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Comparison of Small Incision Lenticule Extraction Surgery With and Without Cyclotorsion Error Correction for Patients With Astigmatism

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Purpose: To evaluate the add-on effect of manual cyclotorsion error correction by the cornea-marking method over standard small incision lenticule extraction (SMILE) surgery in astigmatic eyes.

Methods: Consecutive patients (84) who had preoperative myopic astigmatism of −0.75 diopters (D) or more and were seeking surgical refractive correction by SMILE surgery during July 2017 to August 2017 were included in this study and randomized to treatment with standard SMILE surgery (S group: 30 eyes) or cyclotorsion compensated SMILE surgery (CC group: 54 eyes). The visual acuity and refractive outcomes were analyzed preoperatively and postoperatively. Refractive astigmatic changes were analyzed by the Alpins method.

Results: The S and CC groups were comparable preoperatively regarding age, manifest spherical equivalent, and manifest refractive cylinder. The mean position-related cyclotorsion degree in the enrolled astigmatic eyes for the S and CC groups was 1.7 ± 2.2 degrees (ranging from 0 to 10 degrees) and 2.19 ± 1.74 degrees (ranging from 0 to 10 degrees), respectively. The mean cylinder was −1.67 ± 0.54 D versus −1.72 ± 0.71 D preoperatively. Six months after treatment, the surgical outcomes in the CC group were significantly better than those of the S group, with a postoperative corrected distance visual acuity of −0.07 ± 0.07 versus 0.016 ± 0.13. A vector analysis of astigmatism also yielded better outcomes in the CC group. However, these 2 groups were statistically similar in spherical equivalent.

Conclusions: SMILE surgery combined with cyclotorsion error compensation yielded a significant improvement in surgical outcomes regarding safety, efficiency, and predictability for patients with astigmatism.

Key Words: small incision lenticule extraction surgery, astigmatism, cyclotorsion error correction, cornea marking, axis alignment, cyclotorsion

(*Cornea* 2019;38:723–729)

Position-related cyclotorsion, which occurs during a change from an upright seated position to a supine position, is a normal physical phenomenon that exists in a large proportion of the population.[1,2] Accordingly, when astigmatic patients seek surgical refractive correction this is the main reason for axial misalignment during surgery, leading to suboptimal postoperative visual acuity (VA) and refractive outcomes.[3–5] Studies have shown that when eye cyclotorsion is greater than 2 degrees and not compensated, cylinder correction might be adversely influenced and significant aberrations can be induced during laser treatment, especially in patients with high astigmatism.[6–8] Currently, with the rapid development of refractive surgical technology, personally designed laser platform surgery equipped with pupil-tracking or iris-registration software allows for more precise, safe, and predictable corneal ablation in refractive correction than ever before. However, no acknowledged method of cyclotorsion compensation exists for the VisuMax femtosecond laser system (Carl Zeiss Meditec, Jena, Germany).[8–10] Previous studies have demonstrated that in patients with astigmatism, especially in those with a cylinder greater than −1.25 diopters (D), personalized laser in situ keratomileusis (LASIK) surgery produces superior astigmatism correction as compared with standard small incision lenticule extraction (SMILE).[11] Thus, how to manage the compensation of position-related cyclotorsion error for precise axial alignment in astigmatic patient is still unclear to refractive surgeons.

Before the advent of advanced eye-tracking software, manual cornea marking was used by surgeons for accurate axis alignment, precise cylinder correction, and better visual outcomes in patients with astigmatism who underwent LASIK surgery.[12] Numerous clinical evidence demonstrated that using cornea marks as references for the compensation of position-related cyclotorsion could improve the refractive outcomes of photoastigmatic refractive keratectomy.[12,13] Moreover, when compared with an automatic iris-registration

Received for publication September 29, 2018; revision received February 1, 2019; accepted February 8, 2019. Published online ahead of print April 5, 2019.

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National Natural Science Foundation of China (Grant No.81470626 & 81670848).
The authors have no conflicts of interest to disclose

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tracker, manual cornea marking showed equal effectiveness and safety in LASIK for the correction of myopic astigmatism.[12] Recently, the Food and Drug Administration (FDA) approved the use of Zeiss SMILE for patients with myopia with astigmatism. This approval not only provides an incredible opportunity for patients with compound myopic astigmatism to benefit from SMILE but also brings significant challenges to refractive surgeons. Hence, in this present study, we sought to investigate the efficacy, predictability, and safety of manual cornea marking in SMILE surgery for cyclotorsion error correction by comparison with standard SMILE surgery.

METHODS

Patient Recruitment

This study included 84 eyes from 84 patients diagnosed with myopia with regular astigmatism of 0.75 D or more that required refractive correction by SMILE surgery between July 2017 and August 2017 at the Zhong Shan Ophthalmic Center. The inclusion criteria for this study were myopia of less than −10.00 D with refractive astigmatism of −0.75 D or more, age 20 to 30 years, and stable refraction for at least 1 year. The exclusion criteria were the presence of systemic diseases and severe ocular diseases and a history of intraocular or corneal surgery. The study was approved by the National Ethics Committee and was in accordance with the Declaration of Helsinki (#2017KYPJ087) of the World Medical Association. All subjects signed a written informed consent and were made aware of the study procedure.

Patient Examinations

All subjects underwent a thorough preoperative screening by an experienced ophthalmologist using slit-lamp and funduscopic examinations. Corneal topography, intraocular pressure, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest and cycloplegic refraction were evaluated preoperatively and at 1 day, 1 month, and 6 months postoperatively. The UDVA and CDVA were evaluated by using decimal Snellen and converted to the logarithm of the minimum angle of resolution units using the Holladay method for statistical analysis. Astigmatism was analyzed using the vector method of Alpins.[14]

Surgical Procedure

Levofloxacin was prescribed for each patient 3 days preoperatively, the topical anesthetic Alcaine (Alcon) was applied half an hour preoperatively, and Tobradex was administered 4 times daily for 2 weeks postoperatively. The VisuMax femtosecond laser system (Carl Zeiss, Germany) with a 500 kHz repetition rate was used for refractive correction in all cases, and the target postoperative refractive error is 0.

For Standard SMILE Surgery (S Group)

A small curved interface cone was used and the laser was visually centered on the pupil. After vacuum aspiration was completed, femtosecond incisions were performed using the following parameters: 120 μm flap thickness, 7 to 6.5 mm lenticule diameter and 1.0 mm larger flap diameter, 120 nJ power for lenticule and flap, and a 3-side cut angle of 90 degrees at a circumferential width of 2.0 mm. The minimum residual stromal bed thickness was 280 μm. The cutting cornea depth was based on the manifest refractive error of the patient with VisuMax laser software. They released the suction plate, then afterward dissected the lenticule with a thin spatula and removed it with a serrated McPherson forcep.

For CC SMILE Surgery (CC: Group)

All refractive correction surgical procedures and the cornea marking were performed by K.Y. (the corresponding author), and the surgical procedure was accomplished by using the VisuMax femtosecond laser system (Zeiss, Germany). The cornea reference points were marked on the optical zone of the cornea (7 mm apart at the horizontal meridian) of each eye while the patient was seated upright to identify the axis crossing the pupil center (Fig. 1A); the rotational degree was determined with the patient in the supine position before laser treatment (Fig. 1B), and then the surgical design was modified accordingly. First, the mandible support of the slit-lamp was adjusted to be horizontal to the floor. After the patient was positioned, the light beam was narrowed and the patient was instructed to

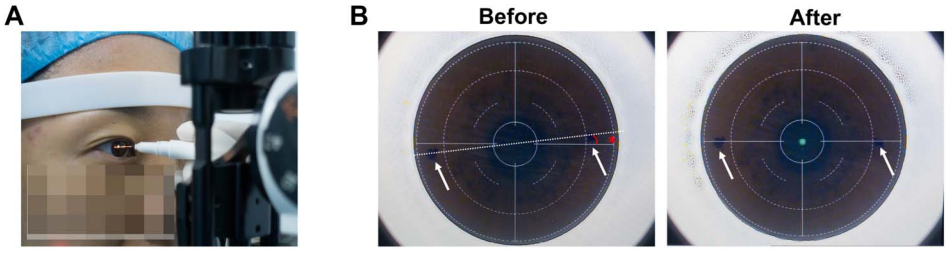


FIGURE 1. Surgical schematic of SMILE surgery with cyclotorsion error correction. A, K.Y. performed cornea marking to identify the axis crossing the pupil center for a patient positioned supine on the operating table. B, The axis misalignment between sitting and supine position. C, The rotation degrees were modified during surgery. White arrows point at the reference points. Red asterisks represent cyclorotation degree. Dotted lines represent the line drawn between the 2 cornea marks.

look straight ahead. Second, the light band was moved to the cornea, crossing the pupil center, and 2 cornea marks were used to identify the horizontal axial line at the 3 and 9 o'clock positions with a sterilized skin marker. Third, after completion of vacuum aspiration, the rotation degree was determined with the laser beam astigmatic meridian (ridicule on the screen of the VisuMax) and the reference points on the cornea when the patient laid down on the operation table (Fig. 1B). Then, the cyclotorsion degree was adjusted by slightly rotating the pressure suction plate so that the laser beam astigmatic meridian overlapped with the cornea reference points. Meanwhile, the patients in the control groups received standard SMILE surgery.

Statistical Analysis

All values are presented as the mean ± SD. The surgical outcomes between the S and CC groups were evaluated using the analysis of variance test with the least significant difference multiple comparison test by SPSS Statistics 19 (SPSS Inc, Chicago, IL). A P value less than 0.05 was considered statistically significant.

RESULTS

Patient Basic Information

This study was conducted between July 2017 and December 2017 at the Zhong Shan Ophthalmic Center, Sun Yat-sen University. A total of 84 eyes from 84 patients with astigmatic myopia (cylinder: >-0.75 D) seeking refractive correction by SMILE surgery were included in this study to explore the effectiveness and safety of cornea marking for the compensation of position-related cyclotorsion error. Before surgery, the UDVA of all eyes was under 1.0 and the CDVA was 1.20 ± 0.23. As shown in Table 1, the 2 groups (S and CC group) were comparable preoperatively regarding age, manifest spherical equivalent (SE), and manifest refractive cylinder, with no significant differences. The average cornea central thickness and the intraocular pressure were in the normal range and suited for refractive surgery.

Operative Information and Surgical Outcomes

Successful surgical correction was achieved in all eyes, and no significant complications occurred either during the surgery or in the follow-up period. Over 6 months of follow-ups, none of the patients required a second surgical procedure or prolonged medication treatment.

As shown in Table 1, the average position-related cyclotorsion degree (absolution) was 1.77 ± 2.2 degrees (ranging from 0 to 10 degrees) and 2.19 ± 1.74 degrees (ranging from 0 to 10 degrees) in the S and CC groups, respectively, ($P = 0.26$).

VA in the S and CC Groups

The UDVA improved in all enrolled eyes after SMILE surgery, with or without cyclotorsion error compensation. The UDVA and CDVA are presented in Tables 1 and 2. In the CC group, the logarithm of the minimum angle of resolution UDVA was improved from 0.17 ± 0.17 preoperatively to −0.04 ± 0.09 postoperatively. By 6 months postoperative, the UDVA of 94.6% of astigmatism eyes was within 1 line of preoperative CDVA, with only 3 eyes that did not obtain the desired UDVA (20/20). There was no significant difference between the preoperative CDVA and 6-month postoperative UDVA (−0.079 ± 0.064 vs. −0.07 ± 0.07, $P = 0.19$). Meanwhile, in the S group, although the standard SMILE surgery significantly improved UDVA, the VA outcomes were worse than those in the CC group. By 6 months postsurgery, 10 of 30 eyes (33.3%) did not obtain the desired

TABLE 1. Preoperative Demographics of the Patients With Astigmatism

	Mean ± SD		
Characteristic	**Standard Group**	**Cyclotorsion Compensated Group**	***P***
Patients	30	54	
Number	30 eyes	54 eyes	
Sex	13 males and 17 females	23 males and 31 females	
Age (yr)	23.5 ± 4.3 yrs	20–30 yrs	0.34
Range	24.2 ± 2.6 yrs	20–30 yrs	
Manifest SE (D)	−7.2 ± 2.2 D	−6.29 ± 1.97 D	0.09
Range	From −1.5 to −11 D	From −1.75 to −10 D	
Manifest refractive cylinder (D)	−1.67 ± 0.54 D	−1.72 ± 0.71 D	0.41
Range	From −0.75 to −4 D	From −0.75 to −4 D	
Snellen CDVA	1.22 ± 0.17	1.21 ± 0.16	0.18
LogMAR CDVA	−0.083 ± 0.059	−0.079 ± 0.064	0.16
Central cornea thickness (μm)	545.6 ± 42.7	545.1 ± 40	0.37
Axial rotation degree, absolute	1.77 ± 2.2 degrees	2.19 ± 1.74 degrees	0.21
Range	From 0 to 10 degrees	From 0 to 10 degrees	
Intraocular pressure (mm Hg)	13.6 ± 1.2	13.5 ± 1.9	0.4

LogMAR, logarithm of the minimal angle of resolution.

TABLE 2. Refractive Data 6 Months Postoperative

	S Group	CC Group	*P*
Postoperative Snellen UDVA	0.92 ± 0.19	1.07 ± 0.11	0.03*
Postoperative LogMAR UDVA	0.02 ± 0.16	−0.04 ± 0.09	0.04*
Postoperative Snellen CDVA	1.0 ± 0.27	1.198 ± 0.2	0.03*
Postoperative LogMAR CDVA	0.016 ± 0.13	−0.07 ± 0.07	0.01*

Reported as means ± SD. S group: Standard SMILE surgery group, 30 eyes. CC group, SMILE surgery, 54 eyes.
*$P < 0.05$.

UDVA (20/20) and 2 eyes (6.6%) lost more than 2-lines vision, compared with preoperative CDVA. More importantly, the difference in visual improvement of the patients with astigmatism between the S and CC groups was significant.

Refractive Outcomes in S and CC Groups

The mean SE of the S group and the CC group was −7.2 ± 2.2 and −6.29 ± 1.97 D, respectively. Six months after the SMILE surgery, the SE was 0.13 ± 0.18 and 0.21 ± 0.2 D in each group, with no significant difference between the 2 groups ($P = 0.33$). The astigmatism results were analyzed by using the Vector analysis method (Tables 3 and 4). The preoperative cylinder refraction of the S group and the CC group was −1.67 ± 0.54 D (range form −0.75 to −4 D) and −1.72 ± 0.71 D (range form −0.75 to −4 D), respectively. As shown in Table 3, the postoperative cylinder refraction of the S group and the CC group was −0.38 ± 0.8 D (range from +0.25 to −1 D) and −0.05 ± 0.61 D (range from +0.25 to −0.5 D), respectively. Moreover, by 6 months postsurgery, only 3 eyes (5.6%) of the CC group had low degree astigmatism, whereas 5 of the 30 eyes (16.7%) in the S group had uncorrected cylinder. Most of the eyes did not obtain the desired UDVA postoperatively, with loss of 1 or 2 lines compared to presurgery CDVA.

TABLE 3. Visual Acuity and Refractive Cylinder, Presurgery and Postsurgery

	S Group (n = 30)	CC Group (n = 54)	*P*
Presurgery cylinder n (%)			0.87
−0.75 to −1.0 D	6 (20%)	10 (18.5%)	
−1.25 to −2 D	16 (53.3%)	29 (53.7%)	
≥−2.25 D	8 (26.7%)	15 (27.8%)	
Postsurgery cylinder n (%)			0.08
+0.25 to −0.25 D	25 (83.3%)	51 (94.4%)	
−0.5 to −0.75 D	3 (10%)	3 (5.6%)	
−1 to −1.25 D	2 (6.7%)	0 (0%)	
Postsurgery UDVA n (%)			0.001*
≥20/25	10 (33.3%)	3 (5.6%)	
≥20/20	10 (33.3%)	12 (22.2%)	
≥20/16	10 (33.3%)	39 (72.2%)	
Postsurgery CDVA n (%)			0.008*
Loss 2 or more line	2 (6.6%)	0 (0%)	
Loss of 1 line	8 (26.7%)	5 (9.3%)	
No change in lines	15 (50%)	31 (57.4%)	
Gain of 1 line	5 (16.7%)	18 (33.3%)	

*$P < 0.05$.

TABLE 4. Vector Analysis of Astigmatism Eyes (6 Months Postoperative)

Parameter	S Group	CC Group	*P*
TIA	1.67 ± 0.54 D	1.72 ± 0.71 D	0.4
SIA	1.30 ± 0.7 D	1.68 ± 0.57 D	0.04*
AE (absolute)	6.7 ± 8.2	3.2 ± 5.9	0.02*
ME	−0.38 ± 0.8	0.05 ± 0.61	0.01*

AE, angle of error; ME, magnitude of error; SIA, surgically induced astigmatism; TIA, Target-induced astigmatism.
*$P < 0.05$.

Clinical Outcomes of the S Group and CC Groups

As mentioned above, the CC SMILE surgery showed better surgical outcomes than the standard SMILE surgery group. Hence, we analyzed the clinical outcomes of the S group and CC group.

Efficiency

At 6 months postoperative, 96% and 80% of treated eyes achieved 20/20 or better UDVA in the S group and the CC group, respectively. As shown in Figure 2A, by 6 months postoperative in the CC group, the UDVA was 20/16 or better in 45 eyes (83%) and 20/20 or better in 52 eyes (96%). Meanwhile, in the S group, the UDVA was 20/16 or better in 10 eyes (33%) and 20/20 or better in 24 eyes (80%).

Safety

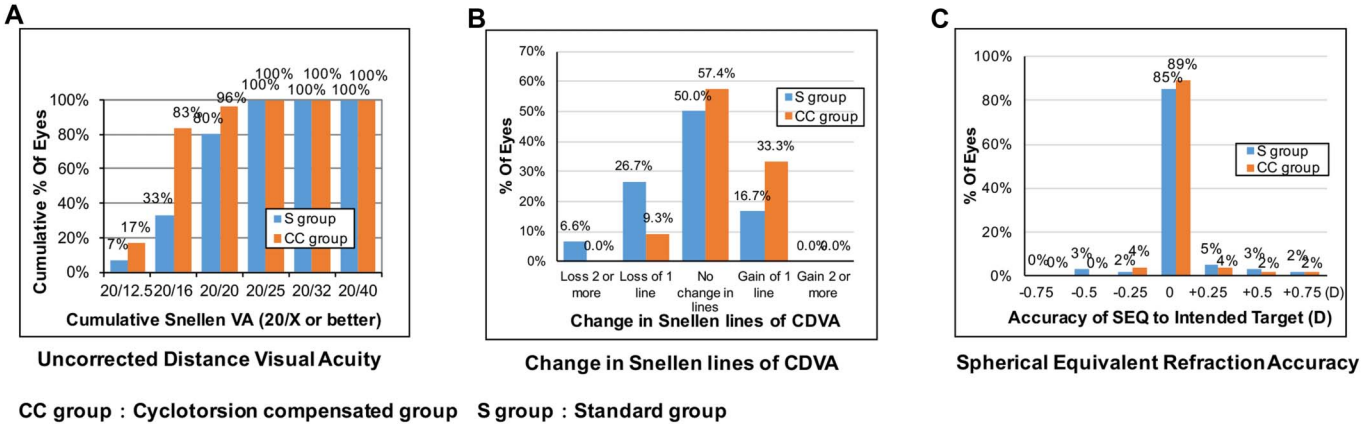
Figure 2B presents the distribution of CDVA at 6 months after refractive correction by SMILE surgery. In the CC group, 31 of 54 eyes (57.4%) showed no change and 18 eyes (33.3%) gained 1 or more lines. No eyes lost 2 lines of CDVA. Meanwhile, in the S group, 15 of 30 eyes (50%) showed no change, 5 eyes (16.7%) gained 1 or more lines, and 2 eyes (6.6%) lost 2 lines of CDVA.

Predictability

By 6 months postoperative, the SE of all enrolled eyes was within ±1 D in both groups (Fig. 2C). More than 90% of eyes were within ±0.25 D in both groups (achieved vs. intended target), and there was no significant difference between the S group and CC group. The scatterplot of the achieved SE corrections versus the attempted corrections is presented in Figure 3 and demonstrates a significant correlation in both groups.

Refractive Outcomes

The refractive outcomes are presented in Figures 4 and 5 and Table 4. The scatterplots of the surgical induced astigmatism vector versus target-induced astigmatism vector (Fig. 4) demonstrate the efficient astigmatic correction of SMILE surgery in both groups. However, a better



CC group : Cyclotorsion compensated group S group : Standard group

FIGURE 2. Clinical outcomes. A, Cumulative percentage of eyes that achieved definite cumulative levels of UCVA 6 months after SMILE surgery in the CC group and S group. B, Percentage of astigmatic eyes in gain/loss of lines of CDVA 6 months after SMILE surgery in the CC group and S group compared with that of preoperative CDVA. C, Accuracy of SE to intended target at 6 months postoperatively in the CC group and S group.

astigmatism correction outcome was achieved in the CC group (1.68 ± 0.57 D), compared with that of the S group (1.3 ± 0.7 D, *$P = 0.04$). Moreover, as shown in Figures 5, A and B, the angle of error of 92.45% eyes in the CC group and 66.67% eyes in the S group was within −5 to 5 degrees (angle of error, S group: 6.7 ± 8.2 and C group: 3.2 ± 5.9, *$P = 0.02$).

DISCUSSION

More than 68% of the eyes experienced a position-related cyclotorsion larger than 2 degrees, which has been considered as one of the main reasons causing axial misalignment and undercorrection after SMILE surgery in patients with astigmatism.[5,15] Several studies have demonstrated the undercorrection of astigmatism after SMILE surgery, whereas LASIK provides a more precise cylinder correction. Khalifa et al[16] reported a mean correction index of 0.88 and 0.99 for SMILE surgery and LASIK, respectively. Another study demonstrated that 50% of eyes had residual cylinder up to 1.0 D after SMILE surgery, whereas 82% of eyes had postoperative cylinder of 0.25 D or less after topography-guided LASIK.[17] Thus, no technical support for cyclotorsion compensation is a potential limitation for this surgical procedure. In the present study, our data demonstrated that the manual cornea-marking method could assist SMILE surgery to yield superior visual and refractive outcomes in patients with myopic astigmatism.

The main reason for unsatisfactory surgical refractive correction is axis misalignment.

Most eyes experience cyclotorsion during transformation in position.[1,2] The mean position-related cyclotorsional degree observed in refractive surgery has been reported to be approximately 3 degrees, ranging from 0 to 10 degrees. Theoretically, in patients with astigmatism, a rotation of 4 degrees would generate an undercorrection of 14%, and as the rotation degree increases, there is an increase in axial misalignment and cylinder undercorrection.[8,9,18] The higher the cylinder refraction, the greater the adverse impact of cyclotorsion on the outcomes of laser surgical correction.[18] In this study, 71% enrolled eyes needed cyclotorsion error compensation. In the S group, although the standard SMILE surgery significantly improved the VA of the eyes with

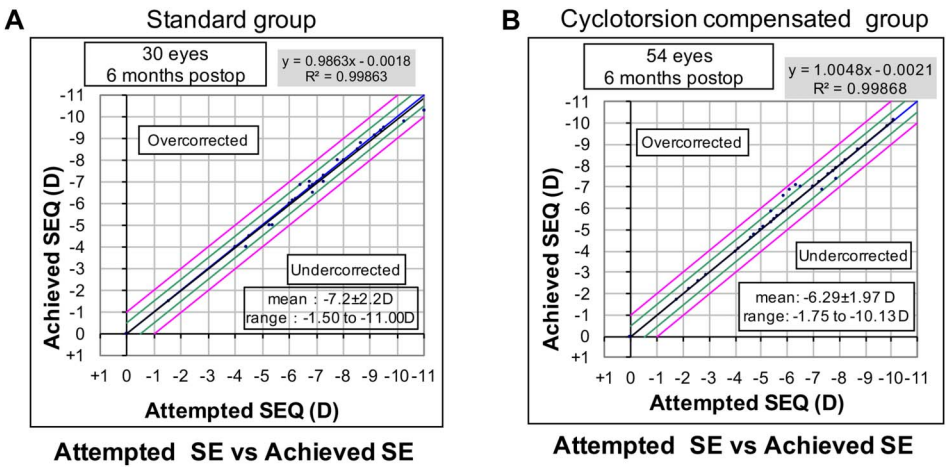


FIGURE 3. SE correction by SMILE surgery at 6 months postoperatively. A, Scatterplot of the achieved SE corrections versus the attempted corrections at 6 months after SMILE surgery in the S group. B, Scatterplot of the achieved SE corrections versus the attempted corrections at 6 months after SMILE surgery in the CC group.

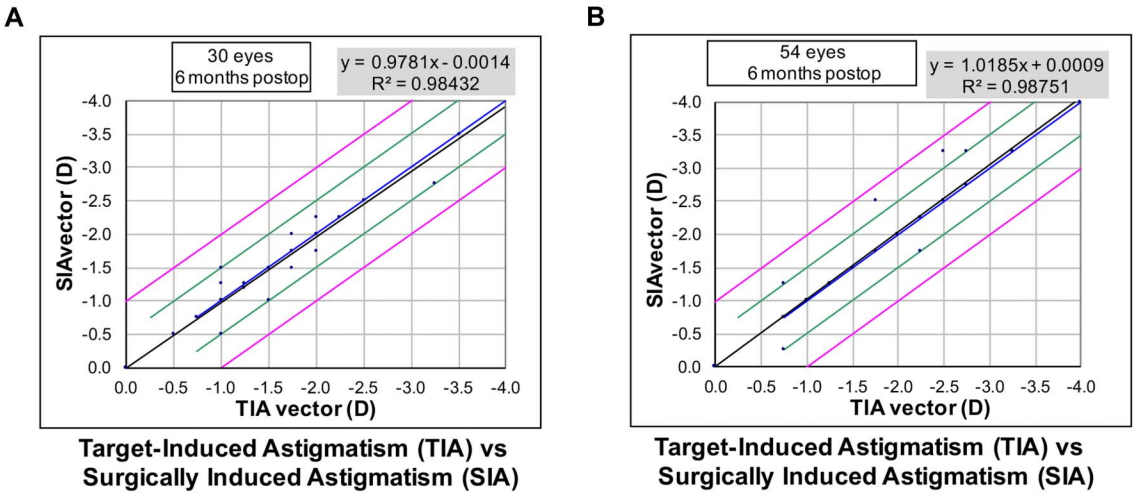


FIGURE 4. Vector analysis for SMILE at 6 months postoperatively. A, Target-induced astigmatism vector versus the surgically induced astigmatism vector 6 months after SMILE surgery in the S group. B, Target-induced astigmatism vector versus the surgically induced astigmatism vector 6 months after SMILE surgery in the CC group.

myopic astigmatism, and the refractive correction outcomes are comparable with the recent FDA premarket approval data[19] of SMILE surgery for patients with astigmatism (postoperative cylinder: 93% within ±0.5 D and 98.5% within ±1.00 D), the postoperative residual cylinder was the leading explanation accounting for 2-line vision loss of UDVA compared with preoperative CDVA. This outcome is in accordance with previous studies, demonstrating the necessity for cyclotorsion error compensation.

In an era of rapid technological change, the FDA approval of spherocylindrical SMILE is a milestone for both patients and refractive surgeons. However, no well-defined method exists for cyclotorsion error correction during SMILE surgery, thus leaving manual compensation as the only choice for refractive surgeons. Cornea marking is one of these choices. Clinical evidence has confirmed the safety and efficiency of cornea-marking methods for cyclotorsion compensation in LASIK surgery.[12,13] Moreover, a 3-month clinical observation has shown that manual cyclotorsional error compensation by cornea marking may be a feasible and effective approach to refine the refractive outcomes of astigmatism with SMILE.[13] Here, by conducting a controlled trial, our data demonstrated that the astigmatic eyes in the CC group achieved more precise axial alignment, more accurate cylinder correction, and better postoperative UDVA compared with the S group, thus further confirming the efficacy of the cornea-marking method for the compensation cyclotorsion error. The predictability and safety analysis also

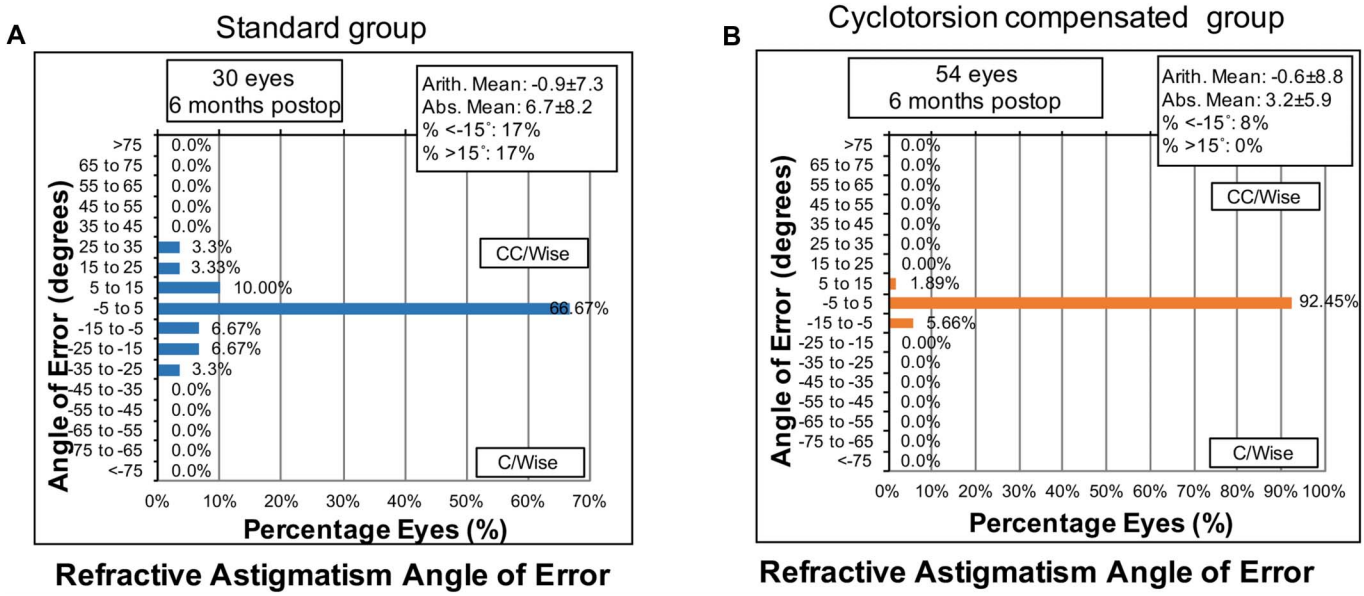


FIGURE 5. Vector analysis for SMILE at 6 months postoperatively. A, Refractive astigmatism angle of error at 6 months postsurgery in the S group. B, Refractive astigmatism angle of error at 6 months postoperative in the CC group.

validated the feasibility of this method. Moreover, no complications occurred because of cone rotation and cornea marking. Thus, the cornea-marking procedure might be an effective and safe approach to improve astigmatism correction with SMILE surgery, given that the latest version still lacks an active eye tracker.

Cornea marking is a convenient and quick way to evaluate cyclotorsion degrees; however, it is a subjective manual measurement that is prone to human errors, such as poor patient coordination. For optimum postoperative visual outcomes, a standard procedure and a trained experienced surgeon are needed for precise cyclotorsion degree evaluation. New generation excimer laser platforms system equipped with advanced eye tracking software could detect and correct eye cyclotorsion automatically. However, these techniques might not be available in patients with large rotation angles, small pupils, or inconspicuous iris details. Thus, manual cornea marking could provide valuable backup protection and can also be used to supplement automatic rotation detection programs.

Meanwhile, a recently published article showed good cylinder correction of SMILE surgery without cyclotorsion compensation for non–wavefront-guided LASIK in eyes with high myopic astigmatism (>3 D).[20] However, as Chan described in his study, the precise axial alignment is important for surgical refractive correction of patients with astigmatism, and the improved results for astigmatism treatment in his study could also be the result of stringent patient positioning and better measurement precision for the high cylindrical axis preoperatively. Moreover, only patients with high astigmatism were included in the study of Chan, whereas, most studies, including our study, collectively analyzed surgical cylinder correction for low to high astigmatism. This might also explain the discrepancy. Thus, in further studies, more investigation of visual outcome analysis and relevant refractive indices between different groups are warranted.

In summary, our data confirmed the add-on effect of the cornea-marking method for the compensation of cyclotorsion error in SMILE surgery for patients with astigmatism. However, a larger sample size and longer follow-up observation are warranted.

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