Non-penetrating Femtosecond Laser Intrastromal Astigmatic Keratotomy in Patients With Mixed Astigmatism After Previous Refractive Surgery

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ABSTRACT

PURPOSE: To report the outcomes of the correction of mixed astigmatism with non-penetrating femtosecond laser intrastromal astigmatic keratotomy in patients with previous refractive surgery.

METHODS: One hundred twelve eyes that had low mixed astigmatism after excimer laser surgery, refractive lens exchange, or phakic intraocular lens implantation underwent intrastromal astigmatic keratotomy using paired symmetrical non-penetrating intrastromal arcuate keratotomies created 60 μm from the surface to 80% depth at 7 mm diameter. Outcome measures included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), subjective refraction, and keratometry. A coupling ratio was calculated to assess the change in spherical equivalent. Average follow-up was 7.6 ± 2.9 months. Patients were divided into two groups: no excimer laser corneal ablation and previous excimer laser surgery. Preoperative and postoperative data were compared between groups and analyses were performed on the whole group of eyes.

RESULTS: Overall, the mean UDVA improved significantly from 0.18 ± 0.14 to 0.02 ± 0.12 logMAR (6/9 to ≈6/6 Snellen) (P < .01). The mean absolute subjective cylinder decreased significantly from 1.20 ± 0.47 diopters (D) preoperatively to 0.55 ± 0.40 D postoperatively (P < .01). Subjective sphere decreased significantly from +0.61 ± 0.33 to +0.17 ± 0.36 D (P < 0.01). The mean CDVA was -0.03 ± 0.08 logMAR (≈ 6/6 Snellen) preoperatively and -0.05 ± 0.09 logMAR (≈ 6/5 Snellen) postoperatively (P = .06). The coupling ratio was 0.92 ± 0.45. There was no statistically significant difference in the preoperative and postoperative sphere, cylinder, UDVA, CDVA, and coupling ratio between groups. No surgical complications occurred.

CONCLUSIONS: Femtosecond laser intrastromal astigmatic keratotomy was effective at reducing refractive error in patients where other surgical options were exhausted. Predictability and efficacy could be improved with nomogram refinement.

[J Refract Surg. 2013;29(3):180-186.]

Despite the increasing accuracy of refractive surgeries, a small percentage of patients undergoing procedures such as LASIK, LASEK, refractive lens exchange, or phakic intraocular lens implantation have residual postoperative astigmatism. Surgical options available to treat undesired postoperative astigmatism include additional laser surgery (on the flat or steep meridians or both),[1] astigmatic keratotomy,[2] and peripheral corneal relaxing incisions.[3]

We report our initial experience with non-penetrating femtosecond-assisted intrastromal astigmatic keratotomy (ISAK) in patients with low mixed astigmatism and a history of refractive surgery. Patients in our study were unsuitable for an excimer laser enhancement (LASIK/LASEK) for various reasons (eg, dry eye syndrome or further ablation would lead to insufficient central corneal thickness).

Astigmatic keratotomy is a well-established method for reducing refractive and keratometric cylinder.[4-10] The precision and accuracy of arcuate incisions in astigmatic keratotomy have significantly improved due to the incorporation of femtosecond laser technology.[11] Promising results have been reported for treatment of high astigmatism that is naturally occurring[12] or due to keratoplasty[13-19] with femtosecond-assisted astigmatic keratotomy. However, the aim of these studies was to reduce a high amount of astigmatism to achieve either spectacle or contact lens tolerance.

In our study, we used the femtosecond laser to create two arcuate non-penetrating intrastromal incisions to correct a low amount of mixed astigmatism and achieve spectacle independence. Because the incisions are not penetrating the cornea and are placed outside the visual axis, we believe this technique could be a safe and minimally invasive alternative for treating such refractions in cases where other surgical op-

<table>
<tr><td colspan="2" align="center">TABLE 1
Author's Nomogram for Femtosecond-assisted Intrastromal Astigmatic Keratotomy in Eyes With Low Mixed Astigmatism[a]</td></tr>
<tr><td>Intended Refractive Cylinder Correction (D)</td><td align="center">Arc Length – 7 mm Optical Zone (degrees)</td></tr>
<tr><td>-0.50 to -1.25</td><td align="center">40</td></tr>
<tr><td>-1.50 to -1.75</td><td align="center">50</td></tr>
<tr><td>-2.00 to -2.75</td><td align="center">60</td></tr>
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D = diopters
[a]All incisions 80% of corneal thickness, 60 microns from epithelium

tions are not possible. Patients with low mixed astigmatism often have reasonable unaided visual acuity and spherical equivalent refraction close to plano. Due to a "coupling effect," astigmatic keratotomy flattens the incised meridian while steepening the opposite meridian[4,6,9,20] and is therefore a good option for treating mixed astigmatism.

PATIENTS AND METHODS

Retrospective data from consecutive patients who underwent ISAK for low mixed astigmatism between March 2010 and September 2011 were analyzed. The study was exempt from full ethics committee approval because it used only retrospective, de-identified patient data. The cases included 60 eyes with previous refractive lens exchange surgery, 5 eyes with phakic intraocular lens implantation, 6 eyes with small stable epithelial ingrowth or flap melt post-LASIK, 16 eyes with severe post-LASIK dry eye syndrome, and 25 eyes that underwent multiple refractive procedures. The 25 eyes that underwent multiple refractive procedures had dry eye syndrome, further ablation would lead to inadequate central corneal thickness, or it was simply not advisable to perform further ablation on corneas with three previous excimer laser procedures.

All patients underwent a preoperative examination that included measurement of autorefraction and tonometry (TONOREF II; Nidek Co. Ltd., Gamagori, Japan), corneal topography and pachymetry (Pentacam; Oculus Inc., Wetzlar, Germany), uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), subjective refraction, cycloplegic refraction (excluding patients with refractive lens exchange), slit-lamp evaluation, and dilated funduscopy. Visual acuities were measured with a Snellen visual acuity chart. Refractions and visual acuities were measured by the same experienced optometrist at the same location to avoid variation in measurements, with a Snellen visual acuity chart at 20 feet.

Follow-up data at 6 months or later were analyzed in this study. The mean time from surgery was 7.6 ± 2.9 months.

Statistical analysis was performed using Microsoft Excel 2007 (Microsoft Corp., Redmond, WA) and STATISTICA 6 (StatSoft Inc., Tulsa, OK) software. Refractive cylinder was displayed on a double-angle plot[21-23] in minus cylinder form. In a double-angle plot, the data for preoperative and postoperative refractive cylinder and axis are converted to an orthogonal x,y coordinate system and the axis of refractive cylinder (ranging from 0 to 180 degrees) is doubled to traverse a circle of 0 to 360 degrees. A modified version of the double-angle plot[22,24] was created by setting the preoperative axis of refractive cylinder to zero and modifying the postoperative axis in relation to the preoperative axis.

SURGICAL PROCEDURE

All patients were informed of the possible intraoperative and postoperative complications and written informed consent was obtained. Surgeries were performed by two experienced surgeons (JV, RB).

A narrow slit-lamp beam was projected in front of the eye, and the corneal limbus was marked at the 90- and 270-degree positions with a sterile disposable ink pen (Devon Fine Skin Marker; Covidien, Mansfield, MA) with the patient sitting upright. The surgical procedure was performed under topical anesthesia (proxymetacaine hydrochloride 0.50%).

The depth of the incisions was set at 80% of the thinnest point of corneal thickness measured within the 7-mm ring of the pachymetry map on the Pentacam. All eyes had paired intrastromal arcuate incisions.

The surgery was performed with the iFS femtosecond laser (software version 2.04; Abbott Medical Optics, Inc., Santa Ana, CA). The IntraLase suction ring was applied and aligned with the 90- and 270-degree corneal marks, and paired symmetric incisions were created on the steepest axis of the manifest cylinder using the IntraLase Enabled Keratoplasty software in the anterior side cut mode. Arcuate incisions were programmed to cut 60 microns from the epithelium toward the endothelium (80% of corneal thickness). All surgeries were performed with a 7-mm diameter, with the arcuate incisions ranging from 40 to 60 angular degrees, based on the magnitude of preoperative refractive cylinder (**Table 1**). The cuts were created with a programmed energy setting of 2 µJ and spot separation of 3 µm. All incisions were intrastromal and were not opened after the procedure.

Patients were instructed to instill topical tobramycin three times daily for 5 days postoperatively.
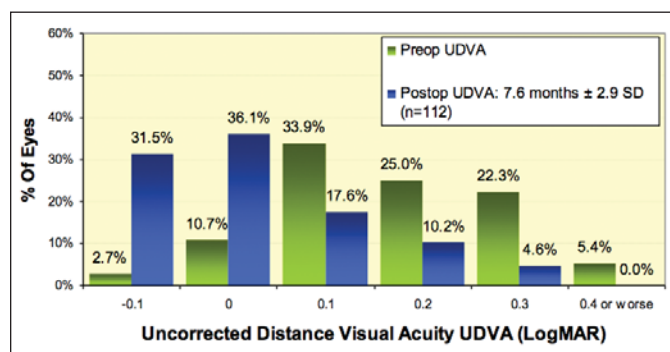
Figure 1. Preoperative and postoperative uncorrected distance visual acuity (UDVA). Note that 85.2% of eyes achieved postoperative UDVA of 6/7.5 (0.1 logMAR) or better.

STATISTICAL ANALYSIS

UDVA and CDVA values were converted to logMAR for statistical analysis. The Wilcoxon rank sum test was used to asses the difference between preoperative and postoperative examination results. A *P* value of less than .05 was considered statistically significant. Data of 112 eyes were divided into two more homogenous groups and compared: 65 eyes that underwent refractive lens exchange or phakic intraocular lens implantation and no excimer laser corneal ablation (no excimer laser corneal ablation group) and 47 eyes that underwent previous excimer laser surgery (previous excimer laser surgery group).

Surgically induced refractive change of subjective cylinder was assessed using the Holladay-Carvy-Koch method.[21] A defocus equivalent was calculated as an absolute value of spherical equivalent (without regard to the sign) plus an absolute value of half cylinder. A coupling ratio[20,21] was calculated as a ratio between flattening of the incised meridian and steepening of the opposite meridian (CRF/S). If the coupling ratio is 1, the flattening of the incised meridian will equal the steepening of the opposite meridian and the spherical equivalent will remain unchanged after astigmatic keratotomy. A coupling ratio greater than 1 indicates a shift of spherical equivalent toward hyperopia and a coupling ratio of less than 1 means a shift of spherical equivalent toward myopia.

RESULTS

One hundred twelve eyes of 98 patients (57 males and 41 females) were included in this study. The mean age at the time of surgery was 56 ± 11.49 years for the whole group, 59 ± 11.30 years for the no excimer laser corneal ablation group, and 52 ± 10.85 years for the previous excimer laser surgery group (*P* < .01).
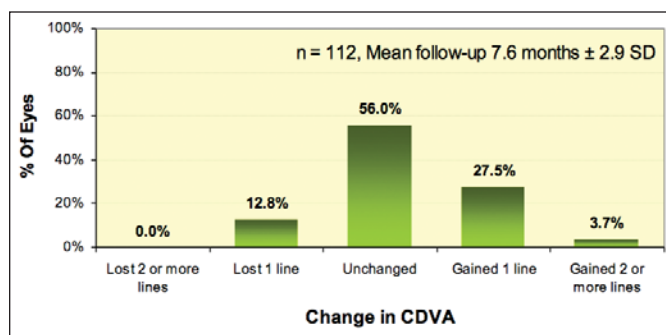
VISUAL ACUITY

Figure 1 displays the preoperative and postoperative UDVA for the whole group of eyes. The mean UDVA improved from 0.18 ± 0.14 to 0.02 ± 0.12 logMAR (6/9 to ≈6/6 Snellen) (*P* < .01), which indicates an average gain of two lines of UDVA; 85.2% of eyes had UDVA 0.1 logMAR (6/7.5 Snellen) or better postoperatively compared to 47.3% preoperatively. When comparing groups, the mean UDVA changed from 0.19 ± 14 to 0.03 ± 0.12 logMAR (≈6/9 to ≈6/6 Snellen) in the no excimer laser corneal ablation group and from 0.16 ± 0.12 to 0.00 ± 0.12 logMAR (≈6/9 to 6/6 Snellen) in the previous excimer laser surgery group (**Table 2**). The preoperative and postoperative difference between two groups was not statistically significant (**Table 2**).

TABLE 2
Comparison of Groups

Variable	Variable No Excimer Corneal Ablation (n = 65 Eyes)	Previous Excimer Laser Surgery (n = 47 Eyes)	*P*
Mean age ± SD (range) (years)	59 ± 11.30 (25 to 80)	52 ± 10.85 (30 to 71)	< .01
Mean preop sphere ± SD (range) (D)	+0.64 ± 0.35 (0.25 to 1.50)	+0.56 ± 0.31 (0.25 to 1.50)	.22
Mean postop sphere ± SD (range) (D)	+0.21 ± 0.39 (-0.25 to 1.25	+0.13 ± 0.31 (-0.75 to 1.00)	.17
Mean preop cylinder ± SD (range) (D)	-1.22 ± 0.49 (-0.75 to -2.75)	-1.15 ± 0.43 (-0.50 to -2.25)	.14
Mean postop cylinder ± SD (range) (D)	-0.58 ± 0.41 (0.00 to -1.25)	-0.49 ± 0.37 (0.00 to -0.75)	.12
Mean preop UDVA ± SD (logMAR)	0.19 ± 0.14	0.16 ± 0.12	.21
Mean postop UDVA ± SD (logMAR)	0.03 ± 0.12	0.00 ± 0.12	.08
Mean preop CDVA ± SD (logMAR)	-0.02 ± 0.07	-0.04 ± 0.09	.11
Mean postop CDVA ± SD (logMAR)	-0.05 ± 0.10	-0.06 ± 0.08	.25
Coupling ratio	0.95 ± 0.37	0.90 ± 0.51	.36

SD = standard deviation; preop = preoperative; D = diopters; postop = postoperative; UDVA = uncorrected distance visual acuity; CDVA = correctd distance visual acuity

Figure 2. Preoperative versus postoperative corrected distance visual acuity (CDVA). No eyes lost two or more lines of CDVA postoperatively and 31.2% of eyes gained one or more lines on preoperative CDVA.

The comparison of preoperative and postoperative CDVA for the whole group of eyes (safety) is plotted on **Figure 2**; 31.2% of eyes gained one or more lines of CDVA. The mean CDVA changed from -0.03 ± 0.08 logMAR (≈6/6 Snellen) preoperatively to -0.05 ± 0.09 logMAR (≈6/5 Snellen) postoperatively (*P* = .06). Both groups started at a similar level of CDVA (no excimer laser corneal ablation group -0.02 ± 0.07 logMAR [≈6/6 Snellen]) and previous excimer laser surgery group -0.04 ± 0.09 logMAR (≈6/6 Snellen) (*P* = .11), and achieved an equally good level of CDVA postoperatively (no excimer laser corneal ablation group -0.05 ± 0.10 logMAR [≈6/5 Snellen] and previous excimer laser surgery group -0.06 ± 0.08 logMAR [≈6/5 Snellen], *P* = .25).

REFRACTIVE OUTCOME

ISAK decreased the mean value of subjective cylinder from -1.20 ± 0.47 D (range: -0.50 to -2.75 D) preoperatively to -0.55 ± 0.40 D (range: 0 to -1.25 D) postoperatively (*P* < .01) in the whole group of eyes. Absolute postoperative refractive cylinder value was 0.50 D or less in 61% and 0.75 D or less in 88.1%. **Figure 3** plots the intended correction of refractive cylinder against the cylindrical component of surgically induced refractive change. There is a trend toward slight undercorrection, although most of the data points (72%) are within ± 0.50 D of the intended correction. Both groups started with the same amount of subjective cylinder (no excimer laser corneal ablation group -1.22 ± 0.49 D, previous excimer laser surgery group -1.15 ± 0.43 D, *P* = .14). The mean postoperative subjective cylinder reduced to -0.58 ± 0.41 D in the no excimer laser corneal ablation group and -0.49 ± 0.37 D in the previous excimer laser surgery group. There was no statistically significant difference in postoperative subjective cylinder between groups (*P* = .12, **Table 2**).

There was statistically significant decreased sphere from +0.61 ± 0.33 D (range: +0.25 to +1.50 D) preop-
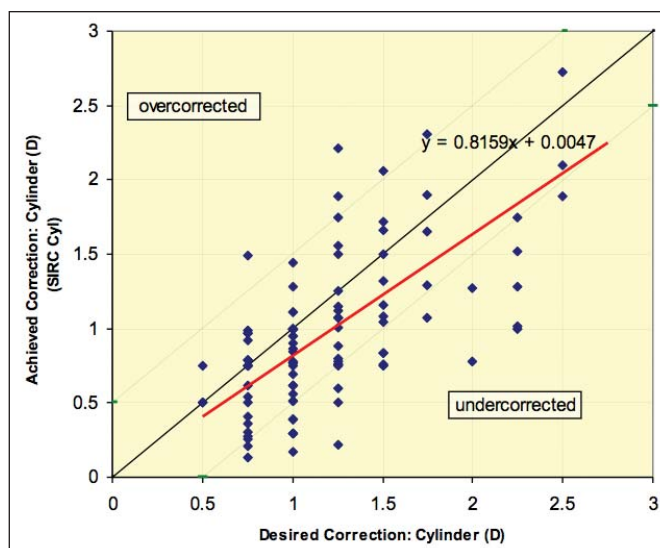

Figure 3. Attempted versus achieved correction of refractive cylinder. Area between two dashed lines represents astigmatic correction within ± 0.50 D of intended correction. The solid red line is the linear regression, which indicates a slight undercorrection. Mean follow-up was 7.6 ± 2.9 months. SIRC = surgically induced refractive change

eratively to +0.17 ± 0.36 D (range: -0.75 to +1.25 D) postoperatively (*P* < .01) in the whole dataset. Defocus equivalent of 0.75 D or better was measured in 27.7% eyes preoperatively and 70.5% of eyes postoperatively (**Figure 4**). Both groups had a comparable amount of preoperative sphere (+0.64 ± 0.35 D in no excimer laser corneal ablation group, +0.56 ± 0.31 in previous excimer laser surgery group, *P* = .22) and there was no statistically significant difference between postoperative sphere in the no excimer laser corneal ablation group (+0.21 ± 0.39 D) and previous excimer laser surgery group (+0.13 ± 0.31 D) (*P* = .17, **Table 2**).

Figure 5 plots the double-angle plot of preoperative and postoperative refractive cylinder in minus cylinder form for the whole group of eyes. The preoperative refractive centroid is close to zero (-0.12 D × 107°). The ellipse surrounding the centroid is twice the standard deviation of x and y values. The ellipse indicates that slightly more patients had with-the-rule or against-the-rule astigmatism and then oblique astigmatism preoperatively. The postoperative ellipse is rounder, demonstrating there was approximately the same amount of with-the-rule, against-the-rule, and oblique astigmatism. The postoperative centroid was -0.10 D × 138° and most of the postoperative data points are closer to the null point and grouped within a 1.0 D circle.
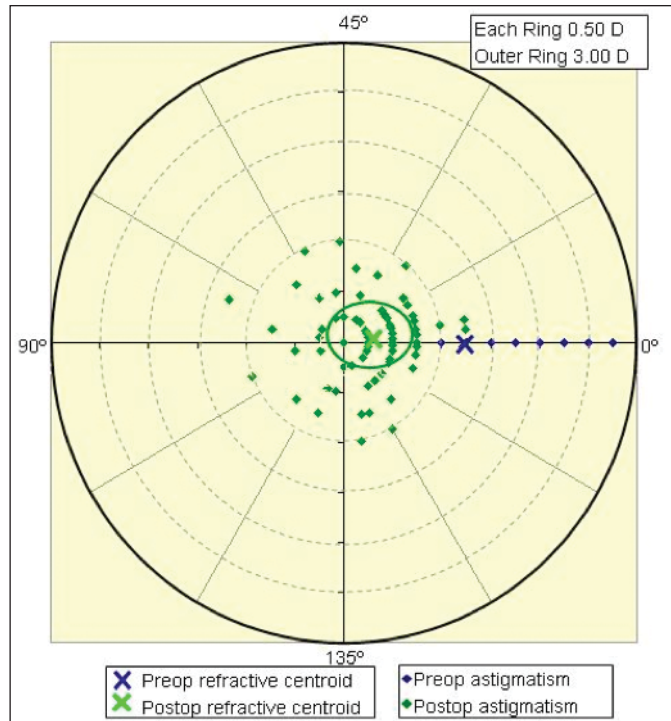
A modified version of the double-angle plot is displayed in **Figure 6** and describes the relationship between the postoperative axis of refractive cylinder and the preoperative axis. Postoperatively, 75.7% of eyes
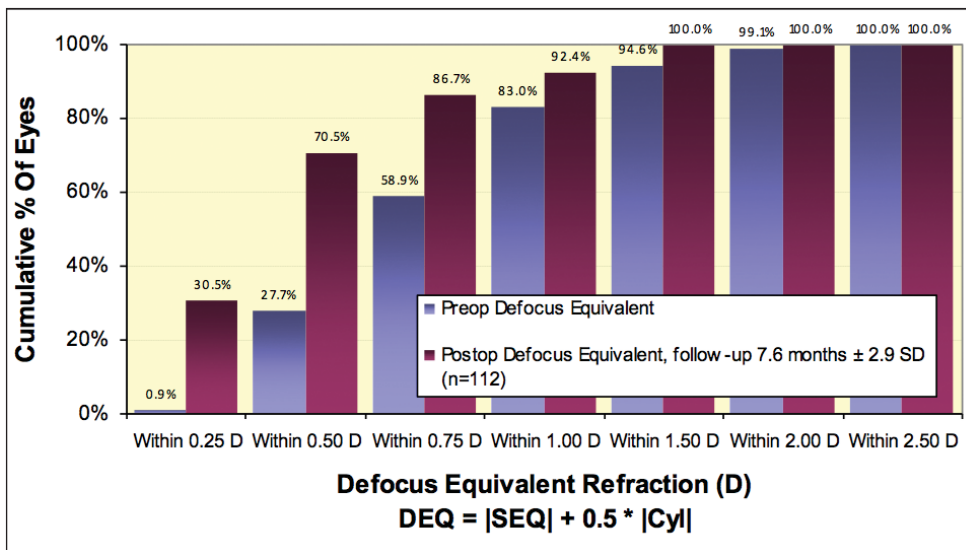
Figure 4. Cumulative preoperative and postoperative defocus equivalent refraction. DEQ = defocus equivalent, SEQ = spherical equivalent, Cyl = refractive cylinder
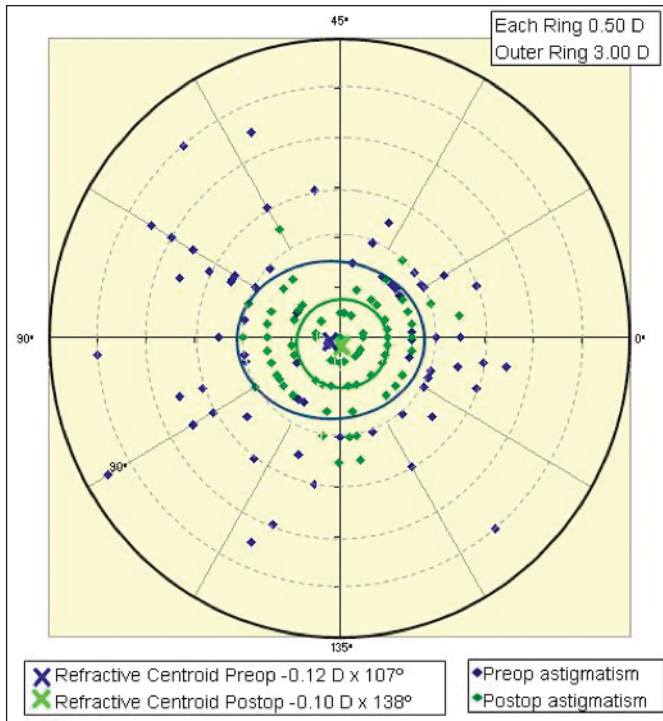
Figure 5. Double-angle polar plot of the preoperative and postoperative refractive cylinder in minus cylinder form. The axes of each ellipse are twice the standard deviation of the x and y values. Both preoperative and postoperative centroids are close to zero, but the ellipse is notably smaller postoperatively.

Figure 6. A modified version of the double-angle plot of preoperative and postoperative refractive astigmatism in minus cylinder form. All preoperative data have axis of astigmatism set to zero and postoperative axis are calculated in the relation to the preoperative axis. Postoperative axis of refractive astigmatism were mostly in the same direction as preoperative with 75.7% of points with ± 45 degrees of the preoperative axis.

were within ± 45 degrees and 50.9% of eyes were within ± 15 degrees of the preoperative axis of astigmatism. Preoperative centroid (blue cross on **Figure 6**) was brought closer to the null point postoperatively (green cross) and stayed in the same direction. Most of the postoperative data points are close to the x-axis on the right side of the plot, indicating mainly on-axis correction and slight undercorrection of refractive cylinder.

COUPLING RATIO

The mean coupling ratio (CRF/S) was 0.92 ± 0.45 for the whole study group. Although the value is close to 1.0, there is a high variation in results with a standard deviation of 0.45. A CRF/S value less than 1 indicates a slight shift of spherical equivalent toward myopia. The coupling ratio was 0.95 ± 0.37 for the no excimer laser

corneal ablation group and 0.90 ± 0.51 for the previous excimer laser surgery group (*P* = .36).

DISCUSSION

Astigmatic keratotomy is a well-established and safe technique to manage astigmatism.[2,4-10] Due to the minimally invasive nature of this technique, it is commonly preferred for astigmatism treatment.[4-10] The major limitations with freehand or mechanical astigmatic incisions are technical difficulties such as incision predictability and complications such as wound dehiscence.[8-10]

Femtosecond laser technology has provided a new surgical modality in corneal surgery.[11] The accuracy, safety, and efficacy of this technology have been reported for several corneal procedures. Theoretically, the femtosecond laser increases the precision of astigmatic keratotomy because of the highly reproducible dimensions and depth of the incisional cuts. The surgeon can better customize the depth and placement of astigmatic keratotomy incisions, which could improve the outcomes. Other advantages include no epithelial injury, a fast procedure, and fast recovery.

Apart from a statistically significant difference in the mean age between the data sets, all preoperative characteristics of the two groups in our study were comparable. In theory, a different effect might be achieved with ISAK in patients in whom corneal tissue was affected by previous refractive procedures. However, we found no statistically significant difference in postoperative sphere, cylinder, UDVA, and CDVA or the coupling ratio (**Table 2**). Therefore, all graphs were plotted for the whole group of eyes.

All patients had a statistically significant improvement in UDVA representing an average gain of two lines of UDVA. The percentage of eyes with UCVA of 6/6 (0.0 logMAR) or better increased from 13.4% to 67.6%.

Comparing preoperative and postoperative CDVA (safety) shows that 31.2% of eyes gained one or more lines postoperatively in the whole dataset. We did not expect a statistically significant change in mean CDVA when treating such low refractions.

We found a statistically significant reduction in the mean value of refractive cylinder with 61% of eyes having a postoperative refractive cylinder of 0.50 D or less compared to 2.5% preoperatively in the whole group of eyes. Previous studies on femtosecond-assisted astigmatic keratotomy[12-19] also proved this technique is effective in reducing refractive cylinder. However, they[12-19] treated much higher astigmatism. To our knowledge, this is the first study of ISAK to fine-tune low refractive error in patients with 'reasonable' UDVA.

The predictability of refractive cylinder, calculated with the Holladay-Carvy-Koch method, shows a slight undercorrection of refractive cylinder (**Figure 3**). A better predictability might be achieved with a more accurate nomogram, but the possibility of overcorrection of the spherical component of the refraction will need to be addressed with any nomogram-related changes.

The modified version of the double-angle plot indicated that 75.7% of eyes were within ± 45 degrees and 50.9% of eyes were within ± 15 degrees of preoperative axis of astigmatism postoperatively (**Figure 6**). A similar analysis was performed by Kumar et al.[19] (femtosecond-assisted astigmatic keratotomy) and Wilkins et al.[24] (mechanical astigmatic keratotomy). In both studies,[19,24] astigmatic keratotomy was performed on eyes with high astigmatism after keratoplasty. Kumar et al.[19] found that additional vectors were induced in other directions, although the postoperative astigmatism centroid was closer to the null point. Wilkins at al.[24] reported that most of the postoperative axes of astigmatism were within ± 15 degrees of the expected axis.

The coupling ratio describes the effect of astigmatic keratotomy on the spherical equivalent.[20,21] The coupling ratio in this study on the basis of change in the refraction was 0.92 ± 0.45 for the whole group. Faktorovich et al.[20] reported a coupling ratio of 0.95 ± 0.10 in eyes with mechanical astigmatic keratotomy. In the same study, a subgroup of patients with preoperative refractive cylinder of 2.00 D or less had a coupling ratio of 0.65 ± 0.15. Although our coupling ratio was close to 1.0, there was a higher variation in results compared to those of Faktorovich et al.[20] Significant variation is possible when working with low refractions; for example, a 0.25 D change in refraction can make a significant difference to the coupling ratio.

No intraoperative or late postoperative complications were seen during the follow-up period. Unlike previous studies of femtosecond-assisted astigmatic keratotomy,[12-19] our arcuate incisions were intrastromal and were not opened. Whether this contributed to the lack of complications remains to be investigated.

The femtosecond laser, with its ability to perform precise corneal incisions at a variety of depths and orientations, is a powerful tool for astigmatic correction, especially for patients where excimer laser surgery is contraindicated. The femtosecond laser allows us to perform arcuate astigmatic incisions at a customized, predetermined depth and incision length. This could enhance the predictability of this procedure, resulting in better final outcomes.

AUTHOR CONTRIBUTIONS

Study concept and design (SS, JV); data collection (RB, MP, JV); analysis and interpretation of data (MP); drafting of the manuscript (MP, JV); critical revision of the manuscript (RB, SS, JV); statistical expertise (MP); supervision (RB, JV)

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