Corneal optical irregularity after excimer laser photorefractive keratectomy

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ABSTRACT

Purpose: To assess the influence of corneal surface microirregularities on objective and subjective visual performance after photorefractive keratectomy (PRK).

Setting: Multicenter clinical trial.

Methods: The alpha version of the Potential Corneal Acuity (PCA) computer program, currently under development, was used to qualitatively and quantitatively analyze the corneal surface of 176 eyes of 176 patients 1 year after PRK. Color maps of corneal surface irregularities were reviewed and quantitative values (PCA) predicting best spectacle-corrected visual acuity (BSCVA) as limited by the cornea were evaluated for associations with qualitative topography patterns, optical zone decentration, and clinical outcomes of BSCVA, uncorrected visual acuity (UCVA), subjective patient satisfaction, and a subjective glare/halo index.

Results: Qualitatively, corneas after PRK were generally characterized by a ring of optical irregularity at the juncture of the ablation zone and untreated cornea. Standard corneal topography maps graded as irregular after PRK had a significantly higher PCA value than those graded as regular. There was a trend toward higher PCA values with greater optical zone decentration that was not statistically significant. Actual BSCVA was identical to that which the PCA value predicted in 32% of patients and was within one Snellen line in 71%, within two lines in 89%, and within three lines in 94%. The correlation between the PCA and the glare/halo index and with subjective patient satisfaction was statistically significant. The relationship between PCA and UCVA was not significant.

Conclusions: A ring of optical microirregularity of the corneal surface can appear at the juncture of the treated and untreated cornea after PRK, indicating that the optical zone edge might affect objective and subjective postoperative visual outcomes. Further understanding of corneal surface topography and refinement of the PCA program should help explain visual outcome after PRK. *J Cataract Refract Surg 1996; 22:197–204*

Clinical trials of excimer laser photorefractive keratectomy (PRK) to treat myopia have yielded encouraging results to date.[1,2] Currently, computer-assisted videokeratoscopy produces an analysis of corneal surface curvature using color maps of corneal power based on the radii of corneal curvature at points interpolated from reflected rings.[3–5] The presence of diffuse or focal optical surface irregularities may also influence the objective and subjective visual outcomes after PRK. For instance, corneal surface irregularities

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have been potentially linked to glare and halo effects PRK patients experience postoperatively.[6]

The Potential Corneal Acuity (PCA) computer program (EyeSys Laboratories), currently under development, graphically depicts focal aberrations of the corneal surface topography. It also assigns quantitative values to the irregularity to predict the best spectacle-corrected visual acuity (BSCVA) as limited by the cornea.

In this study, we qualitatively analyzed PCA topography maps of eyes after PRK and investigated the relationship of PCA value to optical zone decentration and a qualitative assessment of standard topography maps as well as to clinical outcomes of uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA), subjective patient satisfaction, and reports of glare/halo.

Subjects and Methods

The PCA program measures the extent of corneal microirregularity by comparing the video-captured image of the reflected rings of the topography unit to a best-fit ellipse ascribed to them (Figure 1). The computer scales each reflected ring image to an equal size, averages the sizes, and creates a best-fit ellipse based on this average. Each of the original reflected rings is compared with this best-fit ellipse. Point-by-point differences between the ring and the ellipse are measured as the absolute value in microns and are weighted by area and by the Stiles-Crawford effect; these data are used to create a color map depicting corneal surface optical irregularity. To determine the quantitative PCA, the values for the individual points are summed and used to calculate an average irregularity. This average in microns is converted to Snellen equivalent units familiar to the clinician.

The PCA values attempt to predict the BSCVA theoretically supported by the cornea given an entrance pupil of either 3.0 or 6.0 mm. For the former, the rings inside a 3.0 mm zone (approximately four rings) are used in the analysis; for the latter, all rings within a 6.0 mm area (eight rings) are used. The PCA program used in this study centered these 3.0 and 6.0 mm zones at the corneal vertex.

Potential Corneal Acuity topography for 176 eyes of 176 patients who had PRK to correct myopia was derived from standard corneal topographic data as part of an alpha test site study (EyeSys Laboratories, Houston

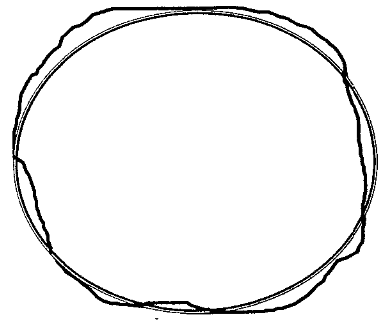

Figure 1. (Hersh) The principle behind analysis of surface irregularity. Deviations of the Placido disk image from a best-fit ellipse are measured at 360 points and used to derive a color map depicting the degree of irregularity and a quantitative assessment of the cornea's optical smoothness.

TX). Videokeratography data taken 1 year after PRK are reported here. All patients fit the criteria for the United States Food and Drug Administration Phase III trials of the Summit Technology, Inc., excimer laser and were enrolled in the national multicenter study of the Summit laser for correction of myopia. Approvals from appropriate institutional review boards and informed consents were obtained in all cases.

The PRK procedure and preoperative and postoperative management are described elsewhere.[7] All patients were treated with a 4.5 or 5.0 mm beam diameter, with attempted corrections ranging from 1.50 to 6.00 diopters (D). Trained technicians measured visual acuity under standardized lighting conditions using an Early Treatment Diabetic Retinopathy Study Chart.

Two observers qualitatively reviewed corneal irregularity maps to identify specific patterns. Both were blind to the clinical results of the PRK during this review. All maps were presented on a standard color scale to facilitate comparison; each color represented a specific predicted visual acuity (i.e., degree of corneal distortion). Quantitative PCA values were collected for the 3.0 and 6.0 mm zones in all cases. Patients were excluded from a specific analysis if necessary clinical outcomes data were unavailable; none were excluded on the basis of the PCA map or value.

The PCA data were compared with the patient's UCVA and BSCVA as well as with procedure decentration with respect to the center of the entrance pupil. The methodology used for measuring optical zone decentration is detailed elsewhere.[8] The data were also compared to a patient index of glare and halo and to subjective patient satisfaction. These two numerical values were obtained by having each patient complete a questionnaire in which they categorized their overall satisfaction on a scale ranging from 0 to 5 (5 = most satisfied). Glare/halo effects were measured individually on an identical scale, with the index measured by taking the higher of the two values.

A previous analysis of the corneal topography of this patient group[7] resulted in the definition of seven treatment zone topography patterns:

1. Homogeneous: a uniform flattening.
2. Smooth toric bowtie with axis: a symmetric treatment zone with a greater induced flattening in the steep preoperative axis.
3. Smooth toric bowtie against axis: a symmetric treatment zone with a greater induced flattening in the flat preoperative axis.
4. Irregularly irregular: generalized irregularities over the treatment zone; defined as more than one area measuring more than 0.5 mm and more than 0.50 D in power from other areas at the same radius from the optical zone center, or one area 1.0 mm or larger and 1.00 D in power that does not conform to the specific criteria of any other patterns described.
5. Keyhole/semicircular: topographic regions, quantitatively measuring 1.0 mm or larger and 1.00 D of relatively less flattening, extending in from the periphery of the ablation zone (keyhole), or a general foreshortening of the ablation zone effect in one meridian (semicircular).
6. Central island: a central area of relatively less flattening measuring 1.0 mm or larger and 1.00 D or more in power.
7. Focal topographic variants: a generally homogeneous pattern with topographic irregularities measuring 1.0 mm or less or 1.00 D or less in power.

The PCA data were compared to these stratified topography categories to determine if this quantitative measurement correlated with the defined qualitative patterns. In addition, two pooled groups were defined: a regular group (homogeneous, toric with axis, toric against axis) and a broader irregular group (irregular, keyhole/semicircular, focal topographic variant). These results were also analyzed for correlations with PCA values.

True mean visual acuities and PCA values were calculated using the logarithmic transformation of the Snellen values.[9] These were calculated by taking the log of the inverse of the Snellen visual acuities, averaging them, and calculating the antilogarithm of this average. The average was multiplied by 20 to give the denominator of the geometric mean Snellen visual acuity. Associations between PCA value and clinical outcomes were tested using Spearman rank correlations and verified using *t*-tests for comparison of means. A Kruskal–Wallis test was used to check for differences in PCA values among qualitative topography patterns, and the Wilcoxon rank sum test was used to compare these patterns after they were collapsed into two groups. The significance level for all tests was 0.05.

Results

Case Reports

Case 1. A 45-year-old man had PRK to correct of 3.00 D of myopia. After 1 year, UCVA was 20/20 and BCVA, 20/16. The patient reported a glare/halo index of 1. Computerized corneal topography showed the optical zone decentered 0.29 mm from the pupil center. The PCA map displayed a homogeneous optical zone surface with a mild ring of irregularity at its edge (Figure 2). The quantitative PCA value measured over the 3.0 mm zone predicted a visual acuity of 20/16, equal to the patient's BCVA.

Case 2. A 35-year-old man had PRK to correct 3.50 D of myopia. The PCA map showed a ring of corneal irregularity overlying the periphery of the treatment zone (Figure 3). Although the PCA value predicted a BCVA of 20/22 for the 3.0 mm zone and 20/83 for the 6.0 mm zone, the patient achieved 20/12 UCVA and 20/10 BCVA. The treatment zone was decentered by 0.46 mm. The patient reported a glare/halo index of 4.

Case 3. A 42-year-old woman had PRK to correct 4.50 D of myopia. The treatment zone was decentered by 0.97 mm, and the patient reported a glare/halo index of 1. Her PCA map showed a relatively wide ring of corneal irregularity overlying the junction of the ablation zone and peripheral cornea (Figure 4). The PCA at the 6.0 mm zone predicted a BCVA of 20/202. However, UCVA was 20/32 and BCVA, 20/10.

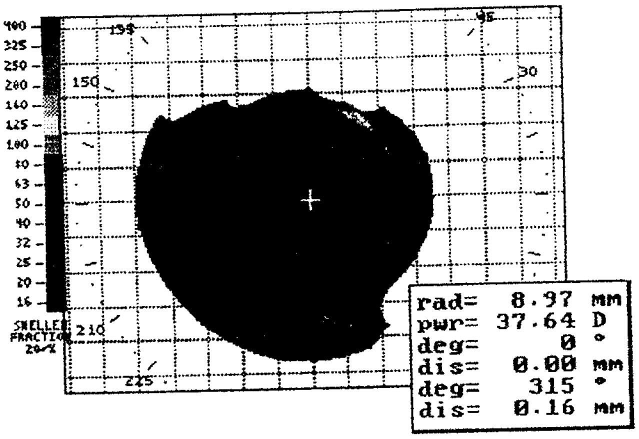

Figure 2. (Hersh) Case 1. A PCA map after PRK shows a homogeneous optical zone with a ring of mild corneal irregularity at its edge. Warmer (redder) colors indicate greater irregularity and cooler (bluer) colors, a smooth corneal surface. The PCA color scale is at the left of the map.

Qualitative Analysis of PCA Maps

In general, the 1 year postoperative PCA maps showed optical microirregularities overlying the edge of the treatment zone (Figures 2 to 4). These appeared as red rings at the juncture of the treated and untreated cornea. The cornea both at the center of the treatment zone and peripheral to its edge usually appeared smooth. The mean 3.0 mm PCA value for all patients was 20/22 and the mean 6.0 mm PCA, 20/48, indicating a greater general degree of corneal irregularity when the more peripheral rings from the 3.0 to 6.0 mm zones were incorporated into the PCA value. The PCA values at the 3.0 mm area ranged from 20/16 to 20/104; and at 6.0 mm, from 20/16 to 20/202.

Clinical Correlations

Visual Acuity. Table 1 compares actual BSCVA of 172 patients with their 3.0 and 6.0 mm PCA values. Predicted BSCVA using the 3.0 mm PCA values was within one Snellen line of the actual BSCVA in 71% of patients, within two lines in 89%, and within three lines in 94% (Table 2). There was no significant correlation of UCVA with the 3.0 or 6.0 mm PCA values.

Optical Zone Centration. The worst average 3.0 mm PCA value, 20/29, occurred in patients with optical zones decentered from 1.00 to 1.25 mm away from the pupil center; the group with least decentration (0.25 mm or less) had the best mean 3.0 mm PCA value (Table 3). Those with decentration less than 0.25 mm also had the best 6.0 mm PCA value, 20/32. The only patient with decentration in the 1.25 to 1.50 mm range had a 6.0 mm PCA value of 20/64, the worst mean value. The trend toward worse PCA values with greater decentration was not statistically significant when comparing groups stratified on the basis of decentrations greater than 0.50 mm (n = 81) and those of 0.50 mm or less (n = 93). The mean 6.0 mm PCA values of these two groups (20/52 and 20/43, respectively) differed by 9 units, approaching statistical significance ($P = .059$, unpaired t-test). The difference in mean of 3.0 mm PCA values of the greater than 0.50 mm decentration group

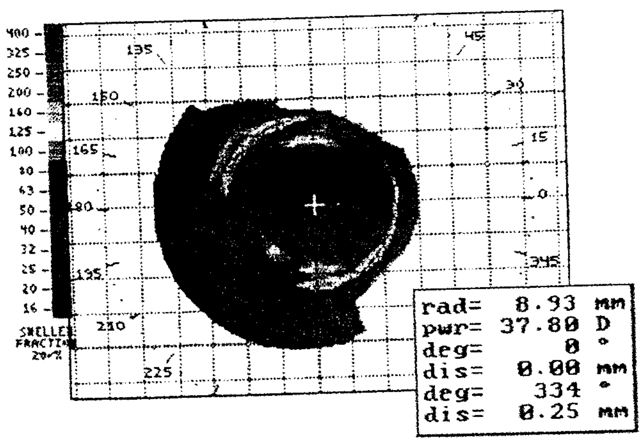

Figure 3. (Hersh) Case 2. A PCA map after PRK shows an increased irregularity overlying the juncture of the ablation zone and the untreated cornea. The 3.0 mm PCA value was 20/22 and 6.0 mm value, 20/83.

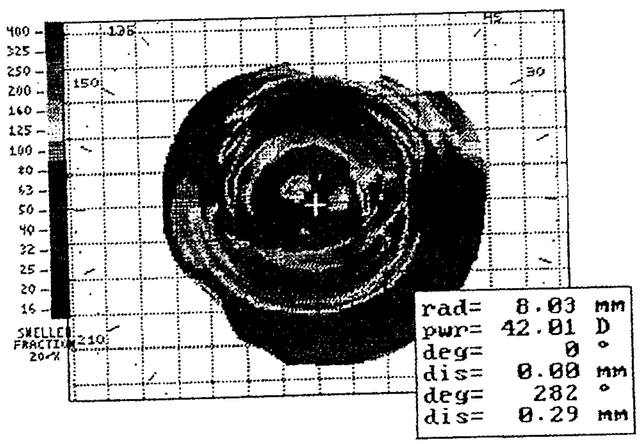

Figure 4. (Hersh) Case 3. Potential Corneal Acuity map after PRK. The PCA map shows a large amount of corneal surface irregularity extending within a 1.5 mm radius of the corneal apex.

Table 1. Best spectacle-corrected visual acuity versus PCA values.

Actual BSCVA	Number of Eyes	3.0 mm PCA		6.0 mm PCA	
		Mean	SD*	Mean	SD*
20/10	12	20/19	1.4	20/46	1.7
20/12	58	20/23	1.7	20/47	2.0
20/16	74	20/22	1.7	20/48	2.0
20/20	20	20/22	1.8	20/55	2.0
20/25	4	20/29	1.6	20/41	1.3
20/32	4	20/28	1.8	20/40	1.6

* Standard deviation in lines of Snellen visual acuity measured on LogMAR scale

Table 2. Accuracy of 3.0 mm PCA in Snellen lines.

Snellen Line Difference Between BSCVA and PCA	Number of Eyes	Cumulative Percentile
0	56	32.0
1	69	71.0
2	32	89.0
3	8	93.6
4	3	95.4
5	5	98.2
6	1	98.8
7	1	99.4
8	1	100

(20/24) and the 0.50 mm or less decentration group (20/20) was not significant ($P = .08$).

Glare/Halo Index. There was a modest trend toward higher subjective glare and halo effects with worse PCA values (Table 4). The worst 3.0 mm PCA value was in patients reporting the most glare/halo. This observation was not statistically significant when comparing the stratified groups (Spearman rank correlation). When analyzing pooled patient categories, however—one group with indices of 0 to 2, the other including the remaining higher indices of 3 to 5—patients with the greater glare/halo index had a statistically significant increase in their 3.0 mm PCA values (20/25 versus 20/21, $P = .009$, unpaired *t*-test).

Subjective Patient Satisfaction. The 1 year postoperative subjective questionnaires of 174 patients showed a mean satisfaction of 3.89 on a 0 to 5 scale (5 = most satisfied) (Table 5); 52.2% indicated a satisfaction level of 5. For these patients, the 3.0 mm PCA value predicted 20/21 visual acuity, the best reported mean 3.0 mm PCA across all satisfaction levels except for patients indicating a high satisfaction level of 4. The worst 3.0 mm PCA value, 20/33, occurred in seven patients who reported a 0 satisfaction level.

A statistically significant relationship was found with satisfaction levels of 4 or 5 associated with better 3.0 mm PCA values (Spearman rank correlation, $P = .05$). A similarly significant statistical finding was not found for the 6.0 mm PCA value, however.

Correlations with Topography Patterns

For all topography patterns, the 3.0 mm PCA value indicated greater surface regularity than the 6.0 mm value (Table 6). The keyhole/semicircular group had the worst PCA values. The differences among the 3.0 mm PCA values were statistically significant both when comparing the six categories ($P = .05$, Kruskal–Wallis test) and when the variables were placed into two broader regular and irregular classifications ($P = .01$, Wilcoxon rank sum test).

Discussion

The notion of corneal "topography" encompasses a variety of different concepts including (1) axial or instantaneous radius of curvature at multiple points on the cornea, (2) corneal image forming power, and (3) corneal surface regularity.[10] Corneal surface smoothness af-

Table 3. Optical zone decentration versus PCA value.

Decentration (mm)	Number of Eyes	Mean 3.0 mm PCA	Mean 6.0 mm PCA
0.25 or less	36	20/17	20/32
0.25–0.50	57	20/21	20/52
0.50–0.75	42	20/22	20/45
0.75–1.00	25	20/25	20/62
1.00–1.25	13	20/29	20/55
1.25–1.50	1	20/16	20/64

Table 4. Glare/halo index versus PCA value.

Glare/Halo Index	Number of Eyes	Mean 3.0 mm PCA*	Mean 6.0 mm PCA
0	30	20/20	20/37
1	51	20/24	20/54
2	28	20/19	20/46
3	34	20/24	20/45
4	14	20/25	20/52
5	11	20/26	20/49

* $P = .009$, *t*-test

ter excimer laser PRK may influence the patient's objective and subjective visual function. In particular, optical aberrations arising from focal or diffuse surface irregularities may be associated with patient complaints of glare and halos and other objective measurements of visual function such as UCVA, BSCVA, and contrast sensitivity.[11,12]

Both a qualitative description of actual surface irregularity and a clinically useful quantification of such irregularity would be useful in explaining the current visual results of PRK and improving optical outcomes in the future. Efforts to quantify corneal surface regularity include the surface irregularity index and surface asymmetry index.[13] The surface regularity index (SRI) determines corneal irregularity by analyzing the power gradient along the reflected mires of the different hemimeridians. The SRI has been shown to correlate with BSCVA.[13] In addition, other investigators have attempted to quantify irregularity by comparisons to best-fit elliptical optical surfaces.[14]

Our study analyzed the corneal surface characteristics of PRK patients using a corneal topography computer program currently under development. With this PCA program, we attempted to define the general qualitative appearance of the corneal surface after PRK; that is, is the surface smooth after PRK and if not, what is the nature of any irregularity? We used analysis of color maps depicting deviations of reflected rings from a single, scaled best-fit ellipse.

In general, our qualitative analysis of the 176 cases at 1 year after PRK revealed a relatively consistent ring of irregularity at and surrounding the junction of the treatment zone and the untreated cornea. Although this is an epithelial surface irregularity, it may be caused by both epithelial and stromal wound healing at this junction, producing an irregular "blend zone". Other investigators have reported such a ring of irregularity using Placido disk imagery.[6] Aberrations caused by optical microirregularities of the corneal surface could theoretically be associated with a glare and halo effect and image degradation.[11] We confirmed this by demonstrating a small but significant increase in average 3.0 mm PCA values in patients with higher reported glare/halo.

In addition to producing a color map graphically depicting corneal irregularity, the PCA program attempts to predict the BSCVA the cornea would support given a 3.0 or 6.0 mm entrance pupil. It accomplishes this by integrating the point-by-point irregularities overlying the entrance pupil, producing a single irregularity value that is scaled in units of predicted Snellen visual acuity. The alpha version

Table 5. Subjective patient satisfaction versus PCA value.

Satisfaction Rating	Number of Eyes	Mean 3.0 mm PCA*	Mean 6.0 mm PCA
0	7	20/33	20/43
1	13	20/25	20/69
2	13	20/25	20/42
3	16	20/24	20/56
4	34	20/20	20/44
5	91	20/21	20/45

* P = .05, Spearman rank correlation

Table 6. Topography classification versus PCA value.

Topography Pattern	Number of Eyes	Mean 3.0 mm PCA*	Mean 6.0 mm PCA
Individual Group			
Homogeneous	91	20/22	20/46
Toric with axis	23	20/21	20/45
Toric against axis	5	20/22	20/49
Irregular	22	20/24	20/50
Keyhole/semicirular	4	20/37	20/61
Focal topographic Variant	8	20/25	20/51
Pooled Group			
Regular	119	20/22†	20/47
Irregular	34	20/28†	20/55

* P = .05, Kruskal–Wallis test
† P = .01, Wilcoxon rank sum test

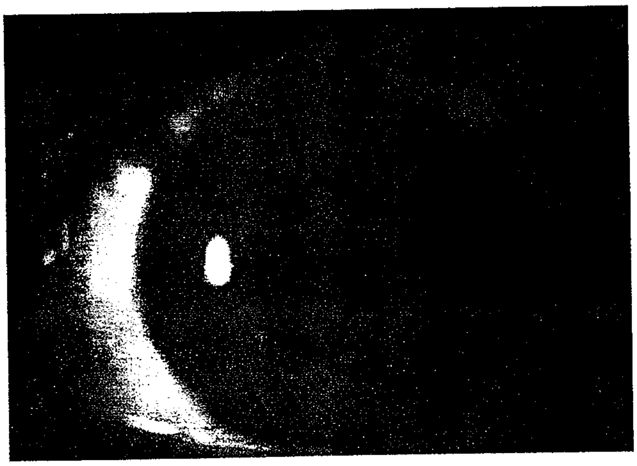

Figure 5. (Hersh) Clinical photograph 3 months after PRK of 4.50 D in a 32-year-old woman. The ring of decreased fluorescein (arrow) denotes the junction of the optical zone with the untreated cornea. Postoperative visual acuity was 20/20 with no complaints of glare or halo.

of the program we used centers the 3.0 and 6.0 mm boundaries over the corneal apex rather than the entrance pupil. Because the entrance pupil is the appropriate referrent following refractive surgery and the excimer laser procedure is centered over the entrance pupil, the predicted PCA values in this study may not quantitate the optical zone portion directly overlying the entrance pupil but might include peripheral, more irregular, parts of the treatment area. In general, however, only eyes with an eccentric pupil or large angle kappa are likely to be significantly affected. The beta version of the PCA program will center the 3.0 and 6.0 mm zones over the entrance pupil to avoid this error and improve the prediction result. Moreover, since most patients in this study maintained excellent BSCVA (all 20/32 or better), it is somewhat difficult to ascertain the predictive capability of the PCA program since there was not a wide range of BSCVA against which to compare quantitative PCA values.

Relatively few patients had PCA values that predicted much worse visual acuity than that actually obtained. Several of these patients showed focal areas of greater irregularity on their PCA maps, usually along the general ring irregularity. Such "hot spots" could, when integrated over the entire area, contribute substantially to a high general PCA value whereas, clinically, they may not actually influence the patient's high-contrast Snellen acuity as much as predicted. That is, a mild yet diffuse surface irregularity may influence visual acuity more than a focal irregularity of greater magnitude superimposed on an otherwise regular corneal surface. Moreover, the location, size, and shape of a focal irregularity would likely also have an effect on visual acuity outcome.

The 3.0 mm PCA value predicted BSCVA better than the 6.0 mm value, which in general underpredicted BSCVA, probably because of the optical zone border ring irregularity noted qualitatively. The irregular ring is incorporated into the 6.0 mm PCA value but is peripheral to the 3.0 mm PCA zone. Although clinically this irregularity does not seem to have the Snellen acuity visual degradation consequences predicted by the 6.0 mm PCA value, in dark conditions with a dilated pupil this peripheral aberration may indeed have visual consequences. This is supported by the general finding of greater subjective symptomatology such as glare and halo in patients with large pupils after PRK.[15] As the pupil dilates in low light situations, bringing the junction of the optical zone and untreated cornea over the entrance pupil, increased forward light scatter may occur with defocused rays reducing the contrast of retinal images similar to the experience with multifocal intraocular lenses.[16] Although high-contrast Snellen acuity is not significantly affected, patients may notice glare and halo and low contrast acuity may be reduced. Future modifications in the laser ablation algorithm,[17] such as novel surface-smoothing techniques, an increased optical zone diameter, and the use of peripheral blend zones, and changes in the postoperative regimen may minimize the surface microirregularities overlying the entrance pupil and, thus, improve overall optical function after PRK.

We found a significant relationship between the degree of corneal microirregularity using a 3.0 mm PCA value and subjective patient satisfaction. Although multifactorial analysis was not performed, a worse PCA value could indicate a surface irregularity overlying the entrance pupil, which would affect the patient's visual function more directly and thus decrease satisfaction.

Given the ring of irregularity at the junction of the treated and nontreated cornea, decentration of the optical zone PRK would be expected to worsen the PCA value, especially using a 6.0 mm zone, because this would bring more of the irregular ring of the PCA map under the area of integration. A trend was found but was not statistically significant. As our results suggest, decentration would affect the 3.0 mm PCA value less because the irregular ring would only be brought over a 3.0 mm entrance pupil with decentrations of approximately 1.0 mm or more, a situation that occurred in only a very small number of eyes.

Quantitative PCA values correlated with our qualitative characterization of topography patterns in this group of patients, supporting the notion that these patterns following PRK are definable and unique.[7] The homogeneous and symmetric toric optical zone patterns showed better PCA values, as would be expected because these patterns most closely conform to regular spherocylinders. The keyhole/semicircular patterns (although only four) demonstrated the worst PCA values, probably because the asymmetric foreshortening of the optical zone leads to substantial focal deviation from the best-fit ellipse.

A general understanding of corneal topography after PRK and careful analysis of the influence of postoperative surface irregularity on visual outcome may improve the PRK procedure. In particular, corneal optical microirregularities may account for side effects that some patients report after PRK such as glare and halos.

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Appendix

The Summit Photorefractive Keratectomy Topography Study Group comprised Daniel Durrie, MD, Timothy Cavanaugh, MD, John Hunkeler, MD, Kansas City, Missouri; Marc Michelson, MD, John Owen, MD, Birmingham, Alabama; Michael Gordon, MD, San Diego, California; Roger Steinert, MD, Carmen Puliafito, MD, Michael Raizman, MD, Boston, Massachusetts; Jay Pepose, MD, St. Louis, Missouri.

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