APACRS EyeWorld
The news magazine of the Asia-Pacific Association of Cataract & Refractive Surgeons
Supplement to EyeWorld Asia-Pacific Spring 2019

Shaping tomorrow's vision:
Technology to improve refractive outcomes

Carl Zeiss Meditec (Jena, Germany) lay yet another milestone in its more than 170-year history. For the first time, the company organized its cataract and refractive surgery user meetings in combination, an acknowledgment of the blurring of the lines between the formerly distinct fields of anterior segment ophthalmic surgery.

Moreover, the combination of presentations shows how the various technologies the company has developed over the years fit together into one overarching strategy, said **Dirk Muehlhoff**, vice president refractive laser, Carl Zeiss Meditec.

While Carl Zeiss Meditec technologies set the benchmark in their respective categories, Mr. Muehlhoff said what's more important is combining the value of these products.

Here we provide an overview of the technologies that have or are expected to have the most impact on the practice of cataract and refractive surgery, as presented by experts at the user meeting's first session. The overview was prefaced by the presentation of the results of a unique randomized trial just completed in Singapore. The comparative study employed novel means to demonstrate the clinical value of small incision lenticule extraction (SMILE), the latest generation of refractive laser surgery pioneered by Carl Zeiss Meditec and performed using the company's VisuMax femtosecond laser.

A randomized fellow-eye clinical trial: SMILE vs. LASIK

Marcus Ang, FRCS, Singapore, shared the results of a unique randomized fellow-eye trial that he and Jodhbir Mehta, FRCS(Ed), had just reported from Singapore.

As a refractive surgeon, Dr. Ang said he prefers the VisuMax femtosecond laser due to its design, which provides a small suction profile that enables easy docking for Asian eyes, and a low suction pressure, which minimizes IOP rise and makes the procedure more comfortable for the patient.

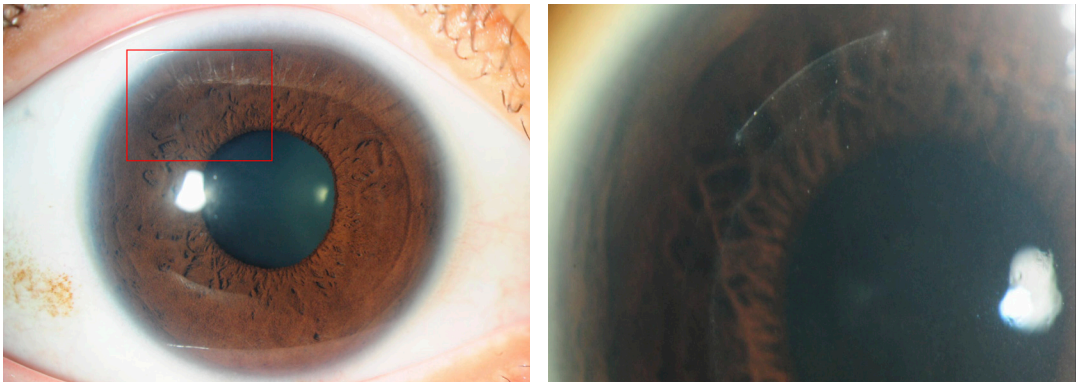
By now, the potential advantages of SMILE are well reported. Being a flapless procedure, it reduces flap-related complications; being a small incision surgery, it cuts fewer corneal nerves, possibly leading to less dry eye with potential for a stronger cornea and reduced inflammation within the cornea.

The visual outcomes—encompassing the visual and night symptoms at 3 months—and refractive outcomes—the efficacy, predictability, and safety—have been reported to be similar between SMILE and LASIK in most published literature. However, Dr. Ang noted that the studies tended to compare data from different cohorts; the main problem, he said, is that the results are difficult to interpret when comparing patients from different groups.

To overcome this limitation, Dr. Ang and his colleagues designed a clinical trial in which LASIK was performed in one eye, SMILE in the fellow eye in the same patient.

The study was conducted in a single tertiary center as a parallel group, single-masked, randomized controlled trial. The primary outcome was predictability at 3 months, with the secondary outcomes being efficacy, safety and predictability at 3 and 12 months. Because LASIK outcomes are so good, Dr. Ang said, it was almost impossible to power the study to demonstrate superiority of SMILE over LASIK; thus, they decided to power the study to demonstrate the non-inferiority of SMILE.

They recruited 70 consecutive patients (mean age 28±5 years, 64% female, 96% Asian) with no difference in preoperative spherical equivalent (SE) between eyes (–5.3±1.8 D versus –5.2 D±1.7 D, *P*=0.865). At 3 months, SMILE was not inferior to LASIK in terms of predictability (99% vs. 97% of eyes achieved SE within ±1.0 D of attempted correction, *P*=1.0). SMILE was also comparable to LASIK in terms of efficacy index (0.97±0.20 vs. 0.99±0.20, *P*=0.560), uncorrected visual acuity (UDVA) ≥20/40 (99% vs. 100%, *P*=1.0), and UDVA ≥20/20 (87% vs. 84%, *P*=0.628). Safety index (1.1±0.2 vs. 1.1±0.2, *P*=0.565) was comparable between SMILE and LASIK at 3 months. At 12 months, SMILE was similar to LASIK in terms of efficacy (85% vs. 83% UDVA ≥20/20, *P*=0.812), predictability (99% vs. 99% ±1.0 D of attempted correction SE, *P*=1.0), and safety (1.15±0.20



SMILE provides a minimally invasive, femtosecond laser refractive option for patients with a smaller corneal wound and thus prevents flap-related complications that can occur with LASIK.

Source: Marcus Ang, FRCS

continued on page 2

vs. 1.15±0.20, *P*=0.932). Most patients had no change or loss of lines, with a similar number of eyes gaining one line in both groups.

Unfortunately, the study was not powered to study biomechanics, although SMILE, Dr. Ang said, seems to be more stable in terms of refractive outcomes by 12 months.

Most patients said they were quite comfortable, though some found SMILE slightly more uncomfortable during manipulation. This is an important insight into patient experience, Dr. Ang said. Surgeons should take a little more time to counsel them regarding the experience of undergoing the procedure.

Most patients, Dr. Ang said, subjectively experienced no difference between their eyes, though some reported occasional blurring of vision in the SMILE eye at 1 month, which disappeared at 3 months.

AT Lisa Trifocal IOL

For those new to multifocals or who have "had their fingers burnt by other multifocal lens products," **Con Moshegov, MD**, Sydney, discussed how surgeons can introduce the AT Lisa Trifocal IOL (Carl Zeiss Meditec) into their practice.

In a refractive cataract practice, Dr. Moshegov said, patients want to be able to see without glasses at all distances and at all light levels, not just in bright conditions.

Dr. Moshegov covered various options and their respective limitations. Monovision isn't always tolerated by patients, and monovision is not as good at distance; accommodating IOLs are nice in theory, but in practice simply do not accommodate; diffractive multifocal IOLs work but at the cost of decreased contrast sensitivity, permanent halos and glare, and poor intermediate vision at higher adds.

The AT Lisa Trifocal IOL, he said, addresses these issues.

The lens is a trifocal lens in the central 4.3-mm diameter zone; outside, it is a bifocal. "Even compared to its own Zeiss sister, the bifocal lens, the intermediate vision is better," Dr. Moshegov said.

The lens is designed to be pupil independent and is non-apodized to optimize light distribution. However, Dr. Moshegov admitted that light transmission is about 85.7%; a monofocal provides more, so there is a slight compromise in terms of how much light reaches the fovea.

An aspheric optic maximizes contrast sensitivity and sharpness of vision.

In addition, the IOL is made using a patented technique that Carl Zeiss Meditec calls the smooth microphase technology, likely contributing to less light scatter and dysphotopsias at night—this borne out by Dr. Moshegov's clinical experience.

The clinical results, he said, have been very good, with 80% having a monocular corrected distance visual acuity (CDVA) of 20/20 or better.

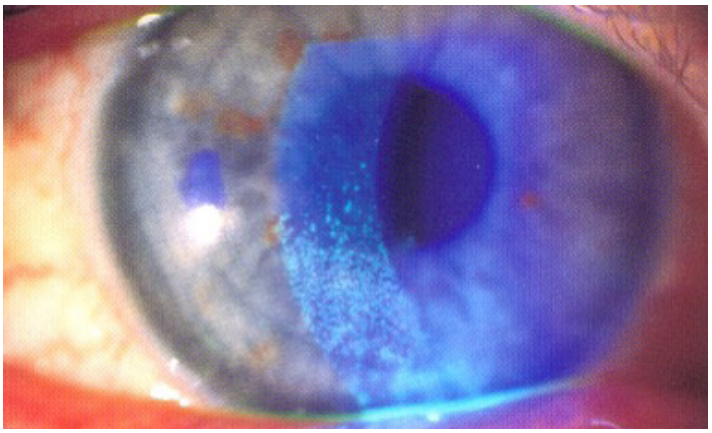
Contrast sensitivity appears to be "very minimally affected in the real world," Dr. Moshegov said.

Most patients in Dr. Moshegov's practice are "absolutely spectacle independent for all distances," he said. "I do cover myself by saying if you have something extremely fine that you need to see, you may need a little bit of assistance."

Satisfaction rates are high, though Dr. Moshegov finds comparative satisfaction rates not a useful gauge, as they are directly related to expectations. Expectation is tempered by numerous factors including adequate counseling. "If you tell them everything will be perfect then satisfaction rates will be affected," he said.

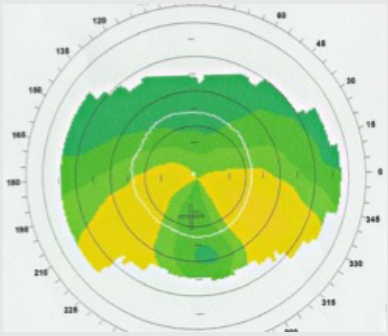
Dr. Moshegov said that the ideal patients in whom to start implanting the AT Lisa are presbyopes, particularly those with a strong desire to be independent of reading glasses, particularly if their distance vision has started to deteriorate as well. The best patients are thus hypermetropic presbyopes.

The ocular surface must also be optimized prior to any refractive procedure. "If they have a poor ocular surface, you're asking for trouble," he



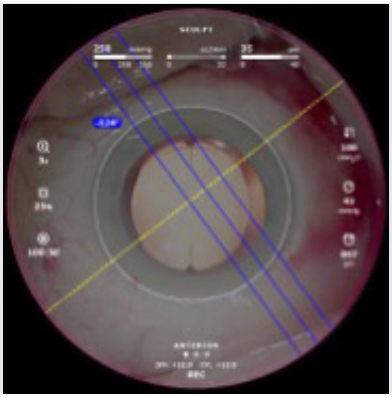
Dry eye seen with fluorescein staining. This diminishes the quality of vision in eyes with multifocal IOLs.

Source: Con Moshegov, MD



Irregular astigmatism on topography makes it unwise to use toric multifocal IOLs.

Source: Con Moshegov, MD



Callisto eye (Carl Zeiss Meditec) facilitates use of toric IOLs to optimize visual outcomes.

Source: Con Moshegov, MD

said. If they have loose zonules as in a variety of possible scenarios, including pseudoexfoliation, Dr. Moshegov avoids the lens, saying that the bag/lens complex in such cases might be in an entirely unpredictable position in 10 years.

The lens should also be avoided in patients who have very thick vitreous floaters. Vitreous debris in the eye will scatter light and make it difficult to achieve good vision.

Dr. Moshegov further advised caution if the vitreous has not yet detached; if the eye has macular degeneration, if the patient had previous refractive surgery, if the patient is amblyopic. Dry eyes are also "particularly trouble" for this type of IOL.

The lens is best used bilaterally, though one may be enough, Dr. Moshegov said.

Topography should be done, and for regular astigmatism, there is a toric version of the lens with a bitoric design that provides equal distribution of toricity between the anterior and posterior surfaces of the optic and a larger usable optic compared with monotoric IOLs, allowing incorporation of even more cylinder into the lens.

Dr. Moshegov noted that any irregularity seen in the topography, even if artefactual due to ocular surface disease, will cause problems, so the cornea must be optimized first.

Prior to implantation, patients must be counseled regarding halos and mild glare that get better over a few months. They should also be counseled regarding the possibility of a secondary laser procedure and a small chance of needing explantation if the patient is dissatisfied with the lens.

Dr. Moshegov no longer mentions loss of contrast or the need for glasses for intermediate vision tasks the way he used to with other multifocal IOLs.

He said to always end counseling the patient on a good note. Always tell them the benefits of these lenses—that with this IOL, they will be able to read an SMS message on their phone; read the menu in a restaurant; see price tags in shops; put on eye makeup; tell the difference between shampoo and conditioner in hotel showers; look closely into the eyes of someone they love. These things, he said, are more important to people than reading a book without glasses.

"You will feel the freedom of not depending on glasses," he said.

If the patient is unhappy with their vision after implantation, look at treating the poor ocular surface, often the case after a long course of preserved medications; treating imperfections in the posterior capsule, including wrinkles; treating residual refractive error—once residual error goes up to and past the 0.75 D range, it will need to be treated.

The challenges in daily practice when using these IOLs include getting reliable and more accurate biometry and keratometry values; placing toric IOLs on the desired axis and having them stay there; and doing these efficiently and confidently. "There are Carl Zeiss Meditec integrated devices that work together to make this easier," Dr. Moshegov said.

"Not all multifocal IOLs are the same," he concluded. "In my practice, the AT Lisa has a high likelihood of putting a smile on patients' faces. Care is needed in the selection of the best candidates and the tools from Carl Zeiss Meditec can make life a lot easier."

Optimal patient outcomes with PRESBYOND

Looking at presbyopia correction, **Sri Ganesh, MD**, Bangalore, said nothing much had changed in the last two centuries since Benjamin Franklin introduced bifocals. "In fact, we are still prescribing bifocals," he said.

More recently, a number of options have come into play, broadly grouped into corneal inlays, laser corneal surface procedures, and refractive lens exchange with a variety of IOL options.

Dr. Ganesh himself became presbyopic about 7 years ago, at which time he began reviewing all the available procedures. He decided he did not want to undergo intraocular surgery; if you do not have a cataract, "the risk-benefit ratio doesn't work out." He also worried about glare and halos, potential loss of contrast, and refractive inaccuracies in other available procedures.

Finally, 2 years prior to this user meeting, he settled on PRESBYOND (Carl Zeiss Meditec).

PRESBYOND increases depth of focus by controlled induction of spherical aberration. It induces a form of micro-monovision with the dominant eye targeted for emmetropia, the non-dominant eye for myopia of approximately –1.5 D. The LASIK-based procedure uses a non-linear aspheric ablation profile, incorporating a pre-compensation factor to modify the spherical aberration. Postoperative spherical aberration falls within a range that provides increased depth of focus without compromising contrast sensitivity and quality of vision.

Dr. Ganesh enumerated four keys to success with PRESBYOND:

1. Patient selection. PRESBYOND is appropriate for any patient suitable for LASIK, with myopia with a spherical equivalent (SE) between –8.00 D and +2.00 D and for cylinder at a maximum value of 2.00 D, or emmetropia; with corrected distance visual acuity (CDVA) no worse than 20/25 in either eye; age 44 and above, presbyopic, and dependent on reading glasses, particularly with multiple glasses for reading, driving, and other tasks. The patient should also be motivated, should pass the +1.5 D tolerance test, have quick suppression and fusion, and tolerate at least –0.75 D of anisometropia.

Avoid PRESBYOND in patients with very high expectations; this is a compromise lifestyle procedure that does not provide perfect vision.

2. Patient counseling. Patients should not compare each of their eyes against the other after surgery. They should be told that adaptation can take about 3 months; they will need dry eye medication; should be made aware of the possibility

continued on page 4

Dr. Ganesh presented keys to success with PRESBYOND:

1. Patient selection
2. Patient counseling
3. Meticulous refraction and micro-monovision assessment

of enhancement in the future—the refractive target must be hit perfectly; there is a risk of early cortical cataract and patients may need cataract surgery in the future. On the other hand, they may not require multifocal IOLs when they do receive cataract surgery.

3. Meticulous refraction and micro-monovision assessment. Step-by-step evaluation should include: verification of refraction and accommodation amplitude to verify the functional age; eye dominance; +1.5 D tolerance test; check suppression and fusion; planning with the CRS-Master (Carl Zeiss Meditec).

Micro-monovision assessment: The standard micro-monovision protocol corrects the dominant eye to plano and non-dominant eye to –1.5 D irrespective of age; patients are tested for tolerance with the intended refraction in place and the amount of cross-blurring reported by the patient during simulation is evaluated; cross-blurring—the lack or reduction of interocular blur suppression—is checked with distance correction in place as diopters are added in the non-dominant eye.

Outcomes: Personal summary

Immediately after the procedure, Dr. Ganesh said he was able to read small print on an eye drop bottle. Just 14 hours later, he was doing live surgery on a complicated cataract surgery, and 2 years down the line he has maintained good vision with J1 plus of reading.

Dr. Ganesh has since the procedure retained good functional vision; easily adjustable, enhancement and reversible; no permanent visual effects—glare and halo for the first couple of months disappeared; any side effects are correctable with glasses; good contrast sensitivity and stereopsis; can maintain blended vision even after cataract surgery, does not interfere with the surgery itself.

With his 2 years of experience of vision after the procedure, Dr. Ganesh said, "I am the proof of the pudding."

Novel uses of the lenticule

To date, more than 750,000 SMILE procedures have been performed in China. Of that number, **Zhou Xingtao, MD**, Shanghai, and his team have performed more than 70,000 SMILE procedures. In their hands, SMILE has resulted in good outcomes in terms of efficacy, stability, predictability, and safety.

With all the lenticules they create and discard, Prof. Zhou and his team wondered, can this discarded tissue be used to reshape the cornea or treat patients with corneal disease?

They posited that refractive SMILE lenticules could be used to treat hyperopia, residual refractive error, myopia with relatively thin corneas, presbyopia, ectasia after laser cornea surgery repair, and other refractive corneal conditions. In addition, the lenticule could be used for granular corneal dystrophy.

Prof. Zhou and his colleagues conducted a pilot observation study looking into lenticule implantation for keratoconus and post-LASIK ectasia. He presented two cases from the study.

First, a 26-year-old patient developed bilateral post-LASIK keratectasia 2 years after undergoing LASIK in 2009. Treated initially with RGP contact lenses, the patient consulted Prof. Zhou in 2015 due to intolerance of the lenses.

A SMILE myopic lenticule was implanted in the patient's left eye. The lenticule had myopic power of –0.70 D/–2.75 D cyl x 180, and measuring 6.9 mm in diameter, 77 µm in thickness. At 30 months, the patient's uncorrected distance visual acuity (UDVA) went from 20/2000 preop to 20/133; manifest refraction (MR) went from –3.25 D/–5.00 D x 160 preop to –5.0 D/–6.25 D x 90; and corrected distance visual acuity (CDVA) went from 20/50 preop to 20/40. The change in corneal thickness remained stable.

Second, a 35-year-old patient who underwent bilateral LASIK in 2003 developed unilateral ectasia 8 years later and consulted Prof. Zhou in 2015, also for intolerance to the RGP contact lens.

In this case, they used a lenticule +5.00/–1.00 x 160, 6.7 mm diameter, with maximum thickness of 112 µm, minimum thickness of 25 µm. At 24 months, the patient's UDVA went from 20/2000 preop to 20/400; MR from –4.00 D/–4.25 D x 70 preop to –1.00 D/–3.00 D x 45; and CDVA from 20/50 preop to 20/63. The change in thickness also remained stable.

Based on their findings, Prof. Zhou said that corneal intrastromal lenticule implantation is feasible and safe for increasing corneal stromal thickness and changing corneal refractive power. The procedure may provide a novel method for keratoectasia and may further be used to treat presbyopia in the future.

However, while implanting an autologous lenticule obtained by SMILE for hyperopia is safe, effective, and stable, Prof. Zhou said that the predictability of the procedure needs to be improved upon in the future.

Tissue addition, he concluded, is a safe and effective method of increasing corneal thickness with resulting increase or decrease in refractive power for post-LASIK ectasia, and may be used to delay or even avoid keratoplasty. In theory, Prof. Zhou thinks the procedure may even benefit corneal biomechanics, though this requires further study.

Based on their findings, Prof. Zhou said that corneal intrastromal lenticule implantation is feasible and safe for increasing corneal stromal thickness and changing corneal refractive power.