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# Visual performance after excimer laser photorefractive keratectomy for high myopia

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**Abstract:**

**PURPOSE:** To evaluate the efficacy, safety, predictability, and visual performance of excimer laser photorefractive keratectomy (PRK) for myopia greater than −8 diopters (D).

**METHODS:** Fifty-four patients (104 eyes) with myopia from −8D to −13D and cylinder up to −4D received surface ablation technique with the Allegretto wave version 1009-1 excimer laser to correct their refractive error. The patients were examined on days 1, 3, 7, and 14 and 1, 3, 6, and 12 months postoperatively. Visual acuity, manifest refraction, corneal haze, topography, intraocular pressure, contrast sensitivity, and wavefront aberration were evaluated.

**RESULTS:** Twelve months postoperatively, 95% of eyes were within 1D of the intended correction. In addition, 94% of eyes had attained uncorrected distance visual acuity of 20/25 or better, and 98% of eyes had improved or remained their corrected distance visual acuity. All eyes exhibited barely detectable corneal haze which peaked during the 1st month with a gradual reduction in the 3rd month. Ninety-five percent of patients had no or only mild degree of night glare.

**CONCLUSIONS:** Excimer laser PRK is an effective and predictive treatment for high myopia greater than −8D with or without astigmatism up to −4D. The incidence of complication is low. All patients who are candidates for laser *in situ* keratomileusis can be candidates for surface ablation, especially those with preoperative thinner cornea or higher risk of corneal flap complications.

**Keywords:**

Excimer laser, myopia, photorefractive keratectomy

## Introduction

Excimer laser photorefractive keratectomy (PRK), as the first excimer laser refractive procedure, has several disadvantages, including painful sensation after the surgery, slow visual activity recovery, corneal haze, the postoperative topical steroid-induced side effects, and occasional myopic regression, especially in high myopic patients. Furthermore, the enhancement procedure may cause the patients suffering the above phenomena again. Conventionally, this technique is mainly applicable to those who have low to medium degree of myopia, hyperopia, or astigmatism.[1,2]

Since its development, laser *in situ* keratomileusis (LASIK) has become the most popular refractive surgical procedure, because of several advantages: less painful sensation, free of haze, and fast visual recovery. However, there are also disadvantages such as complications of corneal flap: irregularity, perforation, displacement, wrinkles, slip, and dislocation. As well, diffuse lamellar keratitis, epithelial ingrowth, and corneal ectasia may also happen subsequently.[3] In addition, the flap may result in more high-order aberration, in contrast to PRK in which the procedure is performed without microkeratome and has no corneal flap-related complications. Moisseiev *et al*.[4] reported that higher preference of

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surface ablation over LASIK between 2008 and 2011 is correlated to the fear of ectasia.

Modifications on PRK procedure is applied to patients who are not suitable for or at high-risk from LASIK, such as those with thin cornea, large pupil size, corneal scar, and corneal epithelial disease, plus those who have received radial keratotomy or keratoplasty.[1] Improvement of the excimer laser from the broad-beam to the flying-spot and enlarged optic zone reduce the enhancement rate. With improvement in PRK technique, visual recovery time is shortened, and there is less postoperative pain, corneal haze, and enhancement rate. As more residual stromal thickness can be preserved, high myopia may no longer be a contraindication to PRK.[2]

Our first priority to the patients who have received the excimer refractive surgery is to maintain a 6.5 mm large optic zone. For patients with thin cornea, we chose PRK to correct myopia higher than 8 diopters (D). We evaluate efficacy, predictability, stability, safety, visual satisfaction, actual optic zone of the procedure, and analyzed their visual performance after the surgery, including contrast sensitivity and wavefront aberrations.

## Methods

From November 2004 to May 2008, we selected 54 patients (47 females and 7 males), involving 104 eyes. Four fellow eyes of 4 patients were <−8D. The average age was 33.5 years, ranging from 25 to 50 years. The patient selection criteria are as follows: older than 20 years old, stable refractive errors, myopic progression <−0.5D within 1 year, residual stromal thickness less than 250 μm with a 160 μm corneal flap and a 6.5 mm optic zone, and those not suitable for LASIK procedure. All patients have myopia from −8D to −13.5D and cylinder <−4D. The average spherical equivalent was−9.64D and the average corneal thickness is 520 μm (ranging from 455 to 603μm). We have preserved at least 300 μm of stromal bed after PRK procedure for all patients. The patient exclusion criteria are as follows: keratopathy, keratoconus, autoimmune disease, severe dry eye, diabetes, glaucoma, those who had missed the surgery follow-up in 3 months, and those who had received previous refractive surgery. All patients had received a complete ophthalmic examination, including uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), cycloplegic refractive error, intraocular pressure, slit-lamp examination, keratometry, corneal thickness, specular microscope, corneal topography, Schirmer's test, and fundus examination with dilated pupil.

All patients have received the same surgical procedure by two doctors (Lin and Liu). Twenty minutes before the operation, patients are given 2 tablets of 10 mg oxazolam (Serenal®, Daiichi Sankyo, Taiwan), 1 tablet of 100 mg gabapentin (Neurontin®, Pfizer, US), topical eye drops of 0.3% ciprofloxacin HCl (Ciloxan®, Alcon, UK), and 0.5% proparacaine hydrochloride (Alcaine®, Alcon, Belgium). Corneal epithelium is removed after soaking with 20% alcohol for 30 s. Wavefront-optimized treatment with Allegretto wave version 1009-1 excimer laser is used to ablate the corneal surface with an optic zone of 6.5 mm diameter. Thereafter, the corneal surface was soaked with 0.04% mitomycin C (MMC) for 20 s, then irrigated with cold balanced salt solution; afterward, topical 0.3% ciprofloxacin HCl (Ciloxan®, Alcon, UK), 0.1% fluorometholone (Efemolin®, Novartis, Switzerland), and 0.5% proparacaine hydrochloride (Alcaine®, Alcon, Belgium) are used in sequence. Therapeutic contact lens is applied to the cornea at the end of the surgery. The medications after the surgery include oral 100 mg gabapentin (Neurontin®, Pfizer, US) once daily for 2 days, topical 0.3% ciprofloxacin HCl (Ciloxan®, Alcon, UK) four times daily for 1 week, and topical 0.1% fluorometholone (Efemolin®, Novartis, Switzerland) four times daily in the 1st month, twice daily in the 2nd month, and once daily in the 3rd month.

All patients are examined postoperatively on days 1, 3, 7, and 14 and 1, 3, 6, and 12 months. The therapeutic contact lens is removed at the scheduled third follow-up (7 days) or after the completion of corneal epithelialization. Uncorrected and best-corrected visual acuity, intraocular pressure by pneumatonometer, slit-lamp examination, corneal haze grading, ultrasonic corneal thickness, specular microscopy, corneal topography, contrast sensitivity, wavefront aberration, and questionnaire for satisfaction (degree of dryness, glare at night, and influences on driving) are also evaluated. Corneal thickness is measured by Pachette Ultrasonic Pachymeter (DGH Technology) and scotopic contrast sensitivity is measured by CVS-1000 HGT (Vector Vision Dayton, OH, USA) in a dark room with a single corrected eye at an 8 feet distance. The gratings are tested in the spatial frequencies of 3, 6, 12, and 18 cycles/degree with the glare lights off and on. Wavefront aberration was measured by wavelight wavefront analyzer with the pupil dilated to 8 mm, and the spherical and high-order aberration were taken in a dark room, and expressed as root-mean-square (RMS, μm as a unit).

We evaluated the following parameters: efficacy, ratio of UDVA better than 20/20, 20/25, and 20/40, predictability, ratio of difference between achieved and target refraction within ± 1D and ± 0.5D, stability, refractive change within 1-year follow-up, safety, ratio of impaired CDVA, complications, subjective visual satisfaction after the surgery, comparison of predicted optic zone with the actual zone measured by topography, adverse events

from the surgery, difference between predicted and actual corneal ablation depth, contrast sensitivity compared to normal individuals and with glare lights off and on, and wavefront aberration. Corneal haze grading system from a previous report was used.[5] The Wavelight Allegro Topolyzer is used to obtain the preoperative and the 3rd-month postoperative anterior tangential maps and to evaluate their differences. The postoperative topographic optical zone (1D color steps) was defined as the area including the blue central circle surrounded by the green area. Then, the lengths of topographic optical zone were measured at the zone of lowest curvature on the difference map, as was described by Ahn *et al*.[6]

Data are analyzed by Microsoft Excel and SPSS (version 22, IBM SPSS Statistics, Chicago) for analysis, and the refractive error is considered as spherical equivalent. Paired *t*-test was used to compare the differences between the predicted and actual corneal ablation depth, between the contrast sensitivity with glare lights off and on, as well as between the visual outcomes in paired eyes. Mann–Whitney U-test was used to compare the difference of predicted and actual corneal ablation depth and the difference of contrast sensitivity. $P < 0.05$ was considered statistically significant. This study has been approved by the Institutional Review Board of Changhua Christian Hospital, and the procedures have conformed to the tenets of the Declaration of Helsinki.

## Results

### Efficacy, stability, and predictability

Two weeks after the surgery, 95.6% of patient's eyes had achieved an UDVA better than 20/40, 92% of eyes attained 20/25 or better, and 79.2% of eyes attained 20/20 or better. Figure 1a shows the preoperative UDVA and the final UDVA at the 12-month follow-up. It indicated that 85% of eyes achieved a final UDVA better than 20/20 and 94% of eyes achieved a final UDVA better than 20/25.

At the 1-, 3-, 6-, and 12-month follow-ups, the mean postoperative absolute spherical equivalents were 0.11D (±0.03D), 0.07D (±0.02D), 0.13D (±0.04D), and 0.13D (±0.04D) respectively, and they remained stable without regression [Figure 1f]. Only 14% of eyes had refractive change more than 0.5D from the 3 months to the 12 months and none of them receive retreatment. Of all eyes, about 95% were within ± 1D and 91% were within ± 0.5D of target refraction, ranging from overcorrection 1.5D to undercorrection 1.75D [Figure 1d]. Figure 1e shows that 91% of eyes had postoperative refractive astigmatism <0.5D and 98% of eyes had final astigmatism less than 1D. There was also a clear evidence of significant improvement of refractive astigmatism after the PRK in these highly myopic eyes. Statistically there was no difference in the spherical equivalents at every follow-up moment as well as the final UDVA and CDVA of 50 individuals who had received PRK treatment for bilateral eyes. Figure 1c shows the distribution of attempted and achieved spherical equivalents. There was a tendency of mild undercorrection for highly myopic eyes in PRK.

### Safety

At 12 months after the operation, 74% of eyes had postoperative CDVA equal to preoperative CDVA, 24% of eyes gained one or more lines, all together, 98% of eyes achieved postoperative CDVA equal to or better than preoperative CDVA [Figure 1b].

Corneal haze, a major concern for high myopia treated by PRK, is shown in Table 1. At 1 month postoperatively, 50% of eyes had corneal haze greater than grade 0.5. It reduced to 20% at the postoperative 3 months and most of them were in grade 0.5, and most of the corneal haze disappeared at 6 months postoperatively. The average haze grading of all eyes was 0.3, 0.17, and 0.05 at postoperative 1, 3, and 6 months, respectively. There was one eye suffered from grade 2 corneal haze with vision deterioration at postoperative 3 months. This patient discontinued the use of topical corticosteroid 1 month postoperatively. Visual acuity of this eye was only 0.6 with −1.75D/−0.5D correction. The corneal haze was removed by phototherapeutic keratectomy combined with MMC therapy at the postoperative 8 months, and the CDVA had since recovered to 20/20 with −2D correction.

One eye had transient ocular hypertension due to corticosteroid use and had delayed corneal epithelial healing up to 25 days. The intraocular pressure had recovered to normal range after stopping corticosteroid use, but the eye was complicated with corneal scar due to delayed corneal epithelial healing resulting in loss of four lines of CDVA without refractive error. One eye had optical zone decentration and symptom of night glare although the UDCA was 20/20.

### Contrast sensitivity

There were only 68 eyes received scotopic contrast sensitivity test postoperatively due to late set up of the equipment. The mean contrast sensitivity of 3, 6, 12, and 18 cycles/degree mildly decreased than normal individuals at postoperative 12 months with glare test off and on. The contrast sensitivity at 18 cycles/degree decreased more significantly as shown in Figure 1g.

**Table 1: Corneal haze over time**

| Postoperative time (months) | Grade 0 eyes (%) | Grade 0.5 eyes (%) | Grade 1 eyes (%) | Grade 2 eyes (%) |
|---|---|---|---|---|
| 1 | 61 (58.7) | 25 (24) | 17 (16.3) | 1 (0.9) |
| 3 | 77 (79.8) | 19 (18.3) | 7 (6.7) | 1 (0.9) |
| 6 | 96 (94.1) | 4 (3.9) | 1 (0.9) | 1 (0.9) |

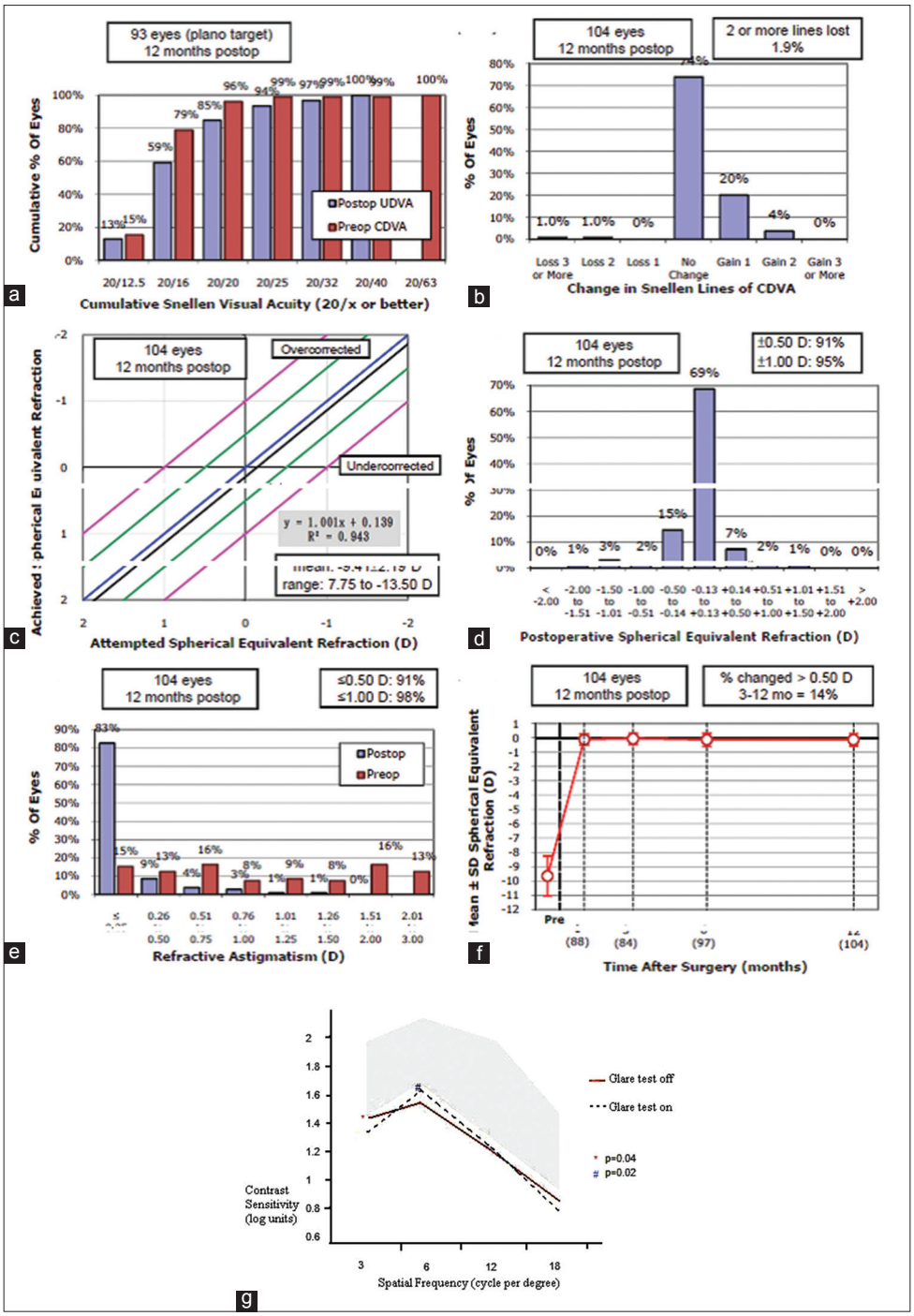


**Figure 1:** (a) The cumulative percentage of preoperative and postoperative uncorrected distance visual acuity. Eyes with target of low myopia or whose preoperative corrected distance visual acuity <20/20 were not included in the postoperative calculation. (b) The change in corrected distance visual acuity after the operation. Most eyes had corrected distance visual acuity equal to or better than preoperative corrected distance visual acuity. Only 1.9% eyes lost two or more lines. (c) The attempted and achieved spherical equivalent. The black line is the slope of attempted versus achieved spherical equivalent for all eyes plotted in Figure 1c. Most eyes had slight tendency to undercorrection. (d) The postoperative spherical equivalent refraction. 91% eyes were within 0.5D and 95% eyes were within 1.0D. (e) The preoperative and postoperative refractive astigmatism. Most eyes had much improvement in refractive astigmatism after the operation. (f) The mean spherical equivalent at the baseline and 1, 3, 6, and 12 months after the surgery. Most eyes reach the stable refraction at the postoperative 1 month. (g) The postoperative contrast sensitivity. The mean contrast sensitivity of 3, 6, 12, and 18 cycles/degree mild decreased at postoperative 12 months with glare test off and on ($P$ = 0.04 and 0.02, respectively)

## Subjective visual satisfaction

The subjective visual satisfaction after PRK is shown in Table 2. Of all patients, 84% had no or mild degree of dry sensation and 16% had significant or severe dry sensation. Ninety-eight percent of patients had distance vision without relying on glasses. No patient had suffered near vision reading, but two eyes had hyperopia due to overcorrection which had subsequently eliminated by

retreatment. Ninety-five percent of patients had no or mild degree of night glare, but 5% had significant or severe night glare. Ninety-six percent of patients had no or mild degree of night halo and 4% had significant or severe night halo. Only 2% patients were disturbed during night driving.

### Wavefront analysis and higher-order aberrations

Due to late set up of the aberrometer, we did not have preoperative wavefront data, but 25 patients had received postoperative aberrometer examination. The postoperative mean spherical aberration was 0.30 ± 0.06 μm and the mean high-order aberration was 0.67 ± 0.10 μm at postoperative 12 months.

### Ablation depth

The comparison of predicted and actual ablation depth at postoperative 12 months is shown in Table 3. The calculation for actual ablation depth was the postoperative corneal thickness subtracted by the preoperative corneal thickness. Paired *t*-test was used to compare the mean value of predicted and actual ablation depth. The mean actual ablation depth was 138 ± 29.4 μm and the mean predicted ablation depth was 140 ± 18.7 μm. The actual ablation depth was well correlated to the predicted depth with no statistically significant difference ($P = 0.46$).

### Optical zone

The planned optic zone of excimer laser PRK was 6.5 mm, and the actual mean optic zone diameter measured by topography was 6.47 ± 0.32 mm.

## Discussion

The improved surface ablation techniques in PRK such as the improvement from broad-beam to flying-spot, enlarged optic zone, MMC use, and the wavefront-optimized software shorten the time of visual recovery, relieve postoperative pain, decrease corneal haze, and avoid complications related to corneal flap. The vast majority of patients have 20/40 or better UCVA within 1 week. PRK has regained its value in refractive surgery in recent years.[4,5] It is proven to be safe and effective in refraction even 10 years after surgery, and its predictability is better in the low myopia group.[7] We find that PRK for high myopia also has a good efficacy. For example, 95.6% of patients have UDVA better than 20/40 and achieve the goal of doing daily activities without wearing glasses 2 weeks after surgery. The UDVA has stabilized 3 months postoperatively and 92% of patients have UDVA better than 20/25 and 79.2% better than 20/20. The subjective satisfaction depends on the difference between postoperative UDVA and preoperative CDVA. Ghadhfan *et al*.[3] used NIDEK EC-5000 Excimer Laser for cases with myopia higher than −6.0D. They reported that 45% of patients have UDVA better than 20/25 and 25% of patients better than 20/20 after PRK.

Bradley *et al*.[8] reported that 81.5% patients have achieved UDVA better than 20/20, comparable to 85% in our study, both rely on identical software of excimer laser. However, the mean preoperative refractive error is – 5.1D in their series much lower than ours at −9.64D. Our result supports that the postoperative UDVA of high myopia is similar to that of moderate myopia.

The percentages in difference of actual and predicted refraction within ± 1D and ± 0.5D are also similar to that reported by Bradley *et al.* in 2007.[8] The earlier studies about PRK for high myopia before 1998 reported only 29%–39% of the cases with the predicted refraction within ± 1D.[9-11] Early devices in different stages with mixed results may be caused by doctors being hesitate to use PRK for high myopia groups. Our study shows that current PRK has a high predictability for high myopia and astigmatism.

In our study, the absolute mean spherical equivalents at postoperative 1, 3, 6, and 12 months range from 0.07D to 0.13D with stable values and no regression. In other long-term studies, the induced refraction stabilizes within 6–24 months after surgery and remains stable afterward.[12-15] Most refractive regression occurs during the first 18 months and correlates significantly to preoperative spherical refraction. The complication rates

**Table 2: Postoperative visual satisfaction (%)**

| Symptoms | No | Mild | Obvious | Severe |
|---|---|---|---|---|
| Dryness | 21 | 63 | 14 | 2 |
| Relying on glasses for far vision | 98 | 2 | 0 | 0 |
| Difficulty at near vision reading | 100 | 0 | 0 | 0 |
| Night glare | 86 | 9 | 5 | 0 |
| Night halo | 89 | 7 | 4 | 0 |
| Night driving disturbance | 94 | 4 | 2 | 0 |

**Table 3: Comparison between actual and predicted ablation depth**

| | Ablation depth | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | <130 um | | | ≥130 um | | | Total | | |
| | *n* | Mean±SD | *P* | *n* | Mean±SD | *P* | *n* | Mean±SD | *P* |
| Actual | 21 | 115.8±18.6 | 0.427 | 52 | 147.5±28.1 | 0.669 | 73 | 138.4±29.4 | 0.464 |
| Predicted | 21 | 119.0±6.9 | | 52 | 149.0±14.6 | | 73 | 140.3±18.7 | |

*P*-value by paired *t*-test. SD = Standard deviation

in our study including undercorrection, overcorrection, or myopic regression are all < 6%. Two eyes (1.9%) lost two or more lines of CDVA including one eye related to corneal haze and the other related to corneal scar. Several methods have been suggested to avoid corneal haze: corticosteroid eye drop, wearing sunglasses,[16] oral Vitamin C,[17] preserving the epithelial flap, irrigating the cornea with cold balanced salt solution,[18] using flying spots instead of broad-beam laser to smooth the ablation surface,[1] and topical MMC.[19] We adapted these suggestions except Vitamin C and flap preservation, as our strategies to prevent cornea haze. All eyes in our study are treated by topical 0.1% fluorometholone (Efemolin®) for 3 months and only one eye (0.96%) has complication of ocular hypertension. The intraocular pressure has recovered to normal range after stopping corticosteroid.

One eye was complicated by corneal scar due to delayed corneal epithelial healing up to 25 days and lost four lines of CDVA. Similar result had been reported by Ghadhfan *et al*.[3] with a complication rate of 2.9%, and all of them were due to delayed corneal epithelial healing. Preoperative detailed examination is recommended for eliminating ocular surface diseases such as dry eye, lagophthalmos, and blepharitis. In this regard, patient's understanding about the potential risks and early treatments of poor corneal epithelial growth are important.

The postoperative mean spherical aberration (SA) was 0.30 ± 0.06 μm, and the mean high-order aberration (HOA) was 0.67 ± 0.10 μm at postoperative 12 months in our study. Since we had no preoperative data, we used historic comparison to understand the magnitude of HOA increase in our study. Khan *et al*.[20] who used the same aberrometer reported that mean spherical aberration was 0.11 ± 0.07 μm and total high-order aberration was 0.92 ± 1.08 μm in high myopic group with average spherical equivalent − 7D ± 1.38D. They found no significant correlation of myopic error with HOA in contrary to Marcos *et al*.[21] who concluded a positive correlation between the two. Using a dual Scheimpflug analyzer, Wang *et al*. reported that mean SA was 0.19 um and HOA was 0.61 um in normal eyes.[22] In the study by Serrao *et al*.,[23] spherical aberration in the high myopia group (−6.30D ± 1.27D) increased significantly from 0.269 um to 0.585 um at post-PRK 1 year; total HOA increased from 0.426 um to 0.847 um (6.0 mm pupil). Similar result was reported by the same group.[24] Compared with above-mentioned data, mean postopeartive SA and HOA measured in this study were not as high, which is consistent with the result that no more than 5% of patients had significant or severe glare or halo. Therefore, PRK-induced increase in SA and HOA in this study may still be acceptable.

The increased high-order aberration, especially the spherical aberration, may affect the optical quality of eyes and induce image distortion.[25,26] Some studies reported that decreased visual quality at night including glare and halo is significantly related to increased high-order aberration induced by laser refractive surgery.[26,27] In our study, 5% of patients have significant or severe night glare, 4% suffer significant or severe night halo, and 2% have experienced difficulty during night driving. Bricola *et al*.[14] reported a 14-year follow-up of a PRK group. In their report, the night vision disturbance described as halo around bright light at night or dusk is about 17% in high myopia patients whose preoperative myopia is more than – 6.0D. However, the surgery was performed during early 1990s with the laser system of a UV 200 excimer laser (Summit Technology Inc., Waltham, Massachusetts, USA). Early laser device may explain for the higher rate of postoperative night disturbance compared with our results. Schwiegerling and Snyder[28] and Mastropasqua *et al*.[29] reported that spherical profiles and small optical zone diameters resulted in degradation of vision under mesopic and scotopic conditions. Introduction of aspheric ablation profiles and larger diameter ablations significantly reduces this problem. It may explain why there are few eyes with glare and halo in our study. The actual ablation depth is highly well compatible with the predicted ablation depth in all the eyes in our study. It confirmed the high predictability of PRK for high myopia correction. Higher myopic eyes have longer ablation time which induces dryer cornea and deeper ablation. Therefore, the diopters input into the excimer laser device must be adjusted according to the nomogram based on empirical values. These adjustments show high accuracy in our study.

Decreased contrast sensitivity after PRK or LASIK is a popular issue. There are several reports trying to explain the mechanism. It was suggested that decreased contrast sensitivity was related to corneal ablation depth, increased aberration of eyeball after PRK and pupil size; it has nothing to do with the degree of corneal haze.[30,31] In our study, the contrast sensitivity generally decreases slightly at postoperative 12 months. In contrast, the study by Wallau and Campos[32] reported an improvement in contrast sensitivity at low spatial frequencies, no change at intermediate frequencies, and a tendency toward decreased values in high spatial frequencies in PRK postoperatively. The mean spherical equivalent refraction error before surgery is – 3.99D in their study. Thorn *et al*.[33] found that simple high myopes have normal contrast sensitivity, while the study by Liou and Chiu[34] reported statistically significant loss of contrast sensitivity in severe myopes (>−12D) with contact lens at 6, 12, and 18 cycles/degree spatial frequencies. Since no preoperative data were available, we cannot determine that mildly decreased

contrast sensitivity at all spatial frequencies in our study was due to decreased retinal function of high myopia or due to the PRK procedure.

## Conclusion

Contrary to the traditional concept, our study finds that PRK is an effective, predictive, stable, and safe treatment for high myopia >−8D with or without astigmatism up to −4D. The incidence of complication is low. The reasons for low incidence of regression may be an improvement of the excimer laser from broad-beam to flying-spot and enlarged optic zone as well as improved treatment profile. All patients who are candidates for LASIK can also be considered for surface ablation, especially those with preoperative thinner cornea or higher risk of corneal flap complications.


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Nil.


### Conflicts of interest

The authors have no any conflicts of interest to declare.

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