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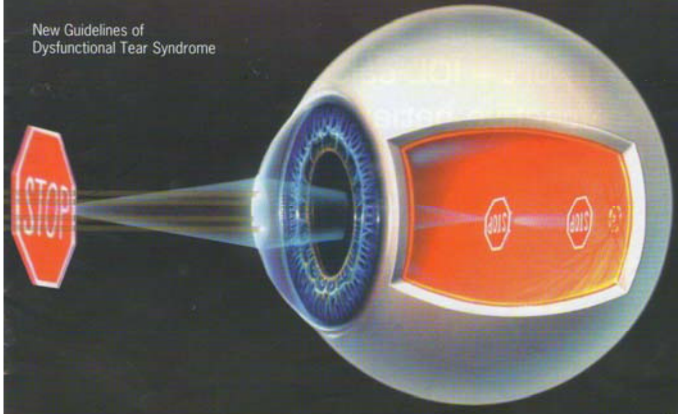

Maria Clara Arbelaez, MD
Muscat Eye Laser Center; Muscat -Sultanate of Oman

Samuel Arba Mosquera, MS
SCHWIND eye-tech-solutions; Kleinostheim, Germany

Camila Vidal, OD
Muscat Eye Laser Center; Muscat -Sultanate of Oman

Maria Clara Arbelaez, MD

# Three-month Clinical Outcomes with Aberration-Free Ablations in LASEK Treatments using the AMARIS Laser System

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## 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[1]. 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[2], which causes halos and reduced contrast sensitivity[3]. 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[4] (obtained, e.g., by Hartman-Shack wavefront sensors) or by using corneal topography-derived wavefront analyses[5,6]. Topographic-guided[7], Wavefront-driven[8], Wavefront-optimized[9], Asphericity preserving, and Q-factor profiles[10] have been proposed as ultimate solutions. Nevertheless, considerations as treatment duration, tissue removal[11], and overall postoperative outcomes make more difficult to establish a universal optimal profile. We evaluated the Laser Epithelial Keratomileusis (LASEK) results using the AMARIS laser system (Schwind eye-tech-solutions, Kleinostheim, Germany). This study was conducted to evaluate safety, predictability, and efficacy of the Aberration-Free profiles implemented in the AMARIS platform, and to evaluate the impact, in terms of high order aberrations.

## Patients and Methods

**Figure 1:** SCHWIND AMARIS system.

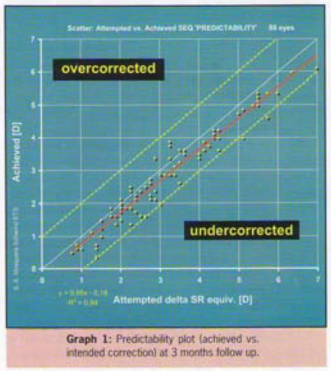
A total of 88 eyes (44 patients) were treated using the Aberration-Free ablation profiles implemented in the AMARIS laser. Three-months follow up was available in 100% of these eyes (88), and their preoperative data were as follows: mean sphere -2.65±1.44 D (range, 0.00 D to -5.75 D); mean cylinder -1.02±0.99 D (range, 0.00 D to -5.00 D); mean spherical equivalent -3.16±1.46 D (range, -0.75 to -7.00 D). In all eyes, we measured corneal topography (Keratron scout, Optikon 2000 S.p.A., Rome, Italy), ocular wavefront with a high resolution Hartmann-Shack sensor[12] (Ocular Wavefront Analyzer, Schwind eye-tech-solutions, Kleinostheim, Germany), manifest refraction, and uncorrected and spectacle-corrected visual acuity. Measurements were performed preoperatively and at one and three months after surgery.

All ablations were non-customised based on Aberration-Free profiles and calculated using the CAM software. The CAM software is able to import, visualize, and analyse diagnostic data of the eye (manifest refraction, corneal wavefront, or ocular wavefront data). The software creates an aspherical ablation profile to optimize the corneal shape. As we used non-customised Aberration-Free profiles in our 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[13]. Thus to compensate for the aberrations induction observed with other types of profile definitions[14], some of those sources of aberrations are those ones related to the loss of efficiency of the laser ablation for non-normal incidence[15,16,17]. 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. A 6.5 mm central fully corrected ablation zone was used in all eyes.

The surgical technique for LASEK was performed as follows:

The contralateral eye and the surrounding areas of the eye under treatment were covered with a sterile drape (Kimberly Clark) and dressed with a frame 10cm x 12 cm of Tegaderm (3m, USA). An eye speculum AE 1042 was used to hold the lids opened (Asico). A dilution of alcohol at 17 % was applied for 30 seconds, and the excess was wiped out with a Merocel sponge (Oasis, USA). A trephine of either 8.0 mm or 9.0 mm diameter was epithelially used (Beuder, Germany). Cold balanced salt solution was applied (Alcon, USA). A spatula AE-2832 (Asico, USA) was used to separate and lift the LASEK flap.

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[18]. The AMARIS laser system works at a repetition rate of 500 Hz and produces a spot size of 0.54 mm (FWHM) with a Supergaussian ablative spot profile[19,20]. High speed eye-tracking at 1050 Hz is accomplished with 3 microseconds latency time[21].



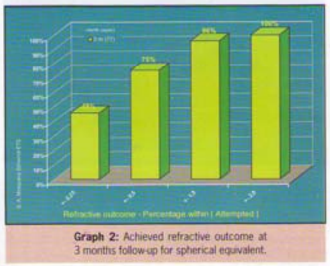
**Graph 1:** Predictability plot (achieved vs. intended correction) at 3 months follow up.

After the ablation procedure, a dilution of Mitomycin C at 0.02% was applied for 30 seconds, followed by balanced salt solution cold wiped out with a sponge of merocel. Finally, the eye was protected with a Biomedics 55, UV 100 contact lens (Vision Humble, UK) and antibiotics.

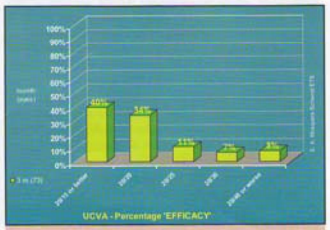
Optical errors centred on the line-of-sight, representing the Wavefront Aberration, are described by Zernike polynomials[22] and coefficients in OSA standard[23], and analyzed for a standardized diameter of 6.00 mm.

## Results

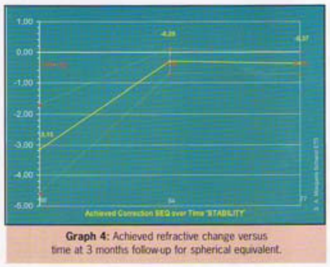
We have included 88 treatments for this study, all of them without adverse events. At three months, mean sphere was -0.12±0.31 D (range, -0.75 D to +1.00 D), mean cylinder -0.41±0.36 D (range, 0.00 D to -1.75 D), and mean spherical



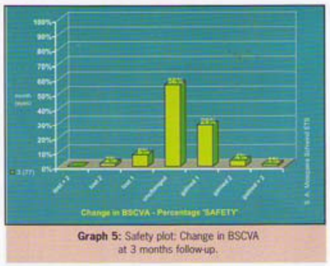
**Graph 2:** Achieved refractive outcome at 3 months follow-up for spherical equivalent.



**Graph 3:** Efficacy plot: Uncorrected Visual Acuity at 3 months follow-up.



**Graph 4:** Achieved refractive change versus time at 3 months follow-up for spherical equivalent.



**Graph 5:** Safety plot: Change in BSCVA at 3 months follow-up.

equivalent -0.33±0.34 D (range, -1.12 D to +0.62 D) (**Graph 1**). Seventy-five percent eyes (58) were within ±0.50 D of attempted correction (**Graph 2**). Uncorrected visual acuity was 20/15 or better in 40% of the treatments (29 eyes), 20/20 or better in 74% (54 eyes), and 20/30 or better in 92% (**Graph 3**). Results were stable between one and three months (**Graph 4**). Regarding safety, 29% of eyes gained one line (22 eyes), and 5% gained two or more lines of spectacle-corrected visual acuity (4 eyes) (**Graph 5**).

Preoperatively, corneal spherical aberration was 0.42 µm. Postoperatively, the value was 0.45 µm for corneal spherical aberration, increasing on average by 0.03 µm for a 6-mm pupil.

Preoperatively, corneal coma aberration was, in average, 0.27 µm and high-order aberration was 0.59 µm in root-mean-square. Postoperatively, the values were 0.21 µm for coma aberration, and 0.59 µm for high-order aberration root-mean-square. On average, induced coma, defined as the difference in coma aberration magnitude[24] postoperatively minus its preoperative magnitude excluding orientation, was -0.06 µm, whereas induced higher-order aberrations, defined as the difference in root-mean square postoperatively minus its preoperative value, was 0.01 µm, both for a 6-mm pupil. See **Table 1** for further details.

| | Preoperativ ely (mean ± std.dev.) | Postoperatively (mean ± std.dev.) |
|---|---|---|
| *Sphere (D)* | -2.45±1.44 | -0.12±0.31 |
| *Cylinder (D)* | -1.02±0.99 | -0.41±0.36 |
| *Spherical Equivalent (D)* | -3.16±1.46 | -0.33±0.34 |
| *Predictability within ±0.50 D (%)* | ----- | 75% |
| *Predictability within ±1.00 D (%)* | ----- | 96% |
| *Spherical Aberration at 6.00 mm (µm)* | 0.42 | 0.45 |
| *Coma Aberration at 6.00 mm (µm)* | 0.27 | 0.21 |
| *High Order Aberration at 6.00 mm (µm RMS)* | 0.59 | 0.59 |

**Table 1:** Pre and Post Comparative Corneal Aberrations.

## Discussion

Higher-order aberrations. In our study, we found on average and induction higher-order aberrations from 0.59 µm in root-mean-square preoperatively to 0.59 µm postoperatively.

Spherical aberration changed, in average, from 0.42 µm preoperatively (corneal) to 0.45 µm for ocular spherical aberration. Induced ocular spherical aberration increased on average by 0.03 µm for a 6-mm pupil. That compares to 0.09 µm per dioptre reported by others for ocular spherical aberrations[25,26] and to 0.17 µm per dioptre reported for corneal spherical aberrations. In terms of aberrations, the induced amount of spherical aberration has been decreased by a factor of six when compared to literature reported values, or to previous experiences using non-optimized profiles and another laser. Nevertheless, spherical aberration was still induced even with the attempted Aberration-Free ablation profiles, which was expected as myopic corrections, especially higher ones, always induce some spherical aberration.

Regarding coma, the induced amount of coma at 3-months follow-up was small (0.06 microns for 6.0 mm pupil) and can be explained by small decentrations of the ablation[27](a decentration of 120 microns will already induce 0.008 microns per dioptre for 6.0 mm pupil[28]).

Topographic systems measure the corneal surface and analyze it through corneal ray tracing to obtain the corneal wavefront error. Topographic systems use as corneal model a "free-of-aberration" corneal surface (Q-value of about -0.56). Nevertheless, statistical analysis over human corneas population has shown as averaged best fitting aspherical surface with a Q-value around -0.25[29,30]. This means that, in general, the healthy human corneas show a "positive spherical aberration", which is balanced by the "negative spherical aberration" of the human lens, resulting in a low ocular spherical aberration[17]. As average, one can say that naturally, the human corneas manifest a corneal spherical aberration around 0.23 µm[1] (OSA standard[11]). As individuals are aging, the asphericity of the crystalline lens changes, reducing the amount of spherical aberration that can be balanced or even showing a certain amount of positive spherical aberration, whereas the corneal asphericity thus, corneal spherical aberration, is relatively stable over the time, disrupting the equilibrium between both.

A problem of optimizing the corneal asphericity only, as proposed in other studies[18], is that this does not take into consideration the overall spherical aberration of the eye, that is, the ocular spherical aberration. By optimizing the corneal aberrations, we do not know whether we should target for the preexisting Q-value, the average Q-value, e.g., -0.25, or the "corneal optimum", e.g., -0.5. It has been known for many years that corneal refractive treatments induce a change in corneal asphericity and recently it has been assumed and argued that corneal refractive treatments preserving the preoperative corneal asphericity might be desirable, thus, the asphericity-based profiles have been developed. Until today there is no prove that the asphericity alone plays a major role in the visual process[31].

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[32]. There are persons with Q -0.25 and poor vision, and others with Q +0.25 and supervision. There is no prove that the more negative the Q-factor is, the better the visual quality. As well, no absolute optimum has been found, despite of some remarkable theoretical works[33,34,35]. 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[36]. Hence, all factors that may induce changes in HOA's[15,37,38] such as biomechanics, need to be taken into account prior to the treatment to ensure that the preoperative HOA's are unchanged after treatment.

However, in recent times there is a clear tendency of targeting a prolate postoperative anterior corneal surface as global optimum in refractive surgery. Sometimes the meaning of the terms prolate and oblate is unclear used. The confusion comes from the false identification between curvature and refractive power: As the average human cornea is prolate[29,30,32] (Q -0.25), the central part of the cornea has a stronger curvature than the periphery. However, refractive power is given by the Snell's Law. As the corresponding Cartesian oval[39] is the free-of-aberrations surface (i.e. the only truly monofocal surface), and it can be described by an aspherical surface with Q-factor $-1/n^2$ (approx. -0.53 for human cornea), then the average 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. In this way, the multifocality towards peripheral just answers the question if the corneal spherical aberration is positive (refractive power increases towards peripheral) or negative (refractive power decreases towards peripheral) but not the question about the geometrical concept of prolate versus oblate.

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[40], 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 huge and smooth Transition Zones.

## 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-Free ablation profiles, as delivered by the AMARIS laser system, are superior to standard ablation profiles.

In summary, this study demonstrated that Aberration-Free profile definitions, which are not standard in refractive surgery, yielded very good visual, optical, and refractive results for corrections of myopia and myopic astigmatism in LASEK. Aberration-Free ablation profiles as demonstrated here, have, therefore, the potential to replace currently used standard algorithms for corrections of non-customized myopic astigmatism.

**REFERENCES**

For detailed and complete References, please visit "Journal Bibliography Section", at our webpage: www.thehighlights.com