Correction of Myopic Astigmatism With Small Incision Lenticule Extraction

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ABSTRACT

PURPOSE: To evaluate the outcome after small incision refractive lenticule extraction (SMILE) in patients with myopic astigmatism.

METHODS: Seven hundred seventy-five eyes from 403 patients with myopia treated with SMILE for a cylinder of 0.75 diopters (D) or more were identified from patient records. Six hundred sixty-nine eyes were defined as receiving low (<2.5 D) and 106 eyes as receiving high (≥2.5 D) astigmatic correction. Patients were examined before and 3 months after surgery. SMILE was performed with a Visumax femtosecond laser (Carl Zeiss Meditec, Jena, Germany). Preoperative and postoperative refractions were converted to polar values. Induced torsion and achieved corrections of sphere and cylinder were determined.

RESULTS: In low astigmatism, the mean preoperative spherical equivalent (SE) was -7.57 ± 1.67 D and the cylinder was -1.22 ± 0.49 D. Three months after surgery, SE was -0.19 ± 0.48 D from target, astigmatism was 0.17 ± 0.42 D undercorrected, and a small but significant torsion of the cylinder axis corresponding to 0.05 ± 0.37 D was found. The astigmatic undercorrection measured 13% per diopter of attempted correction. In high astigmatism, preoperative SE was -5.91 ± 2.56 D and cylinder was -3.22 ± 0.67 D. After surgery, the average astigmatic undercorrection was 0.59 ± 0.65 D, equivalent to 16% per diopter of attempted correction. No undercorrection in SE occurred and no torsion was found.

CONCLUSIONS: SMILE in myopic astigmatism offers predictable correction of SE, but a small, significant undercorrection of the astigmatic error. The undercorrection increases with the attempted treatment. Only very little rotation of the cylinder axis was found.

were examined before and 3 months after surgery. Examinations included manifest refraction and uncorrected (UDVA) and corrected distance visual acuity (CDVA). In a few cases, postoperative anterior segment optical coherence tomography (Heidelberg Spectralis; Heidelberg Engineering GmbH, Heidelberg, Germany) was performed to visualize the intrastromal interface. Specially trained optometrists performed all clinical refractions.

SURGERY

In all patients, surgery was performed using topical anesthesia with two drops of 0.8% oxybuprocaine tetrachloride a few minutes before surgery. SMILE was performed using a 500-kHz Visumax femtosecond laser (Carl Zeiss Meditec, Jena, Germany) as previously detailed.3,4 The patient was asked to fixate the blinking target, the eye was centered under the laser, and suction was applied. The posterior surface of the lenticule was cut initially, followed by the anterior surface that was extended toward the periphery to allow surgical manipulation of the lenticule. A 30°- to 60°-incision was created at the 12-o’clock position. The diameter of the lenticule ranged from 6.0 to 7.0 mm with a transition zone of 0.0 or 0.1 mm. The diameter of the cap ranged from 7.3 to 7.7 mm and the cap thickness varied from 110 to 130 µm.

All surgeries were performed with one of two different laser settings: setting 1 with a laser cut energy index of 25 to 27 (approximately 130 nJ) and a spot spacing of 2.5 to 3.0 µm, or setting 2 with a laser cut energy index of 34 (approximately 170 nJ) and a spot spacing of 4.5 µm. Laser setting 1 was used for surgery in 244 low astigmatic and 28 high astigmatic eyes, whereas setting 2 was used in the remaining 425 low and 78 high astigmatic procedures. A blunt spatula was used to break any tissue bridges after the laser treatment and the lenticule was removed with a pair of forceps. Postoperative treatment comprised chloramphenicol (Takeda Pharma, Roskilde, Denmark) and fluorometholone (Flurolon; Allergan, Upplands Väsby, Sweden) four times a day tapered over 2 weeks.

ANALYSES

All preoperative and postoperative spherocylindrical refractions were converted into spherical equivalent (SE) and two polar values as previously reported.11,12

In brief, to fully characterize the refractive cylinders, we calculated the astigmatic polar values at the main meridian (AKP) and at an oblique meridian 45° counterclockwise to the main meridian (AKP +45°). Surgically induced astigmatism was determined from the change in AKP from before to after surgery (ΔAKP), and surgically induced torsion or rotation of the cylinder axis was determined from the change in AKP +45 (ΔAKP +45°), with negative values indicating a clockwise change. The errors in treatment, AKP error and AKP +45, error, were calculated by subtraction of the achieved change from the intended value.

The average polar values were converted to net cylinder format as previously shown and the blur due to the postoperative refraction (error of treatment) was estimated by calculation of the amount of defocus as previously reported.12

Data were tested for normality using the D’Agostino–Pearson test. Statistics were performed as unpaired t tests, and as a bivariate analysis of the combined mean polar values with calculation of two-dimensional confidence ellipses and determination of Hotelling’s T2 as previously detailed.11,13

RESULTS

A total of 775 eyes with an attempted astigmatic correction of 0.75 D or more were identified. Of these eyes, 669 were treated for astigmatism below 2.50 D, and the remaining 106 eyes were treated for astigmatism of 2.50 D or more. The preoperative and postoperative patient characteristics are given in Table 1.

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TABLE 1

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Low Astigmatism (669 Eyes)</th>
<th>High Astigmatism (106 Eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>39 ± 8 (19 to 56)</td>
<td>36 ± 9 (21 to 54)</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>131/213</td>
<td>23/36</td>
</tr>
<tr>
<td>Preoperative sphere (D)</td>
<td>-6.96 ± 1.69 (-12.50 to 0)</td>
<td>-4.30 ± 2.66 (-9.50 to -0.25)</td>
</tr>
<tr>
<td>Preoperative cylinder (D)</td>
<td>-1.22 ± 0.49 (-2.75 to 0)</td>
<td>-3.22 ± 0.67 (-5.75 to -2.50)</td>
</tr>
<tr>
<td>3-month postoperative sphere (D)</td>
<td>-0.09 ± 0.53 (-3.25 to 2.25)</td>
<td>0.25 ± 0.61 (-1.50 to 2.25)</td>
</tr>
<tr>
<td>3-month postoperative cylinder (D)</td>
<td>-0.44 ± 0.36 (-1.75 to 0)</td>
<td>-0.79 ± 0.58 (-2.75 to 0)</td>
</tr>
</tbody>
</table>

D = diopters

*Data are given as mean ± standard deviation with range in parenthesis.*
Three months after surgery, the intended and achieved spherical equivalent corrections were highly correlated ($R^2 = 0.93; P < .001$) (Figure 1A) with 77% and 95% of the eyes within ±0.50 and ±1.00 D of the intended correction, respectively (Figure 2).

In Table 2, the polar values of the low astigmatic group are detailed. After surgery, the mean reduction in spherical equivalent power was 7.26 ± 1.57 D, and the mean induced surgical flattening at the main meridian was 1.04 ± 0.57 D. However, a significant undercorrection in both spherical power and astigmatic polar value (AKP) was observed. Furthermore, the observed change in astigmatic power at the oblique meridian indicated that a small but significant counterclockwise torsion of the cylinder axis had occurred ($\Delta$AKP$_{45^\circ}$). When examining right and left eyes separately, the $\Delta$AKP$_{45^\circ}$ averaged -0.02 ± 0.35 D in right eyes, and 0.12 ± 0.34 D in left eyes, indicating no torsion in right eyes, but a small significant counterclockwise torsion in left eyes ($P < .001$).

The intended and achieved astigmatic corrections were significantly correlated ($R^2 = 0.50, P < .001$), but linear regression showed an average undercorrection of 13% per diopter of attempted correction (Figure 3A). As seen in Figures 3B-4A, the error in astigmatic correction (AKP$_{\text{error}}$) showed no correlation to the intended spherical correction ($R^2 = 0.003$) or the intended astigmatic correction ($R^2 = 0.03; P = < .001$).

Figure 5A shows the bivariate analysis of the polar values. Confidence ellipses are given for individual samples and for the combined mean, and demonstrate a significant combined error of treatment ($T^2 = 108; P < .001$). The astigmatic error, given in conventional net cylinder format, was 0.17 D at 8° relative to the preoperative stronger meridian, and the mean defocus after surgery was 0.48 ± 0.35 D.

A total of 602 eyes were treated for plano refraction (± 0.25 D), and 487 of these eyes (81%) had a UDVA of 20/25 or better (Figure 6A). By 3 months, 19 eyes had lost two or more lines in CDVA (Figure 6B); however, these patients were offered a late reexamination, and all eyes recovered to within one line of the preoperative CDVA.

**Low Astigmatism**

In low astigmatism, the intended and achieved spherical equivalent corrections were highly correlated ($R^2 = 0.97; P < .001$) (Figure 1A) with 77% and 95% of the eyes within ±0.50 and ±1.00 D of the intended correction, respectively (Figure 2).

**High Astigmatism**

In highly astigmatic eyes, the intended and achieved spherical equivalent corrections 3 months after surgery were strongly correlated ($R^2 = 0.97; P < .001$)
TABLE 2

Mean ± SD Polar Values (D) in Eyes With High and Low Astigmatism

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>Target</th>
<th>Error of treatment</th>
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</thead>
<tbody>
<tr>
<td>High astigmatism</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE power</td>
<td>-7.57 ± 1.67</td>
<td>-0.31 ± 0.55</td>
<td>-0.12 ± 0.29</td>
<td>-0.19 ± 0.48&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>AKP</td>
<td>1.22 ± 0.49</td>
<td>0.18 ± 0.40</td>
<td>0.01 ± 0.13</td>
<td>0.17 ± 0.42&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>AKP&lt;sub&gt;+45&lt;/sub&gt;</td>
<td>0</td>
<td>0.05 ± 0.35</td>
<td>0.00 ± 0.10</td>
<td>0.05 ± 0.37&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Low astigmatism</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE power</td>
<td>-5.91 ± 2.56</td>
<td>-0.14 ± 0.53</td>
<td>-0.09 ± 0.29</td>
<td>-0.05 ± 0.49</td>
</tr>
<tr>
<td>AKP</td>
<td>3.22 ± 0.67</td>
<td>0.61 ± 0.63</td>
<td>0.01 ± 0.16</td>
<td>0.59 ± 0.65&lt;sup&gt;a,c&lt;/sup&gt;</td>
</tr>
<tr>
<td>AKP&lt;sub&gt;+45&lt;/sub&gt;</td>
<td>0</td>
<td>0.03 ± 0.45</td>
<td>0.00 ± 0.16</td>
<td>0.03 ± 0.47</td>
</tr>
</tbody>
</table>

SD = standard deviation; D = diopters; SE = spherical equivalent; AKP = astigmatic polar value, or the astigmatic power, at the main meridian; AKP<sub>+45</sub> = astigmatic power at the reference meridian, 45° counterclockwise from the main meridian.

<sup>a</sup>Significant undercorrection (paired t test, P < .001).

<sup>b</sup>Significant torsion (paired t test, P < .001).

<sup>c</sup>Significant difference from low astigmatic eyes (unpaired t-test; P < .001).

Figure 3. (A) Achieved versus intended astigmatic correction for eyes with low (open circles) and high astigmatism. In the high astigmatic eyes, crosses indicate eyes treated with laser setting 1 and closed circles indicate eyes treated with laser setting 2. Points above and below the dashed lines indicate over- and undercorrection, respectively. (B) Error in astigmatic correction at the main meridian (AKP<sub>main</sub>) as a function of the intended astigmatic correction for eyes with low (open circles) and high (closed circles) astigmatism.

Figure 4. Error in astigmatic correction at the main meridian (AKP<sub>main</sub>) as a function of the intended spherical correction for (A) low and (B) high astigmatic eyes.
A total of 77% of the eyes were within ±0.5 D of the intended correction and 97% were within ±1.0 D (Figure 2).

Table 2 shows the polar values of the high astigmatic eyes. The average reduction in spherical equivalent power was 5.76 ± 2.45 D, and the surgically induced flattening at the main meridian averaged 2.61 ± 0.76 D. A significant undercorrection in AKP was observed. However, in high astigmatic eyes no significant change at the oblique meridian was found (ΔAKP\text{+45}), indicating that no torsion of the cylinder axis had been induced. Similarly, there were no significant differences in ΔAKP\text{+45} between right and left eyes. Comparing the low and high astigmatic groups, significantly more undercorrection was seen after operation for high astigmatism, whereas no difference was observed with respect to the error in spherical correction or induced torsion (Table 2).

The intended and achieved astigmatic corrections were weakly correlated (R\textsuperscript{2} = 0.38, P < .001), with an average undercorrection of 19% per diopter of attempted correction (Figure 3A). Of the 20 eyes with an astigmatic undercorrection of more than 1.00 D, significantly more eyes had been treated with laser setting.
1 (11 of 28 eyes) than with laser setting 2 (9 of 78 eyes) (chi-square test; \( P < .001 \)), and when considering only eyes treated with laser setting 2, the average undercorrection in high astigmatic eyes was reduced to 16% per diopter of attempted correction.

In high astigmatic eyes, the error in astigmatic correction (AKP\text{error}) showed only a weak correlation to the intended spherical correction (\( R^2 = 0.05; P = .03 \)) (Figure 4B) or to the intended astigmatic correction (\( R^2 = 0.12; P < .001 \)) (Figure 3B). Considering all eyes (both low and high cylinders), the correlation between AKP\text{error} and the intended astigmatic correction was still weak (\( R^2 = 0.13; P < .001 \)).

The bivariate analysis of the polar values is given in Figure 5B for eyes with high astigmatism. The confidence ellipse for the combined means showed a significant combined error of treatment (Hotelling’s \( T^2 = 43; P < .001 \)). The astigmatic error, given in conventional net cylinder format, was 0.59 D at 1° relative to the preoperative stronger meridian, and the mean defocus after surgery was 0.60 ± 0.36 D.

In the high astigmatic group, 91 eyes were treated for plano refraction (±0.25 D), and 58 of these eyes (64%) had a UDVA of 20/25 or better (Figure 6A). By 3 months, 1 eye had lost two or more lines of CDVA (Figure 6B).

In Figure 7, an optical coherence tomography image of the changes 3 months after SMILE for high astigmatism is shown. At the main meridian, an abrupt stromal change was observed corresponding to the edge of the removed lenticule. Matching changes in epithelial thickness could be seen in the overlying epithelium (Figure 7A). In contrast, a smooth interface was seen at the 90° orthogonal meridian (Figure 7B).

**DISCUSSION**

The current study demonstrates that SMILE offers precise and safe correction of low to high degrees of myopic astigmatism. Overall, the correction of spherical equivalent power was very precise, although eyes with low cylinders showed a slight undercorrection in contrast to high astigmatic eyes. With respect to the cylinder correction, a significant undercorrection of astigmatism was observed and the error of treatment increased with higher attempted astigmatic correction. On average, the undercorrection was 13% per diopter of attempted cylinder correction in low astigmatic and 16% per diopter in highly astigmatic eyes. In a recent study, we evaluated the outcome of FS-LASIK for high astigmatism in myopic eyes using the Carl Zeiss Meditec MEL-80 excimer laser.9 The patients in this previous study were recruited from the same population as those in the current study and showed similar preoperative characteristics. After FS-LASIK, we found an error in AKP\text{error} of 0.77 ± 0.62 D, which was close to our current observations of 0.59 ± 0.65 D after SMILE. However, in FS-LASIK, an undercorrection of 21% per diopter of attempted cylinder correction in highly astigmatic eyes was found, which was somewhat higher than in the current study. In contrast, the U.S. Food and Drug Administration approval studies for the MEL-80 excimer laser14 found a correction ratio (induced/intended astigmatic correction) of up to 1.42 in eyes with low astigmatism, indicating considerable overcorrection. Similarly, the U.S. Food and Drug Administration approval of the Wavelight Allegretto15 reported a correction ratio of 1.16, again indicating overcorrection of the astigmatic correction after LASIK in predominantly low astigmatic eyes. From a clinical point of view, however, slight undercorrection would be preferred to overcorrection because a change in the direction of the cylinder axis probably is poorly accepted by patients.

No other studies on SMILE have performed a rigorous evaluation of astigmatic corrections. However, one study evaluated the outcome for up to 6 months after 200-kHz femtosecond lenticule extraction in myopic...
Regression after refractive surgery including photorefractive keratectomy and LASIK may occur due to an increase in epithelial thickness after myopic refractive surgery\textsuperscript{19} or due to wound repair with deposition of new stromal tissue.\textsuperscript{19,20} In SMILE, the wound repair has been demonstrated to be limited,\textsuperscript{21} but an increase in central epithelial thickness has been noted.\textsuperscript{22} Most studies have reported little to no regression after SMILE\textsuperscript{22,3}; yet, epithelial hyperplasia could influence the postoperative refraction and contribute to the observed astigmatic undercorrection in this study. In contrast to excimer laser treatments, the peripheral transition zone in SMILE is small. Whereas this probably has little consequence in myopia where the lenticule becomes thinner toward the edge, it could be significant in high astigmatic corrections where the lenticule edge in the main meridian may become very steep. Because abrupt changes in corneal thickness are usually mitigated by compensatory epithelial hyperplasia, this could contribute to undercorrection or postoperative regression of the obtained refractive change at the specific meridian. In optical coherence tomography images, we found a rather prominent stromal change corresponding to the lenticule edge with matching changes in epithelial thickness. In previous studies of keratorefractive procedures, changes in epithelial thickness have been demonstrated to occur within the first few weeks after surgery.\textsuperscript{19} Unfortunately, the temporal changes could not be evaluated in the current study, and it remains to be determined if the changes in epithelial thickness at the main meridian contribute to the observed astigmatic undercorrection and may change further with increasing time after surgery.

In this study, a loss of two or more lines in CDVA was found in 2.8% of low astigmatic eyes and 0.9% of high astigmatic eyes 3 months after surgery. In comparison to LASIK this is a relatively high loss in CDVA.\textsuperscript{23} However, patients with a significant visual loss were seen at an extended follow-up, where all eyes were found to have returned to within one line of their preoperative CDVA. Furthermore, in a recent study we evaluated the complications and safety of the first 1,574 eyes treated with SMILE at our department and found late recovery of CDVA in all 24 eyes with a significant loss by 3 months.\textsuperscript{6}

Patients with low astigmatism generally fared better with respect to UDVA than patients with high cylinders. This was to be expected due to less residual astigmatism in the low astigmatic eyes, although the spherical equivalent refraction was slightly less precise. The observed difference in UDVA between low and high astigmatic eyes matched the average defocus value that was marginally better in low astigmatism.

In SMILE, decentration of the lenticule may contribute to postoperative astigmatism and coma. In this study, induced higher-order aberrations and decentration of the lenticule were not evaluated. However, in a previous study, the average decentration after SMILE was found to be small.\textsuperscript{4} In other studies, femtosecond lenticule extraction and FS-LASIK have been demonstrated to induce similar amounts of coma.\textsuperscript{16} Furthermore, astigmatism induced by decentration would most likely influence the main cylinder axis, and in the current study the observed torsion was small, which is why it seems unlikely that decentration had any major impact on the postoperative cylinder. Nevertheless, docking of the eye in the SMILE procedure may be more challenging in highly astigmatic eyes, and it would be of interest to evaluate the induction of higher-order aberrations in a future study.

Interestingly, we found the laser settings to influence the outcome after SMILE in highly astigmatic eyes. Thus, the initial laser setting (with low energy and close spot spacing) had significantly more eyes with an undercorrection of at least 1 D than the laser setting with higher energy and larger spot spacing. A similar pattern could not be observed in eyes corrected for low astigmatism. Why laser settings should have an impact on the precision of the astigmatic correction is not obvious because the shape of the lenticule should be identical. However, we recently reported that visual recovery is slower after setting 1 than setting 2.\textsuperscript{6} Similarly, other studies have reported that the laser scanning trajectory and energy levels influence the postoperative outcome.\textsuperscript{17,18} Whether additional adjustments in the laser parameters can further improve the astigmatic corrections remain to be elucidated.

In this study, patients were only evaluated after 3 months. However, the refraction may change during the first months after surgery; probably more so after astigmatic corrections than after pure spherical corrections.
The current study demonstrates that predictable and safe correction of myopic astigmatism can be performed with SMILE. However, a small but significant undercorrection was found, in particular for high degrees of astigmatism. In contrast, minimal torsion was induced by the treatment. Overall, the results were on par with previous evaluations of FS-LASIK and femtosecond lenticule extraction.

AUTHOR CONTRIBUTIONS
Study concept and design (AI, JH); analysis and interpretation of data (AI); writing the manuscript (AI); critical revision of the manuscript (JH); administrative, technical, or material support (JH)

REFERENCES