Clinical Ophthalmology

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ORIGINAL RESEARCH

Wavefront-guided versus cross-cylinder photorefractive keratectomy in moderate-to-high astigmatism: a cohort of two consecutive clinical trials

This article was published in the following Dove Press journal:
Clinical Ophthalmology
27 January 2012
Number of times this article has been viewed

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Background: Although there have been many studies of the efficacy and safety of wavefront-guided (WF) and cross-cylinder photorefractive keratectomy (PRK), there are few studies on moderate-to-high astigmatism cases. The aim of this study was to assess and compare the efficacy of WF and cross-cylinder PRK in moderate-to-high astigmatism.

Methods: In a comparative cohort, the results of two before-and-after clinical trials conducted on moderate-to-high astigmatism were studied. In the first trial, 50 eyes of 25 patients with stable refraction were enrolled in a before-and-after clinical trial to undergo WF PRK using the VISX™ (VISX Inc, Santa Clara, CA) system. The second clinical trial enrolled 48 eyes of 24 patients with stable refraction and moderate-to-high astigmatism to undergo PRK by the cross-cylinder method using a NIDEK EC-5000 excimer laser system (NIDEK Co Ltd, Gamagori, Japan).

Results: After 6 months, 80% of the eyes in the WF group had uncorrected visual acuity of 20/20 or better compared to 40% in the cross-cylinder group. Only one eye in the cross-cylinder group and no eyes in the WF group lost more than one line of best corrected visual acuity (BCVA) after 6 months of treatment. No treated eyes in either group lost more than two lines of BCVA. The percentage of eyes with no change in BCVA was 54% and 58.3% in the WF and cross-cylinder groups, respectively. Mean postoperative absolute changes in total root-mean-square higher order aberrations in the WF group and cross-cylinder group were 0.05 ± 0.22 µm and 0.17 ± 0.20 µm, respectively ($P < 0.001$).

Conclusion: Both methods of PRK, using the NIDEK EC-5000 and VISX excimer laser systems, are effective for correcting moderate-to-high astigmatism. The WF approach appeared more successful in improving the refractive results.

Keywords: astigmatism, photorefractive keratectomy, wavefront-guided photorefractive keratectomy, cross-cylinder photorefractive keratectomy

Introduction

Astigmatism treatment has always been a challenge for ophthalmologists and has followed an evolutionary pathway over the years, with experience in several surgical procedures. Since the approval of the excimer laser in 1995 for use in reshaping the cornea, significant developments in treating refractive diseases like myopia, hyperopia, and astigmatism have been achieved.[1] Photorefractive keratectomy (PRK) in general is a surgical procedure using an excimer laser to reshape the central cornea to treat refractive errors. In PRK, the excimer laser is applied by different methods for the correction of astigmatism. Each method has special advantages and drawbacks; however, their

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outcomes are not as satisfactory as those of spherical ablation.[2] Wavefront sensors have been popular in astronomy for many decades, and appeared in the field of ophthalmological science quite recently, to identify and correct low- and high-order aberrations.[3] Wavefront-guided (WF) surgical procedures have shown to be promising in astigmatism treatment.[1] According to the literature, excellent clinical outcomes, safety, and efficacy of various WF and wavefront-optimized LASIK treatments in low-to-moderate myopia are reported. However, data on high myopia are scarce.[4–7]

Cross-cylinder PRK is another technique of interest in astigmatism surgery. Cross-cylinder PRK flattens the steepest meridian with central cylindrical ablation and steepens the flattened meridian with paracentral ablation. Subsequently the edge profile and the effective optical zone are improved. It may result in symmetrical corneal shape, better visual acuity, and less regression.[8,9] Although there are many studies of the efficacy and safety of WF and cross-cylinder PRK, there are few studies on moderate-to-high astigmatism cases. The aim of this study was to compare the efficacy, safety, and predictability of WF and cross-cylinder PRK in moderate-to-high astigmatism.

Methods

In a comparative cohort, the results of two before-and-after clinical trials conducted in Nikoukari University hospital in Tabriz, Iran, between December 2009 and December 2010 were compared. Fifty eyes of 25 patients with stable refraction having moderate-to-high astigmatism were enrolled for a before-and-after clinical trial to undergo WF PRK using the VISX™ system (VISX Inc, Santa Clara, CA). VISX wavefront software (v 3.67.2006.1107) was used. The second clinical trial enrolled 48 eyes of 24 patients with stable refraction having moderate-to-high astigmatism to undergo PRK by cross-cylinder method using a NIDEK EC-5000 (NIDEK Co, Ltd, Gamagori, Japan) excimer laser with repetition rate of 40 HZ (v 1.26 w). All surgeries were performed by one surgeon (MRS) at the Tabriz excimer laser center, Tabriz, Iran.

Except for cohort timing, the inclusion and exclusion criteria were the same for both trials. The inclusion criteria were stable refraction; astigmatism above 1.50 D; and age between 20–50 years. Exclusion criteria were other ocular pathologies; pachymetry less than 470 µm; connective tissue disease; asymmetric astigmatism; and tear film abnormality. The range of cylinders was from 1.5 D to 5.0 D.

Laser treatment parameters for cross-cylinder surgery were: hyperopic cylinder with 6.0–9.0 mm zone; myopic cylinder with 6.5–7.5 mm zone; and spherical equivalent treated at 6.0–7.0 mm (or 6.5–7.5 for large pupils). Under topical anesthesia (tetracaine 0.5%), the epithelium was removed by applying 20% alcohol for 15 seconds at the area of 8.0 or 9.0 mm optical zone marker and the laser was fired. Mitomycin C 0.02% was applied for 15–45 seconds and a bandage contact lens was placed at the end of the procedure.

The primary outcome of interest in this study was the amount of astigmatism corrected during a 6-month period after surgery. The endpoint measurement for this outcome was absolute change in refraction scores during the time period after surgery. The secondary outcomes were visual acuity measured using a Snellen chart, and visual aberrations measured by aberrometry.

Topical ciprofloxacin, betamethasone, and diclofenac were applied 4 times a day. Diclofenac and ciprofloxacin eye drops were discontinued after 2 days and following re-epithelialization, respectively. Betamethasone eye drops were replaced by fluorometholone 2 weeks postoperatively and continued for 3 months.

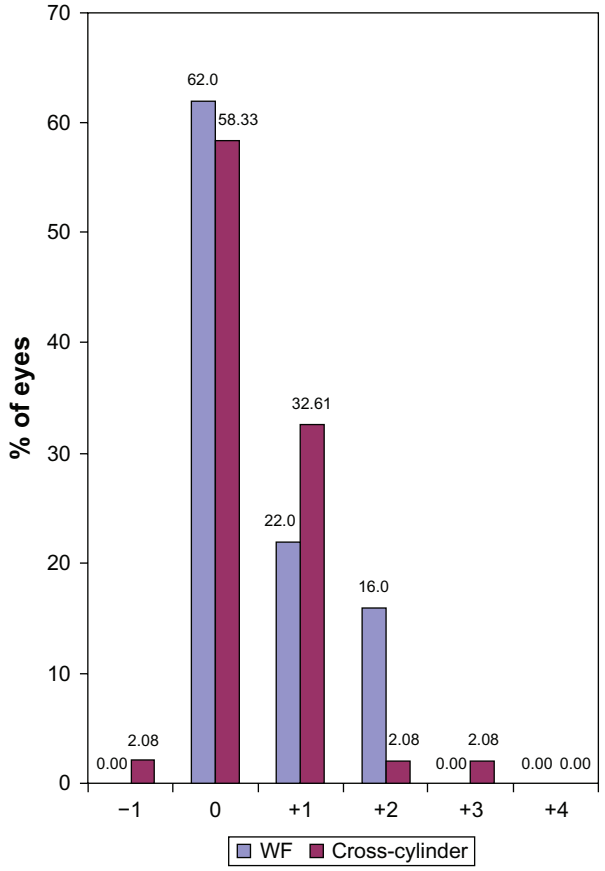

Figure 1 The change in Snellen lines of visual acuity 6 months postoperatively compared between wavefront and cross-cylinder methods.

Data were primarily analyzed using the Stata statistical software package (v 11; Stata, College Station, TX). Simple descriptive statistics and graphs were produced and bivariate comparisons were done. Vector analysis was also performed. The surgically-induced astigmatism (SIA) vector, target-induced astigmatism (TIA) vector, astigmatic correction index (CI), index of success (I0S), angle of error, magnitude of error, flattening effect (FE), and flattening index were analyzed using methods described by Alpins.[10] SIA is the vector of the astigmatic change actually induced by the surgery. TIA is the vector of the astigmatic change intended to be induced by the surgery. CI, preferably 1.0, is the ratio of SIA to TIA. CI >1.0 and CI <1 indicate an overcorrection and undercorrection, respectively. Once the amount of astigmatism to be corrected had been determined, the nomogram was used by aligning the age and preoperative measures.

The difference vector (DV) is the magnitude and axis of astigmatic change that would enable the initial surgery to achieve its intended target. The DV is an absolute measure of success and is preferably zero. IOS is calculated by dividing the DV by the TIA. The IOS is a relative measure of success and is preferably zero. A CI of 1.00 and an IOS of 0 indicate that the desired results have been obtained. The magnitude of error is the difference between the magnitude of SIA and TIA. The angle of error is the difference between the angles of the SIA and the TIA. Flattening effect (FE) is the amount of astigmatism reduction achieved by the effective proportion of the SIA at the intended meridian (FE = SIA Cos2* angle of error). The flattening index, which preferably equals 1, is obtained by dividing the flattening effect by the TIA. Analysis of the mean magnitude SIA was also performed after stratification of the groups based on the preoperative astigmatism (medium: –1.5 to –2.5 D and high: ≥–2.75 D). Higher order aberrations including coma, trefoil, and spherical aberration were measured using the OPD scan.

Although VISX custom has been recommended for astigmatism of <3.25 D, we included higher astigmatism up to 5 D to get the rate of correction in this subgroup too.

The study was approved by the committee of ethics at Tabriz University of Medical Sciences.

Results

The mean age of the patients was 30.4 ± 6.7 years in the WF group (range 23–48 years). The mean age of the patients was 28.4 ± 7.4 years in the cross-cylinder group (range 19–48 years). Pre- and postoperative characteristics of the patients are presented in Table 1. The mean UCVA was statistically significantly different between groups. In the WF group, the percentages of patients with UCVA 20/20, 20/25, and 20/40, or better were 80%, 100%, and 100%, respectively. In the cross-cylinder group the percentages of patients with UCVA 20/20, 20/25, and 20/40, or better were 40%, 79%, and 98%, respectively. The change in visual acuity is compared between groups in Figure 1.

Regarding safety, only one eye in the cross-cylinder group and no eyes in the WF group lost more than one line of BCVA after 6 months of treatment. No treated eyes in either group lost more than two lines of BCVA. The percentage of eyes with no change in BCVA was 54% and 58.3% in the WF and cross-cylinder groups, respectively.

The attempted and achieved SE refraction and astigmatic refraction for the two groups at the 6-month follow-up is shown in Figures 2 and 3.

The mean postoperative absolute changes in higher order aberrations (HOA) were investigated. Total root-mean-square (RMS) higher order aberrations were 0.05 ± 0.22 μm and 0.17 ± 0.2 μm for WF and cross-cylinder methods, respectively. For coma, the measurements were –0.03 ± 0.2 μm and –0.14 ± 0.15 μm, respectively, for WF and cross-cylinder methods. For trefoil, the measures were 0.02 ± 0.25 μm and –0.0 ± 0.16 μm, respectively, for WF and cross-cylinder methods. Spherical aberration measures were 0.0 ± 0.25 μm and 0.08 ± 0.13 μm for WF and cross-cylinder methods, respectively. Table 2 shows the vector analysis results using 6-month refractive data. Mean (± SD) preoperative astigmatism measures were –2.91 ± 1.3 and –2.51 ± 0.98 D, respectively, in the WF and cross-cylinder groups. Mean change in refractive astigmatism after 6 months was 1.57 ± 0.53 D in the WF group and 1.67 ± 0.52 D in the cross-cylinder group. No statistically significant difference was found in this regard.

Table 1 Pre- and postoperative characteristics of the patients compared for two methods

	Preoperative			Postoperative		
	CC1	WF2	*P* value	CC1	WF2	*P* value
Uncorrected visual acuity (LogMAR)	1.12 ± 0.37	0.93 ± 0.45	0.03	0.08 ± 0.15	0.01 ± 0.03	0.03
Best corrected visual acuity (LogMAR)	0.02 ± 0.02	0.03 ± 0.04	0.4	0.02 ± 0.03	0	<0.001
Spherical equivalent (D)	–2.5 ± 0.98	–2.9 ± 1.3	0.2	–0.54 ± 0.43	–0.47 ± 0.93	0.6
Higher order aberrations (μm)	0.36 ± 0.11	0.45 ± 0.19	0.1	0.35 ± 0.21	0.39 ± 0.15	<0.001

Notes: 1 – Cross-cylinder method; 2 – Wavefront method measures in mean ± SD.

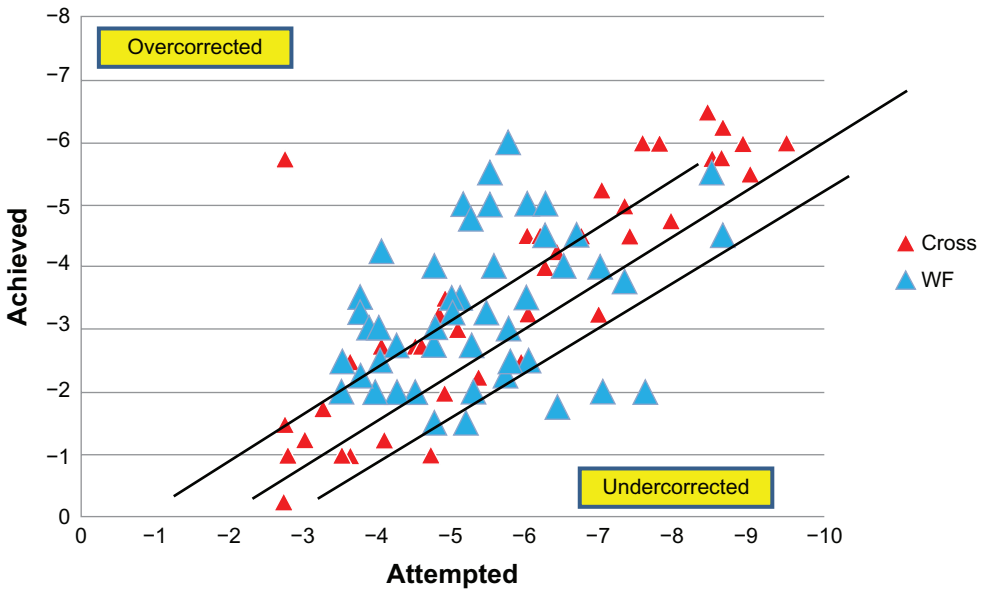

Figure 2 Scatterplot of attempted versus achieved spherical equivalent refraction in eyes that underwent PRK with cross-cylinder and WF methods.
Abbreviations: PRK, photorefractive keratectomy; WF, wavefront-guided.

The vector analysis results based on the level of astigmatism are given in Table 3.

Discussion

Our findings support the hypothesis that both cross-cylinder and WF procedures are predictable, safe, and effective in treating high astigmatism. We found that 80% of patients achieved UCVA 20/20 or better after the WF procedure. This was higher than with the cross-cylinder procedure. This is indicative of higher efficacy for the WF procedure in our study. However this should be interpreted cautiously because the results come from a cohort of clinical trials instead of random assignment of procedures to control for known and unknown confounders. The advantage of the WF method may also not be generalizable to all types of astigmatism and may only apply to high astigmatism cases, even if the comparability of groups is fulfilled. This argument is based on previous research supporting better results for moderate versus high astigmatism.[11,12] However this may not be the case for earlier PRK methods used for astigmatism. Kremer et al, in a 1-year follow-up of PRK for low, moderate, and high primary astigmatism found that the laser used in their study was an efficient tool to correct high and moderate astigmatism but less effective in low astigmatism.[13] Bababeygy et al found both better efficacy and higher safety for WF laser in situ keratomileusis in moderate astigmatism as opposed to high astigmatism.[12] Regarding safety and predictability, the two procedures appeared promising in a similar way, but with little superiority of the WF procedure. In this study, the mean SIA magnitude was less than the mean TIA in both groups. This indicates undercorrection in both groups. Angle of error analysis demonstrated that both arithmetic means were slightly clockwise (−0.71° and −1.26°) and close to zero, which is consistent with the closeness of the vector mean TIA and SIA axes.

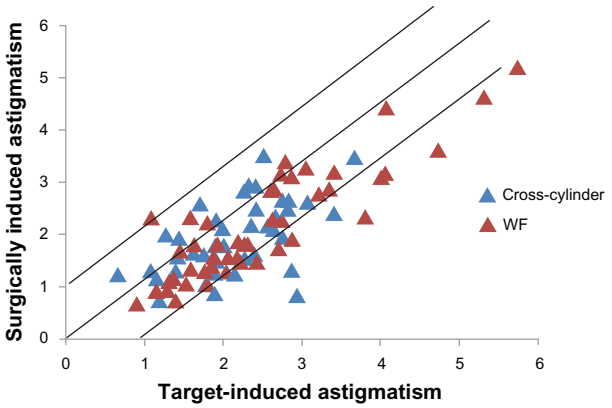

Figure 3 Surgically induced astigmatism versus target-induced astigmatism after 6 months.
Abbreviation: WF, wavefront guided.

Our study found both methods to be acceptable in efficacy, safety, and predictability. Regardless of the differences in percentages and means previously reported in the literature, which may be due to variation in settings and possible confounding factors, our results were in line with previous research. Mostly these studies were done separately for WF-guided astigmatism surgery[4,6,12,14–21] and cross-cylinder procedures.[22–25]

Table 2 Vector analysis using postoperative 6-month refractive data

Parameter	Group		*P* value*
	Cross-cylinder	Wavefront	
Target-induced astigmatism			
Arithmetic mean (D)	2.10 ± 0.66	2.42 ± 1.10	0.08
Axis (degrees)	99	106	
Summated vector mean (D)	1.41	2.06	
Axis (degrees)	2	1	
Surgically induced astigmatism			
Arithmetic mean (D)	1.98 ± 0.57	2.12 ± 1.04	0.45
Axis (degrees)	87	94	
Summated vector mean (D)	1.47	1.81	
Axis (degrees)	1	1	
Difference vector			
Arithmetic mean (D)	0.72 ± 0.46	0.54 ± 0.25	0.037
Axis (degrees)	92	76	
Summated vector mean (D)	0.08	0.31	
Axis (degrees)	76	4	
Mean torque (D)	–0.03 ± 0.36	0.07 ± 0.16	0.48
Absolute torque (D)	0.43 ± 0.36	0.20 ± 0.16	≤0.001
Mean flattening/steepening (D)	2.03 ± 0.64	2.12 ± 1.05	0.61
Mean absolute flattening/steepening (D)	1.95 ± 0.56	2.12 ± 1.05	0.38
Mean angle of error (degrees)	–0.71 ± 1.08	–1.26 ± 4.44	0.70
Mean absolute angle of error (degrees)	5.85 ± 4.63	4.86 ± 12.07	0.60
Mean magnitude of error (D)	0.20 ± 0.09	–0.29 ± 0.53	≤0.001
Mean astigmatic correction index	1.16 ± 0.36	0.87 ± 0.20	≤0.00
Mean index of success	0.39 ± 0.28	0.25 ± 0.12	0.002
Mean flattening Index	1.12 ± 0.35	0.88 ± 0.27	≤0.001
Mean	0.93 ± 0.30	3.02 ± 1.81	0.26

Note: *Student's *t*-test.

Several studies have used comparative designs, but we didn't find any studies that compared WF with cross-cylinder PRK in moderate-to-high astigmatism. Our study didn't benefit from a randomized trial comparison, but had the advantage of substantial comparability considering common population, setting, and surgeon. In this study we found that the WF procedure provided better results regarding UCVA, BCVA, and refraction; although it didn't prove superiority in the final astigmatism assessment. Also it was found that the amount of HOAs, coma, and spherical aberrations were lower in WF versus cross-cylinder procedure.

It can be argued that the custom ablation of VISX should be compared to its own platform of conventional toric ablation. VISX is a variable spot whereas NIDEK laser is a slit-beam ablation pattern so it would have been better to compare the NIDEK to its custom platform.

Table 3 Major vector analysis results using postoperative 6-month refractive data compared for two levels of astigmatism

Parameter	Diopter >3 12 eyes in WF 14 eyes in cross-cylinder			Diopter ≤3 38 eyes in WF 34 eyes in cross-cylinder		
	Cross- cylinder	WF	*P* value	Cross- cylinder	WF	*P* value
Target-induced astigmatism						
Arithmetic mean (D)	2.68 ± 0.65	3.03 ± 1.71	0.84	1.60 ± 0.46	2.15 ± 0.78	0.001
Axis (degrees)	110	118		97	97	
Surgically induced astigmatism						
Arithmetic mean (D)	2.62 ± 0.78	2.48 ± 1.51	0.90	1.81 ± 0.53	1.95 ± 0.89	0.43
Axis (degrees)	96	103		76	94	
Mean astigmatic correction index	1.12 ± 0.77	0.81 ± 0.14	0.04	1.19 ± 0.40	0.98 ± 0.27	0.01
Mean index of success	0.50 ± 0.66	0.25 ± 0.15	0.15	0.42 ± 0.31	0.24 ± 0.10	0.001
Mean flattening Index	1.08 ± 0.73	0.79 ± 0.15	0.08	1.15 ± 0.39	0.94 ± 0.30	0.01

Abbreviation: WF, wavefront guided.

Conclusion

Both methods of PRK using the NIDEK EC-5000 and VISX excimer laser systems are effective for correcting moderate-to-high astigmatism. The WF approach appeared more successful in improving the refractive results. Future randomized clinical trials, preferably on contralateral eyes, are recommended to provide detailed and more trustworthy comparison results. Future studies with larger sample size, stratification of cylinder study, and post-nomogram data gathering with longer follow-up are recommended.

Disclosure

The authors report no conflicts of interest in this work.

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