

Trends in Refractive Surgery and in Presbyopia Correction

In 2015, some novel procedures will continue to be brand-specific.

**BY ROBERT EDWARD ANG, MD; LUDGER HANNEKEN, MD; DETLEF HOLLAND, MD;
AND JODHBIR S. MEHTA, FRCS, FRCOPHTH**

Robert Edward Ang, MD



The LASIK market will continue to be flat in 2015, as there is no earth-shaking development on the horizon in the world of excimer lasers. Machines may become faster and algorithms more refined, but no new innovations are

expected. Additionally, although more buzz and data on ReLEx small incision lenticule extraction (SMILE) will surface, the procedure will continue to be nice to have in one's repertoire, but not yet a must-have.

I believe that LASIK will remain the go-to treatment in the majority of centers next year because of its fast visual recovery, the wide range of refractive powers it can correct, its ability to be enhanced, and its cost to patients.

Another area in which there will be continued interest is presbyopia solutions. The Kamra inlay (AcuFocus) is on the brink of FDA approval; this approval will pave the way for the other corneal inlays, which will be used most often for presbyopia treatment in near-emmetropes. In patients with refractive errors, there are not enough data and experience for a combined excimer-inlay approach to be viable. Excimer-based presbyopia algorithms will continue to be refined and improved; however, the uptake will be minimal, because, just as with SMILE, these novel procedures are brand-specific. Surgeons who do not have the right laser for a proprietary treatment would be hard-pressed to justify acquiring an expensive machine if the market is not clearly going in that particular direction.

In terms of presbyopia-correcting IOLs, trifocals will continue to eat into the market share of bifocal multifocal IOLs. I do not see a downside of trifocals compared with bifocal multifocals, but the potential upside of better intermediate vision will be further established next year.

Presbyopia correction has traditionally been performed in three locations: on the cornea (excimer-based), in the cor-

nea (inlays), and in the lens capsule (IOLs). But a fourth location, in the sulcus (phakic IOLs), will emerge. A phakic IOL with presbyopia-correcting abilities will excite the market.

In terms of principles for presbyopia correction, the most common method—multifocality with either IOLs or excimer-based treatments—will continue to thrive in 2015. However, two new buzzwords that will be trending for presbyopia are *enhanced depth of focus* (EDOF) and *extended range of vision* (EROV). The Symphony (Abbott Medical Optics), WIOL (Medicem), and IC-8 small-aperture (AcuFocus) IOLs will champion these new concepts. While the near-vision gain may not be as strong as with multifocal options, what makes EDOF and EROV lenses attractive is that they reduce unwanted photic phenomena (glare and halos) and, to some extent, diminish the decrease in contrast sensitivity that has been a thorn in the side of multifocality. As EDOF and EROV options continue to emerge, the principle of mini-monovision will become more acceptable.

So far, this is what my crystal ball is showing me. It looks like 2015 will be another exciting year. Let us keep our eyes and ears open.

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Ludger Hanneken, MD



The treatment of presbyopia is still a challenge in refractive surgery, despite the availability of various interventions including corneal (LASIK monovision, corneal multifocal ablation, and

corneal inlays) and lens-based (monovision strategies and multifocal and accommodating IOLs). Yet not one of these techniques restores patients' vision completely in all aspects and across all ranges of distance. Monovision strategies will continue to be used frequently in the upcoming year; however, whether achieved with a corneal- or lens-based approach, monovision will still produce visual limitations including loss of fusion and stereoacuity.

CORNEAL PROCEDURES

One presbyopia-correction strategy that is likely to make headway in 2015 is extending patients' depth of field by means of ablation, insertion of corneal inlays, or IOL implantation. On the other hand, corneal presbyopic surgery with improved diagnostic devices will give us more options for customized treatments. The latest improvements in laser technology, including better eye tracking and control of cyclorotation, will allow more consistent ablations, leading to greater patient satisfaction and broader acceptance among refractive surgeons.

Laser correction with blended vision (nonlinear corneal aspheric ablation) in myopic and hyperopic populations combines two mechanisms: induction of spherical aberration to increase depth of field and micro-monovision (anisometropia of approximately 1.50 D in the nondominant eye). Reinstein et al have reported high degrees of patient satisfaction with Laser Blended Vision (Carl Zeiss Meditec).^{1,2} The intention of this surgical procedure is to use optimized ablation profiles—based on patient age, refraction, preoperative spherical aberration, and tolerance of anisometropia, and with treatment centered on the corneal vertex—to increase depth of field without compromising visual quality, contrast sensitivity, or night vision.

Corneal inlays are also intended to increase depth of field in combination with micro-monovision. Revised surgical techniques seem to have decreased the risk for corneal reactions; however, centration will continue to be an important intraoperative detail. The Kamra (AcuFocus) combined with micro-monovision is a promising approach, but visual outcomes are not always consistent. Furthermore, the safety of corneal inlays is not yet comparable with that of LASIK, with 4% to 6% of patients losing two lines of distance BCVA and experiencing significant decrease in contrast sensitivity (personal data). These issues may continue to affect the adoption of refractive corneal inlays in the upcoming year.

The IC-8 and other EDOF IOLs will likely gain popularity next year as well. Few visual disturbances are expected with the Symphony or the iSert 751 Gemetric lens (Hoya). Graham D. Barrett, MD, FRACO, reported

better image quality with the Gemetric IOL than with negative defocus.³ If emmetropia is targeted in one eye and myopic defocus in the other, the overlap of defocus in the 20/20 to 20/40 range creates a zone of blended vision that avoids the disadvantages of traditional monovision.

Rotationally asymmetric near-addition IOLs such as the Lentis MplusX (Oculentis) with lower near addition are now available and are likely to see increased use in 2015. This IOL provides good intermediate vision, reduces optical phenomena, and produces high patient satisfaction. The use of mix-and-match strategies with different near additions will continue to grow, as individual selection of multifocal IOLs leads frequently to higher patient satisfaction.

The Light Adjustable Lens (LAL; Calhoun Vision) could demonstrate impressive predictive results next year due to its capability for postoperative adjustments with application of ultraviolet radiation. In addition to spherical and astigmatic adjustment, the LAL offers the possibility of providing increased depth of focus for presbyopia correction by inducing negative asphericity in the lens after implantation. One step further is the adjustable blended vision concept, which works by minimizing aberrations in the distance eye and inducing a controlled amount of negative spherical aberration and defocus in the near eye to increase the depth of focus. Spherical aberration and defocus targets are customized preoperatively through the use of the phoropter and trial lenses. Binocular summation is enhanced as the interocular similarity of image quality is increased due to extended monocular depth of focus. A simulation can be performed with the Adaptive Optics Vision Analyzer (Voptica) to determine which preadjustment values the patient prefers. The fascinating possibility of complete reversibility and readjustment until lock-in offers, theoretically, complete customization. I am eager to see more clinical data in 2015.

Another interesting new technology has arrived: the laser-created rhexis-fixated IOL. The Femtis IOL (Oculentis; Figure 1) can produce precise predictability of effective lens position, leading to more precise refractive outcomes, better optic centration, and fewer problems with axial movement over time. The Femtis IOL is the first example of how laser-assisted cataract surgery (LACS) has influenced lens designs and concepts, as it is intended specifically to fit into a laser-created capsulorrhexis. I am sure that we will see more developments concomitant with femtosecond laser use in the coming years. Likewise, the Femtis Top IOL—to be studied in multicenter clinical trial in 2015—will create the potential to turn multifocal IOL implantation into a reversible procedure.

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Detlef Holland, MD



Restoration of accommodation is still one of the greatest challenges in ophthalmology. Fortunately, we see new trends and treatment options every year. Apart from multifocal IOL implantation, which, at the moment, is the most

widely used surgical therapy for presbyopia correction, other treatment options such as intrastromal corneal inlays and scleral expansion systems are also available today.

Which trends in multifocal IOL implantation have the brightest future in 2015? Rotationally asymmetric IOLs such as the Lentis MplusX and the Lentis Comfort (Oculentis) may be expected to gain market share next year. One advantage of IOLs with this type of design is that they produce fewer visual disturbances than rotationally symmetric multifocal IOLs. Another advantage is that they are available in different add powers (1.50 D for the Comfort and 2.00 and 3.00 D for the MplusX). Patients with high demands in near and intermediate vision are candidates for bilateral implantation of the 3.00 D MplusX, for instance. Another option for these patients is the AT LISA tri IOL (Carl Zeiss Meditec), which is also available in a toric version. Patients with high demands in the distance range who want additional benefits in the intermediate can fare well with bilateral implantation of the Comfort and a target refraction of emmetropia. A slightly myopic target refraction (-1.00 to -1.50 D) in both eyes can increase near visual acuity without increasing the risks of halos and glare. An emerging concept is the approach called *comfort blended vision*, with targets of emmetropia in the dominant eye and -1.50 D in the nondominant. This concept was recently introduced by Detlev Breyer, MD.¹

Another new type of IOL design that has potential as a presbyopia treatment is the laser lens, intended for implantation during LACS; the design promotes perfect centration by hooking into the capsulotomy. We have implanted 30 monofocal Femtis Laser Lens IOLs thus

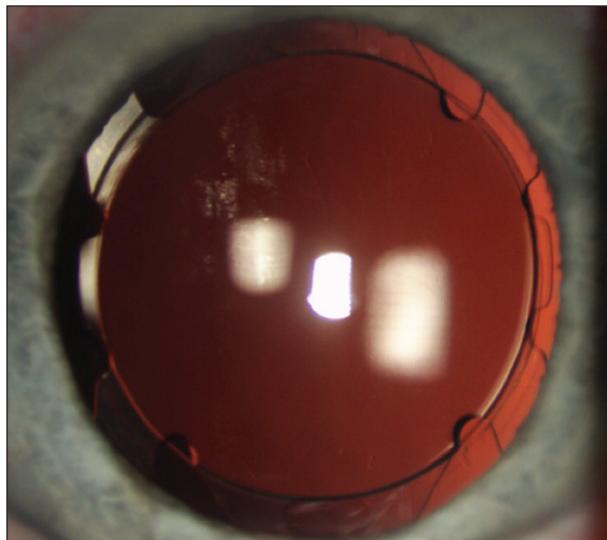


Figure 1. The Femtis Laser Lens.

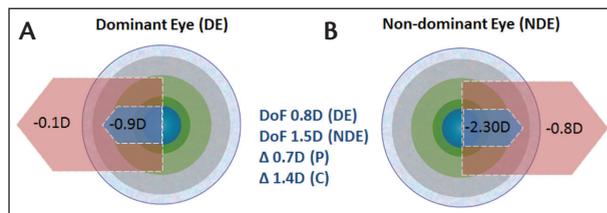


Figure 2. PresbyMax Hybrid: Treatment parameters in the dominant (A) and nondominant (B) eyes.

far. The haptic system is designed to enslave the lens in the capsulotomy, which we create using the Lensar Laser System (Lensar). We have seen no capsulotomy tears or other intra- or postoperative complications; however, clipping the four additional haptics into the capsulotomy requires a short learning curve and minimal additional time. We are interested to see whether lens centration in the capsulotomy will bring long-term benefits in refractive and visual outcomes. The possibility to center the capsulotomy in the line of sight will be an option with the Lensar laser soon, and this will be especially advantageous for multifocal IOL implantation.

Another interesting development is the Lumina accommodating IOL (Akkolens), which is implanted in the sulcus and uses frontal plane forces from the ciliary body to shift the IOL's two components, resulting in a change in focus. In a study in 50 eyes, Alió showed evidence of accommodative restoration ranging from 1.50 to 5.00 D.² If this concept has no side effects, it could be another great option for presbyopia treatment in the future.

The technologies described above are all exciting developments in presbyopia correction; however, each has limitations. In IOL implantation, there are still the risks associated with intraocular surgery (eg, endophthalmitis), and not all

Figures 1 through 3: Courtesy of Detlef Holland, MD

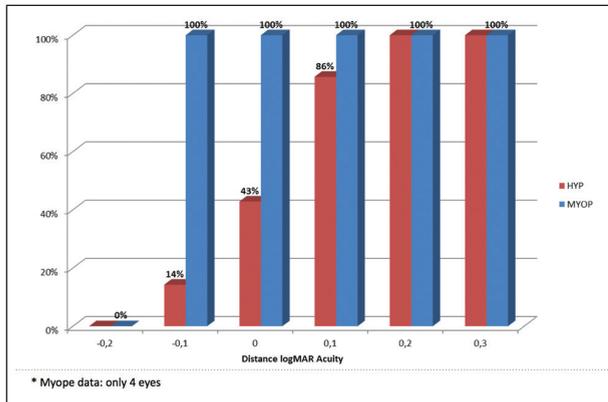


Figure 3. Binocular distance UCVA 6 months after PresbyMax Hybrid.

patients are willing accept these if other options are available. Monovision LASIK and presby-LASIK are good alternatives to clear lens exchange, especially in younger presbyopic patients (less than 55 years). We prefer a biphosphoric presby-LASIK technique performed with the Amaris laser platform (Schwind eye-tech-solutions). The procedure, PresbyMax, is based on the creation of a central hyper-positive area for near vision, leaving the midperipheral cornea for far vision. The latest version of this procedure, PresbyMax Hybrid, uses different ablation patterns in each eye to maximize visual function at all distances (Figure 2).

We have performed PresbyMax in 86 presbyopic patients (mean age, 52 years) with up to 3 years' follow-up. In a subset of 24 patients who underwent PresbyMax Hybrid, binocular distance UCVA improved from 0.51 logMar preoperatively to 0.00 logMar postoperatively (Figure 3); near UCVA improved from 0.49 logRAD to 0.19 logRAD. The loss of lines was comparable with that of multifocal IOL implantation, indicating the safety of this procedure.

To summarize, presbyopia treatment is no longer witchcraft. With the various options available, surgical intervention can lead to good results and happy patients. The key continues to be perfect patient selection, with careful preoperative assessment. Advanced diagnostic devices such as the IOLMaster 700 (Carl Zeiss Meditec) will help to decrease the risk of refractive surprises.

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As early as this year's annual American Society of Cataract and Refractive Surgery (ASCRS) meeting in April and even more so at the European Society of Cataract and Refractive Surgeons (ESCRS) meeting in September, the most evident shift in refractive surgery that I have seen is that ReLEx SMILE has come of age. Although surgeons were apprehensive about adopting this technique in its infancy, now several factors supporting its use have surfaced. First, approximately 125,000 treatments have been performed globally. Second, Carl Zeiss Meditec is in the final stage of its FDA study, and the results are promising. Third, there is more published results on outcomes, both scientific and clinical, showing encouraging results. I believe that, in 2015, we will continue to witness a shift away from conventional LASIK, with many surgeons who are looking to purchase a new femtosecond laser system turning to the VisuMax femtosecond laser (Carl Zeiss Meditec).

Patients have also become more aware of the SMILE procedure over the past 2 years. In my practice, many now come in asking for SMILE specifically, whereas even a few months ago the majority had never heard of it until one of our staff described it to them. It will still take time for ReLEx SMILE to truly catch on—mostly because everyone is so familiar with LASIK—but I expect to see more patients requesting SMILE from the outset. The key fact for this is that patients like that there is no need for a flap. Additionally, I believe that in 2015 we will see an increase in patients contraindicated for LASIK who may be suitable for ReLEx SMILE; however, more research is needed in this area.

The VisuMax femtosecond laser is currently the only laser capable of performing SMILE; however, the Femto LDV (Ziemer) may be capable of performing this or a similar treatment due to its low energy level capability and the liquid interface on the new Femto LDV Z8. Additionally, during the Association for Research in Vision and Ophthalmology (ARVO) meeting in May 2014, I saw a prototype ultraviolet laser system that could potentially perform lenticular extractions. The fact that other companies are researching this type of treatment reinforces the idea that SMILE has come of age.

With that said, this question remains to be answered: Is SMILE superior to LASIK? Maybe equivalence with a better safety profile will be good enough. ■

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