· Clinical Research ·

Factors affecting single-step transepithelial photorefractive keratectomy outcome in the treatment of mild, moderate, and high myopia: a cohort study

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Abstract

● **AIM:** To investigate the effect of preoperative factors on visual acuity, higher-order aberrations (HOAs), and index of success for spherical change (S.IOS) after transepithelial photorefractive keratectomy (t-PRK) for treating different grades of myopia.

● **METHODS:** This was a retrospective one-armed cohort study where patients with high, moderate, or mild myopia treated with single-step t-PRK using Amaris 500 Hz excimer laser were evaluated for visual acuity, refractive status, corneal topography, HOAs, S.IOS, and mean efficiency and safety index before and 6mo after surgery.

● **RESULTS:** A total of 154 eyes of 77 patients with mild (n=59), moderate (n=83), and high (n=12) myopia were reviewed. The efficiency and safety indices for vision recovery by single-step t-PRK were 98% and 100%, respectively. The achieved spherical equivalent (SE) was within 1 diopter (D) in 151 (98%) eyes. The median of the S.IOS was 1.18 [interquartile range (IQR) 1.0, 1.4]. The change in S.IOS was significantly correlated with age (P=0.007), 6.5 mm ablation zone (Mann-Whitney U test, P<0.01), and mild and moderate grade of myopia (Kruskal–Wallis test, P<0.001). Trefoil aberration, spherical aberration, and aberration coefficient types of HOA increased significantly (Wilcoxon test, P<0.001) 6mo post-surgery. There was a significant correlation between spherical aberration and aberration coefficient HOAs by myopia grades (P<0.05).

● **CONCLUSION:** Single-step t-PRK has promising short-term outcomes for refractive corrections and vision improvement to treat all three grades of myopia.

● **KEYWORDS:** myopia; refractive surgery; trans-epithelial photorefractive keratectomy; higher-order aberrations

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INTRODUCTION

Uncorrected refractive errors are one of the major causes of preventable vision impairment worldwide. A systematic review by Naidoo *et al*[1] showed that in 2010 about 7 million people were blind and over 100 million people were visually impaired due to uncorrected refractive errors. Uncorrected refractive disorders pose a significant financial burden; according to a study by Smith *et al*[2] global economic productivity loss due to uncorrected refractive errors was an astounding $268 billion. The estimated pool prevalence of myopia in adults is 26.5% and the prevalence ranges from 4% to 51%[3]. A study by Holden *et al*[4] predicted that by 2050 about 49.8% (4758 million) of the world population will have myopia and about 10% world population (938 million) will have high myopia. The combined prevalence of myopia and astigmatism in adults in the Middle East region is 54%, posing a significant financial burden[5].

Available treatments for correcting myopia include eyeglasses, contact lenses, corneal refractive surgeries, and intraocular lens implantation. High refractive errors usually cannot be corrected by prescription glasses or contact lenses alone. Moreover, many people develop intolerance to contact lenses due to infections, allergies, or improper use of contact lenses. In such cases, alternative methods like refractive surgeries or intraocular lens implantation become necessary.

Photorefractive keratectomy (PRK) was the first laser refractive technique used to treat refractive errors and it is a two-step procedure where the epithelium is first removed manually, followed by laser refractive ablation to remove the stroma[6]. However, PRK became less popular as the surgery had long postoperative recovery time, caused postoperative pain, and was associated with the development of secondary complications like stromal haze. Over the years, with the development of newer generation lasers and improved ablation techniques, many advances have been made to this procedure giving rise to better options that circumvent the above complications. These options include, laser-assisted *in situ* keratomileusis (LASIK)[7-8], laser-assisted subepithelial keratectomy (LASEK)[9-10], and single-step transepithelial PRK (t-PRK)[11].

LASIK, though a popular laser refractive surgery, may not be right for everyone, especially for people who have thin corneas, glaucoma, and other diabetes-related problems[12]. LASEK is an alternate procedure that can be used to treat patients who have thin corneas[13]. However, LASIK and LASEK both can develop procedure-related complications in patients[14].

Single-step t-PRK is a more recent advancement that is unique in that it involves removal of the epithelium and stroma in one single step by an Amaris laser, and studies have found it to be generally safe and efficacious[15-17]. Gadde *et al*[18] compared single-step t-PRK to conventional PRK in eyes with low to high myopia and myopic astigmatism and found that both procedures had similar results with respect to safety and efficacy, though there was a higher incidence of postoperative haze in eyes that underwent single-step t-PRK. Higher-order aberrations (HOAs) are a common complication that often develops after refractive surgeries. Özülken and İlhan[19] compared visual acuity and HOAs in eyes with myopia and myopic astigmatism treated with t-PRK or alcohol-assisted PRK and found both of these techniques to have comparable outcomes in all parameters, except aberration coefficient, which seemed to have a better outcome in alcohol-assisted PRK. Another study investigated the relationship between preoperative and surgical factors and postoperative HOAs in low to moderate myopic eyes. It found that HOAs were positively correlated to age and increased when pupil diameter was 6 mm as compared to when it was 3 mm[20]. A recent study investigated the role of demographics and other preoperative factors following single-step t-PRK to treat myopia and myopic astigmatism and found age to be a strong risk factor for developing ametropia after single-step t-PRK[21].

Our study was conducted in Saudi Arabia. This region has a high prevalence of myopia. Moreover, year-round extreme hot and dry weather makes it difficult to wear contact lenses, and as such, refractive surgeries become necessary and are widely practiced in Middle Eastern countries. Hence, it was important to optimize alternative methods, such as single-step t-PRK of correcting vision. We present outcomes of single-step t-PRK to treat myopia and myopic astigmatism at an institution in central Saudi Arabia. In this study, we collectively analyzed various preoperative and operative factors such as age, ablation zone, and HOAs within three grades of myopia *i.e.* mild, moderate, and severe, and carried out correlation studies between the factors. Single-step t-PRK is a relatively new technique and our study will enrich the literature on this new procedure.

SUBJECTS AND METHODS

Ethical Approval This one-armed cohort study was carried out after the approval of the institution research board. All tenets of the Helsinki Declaration were strictly followed in each stage of the research. This being a retrospective cohort study, the consent of the participants was waived.

The consecutive patients with myopia and myopic astigmatism who underwent t-PRK from August 2019 to February 2020 were included in the present study. Patients aged 18 years and older and with at least 6mo follow-up after t-PRK were included. The surgeries were performed only if stable refraction was noted for at least one year prior to scheduling surgery. In all patients, contact lens usage was discontinued for at least three weeks, and postoperative residual corneal thickness of all eyes was more than 350 μm at the thinnest location. Patients with a history of ocular surgery, active ocular diseases, corneal dystrophy, retinal disease, dry eye, severe eye trauma, irregular astigmatism, or suspected keratoconus, systemic ailments like diabetes mellitus, autoimmune diseases, pregnant or lactating ladies were excluded. A single experienced corneal surgeon operated on all patients.

Demographic information of patients included age, gender, and eye operated. We used Open-Epi's Stat-calculator for estimating the sample size for this cohort study[10]. The logMAR notations were used to document both uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA). We used a Pentacam camera (OCULUS-Netzteil Art., Pentacam HR, Germany) for corneal topography. Sirius (SCHWIND eye-tech-solutions, GmbH, Kleinostheim, Germany) was used for tomography. HOAs like third-order coma value, third-order trefoil value, fourth-order spherical aberration value, aberration coefficient, and Q value were documented. The myopia was graded as mild (<-3.0 D), moderate (-3.0 to -5.9 D), or severe (≥-6.0 D) based on spherical equivalent (SE) values in diopters. The following measurements for each eye were noted for the enrolled patients in the study: UCVA, BCVA, central corneal thickness, keratometry (K_1 and K_2), spherical, cylindrical, and SE refractive power in diopters, cycloplegic refraction, and pupillary diameter in normal daytime illumination in a room.

The ablation was performed using an Amaris 500 Hz excimer laser (SCHWIND eye-tech-solutions, GmbH, Kleinostheim, Germany). Antiseptic chlorhexidine gluconate 0.05% solution (Saudi Medical Solution Company) was used to clean the

Table 1 Refractive status and visual acuity before and 6mo after one step t-PRK to treat myopia and myopic astigmatism

Items	Before t-PRK	6mo after t-PRK	Validation, Wilcoxon test
Spherical			Z=-10.77, *P*<0.001
Median	-3.0	0.25	
Inter quartile range	-4.0, -2.0	0.0, 0.75	
Cylindrical			Z=-7.13, *P*<0.001
Median	-0.75	-0.5	
Inter quartile range	-1.0, -0.5	-0.5, -0.25	
SE			
Median	-3.44	0.125	Z=-10.7, *P*<0.001
Inter quartile range	-4.63, -2.25	-0.125, 0.375	
CCT			
Mean	547.5	469.5	Z=-10.7, *P*<0.001
SD	36.1	29.75, 54.25	
UCVA (logMAR)			
Median	0.55	0.0	Z=-10.0, *P*<0.001
Inter quartile range	0.3, 0.9	0.0, 0.0	
CDVA (logMAR)			
Median	0.00	0.0	*P*<0.001
Inter quartile range	0.0, 0.0	0.0, 0.0	

t-PRK: Transepithelial photorefractive keratectomy; SE: Spherical equivalent; CCT: Central corneal thickness; UCVA: Uncorrected visual acuity; CDVA: Corrected distance visual acuity; SD: Standard deviation.

eyelids before surgery and moxifloxacin 0.5% (Vigamox, Alcon Co.) drops were applied. A wire lid speculum was used to keep the eyes open during surgery. Both the epithelium and the stroma were ablated in a single continuous session using an aberration-free and aspheric profile. The ablation plan utilized 55 µm centrally and 65 µm peripherally based on a population-based epithelium thickness profile. Eye movements throughout the ablation were compensated by static and dynamic cyclotorsion corrections. A sponge soaked with 0.02% mitomycin-C was placed over the ablated stroma for 25-35s. The eye was irrigated using copious amounts of balanced salt solution (BSS; Alcon Laboratories, Fort Worth, TX, USA). A soft bandage contact lens with a high diffusion constant of oxygen permeability (Bausch & Lomb, New York, USA) was placed on the cornea until the complete healing of the epithelium. The treatment aimed at achieving emmetropia.

The accuracy of the refractive correction was considered as excellent if achieved SE was within 1 D of intended SE for all treated eyes[9]. The efficiency was defined as postoperative UDVA in logMAR/preoperative CDVA in logMAR. The safety was defined as CDVA 6mo after T-PRK/preoperative CDVA. To calculate S.IOS, we used the formula, spherical difference/SE correction targeted[11-12].

Statistical Analysis The data were collected on a pretested data collection form. The data was entered into the spreadsheet of Microsoft Excel. The excel spreadsheet was transferred into the spreadsheet of the statistical package for social studies (SPSS 25; IBM, NY, USA). The continuous variables were presented as the median and interquartile range (IQR). The qualitative variables were presented as numbers and percentages. The difference in outcome variables at 6mo and before surgery among subgroups was validated using non-parametric methods such as the Mann-Whitney *U* test, Kruskal-Wallis test, and Wilcoxon test. The *P*<0.05 was considered statistically significant.

RESULTS

Our cohort comprised of 154 eyes of 77 myopic patients (mean age, 25.4±5.2y; females, *n*=47, 61%). Mild, moderate, and severe grades of myopia were in 59 (38.3%), 83 (53.9%), and 12 (7.8%) eyes, respectively.

The refractive status, central corneal thickness, and visual acuity before and 6mo after single-step t-PRK are given in Table 1. All eyes had significant improvement in vision and refractive status 6mo after t-PRK compared to before surgery. The median of K1 was 42.9 (IQR 42.0, 43.8) and K2 was 44.0 (IQR 42.9, 44.9) before surgery. The efficiency index of t-PRK in achieving targeted UCVA was 98% and the safety index was 100%. The success in achieving targeted refractive status in eyes 6mo after t-PRK was in 151 eyes (98%; 95%CI 95.9, 100). The efficiency of reaching targeted SE correction is shown in Figure 1.

The median of the S.IOS was 1.18 (IQR 1.0, 1.4). Determinants of S.IOS and correction of SE 6mo after t-PRK to treat myopia are given in Tables 2, 3. S.IOS was positively correlated to

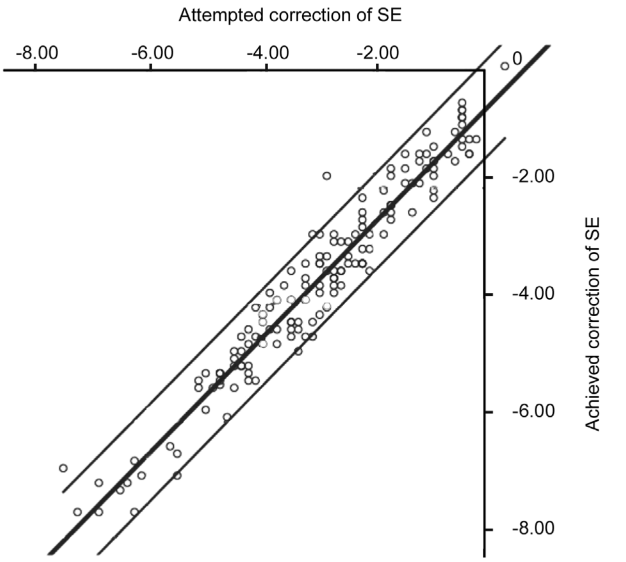

Figure 1 Efficiency of one-step T-PRK to treat myopia Dark blue line shows a correlation line with light-colored lines of upper and lower boundaries of 95%CI of correlation. Values above the upper line are over correction while values below the lower line show under correction performed by t-PRK at 6mo follow up. SE: Spherical equivalent.

Table 2 Determinants of S.IOS and SE corrected 6mo after one step t-PRK to treat myopia and myopic astigmatism

Determinants	S.IOS			SE corrected		
	Median	IQR	Validity	Mean	SD	Validity
Gender			^aP=0.12			P=0.15
Male	1.3	1.1; 1.8		3.21	1.88	
Female	1.2	1.07;1.33		3.82	1.6	
Eye			^aP=0.387			P=0.83
Right	1.2	1.06; 1.41		3.58	1.73	
Left	1.17	1.03; 1.33		3.64	1.68	
Myopia grade			^bP<0.001			P<0.001
Mild	1.44	1.2; 2.0		1.96	0.83	
Moderate	1.12	1.0; 1.24		4.28	0.83	
Severe	1.07	0.98; 1.1		7.09	0.38	
Ablation zone			^aP<0.001			P<0.001
6.5 mm	1.29	1.12; 1.5		2.96	1.46	
7 mm	1.09	1.0; 1.25		4.32	1.66	

S.IOS: Index of success for spherical change; SE: Spherical equivalent; t-PRK: Transepithelial photorefractive keratectomy; IQR: Interquartile range. [a]Mann-Whitney *U* test; [b]Kruskal-Wallis test.

Table 3 Correlation coefficients for ophthalmic variables

Items	S.IOS		SE corrected	
	r^a	P	r^b	P
Age	-0.304	0.007	-0.064	0.58
Pupillary diameter	0.064	0.432	-0.136	0.09
CCT	-0.138	0.087	-0.097	0.23

S.IOS: Index of success for spherical change; SE: Spherical equivalent; CCT: Central corneal thickness; [a]Spearman correlation coefficient; [b]Pearson correlation coefficient.

age (P=0.007), 6.5 mm ablation zone (P<0.01), and mild and moderate grade of myopia (P<0.001). The SE correction was significantly associated with increase in myopia grade and ablation zone size.

The HOAs before and 6mo after t-PRK using 6 mm diameter of analysis were compared (Table 4, Figure 2). Trefoil aberration, spherical aberration, and aberration coefficient types of HOAs increased significantly after surgery (P<0.001). The change in HOAs at 6mo after t-PRK compared to before surgery in eyes of three different grades of myopia is given in Table 5. With increase in grade of myopia, there was a significant decrease in fourth-order spherical aberration and coefficient of spherical aberration (P<0.05).

DISCUSSION

Our study suggests that single-step t-PRK had high efficiency and safety indices 6mo post-surgery in all grades of myopia tested. The achieved SE was within 1 D in 98% of the eyes. The S.IOS was high and it positively correlated with age, ablation zone, and severity of myopia. Though there was a significant increase in three subtypes of HOAs 6mo following t-PRK, eyes with severe and moderate myopia showed significantly more decline in spherical aberration and aberration coefficient values as compared to eyes with mild myopia.

We found that the S.IOS was positively correlated with age; younger patients had better outcomes for refractive correction. Earlier studies have also shown that younger patients had better visual outcomes as older patients tended to have more HOAs[20,22-23]. A positive correlation was also found between S.IOS and the size of the ablation zone, where S.IOS was higher when the ablation zone was 6.5 mm as compared to 7.0 mm. The effect of pupillary size should be noted while correlating the ablation zone to the index for refractive corrections. In our study, S.IOS was also positively correlated with the severity of myopia. With an increase in severity of baseline myopia, the S.IOS declined significantly. This was not unexpected as previously Zheng *et al*[24] also noted that 3mo after t-PRK, eyes with a moderate grade of myopia had a higher risk of hyperopic refraction compared to the eyes with mild myopia[25].

Surgery-induced HOAs are a common complication following refractive surgeries; these are more subtle errors that cannot be easily corrected by the use of simple lenses[26-27]. These HOAs are often responsible for halos, blurring, glares, and ghost images, and poor night vision in patients after corrective surgeries[28-29]. For example, spherical aberration is a fourth-order aberration that causes a decrease in contrast sensitivity and also causes halos around light sources. Trefoil is a third-order aberration that has an effect on image quality, but less so than coma aberration which severely affects vision quality[30-31].

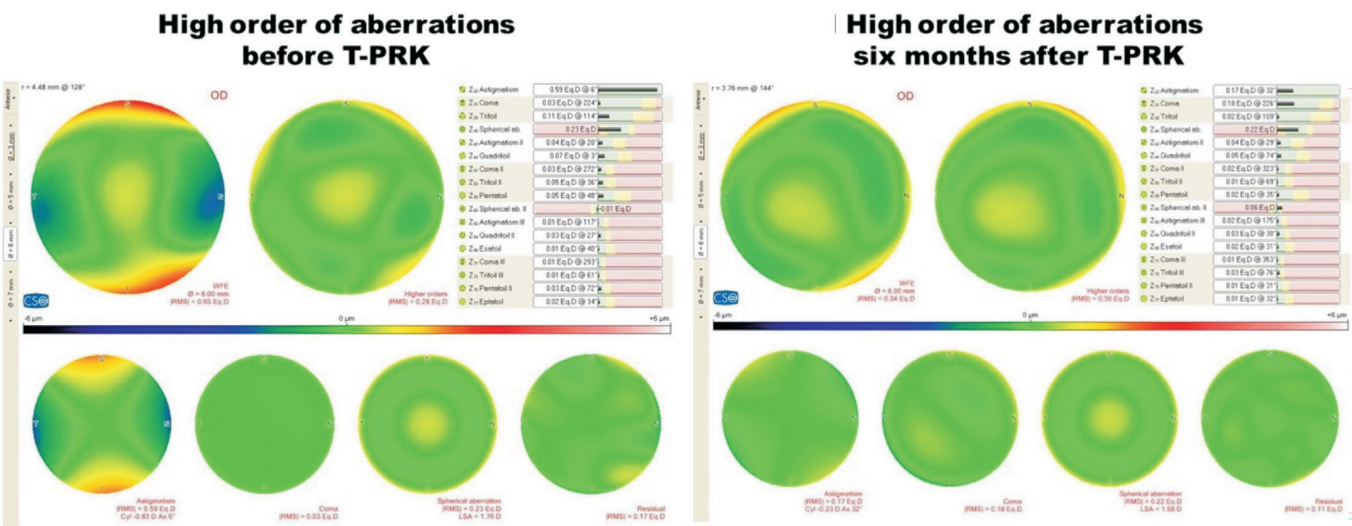

Figure 2 HOAs in myopic eyes before and 6mo after one step t-PRK HOAs: Higher-order aberrations; t-PRK: Transepithelial photorefractive keratectomy.

Table 4 Comparison of high order aberration at 6 mm diameter of analysis before and 6mo after t-PRK to treat myopia and myopic astigmatism *n*=154

Aberrations	Before t-PRK		6mo after t-PRK		Validation (Wilcoxon signed-rank test)
	Median	IQR	Median	IQR	
Third-order coma	0.18	0.12; 0.26	0.21	0.11; 0.28	0.121
Third-order trefoil	0.14	0.09; 0.19	0.17	0.12; 0.24	<0.001
Fourth-order spherical aberration	0.19	0.15; 0.23	0.26	0.19; 0.34	<0.001
Aberration coefficient	0.05	0.03; 0.08	0.09	0.05; 0.13	<0.001
Q value	0.05	0.03; 0.07	0.05	0.03; 0.07	0.461

t-PRK: Transepithelial photorefractive keratectomy; IQR: Interquartile range.

Table 5 Change in high order aberration at 6 mm diameter of analysis from before to 6mo after t-PRK by grades of myopia

Aberrations	Mild myopia (*n*=59)		Moderate myopia (*n*=83)		Severe myopia (*n*=12)		Validation (Kruskal Wallis test)
	Median	IQR	Median	IQR	Median	IQR	
Third-order coma	-0.01	-0.05; 0.06	-0.01	-0.09; 0.06	-0.08	-0.21;0.03	0.192
Third-order trefoil	-0.04	-0.08; 0.001	-0.04	-0.10; 0.03	0.01	-0.11; 0.03	0.761
Fourth-order spherical aberration	-0.01	-0.07; 0.03	-0.10	-0.16; -0.03	-0.19	-0.32; -0.17	<0.001
Aberration coefficient	-0.02	-0.05; 0.01	-0.04	-0.08; 0.00	-0.08	-0.14; -0.02	0.009
Q value	0.00	-0.02; 0.03	0.00	-0.02; 0.03	-0.02	-0.08; 0.01	0.134

t-PRK: Transepithelial photorefractive keratectomy; IQR: Interquartile range.

The preexisting HOAs increased 6mo after surgery. The increase was significant for spherical aberration and aberration coefficient; while an increase of trefoil aberration was not statistically significant. Several studies have previously confirmed a rise in HOA following t-PRK[20,29,32]. Newer versions of equipment and software for the t-PRK need to address these issues to improve vision and contrast and glare sensitivity complaints of patients after refractive surgeries. Serrao *et al*[33] also noted that in high myopic eyes, the rise of HOAs was more compared to eyes with moderate myopia managed by t-PRK. Perhaps the difference in pupillary diameter in high myopic compared to mild and moderate myopia could have influenced HOAs induced by t-PRK[20]. Ablation machine settings for the correction of HOAs need to be based on the grades of myopia, central corneal thickness, as well as pupillary diameter before surgery[34-35].

It is interesting to note that though some of the individual HOAs types increased post-surgery, our study also shows that when we compared HOAs within grades of myopia, both severe and moderate myopia had significantly more decline in spherical aberration and aberration coefficient values than in the eyes with mild myopia[36-37]. Since aberration coefficient is a function of all types of HOAs, a decline in aberration coefficient in higher-grade myopia suggests that surgery-induced aberrations were less pronounced in these groups signaling better quality of vision in these groups[38].

While comparing the efficiency and safety, we noted that different researchers have different postoperative follow-up criteria to document outcomes[38-40]. Hence comparison and conclusive recommendations seem to be a challenge, so study outcomes to address myopic correction should be compared with other studies with caution. A standard protocol for the evaluation of refractive surgery outcomes in both lower and HOAs is needed. In the present study, we divided participants into three groups based on mild, moderate, and severe grades of myopia, and collectively analyzed outcome effects of factors such as ablation zone, age, preexisting HOAs, and other baseline characters between different grades of myopia. Moreover, all patients in our study were operated by a single trained surgeon, which removed variability that can be caused when different surgeons of varying training levels perform operations.

The Middle East region has a high prevalence of myopia (54%). Given the high prevalence of myopia in this region, our study will enrich the literature on refractive surgeries. HOAs and high myopia cannot be easily corrected by the use of contact lenses or prescription glasses and thus, necessitates refractive surgeries. Our study provided additional independent evidence confirming the safety and efficacy of single-step t-PRK and the effect of various factors on the outcome of treating varying grades of myopia so that surgeons can make a well-informed choice and customize treatment to manage myopia in their respective patients.

Our study was limited by some factors. The number of eyes included in the study was low, especially in the severe myopia group, which had only 12 eyes. The follow-up period was only 6mo, which is short for determining if the safety and efficacy of this treatment were maintained long term. Although the procedure was safe and efficacious at 6mo post-surgery, it would be important to note if any of these groups developed HOAs or other complications later in the long term. Further studies with a larger sample size of all grades of myopia, with long-term follow-up, are needed. Since we implicated age as a factor in determining the outcome, it would also be wise to have a wider age range of patients included in the study. Our study has a relatively narrow age range (25.4±5.2y).

In conclusion, this study from a myopic prevalent location clearly indicates the importance of refractive surgeries for all orders of myopia. Single-step t-PRK is a useful refractive surgery for myopia with good indices for efficiency, safety, and SE correction. Grades of myopia, age, and ablation zone are vital factors should be considered before planning surgery which helps to sort out the possibility of HOAs accordingly. Collectively, our study shows promising short-term outcomes for refractive corrections and vision improvement in treating all three grades of myopia. Although a long term follow up period would help to determine the long term effect of the treatment.

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Conflicts of Interest: Al-Mohaimeed MM, None.

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