

Supplement to EyeWorld Asia-Pacific Summer 2017

Taking Vision Further: Update on Innovative Refractive and Cataract Solutions



Sponsored by Carl Zeiss Meditec

Laser Vision Correction — Today and Tomorrow

lunch symposium sponsored by ZEISS (Carl Zeiss Meditec, Jena, Germany) during the 2017 Asia-Pacific Academy of Ophthalmology (APAO) meeting highlighted "Laser Vision Correction – Today and Tomorrow." The session was moderated by **Khairidzan Mohd Kamal, MD**, Kuala Lumpur, Malaysia.

Marcus Ang, MD, Singapore, Cynthia Roberts, PhD, Columbus, Ohio, Jodhbir Mehta, MD, Singapore, and Sri Ganesh, MD, Bangalore, India, focused their presentations on topics related to small incision lenticule extraction (SMILE).

Dr. Roberts discussed the biomechanics of SMILE and the U.S. Food and Drug Administration results. She highlighted information about general biomechanics and the biomechanical response to refractive surgery.

Dr. Roberts discussed two studies. The first was a theoretical study of a finite element comparison of LASIK vs. SMILE, which didn't use actual clinical parameters. She explained that the same diameter SMILE cap and LASIK flap size were used in the study and the same cap/ flap thickness were used as well. although this is different than what would be done in the clinical setting. In comparing a postoperative "ideal cornea" (postop geometry with no change in properties) to the SMILE and LASIK outcomes, Dr. Roberts said that the SMILE eye was closer to the idealized postoperative stress distribution because the cap can carry some stress and cause less of an increase in the residual stromal bed stress. "When you compare SMILE to LASIK, there's biomechanical distribution in SMILE similar to the ideal case." she said.

She discussed a flap vs. cap contralateral study of 10 eyes of five patients. The patients had SMILE in one eye and femtosecond lenticule extraction (FLEx) in the fellow eye. These provided a good comparison, she said, because the SMILE eye had a cap, while the FLEx eye had a flap, and both used the same mechanism for tissue removal. Preoperative and postoperative tomography

were examined, and the study used inverse finite element analysis to determine what change in properties had to occur for the postoperative map to be produced, given the tissue removal. FLEx produced a 49% (range 2-87%) greater mean reduction in stromal collagen fiber stiffness within the flap region than contralateral cap region in SMILE, Dr. Roberts said. There were lower stresses and deformations within the residual stromal bed in SMILE eyes. Looking at the results of what happened when IOP was changed in the model, the FLEx eye with a flap had a greater displacement of residual stromal bed at both IOP levels that were analyzed than SMILE, she said.

Dr. Roberts cautioned that the major biomechanical impact of any refractive surgery is tissue removal, and cap vs. flap is a secondary effect. SMILE weakens the cornea less than LASIK, but the preop cornea is still stronger than both, she said. Do not perform SMILE if you suspect an "at risk" cornea, she said.

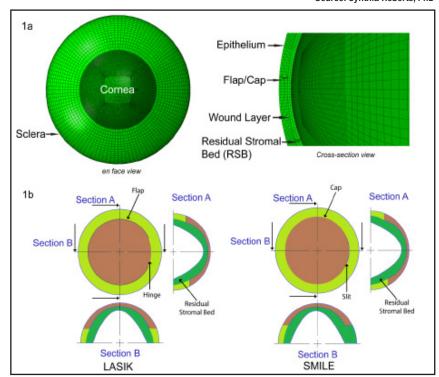
Surgeons need to follow the same general guidelines of laser vision correction for SMILE as they are currently following for LASIK.

Dr. Roberts also discussed the FDA results for SMILE (although she noted that she was not involved in the study) from the prospective, multicenter, open-label, single-arm study. In the study, 336 eyes were treated at five sites in the U.S. There was unilateral treatment with 12-month follow-up, and the study data were submitted when 300 eyes reached 12 months. She highlighted specific inclusion criteria and exclusion criteria. The study showed a higher percentage of patients with postoperative UCVA greater than preoperative BSCVA (70% at 6 months and 74% at 12 months). The study had excellent effectiveness outcomes, Dr. Roberts said. Carl Zeiss Meditec announced that it received U.S. FDA approval for the ReLEx SMILE procedure. With FDA approval, surgeons can now perform SMILE for the correction of myopia in the U.S.

Dr. Ganesh discussed his experience as a doctor and patient with PRESBYOND laser blended vision. He shared details of his own 1 Lenticule cut (underside of lenticule)
2 Lenticule side cut
3 Cap cut (concurrently upper side of lenticule)
4 Cap opening incision

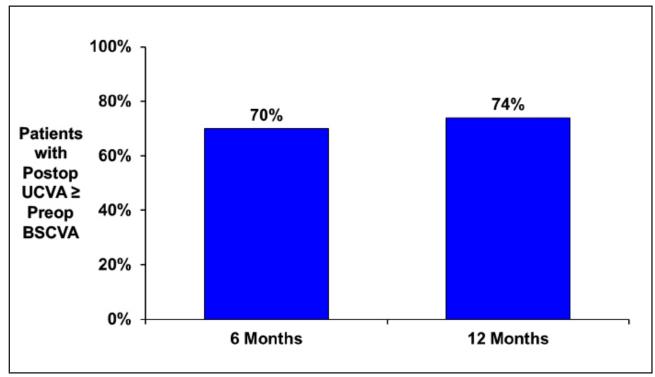
SMILE procedure

Source: Cynthia Roberts, PhD



Finite element comparison of LASIK vs. SMILE. Sinha Roy A, et al. Comparison of biomechanical effects of small-incision lenticule extraction and laser in situ keratomileusis: finite-element analysis. J Cataract Refract Surg. 2014;40:971–80.

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Source: Cynthia Roberts, PhD

When you compare SMILE to LASIK, there's biomechanical distribution in SMILE similar to the ideal case. 55

—Cynthia Roberts, PhD

presbyopia onset and symptoms. Although he had good vision throughout his life, he found he was having problems with near and intermediate vision without glasses with the onset of presbyopia. He noted that it was difficult for him when doing surgery with glasses to look back and forth between the microscope and monitor. Additionally, Dr. Ganesh said that his patients often questioned him about his glasses, and he said it was difficult to convince a patient to undergo a procedure when he was wearing glasses. He decided to get refractive surgery and chose PRESBYOND.

Dr. Ganesh said he selected PRESBYOND because it had the highest patient satisfaction, good functional vision, and the safety and track record of femto LASIK. Plus, he had follow-up data and satisfaction from his staff who had previously undergone PRESBYOND, and he knew it was easily adjustable and reversible, had no permanent visual

effects, and any side effects were correctable by glasses.

PRESBYOND closely simulates the natural condition existing in patients. It provides good contrast sensitivity and stereopsis. He added that you can maintain blended vision even after cataract surgery later in life, and this will not interfere with the surgery itself.

Dr. Ganesh had some mild side effects after his surgery, including mild dry eye, halos at night in the left eye for the first 3 months, and glasses were required for highway driving. However, he said he is satisfied overall with his vision and would strongly recommend the procedure to his colleagues. After 3 months, Dr. Ganesh noted that he was very comfortable, and the halos disappeared and night vision improved, so he no longer requires glasses for driving at night.

Dr. Mehta's presentation covered SMILE enhancement. In some

cases there might be a need for a retreatment because of residual error due to several possible reasons. He shared a number of possible options for enhancement, which include PRK or LASEK, LASIK anterior to previous SMILE cap, secondary SMILE anterior or posterior to the previous one (an off-label use and against the contraindications outlined in the user manual), ICL, intrastromal AK, or converting the previous SMILE pocket into a flap by performing a peripheral laser incision to intersect with a previously created SMILE pocket.

Dr. Mehta shared information from a study evaluating different nomograms for determining which enhancement technique is best. Many factors can play into this, he said, including the type of correction, the depth of the primary SMILE treatment, the degree of hyperopia or myopia needed to be corrected, if it was desirable to try to maintain a flap, and the speed of visual recovery.

Another study he discussed was a retrospective study done at the Singapore National Eye Centre (SNEC) of the first 524 consecutive eyes that underwent SMILE at the center. The incidence and prevalence of enhancements were examined, as well as preoperative and intraoperative factors and outcomes after the enhancement procedure. Dr. Mehta noted that risk factors for enhancement included higher age in the enhancement group, higher spherical equivalent, higher mean myopia, higher astigmatism, and higher rates of suction loss. However, he also

noted that the overall incidence was only 2.7% in the first 2 years, with the enhancement incidence being 2.1% at year 1 and 2.9% at year 2. There was not a single case in the first 500 eyes of true regression, he said. In summary, Dr. Mehta said that enhancement rates are expected to be less with SMILE than with LASIK due to less stromal wound healing response, and he stressed that there are several enhancement options available if necessary, depending on the refractive correction required.

Dr. Ang's presentation was titled "Ready to SMILE? – A Refractive Surgeon's Early Perspective." He discussed reasons he performs SMILE, as well as tips for surgeons who may decide to start SMILE.

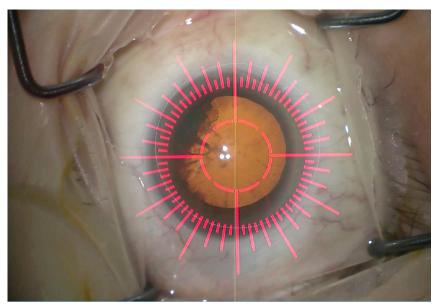
He first highlighted his personal reasons for performing and offering SMILE as an option to his patients.

As a surgeon building your refractive practice, it's good to have an alternative technique to LASIK. "We all know the potential drawbacks of LASIK," he said. These include flap-related complications and dry eyes, which may be reduced with SMILE. SMILE may also be more suitable for active patients who do not wish to have a corneal flap.

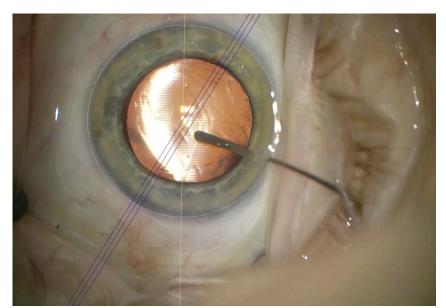
Second, he has witnessed the evolution of ReLEx from FLEx to SMILE, and has seen the clinical evidence that supports the efficacy of SMILE. The third reason is that he is familiar with the VisuMax docking system, which he said provides minimal applanation, low suction, has less visual blackout, and is more comfortable for Asian patients. However, he noted that there is a higher rate of suction loss.

His first tip for those beginning to perform SMILE was to take particular care with patient counseling and selection. Dr. Ang usually shares information on the advantages of SMILE, such as the lack of flap-related complications, a smaller incision that in turn produces less dry eye, and a potential for a biomechanically stronger cornea. He advised that surgeons beginning with SMILE start with a patient who has moderate myopia with low cylinder, for ease of lenticule extraction. He also advised that beginner surgeons do their homework to understand the procedure and the many differences between LASIK and SMILE. This understanding of the technology and parameters are crucial, and he recommended attending a course with hands-on training, with particular attention to techniques for docking and centration, preventing suction loss, and lenticule dissection technique.

Innovations for Precision in Cataract Surgery



The Callisto orientation line is used to orient the ORA intraoperative aberrometer.



The Callisto toric positioning line is used to help the surgeon position an IOL.

Source: Bryan Lee, MD

nother lunch symposium at the APAO meeting in Singapore highlighted "Innovations for Precision in Cataract Surgery." The session was moderated by **Khairidzan Mohd Kamal, MD**, Kuala Lumpur, Malaysia.

Han-Bor Fam, MD, Singapore, presented on "Good Outcomes Made Easy." He discussed optical biometry vs. ultrasound and Asian perspectives. He thinks that optical biometry is superior to ultrasound and highlighted the advantages of the IOLMaster 700. First, he noted that if the patient does not fixate well when determining the biometry, there is a problem, particularly if the patient is not looking at the target. With the IOLMaster 700, you will be able to tell if the patient is looking at the target.

The second thing that is important for the IOLMaster 700 is the one-click system, he said. While previous systems required multiple clicks, this one click does everything for you, Dr. Fam said. The system will also digitally transfer readings to the Callisto system so you can align IOLs in a more precise manner, he said.

This system is particularly useful for dense cataracts, which are often a problem in the Asia-Pacific region. Dr. Fam shared a study looking at 29 dense cataracts using the IOLMaster 700 that found that 27 of 29 eyes were able to be read where earlier versions of the IOLMaster could not give this information.

Dr. Fam then discussed his use of the IOLMaster 700. He noted that prior to installation of the new system, he was using an earlier IOLMaster system for about 85% of patients and ultrasound for about 16% of patients.

Now, after incorporating it into practice and allowing technicians to become familiar with the technology, he said that the IOLMaster 700 is being used in 95% of cases, with ultrasound being used for less than 5%.

In summary, the new IOLMaster is one-click, he said. You can check for fixation, which is very important, and you can acquire the eye image and transfer it digitally to Callisto. "We are able to address denser cataracts," Dr. Fam said.

David Chang, MD, Los Altos, California, gave a presentation on the "Accuracy and Precision of ZEISS Cataract Suite." Dr. Chang highlighted the markerless aspect of the ZEISS platform, which can help with alignment for diffractive presbyopia-correcting IOLs and for astigmatic treatment with either astigmatic keratotomy or toric IOLs. An important requirement for any intraoperative treatment for astigmatism is correctly identifying the astigmatic axis in the supine patient. Due to cyclorotation, the 180 axis must first be determined and marked while the patient is sitting upright. Dr. Chang said that doing so with the typical ink pen can be challenging due to the frequent tendency for squeezing or head movement as the patient senses the approaching pen. The ink marks may bleed or fade, leading to imprecise marking by the time the patient is beneath the operating microscope. "I think every surgeon appreciates the potential inaccuracy of the ink mark methodology," he said.

For the Callisto markerless system, a photograph of the cornea and limbal conjunctiva is taken during biometry with the IOLMaster. The camera is already internally built

Work flow standpoint, the image acquisition is very quick and doesn't require any additional workstation.

—David Chang, MD

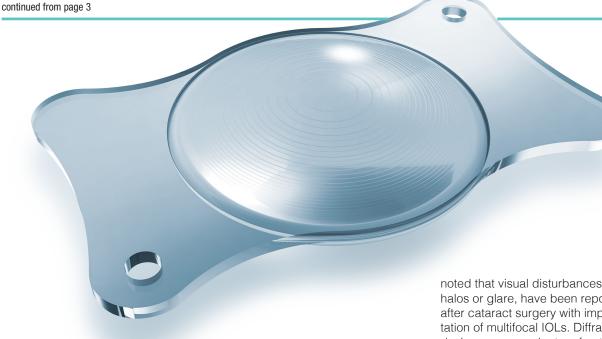
into the IOLMaster 700 model. With the 500 model, a slender, external camera is permanently attached on the patient side of the instrument. Acquiring this reference image simply becomes an additional quick step in the overall biometric sequence for all cataract patients. "The beauty is that from a work flow standpoint, the image acquisition is very quick and doesn't require any additional workstation," Dr. Chang explained. The computer algorithm digitally records the 180-degree axis relative to the nasal and temporal limbal vasculature pattern. It is also able to digitally map the patient's visual axis relative to these same limbal landmarks because the patient is fixating on a target at the moment the photograph is taken. The image is stored with the other biometric data on the instrument hard drive or, in the case of Dr. Chang's clinic, on the ZEISS Forum data management server.

The Callisto computer is integrated into the ZEISS Lumera 700 operating microscope system. The image taken from the IOLMaster can

be imported via a thumb drive on the day of surgery. "We've set up a secure VPN network between the ASC and our office Forum server," Dr. Chang said. This allows the ASC staff to directly import the images into Callisto over a secure network.

The digital markerless program registers the limbal vessel landmarks from the preoperative image with the live image through the operating microscope. It then projects a variety of digital overlays through the surgeon's ocular. "Using a switch on the microscope foot pedal, I can turn this display on or off, and I can cycle through three different overlays," Dr. Chang said. One shows the 180-axis reference line. A second marks the astigmatic axis with three parallel blue lines to permit alignment of either the toric IOL marks or astigmatic keratotomy. "The last overlay projects a 5 mm diameter circle on the plane of the anterior capsule to serve as a guide during the capsulorhexis step," he said. "What is unique is that this

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The AT LISA trifocal 839MP

Source: Carl Zeiss Meditec

is centered on the patient's visual axis, as recorded with the IOLMaster, instead of on the pupil."

Potential initial concerns were whether the system would slow down the office or operating room work flow, and whether the system was reliable enough to completely dispense with preoperative marking at the ASC. "Overall, it has saved us a lot of time in the OR because I don't have to mark the patient preoperatively or intraoperatively with axis ink marks," he said. "But most importantly, the improved precision and accuracy are immediately obvious."

Prin Rojanapongpun, MD,

Bangkok, Thailand, presented "Use of Intraoperative OCT in Cataract Surgery." He first spoke about challenges of clear corneal incisions (CCI) in cataract surgery. Clear corneal incisions are the current standard in cataract surgery, he said. The location of the incision is very important, and you want to be sure not to place it too anteriorly. However, Dr. Rojanapongpun said that judging depth and location for where to put the CCI is not easy because our eyes cannot perceive the exact depth and anatomical location of the limbus.

Wound architecture is very important in creating a self-sealing, watertight closure of CCI, he said, and CCI location affects the surgical technique and wound architecture.

Dr. Rojanapongpun discussed the way intraoperative OCT, which he has been using for several years, can be used to aid in CCI, including getting an in-depth look at the location of the CCI and checking the wound before leaving the eye at the end of surgery. Intraoperative OCT also helps surgeons to understand the different CCI architecture and its integrity in creating CCI using the femto laser.

Dr. Rojanapongpun mentioned that with intraoperative OCT, it is possible to see the cross-sections of CCIs and to gain insight on how to create a better CCI. The need for corneal incision hydration, which is not physiologically favorable, can be eliminated. The need for additional sutures to close the wound can be clearly and visually judged precisely based on intraoperative OCT visualization.

He shared that a new intervention on external wound sealing by soft cotton tip or finger for better wound closure can be demonstrated using RESCAN. Better understanding in this regard leads to better CCI and less traumatic cataract surgery.

He added the intraoperative OCT can be used across several ophthalmic subspecialties, including in cataract, glaucoma, cornea, and retina procedures.

Jorge Alió, MD, PhD, Alicante, Spain, presented on "Evaluating AT LISA Tri Family: Performance and Patient Satisfaction." He first introduced different available bifocal and trifocal IOLs, citing several studies. Bifocal IOLs give high levels of spectacle independence and patient satisfaction, he said, as well as better reading performance compared to refractive multifocal or monofocal IOLs. Dr. Alió

noted that visual disturbances, like halos or glare, have been reported after cataract surgery with implantation of multifocal IOLs. Diffractive designs are superior to refractive IOLs in terms of visual quality, Dr. Alió said, however, intermediate vision may be limited with certain diffractive bifocal IOLs.

Trifocal IOLs were developed to help overcome the limitation in intermediate vision and provide a more optimized visual acuity for intermediate distance, he said. But he stressed that the impact of the generation of a third focal point in eyes implanted with trifocal IOLs on reading performance is still unknown.

He discussed a study comparing AT LISA, AT LISA tri, and ReSTOR (Alcon, Fort Worth, Texas). Binocular contrast sensitivity measurements were done at 1 and 12 months postop. Additionally, patients were asked at 1 and 6 months postop to evaluate their level of perception of glare and halo, which was done subjectively by scaling symptoms in size and intensity using a simulating computer software. Patients completed an in-house questionnaire at 1 and 6 months postop about their level of satisfaction and level of spectacle independence. PCO was evaluated by slit lamp exam at 3, 6, and 12 months postop after mydriatic dilation of the eye.

Significant differences were found among the IOLs in intermediate vision, with a significantly better outcome with the trifocal IOL, Dr. Alió said. Regarding near vision, statistically significant differences were found in the study sample only for binocular DCNVA, with 3-month postop values significantly better in the ReSTOR compared to the AT LISA group. In terms of distance vision, Dr. Alió said no significant differences were found in UDVA among the groups. He added that no significant differences were found among the

IOL groups in postoperative binocular CDVA, which indicates a similar level of visual quality for the three IOLs.

Significantly better visual acuities were obtained 3 and 12 months after surgery with the trifocal IOL compared to the bifocal and the apodized IOLs for defocus lenses simulating intermediate vision. Additionally, postop manifest sphere and cylinder were very close to zero in all three groups, with a significantly more hyperopic postop sphere and spherical equivalent with the trifocal diffractive-refractive IOL compared to the bifocal diffractive-refractive and apodized IOL.

Dr. Alió said that the impact on reading acuity and speed results were similar, as was the postoperative satisfaction score in all groups. He mentioned the anti-PCO design of the AT LISA tri to help prevent PCO formation, which seems successful in the 12-month follow-up.

In conclusion, he said that the trifocal diffractive-refractive AT LISA tri IOL provides enhanced intermediate vision compared to the bifocal diffractive-refractive and apodized IOLs, with comparable distance and near visual outcomes. Near and distance visual performance is not degraded by the addition of a third focal point, he said.

Allan Fong, MD, Singapore, discussed "Advanced Power Modulation for Cataract Surgery," highlighting the VISALIS 500, which he called the "new kid on the block." It is programmable and customizable to fit your particular technique, Dr. Fong said.

The advanced power modulation (APM) function is particularly good for hard cataracts, he said. The VISALIS 500 also has a new advanced irrigation function, which Dr. Fong said helps with a more stable anterior chamber during phacoemulsification. It is a dual gravity and pressure controlled irrigation.

Overall, the combined technology is safer, faster, and more efficient, he said, adding that the VISALIS 500 has a small footprint and is easy to set up.

Dr. Fong shared another feature that he likes about the VISALIS 500. He mentioned the hot swap dual pump system, with both peristaltic and venturi pumps. It's possible to use both types of pumps "on the fly" during one surgery, as it is easy to switch between them on the system to suit individual techniques. For example, he switches from peristaltic to venturi settings after his first piece removal.