Relationship Between Refractive Error and Visual Acuity in the Prospective Evaluation of Radial Keratotomy (PERK) Study

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● As part of the Prospective Evaluation of Radial Keratotomy (PERK) study, we examined the relationship between postoperative refractive error and visual acuity without correction. We included 394 eyes (one eye per patient) with refractive errors ranging from −3.00 to +3.00 diopters one year after radial keratotomy. Within each 1-D range of the spherical equivalent of the refractive error, the visual acuity spanned five to ten Snellen lines. For visual acuities of 20/16 to 20/50, the refractive error spanned 3 to 5 D. Additionally, operated eyes had a better average uncorrected visual acuity than unoperated eyes with a similar refractive error. Within the narrow range of refraction between −2.00 and −2.50 D, the mean uncorrected visual acuity was 20/125 for 56 unoperated eyes and 20/63 for 29 operated eyes, a difference of three Snellen lines.

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Two commonly used measurements for evaluating the outcome of radial keratotomy are residual refractive error and uncorrected visual acuity. Visual acuity is the more meaningful result to the patient, but the refractive error is a more quantifiable, objective, and verifiable measure. However, a given refractive error does not correspond with a specific visual acuity, and the uncorrected visual acuity after radial keratotomy is often better than expected when compared with unoperated eyes with the same refractive error.[1]

We report herein the relationship between the uncorrected visual acuity and the spherical equivalent of the cycloplegic refraction for patients in the Prospective Evaluation of Radial Keratotomy (PERK) study.

PATIENTS AND METHODS

The PERK study is a clinical trial of a standardized technique of radial keratotomy sponsored by the National Eye Institute, Bethesda, Md. Nine centers are involved in this study. The study design[2] and the results one year after surgery[1] have been previously described.

Definition of Study Groups

To determine the correlation between refractive error and visual acuity after radial keratotomy, we selected all patients whose residual spherical equivalent of the cycloplegic refractive error one year after radial keratotomy was between −3.00 to +3.00 diopters. We chose patients in this range of refractive error because all but one had a visual acuity of 20/200 or better. Those patients with a visual acuity worse than 20/200 exceeded the limit of the measurement procedure in the PERK study,[1,2] making it impossible to determine the level of uncorrected visual acuity. Three hundred ninety-four of the 435 PERK patients had refractive errors within this range. Because we elected to report results after only a single surgical procedure, measurements at six months were included for nine eyes (2.3%) in which a second radial keratotomy operation was performed between six months and one year after the original surgery.[1] We report the results of the first operated eye for each individual because observations made of two eyes from the same individual tend to be highly correlated and therefore may skew the results.

To compare the visual acuity before and after surgery within a narrow range of refraction, we selected 29 eyes that had a refractive error between −2.00 and −2.50 D at one year and compared their visual acuity with that of 56 eyes within the same range of refractive error before radial keratotomy. We did not include eyes with refractive errors between −2.62 and −3.00 D because the distributions of refractive error for operated and unoperated eyes were not comparable within this range.

Surgical Procedure

The standardized protocol for the PERK surgical technique has been described pre-
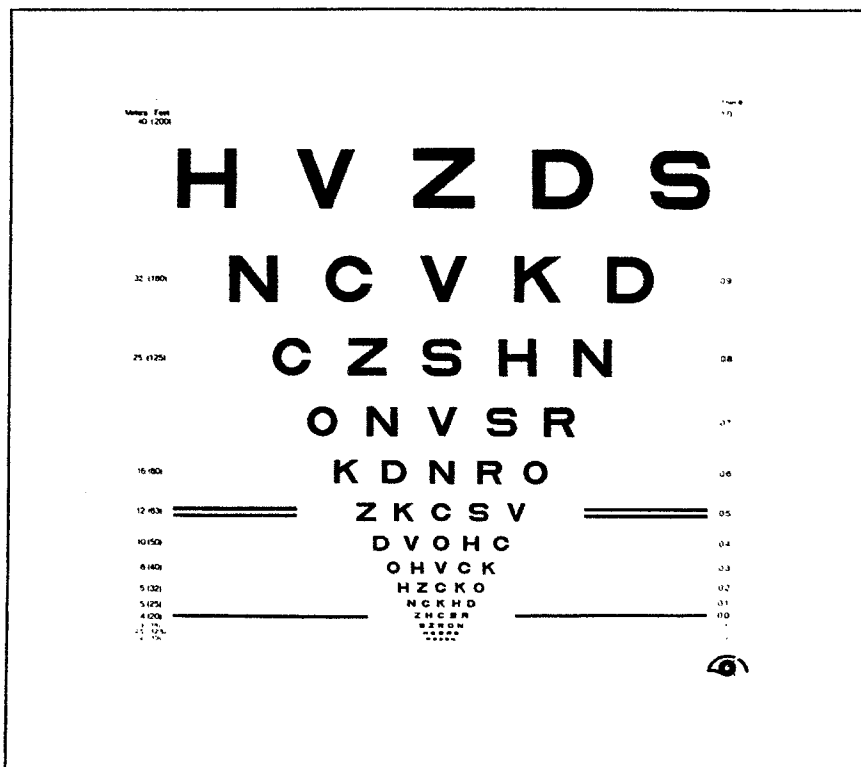
Fig 1.—Visual acuity chart used in PERK study has standardized illumination, 14 lines ranging from 20/200 to 20/10, and five letters on each line.

viously.[12] Briefly, the diameter of the central clear zone was determined by the following preoperative refraction: −2.00 to −3.12 D = 4.0 mm; −3.25 to −4.37 D = 3.5 mm; and −4.50 to −8.00 D = 3.0 mm. The diamond blade of a micrometer knife was extended to a length equal to 100% of the thinnest of four paracentral, intraoperative, ultrasonic pachymetry readings, and the length was verified on a coin-gauge block. The surgeon made eight freehand, centrifugal radial incisions spaced equidistantly around the cornea.

Measurement of Visual Acuity and Refraction

The patient was seated 4 m from a standardized, high-contrast, modified Bailey-Lovie chart[3-5] (Fig 1) that was retroilluminated in a light box at a level of approximately 100 ft-candles. Each line consisted of five Sloan letters of approximately equal difficulty, with a total of 70 letters on 14 lines: 20/10, 20/12, 20/16, 20/20, 20/25, 20/32, 20/40, 20/50, 20/63, 20/80, 20/100, 20/125, 20/160, and 20/200 (Fig 1). To decrease the possibility of patients memorizing the letters, three different charts were used: one for measuring refraction, one for testing the right eye, and one for testing the left eye.

The patient was discouraged from squinting or leaning forward and was urged to read as far down the chart as possible to ensure a clear end point. Uncorrected visual acuity was measured with the pupil undilated to avoid possible glare or distortion.

We counted the total number of letters read and converted to Snellen notation by determining the position on the chart where the patient would have stopped if all the letters had been read in sequence with none missed. The last line on which at least three letters would have been read was used as the Snellen acuity. Mean visual acuity was determined by first calculating the mean number of letters read and then converting this value to Snellen notation.

The cycloplegic refraction was measured 45 to 90 minutes following two topical instillations of 1% cyclopentolate hydrochloride administered five minutes apart. A certified technician-coordinator measured the refraction through a phoropter by retinoscopy and subjective refinement. The refractions were verified by an examiner-ophthalmologist (not the surgeon), and if there was a discrepancy between the two measurements, the refraction was repeated to resolve the conflict. The final cycloplegic refraction was converted to the spherical equivalent for analysis.

To diminish examiner bias, measurements were taken without knowledge of previous results.

Data Management and Analysis

All data were recorded on standardized forms that were forwarded to the PERK Statistical Coordinating Center in Atlanta. One-way analysis of variance, polynomial regression,[6] confidence intervals derived using the polynomial regression equation, and correlation coefficients were used to analyze and describe the data.

RESULTS
Visual Acuity in Operated and Unoperated Eyes With Similar Refractive Errors

Operated eyes one year after radial keratotomy had a better average uncorrected visual acuity than unoperated eyes with similar refractive errors ($P < .0001$). For 56 unoperated eyes with a refraction between −2.00 and −2.50 D, the mean uncorrected visual acuity was 20/125 (range, 20/40 to 20/200). For 29 operated eyes in the same range of refraction one year after radial keratotomy, the mean uncorrected visual acuity was 20/63 (range, 20/32 to 20/125), an improvement over the unoperated eyes by three Snellen lines. Of the unoperated eyes, 82% had a visual acuity of 20/100 or worse, compared with 38% of the operated eyes (Fig 2). The distribution of the refractive error in each of the two groups was similar; therefore, the differences in the visual acuity could not be explained by a greater amount of myopia among the unoperated eyes.

The operated eyes had a slightly greater amount of refractive astigmatism (mean = 0.81 D; SD = 0.63 D) than the unoperated eyes (mean = 0.54 D; SD = 0.39 D) ($P < .02$). There was 0.00 to 1.00 D of astigmatism in 91% of unoperated and 73% of operated eyes, 1.12 to 1.50 D in 9% of unoperated and 17% of operated eyes, and 1.62 to 2.50 D in 10% of operated eyes.

Relationship Between Visual Acuity and Refractive Error After Radial Keratotomy

The visual acuity without correction spanned five to ten Snellen lines within each 0.50- to 1.00-D range of refractive error (Table 1). For example, patients with a residual refraction between −1.12 and −2.00 D after one year had a mean visual acuity of 20/40 and a range of 20/16 to 20/125 (ten Snellen lines). The variability in visual acuity was not restricted to myopic patients. Patients with a refractive error of +1.12 to +2.00 D had a mean uncorrected visual acuity of 20/20 and a range of 20/12 to 20/50 (seven Snellen lines).

We found a curvilinear relationship between the refraction and the uncorrected visual acuity (Fig 3), as described mathematically by the following polynomial regression equation: $VA = 55.74 + 5.67 \text{ (REF)} - 3.80 \text{ (REF}^2) - 0.32 \text{ (REF}^3)$, where VA represents the uncorrected visual acuity in total number of letters read and REF represents the spherical equivalent of the cycloplegic refraction. The
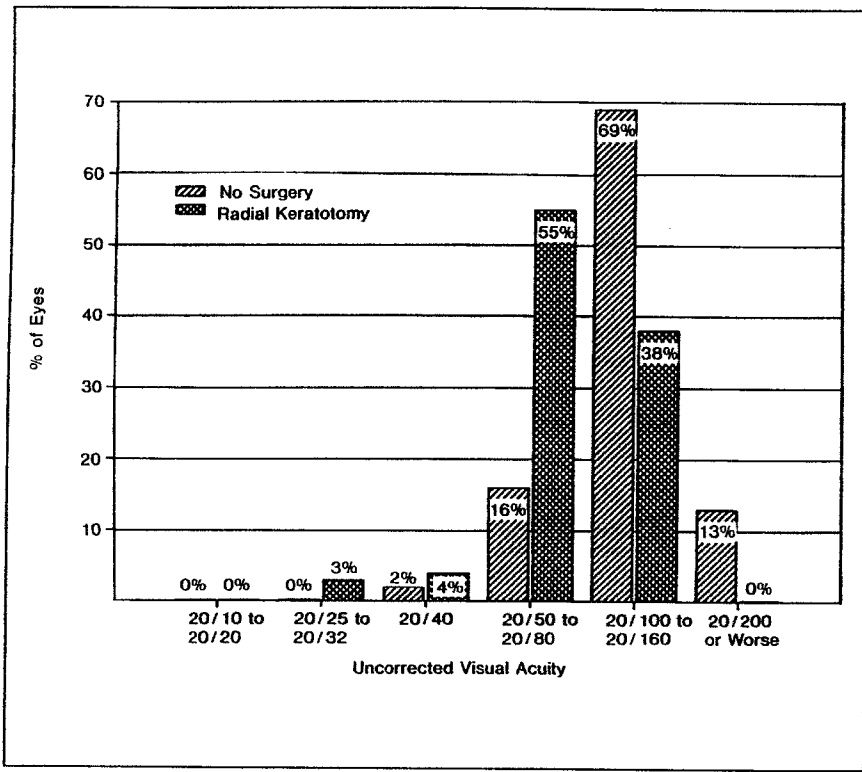
Fig 2.—For eyes with refractive error of −2.00 D to −2.50 D, uncorrected visual acuity was better in operated eyes (n = 29) one year after radial keratotomy than in unoperated eyes (n = 56).

Table 1.—Uncorrected Visual Acuity for Refractive Errors One Year After Radial Keratotomy

	Spherical Equivalent of the Cycloplegic Refraction, %*						
	−2.12 to −3.00 D (n = 38)	−1.12 to −2.00 D (n = 70)	−0.62 to −1.00 D (n = 58)	−0.50 to +0.50 D (n = 149)	+0.62 to +1.00 D (n = 39)	+1.12 to +2.00 D (n = 34)	+2.12 to +3.00 D (n = 6)
Uncorrected visual acuity							
20/10	...	...	...	1	...	...	...
20/12	...	...	...	12	5	12	...
20/16	...	1	7	31	36	29	...
20/20	...	1	29	33	35	18	50
20/25	...	11	33	15	13	29	...
20/32	3	27	17	7	3	3	...
20/40	8	16	7	0.5	...	6	17
20/50	13	22	5	0.5	8	3	33
20/63	11	11	...	...	...	...	...
20/80	8	6	2	...	...	...	...
20/100	26	4	...	...	...	...	...
20/125	18	1	...	...	...	...	...
20/160	8	...	...	...	...	...	...
20/200 or worse	5	...	...	...	...	...	...
Total	100	100	100	100	100	100	100
Mean visual acuity	20/80	20/40	20/25	20/20	20/20	20/20	20/32

*Values express the percent of patients with each visual acuity within the range of refraction such that each column totals 100%.

constant term, 55.74, was the average number of letters seen by an eye that was emmetropic one year after radial keratotomy (20/20 in Snellen notation). The coefficients in the regression equation apply to this data set and cannot be assumed to apply to all patients.

As a measure of the variability in visual acuity for a given refractive error, we used the regression equation to calculate the 90% confidence intervals of the predicted visual acuity given a specific amount of refractive error one year after radial keratotomy (Table 2). Each 90% confidence interval spanned six to seven Snellen lines. For example, we are 90% confident that the visual acuity of a patient with a refraction of −2.00 D one year after radial keratotomy would be between 20/32 to 20/100 (six Snellen lines).

Myopic eyes generally had a worse visual acuity than hyperopic eyes with a refraction of similar magnitude (Fig 3). For example, ten eyes with a myopic refraction of −1.50 D had a mean visual acuity of 20/40 (SD = nine letters), while seven eyes with a hyperopic refraction of +1.50 D had a visual acuity of 20/20 (SD = ten letters).

Another way to look at the relationship between visual acuity and refractive error is to group the eyes according to visual acuity and then examine the variation in the refractive error for each acuity. Within each level of visual acuity between 20/16 and 20/50, the refractive error spanned 3 to 5 D (Table 3). The ranges of refractive error were narrower (0.125 to 2.125 D) within each level of acuity better than 20/16 and worse than 20/50.

Relationship Between Astigmatism and Visual Acuity After Radial Keratotomy

Using a one-way analysis of variance, we compared the average amount of astigmatism among the seven refractive error groups defined in Table 1 and found no significant differences among the groups. The majority of patients (50% to 81%) in each refractive group had between 0.00 and 1.00 D of astigmatism.

Astigmatism reduced visual acuity in patients with smaller spherical equivalent refractive errors. For the 188 eyes with a spherical equivalent of the cycloplegic refraction between −0.50 and +1.00 D, a decrease in visual acuity was somewhat associated with an increase in astigmatism ($r = −.54$). Astigmatism had no significant effect on visual acuity in
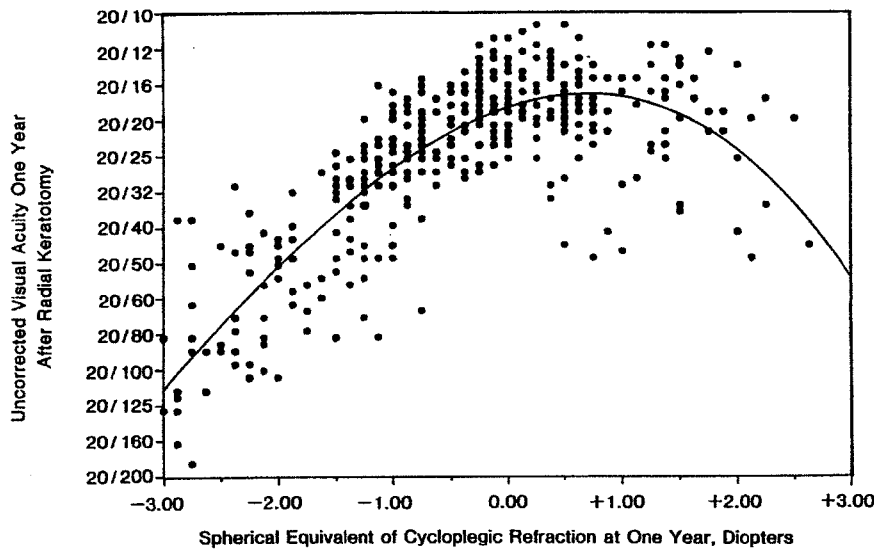
Fig 3.—Scattergram of visual acuity and refraction demonstrates six-Snellen-line range of acuity that exists for most refractive errors. Curved line represents the following polynomial regression equation relating uncorrected visual acuity (VA) and refractive error (REF): VA = 55.74 + 5.67 (REF) − 3.80 (REF^2) − 0.32 (REF^3), for which R^2 = 0.70.

patients with larger refractive errors ($r = -.29$ to $+.18$) in each of the remaining refractive groups.

Effect of Age on Variability in Visual Acuity

For patients with a hyperopic refraction (+0.62 to +3.00 D), an increase in age was somewhat associated with a decrease in visual acuity ($r = -.40$). For each decade increase in age, there was an average decrease of about one Snellen line in the uncorrected visual acuity beginning between the ages of 40 and 45 years. For patients with a myopic refraction (−0.62 to −3.00 D), there was no relationship between age and visual acuity ($r = .11$). The mean ages in years were 37.5 (SD = 7.7) and 32.0 (SD = 6.6) for hyperopic and myopic patients, respectively.

COMMENT

Analysis of the relationship between visual acuity and refractive error in the PERK study revealed three major findings: (1) Uncorrected visual acuity was better by an average of three Snellen lines in operated than in unoperated eyes within the same small range of refractive error, ie, −2.00 to −2.50 D (Fig 2). (2) For a given refractive error, there was wide variability in the visual acuity (Fig 3) (Tables 1 and 2). The uncorrected visual acuity spanned five to ten Snellen lines within each 0.50- to 1.00-D range of the refractive error. (3) For

each level of visual acuity, there was variability in the refractive error (Table 3). The refractive error spanned 3 to 5 D within each level of visual acuity between 20/16 and 20/50, but the range was much narrower, 0.125 to 2.125 D, within each level of visual acuity better than 20/16 and worse than 20/50.

Visual Acuity in Operated and Unoperated Eyes With the Same Refractive Error

To corroborate our finding that eyes after radial keratotomy had a better uncorrected visual acuity than unoperated eyes with similar refractive errors, we reviewed previously published data correlating visual acuity and refraction. Only a report by Crawford and colleagues[7] presented data in sufficient detail to allow comparison. However, the results of any comparison between the two studies are questionable due to the likelihood of differences in testing conditions and patient age. We chose 109 PERK eyes with 0.50 D or less of refractive astigmatism and a cycloplegic refraction between −0.50 and −3.00 D one year after surgery to compare with 313 eyes with no refractive astigmatism and a manifest refraction of −0.50 to −3.00 D reported by Crawford et al.[7]

Operated eyes in the PERK study had a better uncorrected visual acuity one year after surgery than the unoperated eyes reported by Crawford et

al.[7] The percentage and number of eyes with an acuity of 20/40 or better in each range of refractive error were as follows: −0.12 to −0.50 D, 100% (32/32) for the PERK study and 84% (98/117) in the Crawford et al study; −0.62 to −1.00 D, 88% (23/26) in the PERK study and 40% (53/134) in the Crawford et al study; −1.12 to −1.50 D, 82% (14/17) in the PERK study and 3% (1/37) in the Crawford et al study; and −1.62 to −3.00 D, 13% (3/23) in the PERK study and 0% (0/25) in the Crawford et al study.

The reasons for differences in uncorrected visual acuity between operated and unoperated eyes with similar refractive errors are not known. We suggest speculative reasons based on two of the factors that determine the resolving power of the eye: the diameter of the pupil and the optical quality of the cornea.

Diameter of the Pupil.—We compared the cycloplegic refraction with the pupil dilated and the uncorrected visual acuity with the pupil in its normal state. We did not measure uncorrected cycloplegic visual acuity. Patients undergoing radial keratotomy may be slightly more myopic with their pupils dilated and, therefore, they may have a better uncorrected visual acuity with the pupil normal than would be suggested by the cycloplegic refractive error.

The reason for this difference may relate to two optical aberrations that increase the myopic refractive error when the pupil is dilated. The first is the spherical aberration induced by the peripheral cornea and lens.[8] Dilating the pupil allows peripheral rays to enter the eye and to form their clearest image anterior to the original focal point, inducing an overall myopic change. The second aberration is induced by the radial keratotomy; this change is caused by the relative paracentral steepening of the cornea that appears at the edge of the clear zone, sometimes called the paracentral knee. This aberration may produce a slight increase in refractive myopia when the pupil is dilated.

Shape of the Cornea and Size of the Retinal Blur Circle.—When a distant point is imaged by an optical system, the image is not really a point, but instead a small spot or blur circle. The higher the resolution efficiency of the system, the smaller the blur circle. The shape of the normal cornea forms a sphere centrally approximately 3.0 mm in diameter with gradual progressive flattening toward the limbus. After radial keratotomy, the corneal shape is altered so that the central
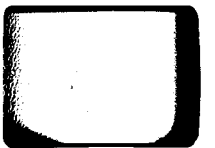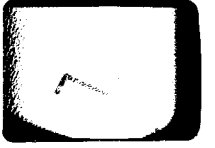
error both before and after radial keratotomy. Unfortunately, we did not measure the diameter of the pupil under manifest conditions and, therefore, could not test the effect of pupil size on visual acuity. We did measure pupil diameter under both scotopic and glare conditions, but we found no correlation between these pupillary diameters and the uncorrected visual acuity ($r = -.04$ under scotopic conditions, $r = -.02$ under glare conditions).

The synkinesis reflex that results in a small pupil during accommodation may explain why hyperopic patients see better than myopic patients.

We also examined the distribution of the refractive error for each level of visual acuity (Table 3). There was a wider (3 to 5 D) span in the refractive error associated with each of the better visual acuities between 20/16 and 20/50, and a narrower (0.125 to 2.125 D) span for those with each level of visual acuity outside this range, whether better (20/10 to 20/12) or worse (20/63 to 20/200 or worse). We would expect eyes with exquisite resolving power (20/10 to 20/12) to have almost no refractive error. Those with good to fair visual acuity (20/16 to 20/50) should manifest the wider spread as a result of normal biologic variation and variation in the new optical conditions produced by radial keratotomy. The narrow range of refractive errors for eyes with a poor uncorrected visual acuity (20/63 to 20/200 or worse) was an artifact of our selection criteria. If myopic patients with more than -3.00 D of refractive error had been included, it is likely that there would also be a broad range of refractive errors for eyes with a poor uncorrected visual acuity.

From this information, we conclude that if a patient's refractive error after radial keratotomy is known, an ophthalmologist can confidently predict the visual acuity only within six or seven Snellen lines. Similarly, if the patient's visual acuity after radial keratotomy is known, the ophthalmologist's ability to predict the refractive error is severely limited unless the patient sees exquisitely well (20/10 to 20/12). The same kind of variability, of course, applies to normal unoperated eyes.[7,9,10] As we gather more information on patients (such as pupil diameter) and increase our understanding of human physiologic optics (including the effects of corneal asphericity), we may be able to better predict an individual patient's visual acuity.

Standardization of Measurement Techniques

Measurement of Visual Acuity.— Although clinical measurement of the visual acuity appears deceptively simple, five variables must be controlled for accurate measurement.

1. The visual acuity chart should be well calibrated. In the PERK study, we used modified Bailey-Lovie charts[3-5] that have the same number of letters (five) per line, lines of approximately equal difficulty, and an orderly geometric change in the height of the letters from one line to the next (Fig 1). These criteria are not present in the standard Snellen chart.

2. Testing conditions should remain the same from one measurement to the next. In the PERK study, we monitored room illumination using a light meter and controlled the illumination and contrast of the acuity charts by placing them in a standardized light box.[4]

3. The method of eliciting responses from the patient should be standardized. In the PERK study, the coordinator, who was certified in a practical course in clinical examination,[1,2] encouraged each patient to read all possible letters without leaning forward or squinting.

The charts were seen only four times during the first year after surgery, limiting the ability of the patients to memorize the 70 letters on 14 lines.

4. A clear end point for best visual acuity should be established. Recording visual acuity as the smallest line on which the patient can read most of the letters, sometimes with an annotation of plus or minus the number of letters read on the adjacent lines, is an imprecise end point. We adopted the system suggested by F. L. Ferris, MD (written communication, September 1984) in the diabetic retinopathy trials of counting the total number of letters read on the chart, dividing it by 5 (the number of letters on each line), and using the smallest line on which three or more letters would have been read as the equivalent Snellen acuity.

5. Visual acuity worse than 20/200 should be measured so that the change in uncorrected visual acuity can be quantified. This was not done in the PERK study.

Measurement of Refractive Error.—To accurately measure the refractive change induced by surgery, a well-trained refractionist must measure the cycloplegic refraction to control for accommodation. Automated refractors may give confusing results after refractive corneal surgery, presumably because of the altered optics of the cornea. Reporting the refractive error as the spherical equivalent is useful, but independent analysis of the amount of cylindrical error must also be reported.

Reporting Results of Radial Keratotomy

Although the cycloplegic refraction is currently the most accurate and precise measure of the change induced by radial keratotomy, reporting the refractive error in the absence of visual acuity provides an incomplete picture of the outcome of radial keratotomy. In the present study, patients within a 1-D range of refractive error had a difference in visual acuity of five to ten Snellen lines (Table 1), so that the refractive error gave little information about the patient's visual acuity. Similarly, many patients with an acuity or 20/20 or better had a significant residual refractive error. For example, 12% (24/198) of the PERK patients with a visual acuity of 20/12 to 20/20 had a postoperative refraction between +1.12 and +3.00 D (Table 3). Presenting these patients' visual acuity without noting the refractive error would obscure the significant overcorrection. Thus, both the cycloplegic refractive error and the visual acuity measured under standardized conditions should be presented together.

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