INTRODUCTION

Laser corneal refractive surgery is based on the use of a laser (typically an excimer one) to change the corneal curvature to compensate for refractive errors of the eye. It has become the most successful technique, mainly due to the submicron precision and the high repeatability of the ablation of the cornea accompanied by minimal side effects. One of the most significant side-effects in myopic LASIK is the induction of spherical aberration, which causes halos and reduced contrast sensitivity. To avoid the induction of spherical aberration, so-called «customized» treatments were developed. Customization of the ablation is possible either using wavefront measurements of the whole eye.

Six-month clinical outcomes in LASIK for high myopia with aspheric «aberration neutral» ablations using the AMARIS laser system

Maria Clara Arbelaez, MD; Camila Vidal, OD; Samuel Arba Mosquera, MSc

PURPOSE: To evaluate the postoperative clinical outcomes and high order aberrations among eyes with myopia higher than 5 D that have underwent LASIK treatments using the Schwind AMARIS laser system. Schwind CAM Aberration-Free Aspheric treatments have been performed in all cases.

PATIENTS AND METHODS: LASIK treatments were performed on 75 eyes (45 patients) with mean spherical equivalent -6.46±1.15 D (range, -8.50 to -5.25 D) using a SCHWIND Pendular microkeratome with a 110 µm cutting head and the SCHWIND AMARIS excimer laser. In all cases pre- and postoperative autorefractor measurements, manifest refraction, best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity (UCVA), topography and corneal wavefront analysis using the Optikon Keratron Scout, and ocular wavefront analysis using the SCHWIND Ocular Wavefront Analyzer as well as complications, were performed. Ablations were calculated using the ORK-CAM software.

Clinical outcomes were evaluated in terms of efficacy, predictability, stability, refractive outcome, safety, and wavefront aberrations.

RESULTS: At six months, mean spherical equivalent manifest refraction was -0.30±0.34 D (range, -1.12 to +0.38 D). Eighty-one percent eyes (61) were within ±0.50 D of attempted correction. Uncorrected visual acuity was 20/20 or better in 81% (61 eyes), and 20/32 or better in 97% (73 eyes). Average root-mean-square of the high order aberrations (RMSHOA) increased 0.14 µm after the treatment, mean spherical aberration increased 0.12 µm after the treatment, and mean coma increased 0.04 µm after the treatment (all for 6.0 mm analysis diameter).

CONCLUSIONS: Our results show that non-customised «aberration neutral» ablation profiles derived from wavefront analysis are able to minimize the amount of induced aberrations even for myopic refractive corrections up to -9 D.
In this study, ablations were optimized to induce no change in Wavefront aberration (within Optical Zone, OZ) other than Sphere and Cylinder components, leaving all existing high order aberrations (HOA) unchanged because the best corrected visual acuity, in this patient, has been unaffected by the pre-existing aberrations. Thus to compensate for the aberrations induction observed with other types of profile definitions, some of those sources of aberrations are those ones related to the loss of efficiency of the laser ablation for non-normal incidence. Based on the existing corneal shape and the keratometric values of the cornea, the ideal ablation profile is then calculated compensating, among others, for the cosine effect.

This study was conducted to evaluate, among myopic treatments of -5 D of more of spherical equivalent, safety, predictability, and efficacy of the «Aberration neutral» Profiles implemented in the SCHWIND AMARIS, and to evaluate the impact, in terms of high order aberrations, of the ORK-CAM «Aberration neutral» Profiles.

**PATIENTS AND METHODS**

A total of 75 eyes (45 patients), with myopic spherical equivalent of -5 D or more, were consecutively treated using ORK-CAM «Aberration neutral» Aspheric ablation profiles and retrospectively analysed. Inclusion criteria comprised: preoperative myopia higher than -5 D spherical equivalent targeted for emmetropia, preoperative BSCVA ≥ 20/25 (logMAR ≤ 0.1), preoperatively <0.6 µm RMS HOA for 6 mm diameter, postoperatively successful completion of 6 months follow-up. Exclusion criteria comprised: preoperativeactive ocular disease, preoperative dry eye, preoperative ectatic corneal disease, preoperative monocular patients, preoperative immunocompromised disease, preoperative systemic or retinal vascular disease, preoperative pregnancy.

Visual acuity was measured using the CSO Vision Chart. CSO Vision Chart is a state-of-the-art for computerized charts for visual testing. We selected Snellen fraction US (feet), with optotypes following the standard EN ISO 8596-8597 and used 85 cd/m² Sloan letters optotypes in LogMAR progression automatically randomized to avoid patient's memorization.

Six-months follow-up was available in 75 of these eyes (100%), and their preoperative data were as follows: mean spherical equivalent refraction -6.46±1.15 D (range, -8.50 to -5.25 D); and mean cylinder magnitude 0.80±0.70 D (range, 0 to 5.00 D). In all eyes, we measured corneal topography and derived corneal wavefront analyses (Keratron scout, Optikon 2000 S.p.A., Rome, Italy), ocular wavefront with a high resolution Hartmann-Shack sensor (ORK-Wavefront Analyzer, Schwind eye-tech-solutions, Kleinostheim, Germany), manifest refraction, and uncorrected and best spectacle-corrected Snellen visual acuity. Measurements were performed preoperatively and at one, three, and six months after surgery.

All ablations were non-customised based on «aberration neutral» profiles and calculated using the ORK-CAM software. Aspheric aberration neutral (Aberration-Free™) profiles are not based on the Munnerlyn proposed profiles, and go beyond that by adding some aspheric characteristics to balance the induction of spherical aberration (prolateness optimization).

The aberration neutral (Aberration-Free™) profile is aspherical-based, including a multidynamic aspheric transition zone, aberration and focus shift compensation due to tissue removal, pseudo-matrix based spot positioning, enhanced compensation for the loss of efficiency, and intelligent thermal effect control; all based on theoretical equations validated with ablation models and clinical evaluations.

Real ablatove spot shape (volume) is locally considered through a self-constructing algorithm. In addition, there are randomized flying-spot ablation pattern and controls for the local repetition rates to minimize the thermal load of the treatment (smooth ablation, no risk of thermal damage). Therefore, the ablated surface in the aspheric aberration neutral (Aberration-Free™) profiles should be very smooth, so that there will be some benefits in high order aberrations. Finally, all these optimizations theoretically diminish the induced wavefront aberration after myopic LASIK.

A 6.3 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 (7.3 mm to 8.7 mm). The ablation was performed using the AMARIS excimer laser (SCHWIND eye-tech-solutions, Kleinostheim, Germany) which is a flying-spot laser using randomized spot distribution to minimize thermal effects. The AMARIS laser system works at a repetition rate of 500 Hz and produces a beam size of 0.54 mm Full-Width-at-Half-Maximum (FWHM) with a superGaussian ablative spot profile. High-speed eye-tracking (pupil tracker with cyclotorsional track-
ing) with a 1050-Hz acquisition rate is accomplished with a 3-ms latency time.

All flaps were created using a Pendular microkeratome with 110 µm cutting head (SCHWIND eye-tech-solutions).

Optical errors centred on the line-of-sight, representing the Wavefront Aberration, are described by Zernike polynomials and coefficients in OSA standard, and analysed for diameters of 6, 7 and 8 mm diameter zones, to include the total treatment zone and transition zone and junction zone, as well.

We assessed the statistical significance of the postoperative status compared to the preoperative baseline using paired Student’s T-tests. The level of statistical significance was taken as p<.05.

RESULTS

We have included 75 treatments for this study, all of them without adverse events. At six months, mean manifest refraction spherical equivalent was -0.30±0.34 D (range, -1.12 to +0.38 D) and mean cylinder magnitude 0.32±0.24 D (range, 0 to 1.00 D). Eighty-one percent eyes (61) were within ±0.50 D of attempted correction (Figure 1). Uncorrected visual acuity was 20/20 or better in 81% of the treatments (61 eyes) and 20/32 or better in 97% (73 eyes) (Figure 2). Results were stable between one and six months (Figure 3). Regarding safety, 23% of eyes gained one line (17 eyes), and 7% gained two lines of best spectacle-corrected visual acuity (5 eyes) (Figure 4).

Preoperatively, mean spherical aberration was +0.27±0.15 µm (range +0.14 to +0.52 µm). Postoperatively, the values were +0.39±0.15 µm (range +0.14 to +0.67) (P < 0.0001).

Preoperatively, mean coma magnitude was 0.26±0.27 µm (range 0.02 to 0.50). Postoperatively, the values were 0.30±0.13 µm (range 0.01 to 0.62) (P = 0.09).

Figure 1. Achieved refractive outcome at 6 months follow-up for spherical equivalent.

Figure 2. Efficacy plot: Uncorrected Visual Acuity at 6 months follow-up.

Figure 3. Achieved refractive change vs. Time at 6 months follow-up for spherical equivalent.

Figure 4. Safety plot: Change in BSCVA at 6 months follow-up.

Preoperatively, RMSHOA was, on average, 0.44±0.09 µm (range 0.26 to 0.82). Postoperatively, the values were 0.58±0.21 µm (range 0.32 to 0.88) (P < 0.0001).
At 7 mm, preoperatively, mean corneal spherical aberration was +0.42±0.15 μm (range +0.22 to +0.81). Postoperatively, the values were +0.69±0.25 μm (range +0.20 to +1.16) (P < 0.0001). Preoperatively, mean corneal coma was 0.38±0.18 μm (range 0.02 to 0.73). Postoperatively, the values were 0.48±0.25 μm (range 0.01 to 0.98) (P = 0.003). Preoperatively, mean RMSHOA was, on average, 0.65±0.21 μm (range 0.38 to 1.22). Postoperatively, the values were 1.07±0.25 μm (range 0.54 to 1.50) (P < 0.0001).

At 8 mm, preoperatively, mean corneal spherical aberration was +0.61±0.22 μm (range +0.32 to +1.18). Postoperatively, the values were +1.18±0.41 μm (range +0.32 to +1.93) (P < 0.0001). Preoperatively, mean corneal coma was 0.53±0.25 μm (range 0.03 to 1.02). Postoperatively, the values were 0.71±0.37 μm (range 0.02 to 1.46) (P < 0.0001). Preoperatively, corneal RMSHOA was, on average, 0.93±0.31 μm (range 0.55 to 1.74). Postoperatively, the values were 1.79±0.39 μm (range 0.85 to 2.38) (P < 0.0001).

**DISCUSSION**

75 high-myopic treatments were analysed at 6M follow-up. Aberration-Free Treatments with the SCHWIND AMARIS are safe and very predictable (no eye lost >=2 lines BSCVA, 7% (5 eyes) gained >=2 lines BSCVA). Results were achieved without applying additional nomograms (residual sphere about -0.1 D, residual cyl about -0.3 D) (81% within 0.50 D, 96% within in 1.0 D). 6-months follow-up time shows the excellent performance of the system (25% eyes 20/16 or better UCVA, 93% eyes 20/25 or better UCVA). From post-op VA, we have got 81% eyes in UCVA 20/20 or better and 29% eyes improved their pre-op BSCVA, due to the minimum aberrations induction by the AMARIS-CAM profile. From the achieved correction, both sphere and cylinder are quite accurate, predictable and stable from the first week follow-up (residual refraction increased by only -0.1 D in 6M). HOA were effectively preserved (at 6.0 mm, induced spherical aberration 0.12 μm; induced coma aberration 0.04 μm; induced HOA 0.14 μm RMS).

In our study, for 6 mm analysis diameter, we found on average an induction high-order aberrations of 0.14±0.16 μm corneal wavefront. Regarding coma, aberration changed, on average, 0.04±0.13 μm corneal wavefront. Spherical aberration changed, on average, 0.12±0.12 μm corneal wavefront. Induced spherical aberration was correlated to achieved defocus correction (P < 0.0001) and increased on average by 0.03 μm per dioptre of achieved defocus correction for a 6-mm pupil for corneal wavefront. That compares to 0.09 μm per dioptre reported by Marcos et al. and by Llorente et al. for ocular spherical aberrations, and to 0.17 μm per dioptre reported for corneal spherical aberrations.

That compares as well to 0.04 μm per dioptre reported by Kohnen et al. In terms of aberrations, the induced amount of spherical aberration has been decreased when compared to literature reported values, or to previous experiences using simplified Munnerlyn profiles on the same laser. Nevertheless, spherical aberration was still induced even with the attempted «aberration neutral» ablation profiles, which was expected as myopic corrections, especially higher ones, always induce some spherical aberration.

Compared to other studies, Farooqui and Al-Muammar found after conventional LASIK treatments a postoperative ocular spherical aberration of +0.24 μm and a postoperative ocular coma of 0.24 μm compared to our values of +0.39 μm and 0.30 μm respectively.

Kohnen et al. found after non-customised LASIK a change in corneal RMSHOA of 0.17±0.18 μm, a mean induction of corneal coma of 0.09±0.20 μm and for corneal spherical aberration a significant increase 0.13±0.12 μm, this compares to our values of 0.14±0.16 μm, 0.04±0.13 μm and 0.12±0.12 μm respectively.

Induced HOA in our sample shows similar results to those found by Farooqui et al. and Kohnen et al. after conventional LASIK treatment, however the sample of these studies showed defocus of -3.15±1.41 D (-0.50 to -6.25D), and of -4.22±1.78 D (-1.25 to -8.00 D) respectively, compared to -6.46±1.15 D (range, -8.50 to -5.25 D) in our sample. From this, it can be inferred that our treatments induced less HOA per diopter of correction.

Remarkably, in our sample astigmatism up to 5D was treated. In fact, 12% of the treatments (9 eyes) were planned with astigmatism higher than 1.5D. In general, the correction of astigmatism induces more HOA than the correction of defocus since it induces similar amount of C[4,0] but larger amounts of C[4,+-2].

Until today there is no prove that the asphericity alone plays a major role in the visual process. We still do not know whether an asphericity Q -0.25 is better than Q +0.50, we only know that the asphericity of the «averaged» human cornea is about -0.28. As well, no absolute optimum has been found, despite of some remarkable theoretical works. When a patient is selected for non customized aspherical treatment, the global aim of the surgeon should be to leave all existing high order aberrations (HOA) unchanged because the best corrected visual acuity, in this patient, has been unaffected by the pre-existing aberrations. Hence, all factors that may induce changes in HOAs, such as biomechanics, need to be taken into account prior to the treatment to ensure that the preoperative HOAs are unchanged after treatment.

As the corresponding Cartesian oval is the free-of-aberrations surface (i.e. the only truly monofocal sur-
face), and it can be described by an aspherical surface with Q-factor $-1/n^2$ (approx. -0.53 for human cornea), then the mean human cornea (Q -0.25) is less prolate (so more oblate) than the corresponding Cartesian oval, thus the refractive power of the outer corneal surface increases from central towards peripheral.

The first that we should clarify is that even the amount of corneal spherical aberration and the asphericity are intrinsically related; the goal is always described in terms of change in spherical aberration\textsuperscript{39}, because this is the factor related to the quality and sharpness of the retinal image.

Furthermore, the main high order aberration effects post-op (coma and spherical aberration) are coming from decentration and «edge» effects, the strong local curvature change from Optical Zone to Transition Zone and from Transition Zone to non-treated cornea. Then it is necessary to emphasize the use of huge Optical Zones, covering the scotopic pupil size plus some tolerance for possible decentrations, and well-defined smooth Transition Zones. In our study this was approached by the use of a 6.3 mm diameter fully corrected ablation zone with a multidynamic aspherical transition zone automatically provided by the laser related to the planned refractive correction (7.3 mm to 8.7 mm diameter).

Since we have available corneal wavefront information, we have addressed the following question. The optical high order aberrations were measured at a 6-mm pupil diameter, as is customary. The optical zone diameter was 6.3 mm. Most spherical aberration induction occurs at the junction between the central treatment zone/transition zone/untreated zone, and since some patients may have a mesopic/scotopic pupil diameter greater than 6 mm, the values within a 6-mm zone may not correspond with the real-life visual function of the patient in terms of glare and halos. In order not to limit the topographic analysis to 6 mm, and this way, to omit the transition zone and junction zone from the entire analysis, and although the information is most interesting and useful from a «6-mm point of view», it may miss the practical clinical point of the effect of changes in aberrations outside the 6-mm zone. Therefore, we have analyzed the available topographic information independently, reporting the corneal wavefront findings for a larger diameter zone, in this case 7 and 8 mm, to include the total treatment zone and transition zone and junction zone, as well.

To check whether the increasing in aberration magnitude was only due to the larger analysis diameter, analysis has been performed in defocus equivalent (DEQ). On virgin eyes, defocus equivalent as proposed by Thibos et al\textsuperscript{40} seems to be relative insensitive to different analysis diameters.

The change in corneal spherical aberration DEQ was, on average, $+0.09\pm0.10$ D at 6 mm analysis diameter, $+0.15\pm0.12$ D for 7 mm diameter, and $+0.25\pm0.16$ D for 8 mm. For corneal coma the change in DEQ was, on average, $0.03\pm0.13$ D at 6 mm analysis diameter, $0.06\pm0.15$ D for 7 mm diameter, and $0.08\pm0.17$ D for 8 mm, whereas for corneal RMSHOA was, on average, $0.11\pm0.12$ D at 6 mm analysis diameter, $0.24\pm0.14$ D for 7 mm diameter, and $0.37\pm0.17$ D for 8 mm.

This fact confirms for our study, that actually the change in aberration magnitudes increased with the analysis diameter. This could be expected as the tested profile attempts to be neutral for aberrations within the disc limited by the optical zone size (6.3 mm diameter for this study) which was closely achieved, and increases when we include analysis diameters beyond optical zone.

Limitations. Limitations of our study include the short follow up and the lack of a control group. Despite these limitations, we were able to demonstrate that «aberration neutral» ablation profiles are superior to standard ablation profiles for the corrections of myopia between -5 and -9 D.

In summary, this study demonstrated that «aberration neutral» profile definitions, which are not standard in refractive surgery, yielded very good visual, optical, and refractive results for corrections of myopia and myopic astigmatism up to -9 D of spherical equivalent. «Aberration neutral» ablation profiles as demonstrated here, have, therefore, the potential to replace currently used standard algorithms for corrections of non-customised myopic astigmatism.

REFERENCES

4. Thibos L, Bradley A, Applegate R. Accuracy and precision of objective refraction from wavefront aberrations. ISSN 1534-7362, 2003 ARVO.
5. Salmon TO. Corneal contribution to the Wavefront aberration of the eye. PhD Dissertation; 1999; 70.