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Innovation: Seeing beyond

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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 9.1 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.

Other complications can manifest later. Among them are filamentous keratitis, which can appear two years postop, and superficial punctate keratitis (SPK), which can manifest as far out as 12 years postop. Thus, in order to avoid these and other complications, Dr. Shimizu decided to stop performing LASIK completely in 2008.

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; rather, they remove tissue by photodisruption. For laser vision correction based on lenticule creation and extraction (ReLEx), a balanced relation between spot spacing and energy is desirable to create a smooth surface.

The VisuMax is currently the only femtosecond system on the market that is able to perform ReLEx. It creates a precisely shaped lenticule that consists of two cuts referring to each other with high precision, and the laser settings can be adjusted according to the optimal combination between spot size and energy.

SMILE vs. FLEx

Dr. Shimizu compared two iterations of ReLEx—femtosecond lenticule extraction (FLEx) and small incision lenticule extraction (SMILE)—looking at 60 eyes of 30 patients. In both procedures, a lenticule of intrastromal corneal tissue is removed to alter the shape and hence refractive characteristics of the cornea; the difference is that FLEx still requires a flap for removal of the lenticule, while SMILE constitutes a further development of the procedure and allows the extraction of the lenticule through a small incision that is also created using the femtosecond laser.

Refractive outcomes were comparable between the two procedures in terms of manifest spherical equivalent (SMILE –4.09±1.60 D vs. FLEx –3.99±1.66 D, *p*=0.61), manifest cylinder (SMILE –0.57±0.72 D vs. FLEx –0.69±0.75 D, *p*=0.19), logMAR uncorrected visual acuity (UCVA; SMILE 1.12±0.22 vs. FLEx 1.07±0.27, *p*=0.06), and logMAR best corrected visual acuity (BCVA; SMILE –0.23±0.06 vs. FLEx –0.23±0.06, *p*=0.67).

The visual outcomes remained comparable one year postop. There was no difference in terms of visual acuity, efficacy index (SMILE 0.80 vs. FLEx 0.80), safety index (SMILE 0.90 vs. FLEx 0.90), stability (one month – one year: SMILE –0.12 D vs. FLEx –0.09 D), and predictability (SMILE 100% vs. FLEx 100%).

One difference that emerged in the study was in terms of indices of comfort: On the visual analog scale (VAS), SMILE scored an average of 34.8, 31.7, and 38.6, while FLEx scored an average of 93.1, 86.7, and 87.1 (*p*<0.001) for pain, tearing, and discomfort, respectively.

The Schirmer test also decreased more in the with-flap FLEx surgery than with SMILE, but the difference was small and mostly disappeared by six months (SMILE 12.4 vs. FLEx 12.1).

A bigger difference was seen in terms of tear breakup time (TBUT). TBUT remained stable after SMILE surgery, but decreased over time up to one year postop with FLEx surgery (*p*<0.001 at each time point).

The differences of pain and TBUT (and subsequently dry eye) may have to do with the effect each procedure has on the subbasal nerve plexus of the cornea. Flap making damages the nerve plexus as shown by examination of the cornea under confocal microscopy after the two procedures at different time points: preop and postop one month, three months, and one year. Subbasal nerve density was consistently higher postop with SMILE. Nerve density was reduced to about 50% with SMILE, and went down to about 10% with FLEx (*p*<0.05).

SMILE is therefore the less invasive procedure. One year after the surgery, fluorescein staining revealed a better ocular surface with SMILE.

ReLEx: Two-year data

At the Kitasato University School of Medicine, Dr. Shimizu has performed ReLEx on 202 eyes (101 FLEx, 101 SMILE). ReLEx scored consistently high at different time points in terms of safety index (from 0.79 at one day to a peak of 0.98 at one year, leveling off at 0.93 at two years postop) and efficacy index (0.65 at one day, rising to and leveling off at 0.86 by six months postop). The refraction also remained stable up to two years, and predictability of ±0.5 D was 100% by two years—better results than with LASIK.

There were some complications. Intraoperatively, suction loss was observed in four cases (2.0%). The most common postoperative complication observed was transient interface haze (15 cases, 7.4%); however, haze disappeared after administration of topical steroids. Diffuse lamellar keratitis was seen in two cases (1.0%), while one patient requested a small enhancement (0.5%). There were no cases of infection or of epithelial ingrowth.

ReLEx vs. LASIK

Dr. Shimizu compared ReLEx with LASIK in terms of higher order aberrations (HOAs), 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 (*p*<0.001) in terms of fourth-order aberrations (ReLEx 0.07 microns change in HOAs, LASIK 0.29 microns change in HOAs).[1] 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 PRK, mini-PRK, 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

1. Kamiya K, Shimizu K, Igarashi A, Kobashi H, Komatsu M. Comparison of visual acuity, higher-order aberrations and corneal asphericity after refractive lenticule extraction and wavefront-guided laser-assisted in situ keratomileusis for myopia. *Br J Ophthalmol.* Published online first 25 December 2012.

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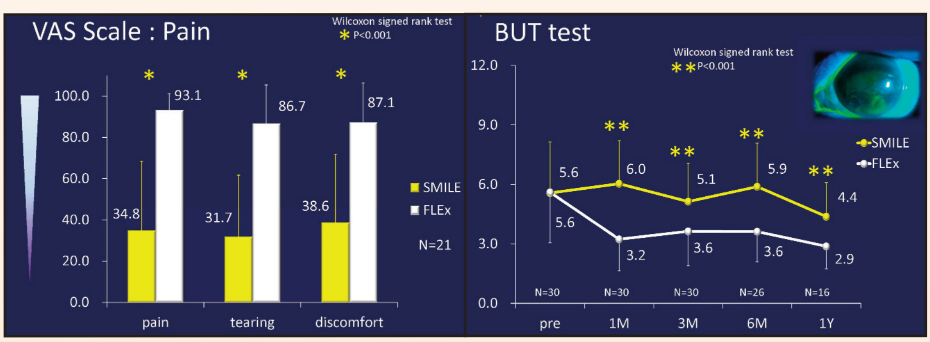


Pain and TBUT were the most significant differences between SMILE and FLEx.

SMILE: An intrastromal form of keratomileusis

Dan Z. Reinstein, MD, MA(Cantab), FRCSC, DABO, FRCOphth, FEBO

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 photoablation by an excimer laser. Early studies were made using picosecond lasers (1996)[1,2] and femtosecond lasers (1998-2003),[3-5] however, these did not culminate in actual clinical trials.

Following the introduction of the VisuMax femtosecond system (Carl Zeiss Meditec Inc., Jena, Germany) in 2006,[6] 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.[7-9] 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.[10-12]

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 cornea when 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,[13] laser fluence projection and reflection losses,[14] and other environmental factors.[15] 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.[16] 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 strength 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 Randleman et al.[17] In their 2008 study, they measured the tensile strength of strips of stromal lamellae cut from different depths within the cornea and 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, the actual residual stromal thickness in SMILE should be calculated as the total uncut stroma (i.e., the stroma above the lenticule as well as the stroma below the lenticule).

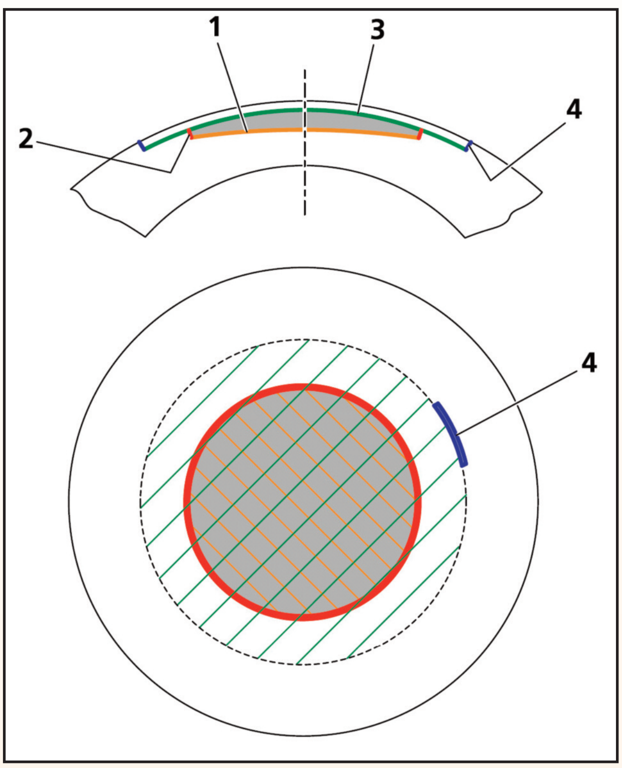
But given the decreasing strength of stroma with depth, we also need to start thinking more in terms of tensile strength rather than simply in terms of residual stromal thickness, which is something that we have done by developing a postoperative tensile strength calculator[18] based on the Randleman data.[17] The model predicted that the postop tensile strength after SMILE was approximately 10% higher than PRK and 25% higher than LASIK. For example, the postoperative relative total tensile strength would be 60% for an ablation depth of 73 µm in LASIK (approximately –5.75 D), 132 µm in PRK (approximately –10.00 D), and 175 µm in SMILE (approximately –13.50 D), translating to a 7.75 D difference between LASIK and SMILE for a cornea of the same postoperative relative total tensile strength.

The other factor is that no side cut is created in SMILE, which minimizes the corneal biomechanical change as fewer stromal lamellae are severed. This has recently been demonstrated in a study on cadaver eyes by Knox Cartwright et al.[19] who found that the increase in strain was the same for a side cut only as a LASIK flap, whereas there was a very small increase in strain with the delamination cut only.

3. Reduction in postoperative dry eye

The other major potential advantage of the flapless micro-invasive SMILE procedure is the reduction in postoperative dry eye compared with that observed after PRK and LASIK. The cornea is one of the most densely innervated peripheral tissues in humans with the majority of the nerve bundles within the anterior stroma. These anterior nerves are cut by the microkeratome or femtosecond laser in LASIK and by the ablation in PRK, which results in dry eye symptoms.

In SMILE on the other hand, the anterior stromal nerve plexus is disrupted significantly less since no side cut is created, which should result in fewer dry eye symptoms and a faster recovery of postoperative patient comfort. Indeed, studies have shown the faster recovery of corneal sensation after SMILE[20] with recovery to baseline by three months compared with six to 12 months after LASIK.



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 superotemporally. The lenticule interfaces are separated using a flap separator and the lenticule is extracted manually, all via the small incision.

Summary

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 Jose Ignacio Barraquer's original concept of keratomileusis to be effectuated through

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PRESBYOND Laser Blended Vision: My solution of choice for presbyopia in emmetropic, myopic, or hyperopic patients

Dan Z. Reinstein, MD, MA(Cantab), FRCSC, DABO, FRCOphth, FEBO

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 fully 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 stereoacuity. Preferably the procedure should be reversible and repairable if complications arise. This was the set of goals I 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 PRESBYOND Laser Blended Vision.

Concept behind PRESBYOND 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 disseminates 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 pseudoaccommodating solution. Thus, the spherical aberration of the eye can be modulated on the cornea by LASIK to increase the depth of focus of the entire visual system by working within the natural processing range of cortical 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 (*inter*ocular rivalry, not *intra*ocular). 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 stereoacuity—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) stereoacuity.

In PRESBYOND 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, stereoacuity, or night vision.

At one year after PRESBYOND Laser Blended Vision, binocular UDVA was 20/20 or better and

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a micro-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 alike.

References

1. Ito M, Quantock AJ, Malhan S, Schanzlin DJ, Krueger RR. Picosecond laser in situ keratomileusis with a 1053-nm Nd:YLF laser. *J Refract Surg*. 1996;12:721-728.
2. Krueger RR, Juhasz T, Gualano A, Marchi V. The picosecond laser for nonmechanical laser in situ keratomileusis. *J Refract Surg*. 1998;14:467-469.
3. Kurtz RM, Horvath C, Liu HH, Krueger RR, Juhasz T. Lamellar refractive surgery with scanned intrastromal picosecond and femtosecond laser pulses in animal eyes. *J Refract Surg*. 1998;14:541-548.
4. Heisterkamp A, Mamom T, Kermani O, Drommer W, Welling H, Ertmer W, Lubatschowski H. Intrastromal refractive surgery with ultrashort laser pulses: in vivo study on the rabbit eye. *Graefes Arch Clin Exp Ophthalmol*. 2003;241:511-517.
5. Ratkay-Traub I, Ferincz IE, Juhasz T, Kurtz RM, Krueger RR. First clinical results with the femtosecond neodynium-glass laser in refractive surgery. *J Refract Surg*. 2003;19:94-103.
6. Reinstein DZ, Archer TJ, Gobbe M, Johnson N. Accuracy and Reproducibility of Artemis Central Flap Thickness and Visual Outcomes of LASIK With the Carl Zeiss Meditec VisuMax Femtosecond Laser and MEL 80 Excimer Laser Platforms. *J Refract Surg*. 2010;26:107-119.
7. Sekundo W, Kunert K, Russmann C, Gille A, Bissmann W, Stobrawa G, Sticker M, Bischoff M, Blum M. First efficacy and safety study of femtosecond lenticule extraction for the correction of myopia: six-month results. *J Cataract Refract Surg*. 2008;34:1513-1520.
8. Blum M, Kunert KS, Engelbrecht C, Dawczynski J, Sekundo W. Femtosecond lenticule extraction (FLEx) – Results after 12 months in myopic astigmatism. *Klin Monbl Augenheilkd*. 2010;227:961-965.
9. Vestergaard A, Ivarsen A, Asp S, Hjortdal JO. Femtosecond (FS) laser vision correction procedure for moderate to high myopia: a prospective study of ReLEx flex and comparison with a retrospective study of FS-laser in situ keratomileusis. *Acta Ophthalmol*. 2012.
10. Sekundo W, Kunert KS, Blum M. Small incision corneal refractive surgery using the small incision lenticule extraction (SMILE) procedure for the correction of myopia and myopic astigmatism: results of a 6 month prospective study. *Br J Ophthalmol*. 2011;95:335-339.
11. Shah R, Shah S, Sengupta S. Results of small incision lenticule extraction: All-in-one femtosecond laser refractive surgery. *J Cataract Refract Surg*. 2011;37:127-137.
12. Hjortdal JO, Vestergaard AH, Ivarsen A, Ragunathan S, Asp S. Predictors for the outcome of small-incision lenticule extraction for myopia. *J Refract Surg*. 2012;28:865-871.
13. Dougherty PJ, Wellish KL, Maloney RK. Excimer laser ablation rate and corneal hydration. *Am J Ophthalmol*. 1994;118:169-176.
14. Mrochen M, Seiler T. Influence of corneal curvature on calculation of ablation patterns used in photorefractive laser surgery. *J Refract Surg*. 2001;17:S584-587.
15. Schena E, Silvestri S, Franzesi GT, Cupo G, Carito P, Ghinelli E. Theoretical model and design of a device to reduce the influence of environmental factors on refractive surgery outcomes. *Conf Proc IEEE Eng Med Biol Soc*. 2006;1:343-346.
16. Reinstein DZ, Archer TJ, Gobbe M. Accuracy and Reproducibility of Cap Thickness in Small Incision Lenticule Extraction (SMILE). *J Refract Surg* [In Press]. 2013.
17. Randleman JB, Dawson DG, Grossniklaus HE, McCarey BE, Edelhauser HF. Depth-dependent cohesive tensile strength in human donor corneas: implications for refractive surgery. *J Refract Surg*. 2008;24:S85-89.
18. Reinstein DZ, Archer TJ, Randleman JB. Mathematical Model to Compare the Relative Tensile Strength of the Cornea After PRK, LASIK, and Small Incision Lenticule Extraction. *J Refract Surg*. 2013;29:454-460.
19. Knox Cartwright NE, Tyrer JR, Jaycock PD, Marshall J. Effects of Variation in Depth and Side Cut Angulations in LASIK and Thin-flap LASIK Using a Femtosecond Laser: A Biomechanical Study. *J Refract Surg*. 2012;28:419-425.
20. Wei S, Wang Y. Comparison of corneal sensitivity between FS-LASIK and femtosecond lenticule extraction (ReLEx flex) or small-incision lenticule extraction (ReLEx SMILE) for myopic eyes. *Graefes Arch Clin Exp Ophthalmol*. 2013.

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A (r)evolutionary step in multifocality: Introducing the trifocal AT LISA tri 839MP

Detlev Breyer, MD

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,[1] **Nick Mamalis, MD**, found that while 90% of bifocal multifocal IOL (MIOL) patients were happy, 4% were unhappy and 1% underwent explantation; 3% of all explanted IOLs were MIOLs, and the leading reasons for explantation were halo and optical aberrations.

It has been suggested that the reasons for these aberrations have to do with the MIOL's sensitivity to centration or pupil dependence. It has also been theorized that the two foci of bifocal MIOLs were too widely separated, or that MIOLs have too many rings. It is thought that a patient's will to adapt to MIOLs or advanced age may also influence outcomes.

The AT LISA trifocal concept

The new AT LISA tri 839MP (Carl Zeiss Meditec Inc., Jena, Germany) is a trifocal IOL. Its optic is trifocal by diffraction 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[2]) and—in worst-case scenarios—ease of explantation even after years.

The optic itself utilizes the proven Smooth Micro Phase technology for the lens surface, which means that the AT LISA tri optic does not have any sharp angles, resulting in ideal optical image quality with reduced light scattering. Would it therefore also reduce photopsia?

Dr. Breyer conducted a comparative study of the new lens (near add +3.33 D and intermediate add +1.66 D) vs. the AT LISA 809MP aspheric bifocal (near add +3.75 D), looking at 38 patients with the trifocal AT LISA tri 839MP and 23 patients with the bifocal AT LISA. In addition to analyzing photopsia, the study consisted of a retrospective analysis of subjective refraction, visual acuity at distinct distances (mono- and binocular), contrast sensitivity (using the Ginsburg box), a comparison between femtosecond laser-assisted capsulotomy and manual rhexis, and a questionnaire for patients.

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UNVA 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.

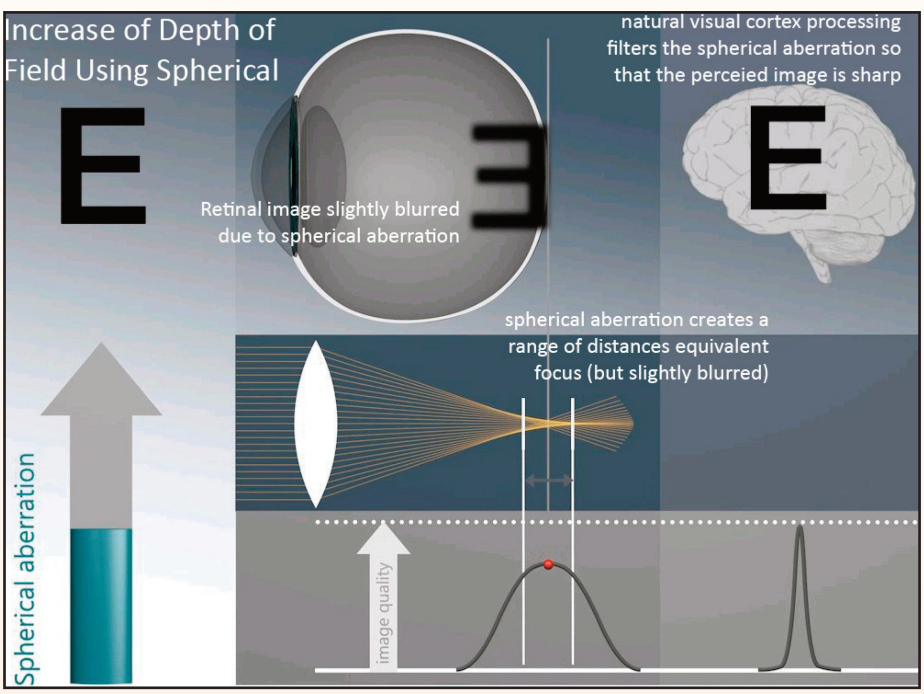

Diagram showing increase in depth of field using filtering of spherical aberration

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 low 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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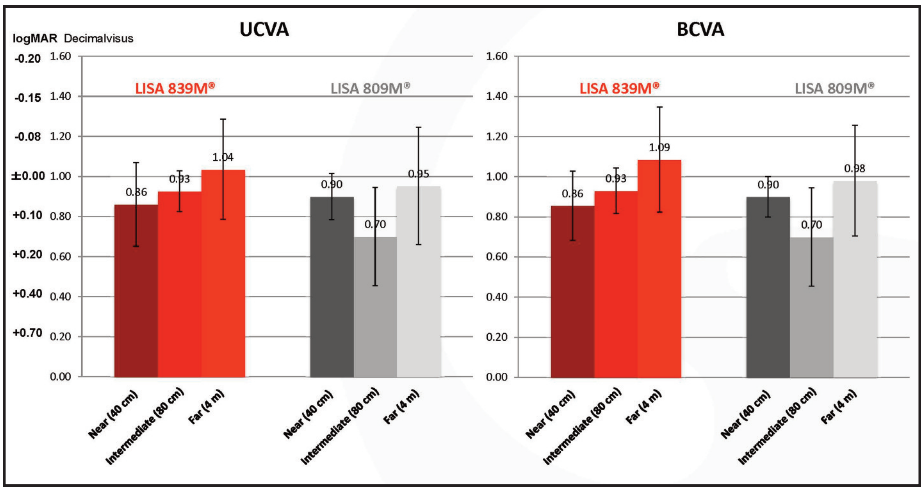
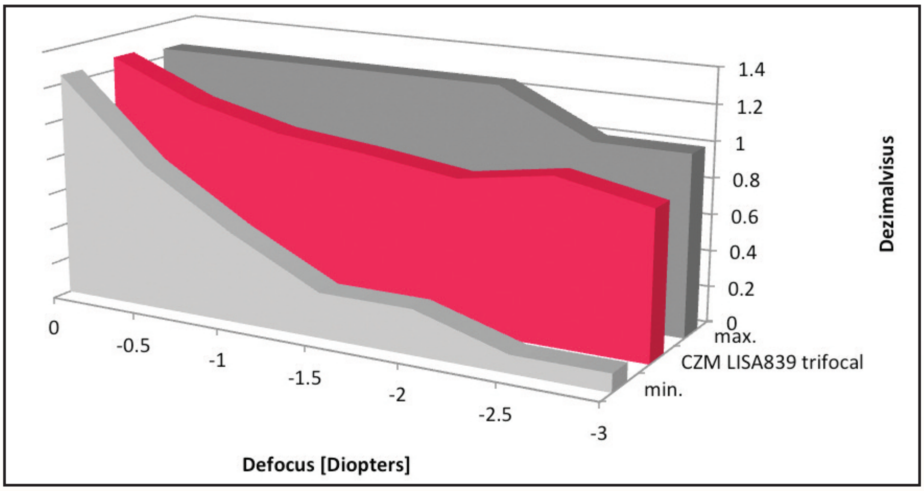


Comparison of the uncorrected and best corrected visual acuities with the AT LISA tri 839MP and AT LISA 809MP



Area under defocus curve. Defocus results from –3.0 D to 0.0 D were area-plotted and integrated. Areas from juvenile phakic eyes (dark grey), monofocal IOL (light grey), and the respective trifocal IOL (red) are displayed. The results deliver a comparative aspect of an IOL: the capacity of an IOL in comparison to phakic juvenile eyes. Integration of juvenile phakic eyes represent 100%, a monofocal IOL shows only 46% area, whereas the trifocal IOL shows a capacity of 82%, which represents the highest yielded capacity among the investigated IOL portfolio.

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

1. Mamalis N, Brubaker J, Davis D, Espandar L, Werner L. Complications of foldable intraocular lenses requiring explantation and secondary intervention—2007 survey update. *Journal of Cataract and Refractive Surgery*. 2008;34:1584-1591.
2. Breyer D, Kaymak H, Klabe K, Dillner F, Pohl, C. Optical quality and capsular bag stability of 4-point haptic toric IOL implantation. Presented at the 2013 ASCRS•ASOA Symposium & Congress, San Francisco, April 2013.

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The complete anterior segment imaging solution

Jodhbir Mehta, BSc, FRCSEd, FRCOphth

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 corneal 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 photographs 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 photography 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 uses strict criteria to prevent potential misalignment.

Once the target—the corneal vertex—is acquired, a pachymetry mode in 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, FRCOphth**, 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 (LOA) 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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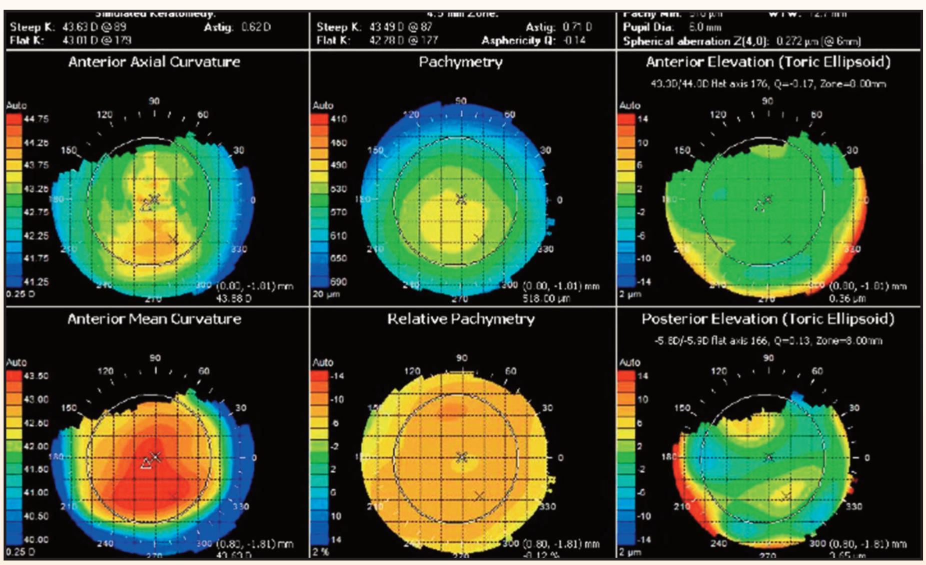

Typical Visante *omni* readout of a normal cornea

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