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Review on Centration, Astigmatic Axis Alignment, Pupil Size and Optical Zone in SMILE

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Abstract: The advent of "flapless" small-incision lenticule extraction (SMILE), employing all-in-one technology, has resulted in a revolutionary breakthrough in refractive surgeries. SMILE has been gaining popularity due to fewer potential complications, such as postoperative dry eyes and greater biomechanical stability, etc. However, attention must be given to 1) the centration on the corneal vertex, 2) the proper alignment of the astigmatic axis, and 3) the relationship between pupil size and treatment diameter, to achieve good SMILE results. There is no pupil-tracking system to ascertain the accuracy of centration during the SMILE surgery. To improve the centration accuracy, our center uses two corneal topographers (Pentacam and Sirius) to measure and determine corneal vertex. Proper predicted optical zone diameter is not clearly defined yet in SMILE. Some scholars insist that mesopic pupil size should be taken into consideration when setting the predicted optical zone. Meanwhile, the issue of "functional optical zone" still has many unresolved issues and warrants further studies.

Key Words: astigmatic axis alignment, centration, optical zone, pupil size, SMILE

(*Asia Pac J Ophthalmol (Phila)* 2019;8:385–390)

"Flapless" SMILE surgery has been widely performed in China as a result of its all-in-one technology and advantages of fewer potential complications, such as dry eyes, greater biomechanical stability, and less induction of higher-order aberrations (HOAs), when compared with femtosecond laser-assisted LASIK (FS-Lasik).[1–4] A single laser, femtosecond, used in SMILE, precisely creates a 3-dimensional lenticule, which is extracted through a small corneal incision. Studies have demonstrated that SMILE has promising efficacy, predictability, safety, stability, and patient comfortability.[1,2,5]

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Submitted June 28, 2019; accepted August 6, 2019.
The authors have no conflicts of interest to disclose.

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ISSN: 2162-0989
DOI: 10.1097/01.APO.0000580144.22353.46

However, SMILE still has some limitations, such as not having eye-tracking system. Centration during docking and suction depends mainly on the experience and skill of the surgeons, which are less adequate for beginning and inexperienced surgeons. As for the optimum treatment diameter in relationship to the mesopic or scotopic pupil size, there is no international benchmark yet. Moreover, the postoperative effective/functional optical zone is not clearly defined yet.

To achieve good visual outcomes after SMILE, we should address properly the issues of angle kappa, centration, and treatment diameter in relationship to the mesopic pupil diameter.

MAIN CENTRATION AXES IN CORNEAL REFRACTIVE SURGERY

The human eye, an optical system, comprises of 4 main noncoaxial optical elements (anterior and posterior surfaces of the cornea and lens), an aperture stop (pupil), and an imaging film called the retina. Each optical element has its own optical (axis containing the center of curvatures of the optical surfaces of the eye) and neural axes (axis of receptors and retinal neurons peaking at the foveola and declining monotonically with increasing eccentricity).[6–8] To achieve good postoperative outcomes especially the visual quality, several optical axes/points should be taken in consideration, including visual axis, pupillary axis, and corneal vertex (Fig. 1).

Visual axis is in line with the fixation target and the fovea of the retina.[6] Although the corneal intercept of the visual axis has been recommended as the ideal centration point for refractive surgery, it is difficult to precisely locate this point in practice. Pupillary axis is defined as the normal line to the corneal surface that passes through the center of the entrance pupil and the center of curvature of the anterior corneal surface, which could be observed from the reflected image of this source (when viewed from the microscope) centered on the entrance pupil. However, the pupil center is unstable because it shifts with pupil size under different light settings. The normal corneal vertex could be measured by corneal topography machines, with a Scheimpflug camera and/or a Placido system.[9,10] Corneal vertex, a stable reference of the cornea, has been recommended to be the central point of alignment for laser corneal refractive surgeries, because it has been proven to be closest to the corneal intercept of the visual axis.[7,11–13]

Decentered ablation/lenticule during refractive surgeries would give rise to undesirable side effects, such as halos, glare, monocular diplopia, and a reduction in visual acuity.[7,14] To achieve better results, the active eye-tracking systems were introduced to the Excimer laser machines long time back. However, SMILE machine has no active eye-tracking system. The risk

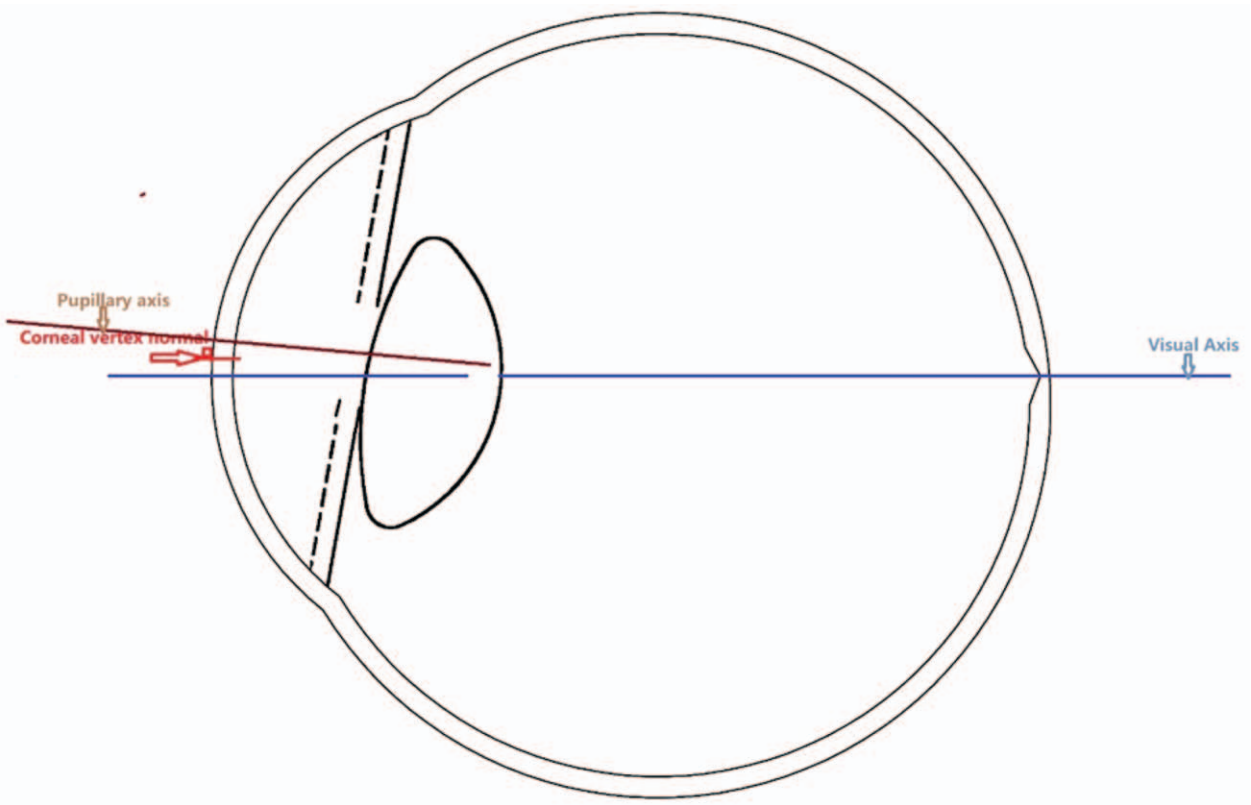

FIGURE 1. Schematic sketch of a selection of ocular axes. The axes are indicated by the following lines: solid brown (pupillary axis), dashed blue (visual axis), dark red (corneal vertex normal).

of decentration is higher in beginning or inexperienced SMILE surgeons.[15]

Previous studies have demonstrated that visual outcomes of SMILE procedure centered on corneal vertex were comparable when compared with FS-LASIK equipped with active eye tracking systems.[16] Moreover, our study also showed that the closer the center of the lenticule to the corneal vertex was, the better the refractive was.[12] The postoperative refractive outcomes would significantly decrease when the deviation of the center of the lenticule from the corneal vertex was >0.3 mm. When the decentration is significant, there would be more anterior corneal astigmatism, corneal coma, and total HOAs. There is also a positive correlation with the decentration distance. However, the lower-order astigmatic correction was not affected.[12] It is noteworthy that vertical decentration was observed more common among the lenticule decentrations, and postoperative induced HOAs, including vertical coma and spherical aberration occurred more frequently among the surgeons at their early learning stage.[10,11,17,18]

Ideally, surgeons should take angle kappa into consideration for the centration of the SMILE surgery. Angle kappa is the angle between the visual axis and the pupillary axis of the eye.[9] However, it takes experience for you to do that with ease and beginning surgeons are commonly advised to simply center at the pupil. Our previous study showed that when the value of angle kappa was within the range of 0.3 mm, the visual outcomes would not be affected no matter you took the corneal vertex or pupillary center as the treatment center.[12] Therefore, it would be important to measure angle kappa before the surgery. Another study concluded that patients with angle kappa of more than 0.6 mm should not have their lenticular center close to the pupillary center.[19] It would also be a good idea for beginning surgeons to avoid patients with large angle kappa.

In summary, the corneal vertex and/or the angle kappa data would help you locate the corneal intercept of the visual axis, which are recommended to be treatment or lenticular center. Studies to further correlate impacts brought by the amount of decentration outcomes, in terms of quality and quantity, are warranted.

CENTRATION METHOD DURING SMILE PROCEDURE

Precise centration of the laser treatment in SMILE surgery can never be overemphasized.[11,12,20–23] It consists of 2 parts: the center of lenticule on the corneal vertex and the proper alignment of the astigmatic axis.

To improve the accuracy of centration on the corneal vertex, several steps should be properly followed. In our center, the angle kappa values are represented by 2 corneal topographers (Pentacam and Sirius) independently. We then use the "centration map" (Fig. 2) which was invented by our team to help mark the corneal vertex coordinates. This map consists of 2 orthogonal coordinate axes (horizontal-x and vertical-y) and polar coordinates. In our centration map, the pupillary center is at the central point of the circular rings and the distance between 2 circular rings is 0.2 mm. The data obtained from the Pentacam and Sirius machines are plotted into the centration map. For example, the corneal vertex of the left eye of a patient lies on (x, y = 0.10, 0.16) (Pentacam) and on (0.16 @ 52 degree) (Sirius); the corneal vertex is located slightly inferonasally.

Second, during docking and before vacuum suction, the patient was asked to stare at the internal blinking green light of the VisuMax machine. The surgeon would be able to see the reflexed point of the corneal intercept (corneal vertex) directly (Fig. 3).

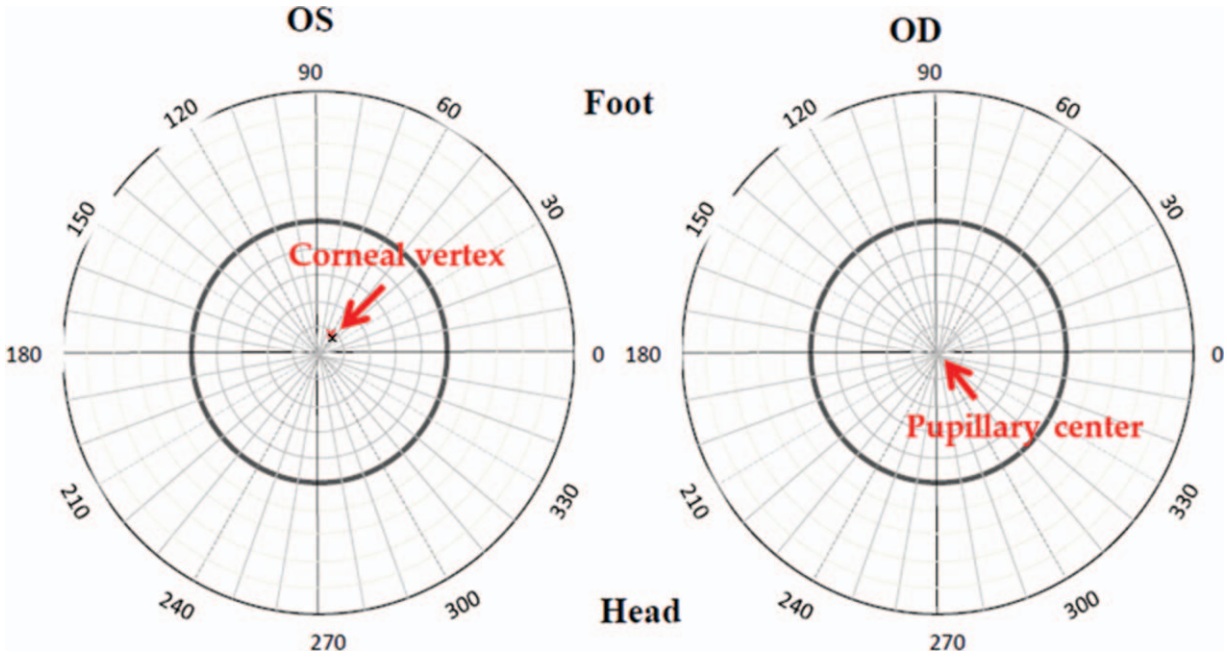

FIGURE 2. The ''Centration Map'': The central point of the map of defines the pupillary center; the ''X'' marks (measurements taken under photopic condition; red cross: Pentacam data; black cross: Sirius data) represent the locations of the corneal vertexes measured by Pentacam and Sirius respectively.

After the insertion of the eye speculum, the patient is asked to fixate at the green blinking internal fixating light, which is mounted coaxial with the femtosecond laser beam. The surgeon observes the eye through the microscope and moves the position of the operating table with a joystick. As the operating table moves upwards slowly, the surgeon should be able to see a light reflex (Fig. 3) representing the corneal vertex and a blurry pupil. The surgeon should aim at superimposing the light reflex on the corneal vertex location (shown in the centration map). When the cornea touches the cone of the machine, the light reflex disappears, but the pupil is more clearly seen and there is a "touch zone" produced by the contact between the cornea and the cone. The operating table is moved up further to increase the touch zone to 80%–90% of the cone size. It is important to keep the touch zone relatively concentric to the margins of the cone. The touch zone is expected to be circular and slightly oval in eyes without and with significant astigmatisms, respectively. Centration is accepted when the desired corneal vertex location (shown in the centration map) superimposes on the center of the "touch zone." Activation of the vacuum suction can then be made. The centration is double checked before laser application. If the centration is not satisfactory, simply release the suction and repeat the process of centration and suction activation. Laser application will only be proceeded after satisfactory centration is achieved (Fig. 4).

For eyes with astigmatism of $\geq$0.75 diopter (D), it is highly desirable to premark the astigmatic axis over the cornea because of the common phenomenon of eye cyclotorsion when one lies down in the supine position. The corneal marking is best done under the slit lamp where we can project a horizontal light beam between 0 and 180 degree (Fig. 5). A standard corneal marking pen is used to put up 2 tiny marks about 7 mm apart centering at

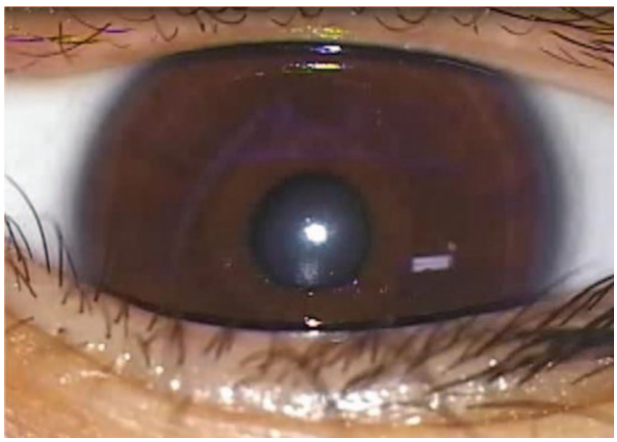

FIGURE 3. The surgeon can see through the operating microscope the light reflex located at the corneal intercept (corneal vertex) when the patient is starring and fixating at the green blinking internal fixating light of the VisuMax machine.

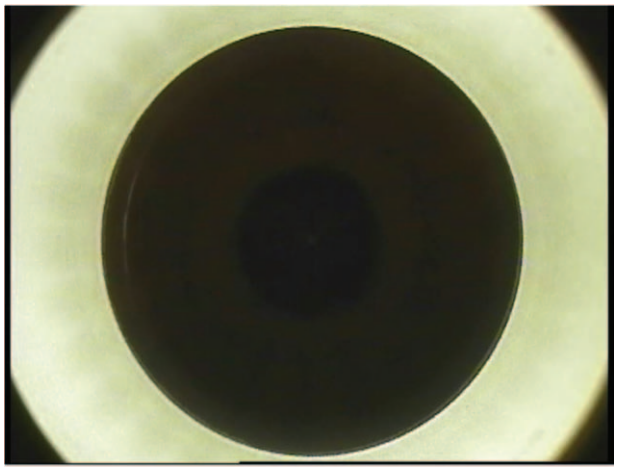

FIGURE 4. Photo showing what could be seen through the microscope of the VisuMax system during the docking procedure in SMILE.

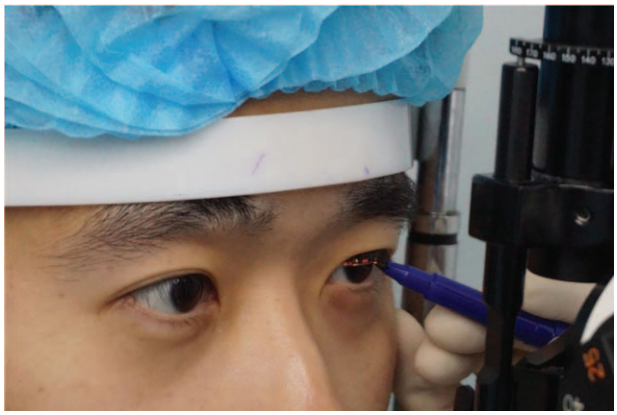

FIGURE 5. Using a horizontal slit beam to help mark accurately the cornea for eyes having astigmatism of ≥0.75D.

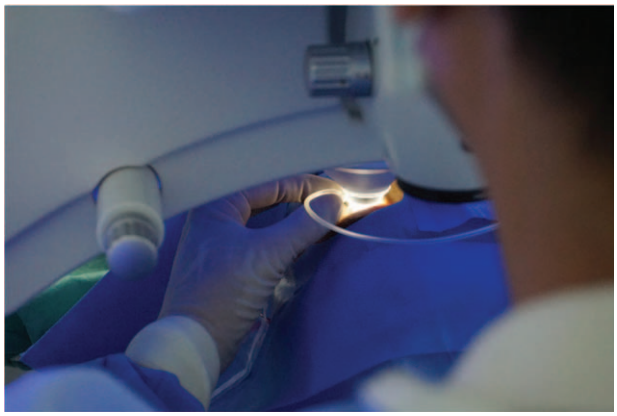

FIGURE 6. Manual manipulation of the cone to compensate for the cyclotorsion happened after the patient lying down in the supine position.

the pupil center. If it is too central, laser ablation will be affected; if it is too peripheral, the marks can be outside the touch zone and cannot be seen. Moreover, the marking is best to be done within 30 minutes before the surgery; otherwise, there may be significant fainting of the marks. The manual compensation of cyclotorsion during SMILE was recommended for astigmatism of ≥0.75 D (Figs. 6 and 7).[22]

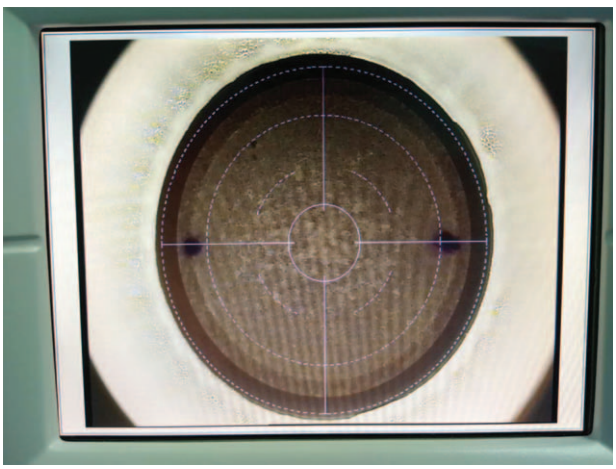

FIGURE 7. Photo showing a cyclotorsion of about 5 degree and adjustment of the cone is needed to make the horizontal marks on the eye in alignment with the horizontal axis of the reticule.

Pupil Size

Pupil size is measured and reported under different illumination conditions: scotopic (low light, < 0.05 lux), photopic (ambient light), and mesopic (between photopic and scotopic, between 0.05 and 50 lux).[24] Scotopic vision is where only the rod receptors are used for perception and vision is limited to approximately 20/200 and without color. Mesopic conditions imply that the light level is low enough for both rods and cones contributing to vision. Mesopic testing should technically be done in "dim light." Pupil diameter in dim environments has been reported to be within the range from 6.0 to 7.0 mm for patients aged 20 to 40 years.

Many devices are available for pupil size measurement. These include the Colvard pupillometer (Oasis Medical, Glendora, CA), video vision analyzer, Rosenbaum card, infrared Procyon pupillometer (Procyon Instruments, Ltd., London, United Kingdom), Sirius device, and others. Because of subjectivity, steep learning curve involved, and variability of results, and so on, no conclusion has been made regarding the best device for pupil size evaluation. Early in 1999, infrared pupillometry was compared with Rosenbaum pupillometry, and the authors found that infrared pupillometry was more accurate for pupil diameter measurement.[25] Infrared pupillometry (Fig. 8) and Sirius devices (Fig. 9) have been used in our team for evaluating photopic, mesopic, and scotopic pupil diameters. Consistent with the previous research, for most healthy eyes, the photopic pupil diameter ranges from 3 to 4 mm; the mesopic ranges from 4 to 6 mm; and the scotopic usually exceeds 6 mm.[26] However, even under the same illumination condition, the diameter of pupil varies among different devices. As such, it is difficult to establish a criterion standard for measuring the pupil diameter.

Optical Zone

The contribution of pupil size to the outcomes of corneal refractive surgeries has been a matter of much debate. Nevertheless, complaints of vision drop and visual quality in dim environments in patients after corneal refractive surgeries have been well reported and attention has been paid to the preoperative pupil diameters under different light conditions.

Some scholars insist that there was no correlation between the optical zone based on preoperative pupil size and visual complaints.[24] However, there was also a study which pointed

FIGURE 8. Infrared pupillometry.

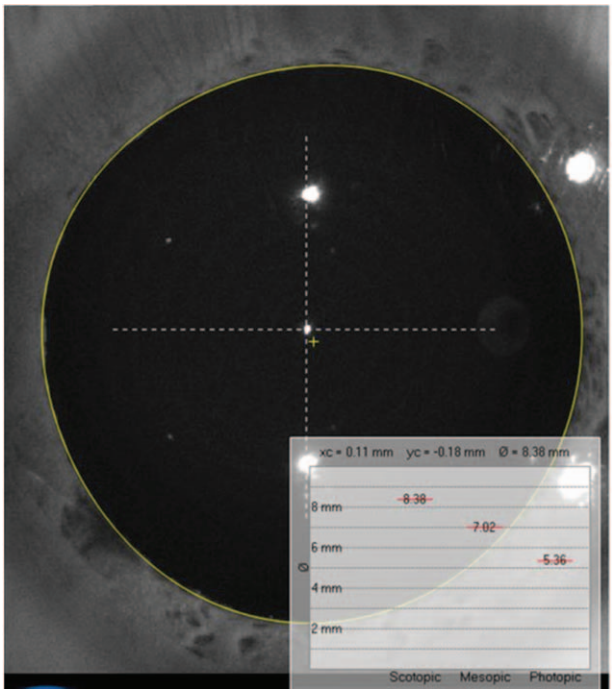

FIGURE 9. Pupillary diameter measured by Sirius.

out that optical treatment zone of >6.5 mm resulted in less induced HOAs than that of 6.0 mm after surgery under scotopic condition.[27] A subjective assessment of mesopic visual function demonstrated that the pupil size itself did not have direct relationship with glare after LASIK, and those who were with worsened glare complaints after surgery often had inborn large pupil size.[28] Generally speaking, human eyes have the optimal visual quality at the pupil diameter of 2 to 3 mm, and the visual quality is stable within the diameter of 4 mm. Along with the increase in pupil size, there is increase in corneal spherical aberration, followed by decrease in quality of retinal imaging. The theory about "pupil fraction" (the percentage of pupil area with good retinal imaging on the total pupil area) reveals that visual quality is based on the pupil area with excellent image quality. Therefore, more and more researchers tend to consider "effective/functional optical zone" as tenable theory.

Pentacam has been used to evaluate the "effective/functional optical zone," according to the refractive power errors between pre and postoperation. It has been demonstrated that the postoperative "effective/functional optical zone" is significantly larger in SMILE than that in FS-LASIK based on the same diameter of optical treatment zone.[29–32] However, it seems that the functional optical zone was not clear, even with the same predicted optical zone, during SMILE procedure.[30,32] Therefore, more studies are warranted on the issue of functional optical zone.

Theoretically, the amount of light from surrounding drop leads to pupil size enlargement; subsequently more abnormal HOAs were received by the retina and led to abnormal visual quality. If the optical zone is far less than the mesopic pupil size, postoperative poor visual quality would occur consequentially. Therefore, it is necessary to measure mesopic pupil size precisely before surgery.

Last but not least, in our recent study (unpublished data), we measured the mesopic pupil size with infrared pupillometry and found that when the mesopic pupil size was ≤7 mm, optical zone no less than mesopic pupil size could result in superior contrast sensitivity and less induced HOAs after SMILE; when mesopic pupil size was ≥7 mm and when optical zone is less than mesopic pupil size, there will be more induced HOAs; but when the difference was within 0.2 mm, the visual outcomes would not be affected.

CONCLUSIONS

Centration and pupil size should be properly evaluated and taken into full consideration before the SMILE surgery. Centering on the corneal vertex and the proper alignment of the astigmatic axis are important during the SMILE surgery. With regard to the mini-mum treatment diameter in relationship to pupil size and the issue of functional optical zone, there are still controversies. Further studies are warranted.

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