Fifteen years follow-up of photorefractive keratectomy up to 10 D of myopia: outcomes and analysis of the refractive regression

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ABSTRACT

Purpose To evaluate outcomes of photorefractive keratectomy up to −10.00 D of myopia and −4.50 of astigmatism and to develop a predictive model for the refractive changes in the long term.

Setting Vissum Corporation and Miguel Hernandez University (Alicante, Spain).

Design Retrospective-prospective observational series of cases.

Methods This study included 33 eyes of 33 patients aged 46.79±7.04 years (range 40–57) operated with the VISX 20/20 excimer laser with optical zones of 6 mm. No mitomycin C was used in any of these cases. The minimum follow-up was 15 years. The main outcome measures were: uncorrected and corrected distance visual acuity, manifest refraction and corneal topography. Linear regression models were developed from the observed refractive changes over time.

Results Safety and efficacy indexes at 15 years were 1.18 and 0.83, respectively. No statistically significant differences were detected for any keratometric variable during the follow-up ($p \geq 0.103$). 15 years after the surgery 54.55% of the eyes were within ±1.00 D of spherical equivalent and 84.85% within ±2.00 D. The uncorrected distance visual acuity at 15 years was 20/25 or better in 60.6% of the eyes and 20/40 or better in 72.73% of the eyes. The correlation between the attempted and the achieved refractions was $r=0.948$ ($p<0.001$) at 1 year, and $r=0.821$ ($p<0.001$) at 15 years. No corneal ectasia was detected in any case during the follow-up.

Conclusions Photorefractive keratectomy is a safe refractive procedure in the long term within the range of myopia currently considered suitable for its use, although its efficacy decreases with time, especially, in high myopia. The model developed predicts a myopic regression of 2.00 D at 15 years for an ablation depth of 130 μm.

INTRODUCTION

It is over 25 years since the first photorefractive keratectomy (PRK) procedure was performed in 1987 by Dr Theo Seiler in Berlin.[1] In October 1995, PRK became the first Food and Drug Administration approved laser treatment for the correction of myopia and myopic astigmatism.[2–4]

In the year 1990, the first laser in situ keratomileusis (LASIK) procedure was performed and this technique started to gain popularity, based principally on the rapid and painless visual rehabilitation of the patients.[5] Also, corneal haze is less prominent after LASIK than after PRK.[6–11] These factors made LASIK the first option for surgeons to correct ametropia for a long period of time.

However, it has been shown that both techniques, LASIK and PRK, are safe, efficient and predictable in correcting myopia.[12] Moreover, despite the previously mentioned disadvantages of PRK compared with LASIK, PRK has its advantages such as lower risk of corneal ectasia after surgery, steeper learning curve and lower financial cost. These reasons have led surgeons to reconsider the use of this refractive technique in recent years.

Although there are some long-term reports about PRK,[12–14] there are very few studies evaluating the outcomes of PRK with follow-up longer than or equal to 15 years.[15 16]

The main purpose of the present study is to analyse the topographical and refractive stability of myopic eyes within the range of ametropia accepted as suitable for this surgery, 15 years postoperatively. In addition, based on the observed outcomes, a model to predict the refractive status in the long term is developed.

PATIENTS AND METHODS

Study design

Retrospective-prospective observational series of cases.

Patients

Thirty-three eyes of 33 patients (13 male and 20 female) aged 46.79±7.04 years (range 40–57) with myopia up to −10.00 D and astigmatism up to −4.50 D were evaluated 15 years after PRK. Data of up to 10 years follow-up were obtained from our databases, while most of the data at 15 years had to be obtained by contacting the patients by phone. At 15 years, there was an important number of dropouts compared with the sample analysed in previous studies with follow-up of 10 years,[13 14] because some of the patients could not be contacted because of changes in address or phone number, because some patients were living abroad or because they declined to participate in the study.

The mean value of the spherical refractive error was −3.92±2.52 (−10.00 to 0.00). The mean value of the cylinder was −1.12±0.87 (−4.50 to 0.00), and the mean spherical equivalent (SE) was −4.16±0.57 (−1.25 to −10.75). The distribution of the refractive error was as follows: 12 eyes (36.36%) had SE less than or equal to −3.00 D, 11 (33.33%) between −3.00 and −6.00 D and 10 (30.30%) higher than −6.00, up to −10.75 D. The mean preoperative pachymetry was 543.68±46.87 (475 to 647) and the ablation depth was 63.99 ±31.37 (13.53 to 135). All the optical zones ablated were 6 mm.

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Preoperative and postoperative examinations

A complete ophthalmological examination was performed preoperatively and postoperatively, including measurement of manifest refraction, cycloplegic refraction, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), slit lamp biomicroscopy, dilated funduscopy, applanation tonometry and corneal thickness using the DGH-500 pachymeter (DGH Technology, Exton, Pennsylvania), or Alcon Ocuscan RxP Ophthalmic Ultrasound System (Alcon Laboratories, Forth Worth, Texas). Visual acuity was measured using a standard Snellen acuity chart at 6 m. Corneal topography was evaluated using EyeSys topographer (EyeSys Corneal Analysis System, Houston, Texas; preoperative to 5 years of follow-up), Orbscan I slit-scanner (Bausch & Lomb; only at 5 years or 10 years of follow-up) and Costruzione Strumenti Oftalmici (CSO) corneal topography system (CSO, Florence, Italy) at 10 years and 15 years follow-up.

To obtain the preoperative measures, patients stopped using contact lenses 4 weeks before the surgery. The follow-up consisted of evaluations at 3 months, 1 year, 2 years, 5 years, 10 years and 15 years.

Inclusion and exclusion criteria

Inclusion criteria for surgery were: patients over 25 years old with stable refraction for at least 6 months before surgery, normal peripheral retina or treated with photocoagulation when necessary, no previous ocular surgery, and no corneal diseases, glaucoma or history of ocular trauma. Exclusion criteria for surgery were: patients under 25 years old, or keratoconus suspect, active ocular or systemic disease likely to affect corneal wound healing, pregnancy and nursing.

Surgical technique

All cases were operated at the same institution (Vissum IOA, Alicante, Spain). The procedure was carried out using topical anaesthesia of oxybuprocaine 0.4%. A 193 nm VISX 20/20B excimer laser, software V.3.2, (VISX, Santa Clara, California, USA) was used. During surgery, patients fixated on the laser's helium-neon fixation light. Optical zones of 6 mm were used. Astigmatism was corrected by sequential ablation with an area of 6.0×4.5 mm. Epithelial debridement was performed up to 7–8 mm using manual debridement. Re-treatments were performed by reablating the stromal bed after manual or laser de-epithelisation. No case of this study received treatment with mitomycin C for haze prevention.

Statistical analysis

For the statistical treatment of the data, V.17.0 of SPSS for Windows (SPSS, Chicago, Illinois, USA) was used. Kolmogorov-Smirnov test was applied for all data samples in order to check normality. When parametric statistical analysis was possible, Student's t test for paired data was applied to assess the significance of differences between preoperative and postoperative data, whereas the Wilcoxon rank-sum test was applied when it was not possible. For the comparison of several related samples the Friedman test was used. The level of significance used was always the same ($p<0.05$). Bivariate correlations were evaluated using Pearson's or Spearman's correlation coefficients, depending on whether normality could be assumed or not.

RESULTS

In table 1 we show the relevant data of the refractive and visual outcomes observed in this series.

Visual outcomes

UDVA (in decimal scale) changed from 0.20±0.45 (range 0.05–0.60) to 0.57±0.27 (range 0.20–1.00) 3 months after surgery ($p<0.001$, Wilcoxon test). UDVA increased significantly from 3 months to the 2nd year after the operation ($p=0.006$, Wilcoxon) and, remained stable during the rest of the follow-up ($p=0.195$, Friedman test).

CDVA decreased from 0.83±0.20 (range 0.40–1.20) to 0.78 ±0.19 (range 0.50–1.00) 3 months after surgery ($p=0.030$, Wilcoxon). During the rest of the follow-up there was a continuous trend towards the improvement of CDVA ($p<0.001$, Friedman test). CDVA at 15 years was significantly better than the preoperative value ($p=0.002$, Wilcoxon). Figure 1A shows the change in Snellen lines at 15 years. At 1 year the safety index was 0.97±0.21 and 69.70% of the eyes gained lines of vision or remained the same while at 15 years 90.91% of the eyes gained lines of vision or remained the same. The safety index at 15 years was 1.18±0.32, significantly higher than the value achieved at 1 year ($p<0.001$, Wilcoxon).

The efficacy indexes at 1 year and 15 years were: 0.79±0.32 and 0.83±0.39, respectively. No statistically significant differences were found between these variables ($p=0.360$, Student's t test for paired samples). As can be seen in figure 1B, 60.6% of the eyes had UDVA equal to or better than 20/25 15 years after the surgery.

Refractive outcomes

The refractive evolution of the sample is shown in figure 2. The mean value of the sphere changed from a preoperative value of −3.92±2.52 D (range 0 to −10.00) to −0.51±1.04 D (range −3.00 to +2.75) 3 months after the surgery ($p<0.001$, Wilcoxon). Refractive cylinder changed from −1.12±0.87 D (range −4.50 to 0.00) to −0.31±0.42 D (range −2.00 to 0.00) and the SE from −4.16±3.96 (range −10.75 to −1.25) to −0.57±0.95 (range −3.50 to 2.38) 3 months after surgery ($p<0.001$, Wilcoxon).

The attempted versus achieved SE refraction is present in figure 3A, B. The predictability at 1 year was $r^2=0.948$ ($p<0.001$), and $r^2=0.821$ ($p<0.001$) at 15 years.

After the surgery, no statistically significant differences were detected in the sphere or the SE during the whole follow-up ($p>0.251$, Friedman test). However, a statistically significant increase in the refractive cylinder was found ($p<0.001$, Friedman test). The comparisons between 3 months and 15 years or 1 year and 15 years showed no statistically significant differences for the sphere or the SE except for the cylinder (see table 1).

The total myopic increase in the sphere during the follow-up was −0.10±0.60 D and −0.61±0.60 in the cylinder. This represents a mean myopic increase of −0.028 D in the SE per year.

Fifteen years after the surgery 54.55% of the eyes were within ±1.00 D and 84.85% within ±2.00 D.

Keratometric changes

The mean keratometry changed from a preoperative value of 44.05±1.34 D (range 41.38–43.68) to 40.90±2.15 D (36.63–44.13) 3 months after the surgery. No significant differences were detected in any keratometric variable during the complete period of the follow-up ($p\geq0.103$, Friedman test) and the comparisons between 3 months and 15 years or 1 year and 15 years did not show any statistical differences either.

Re-treatments

A total of 13 eyes were re-treated (39.39%): during the 1st postoperative year 11 eyes (33.33%) were re-treated; considering

Table 1 Keratometric refractive and visual evolution and comparisons at different moments of the follow-up

Variable	3 months	1 year	2 years	5 years	10 years	15 years	Global comparison (Friedman test. p Value)	3 months–15 years comparison (Wilcoxon test. p Value)	1 year–15 years comparison (Wilcoxon test. p Value)
UDVA									
Mean±SD	0.57±0.27	0.65±0.26	0.73±0.26	0.67±0.27	0.69±0.28	0.70±0.28	0.111	0.090	0.690
95% CI	(0.46 to 0.66)	(0.54 to 0.75)	(0.62 to 0.83)	(0.58 to 0.78)	(0.56 to 0.77)	(0.55 to 0.77)			
CDVA									
Mean±SD	0.78±0.19	0.81±0.18	0.84±0.17	0.84±0.16	0.88±0.17	0.95±0.15	<0.001	<0.001	<0.001
95% CI	(0.68 to 0.84)	(0.71 to 0.87)	(0.75 to 0.90)	(0.78 to 0.90)	(0.81 to 0.95)	(0.90 to 1.00)			
Sphere (D)									
Mean±SD	−0.51±1.04	−0.18±0.60	−0.19±0.66	−0.35±0.70	−0.29±0.81	−0.63±1.17	0.277	0.867	0.283
95% CI	(−0.77 to 0.01)	(−0.32 to 0.20)	(−0.37 to 0.22)	(−0.56 to 0.10)	(−0.53 to 0.15)	(−1.07 to 0.15)			
Cyl (D)									
Mean±SD	−0.31±0.42	−0.21±0.31	−0.27±0.41	−0.55±0.76	−0.57±0.49	−0.80±0.38	<0.001	<0.001	<0.001
95% CI	(−0.58 to −0.18)	(−0.65 to −0.09)	(−0.55 to −0.11)	(−0.80 to −0.25)	(−0.92 to −0.43)	(−1.14 to −0.73)			
Sph Eq (D)									
Mean±SD	−0.57±0.95	−0.32±0.61	−0.38±0.66	−0.49±0.70	−0.46±0.69	−0.93±1.15	0.251	0.213	0.056
95% CI	(−0.96 to −0.19)	(−0.46 to −0.03)	(−0.49 to 0.01)	(−0.79 to −0.20)	(−0.82 to −0.18)	(−1.47 to −0.52)			
K1 (D)									
Mean±SD	40.29±2.21	39.99±2.22	40.20±2.11	40.16±1.93	40.20±1.83	40.12±2.11		0.779	0.172
95% CI	(39.77 to 41.28)	(39.28 to 40.93)	(39.43 to 40.98)	(39.53 to 40.94)	(39.63 to 40.97)	(39.37 to 40.87)	0.103		
K2 (D)									
Mean±SD	41.51±2.17	41.27±2.24	41.50±1.95	41.46±1.77	41.38±1.71	41.26±2.00	0.740	0.556	0.336
95% CI	(40.97 to 42.48)	(40.54 to 42.20)	(40.78 to 42.22)	(40.85 to 42.15)	(40.77 to 42.07)	(40.55 to 41.97)			
KM (D)									
Mean±SD	40.90±2.15	40.63±2.19	40.85±1.99	40.81±1.79	40.79±1.70	40.69±2.02	0.172	0.640	0.140
95% CI	(40.39 to 41.86)	(39.92 to 41.55)	(40.12 to 41.58)	(40.21 to 41.52)	(40.22 to 41.50)	(39.98 to 41.41)			

CDVA, corrected distance visual acuity; KM, mean curvature power; UDVA, uncorrected distance visual acuity.

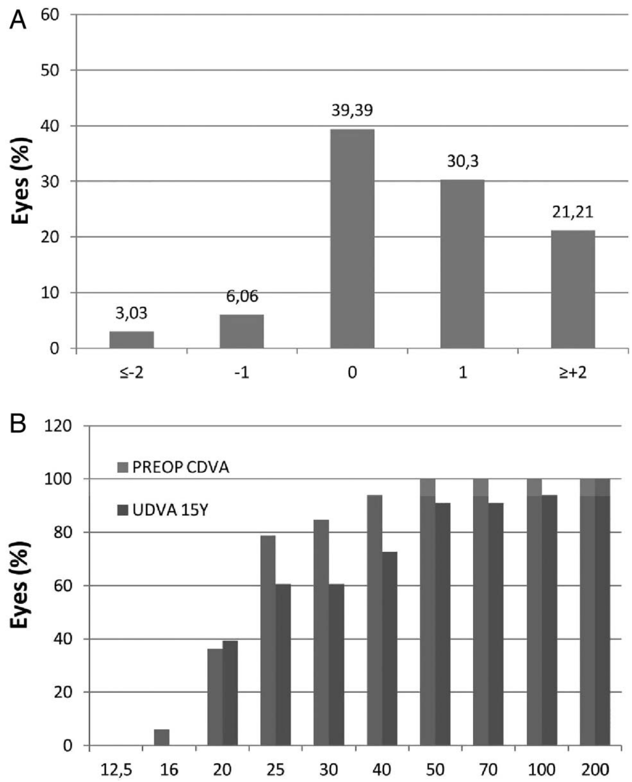


Figure 1 (A) Change in Snellen lines 15 years after photorefractive keratectomy. (B) Cumulative Snellen visual acuity (20/_) at 15 years.

5 years after the surgery, 13 eyes (39.39%) had undergone re-treatment. Out of these 13 eyes, 6 had only one re-treatment, 6 two re-treatments and 1 three re-treatments. After this period of time none of the eyes was re-treated.

Complications related to the surgery

The most frequent complication after PRK was haze. Haze was barely perceptible or traces in all patients except in one case in which it was mild to moderate and persisted 2 years after the surgery. Few other complications were found. One patient developed endothelial pigment dispersion without affecting visual acuity. One patient developed sterile peripheral stromal infiltrates but they resolved spontaneously. No corneal ectasia was detected during the follow-up.

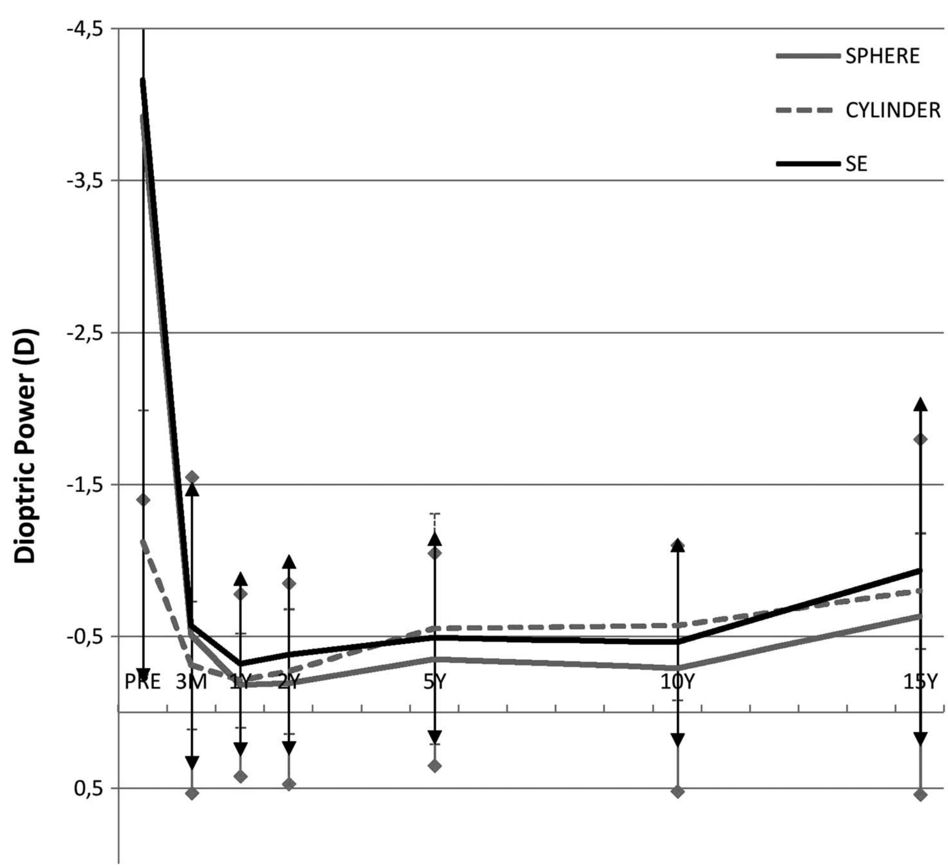
Correlation analysis

The preoperative sphere was significantly correlated with the myopic regression in the SE (r=0.586, p=0.002, Spearman). The ablation depth was correlated in a similar manner with the refractive regression (r=−0.603, p=0.001, Spearman). This is because the preoperative sphere and the ablation depth are also strongly correlated to each other (r=−0.977, p<0.001, Spearman).

Two linear regression models were developed. The first one for the relation between the preoperative sphere and the cylinder and the ablation depth:

$$\text{Ablation depth} = 6.929 - 12.072 \times \text{Preop Sphere (D)} - 2.952 \times \text{Preop Cylinder (D)} \quad (1)$$

Figure 2 Refractive evolution during the follow-up.



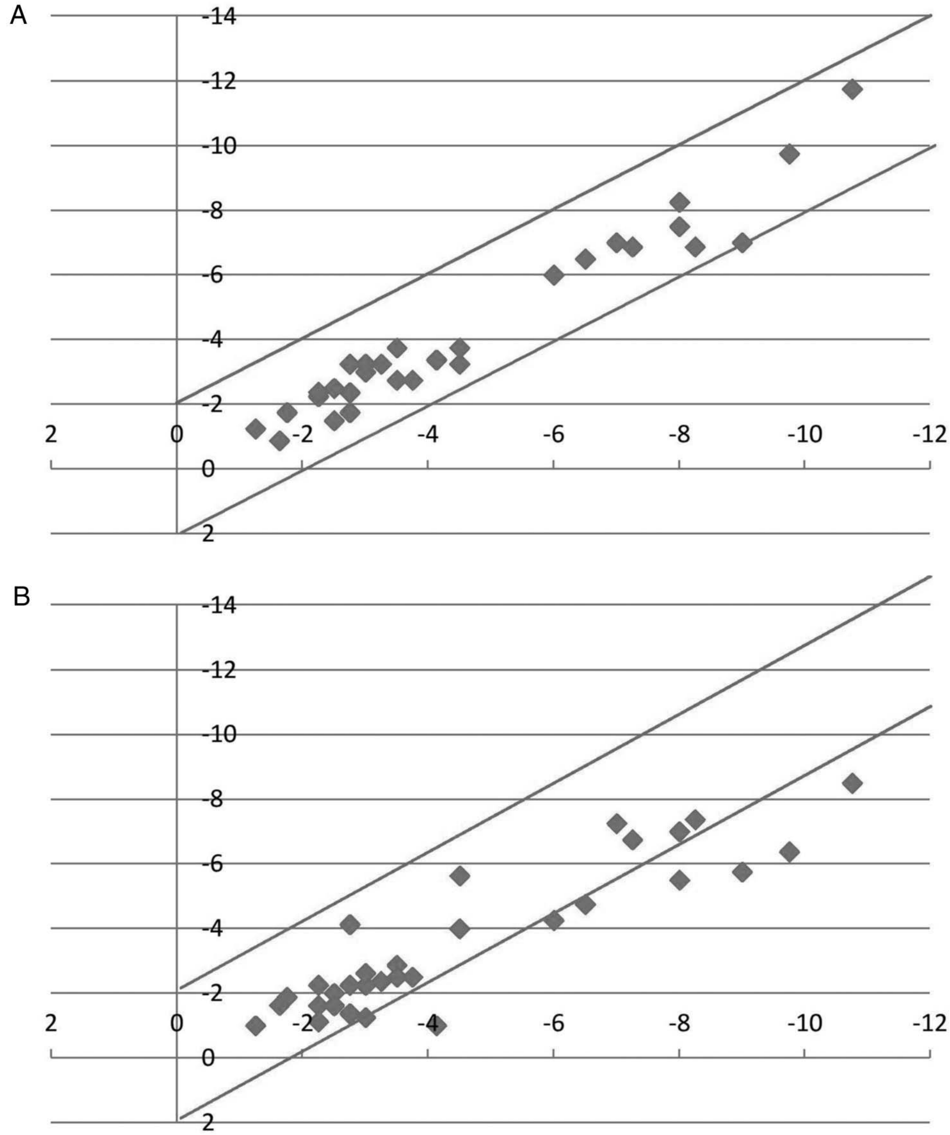


Figure 3 (A) Attempted versus achieved spherical equivalent refraction (D) 1 year after photorefractive keratectomy (PRK). (B) Attempted versus achieved spherical equivalent refraction (D) 15 years after PRK.

Predictability was $R^2=0.969$, $p<0.001$. No influential points or outliers were detected: Mean Cook distance=0.077±0.031. The unstandardised residuals were normally distributed (p=0.200) confirming homoscedasticity of the model. The value of the Durbin-Watson test was 1.993 showing the independence of the residuals. Multicollinearity tests were also examined, providing VIFS (variance inflation factors) equal to 1.187. Low values for the condition indexes were confirmed with a maximum value of 4.332.

This regression model showed an ablation depth of about 12.1 μ for each dioptre of myopia and nearly 3 μ per dioptre of astigmatism for the VISX 20/20 excimer laser for a 6 mm optical ablation zone. This represents around 13.6 μ per dioptres of the SE.

The second linear regression model correlates the regression in myopic regression at 15 years after the surgery and the ablation depth:

$$\text{Sphere regression at 15 years} = 1.781 - 0.029 \times \text{Ablation Depth}\,(\mu) \qquad (2)$$

Predictability was $r^2=0.317$, $p=0.003$.

From equation (1), for a preoperative sphere of −10 D and −5.00 D of astigmatism an ablation depth of 142.41 μ is predicted. If we use this value in equation (2) a regression of –2.35 D is predicted 15 years after the surgery (see table 2).

DISCUSSION

In the present study we confirmed that PRK is a safe technique in the long term for as far as 15 years. This confirms previous studies also with a long follow-up albeit shorter than in our study.[12–14 17–21]

The CDVA increased significantly after the third postoperative month because of the decrease in the corneal haze. The UDVA increased significantly from the 3 month to the 2nd year after the operation (p=0.006, Wilcoxon). Afterwards, there was a slight decrease in UDVA, possibly because of regression and/or increase in lenticular sclerosis.

Regarding predictability of the refraction, the results vary among different studies. This is due, in our opinion, to differences of the populations under study. The preoperative refractive error, age of the patients, optical zone used and duration of the follow-up have an important impact in the postoperative refractive error. In the present study we found that 54.5% of eyes were within ±1.00 D and 84.85% within ±2.00 D, 15 years after PRK.

In a previous study of our investigational group, focused on eyes with myopia higher than 6 D,[14] we found that 58% of eyes

Table 2 Ablation depth and myopic regression 15 years after PRK predicted by equations (1) and (2) derived from Visx 20/20 laser data for an ablation zone of 6 mm

Preoperative sphere (D)	Preoperative cylinder (D)	0.00	−1.00	−2.00	−3.00	−4.00	−5.00
−4.00	Ablation depth (μm)	55.22	58.169	61.121	64.073	67.025	69.977
	Predicted regression 15 years after PRK (D)	0.18	0.09	0.01	−0.08	−0.16	−0.25
−6.00	Ablation depth (μm)	79.36	82.31	85.27	88.22	91.17	94.12
	Predicted regression 15 years after PRK (D)	−0.52	−0.61	−0.69	−0.78	−0.86	−0.95
−8.00	Ablation depth (μm)	103.51	106.46	109.41	112.36	115.31	118.27
	Predicted regression 15 years after PRK (D)	−1.22	−1.31	−1.39	−1.48	−1.56	−1.65
−10.00	Ablation depth (μm)	127.65	130.60	133.55	136.51	139.46	142.41
	Predicted regression 15 years after PRK (D)	−1.92	−2.01	−2.09	−2.18	−2.26	−2.35

PRK, photorefractive keratectomy.

were within ±1.00 D and 78% were within ±2.00 D 10 years after PRK.

In 2012, Guerin *et al*[15] published the results of 39 eyes with myopia up to −7.00 D and astigmatism up to −1.50 D, 16 years after surgery. They reported that 79.5% of the eyes were within ±1.00 D and 94.9% between ±2.00 D. So, the residual spherical error was lower in that study. However, the preoperative refractive error of the patients was lower (in the present study up to −10.00 D of myopia and −4.50 D of astigmatism). Moreover, the optical zone in the study by Guerin *et al* was 5 mm, less than in our study (6 mm). These differences result in a higher mean ablation depth in our group of patients (strongly correlated with the myopic regression). This may explain the differences obtained in the residual refractive error.

Another recent study was developed by Vestergaard *et al*,[16] with high and low myopic eyes and a follow-up of between 13 years and 19 years. They showed that in the low myopia group 72% of eyes were within the range ±1.00 D of spherical error at the end of the follow-up and 47% of the eyes in the high myopia group were within ±1.00 D. Therefore, the average percentage of eyes in this range is not very different from the percentage found in the current investigation (also with eyes with low and high myopia).

Other studies of PRK for moderate myopia with a follow-up of 2 years or less, found that between 40.5% and 90% of eyes were within ±1.00 D after surgery, confirming the variability in the results mentioned.[4 7 22 23]

Long-term studies of myopic regression after PRK for low to moderate myopia reported that the refraction stabilises between 3 months and 6 months, but the time for stabilisation is longer for the higher corrections.[17–19] In our group of patients, the SE was stable between 2 years and 10 years after the surgery. After this time we observed a slight but continuous increase in the refractive error. This refractive change may be associated with keratometric regression and lenticular sclerosis.

We found that the preoperative sphere and the ablation depth were significantly correlated with the refractive regression. The predictive model developed revealed a myopic regression of −0.029 D at 15 years/μ of cornea ablated.

As can be seen in table 2, the refractive regression depends on the sphere and the cylinder. The combination of both parameters must be taken into account to predict the changes in the refraction. Moreover, the quantity of the astigmatism could be a notable limitation for this surgery because a combination of a high sphere with a high cylinder would lead to extreme flattening of one of the meridians.

It should be mentioned that the ablation depth is also related to the size of the optical zone. The larger the optical zone, the greater the ablation depth. The ablation of large optical zones is desirable to diminish effects such as halos and glare as much as possible, but the side effect is an increase in the ablation depth. However, the new generation excimer lasers, based on multiple ablation zones, allow correction of each dioptre of the SE with an ablation of around 15 μm for a standard myopic ablation zone of 6.7 mm. This quantity is greater than that found for the Visx 20/20 (13.6 μ/D of the SE for an optical zone of 6.0 mm) but the difference is not great and leads us to think that the long-term result of PRK with the new generation lasers will not differ greatly from the results of the current study.

Regarding re-treatments, previous studies with a shorter follow-up found a re-treatment rate ranging between 23% and 50% after PRK for moderate myopia.[7 22 24] We found a rate of 33.3% in the 1st year after the surgery and 39.9% 5 years after PRK.

The most common complication after surgery was haze. However, no patients had haze after 15 years and only one showed mild haze after 2 years. In addition, we found a higher incidence of haze in eyes with high myopia. This coincides with the findings of O'Connor *et al*. They reported that most of the eyes with haze were myopic by over −5.00 D.[19] In our study a total of 12 eyes had myopia higher than −5.00 D. Seven of these eyes (58.33%) had haze at some time during the follow-up, while 9 of 21 eyes (42.86%) with myopia lower than 5.00 D had haze at some time. Another study[25] also showed that the risk of haze is greater when the ablation is greater than 80 μm. This is also consistent with the study of O'Connor and the current study.

In conclusion, PRK has been seen in this study to be a safe procedure for the correction of myopia in the long term up to 15 years when performed within the limits of today's standards for the indication of excimer laser myopia surgery. However the efficacy is lower and the rate of complications higher if the ablation depth increases. In mean terms, after 15 years, corneal keratometry was relatively stable and corneal haze was transient and continued to fade over time. Finally, based on the outcomes observed in this investigation, we have developed a predictive model, which may help refractive surgeons to predict the outcomes of PRK for periods of over 5 years.

Contributors design of the study (JLA); conduct of the study (JLA, FAS, AA, PP-G); collection and management of the data (FAS); analysis and interpretation of the data (JLA, PP-G); preparation of the manuscript (PP-G, AA, FAS, JLA); and review and approval of the manuscript (JLA, FAS, AA, PP-G).

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Spanish Ministry of Health, Instituto Carlos III, Red Temática de Investigación Cooperativa en Salud "Patología ocular del envejecimiento, calidad visual y calidad de vida", Subproyecto de Calidad Visual (RD07/0062).

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