



Clinical outcomes of corneal wavefront customized ablation strategies with SCHWIND CAM in LASIK treatments

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Abstract

Purpose: To evaluate the clinical outcomes of aspheric corneal wavefront (CW) ablation profiles in LASIK treatments.

Methods: Thirty eyes treated with CW ablation profiles were included after a follow-up of 6 months. In all cases, standard examinations including preoperative and postoperative wavefront analysis with a CW topographer (Optikon Keratron Scout) were performed. Custom Ablation Manager (CAM) software was used to plan corneal wavefront customized aspheric treatments, and the ESIRIS flying spot excimer laser system was used to perform the ablations (both SCHWIND eye-tech-solutions, Kleinostheim, Germany). Clinical outcomes were evaluated in terms of predictability, refractive outcome, safety, and wavefront aberration.

Results: In general, the postoperative uncorrected visual acuity and the best corrected visual acuity improved ($p < 0.001$). In particular, the trefoil, coma, and spherical aberrations, as well as the total root-mean-square values of higher order aberrations, were significantly reduced ($p < 0.05$) when the pre-existing aberrations were greater than the repeatability and the biological noise.

Conclusions: The study results indicate that the aspheric corneal wavefront customized CAM approach for planning ablation volumes yields visual, optical, and refractive results comparable to those of other wavefront-guided customized techniques for correction of myopia and myopic astigmatism. The CW customized approach shows its strength in cases where abnormal optical systems are expected. Apart from the risk of additional ablation of corneal tissue, systematic wavefront-customized corneal ablation can be considered as a safe and beneficial method.

Keywords: aberrations, ablation, aspheric, customized, excimer, laser *in situ* keratomileusis, refractive surgery, wavefront

Introduction

The proper definition of an optimal ablation profile for corneal refractive surgery is still debated. Laser corneal refractive surgery is based upon the use of a laser

(typically an excimer laser) to change the corneal curvature and compensate for refractive errors of the eye (Munnerlyn *et al.*, 1988). It is currently the most successful technique, mainly due to its submicron precision and capacity to achieve highly repeatable ablation of the cornea with minimal side effects. Although standard ablation profiles for the correction of myopic astigmatism based upon the removal of convex–concave tissue lenticles with spherocylindrical surfaces, has proved effective to compensate for primary refractive errors, the quality of vision deteriorates in proportion to the achieved refractive correction, especially under mesopic and low-contrast conditions (Mastropasqua *et al.*, 2006). Preoperative wavefront analyses (either corneal or ocular) of the eyes have created

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individualized ablation patterns to compensate for pre-existing aberrations (Mrochen *et al.*, 2003). Topographic-guided (Alio *et al.*, 2003), wavefront-driven (Mrochen *et al.*, 2001), wavefront-optimized (Mrochen *et al.*, 2004), asphericity preserving, and Q-factor profiles (Koller *et al.*, 2006) have all been put forward as solutions. Nevertheless, considerations such as treatment duration, tissue removal (Gatinel *et al.*, 2002), tissue remodeling, and overall postoperative outcomes have made it difficult to establish a universally-optimal profile.

This study evaluates the postoperative outcomes of eyes that had undergone LASIK treatments using corneal wavefront (CW) customized aspheric profiles. Efficacy, predictability, stability, refractive outcome, and safety of the corneal wavefront customized profiles implemented in the SCHWIND Custom Ablation Manager (CAM) software platform (SCHWIND eye-tech-solutions, Kleinostheim, Bayern, Germany) as well as their impact on high order wavefront aberration were evaluated.

Materials and methods

Fifteen patients (30 eyes) seeking laser correction at the Muscat Eye Laser Centre in the Sultanate of Oman were enrolled into the study. The treatment plan was developed using CW customized aspheric profiles based on corneal ray tracing (Salmon, 1999). Using the Keratron Scout videokeratoscope (Mattioli and Tripoli, 1997) (Optikon 2000 S.p.A, Rome, Italy), the topographical surface and corneal wavefront were analyzed (up to the 7th order). Considering a balanced-eye model (Q-Val – 0.25) the departure of the measured corneal topography from the theoretically optimal corneal surface was calculated. Optical errors centered on the line of sight were described by the Zernike polynomials (Zernike, 1934) and the coefficients of the Optical Society of America (OSA) standard (Thibos *et al.* 2002).

Ray tracing is a procedure classically performed by applying Snell's law to the corneal surface. However, it is much simpler to understand corneal wavefront in terms of optical path difference and calculate it by Huygens–Fresnel or 'least time' Fermat principles (Salmon, 1999; Guirao and Artal, 2000).

In corneal wavefront analysis, the type and size of any optical error on the anterior corneal surface are registered, thus allowing a very selective correction. The defects are corrected exactly at their origin – the anterior corneal surface. In this context, the precise localization of defects is crucial to successfully achieving optimal results in laser surgery. The corneal wavefront allows for a very precise diagnosis, thus providing an individual ablation of the cornea in order to obtain perfect results.

Applying this treatment strategy, measurement does not require pupil dilation of the eye, so that the

treatment zone is not limited by the pupil and accommodation does not influence the measuring results.

Mention is made that in this way forcing a fixed asphericity quotient (Q) on the eyes through the treatment is avoided. Instead, this strategy employs a dynamic postoperative expected asphericity quotient (de Ortueta and Arba Mosquera, 2008), being expressed as:

$$Q_{\text{exp}} = \frac{\frac{1}{n^2} - \frac{1}{4}}{\left(1 + \frac{R \cdot \text{SE}_{\text{qcp}}}{n-1}\right)^3} - \frac{1}{n^2} \quad (1)$$

where Q_{exp} is the expected/predicted corneal asphericity quotient; R the apical radius of curvature of the preoperative cornea; SE_{qcp} the spherical equivalent to be corrected at the corneal plane; and n the refractive index of the cornea.

The expected quotient of asphericity does not incorporate any compensation for the effect of postop corneal biomechanics/healing response, and it is derived instead from a pure optical model of the cornea.

Treatment selection criteria

Corneal wavefront customized aspherical treatments with $>0.25 \mu\text{m}$ root mean square (RMS) higher order (HO) aberrations at 6 mm analysis diameter measured by the OPTIKON Keratron Scout were performed.

Preoperative topography and corneal aberrometry measurements were taken, and visual acuity, and mesopic pupil size were measured. Each eye was planned according to the manifest refraction using the CAM wavefront customized treatments. Immediately before ablation, the laser was calibrated according to the manufacturer's instructions and the calibration settings were recorded.

All operations were performed by the same surgeon (MCA). LASIK flaps were created with a nominal flap thickness of $110 \mu\text{m}$ and a superior hinge using a Carriazo-Pendular microkeratome (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany) creating planar flaps (de Ortueta, 2008). The ablation was carried out with an ESIRIS excimer laser (SCHWIND eye-tech-solutions GmbH) (Zhou *et al.*, 2007). 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, FWHM) with a paraGaussian ablative flying-spot profile (Huang and Arif, 2002; Guirao *et al.*, 2003). High-speed eye-tracking with 330 Hz acquisition rate is accomplished with a 5-ms latency period (Bueeler and Mrochen, 2005).

All ablations used the CAM (Customized Ablation Manager) on the ESIRIS without a nomogram to plan the ablations. The CAM aspherical profiles were devel-

oped with the aim of compensating for the induction of aberrations observed with other types of profile definitions (Marcos *et al.*, 2003): some of these sources of aberrations are those related to the loss of efficiency of the laser ablation for non-normal incidence (Dorrnsoro *et al.*, 2006; Arba Mosquera and de Ortueta, 2008). 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 (K (Keratometry)-reading). The software provides K-reading compensation, which considers the change in spot geometry and reflection losses of ablation efficiency.

Real ablative spot shape (volume) is considered through a self-constructing algorithm. In addition, there are a randomized flying-spot ablation pattern, and controls for the local repetition rates to minimize the thermal load of the treatment (Bende *et al.*, 1988) (smooth ablation, no risk of thermal damage).

Manifest refraction, visual acuity, topography, and corneal aberrometry measurements were taken in each eye preoperatively and at the 1-month, 3-month, and 6-month postoperative follow-ups.

For statistical analysis, *t*-tests were used in which $p < 0.05$ was considered to be statistically significant.

Results

Thirty treatments using ESIRIS corneal wavefront customized aspheric profiles and a 6.50 mm optical zone (OZ) were performed. No adverse events could be found in any of the cases. A comprehensive evaluation of all eyes was performed at the 6-month follow-up session. *Table 1* shows the study population statistics.

Figure 1 shows that 6 months postoperatively an uncorrected visual acuity (UCVA) $\geq 20/20$ could be found in 80% of the eyes treated with the CW strategy.

Preoperatively, the average defocus of the patients was -2.78 ± 1.72 D (ranging from -6.38 to 0.00 D), compared to an average of -0.11 ± 0.29 D postoperatively (ranging from -0.75 to $+0.50$ D).

Preoperatively, the average astigmatism of the patients was -0.89 ± 1.29 D (ranging from -4.75 to

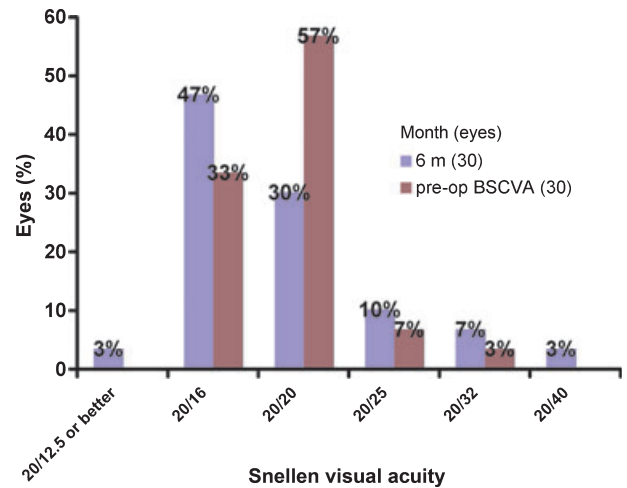


Figure 1. Distribution of uncorrected visual acuity at the 6-month follow-up, and of the best-corrected spectacle visual acuity, for the CW group.

0.00 D), compared to an average postoperative astigmatism of -0.26 ± 0.28 D (ranging from -1.00 to 0.00 D).

The achieved refractive change (*Figure 2*), defined as the vectorial difference in the astigmatism space of postoperative and preoperative manifest refraction, was significantly correlated with the intended refractive correction ($r^2 = 0.97$, $p < 0.0001$ for spherical equivalent; $r^2 = 0.87$, $p < 0.0001$ for astigmatism). Furthermore, the slope of the regression was 0.97 for spherical equivalent and 1.05 for astigmatism, and in this way very 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. *Figure 3* plots the progression with time of the residual defocus refraction.

Figure 4 shows the refractive outcome. 6 months postoperatively, 60% of the eyes treated with the CW strategy were within ± 0.25 D, and 80% within ± 0.50 D.

Preoperatively, the average decimal best spectacle-corrected visual acuity (BSCVA) of the patients was 1.09 ± 0.19 (ranging from 0.62 to 1.25), whereas

Table 1. Preoperative and postoperative refractive and corneal wavefront data

	Preoperatively		Postoperatively	
	Mean \pm S.D.	Range	Mean \pm S.D.	Range
Defocus (D)	-2.78 ± 1.72	-6.38 to 0.00	-0.11 ± 0.29	-0.75 to $+0.50$
Astigmatism (D)	0.89 ± 1.29	0.00 to 4.75	0.26 ± 0.28	0.00 to 1.00
BSCVA	1.09 ± 0.19	0.62 to 1.25	1.21 ± 0.30	0.80 to 1.60
Coma (μ m RMS) (6.0 mm)	0.25 ± 0.14	0.09 to 0.47	0.30 ± 0.10	0.16 to 0.56
Trefoil (μ m RMS) (6.0 mm)	0.24 ± 0.09	0.10 to 0.41	0.12 ± 0.05	0.02 to 0.36
Spherical aberration (μ m) (6.0 mm)	$+0.09 \pm 0.25$	$+0.01$ to $+0.48$	$+0.20 \pm 0.40$	$+0.06$ to $+0.58$
RMS(HO) (μ m RMS) (6.0 mm)	0.49 ± 0.09	0.32 to 0.72	0.69 ± 0.17	0.19 to 0.97

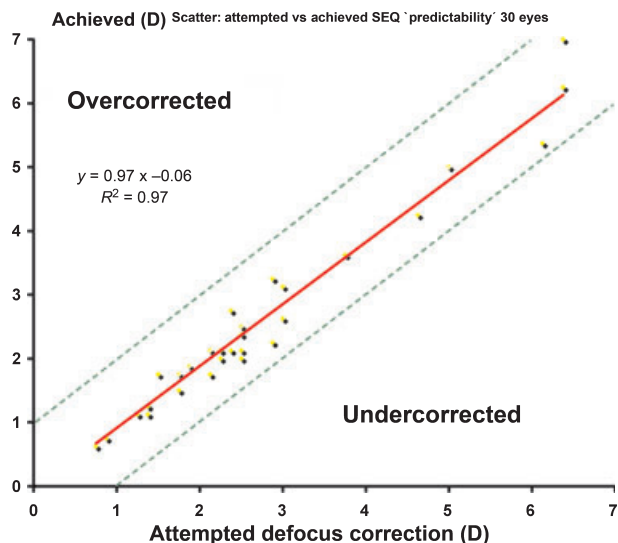


Figure 2. Scattergram plot showing the achieved vs attempted spherical equivalent correction at the 6-month follow-up for the CW group.

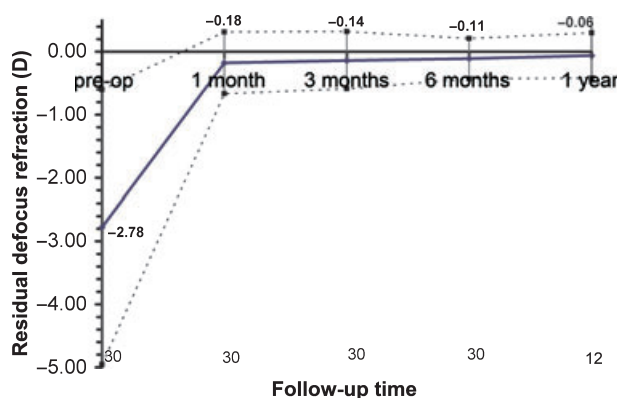


Figure 3. Stability plot showing spherical equivalent vs follow-up time for the CW group.

postoperatively, the average decimal BSCVA of the patients was 1.21 ± 0.30 (ranging from 0.80 to 1.60).

The safety results are shown in *Figure 5*. A total of 47% of the eyes treated with the CW strategy had an improved best spectacle corrected visual acuity (BSCVA) and none of the eyes had lost even one line of BSCVA. The results were positive, and the improvement in safety was statistically significant ($p < 0.001$) due to the minimal aberration induction by the CAM profile.

Preoperatively, the average coma aberration of the patients was $0.25 \pm 0.14 \mu\text{m}$ (ranging from 0.09 to $0.47 \mu\text{m}$), whereas postoperatively, the average coma component of the patients was $0.30 \pm 0.10 \mu\text{m}$ (ranging from 0.16 to $0.56 \mu\text{m}$) ($p = 0.03$). The achieved coma aberration correction showed a correlation tendency with the intended coma correction ($r^2 = 0.22$, $p = 0.01$) (*Figure 6*); the achieved/intended ratio (the

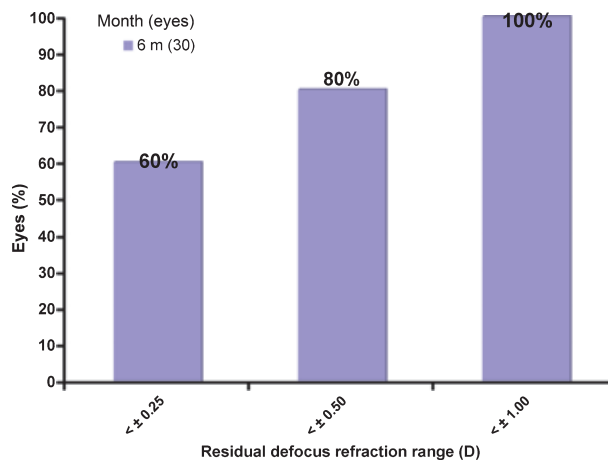


Figure 4. Refractive outcome plot at the 6-month follow-up for the CW group.

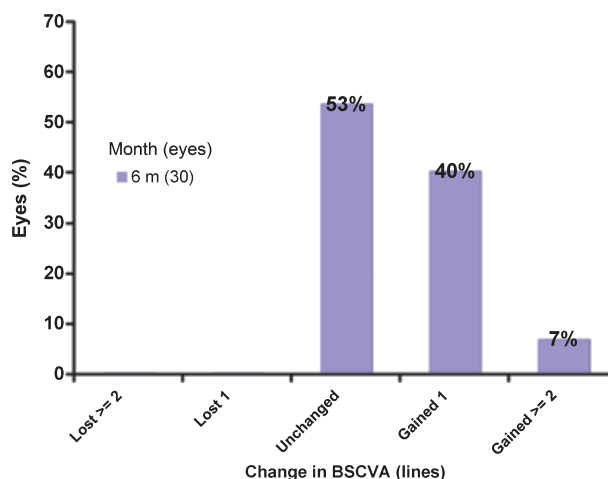


Figure 5. Distribution of the change in best-corrected spectacle visual acuity at the 6-month follow-up for the CW group.

slope of the regression) was 0.90. Postoperative coma was correlated with the achieved defocus correction ($r^2 = 0.40$, $p = 0.002$). However, a stronger correlation between the postoperative coma and the achieved cylinder correction could be observed ($r^2 = 0.50$, $p < 0.0001$).

Preoperatively, the average trefoil component of the patients was $0.24 \pm 0.09 \mu\text{m}$ (ranging from 0.10 to $0.41 \mu\text{m}$), whereas the average postoperative trefoil component was $0.12 \pm 0.05 \mu\text{m}$ (ranging from 0.02 to $0.36 \mu\text{m}$) ($p = 0.01$). The achieved trefoil aberration correction did not correlate with the intended trefoil correction ($r^2 = 0.10$, $p = 0.1$); the achieved/intended ratio (the slope of the regression) was 0.34 (*Figure 7*).

Preoperatively, the average spherical aberration of the patients was $+0.09 \pm 0.25 \mu\text{m}$ (ranging from $+0.01$ to $+0.48 \mu\text{m}$), compared to an average postoperative spherical aberration of $+0.20 \pm 0.40 \mu\text{m}$ (ranging from $+0.06$ to $+0.58 \mu\text{m}$) ($p < 0.001$). The achieved

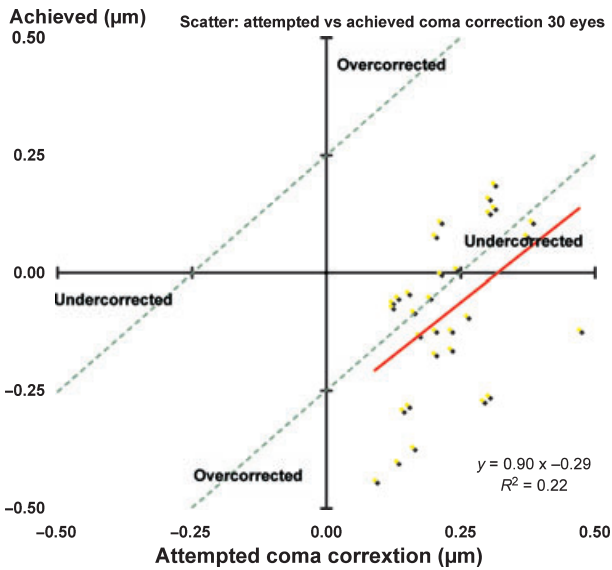


Figure 6. Achieved vs attempted coma correction for CW profiles at the 6-month follow-up analyzed for a 6.0 mm pupil diameter measured with the OPTIKON Keratron Scout.

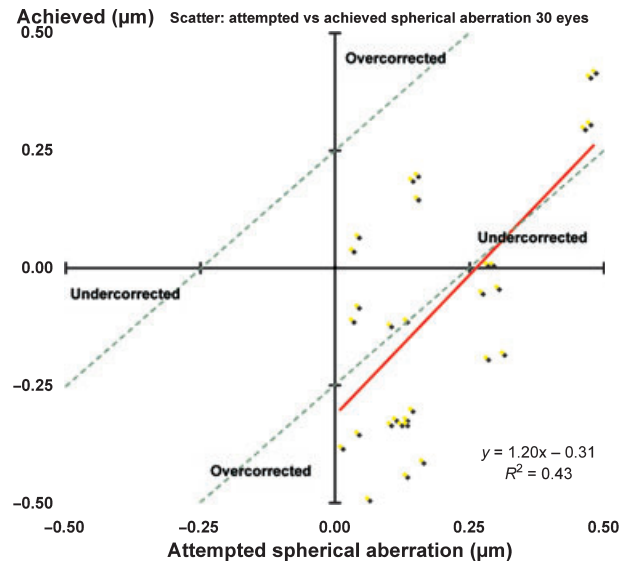


Figure 8. Achieved vs attempted spherical aberration correction for CW profiles at the 6-month follow-up analyzed for a 6.0 mm pupil diameter measured with the OPTIKON Keratron Scout.

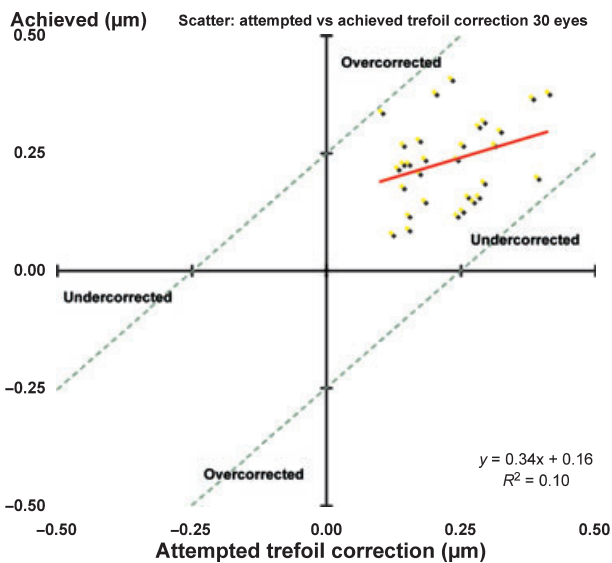


Figure 7. Achieved vs attempted trefoil correction for CW profiles at the 6-month follow-up analyzed for a 6.0 mm pupil diameter measured with the OPTIKON Keratron Scout.

spherical aberration correction was correlated with the intended spherical aberration correction ($r^2 = 0.43$, $p < 0.0001$); the achieved/intended ratio (the slope of the regression) was 1.20 (Figure 8). Postoperative spherical aberration was correlated with neither the achieved defocus correction nor with the achieved coma correction.

A comparison of the preoperative findings and of the postoperative evaluation at the 6-month follow-up are presented in Table 1, confirming the efficacy and safety of this customization strategy.

It is notable that low scatter, i.e. narrow deviation was observed throughout all above mentioned measurement series.

Discussion

Corneal wavefront guided treatments showed promising results in this study. Based on the findings 6 months postoperatively, it could be concluded that the CW customized treatments planned with CAM produced both safe and predictable ablation of the cornea.

For the evaluation of this customized approach – and in particular for the myopic astigmatic patient group treated – the standard parameters used to assess refractive surgery results, i.e. efficacy, predictability, refractive outcome, stability, and safety, were not sufficient.

When evaluating the outcomes of wavefront customization strategies, wavefront aberration analysis is mandatory to be able to determine whether the customization aims could be achieved.

The analysis of Table 1 shows that the average coma, trefoil and spherical aberrations changed by +23%, -51%, and +105%, respectively. This might indicate that the ablation strategies were partly unsuccessful, however, the small amount of aberration found in this group, similar to the repeatability/accuracy (approximately 0.2 µm) of the devices when measuring living tissue, introduced some scatter. This value of 0.2 µm comes from our experience, and a similar value can be found with aberrometers as well when measuring living tissue and not test lenses or static objects, and similar values are reported in the literature (Padmanabhan

et al., 2008). Furthermore, since the ablation procedures were performed in a physical world, they suffered from different types of unavoidable and inherent errors (Lipshitz, 2002) that led to aberrations (Marcos, 2001), including biomechanical reactions due to the flap cut (Durrie and Kezirian, 2005; Tran *et al.*, 2005), blending zones, cyclotorsion (Smith and Talamo, 1995; Bueeler *et al.*, 2003), centration errors (Uozato and Guyton, 1987; Guirao *et al.*, 2001), spot size limitations (Huang and Arif, 2002; Guirao *et al.*, 2003), active eye-tracking (Tsai and Lin, 2000; Bueeler and Mrochen, 2005) capabilities, and biomechanical reactions due to the ablation process itself (Yoon *et al.*, 2005). It has been suggested, as well, that the surface ablation procedures are better suited for the wavefront guided ablation as they would avoid the induction of aberrations due to the flap and interface (Buzzonetti *et al.*, 2004; Chung *et al.*, 2006). Now with the introduction of thin and ultrathin planar flaps with femtosecond laser and the newer microkeratomes, such as the pendular microkeratome, this aspect of the debate will require further research.

Topography is measured under bright light conditions which might cause pupil constriction and also pupil center shift relative to that in normal photopic levels. In this study potential pupil center shifts were not compensated and laser ablation was directly centred at the pupil as measured under the laser; however topography acquisition was made at a luminance level of 1500 lux, similar to the value under the laser system.

For all these reasons we split the analysis between eyes exhibiting aberration modes assuming values below 0.2 μm in the preoperative findings and those with values above 0.2 μm . The two new subgroups are referred to as corneal wavefront low (CWl) and corneal wavefront high (CWh).

The CWl group showed an average change in coma from 0.12 to 0.33 μm (+165%) ($p = 0.008$), in trefoil from 0.13 to 0.14 μm (+3%) ($p = 0.48$), and in spherical aberration from -0.49 to +0.12 μm (-123%) ($p = 0.001$).

The CWh group showed an average change in coma from 0.38 to 0.31 μm (-19%) ($p = 0.04$), in trefoil from 0.35 to 0.12 μm (-66%) ($p = 0.0005$), and in spherical aberration from +0.14 to +0.08 μm (-48%) ($p = 0.02$).

Corneal wavefront customized treatments can only be successful if the pre-existing aberrations are greater than the repeatability and the biological noise, which is also demonstrated by our selective group split on the basis of preoperative aberration values (intended corrections). Considerations such as treatment duration or tissue removal (Gatinel *et al.*, 2002) make it more difficult to establish a universal optimal profile.

Furthermore, coupling effects between different high order aberration terms, and between HOAs and manifest refraction is still one of the major sources of residual aberrations after refractive surgery. This topic has been discussed from a theoretical perspective by Guirao *et al.* (2001) or by Bará *et al.* (2006) and from a clinical perspective by MacRae (2007) or Bühren *et al.* (2007). They all found mutually affecting interactions, for example, between defocus and spherical aberration, or between 3rd order aberrations and low order terms, between spherical aberration and coma, or between secondary and primary astigmatism.

The accuracy, predictability, and stability of the refractive power change, together with the minimal external impact of the CAM ablation profiles on the HOAs, led to very good results in terms of visual quality.

A limitation of this study is the small series size of the data being presented. A contralateral eye study would have been more enlightening but the difficulty with this design is established. However, this study has corroborated other findings that have been recently published. The fact that in order to appropriately treat patients with profiles such as these described, the patients need to have a significant level of preoperative aberrations. Recently published independent studies by Stonecipher and Kezirian (2008) and by Venter (2008) illustrated similar findings. The Wavelight laser and the Schwind laser share fundamental characteristics. It is these characteristics that strengthen the outcomes of this study for the size of that series was larger. These facts are confirmed with the study by Venter (2008) using a different device (Nidek, Gamagori, Japan).

In summary, our study demonstrated that aspheric CW ablation profiles, designed with CAM software for the ESIRIS laser platform, yielded visual, optical, and refractive results comparable to those of other wavefront-guided customized techniques for correction of myopia and myopic astigmatism (Mrochen *et al.*, 2001; Koller *et al.*, 2006). The CW customized approach shows its strength in cases where abnormal optical systems are expected. Apart from the risk of minimal additional ablation of corneal tissue, systematic wavefront-customized corneal ablation can be considered as a safe and beneficial method.

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