Alcon at APACRS 2024:
Formal Introduction of the WaveLight Plus

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CHENGDU, China — This year's APACRS served as the formal launch in Asia of Alcon's latest refractive device, the WaveLight Plus. Several experts spoke about the device's attributes, among them its ability to create a 3D eye, which allows surgeons to truly personalize each patient's treatment.

Introducing the WaveLight Plus

Co-moderator Chandra Bala, PhD, BSc(Med), MBBS, FRANZCO (Australia) has performed more than 2,000 surgeries with the WaveLight Plus; he recently completed a study (N=400) that showed more than 80% of the patients achieved 20/16 vision or better.

An advantage of the WaveLight Plus is its InnovEyes Sightmap, a single, non-contact-ophthalmic diagnostic device designed to capture images of the anterior segment of the eye, which includes the cornea, pupil, anterior chamber and lens. Furthermore, it provides the axial dimensions and is indicated to analyze the optical aberrations of the eye by use of wavefront technology."

"The patient doesn't get up and move anywhere," Prof. Bala said. "Everything — refraction, aberrometry, topography — all these metrics are measured in one sitting and they're aligned to the patient's corneal vertex."

"No longer do we need to treat their glasses; we're treating each and every dot on their cornea as an individual dot. It's truly personalized to their eye," he said.

In his experience, Prof. Bala has only encountered three instances where he could not get the pupil to dilate enough to take a measurement.

Real-world results

In his real-world study[1] of 400 myopic eyes (range ≤-8.25D; astigmatism 0 to -4.25D) that were treated with the WaveLight Plus and having a 3D eye model generated with a customized LASIK ablation profile, Prof. Bala said "in more than half the cases, we were able to achieve 20/12.5. In fact, we were able to get 20/10 in 8% of cases."

He added his real-world outcomes are "not that surprisingly different from the multicenter trial. In our study, 89% of our patients achieved 20/16; "Analysis of lines of change from preoperative CDVA to month 3 CDVA showed that 46.5% eyes had no change, 40.3% eyes gained 1 line, and 8.0% eyes gained 2 lines of visual acuity. None of the eyes lost 2 or more lines of CDVA compared with preoperative CDVA."

With more than half the patients seeing 20/16 or better, "my touch-up rate has gone down," Prof. Bala said, adding that most of those are in eyes with higher cylinder. Preoperative higher-order aberrations (HOAs) were 0.308±0.102, and post-LASIK they were 0.371±0.135; these increases were not clinically significant.. Additionally, spherical aberration decreased.

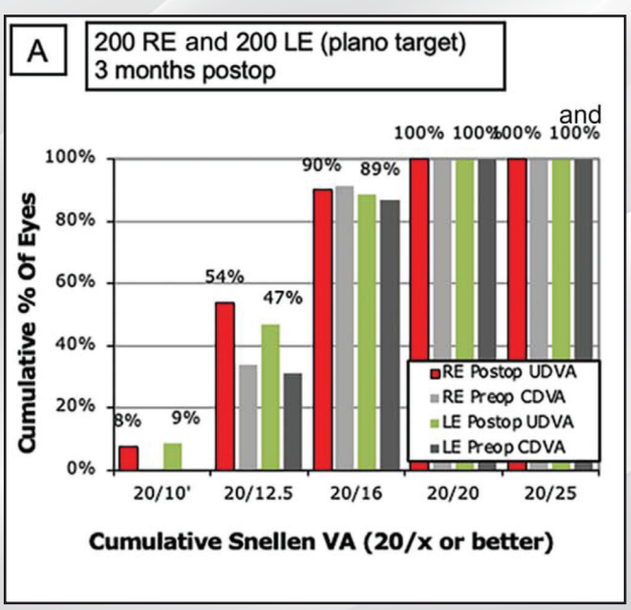
"This is the first time we are seeing a systematic reduction in spherical aberration, and that is an achievement for engineering technology at a 6mm zone. Remember, this is not at the 4mm zone," he said.

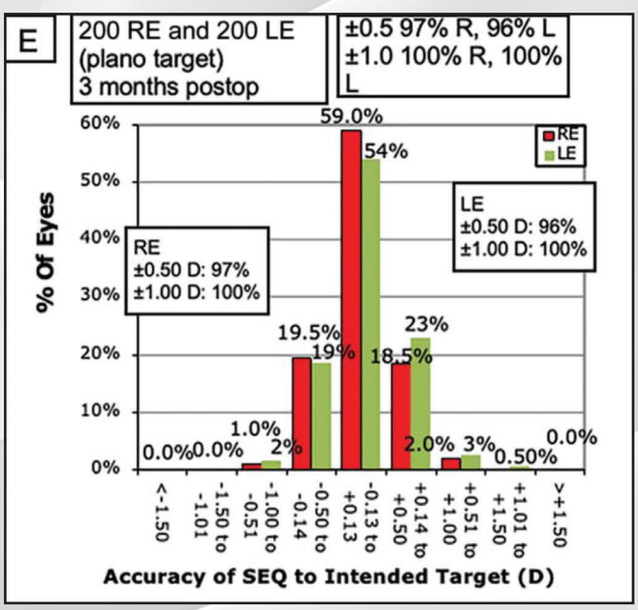
Using one device to redefine refractive surgery

Accurate refraction is the most important parameter for a successful laser vision correction (LVC) surgery, and refraction is based on the cycloplegic and the manifest or subjective refraction, with manifest refraction being the gold standard for LVC, co-moderator Prof. Yueguo Chen, MD (China) said. Errors introduced in the subjective refraction (inadvertently from technicians or optometrists and/or patients) can lead to clinically significant refractive surprises.

The question becomes, How accurate is the wavefront-based objective refraction and can it replace manifest refraction or be used with a nomogram adjustment? The WaveLight Plus creates the ablation profile by creating a 3D eye model (InnovEyes) and an ablation profile incorporating 2,000 rays of light from the corneal anterior surface to the retina. It then takes into account the geometrical and optical properties of the entire cornea and intraocular segments, he said.

In unpublished data on the consistency between the subjective refraction and the objective wavefront refraction in 500 eyes (average age was under 30 years), Dr. Chen found both the wavefront refractive sphere and cylinder (-6.18D and -1D,





In a 400-eye cohort, 89.3% of eyes achieved 20/16 or better uncorrected distance visual acuity after myopic LASIK with the WaveLight Plus.

> *No longer do we need to treat their glasses; we're treating each and every dot on their cornea as an individual dot. It's truly personalized to their eye.* Chandra Bala, PhD, BSc(Med)

respectively) to be higher than the subjective refractive sphere and cylinder (-5.59D and -0.90D, respectively). There were also different gaps in the type of astigmatism between the two refractions.

"Use of wavefront-based objective refraction and whole eye ray-tracing customized ablation can further improve uncorrected VA (UCVA) and visual quality," he said.

A. John Kanellopoulos, MD (Greece) told attendees that previous refractive surgery techniques negatively impacted the cornea as an optical surface even when providing spectacle independence.

"Ray-tracing is a different story. This device uses data from epithelial remodeling according to the spherical equivalent you're treating," he said. "WaveLight Plus has its own algorithm through the Eyevatar to calculate the low-order myopia and astigmatism as well as the higher order aberrations (HOAs) automatically." Surgeons do not need to make any nomogram adjustments as a result, and the device recommends the optimal treatment. Plus, the WaveLight Plus technology "takes into account the tilt between the cornea's elliptical system and the lens' elliptical system," Prof. Kanellopoulos said.

A multicenter, multinational published study[2] found "a significant reduction of the astigmatism to essentially nil," Prof. Kanellopoulos said. Some eyes even gained 2 lines of vision, he added. Another paper[3] showcased Prof. Kanellopoulos' own ray-tracing cohort outcomes postoperatively and "established that the data are stable even 2 years out," he said. "Postop contrast sensitivity is better than the preop."
In short, he said, "we have the opportunity to improve the visual optics of the eye for the rest of the patient's life."

Personalized plans improve visual outcomes

Fengju Zhang, MD, PhD (China) showed results from her real-world clinical study (51 patients, 99 eyes). She included patients with a pupil size >4.5 mm, and used the Sightmap to evaluate anterior chamber depth, central corneal thickness, wavefront refraction, and topography. She used the WaveLight FS200 to make the customized flaps on her patients, with a thickness of 110 µm and a diameter ranging from 8.6 mm to 8.8 mm (depending on the customized ablation profile). She used the WaveLight EX500 to create optical zones of 6.0 mm to 6.7 mm.

"If the difference between the subjective refraction and the wavefront-measurement was more than 0.5 D to 0.75 diopters, I will make a little bit of adjustment," she said.

At postop Month 1 (n=44 patients/87 eyes), 56% of the eyes gained ≥1 line of CDVA, she said, adding that UDVA was better than 20/20 in 99% of eyes, was 20/16 in 66% of eyes, and 20/12.5 in 15% of eyes. Further, UDVA was within 1 line of preop CDVA in all eyes.

Spherical equivalence was within ±0.5 D of target in 77% of eyes and was within ±1.00 D of target in 98% of eyes. At postop Month 1, 75% of eyes were within ±0.25 D of cylinder. The mean difference vector was 0.05D, and the correction index was 0.98, she said.

At postop Month 3 (n=30 patients/59 eyes), "the refraction remained quite stable," she said; UDVA was ≥20/20 in 98% of eyes, ≥20/16 in 64% of eyes, and ≥20/12.5 in 15% of eyes.

When the InnovEyes manifest refraction is "a bit high compared to the cycloplegic refraction, I will reduce the spherical correction," she said. In younger eyes that may have postop regression, "I keep the cycloplegic refraction the same in the dominant eye."

WaveLight Plus is "truly an incredible driver for personalized myopia correction," said Pierce Lin, MD, PhD (Taiwan), and the InnovEyes Sightmap leverages the unique ray-tracing technology by iteratively tracing 2,000 rays of light.

"This allows us to measure from the cornea to the crystalline lens, then to the retina, creating a personalized 3D eye model to help identify the best ablation profile for our patients," Dr. Lin explained in a video.

Dr. Lin presented unpublished data comparing outcomes with the WaveLight Plus (n=58) and Alcon's Contoura (n=106). Gender and age distribution was similar between the two groups, but the Contoura group had much higher spherical equivalent (-6.83±1.89 D) than the WaveLight Plus group (-4.66±1.55 D).

At postop month 1 there was "excellent efficacy" in UCVA, with 41% of eyes in the WaveLight Plus group and 10% of eyes in the Contoura group achieving 20/12.5.

The predictability was also excellent in both groups, with "a majority of patients within 0.5 D," Dr. Lin said: 96.6% of patients in the WaveLight Plus group were within ±0.5 D, compared to 89.4% of patients in the Contoura group.
Dr. Lin said surgeons should think of traditional lenticular extraction as buying a suit "off the rack," whereas the WaveLight Plus is more like "having a suit custom-made for the buyer."

Reference:

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3. Kanellopoulos AJ. Ray-Tracing Customization in Myopic and Myopic Astigmatism LASIK Treatments for Low and High Order Aberrations Treatment: 2-Year Visual Function and Psychometric Value Outcomes of a Consecutive Case Series. Clin Ophthalmol. 2024 Feb 22;18:565-574. doi: 10.2147/OPTH.S444174.

4. InnovEyes™ Sightmap Diagnostic Device User Manual

5. RFP911-P001 Postmarket Study of Outcomes from WaveLight EX500 InnovEyes