Clinical outcomes of wavefront-guided laser in situ keratomileusis to treat moderate-to-high astigmatism

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Purpose: The purpose of this study was to evaluate the refractive and visual outcomes of wavefront-guided laser in situ keratomileusis (LASIK) in eyes with myopic astigmatism and cylindrical component ≥2.0 diopter (D).

Methods: In this retrospective study, 611 eyes that underwent LASIK for simple or compound myopic astigmatism were analyzed. Preoperative refractive cylinder ranged from −2.00 D to −6.00 D (mean −2.76±0.81 D), and the sphere was between 0.00 D and −9.75 D (mean −2.79±2.32 D). Predictability, visual outcomes, and vector analysis of changes in refractive astigmatism were evaluated.

Results: At 3 months after LASIK, 83.8% of eyes had uncorrected distance visual acuity of 20/20 or better, 90.3% had manifest spherical equivalent within ±0.50 D, and 79.1% had residual refractive cylinder within ±0.50 D of intended correction. The mean correction ratio for refractive cylinder was 0.92±0.14, the mean error of angle was −0.45°±2.99°, and the mean error vector was 0.37±0.38 D. A statistically significant correlation was found between the error of magnitude (arithmetic difference in the magnitudes between surgically induced refractive correction and intended refractive correction) and the intended refractive correction (r=0.26, P<0.01).

Conclusion: Wavefront-guided LASIK for the correction of myopic astigmatism is safe, effective, and predictable.

Keywords: myopic astigmatism, wavefront-guided LASIK, Hartmann–Shack aberrometer

Introduction
Refractive errors with some degree of astigmatism are relatively frequent. In a recent population-based study, 32.3% of adult participants were found to have refractive cylinder of >0.50 diopter (D).¹ However, the prevalence of moderate or high degree of astigmatism is significantly lower, with as little as 4.61% of patients having cylindrical error of 2.50 D or more.² Surgical correction of astigmatism by means of an excimer laser ablation is technically more difficult and less effective than the treatment of plain spherical refraction.³ Studies reporting outcomes of moderate-to-high astigmatic treatment are relatively scarce,⁴ and often combine different degrees of preoperative refractive cylinder, or lack rigorous analysis of vector parameters of astigmatic refraction.

Several factors can play a role in the inaccuracy of astigmatic surgical correction with excimer lasers. These include precise determination of preoperative magnitude and axis of refractive cylinder, the technology involved in adequate centration of the elliptical ablation profile during surgery,⁵–⁷ as well as understanding the biomechanics of corneal healing⁸ and incorporating it into the treatment nomogram.

In this study, we evaluated the results of wavefront-guided (WFG) laser in situ
keratomileusis (LASIK) in a large cohort of patients with simple or compound myopic astigmatism and refractive cylinder ≥2.00 D. To our knowledge, this is the first study reporting WFG excimer laser astigmatic correction for such large dataset.

**Patients and methods**

This retrospective, noncomparative study was deemed exempt from full review by the Committee of Human Research at the University of California, San Francisco, because it used only retrospective, de-identified patient data. Informed consent to undergo LASIK procedure was obtained from all patients.

Data were extracted from electronic database using the following criteria: primary LASIK procedures targeted for emmetropia; successful completion of 1 week, 1 month, and 3 months postoperative exam; preoperative simple or compound myopic astigmatism between 2.0 D and 6.0 D with no more than manifest spherical equivalent (MSE) of −12.0 D; surgeries performed with the VISX STAR S4 IR excimer laser (Abbott Medical Optics Inc., Santa Ana, CA, USA) using a WFG ablation profile derived from the iDesign Advanced WaveScan System (Abbott Medical Optics Inc.); visual acuity correctable to 20/32 or better prior to LASIK in both eyes; and age of 18 years or older. Data extraction techniques have been previously described.15

Exclusion criteria were active ophthalmic diseases, abnormal corneal shape, concurrent medications, or medical conditions that could impair healing of the ocular surface, and calculated postoperative corneal stromal bed thickness <250 μm in each eye. Soft contact lens wearers were asked to discontinue use at least 1 week prior to the procedure. Hard contact lens users (polymethylmethacrylate or rigid gas-permeable lenses) removed their lenses at least 3 weeks prior to baseline measurements and had two central keratometry readings and two manifest refractions taken at least 1 week apart that did not differ by >0.50 D in either meridian.

The preoperative ophthalmic examination included manifest and cycloplegic refraction, monocular and binocular uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) using a calibrated projected eye chart, low-light pupil diameter, slit lamp biomicroscopy, dilated fundus examination,planation tonometry, corneal topography, ultrasound pachymetry, and wavefront aberration measurement.

Postoperative visits were scheduled for 1 day, 1 week, 1 month, and 3 months. On the first postoperative visit, a detailed slit lamp examination was performed to evaluate flap position and the integrity of the cornea. At the remaining visits, manifest refraction, UDVA, CDVA, and slit lamp examinations were performed.

**Surgery**

All LASIK procedures were performed by experienced surgeons. Superior-hinge flaps were created by a femtosecond laser (iFS, Abbott Medical Optics Inc.). The diameter of the femtosecond flaps ranged from 8.0 mm to 9.2 mm, and the programmed depth ranged from 100 μm to 120 μm. Preoperative aberrometry was measured with the iDesign System, and the calculated ablation profile incorporated both higher order and lower order aberrations. The features of this aberrometer have been previously described.16 A nomogram was used to adjust the sphere according to the magnitude of the aberrometer-derived cylinder16 to avoid overcorrection of sphere. After the flaps were lifted, the programmed treatment was applied once iris registration was achieved. All surgical procedures were performed under topical anesthesia. Standard topical postoperative treatment was administered to all patients, consisting of a topical antibiotic and steroid drops four times a day for 1 week and preservative-free artificial tear drops, as necessary.

**Statistical analysis**

Parametric statistics were used to analyze differences between preoperative and postoperative outcomes (paired Student’s t-test), and Pearson correlation coefficients were used to assess the correlation between different variables. Vector analysis of change in refractive cylinder was performed, using a previously described technique.17 Prior to calculations, axes of left eye refractions were transformed (180° minus the original axis) to avoid certain errors when averaging data for right and left eyes.17 Astigmatic data were displayed on a double-angle plot. 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°) is doubled to traverse a circle of 0°–360°. Additionally, a normalized version of double-angle plot was constructed by setting the preoperative axis of refractive cylinder as zero, and modifying the postoperative axis in relation to the preoperative axis. Basic definitions of all vector parameters used in this study are presented in Table 1. All data were analyzed using Microsoft Office Excel 2007 program (Microsoft Corporation) and STATISTICA (StatSoft Inc.) on a personal computer. A level of significance of P=0.05 was used.
The vector difference between the preoperative astigmatic correction vector and the target postoperative cylinder vector. If the target refractive state is emmetropia, the IRC vector is equal to the preoperative astigmatic correction vector.

SIRC (D)

The vector difference between the preoperative and postoperative astigmatic correction vectors. SIRC represents the achieved correction.

EV (D)

The vector difference between the IRC and SIRC. When the refractive target is emmetropia, the EV is identical to the postoperative astigmatic correction vector.

ER

The proportion of the intended correction that was not successfully treated (|EV|/|IRC|). A ratio of 1 is ideal, whereas <1 implies undercorrection and >1 implies excessive application of the treatment.

CR

The ratio of the achieved correction magnitude to the required correction (|SIRC|/|IRC|). The angular difference between the achieved treatment and the intended treatment. The EA is negative if the SIRC is clockwise from the IRC and positive if the SIRC is counterclockwise from the IRC.

EM (D)

The arithmetic difference of the magnitudes between SIRC and IRC (|IRC|–|SIRC|).

The changes in CDVA between preoperative and 3 months postoperative visit were as follows: loss of two lines or more, 0.8% (five eyes); loss of one line, 6.1% (37 eyes); unchanged, 65.1% (398 eyes); gain of one line, 23.6% (144 eyes); and gain of two lines or more, 4.4% (27 eyes).

Refractive outcomes

Figure 2 plots attempted MSE against achieved MSE at 3 months postoperatively. The linear regression of the scattergram has a slope of 0.98 and the intercept of −0.07. At 3 months, 90.3% (n=552) of eyes were within ±0.50 D, and 99.2% (n=606) were within ±1.0 D of emmetropia. The percentage of eyes with residual refractive cylinder of ≤0.50 D, ≤0.75 D, and ≤1.00 D was 79.1% (483 eyes), 88.5% (541 eyes), and 95.7% (585 eyes), respectively. Table 3 shows the stability of refractive error between 1 week and 1 month, and between 1 month and 3 months visits. There was a small, but statistically significant change in refractive cylinder.
between 1 month and 3 months (−0.03±0.34 D, P=0.01), while sphere and MSE remained stable between the two visits.

**Vector analysis of refractive cylinder**

Figure 3 plots the intended refractive correction (IRC) versus surgically induced refractive correction (SIRC) at 3 months, postoperatively. Table 4 summarizes all vector parameters, stratified by the magnitude of preoperative refractive cylinder. The correction ratio for the whole study group was 0.92±0.14, indicating a slight undercorrection. There was a statistically significant correlation between IRC and error vector (r=0.29, P<0.01) and between IRC and error of magnitude (r=0.26, P<0.01). The percentage of eyes with error of angle within 5° and 10° was 89.2% (545 eyes) and 98.4% (601 eyes), respectively.

Figure 4 plots preoperative and 3 months postoperative refractive cylinder in a double-angle plot. The centroid of postoperative cylinder moved closer to the null point, and the shape of the ellipse (standard deviation of x and y data points) reduced significantly. Figure 5 depicts the normalized error vector. At 3 months, 71.0% and 84.1% of eyes had axis shift within ±15° and ±30°, respectively.

**Discussion**

Findings of this study indicate that WFG LASIK in myopic eyes with high cylinder is safe, efficient, and predictable. Three months postoperatively, 90.3% (n=552) of eyes had MSE within ±0.50 D of intended correction, and 83.8% (n=512) had postoperative UDVA 20/20 or better. There was a statistically significant improvement in CDVA from −0.04±0.07 logMAR preoperatively to −0.07±0.06 logMAR 3 months postoperatively. The comparison with other studies is difficult mainly because in most of the studies of myopic astigmatism, there is no differentiation between different degrees of refractive cylinder. Studies summarized in Table 5 present results specifically for myopic eyes with moderate-to-high cylinder. We achieved favorable outcomes in comparison to the literature review. Although the mean preoperative refractive cylinder in our study group is slightly lower than in most of the other studies, Table 4 shows error vector (which essentially equals to the magnitude of residual refractive cylinder) stratified by preoperative cylinder. The highest error vector we achieved was 0.74±0.55 D in the subgroup of eyes with preoperative refractive cylinder between 5.00 D and 6.00 D.
We observed a small, but statistically significant, regression in refractive cylinder between 1-week and 1-month visits (−0.08±0.39 D, \(P<0.01\)), and 1-month and 3-month visits (−0.03±0.34, \(P=0.01\)), while a small hyperopic shift in sphere between 1-month and 3-month exams was not statistically significant (+0.02±0.30, \(P=0.10\)). This contradicts the study of Igarashi et al\(^6\) where changes in spherical and cylindrical error were longitudinally assessed over a 1-year period following LASIK for moderate-to-high myopic astigmatism. The authors found significant regression in sphere but no statistically significant change in cylinder between 1-week and 1-year exams (mean cylinder −0.67±0.54 D at 1 week and −0.63±0.63 D at 1 year).\(^7\) The study was conducted on 48 eyes with preoperative refractive cylinder of −2.74±0.99 D.

Similar findings were presented in the study of Hasegawa et al\(^8\) where refractive cylinder remained stable up to 12 months postoperatively in patients with moderate-to-high myopic astigmatism. A small change in refractive cylinder in our study showed statistical significance probably due to the large sample size (compared to other studies); however, it would be interesting to evaluate whether there was a further change beyond the 3-month postoperative visit.

The vector analysis of refractive cylinder revealed slight undercorrection with the correction ratio (ratio of the magnitude of SIRC to IRC) of 0.92±0.14 at 3 months postoperatively. The mean error of magnitude (arithmetic difference in magnitude of SIRC to IRC) of 0.92 ±0.30, \(P=0.01\) was found. This variable was correlated to the IRC (\(r=0.26, P<0.01\)). The error of angle was minimal and slightly clockwise (−0.45°) with a relatively low standard deviation of 2.99°. In comparison to other studies reporting vector analysis of high myopic astigmatism, Alió et al\(^9\) found a similar mean error of angle of −0.49° but higher standard deviation (4.41°) in a group of patients with the mean preoperative refractive cylinder of −3.64±0.55 D. Wavefront-optimized ablation profile with cyclotorsion control was used in this study, and similar undercorrection was seen (correction ratio 0.91±0.13). Katz et al\(^10\) using a wavefront-optimized ablation profile, achieved a median correction ratio of 1.06, and the median error of angle of 3.60° (95% confidence interval 2.28°−6.28°) in eyes with preoperative refractive cylinder greater than 3.00 D. In our study, the absolute error of angle was <2° for each subgroup of preoperative refractive cylinder (Table 4), and the standard deviation was low in each category.

Astigmatic correction requires adequate centration of the treatment and control of cyclotorsional movements. Cyclotorsion that can occur when patients change from an

| Table 3 Stability of refraction between 1 week, 1 month, and 3 months postoperative visits (n=611) |
|-----------------|-----------------|-----------------|
| Change in sphere by ±0.5 D | 94.4% (577 eyes) | 95.1% (581 eyes) |
| Mean change in sphere ± SD (P-value) | +0.04±0.32 (\(P<0.01\)) | +0.02±0.30 (\(P=0.10\)) |
| 95% CI | +0.01 to +0.06 | −0.00 to −0.04 |
| Change in Cyl by ±0.5 D | 88.1% (538 eyes) | 93.3% (570 eyes) |
| Mean change in Cyl ± SD (P-value) | −0.08±0.39 (\(P<0.01\)) | −0.03±0.34 (\(P=0.01\)) |
| 95% CI | −0.11 to −0.05 | −0.06 to −0.01 |
| Change in MSE by ±0.5 D | 93.1% (569 eyes) | 92.1% (563 eyes) |
| Mean change in MSE ± SD (P-value) | 0.00±0.32 (\(P=0.85\)) | 0.00±0.31 (\(P<0.82\)) |

**Abbreviations:** D, diopter; SD, standard deviation; CI, confidence interval; Cyl, cylinder; MSE, manifest spherical equivalent.
upright to supine position is a known source of astigmatic undercorrection. On average, the cyclotorsional errors are approximately 2° but could be much higher in a small percentage of patients.

A 4° and a 10° misalignment would theoretically result in a 14% and a 35% undercorrection of astigmatism, respectively. The misalignment can also result in induction of higher order aberrations (HOAs), which would defeat the object of WFG laser correction. In this study, we used a new Hartmann–Shack device (iDesign System) that uses an enhanced iris registration system with a high-definition camera and increased capture rate, which could have had an impact on the astigmatism accuracy achieved in this study. Postoperative HOAs were not assessed in this study, which would be interesting to evaluate, since a new diagnostic device was used. Currently, there is only one study reporting changes in postoperative HOAs of WFG LASIK linked to the iDesign System. The study found minimal induction of HOAs, which was poorly correlated to the level of preoperative myopia, and there was a decrease in HOAs recorded in 30.4% of eyes. However, it would be interesting to evaluate changes in HOAs, specifically in patients with high refractive cylinder, which could be a subject of future prospective studies.

### Table 4 Vector analysis of changes in refractive cylinder stratified by the magnitude of preoperative cylinder

<table>
<thead>
<tr>
<th>Vector parameter</th>
<th>All eyes</th>
<th>Preoperative cylinder (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=611</td>
<td>2.00–2.99</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>Range</td>
<td>n=410</td>
</tr>
<tr>
<td>irC (D)</td>
<td>2.76 (0.81)</td>
<td>2.00–6.00</td>
</tr>
<tr>
<td>sirC (D)</td>
<td>2.53 (0.80)</td>
<td>0.85–5.50</td>
</tr>
<tr>
<td>EV (D)</td>
<td>0.37 (0.38)</td>
<td>0.00–2.00</td>
</tr>
<tr>
<td>ER</td>
<td>0.13 (0.14)</td>
<td>0.00–0.78</td>
</tr>
<tr>
<td>CR</td>
<td>0.92 (0.14)</td>
<td>0.38–1.48</td>
</tr>
<tr>
<td>EM (D)</td>
<td>0.22 (0.40)</td>
<td>–1.25 to 1.71</td>
</tr>
<tr>
<td>EA (°)</td>
<td>–0.45 (2.99)</td>
<td>–22.33 to 10.78</td>
</tr>
<tr>
<td>Absolute EA (°)</td>
<td>1.52 (2.62)</td>
<td>0.00–22.33</td>
</tr>
</tbody>
</table>

**Abbreviations:** D, diopter; SD, standard deviation; irC, intended refractive correction; sirC, surgically induced refractive correction; EV, error vector; ER, error ratio; CR, correction ratio; EM, error of magnitude; EA, error of angle.

### Figure 4 Double-angle polar plot of preoperative and postoperative (3 months) refractive cylinder in plus cylinder form.

**Note:** The centroid is the mean of x and y data points, and the axes of each ellipse are twice the standard deviation of the x and y values.

**Abbreviation:** D, diopter.

### Figure 5 Distribution of NEV.

**Note:** NEV is calculated by setting the preoperative axis of refractive cylinder to zero and modifying the postoperative axis in relation to the preoperative axis.

**Abbreviation:** NEV, normalized error vector.
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The limitation of this study was that we concentrated on accuracy of astigmatic correction in patients with high preoperative cylinder, but we were unable to comment on changes in postoperative HOAs, which would prove difficult in such a large cohort. Since we observed a change in refractive cylinder, it would be of interest to assess the refractive change over a longer period of time, which was not possible with our retrospective data.

Although our study confirms that correction of cylinder is not as effective as the spherical component and slight undercorrection was seen in our dataset, clinically acceptable results were achieved in a large cohort of patients with a significant portion of eyes achieving 20/20 visual acuity. Despite some drawbacks, this study is, to the best of our knowledge, one of the few studies presenting results of WFG LASIK in patients with high refractive cylinder.

Disclosure

Steven C Schallhorn, MD, is a consultant of Abbott Medical Optics Inc. and Zeiss, and a Global Medical Director of Optical Express. The other authors report no conflicts of interest in this work. None of the other authors have a financial or proprietary interest in the products and materials presented in this paper.

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