Comparative analysis of outcomes after wavefront-guided and wavefront-optimized laser in-situ keratomileusis in high myopic eyes

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Purpose

The aim was to evaluate and compare the clinical outcomes after laser in-situ keratomileusis (LASIK) in high myopia using wavefront-guided (WFG) and wavefront-optimized (WFO) ablation profiles provided by two different excimer laser platforms.

Patients and methods

Prospective, consecutive, comparative, and masked clinical trial including 41 high myopic eyes treated with WFG LASIK using the Advanced CustomVue system (WFG group) and 40 eyes treated with a WFO profile using the Allegretto EX-500 platform (WFO group). Visual, refractive, contrast sensitivity (CVS-1000), and aberrometric outcomes were evaluated in both groups of eyes during a 6-month follow-up.

Results

The efficacy index was significantly better in the WFG group compared with the WFO (1.01±0.11 vs. 0.96±0.12, P=0.038). The safety index was also significantly better in the WFG group (1.03±0.12 vs. 0.94±0.11, P=0.011). All eyes achieved postoperatively an uncorrected distance visual acuity of 20/25 or better in the WFG group, whereas 87.5% of eyes achieved this uncorrected distance visual acuity in the WFO group. More eyes gained one line of corrected distance visual acuity in the WFG group (36.5 vs. 15.0%, P=0.015). Significantly lower postoperative manifest refraction spherical equivalent (P=0.045) and cylinder (P=0.005) were found in the WFG group. Manifest refraction spherical equivalent was within ±1.00 D in 90.3% and 80% of eyes in WFG and WFO groups, respectively (P=0.001). Contrast sensitivity decreased significantly only in the WFO group (P≤0.0397). More significant increase in high-order aberrations was found in the WFO group (P≤0.005).

Conclusion

WFG LASIK provides better efficacy, safety, predictability, and preservation of visual quality in high myopic eyes than WFO LASIK.

Keywords:

aberrations, contrast sensitivity, high myopia, laser in-situ keratomileusis, wavefront-guided laser in-situ keratomileusis, wavefront-optimized laser in-situ keratomileusis

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Introduction

Laser in-situ keratomileusis (LASIK) has significantly evolved since its development in the 1990s. Conventional treatments have demonstrated to be effective and predictable at correcting high refractive errors, but with significant induction of higher-order aberrations (HOAs) due mainly to changes in corneal asphericity [1]. These changes in corneal shape after laser photoablation may induce a significant reduction in visual quality leading the patients to impairment and a variety of subjective symptoms even without residual refractive error and with an acceptable high-contrast visual acuity [2,3]. This is especially concerning high myopia treatments as the laser ablates more tissue to achieve a complete refractive correction and generates a complete transformation of the corneal profile into an oblate shape [4].

Technological advances during the last two decades have led to the development of new laser ablation algorithms which are used in wavefront (WF)-based LASIK treatments [5]. These treatments can be grouped into two broad categories: wavefront-optimized

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(WFO) and wavefront-guided (WFG) treatments [5]. WFO algorithms aim to minimize the induction of spherical aberration (SA) through a customized approach based on refraction and keratometry (aspheric profile). On the other hand, WFG profiles are designed considering the preoperative magnitude of low- and highorder aberrations and specifically considering the root mean square (RMS) values. Aspheric profiles have been fully incorporated into the different excimer laser platforms to avoid the generation of a significant degradation of visual quality after laser refractive surgery [5]. However, according to the scientific evidence reported to this date [6,7], WFG treatments may be the most adequate option in high myopic eyes.

The purpose of our clinical investigation was to evaluate and compare the clinical outcomes after LASIK in high myopia using WFG ablation (Advanced CustomVue; Abbot Medical Optics Inc., Santa Ana, California, USA) and WFO ablation (EX-500 platform; Alcon) in order to investigate the potential benefit of one technique over the other in this group of patients.

Patients and methods

A prospective, consecutive, comparative, and masked clinical trial was performed at the Horus Vision Correction Centre (HVCC) to evaluate visual and aberrometric outcomes of LASIK in 81 high myopic eves using WFG group or WFO ablation profile (WFO group). Specifically, 41 eyes of 21 patients were treated with a WFG ablation profile (Advanced CustomVue platform; Abbott Medical Optics Inc.) calculated according to the aberrometric measurements obtained with a high-resolution Hartmann-Shack aberrometer (WFG group), and 40 eyes of 20 patients were treated with a WFO profile (EX-500 platform, Allegretto Q-500 excimer laser; Alcon, Fort Worth, Texas, United States) (WFO group). A total of 13 women and eight men were included in the WFG group and 11 women and nine men in the WFO group (P=0.315). The mean age was 24.3±6.4 and 27.1±4.7 years in the WFG and WFO groups, respectively (P=0.22).

Exclusion criteria in WFG and WFO groups were myopic spherical equivalent of less than -6 D or over -12 D, monocular preoperative CDVA of less than 20/25 (high myopia), unstable refraction for the last 12 months, residual corneal bed thickness of less than 300 µm, inability to return for the scheduled follow-up examinations at 1, 3, and 6 months after surgery, previous diagnosis of dry eye, any corneal opacity including but not limited to arcus senilis, haze or scar tissue, significant pathology of the anterior segment, significant residual, recurrent or active ocular disease, previous intraocular or corneal surgery, history of herpetic keratitis, diagnosis of immunodeficiency, systemic connective tissue diseases or atopic syndrome, insulin-dependent diabetes mellitus, participants taking systemic medications likely to affect wound healing or vision, unstable or irregular topography readings (especially corneal ectatic diseases), intraocular pressure of more than 23 mmHg, history or suspect of glaucoma, media opacities, participants with iris coloboma or any other irregularity of the pupil margin, and pregnancy or breastfeeding. There was no restriction on patients with large, low-mesopic pupil diameter measured with an infrared pupilometry The study received the approval of the HVCC Ethics Committee. Following the tenets of the Declaration of Helsinki, the patients were informed about the surgery and the clinical study, and provided informed consent to participate in it.

All patients underwent a complete preoperative ophthalmological examination that included ocular and medical history, measurement of uncorrected [uncorrected distance visual acuity (UDVA)] and corrected distance visual acuity (CDVA), manifest and cycloplegic refraction, slit-lamp examination, Scheimpflug imaging-based corneal topography by means of the Pentacam HR system (Oculus Optikgeräte, GmbH Wetzlar, Germany) in the WFG group and Placido ring-based corneal topography with the WaveLight Topolizer system (Alcon) in the WFO group, pachymetry, applanation tonometry, contrast sensitivity (CS) testing (CVS-1000; Vistech, vistec, Jena, Germany), fundoscopy and WF aberration measurement (iDesign aberrometer) in both groups, calculating and recording the magnitude of RMS-HOAs and SA for a pupil aperture of 5 mm. The iDesign aberrometer is an optimized WF sensor developed with a higher quantity and density of lenslets to allow the analysis of 1257 points for a 7.0 mm pupil and a higher dynamic range -16 to +12 D of sphere, 0-8 D of cylinder, and up to 8 µm of HOA [8]. In our study, all aberrometric measurements were performed under physiological conditions in dim illumination by experienced operators and without pupil dilation. Soft contact lenses and rigid gas permeable contact lenses were removed at least 1 week or 3 weeks, respectively, prior to preoperative examination.

All surgeries were performed by the same surgeon (M.K.) under topical anesthesia in the HVCC (Alexandria, Egypt; WFG) and in the Alex LASIK

Center (Alexandria, Egypt; WFO). Preoperatively, the eyes undergoing surgery were prepared by cleansing the periocular zone and two drops of a topical anesthetic were instilled. Corneal flaps were created using the M2 microkeratome (Moria, Antony, France), with intended flap thickness of 110 µm. In the WFG group, the VISX STAR S4IR excimer (visx abott, AMO: Santa Ana, California, United States) laser and a WFG ablation calculated according to the iDesign aberrometer measurements were used. In the WFO group, an optimized ablation was applied by means of the Allegretto EX-500 platform. In the WFG group, an intended diameter of 6.0 and 8.0 mm were programmed for the optical zone and the transition zone, respectively, whereas in the WFO group a 6.5-mm optical zone diameter was programmed, but the transition zone diameter was adjusted automatically by the excimer laser software. In all patients, a torsional registration was previously performed and applied, if necessary. Likewise, treatments were programmed assuming a refractive target of emmetropia in all cases. Standard topical postoperative treatment was administered to all patients consisting of a combination of dexamethasone and tobramycine four times a day during 1 week. Also, the patients were instructed to use an artificial tear solution at least every 2 h a day after the surgery and at least four times a day during 1 month.

Postoperatively, all patients followed a schedule of programmed visits, including examinations at 1, 3, and 6 months after surgery. These postoperative examinations included UDVA and CDVA measurements, manifest refraction, slit-lamp examination, and topographic analysis. At 6 months postoperatively, CS and aberrometric outcomes for a 5-mm pupil were also evaluated and compared with those outcomes obtained at preoperative baseline.

Statistical analysis

Statistical analyses were performed with a commercially available software package (SPSS for Mac, Version 20.0; IBM Corporation, Armonk, New York, USA). The sample size estimation was calculated for each statistical test or comparison planned to be done. The Dupont and Plummer [9] approach was used. Normal distribution of the preoperative and postoperative data was assessed by the Shapiro-Wilk test. All comparisons of means were performed using the paired Student's t-test when data samples were normally distributed and the Wilcoxon signed-rank test when they were not. Comparison of percentages was performed using the χ^2 -test. All P values were two sided and considered statistically significant when less than 0.05.

Results

No statistically significant differences between groups were found in preoperative mean keratometry (WFG 43.37±2.12 D vs. WFO 43.67±2.75 D, P=0.146) and central corneal thickness (WFG 546±38 µm vs. WFO 542±44 µm, P=0.426). Likewise, there were no significant differences among groups in preoperative manifest refraction spherical equivalent (MRSE) (WFG -11.63±1.50 D vs. WFO -11.38±1.53 D, P=0.236) and manifest cylinder (WFG -1.40±1.55 D vs. WFO -1.26±1.19 D, P=0.061). No significant differences among groups were found in scotopic pupil size (P=0.553). Torsional registration during surgery was intended in the WFO group, but it was only enabled in 60% of eyes. In the WFG group, iris registration was enabled in 100% of eyes.

Visual outcomes

Mean 6-month postoperative decimal UDVA was 0.90 ± 0.11 (range: 0.8–1.2) (decimal scale) and 0.85 ± 0.12 (range: 0.6–1.2) in WFG and WFO groups, respectively. The difference among groups in this parameter was statistically significant (*P*=0.0032). Mean 6-month postoperative decimal CDVA was 0.92 ± 0.11 and 0.95 ± 0.11 in WFG and WFO groups, respectively. The difference although small was statistically significant (*P*=0.033). However, it should be considered that there was already a significant difference among groups in CDVA preoperatively (WFG 0.89 ± 0.14 vs. WFO 0.96 ± 0.11 , *P*=0.011).

In the WFG group, all patients achieved a 6-month postoperative UDVA of 0.8 (20/25) or better, whereas in the WFO group, a total of 87.5% of eyes (35 eyes) achieved this level of UDVA (Fig. 1). Regarding CDVA, all patients in both groups reached at least a 6-month postoperative CDVA of 0.8 (20/25) or better. In the WFG group, no eyes lost CDVA and 36.5% of eyes gained one (11 eyes) or two lines (four eyes) of visual acuity, whereas in the WFO group 7.5% of eyes lost one line (two eyes) or two lines (one eye) of CDVA (Fig. 2). The percentage of eyes gaining one line of CDVA was significantly higher in the WFG group compared with WFO (WFG 36.5% vs. WFO 15.0%, P=0.015) (Fig. 2).

Refractive outcomes

In the WFG group, the mean preoperative MRSE decreased from -7.59 ± 1.50 D (range: -6.13 to -11.63) to -0.38 ± 0.29 D (range: 0 to -1.75) at the end of the postoperative follow-up (*P*<0.001). Likewise, the mean manifest cylinder changed from -1.40 ± 1.55 D

(range: 0.00 to -5.46) preoperatively to -0.28 ± 0.34 D (range: 0.00 to -1.5) postoperatively (P<0.001) (Fig. 3). In WFO, significant changes were also observed in MRSE (preoperatively -7.61±1.53 D vs. postoperatively -0.67±0.41 D, P<0.001) and manifest cylinder (preoperatively -1.26±1.19 D vs. to postoperatively -0.31±0.25 D, P<0.001) (Fig. 3). In spite of being manifest cylinder significantly higher in absolute terms in the WFG group compared with WFO (P=0.001)preoperatively, postoperative cylinder was significantly lower in the WFG group (P=0.045). Likewise, the 6-month postoperative MRSE was also significantly lower in the WFG group compared with WFO (P=0.005) (Fig. 3).

In the WFG group, 90.3% of eyes (37 eyes) had an MRSE within ± 1.00 D, whereas in the WFO group, only 80% of eyes (32 eyes) achieved that outcome (*P*=0.001). The percentage of eyes with a postoperative MRSE within ± 0.25 D was significantly higher in the WFG group compared with WFO (WFG 73.2% vs. WFO 60.0%, *P*=0.032). Likewise,

Figure 1



Distribution of preoperative corrected distance visual acuity and postoperative uncorrected distance visual acuity at 6 months after surgery in wavefront-guided and wavefront-optimized groups.





Changes in lines of corrected distance visual acuity at 6 months after surgery in wavefront-guided and wavefront-optimized groups.

the percentage of eyes with a 6-month postoperative manifest cylinder of 0.25 D or below was significantly higher in the WFG group compared with WFO (WFG 68.3% vs. WFO 45.0%, P=0.025).

Contrast sensitivity outcomes

In the WFG group, a slight but nonsignificant decrease of CS was observed for the spatial frequencies of 3 (P=0.084), 6 (P=0.365), and 18 cpd (P=0.214) (Fig. 4). In contrast, CS improved for a spatial frequency of 12 cpd from 5.70±1.16 preoperatively to 5.88±0.90 postoperatively, although this change did not reach statistical significance (P=0.685). In the WFO group, CS decreased significantly for all spatial frequencies (3 cpd, P=0.0024; 6 cpd, P=0.005; 12 cpd, P=0.0397; 18 cpd, P=0.001; Fig. 4).

Aberrometric outcomes

The difference among groups in the level of induced HOAs was statistically significant. Change in RMS-HOA was significantly higher in the WFO group (0.21 $\pm 0.34 \mu$ m, range: -0.24 to 1.43) compared with the













WFG group $(0.08\pm0.26\,\mu\text{m}, \text{ range: }-0.39 \text{ to } 0.48)$ (*P*=0.007). Also, the change in SA (*P*=0.003), trefoil (*P*=0.005), and coma aberration (*P*=0.002) was significantly higher in the WFO group compared with the WFG group (Fig. 5).

Discussion

Corneal ablation surgical procedures are usually the preferred option by refractive surgeons for correcting refractive defects. However, the range of safe dioptric correction for these procedures has been frequently brought into question as a consequence of the midlong-term complications observed term and particularly in cases of high refractive error, such as keratectasia [10], corneal haze [11], regression [12], dry eye [13], and poor postoperative visual quality [4,14]. Keratorefractive procedures using conventional ablation profiles induce significant amounts of HOAs resulting in a deterioration of visual quality, especially in an increase of SA and coma-like aberrations and consequently in a significant reduction in the CS function leading to patient dissatisfaction [3,14,15]. This was significantly improved with the introduction of WFO and WFG ablation profiles [5]. In the last years, an additional improvement was reached with the development and introduction of high-resolution aberration sensors, avoiding some of the limitations of previous aberrometers [8]. Likewise, highly optimized aspheric algorithms have been progressively developed and applied providing good visual, refractive, and even aberrometric outcomes [16–18]. Most of comparative studies evaluating the outcomes with WFG and WFO treatments in myopia show some type of clinical benefit of WFG over WFO treatments [19-22]. However, there are some studies





Distribution of the postoperative change in higher-order aberrations in wavefront-guided and wavefront-optimized groups.

reporting no significant differences among both types of ablation profiles [23,24]. The current study was aimed at comparing the outcomes of WFG and WFO treatments in high myopic eyes in which the induction of aberrations is higher.

In our study, WFG treatments were performed using the VISX STAR S4IR excimer laser which has widely demonstrated safety and effectiveness in the correction of different levels of refractive error [22,24]. WFO treatments were performed using the WaveLight Allegretto EX-500 platform whose delivery program is designed to maintain a natural postoperative corneal shape by adjusting for corneal asphericity and minimizing the induced SA [25]. This platform has also shown good clinical outcomes in the correction of myopia [25,26]. Previous studies have also compared the effectiveness of WFG and WFO treatments using the predecessors of these two specific excimer laser platforms for the correction of myopic refractive errors [22]. Moshirfar et al. [22] conducted a randomized, prospective, single-masked, fellow eye study to compare the LASIK outcomes in myopia using also the WaveLight Allegretto EX400 and VISX CustomVue procedure using the WaveScan system. These authors found that both laser platforms had equal visual and safety outcomes [22]. In our series, better efficacy and safety were found in those eyes receiving WFG treatment. It should be considered that the study of Moshirfar et al. [22] also included low to moderate myopic eyes and used an aberrometer of less resolution. He et al. [20] also compared the outcomes of WFO LASIK using the WaveLight Allegretto platform and WFG LASIK using the VISX CustomVue procedure in another prospective, randomized, fellow-eye-controlled study. These authors concluded that the WFG treatment offered significant advantages over WFO in terms of residual refractive error, uncorrected distance acuity, and CS. In series, using high-resolution aberrometer our measurements for defining WFG ablation profiles, better postoperative UDVA, lower residual MRSE and cylinder, better predictability, and preservation of CS were observed in eyes receiving WFG treatments compared with WFO. Therefore, the use of WFG ablation profiles with the excimer laser platform evaluated seems to be more adequate in high myopia than WFO treatments as a more optimized visual outcome is achieved. It should be considered that the optical zone used was smaller in the WFG group compared with the WFO group (6.0 vs. 6.5 mm) and no significant differences among groups were present in scotopic pupil size. Therefore, the differences between treatments may be

even higher when using identical optical zone treatments. Likewise, a potential influence in the outcomes of differences in the profile of the peripheral ablation pattern should be also considered, but this information is not provided specifically by the manufacturer.

The main reasons for the better visual outcome obtained with WFG ablation profiles in our series are the higher levels of predictability and control of HOAs of such profiles compared with the WFO. Recently, Toy et al. [19] have shown in a comparative study that WFG treatments produced slightly more predictable astigmatic corrections analyzed by vector analysis than WFO treatments using the same laser platform. In our series, the percentage of eyes with a postoperative MRSE within ±0.25 D and manifest cylinder of 0.25 D or below was significantly higher in the WFG group compared with the WFO. Likewise, we have observed a more significant change in HOAs with WFO treatments. This is consistent with other comparative studies evaluating WFG and WFO LASIK in myopic eyes, including also cases of low to moderate myopia [20–22,24]. Moshirfar et al. [22] found in a comparative study that total HOA, coma, and SA increased in eyes receiving WFO ablation profiles 4, 11, and 19%, respectively, whereas in eyes treated with WFG treatments total HOA, coma, and SA decreased by 9, 18, and 27%, respectively. Khalifa et al. [27] found similar visual and refractive outcomes with aspheric ablation using the variable spot scanning system of the VISX STAR S4IR (Abbott) and the WaveLight Allegretto (Alcon) excimer laser platforms, but the WaveLight-optimized profiles induced greater amounts of SA. More induction of HOAs with WFO treatments compared with WFG has been also reported by El Awady et al. [28] and Padmanahban et al. [29]. Likewise, these last authors confirmed, as in our series, that WFG LASIK was associated with better CS than WFO. In this study, the less high-order induction of aberrations, more predictability of cylinder correction, and more preservation of preoperative CS may be attributed to variable factors such as better axial and torsional registration with centroid shift, high-resolution detection of the aberrations with more detailed ablation profile, and more delivery of energy to the midperiphery of the cornea.Our results should be considered with caution when compared with those obtained in comparative studies evaluating WFG and WFO systems, as we have evaluated and compared the outcomes in a sample of eyes with high myopia in which is expected a more significant benefit of the

WFG ablation. Sáles and Manche [30] found in a comparative case series that WFG and WFO LASIK had similar clinical outcomes at 12 months, but in hyperopic eyes. Likewise, Toy *et al.* [19] reported that WFG and WFO LASIK using the Alcon WaveLight Allegretto Eye-Q 400-Hz excimer laser platform produce similar astigmatic results in myopic patients, but with low to moderate myopia. He and Manche [31] did not identify a difference in uncorrected visual acuity or contrast acuity between eyes undergoing WFG or WFO treatment, but only at 3 months after photorefractive keratectomy and in low to moderate myopic eyes.

This study has some limitations. First, a contralateral study would have been a better design for the study, but this study was conducted in a private center and it has been very difficult to convince patients of being operated on without knowing exactly the type of technique used. Second, the unmasked character of the study for the examiner during the follow-up can be considered also a limiting factor for the study. Third, we have included the data from both eyes of each patient and this theoretically may introduce some bias as the correlation of clinical data of fellow eyes can lead to some errors in statistical trends. However, we have checked that the significant differences among groups that were found in the whole sample were also present when only right or left eyes of each group were considered. Fourth, we used the same aberrometer for planning the surgical treatment and for measuring the postoperative level of aberrations as another type of aberrometer was not available in our clinical setting. This could be considered as an additional factor introducing bias, but it should be considered that the same type of aberrometer was used for both postoperative preoperative and examinations. Finally, patient satisfaction and subjective quality of vision was not evaluated by means of a validated questionnaire and this would have completed the examination protocol of the study.

In conclusion, WFG LASIK is a more adequate option for the correction of high myopia than WFO as it provides better efficacy and safety, predictability, and preservation of visual quality. In cases of high myopia combined with astigmatism, WFG LASIK provides a more predictable correction of the astigmatic error than WFO treatments. Future studies should be conducted to compare the outcomes of WFG LASIK performed with both laser platforms, as the Allegretto platform also offers the possibility of generating WFG ablations. Financial support and sponsorship Nil.

Conflicts of interest

There are no conflicts of interest.

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