

Astigmatism Correction Using SMILE

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Abstract: Small incision lenticule extraction (SMILE) was introduced in the recent decade for the treatment of myopia and myopic astigmatism. This flap-free technique has a high efficacy and safety profile and also carries potential advantages over laser in situ keratomileusis such as a better corneal biomechanical stability, reduction in dry eyes rate, and the avoidance of flap complications. However, there have been concerns regarding the precision of astigmatism correction that undercorrection has been reported to be apparent. Various factors that affect astigmatism correction have been identified in the literature. The purpose of this review is to discuss the factors that affect astigmatism correction in SMILE and several techniques to improve the refractive outcomes.

Key Words: astigmatism, lenticule extraction, myopia, SMILE

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BACKGROUND

Small incision lenticule extraction (SMILE) was first introduced in 2011, mainly for the treatment of myopia and myopic astigmatism.¹ This flap-free technique was approved by the US Food and Drug Administration (FDA) in 2016 for treating myopic refractive error of -1.00 to -8.00 diopters (D). Regarding astigmatism correction, the precision in refractive outcome has raised several concerns. In SMILE, with the application of femtosecond laser, an intrastromal lenticule is created and removed through a small incision. It preserves most corneal nerve fibers and theoretically has a better corneal biomechanical strength, which leads to a reduced incidence of postoperative dry eyes and possible corneal ectasia.^{2–8} Comparing with laser in-situ keratomileusis (LASIK), SMILE has also been shown to have a high efficacy and safety profile in the correction of myopia and astigmatism.^{9,10} Additionally, SMILE seems to have less postoperative halo and glare in eyes with a larger pupil. This could be

because of its more uniform corneal refractive power, leading to fewer changes in corneal higher order aberrations.⁶ Last year, SMILE was approved by the FDA for the treatment of myopic astigmatism up to 3.00 D. However, astigmatism correction remains a challenge in SMILE, especially for surgeons new to the technique. The purpose of this review is to discuss the factors that affect astigmatism correction in SMILE and to discuss techniques to improve refractive outcomes.

FACTORS AFFECTING ASTIGMATISM CORRECTION USING SMILE

Undercorrection

Although SMILE shows high efficacy, safety, and predictability,^{11–13} there has been a clear tendency toward undercorrection when treating astigmatism,^{14–16} in which the greater the preoperative astigmatism, the higher the degree of undercorrection,^{14,17–19} which also leads to a higher rate of retreatment.¹⁵ Pedersen et al¹⁴ reported astigmatic undercorrection to be approximately 11%. Ivarsen et al¹⁵ reported a 13% per diopter undercorrection in a low astigmatism correction attempt, and a 16% per diopter undercorrection in a high astigmatism correction attempt after SMILE. There have been suggestions in the adjustment of current treatment nomograms to a 10% increment in the magnitude of astigmatism correction.^{14,20} Currently, there are no standardized nomograms for astigmatism correction.

When comparing SMILE with LASIK, studies using vector analysis showed that SMILE has slightly worse results in correcting low-to-moderate astigmatism.^{17–19} As for correction of high astigmatism (>3.00 D), a recent study showed comparable results between SMILE and LASIK.²¹ Undercorrection was noted in both SMILE and LASIK for high astigmatism correction, but better outcome was noted in LASIK for low-to-moderate astigmatism correction.^{22,23}

Cyclotorsion

Undercorrection can be attributable to the lack of cyclotorsion control, which has been a major issue in astigmatism correction. Causes of cyclotorsion include ocular torsion caused by the vestibular system, movement of the head and body under laser, and unmasking of cyclophoria.²⁰ As high as 82% of patients are expected to have cyclotorsion when they lie flat, which has been reported as the main contributing factor to postoperative undercorrection.²⁴ Cyclotorsion can be static or dynamic; this change in eye rotation induces misalignment and can lead to inaccuracy in treatment orientations. Static cyclotorsion occurs when a patient changes from an upright position to a supine one. Dynamic cyclotorsion occurs when there is a torsional eye

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movement during laser application intraoperatively. The effect of dynamic cyclotorsion is expected to be minimal because the eye is fixed by the treatment cone during laser application in SMILE. Cyclotorsion has been reported to be the main reason for suboptimal visual outcomes in the correction of myopic astigmatism with SMILE, an error of only a few degrees can already lead to undercorrection.^{25,26} Ganesh et al²⁴ reported that up to 20% of eyes showed a cyclotorsion of >5 degrees. Chernyak et al²⁷ reported cyclotorsion to be as high as 9.5 degrees when patient adopts a supine position. It has been reported that during refractive surgery, 38% of eyes rotate >5 degrees in static cyclotorsion, and as many as 68% of eyes rotate >2 degrees in both static and dynamic cyclotorsion.²⁸ Hori-Komai et al²⁹ reported a cyclotorsion of 4 degrees will lead to 14% under correction, whereas a cyclotorsion of 6 degrees will result in 20% under correction, and a 10 degrees cyclotorsion will result in 35% undercorrection in astigmatism after LASIK. Hence, cyclotorsion should be compensated in astigmatism correction, as correct axis alignment is crucial in achieving accurate outcome.

To compensate for cyclotorsion, manual compensation was suggested during SMILE. Preoperatively, limbal marks at 0 and 180 degree can be made while patient is sitting in an upright position. Upon supine positioning, the limbal markings can serve as a guide to detect any cyclotorsion. Head adjustment can be performed according to the alignment between the limbal markings and reticule on the screen of the SMILE platform. Some surgeons prefer to rotate the treatment cone after docking. In this technique, corneal markings are needed to enable visualization of the markings and cyclotorsion compensation is done by gentle rotation of the contact glass. A recent study evaluated manual cyclotorsion compensation by preoperative corneal marking and rotation of the treatment cone. The study evaluated high cylinder group of a mean preoperative cylinder of -2.48 D, with manual cyclotorsion compensation; the postoperative cylinder at 3 months was -0.31 D and the correction index was 0.93.²⁴ However, manual compensation can lead to inaccuracy in aligning the markings and the reticule of the platform. To improve so, a triple centration technique suggested by Jun et al³⁰ can be adopted. Before surgery, with the patient in a sitting position and fixating onto the slit lamp beam, 3 centration points can be marked at the cornea. Two markings should be marked at the horizontal meridian 7 mm apart, bisecting the first Purkinje reflex or the coaxially sighted corneal light reflex. A third marking can be marked at the inferior cornea by vertically rotating the slit lamp beam to a point which bisects the first Purkinje reflex or the coaxially sighted corneal light reflex. The triple centration technique was shown to be effective and it provided predictable outcomes for the correction of high myopic astigmatism.³⁰ So far, there is no standard protocol to address such problem and technological improvement of the laser platform should be expected. A recent study suggested manual correction to be done for any astigmatic correction >0.75 D.²⁴ Manual cyclotorsional compensation should be seriously taken into account when treating astigmatism.

Center of Optical Zone

Achieving accurate centration is of great importance in laser refractive surgeries. The potential limitation of SMILE is its dependence on centration by the surgeon during docking. This could increase the risk of decentered treatment and lead to unfavorable visual outcome. Currently, there is no standardized method

to determine the center of the optical zone. Center of the optical zone is highly dependent on the surgeon's preference, which can be mainly done by using the pupil center (PC) or the corneal vertex normal (CVN). The PC has the benefit of being easy to interpret; however, it has potential limitations owing to unstable movements in the fluctuation of pupil size throughout the surgery, which can be affected by the change in luminance in the environment.³¹ The CVN is the light reflection on the anterior corneal surface, which is closest to the corneal intercept of the visual axis.³² Although the ideal centration reference is still being debated, studies have found that CVN is a better choice of reference for optic zone centration for SMILE as compared with PC.³³⁻³⁵

Angle Kappa

Angle kappa is the angle between the visual axis and the pupillary axis. The measurement is important in refractive surgery, as it affects proper centration.³⁶ In optical zone centration, centration using the PC has been widely adopted; this is mainly because of the ease in centration with visible pupil structures. However, the pupillary axis is different from the visual axis. The pupillary axis is the line passing through the PC perpendicular to the cornea. The visual axis is the line connecting the fovea with the fixation point; this line passes through the nodal point of the eye and is purely a theoretical concept that cannot be visualized. Angle kappa has been reported to be larger in hypermetropes compared with myopic eyes. Therefore, adjusting laser centration for angle kappa is actually more important in eyes with hyperopia.³⁷ However, the centration on the PC will create new aberrations in myopic astigmatism cases with a large angle kappa, which is a large misalignment between the PC and the visual axis. This will lead to decentered ablation and will induce symptoms of halo and glare.³⁸ A recent study evaluated intraoperative decenteration from PC and kappa intercept during SMILE, concluding that a decenteration of 0.13 mm from the PC would not cause any effect but a decenteration >0.6 mm from the kappa intercept was found to compromise visual outcomes.³⁹ The study also suggested patients with a large kappa intercept (>0.6 mm) should have their lenticule created 0.4 to 0.6 mm from the kappa intercept and not close to the pupil. For SMILE, patients with a large angle kappa carry a high chance of decenteration, and these cases might have to be excluded when considering treatment. Sometimes, adjustment of the treatment location can be made to compensate for any large angle kappa, which can be done based on the locations of the visual axis and the PC obtained from preoperative topography.

Anterior Corneal Curvature

In SMILE, a contact glass is used for docking before suction and laser application. This calibrated curved surface of the contact glass was designed to best fit the anterior corneal curvature to lessen mechanical corneal compression and to minimize ocular irritation. Although different sizes are available for different corneal diameters, the curvature of the contact glass remains constant. Hence, the anterior corneal curvature actually conforms to the concave contact glass surface during suction. In astigmatism correction with SMILE, the lenticule created has a different posterior surface when compared with those in myopic correction. In astigmatism correction, the lenticule has an oval posterior surface; however, in myopic correction, the lenticule was created in a concentric shape. This oval posterior surface results in a smaller diameter of the cleavage plane along its steep axis than its

flat axis.⁴⁰ A recent study reported that the magnitude of optical zone decentration was associated with keratometric astigmatism, in which the higher the anterior keratometric astigmatism, the larger the discrepancy between the 2 meridional curvatures and a greater treatment decentration was observed.⁴¹ The reason can be a mismatched contact surface between an astigmatic cornea and the posterior surface of the contact glass; another reason is due to the difference in the cleavage plane on the oval posterior surface. The study concluded that anterior cornea astigmatism affected the treatment centration in SMILE, but this was not observed in LASIK.⁴¹ Hence, special attention should be taken when a high anterior corneal curvature was observed.

Patient Positioning

Despite cyclotorsion being a major contributing factor to postoperative under correction, preoperative postural misalignment was also noted to be a key factor. Prickett et al⁴² reported most of the rotations previously attributed to torsional components were probably because of noncyclotorsional components such as postural misalignments. Meticulous patient positioning to avoid head tilting is necessary. A recent study reported that stringent patient positioning in order to avoid head rotation could improve results of astigmatism correction with SMILE.²¹ Hence, meticulous patient positioning should be done preoperatively to minimize any chance of misalignment.

Ocular Residual Astigmatism

Ocular residual astigmatism (ORA) refers to astigmatism not attributable to anterior corneal surface.⁴³ Although the anterior cornea surface contributes significantly to manifest astigmatism, the posterior corneal surface and the crystalline lens also play a part in it and these are termed as the ORA. A recent study evaluated the influence of the ORA on the correction of astigmatism in SMILE, demonstrating that a higher ORA would lead to a higher postoperative manifest astigmatism.⁴⁴ Similar results on ORA were also reported in LASIK astigmatism correction.^{45–47} These findings stress the importance in the consideration of ORA before performing SMILE rather than just taking into account the astigmatism by anterior corneal curvature. Chan et al⁴⁸ suggested the use of vector planning in high ORA cases. Vector planning integrates topography parameters into the surgical planning to improve refractive outcomes in astigmatism correction. Vector planning has been shown to reduce corneal toricity and postoperative ORA.⁴⁹ Hence, preoperative ORA calculation can be performed in astigmatism correction with SMILE; vector planning should also be considered in high ORA cases.

Location of Opening Incision

The effect of the location of opening incision in SMILE was also thought to be of concern in astigmatic correction. A recent study compared the effect of the location of opening incision on astigmatic correction in SMILE with temporal incision done in one eye and identical procedure except for superior incision done in the fellow eye.⁵⁰ The study reported no significant effect on the location of opening incision in astigmatic correction. Hence, the location of the opening incision does not affect the degree of correction.

With-the-rule or Against-the-rule Astigmatism

Limited studies have discussed the effect of the preoperative axis on the outcome of astigmatism correction using SMILE. In

cases presenting for refractive error correction, majority of them are with-the-rule (WTR) astigmatism; this is probably because of the relatively younger age of the population.⁵¹ A recent study using vector analysis concluded that almost 25% of the variation after SMILE for myopic astigmatism might be explained by the size of the attempted correction and the axis of the astigmatism, where SMILE induced 0.35 D less undercorrection in against-the-rule (ATR) than in WTR astigmatism.⁵² The study also suggested an intended overcorrection of up to 0.125 D per diopter of attempted cylinder correction and a constant 0.25 D undercorrection in ATR astigmatism, irrespective of the attempted cylinder correction.⁵²

Lenticule Extraction

The method of lenticule extraction and the completeness of the lenticule extracted may also affect the refractive outcome. The conventional method of lenticule extraction is by forceps removal; recently, new surgical techniques such as hydroexpression have been discussed. A recent study compared the new hydroexpression technique with conventional forceps method for SMILE lenticule extraction; the study concluded that hydroexpression is a simple and safe technique with comparable refractive accuracy as conventional forceps technique and hydroexpression are particularly useful in cases with more adhesions between the lenticule and anterior cap and for beginner SMILE surgeons.⁵³ In addition, the completeness of the lenticule extracted has also been reported to affect the refractive outcome. Retained lenticule can cause postoperative suboptimal visual acuity and refractive surprise with irregular astigmatism.⁵⁴ Ng et al reported 4 cases of residual intrastromal lenticule; irregularities in the corneal curvature and elevation were shown with corneal topography and tomography.⁵⁵ Early secondary lenticular remnant removal was done, which showed improvement in visual acuity and refraction. Complete lenticule removal and careful inspection of the extracted lenticule for completeness are essential in achieving accurate refractive outcome.

Learning Curve

The learning curve of SMILE can be challenging; lenticule dissection and extraction were noted to be the most difficult steps, and decentration can also occur from initial decentration or from involuntary eye movements during treatment.⁵⁶ A recent study reported a faster visual recovery, better safety profile with increased surgical experience.⁵⁷ The study also reported that eyes receiving astigmatic correction had better astigmatic outcome during the later phase of the learning curve. A hypothesis was the reduction in additional maneuvers such as suction cap position adjustment during docking, back and forth movement of the dissecting spatula, and repeated grasping attempts of the dissected lenticule along the learning curve, which all these could affect treatment position and centration.⁵⁷ However, a recent study suggested that in the early phase of the learning curve of SMILE, surgeons could achieve accurate centration and good visual quality.⁵⁸ This provides a promising result for SMILE especially in the treatment of astigmatism, wherein centration is particularly crucial.

SURGICAL PEARLS IN ASTIGMATISM CORRECTION USING SMILE

Preoperative Planning

The amount of cylinder correction, the angle kappa, and the ORA should be considered in the planning of SMILE surgery,

which should be discussed while the patient's expectations should be managed. In cases of high cylinder correction (>3.00 D) and a large angle kappa, a higher chance of undercorrection should be expected. In cases of high ORA, vector planning integrating topography parameters can be performed.

Preoperative Marking

While the patient is sitting in an upright position limbal markings should be done at 0 and 180 degrees.

Meticulous Positioning

The patient's posture should be meticulously positioned to avoid swinging of the body and head tilting before docking. After that, the horizontal axis of the laser treatment should be aligned with the limbal markings. Head rotation should be performed if misalignment is noted with >5 degrees.

Docking

During docking the patient will be instructed to fixate onto the green fixating light while a contact glass will be placed over the cornea. The visual axis should be exactly in the center of the contact glass, and the reflex of the ring-shaped treatment illumination should also be in the center. The relative positions of visual axis and PC (angle kappa) should match the respective positions obtained from the preoperative topography during docking. Once the contact glass touches the cornea, the fixating light will be well focused and clearly visible to the patient. Fine adjustment can be made when the cornea is in contact with the glasses of the suction cone to compensate for any decentration of the optical zone. Once centered, suction will then be applied.

Application of Femtosecond Laser

Once suction is applied, it is advisable to start the laser procedure immediately. It is important to let the patient know that there might be changes in the green fixation light intensity and its location during laser application. The patient should be reassured and constantly reminded to keep looking straight ahead to maintain stability of the eyes.

Lenticule Extraction

Lastly, it is important to ensure smooth dissection and complete lenticule extraction. To ensure smooth dissection, entering the cap side cut with a Sinsky hook and care should be taken to delineate the anterior and posterior lamellar plane. The anterior corneal layer will then be separated from the anterior surface of the lenticule followed by the posterior layer. The lenticule can be extracted through the side cut incision with microforceps or hydroexpression. To ensure complete lenticule extraction, careful inspection is needed to ensure completeness of the cap and lenticule cut.

Enhancement

In cases of undercorrection, enhancement can be performed. The incidence of postSMILE enhancement is reported to be between 2.2% and 2.9% with risk factors including older age, greater preoperative myopia, greater preoperative astigmatism, and the occurrence of intraoperative suction loss.^{59,60} Options for retreatment include surface ablation, thin-flap LASIK, and subcap lenticule extraction.^{60–63} Enhancement using surface ablation techniques such as photorefractive keratectomy over the treatment zone is commonly used.⁵⁹ Although surface ablation seems

to be safe and efficacious, it carries the risk of corneal haze and postoperative pain, and has a longer recovery time.⁶⁰ However, subcap lenticule extraction can be difficult and results on this approach are currently limited. Recently, conversion of the SMILE cap into a full flap using the CIRCLE approach, followed by excimer ablation, seems to be a reasonable alternative for enhancement.⁶⁴ CIRCLE enhancement is first done by cutting a lamellar ring around the original cap at the same depth as the primary cap. Then, a flap side cut is created around the new incision plane leaving behind an uncut area forming the hinge of the flap. Finally, another cut parallel to the side cut is created to form a connection between the planes of the primary cap and the lamellar ring to create one large connected plane. It has been shown that CIRCLE enhancement is a safe and effective treatment for undercorrection; results are also comparable to surface ablation retreatment.⁶⁵ Recently, the first study comparing surface ablation and CIRCLE enhancement was published. The study concluded that both methods yielded comparable results; however, CIRCLE enhancement showed a markedly increased speed of recovery postoperatively.⁶⁶ Currently, regarding undercorrection, there are various surgical methods in SMILE enhancement; more large-scale long-term studies will be needed to determine its superiority.

CONCLUSIONS

SMILE has a high efficacy, stability, predictability, and a high safety profile in the correction of astigmatism. When comparing SMILE with LASIK, SMILE was found to be slightly inferior and more undercorrection would be caused when treating low-to-moderate astigmatism, but it was found to be comparable with similar rate of undercorrection when treating high astigmatism. The need for careful preoperative planning, cyclotorsional compensation, meticulous positioning of the patient and its treatment zone, and complete extraction of lenticule are essential in obtaining good treatment outcomes. The ability to allow for adjustment of treatment zone after docking under suction could be beneficial to the fine-tuning of the treatment centration. Advances in technology regarding centration with axial and torsional registration should significantly improve the accuracy of astigmatic correction.

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