One-year Results of Photorefractive Keratectomy With and Without Surface Smoothing Using the Technolas 217C Laser

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ABSTRACT

PURPOSE: To assess the efficacy, predictability, stability, and safety of a smoothing technique in patients with myopia immediately after photorefractive keratectomy (PRK) using a scanning-spot excimer laser.

METHODS: Using the Technolas 217C excimer laser, PRK was performed on 100 eyes of 54 patients. Ablation zone diameter was 6.0 mm and transition zone diameter was 9.0 mm. The eyes were randomized into two groups: in 50 eyes PRK alone was performed and in the other 50 eyes, a smoothing technique was performed after the initial ablation. Preoperative mean spherical equivalent refraction was -4.98 ± 1.71 D in the PRK only group (range -2.25 to -8.60 D) and -4.82 ± 1.61 D in the smoothing group (range -2.00 to -8.00 D). Follow-up was 12 months for all patients.

RESULTS: At 1 year after surgery, mean manifest spherical equivalent refraction was -0.61 ± 0.50 D (range -2.25 to +0.62 D) in the PRK only group and in the smoothing group, +0.02 ± 0.32 D (range -0.75 to +0.75 D). Postoperative regularity topographic indices were lower in the smoothing group than in the PRK group (*P*<.001).

CONCLUSIONS: Smoothing after PRK for correction of myopia up to -6.50 D increased surface regularity, as expressed by lower topography surface regularity indices, and reduced the incidence and severity of postoperative haze. We observed higher predictability throughout follow-up in the smoothing group, which may be addressed by a nomogram adjustment in the PRK only group. [*J Refract Surg* 2004;20:444-449]

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Several factors can affect smoothness of the cornea following excimer ablation of the stroma: head and eye movements, scanning laser beam diameter[1], laser beam homogeneity, the ejected molecular ablative debris deposited back onto the corneal surface, and the thermal component of the ablation process. Most refractive surgery techniques are associated with irregularities on the corneal surface which, in turn, may cause an increase in the number high order aberrations and reduced visual acuity in certain light conditions.

The reduction in the regularity of the first corneal surface after the photoablation phase of photorefractive keratectomy (PRK) can lead to three undesirable phenomena: a decrease in corneal transparency[2], regression of refractive outcome[3], and a decrease in contrast sensitivity.[4]

The irregularity of the ablated surface is the "primum movens" for delayed wound healing and abnormal epithelial and stromal remodeling. Abnormalities include stromal thickening and epithelial hyperplasia or distortion of the existing tissue.[5-7]

In our opinion, none of the laser systems developed to date produce a sufficiently smooth stromal surface. This, in addition to patient eye and head movements during laser refractive surgery, result in erroneous targeting of the surgical beam and hence a sub-optimal correction.[8] Efforts by laser manufacturers to produce more sophisticated eye tracking devices[9] and to improve the quality of the emitted laser light have not yet produced an optimal outcome.

Carones demonstrated that even when the most effective eye tracking system was employed, Maloney's topographic regularity index (BFTI) did not significantly differ from that achieved when other devices were used. The eye tracker device is advantageous, especially in uncooperative patients or in the presence of nystagmus.[9]

Many authors have evaluated the physical characteristics of various types of excimer lasers. Huang and Arif simulated corneal ablations using different beam diameters and beam profiles similar to those currently used in commercial excimer laser systems.[1] Their aim was to study the efficacy of the scanning laser in correcting high order aberrations. They concluded that beam sizes ≤1 mm should be sufficient for elimination of most high order optical aberrations.

Other authors have compared the operative outcome with a broad beam laser to that observed with scanning spot and scanning slit lasers. They concluded that the corneal surface was smoothest following scanning spot laser surgery.[10] At present, it is widely held that a smooth postoperative ablation surface is mandatory if refractive surgery is to be considered maximally effective. Benefits of a regular corneal surface include faster re-epithelialization, less haze and regression, and improved visual performance. As suggested by Vinciguerra and colleagues, the smoothing technique is an effective procedure for achievement of a smoother ablated stromal surface.[2]

In spite of the fact that the results following PRK performed using the Technolas 217C are satisfactory, all users must include some hypercorrection in the treatment planning (about 5% to 10% of the spectacle correction). This is done to avoid the overcorrection consequent to regression of refractive outcome that occurs in the months following surgery. We believe that this regression is due to the irregularity of the ablated corneal surface. We present results obtained when a smoothing technique was performed after refractive treatment (PRK) using a scanning spot laser system.

The smoothing technique was used to obtain a smooth ablation surface, thus eliminating gross and small irregularities and flattening the borders of the ablation edges. This technique is similar to phototherapeutic keratectomy (PTK), which is useful for treatment of corneal diseases such as Reis-Bückler's dystrophy or band-like keratopathy, and in order to achieve corneal smoothness after pterygium excision.[11]

Other studies[2,3] have demonstrated that smoothing after PRK using a scanning slit laser, such as the the Nidek EC-5000, facilitates a better optical surface, better visual results, and less haze and regression. Alió and colleagues demonstrated that the Technolas 217C laser used in PTK mode with a masking fluid was useful for treating irregular corneal astigmatism caused by previous refractive corneal surgery.[12] In this study, we compare the refractive data and corneal regularity indices of eyes treated using the same excimer laser system (Technolas 217C), with PRK alone and PRK with smoothing.

PATIENTS AND METHODS

Patients

Fifty-four patients (35 women and 19 men) between 22 and 50 years of age (mean 33.8±6.21 yr) were recruited for a total of 100 treated eyes. Patients were randomly enrolled from the excimer laser surgery waiting list of the Department of Ophthalmology of the Catholic University of Rome.

Inclusion criteria were the absence of ocular pathology, no previous ocular surgery, refractive astigmatism less than 1.50 diopters (D), and at least 1 year of refractive stability. Patients wearing contact lenses were asked to discontinue use for at least 4 weeks prior to preoperative evaluation. Informed consent was obtained from all patients.

Preoperative evaluation included the determination of manifest and cycloplegic refraction, uncorrected visual acuity (UCVA) both for reading and distance, best spectacle-corrected visual acuity (BSCVA), and autorefraction (Nidek AR-600, Tokyo, Japan). Slit-lamp microscopy, tonometry, and fundus examination were also performed. Corneal thickness was measured using a contact ultrasound pachymeter (Optikon 2000, Rome, Italy) and corneal topography was performed with the Keratron Scout (Optikon). Emmetropia was the refractive goal in all eyes.

We randomized the eyes into two groups using a statistical package (Matlab, software version 6.5). In one group (26 patients; 16 women and 10 men, mean age 34.7 ± 4.97 yr; 50 eyes) PRK only was performed, whereas in the second group (28 patients; 19 women and 9 men, mean age 31.7 ± 7.45 yr; 50 eyes), smoothing was performed immediately after PRK.

Mean preoperative refraction (mean cycloplegic spherical equivalent refraction ± standard deviation) was -4.98 ± 1.71 D in the PRK only group (mean cylinder -0.58 ± 0.41 D) and -4.82 ± 1.61 D in the smoothing group (mean cylinder -0.55 ± 0.53 D).

Statistical comparison of preoperative data in both groups revealed no significant differences (Fischer test, P>.05). Statistically significant differences between means of the two study groups were determined by the Student's paired t-test. P-values less than .05 were considered significant.

Table
Mean Cycloplegic Spherical Equivalent Refraction (D) Before and After PRK, With and Without Smoothing, in 100 Eyes of 54 Patients (Number of Eyes Examined)

Refractive Range (D)	Preoperative	Postoperative			
		1 mo	3 mo	6 mo	1 yr
PRK with smoothing					
-1.75 to -3.00	-2.21 ± 0.43 (4)	-0.03 ± 0.51 (4)	-0.00 ± 0.36 (4)	-0.21 ± 0.25 (4)	-0.15 ± 0.25 (4)
-3.12 to -6.00	-4.26 ± 0.77 (34)	+0.25 ± 0.57 (34)	+0.11 ± 0.39 (34)	+0.04 ± 0.33 (34)	-0.00 ± 0.31 (34)
-6.12 to -9.00	-7.15 ± 0.66 (12)	+0.33 ± 0.54 (12)	+0.27 ± 0.74 (12)	+0.19 ± 0.49 (12)	+0.19 ± 0.33 (12)
PRK only					
-1.75 to -3.00	-2.74 ± 0.31 (6)	-0.06 ± 0.38 (6)	-0.40 ± 0.41 (6)	-0.44 ± 0.50 (6)	-0.50 ± 0.39 (6)
-3.12 to -6.00	-4.68 ± 0.93 (30)	-0.12 ± 0.69 (30)	-0.38 ± 0.52 (30)	-0.53 ± 0.48 (30)	-0.53 ± 0.44 (30)
-6.12 to -9.00	-7.19 ± 0.88 (14)	-0.53 ± 0.88 (14)	-0.63 ± 0.79 (14)	-0.70 ± 0.77 (14)	-0.88 ± 0.66 (14)

Surgical Technique

Surgery was performed by one surgeon (SS) under topical anesthesia achieved using oxybuprocaine hydrochloride eye drops. The corneal epithelium was removed using the Amoils brush. Laser ablation was performed using the Bausch & Lomb Technolas 217C Planoscan excimer laser (Bausch & Lomb Chiron Technolas, Dornach, Germany; wavelength 193 nm). Ablation zone diameter was 6.0 mm and transition zone diameter was 9.0 mm. This laser is also equipped with an active eye tracker device and utilizes a 2-mm flying-spot laser beam. The fluence at the corneal plane was 120 mJ/cm², the ablation rate was 0.25 µm per pulse, and the repetition rate (frequency) was 50 Hz. No nomogram adjustment was used in this study.

Final smoothing was performed with the same laser in PTK mode. The maximum diameter of the ablation zone was 9.00 mm. A viscous solution of 0.25% sodium hyaluronate was used for masking the cornea. The fluence, ablation rate, and frequency in the PTK mode were the same as in PRK mode. Before the procedure, we re-targeted the ablation area at the center of the pupil and fixed it with the eye tracking device.

We standardized the smoothing procedure using the Technolas 217C laser. Ablation depth was set at 10 µm (divided into four intervals for a total of 428 spots) and a spatula was used to spread the masking fluid on the corneal surface.

The viscous masking solution formed a stable and uniform coating on the surface of the eye. In particular, it filled the depressed areas on the cornea and efficaciously masked the tissue to be protected against ablation by the laser pulses.

Postoperatively, patients were prescribed micronomicin preservative-free eyedrops six times daily until complete re-epithelialization of the cornea, sodium diclofenac 0.1% preservative-free eyedrops three times daily for 3 days, topical fluorometholone 0.1% twice daily for 1 month after complete re-epithelialization, and sodium hyaluronate 0.18% hypotonic solution preservative-free eyedrops five times daily for 6 months after surgery. A bandage contact lens was applied until the third postoperative day.

Twelve-month follow-up included evaluation of corneal haze, UCVA and BSCVA, refraction, corneal topography, evaluation of high order aberrations from the first corneal surface, pachymetry, and tonometry.

RESULTS

At 1-year follow-up, mean cycloplegic spherical equivalent refraction in the PRK only group was -0.61 ± 0.50 D; in the smoothing group it was +0.02 ± 0.32 D (Table). Differences in spherical equivalent refractive error observed in the two groups at 1 month (P<.05), 3 months (P<.05), 6 months (P<.05), and 1 year (P<.05) following surgery were all statistically significant.

The scattergram of the attempted versus the achieved correction for both groups is shown in Figure 1. Twenty-six eyes (52%) had a manifest spherical equivalent refraction within ±0.50 D of emmetropia in the PRK only group, whereas this result was achieved in 46 eyes (92%) in the smoothing group; 41 eyes (81%) were within ±1.00 D in the PRK only group and 50 eyes (100%) were within ±1.00 D in the smoothing group. Figure 2 shows mean spherical equivalent refraction during follow-up in the two groups.

Preoperative refractive astigmatism ranged from 0 to -1.50 D in both groups, with a mean of -0.58 ±

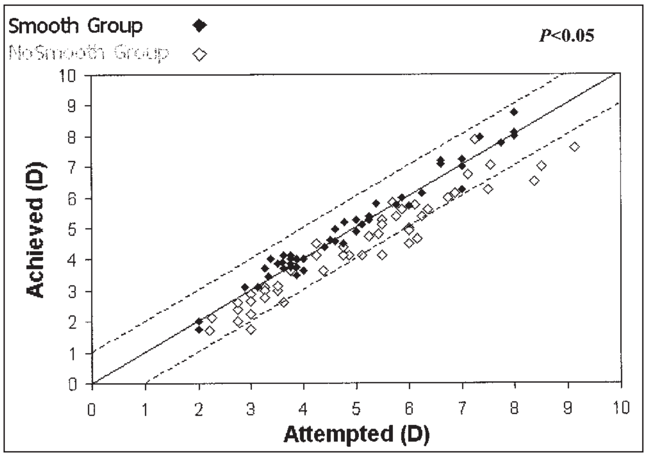

Figure 1. Scattergram at 1 year after PRK shows slight overcorrection of the refractive target in the PRK only group (50 eyes) and the high predictability of the refractive results in the PRK with smoothing group (50 eyes). The *P*-value was calculated using Student's paired *t*-test (*P*<.05).

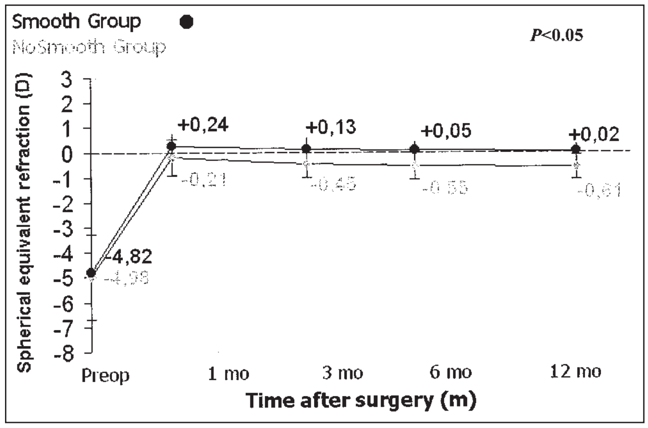

Figure 2. Mean (SD) change in cycloplegic refraction during follow-up in the two study groups. There was a slight hyperopic shift in the smoothing group during the early postoperative period. A regression of the refractive effect occurred in the PRK only group between the 1st and 3rd postoperative months. *P*-value was statistically significant (*P*<.05) at each follow-up examination.

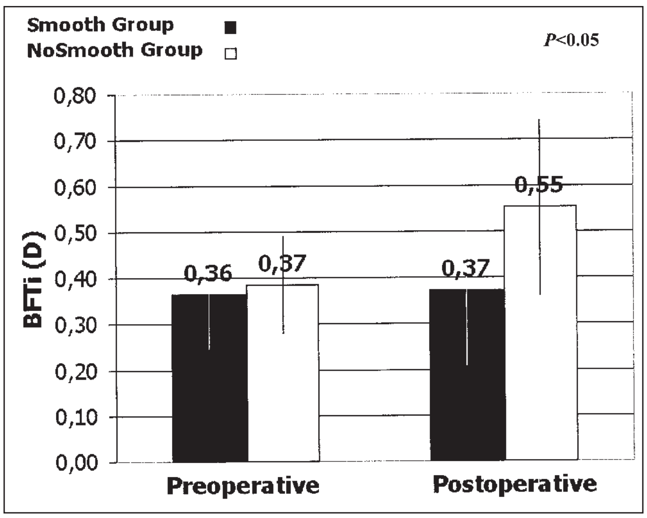

Figure 3. At the end of follow-up, an increase in the postoperative topographic irregularity index (BFTI) was observed in the PRK only group. The regression observed in this group may be explained by the more marked irregularity of the ablated corneal surface. The *P*-value was <.05.

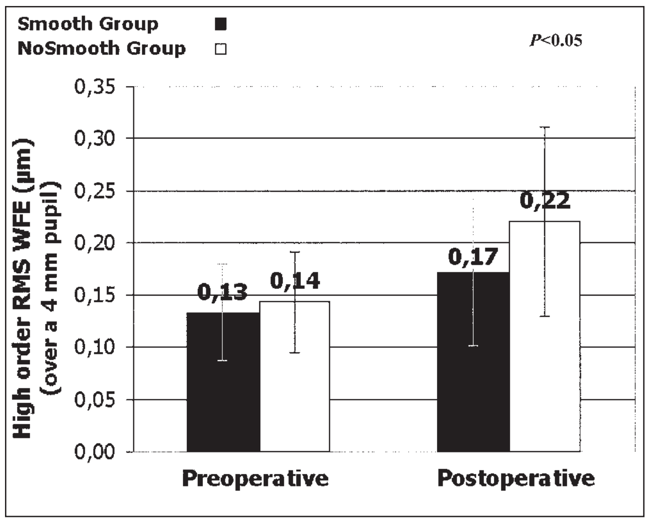

Figure 4. At 1 year after PRK with and without smoothing, the ablated first corneal surface showed a mean increase of the 3rd to 6th high order optical aberrations. The smoothing technique performed at the end of the PRK procedure reduced postoperative stromal irregularities, facilitating a more even surface with respect to PRK only. The mean induced high order optical aberrations in the PRK with smoothing group was less marked (*P*<.05).

0.41 D in the PRK only group and -0.55 ± 0.53 D in the smoothing group. At 1 year, refractive astigmatism was reduced to a mean -0.37 ± 0.40 D in the PRK only group and +0.05 ± 0.51 D in the smoothing group, with no surgically-induced astigmatism.

No eye lost any Snellen lines of spectacle-corrected visual acuity during follow-up. The safety index was 1.02 in the PRK only group and 1.06 in the smoothing group. In the smoothing group, 10 eyes (20%) gained 2 or more lines of Snellen visual acuity with an efficacy index of 1.03 versus 0.97 in the PRK only group, where only two eyes (4%) gained 2 or more lines of Snellen visual acuity.[13]

Two eyes (4%) in the smoothing group and six eyes (12%) in the PRK only group had haze greater than grade 1.[6]

The regularity of the first corneal surface was determined using two topographic indices: Best Fit Topographic Irregularity (BFTI)[14] and the high order root-mean-square wavefront error (RMS).

The BFTI is measured in diopters and is fit to the central 4-mm-diameter circle at the center of the videokeratograph to approximate the size and location of the entrance of the pupil; it is defined as the root-mean-square sum of the differences between the measured cornea and the best-fit spherocylinder that minimizes the distance between the two surfaces.

High order RMS is measured in microns and represents the difference between the measured corneal wavefront and an aberration-free wavefront. We calculated RMS over a 4-mm-diameter pupil and for 3rd to 6th Zernike orders.

Figures 3 and 4 show preoperative and 1-year postoperative values for BFTI and RMS in the two study groups. Postoperative values were greater than preoperative values, showing that ablation caused an increase in irregularity; the increase was less consistent in the smoothing group and the difference was statistically significant ($P<.05$). A postoperative reduction in RMS was observed in nine eyes (18%) in the smoothing group, but in only two eyes (4%) in the PRK only group.

DISCUSSION

In accordance with other reports[3], we observed that the outcome of refractive surgery was influenced primarily by final optical quality of the ablated corneal surface. In experimental settings, a PTK-type treatment at the end of PRK allows for a smoother ablation.[10,15,16] Smoothing of the corneal surface involves the use of a fluid that, when applied to the cornea, masks deeper tissues while at the same time leaves protruding irregularities exposed[17]; subsequent ablation of the irregular anterior stromal surface should therefore focally excise elevated corneal tissue, thereby reducing surface irregularities.

The ideal fluid to be used in this technique has not yet been established. The 0.25% sodium hyaluronate masking fluid that we used is a moderately viscous solution with an ablation rate similar to that of corneal tissue. Thanks to these properties, it can cover the irregular surface uniformly and not run off too quickly, hence, only stromal peaks are left exposed.

A smoother surface allows for better epithelial adhesion and migration. Experimental studies have shown that epithelial migration can be inhibited by irregularities in the surface of the substratum.[18,19]

Correct and rapid re-epithelialization is the principal process that regulates epithelial and stromal remodeling after PRK. Postoperative ablation irregularities induce a more pronounced healing response when compared to a smoother ablation surface.[21] Altered wound healing is the first step toward the onset of haze and a less than desirable refractive outcome.[20-22]

In our PRK study, we used a 2-mm beam spot size device. In one group, smoothing was performed immediately after PRK. Results confirm that the smoothing technique improved the quality of the ablated corneal surface and visual outcome, especially in eyes with a spherical equivalent refraction up to -6.50 D. The observed hyperopic shift was due to the diameter of the optical zone of the Technolas 217C laser. This instrument allows for a maximum PTK zone of 6 mm with a 3-mm transition zone. When this smoothing technique is performed using a Nidek EC-5000 laser with a 9-mm PTK zone without transition, it did not induce a consistent hyperopic shift for such a limited tissue ablation (up to 20 µm).[3]

Many authors report induction of a hyperopic shift for attempted correction as the major complication of PTK.[23] Various techniques have been proposed to minimize the refractive shift: use of a masking agent to reduce the real depth of tissue ablation, use of a large ablation zone with a transition zone, and setting a low ablation depth.[24-27] Corneal topography analysis can identify whether or not the better result was due only to the hyperopic shift. For this reason, we analyzed the topographic indices and the topographic wavefront. The BFTi and the RMS over a 4-mm-diameter pupil and for 3rd to 6th Zernike orders demonstrated a difference between the two groups: the smoothing group had a result closer to emmetropia but it was also associated with better topographic indices.

In our clinical study, the eyes in which smoothing was performed postoperatively had higher predictability for the refractive target; this may be explained by the hyperopic shift induced by PTK, and might also be achieved in the PRK only group by a nomogram adjustment. In the smoothing group, we found a more regular first corneal surface as expressed by topography indices and better visual acuity, compared to the PRK only group.

This smoothing procedure, which facilitated a smoother anterior stromal surface compared to PRK alone, permitted faster re-epithelialization[7,28,29] with less haze and better visual outcome. Performing smoothing at the end of PRK was an effective means to improve corneal regularity after PRK with a scanning laser system, with a beam size of more than 1 mm in diameter.

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