SMILE After DALK to Reduce Residual Refraction: Two-Year Results

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Research Article

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Abstract

Purpose

To determine the two-year results of small incision lenticule extraction (SMILE) for correcting post-keratoplasty myopia and myopic astigmatism.

Methods

In this case-series study, 10 eyes of 10 patients with a 6-10-year history of successful deep lamellar keratoplasty (DALK) underwent SMILE using VisuMax laser platform. Ophthalmologic examinations and visual acuity and refraction measurement were done pre- and 1, 3, 6, 12, and 24 months postoperatively. Pentacam and Sirius imaging was done in the first and last follow-up session.

Results

The mean age of the patients was 39.60±7.86 years. Six subjects were male. After two years, uncorrected distance visual acuity did not change in one eye and improved 1-6 lines in other eyes. Corrected distance visual acuity decreased in one eye, did not change in four eyes, and improved 1-8 lines in other eyes. The mean decrease of spherical equivalent, spherical error, and cylinder power was 1.92±1.96 diopter (D) (P=0.013), 0.70±3.05D (P=0.213), and 2.42±2.91D (P=0.024), respectively. The vector mean target induced astigmatism, surgical induced astigmatism, and difference vector was 1.30D@44˚, 1.11D@24˚, and 0.86D@73˚, respectively. Two years after surgery, vertical coma, horizontal coma, and spherical aberration increased by 0.44±0.51, 0.23±0.32, and 0.02±0.16μm respectively (all P>0.05) while trefoil reduced by 0.29±0.75μm (P=0.428).

Conclusion

SMILE is a successful procedure for reducing refraction and astigmatism after DALK in patients with moderate myopia and moderate to severe astigmatism and improves the visual acuity in these patients. Axis rotation during surgery may result in under-correction of astigmatism. Refinement of SMILE treatment nomogram for post-DALK cases seems necessary.

Introduction

Corneal Penetrating keratoplasty (PK) may result in anisometropia and increased corneal higher order aberrations (HOAs) and impair visual rehabilitation after graft surgery (1). Different treatments have been proposed, including spectacles, contact lenses, and surgical procedures (relaxing incision, excimer laser, and intraocular lenses) to reduce anisometropia and irregular astigmatism after corneal graft surgery. Although these corrective methods shown favorable results, they are associated with the possibility of graft rejection as well as certain complications. Correction with spectacles is not very successful for visual rehabilitation in these patients due to anisometropia and irregular astigmatism. Although rigid contact lenses have shown better results compared to spectacles, they are associated with several

drawbacks like intolerance and peripheral neovascularization (2). Suture-based methods including relaxing incisions, wedge resection, single continuous suture adjustment, and selective suture removal reduce the effectiveness of treatment (3).

Refractive surgery methods such as photorefractive keratectomy (PRK) with or without mitomycin C can reduce residual refractive errors after corneal grafting; however, the long-term results of this procedure have shown unacceptable predictability. According to the literature, significant regression, irregular astigmatism induction, limited astigmatic correction, and haziness are among the most important drawbacks of this surgical method (4). Laser in situ keratomileusis (LASIK) is preferred to PRK due to better correction and less haziness (5); however, flap complications and corneal decompensation are the disadvantages of this procedure. On the other hand, thinning of the graft-host interface increases the risk of wound dehiscence. Moreover, flap dislocation is increased in eyes with a low endothelial cell count due to possible corneal edema (5). Toric intraocular lens implantation corrects amteropia effectively but this method is also associated with a number of complications including endophthalmitis, endothelial cell loss, and lens rotations (6, 7). Graft rejection is an important complication of all of the above methods.

Small incision lenticule extraction (SMILE) is a new refractive surgery technique for correction of myopia and myopic astigmatism. Since the epithelium remains intact in this method and a lenticule is extracted from the stroma without flap removal, it is preferred to PRK and LASIK in eyes with no history of ocular surgery. The safety and efficacy of this procedure have been confirmed as well (8, 9). To the best of our knowledge, only one study reported the 6-month results of this procedure in post-PK patients (10). Considering the instability of the results of vision and refraction after PK, especially in subjects with high astigmatism, the present study was conducted to evaluate the two-year safety, efficacy, predictability, and visual performance of SMILE for correction of post-PK astigmatism in subjects with high astigmatism.

Material And Methods

This case series study was conducted on 10 patients with a history of deep lamellar keratoplasty (DALK) using the big bubble technique in Noor Eye Hospital, Tehran, Iran in 2019. All of the subjects underwent DALK due to advanced KC. The inclusion criteria were age ≥ 20 years, time from corneal grafting ≥ 2 years and time from suture removal > 6 months, a ≥ 2 Snellen lines difference between corrected distance visual acuity (CDVA) and uncorrected distance visual acuity (UDVA), and a residual stromal bed (RSB) of at least 280 microns. The exclusion criteria were a history of graft rejection, any history of corneal surgery other than PK, and corticosteroid contraindication. The patients were advised to stop wearing their contact lenses four weeks before surgery.

Ethical considerations

The protocol of the study was approved by the Ethics Committee of Tehran University of Medical Sciences (IR.TUMS.MEDICINE.REC.1400.102). The objective, method, and possibility of incomplete refractive correction in high myopic patients were explained to subjects and informed consent was obtained from volunteers. The study was conducted in accordance with the Declaration of Helsinki.

SMILE procedure

After Topical anesthesia, the patient was asked to fixate on an internal light source. The procedure was done using the VisuMax laser platform (Carl Zeiss Meditec AG, Jena, Germany) according to the standard method. First, the posterior surface of the lenticule was incised from the periphery to the center and then the anterior surface was incised inversely. The lenticule creation parameters were as follows: cap thickness = 120 µm, cap diameter = 7.7 mm, optical zone = 6.5 mm, and transition zone = 0.1 mm for cases of moderate myopia, and cap thickness = 110 µm, cap diameter = 7.2 mm, incision, optical zone = 6.0 mm, transition zone = 0.1 mm for high myopia. In the postoperative period, 0.5% chloramphenicol eye drops (Sina Darou, Tehran, Iran) were administered four times a day for three days. Betamethasone 0.1% drops (Sina Darou, Tehran, Iran) were tapered as four times a day in the first month, two times a day in the second month, and once a day in the third month) and preservative free artificial tears (Hypromellose) were instilled four times a day for one month.

Examinations

The patients were examined before and 1, 3, 6, 12, and 24 months after the surgery. In addition to slit lamp biomicroscopy (Haag-Streit, Ohio, USA), uncorrected and corrected distance visual acuity (UDVA and CDVA) were evaluated using the Snellen SC-2000 system (Nidek Inc., Tokyo, Japan). Subjective refraction was measured using retinoscopy (ParaStop HEINE BETA 200; HEINE Optotechnik, Herrsching, Germany) in all visits. Corneal tomography and aberrometry was done using the Pentacam HR (Oculus, Inc., Lynnwood, WA) before and 24 months after the procedure. The refractive maps and Belin/Ambrósio display of the Pentacam were used to evaluate corneal ectasia, and total corneal higher order aberrations (HOA), total vertical and horizontal coma, total spherical aberrations, and total trefoil were extracted to assess postoperative aberrometric changes.

Statistical analysis

Statistical analysis was done using the SPSS version 21 (IBM Corp., Armonk, NY, USA) and Microsoft Excel 2010 (Microsoft corp., Redmond, WA, USA). The Alpine method (11) was applied for astigmatic analysis and the graphs were generated using the AstigMATIC software (12). The mean values and vectors of surgical induced astigmatism (SIA), target induced astigmatism (TIA), correction index (CI), difference vector (DV), and index of success (IoS) were calculated to evaluate astigmatic changes. Spherical equivalent refraction (SE) was calculated as spherical error ± 1/2cylindrical error. Safety was measured as postoperative CDVA / preoperative CDVA and efficacy was calculated as postoperative UDVA / preoperative CDVA. Repeated measures analysis of variance was applied to assess refraction stability.

Results

Ten eyes of 10 patients with a mean age of 39.60 ± 7.86 years (range: 28.00 to 53.00 years). Six subjects were male and the rest were female. The mean time between DALK and SMILE was 9.00 ± 1.41 years

(range: 6.00 to 10.00 years).

Vision

After two years, the mean UDVA reduced from 1.14 ± 0.44 to 0.42 ± 0.29 LogMAR ($P < 0.001$) and the mean CDVA decreased from 0.23 ± 0.18 to 0.13 ± 0.13 LogMAR ($P = 0.231$). UDVA did not change in one eye and improved 1 to 6 lines in the rest of eyes. CDVA reduced in one eye, did not change in 4 eyes, and improved 1 to 8 lines in the rest of eyes (Fig. 1).

After two years, three eyes had a visual acuity of 20/20 and six eyes had a visual acuity of 20/25 or better. Two-year safety and efficacy indices were 1.53 ± 1.27 and 0.68 ± 0.33, respectively (Fig. 1).

Refraction

The mean SE reduced from − 4.74 ± 2.63 diopter (D) to -2.82 ± 2.33 D two years postoperatively ($P = 0.013$) and two eyes became emmetropic. The mean refraction reduced significantly one month after the surgery compared to baseline from − 4.74 ± 2.63 D to -1.76 ± 2.05 D ($P = 0.022$); this significant difference was observed for two years (all $P < 0.05$) with no significant difference between follow-ups (Fig. 2). The mean spherical error reduced from − 1.92 ± 3.04 D to -0.67 ± 2.62 D ($P = 0.135$). The spherical error of the subjects is presented in Fig. 2.

The mean cylindrical error reduced from − 5.62 ± 2.95 D to -3.20 ± 1.84 D two years postoperatively ($P = 0.024$). The two-year mean values of SIA, TIA, CI, DV, and IoS was 2.69 ± 2.77 D, 5.62 ± 2.95 D, 0.43 ± 0.25 D, 2.93 ± 1.68 D, and 0.56 ± 0.25 D, respectively. Table 1 presents the mean value of these indices for each subject. The vector mean TIA, SIA, and DV was 1.30D@44˚, 1.11D@24˚, and 0.86D@73˚, respectively. The polar graph of these indices is shown in Fig. 3.

Table 1
Mean target induced astigmatism (TIA), surgical induced astigmatism (SIA), correction index (CI), difference vector (DV) and index of success (IoS) two years after Small incision lenticule extraction (SMILE) in cases with keratoplasty

	TIA	SIA	CI	DV	IoS
Case 1	1.50	0.25	0.17	1.25	0.83
Case 2	7.00	3.64	0.52	3.36	0.48
Case 3	4.00	1.54	0.38	2.46	0.62
Case 4	4.50	0.75	0.17	3.75	0.83
Case 5	4.25	3.00	0.71	1.25	0.29
Case 6	12.00	10.00	0.83	2.00	0.17
Case 7	6.00	1.00	0.17	5.00	0.83
Case 8	8.00	2.25	0.28	5.75	0.72
Case 9	6.00	2.22	0.37	3.78	0.63
Case 10	3.00	2.26	0.75	0.74	0.25

Aberrations

HOAs, vertical coma, horizontal coma, and spherical aberration increased from 3.44 ± 0.72 to 3.73 ± 0.82 µm, from 1.84 ± 0.78 to 2.27 ± 1.03 µm, from 1.47 ± 0.87 to 1.70 ± 0.97 µm, and from 1.59 ± 0.37 to 1.61 ± 0.38 µm respectively but none of the changes was significant (all $P > 0.05$). On the other, trefoil reduced from 1.27 ± 0.81 to 0.97 ± 0.21 µm ($P = 0.428$).

Complications

According to Fig. 1, patient number 7 lost two lines of CDVA but gained one line of UDVA. This patient had a CDVA of 20/32 at baseline and 20/100 in the one-month follow-up (loss of four lines); however, he gained one line of CDVA in the 3rd month and one line in the 12th month, reaching 20/50 in the second year. Spherical error remained unchanged and astigmatism reduced by 1.0 D in the same axis.

Patient number 5 developed stromal rejection one week after SMILE and UDVA and CDVA decreased to 2/400 and 20/36, respectively. After corticosteroid oral administration and subtenon injection, the above parameters increased to 20/63 and 20/25 respectively and the graft became completely clear. UDVA and CDVA improved to 20/40 and 20/20 in the second year respectively and there was no need for repeat transplantation. The details of this case are presented in another paper (13).

No other complications were observed in the rest of the patients during two-year follow-up. Moreover, there were no cases of suction loss during the operation.

Discussion

Residual refractive error is one of the complications in patients with a history of successful PK. Several surgical and non-surgical methods have been used to manage this complication, which either did not have an acceptable effectiveness or were associated with serious consequences. According to the literature, there is no standard method for treatment of post-keratoplasty refractive error (10). On the other hand, SMILE, as a safe, efficacious, predictable, and stable method for correction of myopic and astigmatic error (14–16), has raised hopes for finding a new method for correction of high residual refractive error after keratoplasty. To the best of our knowledge, this is the first case series with a mid-term follow-up investigating the efficacy and safety of SMILE for correction of post-DALK refractive error in patients with moderate myopia (mean: 4.7 D) and high astigmatism (mean: 5.6 D). Although the present study had a small sample size and a single-arm design without a control group, the results provide valuable information regarding the application of this procedure for correction of post-DALK residual refractive error. Massoud et al (10) reported that the short-term (6-month) results of this procedure were acceptable in patients with a history of PK that had high myopia (mean: 6.8 D) and moderate astigmatism (mean: 3.1 D).

Vision

According to the two-year results, SMILE was a safe procedure for correction of post-DALK residual refractive error. The mean CDVA improved from 0.23 LogMAR to 0.13 LogMAR indicating an acceptable safety index (1.53). In the study by Massoud et al (10), CDVA reduced from 0.73 LogMAR to 0.82 LogMAR 6 months after the procedure, safety index was 1.12, but none of the cases experienced a reduction in CDVA. However, in the present study, CDVA reduced in one of the patients in the first month, which improved gradually from the 3rd month to the 24th month. Considering the trend of improvement after the third month, it is expected that patient gains the preoperative or even a better visual acuity in the next follow-ups. A study that analyzed the results of post-PK refractive surgery procedures found a 0.1 LogMAR loss of CDVA after PRK (from 0.45 to 0.36) and a 0.04 LogMAR loss of CDVA after LASIK (from 0.39 to 0.35) (17). Since the prevalence of CDVA loss $\geq$ 1 line is 1.04% after SMILE and 0.51% after LASIK (18) in normal subjects with no history of PK, it seems that our results are acceptable compared to other corrective methods in subjects with a history of PK as well as normal individuals.

The results showed an efficacy of about 0.7. According to Fig. 1, postoperative UDVA was one line better than the preoperative CDVA in one of the cases (patient number 3), and postoperative UDVA reached preoperative CDVA despite stromal rejection in another case (patient number 5). In three eyes, postoperative UDVA was one line less than preoperative CDVA. Attention should be paid to the precision of the examiner and patient status due to the subjective nature of the test. In the remaining five cases, differences of 2 to 4 lines were observed. In these cases, although the postoperative UDVA did not

reached to preoperative CDVA, it improved 1 to 4 lines. Massoud et al (10) reported a 6-month efficacy of 0.93. The difference might be due to the shorter follow-up duration. In this regard, Fadlallah et al (19) found that the efficacy of femto arcuate keratotomy for correction of post-PK residual refraction was 0.81 after one year and 0.67 after two years. An efficacy of 1.04 has been reported in normal subjects with moderate to high myopic astigmatism. It seems that the efficacy of this procedure is lower in post-PK cases compared to normal subjects.

Refraction

In the present study, SE and spherical error decreased by almost 2.0 and 1.2 D after two years, respectively. Massoud et al (10) reported a mean reduction of 4.5 and 5.4 D in SE and spherical error after six months, respectively. There were no cases of over-correction in our study; however, considering the over-correction cases in the above study, they could have reached different results in a longer follow-up. Kovoor et al (17) found a spherical error reduction of 3.6 D after PRK. This decrease was 1.94D in a study by Shen (20).

One reason for the lower spherical correction in our study could be the lower preoperative sphere. The mean preoperative sphere was 1.9 D in our study, 5.3 D in the study by Massoud et al (10), 5.1 D in the study by Kovoor et al (17), and 2.6 D in the study by Shen et al (20).

Two years after SMILE, astigmatism had an arithmetic mean reduction of 0.75 to10.0 D in eight cases and remained unchanged in two cases (0.25 D). According to the results of vector analysis, in our study SIA, TIA, and DV was 2.7 D, 5.6 D, and 2.9 D, respectively. These values were reported 2.1 D, 2.6 D, and 1.1 D by Massoud et al (10). The IoS was 0.6 in the present study, indicating that SMILE corrected up to 60.0% of post-PK astigmatism. Regardless of the follow-up differences between the two studies, the mean error of astigmatic correction increases in the presence of high astigmatism, and this direct correlation is confirmed in normal subjects (21). Studies have shown that in normal corneas, the probability of residual astigmatism increases by up to 16% for each one-diopter increase in astigmatism (14). The difference in axis orientation of TIA, SIA, and DV indices indicated that axis rotation of astigmatism is one of the reasons for under-correction. In addition, according to the available nomogram, astigmatic correction in patients with no history of keratoplasty requires 10% adjustment (19, 21). This is while this nomogram is related to cases with no history of keratoplasty and it seems that it requires re-adjustment for refractive error correction in patients with history of keratoplasty. In addition, lack of automated cyclotorsion control and centration in Visumax could be other reason for under-correction in SMILE compared to other methods (22).

Aberrations

HOAs, except trefoil, showed a non-significant increase in the current study. HOA changes had a similar trend to normal corneas undergoing SMILE (9). Two points should be kept in mind. The first one is the contribution of these changes to the quality of vision and visual function, since visual performance is affected by adaptation, scatter, and neural adaptation (23). The satisfaction of the patients with the

surgical outcome indicated that the increase in aberrations did not reduce the quality of vision or the reduction in the quality of vision was not significant compared to the increase in visual acuity. The second point is the repeatability of aberration measurements in grafted corneas. To the best of our knowledge, no study has evaluated the repeatability of these indices (measured by the Sirius) in subjects undergoing DALK. A study reported that a within-subject standard deviation of 0.01 to 0.05 μmin these indices in patients with keratoconus (24). However, post-PK corneal irregularities reduce the repeatability of the measurements. If these data were available for grafted corneas, comparison of the two-year changes of these indices with their measurement error could improve our conclusion.

Finally, according to the two-year results, SMILE is a safe, effective, predictable, and stable method for reducing post-DALK refractive error. Under-correction of astigmatism may be due to axis rotation during surgery. Refinement of SMILE treatment nomogram for post-DALK cases seems necessary. This procedure can facilitate the use of spectacle or even contact lenses through improving vision and reducing refraction. However, considering the possibility of graft rejection, longer durations of corticosteroid therapy and more intensive monitoring are required in the post-operative period.

Abbreviations

PK
Penetrating keratoplasty
HOA
higher order aberrations
PRK
photorefractive keratectomy
LASIK
laser in situ keratomileusis
SMILE
small incision lenticule extraction
D
diopter
DALK
deep lamellar keratoplasty
CDVA
corrected distance visual acuity
UDVA
uncorrected distance visual acuity
RSB
residual stromal bed
SIA
surgical induced astigmatism
TIA

target induced astigmatism
CI
correction index
DV
difference vector
IoS
index of success
SE
spherical equivalent refraction

Declarations

Ethics approval and consent to participate: Approval for this study was obtained from the Ethics Committee of Tehran University of Medical Sciences (IR.TUMS.MEDICINE.REC.1400.102). The study adhered to the tenets of the Helsinki Declaration at all stages. Prior to enrollment, the goals and methods of the study were explained to the parents in the presence of the patients, and signed parent informed consents were obtained.

Consent for publication: Not applicable.

Availability of data and materials: The data are presented in the text.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: Design of study (HH and SA); Data collection (MM); Analysis and interpretation of data (SA, SS, and AM); Writing of article (SA and MM); Critical revision and final approval of article (All authors).

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Figures

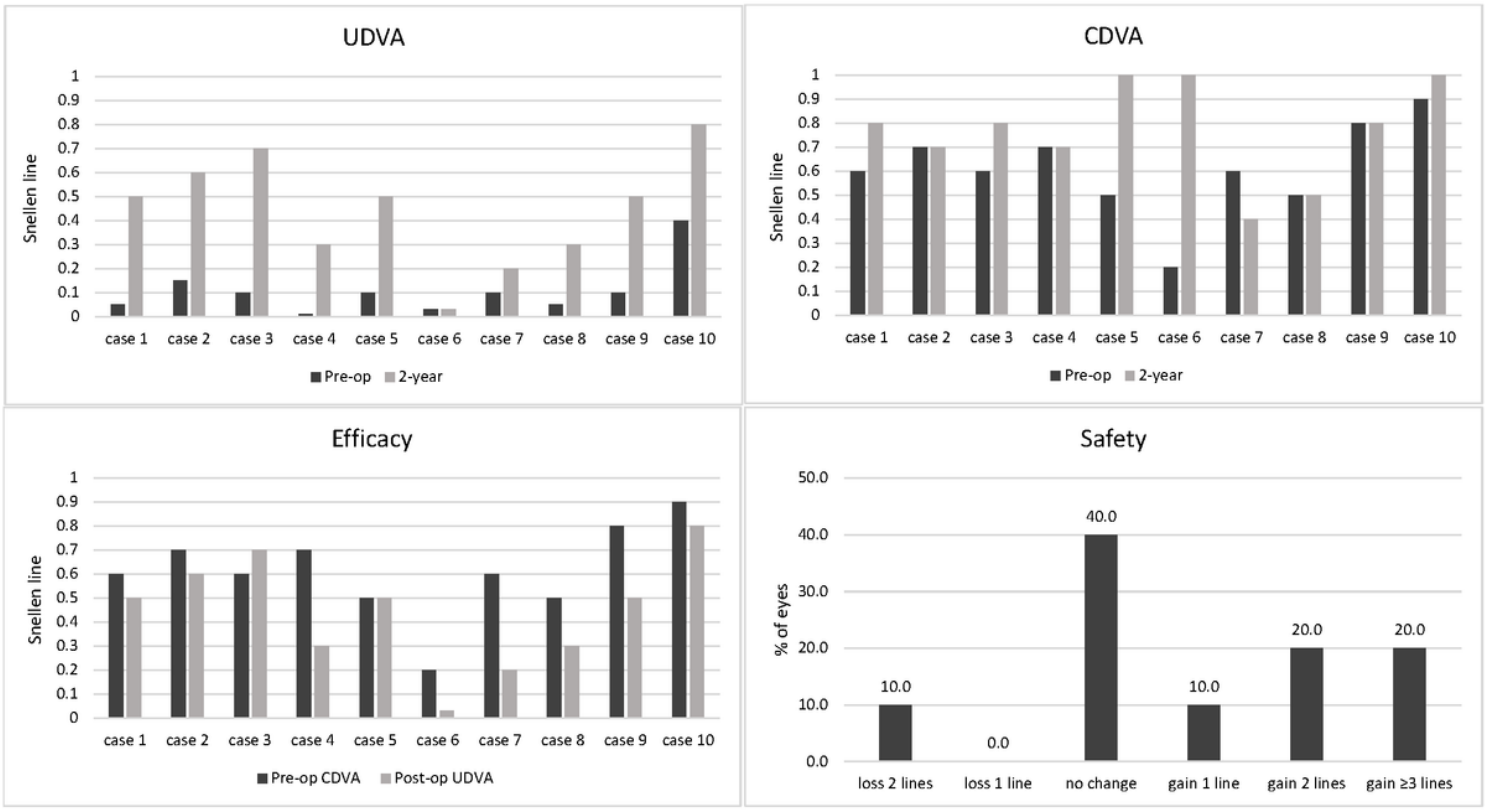

Figure 1

Two-year visual results after small incision lenticule extraction in post keratoplasty patients. Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA)

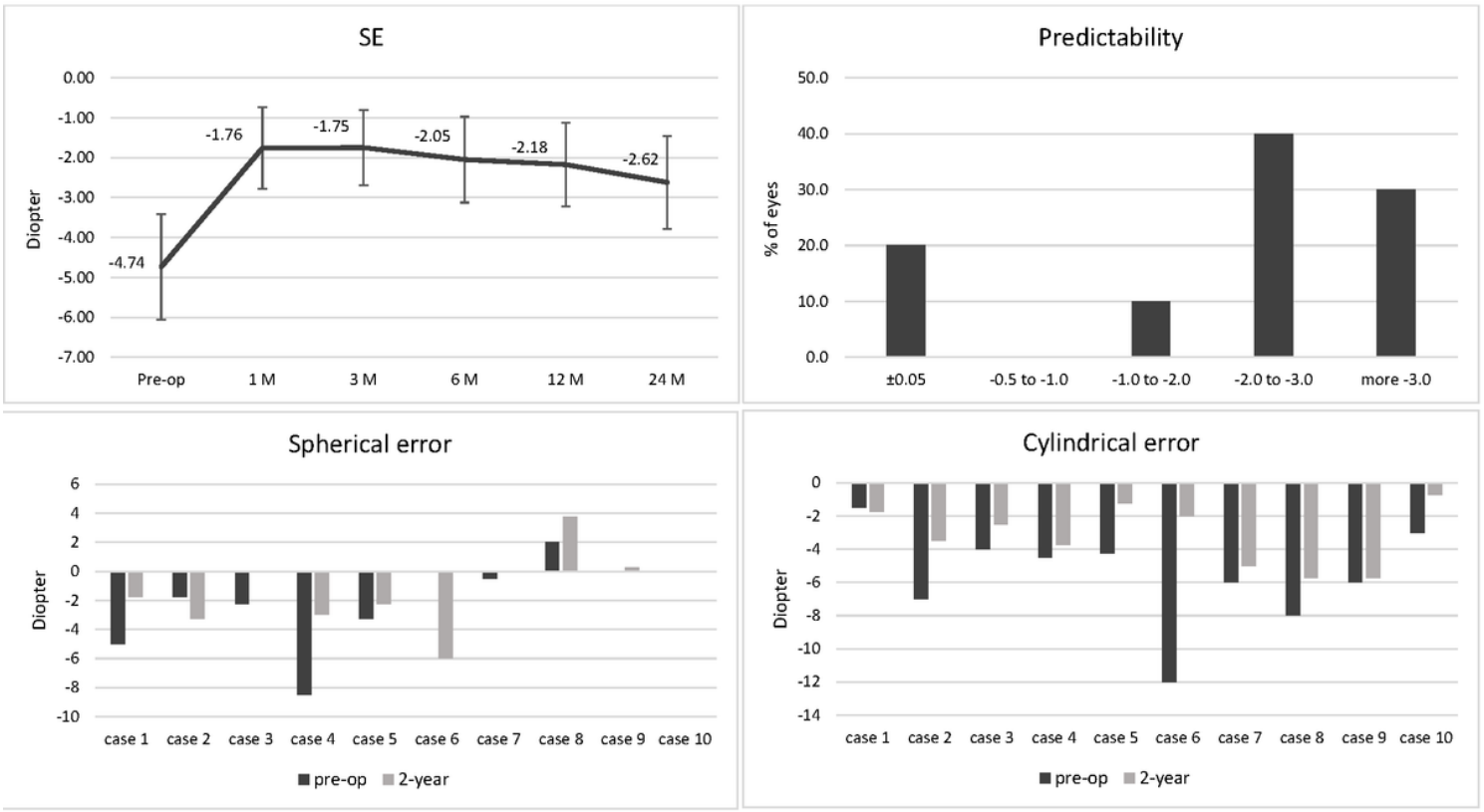

Figure 2

Two-year refractive results after small incision lenticule extraction in post keratoplasty patients. Spherical equivalent (SE)

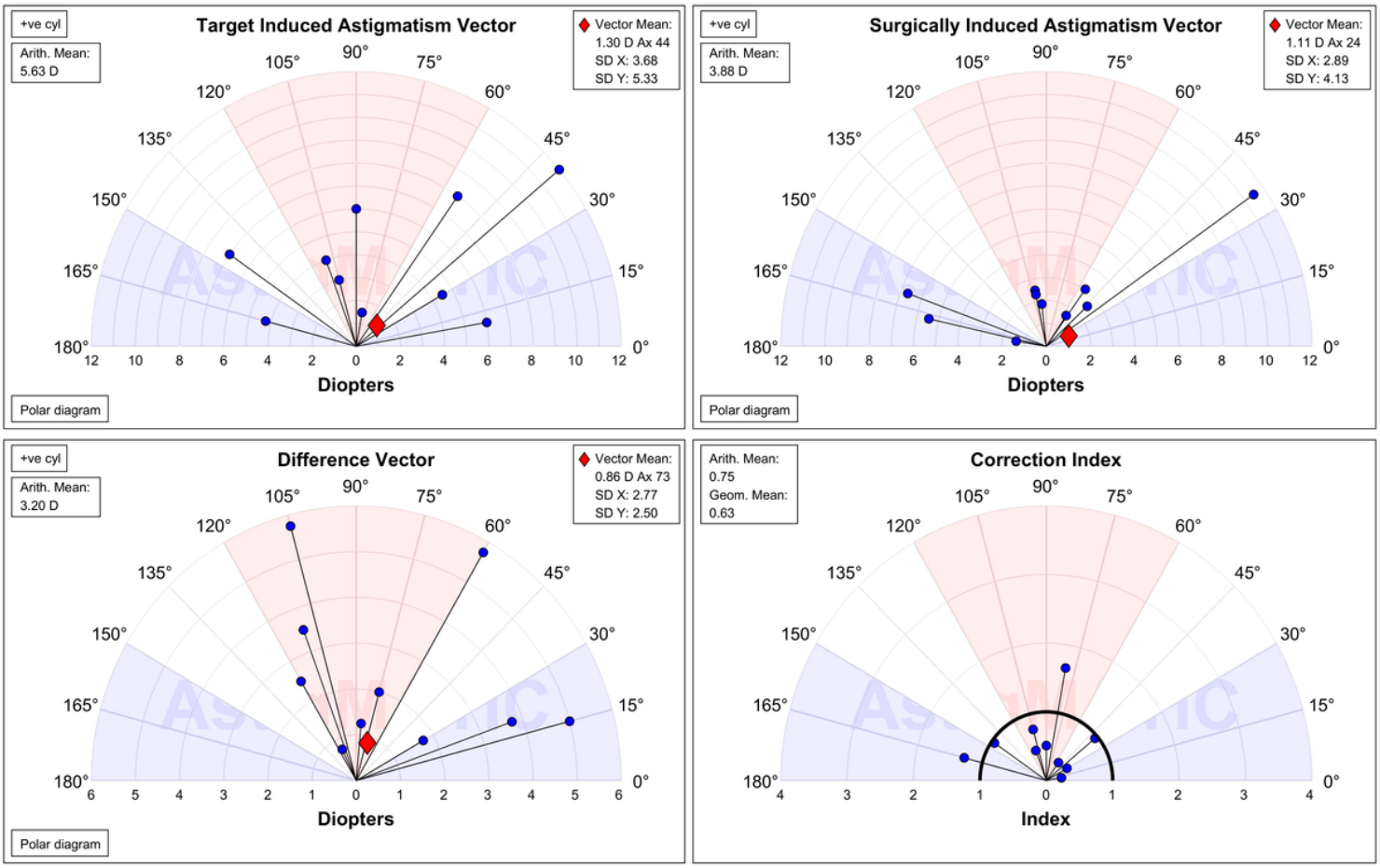

Figure 3

Two-year vectorial astigmatic results after small incision lenticule extraction in post keratoplasty patients.