HANGHAI, China, April 2018—ZEISS (Jena, Germany) has reached yet another milestone in its over 170-year history. For the first time, the company has combined refractive surgery user meetings, an acknowledgement of the blurring of the lines between the formerly distinct fields of anterior segment ophthalmic surgery.

Perhaps the most significant milestone reached by ZEISS in the last decade or so is its small-incision lenticule extraction (SMILE) procedure that to date remains possible with the precision optics of the VisuMax femtosecond laser.

"SMILE is a fascinating procedure," said Tae-im Kim, MD, Seoul, South Korea, one of the most advanced technology among the refractive procedures available today. As benefits a procedure that occupies center stage in modern refractive surgery, the ZEISS user meeting focused significantly on this cutting-edge procedure. Dr. Kim discussed the quality of vision after SMILE, sharing her approach to meet patients’ expectations from the premium procedure, while a faculty of experts shared their own experiences and pearls during a Rapid Fire “SMILE Learning” session.

SMILE more: Quality of vision

All surgeons who perform SMILE are satisfied with the refractive outcome it provides, Dr. Kim reported. However, she wondered, what about the patient? Although Dr. Kim said that patients end up feeling good about their vision, they also pay more and in turn expect more from the procedure.

To meet their expectations, Dr. Kim pays particular attention to minimizing decentration, a problem that can lead to corneal aberrations.

Dr. Kim said that SMILE follows the Munneryn formula and is centered on the corneal vertex. Optical zone centration is targeted to the coaxial corneal light reflex, also known as the first Purkinje image.

SMILE is performed under mild suction and does not involve an eye tracking system. The alignment of the refractive lenticule thus relies heavily on the patient’s cooperation. Decentration have been reported in literature due to presumed difficulty in terms of patient cooperation and docking (Lee H, et al. Relationship Between Decentration and Induced Corneal Higher-Order Aberrations Following Small-Incision Lenticule Extraction Procedure. Invest Ophthalmol Vis Sci. 2018 May 1;59(6):2316-2324).

To evaluate SMILE in her practice, Dr. Kim first measured decentration during the procedure. She conducted a retrospective study on 360 eyes (360 patients) to investigate the amount of lenticule decentration following SMILE. Eyes were evaluated with use of the Keratron Scout (Optikon, Italy) Tangential Topography Difference Map. Dr. Kim and colleagues also investigated the relationship between magnitudes of total decentration and induced corneal higher-order aberrations (HOAs). They defined the optical zone as the central zone up to the mid-peripheral power inflection point.

Performing a piecewise linear regression of changes in root-mean-square (RMS) spherical aberration with total centered displacement, the estimated breakpoint between induced RMS spherical aberration and total decentration is 0.355 mm. This measurement was used to differentiate Group I (total centered displacement ≤ 0.335 mm) and Group II (total centered displacement > 0.335 mm).

Although decentration was higher in Group II, the mean postoperative uncorrected distance visual acuity (UDVA) (1.30 ± 0.20, range 0.60 to 1.50 vs. 1.27 ± 0.21, range 0.60 to 1.50 in Groups I and II, respectively; P = 0.179) and post operative mean refractive spherical equivalent (MRSE) (0.03 ± 0.25, range –1.50 to 1.07 vs. 0.03 ± 0.31, range –1.19 to 0.75, respectively; P = 0.419) were similar.

However, more decentration induced larger total HOAs, coma, vertical coma, horizontal coma, and spherical aberration (Figure 1). Decentration of less than 0.335 mm could thus yield more satisfactory results with regard to aberrations, and accurate centration is crucial to reduce induction of corneal HOAs.

Based on these findings, Dr. Kim initiated a second study to investigate lenticule decentration following SMILE via the subjective patient fixation method (Kang DSY, et al. Comparison of the Distinct but Similar Models of Lenticule Decentration Following SMILE by Subjective Patient Fixation or Triple Marking Centration. J Refract Surg. 2018 Jul 1;34(7):446-452) or triple-marking centration method and to compare induction of corneal HOAs between the two methods. Dr. Kim wanted to show how decentration can be minimized.

For patients using the subjective patient fixation method (subjective centration group), alignment relied entirely on the patient’s fixation to the target light. At the moment of contact between the individually calibrated curved contact glass and the cornea, the surgeon instructs the patient to look directly at the green light. A meniscus tear film appears, at which point the patient is able to see the fixation target clearly because the vergence of the fixation beam is adjusted according to the individual eye’s refraction.

The triple-marking centration method is performed at the slit lamp. Using a horizontal slit beam for reference, the patient stares at the light, and markings are made at the 3 and 9 o’clock positions. The slit beam is then turned to the vertical position bisecting the coaxial corneal light reflex, and a marking is made at the 6 and 12 o’clock position. These markings are used as a reference to ensure correct centration while docking.

Visual and refractive outcomes were comparable, although more eyes undergoing SMILE with the triple-marking method gained 2+ lines and achieved greater astigmatism correction (Figure 2). Eyes undergoing SMILE with subjective fixation were more centered, with greater scatter around the corneal vertex. Moreover, SMILE with the triple-marking method significantly reduced total aberrations, coma, and spherical aberrations.

Finally, Dr. Kim and her colleagues conducted a retrospective case series of 89 eyes (45 SMILE with triple-centration eyes and 44 eyes with corneal wavefront-guided transepithelial PRK [CWfG transPRK]) to investigate the clinical outcomes and vector analysis of myopia patients with high astigmatism treated with the two procedures. Dr. Kim said that CWfG transPRK has been shown previously to perform well in correcting high astigmatism.

The refractive outcomes were very similar, but Dr. Kim more frequently observed a 2+ line gain in transPRK; 20% of SMILE eyes versus 32% of CWfG transPRK eyes gained at least 1 line of visual acuity (Figure 3). Refractive astigmatism correction was comparable between the two procedures, and both procedures induced very mild HOA. However, although more spherical aberrations were seen in CWfG transPRK, more coma was induced by SMILE.

Based on these three studies, Dr. Kim concluded that having decentrated distances of less than 0.335 mm could yield more satisfactory results with regard to visual outcome and total HOAs, coma, vertical coma, and spherical aberration. Performing SMILE with the triple-marking centration method can improve treatment centration,
accompanied by smaller induction of total HOAs, coma, and spherical aberrations. Both SMILE with triple centration and CWFG transPRK are effective and provide predictable outcomes for the correction of high-myopia astigmatism.

**SMILE learning:**
**Pearls for SMILE**
Ten leading experts from around the world offered their pearls for SMILE during the Rapid Fire “SMILE Learning” session.

**SMILE “On Boarding Process” with ZEISS**
Amir Hamid, FRCophth, Optegra Eye Hospital, London, UK, an experienced refractive surgeon who has performed several thousand LASIK and LASEK laser eye surgeries, described his experience with the ZEISS “SMILE onboarding process” training program and subsequently reviewed the results with his first 200 eyes.

Dr. Hamid noted that there has been a slightly negative perception in the West concerning laser vision correction and its potential for complications, highlighting the importance of mitigating complications even during the learning curve while still ensuring high-quality results and achieving high patient satisfaction. Dr. Hamid and his colleagues achieved this by working closely with ZEISS.

ZEISS’s “SMILE On Boarding Process” begins with online training for the basics and flap creation with the VisuMax femtosecond laser; on-site training sessions with hands-on wet labs, requiring the satisfactory completion of flaps in six porcine eyes before continuing to the next phase; and continuous support and monitoring of flap creation through clinical apps, requiring satisfactory completion of 50 eyes before finally proceeding to SMILE training. User nomograms can be developed later in the training.

Dr. Hamid highlighted the importance of working with clinical apps, as technique is not the sole determinant for outcomes. Laser optimization is particularly important when performing SMILE, as using the least amount of energy that produces the least amount of resistance when performing dissection will allow more rapid visual recovery and better visual results. Another essential part of the process was gaining

(Continued on next page)
experience in the surgical technique at a Zeiss-Approved training centre, which in his case was in India.

In reviewing his first 200 eyes, Dr. Hamid used a control group of femtosecond LASIK (Femto-LASIK) eyes for comparison, matching the two groups as closely as possible. They compared unaided distance visual acuity (UDVA) and near visual acuity, spherical refraction, and fluorescein tear breakup time. Patient satisfaction data also were collected.

There was no statistically significant difference in UDVA between the two groups, with 94.3% (199/211) of LASIK eyes and 95.9% (116/121) of SMILE eyes achieving 20/20 or better binocular UDVA at 3 months. SMILE also was comparable to LASIK in terms of predictability and ocular surface performance, with 87.9% (391/445) of LASIK eyes and 90.4% (197/218) of SMILE eyes achieving spherical equivalent refraction within 0.5 D.

Reported patient satisfaction was high in both groups. There was no statistically significant difference in tear breakup time.

These results demonstrate that ZEISS’s structured training program can produce excellent visual results within a safe and ethical environment, Dr. Hamid concluded.

Patient selection
Following Dr. Hamid, S.K. Sundaramoorthy, MD, detailed his process for selecting candidates for SMILE.

As with any refractive procedure, Dr. Sundaramoorthy said that patient selection is essential for success with SMILE. Careful patient selection ensures that the procedure achieves results-based patient satisfaction and stable refractive correction while preventing complications and excluding unsuitable patients. SMILE is the first choice for very active and busy patients who travel for business, want to return to work early, do not want to risk flap displacement, and generally prefer a treatment that provides the chance to have less impact on their lifestyle. SMILE, based on a flapless surgical principle, has to potential to be well suited for patients who engage in extreme or contact sports, are in the military or law enforcement, or those who work as computer professionals or professional night drivers, Dr. Sundaramoorthy said.

It seems to be ideal to know patients well and to understand their visual needs and whether the attainable level of satisfaction is acceptable to them, Dr. Sundaramoorthy said. Patients should be educated about the benefits as well as the risks and side effects of the procedure, Dr. Sundaramoorthy said.

Dr. Sundaramoorthy selects patients who are 18 years old with a stable refraction for 1 year and with an acceptable yearly change of < 0.50 D that can be verified with old prescriptions. He also considers whether a patient has a family history of myopic complications. Other considerations are systemic conditions such as anxiety, uncontrolled diabetes, skin or autoimmune diseases, the use of drugs, and phobias. Pregnancy and nursing should be verified—he recommends waiting two menstrual cycles after delivery or 1 month after nursing is stopped.

The eye’s anatomy and condition should be carefully evaluated in terms of the brow and nose, set of orbit, palpebral fissure, and the presence of lid abnormalities or pterygium. The cornea should be evaluated for size and thickness, scars, dystrophy, and infections, and the patient should be evaluated for chronic allergic conjunctivitis, cataract or subluxation, glaucoma, and retinal pathologies, Dr. Sundaramoorthy said.

Dr. Sundaramoorthy selects patients whose mesopic pupils are < 6 mm; have a cycloplegic versus manifest refraction < 0.75 D; have an angle kappa < 5’; have HOA – RMS 0.3 μm; and have a vertical coma < 0.15 μm.

Dry eye and contact lens wear should be managed before the procedure. Exclude patients with suspicious or early keratoconus, forme fruste keratoconus, a family history of corneal pathology, or pellucid marginal degeneration, Dr. Sundaramoorthy advised.

Corneal thickness should allow caps of around 110 to 120 μm and a residual stromal thickness of a minimum 250 μm.

**SMILE vs. transPRK**

Deng Yingping, MD, conducted a comparative analysis of the visual results following the treatment of low to moderate myopia with SMILE versus transPRK. The two procedures represent the current state of cataract and surface refractive surgery, respectively, highlighting the development toward greater comfort, safety, and accuracy, with further improvement in visual acuity and reduction of complications.

The comparative analysis was a prospective case-controlled study on 47 SMILE cases (94 eyes) and 22 transPRK cases (44 eyes). Uncorrected distance visual acuity, best corrected distance visual acuity, spherical refraction, contrast sensitivity, HOAs, modulation transfer function (MTF), and Strehl ratio were evaluated, and patients were administered the Quality of Life Impact of Refractive Correction Questionnaire.

There was no statistically significant difference between the two groups in terms of uncorrected visual acuity, refraction, and HOAs, but a statistically significant difference was seen for the MTF (total MTF of 0.54 ± 0.11 with SMILE and 0.43 ± 0.11 with transPRK, P < 0.05), Strehl ratio (total SR of 1.45 ± 0.05 with SMILE and 1.10 ± 0.08 with transPRK, P < 0.05), contrast sensitivity (P < 0.05), and visual quality rating scale (P < 0.05).

**Predictive modeling in SMILE**

Is there a way to predict whether a cornea with a normal-looking topography will have normal healing or progress to ectasia after refractive surgery? Predictive modeling can help determine whether a patient is suitable for a particular refractive procedure, Rohit Shetty, MD, said.

Research on biomechanics after various refractive procedures has been done previously. To produce their prediction model, Dr. Shetty and a group of mathematicians looked at every component of the procedure. In each of the study’s 25 participants, Dr. Shetty performed LASIK in one eye and SMILE in the other. They paused each procedure after the initial flap cut and cap cut for 4 hours and evaluated the corneal biomechanics at the end of that time period before proceeding with flap lift and ablation and lenticule removal. Patients were followed up at 1, 7, and 30 days after the procedure.

In LASIK eyes, the flap cut caused corneal biomechanical changes in 37% of the indices. In contrast, in SMILE eyes, the cap cut caused changes in only 13% of the indices. This indicates that, as expected in theory, there is a large change in corneal biomechanics just with the creation of a flap.

Dr. Shetty’s study provides data for the contribution of the flap or cap cut and ablation separately. It also demonstrates a significant difference in biomechanics after the flap cut but not after cap cut and allows for a better understanding of the improved biomechanics reported in SMILE, in turn allowing for better predictive modeling.

**Clinical outcomes of SMILE after retinal detachment surgery**

Sung Min Kim, MD, Nunemuso Eye Clinic, Seoul, South Korea, said that various complications can occur during any refractive procedure due to high suction pressure. These range from relatively mild complications such as conjunctival hemorrhage to disastrous unilateral simultaneous retinal detachment during laser cutting. However, SMILE is known to be much safer because of the curved contact lens used by the VisuMax femtosecond laser, with only low suction needed to immobilize the eye, allowing lower, more stable pressures during the procedure.

To evaluate this, Dr. Kim and colleagues conducted a study on the long-term clinical outcomes of SMILE after previous retinal detachment surgery. They also evaluated the safety of the low and stable suction system used in SMILE. They performed a simple case review of two eyes in two subjects who had undergone scleral buckling and cryoablation prior to SMILE, evaluating results up to 6 months. The second case was evaluated as having a moderate risk of ectasia, hence SMILE Xtra (OFF Label) was performed.

Based on these cases, Dr. Kim concluded that SMILE and SMILE Xtra (OFF Label) did not aggravate postoperative retinal status. With proper use, the low and stable suction system used in SMILE allows for a safe procedure for patients with previous scleral buckling and cryotherapy. Scleral buckling and cryotherapy prior to SMILE and SMILE Xtra (OFF Label) did not affect long-term clinical results.

Dr. Kim and his colleagues believe that a surgical history of scleral buckling is irrelevant to the visual and refractive outcomes of SMILE. SMILE and SMILE Xtra (OFF Label) may be safe and effective modalities to correct myopia and myopic astigmatism in patients with previous retinal detachment surgery.

**SMILE, LASEK, LASEK-CX for thin corneas**

LASK is effective for the correction of myopia and has an excellent ability to correct refractive error. However, there is a risk of ectasia in patients with thin corneas because of insufficient residual stroma after surgery. Thus, a central corneal...
thickness (CCT) of less than 490 to 500 μm is a relative contraindication to LASIK.

Seongjun Lee, MD, Daejeon, South Korea, evaluated the visual outcomes of SMILE, LASEK, and LASEK combined with corneal crosslinking (LASEK-CXL) as other options to correct myopia in eyes with thin corneas. Although LASEK may be a practical alternative to LASIK for thin corneas, SMILE has less biomechanical impact than surface ablation or LASIK. Cross-linking increases the biomechanical stability of the cornea.

In their study, Dr. Lee and colleagues found that SMILE, LASEK, and LASEK-CXL appear to be safe and effective for myopic correction in patients with thin corneas. However, SMILE provided significantly better refractive predictability than LASEK and marginally better predictability than LASEK-CXL (which was marginally better than LASEK). Also, the SMILE group had fewer postoperative complications and less induction of HOA compared with the LASEK and LASEK-CXL groups.

SMILE and cyclotorsion-compensated wavefront-optimized PRK in myopic astigmatism

Dalwoong Huh, MD, compared the astigmatic correction between SMILE and PRK with eye registration in myopic eyes with > 0.75 D astigmatism. The SMILE group consisted of 277 patients (382 eyes), and the PRK group consisted of 250 patients (434 eyes). The groups were followed up to 1 year.

By 1 year, Dr. Huh saw no statistically significant difference between the two groups in terms of visual acuity (no eye had a decrease in best spectacle-corrected visual acuity), spherical equivalent, refraction cylinder, and predictability. He concluded that both SMILE and PRK with eye registration are safe, effective, and provide predictable outcomes in treating myopic astigmatism. SMILE had comparable results to PRK in treating astigmatism.

Anterior segment changes after FS-LASIK and SMILE

Evaluating the anterior segment changes after Femto-LASIK and SMILE, Bu Ki Kim, MD, used the dual-rotating Scheimpflug analyz-