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Optimizing SMILE

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Effect of angle kappa on visual outcomes in SMILE

Jodhbir Mehta, MD, Singapore

The centration of any refractive surgery is vital, said **Jodhbir Mehta, MD**, Singapore. Accurate centration reduces photic phenomena such as glare, halos, and induced higher order aberrations that can occur postoperatively.

Experience with LASIK, Dr. Mehta said, has shown that accurate centration is achieved by several means—via faster lasers, greater accuracy with smaller spot sizes, and the use of eye trackers. There are also several options for centration: It can be done centering on the pupil, the visual axis, the corneal vertex or the coaxial sighted corneal light reflex. Some of these, he said, are easier and more well defined than others.

Kappa intercept	Decentration from kappa intercept				
	<0.2	0.2 to <0.4	0.4 to <0.6	At least 0.6	Total
0 to < 0.1	5	0	0	0	5
Proportion	23.8%	0.0%	0.0%	0.0%	3.1%
0.1 to < 0.2	7	13	0	0	20
Proportion	33.3%	24.5%	0.0%	0.0%	12.3%
0.2 to < 0.3	6	19	3	0	28
Proportion	28.6%	35.8%	7.1%	00%	17.3%
0.3 to < 0.4	3	13	12	0	28
Proportion	14.3%	24.5%	28.6%	0.0%	17.3%
0.4 to < 0.5	0	8	17	5	30
Proportion	0.0%	15.1%	40.5%	10.9%	18.5%
0.5 to < 0.6	0	0	6	8	14
Proportion	0.0%	0.0%	14.3%	17.4%	8.6%
0.6 to < 0.7	0	0	4	8	12
Proportion	0.0%	0.0%	9.5%	17.4%	7.4%
0.7 to < 0.8	0	0	0	10	10
Proportion	0.0%	0.0%	0.0%	21.7%	6.2%
0.8 and above	0	0	0	15	15
Proportion	0.0%	0.0%	0.0%	32.6%	9.3%

Figure 1. Patients who had the greatest decentrations were also those who had the highest degree of angle kappa preop.

Reference points, axes, angles

When centering a refractive procedure, it is important to understand the relationship between various reference points, axes, and angles: *angle kappa*, the angular distance between the visual and pupillary axes; the *pupillary axis*, a line passing through the center of the pupil perpendicular to the cornea; the *visual axis*, connecting the fovea with a fixation point, passing the nodal point of angle lambda; *angle lambda*, the angular distance between the pupillary axis and line of sight; *line of sight*, the line running through the center of the pupil to a fixation point; the *corneal vertex*, the point of maximum elevation when viewing a target, near the line of sight, reproducible independent of pupil size; and Purkinje images.

Dr. Mehta focused on the effect of angle kappa on SMILE outcomes.

Considering angle kappa

Several corneal topographers currently available provide measurements of angle kappa, though surgeons should be aware that some provide them in polar coordinates, others in Cartesian coordinates; these can be interchanged using appropriate mathematical formulations.

In terms of distribution, angle kappa trends smaller in myopic eyes, tending to be larger in the left eye and reducing with age, but varies such that some myopic eyes have no angle kappa and others have negative angle kappa—an important consideration for myopic treatments.

One other consideration for surgeons: While docking with the femtosecond laser obviates the need for an eye tracker, this means that centration must be accurate at the time of docking—being based on patient fixation, the docking does not aim for the center of the pupil.

Angle kappa and SMILE

Studies have looked into basic centration with SMILE, showing it to be comparable to centration with LASIK. However, all studies rely on comparison with topography scans following patient treatment; what surgeons really need to know with regard to centration, Dr. Mehta said, is whether there is something they can do either intraoperatively or before treatment to predict whether a procedure will go badly.

Dr. Mehta and his colleagues conducted a retrospective study on 164 consecutive eyes to evaluate centration during SMILE, investigating the impact on predictability, efficacy, and safety.

Correlating outcomes with decentration from the pupillary center, there was a tendency toward better vision with around 0.2 mm of decentration; visual acuities of 20/20 or better were achieved by 78.6% of eyes with more than 0.2 mm of decentration, compared with only 68.8% in eyes with less than 0.1 mm of decentration and 66.7% in eyes with between 0.1 mm and 0.2 mm of decentration.

Correlating outcomes with decentration from the angle kappa, on the other hand, showed that better uncorrected visual acuity was achieved with from 0.4 mm to less than 0.6 mm of decentration.

Moreover, all of the patients who had the greatest decentrations of 0.6 mm or above were the patients who had the highest degree of angle kappa preoperatively; patients with large angle kappa preop show a large offset from the pupil center after docking (Figure 1).

The surgeon can therefore predict this outcome preoperatively by measuring the angle kappa.

Aiming for centration close to the visual axis is supposed to provide the best visual outcomes. The study confirms that SMILE lenticules not centered on the pupil center provide better visual outcomes for patients with large angle kappa.

In April 2017, Carl Zeiss Meditec (Jena, Germany) conducted a user meeting in Singapore. More than just a showcase for their latest technologies, the company's user meeting has grown into a venue for peer-to-peer information sharing, where the world's top ophthalmic surgeons come not only to teach, said symposium chair Gerard Sutton, MD, but also to learn.

The second symposium of the meeting focused on optimizing SMILE (small incision lenticule extraction) performed with the ZEISS VisuMax femtosecond laser.

Pearls in the learning curve

Gerard Sutton, MD, Sydney, Australia

Learning curve tips

1. Energy settings are important
2. Room temperature and humidity
3. Screen properly for ectasia risk
4. Tear film management
5. Centration technique/handling the patient during the procedure
6. Accessible troubleshooting protocol
7. Develop your own nomogram
8. Adjust lenticule thickness in low myopes
9. Create anterior and posterior pockets
10. Counsel patients regarding visual recovery

When we see new technology, it comes with a lot of hype. At first, many people might embrace it, but as they accumulate experience, the technology is revealed to be imperfect, and the pendulum, said **Gerard Sutton, MD**, Sydney, Australia, begins to swing the other way. This applies to new refractive procedures. Some refractive technologies might not find their equilibrium; SMILE, Dr. Sutton argued, has.

Though Dr. Sutton was a relatively late starter, over the last 2 years SMILE has become the most common corneal refractive surgical procedure he performs.

However, he said, it wasn't always smooth sailing. Even in the literature, refractive accuracy, visual outcomes, and safety as reported vary widely. Dr. Sutton thinks these discrepancies are accounted for by variations in technique, variations in the way lasers deliver treatment, and deriving data from snapshots taken at different points in surgeons' learning curves.

Looking at his first 500 cases—through which his enhancement rate went from 2.4% in the earlier cohort to less than 1% in the last 250 cases—Dr. Sutton discussed how he thinks things improved, providing 10 key points to flatten the learning curve.

1. Energy settings are important
The amount of time Dr. Sutton together with the ZEISS application team spent to get the energy settings correct was significant, but important; you must know and understand your laser.

2. Room temperature and humidity
Moving the lasers into a room that had good control of temperature and humidity made a big difference in Dr. Sutton's practice. Maintain room temperature at 22–24 degrees C, humidity at 55–65%.

3. Screen properly for ectasia risk
Surgeons still need to screen properly for ectasia. If a patient does not appear suitable for LASIK because of concerns over aspects of corneal topography or tomography, he or she is not suitable for SMILE.

4. Tear film management
Dr. Sutton follows what he calls his "Goldilocks rule," not too wet, not too dry, just right, achieved by using two drops of oxybuprocaine 0.4% minims, three wet spears, three dry spears, and an aspirating speculum on low during the procedure.

5. Centration technique/handling the patient during the procedure
Communication with the patient is very important. Dr. Sutton asks patients to look at the green light fixation target in the VisuMax and centers on the first Purkinje image. He then warns them that they will feel a touch, pausing when there is a small meniscus until he can recenter on the Purkinje image. He tells them that the green light will disappear, cautioning them against looking for it when it does.

6. Accessible troubleshooting protocol
While the actual incidence of suction breaks and similar problems is extremely low, this means that when these problems do occur, surgeons and technicians might not remember how to deal with them. Having a clear troubleshooting protocol accessible is thus very important.

7. Develop your own nomogram
If you are doing any volume of surgery, ask the ZEISS application team to find and set your own clinical nomogram.

8. Adjust lenticule thickness in low myopes
This is very easy to do and makes the surgery easier as well. Slightly increase the minimum lenticule thickness in low myopic cases.

9. Create anterior and posterior pockets
Whether you use forceps or dissect the lenticule, identifying the outlines of the lenticule is one of the key surgical steps that allows the procedure to be straightforward.

10. Counsel patients regarding visual recovery
Following other refractive procedures, Dr. Sutton's patients routinely have 6/6 vision 4 hours after surgery. SMILE patients, he said, are more likely to be around 6/9 after 4 hours. It takes a little bit longer for them to get their visual acuity, and patients should be informed, especially if they were referred by others who had LASIK surgery.

There is room for improvement, which Dr. Sutton views as opportunities to further improve surgical outcomes. However, he said, SMILE has made it, and the procedure is being incorporated into the refractive surgery degree at Sydney University.

Science of SMILE

Glenn Carp, MD, London, U.K.

There has been a lot of science on SMILE in the last 9 years that is now being correlated clinically, influencing the way surgeons approach the procedure, as well as how they approach patients themselves. **Glenn Carp, MD**, London, U.K., went through some commonly held beliefs regarding SMILE, parsing the science to determine whether each one is a fact or a myth. Some of these topics are describing an off-label use of the VisuMax but have been discussed to provide a real overview and for the sake of completeness.

Common beliefs regarding SMILE: Fact or myth?

1. Centration: SMILE vs. LASIK
It has been claimed that SMILE is not as accurate as LASIK due

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Science of SMILE

1. Centration: SMILE vs. LASIK
2. Control for cyclotorsion
3. Treating high cylinder
4. Patients with low myopia
5. Custom ablations
6. Tissue consumption
7. Retreatment options

to the lack of an eye tracker. Dr. Carp's own study[1] in 2015 on 100 consecutive SMILE eyes matched to a LASIK control group showed very good similarity between the two groups (mean offset of 0.20 ± 0.11 in SMILE vs. 0.18 ± 0.11 in LASIK, p=0.08).

You can't beat the human eye for tracking, Dr. Carp said. If the patient is autocentrating, that's the best tracker you're going to get, and once you apply suction the centration is locked in.

The key is never apply suction if you're not sure if the patient is looking. This can be checked using the Hirschberg test or an Atlas eye image.

2. Control for cyclotorsion
If the patient is marked at the slit lamp, the contact glass can be rotated if there is significant cyclorotation. Dr. Carp recommended using the visual screen rather than looking through the microscope, as the reticle might not be calibrated well; the VisuMax monitor screen overlay provides better representation of where you're rotating to.

3. Treating high cylinder
In the early days, there were issues with undercorrections. However, adjustments in nomogram covering both axis and power have accounted for these issues.

4. Patients with low myopia
Treating low myopia is, Dr. Carp said, "not too much of a challenge"—these cases should be approached the same way as any other, except that the minimum thickness of the lenticule should be increased so the lower bubble does not interfere with the upper bubble pattern.

5. Custom ablations
Why would you even want to perform wavefront-guided procedures? Dr. Carp asked. He said that they haven't done wavefront-guided ablations at their clinic since 2002; all cases are wavefront-optimized. Preexisting higher order aberrations, he said, aren't treated because they are negligible. It's all about not inducing spherical aberration.

Topography-guided treatments *are* outside the realm of SMILE; however, Dr. Carp said, this is more for repair work—zone expansions or decentrations.

6. Tissue consumption
SMILE does consume slightly more tissue; however, SMILE retains more tensile strength. The higher cohesive tensile strength of the anterior cornea—50% stronger than the posterior—is retained in the absence of sidecuts and flaps.

7. Retreatment options
Dr. Carp said that in their practice, they never perform PRK for SMILE. PRK leads to a large hyperopic shift in the first few months due to the thickening of the epithelium after any ablation. Instead, they perform thin-flap LASIK.

LASIK enhancement does introduce the risk of epithelial ingrowth. However, primary LASIK after SMILE has a very low risk of epithelial ingrowth; SMILE then LASIK, Dr. Carp said, is probably safer than LASIK then LASIK.

In the end, Dr. Carp said, SMILE is as impressive as LASIK, but it is not LASIK. SMILE is not a replacement, it's an adjunct. LASIK is not a bad treatment, but SMILE certainly has its own advantages.

Reference

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Aberrations and SMILE

David S.Y. Kang, MD, Seoul, South Korea

The literature on SMILE is now broad enough to cover everything from biomechanics and clinical outcomes to aberrations and enhancements. **David S.Y. Kang, MD**, Seoul, South Korea, focused on higher order aberrations.

Performing a PubMed search for "SMILE" and "aberrations" brings up 42 peer-reviewed publications. Every single one, Dr. Kang said, cite induction of vertical coma after SMILE.

Dr. Kang said he is tired of hearing about vertical coma. Analyzing the situation, he discussed pulse energy, optical zone, and centration to adopt means to ameliorate aberrations.

Pulse energy

Studies have shown that the surface regularity index decreases as pulse energy increases[1] and that lower energy levels improve visual recovery in SMILE.[2] Dr. Kang and his colleagues conducted a prospective, randomized clinical trial on 150 eyes of 150 patients to investigate the correlation of pulse energy with morphological characteristics of the lenticule surface by scanning electron microscopy, quantifying the surface irregularity with atomic force microscopy (AFM).[3] They found a linear increase in the morphologic roughness of human lenticule with increasing pulse energy. Even quantified using AFM, all three variables examined—average roughness, RMS roughness, and 10-point mean height roughness—revealed a correlation coefficient showing this linear increase.

The surface irregularity after a 150 nJ treatment is about threefold that of a 100 nJ treatment. Significantly, in human lenticules in the near-threshold group—treated at 100 nJ, 105 nJ, and 110 nJ—there was no statistically significant difference in the surface roughness found by AFM in both anterior and posterior surfaces.

Further investigating the possibility of lowering energy settings in SMILE, Dr. Kang conducted another prospective, randomized clinical trial on 150 eyes in 150 patients.[4] The eyes were randomized into two groups across the range of energy settings from 100 nJ to 150 nJ, with an arbitrary cutoff of 115 nJ—set following the earlier observations regarding near-threshold energy level eyes—dividing the low energy SMILE group (L-SMILE) from the conventional energy

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SMILE group (C-SMILE). Within each of the two groups, the eyes were further subdivided into smaller groups of just under 20 eyes per energy setting across the inclusive ranges.

Clinically, there was faster visual rehabilitation on day 1 in the L-SMILE group, with the difference between the two groups lasting up to 1 week. The difference was also seen in terms of total higher order aberrations, spherical aberrations, and coma.

Correlations of postoperative outcomes and femtosecond laser energy for SMILE were significantly different at day 1 ($p<0.001$).

The dissection at near-threshold energy levels is not any different than at conventional energy levels.

Dr. Kang noted, however, that as every femtosecond laser is different the way every surgeon is different, it is critical for surgeons to find the optimal pulse energy and spot separation settings in their respective practices.

Optical zone

Analyzing 200 consecutive eyes, Dr. Kang found that increasing optical zone size does reduce total RMS. Zero induction of RMS is seen at an optical zone size of around 6.9 mm; however, he noted that this is not a foolproof way of preventing induced aberrations.

Moreover, optical zone has "nothing to do" with the induction of vertical coma.

Centration

Dr. Kang and his colleagues conducted a follow-up study comparing clinical outcomes and corneal aberrations between subjective centration and a triple marking centration technique for SMILE.[5] The triple marking technique uses two points on the horizontal meridian and a third inferior point aligned with the coaxially sighted corneal light reflex to locate the corneal vertex.

The retrospective, non-randomized observational case series looked at 191 eyes (191 patients). They found that subjective centration resulted in significantly greater decentration than triple centration (0.340 ± 0.189 mm vs. 0.191 ± 0.129 mm, respectively; $p<0.0001$), with greater induced total RMS (0.1157 ± 0.202 μm vs. 0.041 ± 0.178 μm, respectively; $p=0.0069$) and coma (0.106 ± 0.195 μm vs. 0.032 ± 0.207 μm, respectively; $p=0.012$). Only 48% of the subjective centration group had decentrations within 0.3 mm, compared to 82% in the triple centration group.

While visual outcomes were not significantly different, better predictability was seen with triple centration.

Most significantly, Dr. Kang's group found that greater decentration induces greater vertical coma, and better centration results in less vertical coma induction.

While their findings also indicate that there exists an inherent systematic intercept for the induction of vertical coma that needs to be addressed with more refined marking and centration techniques, vertical coma can, after all, be reduced in SMILE.

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OCT-based investigation of epithelial remodeling after SMILE vs. LASIK

Ik-Hee Ryu, MD, Seoul, South Korea

The last 3 years in what **Ik-Hee Ryu, MD**, Seoul, South Korea, called "the era of the third generation of laser refractive surgery" has seen the number of SMILE procedures performed in South Korea skyrocket—from 19,160 in 2014 to 43,100 in 2016. This, Dr. Ryu said, is due to the advantages in biomechanical stability provided by SMILE.

Dr. Ryu reiterated how SMILE retains the anterior cornea—the strongest portion of the cornea—by cutting the lenticule below it, whereas PRK ablates it and LASIK cuts into it to create a flap. Even if SMILE removes more tissue, he said, the procedure still leaves the cornea stronger than LASIK.

There are various modalities currently available to measure corneal biomechanics. Unfortunately, Dr. Ryu said, many are not reliable. From this perspective, he and his colleagues attempted to measure corneal biomechanics using Fourier domain ocular coherence tomography (FD-OCT).

They used FD-OCT to measure corneal epithelial thickness after SMILE and LASIK surgery. Corneal epithelial hyperplasia has been hypothesized to be caused by a thinned, biomechanically unstable cornea. Prior to their study, Dr. Ryu said that epithelial remodeling patterns following SMILE and LASIK had not been compared. However, since epithelial hyperplasia may also be a response to focal curvature changes, they also measure posterior corneal curvature.

In SMILE, they expected that the preservation of the anterior stroma would provide less disturbance to corneal biomechanics than in LASIK.

Comparing 175 myopic eyes (62 undergoing FS-LASIK, 113 undergoing SMILE), they found greater central corneal epithelial thickening 1 month after FS-LASIK (3.44 ± 2.89 μm) compared with SMILE (2.51 ± 2.36 μm) ($p=0.024$), increasing at 3 months (4.37 ± 2.75 μm vs. 2.97 ± 3.36 μm, respectively; $p=0.006$). On the other hand, mid-peripheral thickening was less in the FS-LASIK group than in the SMILE group at 1 month (2.10 ± 2.75 μm vs. 4.49 ± 2.52 μm, respectively; $p<0.001$), also increasing in both groups at 3 months (2.87 ± 2.44 μm vs. 4.86 ± 2.68 μm, respectively; $p<0.001$).

Meanwhile, K values from preop to postop 3 months remained relatively stable with SMILE (from –6.11 ± 0.25 to –6.11 ± 0.20, $p=0.018$), but steepened with FS-LASIK (from –6.15 ± 0.21 to –6.20 ± 0.20, $p=0.0007$).

In Dr. Ryu's study, they found that both SMILE and FS-LASIK surgery induced epithelial thickening postoperatively. However, epithelial remodeling seemed to stabilize faster following SMILE compared to FS-LASIK.

The cause of these apparent differences is unclear, but Dr. Ryu and his colleagues assume contribution from differences in corneal biomechanics. He concluded that the absence of the corneal flap in SMILE might affect corneal biomechanics and postop corneal remodeling differently than LASIK.