A Long-term Study of Photorefractive Keratectomy

12-Year Follow-up

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Objective: To evaluate long-term refractive stability of excimer laser myopic photorefractive keratectomy (PRK).

Design: A long-term (12 years) prospective follow-up study.

Participants: Sixty-eight patients (56.6%) of the original cohort of 120 who participated in the first United Kingdom excimer laser clinical trial underwent detailed clinical assessment at 12 years after myopic PRK.

Intervention: Myopic PRK was performed using the Summit Technology UV 200 excimer laser with a 4-mm ablation zone. Patients were allocated to 1 of 6 treatment groups based on their preoperative refraction. Each group received one of the following spherical corrections: −2, −3, −4, −5, −6, or −7 diopters (D). Patients in each group received an identical treatment, and therefore, emmetropia was not the primary aim.

Main Outcome Measures: Refractive stability, refractive predictability, best spectacle-corrected visual acuity (BSCVA), and corneal haze.

Results: The postoperative refraction remained stable at 12 years, with no significant change in mean spherical equivalent refraction between 1, 6, and 12 years. Seventy-five percent of patients who underwent a −2-D correction and 65% of patients who received a −3-D correction were within 1 D of intended correction at 12 years. Fifty-seven percent of the −4-D group and 50% of the −5-D group were within 1 D, and this was further reduced to 25% and 22% in the −6-D and −7-D groups, respectively. Four percent had residual corneal haze, and 12% had persistent nighttime halos at 12 years. Dry eyes were encountered in 3% of patients, and none of the eyes developed corneal ectasia in the long term.

Conclusions: In myopic PRK, refractive stability achieved at 1 year was maintained up to 12 years with no evidence of hyperopic shift, diurnal fluctuation, or late regression in the long term. Corneal haze decreased with time, with complete recovery of BSCVA. Night halos remained a significant problem in a subset of patients due to the small ablation zone size. *Ophthalmology 2004;111:1813–1824 © 2004 by the American Academy of Ophthalmology.*

In 18 years, excimer laser surgery of the cornea has evolved from a series of experiments in animals to millions of clinical procedures.[1–6] In the early days, excimer laser surgery was performed to treat low to moderate myopia and was exclusively undertaken by photorefractive keratectomy (PRK). This technique saw the emergence of a number of commercial laser systems and treatment algorithms, together with a progressive increase in the size of ablation zones.[7–11] The short-term problems associated with PRK were pain in the first 24 hours; a delay in visual recovery lasting 3 to 5 days during epithelial healing; and a transient loss of corneal transparency, termed *haze*, for a period of weeks to months after surgery.[2,12,13]

In 1991, a major change was seen in the field of refractive surgery with the advent of LASIK.[14,15] This technique was introduced with a number of claimed advantages—namely, an increase in the diopter range of surgery, elimination of pain, and haze.[16] Subsequent to a number of clinical trials, LASIK has not been shown to extend the range significantly, but did remove the complications of pain and haze, thus facilitating a more rapid visual rehabilitation.[17–21] Although the risks associated with LASIK were considered to be low, intraoperative and postoperative flap-related complications are sight threatening and have resulted in permanent loss of best spectacle-corrected visual acuity (VA).[22–26] Ectasia is a further problem of this form of surgery, and the incidence and prevalence of this condition require long-term analysis.[23,25,27] Compilation of such data

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is further complicated by the lack of organized clinical trials.

For any corneal refractive surgical procedure, it is essential to monitor long-term stability and efficacy. To date, the longest prospective follow-up studies are confined to PRK and do not exceed 6 years.[28–32] With only one study at 6 years, possibilities of chronic stromal remodeling and insidious regression could not be excluded. It was therefore thought appropriate to re-evaluate the original cohort of patients who participated in the first PRK trial (1990) in the United Kingdom.[2] The present study evaluates 68 of the original 120 patients followed-up for 12 years (range, 11.8–12.7 years). The long-term refractive stability reported in this study shows no significant changes from that reported at 6 years, and there was no incidence of delayed complications.

Materials and Methods

Study Design

The original PRK trial was initiated in 1990 when 120 patients (age range, 24–60 years) had their eyes corrected up to −7 diopters (D) with a UV 200 Excimer laser (Summit Technology, Inc., Waltham, MA) using a 4-mm ablation zone. To minimize the number of variables in this study, patients were allocated to 1 of 6 groups (n = 20 in each) based on their preoperative myopia. Within each individual group, all 20 patients received identical treatment (i.e., in the 2-D group, all patients had an attempted correction of −2 D). The study aimed to determine the predictability of the procedure and not necessarily to achieve emmetropia. The range of preoperative refraction was −1.5 to −17.5 D (spherical equivalent [SE]).

Ethical committee approval was obtained for the original trial, and patients were requested to sign an informed consent form before treatment and for further follow-up examinations. Full details of patient selection, surgical procedures, and postoperative regimens have been given in previous publications.[2,29,32] The surgical technique, size of ablation zone (4 mm), and postoperative regimens were standardized.

Of the original group of 120 patients, 68 (56.6%) attended the 12-year follow up visit and underwent a detailed ophthalmic examination, previously described.[32] The mean age of the patients who attended the 12-year follow up was 46±9 years (age range, 34–70). There was no significant difference in the mean age of patients between the 6 treatment groups ($P>0.05$). The preoperative mean SE refraction was −4.06±1.73 D. At 12 years, 50 of the 68 patients had had PRK in both eyes, leaving 18 with a control eye. Fifty-two patients (43%) from the original cohort were lost to follow-up at 12 years. This group comprised 30 eyes that had undergone PRK for 2 to 4 D and 22 eyes with 5- and 7-D treatment. The mean preoperative SE refraction of the lost group was −4.42±1.86 D, which did not significantly differ from that of the patient group followed at 12 years ($P = 0.27$).

Laser and Treatment Parameters

The laser used in this study was a Summit Technology UV 200 Excimer laser with an emission wavelength of 193 nm, a fixed pulse repetition rate of 10 Hz, a maximal beam diameter of 4 mm, and radiant exposure of 180 millijoules per cm^2.

Postoperative Evaluation

Postoperative follow-up occurred at 5 days, 2 weeks, 1 month, 3 months, 6 months, 1 year, 1.5 years, 3 years, 6 years, and 12 years. The 1-, 1.5-, and 6-year results have been published previously.[2,29,32] Uncorrected and best-corrected VA (UCVA and BCVA) were measured using Snellen acuity charts. Loss of UCVA and BCVA was recorded. Patients were questioned regarding symptoms of foreign body sensation, dryness, quality of nighttime vision, and contact lens wear. Corneal haze was measured by both objective and subjective methods.[32,33]

Objective Measurements of Corneal Haze

Clinically, corneal haze was assessed subjectively and scored on a scale of 1 to 4, with 4 being the most marked. Because of both interobserver and intraobserver variations in subjective grading of corneal haze, an objective system was developed.[34] This system used a charge-coupled device camera (Photonic, EEV, London, United Kingdom) with cross polarizers to differentiate the effects of haze on backscatter and reflected light, as described in our previous studies. The grayscale values of backscatter were calculated by a computerized digitizer and analyzed as mean ± standard deviation over a time course.

Corneal Topography and Anterior Corneal Aberrations

A topography-guided wavefront analyzer (Keratron, Optikon, Rome, Italy) with a 28-mire cone was used to analyze topography after PRK at 12-year follow-up, and higher order aberrations of the anterior corneal surface in patients with a loss of BCVA were analyzed. The root mean square of total higher order aberrations, spherical aberration, and coma were recorded. The scotopic pupil size was measured using a slit lamp, as previously described.[34–36]

Subjective Questionnaire

Many published studies have used questionnaires to assess patient satisfaction. Given that the aim of this study was not necessarily to induce emmetropia, it was considered that previous questionnaires would be inappropriate. Therefore, in this study a questionnaire was specifically designed to assess night driving vision and satisfaction secondarily. In each case, a visual analogue scale (1–10) was used, with 1 meaning very dissatisfied and 10 indicating extreme satisfaction.

Statistical Analysis

The mean SE (MSE) refraction was calculated taking into account the attempted and achieved correction during each follow-up visit. The change in MSE was plotted over time to determine long-term stability. The difference in mean SE refraction as a function of time was analyzed using paired 2-tailed t tests ($P<0.05$ being significant). The slope of regression curves was studied within the individual diopter groups at time intervals of 0 to 3 months, 3 to 6 months, 6 to 12 months, and 1 to 12 years.

Results

Postoperative Refraction

There was no significant difference in the refractive error between the 6- and 12-year follow-ups (Fig 1). Table 1 shows the MSE

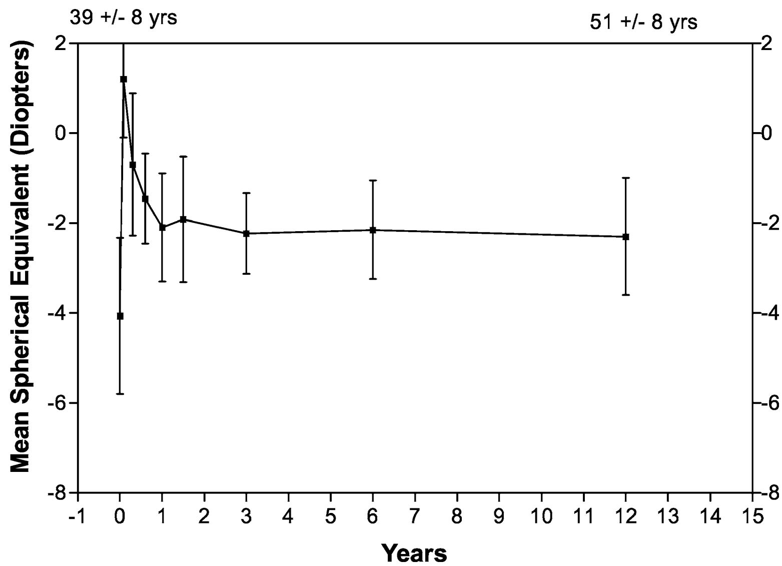

Figure 1. Mean spherical equivalent change after myopic photorefractive keratectomy over a 12-year follow-up period showing refractive stability being achieved at 1 year postoperatively after an early hyperopic shift (0–4 weeks) and rapid regression (3–6 months), with no significant change in refractive stability between 1 and 12 years. The error bars represent ±1 standard deviation.

refraction achieved at 1 and 12 years after the operation in the individual treatment groups. The refractive stability in individual treatment groups is shown in Figure 2, and the predictability of postoperative MSE at 12 years is shown in Figure 3 and Table 2. Although these data demonstrate remarkable stability over a 12-year period, the regression curve was biphasic, with a much steeper slope within the first postoperative year (Table 3). It can be seen that the magnitude of regression was related to the height of the hyperopic shift, which in turn correlated with the value of attempted myopic correction. At 12 years there was no significant change in the percentage of patients achieving ±1 D of their attempted correction in any of the groups when compared with the 6-year data (Fig 3).

In the 18 patients who had undergone surgery in one eye, 7 patients (40%) had adapted to monovision successfully and were independent of spectacles for both distance and near vision. These patients had unaided VAs of 20/32 or more in the operated eye and <2 D of anisometropia between the eyes.

At 12 years, 6 patients (preoperative myopia range, 6–10 D) who had undergone unilateral PRK had evidence of myopic progression (1–3.2 D) in the unoperated eye. This late myopic progression had occurred between the ages of 28 to 36 years. It is interesting that one of these patients was newly diagnosed at this follow-up to have syndromic myopia (Saethre–Chotzen syndrome). This individual should have been excluded from the initial study, given the requirement for no ophthalmic pathology. Over the period of 1 to 12 years, this individual had 3 D of myopic progression in both operated and unoperated eyes.

Table 1. Mean Spherical Equivalent (MSE) Refraction at 12 Years in 6 Treatment Groups (2–7 Diopters [D])

Diopter Groups	No. of Eyes	Postoperative MSE (1 yr)	Postoperative MSE (12 yrs)	*P* Value
2 D	8	−0.48±0.8	−0.30±1	0.78
3 D	20	−0.93±0.6	−1.03±0.6	0.59
4 D	7	−2.1±1.2	−2.30±1.4	0.79
5 D	8	−2.2±1.3	−2.50±1.1	0.56
6 D	16	−2.4±1.8	−3.15±2.07	0.26
7 D	9	−4.1±1.4	−4.47±1.6	0.61

Unaided and Best Spectacle-Corrected Visual Acuity

At 12 years, 64 eyes (94%) had BCVA better than or equal to preoperative BCVA (Fig 4). The gain in Snellen lines reported during the 6-year follow-up was retained during this study. Eight eyes (11%) had retained the gain in 1 Snellen line, and a 2-line gain was seen in 3 eyes (4%). Similarly, the patients who had lost lines had no further loss of lines in the interim period between the 6-year and present follow-ups, with one eye (1.4%) having a 2-line loss and 3 eyes (4%) a 1-line loss of BCVA. It should again be emphasized that emmetropia was not an aim of the original study, and therefore, a significant group of patients (66%) were dependent on spectacles or contact lenses, even though they had achieved the full attempted correction.

Corneal Haze

The loss of corneal transparency, termed *haze*, was noted in all treatment groups in the immediately postoperative period. Objectively, haze increased to a maximum between 3 and 6 months, after which it declined rapidly until 1 year and slowly thereafter until 6 years, with little further change up to 12 years (Fig 5). At this follow-up, 64 (94%) eyes had clear corneas, and none of the patients had developed late haze or worsening of haze. At 12 years, 1 of 68 eyes had a subjective haze grade of 1, and 3 eyes had a grade of 0.5. Visual acuity was retained in each of these eyes, and there was no loss of BCVA.

Corneal Topography and Higher Order Aberrations

All patients showed a marked change in the diopteric value between the central 4-mm ablation zone and the peripheral unablated cornea (Fig 6). This topographic change was seen in all 6 treatment groups, and the corneas showed little evidence of significant re-

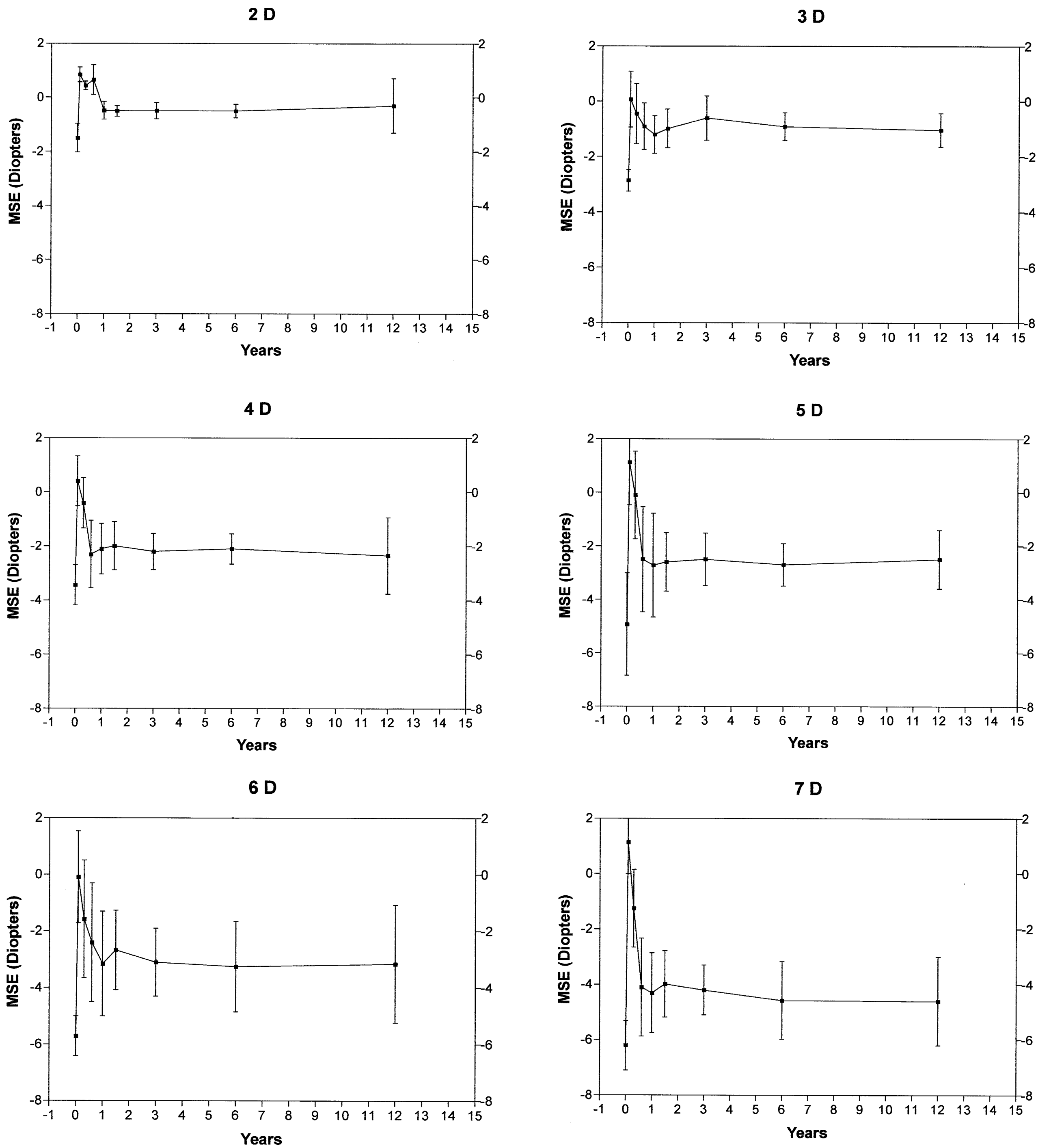

Figure 2. Mean spherical equivalent (MSE) change (±1 standad deviation) in 6 individual treatment groups (2–7 diopters [D]) demonstrating a progressive increase in early hyperopic shift and refractive regression with increasing diopter corrections up to 1 year. Refractive stability was achieved in all treatment groups between 6 and 12 months and maintained thereafter for up to 12 years.

modeling as the result of wound-healing processes. Although the rate of change of diopter power was smaller in lower order correction (−2 D) than in high myopic correction (−7 D), the difference between the ablated and unablated corneas was readily apparent (Fig 7). Although refraction showed no measurable change in astigmatism between preoperative and postoperative examinations, all eyes showed some degree of asymmetry within the ablated zone, with a bowtie distribution in the horizontal plane.

On evaluation of lost lines, the single eye with a 2-line loss had a decentered ablation that resulted from a progressive tilt in the visual axis during surgery. The corneal topography confirmed the decentered ablation pattern, and the corneal wavefront revealed an increased higher order root mean square of 1.6 μm, of which 66% was attributed to increased coma (1.1 μm). This eye had a subjective haze of 0.5 (objective score of 26 grayscale units). The 2 eyes that had lost 1 line of BCVA had irregular astigmatism, with

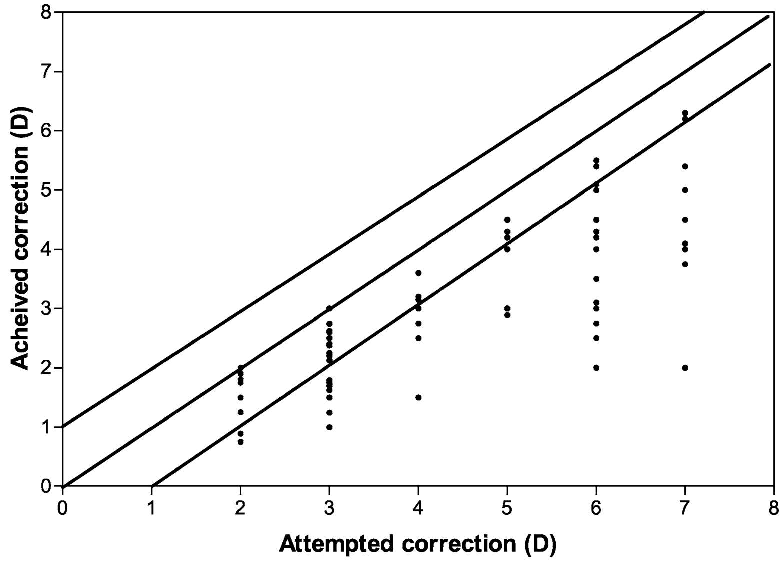

Figure 3. Predictability of postoperative refraction at 12 years after photorefractive keratectomy showed a decreasing percentage of eyes within 1 diopter (D) with increasing diopter corrections. No significant change in predictability was observed between 1 and 12 years.

an increased higher order root mean square (1.4 and 1.56 μm) on wavefront analysis. The posterior segment and the lens were normal, and no haze was recorded in these eyes. Although full astigmatic spectacle correction was given postoperatively, the residual irregular astigmatism that could not be corrected by spectacles or contact lenses resulted in a 1-line loss of BCVA in these 2 eyes.

Night Vision after Photorefractive Keratectomy

The number of patients who had night vision disturbances at 12 years did not differ significantly from that at 6 years, with 8 patients (12%) experiencing problems. The symptoms described by these patients were halos during night driving or while looking at streetlights at dusk. However, all 8 patients reported subjective improvement in their night vision over the 12-year follow-up period. The age range of symptomatic patients was 36 to 48 years at final follow-up, and their scotopic pupil size averaged 6.6±0.35 mm (range, 6–7 mm). Within this group, patients who had undergone high myopic corrections had more debilitating halos than those who had <4-D corrections. Two patients reported improvement in symptoms while wearing myopic spectacle correction, and one of them used diluted pilocarpine 0.5% to relieve the symptoms.

Table 2. Long-term Refractive Predictability of Photorefractive Keratectomy Using a 4-mm Ablation Zone

Refractive Predictability	No. of Eyes (%) (n = 68)
±1 D	33 (48)
±2 D	56 (82)
±3 D	62 (91)
±4 D	68 (100)

D = diopters.

Slit-Lamp Evaluation

The integrity of the cornea was well preserved in all 68 eyes, and there was no evidence of ectasia or progressive thinning of the central cornea. Four patients (6%) complained of occasional foreign body sensation in the operated eye; 2 of the 4 (3%) had a Shirmer positive test. None had epithelial stippling or a history of recurrent corneal erosions. Subepithelial iron lines in the inferocentral cornea just below the treatment zone were apparent in 10 (15%) eyes, but VA was unaffected. Two patients, 68 and 70 years old, showed evidence of age-related nuclear sclerosis, but none had developed retinal tears or macular pathology. The intraocular pressure measured by Goldmann applanation tonometry was within normal limits (<21 mmHg) in all 68 eyes, including the 2 eyes that had a transient steroid-induced rise in the immediately postoperative period.

Satisfaction Score

At the current follow-up, 51% of patients were extremely happy with the outcome of PRK, whereas 15% (10 patients) were dissatisfied. This comprised 8 patients (12%) who had night vision disturbances, the patient with one eye with decentered ablation, and a patient with one eye with significant regression.

Discussion

This study addresses the vital issue of long-term refractive stability in a cohort of patients who underwent myopic PRK

Table 3. Early and Long-term Refractive Shift after Low and High Myopic Photorefractive Keratectomy

Diopter (D) Groups	0–3 mos	3–6 mos	6–12 mos	1–12 yrs
−2 D	4.68±4.5	−2.5±1.3	−0.6±0.2	−0.3±0.14
−7 D	10.6±8.7	−7.4±7.5	−0.52±0.5	−0.9±0.3

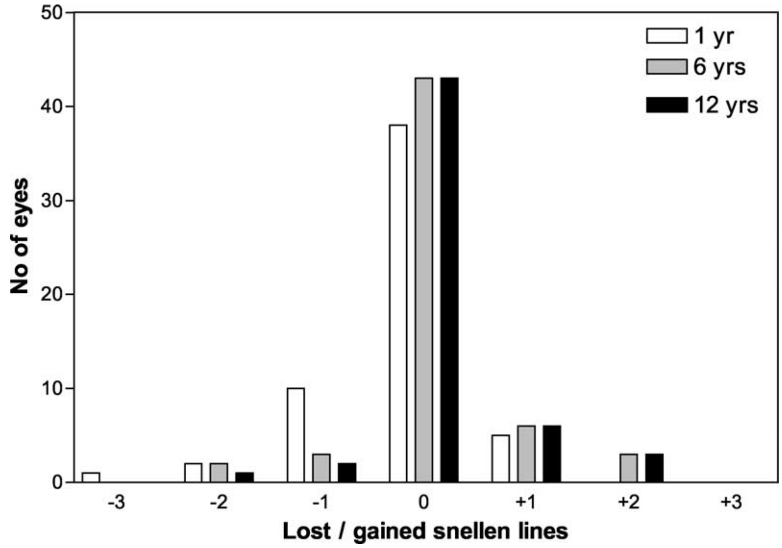

Figure 4. Best spectacle-corrected Snellen acuity, showing gradual improvement in eyes with lost lines between 1, 6, and 12 years and no loss of gained lines over 12 years.

in 1990 with a 4-mm ablation zone using a first-generation algorithm.

Long-term Refractive Stability

The progression of refractive change in the immediately postoperative and early postoperative periods has been reported in previous studies at 1.5- and 6-year follow-ups.[29,32] In summary, these studies demonstrated that (1) all ablations were accompanied by a hyperopic shift; (2) the magnitude of the hyperopic shift increased with the magnitude of attempted correction; (3) there was a period of regression that compensated for the hyperopic shift that stabilized between 3 and 6 months, with the time longest for higher order corrections; (4) the standard deviation of the postoperative refractive outcome increased with an increase in attempted correction; and (5) no significant further regression was encountered between 1.5 and 6 years. These observations have been confirmed by other studies of PRK (follow-up range, 1–5 years), which have shown that refractive stability was achieved between 6 months and 1 year and maintained thereafter for up to a period of 5 years.[21,31,37,38] Since the early days of PRK, the possibility of long-term regression, persistent haze, and a putative decrease in biomechanical strength have been cited as progressive or late-stage complications and have identified a need for long-term studies.[39,40] The present study has shown that the postoperative refraction continues to be stable for up to 12 years. More importantly, there was no significant evidence of late regression or progressive hyperopic shift. These observations infer that chronic stromal remodeling and corneal ectasia are unlikely events in PRK. The findings were in contrast to those of the prospective evaluation of radial keratotomy trial, which showed a progressive hyperopic

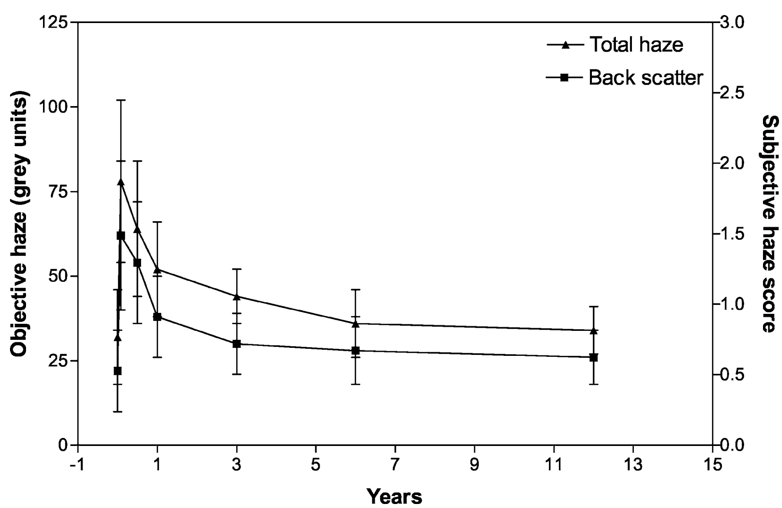

Figure 5. Objective and subjective haze scores (mean ± 1 standard deviation) decreased rapidly between 6 and 12 months, with further gradual reduction up to 3 years. There was no evidence of a late-onset increase in corneal haze between 1 and 12 years.

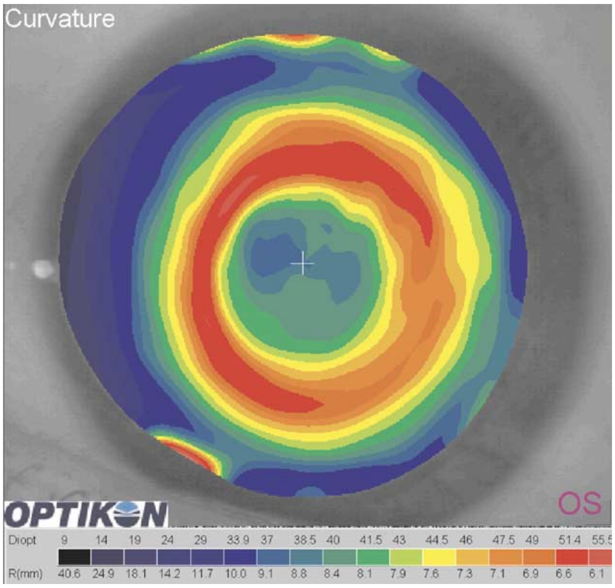

Figure 6. Corneal topography after photorefractive keratectomy (−6 diopters) with a 4-mm diameter excimer laser beam showing the curvature map with central flattening and an abrupt diopter change at the edge of the 4-mm ablation zone to unablated midperipheral cornea at 12 years. OS = left eye; R = radius of curvature.

shift manifesting at 5 years postoperatively.[41] The 12-year results on refractive stability (Figs 1, 2) are reassuring for refractive surgeons who undertake surface ablation including PRK and laser epithelial keratomileusis (LASEK).

For any elective procedure, there is a requirement that the desired end point should be achieved in a predictable fashion, and the effect should be maintained over a long period of time without incurring late-phase secondary events. Photorefractive keratectomy was monitored in a comprehensive fashion in the early phases before Food and Drug Administration approval. The regulatory interest resulted in several trials, which demonstrated predictability and stability up to a period of 3 years.[11,29,30] Such reports were extended with follow-up at 6 years[32] and, in the present case, 12 years. By contrast, the somewhat faster regulatory approval process of LASIK resulted in fewer peer-reviewed studies of predictability and very few publications on stability. The 2-year studies on stability are further complicated by the inclusion of patients with higher preoperative refractive errors.[26] In summary, although millions of LASIK procedures have been performed worldwide since 1990, there is only one long-term study that reports the outcome at 6 years.[42] This study, by Sekundo et al, showed a trend, though nonsignificant, towards myopic regression at 6 years, with 46% of the eyes within 1 D. The mean preoperative myopia in their group was −13.65 D. A trend towards significant myopic regression was reported by Han et al at 2 years in a study attempting to treat high myopia (−9 to −25 D).[43] By contrast, other LASIK studies with preoperative myopia of <6 D have reported refractive stability achieved at 3 to 6 months and sustained to 2 years.[26] The American Academy of Ophthalmology, evaluating randomized trials comparing LASIK and PRK, found no significant differences in safety and efficacy between the procedures in the treatment of low to moderate myopia at 2 years.[26] Our study is important in this perspective in that it shows refractive stability up to 12 years after PRK. Such evidence is presently unavailable for LASIK.

The mean age of the present cohort of patients at 12 years was 51±9 years, and therefore, the natural history of age-related refractive changes needs to be considered when assessing refactive stability (Figs 8–10).[44,45] In a cross-sectional study, Bengtsson and Grodum had demonstrated a true hyperopic shift of 0.6 D every 10 years between 50 and 70 years of age.[46] A similar trend of hyperopic shift between 50 and 65 years of age, followed by myopic drift after 65 years, was demonstrated in the Blue Mountains Eye Study.[47] In a study comprising myopic individuals, a myopic drift of −0.39 and −0.29 D was encountered in the third and fourth decades, respectively, and the hyperopic shift became apparent thereafter until 60 years.[48] In analyzing the refractive stability of PRK in 3 age groups (30–40, 40–50,

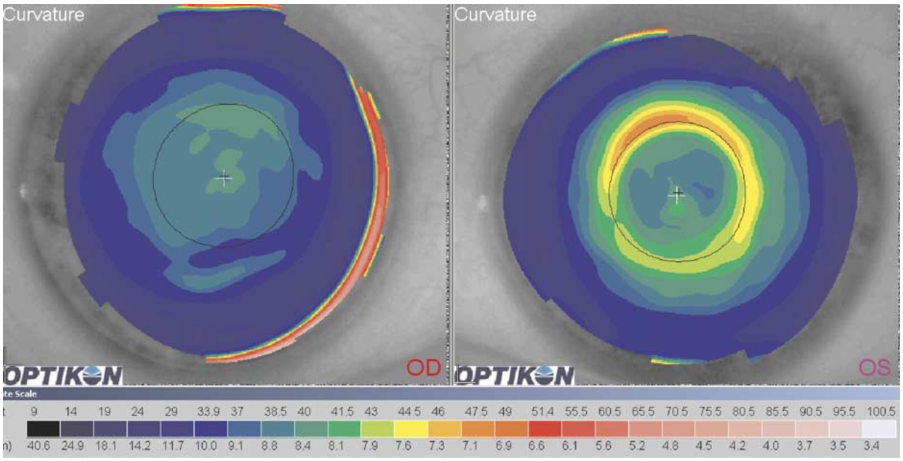

Figure 7. Topography curvature maps showing a decrease in magnitude of diopter (D) change at the edge of the ablation zone in a −3-D treated right eye (OD) relative to a −6-D treated left eye (OS), which correlated with induced spherical aberrations measured by a topography-based wavefront analyzer.

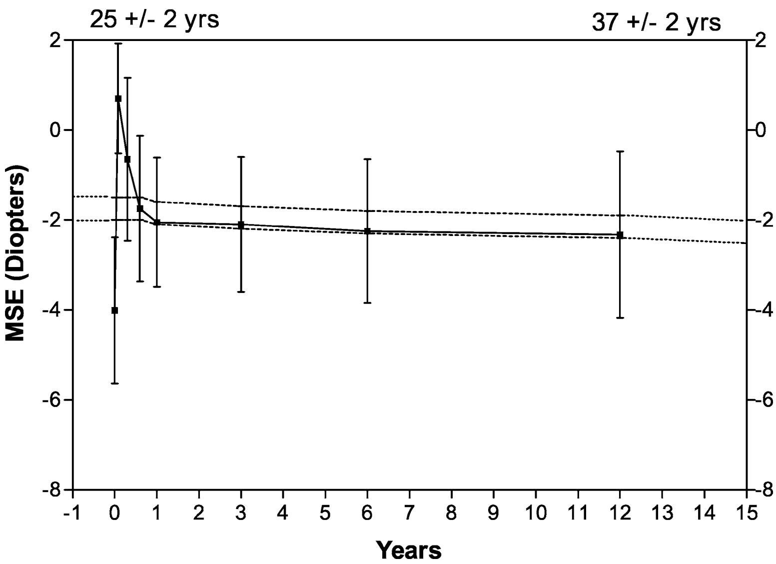

Figure 8. Postoperative mean spherical equivalent (MSE) change (±1 standard deviation) in photorefractive keratectomy (PRK) in patients 30 to 40 years old showing a mean myopic regression of −0.32 diopters between 1 and 12 years (*P*>0.05). The long-term refractive drift after PRK was within the normal age-related refractive change observed in the third decade of the population (dotted lines).

and 50–60 years), the present study found a similar refractive change of −0.32 D in the 30- to 40-year age group (Fig 8), −0.08 D in the 40- to 50-year group (Fig 9), and +0.2 D in the 50- to 60-year group (Fig 10) over the 12-year period. Although the magnitude of hyperopic shift in the 50- to 60-year group was minimal (0.2 D), the possibility that this reflects a summation of age-related hyperopic shift in the presence of myopic regression could not be excluded. Further considerations in monitoring long-term refractive change are the age-related keratometric change from with-the-rule to against-the-rule astigmatism and lenticular changes that could result in changes in measured refractive outcome. It is reassuring that all data points of patients in the 3 age groups fall within the range of the normal aging population (Figs 8–10).

Although myopic progression is common in the first 2 decades of life, some measure of late myopic progression in comparison to myopic regression after surgery was obtained from 6 of 18 patients who had the procedure in only one eye. There was progression of myopia in both the operated and unoperated eyes of patients who had undergone unilateral PRK. In bilateral cases, this could have been misinterpreted as late regression. This is particularly a helpful observation, as any potential change in myopia due to late progression could confound follow-up studies.[48] In summary, the possibility of myopic progression should be con-

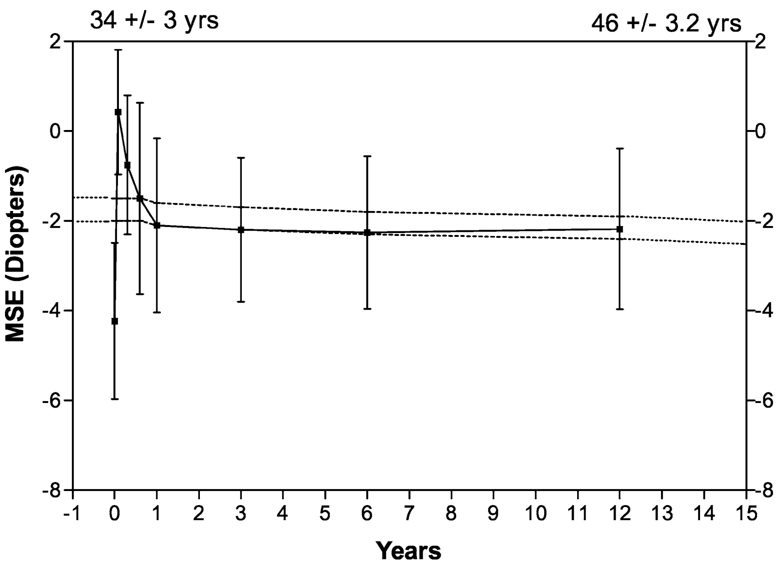

Figure 9. Postoperative mean spherical equivalent (MSE) change in photorefractive keratectomy in patients 40 to 50 years old showed a mean myopic regression of −0.08 diopters between 1 and 12 years (*P*>0.05), which was within the normal range observed in population-based studies (dotted lines).

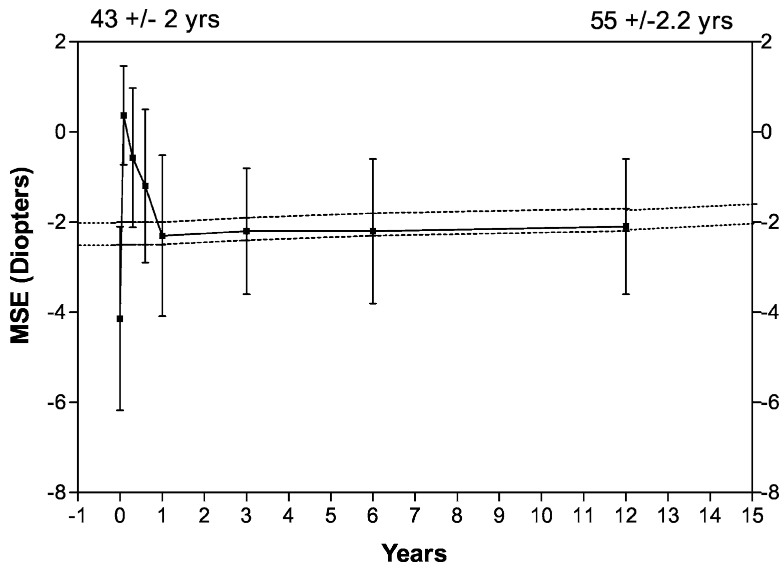

Figure 10. Postoperative mean spherical equivalent (MSE) change in photorefractive keratectomy in patients 50 to 60 years old showed a mean hyperopic shift of +0.2 diopters (D) between 1 and 12 years ($P>0.05$). Dotted lines indicate the normal age-related hyperopic shift (+0.6 D) seen in the fifth decade of the normal population.

sidered and relayed to patients giving informed consent for refractive surgery, even in older myopic individuals.

Visual Outcome

In the present study, in which the attempted correction was between 2 and 7 D, there was no significant change in BCVA between the 6-year and 12-year follow-up periods. By contrast, in the only long-term LASIK study,[42] Sekundo et al had reported an increased number of subjects with a ≥2-line loss of BCVA at 6 years relative to 1 year postoperatively. These results show that BCVA achieved in the early postoperative period after LASIK could be compromised in the long term by the late onset of complications related to the stromal flap, interface, or biomechanical strength of the cornea. In summary, BCVA after PRK improved with time.

In those patients who had undergone unilateral treatment, there was good satisfaction with monovision. This supports published studies demonstrating the acceptability of monovision in patients in whom the occupational need for binocularity was minimal.[49–51] A further confirmation was that monovision became more desirable in presbyopic years, and there was no untoward effect on quality of sight or life in these patients.

Corneal Aberrations

The anterior corneal surface contributes to 80% of the higher order aberrations after corneal refractive surgery, with the posterior corneal surface and lens playing a negligible role.[32,52] Topography-based corneal wavefront analysis of eyes with BCVA loss (4%) showed increased higher order aberrations (coma, trefoil, irregular astigmatism). None of the eyes that had lost lines had haze measurements greater than grade 0.5.

Patient Satisfaction

Although objective measurements of various aspects of image formation are the current criteria for comparing data at different time intervals, between techniques and clinics, they do not necessarily reflect patient perception of the outcome. Several studies have been undertaken to determine patient satisfaction, and all of these have involved some form of questionnaire. Good examples of such data collection systems are those published by Lawless and Brunette et al.[53–55] These were designed primarily to determine patient satisfaction, with emmetropia as the goal. Emmetropia was not the primary aim of the procedures undertaken in this study, and therefore, an abbreviated questionnaire was used. However, extreme satisfaction, as measured by this system, was scored only by patients in whom UCVA approximated to emmetropia.

Late Complications

No late-stage complications were found in this study. The only negative change was that 2 patients were found to have dry eyes at 12 years (Table 4). Although dryness was not a problem in PRK eyes, it is clearly a problem in patients undergoing LASIK.[22,56,57] The major problem of small-zone PRK was an increased percentage of patients with significant night vision disturbances. This was noticed at all follow-up visits, with 10%, 12%, and 12% reporting troublesome halos at 1.5, 6, and 12 years, respectively. The origin of night vision disturbances after PRK has been addressed in previous publications.[35,36,58] It has been shown that starburst symptoms resulted from cornea haze, and that halos were myopic blur circles caused by an untreated paracentral area of the cornea in the presence of large pupils. A recent study has implicated other factors such as age, attempted correction, optical zone, and postoperative SE as the major risk factors for night vision complaints after

Table 4. Long-term Complications after Photorefractive Keratectomy

Complication	Immediately Postoperative	3–6 mos	1.5 yrs	6 yrs	12 yrs
Decentered ablation	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)
Infection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Raised IOP		8 (12%)	0 (0%)	0 (0%)	0 (0%)
Halos		53 (78%)	7 (10%)	8 (12%)	8 (12%)
Haze		62 (92%)	9 (13%, grade 1)	5 (7%, grade 0.5)	3 (4%, grade 0.5)
Dry eyes		0 (0%)	0 (0%)	0 (0%)	2 (3%)
Iron lines				9 (14%)	8 (12%)

IOP = intraocular pressure.

LASIK.[59] Interestingly, night vision complaints were not correlated to pupil size in this study. In our study, though there was a marked resolution of starbursts at 1 year postoperatively, halos persisted in a minority of patients. During the present follow-up, all symptomatic patients reported improvement in symptoms over time, and none had worsened. This could be attributed to factors such as age-related decrease in pupil size and cortical and retinal adaptation. Corneal haze decreased in intensity over time, with maximal resolution in the first year. Slit-lamp evidence of haze (grade 0.5) was seen in 4 eyes at 12 years, and none of the patients developed late haze or worsening during the follow-up. Epithelial iron lines are an interesting but harmless finding in 12% of the eyes. The likely mechanism seems to be the deposition of iron pigments derived from the tear film in the subepithelial layers.[32] Ocular foreign body sensation was reported in 7% of cases at 12 years, relative to 16% at 18 months. It is encouraging to note that 46% of patients were able to wear contact lenses with no untoward effects. None of the patients had retinal, lens, or corneal side effects that could be attributed to ultraviolet exposure.

During the early years, PRK was performed with a 4-mm ablation zone to conserve stromal tissue. Over the years, enlargement of the ablation size had not only minimized nighttime glare but had also resulted in less postoperative hyperopic shift, less regression, and better refractive predictability.[9–11] Since the original trial began in 1990, the observations made on this cohort of patients have paved the way for a number of prospective studies, including ones on the role of topical steroids and local anesthetic use in refractive surgery.[7,60–63] Based on the initial results, there have been a number of changes to the treatment algorithms to improve predictability. A prospective randomized trial to investigate the presumptive advantage of increasing ablation zone size clearly showed better predictability in 5- and 6-mm zone groups at 1 year.[11] The long-term follow-up of these patients relative to the 4-mm group will be reported in a subsequent article. In present-day practice, improvements in treatment algorithms and laser delivery and enlargement in ablation sizes have all improved predictability and reduced scatter of refractive outcome after surface ablation.[56,64–68] In a randomized trial comparing PRK and LASEK,[66] Autrata et al recently reported a predictability of $\pm$1 D in 91% of PRK patients and 92% of LASEK patients in a 2-year follow-up study. Thus, predictability of PRK continues to improve in patients undergoing modern surface ablative techniques in the treatment of low to moderate myopia.

In conclusion, we have shown that refractive stability was maintained for up to 12 years in the treatment of mild to moderate myopia. There was no evidence of progressive time-dependent hyperopic shift, late regression, or late-onset corneal haze after PRK. Corneal haze was transient and resolved by 1 year in a majority of patients and continued to fade with time. There were no sight-threatening complications in this study, although a small group of patients were troubled by nighttime glare as a result of the 4-mm ablation zone.

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