multifocal approaches

Multifocal approaches require the patient to adjust to the unnatural situation of having to differentiate between two images in the same eye and require a significant increase in aberrations to achieve these two focal points, so it is no surprise that these procedures are associated with loss of contrast sensitivity and night vision disturbances and even best spectacle corrected vision.

Multifocality has been induced in the cornea by discontinuous excimer laser ablation profiles, femtosecond cylindrical intrastromal keratotomy incisions or corneal inlays. Intraocular multifocality by intraocular lens implants has also been employed requiring either clear lens or cataract extraction. While there have been significant improvements both in corneal and intraocular lens multifocal solutions over the years, multifocality will always rely on the patient’s ability to adapt to this new and unnatural intraocular rivalry. Multifocal corneal treatment options are usually limited to a small range of refractive error and difficult to reverse, while intraocular solutions involve the relatively higher risk of implant exchange procedures.

Pinhole inlay

A pinhole inlay technology has been available worldwide since 2005 and at the time of writing, is in final phase FDA clinical trials in the U.S. Implantation of this device deep into the corneal stroma in one eye produces increased depth of field, which can significantly improve reading vision in emmetropic or myopic eyes with the advantage of retaining good distance acuity. However, the technique must be combined with LASIK for correction of presbyopia with ametropia. And since the pinhole mechanism inherently cuts down the amount of light entering the eye (and hence luminosity (along with contrast sensitivity to a certain degree), it does not provide comfortable reading vision in low lighting conditions.

Summary

In summary, PRESBYOND Laser Blended Vision is a solution for presbyopia that in the presence of a patient who is physically a candidate for LASIK, meets all the goals of good binocular vision at all distances, minimizes any compromise in safety, contrast sensitivity, or night vision, and results in binocular vision with retention of functional stereo acuity. The procedure is immediately reversible by wearing spectacles, or a simple retreatment can be done using a standard ablation with the advantage of keeping the depth of field. All of this is achieved while simultaneously correcting emmetropic presbyopic patients as well as patients with a wide range of refractive errors including astigmatism.

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Innovation: Seeing beyond

Subjective refraction and defocus curves
In terms of mean subjective refraction, the trifocal lens achieved a slightly better postoperative spherical equivalent than the bifocal—47% achieved emmetropia with the trifocal lens compared to 27% with the bifocal lens. This is extremely important, since multifocal lenses do not work if they don’t achieve emmetropia.

In terms of uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA), the trifocal IOL provides a clear advantage over the bifocal lens in the intermediate range. The near vision was slightly better with the bifocal IOL.

However, Dr. Breyer speculates that the bifocal IOL’s near vision advantage may be an artifact of the small sample size, since the defocus curves do not reflect this result. The defocus curves indicate comparable near and far vision performance between the two IOLs, with an increased plateau at 70 cm (-1.5 D defocus) with the trifocal IOL—indicating high level intermediate visual acuity without loss of near and far.

Dr. Breyer thinks that it is necessary to introduce a new term in the MIOL world to evaluate a comparable MIOL performance. To describe MIOL capacity they integrated the area under the defocus curve ranging from -3.0 to 0.0 diopters. They chose this range due to the relevance of a patient’s visual routine.

Light transmission
Multifocals typically have problems with light transmission, leading to patients complaining about reading at night. The AT LISA tri 839MP increases the light transmission from older IOL generations, with 87% mean transmission over a wide range of pupil diameters.

Using a Ginsburg box, Dr. Breyer found that the two AT LISA IOL models provide photopic vision almost similar to the juvenile phakic eye. Mesopic vision dropped compared with the juvenile phakic eye, as is typical for MIOLs, but Dr. Breyer did not find the drop as significant as with other MIOLs measured with the Ginsburg box.

Clinically, the trifocal IOL patients did not complain about dim light reading vision as much as with other IOLs.

Photopsia
Returning to the question of photopsia, the AT LISA tri 839MP’s diffractive pattern features a different optical architecture compared to other MIOLs. In order to see whether the new pattern reduces photopsia and enhances contrast sensitivity as intended, Dr. Breyer had patients subjectively evaluate their vision by software simulation.

Given three different halo types—type 1 (T1), diffuse ring; type 2 (T2), spider web; type 3 (T3), grained ring—patients were asked to estimate individually the type of halo and corresponding size and intensity.

T1 halos had been the most common type of photopsia experienced by Dr. Breyer’s patients. However, with the AT LISA tri 839MP, patients described a new phenotype of halo—spider web without starburst, designated T2. Some patients still reported T1 halos, but bluish light sources were always associated with T2 halos. At any rate, compared with the AT LISA 809MP, the overall halo and glare intensity was very similar, with both IOLs causing very minor photopsia.

Rhexis: Laser vs. manual
Dr. Breyer and his colleagues also compared refractive outcomes between patients receiving the AT LISA 839MP but with different rhexis methods. They found that while there was no significant difference in postop spherical equivalent between laser-assisted and manual rhexis, there was a mild tendency toward myopia with laser-assisted rhexis.

In terms of performance analysis, laser-assisted rhexis produced more “perfect” outcomes, while manual rhexis produced slight undercorrection.

Experience
At the end of their study, Dr. Breyer and his colleagues asked their patients to fill out questionnaires about their general and individual experiences with the IOL. The patients reported very high contentment with reading, intermediate, and far distance vision. They also reported not needing glasses almost 100% of the time for daily routines, bringing the idea of true spectacle freedom closer to reality.

Individual patients reported excellent vision for working all day at a computer, using vehicles under mesopic conditions—both reading the instrument panel and seeing far distance objects without glasses—and even reading instruction manuals or product information.

In Dr. Breyer’s experience, no other IOL has produced similar positive results, in terms of refractive outcomes and patient response. With the new AT LISA tri 839MP trifocal IOL, he can confidently say that the multifocal IOL glass is half full.

References

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The complete anterior segment imaging solution

Jodhbir Mehta, BSc, FRCSed, FRCorophth

History of imaging and existing technologies

Imaging technology has come a long way since the first significant development in 1619, when Scheiner provided the first accurate description of the anatomy of the eyeball. He compared the eye to the known curvatures of glass balls. Data generated from advanced keratometry systems now available tells us more about anterior shape, curvature, elevation, and thickness.

Two of the most popular systems today are the Orbscan II (Bausch + Lomb, Rochester, N.Y.) and the Pentacam (Oculus, Wetzlar, Germany).

The Orbscan II uses a slit system combined with Placido disc imaging of the surface. During data acquisition, the system projects 40 slits onto the cornea, 20 on each side. This is done in a scanning fashion at an angle of 45 degrees, with the backscattered light captured by a digital camera. The system captures light from 240 points extracted from the slits that are then processed by the system’s software to calculate different variables, including anterior and posterior floats, keratometry, and corneal thickness.

However, surgeons need to be careful when interpreting maps from the Orbscan. The Orbscan II determines the shape of the cornea through curvature rather than elevation maps. The system works well for normal corneas, but abnormal situations or even post-refractive cases may result in spurious readings.

In contrast, Pentacam uses the Scheimpflug photography technique. The technique was devised in 1906 to enhance the quality of aerial photography by taking several images from different angles. Using the Scheimpflug technique, the Pentacam takes images around the surface of the cornea from different angles, thus providing a better appreciation of elevation and depth. The latest version, the Pentacam HR, has improved resolution, with data processed from 138,000 points.

By working with proper elevation maps, the system allows surgeons to take a more detailed look at different parameters, allowing them to track the corneal thickness from the center of the cornea outward. This is particularly advantageous in post-refractive cases, especially when monitoring for ectasia, which necessitates more accurate monitoring of thickness than can be achieved with standard Orbscan topography.

The main issue with Scheimpflug photograpy is reproducibility: Any movement of the eye or errors in fixation during image capture will cause distortions in the final image and subsequent data.

All-in-one imaging

Visante omni, the latest imaging solution from Carl Zeiss Meditec Inc. (Dublin, Calif.), combines two already successful systems: the ATLAS Corneal Topographer, a reliable imaging system for anterior topography, and the Visante OCT, which measures and analyzes anterior and posterior elevation, pachymetry, and full-width anterior segment imaging.

The Visante omni fits the ATLAS and the Visante OCT onto the same workbench. The process begins with an image taken with the ATLAS. The system’s proprietary V-Trac Registration System precisely defines the corneal vertex. This precise corneal vertex registration ensures reliable corneal posterior topography. V-Trac Registration System uses strict criteria to prevent potential misalignment.

Once the target—the corneal vertex—is acquired, a pachymetry mode of the Visante omni system is used to measure the corneal thickness all the way around. The system then calculates anterior elevation data on the ATLAS and uses the corneal thickness map from the OCT to accurately determine posterior curvature and elevation.

The system thus provides comprehensive corneal analysis including anterior topography, pachymetry and relative pachymetry, and anterior and posterior elevations to improve detection of keratoconus. The ATLAS Pathfinder II software then classifies anterior topography into several categories using the Support Vector Machine algorithm and clinical database, giving surgeons a better idea of unusual corneal thickness values that may lead to suspicions of forme fruste keratoconus, enhancing patient selection and advancing diagnostic confidence.

The typical readout from the system provides the surgeon with white-to-white measurements of the steep Ks both on the anterior and posterior cornea, a relative pachymetry map based on a normative database, and a toric ellipsoid reading that can be changed to a different setting by altering the program software.

Clinical data

In order to see its accuracy, Jodhbir Mehta, BSc, FRCSed, FRCorophth, Singapore, conducted an intra-/interobserver study in which 40 patients with normal corneas were examined using the Visante omni system. The results were compared with standard machines available on the market. The parameters examined were anterior surface elevations, posterior surface elevations, Sim Ks, and aberration. The statistical data was analyzed using Bland-Altman analysis, typical when comparing two instruments. The mean bias was examined when comparing two values taken from two different observers.

The data showed that the intra- and interobserver values were very accurate. The mean bias was very small, p-values high, and limits of agreement (LOAs) comparable for Sim Ks (intraobserver -0.012, p=0.7, LOA -0.38 – 0.36; interobserver 0.014, p=0.69, LOA -0.41 – 0.44), flat Ks (intra 0.018, p=0.5, LOA -0.31 – 0.35; inter 0.05, p=0.8, LOA -0.35 – 0.36), and anterior corneal curvature along the X-axis (intra 0.452, p=0.22, LOA –3.9 – 4.8; inter 0.04, p=0.9, LOA –4.0 – 4.12) and along the Y-axis (intra –0.114, p=0.74, LOA –4.4 – 4.2; inter –0.612, p=0.097, LOA –0.15 – 0.19).

Summary

Technological improvements in all types of refractive surgery, including cataract and laser-based procedures, call for more detailed analyses of corneas than surgeons have been used to with surface readings. Improvements in technology with regard to consistency between normal eyes and abnormal eyes provide surgeons with a whole range of detailed information with newer topography machines. By using the ATLAS together with the Visante OCT, the Visante omni system combines two well-established technologies to provide more information about the cornea.

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