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ORIGINAL RESEARCH

The Association Between Ocular Residual Astigmatism and the Efficacy of Astigmatism Correction Via Small Incision Lenticule Extraction (SMILE)

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ABSTRACT

Introduction: Astigmatism correction after small-incision lenticule extraction (SMILE) surgery is affected by several factors, including ocular residual astigmatism (ORA), which accounts for the vector difference between refractive and corneal astigmatism. Previous studies revealed the relationship between ORA and astigmatism correction after laser-assisted in situ keratomileusis (LASIK). However, in SMILE surgery, no comprehensive study exploring the link between these two variables has been performed. We have therefore assessed the association between ORA and astigmatism correction after SMILE.

Methods: This was a retrospective, single-centered study. Patients with myopia or myopic astigmatism who underwent SMILE surgery using the 500-kHz Visumax laser platform and were followed up for at least 3 months were included. Patients' demographic and clinical characteristics, such as visual acuity, refractive status and corneal tomography, were recorded. ORA was calculated using Alpins Statistical System for Ophthalmic Refractive Surgery Techniques (ASSORT) Ocular Residual Astigmatism calculator.

Results: A total of 888 eyes (408 eyes from males and 480 eyes from females) from 444 patients (mean age [standard deviation] 32.4 ± 7.1 years) were included in our study. Mean (± SD) preoperative sphere and cylinder were − 5.45 ± 1.98 (range − 10.00–0.00) diopter (D) and − 0.89 ± 0.70 (range − 4.00–0.00) D, respectively. Calculated mean ORA was 0.68 ± 0.35 (range 0.07–3.53) D. Postoperative logMAR uncorrected visual acuity was 0.03 ± 0.31. Mean postoperative sphere and cylinder were − 0.10 ± 0.56 (range − 1.5 to 1.0) D and − 0.51 ± 0.37 (− 1.5 to 0.0) D, respectively. The Pearson correlation test revealed preoperative sphere, steep keratometry (steep-K) and ORA were statistically correlated with the amplitude of astigmatism correction ($P < 0.001$), and the generalized estimating equations analysis showed that ORA was

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negatively correlated with the amplitude of astigmatism correction ($P < 0.001$).

Conclusion: The results of our study suggest that preoperative higher ORA may be associated with a lower magnitude of astigmatism correction after SMILE surgery in patients with all levels of astigmatism preoperative.

Trial Registration: ClinicalTrials.gov: NCT05604872. Registered 3 November 2022—Retrospectively registered. https://clinicaltrials.gov/ct2/show/NCT05604872.

Keywords: Ocular residual astigmatism; Small-incision lenticule extraction; Refractive surgery; Corneal astigmatism

Key Summary Points

Why carry out this study?

Previous studies have shown that ocular residual astigmatism (ORA) could affect astigmatism outcome after small-incision lenticule extraction (SMILE) surgery, but the participants in these studies were limited to patients with low to moderate refractive astigmatism or to sampling a single eye from one patient.

The aim of our study was to provide a more comprehensive analysis of the relationship between ORA and the amplitude of astigmatism correction in patients who undergo SMILE.

Our null hypothesis is that ocular residual astigmatism is not associated with refractive astigmatism correction.

What was learned from the study?

The results of the study showed that a higher preoperative ORA was associated with a lower magnitude of astigmatism correction after SMILE in patients with low to severe astigmatism.

Our study showed that the astigmatism outcomes after SMILE refractive surgery not only relied on manifest refractive astigmatism itself, but that physicians should also consider the difference between manifest refractive astigmatism and corneal astigmatism.

INTRODUCTION

Uncorrected refractive error was one of the leading causes of moderate to severe vision impairment around the world in 2015 [1]. The prevalence of myopia in the global population is 28.3%, and it is even higher in East and Southeast Asia [2]. The prevalence of astigmatism worldwide ranges from 8% to 62% and is higher among elderly individuals [3].

Small incision lenticule extraction (SMILE) is an effective refractive surgery for correcting myopia or myopic astigmatism [4, 5]. In 2020, the US Food and Drug Administration (FDA) approved a treatment for astigmatism with cylinder range of within − 3.00 diopters (D) [6]; the Taiwan FDA approved cylinder treatment up to − 5.00 D. However, several studies have shown that SMILE results in a higher risk of postoperative residual astigmatism than laser in situ keratomileusis (LASIK) [7–9], such that retreatment may be needed [10]. A recent review reported on factors that could impact the efficacy of SMILE for correcting astigmatism, including cyclotorsion, center or optic zone, angle kappa, patient positioning, incision location, types of astigmatism (with-the-rule or against-the-rule) and ocular residual astigmatism [11].

Ocular residual astigmatism (ORA) is defined as the vector difference between refractive and corneal astigmatism, and it has been reported that patients with high ORA are negatively affected by postoperative residual astigmatism or induced astigmatism if they undergo LASIK [12]. In normal astigmatic eyes, the ORA can range from 0.01 to 1.87 D [13]. The importance of ORA in astigmatism correction has been reported in previous studies, in which a higher ORA or higher ORA ratio was observed to be associated with a lower risk of postoperative astigmatism correction after SMILE [14, 15]. Recent studies reported that patients without preoperative astigmatism who underwent refractive correction with SMILE experienced postoperative astigmatism [16] and that using the vector analysis method to correct astigmatism in patients with high ORA could yield acceptable refractive outcomes [17]. However, the patient populations of these studies were limited to patients with low to moderate refractive astigmatism or to sampling a single eye from one patient. The aim of our study was to provide a more comprehensive analysis of the relationship between ORA and the amplitude of astigmatism correction in patients who undergo SMILE.

METHODS

This study was retrospectively conducted from 2020 to 2021 at the Taipei Nobel Eye Clinic and was approved by the Ethics Committee of National Changhua University of Education (Changhua, Taiwan). It was registered on ClinicalTrials.gov (identifier NCT05604872, date of approval: November 3, 2022). All procedures performed were conducted in accordance with the tenets of the Declaration of Helsinki and its later amendments. Informed consent was not needed in the study.

The inclusion criteria for this study were: age between 20 and 50 years; corrected distance visual acuity (CDVA) of both eyes reaching 0.1 logarithm of the minimum angle of resolution (logMAR); and stable refractive errors of myopia (− 0.50 to − 10.00 D) and astigmatism (0.00 to − 5.00 D). The exclusion criteria were: cataract; corneal opacities or irregularities; dry eye (Schirmer's test $I \leq 5$ mm); amblyopia; coexisting ocular pathologies; glaucoma; nondilating pupil; history of intraocular surgery, laser therapy or retinopathy; optic nerve or macular diseases; estimated postoperative cornea residual stromal thickness < 250 μm; pregnancy or current lactation; uncontrolled diabetic mellitus or systemic immune disease; and refusal or inability to maintain follow-up.

Ophthalmic Examinations

The patients were examined preoperatively as well as at 1 day, 1 week, 1 month and 3 months after surgery as scheduled. At each visit, a thorough ophthalmologic examination was performed that included tests for uncorrected visual acuity (UCVA) and CDVA, in addition to manifest refraction, biomicroscopy and pneumotonometry. Fundus examination, cycloplegic refraction and corneal tomography were performed before surgery. Cycloplegic refraction was applied after instilling 1 drop of 1% Mydrin P (tropicamide 0.5%, phenylephrine HCl 0.5%) 3 times at 5-min intervals. Autorefraction data were collected before and after cycloplegia with Topcon KR-8900 (Topcon, Tokyo, Japan). Corneal astigmatism values were exported from the Pentacam (Pentacam HR; Oculus GmbH, Wetzlar, Germany) machine as measured by the Scheimpflug keratometry system. The magnitude of astigmatism correction was defined as the postoperative cycloplegic subjective astigmatism minus the preoperative cycloplegic manifest astigmatism.

Surgery

The triple centration technique marking under slit-lamp at 3, 6 and 9 o'clock was used for all patients on the same day before surgery to prevent cyclotorsion. To achieve proper alignment, the operator could rotate the applanation cone clockwise or counterclockwise after suction fixation was applied and before femtosecond laser scanning started. A 500-kHz Visumax (Carl Zeiss Meditec AG, Jena, Germany) femtosecond laser was used with cap thicknesses ranging from 100 to 130 μm and cap diameters ranging from 7.3 to 7.9 mm. The lenticule was dissected with a blunt spatula through a 30- to 60-degree incision at the 10 o'clock position and removed using forceps afterward. Treatment targets of both eyes were set to emmetropia, and the refraction corrections were based on manifest refractions. Levofloxacin and prednisolone acetate eyedrops were prescribed 4 times daily after surgery for 1 week.

Statistical Analysis

The preoperative demographics and postoperative outcome variables were collected according to our chart review. The sample size needed for the study was assessed by the software PS Power and Sample Size Calculations Version 3.0 [18]. Prior data indicate that the standard deviation (SD) of ORA is 0.4 and that for the regression errors is 0.7. The slope of the line obtained by regressing the change in astigmatism against ORA is − 0.25. Taking all factors into account, it was determined that 842 eyes should be included in the study in order to be able to reject the null hypothesis that this slope equals zero with a probability (power) of 0.8 under a type I error rate < 0.001 [18]. To analyze the primary outcome measure, statistical significance was set at $P < 0.001$. Correlations between variables were tested using Pearson's correlation analysis. A generalized estimating equation (GEE) approach was used to adjust the clustering effect between the left and right eyes from the same patient [19]. Stata Version 13.0 was used for data analysis (StataCorp, College Station, TX, USA). Vector analysis included the targeted induced astigmatism vector [20], surgically induced astigmatism vector (SIA), difference vector (DV) (remaining refractive astigmatism after surgery) and correction index (CI) (the ideal CI = 1, whereas CI > 1 indicates overcorrection, and CI < 1 indicates undercorrection) were calculated using AstigMATIC software Version 2.0 [21]. The ORA was calculated by Alpins Statistical System for Ophthalmic Refractive Surgery Techniques (ASSORT) Ocular Residual Astigmatism calculator (https://assort.com/assort-vector-calculator) after calculating the vector difference between the manifest refractive astigmatism and corneal astigmatism values [20].

RESULTS

A total of 888 eyes (408 eyes from males and 480 eyes from females) from 444 patients (mean age ± standard deviation [SD] 32.4 ± 7.1 years) were included in our study. Table 1 presents the patients' demographic and clinical characteristics, including preoperative visual acuity, refractive status, corneal keratometry data, postoperative visual acuity, UDVA, CDVA and spherical equivalent. The mean (± SD) preoperative spectacle plane sphere and cylinder were − 5.45 ± 1.98 D and − 0.89 ± 0.70 D, respectively. The mean ORA was 0.68 ± 0.35 D. All surgical procedures were conducted smoothly. The postoperative mean sphere was − 0.10 ± 0.56 D, and the mean cylinder was − 0.51 ± 0.37 D. Figure 1 presents the vector analysis results for target induced astigmatism (TIA, the astigmatic change that the operator intended to induce), SIA, DV and CI; the mean

Table 1 Patient demographics, clinical characteristics, postoperative visual acuity and refractive status

Patient characteristics	Measured values	Range
Preoperative		
CDVA (logMAR)	0.002 ± 0.02	0.00–0.25
Sphere (D)	− 5.45 ± 1.98	− 10.00 to 0.00
Cylinder (D)	− 0.89 ± 0.70	− 4.00 to 0.00
Flat-K (D)	42.8 ± 1.4	38.4–47.5
Steep-K (D)	44.2 ± 1.5	39.1–48.9
ORA (D)	0.68 ± 0.35	0.07–3.53
Postoperative		
UDVA (logMAR)	0.03 ± 0.31	− 0.1 to 0.9
CDVA (logMAR)	0.00 ± 0.08	− 0.1 to 0
Sphere (D)	− 0.10 ± 0.56	− 1.5 to 1.0
Cylinder (D)	− 0.51 ± 0.37	− 1.5 to 0

Measured values are presented as the mean ± standard deviation (SD)

CDVA Corrected distance visual acuity, *D* diopter logMAR logarithm of the minimum angle of resolution, *K* keratometry, *logMAR* logarithm of the minimum angle of resolution, *ORA* ocular residual astigmatism *UDVA* uncorrected distance visual acuity, *SD* standard deviation

DV was 0.47 D with a CI of 1.01, indicating acceptable surgical outcomes.

The analysis of the relationship between the amplitude of astigmatic correction and patient demographics is summarized in Table 2. Steep keratometry (steep-K) was found to be positively correlated with the amplitude of astigmatic correction, whereas ORA and sphere were negatively correlated with the amount of correction. These results revealed that higher preoperative ORA and sphere may be related to a weaker efficacy of astigmatic correction.

Table 3 shows the GEE analysis of independent variables of the amplitude of astigmatism correction. Age and sex were not related to astigmatism correction, and the results of this analysis reconfirmed that with increasing ORA, the amount of astigmatism correction could be negatively decreased. Figure 2 shows that after adjusting for age, the ORA was negatively related to the amplitude of astigmatism correction

Table 2 Pearson correlation of baseline demographics to amplitude of astigmatism correction

Variables	Pearson correlation coefficient	*P* value
Age	− 0.06118	0.0689
Preoperative CDVA (logMAR)	0.07284	0.0302
Sphere (D)	− 0.86873	< 0.0001***
Flat-K (D)	− 0.05502	0.1019
Steep-K (D)	0.21875	< 0.0001***
ORA (D)	− 0.14828	< 0.0001***

***Significant at $P < 0.001$. There was a significant positive correlation between steep-K and amplitude of astigmatic correction, and a significant negative correlation between ORA and sphere with the amount of correction

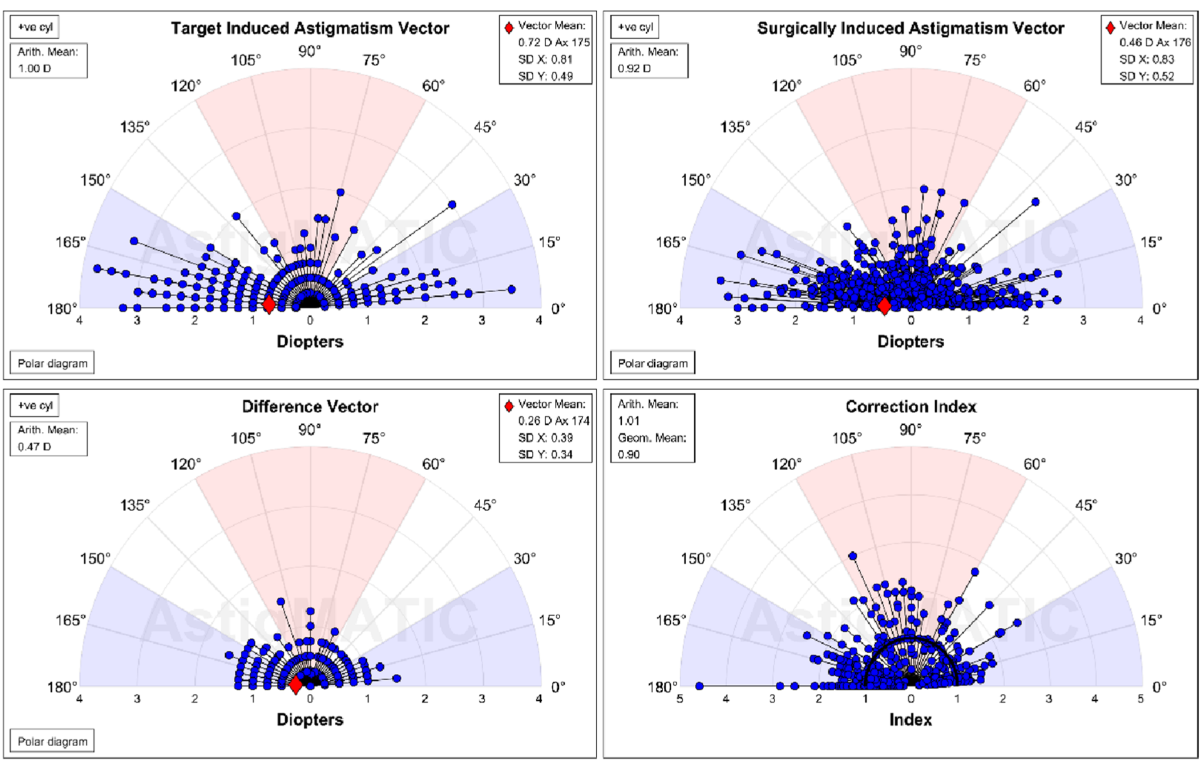


Fig. 1 Single-angle polar plots for the target-induced astigmatism vector [20], surgically induced astigmatism vector, difference vector and the correction index at 3 months after small-incision lenticule extraction (SMILE) surgery. *Ax* Axis, *cyl* cylinder, *D* diopter, *SD* standard deviation

and that the trend was consistent within the low, moderate and high astigmatism groups for both male and female patients.

DISCUSSION

This study is the first large-scale, comprehensive study covering various degrees of preoperative astigmatism, and the results showed that ORA was associated with a lower magnitude of astigmatism correction after SMILE. Other factors that may affect astigmatism correction have been described in previous studies. Regarding types of astigmatism, undercorrection may be noted in with-the-rule astigmatism and overcorrection in against-the-rule astigmatism [11], although overcorrection with-the-rule astigmatism was noted in a previous study [22]. Cap thickness, cap diameter, incision width and incision position were not found to be associated with astigmatism outcomes [23, 24]. Large-angle kappa and decentration from the pupil center and kappa intercept are associated with increased higher-order aberration and compromised visual outcomes; nevertheless, their association with astigmatism correction has not been elucidated [25, 26]. Cyclotorsion during docking and femtosecond laser scanning procedures would partially offset the effect of astigmatism correction, which can be checked by the marking position using the triple centration technique marking and manually repositioned by a rotating applanation interface cone after suction fixation is applied; however, the accuracy of this approach is still not comparable to that of the image-guided system [27].

Fig. 2 Generalized estimated equation analysis showing that ORA was negatively related to the amplitude of astigmatism correction in the low, moderate and high astigmatism groups for both males and females after adjusting for age. *D* Diopter, *ORA* ocular residual astigmatism

The concordance of refractive astigmatism and corneal astigmatism has been deciphered, and a linear regression line can be plotted in a coordinate system using keratometric astigmatism as the abscissa and refractive astigmatism as the ordinate [28]. Nonetheless, the measurement of refractive astigmatism might be influenced by patients' perceptual preference for objects or by behaviors of the optometrist [29]. Intra- or interobserver variability can also yield different refractive astigmatism measurement outcomes. In a previous study measuring 40 eyes for cylinder power and axis, the repeatability of cycloplegic subjective power measurement accounted for only 92.5% of the variability within 0.25 D; furthermore, the

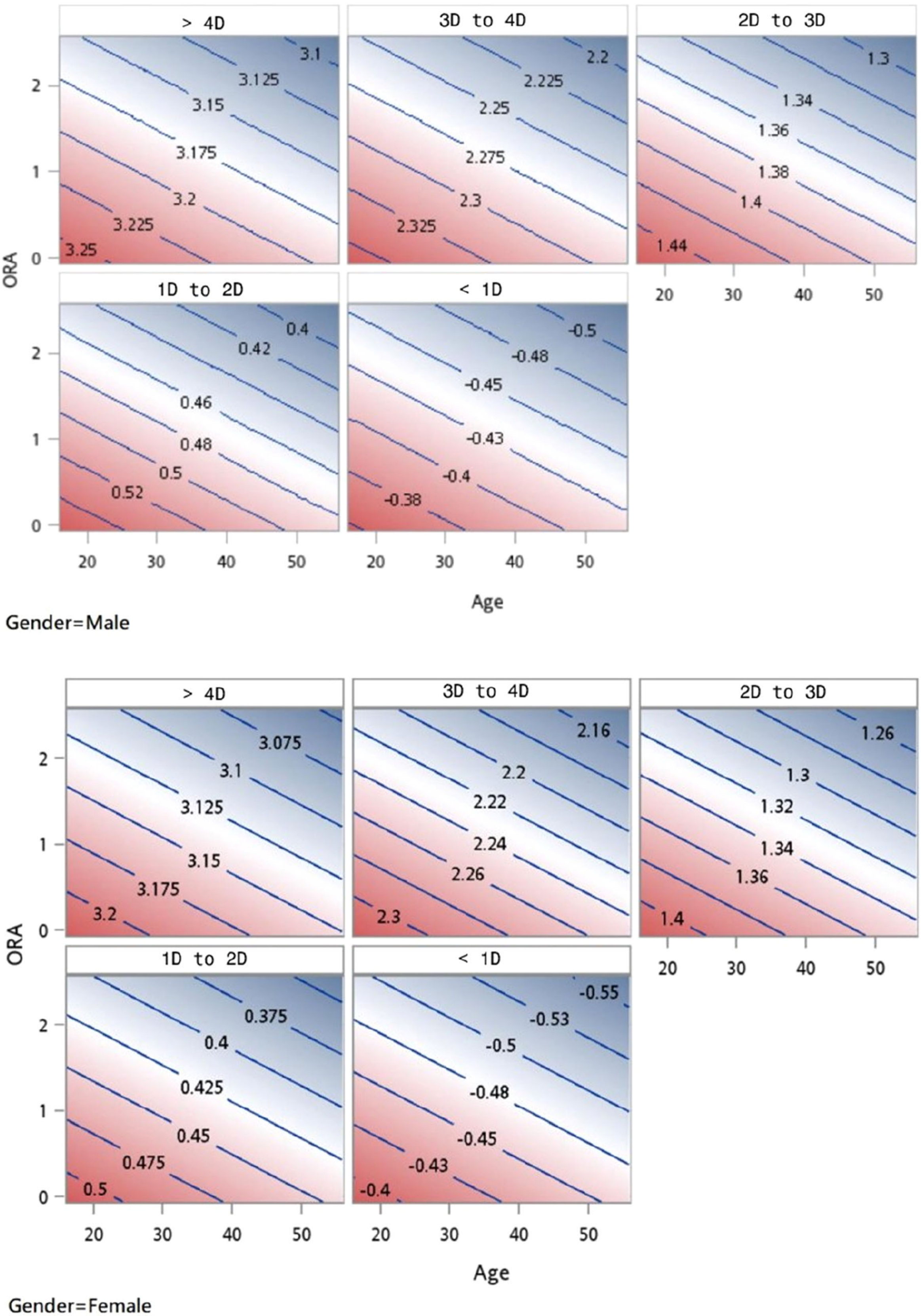
Table 3 Effect estimation of independent variables on amplitude of astigmatism correction from generalized estimating equations analysis assuming an unstructured correlation structure

Variables	Estimation	95% Confidence interval	*Z*	Pr >|*Z*|
Age	− 0.0052	− 0.0135, 0.0031	− 1.22	0.2221
Gender	− 0.0758	− 0.1977, 0.0461	− 1.22	0.2231
ORA	− 0.2351	− 0.3666, − 0.1037	− 3.51	0.0005***

Estimated correlation matrix

	Left	Right
Left	1.00	0.574
Right	0.574	1.00

***Significant at $P < 0.001$



> 4D
3D to 4D
2D to 3D
1D to 2D
< 1D
3.1
3.125
3.15
3.175
3.2
3.225
3.25
2.2
2.225
2.25
2.275
2.3
2.325
1.3
1.34
1.36
1.38
1.4
1.44
0.4
0.42
0.46
0.48
0.5
0.52
-0.5
-0.48
-0.45
-0.43
-0.4
-0.38
ORA
Age
Gender=Male
3.075
3.1
3.125
3.15
3.175
3.2
2.16
2.2
2.22
2.24
2.26
2.3
1.26
1.3
1.32
1.34
1.36
1.4
0.375
0.4
0.425
0.45
0.475
0.5
-0.55
-0.53
-0.5
-0.48
-0.45
-0.43
-0.4
ORA
Age
Gender=Female

repeatability of cycloplegic subjective axis measurement accounted for up to 62.5% of variability, with a shift of the axis of > than 5° [30]. For astigmatism correction in refractive surgery, Alpins advocated considering both refractive and corneal astigmatism, and the term "ocular residual astigmatism" was coined to describe the vector difference between these two kinds of astigmatism [31].

Higher ORA could offset astigmatism correction after SMILE, as noted by the authors of previous studies, although it was noted that it was confined to eyes with low to moderate astigmatism. In Qian's series, 122 right eyes of 122 patients were included, with the correction range of sphere being − 3.5 to − 10.75 D and that of the cylinder being 0.25–3.00 D; the cutoff point of ORA was set at 1.00 D, whereas the mean postoperative manifest astigmatism was higher in patients within the high ORA group [14]. Chan et al. compared patients (134 eyes of 134 patients) with a higher ORA ratio (defined value of ORA as the nominator and preoperative refractive astigmatism as the denominator), which tended to result in a lower index of success in vector analysis compared with the lower ORA ratio group [15]. In a clinical trial including 114 eyes of 114 patients with mild to moderate astigmatism (< 2.50 D), in which the high ORA group was designated as ORA > 0.75 D, the high ORA eyes were randomized into the manifest planning group (astigmatism corrected 100% by refractive astigmatism) and vector planning group (astigmatism corrected 60% by refractive astigmatism and 40% by corneal astigmatism), respectively [17]. The vector planning group yielded better postoperative refractive outcomes [17]. Our study further broadened the scope from previous studies in that we included a larger sample size, examined both eyes of each patient and observed a continuous, consistent trend of ORA outcomes from low to high preoperative refractive astigmatism rather than a binary trend.

Our study has a number of limitations. First, the study had a retrospective design; therefore, we could only determine the association between variables. Additionally, the large sample size and statistical methods applied to decrease the effect of selection bias led to some patients being lost to follow-up, probably due to unsatisfactory results. Second, there was no adjustment for other confounding factors that may affect the refractive outcomes, such as cyclotorsion or decentration from the pupil center and kappa intercept. Third, this was a single-center, single-surgeon study, and the results of our study may not be generalizable to other patient populations and centers.

CONCLUSIONS

Our study showed that a higher preoperative ORA was associated with a lower magnitude of astigmatism correction after SMILE in patients with astigmatism ranging from low to severe. Further prospective, multicenter studies may need to be conducted to reconfirm this trend.

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Compliance with Ethics Guidelines. This study was retrospectively conducted from 2020 to 2021 at the Taipei Nobel Eye Clinic and was

approved by the Ethics Committee of National Changhua University of Education (Changhua, Taiwan). It was registered on ClinicalTrials.gov (identifier NCT05604872, date of approval: November 3, 2022). All procedures performed were conducted in accordance with the tenets of the Declaration of Helsinki and its later amendments. Informed consent was not needed in the study.

Disclosures. All named authors confirm that they have no conflicts of interest to declare.

Data Availability. The data are available upon reasonable request to the corresponding author.

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