Wavefront-Guided Ablation Retreatment Using Iris Registration

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Purpose: To evaluate the efficacy, predictability, safety, and intraoperative and postoperative complications of laser in situ keratomileusis (LASIK) retreatment in myopic eyes using wavefront-guided ablation with iris registration (IR).

Methods: Retrospective analysis was used to evaluate wavefront-guided retreatment with IR in a consecutive cohort of 77 eyes (57 patients) after LASIK. The eyes were divided into two groups: no previous retreatment group (group 1) ($n = 63$) and previous LASIK retreatment group (group 2) ($n = 14$). The primary outcome variables assessed postoperatively at 1, 3, and 6 months were uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), and pre- and postretreatment changes in manifest refraction.

Results: The mean preretreatment spherical equivalent in group 1 was reduced from -0.5 ± 1.0 diopter (D) (range -3 to 2.4) to 0.06 ± 0.3 (range -0.9 to 0.6) ($P < 0.002$) at 6 months. In group 2, the mean preretreatment spherical equivalent was reduced from -0.9 ± 1.24D (range -3.1 to -0.5) to 0.04 ± 0.5 (range -1.0 to 1.1) ($P < 0.049$) at 6 months. At 6 months, UCVA was 20/20 or better in 92% in group 1 and 64% in group 2, of patients, respectively. No eyes lost more than one line of BCVA in group 1 and one eye (7%) lost two lines of BCVA in group 2.

Conclusion: Wavefront-guided LASIK retreatment with IR after LASIK is an effective, predictable, and safe procedure in cases requiring a single retreatment. In contrast, eyes with previous retreatments showed less predictability and lower percentage of eyes with postoperative 20/20 UCVA.

Key Words: Wavefront-guided LASIK retreatment.

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Retreatment rates for primary myopic keratorefractive surgery range from 20% to 30%.[1,2] Persistence of residual refractive error is one of the most frequent causes of retreatment after laser in situ keratomileusis (LASIK).[3] Many other factors, such as individual patient expectations, developing of disturbing night vision symptoms because of glare, and halos and surgeon preference can lead patients to desire a retreatment procedure.[4,5] Standard refractive surgeries also induce high-order optical aberrations (HOA).[6−8] For some patients, HOA induction causes visual symptoms such as halos, starburst, glare, and double vision with a decrease of best-corrected visual acuity (BCVA) and/or contrast sensitivity.[9] Wavefront technology has emerged as a novel procedure for measuring and treating optical aberrations that yield better quality of vision as compared with conventional ablation.[10,11]

Customized ablation formulas require precise alignment to the mapped corneal areas. If cyclotorsion occurs and is not compensated for, rotational misalignment errors could negatively impact the outcome of retreatment refractive surgery by under-correcting existing aberrations and inducing new ones. Hence iris registration (IR) technology evolved to assure that common coordinate axes between the wavefront and the eye is applied to compensate for cyclotorsional eye motion.[12]

In this study, the efficacy, predictability, and safety of the Visx S4 IR (AMO, Inc., Irvine CA) wavefront platform are evaluated in cases of LASIK retreatment. In addition, our analyses sought to detect any differences between the visual outcome between eyes that had no previous retreatment after their initial keratorefractive surgery and those with multiple previous retreatment procedures.

METHODS

A retrospective analysis was carried out on 77 consecutive eyes of 57 patients undergoing LASIK retreatment at University of Texas Southwestern Medical Center at Dallas. All had undergone initial LASIK procedures from August 2005 to September 2008. Institutional Review Board approval was obtained for this retrospective analysis. Before all primary procedures or subsequent LASIK retreatments, patients underwent a full ophthalmologic examination, including manifest and cycloplegic refraction, determination of uncorrected visual acuity (UCVA) and BCVA, elevation computerized videokeratography (Pentacam, Oculus Inc., Lynwood, WA), Wavescan aberrometer (AMO Inc.), slitlamp biomicroscopy, pneumometer tonometry, binocular indirect ophthalmoscopy through dilated pupils, and pachymetry. Postoperative assessments were routinely performed at 1 day, 1 week, and 1, 3, and 6 months after surgery.

Based on the number of previous retreatments, eyes were divided into two groups: group 1 ($n = 63$) included eyes with no previous retreatments; and group 2 ($n = 14$) included eyes with previous retreatments. Group 2 had 11 eyes (79%) with one previous retreatment and three eyes (21%) with two previous retreatments.

Initial Laser In Situ Keratomileusis Procedure

All eyes had myopia or compound myopic astigmatism before initial refractive surgery. A variety of excimer laser platforms were

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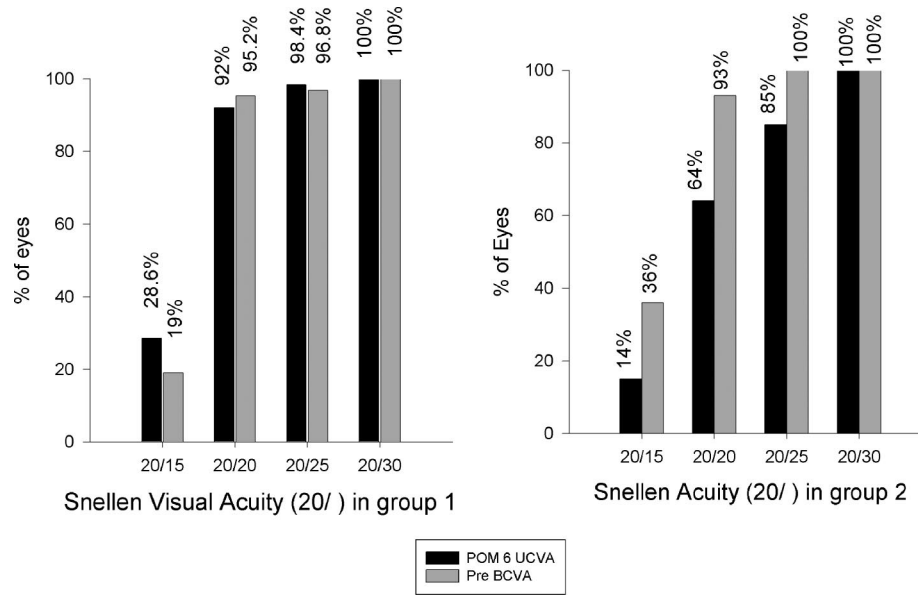

FIG. 1. Efficacy: preoperatively and 6 months postoperative.

used in the initial LASIK procedures: Visx Laser platform in 60 eyes (78%), LADARVision Laser platform (Alcon Laboratories INC, Ft Worth, TX) in 15 eyes (19.5%), WaveLight Laser platform (Wavelight Laser Technologie AG, Erlangen, Germany) in two eyes (2.5%). As regards the primary or secondary retreatment in group 2, Visx laser platform was used in all eyes.

Of the 77 study eyes, 35 eyes (45%) had prior conventional LASIK and 42 eyes (55%) had prior wavefront-guided (WFG) LASIK. The 77 eyes had one of two flap procedures, 39 (51%) had their flaps cut by Hansatome microkeratome (Bausch and Lomb, Rochester, NY) and in 38 eyes (49%) Femtosecond laser (IntraLase Inc, Irvine, CA) was used. Figure 1 shows the different combinations of settings of initial LASIK procedure. The flap thickness was either 120 μm or 180 μm.

Laser In Situ Keratomileusis Retreatment Techniques

The LASIK enhancement procedure in this study was aimed at achieving emmetropia in all cases. Study inclusion criteria included: (1) previous LASIK surgery with residual myopia, hyperopia, or mixed astigmatism; (2) patient dissatisfaction of his/her visual results; (3) no intraoperative complications in the initial procedure; (4) stable refractive error for at least 3 months before surgery; (5) sufficient residual central corneal thickness ($>$250 μm); and (6) no contact lens wear for two weeks before the baseline retreatment examination. Study exclusion criteria included: (1) corneal ectasia, keratoconus suspect, or decentration; (2) marked pupillary decentration; (3) eyes that undergone $\geq$3 previous retreatments; (4) previous keratoplasty or intraocular surgery such as cataract surgery or scleral buckle; (5) ocular or systemic disease likely to affect corneal wound healing; and (6) pregnancy or nursing. Preoperative data required for WFG ablation were collected by an integrated diagnostic workstation with elevation topography (Pentacam, Oculus Inc.) and Wavescan aberrometry. All eyes had a valid iris capture of wavescan of 6 mm or more. The treatment file was downloaded to the Visx S4 IR laser to be applied on the ablation surface. The Visx S4 IR laser platform has an iris registration program, which is a hardware product upgrade installed in the Visx Star4 laser. This program, which detects eye position and alignment, was designed to measure and compensate for pupillary center shift and ocular cyclorotation, allowing surgeons to more precisely perform laser treatment in the corrected area with the aim of providing better visual and optical results.[13]

A fluence test was carried out. The same nomogram was used in all cases. The physician was allowed an adjustment of the sphere ($\pm$0.75 diopter [D]). There was no adjustment to the programmed optical or treatment zone. The eye tracker was used in all cases. The procedures were performed by four surgeons (W.B, D.C, V.M, and J.M) using same technique. The eyes were retreated by their initial surgeons. Patients were given 5 mg of diazepam (Valium, Roche, Basel, Switzerland) orally. The eyes were marked at the slitlamp for cyclotorsional registration and then brought to the laser. The lids were retracted with LASIK Libermann speculam. Proparacaine 0.5% eye drop was used for topical anesthesia. The cornea was marked with an eccentric 3.0-mm optical zone marker stained with methylene blue. All flaps were lifted by careful dissection with a Sinskey hook. The flap was then gently lifted with a forceps and retracted, creating a sharp demarcation along the epithelial edge (epithelirhexis) as described by Perez-Santonja et al.[14] Active eye tracking was used. After ablation was completed, the interface was irrigated copiously, and the flap was replaced in its original position and dried for 5 min. The patient was instructed to apply topical Moxifloxacin HCI four times a day for a week and prednisolone acetate every hour for the first day then every 2 h for the second day and then four times a day for a week and then tapered gradually over a month. Follow-up examinations were performed at first day, first week, and first, third, and sixth months after surgery.

Primary outcome variables including UCVA, manifest refraction, and complications were assessed and analyzed at 1, 3, and 6 months. Postretreatment high-order aberrations data were available for a subset of 22 eyes.

Data Analysis

Statistical analyses were performed with the Student test, paired *t* test, Wilcoxon signed-rank test, and the Spearman correlation test

TABLE 1. *Demographics of Patients With LASIK Retreatment in Both Groups*

	Group 1	Group 2	Both groups
No. eyes	63 (81%)	14 (19%)	77
No. patients	46 (81%)	11 (19%)	57
Females	21 (46%)	4 (36%)	25
Males	25 (54%)	7 (64%)	32
Age	42.7 ± 1.2	49.8 ± 7.3	46.25 ± 7.3
Months after primary procedure	29 ± 30	19.5 ± 29.05	24.25 ± 29.5

Group 1, no previous retreatment; Group 2, previous retreatment.

using Sigmastat 3.5 statistical program. A P value of 0.05 or less was considered significant. Snellen's visual acuity (VA) measurements were converted to decimal fraction for the purpose of statistical analyses.

RESULTS

Fifty-seven patients (77 eyes) underwent LASIK retreatments of whom 25 (44%) were females and 32 (56%) were males. The mean age was 46.25 ± 7.3 years with a range of 19 to 63 years. The demographics of each group are presented in Table 1. Forty-five of 77 eyes (58%) underwent retreatment for undercorrection, 15 eyes (19%) for overcorrection, and 17 eyes for mixed astigmatism (23%).

On comparing both groups as regards their initial data and postoperative data the following differences were found as shown in Table 2. It should be stated that all preoperative data related to group 2 refers to the findings after the initial procedure.

Uncorrected visual acuity after retreatment was significantly better than the values before retreatments at all follow-up visits in both groups (Table 3).

The differences between preretreatment and postretreatment spherical equivalent (SE)were statistically significant at all follow-ups in both groups. The mean preretreatment SE in group 1 was reduced from −0.5 ± 1.0D (range −3 to 2.4) to −0.02 ± 0.4 (range −1.25 to 1.25) ($P < 0.001$) at 3 month; and to 0.06 ± 0.3 (range −0.9 to 0.6) ($P < 0.002$) at 6 months. In group 2, the mean preretreatment SE was reduced from −0.9 ± 1.24D (range −3.1 to −0.5) to −0.1 ± 0.3 (range −1.0 to 0.4) ($P < 0.04$) at 3 month; and to 0.04 ± 0.5 (range −1.0 to 1.1) ($P < 0.049$) at 6 months.

There was no significant difference between preretreatment wavefront and manifest sphere, cylinder, or SE measurements in both groups ($P = 0.88$, 0.66, and 0.77, respectively).

TABLE 2. *Difference Between Group 1 and Group 2*

	Group 1	Group 2[a]	P
Age	42.7 ± 1.2	49.8 ± 7.3	0.008[b]
Months after primary procedure	29 ± 30	19.5 ± 29.05	0.01[b]
Initial SE	−4.9 ± 2.9	−7.6 ± 3.5	0.03[b]
Initial K	43.9 ± 1.6	44.9 ± 1.56	0.038[b]
Initial pachymetry	556.8 ± 30	572.1 ± 303	0.16
Pre-UCVA	0.62 ± 0.25	0.74 ± 0.3	0.1
Pre-BCVA	1.03 ± 0.13	1.1 ± 0.15	0.3
Pre-SE	−0.5 ± 1	−0.9 ± 1.24	0.32
POM 6 UCVA	1 ± 0.2	0.94 ± 0.2	0.35
POM 6 BCVA	1.04 ± 0.1	1.06 ± 0.1	0.48
POM 6 SE	−0.11 ± 0.3	0.04 ± 0.5	0.45
Preoperative pachymetry	496.5 ± 45.6	501.1 ± 38	0.7

[a]All preoperative data related to group 2 in this table are collected from data before the primary retreatment.

[b]Statistically significant.

SE indicates spherical equivalent; UCVA, uncorrected visual acuity; BCVA, best-corrected visual acuity; POM, postoperative month.

TABLE 3. *UCVA Pre- and Postretreatment*

	P value group 1	P value group 2
Pre-UCVA POM 1 UCVA	0.001[a]	0.013[a]
Pre-UCVA POM 3 UCVA	0.001[a]	0.009[a]
Pre-UCVA POM 6 UCVA	0.001[a]	0.024[a]

[a]Statistically significant.

UCVA indicates uncorrected visual acuity; POM, postoperative month.

Efficacy

The UCVA (Snellen decimal VA) improved from 0.62 ± 0.25 preoperatively to 1 ± 0.2 at 6 months follow-up in group 1 and from 0.74 ± 0.3 preoperatively to 0.94 ± 0.2 at 6 months follow-up in group 2. Efficacy is evaluated by calculating the percentage of eyes having a postoperative UCVA of 20/20 and 20/40 or better at the end of the follow-up period (Fig. 1). The efficacy index (ratio of postoperative UCVA and preoperative BCVA) is 0.97 in group 1 and 0.85 in group 2.

Safety

Six months after surgery, one eye (7%) had lost two lines of BCVA in group 2 (Fig. 2). Two eyes (3.2%) in group 1 and one eye (7%) in group 2 had lost one line of BCVA, whereas 42 eyes (66.6%) in group 1 and 7 eyes (50%) in group 2 that remained unchanged after surgery. Fifteen eyes (23.8%) in group 1 and four eyes (29%) in group 2 gained one line of BCVA, four eyes (6.3%) in group 1 and one eye (7%) in group 2 gained two lines, and no eyes gained >2 lines of BCVA. The safety index (ratio of postoperative and preoperative BCVA) at 6 months was 1.001 in group 1 and 0.96 in group 2.

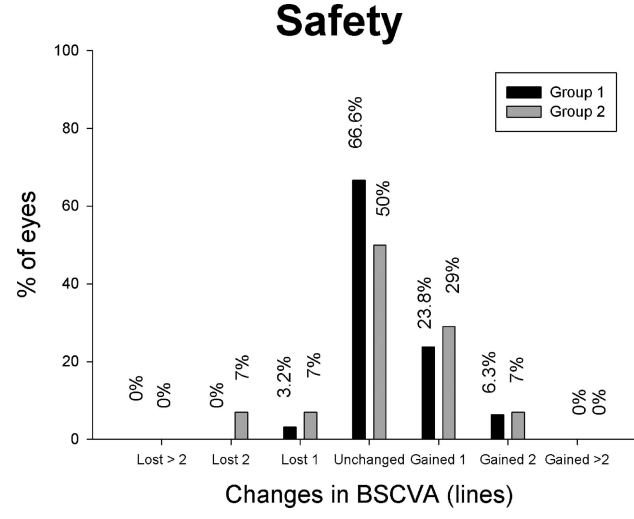

FIG. 2. Changes in best-corrected visual acuity (BCVA) 6 month after laser in situ keratomileusis (LASIK) retreatment.

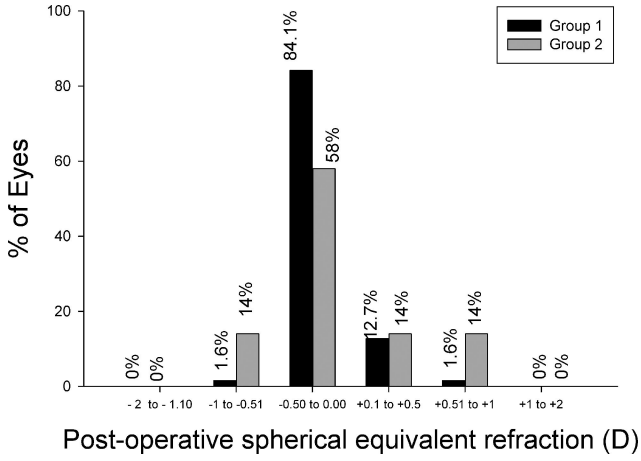

FIG. 3. Predictability: at 6 months, 83.3% of eyes were within ±0.50D of emmetropia and 92% within ±1D.

Predictability

The mean postoperative SE was −0.11 ± 0.three dimensional (range −0.9 to 0.6D) and −0.04 ± 0.5D (range −1 to 1.1D) at 6 months in group 1 and group 2, respectively (Fig. 3). At 6 months, all eyes were within ±1D of the aimed refractive change in both groups (61 eyes [97%] and 12 eyes [86%] were within ±0.5D of the target refractive change in group 1 and 2, respectively).

Stability

The stability of refraction is shown in Figures 4 and 5. Analysis of preoperative and postoperative SE showed a significant change in refraction.

There was no difference between the eyes treated with different platforms in initial LASIK either the preretreatment parameters or in the postretreatment parameters as UCVA, BCVA, and SE in both groups.

Also, there was no correlation between the initial, preoperative, and postoperative SE at 6 months in group 1. However, there was statistically significant strong positive correlation in group 2 between initial SE and preoperative SE ($P < 0.001$) in such a way that the higher the initial SE the higher the myopia before retreatment.

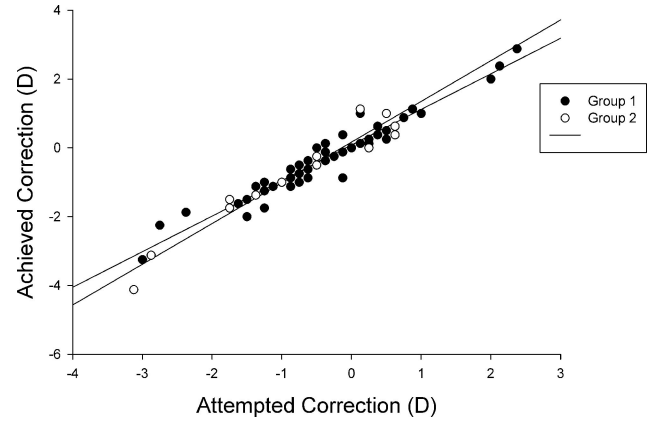

FIG. 5. Attempted versus achieved correction 6 month after LASIK enhancement.

Higher-Order Wavefront Aberrations

Higher-order wavefront aberration analysis of a subset of 22 eyes found that the mean HOA root mean square (RMS) error was the same as the initial value of 0.5 ± 0.3 mm (range 0.14 to 1.23 mm). There was a slight reduction in: (1) total coma from a preoperative value of 0.31 ± 0.23 mm (range 0.03 to 0.84 mm) to 0.27 ± 0.19 mm (range 0.04 to 0.64 mm) ($P = 0.4$); (2) trefoil preoperative value of 0.2 ± 0.13 mm (range 0.03 to 0.94 mm) to 0.19 ± 0.15 mm (range 0.01 to 1.01 mm) ($P = 0.21$); (3) spherical aberration preoperative value of: 0.23 ± 0.21 mm (range −0.17 to 0.59 mm) to 0.22 ± 0.23 mm (range −0.16 to 0.64 mm) ($P = 1$).

Complications

There were no intraoperative complications. No flap displacement was found after retreatment. Haze or scarring was minimal after retreatment in group 1 and one eye (7%) in group 2 developed diffuse lamellar keratitis at 1 month, which resolved after medical treatment. At the 3 month follow-up visit, three eyes (4.7%) and two eyes (14%) in group 1 and 2, respectively, had fine microstriae. The microstriae were confined to the flap, did not affect VA, and remained unchanged throughout the follow-up period.

At 1 month, nine eyes (14%) had flap interface epithelial ingrowth. It was progressive in one eye (group 1) that required intervention by lifting the flap, whereas in group 2, two eyes (14%)

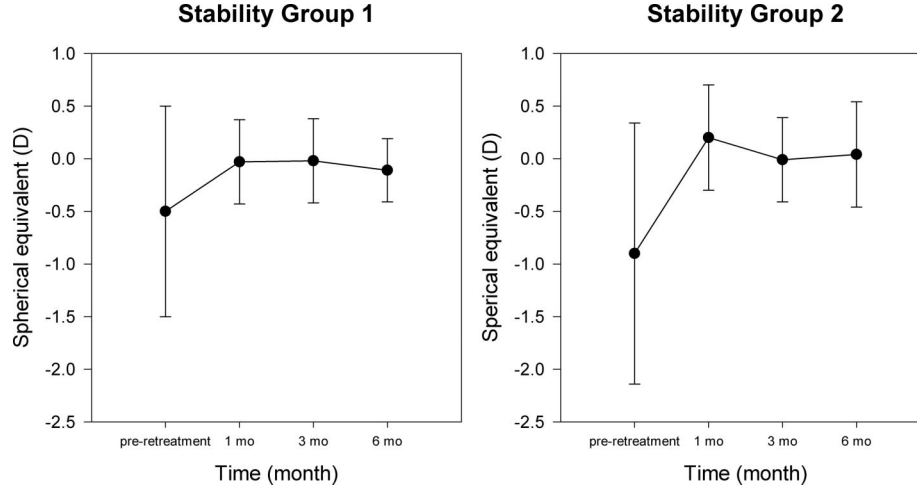

FIG. 4. Graph showing the mean value of spherical equivalent (SE) before surgery and 1, 3, and 6 months after LASIK retreatment.

showed interface epithelial ingrowth and both required lifting of the flap for resolution. Over the 6 month follow-up, the total number of eyes that had epithelial ingrowth was 11 eyes (17%) in group 1 and four eyes (28%) in group 2. The most common site of epithelial ingrowth was temporal and inferior. No flap melting or necrosis was observed throughout the follow-up period.

DISCUSSION

With the popularity and volume of refractive surgery, surgeons inevitably encounter some problems that result in less than satisfactory vision for the patient after the procedure. Among these problems are under or over corrections and "ghosting" symptoms. Wavefront-guided treatments are now the focus of customized corneal ablation to achieve emmetropia and induce less ocular aberrations than conventional technology. Our study presents a 6-month clinical follow-up result in 77 eyes that had WFG enhancement with IR after previous LASIK surgery to correct all types of residual refractive errors by relifting the flap and reablating the stroma.

Uncorrected visual acuity is the main criterion used to assess the effectiveness of a refractive procedure.[15] Ninety-two percent of the patients in retreatment group 1 who had one prior procedure achieved UCVA of 20/20. Although 64% of the patients in the other study arm (group 2) who had already had one or more retreatments achieved UCVA of 20/20. One eye in group 2 lost two lines of BCVA, whereas no eye in group 1 lost more than one line of BCVA after LASIK retreatment with IR. These outcomes support the use of WFG ablation in conjunction with IR for achieving excellent success in situations where the initial procedures have failed to do so.

The potential of superiority of WFG ablation for LASIK retreatments has been challenged in some studies. Jin and Merkley[16] compared conventional and WFG retreatments where conventional retreatment was more predictable and safer than WFG retreatments. Their data showed that in 23 eyes, only 35% had a UCVA ≥20/20, 65% of the eyes were within ±0.50D, and 17% lost two lines of BCVA. This contradicts an earlier report by Alio and Montes-Mico[17] who showed better results with WFG retreatments. The authors found in a 20 eyes series 100% had UCVA of 20/25, 94.4% were within ±0.50D, and no eyes lost lines of BCVA over 6 months follow-up.

In particular, our results are favorable when compared with the study by Febbraro et al.[18] who used a Visx Laser without wavefront for retreatment after previous LASIK. Specifically, the efficacy with wavefront retreatment was better than traditional retreatment at 3 month, with fewer than 75% of eyes having visual acuities of 20/20 or better (compared with 98% in group 1 and 85% in group 2 with wavefront IR) and 95% of eyes having acuities of 20/30 or better (compared with 100% with wavefront IR in both groups).

In comparison with the Brahma et al.[19] study, our wavefront technique also yielded improved predictability at 6 months. A higher percentage of eyes undergoing wavefront was within ±0.50D (90% in our studycompared with ~58%), and ±1.00D (100% in our study compared with ~79%), respectively. Similarly, wavefront retreatment provided a better safety profile such that at 6 months, only 3.8% of the wavefront eyes had lost one line BCVA compared with 16% of the traditional retreatment eyes. Thus, our results using custom wavefront with IR retreatment appear superior to those with traditional enhancement with a greater percentage of eyes achieving better levels of UCVA, improved predictability, and better safety profiles at 3 months. Montague and Manche[20] conducted a similar study on WFG LASIK retreatment (Visx S4) on larger sample number (120 eyes). They had a shorter follow-up period (3 months), and the WFG ablation was with no IR. Their study reported 83% of eyes with SE within ±0.5D at a 3 month follow-up (compared with 89% with WFG LASIK with IR in our study). The loss of one or more lines of BCVA at 3 month follow-up in the study of Montague and Manche was 5% while in group 1 it was 3.2% and 10% in group 2.

The IR innovation allows for compensation of the cyclotorsional rotation of the eye in addition to the following functions: (1) IR allows images taken by different cameras with different illumination sources to be aligned, (2) enables images of the eye taken after the LASIK flap has been lifted to be used, and (3) compensates for variations in pupil size between the diagnostic and treatment conditions.[12] Laria et al.[21] demonstrated that a refractive procedure that results in fixation loss may decompensate latent strabismus and cause cyclotorsion that may exceed 15 degrees. Eyes with the greater extents of cyclotorsion have the greatest risk of sustaining induced aberrations that could be minimized by IR and potentially eyes with lower degrees would have some benefit by the reduction of this variable. Zhang et al.[22] found that WFG ablation with IR eyes had significantly better UCVA and mean SE residual refractive error over conventional method in primary treatment and our data found encouraging results on using this technology in cases of retreatment.

Gimbel et al.[13] used Nidek NAVEX platform which has a cyclotortional control in conjunction with infrared eye tracker yet superimposition of the cyclotorsion control's video image and the eye's axis must be performed manually. No visual outcomes were reported from Gimbel et al., however, they reported that the variable postoperative RMS HOA did not always relate to the visual function.

Gimbel et al.[13] examined 20 eyes of 19 patients and found a mean RMS of HOA preretreatment was 0.66 (range 0.44 to 1.2), and the mean postretreatment RMS of HOA was 0.6 (range 0.42 to 0.78), which was similar to the results of our study which found that RMS of HOA was 0.5 ± 0.3 mm (range 0.14 to 1.23 mm) preoperatively and did not change 6 month postretreatment. However, Hiatt et al.[23] and Chalita et al.[9] found a significant decrease in higher-order aberration, coma, and spherical aberration.

Although, the incidence of epithelial ingrowth postLASIK retreatment varies in previous reports from zero[17] to 5%[24] to 31%,[25] our study showed epithelial ingrowth in 11 eyes (17%) in group 1 and four eyes (28%) in group 2. It is usually limited to the edge of the flap, does not progress, and does not affect VA. However, epithelial ingrowth may lead to a more serious complication such as flap melting or necrosis of the flap,[3] none of which were noted in this study.

To the best of our knowledge, there are no known predictors of eyes that might indicate, which eye will need none, one or multiple retreatments. Our results showed that there is statistically significant difference between both groups in age ($P = 0.008$), interval between initial LASIK and retreatment ($P = 0.01$), initial SE ($P = 0.03$) and initial keratometric power ($P = 0.038$). By running a correlation test, we can conclude that the higher the initial SE and

initial keratometric readings, the higher the number of retreatments required to reach the aimed emmtropia will be. In addition, the shorter the interval is between the initial LASIK treatment and the retreatment, the more likely eyes will require several retreatments. Although the exact time period is not defined particularly, there should be an adequate time for the refraction to be stable before proceeding to retreatment. Other results presented yield some trends; although statistically insignificant however they can be further investigated as group 2 had a higher initial corneal thickness. In addition, 12 eyes (86%) in group 2 had initial conventional LASIK and flaps were cut with a microkeratome in 13 eyes (93%), which indicates that these two parameters may have a higher risk of increased number of retreatments. More studies should address the predictors, the effect of multiple retreatments and the interval period between retreatments on visual outcome.

We understand that our study has limitations: postoperative wavescan readings were not available for all eyes and in the future analyzing such data on a larger group over a longer period of time is recommended. Also as the study was retrospective there was no correlation between the visual outcomes and the values of HOA aberrations on one hand and the patient's symptoms on the other hand. A prospective randomized study of eyes that had no previous retreatment and eyes that had several previous retreatments would be more ideal.

In conclusion, our findings suggest that WFG retreatment with IR provides excellent UCVA and BCVA results with excellent predictability and safety profiles with superior efficacy, predictability, and safety in eyes requiring a single retreatment versus eyes requiring multiple retreatments.

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