Results of Excimer Laser Photorefractive Keratectomy for the Correction of Myopia

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Purpose: This report summarizes the authors' 3-year experience with excimer laser photorefractive keratectomy on 240 eyes of 161 patients.

Methods: With constant laser emission parameters, nitrogen flow across the cornea was used on 79 eyes, whereas 161 eyes had no nitrogen flow. Of the 240 eyes, 74 were operated on without suction ring fixation. Postoperative pain management included patching and oral analgesics in 77 eyes and the use of topical diclofenac or ketorolac and a therapeutic soft contact lens in 163 eyes. Follow-up ranged from 1 month (206 eyes) to 36 months (10 eyes).

Results: At 3 months, 88% (144 eyes) had uncorrected visual acuity of 20/40 or better; 86% (151 eyes) had corrected visual acuity to within ±1 diopter of intended correction, and 10% (17 eyes) lost two or more lines of best-corrected visual acuity. At 12 months, 89% (122 eyes) achieved uncorrected visual acuity of 20/40 or better, 79% (115 eyes) had corrected visual acuity to within ±1 diopter of intended correction, and 4% (6 eyes) lost two or more lines of best-corrected visual acuity. At 24 months, 92% (44 of 48 eyes) had uncorrected visual acuity of 20/40 or better, 86% (44 of 51 eyes) had corrected visual acuity to within ±1 diopter of intended correction, and 5% (2 eyes) lost two or more lines of best-corrected visual acuity. At 36 months, 90% (9 eyes) achieved an uncorrected visual acuity of 20/40 or better, 90% (9 eyes) had corrected visual acuity to within ±1 diopter of intended correction, and no eyes lost two or more lines of best-corrected visual acuity.

Conclusions: The results obtained with one procedure are within accepted standards of accuracy for refractive surgery, and there is the potential for refinement of the final optical correction. Complication rates are low and are not vision threatening. They included increased intraocular pressure, epithelial "map dot" changes, and recurrent corneal erosion syndrome, "central islands," and others. Photorefractive keratectomy appears to be a safe procedure over the short and medium term.

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For the last 3 years, several centers in the United States and worldwide have been evaluating the 193-nm argon-fluoride excimer laser for correcting myopia with photorefractive keratectomy (PRK).[1–8] Since October 1990, our group at Cedars Sinai Medical Center has taken part in clinical trials of PRK, guided by the United States Food and Drug Administration, under an Investigational Device

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Exemption. Our group participated in phases IIb and III of the trials using the Visx Model Twenty-Twenty excimer laser (Santa Clara, CA). This report encompasses the results obtained over the last 3 years on a sample of 240 eyes of 161 patients. We previously reported our 2-year results on 160 myopic eyes of 128 patients.[6]

Patients and Methods

Our previous report provides a detailed description of the methods used in this clinical trial. Emphasis will therefore be made on any changes in methods that occurred since the last report.[6] The methods of patient selection and of preoperative and postoperative evaluation remain unchanged.

Patient Population and Follow-up

On the 161 patients who participated in the study, 240 PRKs were performed since October 1990. Included in the study were 85 men and 76 women, ranging in age from 19 to 70 years (mean age, 39.8 years). Three patients (3 eyes) were lost to follow-up. This report includes a 1-month follow-up on 206 eyes, a 3-month follow-up on 177 eyes, a 6-month follow-up on 189 eyes, a 12-month follow-up on 149 eyes, a 24-month follow-up on 59 eyes, and a 3-year follow-up on 10 eyes. A ±2-week window is allowed for performing a follow-up visit on a given patient. This explains the discrepancy in the number of eyes followed at various time periods. A total of six investigators performed the procedures. Patients were recruited from the investigators' practices and with the aid of advertisements in local newspapers, the contents of which followed Food and Drug Administration guidelines.

Eye Fixation

A handheld suction ring initially was used during ablation to stabilize the globe with mild suction and to provide nitrogen gas flow across the cornea. With the use of the suction ring and nitrogen flow, 79 eyes underwent the procedure. Due to the concern that excessive corneal haze might be related to the flow of nitrogen,[9] the remaining 161 eyes were operated on without nitrogen flow. In addition, 74 eyes underwent the procedure without the use of the suction ring and with total dependence on patient fixation during the procedure.

Surgical Technique

The laser was calibrated by ablating a polymethylmethacrylate target, and the operative parameters were entered into a computer with proprietary software, as previously described.[6] The patient received several drops of 0.5% tetracaine before being brought to the procedure room. The patient was placed in the supine position, prepared for surgery, and draped, and a wire lid speculum was placed. The optical center was marked with a blunt hook and a 6.0-mm optical zone was marked with a cross-haired trephine. The corneal epithelium was removed with a blunt spatula, #64 Beaver blade, or Took knife, depending on the discretion of the surgeon. Corneal ablation then was performed on the eyes that underwent the procedure with nitrogen flow after the suction ring was applied. The eyes that underwent the procedure without nitrogen flow received one drop of nonpreserved artificial tears (Tears Naturale, Alcon, Fort Worth, TX), and excess fluid was removed gently with a cellulose sponge. Laser ablation was completed with or without the use of a suction ring.

Postoperative Care and Follow-up Schedule

Immediately after laser ablation, the eye was irrigated with balanced salt solution. Initially, one drop of 2% homatropine followed by a combination of tobramycin and dexamethasone ointment, along with a pressure dressing, were used. A variety of analgesics were used to control postoperative pain without noticeable success. Using this regimen, 77 eyes were treated.

Subsequently, Sher et al[10] reported effective postoperative pain control with the combined use of topical nonsteroidal anti-inflammatory (NSAID) drops and a soft contact lens. The immediate postoperative regimen, therefore, was changed as follows: after irrigation with balanced salt solution, a drop of diclofenac sodium (Voltaren) and a drop of ciprofloxacin (Ciloxan) were applied. A disposable soft contact lens was fitted, and the patient's eye was left unpatched. Patients then were instructed to use both diclofenac sodium and ciprofloxacin drops four times daily. A small subset of patients used topical ketorolac (Acular) as an alternative NSAID with similar success.

Follow-up began 24 hours after surgery. A patch and ointment were re-applied daily until full epithelization of the cornea occurred. Patients fitted with therapeutic contact lenses were examined daily, and the contact lens was removed when the cornea was covered totally with epithelium. With both regimens, this occurred within 2 to 4 days, at which point, fluorometholone 0.1% (FML) was prescribed to be used in a tapered dose regimen over the next 4 months as previously described.[6]

Statistical Analysis

Statistical analysis was performed with the two-sided Student's *t* test, the Fisher's exact test, and the Newmann Keuls matched-pairs *t* test.

Results

Distribution of Preoperative Parameters

Of the 240 eyes in the study, 110 had a spherical equivalent (SE) refraction of −1.00 to −3.50 diopters (D) and 130 eyes had an SE refraction of −3.60 to −7.75 D. In 18 eyes, there was an SE refraction of more than −6.00 D, the upper limit of SE correction allowed in phases IIb and III of this trial. These 18 eyes were treated to correct only

Table 1. Distribution of Preoperative Spherical Equivalent (n = 240)

Spherical Equivalent (D)	No. of Eyes
1.00–2.00	20
2.10–3.00	56
3.10–4.00	48
4.10–5.00	52
5.10–6.00	46
6.00–7.75	18

D = diopter.

6.00 D with the consent of the patients, often for the monocular correction of presbyopia. These eyes were excluded from the analysis of postoperative uncorrected visual acuity. Table 1 provides the detailed distribution of preoperative SE refractions. Astigmatism did not exceed 1.50 D in patients enrolled in phase IIb of the trial and 1.00 D in those enrolled in phase III.

Uncorrected preoperative visual acuity was 20/200 or worse in all eyes, except for four eyes in which visual acuity was 20/100 and one eye in which visual acuity was 20/80. Corrected preoperative visual acuity was 20/20 or better in 212 eyes, 20/25 in 22 eyes, 20/30 in 4 eyes, and 20/40 in 2 eyes.

Uncorrected Visual Acuity

Figure 1 summarizes the accuracy of postoperative uncorrected visual acuity at the different time periods between 1 and 36 months postoperatively. Eighty percent of eyes (1 month postoperatively) to 92% (24 months postoperatively) had visual acuity of 20/40 or better and 22% (1 month postoperatively) to 48% (24 months postoperatively) had visual acuity of 20/20 or better. These results appear to demonstrate that stability of uncorrected visual acuity occurs between 3 to 6 months postoperatively.

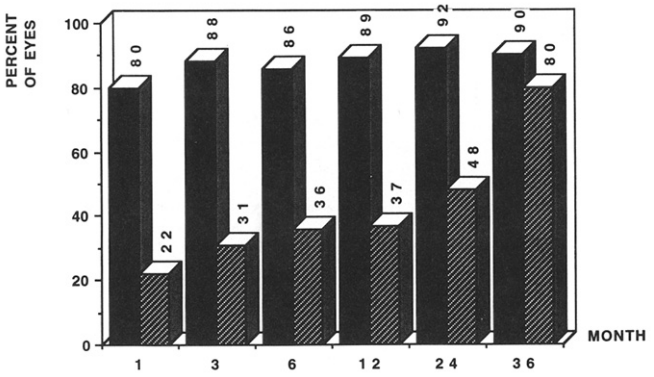

Figure 1. Uncorrected visual acuity over time (n = 240). Solid bars = visual acuity of 20/40 or better. Hatched bars = visual acuity of 20/20 or better.

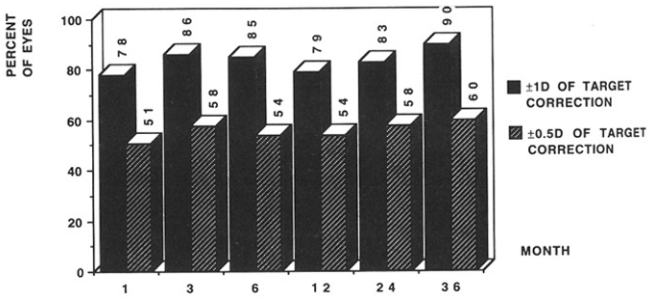

Figure 2. Refractive outcome over time (n = 240).

Refractive Outcome

Figure 2 shows the distribution of postoperative SE refraction, based on the targeted correction at the different time periods 1 to 36 months postoperatively. At 1 month postoperatively, 78% of eyes were within ±1.00 D and 51% were within ±0.50 D (SE) of attempted target correction. The remaining time periods show stability of refractions except at 12 months. At that time, the percentage of eyes within ±1.00 D of targeted correction decreases to 79%. There is no clinically rational explanation for this finding, and the difference in the ±1.00-D refractive outcome between months 6, 12, and 24 is not statistically significant.

Figures 3 to 8 represent scattergrams of achieved correction versus intended correction at the different time periods. They reflect the following findings: (1) results of eyes corrected for "low myopia," between 1.00 and 3.50 D, show less scatter, and data points are mostly confined to within ±1.00 D of emmetropia; (2) the eyes with preoperative myopia higher than 3.50 D show more scatter in the distribution of the data points throughout these figures; (3) there is a relatively high number of overcorrections at 1 month postoperatively, mostly in eyes with preoperative myopia of more than 3.50 D; and (4) overcorrections are relatively rare thereafter, and outlying data points beyond ±1.00 D are mostly undercorrections. Table 2 shows the distribution of undercorrected and overcorrected eyes 1 year after surgery in eyes with low myopia (range, 1.00–3.50 D) and in eyes with moderate my-

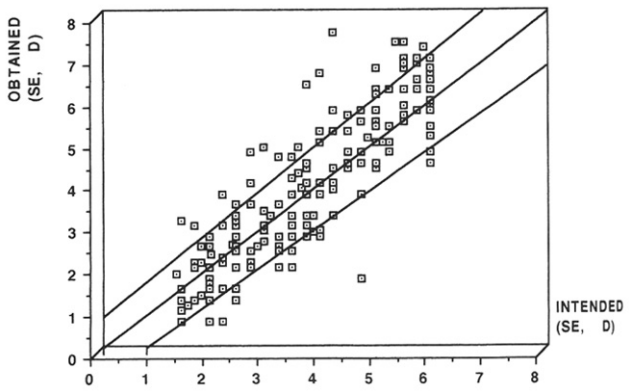

Figure 3. Refractive outcome 1 month postoperatively (n = 206).

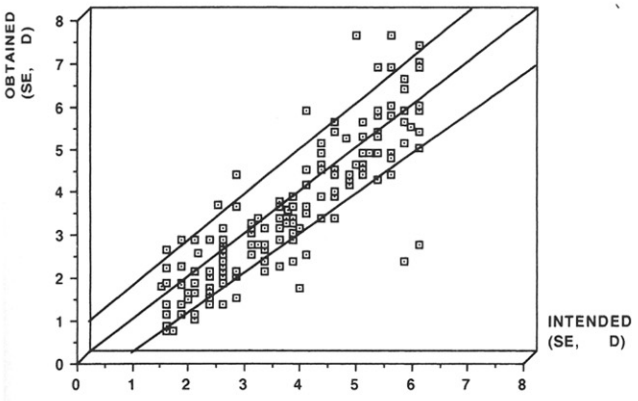

Figure 4. Refractive outcome 3 months postoperatively (n = 175).

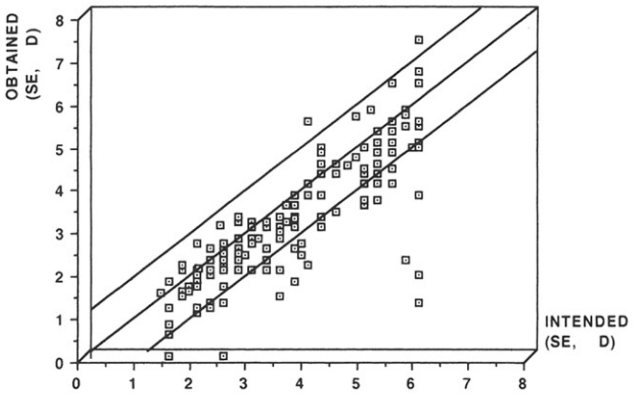

Figure 6. Refractive outcome 12 months postoperatively (n = 149).

opia (range, 3.60–6.00 D). The higher myopia group shows a fourfold increase of overcorrections and undercorrections, whereas in both groups undercorrections are predominant.

Best-corrected Visual Acuity

Changes in best spectacle-corrected visual acuity may reflect the presence of reticular haze and mild irregular astigmatism, typical of the early healing phases of PRK. A loss of two or more lines of best-corrected visual acuity appears to be functionally significant. Figure 9 shows the percentage of eyes that have lost two or more lines of best-corrected visual acuity. At 1 month postoperatively, the number of eyes is 20% of the total sample, whereas subsequently, however, the incidence is reduced to between 4% to 7%. Loss of three lines occurred in 4.7% of eyes 1 month postoperatively, 1.2% and 1.7% of eyes 6 months postoperatively, and in none of the operated eyes 12 months and later postoperatively.

Postoperative Induced Astigmatism

Figure 10 demonstrates the presence of postoperative induced astigmatism of 1.00 D or more in 7% to 12% of the eyes. For most eyes, the axis of astigmatism remained within 20° of the preoperative axis; therefore, no vectorial analysis was performed.

Postoperative Corneal Clarity

Varying degrees of corneal haze were visible postoperatively in the area of laser ablation. The investigators were required to grade this type of opacification on a scale of 1 to 4, with 0.5 increments. Any score of 1.5 units or more was deemed functionally significant. Table 3 shows the number of eyes that scored 1.5 units or more at any time during the postoperative follow-up period. These scores were entered mainly during the first 6 months postoperatively (46 of 53 entries). The most severe case scored 3 units in one eye. This particular case was described in our previous report.[6] Only three eyes scored 1.5 units at the last follow-up visit, reflecting the transitional nature of this finding.

The Effect of Nitrogen Flow on the Mean Spherical Equivalent Correction over Time

Tables 4 to 6 describe, respectively, the variations in the mean SE refraction at 1 to 36 months postoperatively, for the surgeries performed with nitrogen flow and for the surgeries performed without nitrogen flow. Figure 11

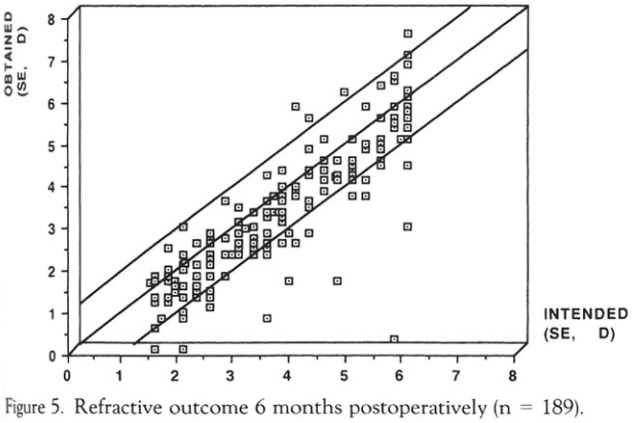

Figure 5. Refractive outcome 6 months postoperatively (n = 189).

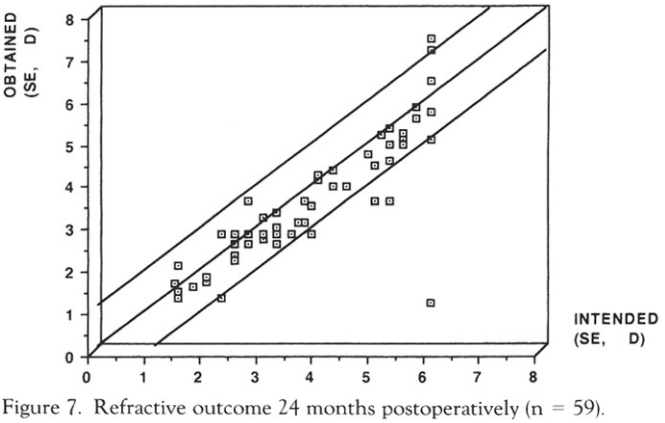

Figure 7. Refractive outcome 24 months postoperatively (n = 59).

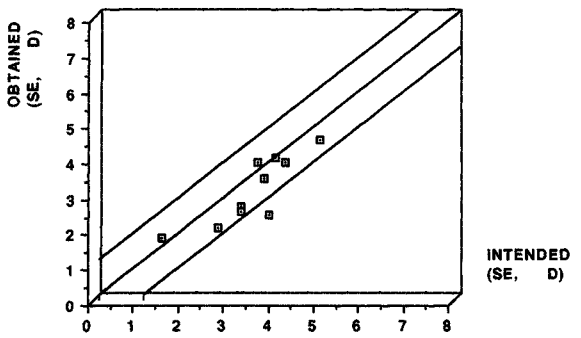

Figure 8. Refractive outcome 36 months postoperatively (n = 10).

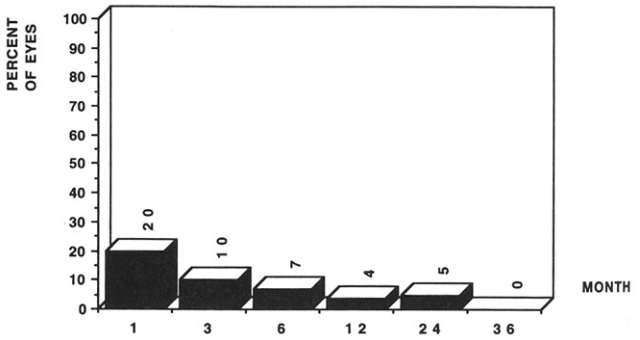

Figure 9. Best-corrected visual acuity loss of two or more lines (n = 240).

shows the same data for all three groups. From the evaluation of these data, it appears that an initial mean overcorrection is present at 1 month in the total sample of eyes and in the subgroup of eyes that underwent PRK with nitrogen flow. The mean SE refraction is close to emmetropia at 1 month in the subgroup of eyes that underwent PRK without nitrogen flow. In all groups, a decrease in mean refraction occurs over 3 to 6 months postoperatively, at which point, the mean SE correction stabilizes. Statistical analysis of mean corrections over time confirms this observation (Tables 4–6). The intervals between all time periods were analyzed in all three groups and were found to be highly significant between 1 and 3 months. Beyond the 6-month time period, the difference in mean correction over time in all groups was not statistically significant; therefore, corrections were stable over that period of time. At this point, it appears that the mean SE correction in the group of eyes that underwent PRK with nitrogen flow is closest to emmetropia, whereas the mean SE correction of the subgroup operated on without nitrogen flow appears undercorrected.

Complications

Increased Intraocular Pressure

A total of 26 (10.8%) patients had intraocular pressures (IOPs) of 21 mmHg or more measured at any time during their follow-up. Four (1.7%) patients had IOPs of 25 mmHg or more, and the highest value measured was 32 mmHg. In all patients, it was believed that the rise in IOP was due to steroid response. In all patients in whom it was deemed necessary, IOP control was achieved with topical beta-blockers. Intraocular pressures that were high returned to normal in all patients after discontinuation of topical steroids.

Table 2. Distribution of Overcorrections and Undercorrections of More Than ±1.00 diopter One Year Postoperatively

	Low Myopia (1.00–3.50 D) (n = 67)	Moderate Myopia (3.60–6.00 D) (n = 81)
Undercorrections (%)	7.5	25.9
Overcorrections (%)	0	2.5
Total (%)	7.5	28.4

D = diopter.

Epithelial "Map Dot" Changes and Recurrent Corneal Erosion Syndrome

We report four patients with recurrent corneal erosion syndrome that occurred after PRK. All patients were screened for ophthalmic disease before surgery by their surgeons, and no evidence of corneal epithelial dystrophy was found. Two patients (1 bilateral) display both the symptoms and clinical signs of the disease. One patient has intra-epithelial microcysts and is asymptomatic. One patient shows the symptoms but not the clinical signs of this syndrome. All patients who had both the clinical features and symptoms had the dystrophic lesions outside the ablation zone, whereas the patient without symptoms showed corneal microcysts within the ablation zone.

Central Islands

Parker and Klyce (oral communication) first reported a postoperative corneal topographic finding consisting of

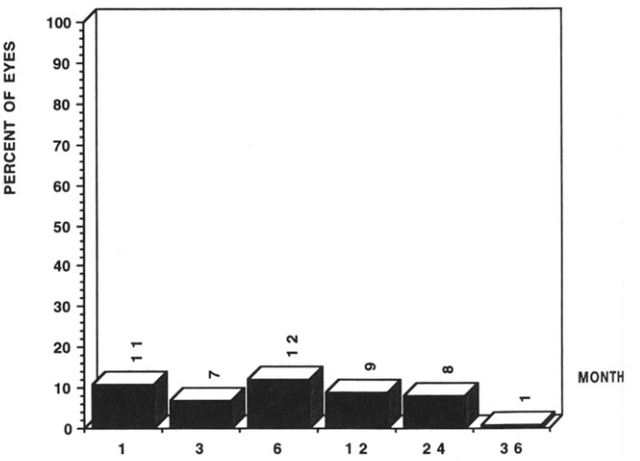

Figure 10. Postoperative-induced astimatism (≥1 diopter) (n = 240).

Table 3. Corneal Haze Scores at Any Time Postoperatively

Score	No. of Eyes
1.5	42
2.0	10
3.0	1

central corneal steepening after PRK. Over time, it became clear that this finding is usually transient. In some patients, the "central islands" persist and are functionally significant, inducing irregular astigmatism or undercorrections. The definition of a central island varies among authors. The size of the island ranges from 1 to 3 mm. The amount of steepening ranges from 1 to 3 D. The postoperative period after which an island is not considered transient is not defined. In our series, a total of 12 (5%) eyes showed central islands 3.0 mm in diameter, 3.00 D steeper than the surrounding cornea, and present between 3 to 6 months postoperatively. All eyes with central islands underwent PRK without nitrogen flow. In 3 (1.25%) eyes, this finding remained beyond 6 months postoperatively. The remaining eyes did not show central islands beyond 6 months. It is possible that the number of "transient central islands" we have reported is underestimated because not all patients underwent corneal mapping frequently enough to uncover this finding in the early postoperative period.

Decentration of the Ablation Zone

A group of 50 consecutive patients operated on by a single surgeon (JJS) were evaluated for decentration of the ablation zone on topographic maps 6 months postoperatively. With the use of the suction ring for fixation, 29 patients were operated on, whereas 21 patients voluntarily fixated during surgery. The mean (± standard deviation) decentration was 0.62 ± 0.47 mm (range, 0–2.1 mm). An attempt was made to evaluate the influence of the use of the suction ring during PRK. With a suction ring, 29 patients of this group were operated on, whereas 21 patients underwent PRK with voluntary fixation. The mean decentration with suction ring was 0.65 ± 0.58 mm, and 0.52 ± 0.25 mm without the suction ring. Table 7 shows the distribution of the two groups. The difference between the two groups was not statistically significant.

Other Complications

Two eyes regressed after PRK to approximately preoperative refraction. One of the eyes was described previously[6] and was associated with moderately severe corneal haze and irregular astigmatism. This eye was retreated, and on the last follow-up visit best-corrected visual acuity was 20/50 + 3, with a refraction of −5.00 − 1.00 × 10, 14 months after retreatment. The second eye regressed while the cornea remained clear. This patient was lost to follow-up.

In one eye, a paracentral corneal infiltrate developed inside the ablation zone the day after surgery, which was associated with redness and pain. This eye was treated postoperatively with topical NSAID, a bandage contact lens, and topical ciprofloxacin. The contact lens was removed promptly, and intensive topical antibiotic therapy was begun after corneal scrapings were taken. The cultures yielded no growth. The patient promptly recovered, and the remaining postoperative course was uneventful.

Discussion

Over the last year, the literature and research on PRK have grown exponentially. Worldwide experience now encompasses thousands of cases. In evaluating the published material,[1-10] one is impressed by the similarity of the results. In these reports, the final optical correction of ±1 D and the uncorrected visual acuity of 20/40 or better range from 70% to 92%. Our series falls well within these parameters (range, 78%–86%). The final refraction appears to stabilize 3 to 6 months postoperatively. The above findings correlate fairly well with the figures of uncorrected visual acuity over time, which remain stable from 3 to 36 months. There is an increase in the number of patients with visual acuity of 20/20 or better without correction between 12 (36%) and 24 months (48%) postoperatively, reflecting perhaps subtle improvement in corneal clarity and surface irregularity during that time interval. The loss of two or more lines of best-corrected visual acuity is significant during the first month postoperatively (20%) and decreases to 5% at the 24-month time period. The decrease in best-corrected visual acuity appears to be due to the combined presence of corneal haze and irregular astigmatism. Gas-permeable contact lenses were tried on these patients, and vision improved partially for as long as corneal haze was present. Induced astigmatism of 1.00 D or more remains of some concern. We have now performed

Table 4. Mean Spherical Equivalent Refraction over Time

	1 mo	3 mos	6 mos	12 mos	24 mos	36 mos
Mean ± SD (D)	0.23 ± 0.95	−0.26 ± 0.86	−0.45 ± 0.81	−0.47 ± 0.76	−0.36 ± 0.84	−0.44 ± 0.53
P	<0.0001	<0.03	0.82 (NS)	0.36 (NS)	0.22 (NS)	

SD = standard deviation; D = diopter; NS = not statistically significant.

Table 5. Mean Spherical Equivalent Refraction over Time: Nitrogen Flow Subgroup

	1 mo	3 mos	6 mos	12 mos	24 mos	36 mos
Mean ± SD (D)	0.79 ± 1.00	0.21 ± 0.96	−0.19 ± 0.98	−0.35 ± 0.86	−0.25 ± 0.61	−0.44 ± 0.53
P	<0.001	0.02	0.33	0.46	0.35	
		(NS)	(NS)	(NS)	(NS)	

SD = standard deviation; D = diopter; NS = not statistically significant.

arcuate keratotomies on three patients after PRK who had greater than 2.00 D of postoperative corneal and refractive astigmatism.

An attempt was made to evaluate the impact of a major change in technique on the final optical correction, namely discontinuing the use of nitrogen flow during the procedure. Piebenga et al[8] were the first to report the improvement in results after this modification and showed significant improvement in corneal clarity over time. However, there appears to be an undercorrection of the mean postoperative refraction over time in the subgroup of eyes that underwent PRK without nitrogen flow. This finding mirrors what was found in our series. These results did not appear to impact the uncorrected visual acuities in Piebenga et al's series (100% of eyes with visual acuity of 20/40 or better 6 months postoperatively) for a sample of 17 patients. In our series, 85% of all eyes at 6 months had uncorrected visual acuity of 20/40 or better, whereas 88% of eyes in the subgroup operated on without nitrogen flow had uncorrected visual acuity of 20/40 or better. A comparison of the uncorrected visual acuity and refractive outcome between these two groups shows similar results. It is believed that a comparison of refractive outcome and uncorrected visual acuity between eyes operated on with and without nitrogen flow in this study is somewhat skewed because of the significant mean undercorrection obtained in the series performed without nitrogen flow. The accuracy of the final optical correction could be improved by adapting these findings into the algorithm used to calculate the amount of ablated tissue, thereby further refining the final future result and allowing a better comparison between the two techniques. The cause of undercorrection in the group operated on without nitrogen flow is not well understood at this point. Work by Dougherty (oral communication) may shed some light on this phenomenon because it appears to demonstrate that the rate of ablation of the cornea with the 193-nm excimer laser is affected by the hydration of the cornea. Blowing gases over the cornea during ablation might alter its hydration thereby having an impact on the ablation rate.

Pain control with topical NSAID and soft contact lenses is a major improvement over the previous regimen of patching and oral narcotic analgesics. This approach has become the method of choice for this purpose. At the same time, patients using this new regimen should be followed carefully because corneal infiltrates associated with the use of disposable extended wear lenses can occur[11] and should be treated promptly because the risk for infection may be far greater with the type of epithelial defect caused by PRK. A follow-up regimen of every 24 to 48 hours is recommended until the epithelium covers the cornea completely.

The patients with severe corneal haze and/or regression of the correction obtained postoperatively are few, yet the phenomenon is of concern. Several groups are attempting to correlate these occurrences to pre-existing abnormalities. Lohman and Marshall[12] demonstrated higher preoperative plasmin levels in the tears of three patients who subsequently had regression of their correction. The ability to detect such findings preoperatively would be an important breakthrough. We currently are subjecting our patients to tear analysis of several factors to find a preoperative screening method that is clinically applicable.

The finding of corneal "map dot" changes with or without clinically significant recurrent corneal erosions in four patients is of concern because Bowman's membrane is removed in the ablation zone during PRK. The incidence of this phenomenon is within the reported incidence of Map Dot Fingerprint Dystrophy in the population.[13,14] In addition, the clinical features of this epithelial dystrophy may be absent even though they may develop later. Therefore, one is unable to rule out the possibility that epithelial dystrophy pre-existed in these eyes, and only time and further research will indicate

Table 6. Mean Spherical Equivalent Refraction Over Time: No Nitrogen Flow Subgroup

	1 mo	3 mos	6 mos	12 mos	18 mos
Mean ± SD (D)	−014 ± 0.76	−0.55 ± 0.66	−0.69 ± 0.86	−0.89 ± 1.06	−0.80 ± 1.00
P	<0.0001	0.02	0.18	0.2	
		(NS)	(NS)	(NS)	

SD = standard deviation; D = diopter; NS = not statistically significant.

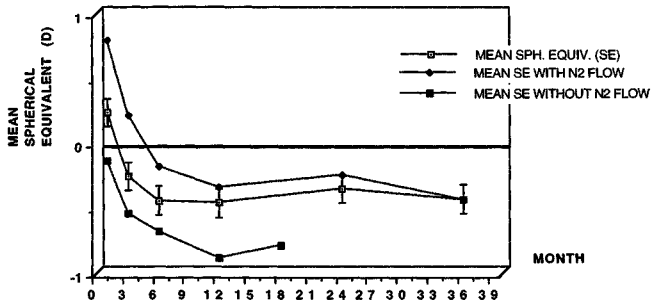

Figure 11. Mean correction over time (± standard deviation of error) (n = 240).

whether this observation is of concern. These findings suggest perhaps multiple causes for this syndrome. The frequent use of topical anesthetics and/or the physical force applied to the epithelial sheath during debridement with a blunt instrument could have an impact. It is a widely accepted observation among surgeons performing PRK that some epithelia can be debrided much easier than others. This may occur because the hemidesmosomal attachments are sometimes weaker, and the added trauma of frequent topical anesthetics, the debridement, and perhaps, in some way, the photoablation contribute to the occurrence of this finding.

To compare the performance of PRK by our group to radial keratotomy (RK), the refractive outcome and uncorrected visual acuity of 148 eyes that underwent PRK 12 months previously were compared with the Prospective Evaluation of Radial Keratotomy (PERK) data at 1 year postoperatively. The PERK data were retabulated to accommodate the reporting standards of PRK, namely, into groups of low (range, 1.00–3.00 D) and moderate (range, 3.10–6.00 D) myopia (M. Lynn, oral communication). Table 8 compares the refractive outcome between the two procedures. In the low myopia group, both procedures appear to perform extremely well. In the moderate myopia group, PRK appears to perform better than RK (P = 0.0009). Table 9 shows that the same phenomenon can be observed in comparing the uncorrected visual acuity between the two procedures, and the difference in performance between RK and PRK in the moderate myopia group is of borderline statistical significance (P = 0.082).

Table 7. Distribution of Decentrations of the Ablation Zone with and without the Use of a Suction Ring for a Single Surgeon*

Decentration (mm)	% with Suction Ring (n = 29)	% without Suction Ring (n = 21)
0.00–0.50	55.2	47.6
0.51–1.00	20.7	47.6
1.10–1.50	10.3	4.8
1.50–2.00	10.3	0
>2.00	3.5	0

* There were no statistically significant differences.

Table 8. Comparison between Photorefractive Keratectomy and Radial Keratotomy Refractive Outcome: Percent of Eyes with ±1.00 Diopter of Emmetropia 12 Months Postoperatively

	−1.00–3.00 D Preoperative (% of eyes)	−3.10–6.00 D Properative (% of eyes)
RK	84	55
PRK	93.9 (NS)	74.7
P	0.12 (NS)	0.0009

D = diopter; RK = radial keratotomy; PRK = photorefractive keratectomy; NS = not significant.

In summary, our results of PRK are within the accepted standard for refractive surgery over the short and medium term. These results were obtained with one procedure for all eyes, except the two that were retreated. This is a vast improvement over the performance of RK. To obtain similar results with RK, one must resort, in many cases, to reoperations ("enhancements"). In our series, complications rates are low and are not vision threatening. As more insight is gained into the interaction of the 193-nm excimer laser with the cornea, a more refined ability to control the final optical correction and to prevent complications is desired. The results shown by our group and others justify, in our view, permission by the United States Food and Drug Administration to perform an added number of surgeries while its approval is pending so that the procedure can be refined and a better outcome can be offered when it becomes available to all.

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Table 9. Comparison between Photorefractive Keratectomy and Radial Keratotomy Uncorrected Vision: Percent of Eyes with 20/40 or Better Visual Acuity 12 Months Postoperatively

	−1.00–3.00 D Preoperative (% of Eyes)	−3.10–6.00 D Preoperative (% of Eyes)
RK	92	76
PRK	95.9	84.8
P	1.0 (NS)	0.082 (NS)

D = diopter; RK = radial keratotomy; PRK = photorefractive keratectomy; NS = not significant.

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Discussion
by
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Most refractive surgical procedures undergo progressive, stepwise modification from their inception to the point at which they are recognized by the ophthalmic community as efficacious and safe. We have witnessed this maturation phenomenon in the development of incisional keratotomy over the last decade and a half, during which time accumulated information from different surgical techniques, patient response, gains in our understanding of corneal biomechanics and wound healing, and improved instrumentation have altered the manner in which we use and perform these procedures. Photorefractive surgery is still in the earliest phases of this developmental metamorphosis and is undergoing procedural mutation as accumulated clinical experience provides greater understanding of photoablative surgery and its physiologic consequences.

In presenting their data, Maguen and colleagues have provided us with the longitudinal results of their series of photorefractive keratectomy (PRK) for myopia over a 3-year period and have contributed to the burgeoning corpus of clinical information on the applicability and results of PRK. The investigators have concluded that their results are in general agreement with those of other groups worldwide, demonstrating a final optical correction of within ±1 diopter of the desired result and an uncorrected visual acuity of 20/40 or greater in 78% to 86% of patients. In addition, they suggest that, based on this series, the refraction after PRK stabilizes between 3 and 6 months postoperatively. Interestingly, visual acuity improved between 12 and 24 months postoperatively, perhaps based on subtle improvement in corneal clarity and surface regularity.

The authors also have validated the discontinuation of nitrogen flow as first suggested by Campos et al[1] and Piebenga et al[2] by comparing results from the procedures performed with and without nitrogen flow in their study. They have demonstrated that its discontinuation did not adversely affect the refractive results. Although their data suggest that the eyes in the "no nitrogen flow" subgroup were undercorrected, they conclude that an adjustment of the algorithm will correct the problem. Finally, they have confirmed that postoperative management is improved with the combined use of nonsteroidal anti-inflammatory agents and the application of therapeutic lenses as previously suggested by Sher et al (unpublished data; presented at the 1993 ARVO Annual Meeting).

What information can we *not* glean from this study? First, although their presentation provides us with the data over a 3-year experience with the procedure, only 4% of the total number of eyes have reached the 3-year gate and only 24% of the total have been followed to the 24-month time period. The current information must be interpreted, therefore, with modest caution as medium- and long-term outcomes. Although the results for the ten patients who reached the 3-year time period do not appear to alter the study's conclusions, we must recognize that the results are not final.

Second, the study does not formally address *quality* of visual perception either subjectively or objectively from the patient's point of view. As in the early phases of evaluation of all refractive procedures, the measure of success is gauged solely by Snellen visual acuity. Non-acuity parameters such as contrast sensitivity and glare disability are not addressed. Ever directed toward the goal of emmetropia, we measure success in Snellen units from the point of view of the refractive surgeon rather than the patient. However, similar to the procedure, its scientific evaluation is undergoing evolutionary modification, and as we continue to refine the photoablative correction of refractive error, we will, no doubt, refine our own measures of the real-world quality of vision it affords. Hopefully, the authors will analyze their patient base for measures of visual quality and satisfaction.

This series clearly demonstrates that despite what appears to be a safe and efficacious procedure, there is need for both patient awareness and careful surgeon monitoring of potential complications. Patients must clearly understand that there is a 4% to 7% chance of loss of two or more lines of best-corrected visual acuity. Likewise, they must be apprised of potential postoperative problems related either to the surgery or its postoperative care, including a small incidence of refractive regression, the development of recurrent erosion, varying degrees of corneal haze, microbial keratitis, and induced glaucoma.

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As such, this series clearly demonstrates that despite being a relatively straightforward mechanized procedure with results equal to or exceeding the more difficult-to-perform incisional keratotomy, PRK requires a thorough medical understanding of corneal physiology and disease, the principles and pitfalls of manipulating anti-inflammatory agents, the appropriate selection of contact lenses, and a thorough grasp of the diagnosis and management of infectious keratitis. From a separate series of excimer procedures, I have managed two such postoperative complications, and they certainly are not trivial. The photorefractive surgeon must be equipped with much more than the simple capability of manipulating a computer algorithm by pressing a few buttons. Rather, the surgeon must be fully prepared to manage the physiologic and pathophysiologic responses of the eye to photoablation and its adjunct therapy. For this reason, the procedure clearly must remain in the purview of the ophthalmologist.

The authors are to be congratulated on the careful analysis of their data, and we look forward to the further results of their series as both PRK and our ability to analyze its place in the armamentarium of refractive surgery undergo further metamorphosis toward refinement.

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