Clinical Outcomes of LASIK for Myopia Using the SCHWIND Platform With Ocular Wavefront Customized Ablation

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ABSTRACT

PURPOSE: To evaluate the clinical outcomes of aspheric ocular wavefront ablation profiles in LASIK treatments.

METHODS: Thirty eyes treated by ocular wavefront were retrospectively analyzed at 6-month follow-up. Custom Ablation Manager (CAM) software was used to plan wavefront-customized aspheric treatments, and the ESIRIS system was used to perform ablations (SCHWIND eye-tech-solutions). Outcomes were evaluated in terms of efficacy, predictability, refractive outcome, safety, and pre- and postoperative wavefront aberration analysis (SCHWIND Ocular Wavefront Analyzer).

RESULTS: At 6 months postoperatively, 47% of eyes achieved uncorrected visual acuity 20/20 or better. Average defocus was reduced from $-3.49 \pm 2.38$ diopters (D) preoperatively (range: $-10.63$ to $0.00$ D) to $-0.14 \pm 0.31$ D postoperatively (range: $-1.75$ to $0.00$ D). Astigmatism was reduced from $-0.81 \pm 1.15$ D (range: $-4.25$ to $0.00$ D) to $-0.25 \pm 0.37$ D (range: $-1.25$ to $0.00$ D). Eighty-six percent of eyes were within $0.50$ D. Best spectacle-corrected visual acuity (logMAR) improved from $0.12 \pm 0.08$ (range: $0.0$ to $0.2$) to $-0.05 \pm 0.13$ (range: $-0.2$ to $0.2$) ($P = .04$). The treatment did not change coma or spherical aberration, and reduced the trefoil from $0.21 \pm 0.13 \mu$m (range: $0.05$ to $0.53 \mu$m) to $0.08 \pm 0.13 \mu$m (range: $0.01$ to $0.39 \mu$m) ($P = .002$).

CONCLUSIONS: The study results indicate that the aspheric ocular wavefront customized CAM approach for planning ablation volumes is safe and effective.

best spectacle-corrected visual acuity (BSCVA) 20/20 or worse.

**Preoperative Testing**

In all cases, pre- and postoperative autorefractor measurements, manifest refraction, uncorrected visual acuity (UCVA), BSCVA, topography (Keratron Scout; Optikon 2000 S.p.A., Rome, Italy), and ocular wavefront analysis up to the 8th Zernike radial order as well as complications were recorded.

The treatment plan was developed using ocular wavefront customized aspheric profiles based on Hartmann-Shack sensing.7 The high-resolution Hartmann-Shack measurements (>800 points for a 7.0-mm pupil) referred to the entire eye. Optical errors centered on the line-of-sight were described by the Zernike polynomials,8 and the coefficients of the Optical Society of America standard.9

**Treatment Modality**

Preoperative topography and aberrometry measurements were taken, and visual acuity and mesopic pupil size were measured. To determine the ablation profile of the CAM, manifest refraction was measured in each eye and crosschecked with objective refraction from the SCHWIND Ocular Wavefront Analyzer.10 Each eye was planned according to the manifest refraction using the CAM wavefront customized treatments and targeted for emmetropia.

All ablations used the CAM on the ESIRIS excimer laser (SCHWIND eye-tech-solutions) without nomogram adjustments. The CAM aspheric profiles were developed with the aim to compensate for the induction of aberrations (especially but not only spherical aberration) observed with other types of profile definitions; some of these sources of aberrations are those related to the loss of efficiency of the laser ablation for non-normal incidence.12,13 Optimization is realized by taking into account the loss of efficiency at the periphery of the cornea in relation to the center, as there is a tangential effect of the spot in relation to the corneal curvature (keratometry [K]-reading). The software provides K-reading compensation, which considers the change in spot geometry and reflection losses of ablation efficiency.

The baseline for correcting refraction (sphere and cylinder) is aspheric, whereas the higher order aberrations measured based on Hartmann-Shack sensing of the entire eye are combined with manifest refraction.

Real ablative spot shape (volume) is considered through a self-constructing algorithm. In addition, a randomized flying-spot ablation pattern and controls for the local repetition rates minimize the thermal load of the treatment.14

A 6.25-mm central fully corrected ablation zone was used in all eyes with a variable transition size automatically provided by the laser related to the planned refractive correction (6.55 to 8.70 mm). Immediately before the ablation, the laser was calibrated per manufacturer's instructions, and the calibration settings were recorded.

All operations were performed by the same surgeon (M.C.A.). Laser in situ keratomileusis flaps were created with a superior hinge using a Carriazo-Pendular microkeratome13 (SCHWIND eye-tech-solutions) using a 130-µm head. The ablation was carried out with an ESIRIS excimer laser.16 The ESIRIS laser system works at a repetition rate of 200 Hz and produces a spot size of 0.8 mm (full width at half maximum) with a para-Gaussian ablative flying-spot profile.17,18 High-speed eye-tracking with 330-Hz acquisition rate is accomplished with a 5-ms latency period.19

**Postoperative Outcomes**

Manifest refraction, visual acuity, topography, and aberrometry measurements were taken in each eye at 1, 3, 6, 9, and 12 months postoperatively. A comprehensive evaluation of all eyes was performed at 6-month follow-up, and the reported results are based on the 6-month data except for the stability data.

**Statistical Methods**

For statistical analysis, t tests were used to compare postoperative versus preoperative results within each group. For correlation tests, the coefficient of determination (R²) was used and the significance was evaluated considering a metric distributed approximately as t with N-2 degrees of freedom, where N is the size of the sample. For all tests, P<.05 was considered statistically significant.

**Results**

The percentage of complete follow-up at each time interval was 100% (n=30) at 1, 3, and 6 months; 60% (n=18) at 9 months; and 37% (n=11) at 12 months. The reported results correspond to the last session with a follow-up rate of 100% (ie, 6-month data) except for the stability data.

A comparison of the preoperative findings and postoperative evaluation at 6-month follow-up are presented in Table 1.

At 6 months postoperative, UCVA better than 20/20 was found in 47% of eyes treated with the ocular wavefront strategy, whereas 90% achieved UCVA of 20/25 or better (Fig 1). Figure 2 shows the refractive outcome.

The achieved refractive change (Figs 3 and 4), defined as the vectorial difference in the astigmatism space of
postoperative and preoperative manifest refraction, was significantly correlated with the attempted refractive correction ($R^2=0.96$, $P<.0001$ for spherical equivalent refraction; $R^2=0.97$, $P<.0001$ for astigmatism). Furthermore, the slope of regression was 1.00 for spherical equivalent refraction (see Fig 3) and 0.94 for astigmatism (see Fig 4), which was close to the ideal correction.

Based on the refractive power change (in terms of achieved correction), both the sphere and cylinder corrections were relatively accurate, predictable, and stable after the first month of follow-up (Fig 5).

The safety results are shown in Figure 6. Of the eyes treated with the ocular wavefront strategy, 33% had improved BSCVA and 7% of eyes lost one line of BSCVA. The results were positive, and the improvement in safety was statistically significant ($P=.04$).

The increase in coma was not statistically significant ($P=.22$). The achieved coma aberration correction correlated with the attempted coma correction ($R^2=0.21$, $P=.04$) (Fig 7); the achieved/attempted ratio (the slope of the regression) was 0.72. Postoperative coma did not correlate with the achieved defocus correction ($R^2=0.10$, $P=.17$). Postoperative coma also was not correlated with the achieved cylinder correction ($R^2=0.03$, $P=.45$).

Mean trefoil component of the patients was reduced by $-0.13$ µm. The decrease in trefoil was statistically significant ($P=.002$). The achieved trefoil aberration correction correlated well with the attempted trefoil correction ($R^2=0.67$, $P<.0001$); the achieved/attempted ratio (the slope of the regression) was 0.63 (Fig 8).

Mean spherical aberration was reduced by $-0.04$ µm.

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**TABLE 1**

Comparison of Preoperative and 6-month Postoperative Refractive Data for 30 Eyes That Underwent Ocular Wavefront Ablation*

<table>
<thead>
<tr>
<th></th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>Preop to Postop</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defocus (D)</td>
<td>$-3.49\pm2.38$ (–10.63 to 0.00)</td>
<td>$-0.14\pm0.31$ (–1.75 to 0.00)</td>
<td>$&lt;.0001$</td>
<td>$&lt;.0001$</td>
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<tr>
<td>Astigmatism (D)</td>
<td>$-0.81\pm1.15$ (–4.25 to 0.00)</td>
<td>$-0.25\pm0.37$ (–1.25 to 0.00)</td>
<td>$&lt;.0001$</td>
<td>$&lt;.0001$</td>
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<tr>
<td>BSCVA (logMAR)</td>
<td>$+0.12\pm0.08$ (0.00 to +0.20)</td>
<td>$-0.05\pm0.13$ (–0.20 to +0.20)</td>
<td>$0.04$</td>
<td>—</td>
</tr>
<tr>
<td>Coma (µm)</td>
<td>$0.13\pm0.09$ (0.01 to 0.41)</td>
<td>$0.19\pm0.20$ (0.01 to 0.45)</td>
<td>$0.22$</td>
<td>$0.08$</td>
</tr>
<tr>
<td>Trefoil (µm)</td>
<td>$0.21\pm0.13$ (0.05 to 0.53)</td>
<td>$0.08\pm0.13$ (0.01 to 0.39)</td>
<td>$0.002$</td>
<td>$&lt;.0001$</td>
</tr>
<tr>
<td>Spherical aberration (µm)</td>
<td>$+0.07\pm0.23$ (–0.23 to +0.71)</td>
<td>$+0.04\pm0.17$ (–0.18 to +0.30)</td>
<td>$0.45$</td>
<td>$0.009$</td>
</tr>
<tr>
<td>RMS(HO) (µm)</td>
<td>$0.39\pm0.13$ (0.25 to 0.74)</td>
<td>$0.39\pm0.16$ (0.14 to 0.78)</td>
<td>$0.22$</td>
<td>—</td>
</tr>
</tbody>
</table>

*BSCVA = best spectacle-corrected visual acuity

*Overall there was no induction of coma, spherical aberration, or higher order aberration in root-mean-square (RMS); and trefoil was significantly decreased.

Note. Coma, trefoil, spherical aberration, and higher order RMS were measured at 6-mm diameter.

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**Figure 1.** Uncorrected visual acuity (UCVA) at 6-month follow-up for eyes that underwent ocular wavefront ablation.

**Figure 2.** Refractive outcome at 6-month follow-up for eyes that underwent ocular wavefront ablation.
The decrease in spherical aberration was not statistically significant ($P=.44$). The achieved spherical aberration correction was correlated with the attempted spherical aberration correction ($R^2=0.71$, $P<.0001$); the achieved/attempted ratio (the slope of the regression) was 0.77 (Fig 9). Postoperative spherical aberration was not correlated with the achieved defocus correction or achieved coma correction.

No adverse events were found in any of the cases.

**DISCUSSION**

In this study, all ablations were customized based on Hartmann-Shack measurements of the wavefront aberration of the entire eye and calculated using the CAM software. The CAM software is able to import, visualize, and combine diagnostic data of the eye (manifest refraction and ocular wavefront data in this case) into a customized aspheric ablation profile to optimize the corneal shape. As we used ocular wavefront–based profiles in our study, ablations were optimized to reduce the wavefront aberration of the entire eye (within the optical zone) close to a zero level, compensating, as well, for the aberration induction observed with other types of profiles.
Figure 7. Achieved versus attempted coma correction for ocular wavefront profiles at 6-month follow-up analyzed for a 6-mm pupil diameter measured with the SCHWIND Ocular Wavefront Analyzer.

Figure 8. Achieved versus attempted trefoil correction for ocular wavefront profiles at 6-month follow-up analyzed for a 6-mm pupil diameter measured with the SCHWIND Ocular Wavefront Analyzer.

Figure 9. Achieved versus attempted spherical aberration correction for ocular wavefront profiles at 6-month follow-up analyzed for a 6-mm pupil diameter measured with the SCHWIND Ocular Wavefront Analyzer.
The improvement in safety was statistically significant ($P=.04$), with 33% of eyes having improved BSCVA. Although 7% of eyes lost one line of BSCVA in this study, no single eye lost more than one line of BSCVA. The repeatability of the BSCVA within individuals from day to day is approximately one line of BSCVA. Because only two eyes lost one line of BSCVA, we reviewed previous follow-up examinations of those eyes and observed that in one eye this loss was present at all follow-up examinations, whereas the other eye showed the above mentioned variability, ie, no loss at 3-month follow-up compared to baseline.

Coma aberration of the patients did not increase significantly ($P=.22$). Notably, the achieved coma correction was only marginally correlated with the attempted coma correction (see Fig 6). This might have been due to small decentrations of the ablation pattern that also induce coma aberration and because ocular coma is a coupling of corneal and internal coma.

The correction of trefoil terms was successful both in magnitude ($P=.002$) and correlation attempted versus achieved ($P<.0001$) (see Fig 8), whereas the decrease in spherical aberration was not statistically significant ($P=.45$), but correlation attempted versus achieved was significant ($P<.0001$) (see Fig 9).

The small amount of aberration found in this group, similar to the repeatability/accuracy (~0.2 µm), introduced some scatter. Furthermore, because the ablation procedures were performed in a clinical setting, they suffered from different types of unavoidable and inherent errors that led to aberrations, including biomechanical reactions due to the flap cut, blending zones, cyclo-torsion, centration errors, spot size limitations, active eye-tracking capabilities, and biomechanical reactions due to the ablation process itself. It should be noted that opposing the preoperative wavefront aberration in laser refractive surgery constituted only a first approximation of a perfect refractive correction, as tissue removal occurs. Considerations such as treatment duration or tissue removal make it even more difficult to establish a universal optimal profile.

For all of these reasons, we analyzed the results for coma, trefoil, and spherical aberration by separating the study population into a ocular wavefront low group (preoperative RMS value <0.2 µm) and ocular wavefront high group (preoperative RMS value ≥0.2 µm) (Tables 2 and 3).

Our data suggest that ocular wavefront customized treatments can only be successful if the pre-existing aberrations are greater than the repeatability and the
biological noise, as evidenced by the ocular wavefront high group data for coma, trefoil, and spherical aberration, and by the fact that this study selected eyes with preoperative higher order aberrations >0.25 μm RMS.

This study has corroborated recently published findings. To appropriately treat patients with profiles such as those described, patients need to have a significant level of preoperative aberrations.

Despite a small sample size, our study demonstrated that aspheric ocular wavefront ablation profiles, designed with CAM software for the ESIRIS laser platform, are safe and yielded visual, optical, and refractive results comparable to those of other wavefront-guided customized techniques for correction of myopia and myopic astigmatism. In particular, the ocular wavefront customized approach is highly efficient in eyes with >0.25 μm RMS ocular higher order aberrations, or where individual components of the ocular wavefront such as coma, trefoil, or spherical aberration are >0.2 μm RMS.

The optimal result of refractive surgery is to balance the effects of wavefront aberration and to provide normal eyes with the best quality of vision. In this context, ocular wavefront treatments have the advantage of being based on objective refraction of the whole eye, corneal wavefront treatments have the advantage of being independent of accommodation effects or light/pupil conditions, and aspheric treatments based on aberration-neutral profiles have the advantage of saving tissue and time, and due to their simplicity, offer a high predictability.

Corneal wavefront treatments with the same platform (ESIRIS) by our group have shown significant increases in coma aberration, with a significant correlation of the coma aberration correction, significant reduction in trefoil aberration, and significant increases in spherical aberration, with a significant correlation of the spherical aberration correction. Treatments based on aberration-neutral profiles with the same platform by our group have shown an induction of higher order aberrations of 0.04±0.14 μm ocular wavefront and 0.06±0.16 μm corneal wavefront and spherical aberration of 0.07±0.12 μm ocular wavefront and 0.08±0.12 μm corneal wavefront, which correlate to 0.028 μm/D of achieved defocus correction for a 6-mm pupil in ocular wavefront and 0.030 μm/D of achieved defocus correction for corneal wavefront.

AUTHOR CONTRIBUTIONS

Study concept and design (M.C.A., S.A.M.); data collection (M.C.A., C.V.); analysis and interpretation of data (M.C.A., S.A.M.); drafting of the manuscript (M.C.A., S.A.M.); critical revision of the manuscript (M.C.A., C.V.); statistical expertise (M.C.A.); obtained funding (M.C.A.); administrative, technical, or material support (M.C.A., C.V.)

REFERENCES


