

PanOptix[™] Enlightening Conversation

Highlights from the Prague 2016 Alcon Multifocal IOL User Meeting

Alcon Consultancy Panel:

Thomas Kohnen, Frankfurt, Germany José Alfonso, Oviedo, Spain Francesco Carones, Milan, Italy Ruth Lapid-Gortzak, Amsterdam, The Netherlands Joaquim Murta, Coimbra, Portugal Kjell Gunnar Gundersen, Haugesund, Norway Bilgehan Sezgin Asena, Izmir, Turkey Martin Kacerovský, Prague, Czech Republic Mike Holzer, Heidelberg, Germany Ozana Moraru, Bucharest, Romania Dominique Monnet, Paris, France Mayank Nanavaty, Brighton, UK Islam Hamdi, Jeddah, Saudi Arabia Ahmed Sedky, Cairo, Egypt

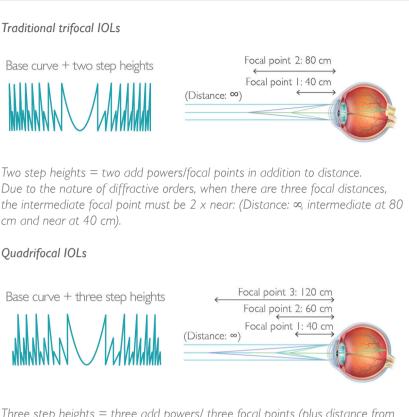
This supplement reflects the opinions and experiences of meeting participants in Prague on June 24, 2016. Data presented are representative of each participating surgeons' own experience, and do not arise from formal clinical studies. Trademarks are the property of their respective owners.

Today, patients are increasingly undergoing cataract surgery earlier in life, and the procedure has become an extremely rapid and refined process: small incisions, quick recoveries, and typically, great visual outcomes. For well over a decade now, surgeons have been able to offer presbyopia-correcting intraocular lenses (IOLs), and with them, the option of spectacle independence for presbyopes. Until fairly recently, multifocality meant bifocality: light energy is primarily directed to near and far focal points.

Multifocality, by its nature, is an optical compromise – and the trade-off of two or more focal points on the retina is associated with some level of photic phenomena, such as halo and glare (I). Most bifocal IOLs typically deliver excellent near and distance vision – but at the expense of intermediate vision. So the challenge when designing a better multifocal IOL is to provide continuous visual acuity over near, intermediate and distance, with minimal photic phenomena, with the greatest amount of light reaching the retina for optimal contrast sensitivity.

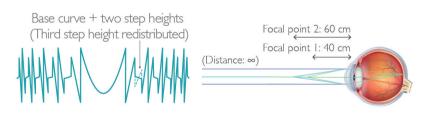
In July of 2015, Thomas Kohnen, MD, PhD, professor and chair of the Department of Ophthalmology, Goethe University in Frankfurt, Germany, implanted the first Alcon AcrySof® IO PanOptix[™] IOL worldwide into a patient (2). PanOptix[™] is Alcon's latest multifocal IOL, a trifocal lens that features an innovative optical technology designed to help patients adjust more naturally to their new vision. It does this in part by providing a comfortable range of near to intermediate vision (40-80 cm) with a crisp focal point at 60 cm, and by optimizing light transmission to the retina (3-7).

Since its launch, PanOptix[™] has been adopted by some leading surgeons, some of whom assembled in Prague on Friday, June 24, 2016. They shared their



Three step heights = three add powers/ three focal points (plus distance from base curve). Due to the diffractive principle, when there are four focal distances, the first intermediate focal point must be $1.5 \times$ near, and the second intermediate focal point must be $3 \times$ near (Distance: ∞ , extended intermediate at 120 cm, preferred intermediate at 60 cm, and near at 40 cm).

ENLIGHTEN[™] Optical Technology



The quadrifocal design is manipulated so that the extended intermediate focal point (120 cm) is redistributed to the distance focal point for amplified performance. This results in two step heights = two add powers/two focal points (plus distance from base curve). Light is still split three ways (Distance: ∞ , preferred intermediate at 60 cm, and near at 40 cm).

Box I: The technology that underpins PanOptix[™] (3, 8, 9)



experience with the lens, their outcomes, and their thoughts on patient selection.

How does PanOptix[™] work?

Prof. Kohnen explained that it's perhaps easiest to view PanOptix[™] as a guadrifocal IOL manipulated to act as a trifocal one. "In essence, the guadrifocal design is modified so that the extended intermediate focal point (120 cm) is redistributed to the distance focal point for amplified performance," explained Prof. Kohnen. Alcon calls this innovative diffractive lens design ENLIGHTEN™ (ENhanced LIGHT ENergy), and it results in the creation of three foci; distance, an intermediate at 60 cm, and near at 40 cm (See Box I, "The Technology That Underpins PanOptix™''). At a 3 mm pupil diameter, PanOptix[™] transmits 88% of light to the retina, which is higher than other traditional trifocal multifocal IOLs, like FineVision (PhysIOL) and the AT LISA tri 839 (Zeiss) (3, 6, 10, 11).

Ruth Lapid-Gortzak, MD, PhD of the Academic Medical Center in Amsterdam and Retina Total Eye Care Clinic, Driebergen, The Netherlands, provided some practical examples of the importance of the 60 cm distance in daily life: cooking, taking food from the fridge, and using a computer. PanOptix[™], uniquely, provides a 60 cm intermediate focal point (6,7). It's also less dependent on pupil size than its predecessor multifocal IOL design, the AcrySof® IQ ReSTOR[®], due to the fixed light allocation within the its 4.5 mm diffractive diameter. compared with the 3.4 mm and 3.6 mm diffractive zones present in ReSTOR® +2.5 and +3.0, respectively (3, 12, 13).

How well does PanOptix[™] work?

José Alfonso, MD, PhD, of the Corneal and Lens Surgery Department at the Instituto Oftalmológico Fernández-Vega, University of Oviedo, Spain, has implanted PanOptix[™] since July 2015, and he presented his own six-month

	Preoperative	Postoperative
UDVA	0.37±0.24 (0.05–1.0)	0.73±0.24 (0.2–1.0)
Sphere	0.51±2.24 (-6.50–6.00)	-0.09±0.36 (-1.00–1.00)
Refractive cylinder	-0.48±0.46 (-1.50–0.00)	-0.28±0.33 (-1.00–0.00)
Keratometric cylinder	0.55±0.40 (0.00–1.50)	0.39±0.35 (0.00–1.50)
CDVA	0.79±0.26 (0.1–1.0)	0.89±0.20 (0.2–1.0)

Table I. Patients' (n=90) refractive and decimal visual acuity results preoperatively and six months after PanOptix[™] IOL implantation. CDVA, distance-corrected visual acuity; UDVA, uncorrected distance visual acuity. Data courtesy of Dr. Alfonso.

follow-up results of the efficacy, safety and predictability of the lens in 90 eyes (45 patients, aged 65.18±8.45 years) after successful IOL implantation. PanOptix[™] was not implanted in patients with cornea, retina or optic nerve pathology, or in eyes with previous ocular surgery.

He operated on both eyes during the same week, and all were femtosecond laser-assisted procedures, performed with an Alcon LenSx[®] laser system to, in all cases, make a 4.8 mm-diameter capsulotomy (ideal for the 4.5 mm optic zone of the lens). The visual acuity and refraction results were satisfactory (Table I) – great improvements were seen in postoperative uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), sphere and cylinder correction, compared with preoperative values, where 89% of the eyes were within ± 0.50 D of the attempted spherical correction; all eyes were within ± 1.0 D using SRK-T and Holladay II formulas and A-constant of 119.1. The efficacy (postoperative UDVA/preoperative CDVA) and safety (postoperative CDVA/preoperative CDVA) indices were 0.92 and 1.13, respectively, which are great results taking into account the high preoperative

CDVA of the patients. Dr. Alfonso emphasized that, "all patients with cataract in this cohort experienced improvements in vision, and only two hyperopic eyes lost one line of vision – although this was likely attributable to the lower image magnification that is typical of all diffractive implants."

Dr. Lapid-Gortzak reinforced the theme of PanOptix[™]'s association with refractive stability and accuracy. She presented the results of her first 50 bilateral implantations (25 patients aged 54.8±8.1 years). In terms of refractive accuracy, she found that 79.4% of eyes were within ±0.25 D of target, and 100% were within ± 0.5 D. PanOptix[™] improved UDVA, CDVA and uncorrected near and intermediate visual acuity (UNVA, UIVA) following surgery, and these gains were stable over the three-month follow-up period. Figure I represents the photopic binocular defocus curve three months postoperatively, showing a continuous range of vision (visual acuity above 0.1 LogMAR) from 0 D to -3.0 D defocus, which corresponds to distance to 33 cm.

Dr. Lapid-Gortzak asked her patients if they were satisfied with PanOptix™; 88.2% of the patients were very satisfied.



Figure 1. Binocular defocus curve evaluation of PanOptix[™] IOL after 3-month follow-up. Green line indicates visual acuity of 0.1 LogMAR (0.8 decimal scale). Data courtesy of Dr. Lapid-Gortzak.

One claimed incomplete satisfaction – despite having visual acuity above 20/20, he reported some shadows. Another patient was dissatisfied because of some residual refraction. "What I found interesting was the incidence of halos. Not a single patient of mine spontaneously reported them." When asked, 70.6% said they saw none, 11.8% said they saw them once in a while, and only 17.6% reported that halos were present.

Similarly, Bilgehan Sezgin Asena, MD, Head Physician, Ophthalmologist at Kaskaloglu Eye Hospital, Izmir, Turkey, presented results that showed that, out of 24 patients that were bilaterally implanted with PanOptix[™], after onemonth follow-up, 18 reported that they had never experienced glare or halos in their daily lives, whereas only 6 patients experienced them "sometimes".

Overall, Drs. Alfonso and Lapid-Gortzak experienced predictable outcomes, very good refractive and visual results, and excellent defocus curve results consistent with a continuous range of vision, with PanOptix[™]. Dr. Alfonso, in particular, highlighted the opportunity PanOptix™ offers to reinforce the concept of increased spectacle independence after cataract surgery to patients, and Dr. Lapid-Gortzak took the opportunity to reflect upon the lower glare and halo perception of her patients, relative to that experienced by patients implanted with other trifocal IOLs. Mayank Nanavaty, MD, a consultant ophthalmic surgeon at Brighton and Sussex University Hospitals, United Kingdom, reinforced the point, noting that his PanOptix[™]-receiving patients also experienced low rates of dysphotopsia.

Selecting more patients

The consensus amongst the surgeons was that PanOptix[™] is suitable for a significant proportion of patients who desire spectacle independence. Dr. Sezgin Asena noted that with PanOptix[™], "Brain time for patient selection in my practice has significantly decreased."

The Happy Patient Study included 183 patients implanted with a variety of nontoric multifocal IOLs (14), and although

its primary focus was to establish the personality characteristics that might influence patient satisfaction following multifocal IOL implantation, it did find that four key factors were correlated with overall satisfaction of the procedure (irrespective of personality type). These were: low astigmatism, good visual function, low spectacle dependence, and fewer halos/ less glare. Dr. Sezgin Asena reported that PanOptix[™]'s attributes may play a key role in assuring patient satisfaction, and noted that one could leverage this to expand the patient pool suitable for this form of presbyopia correction. According to Dr. Sezgin Asena, "Multifocal IOL candidates could take too much chair time and sometimes I have seen unhappy patients. Multifocal IOLs significantly reduce contrast sensitivity, because of splitting light, and patients may still need glasses for intermediate tasks, such as computer work or seeing prices on supermarket shelves. PanOptix[™] could address most of these concerns."

"In essence, the quadrifocal design is modified so that the extended intermediate focal point is redistributed to the distance focal point for amplified performance."



Compared with other presbyopiacorrecting IOLs...

There are a number of presbyopiacorrecting IOLs available on the market today, each with unique optical properties. In the absence of published comparative, controlled clinical trials, it's hard to understand how these IOLs perform against each other. Fortunately, the surgeons perform many hundreds of cataract procedures per month, and have clinical experience with the most implanted presbyopia-correcting IOLs: PanOptix[™], AT LISA tri, FineVision Tri and Tecnis Symfony.

PanOptix[™] and AT LISA tri

Martin Kacerovský, MD, Head Surgeon at the Somich Eye Clinic in Prague, Czech Republic, compared the six-month visual acuity, photic outcomes and posterior capsule opacification (PCO) rates in patients who received bilateral PanOptix™ implants (n=100; 200 eyes) and AT LISA tri implants (n=100; 200 eyes). All patients underwent femtosecond laser-assisted surgery with an Alcon LenSx[®] system – and baseline demographic and refractive error was similar in both groups.

Uncorrected visual acuity at distance, near (40 cm) and at two intermediate distances (60 and 80 cm) were assessed. It was similar for both trifocal IOLs at distance, near and at 80 cm (intermediate), but PanOptix[™] was significantly better (p=0.039) than AT LISA tri at 60 cm intermediate distance (Figure 2). He noted that, "Halo and glare rates were similar for both trifocal IOLs: ~70% of patients who received either lens experienced these phenomena rarely or never."

After six months, only one eye (0.5%) that received a PanOptix[™] IOL required Nd:YAG capsulotomy for PCO, whereas statistically significantly more eyes (n=12, 6%, p=0.021) that received AT LISA tri required this procedure (Figure 3). Dr.

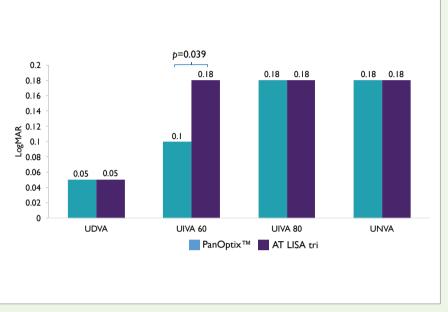


Figure 2. Uncorrected distance, intermediate (60 and 80 cm) and near LogMAR visual acuity. Statistically significant difference, p<0.05. UDVA: uncorrected distance visual acuity; UIVA: uncorrected intermediate visual acuity; UNVA: uncorrected near visual acuity. Data courtesy of Dr. Kacerovský.

Kacerovský reported that the mean value of incidence of PCO in the AT LISA tri group was 70%, with PCO occurring between 3–48 months after implantation and considering YAG laser procedure performed at 6-months post-op.

He concluded that both IOLs performed in a similar way (visual acuity, halos, glare and patient satisfaction), but patients receiving PanOptix[™] showed superior visual acuity at 60 cm and required fewer Nd:YAG procedures than those who received AT LISA tri.

PanOptix[™] and FineVision

Kjell Gunnar Gundersen, MD, Haugesund Medical Center, Norway, presented his own experience with PanOptix[™] (32 patients) and FineVision (36 patients) trifocal IOLs after one year. Table 2 shows binocular decimal uncorrected visual acuity at distance, intermediate (60 cm for PanOptix[™] and 80 cm for FineVision) and near (40 cm) for both evaluated IOLs.

He highlighted excellent refractive

accuracy with PanOptix[™], showing not just a plano manifest spherical equivalent from one week to three months postoperatively, but also very high patient satisfaction rates. In comparison with FineVision, Dr. Gundersen reported better near performance for PanOptix[™] too, on top of being built in a well-known AcrySof [®] platform.

Further, Dr. Alfonso also presented three-month follow-up defocus curves that showed a more continuous range of vision is achieved with PanOptix[™] than with other trifocal IOLs (Figure 4).

PanOptix[™] and Symfony

Mike Holzer, MD, PhD, a professor at the University Eye Clinic, Heidelberg, Germany, presented results on 16 PanOptix[™]-implanted eyes (8 patients) with a follow-up of up to 3 months. All his procedures involved clear corneal incisions, femtosecond laserassisted surgery with LenSx[®] and 5.0 mm capsulotomies. He also presented his early experience with the

	UDVA (± SD)	UIVA (± SD)	UNVA (± SD)
PanOptix™ IOL	1.15 ± 0.16	1.09 ± 0.14 (at 60 cm)	1.07 ± 0.14
FineVision IOL	1.10 ± 0.10	0.99 ± 0.03 (at 80 cm)	1.01 ± 0.06

Table 2. Decimal visual acuity outcomes six months follow-up after PanOptix[™] and FineVision trifocal IOLs. UDVA: uncorrected distance visual acuity; UIVA: uncorrected intermediate visual acuity; UNVA: uncorrected near visual acuity. Data courtesy of Dr. Gundersen.

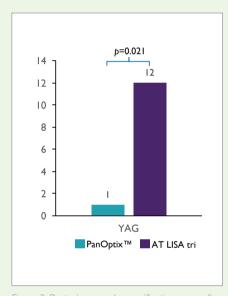


Figure 3. Posterior capsule opacification cases after six months that required Nd:YAG capsulotomy. Statistically significant difference, p<0.05. Data courtesy of Dr. Kacerovský.

Symfony IOL at three-month follow-up in 13 patients bilaterally implanted with the micro-monovision approach.

Binocular uncorrected visual acuity results for PanOptix[™] were very satisfactory achieving values of 20/20 or better for distance, intermediate at 60 cm and near at 40 cm. The Symfony IOL showed similar visual performance for distance and intermediate, but inferior values for UNVA (40 cm) between 20/25 and 20/32 – these differences were attributed to the differences in lens design. This effect was also observed during the defocus curve evaluation – PanOptix[™] showed a continuous range of vision (0.1 LogMAR or better) from 0 to -3 D of range (from distance to 33 cm), whereas Symfony achieved 0.1 LogMAR or better from 0 to 1.75 D (from distance to 57 cm).

Prof. Holzer also used guestionnaires to assess patients' visual disturbances and spectacle independence. To assess the former, patients were asked to assign a score (none, mild, moderate, noticeable, severe) for day glare, night glare, painful/ burning eyes, halos, double images, vision problems under bright light, normal light, and dim/ low light conditions. Patients who received PanOptix[™] reported moderate halos and mild night glare - all other evaluated parameters were ranked lower than mild. By comparison, patients implanted with Symfony also reported moderate halos and mild vision problems under low light conditions; other evaluated parameters were lower than mild. In terms of spectacle independence, both PanOptix[™] and Symfony-receiving patients reported that they "never" needed glasses for distance or intermediate vision – the difference between the IOLs arose with reading: on average, patients who received PanOptix[™] reported "never" needing glasses, whereas patients who received Symfony reported that their need for spectacle use was either "sometimes" or "seldom."

Alcon Multifocal IOLs Portfolio

After their first PanOptix[™] implantations,

the panelists were asked to comment how they felt the PanOptix[™] and ReSTOR[®] platforms compared.

The panelists agreed that patients' near vision with PanOptix[™] was as good as patients who received bifocal lenses like ReSTOR[®] +3.0 – PanOptix™ provides intermediate vision, and this meant that they preferred this option over blended vision. Dominique Monnet, MD, Head Ophthalmologist at Hospital of Paris, France, and Ozana Moraru, MD, Consultant Ophthalmologist at Oculus Eye Clinic Bucharest, Romania, concurred, with both reporting no subjective complaints with PanOptix[™] versus mild subjective complaints with blended ReSTOR[®]. Islam Hamdi, MD, an Ophthalmology Consultant at the Eye Consultants Center, Jeddah, Saudi Arabia, commented that PanOptix[™] ultimately limits the requirement to tailor lenses for different cases or for mixing and matching, as it's well accepted by both myopic and emmetropic patients. Similarly, in their practices, they agreed that most patients prefer trifocal over bifocal technology. Dr. Sezgin Asena explained "there are still some specific cases when you might choose ReSTOR® +2.5 over bilateral PanOptix™, for example, in younger patients (especially those who were previously emmetropic), patients concerned by quality of vision and still asking for additional range of vision to that of a monofocal IOL, and those with a distance-dominated professional task, such as driving a commercial vehicle."

Maximizing outcomes with advanced technology equipment

"I believe that we are unanimous in our opinion that PanOptix[™] provides good vision over all distances, but we need to apply a holistic approach to achieving the best possible outcome for our patients, and that means also selecting advanced equipment to plan and perform the



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surgery," says Ahmed Sedky, Chairman and Consultant Ophthalmologist at the Eye Subspecialty Center in Cairo, Egypt.

Francesco Carones, MD, Carones Ophthalmic Center, Milano, Italy, explained that it's essential that the practice of cataract surgery is one of a continual journey to improve safety, accuracy and efficiency. Patients understand and accept that as the technology evolves, there will be fewer complications and more eyes closer to the refractive target - and that modern instruments like LenSx[®] and Verion[™] may help the surgeon to perform a better procedure. The instruments aid surgeons' efficiency too - integrated systems streamline the surgical process from biometry onwards, and should minimize inter-individual differences. These are important - modern technology is not without cost, and the surgeon needs to see a return on their investment.

Dr. Carones presented a case series of 60 patients of his (120 eyes; axial length 22.0-24.5 mm, with preoperative corneal astigmatism >1.00 D) who received either the AcrySof[®] IQ toric or AcrySof[®] ReSTOR[®] toric IOL. The patients were split into three groups (20 patients, 40 eyes per group): standard phacoemulsification (2.0 mm temporal incision, bimanual irrigation/aspiration and manual marking); femtosecond laser-assisted cataract surgery (FLACS; as above, manual marking, but with LenSx® capsulotomy), and FLACS plus Verion™ for all phases. What he found was that Verion[™] helped provide an efficient data feedback and workflow loop (Table 3) and significantly better refractive results, with less residual cylinder and lower axis rotation (Figure 5).

It's long been known that a precise capsulotomy is essential for the successful implantation of premium IOLs – proper centration, and the correct effective lens position (ELP), and particularly with toric

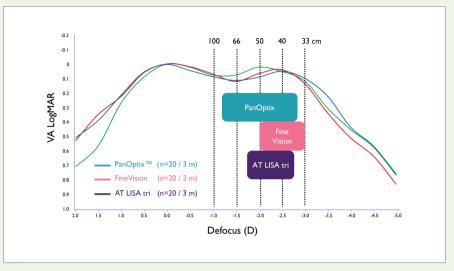


Figure 4. Binocular defocus curve after three-month follow-up for PanOptix[™], FineVision and AT LISA tri IOLs. Data courtesy of Dr. Alfonso.

Preoperative (Standard values utilized when planning pre-op	Intraoperative	Postoperative	
SIA: 0.28 D for OD, 0.09 D for OS for toric IOLs	LenSx® Digital marker	Data feedback and surgical factors update (SIA and A-constant)	
SRK-T A-constant optimization: 119.46 for ReSTOR® +2.5	Digital marker at the microscope		

Table 3. How Verion[™] helped provide an efficient data feedback and workflow loop for Dr. Carones in a case series of 60 patients with corneal astigmatism >1.0 D who received AcrySof® IQ toric or AcrySof® ReSTOR® Toric IOLs. SIA: surgically induced astigmatism.

IOLs, the minimization of postoperative rotation is crucial with these lenses to ensure the best possible outcomes. Femtosecond lasers promise precise and reproducible capsulotomies. But are they that much more precise than can be achieved by hand?

According to Prof. Kohnen, yes. He presented the results of a prospective, randomized comparison of FLACS capsulotomy versus manual capsulorhexis that involved 39 patients (15). What was found was that the laser-created capsulotomies were significantly more precise in size and shape than those created manually. One historical concern with femtosecond lasers was that they had been thought to induce greater levels of cell death in the surrounding tissue than manual capsulorhexes, but Prof. Kohnen highlighted the work of Mayer et al. (16), which demonstrated that a laser pulse energy of 5 μ J, delivered via a curved interface and a soft contact lens-fitted femtosecond laser system (in this case, Alcon's LenSx[®]) resulted in cell death levels that were comparable to those seen with manual capsulorhexes.

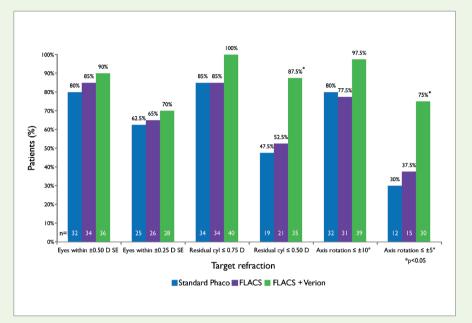


Figure 5. Proportion of patients meeting the target parameter who underwent manual cataract surgery, FLACS, or FLACS plus Verion™ surgery. FLACS, femtosecond laser-assisted cataract surgery. SE, spherical equivalent. *Statistically significant differences (p<0.05). Data courtesy of Dr. Carones.

Best practice should bring the best possible end result, though. Joaquim Murta, MD, PhD, Director of the Ophthalmology Service, Coimbra Hospital and University Centre, Portugal, gave an example of how he uses the Alcon cataract refractive suite to optimize outcomes (Verion[™] and LenSx[®]). He spoke of his use of the microscopemounted intraoperative aberrometry with ORA[™] – the Optiwave[®] Refractive Analysis device (which can be adapted to all kinds of operating microscopes). ORA[™] measures refraction during surgery, giving the surgeon intraoperative information about axis and magnitude of astigmatism, plus IOL selection and placement. He reported that it helps guide IOL placement, and verify the right IOL choice has been made, as different devices in the market give slightly different keratometric values, ORA™ can adjust the results intra-operatively. Prof. Murta noted that "ORA™ that is not only helpful in patients with prior refractive surgery but also in premium

IOL implantation by optimizing accuracy and patient outcomes, while decreasing potential enhancement rate."

Ultimately, patients who undergo refractive cataract surgery expect excellent outcomes. Part of this comes down to diligent assessment of patients' needs and expectations after surgery, and making the most appropriate choice together with them. The other part comes down to the pursuit of excellence and precision, and according to all meeting participants, it's this that should be consistently achievable with products like PanOptix[™], the Verion[™] Image Guided System, LenSx[®] and ORA[™].

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