

Long-Term Results of Excimer Laser Surface Ablation with Smoothing for High Myopia

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Abstract: *Purpose:* To evaluate long-term refractive, aberrometric and anatomical results of surface ablation plus corneal PTK-style smoothing for myopia greater than -7.00 D.

Methods: One-hundred-and-fourteen eyes of 69 patients (mean age: 37.7 ± 8.3 years) underwent PRK with the NIDEK EC-5000 excimer laser (NIDEK Co. Ltd., Gamagori, Japan) using multiple optical zones ranging in diameter from 4.89 mm to 7.0 mm, and transition zones (TZ) that were at least 3 mm wider than the optical zones (OZ). A cross-cylinder technique was used for treating astigmatism greater than 0.50 D. All eyes underwent a phototherapeutic keratectomy (PTK) smoothing technique using masking fluid. The Student's t-test was used to determine a statistically significant change after surgery. A p value less than 0.05 was considered statistically significant.

Results: Preoperative corrected distance visual acuity (CDVA) was 0.88 ± 0.16 with -9.53 ± 1.18 D cycloplegic spherical equivalent (SE). Preoperative corneal pachymetry was 560.4 ± 30.1 μ . Three years after surgery uncorrected visual acuity (UCVA) was 0.79 ± 0.26 , CDVA was 0.92 ± 0.19 with -0.56 ± 0.90 D SE. Mean corneal haze was highest 1 month after surgery (0.58 ± 0.35), then progressively decreased to 0.11 ± 0.32 by 3 months postoperatively. Following year one, refraction and corneal curvature remained stable. There were no cases of keractasia to date. There was no hyperopic induction due to PTK. Two eyes required retreatment due to undercorrection. Total wavefront error did not change significantly, while astigmatism decreased and coma increased (both with $p < 0.001$).

Conclusion: Surface ablation for the treatment of high myopia using PTK smoothing with a masking fluid was safe and effective. Wide optical and transition zones prevented induction of spherical aberration and the incorporation of the smoothing technique created a regular corneal surface with regular healing and trace to no haze after surgery.

Keywords: High myopia, excimer laser, PRK, smoothing, long-term results.

INTRODUCTION

Highly myopic individuals (e.g. eyes greater than 7.00 D of myopia) represent a significant portion of the population seeking comfortable, safe and effective correction of their refractive error. Excimer laser refractive surgery initially seemed a promising solution even for very high myopia [1]. Photorefractive keratectomy (PRK) does not consume part of the stroma for flap creation. This allows more tissue available for laser ablation compared to laser in situ keratomileusis. However, the drawback was regression and haze due to an increased subepithelial healing response elicited by the deeper ablation for high myopia [2, 3]. The introduction of aspheric ablations and custom ablation both of which consume more tissue than conventional excimer laser ablation [4, 5] has led a renewed interest in the surface ablation for the treatment of refractive errors. Additional strategies for mitigating corneal haze and regression, such as the use of mitomycin C intraoperatively, postoperative use of amino acids and a smooth corneal surface post

ablation have resulted in a resurgence of surface ablation (PRK and laser epithelial keratomileusis) [6-10]. Strategies for preventing haze and regression have also renewed interest in the correction of high myopia using the excimer laser [6-8]. In the 1990s, we developed and have consistently used a smoothing technique for all surface ablation procedures [8]. In this study, we evaluated the long-term outcomes of surface ablation with corneal smoothing for high myopia.

MATERIALS AND METHODS

In this retrospective study, all patients with myopia greater than 7 D that underwent PRK at the Ophthalmology Department, Istituto Clinico Humanitas in Milano, Italy between June 2000 to June 2002 were evaluated. Patients underwent PRK if they were 21 years or older, had a documented stable refraction longer than one year, had no previous refractive surgery, no history of keloids, no metabolic diseases (eg. diabetes) or collagenopathies, corneal thickness greater than 500 μ m, no contact-lens induced corneal warpage, no corneal topographic abnormalities that indicated forme fruste keratoconus, keratoconus or pellucid marginal degeneration. Patients with corneal topography suspicious for keratoconus were further evaluated using corneal pachymetry with the Orbscan

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to rule out focal corneal thinning (Bausch and Lomb Inc., Rochester, NY, USA).

Preoperative examination included general and ophthalmic medical history, uncorrected visual acuity (UCVA) (decimal notation), best corrected visual acuity (BCVA) (decimal notation), manifest refraction ("pushing plus" method), cycloplegic refraction, pupillometry, slit-lamp microscopy, tear film testing using the Schirmer test, Goldmann tonometry, Orbscan corneal topography and pachymetry, topography-derived corneal surface coma and corneal spherical aberration measurements (Costruzione Strumenti Oftalmici, Florence, Italy), and dilated retinal examination with identification of rhegmatogenous retinal lesions. Prophylactic laser treatment was performed if a retinal lesion was a superiorly located lattice degeneration with holes.

Postoperatively, all patients underwent an ophthalmologic examination at 1 day, 1 week, and 1, 3, 6, 12, 24 and 36 months. At 1 week postoperatively, UCVA was measured and a slit lamp examination was conducted. From 1 month postoperatively onwards, patients underwent the same examinations as preoperatively with the exception of cycloplegic examination and a dilated retinal examination unless clinically warranted. Corneal haze was graded based on the scale reported by Epstein *et al.* [11].

Our surgical technique of that period has been previously described [12]. All eyes underwent conventional laser ablation with the NIDEK EC 5000 excimer laser (NIDEK Co. Ltd., Gamagori, Japan) without eyetracking. The cross cylinder technique with multizone treatments and personalized nomogram was used to treat all cases with astigmatism greater than 0.50 D. The cross cylinder technique has as a cornerstone the division of the cylinder power in two symmetric parts. I.e., 50% of the cylinder is treated as negative, and 50% as positive. The spherical equivalent generated must be taken into account and added to the spherical correction [13, 14].

The programmed transition zone (TZ) was at least 3 mm larger than the optical zone (OZ). The OZ ranged from 4.80 mm to 7.00 mm.

PTK smoothing with a masking fluid [13] (4% hyaluronic acid, Laservis, Chemedica Ltd., Munich, Germany) was performed after the refractive ablation. The PTK mode was set at 10 Hz frequency to avoid a refractive change with a programmed OZ of 10 mm to reduce thermal effects of the laser beam. Laservis was

instilled on the cornea and continuously distributed with a Buratto spatula (Medtronic Inc., Jacksonville, FLA, USA) during the PTK ablation. PTK was limited to 10 μ of total ablation in all cases.

Refractive outcomes, corneal coma and corneal spherical aberration for 5 mm diameter to the 8th Zernike order were calculated preoperatively and for the last visit postoperatively.

Proper informed consent was obtained from each patient, for both the treatment and use of their de-identified clinical data for publication. The Independent Review Board of the institute evaluated the study and stated that the investigation in this form is not subject to Medical Research Involving Human Subjects Act.

Statistical Analysis

Data were described as number and percentage or mean and standard deviation, where appropriated. Comparisons between groups were performed by chi-square test or Wilcoxon test, where appropriated. A p value <0.05 was considered statistically significant.

All analysis were made with stata13 (StataCorp LP, College Station, Texas).

RESULTS

One-hundred-and-fourteen eyes of 69 patients (11 males, 58 females) were included in the study of which 88 (77%) eyes were evaluated at the last postoperative visit. Mean age at the time of surgery was 34.7 ± 8.3 years (range, 21 years to 56 years). Preoperative refractive data are presented in Figure 1. The mean preoperative corneal pachymetry was 560.0 ± 30.20 μ m. The mean follow up was 3.10 ± 1.60 yrs (range, 509 days to 1920 days).

Refractive outcomes at last visit are presented in Figure 1. The intended versus achieved cycloplegic spherical equivalent is plotted in Figure 2. The mean intended cycloplegic spherical equivalent correction was -9.53 ± 1.81 , the mean achieved cycloplegic spherical equivalent was $-8.99 \text{ D} \pm 2.17 \text{ D}$. Safety at last visit is plotted in Figure 3. Two (2%) eyes lost 2 or more lines of CDVA and 26 (30%) eyes gained 2 or more lines of CDVA (Figure 3). Preoperative CDVA compared to postoperative UCVA is plotted in Figure 4. Preoperatively no eyes had a CDVA of better than 20/15, at last visit postoperatively 8 (9%) eyes had distance of UCVA better than 20/20. Stability is plotted in Figure 5.

Preoperative (n=114)	mean ± SD	range
CDVA(decimal notation)	0.88 ± 0.16	0.45 – 1.0
Cycloplegic SE (D)	-9.53 ± 1.81	-7.50 to -14.25
Cycloplegic Sphere (D)	-8.80 ± 1.85	-7.00 to -14.25
Cycloplegic Cylinder (D)	-1.41 ± 0.99	0.00 to – 4.00
Final examination (n=88)		
CDVA(decimal notation)	0.9 ± 0.20	
Cycloplegic SE (D)	-0.45 ± 0.83	0.00 to -2.50
Cycloplegic Sphere (D)	-0.26 ± 0.83	-2.50 to +0.25
Cycloplegic Cyl (D)	-0.37 ± ± 0.46	-0.00 to -1.50

Legenda. CDVA: best spectacle corrected visual acuity; SE: spherical equivalent.

Figure 1: Preoperative and last visit refractive data of eyes that underwent photorefractive keratectomy for high myopia with surface smoothing.

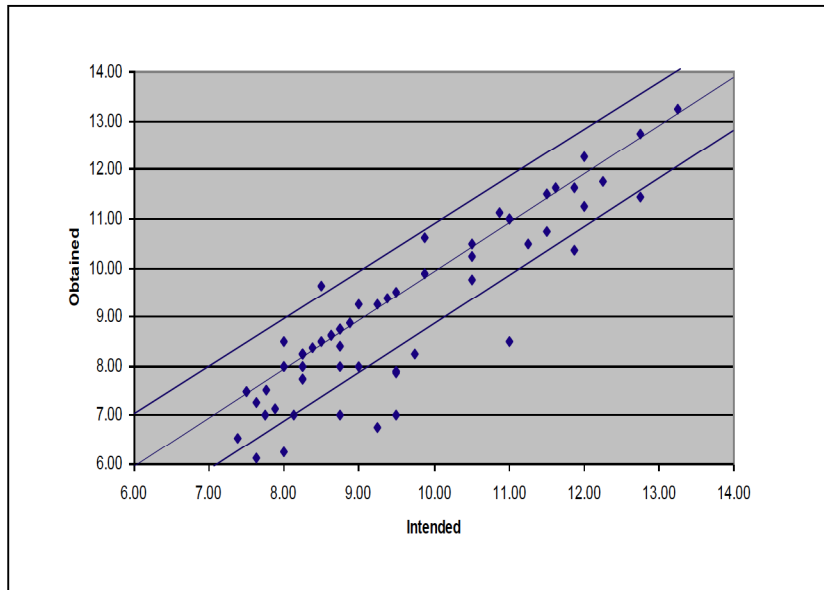


Figure 2: Postoperative intended versus obtained cycloplegic refractive spherical equivalent of 114 eyes that underwent myopic photorefractive keratectomy.

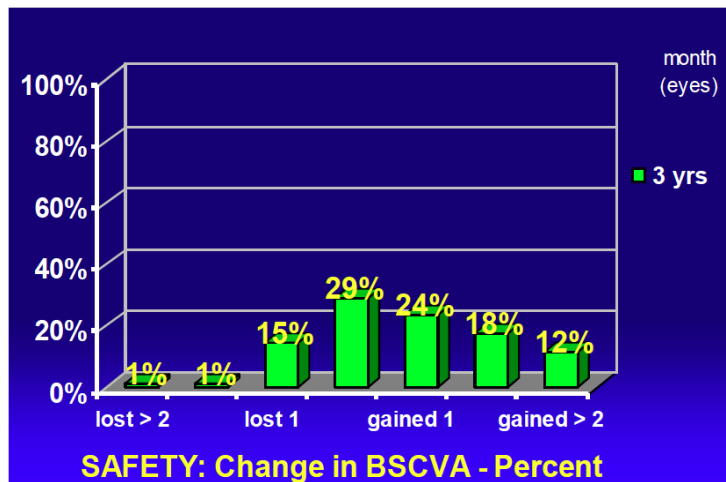


Figure 3: Safety of 114 eyes that underwent myopic photorefractive keratectomy. CDVA denotes best spectacle corrected visual acuity.

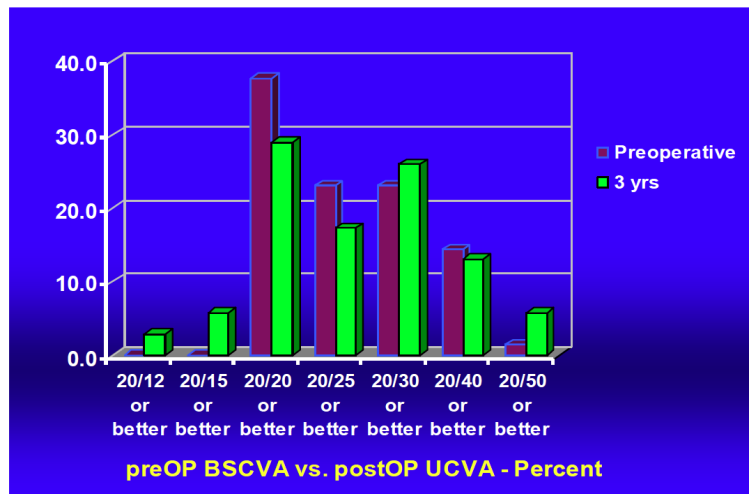


Figure 4: Preoperative best spectacle corrected visual acuity (CDVA) compared to 3 year postoperative uncorrected visual acuity of 114 eyes that underwent myopic photorefractive keratectomy.

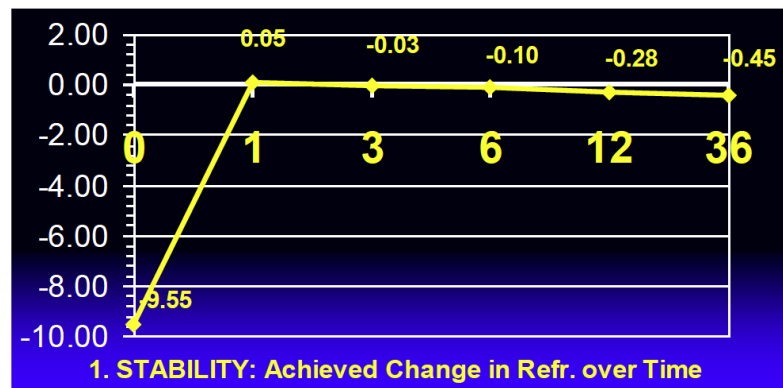


Figure 5: Stability of 114 eyes that underwent myopic photorefractive keratectomy.

Corneal coma aberration was $0.14 \pm 0.10 \mu\text{m}$ (range, $0.00 \mu\text{m}$ to $0.79 \mu\text{m}$) preoperatively and $-0.19 \pm 0.12 \mu\text{m}$ (range, $-0.01 \mu\text{m}$ to $1.30 \mu\text{m}$) at the last visit ($p < 0.005$). Corneal spherical aberration was $-0.21 \pm 0.86 \mu\text{m}$ (range, $-0.04 \mu\text{m}$ to $0.00 \mu\text{m}$) preoperatively and $-0.27 \pm 0.12 \mu\text{m}$ (range, $-0.66 \mu\text{m}$ to $0.01 \mu\text{m}$) at last visit ($p > 0.05$).

0.29 (range, 0 to 1). At the last visit, 74 (84%) of eyes had no corneal haze (grade 0).

Mean corneal haze over time is plotted in Figure 6. At last visit, mean corneal haze was graded at $0.11 \pm$

There were no intraoperative complications. Both eyes of a 67 year old female patient were undercorrected, by -2.75 D sphere in the right eye and -1.50 D sphere in the left eye, with CDVA of 20/20 in each eye at 12 months postoperatively. Both eyes were successfully retreated with a myopic ablation 2 years postoperatively. There were no other postoperative

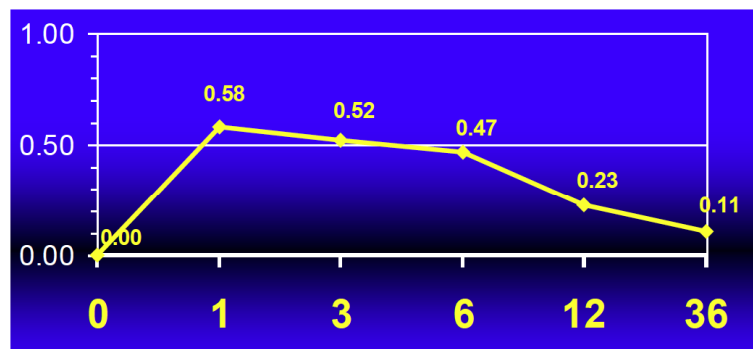


Figure 6: Corneal haze over time of 114 highly myopic eyes that underwent photorefractive keratectomy.

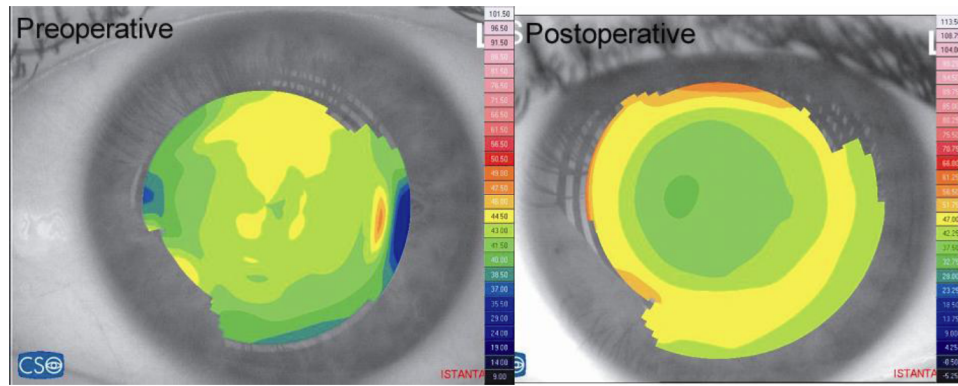


Figure 7: Preoperative and 3 years postoperative instantaneous corneal topographies of an eye that underwent photorefractive keratectomy for high myopia (-9.50 D spherical equivalent) with surface smoothing.

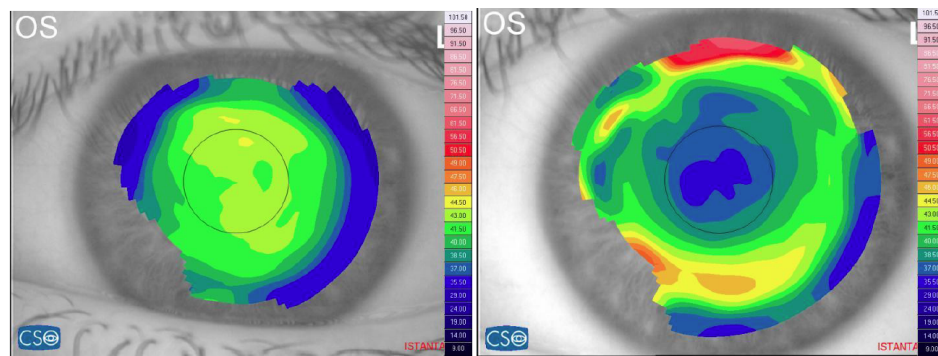


Figure 8: Preoperative and 2.2 years postoperative instantaneous corneal topographies of an eye that underwent photorefractive keratectomy for high myopia (-11.50 D spherical equivalent) with surface smoothing. Final visual acuity was 1.0 with -0.50 -0.50 (175).

complications in the study cohort. Specifically, corneal ectasia or retinal detachment did not occur in any of the treated eyes. In one eye, vision was limited due to previous subretinal neovascular membrane.

Figure 7 shows the case of the left eye of a 34 year old female with preoperative cycloplegic refraction of -8.75 -1.50 X180 with CDVA of 1.0. Three years postoperatively the eye had -0.75 D sphere with CDVA of 1.0. The longitudinal spherical aberration was $-0.13 \mu\text{m}$ preoperatively and $-0.24 \mu\text{m}$ 3 years postoperatively. Figure 8 shows the case of the left eye of a 43 year old female with preoperative cycloplegic refraction of -11.50, with CDVA of 1.0. Two years postoperatively, the eye had -0.50 D -0.50 (175) with CDVA of 1.0. RMS aberrations were $-0.92 \mu\text{m}$ preoperatively and $-0.77 \mu\text{m}$ 3 years postoperatively.

DISCUSSION

In this study of the long term outcomes of multiple-zone PRK with smoothing for the treatment of high myopia (greater than -7.00 D) we found the procedure to be safe, effective and stable. For example, only 2 (2%) eyes lost two or more lines of CDVA (Figure 3).

Corneal haze greater than grade 1 did not occur over the 3 year study period. UCVA was better than preoperative CDVA in 9% (8/88 eyes) indicating excellent efficacy. Stability was demonstrated by an overall rate of change of the cycloplegic refractive spherical equivalent of 0.01 D/month (0.16 D/year) (Figure 5). A statistically significant change in corneal coma was found likely due to subclinical decentration as an eye tracker was not available at the time of treatment. We believe the induced coma was clinically insignificant as no patient complained of ghosting or shadowing postoperatively.

Excimer laser treatments in high myopes have been associated with some complications. For example, PRK has been limited to the treatment of low to moderate myopia due to the increased chances of haze after higher corrections [16]. The risk of inducing ectasia postoperatively has limited the refractive range of LASIK. The safe upper limits of correction appear to be approximately -10 D [2, 3]. Increased risk of halos and glare at night due to increasing spherical aberration and decreasing effective optical zones, with increasing myopia is another factor that has limited the range of treatments for LASIK and PRK [17].

Additionally, severe changes in corneal curvature induced by delivering conventional ablation algorithms for high myopia may stimulating an aggressive wound healing response causing regression [18, 19].

Surface ablation for high myopia is advantageous due the greater tissue available and the ability to treat steeper or flatter corneas compared to LASIK. Additionally there is a reduced biomechanical effect with PRK and reduced risk of ectasia compared to LASIK [20]. Lastly, better contrast sensitivity in high myopes has been reported after PRK compared to LASIK [21]. Based on these factors and avoiding the attendant risks of flap creation, PRK for high myopia with a concomitant haze mitigating strategy is a reasonable surgical alternative to LASIK [22].

Corneal irregularity is induced by laser ablation and microsaccades [23]. This irregularities may be accentuated in cases of high myopia. Animal [23] and human studies of high myopia indicate greater stromal irregularity with ablation depth [18, 19]. Our previous studies [8, 24] and Serrao and colleagues [25] investigation have documented the association of haze and stromal irregularity and the reduction of haze after PTK smoothing. Hence, intraoperative smoothing technique may reduce the incidence or severity of corneal haze postoperatively, as showed by Netto *et al.* even for high myopia [26]. Their results demonstrated a relationship between the level of corneal haze formation after PRK and the level of stromal surface irregularity. PTK-smoothing with methylcellulose in their animal model was an effective method to reduce stromal surface irregularity and decreased both haze and associated myofibroblast density. They hypothesized that stromal surface irregularity after PRK for high myopia results in defective basement membrane regeneration and increased epithelium-derived TGFbeta signalling to the stroma that increases myofibroblast generation [26]. In the current study, we found clinically insignificant haze postoperatively. As we recently published, stromal surface regularity, epithelial wound healing, stromal haze and final refraction are all apparently related [27]. As early as 1998 we showed that phototherapeutic-like smoothing improved corneal stromal surface regularity immediately after PRK and provided better refractive and optical outcomes [8, 24].

Our treatment strategy of using small optical zone and extremely wide transition zones may also play a role in reducing the severe changes of corneal curvature normally seen after conventional laser ablation for high myopia. The use of this strategy has shown greater effective optical zone and better visual

quality compared to conventional ablation with standard treatment zones [5]. There was no statistical change in spherical aberration despite using a conventional ablation algorithm in high myopia. Generally treatment of high myopia with conventional ablation induces significant spherical aberration [17]. A smoother postoperative corneal surface with reduced corneal curvature changes due to lower collagen deposition (see Figure 7) may also reduce the chances of regression and increase stability. We found -0.50 D change in MRSE over three years indicating the stability of the procedure. Whether surface smoothing or the incorporation of wide transition zones are responsible for the results in the current study remains the subject of a future investigation. We suspect both factors play a role in the visual and refractive outcome report here.

The cross cylinder technique for the treatment of astigmatism provides to an aspherical corneal profile, with reduction in postoperative spherical aberration and eccentricity [13, 14]. This approach provides better precision, less haze, with an optimal final result [14, 28].

The outcomes of the current study compare favourably with outcomes reported in similar studies [29, 30] of both PRK and LASIK. For example, Rosman and colleagues [28] reported 14% of high myopes who underwent PRK (without PTK smoothing) and 6% of high myopes who underwent LASIK lost two or more lines 2 years postoperatively, which is higher than the 2% found in our study (Figure 3). One of the longest term studies on PRK, by Alio *et al.* showed that this a safe refractive procedure in the long term within the range of myopia currently considered suitable for its use [31].

In summary, we found PRK with PTK smoothing with a masking solution, an effective, predictable and stable treatment for high myopia. The incorporation of a multizone, wide transition zone treatment may prove beneficial. The clinically insignificant corneal haze and spherical aberration are benefits of this combined treatment strategy.

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