Introducing the Next Generation TECNIS™ Presbyopia-Correcting EDOF IOL

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At the 39th Asia-Pacific Academy of Ophthalmology (APAO) Congress held in conjunction with the 49th PERDAMI, or the Indonesian Ophthalmologists Association (IOA) Annual Meeting in Bali, Indonesia in February 2024, three highly regarded ophthalmologists came together to speak about the next generation presbyopia-correcting intraocular lens (PCIOL).

History and Evolution of Presbyopia-Correcting IOLs (PCIOLs)

Gerd Auffarth, MD, FEBO (Germany) offered a unique perspective on his experience with various PCIOLs. In terms of technology, Dr. Auffarth agrees that everything is there for the clinicians. "We just have to pick the right lens for the right patient," he said. "The question is, what lens do we choose? In Germany, we have so many lenses. There are too many choices, and it can get very confusing."

Thinking back to the EDOF concept, the TECNIS Symfony™ IOL was one of the first EDOF lenses that was engineered with the Echelette design. Although real world data was strong for the TECNIS Symfony™ IOL, patients were still experiencing dysphotopsia, and the lens was primarily targeted for intermediate vision. "In order to get to the point where you get extremely good spectacle-free near vision, you have to have a combination of TECNIS Symfony™ with a bifocal diffractive lens," Dr. Auffarth explained.

This resulted in the TECNIS Synergy™ IOL, which creates a very flat defocus curve over a wide range of diopters while delivering continuous high contrast.

"But we have to know that depth of field and dysphotopsia are directly related to one another," Dr. Auffarth continued, "and are dependent on the technology we are using in our optics." In a plano eye, the light rays are directly focused on the fovea. In a myopic eye, the focus is in front of the retina, and patients can experience a shine around the point source of light. Thus came the lens: the TECNIS Eyhance™ IOL, which aims for mid-range visual acuity while maintaining correction of primary spherical aberration.

Similar to Dr. Auffarth's experience, in a European Society Of Cataract & Refractive Surgeons (ESCRS) Clinical Trends Survey conducted in 2021, Tim Roberts, MBBS, MMed, FRANZCO, GAICD (Australia) saw that 66% of responding ophthalmologists were most interested in using an extended depth of focus (EDOF) intraocular lens (IOL) in their practice, more so than trifocal, shape-changing, or light-adjustable IOLs. However, the ophthalmologists' biggest concerns and unmet needs regarding PCIOLs were night-time quality of vision and loss of contrast visual acuity.

Dr. Roberts explained that the ideal EDOF IOL would provide a sharp focus over a wide range without unwanted dysphotopsia or any visual side effects. This wide range would give patients excellent distance and intermediate vision. "This ideal is theoretical," Dr. Roberts explained, "and it doesn't exist. You want predictable results. If you implant 100 lenses, and you get 10 or 15 patients that are thrilled, most are not happy, and you are not exactly sure which patient is going to get that result. This is a little bit of a disincentive for introducing a new lens."

J&J Introduces the Next-Generation Refractive EDOF IOL for Presbyopia Correction

Nevertheless, recent technical developments have resulted in a new generation IOL: the TECNIS PureSee™ IOL. The refractive



TECNIS PureSee™ IOL

design of the TECNIS PureSee[™] IOL is based on a continuous change in power. "What the research and development team has done is extend the wavelength so that there is progressive focusing from distance to intermediate to near vision," Dr. Roberts said. "There is not a zone for intermediate nor for distance vision. This is a smooth, continuous, and elongated posterior surface." The TECNIS PureSee[™] IOL's front optics compensate for the spherical aberrations of the cornea, while the posterior optics maintain a dysphotopsia profile comparable to a monofocal IOL and provide a uniform depth of field from distance to near.

Comparing the TECNIS PureSee[™] IOL to other EDOF IOLs, Dr. Auffarth explained that the quality of vision, the modulation transfer function (MTF), for TECNIS PureSee[™] stays stable over several millimeters of aperture, while other EDOF lenses show a greater loss in MTF as pupil diameter increases.

TECNIS PureSee™ IOL: What are the Clinical Merits? Clinical Outcomes with the Next-Generation Refractive EDOF IOL

In the proof-of-concept study that Dr. Roberts took part in, a total of 117 patients from six sites in Australia and one site in New Zealand were evaluated. This prospective, randomized, double-blinded study analyzed 60 patients receiving the TECNIS PureSeeTM IOL and 57 patients receiving the TECNIS EyhanceTM IOL, an enhanced monofocal IOL, at 6-month follow-up. Dr. Roberts stated that the results were excellent: distance vision for those implanted with the TECNIS PureSeeTM IOL was statistically non-inferior to those implanted with the monofocal IOL, and 100% of TECNIS PureSeeTM IOL eyes achieved 0.20 logMAR or better. The take home message is that the quality of distance vision with the TECNIS PureSeeTM IOL is as good as we are getting with a monofocal lens," Dr. Roberts reiterated.

Furthermore, when looking at monocular distance-corrected intermediate vision, 82% of TECNIS PureSee™ IOL eyes achieved 0.20 logMAR or better compared to only 60% of TECNIS Eyhance™ IOL eyes, a statistically significant result.¹ Additionally, the monocular range of vision at 0.2 logMAR was 0.7 D larger in patients implanted with the TECNIS PureSee™ compared to those implanted with the TECNIS Eyhance™ six months after surgery. "The TECNIS PureSee™ IOL is a very good lens if you're targeting emmetropia," Dr. Roberts explained. "Across a cohort of patients, if your mean absolute error is a little bit plus or a little bit minus, the uncorrected quality of vision with this lens is maintained, so we're getting a really good range across refractive errors."

For those who are concerned about moving from a monofocal to an EDOF lens, the results of the proof-of-concept study further showed that TECNIS PureSeeTM provides high distance image quality comparable to a monofocal as well as more tolerance to refractive errors. From validated patient-reported questionnaires,







Dr. Tim Roberts

Dr. Gerd Auffarth

Dr. Tae-im Kim

not many had a problem with halos, starbursts, and glares. The results showed that more than or equal to 98.3% of patients who experienced halos, starbursts, or glares "often" or "always" were not bothered or were slightly bothered by these visual symptoms. Statistically, there was no difference between the TECNIS Pure-SeeTM IOL and the TECNIS EyhanceTM IOL in terms of bothersome symptoms. 1,2

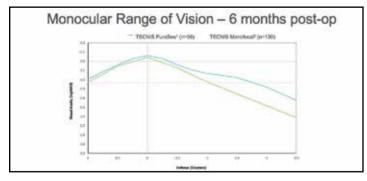
Furthermore, 88.3%, 96.7%, and 100.0% of patients reported that they never, rarely, or sometimes experienced halos, starbursts and glare, respectively.¹

"My early experience has been positive," Dr. Roberts remarked. "The common unsolicited feedback I hear from patients is that 'I can see well over a range of vision, and my distance vision is lovely and clear." Dr. Roberts also found that patients experienced minimal to no dysphotopsia. "Day to day, it's a pretty robust lens."

"I have had the pleasure to be among the first in Europe to use the TECNIS PureSee™ IOL," Dr. Auffarth remarked. "I was able to implant 18 lenses."³ From case videos, Dr. Auffarth shared various tips for a smooth surgical experience. "When I do this kind of premium IOL cataract surgery, I like to have a nice capsulotomy, and I may use a femtolaser," he said. "It is important to secure the lens in the capsular bag. I usually center the lens on the horizontal plane, but you can do it as you like. Keep the rhexis and lens centered with some small overlap. Then, you will have the best options for long-term outcomes. Removing the viscoelastic is also important." Finally, the hydrophobic acrylic material, Dr. Auffarth explained, tends to result in less posterior capsule opacification (PCO), especially for the first three to five years.

The TECNIS PureSee™ IOL implanted in 18 eyes³ by Dr. Auffarth himself resulted in a mean uncorrected distance visual acuity (4 m) of 0.02 logMAR and a mean uncorrected near visual acuity (40 cm) of 0.30 logMAR at 3 months after surgery; most of the patients with residual refractive error in one or both eyes did not need spectacles and were satisfied with their distance vision. "We are very happy with the first implantations," Dr. Auffarth said. "Vision quality is excellent, and patients are very happy. There will be a future with this type of IOL."

Tae-im Kim, MD, PhD (South Korea) shared similar experiences with that of Dr. Roberts and Dr. Auffarth. "The continuous range of vision is very important in order to meet patients' expectations," she said. For Dr. Kim, dysphotopsia is the major obstacle with multifocal IOLs. "Even though we try our best, we can't reach perfect vision. Some residual astigmatism and residual refractive



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TECNIS PureSee[™] can be a good lens for surgeons to move from monofocal to presbyopia-correcting lenses **— —**

errors always interfere with a patient's performance of vision," she said.

However, Dr. Kim's experience with TECNIS PureSeeTM "makes us feel better with minimized dysphotopsia and extended tolerance of residual refractive errors," she said. Although Dr. Kim remains careful with optimizing her IOL centration technique, the increased tolerance of the TECNIS PureSeeTM allows her to perform surgery with more ease, unlike other IOLs. "It makes me feel more comfortable with the surgery."

"Now, in my patients, I implant 30% TECNIS PureSee™ IOLs, 30% TECNIS Eyhance™ IOLs, and the remaining receive a monofocal IOL," Dr. Kim explained. Though she does not implant TECNIS PureSee™ in patients with retinal comorbidities such as maculopathy, "I try to persuade my patients that the TECNIS PureSee™ is a good option because you can minimize photic phenomenon and you can have EDOF for daily life." Dr. Gerd stated that he implants 50% TECNIS PureSee™ and 50% trifocal lenses. "Now that the refractive technology is catching up, we are getting to the point where trifocal is not as dominant," he said.

Potential Entry-Level PCIOL

Dr. Roberts believes the data is very strong for patients who are slightly hyperopic, and early results have shown strong consistency and predictability in the range of vision for patients. "This could be a good lens for surgeons to move from monofocal to presbyopia-correcting lenses," he said. For surgeons who are only using monofocals, Dr. Roberts suggests that if a surgeon introduces the TECNIS PureSee™ into his or her practice by carefully selecting patients with healthy eyes that are slightly hyperopic, "you will get very happy patients, very few negative comments in your waiting room, and a greater lifestyle outcome without introducing bothersome glares and halos."

As Dr. Auffarth also pointed out, the best patients suited for the TECNIS PureSee™ IOL include those who are hyperopic, emmetropic, and myopic with refractive tolerability, though reading spectacles for patients may be selectively required. Patients who participate in sports and outdoor activities, patients who perform computer and/or desktop work, and patients who drive cars may find good outcomes with the TECNIS PureSee™ IOL, especially with the very low risk for dysphotopsia.

"You will get predictable results; it's a good robust lens on a familiar IOL platform with routine biometry and calculations," Dr. Roberts added. "My early experience will be considering the TECNIS PureSee™ IOL as a first line lens for cataract patients who want lifestyle vision and don't want to compromise quality of vision."

References:

- 1. Corbett D et al. Quality of vision clinical outcomes for a new fully-refractive extended depth of focus Intraocular Lens. Eye (Lond). 2024; 38(Suppl 1):9-14.
- 2. Black DA et al. Tolerance to refractive error with a new extended depth of focus intraocular lens. Eye (Lond). 2024;38(Suppl 1):15-20.
- 3. Data on file at International Vision Correction Research Centre (IVCRC).