Evaluation of visual and refractive outcomes of wavefront optimized versus wavefront guided laser-assisted *in situ* keratomileusis in patients with myopia and myopic astigmatism

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Purpose

The aim of this study was to compare the visual and refractive outcomes of wavefront optimized (WFO) ablations with wavefront guided (WFG) ablations in patients with myopia and myopic astigmatism.

Patients and methods

Two consecutive groups of eyes were treated for myopia and myopic astigmatism with laser insitu keratomileusis. One group was treated with WFO ablation, and the other group was treated with WFG ablation. Refractive evaluation (efficacy, safety, predictability, accuracy, stability, and refractive astigmatism), higher-order aberrations (HOAs), and contrast sensitivity were analyzed preoperatively and at 1, 3, and 6 months postoperatively.

Results

The WFO ablation group comprised 20 eyes of 11 patients who showed a change in the mean spherical equivalent refraction from − 3.34 ± 1.64 D preoperatively to − 0.21 ± 0.30 D at 6 months postoperatively, and the WFG ablation group comprised 34 eyes of 17 patients who showed a change in the mean spherical equivalent refraction from − 3.54 ± 1.50 D preoperatively to − 0.23 ± 0.57 D at 6 months postoperatively. A statistically significant difference was found when comparing within the group preoperatively versus 6 months postoperatively as regards contrast sensitivity, HOAs, trefoil root mean square (RMS), and spherical aberration. However, there was no significant difference in induced coma and spherical aberration RMS within each group preoperatively and at 6 months postoperatively. A statistically significant difference was found when comparing the two groups at 6 months postoperatively with respect to contrast sensitivity, induced HOA RMS, induced trefoil RMS, and spherical aberration. There was no significant difference between the two groups, except for induced coma and spherical aberration RMS.

Conclusion

Both the WFG group and the WFO showed comparable accuracy, efficacy, and safety with nearly equal induction of all HOAs.

Keywords:
higher order aberration, wavefront guided, wavefront optimized

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Introduction

Excimer laser keratorefractive surgeries such as photorefractive keratectomy or laser-assisted *in situ* keratomileusis (LASIK) successfully reduce refractive errors. This eliminates lower order aberration (sphere and cylinder) and allows higher-order aberration (HOA) to take the upper hand in degrading retinal image quality. Moreover, refractive surgeries induce HOAs, and this results in some patients still complaining about glare and halos under dim conditions and poor night vision despite the fact that visual acuity has been raised [1–3].

The wavefront optimized (WFO) ablation profile using Allegretto Wavelight machine maintains a more natural corneal shape by adjusting for the asphericity of the cornea based on the anterior curvature readings. When laser light contacts the center of the cornea, it is fully absorbed. However, in the periphery, the angle of incidence, resulting from the cornea's curved shape, may cause energy reflections. Controlling the peripheral ablation allows the laser to create large, true optical zones with a minimized transition zone. WFO LASIK places more pulses in the peripheral area to compensate for energy loss and reflections. This provides a nearly 100% optical zone and a minimized transition zone. At the same time, the natural aspheric shape of the cornea is more preserved and the induction of spherical aberrations is minimized [4,5].

Wavefront guided (WFG) LASIK may have several proposed advantages over existing LASIK techniques. Among the proposed benefits are the potential for reducing post LASIK night vision problems, which are frequently caused by an increase in postoperative aberrations. It is believed that WFG LASIK may decrease the amount of induced aberrations and would probably reduce pre-existing aberrations. Moreover, the use of small spot scanning lasers with active eye tracking in WFG ablations may result in the application of larger optical zones with less need for tissue ablation for a given spherocylindrical refractive error, as the ablation is tailored based on the scotopic pupil size [6]. Wavefront (WF) measurements in a normal eye have shown that removal of WF errors up to the fourth Zernike order is sufficient to achieve diffraction limited optical performance for a pupil 3.4 mm in diameter. For a 7.3 mm pupil, however, removal of aberrations up to the eighth Zernike order is sufficient [7].

This study was performed with the aim of evaluation and comparison of the visual and refractive outcome of WFO versus WFG LASIK.

Patients and methods

This is a prospective nonrandomized controlled clinical study. The study included two groups of patients who underwent LASIK surgery: group 1 (WFO) included 20 eyes of 11 patients for whom corneal refractive surgery was performed using WFO ablation profile of wavelight (Wavelight; ALCON, Erlangen, Germany) Allegretto Eye-Q platform, and group 2 (WFG) included 34 eyes of 17 patients for whom corneal refractive surgery was performed using VISX STAR S4/IR platform (Abbot medical optics, Santa Clara, CA, USA).

Inclusion criteria

Inclusion criteria were as follows: myopia up to 6 D, myopic astigmatism up to 4 D, and age older than 18 years.

Exclusion criteria

Exclusion criteria were as follows: high myopia over – 6 D, eyes with keratoconus or irregular astigmatism as proved by corneal topography and Pentacam, eyes with corneal thickness less than 500 μm, previous corneal refractive surgery, corneal scars, history of or recurrent herpetic eye disease, patients with glaucoma, cataract, uveitis or any posterior segment abnormality, pregnancy or lactation, and complicated cases during surgery.

The study was conducted between 2013 and 2015 at Roayah Vision Correction Centers and Alforsan Eye Center.

The study protocol was approved by the Ethics Committee of the Faculty of Medicine, Assuit University.

Preoperative evaluation

Complete ophthalmic examination was conducted for every patient, including anterior segment examination with slit-lamp biomicroscopy, uncorrected distance visual acuity (UDVA), manifest, cycloplegeic refraction, corrected distance visual acuity (CDVA), applanation tonometry, fundus examination, corneal topography using Magellan mapper (NIDEK Corporation, Tokyo, Japan) or Pentacam using Allegro Oculyzer (Wavelight; ALCON, Erlangen, Germany), corneal thickness using ultrasonic pachymetry SP-100(NIDEK Corporation) or using Pentacam, contrast sensitivity testing (Test Chart 2000 Xpert; Thomson Software, London, UK), and WF analysis using Zernike analysis through nondilated pupil using VISX Wavescan System (Abbot Medical Optics, Santa Clara, California, USA).

Ethical considerations

The risks and advantages of the procedure were explained and informed consent was obtained from all patients for whom all details of the procedure were explained, with emphasis on the intended outcome and possible complications.

Surgical technique

For the WFO group, LASIK was performed using wavelight Allegretto Eye-Q platform (ALCON Wavelight), in which manifest refraction was entered directly into a laptop of the machine. For the WFG group, LASIK was performed using VISX STAR S4/IR platform (Abbot Medical Optics) in which refractive data were transmitted to the machine by flash memory from WF aberrometer. Flap was created using Moria M2 Microkeratome (Moria, Antony, France) with a planned thickness of 130 μm in both groups. Ring choice was based on nomogram provided by manufacturer.

Postoperative evaluation

Follow-up was carried out at 1, 3, and 6 months postoperatively for both groups where UDVA, CDVA, manifest refraction, contrast sensitivity, and WF error (HOA, coma, trefoil, and spherical aberration) were measured.

Statistical analysis

Data analysis was performed using the software statistical package for the social sciences for Windows version 20.0 (SPSS; SPSS Inc., Chicago, Illinois, USA).

Normality of data samples was evaluated by means of the Kolmogorov–Smirnov test. When parametric analysis was possible, paired *t*-test was used for comparisons between the preoperative and postoperative data, whereas the Wilcoxon rank sum test (for comparisons between the preoperative and postoperative data) and the Mann–Whitney *U*-test (for comparison between postoperative data of both groups) were applied to assess the significance of such differences when parametric analysis was not possible. Bivariate regression analysis was carried out to predict achieved spherical equivalent (SEQ) accuracy using the attempted SEQ data. Correlation coefficients (Pearson or Spearman depending on whether normality condition could be assumed) were used to assess the correlation between different variables. For qualitative data (patients' questionnaire), numbers and percentages were used to present the results. The χ^2-test and Monte-Carlo tests of significance were used to compare patients' responses in the two groups. Differences were considered to be statistically significant when the associated *P* value was less than 0.05. Standard graphs for reporting the outcomes in refractive surgery, according to the Waring Protocol and its modifications [8–10], were used for displaying and summarizing the refractive outcomes of this study for each group postoperatively.

Results

Demographic characteristics

The mean age in the WFO group was 27.4 ± 4.29 years ranging from 21 to 33 years, and the mean age in the WFG group was 24.82 ± 4.88 years ranging from 18 to 37 years. As regards the sex distribution, in the WFO group there were four (36.36%) female and seven (63.64%) male patients and in the WFG group there were 12 (70.59%) female and five (29.41%) male patients.

The mean corneal thickness was 560.40 ± 29.22 μm in the WFO group and 549.62 ± 42.62 μm in the WFG group. The mean average Ks was 43.76 ± 1.71 D in the WFO group and 43.80 ± 1.40 D in the WFG group. The mean spherical error was – 2.94 ± 1.40 D in the WFO group and – 2.78 ± 1.43 D in the WFG group. The mean cylindrical error was – 0.83 ± 0.89 D in the WFO group and – 1.51 ± 1.43 D in the WFG group. The mean SEQ was – 3.34 ± 1.63 D in the WFO and – 3.53 ± 1.50 D in the WFG group.

Result of refractive evaluation of the two procedures

As regards efficacy, the WFO group had preoperative mean CDVA of 0.94 ± 0.16. At 6 months postoperatively, the mean UDVA was 0.93 ± 0.15 with an efficacy index of 101.9%: 80% of eyes had a preoperative CDVA of 0.8, which increased to 95% at 6 months postoperatively with a UDVA of 0.8; 70% of eyes had a preoperative CDVA of 1.0, which decreased to 40% at 6 months postoperatively with a UDVA of 1.0; and 10% of eyes had a preoperative CDVA of 1.2, which increased to 15% at 6 months postoperatively with a UDVA of 1.2. The WFG group had a preoperative mean CDVA of 0.87 ± 0.18. At 6 months postoperatively the mean UDVA was 0.96 ± 0.16 with an efficacy index of 113.06%: 79.41 and 44.18% of eyes had a preoperative CDVA of 0.8 and 1.0, which increased to 88.24 and 73.96% at 6 months postoperatively with a UDVA of 0.8 and 1.0, respectively, and 2.94% of eyes had a preoperative CDVA of 1.2, which increased to 14.71%. There was a statistically significant difference on comparing the efficacy of the two groups at 6 months postoperatively ($P = 0.012$).

As regard safety, in the WFO group, about 35% of eyes gained two lines or more and none of the eyes lost lines, with a safety index of 111.40%. In the WFG group, about 35.29% of eyes gained two lines or more and 2.94% of eyes lost two or more lines, with a safety index of 117.38%. There was no statistically significant difference on comparing the safety between the WFG group and the WFO group ($P = 0.22$) (Figs 1 and 2).

The WFO group showed high predictability as 90% eyes were within ± 0.5 D and 100% of the eyes were within ± 1.0 D of emmetropia at 6 months postoperatively. As regards refractive predictability in the WFG group, 68% eyes were within ± 0.5 D and 91.18% of the eyes were within ± 1.0 D of emmetropia at 6 months postoperatively (Figs 3 and 4).

As regards accuracy of correction of astigmatism, 100% of the eyes in the WFO group and 67.65% of eyes in the WFG group were within ± 0.5 D of emmetropia. Totally 100% of the eyes in the WFO group and 97.07% of eyes in the WFG group were within ± 1.0 D of emmetropia at 6 months (Figs 5 and 6).

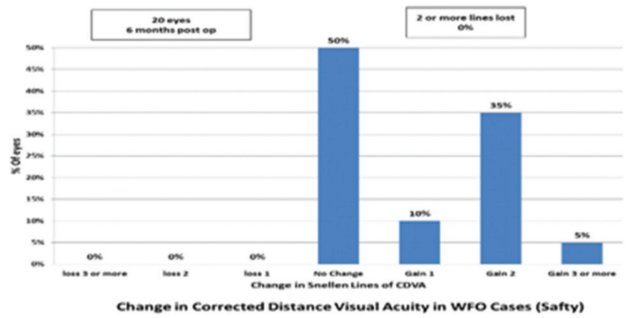
The two techniques showed good refractive stability of eyes during the follow-up. At 6 months postoperatively none of eyes in the WFO group and 14.70% of the eyes in the WFG group changed greater than 0.50 D (Figs 7 and 8).

As regards accuracy, Figs 9 and 10 showed the attempted versus the achieved MRSE with a strongly positive correlation ($r = 0.979$) for the WFO group and ($r = 0.928$) for the WFG group; both were effective in reaching attempted.

Higher-order aberrations

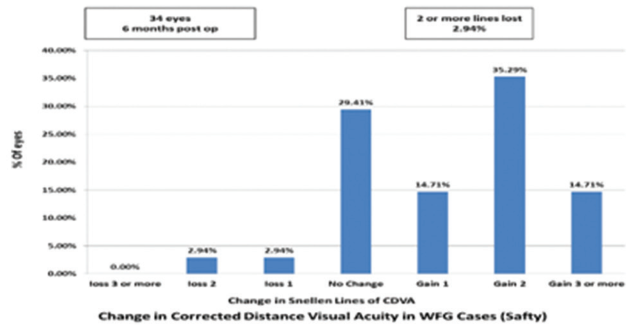
In the WFO group, the mean preoperative HOA root mean square (RMS) was increased significantly

Figure 1



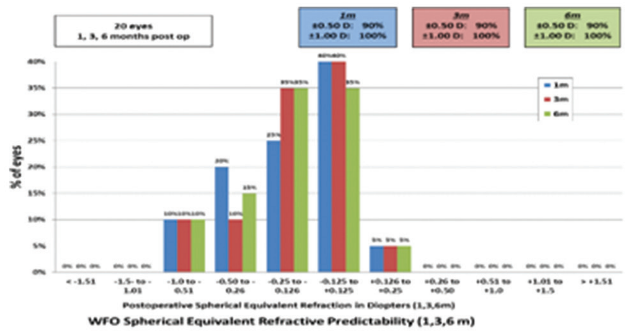
Change in corrected distance visual acuity postoperatively in the wavefront-optimized group.

Figure 2



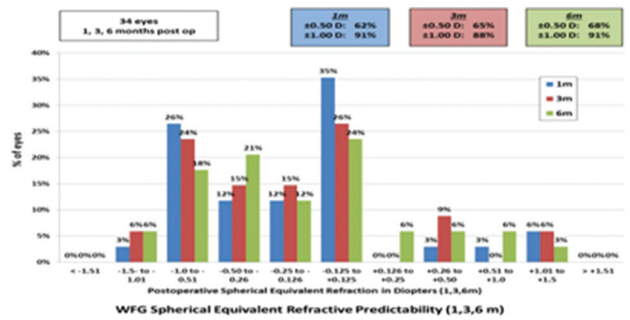
Change in corrected distance visual acuity postoperatively in the wavefront-guided group.

Figure 3



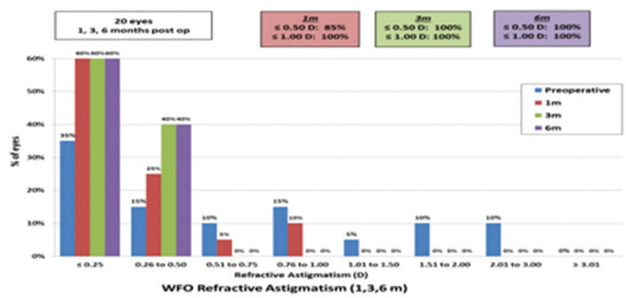
Postoperative spherical equivalent (1, 3 and 6 months) in the WFO.

Figure 4



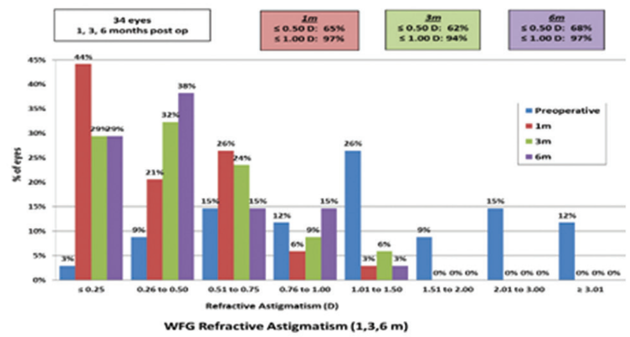
Postoperative spherical equivalent (1, 3 and 6 months) in the. WFG.

Figure 5



Refractive astigmatism of the wavefront-optimized group (1, 3, and 6 months).

Figure 6



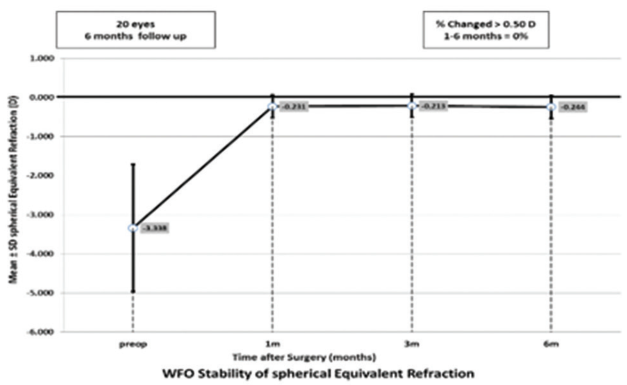
Refractive astigmatism of the wavefront-guided group (1, 3, and 6 months).

from 0.218 ± 0.130 to 0.467 ± 0.255 μm at 6 months postoperatively (P = 0.000). This resulted in a statistically significant induction of HOA RMS with a mean of 0.250 ± 0.211 μm (P = 0.003). In the WFG group, the mean preoperative HOA RMS increased significantly from 0.354 ± 0.131 to 0.444 ± 0.138 μm at 6 months postoperatively (P = 0.000). This resulted in a statistically significant induction of HOA RMS with a mean of 0.090 ± 0.114 μm (P = 0.003). There was a statistically significant difference between the WFG group and the WFO group (P = 0.002).

In the WFO group, there was a statistically significant change in the absolute value of spherical aberration from −0.087 ± 0.162 preoperatively to −0.010 ± 0.207 at 6 months postoperatively (P = 0.000). This resulted in a statistically significant induction spherical aberration with a mean of 0.077 ± 0.207 μm (P = 0.04). In the WFG group, there was a statistically significant change in the absolute value of spherical aberration from −0.037 ± 0.115 preoperatively to 0.120 ± 0.189 at 6 months postoperatively (P = 0.05). This resulted in a statistically significant induction spherical aberration with a mean of 0.157 ± 0.158 μm (P = 0.04).

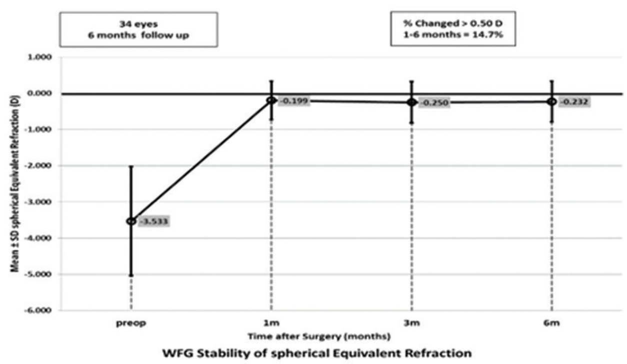
In the WFO group, there was no significant change in the mean spherical aberration RMS from

Figure 7



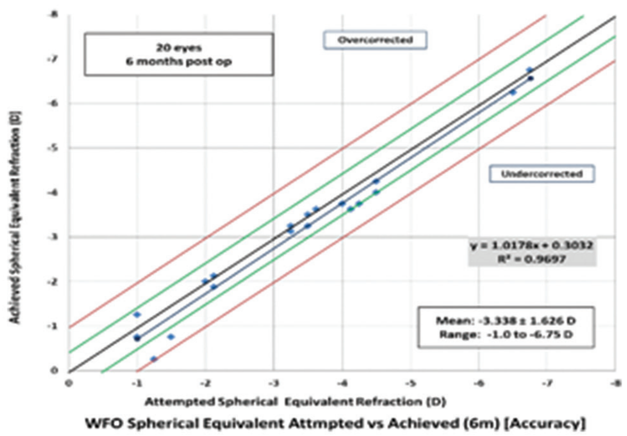
Postoperative stability in the wavefront-optimized group.

Figure 8



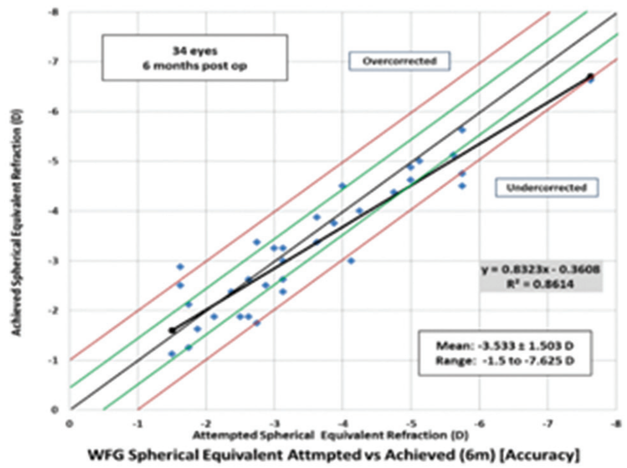
Postoperative stability in the wavefront-guided group.

Figure 9



Spherical equivalent attempted versus achieved 6 months in the wavefront-guided group. WFG, wavefront-guided.

Figure 10



Total induced root mean square in the two groups at 6 months postoperatively. WFO, wavefront-optimized.

0.130 ± 0.122 μm preoperatively to 0.164 ± 0.121 μm at 6 months postoperatively (*P* = 0.24). However, in the WFG group, there was a significant change in the spherical aberration RMS from 0.092 ± 0.076 μm preoperatively to 0.177 ± 0.136 μm at 6 months postoperatively (*P* = 0.006).

There was a statistically significant difference when comparing induced spherical aberration between the WFG group and the WFO group at 6 months postoperatively (*P* = 0.018). However, there was no statistically significant difference between the two groups in terms of induced spherical aberration RMS at 6 months postoperatively.

As regards coma RMS, both groups showed no statistically significant change in the coma RMS at 6 months postoperatively, and hence there was no significant difference between the two groups in induced coma RMS.

In the WFO group, there was a statistically significant decrease in the mean trefoil RMS from 0.257 ± 0.219 μm preoperatively to 0.164 ± 0.145 μm at 6 months postoperatively (*P* = 0.023), and the mean induced trefoil RMS was −0.093 ± 0.232 μm. In the WFG group, there was no statistically significant increase in the mean trefoil RMS, which increased from 0.175 ± 0.088 preoperatively to 0.210 ± 0.158 at 6 months postoperatively (*P* = 0.478), and the mean induced trefoil RMS was −0.035 ± 0.149 μm. This resulted in a statistically significant difference between the WFO group and the WFG group at 6 months postoperatively (*P* = 0.005) (Fig. 11 and Table 1).

Contrast sensitivity

When tested at a frequency of three cycles per degree, in the WFO group there was a statistically significant increase in the mean contrast sensitivity value from 1.54 ± 0.31 preoperatively to 1.86 ± 0.10 at 6 months postoperatively (*P* = 0.000). In the WFG group there was a statistically significant increase in the mean contrast sensitivity value from 1.68 ± 0.12 preoperatively to 1.85 ± 0.17 at 6 months postoperatively (*P* = 0.000).

There was a statistically significant difference between the two groups ($P = 0.000$) preoperatively. This resulted comparison postoperative unequivocal as shown in Fig. 12.

Discussion

When HOAs cannot be corrected, image quality may suffer Kulkamthorn *et al.* [11]. The HOA calls for more advanced optical measurements and more sophisticated laser algorithms. These laser algorithms are found in WF-based treatments, which have been shown to diminish induced HOAs compared with traditional LASIK, and increase the predictability of visual outcomes [12,13]. As WF-based methods have evolved rapidly over the years, our aim was the evaluation and comparison of the visual and refractive outcome of WFO LASIK and WFG LASIK in terms of predictability, safety, efficacy, HOA, and contrast sensitivity.

As regards efficacy, in the WFO group UDVA was 1.0 in 40% of eyes, which is less than that reported by Perez-Straziota and colleagues [14–17], 85% of eyes had UDVA of 20/20 or better [12], 91% of eyes had UDVA of 20/20 or more [18], and 95% of eyes had UDVA of 20/20 or more. However, in the WFG group, UDVA was 1.0 in 73.96% of eyes; this result was less compared with that reported by Moshirfar and colleagues [12,14,15,17,18].

There was no statistically significant difference between the WFG group and the WFO group as regards safety ($P = 0.22$). The safety index was 111.40% for the WFO group and 117.38% for the WFG group. These results are more than that obtained by Nuijits *et al.* [19]. Their safety index was 1.12 in the WFG group.

As for accuracy, both the WFO group and the WFG group were accurate in the correction of manifest refraction spherical equivalent (MSRE) with similar results. There was a statistically significant difference between attempted versus achieved ($P = 0.000$) in each group.

The WFO group is superior to the WFG group as regards predictability. This result was different from that obtained by Perez-Straziota and colleagues [14,15,18]. However, they are higher than those obtained by Padmanabhan *et al.* [16].

The WFO group was superior to the WFG group in correction refractive astigmatism and refractive stability, with some myopic shift in the WFG group. This may be attributed to the fact that WFG techniques had some limiting factors, including pupil size requirements, mismatch to manifest refraction, which was mostly due to overaccommodation, and the timely process of uploading WF data. The Allegretto Wavelight Eye-Q laser functions at a higher frequency, therefore allowing faster operating times. In addition, the Allegretto platform does not require iris registration, which can sometimes be difficult to obtain intraoperatively, and there is no issue with mismatch to manifest refraction.

Higher-order aberrations root mean square and induced higher-order aberrations root mean square

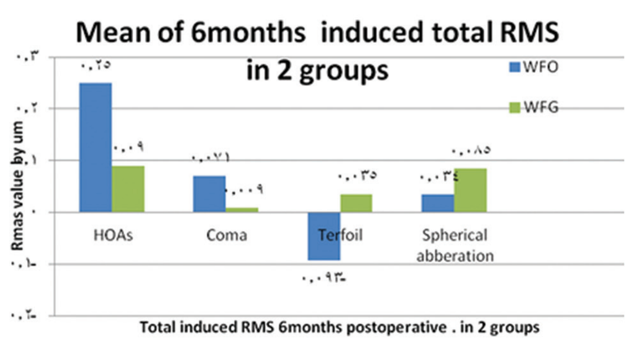
The increase in total HOA in the WFO group was higher than the increase reported by Miraftab

Table 1 Comparison of induced higher-order aberration in the two groups at 6 months postoperatively

Induced aberration	WFO RMS value (μm)	WFG RMS value (μm)	*P*
HOA	0.250±0.211	0.090±0.114	0.002*
Trefoil	−0.093±0.232	0.035±0.149)	0.005*
Spherical aberration	0.034±0.115	0.085±0.171	0.467
Coma	0.071±0.225	0.009±0.300	0.835

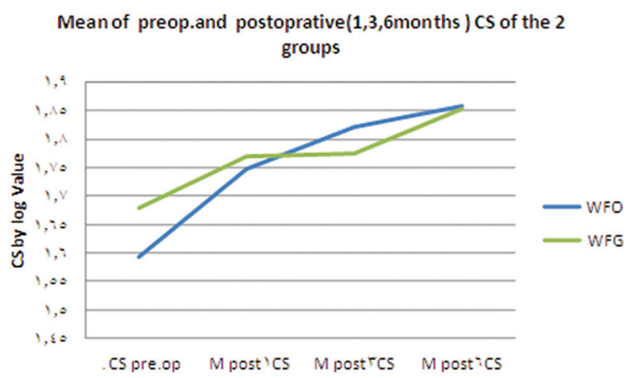
HOA, higher-order aberration; RMS, root mean square; WFG, wavefront-guided; WFO, wavefront-optimized. $P \leq 0.05$, significant. *Statistically significant differences.

Figure 11



A comparison between contrast sensitivity test preoperatively and 6 months postoperative. WFG, wavefront-guided.

Figure 12



A comparison betwen contrast sensitivity test preoperative and 6 months postoperative.

et al. [17], who reported that HOA increased from 0.26 ± 0.08 μm preoperatively to 0.45 ± 0.16 μm at 3 months postoperatively, and Moshirfar *et al.* [12] reported an increase in HOA of about 4%. This difference may be because Miraftab *et al.* [17] and Moshirfar *et al.* [12] conducted the study on a larger sample size of 41 and 44 eyes, respectively. Moshirfar *et al.* [12] created LASIK flap using femtosecond laser, which theoretically induces less HOAs. In the WFG group of this study the increase in HOA was less than that reported by Miraftab *et al.* [17], who found that HOA increased from 0.28 ± 0.08 μm preoperatively to 0.45 ± 0.17 μm, and Moshirfar *et al.* [12] reported an increase in HOA of about 9%.

The WFO group showed the higher value of induced total HOA RMS, and the WFG group showed a lower value, with a statistically significant difference between the WFG and the WFO group in induced HOA at 6 months postoperatively ($P = 0.002$). This result is in agreement with Padmanabhan *et al.* [16]. Moreover, the result differs from that reported by Stonecipher and Kezirian [15] (the changes in HOAs were not statistically significant between the WFO group and the WFG group with preoperative RMS HOA <0.3 μm). This is because both WFO and WFG ablation theoretically does not increase HOA and those patients had preoperative HOA RMS less than 0.3 μm. This low value in both techniques had the same effect on corneal aberration and Perez-Straziota *et al.* [14] reported no significant differences in HOAs between the WFG and WFO groups irrespective preoperative total RMS.

Spherical aberration root mean square and induced spherical aberration root mean square

There was a statistically significant difference in induced spherical aberration at 6 months between the WFG group and the WFO group ($P = 0.018$); it was less in the WFO group. This contradictory to that reported by Moshirfar *et al.* [12], who reported decreased spherical aberration of about 27% ($P = 0.713$) in the WFG group, whereas in the WFO group it increased to about 19% ($P = 0.214$). Spherical aberration shows the largest increase after excimer laser refractive surgery [4]. This increase in spherical aberration was highly correlated with preoperative refraction [5,20]. Therefore, the change in corneal asphericity induced by myopic ablations is an important factor influencing the increase in spherical aberration after laser refractive surgery [21]. Dupps and Roberts [22] demonstrated that the peripheral corneal lamellae retracted and thickened after surface-based phototherapeutic keratectomy. However, no statistically significant difference was found between the two groups in spherical aberration RMS postoperatively.

Coma root mean square and induced coma root mean square

Both groups showed no significant changes between the mean coma RMS preoperatively and at 6 months postoperatively, with no significant difference in induced coma between the two groups.

Trefoil root mean square and induced trefoil root mean square

The WFO group was superior to the WFG group in the management of preoperative trefoil, with a statistically significant difference between the WFG group and the WFO group.

Our results showed a significant reduction in preoperative trefoil from 0.257 ± 0.219 μm preoperatively to 0.164 ± 0.145 μm at 6 months postoperatively ($P = 0.023$) in the WFO group. This is higher than that reported by Moshirfar *et al.* [12], who reported that trefoil decreased to 5% in the WFO group ($P = 0.490$). This differs from that reported by Stojanovic *et al.* [23], who conducted a study on WFO photorefractive keratectomy and not LASIK and found that trefoil changed only nonsignificantly (from 0.163 ± 0.081 μm before surgery to 0.191 ± 0.092 μm after surgery). The WFG group in the current study had a nonsignificant increase in postoperative trefoil RMS as reported by Moshirfar *et al.* [12]; who reported that trefoil decreased 19% ($P = 0.660$).

Contrast sensitivity

A statistically significant difference was reported when comparing preoperatively and 6 months postoperatively in the WFO group CS value ($P = 0.001$) and the WFG group ($P = 0.000$). However, WFG and WFO had improved similarly in postoperative contrast sensitivity value. No statistically significant difference was found preoperatively between the WFG and the WFO group ($P = 0.061$) and at 6 months postoperatively ($P = 0.97$).

The clinical results in this study demonstrate a good visual and optical outcome in the two groups. Verdon *et al.* [24] reported a strong correlation between the correction of higher-order optical aberrations and best-corrected visual acuity and glare visual acuity.

This difference between this study and other studies may be related to individual abnormal healing responses, as we conducted each technique on different patient. This was avoided in some studies such as Padmanabhan *et al.* [25] and Koller *et al.* [26], who compared fellow eyes with WFG and the other eye was treated with WFO. The results were also related to the use of a different machine for each technique have different platform and LASIK operation was performed by different surgeons.

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Conflicts of interest

There are no conflicts of interest.

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