Despite continued innovations in cataract and refractive surgery, there have been persisting unmet needs in presbyopia correction and treatment for astigmatism. New technologies are designed to address these challenges and were the topic for two symposia held during the XXXIII Congress of the ESCRS in Barcelona, Spain.

This supplement captures the highlights of those sessions. The first three articles spotlight the new Extended Range of Vision Intraocular Lens (IOL) as an innovative concept with proven advantages for presbyopia correction after cataract surgery. The following articles discuss three new solutions for better astigmatism management in cataract and refractive surgery – Extended Range of Vision Toric IOL; laser cataract surgery suite with arcuate incision technology; and high-definition wavefront-guided laser vision correction for state-of-the-art accuracy in measurement, treatment planning, and ablation in regular and irregular corneas.
The Innovative Optics of the Extended Range of Vision IOL

Leonard Borrmann PhD

The TECNIS® Symfony IOL was designed with the aims of providing cataract patients a presbyopia-correcting implant able to deliver a full range of high-quality uncorrected vision with the same low incidence of halos and glare associated with monofocal IOLs.

As presented by Leonard Borrmann PhD, USA, findings from laboratory and clinical studies provide conclusive evidence that the optical engineers at Abbott Medical Optics who developed the TECNIS® Symfony IOL successfully achieved these goals.

"Traditional IOL options for correcting presbyopia after cataract surgery have bifocal or trifocal optics that work on the principle of simultaneous vision by splitting light into more than one focal point, or are accommodating IOLs depending on ciliary muscle contraction to alter optic shape or position to change the power. With these designs, functional vision was evaluated based on discrete distances – far, intermediate or near," said Dr Borrmann.

“The aims for developing a novel IOL optic were to create a lens that would provide a continuous range of vision while simultaneously addressing the problems of reduced contrast sensitivity and bothersome dysphotopsias that patients may experience with multifocal IOLs that distribute light to different, discrete foci,” he explained.

The science of the Symfory

The TECNIS® Symfony IOL achieves its performance goals by merging two complementary, enabling diffractive optics technologies – a proprietary echelette design that elongates depth of focus and a proprietary design that corrects chromatic aberration.

Dr Borrmann explained that the shape, height and spacing of the echelettes in a diffractive lens determine the phase shift of transmitted light. Whereas the design of a multifocal IOL results in two or three distinct focal points, the height and profile of the echelettes in the TECNIS® Symfony IOL are optimised to achieve constructive interference of light from different zones, thereby elongating the focus (Figure 1).

Recognising that reduction in image quality comes as a tradeoff with focus elongation, proprietary achromatic technology combined with spherical aberration correction were incorporated in the optic design as compensating features. The achromatic technology corrects the eye’s intrinsic positive chromatic aberration that causes blur and loss of contrast.

Proof of performance

Modulation transfer function (MTF) calculations from bench studies demonstrate that the combination of spherical and chromatic aberration correction in an IOL enhances contrast and retinal image quality compared with spherical correction alone. Dr Borrmann presented bench testing data showing that the MTF at distance vision for the TECNIS® Symfony IOL was very similar to that of the TECNIS® aspheric monofocal IOL and significantly higher than that of multifocal IOLs lacking chromatic aberration correction (Figure 2).

Laboratory assessment was also undertaken to investigate dysphotopsia potential, and the results showed reduced halo intensity with the TECNIS® Symfony IOL compared with a +4.0D multifocal IOL.

“We would predict from these data that experience with bothersome halos after implantation of the TECNIS® Symfony IOL would be less than with a multifocal IOL and similar to what occurs with a monofocal IOL. Findings in clinical trials and clinical experience with the TECNIS® Symfony IOL corroborate those predictions. Other results from early clinical trials are also consistent with the outcomes of laboratory evaluations,” he said.

A defocus curve constructed from testing of 31 patients bilaterally implanted with the TECNIS® Symfony IOL showed that the lens had an extended depth of focus that was suitable to generate functional near, intermediate, and far vision in a continuous fashion. The TECNIS® Symfony IOL sustained uncorrected visual acuity of 20/25 or better over more than 1.5D of defocus and mean visual acuity of 20/32 or better through more than 2.2D of defocus.

Results from contrast sensitivity testing performed at 3 months post-surgery provided clinical substantiation that the TECNIS® Symfony IOL affords high-quality distance contrast vision. Even under mesopic conditions with glare, monocular contrast sensitivity was similar across all frequencies comparing eyes implanted with the TECNIS® Symfony IOL (n=23) and controls implanted with an aspherical monofocal IOL (n=24).
Helping Patients to See the Maximum: New Treatment Options in Presbyopia and Astigmatic Correction

**Large Scale Clinical Trial Results with the Extended Range of Vision IOL**

Gerd Auffarth MD, PhD

Results from two large multicentre European clinical trials, HARMONY and CONCERTO, demonstrate that the TECNIS® Symfony Extended Range of Vision IOL (TECNIS® Symfony IOL) is associated with good functional vision and spectacle independence across a full range of distance, no to minimal dysphotopsias, and highly satisfied patients, said Gerd Auffarth MD, PhD, Germany.

"The TECNIS® Symfony IOL is based on an ingenious and unique optical design. It uses all of the incoming light rather than dividing it into discrete foci and uniquely corrects chromatic aberration. Consequently, it provides a continuous range of high-quality vision," said Dr Auffarth.

**The HARMONY Clinical Study**

Dr Auffarth reviewed three-month outcomes for the HARMONY study that included 146 bilaterally implanted patients targeted for: 1) micro-monovision (≥-0.5D in one eye, ±0.5D in the other); 2) bilateral emmetropia (bilateral ±0.5D); or 3) bilateral myopia (bilateral >-0.5D).

Visual acuity (VA) data are shown in Figure 1. Mean binocular uncorrected distance and intermediate VA (UCDVA and UCIVA) were close to or better than 0.0 logMAR (Snellen 20/20). Mean binocular uncorrected near VA (UCNVA) was 0.17logMAR (20/32+) at 40cm and improved to 0.06logMAR (better than 20/20) at patients' best distance (mean 47.6 ± 7.3cm). With distance correction, mean near VA was -0.02logMAR.

Overall, more than 90 per cent of patients achieved binocular UCDVA and UCIVA of 20/25 or better, while 90 per cent achieved 20/40 or better UCNVA. Reading tests showed good performance reading normal print sizes (newspaper, magazine) without glasses at distances of intermediate and near.

Subgroup analyses showed that, compared with bilateral emmetropia, the micro-monovision strategy afforded a slight improvement in mean UCIVA to better than 20/20 with maintenance of better than 20/20 mean UCDVA and an approximate one-line gain in UCNVA, corresponding with an increase of about 20 per cent in the proportion of patients able to read without glasses. Patients targeted for bilateral myopia achieved the best UCNVA and maintained mean UCDVA better than 20/20 with a slight drop in UCNVA to ~20/20 -1.

Overall, about 95 per cent of patients reported comfortable visual function without glasses for far and intermediate vision tasks and about 75 per cent said they were comfortable without glasses for near vision. Good to complete satisfaction without glasses was reported by 94 per cent of patients for overall vision, 97 per cent during the daytime, and 84 per cent during nighttime.

Review of ocular symptoms showed that 99 per cent of patients reported having no severe halos or night glare.

**The CONCERTO Observational Study**

The CONCERTO study was an observational study that enrolled an impressive 411 patients at 40 sites in seven European countries. Data from the final visit (four to six months) were presented for the whole cohort, which included 112 patients implanted with a micro-monovision approach.
Helping Patients to See the Maximum: New Treatment Options in Presbyopia and Astigmatic Correction

Milind Pande MD

The TECNIS® Symfony Extended Range of Vision IOL represents a new era in presbyopia-correcting IOL technology that has significant advantages over older traditional multifocal/trifocal IOL technologies and is delivering excellent clinical results that translate into very happy patients, said Milind Pande MD, UK: “In our hands, binocular implantation of the TECNIS® Symfony IOL is providing amazing outcomes,” said Dr Pande. “Unlike multifocal IOL technologies, it provides a full range of uncorrected vision with minimal or no trade-offs relating to quality of vision. Therefore, it also makes the process of patient counselling much easier because surgeons don’t have to give as many caveats and cautions about the limits of functional performance, contrast loss, and photic phenomena.”

Dr Pande explained that understanding functional outcomes with presbyopia-correcting IOLs is the basis for matching patients with a lens that will satisfy their expectations. To that end, he developed “panfocal VA” testing as a means to characterise performance profiles for different models. Panfocal VA includes four measures – photopic distance, intermediate and near, and mesopic near – all tested without correction and with distance correction, monocularly and binocularly.

Based on the results from panfocal VA testing and various questionnaires, Dr Pande offered guidance for surgeons on selecting their first TECNIS® Symfony IOL patients (Table 1).

He reported data from 113 eyes that had undergone panfocal VA testing four to eight weeks after implantation of the TECNIS® Symfony IOL showing that 100 per cent achieved monocular VA of 6/12 or better for all eight measures. Furthermore, assessments of unaided monocular performance for a variety of near and intermediate vision tasks showed the vast majority of patients could do work at their computer or laptop (≥90 per cent) and read a magazine or newspaper (≥88 per cent) under photopic conditions. Additionally, the majority (59-75 per cent) could read a telephone directory in bright light and a book or magazine in dim light.

With the idea that achieving 6/9 (20/30) or better VA in all four uncorrected panfocal VA measures would equate with complete spectacle freedom, Dr Pande implemented a “nanovision” approach for TECNIS® Symfony IOL implantation, and the results have achieved high to its success experience with the TECNIS® Symfony IOL. Mean scores for surgeon assessments of the implantation, achievement of target refraction, visual performance, and overall satisfaction ranged from 8.67 to 9.48.

“CONCERTO is real-world study of the TECNIS® Symfony IOL on a large scale, and it is reassuring and impressive to see that the outcomes were equal to or better than the excellent results of the HARMONY clinical study,” said Dr Auffarth.

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Patient selection guidance for the TECNIS® Symfony IOL

- Has cataract but otherwise healthy eyes
- Was previously hyperopic
- Wants to maximise spectacle independence without compromising quality of vision
- Deprioritises activities at 30-45cm vs those from 45cm to distance
- Accepts potential to need occasional reading spectacles
- Satisfaction is not dependent on being fully spectacle independent at 30-45cm

Table 1

Figure 1 and 2: Data on File DOF2015OTH0002 – Post-Market Clinical Follow-up Investigation of an Extended Range of Vision IOL. Abbott Medical Optics. Santa Ana, CA. March 16, 2015.

Adopting the Extended Range of Vision IOL into a premium practice

Milind Pande MD

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Helping Patients to See the Maximum: New Treatment Options in Presbyopia and Astigmatic Correction

Optimising satisfaction

Dr Pande suggested surgeons should understand patients’ needs when choosing the TECNIS® Symfony IOL and consider starting out by choosing presbyopic hyperopes who are generally easy to satisfy.

However, success with the TECNIS® Symfony IOL also depends on the surgeon’s ability to perform flawless surgery, of which accurate planning is a component. Dr Pande pointed out the need to pay attention to refractive targeting, precision with preoperative measurements, and performing outcomes analyses to personalise surgical constants.

“It is important to do a manual refraction and to use the maximum plus technique, starting with +1D instead of from the refraction in glasses in order to avoid getting depth of field from the elongated focal point of the TECNIS® Symfony IOL,” he said.

Finally, he pointed to the importance of modulating expectations.

“The TECNIS® Symfony IOL is amazing new technology. However, it is always best to deliver more than we promise, and the best way to achieve that is to promise less,” Dr Pande said.

A New IOL to Treat Astigmatism and Presbyopia

Oliver Findl MD

The TECNIS® Symfony Extended Range of Vision Toric Intraocular Lens (TECNIS® Symfony Toric IOL) (Figure 1) is a valuable new option for treating presbyopia and astigmatism in cataract surgery patients, said Oliver Findl MD, Austria.

His conclusion considered the advantages of both the TECNIS® Symfony IOL for addressing presbyopia and of a toric IOL for astigmatism correction along with early clinical results with the TECNIS® Symfony Toric IOL.

Goals and options for presbyopia correction

Dr Findl said that when it comes to presbyopia correction, good uncorrected intermediate VA that would allow spectacle-freedom for activities such as computer work, shopping, and hobbies is a more important priority than spectacle-free near vision for many cataract surgery patients today. Multifocal IOLs, however, may fall short in addressing that desire. Furthermore, they can be associated with bothersome visual symptoms (blur, halo, glare, starbursts), especially at night, and potentially relevant contrast sensitivity loss.

As support for his statements, Dr Findl cited a study of dissatisfied multifocal IOL patients that documented blurred vision in 95 per cent of the 76 implanted eyes and photic phenomena in 38 per cent.1 Mini-monovision with monofocal IOLs targeting emmetropia in one eye and -1.25D to -1.50D in the other is another approach to pseudophakic presbyopia correction. However, the idea of a difference in refraction between eyes is intimidating to some patients, and as reported in a recently completed randomised trial, mini-monovision reduces stereopsis.

Dr Findl said the TECNIS® Symfony IOL overcomes the limitations of the above alternatives for presbyopia correction. It is the first commercially available IOL providing a continuous range of functional vision from far to near, and it does so while maintaining good contrast at distance and with a low incidence of photic phenomena. Its unique clinical performance is the result of an innovative optic design that optimises the echelettes and integrates correction of chromatic and spherical aberration. (See Page 1)

“Results from an open-label study enrolling 150 patients at 14 European sites, showed the TECNIS® Symfony IOL provided a high degree of spectacle independence and patients reported little to no dysphotopsias. Use of a micro-monovision approach with refractive targets of emmetropia and -0.50D in fellow eyes improved uncorrected near vision without compromising visual performance at intermediate and far,” Dr Findl said.

“And, because the TECNIS® Symfony IOL provides functional vision over a broad defocus range, it seems to be more tolerant of deviations from target refraction than multifocal IOLs.”

Astigmatic correction options

The importance of treating astigmatism when using a presbyopia-correcting IOL is underscored by data on its prevalence and impact on vision. An investigation of more than 23,000 eyes found astigmatism ≥1D in about one-third of eyes (Figure 2).2 In other studies, 1D of astigmatism was identified as the cut-off for achieving good presbyopic correction with a multifocal IOL, and residual astigmatism was identified as a leading etiology for patient dissatisfaction with a multifocal IOL.1,2

“Limbal relaxing incisions can be used to correct astigmatism with multifocal IOL implantation, but results of a randomised controlled trial showed much better predictability in astigmatism reduction with implantation of a toric multifocal IOL,” Dr Findl said.

Optical Characteristics of TECNIS® Symfony Toric IOL

<table>
<thead>
<tr>
<th>SE Power</th>
<th>+5.0 D to +34.0 D in 0.5 diopter increments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model number</td>
<td>ZXT100</td>
</tr>
<tr>
<td>Cylinder Powers - IOL Plane</td>
<td>1.00 D</td>
</tr>
<tr>
<td>Cylinder Powers - Corneal Plane</td>
<td>0.69 D</td>
</tr>
</tbody>
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Figure 1: Patient reported outcomes with TECNIS® Symfony IOL nanovision
Helping Patients to See the Maximum: New Treatment Options in Presbyopia and Astigmatic Correction

Femtosecond laser-assisted cataract surgery (FLACS) is being adopted in the last few years. Recent articles discuss the potential advantages of using this emerging technology including opportunity for zero ultrasound surgery, improved capsulorhexis circularity, reduction of endothelial cell loss, and more accurate and predictable intraoperative correction of astigmatism.

Speaking about the particular benefits of the Catalys® Precision Laser System, Burkhard Dick MD, PhD, Germany, said that it also stands out from the competition based on its personal interface, imaging system and speed.

The Catalys® system features a non-applanating liquid optics personal interface that is available in two sizes (14.1mm and 12mm), causes minimal increase in intraocular pressure (10mmHg), and has a wide aperture that is optimised for corneal incisions.

The Catalys® proprietary high-resolution, 3-D SD OCT imaging technology provides live streaming, tilt compensation for all incisions, and the ability to customise the capsulotomy by scanning the capsule. Capsulotomy creation takes <1 second, which is faster than any other femtosecond laser, said Dr Dick.

He also reviewed results of a series of prospective, randomised, intraindividual comparison trials showing benefits of cataract surgery using the Catalys® system compared with standard phacoemulsification for minimising postoperative corneal oedema, endothelial cell loss, capsular bag shrinkage, and inflammation.1-4

Dr Dick's analyses also showed use of the Catalys® laser practically eliminated the need for ultrasound.5 He reported that in a consecutive series of 1,200 eyes, 91 per cent of cases were completed with zero ultrasound, and that percentage rose to 97 per cent in an analysis including only the last 100 cases that also benefited from optimisation in a variety of surgical techniques (Figure 1). Subgroup analyses showed that use of the laser for lens fragmentation significantly reduced effective phacoemulsification time in all grades of cataract (Figure 2).

References
Correction of Astigmatism with the Catalys®

The importance of having a tool for precisely treating astigmatism during cataract surgery is highlighted by recognition that three-fourths of patients have a visually significant level of pre-existing astigmatism, Dr Dick said.

“The Steep Meridian Registration Technology (SMRT) of the Catalys® laser increases the ease and precision of astigmatic correction and makes great technology even better,” he stated.

SMRT represents an integrated method for measuring and displaying the steep meridian of astigmatism to guide accurate placement of arcuate incisions, and, as a new capability of the laser, toric IOL alignment incisions (Figure 3).

“Catalys® system with SMRT eliminates ink markings and the need for another device to measure astigmatism, which is necessary with other laser systems. By fully integrating the diagnostic and treatment steps, the Catalys® laser makes astigmatic correction with arcuate incisions or toric IOLs more accurate and more efficient,” said Dr Dick.

He reported that in a feasibility trial, SMRT was able to determine the steep meridian in 97 per cent of eyes, showed good agreement with data from other measurement technologies, and received high comfort ratings from patients.

Dr Dick also noted that a study by William Culbertson MD established that anterior penetrating arcuate incisions made with the Catalys® laser were highly accurate in terms of minimal deviation from intended axis, length, and optical zone diameter.6

Now, in addition to penetrating arcuate incisions, the Catalys® laser can be used to make titratable or intrastromal incisions. The titratable incisions can be opened postoperatively at the slit-lamp by the surgeon if more correction is needed, whereas the intrastromal technique offers an option for correcting up to 1.5D of astigmatism with the benefits of a non-penetrating technique.

References

6. Culbertson W. Optimization of corneal incision parameters with a femtosecond laser for cataract surgery. XXX Congress of the ESCRS. Congress, Milan Italy.

High Definition Wavefront Guided Laser Correction of Astigmatism

Mohamed Shafik Shaheen MD

High definition wavefront guided (WFG) laser vision correction (LVC) performed with the Star S4 IR® laser and an ablation profile derived from the iDesign System (both Abbott Medical Optics) provides effective treatment of corneal astigmatism even in the most challenging cases, according to Mohamed Shafik Shaheen MD, Egypt.

“The results from our center and in the literature demonstrate that this high definition WFG LVC system is the state-of-the-art for cylinder correction,” he said.

Achieving accuracy in astigmatism correction

Dr Shafik explained that accurate preoperative measurement is essential for effective astigmatism correction. That is why WFG LVC is better than phoropter-driven procedures.

“Treatment of astigmatism is not all about manifest refraction (Figure 1). Patients treated with a conventional or wavefront-optimised LVC method might be left with higher-order aberrations (HOAs) that will cause them to be unhappy with their vision,” Dr Shafik said.

A good measurement, however, means nothing if the ablation is not well-centred, and so iris registration is mandatory as well.

The iDesign is a high-resolution Hartmann-Shack wavefront sensor that addresses both of these needs. By taking more sampling points than other Hartmann-Shack devices and implementing Fourier reconstruction algorithms using up to 1,257 micro-refractions over a 7mm wavefront, the iDesign maximises capture rates and provides a precise reconstruction map for optimal ablation planning, even in highly aberrated eyes.

It also features a high definition camera providing improved iris and iris boundary imaging relative to other technologies and thus high registration rates in the operating room.

Clinical results

Dr Shafik presented results from a masked study that showed the superiority of treating myopic astigmatism with the high definition WFG procedure compared with the latest generation of WFO LASIK performed with the Allegretto EX-500 excimer laser (Alcon Laboratories).1 In this parallel group trial including 300 eyes, registration was achieved in 100 per cent of WFG cases (iris/torsional registration), but in only 68.4 per cent of WFO eyes (torsional registration). At six months, outcomes were significantly better for the WFG group than the WFO group for mean cylinder (-0.132D vs -0.248D; P=0.0071), percentage of eyes with ≤0.25D cylinder (84 per cent vs 63.2 per cent; P<0.05), and percentage of eyes achieving “supervision” (decimal UCVA 1.2 or better, 22 per cent vs 7.2 per cent; P<0.05) (Figure 2a-2b).

Dr Shafik also reviewed findings from a study demonstrating the predictability of the high definition WFG LVC for astigmatism correction.2 Linear regression analysis of data from the 247 eyes included in the analyses showed a very tight correlation between the magnitude of the surgically induced refractive correction at one month postoperatively and the intended refractive correction (R2 = 0.9392).

In addition, Dr Shafik shared his experience with high definition WFG LVC to treat astigmatism in irregular corneas. In a published study, visual function was successfully restored in a series of 20 eyes.

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with a history of keratoconus treated by corneal crosslinking (CXL), radial keratotomy, or LASIK with a centred or irregular ablation. With past aberrometers we would not have been able to read highly irregular corneas, but the majority can now be captured using the iDesign," he said. Dr Shafik presented one case from the keratoconus subgroup – a 20-year-old woman who had severe ghosting and monocular diplopia (Figure 3), one year after stabilising her cornea by a successful CXL. She underwent WFG photorefractive keratectomy (PRK) with improvements in manifest refraction (-4.00 -3.00 x 152 to 0.00 -0.5 x 154), BCVA (0.4 to 0.9), and UCVA (0.3 to 0.8).

"The high definition WFG procedure spared this patient from keratoplasty," Dr Shafik said.

He now has accumulated a series of 34 sequential eyes with keratoconus that underwent WFG PRK after CXL. Analyses of preoperative and 12-month postoperative data showed reduction in astigmatism (-2.79D to -1.06D) and total SE (-3.22D to -0.68D). Residual cylinder was <0.5D in about half of eyes and <1.0D in more than two-thirds. No eyes lost any BCVA, whereas about 80 per cent gained one or more lines. Total RMS was significantly reduced as was RMS for coma, trefoil, and total HOAs.

"With high definition WFG LVC, we can for the first time get a reliable ablation profile to target emmetropia and meet the challenges of treating irregular astigmatism," Dr Shafik concluded.

References
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Contact information
Leonard Borrmann: leonard.borrmann@amo.abbott.com
Gerd Auffarth: gerd_auffarth@med.uni-heidelberg.de
Milind Pande: visionsurgery@gmail.com
Oliver Findl: oliver.findl@meduniwien.ac.at
Burkhard Dick: burkhard.dick@kk-bochum.de
Mohamed Shafik Shaheen: m.shafikshaheen@gmail.com

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