



TECNIS Symphony TORIC
Adopting the Extended
Range of Vision IOL Into a
Premium Practice

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California From OPTOS
Peripheral Lesions Detected
by Optomap

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Amico Yasna Pars

Ophthalmology Newsletter

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Dear Valued Partners;

Though there is no day of the year which one does not wish all happiness to ones friend, this is the day in which the heart goes forth in particular vows and wishes for the welfare of those we respect. It is the birth of a new year, whose entrance we would salute, and hope auspicious. Nor is this particular mark of time of little use, it teaches us to number our days, which a wise man thought an incitement to the well spending of them. And indeed, did we consider how much the pleasure and profit of our lives depend upon the economy of our time, we should not waste it, as we do, in idle reflection on the past , or in a vain,unuseful regard for future.

Thank you for giving us an opportunity to serve your community. You are our prestigious partners and We will do your work with top care and priority.

Happy and Prosperous New year.

Amico Yasna Pars

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Discussion

Adopting the Extended Range of Vision IOL into a premium practice

Milind Pande MD



The TECNIS® Symphony 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® Symphony 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 VA, and mesopic near VA – 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® Symphony IOL patients (Table 1).

Patient selection guidance for the TECNIS® Symphony IOL

Table 1

- 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

BILATERAL SYMPHONY: PATIENT REPORTED QUALITY OF SPECTACLE FREE VISION: % OF PATIENTS: N=38

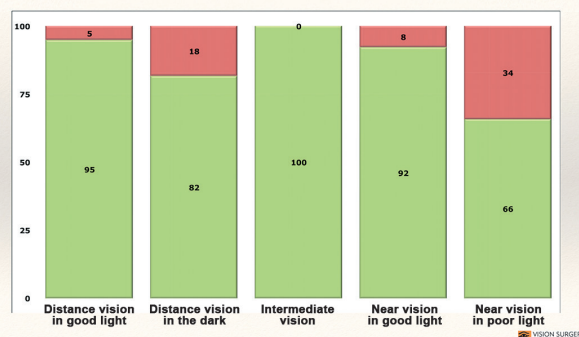


Figure 1: Patient reported outcomes with TECNIS® Symphony IOL nanovision

He reported data from 113 eyes that had undergone panfocal VA testing four to eight weeks after implantation of the TECNIS® Symphony 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® Symphony IOL implantation, and the results he has achieved speak to its success.

Nanovision, which he differentiated from full monovision, mini-monovision, and micro-monovision, targets an intereye refraction difference of <-0.75D.

Dr Pande explained: "Nanovision aims to achieve an extra line of near vision by using less than -0.75D myopia. That is well within the normal range of distribution of refractive error in the population, is not considered anisometropia, and I do not think it can be called monovision."

Dr Pande reported that of 48 patients operated on with a nanovision approach, 38 had panfocal VA results from testing at four weeks after surgery. Their results showed that in unaided testing, 6/9 or better VA was achieved by 100 per cent of patients at both distance and intermediate in photopic conditions, 95 per cent of patients at near in photopic conditions, and by 50 per cent at near in mesopic conditions. Rates of 6/9 or better VA for those four measures with distance correction were 100 per cent, 100 per cent, 68 per cent, and 26 per cent, respectively.

"The results from binocular task performance were incredible in this population, with almost 100 per cent of patients able to do all intermediate and near vision tasks under photopic conditions and all near tasks in dim light apart from reading a telephone directory," said Dr Pande.

A questionnaire asking patients about spectacle-free vision for distance, intermediate and near vision in good and poor light generated results that were consistent with the reports about performance of specific tasks (Figure 1).

Optimising satisfaction

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

However, success with the TECNIS® Symphony 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® Symphony IOL," he said.

Finally, he pointed to the importance of modulating expectations. "The TECNIS® Symphony 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.

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® Symphony Extended Range of Vision IOL (TECNIS® Symphony 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® Symphony 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 ($\geq -0.5D$ in one eye, $\pm 0.5D$ in the other); 2) bilateral emmetropia (bilateral $\pm 0.5D$); 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 ± 7.3 cm). 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 UCIVA better than 20/20 with a slight drop in UCDVA to ~20/20 -1.

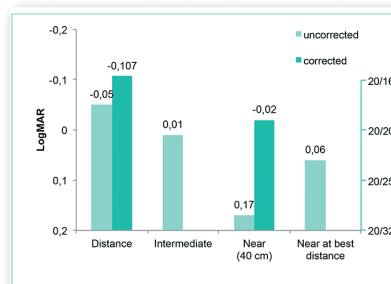
Overall, about 95 per cent of patients reported comfortable visual function without glasses for far and intermediate vision tasks and about 75 per cent said they were comfortable without glasses for near vision. Good to complete satisfaction without glasses was reported by 94 per cent of patients for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

Decimal mean UCDVA, UCIVA, and UCNVA values were 0.95, 0.81, and 0.68 for the entire population. As in HARMONY, the micro-monovision group had almost the same distance UCVA (0.94), but better uncorrected VA at intermediate and near (0.86 and 0.74).

Data on spectacle use also showed even greater independence than was reported in HARMONY. Whether looking at all patients or the micro-monovision group, about 90 per cent of patients reported never or only occasionally using glasses for distance or intermediate vision, while 74.5 per cent of the entire population and 80.8 per cent of the micro-monovision group never or only occasionally wore glasses for near.

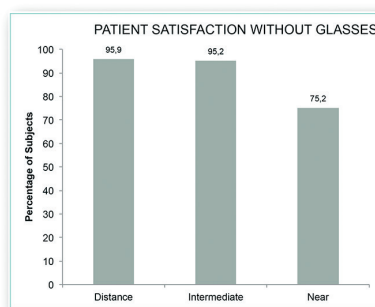
Responses to questions about photic phenomenon (halos, glare, starburst, and other) were generally similar for the overall population and micro-monovision groups. No or only mild halos, glare, starburst, or other photic phenomenon were reported for ≥ 90 per cent of eyes overall. Scores for patient satisfaction with visual performance at distance, intermediate, and near were consistently high; means ranged from 7.85 to 8.84 (scale: 0 = not at all satisfied, 10 = very satisfied), with the micro-monovision group having higher

Figure 1 20/20 BINOCULAR UCDVA & UCIVA AND 20/32+ UNCORRECTED NEAR VA



Mean distance for best (comfortable) near vision:
 47.6 ± 7.3 cm

Figure 2 SPECTACLE INDEPENDENCE



Good to completely satisfaction without glasses:
94% overall vision
97% during daytime
84% 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.

mean scores for intermediate and near vision and a slightly lower score for distance vision compared with the overall population.

Overall, 91-94 per cent of patients in the overall population and micro-monovision group said they would recommend the procedure to friends and family and would choose the same lens again.

Surgeons also highly rated their experience with the TECNIS® Symphony 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® Symphony 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.

Reference

Figures 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.

Rotational Stability of a Single-Piece Toric Acrylic Intraocular Lens: A Pilot Study

NINO HIRNSCHALL, SOPHIE MAEDEL, MARIA WEBER, AND OLIVER FINDL

- **PURPOSE:** To evaluate the visual performance and rotational stability of the Tecnis Toric 1-piece intraocular lens (IOL) during the first 3 postoperative months.
- **DESIGN:** Prospective, single-center study.
- **METHODS:** In this study, patients with age-related cataract and corneal astigmatism of 1.0 to 3.0 diopters measured with the IOLMaster 500 (Carl Zeiss Meditec AG) were included. Before surgery, rotating Scheimpflug scans (Pentacam HR; Oculus) were performed and the cornea was marked in the sitting position at the slit lamp. Patients received a single-piece toric hydrophobic acrylic IOL (Tecnis Toric; AMO). Immediately and 3 months after surgery, retroillumination photographs were obtained to assess the rotational stability of the IOL. Additionally, Autorefracton (Topcon), subjective refraction, uncorrected and distance-corrected visual acuity, keratometry, and Scheimpflug and ocular wavefront (WASCA, Carl Zeiss Meditec AG) measurements were performed at the 3-month follow-up.
- **RESULTS:** Thirty eyes of 30 patients were included in this study. Mean absolute difference between the IOL axis at the 3-month and 1-hour follow-up was 2.7 degrees (standard deviation, 3.0 degrees). The IOL rotation was less than 3 degrees and less than 6 degrees in 62% and 95% of all cases, respectively.
- **CONCLUSIONS:** The Tecnis Toric 1-piece IOL is rotationally stable and shows excellent capsule bag performance and refractive outcomes. (Am J Ophthalmol 2014;157:405–411. © 2014 by Elsevier Inc. All rights reserved.)

MANY OF THE FIRST DESIGNS OF TORIC INTRAOCULAR lenses (IOLs) in the early 1990s showed an IOL rotation of more than 30 degrees in one fifth of the patients.¹ By contrast, modern toric IOLs typically show a mean absolute rotation of 3 to 5 degrees,^{2–4} which would result in a loss of approximately 10% to 15% of the astigmatism-reducing effect of the toric IOL.

The rotational stability of a toric IOL is determined by the interaction between the toric IOL and the capsule bag. The misalignment of the toric IOL, however, depends on several other factors in addition to rotational stability. In the current study, misalignment is defined as the difference between the intended axis of the toric IOL and the actual axis, measured 3 months after surgery.

During surgery, misalignment can occur because of cyclotorsion of the eye (resulting from the supine position of the patient or from peribulbar anaesthesia), imprecision of the surgeon when positioning the IOL relative to the intended meridian, or both. Both of these factors can be controlled more precisely by marking the eye before surgery with the patient in the sitting position and by diligence on the part of the surgeon.

After surgery, the IOL may rotate because it is either undersized for the capsule bag or because of capsule shrinkage during fibrotic contraction of the capsule bag during the postoperative period. Most current IOLs are slightly oversized for the capsule bag; therefore, the former is observed rarely and would be more likely in long eyes, which tend to have a larger capsule bag diameter.^{5,6} However, capsule bag shrinkage is thought to induce rotation in IOLs with open-loop haptics because of the asymmetry of the haptic design. Typical IOL haptic designs that improve rotational stability are either plate haptic IOLs or special Z-haptic-shaped open-loop haptics that are designed to counteract the rotational effect of compression of the shrinking bag.^{7,8} Disadvantages are associated with both of these IOL designs, however. Plate haptic IOLs have an increased risk of posterior capsule opacification because of a less effective lens epithelial barrier effect of the optic edge. Additionally, this design may show more rotation immediately after surgery because of a shorter haptic length. The Z-haptic IOL, however, is cumbersome to implant and is prone to damage during implantation. With the limitations of current IOL haptic designs in mind, the aim of the present study was to evaluate the rotational stability of a novel single-piece hydrophobic acrylic toric IOL with an open-loop haptic design.

Accepted for publication Sep 30, 2013.

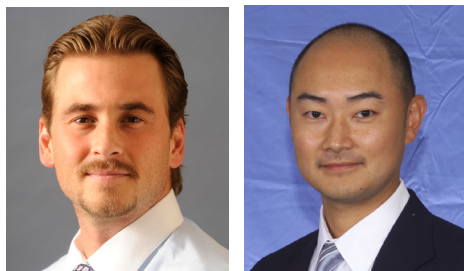
From the Vienna Institute for Research in Ocular Surgery, Karl Landsteiner Institute, Hanusch Hospital, Vienna, Austria (N.H., S.M., M.W., O.F.); and the Moorfields Eye Hospital NHS Foundation Trust, London, United Kingdom (O.F.).

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METHODS

THE TRIAL WAS APPROVED BY THE ETHICS COMMITTEE OF the City of Vienna and adhered to the tenets of the Declaration of Helsinki. All patients signed an informed consent

Intraoperative and postoperative steps to success with toric IOLs



Attention to detail is crucial in reducing spectacle dependence

When patients invest in premium technology, such as toric intraocular lenses (IOLs), they expect premium outcomes, said **Jeremy Z. Kieval, MD**, director of cornea, cataract, and refractive surgery, Lexington Eye Associates, Lexington, Mass., during a presentation at the 2015 ASCRS•ASOA Symposium & Congress in April.

To meet these expectations, surgeons must optimize each surgical step and be prepared to provide enhancements if necessary.

Intraoperative strategies

Stability of toric IOLs is critical (Figure 1). For each degree of IOL rotation, the patient loses approximately 3.3% of the power of the cylinder, said **Francis S. Mah, MD**, director of cornea and external disease, and co-director of refractive surgery, Scripps Clinic, La Jolla, Calif., during the ASCRS program.

Surgeons can choose from low- and high-tech marking methods to guide IOL alignment; the key is that surgeons should mark and help alignment from the beginning. With manual marking techniques, precision and accuracy are key. Surgeons should make preoperative reference marks on the cornea while the patient is sitting up looking off into the distance to avoid excyclorotation, which invariably occurs when patients lie down, Dr. Mah said. When the patient is supine, the axis of toric IOL placement and the incision should be marked using the preoperative reference marks. If possible, to reduce some of the cylinder, he said, it helps to operate on the steep meridian.

In addition, an array of total cataract refractive suites allow clinicians to capture information in a clinical area and transfer it to the intraoperative area, reducing the risk of error and helping to refine technique and improve outcomes. Although these technological advances are available, they are not essential to get started in the toric IOL arena, Dr. Mah

Degree of rotation	Percentage cylinder power loss
1°	3%
5°	17%
10°	35%
15°	52%
30°	100%

90° doubles astigmatism

Figure 1. The importance of stability of toric IOLs and effect of rotation on vision

Source: Francis S. Mah, MD

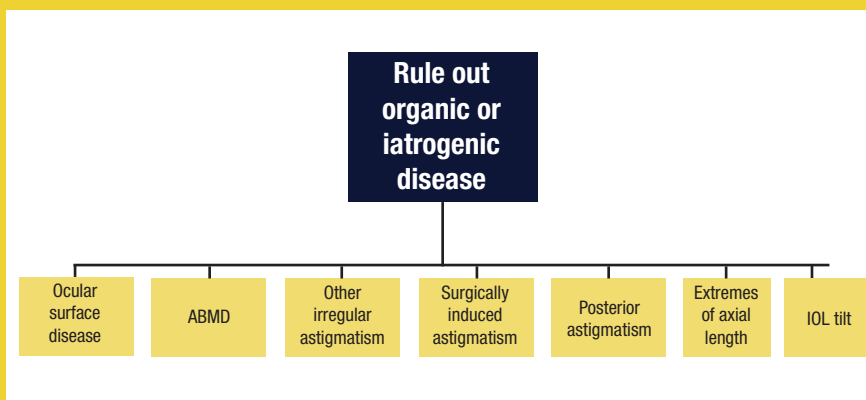


Figure 2. Ruling out organic or iatrogenic disease

Source: Jeremy Z. Kieval, MD

said. It is only when the surgeon wants to try to improve the outcomes and fully invest in the technology that the new equipment is useful, he said.

Dr. Mah highlighted 6 steps to minimize postoperative rotation. First, the surgeon ensures that accurate alignment marks are placed on the limbus before surgery and used to finalize the IOL position.

Second, good wound construction and correct capsulotomy size are necessary. Third, Dr. Mah uses a cohesive OVD in the IOL injection cartridge and to inflate the capsular bag. "You want to make sure that the implant lens is completely unfolded," he said. He rotates the lens to be sure the haptics are fully deployed into the capsular apex and aligns the IOL marks with the preoperative marks.

Subsequently, he removes all OVD from the eye. After OVD removal, he taps down on the center of the implant or applies gentle pressure so that the optic is in contact with the posterior capsule.

Next, the wounds must be adequately hydrated and watertight, and the eye must not be overinflated. "Then you want to make sure that you check the wounds at the end of the surgery," he said.

Postoperative astigmatism

Because patients do not expect to wear glasses full time after toric IOL implantation, enhancements are a strong consideration for residual astigmatism after surgery, Dr. Kieval said.

optomap

PERIPHERAL LESIONS DETECTED BY OPTOMAP ASSOCIATED WITH NEARLY 5 FOLD RISK OF PROGRESSION IN DISEASE

The presence of predominantly peripheral lesions were associated with an almost 5 fold risk in the progression of diabetic retinopathy (DR) over 4 years.

A study published in Ophthalmology finds 40% of diabetic lesions located outside the area of ETDRS Gold Standard area. These lesions might result in a more severe grade of retinopathy in 10% of eyes.

The results of several clinical studies comparing **optomap**[®] ultra-widefield images have indicated that there is substantial agreement with Early Treatment Diabetic Retinopathy Study (ETDRS) 7-standard (ETDRS) film photographs and dilated fundus examination in determining diabetic retinopathy severity^{1,2}. The peripheral lesions identified using ultra-widefield images in this cohort suggested a more severe assessment of diabetic retinopathy in 10% of eyes than was suggested by the lesions within the ETDRS fields. The presence of predominantly peripheral lesions were associated with the progression of diabetic retinopathy (DR) over 4 years, independent of baseline severity and A1C.³

“The presence of DR lesions located predominantly in this peripheral area seemed to identify a subset of eyes at greatly increased risk of DR progression and onset of PDR...the rigorous evaluation of the peripheral retina may become an essential and routine component of accurately characterizing DR severity, and thus may prompt a revision of the ETDRS grading algorithms to best optimize the association of DR severity grade and clinical outcome.¹”

Ophthalmology, 2013.

See how **optomap** will help you manage your diabetic patients.

¹ Nonmydriatic Ultrawide Field Retinal Imaging Compared with Dilated Standard 7-Field 35mm Photography and Retinal Specialist Examination for Evaluation of Diabetic Retinopathy. American Journal of Ophthalmology. 2012

² Peripheral Lesions Identified by Mydriatic Ultrawide Field Imaging: Distribution and Potential Impact on Diabetic Retinopathy Severity. Ophthalmology. 2013

³ Peripheral Lesions Identified on Ultrawide Field Imaging Predict Increased Risk of Diabetic Retinopathy Progression over 4 Years. Ophthalmology 2015.

Building **The** Retina Company



CLINICAL SUMMARY

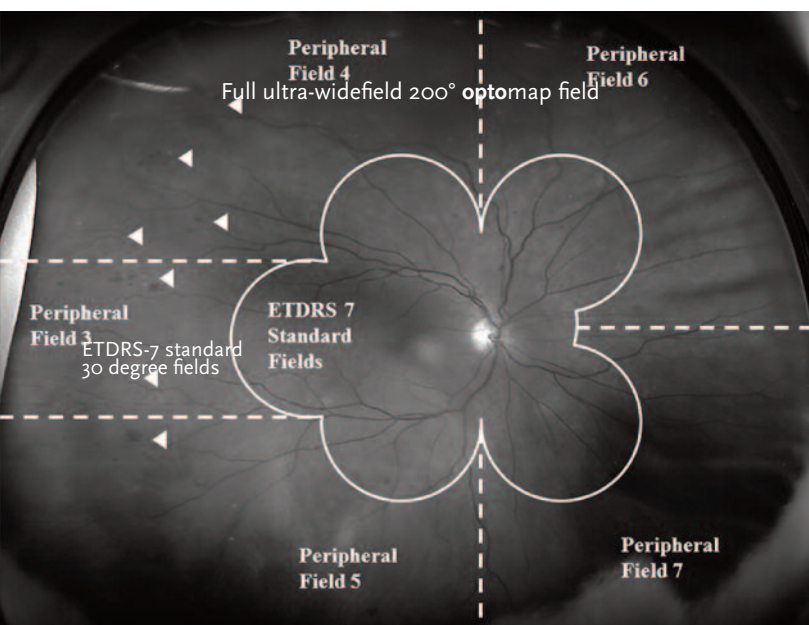
Peripheral Lesions Identified on Ultrawide Field Imaging Predict Increased Risk of Diabetic Retinopathy Progression over 4 Years.

Silva, Cavallerano, Haddad, Kwak, Dyer, Omar, Shikari, Aiello, Sun, Aiello
Ophthalmology - 2015

The results of a clinical study validates **optomap** images had substantial agreement with the gold standard Early Treatment Diabetic Retinopathy Study (ETDRS) film for the diagnosis and severity grading of diabetic retinopathy.

In addition, the study identified that 40% of the lesions were in the area outside of ETDRS and that in 10% of patients these lesions suggested a more severe grade of retinopathy.

The presence of predominantly peripheral lesions were associated with the progression of diabetic retinopathy (DR) over 4 years, independent of baseline severity and A1C.



Comparison field of view between **optomap** and the area covered by a standard ETDRS montage.

- Eyes with predominantly peripheral lesions (defined as outside of ETDRS 7 standard field) had a 4.7 fold increased risk of progression to proliferative diabetic retinopathy (PDR).
- Eyes with predominantly peripheral lesions had a 3.2 fold risk of 2 step progression in DR.
- There are ongoing longitudinal studies in this cohort to determine the clinical significance of these peripheral lesions.
- This paper suggests "Given that evaluation of these peripheral lesions may substantially alter risks of DR progression and onset of PDR, revision of the current ETDRS standard grading system may become necessary."
- The patented ultra-widefield scanning laser technology from optos provides a photograph of the fundus that supports the detection, diagnosis, analysis, documentation and management of ocular pathology and systemic disease, especially those that first present in the periphery.

Events

First OPTOS California was installed in Iran

Amico Yasna Pars has the honor of presenting the latest technologies in different fields of ophthalmology. Our last achievement in this category is to offer our great vitreoretinal specialists with ultra wide field retinal imaging and offering them OPTOS California. Last month we successfully installed first OPTOS California in Farvardin Eye Clinic located in Shiraz.

We also held a scientific seminar with participation of company representative, Mr. Ahmad Sarhan in Khalili hospital. During this event technological and technical aspects of using this device were introduced.



Upcomming Events

11-14 April 2017

1st Spring Ophthalmology Meeting

Thran, Iran

19-21 April 2017

10th Annual Meeting of Vitreoretinal

Yazd, Iran

26-28 April 2017

23rd Annual Seminar of Farabi

Tehran, Iran

10-12 May 2017

25th Annual Ophthalmology Seminar of Shiraz Medical Science University

Shiraz, Iran