Photorefractive Keratectomy for Myopia With a 6-mm Beam Diameter

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ABSTRACT

BACKGROUND: Earlier studies have reported clinical outcomes for up to 2 years following photorefractive keratectomy (PRK) using a 5.0-mm treatment zone with the Summit excimer laser. We present results of PRK using a 6-mm ablation zone with the same laser.

METHODS: Forty-five eyes of 45 patients underwent excimer laser PRK for correction of myopia using a 6-mm excimer laser beam diameter. Attempted corrections ranged from 1.50 diopters (D) to 6.00 D. Data on outcomes of uncorrected visual acuity, spectacle-corrected visual acuity, predictability, corneal haze, subjective glare/halo effects, and patient satisfaction with the procedure were analyzed over a follow-up period of 6 months.

RESULTS: All patients obtained a postoperative uncorrected visual acuity of at least 20/40; 28 eyes (62%) achieved at least 20/20. Postoperative spectacle-corrected visual acuity was at least 20/20 in all patients; no patients lost more than one Snellen line of spectacle-corrected visual acuity. Twenty-eight patients (62.2%) achieved within ±0.50 D of the attempted correction; 40 patients (84.4%) achieved within ±1.00 D. Mean spherical equivalent refraction was -4.99 D preoperatively and +0.44 D at 1 month, +0.04 D at 3 months, and +0.09 D at 6 months. At 6 months, 40 eyes (88.9%) were graded as clear, 4 eyes (8.9%) as having trace subepithelial haze, and 1 eye (2.2%) as having mild subepithelial haze. The mean glare/halo index for all of the patients was 0.59 on a scale of 0 to 5. Mean subjective patient satisfaction was 4.68 (on the same scale).

CONCLUSIONS: Clinical outcomes following excimer laser PRK for myopia using a 6-mm treatment zone are encouraging. Postoperative subjective glare/halo were minimal, suggesting an optical advantage in using the larger ablation zone. [*J Refract Surg.* 1996;12:341-346.]

Excimer laser photorefractive keratectomy (PRK), an evolving refractive surgical procedure for the correction of myopia, is currently undergoing clinical trials with encouraging results [1-12] Optical side effects such as glare and halo may be decreased with larger ablation zones [13-18]

In this article, we assess the clinical outcomes of 45 patients who underwent PRK for treatment of myopia from 1.50 to 6.00 diopters (D) using the Summit Technology, Inc (Waltham, Mass) laser with a 6.0-mm ablation zone

PATIENTS AND METHODS

Study Design

As part of the US Food and Drug Administration (FDA)-monitored clinical study of the Summit Technology excimer laser, 45 eyes of 45 patients (33 men and 12 women) underwent PRK for myopia at a single center by one surgeon (P.H.) using a 6-mm ablation zone diameter. Patient ages ranged from 20 to 67 years (mean, 39.0 years). The mean preoperative spherical equivalent refraction was -4.99 ± 1.43 D. For the 6.0-mm beam diameter, a correction multiplier of 0.85 was used to modify the original laser ablation algorithm, designed for a 5-mm ablation zone. For example, if a 4.00 D correction was desired, a 3.40 D correction was nominally pro-

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grammed into the laser's computer. In reporting our results, we used the actual, not the nominal correction values. Using this correction multiplier, actual attempted corrections ranged from -2.20 to -6.80 D, with a mean of -4.61 D.

All entry criteria conformed to the guidelines of the FDA under an Investigational Device Exemption granted to Summit Technology, Inc. Informed consent was obtained in all cases. Postoperative management varied: of the 45 patients studied, 35 had been randomized to a topical nonsteroidal versus placebo drop postoperatively, as well as to a long-term corticosteroid versus placebo drop (see below).

Photorefractive Keratectomy Procedure

PRK was performed with the Summit Technology OmniMed excimer laser system. Laser parameters included a repetition rate of 10 Hz, a fluence of 180 mJ/cm^2, and a pulse duration of 14 ns, resulting in an estimated ablation rate of corneal stromal tissue of 0.25 μm per pulse. All patients were treated with a 6-mm beam diameter. Preoperative calibration of the excimer laser beam and specifics of the photorefractive keratectomy procedure are detailed elsewhere.[1]

Postoperatively, an antibiotic-corticosteroid ointment and a patch were applied. The ointment was continued five times daily until epithelialization was complete. In addition, 35 of the 45 patients were enrolled in a study to evaluate pharmaceutical agents; these patients were randomized to either topical Ketorolac 0.5% or a placebo drop four times daily for 3 days postoperatively. In addition, these subjects were further independently randomized to either fluoromethalone 0.1% or placebo after epithelialization was complete. The corticosteroid or placebo was administered four times daily for 1 month, 3 times daily for 1 month, twice daily for 2 weeks, once daily for 1 week, and then tapered at the individual surgeon's discretion. The 10 patients who were not enrolled in the pharmaceutical study received no Ketorolac 0.5% and received fluoromethalone 0.1% on the tapering regimen described. All patients were off corticosteroids at the 6-month follow-up examination.

We report only the overall results achieved using the 6.0-mm beam diameter, without regard to the postoperative regimen. This should provide a general comparison of the results achieved with the laser system used at one center with results of other laser systems. Results of the multicenter pharmaceutical study in which our center participated have not yet been analyzed.

Patient Examinations

Patients were seen postoperatively each day until slit-lamp examination demonstrated that the cornea had completely reepithelialized. They were again examined at 1, 3, and 6 months following the procedure. Preoperative and follow-up examinations included a detailed ophthalmologic examination with both manifest and cycloplegic refractions by two independent observers, visual acuity measurement under controlled lighting conditions using an ETDRS chart, keratometry, glare testing with the Brightness Acuity Tester (Mentor, Norwell, Mass), contrast sensitivity (VectorVision, Dayton, Ohio), computer-assisted videokeratography (EyeSys Laboratories, Houston, Tex), and anterior segment photography.

At the preoperative and 6-month postoperative examinations, patients were asked to fill out a subjective questionnaire in which they were asked to independently assess glare and halo effects on a 0 to 5 scale, with 0 indicating an absence of such symptoms. For analysis, the greater of these two numbers was taken as the *glare/halo index* in order to maximize detection of postoperative glare and halo. Subjective patient satisfaction with the procedure was also assessed on a 0 to 5 scale, with 5 indicating the highest level of satisfaction. Anterior stromal haze was graded as clear, trace, mild, moderate, and marked.[10] A clear cornea appeared normal by slit-lamp biomicroscopy; trace subepithelial haze could be noted only by broad slit-beam illumination; mild haze could be seen with direct illumination by a thin slit beam; moderate haze partially obscured iris detail; and marked haze obscured iris visualization substantially.

Data Acquisition and Analysis

The data were compiled and entered into a spreadsheet program (Excel, Microsoft, Seattle, Wash). The outcome of predictability was defined as the achieved minus the attempted correction. Postoperative refraction stability was determined by taking the mean spherical equivalent at each postoperative examination point.

RESULTS

Uncorrected Visual Acuity

Table 1 shows uncorrected visual acuity preoperatively and at 1, 3, and 6 months postoperatively. One month following PRK, 43 patients (95.5%) achieved at least 20/40 visual acuity. At 3 months, this increased to 44 patients (97.7%), and at 6 months, all 45 patients had achieved this level. Also

Table 1
Uncorrected Visual Acuity Following PRK for Myopia in 45 Eyes (% of eyes)

		Time After Surgery (mos)		
	Preoperative	1	3	6
≥20/12.5	0	0	0	2.2
≥20/16	0	20.0	31.1	28.8
≥20/20	0	46.6	51.1	62.2
≥20/25	0	73.3	80.0	86.6
≥20/32	0	91.1	93.3	97.7
≥20/40	0	95.5	97.7	100
≥20/50	0	95.5	97.7	—
≥20/63	4.5	97.7	100	—
≥20/80	9.1	100	—	—
≥20/100	13.6	—	—	—
≥20/125	25.1	—	—	—
≥20/160	34.0	—	—	—
≥20/200	68.1	—	—	—
<20/200	31.9	—	—	—

at 6 months, 28 eyes (62.2%) achieved 20/20 or better uncorrected visual acuity.

Predictability

Data on the accuracy of the procedure, as defined by the achieved minus the attempted correction, are shown in Table 2 and Figure 1. One month following PRK, the visual acuity of 38 patients (84.4%) fell within 1.00 D of the attempted correction. This improved to 41 (91.1%) were within 1.00 D at 3 months. At 6 months, 38 eyes (84.4%) were within 1.00 D, and 44 (97.7%) were within 2.00 D of the attempted correction. Five patients were undercorrected by more than 1.00 D and one was overcorrected by more than 1.00 D.

Stability of Refraction

The change in refraction over time is illustrated in Figure 2. Preoperatively, the mean spherical equivalent was -4.99 ± 1.43 D. At 1 month, the mean refraction was +0.44 ± 0.88 D. At 3 months, the mean spherical equivalent refraction decreased to +0.035 ± 0.64 D. Six months following the procedure, the mean spherical equivalent refraction remained stable at +0.09 ± 0.60 D.

Spectacle-Corrected Visual Acuity

Six months following PRK, all 45 patients had a spectacle-corrected visual acuity of 20/20 or better (Table 3). Table 4 shows the change in spectacle-corrected visual acuity at 6 months. Twenty-four of 45 (53.3%) of the patients showed no change. Eleven (24.4%) had lost one line of Snellen acuity: in 10 of

Table 2
Difference Between Achieved and Attempted Correction Following PRK for Myopia in 45 Eyes (% of Eyes)

	Time After Surgery (mos)		
Range of Refraction* (D)	1	3	6
0	22.2	42.2	24.4
±.50	60.0	80.0	62.2
±1.00	84.4	91.1	84.4
±1.50	91.1	97.7	93.3
±2.00	91.1	100	97.7
>2.00	8.9	—	2.3

*Spherical equivalent manifest refraction.

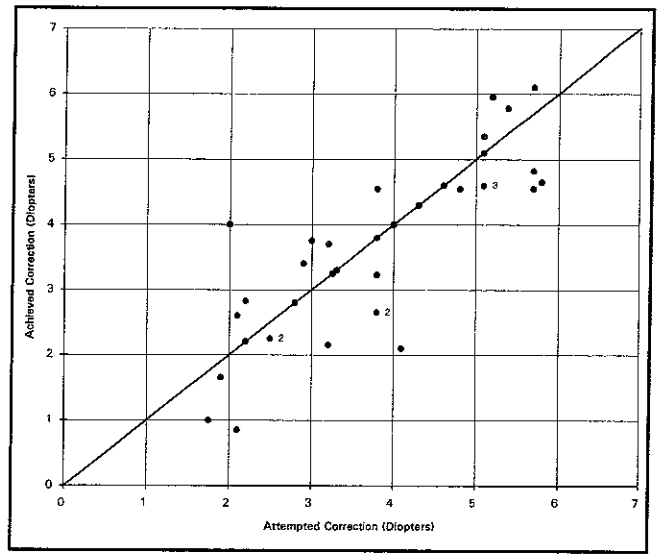

Figure 1: Scattergram showing achieved vs attempted refractive correction. A number indicates that a specific point represents more than one patient.

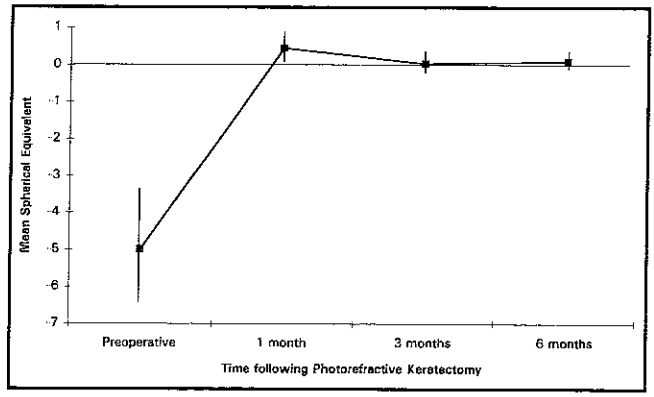

Figure 2: Change in refraction over time. Each point represents the mean spherical equivalent refraction of 45 eyes. Vertical bars indicate the standard deviation of the refractive error.

Table 3
Spectacle-Corrected Visual Acuity Following PRK for Myopia in 45 Eyes

	Preoperative	6 Months
Range	No. of Eyes (%)	No. of Eyes (%)
≤20/10	0 (0)	1 (2.2)
≤20/12.5	1 (2.2)	2 (4.4)
≤20/16	27 (60.0)	26 (57.7)
≤20/20	45 (100)	46 (100)

Table 4
Change in Spectacle-Corrected Visual Acuity Following PRK for Myopia in 45 Eyes

Change in Snellen Lines	No. of Eyes (%)
−1	11 (24.4)
0	24 (53.3)
+1	9 (20)
+2	0 (0)
+3	1 (2.2)

them, it decreased from 20/16 to 20/20, and in another, it decreased from 20/20 to 20/25. No patient lost more than one line of Snellen acuity. Spectacle-corrected visual acuity improved in 10.

Epithelialization

The mean time required for the cornea to reepithelialize after surgery was 2.64 days. In 12 (26.6%), it took 2 days. In all except one, it was complete by 3 days.

Corneal Haze

Four of the 45 (8.9%) patients had trace anterior corneal stromal haze at 6 months. Forty (88.9%) had clear corneas without any stromal haze visible by slit-lamp biomicroscopy. One had mild corneal haze.

Glare/Halo Index

The glare/halo index, reported on a scale of 0 to 5, with 0 indicating no glare/halo, averaged 0.59 ± 0.68 at 6 months. Twenty-two patients (49%) reported a glare/halo index of 0; 18 patients (40%) reported an index of 1. The highest was grade 2, reported by five patients (11%).

Subjective Patient Satisfaction

Patient satisfaction, graded from 0 to 5, with 5 indicating the highest satisfaction, averaged 4.68 ± 0.92. Twenty-four patients (47.7%) reported the maximum level of satisfaction; 19 (41.0%) rated it as 4; three (6.7%) as 3; one (2.2%) as 2; and one as 1.

Of the five patients who reported satisfaction levels below 4, three (6.7%) had an uncorrected visual acuity worse than 20/20: for two (4.4%), it was 20/32; and for the other (2.2%), 20/40. All three of these patients were undercorrected, two by 1.25 D, and the other by 1.50 D. Another one was overcorrected by 0.625 D and exhibited a trace amount of haze and a glare/halo index of 1. The other patient, despite an uncorrected visual acuity of 20/20, experienced postoperative pain.

DISCUSSION

Most reports of PRK with the Summit Technology excimer laser have analyzed clinical outcomes achieved using a 4.5- to 5.0-mm ablation zone. Some authors have suggested that larger ablation zones might reduce the effects of procedure decentration[18] as well as decrease postoperative glare and halo, because the entrance pupil would more likely be covered completely.[16,17] One prospective, randomized study indeed has shown that use of a 6.0-mm as contrasted with a 5.0-mm ablation zone improved a number of clinical outcomes.[13]

Uncorrected Visual Acuity

A recent multicenter study of 166 patients who underwent PRK using the Summit laser and a 4.5- to 5.0-mm ablation zone found that 149 (90%) had 20/40 or better uncorrected visual acuity 1 year following the procedure.[1] The mean attempted correction in that investigation was 4.24 D. In the present study using the Summit laser and a 6.0-mm ablation zone, we found that all 45 of the patients studied achieved 20/40 uncorrected visual acuity 6 months following surgery; the mean attempted correction was 4.61 D. All except one achieved 20/32 or better uncorrected visual acuity. Other investigators have reported similar findings with other laser systems.[11,12]

Predictability and Stability of Refractive Correction

In the above-mentioned multicenter study using a 4.5- to 5.0-mm ablation zone, 94 (53%) of the patients achieved within 0.50 D of the attempted correction, 133 (75%) within 1.00 D, and 163 (92%) within 2.00 D.[1] We found, using a 6.0-mm ablation zone, that 28 (62%) of the patients achieved within 0.50 D of the attempted correction, 38 (84%) within 1.00 D, and 44 (98%) within 2.00 D at the 6-month follow-up examination. Although these two studies cannot be compared directly, because the postoperative regimen

varied in some patients and they were not randomized to the two treatment zones, apparent improvement in predictability seen with the 6.0-mm zone size could possibly result from a difference in edge effects on postoperative epithelial and stromal wound healing. This theory is supported by the findings of O'Brart and coworkers in their study comparing the effects of different-sized ablation zones.[13]

Similar to findings in 5.0-mm ablation zone studies, we noted a slight mean overcorrection (0.44 D) at the 1-month follow-up examination. These overcorrections resolved and visual acuity stabilized after 3 months. The mean final refraction was near plano. O'Brart similarly reported a less profound initial hyperopic shift with a 6.0-mm as compared with a 5.0-mm ablation zone.[13]

Complications and Side Effects

Epithelialization was rapid in our patients and no epithelial dysadhesion occurred during the 6-month study period. The incidence and severity of corneal stromal haze was quite low: 40 of the 45 eyes (88.8%) surprisingly had a clear cornea and no haze at 6 months. Similarly, spectacle-corrected visual acuity was retained by most of the patients, with none losing more than one Snellen line of spectacle-corrected visual acuity.

A number of investigators have suggested that using a larger ablation zone also might reduce symptoms such as glare and halos.[13-18] In an earlier study, we found a mean glare/halo index of 1.89 on a 0 to 5 scale in patients treated with 4.5- or 5.0-mm beam diameters.[1,15] The mean glare/halo index was 2.05 for the 4.5-mm group and 1.79 for the 5.0-mm group, a statistically insignificant difference. In the current study, the mean glare/halo index was 0.59, suggesting a diminution of such symptoms with the 6.0-mm ablation zone. Although these two studies are not directly comparable, there are good reasons for concluding that the larger ablation zone played a role in this reduced symptomatology. First, with a large optical zone, optical edge effects, which would be exacerbated by either procedure decentration or a large entrance pupil, should be reduced. Such edge effects include optical irregularities at the junction of the clear zone and untreated cornea.[14,15] Second, when the entrance pupil size is larger than the treatment zone, the ratio of focused to unfocused light would be beneficially increased, because, with a larger ablation zone, the surface area of cornea focusing light properly is much greater. Despite the relatively low glare/halo index we found using a 6.0-mm ablation zone, the actual significance of the difference in the glare/halo indices found with the two different-sized ablation zones is unclear. Moreover, because the data in the present study was from patients who had only one eye treated, glare and halo symptoms may have been less obvious to them than they were to patients in other studies who had undergone PRK in both eyes.

Our clinical outcomes appear as good or better than those reported in other PRK studies. Further studies rigorously comparing the clinical outcome and optical effects of different ablation zone diameters as well as edge contours should help improve PRK.

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