

Safety, Efficacy, Predictability and Stability Indices of Photorefractive Keratectomy for Correction of Myopic Astigmatism with Plano-Scan and Tissue-Saving Algorithms

Mehrdad Mohammadpour, MD¹ • Hassan Hashemi, MD^{2,3} • Mahmoud Jabbarvand, MD³
Firoozeh Rahimi, MD³ • Amir Houshang Beheshtnejad, MD⁴ • Mohammad Naser Hashemian, MD³
Mohammad Ali Zare, MD⁴ • Mohammadreza Fallah Tafti, MD⁴
Asieh Aslani, MD⁵ • Mehdi Zandian, MD⁵ • Sare Safi⁵

Abstract

Purpose: To assess the safety, efficacy and predictability of photorefractive keratectomy (PRK) [Tissue-saving (TS) versus Plano-scan (PS) ablation algorithms] of Technolas 217z excimer laser for correction of myopic astigmatism

Methods: In this retrospective study one hundred and seventy eyes of 85 patients (107 eyes (62.9%) with PS and 63 eyes (37.1%) with TS algorithm) were included. TS algorithm was applied for those with central corneal thickness less than 500 μm or estimated residual stromal thickness less than 420 μm . Mitomycin C (MMC) was applied for 120 eyes (70.6%); in case of an ablation depth more than 60 μm and/or astigmatic correction more than one diopter (D). Mean sphere, cylinder, spherical equivalent (SE) refraction, uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA) were measured preoperatively, and 4 weeks, 12 weeks and 24 weeks postoperatively.

Results: One, three and six months postoperatively, 60%, 92.9%, 97.5% of eyes had UCVA of $20/20$ or better, respectively. Mean preoperative and 1, 3, 6 months postoperative SE were -3.48 ± 1.28 D (-1.00 to -8.75), -0.08 ± 0.62 D, -0.02 ± 0.57 and -0.004 ± 0.29 , respectively. And also, 87.6%, 94.1% and 100% were within ± 1.0 D of emmetropia and 68.2, 75.3, 95% were within ± 0.5 of emmetropia. The safety and efficacy indices were 0.99 and 0.99 at 12 weeks and 1.009 and 0.99 at 24 weeks, respectively. There was no clinically or statistically significant difference between the outcomes of PS or TS algorithms or between those with or without MMC in either group in terms of safety, efficacy, predictability or stability. Dividing the eyes with subjective $SE \leq 4$ D and $SE \geq 4$ D postoperatively, there was no significant difference between the predictability of the two groups. There was no intra- or postoperative complication.

Conclusion: Outcomes of PRK for correction of myopic astigmatism showed great promise with both PS and TS algorithms.

Keywords: Photorefractive Keratectomy, Myopia, Astigmatism

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1. Assistant Professor of Ophthalmology, Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran
2. Noor Ophthalmology Research Center, Noor Eye Hospital, Tehran, Iran
3. Professor of Ophthalmology, Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran
4. Associate Professor of Ophthalmology, Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran
5. Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran

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Correspondence to: Mehrdad Mohammadpour, MD

Assistant Professor of Ophthalmology, Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran

Email: mahammadpour@yahoo.com

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Introduction

Refractive surgery is a widespread ophthalmic procedure these days. The two most commonly used procedures to correct myopia are photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK).¹⁻⁴ PRK with application of Mitomycin C (MMC) can be a safe procedure with excellent visual outcomes and few complications.³

The Technolas 217z excimer laser (Bausch and Lomb) has different ablation programs: the Plano-scan (PS) to perform conventional treatments, the Zyoptix Tissue-saving (TS) algorithm which permits removal of less corneal tissue than conventional treatments, the Aspheric Algorithm for correction of significant amounts of myopia while preserving the prolate shape of the cornea in patients with adequate corneal thickness, and the customized ablation program for retreatment and/or eyes with significant preoperative higher order aberrations (HOA).

The main advantage of Zyoptix TS algorithm among other ablation programs is that it can decrease the amount of ablated corneal tissue through the smaller blended zone and more high myopic patients could be candidated for this procedure. Although the result of Zyoptix TS surgical outcome compared to conventional program in low to moderate myopia has recently been studied,⁵ however, neglecting high myopia may influence on the surgical outcome results.

The purpose of this retrospective study was to evaluate the safety, efficacy, stability and predictability of PRK with TS algorithm for low to high myopic patients with or without astigmatism.

Methods

This study comprised one hundred and seventy eyes of 85 patients with myopia astigmatism who underwent PRK with Technolas 217z excimer laser (PS & TS algorithms) from January 2008 to December 2008 at Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran.

Study approval was gained from the ethical committee at Farabi Eye Hospital and written informed consents were obtained from all patients before surgery.

Inclusion criteria were at least 18 years of age, stable refraction for at least one year; a best corrected visual acuity (BCVA) of at least

$20/20$ or better, spherical equivalent (SE) ranged between -1.00 to -9.00 diopter (D) and minimum corneal thickness of at least 480 μm . Discontinuing soft contact lenses for at least two weeks and hard lenses for at least three weeks. The subjects were excluded if they had anterior or posterior segment pathology, amblyopia, clinical signs of progressive or unstable myopia, keratoconus, keratoconus suspects, history of ocular surgery, diabetes mellitus, auto-immune diseases and dry eye.

Preoperative examinations

Patients had a complete ophthalmic examination consist of uncorrected visual acuity (UCVA) and BCVA, manifest and cycloplegic refraction, slit-lamp examination, tear assessment, automated keratometry, applanation tonometry, corneal topography and pachymetry (OrbscanIIz topographer, Bausch and Lomb) and fundoscopy. The procedures were planned based on subjective refraction.

Surgical technique

All procedures were performed by one surgeon (M.M.) using the same Technolas 217z 100 excimer laser, with the room temperature set at 20°C and humidity between 25% and 35%. Two hours preoperatively, diclofenac sodium 0.5% drops were instilled in each eye twice 10 minutes apart. Eyes were anesthetized by instilling two drops of topical tetracaine hydrochloride 0.5% five minutes apart before the procedure. During the procedure, the eye was first irrigated with balanced salt solution (BSS) and after exposure to alcohol 20% for 20 seconds, the epithelium was removed with a hockey knife and photoablation was performed. At the end of the procedure, MMC 0.02% was applied for ablation depths more than 60 μm and/or astigmatic corrections more than 1.00 D for up to 45 seconds, and the corneal surface was irrigated with 30 cc of BSS. Finally, an Acuvue Advance with Hydraclear soft contact lens (Johnson & Johnson Vision Care, Inc., Jacksonville, FL, USA) was placed over the cornea at the end of procedure.

Postoperative management and follow-up

The postoperative regimen included chloramphenicol 0.5% and diclofenac sodium

0.5% eye drops four times daily for five and three days, respectively. Betamethasone 0.1% eye drops four times daily for three weeks, substituting it with fluorometholone 0.1% drops four times daily that was tapered over 8 weeks depending on the clinical appearance and refraction. Preservative free artificial tear (Artelac, Bausch and Lomb) was prescribed four times per day for three weeks and then tapered over eight weeks. Postoperatively, visits were scheduled for every day until complete epithelial healing, and then at 4, 12, and 24 weeks, with additional visits as needed. The contact lens was removed when epithelialization was completed (between three and five days postoperatively).

The safety index was defined as the ratio of mean postoperative BCVA to mean preoperative BCVA.⁷ The efficacy index calculated by the ratio of mean postoperative UCVA to mean preoperative BCVA.⁷

Statistical Analysis

Data was collected on a specific data sheets and then entered into a database for analysis.

Descriptive indices such as frequency, percentage, mean±standard deviation (SD) were used for summarizing data.

Results

One hundred and seventy eyes of 85 patients (23 men and 62 women) was included in this study. The mean age was 25.8±4.7 years (19 to 40 years).

Preoperative mean SE, sphere, cylinder and central corneal thickness were -3.48±1.28 D (range, -1.00 to -8.75 D), -3.11±1.29 D (range, -0.50 to -7.75 D), -0.73±0.55 D (range, 0.00 to -2.25 D) and 541±29.5 µm (range, 480 to 628 µm), respectively (Table 1) and also, all eyes had BCVA of ²⁰/₂₀, preoperatively.

The ablation profile was PS in 107 eyes (62.9%) and TS in the other 63 eyes (37.1%).

Mean ablation depth was 63.89±16.7 µm (range, 27 to 120 µm). Mean pulse number was 1729±590.6 (range, 553 to 3745). Intraoperative MMC was applied on 120 eyes (70.6%) for duration of 10 to 45 seconds.

Data was available for analysis for all 170 eyes at four weeks and 12 weeks, and for 40 eyes at 24 weeks.

Postoperative data at four weeks

Mean sphere was 0.4±0.62 D. Mean cylinder was -0.98±0.620 D (Table 2). Mean SE was -0.08±0.62 D (Table 3); 68.2% (116 eyes) were within ±0.5 D of emmetropia and 87.6% (149 eyes) were within ±1.0 D of emmetropia. One hundred and two eyes (60%) had UCVA of ²⁰/₂₀ or better and 167 eyes (98.2%) had UCVA of ²⁰/₄₀ or better (Figure 1). About 6.5% of the eyes had achieved target refraction; 52.9% of the eyes were within ±0.5 D of their target refraction and 81.2% were within ±1.0 D of target refraction (Figure 2). We had a 24.7% rate of over correction and 68.80% under-correction as compared to target refraction at this time.

Postoperative data at 12 weeks

Mean sphere was 0.17±0.55 D. Mean cylinder was -0.4±0.4D (Table 2). Mean SE was -0.02±0.57 D (Table 3); the SE was within ±0.5 D and ±1.0 D of emmetropia in 128 eyes (75.3%) and 160 eyes (94.1%), respectively. One hundred fifty-eight eyes (92.9%) had UCVA of ²⁰/₂₀ or better and all of the eyes (100%) had UCVA of ²⁰/₄₀ or better (Figure 1).

BCVA was ²⁰/₂₀ in 167 eyes (98.2%). About 12.9% of eyes had achieved target refraction; 62.9% of them were within ±0.5 D and 89.4% were within ±1.0 D of their target refraction (Figure 2). Rates of over correction and under-correction, as compared to target refraction, were 26.50% and 60.60%, respectively.

Postoperative data at 24 weeks

Mean sphere was 0.13±0.29 D. Mean cylinder was -0.28±0.26 D (Table 2). Mean SE was -0.004±0.29 D (Table 3); 38 eyes (95%) were within ±0.5 D of emmetropia and 100% (40 eyes) were within ±1.0 D of emmetropia. Thirty-nine eyes (97.5%) had UCVA of ²⁰/₂₀ or better and all eyes (100%) had UCVA of ²⁰/₄₀ or better (Figure 1). All eyes had BCVA of ²⁰/₂₀. About 7.5% of the eyes had achieved target refraction; 77.5% of eyes were within ±0.5 D and 97.5% were within ±1.0 D of their target refraction (Figure 2), with 13% over correction and 80% under-correction.

Safety

None of the eyes had lost more than one line of BCVA at three and six months. The safety index, were 0.99 and 1.009 at 12 and 24 weeks, respectively (Figure 3).

Efficacy

The efficacy index was 0.99 at 12 and 24 weeks (Figure 3).

Predictability

Mean difference between postoperative SE and target refraction was -0.35 D at four weeks, -0.29 D at 12 weeks, and -0.33 D at 24 weeks (Figure 4).

Tissue saving versus Plano-scan

A total of 107 eyes were ablated using the PS profile, and we used TS in the remaining 63 eyes.

Mean UCVA in both groups was ²⁰/₂₂ at four weeks and ²⁰/₂₀ at 12 and 24 weeks, postoperatively. Mean BCVA was ²⁰/₂₀ in both groups at 12 and 24 weeks, postoperatively. Mean differences between postoperative SE and target refraction were -0.29 D, -0.24 D, and -0.39 D at 4, 12 and 24 weeks in the PS group, and -0.47 D, -0.4 D, and -0.2 D,

respectively, in the TS group (Figure 5). Frequencies of under-correction were 65.40% at four weeks, 57.90% at 12 weeks, and 85.70% at 24 weeks in the PS group, and 74.60%, 65.07%, and 66.66% in the TS group, respectively. Over-correction in the PS group was 28.03% at 4 weeks, 28.90% at 12 weeks and 16.60% at 24 weeks (Figures 6 and 7), and 19.04%, 22.22%, and 25% in the TS group, respectively.

Dividing the eyes with subjective SE≤4 D and SE≥4 D at four, 12, and 24 weeks postoperatively, there was no significant difference between the predictability of the two groups (p>0.05) (Figures 8 and 9).

Complications

There was no intra- or postoperative complications. We observed no case of corneal haze or MMC-related toxic effects during the study follow-up period.

Table 1. Preoperative characteristics

Parameter	Total
Patients (n)	85
Age (y)	
Mean (SD)	25.8±4.7
Range	19 to 40
Sphere (D)	
Mean (SD)	-3.11±1.29
Range	-0.5 to -7.75
Cylinder(D)	
Mean (SD)	-0.73±0.55
Range	0 to -2.25
Spherical equivalent (D)	
Mean (SD)	-3.48±1.28
Range	-1.00 to -8.75
Central pachymetry (µm)	
Mean (SD)	541±29.5
Range	480 to 628

µm: Micrometer

Table 2. Predictability of mean manifest cylinder

Postoperative (Weeks)	Number of eyes	Cylinder Mean±SD	Range (D)	Degree (%)	
				≤1.0 D	≤0.5 D
4	170	-0.98±0.62	-4.00 to 0.00	67.1	31.2
12	170	-0.40±0.40	-1.75 to 0.50	94.1	74.7
24	40	-0.28±0.26	-0.75 to 0.00	100	87.5

D: Diopter, SD: Standard deviation

Table 3. Predictability of mean manifest spherical equivalent

Postoperative (Weeks)	Number of eyes	Cylinder Mean±SD	Range (D)	Degree (%)	
				≤1.0 D	≤0.5 D
4	170	-0.08±0.62	-1.62 to 1.38	87.6	68.2
12	170	-0.02±0.57	-2.25 to 1.50	94.1	75.3
24	40	-0.004±0.29	-0.75 to 0.88	100	95

D: Diopter, SD: Standard deviation



Figure 1. Percentage of eyes with uncorrected visual acuity≥20/20 and uncorrected visual acuity≥20/40 at 4, 12, and 24 weeks postoperatively

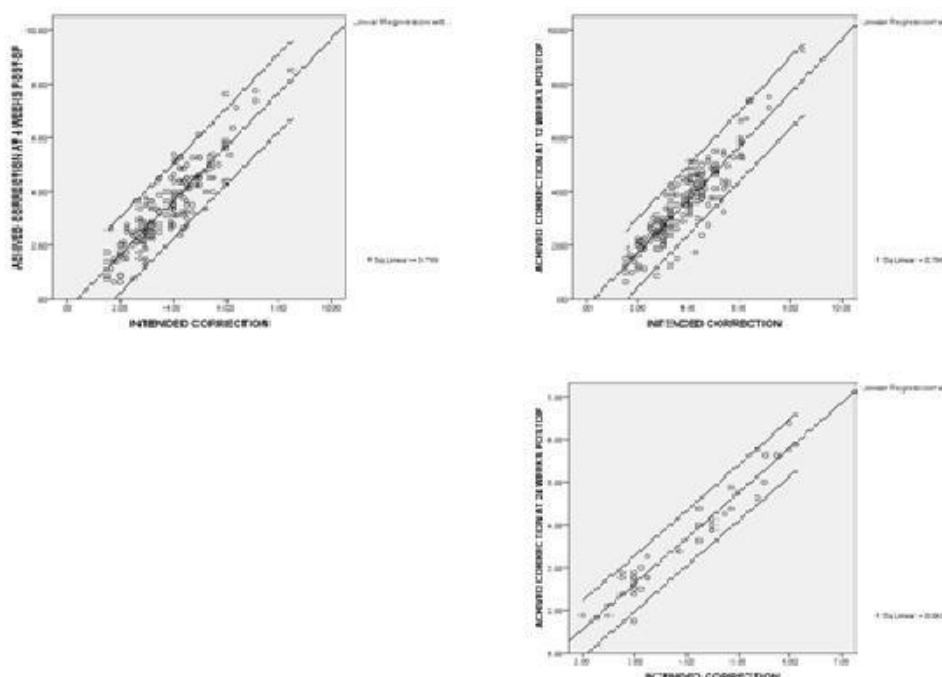


Figure 2. Predictability graphs in all treated eyes. At four weeks 6.5% of eyes had achieved target refraction; 52.9% of eyes were within ±0.5 D of target refraction and 81.2% were within ±1.0 D of target refraction. 28 eyes had under correction>1.0 D and four eyes had over correction>1.0 D (170 eyes). At 12 weeks 12.9% of eyes had target refraction. 62.9% of eyes were within ±0.5 D and 89.4% were within ±1.0 D of target refraction. 17 eyes had under correction>1.0 D and one eye had over correction>1.0 D (170 eyes). At 24 weeks, 7.5% of eyes had target refraction. 77.5 % of eyes were within ±0.5 D and 97.5% of eyes were within ±1.0 D of target refraction. One eye had under correction>1.0D (40 eyes).

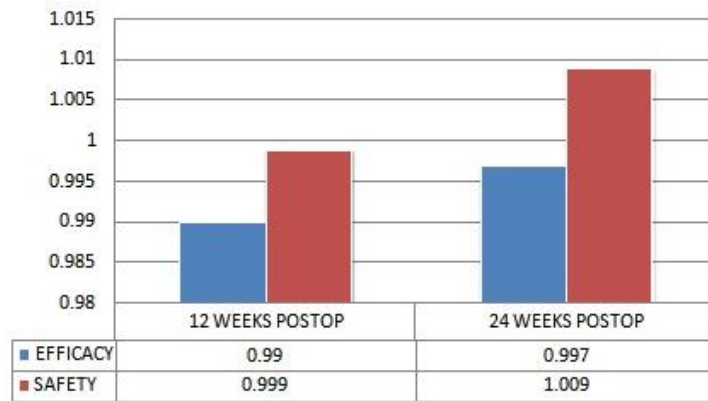


Figure 3. Safety and efficacy indices at 12 and 24 weeks postoperatively.

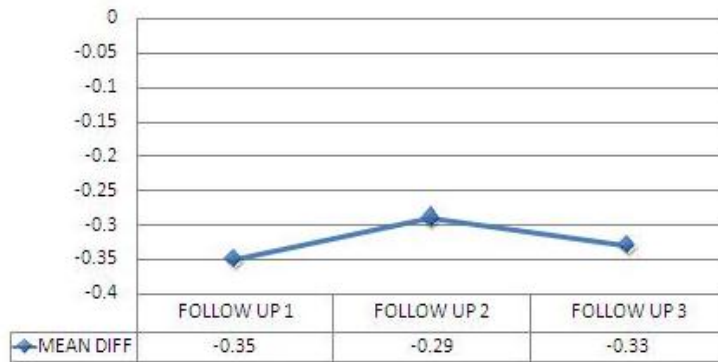


Figure 4. Mean deviation of the postoperative spherical equivalent from the target refraction

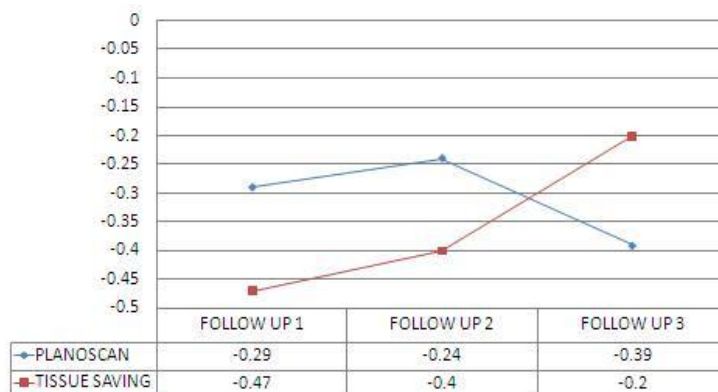


Figure 5. Mean deviation of the postoperative spherical equivalent from the target refraction at each follow-up in Tissue-saving and Plano-scan groups. 170 eyes were available at four weeks (follow-up 1) and 12 weeks (follow-up 2) and 40 eyes at 24 weeks (follow-up 3).

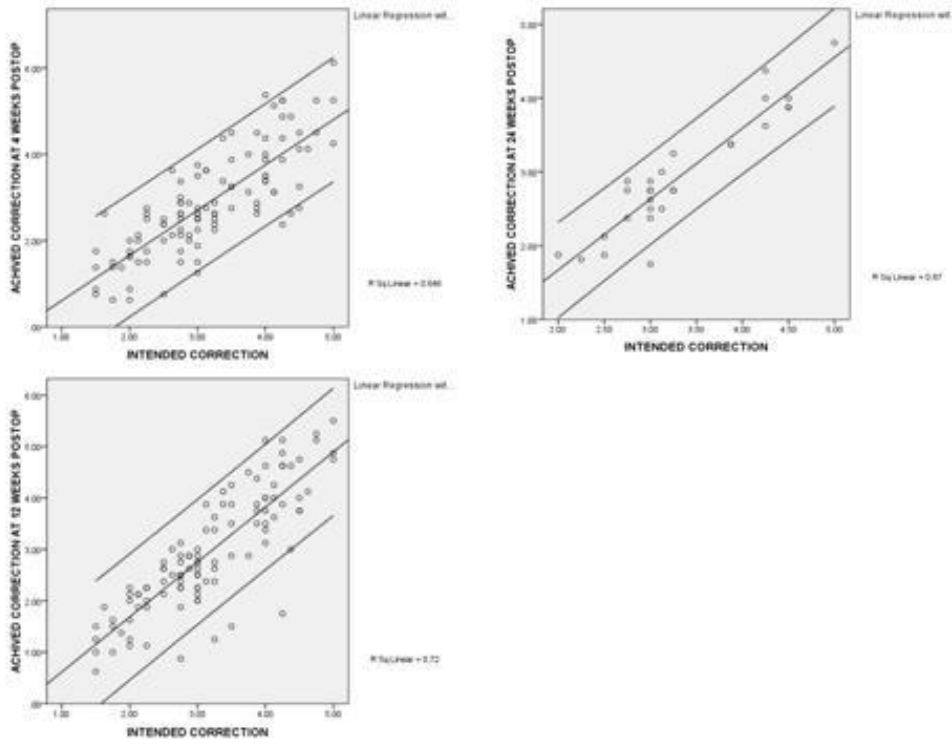


Figure 6. Predictability graphs in the Plano-scan group at 4, 12, and 24 weeks postoperatively

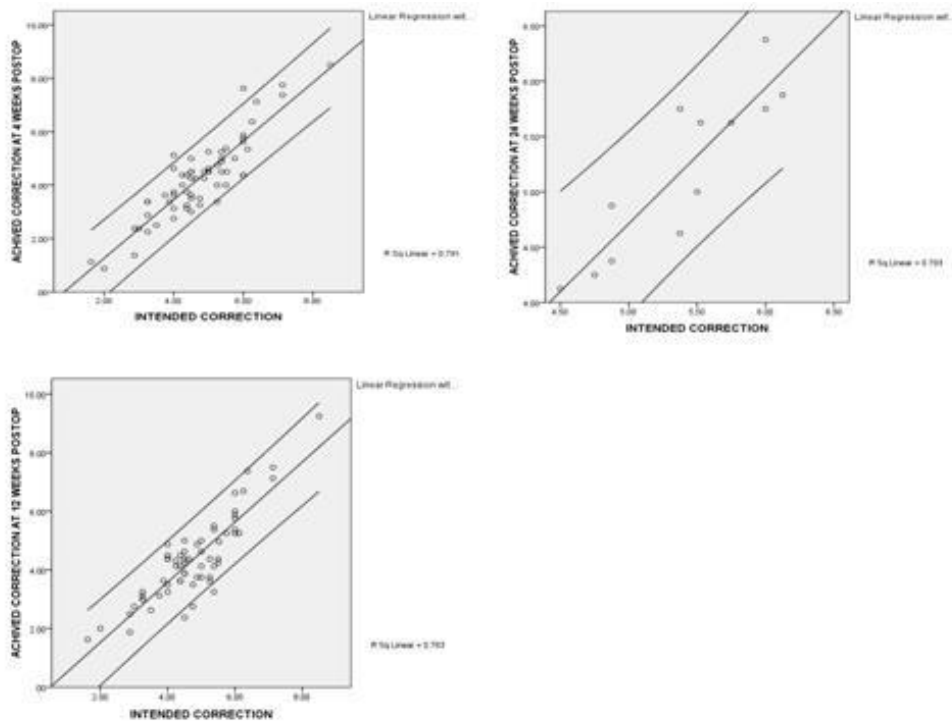


Figure 7. Predictability graphs in the Tissue-saving group at 4, 12, and 24 weeks postoperatively

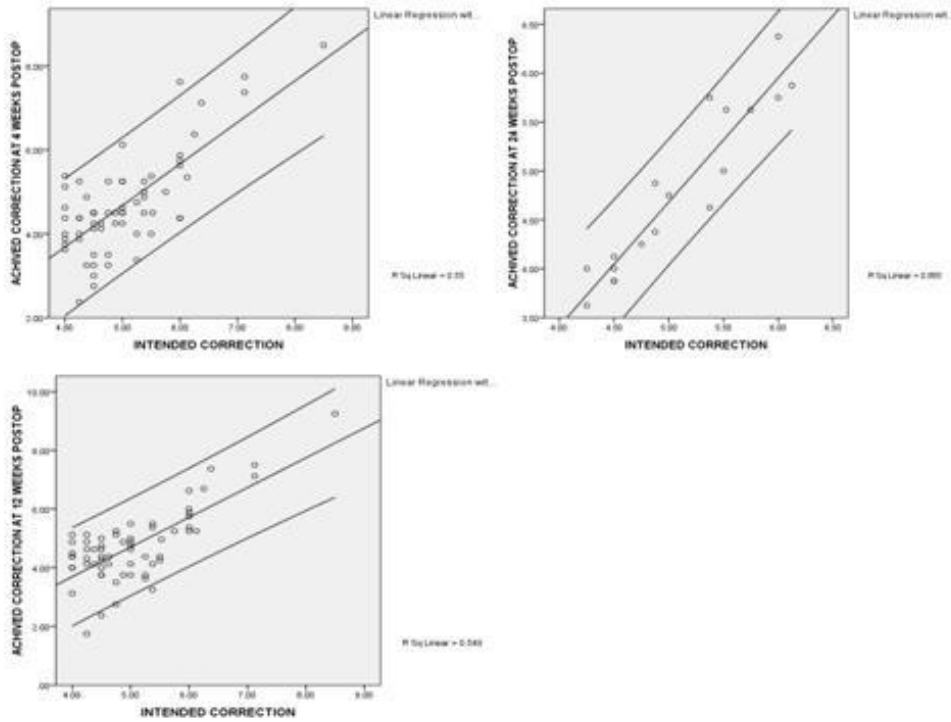


Figure 8. Predictability graphs in the eyes with subjective spherical equivalent ≤ 4.0 D at 4, 12, and 24 weeks postoperatively.

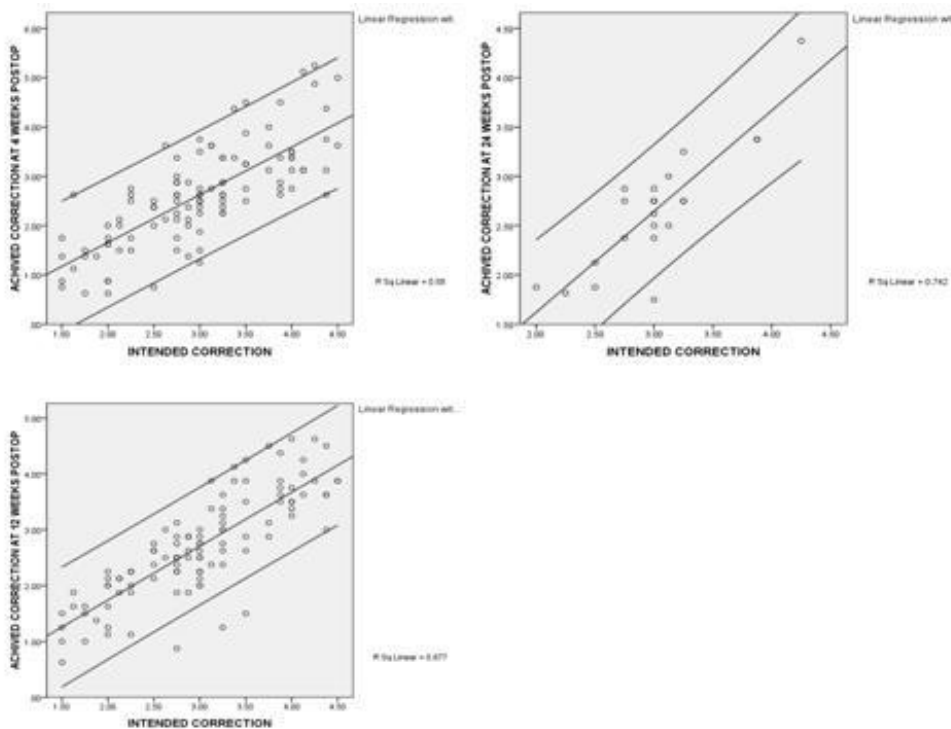


Figure 9. Predictability graphs in the eyes with subjective spherical equivalent ≥ 4.0 D at 4, 12, and 24 weeks postoperatively.

Discussion

Preoperative mean SE was -3.4 D that decreased to -0.08 D at four weeks and -0.02 D at 12 weeks and -0.004 D at 24 weeks, reaching its plateau at four weeks (Figure 10). The preoperative mean cylinder however, which was -0.7 D, increased to -0.9 D at four weeks. This can be explained by the irregular surface of the cornea due to removing the epithelium and the time needed for complete reepithelialization; it then decreased to -0.4 D at 12 weeks and to -0.2D at 24 weeks (Figure 11). In terms of efficacy, cylinder needs more time to stabilize than SE.

At 12 weeks, 158 eyes (92.9%) had UCVA of $20/20$ or better, 167 eyes (98.2%) had BCVA of $20/20$, and only three eyes had BCVA of less than $20/20$ ($20/22$), two of which achieved $20/20$ UCVA by 24 weeks and one was lost to follow-up. At 24 weeks, all eyes had BCVA of

$20/20$ and only one eye had UCVA of less than $20/20$ (i.e., $20/22$), that demonstrate good safety at the last follow-up. Lee et al reported that UCVA was $20/20$ in 86% and $20/40$ or better in 98% of all operated cases 24 weeks after operation.³ In another study by Lee et al⁶ for comparing laser epithelial keratomileusis and PRK for low to moderate myopia, it was noted that at four weeks, 44% of the eyes had UCVA of $20/20$ or better and at 12 weeks only 26% of the eyes had BCVA of $20/20$ or better. It seems that the present results are better than the two abovementioned studies.

In the majority of the eyes (92.90%), it took 12 weeks for the BCVA to return to preoperative levels ($20/20$) and actually this time can be an indicator of the wound healing process. Our efficacy and safety indices were close to 1.0 at 12 and 24 weeks.

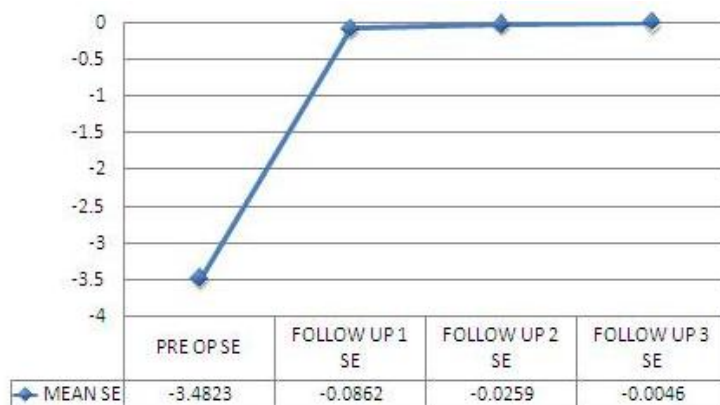


Figure 10. Mean spherical equivalent preoperatively and at 4, 12, and 24 weeks postoperatively

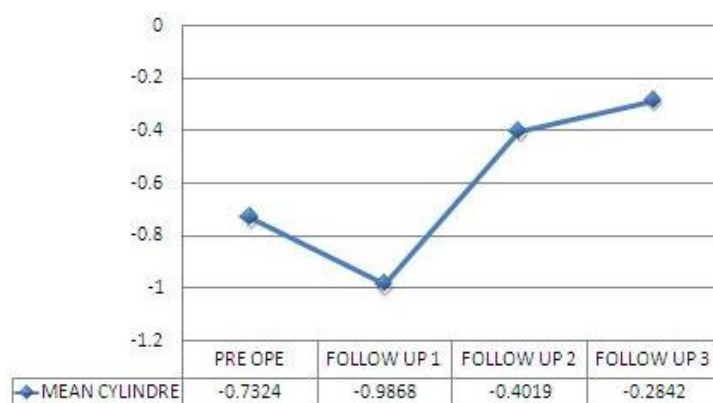


Figure 11. Mean cylinder preoperatively and at 4, 12, and 24 weeks postoperatively.

After 24 weeks, 100% of the eyes were within ± 1.0 D and 95% were within ± 0.5 D of emmetropia. In a study performed on 1,011 eyes which underwent PPK with intraoperative application of MMC, Lee et al showed, that six months postoperatively, SE in 86% of the eyes were within ± 0.50 D and in 93% of the eyes were within ± 1.00 D.³ Mean difference between the postoperative SE and the target refraction in the PS group was lower than that in the TS group at four weeks and 12 weeks. However, at 24 weeks the difference was higher in the PS group compared to the TS group.

In the Plano-scan algorithm, an additional nonadjustable 3.0 mm blend zone surrounds the optical zone. In Zyoptix treatments, the blend zone is considerably smaller. As a result, less tissue is removed with the Zyoptix TS than the conventional Plano-scan algorithm. However, as reported by Kirwan and O'Keefe,⁸ a smaller blend zone in Zyoptix TS treatments could result in a greater increase in HOAs postoperatively when compared with conventional Plano-scan treatments.

PRK carries the risk of corneal haze, specially in high myopic corrections. However, we had no corneal haze during the follow-up period. This finding can be attributed to the intraoperative application of MMC, which is in fact an effective method to prevent haze formation after corneal ablation. We used MMC for patients with astigmatism higher than 1.0 D or ablation depths more than 60 μm . In a study performed by Thomas et al⁹ preoperative astigmatism was found to be a risk factor for post-PRK corneal haze. They suggested that surgeons should consider the prophylactic use of MMC during PRK procedures for patients with moderate to high astigmatism (≥ 1.25 D).

To our knowledge, there is only one recent retrospective study that strongly recommends the intraoperative use of MMC in cases with more than 1.0 D astigmatic correction.⁹ However, a great number of articles are now emerging that define the indications for judicious application of MMC while presenting its probable complications.¹⁰⁻¹⁷

Previous studies¹¹⁻¹⁷ have shown that shorter application times may be associated with late-onset corneal haze and exposures longer than 45 seconds may have adverse effects on the corneal endothelium with no proven benefit. Hence, MMC is a two edged sword, and beneficial application times need to be determined.

We usually observe haze formation in the axis of minus cylinder treatment with conventional PRK which may be due to significant change in the rate of corneal curvature as mentioned by the authors. Another possible explanation for this clinical finding is that the ablation pattern for astigmatic correction is ellipsoid. In correction of myopic astigmatism, the steeper meridian with more tissue removal corresponds to the smaller diameter of the ellipse and the flat meridian corresponding to the minus cylinder correction is relevant to the larger axis of the ellipse, leading to more peripheral tissue ablation in the minus cylinder axis. Interestingly, haze is usually seen in the minus cylinder axis in the paracentral area extending to the area in common with the steep axis with smaller ablation profile. One can imagine that the more peripheral the ablation, the higher the risk of corneal haze formation. However, we used the TS algorithm for those with central corneal thickness readings less than 500 μm or estimated residual stromal thickness values less than 420 μm . We did not measure HOA or contrast sensitivity in our cases that may be an issue of interest for future studies.

Present study has some limitations due to its retrospective design and also at the last follow-up (24 weeks), only the data of 40 eyes were available for analysis.

Conclusion

In conclusion, outcomes of PRK for correction of myopic astigmatism showed great promise with both PS and TS algorithms with and without MMC. There was no clinically or statistically significant difference between the outcomes of PS or TS algorithms or between those with or without MMC in both groups in terms of safety, efficacy, predictability or stability.

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