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Characteristics Influencing Outcomes of Excimer Laser Photorefractive Keratectomy

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Purpose: To identify preoperative and intraoperative characteristics associated with outcomes of photorefractive keratectomy (PRK).

Methods: In the phase III multicenter clinical trials of the Summit Technology excimer laser for corrections of 1.5 to 6.0 diopters (D) of myopia, three principal outcomes of PRK on 612 patients were examined: (1) uncorrected visual acuity of 20/40 or better, (2) predictability of refractive outcome within 1.0 D of attempted correction, and (3) stability of refractive result between 12 and 24 months. Multiple logistic regression was used to test for independent associations of multiple preoperative and intraoperative characteristics with each of these outcomes.

Results: Older age was independently associated with lesser likelihood of achieving 20/40 or better uncorrected visual acuity (odds ratio = 1.08 per incremental year of age, 95% confidence interval [CI] = 1.04–1.12) and with decreased predictability, specifically with overcorrection (odds ratio = 1.09, 95% CI = 1.06–1.12), but age was not associated with stability of refraction. Greater attempted correction was associated independently with a decreased likelihood of 20/40 or better uncorrected visual acuity (odds ratio = 2.78 for corrections of 3.5–5.5 D, 95% CI = 1.18–6.75; odds ratio = 4.19 for corrections of ≥5.5 D, 95% CI = 1.66–10.58), with decreased predictability (odds ratio = 1.72 for corrections of 3.5–5.5 D, 95% CI = 1.05–2.85; odds ratio = 2.95 for corrections of ≥5.5 D, 95% CI = 1.65–5.26), and with a reduced likelihood of stability of refraction (odds ratio = 3.46 for corrections of ≥5.0 D, 95% CI = 1.32–9.11). No intraoperative characteristics were associated with any of the outcomes assessed.

Conclusions: Using this specific excimer laser system with an optical zone of 4.5 or 5.0 mm, patient age and attempted correction are important preoperative characteristics associated with postoperative uncorrected visual acuity and predictability of PRK. Stability of refraction is strongly associated with attempted correction. Such information may help guide patient selection, determine timing of fellow eye treatment, and suggest changes in the laser treatment algorithm for individual patients. Although these findings may be representative of PRK in general, similar analyses should be performed before modifying patient treatments using either a 6.0-mm treatment zone or other laser systems.
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Excimer laser photorefractive keratectomy (PRK) is a promising modality for the correction of myopia and has been approved recently by the United States Food and Drug Administration.[1–5] To date, procedures have been performed based on theoretical optics and mathematical algorithms designed to remove a specified tissue lens from the corneal surface.[6,7] This has been done without regard to individual patient characteristics which might have an influence on the outcomes of the procedure. In the future, it is likely that biologic and wound-healing differences among patients will be identified and incorporated into individual PRK treatments.

Clinically, the influence of surgical and perioperative variables on results of PRK are, as yet, unclear. In this multicenter phase III study of PRK using the Summit Technology excimer laser (Summit Technology, Inc, Waltham, MA) with a 4.5- or 5.0-mm beam diameter, we have analyzed associations of preoperative and surgical characteristics with defined outcomes of PRK. Such associations should aid in elucidating factors predictive of either good or poor outcomes after the excimer laser procedure. This knowledge should help to improve patient selection, suggest appropriate variations in laser treatment algorithms, and guide postoperative care strategies for the individual patient.

Patients and Methods

Study Design

As part of the phase III multicenter clinical study of the Summit Technology excimer laser conducted in accordance with United States Food and Drug Administration regulations, an observational study of the first eye treated of 701 patients was performed to assess the safety and efficacy of PRK for treating myopia. The treatments were performed at ten clinical centers between June 1991 and February 1992. All patients entered in the study had between −1.25 and −7.25 diopters (D) of myopia (spherical equivalent) and less than or equal to 1.00 D of regular astigmatism. Attempted corrections ranged from 1.50 to 6.00 D (mean, 4.24 D). Data analyzed in this study were from the 2-year follow-up visit. Two-year data were available on 612 eyes of 612 patients. Only the first eye treated of each patient was included in the analysis.

All study centers conformed to standardized patient entry criteria under an investigational device exemption granted to Summit Technology, Inc. Approvals from appropriate institutional review boards were obtained. Preoperative and follow-up visits included a detailed ophthalmologic examination with both manifest and cycloplegic refractions by two independent observers, measurement of visual acuity under controlled lighting conditions by trained technicians using an Early Treatment of Diabetic Retinopathy Study chart (Lighthouse for the Blind, New York, NY), manual keratometry, glare testing with the brightness acuity tester (Mentor, Norwell, MA), contrast sensitivity (VectorVision, Dayton, OH), videokeratography (EyeSys Laboratories, Houston, TX), and anterior segment photography.

Photorefractive Keratectomy Procedure

Photorefractive keratectomy was performed with the Summit ExciMed UV200LA excimer laser system (Summit Technology, Inc). Laser parameters included a repetition rate of 10 Hz, radiant exposure at the corneal plane of 180 mJ/cm^2, and pulse duration of 14 nseconds, resulting in an ablation rate of corneal stromal tissue of approximately 0.25 μm per pulse. Treatment zone size was 4.5 mm in 251 (35.8%) of the 701 patients treated and 5.0 mm in 450 (64.2%) of these patients.

The standardized PRK procedure used has been published previously.[8] In brief, to ensure appropriate laser energy and beam homogeneity, ablation and beam profile characteristics were tested at the beginning of each treatment day by the rate and pattern of ablation of a 100-μm–thick gelatin filter (Kodak #1497890, Rochester, NY) and standardized ablations on a polymethylmethacrylate disc. The surgical eye received 1% pilocarpine and topical anesthetic drops. The ablation was centered over the entrance pupil as suggested by Uozato and Guyton.[9] The centration procedure is described in detail elsewhere.[10]

Two training sessions were performed to familiarize the patient with the procedure and to ensure proper fixation subsequently. The first training session involved the application of 1% methylcellulose to the cornea before ablation to block the incoming laser beam. The second session was performed on dry epithelium using 25 pulses of the laser at its maximum aperture. The optical zone then was marked around the entrance pupil with a 6.0-mm optical zone marker, the epithelium within this area was removed with a microsurgical blade, and the laser ablation was performed. In general, the manifest refraction spherical equivalent at the spectacle plane was programmed into the laser, although differences of up to ±1.0 D from this amount were allowed at the surgeon's discretion. In these patients, the intended correction was entered.

Postoperatively, a combination antibiotic–steroid ointment and a patch were applied. The ointment was continued five times daily until the cornea had re-epithelialized. Drops of 1.0% fluorometholone then were administered five times daily for 1 month. The dosage then was reduced to 0.1% fluorometholone drops four times daily for 1 month and then three times daily for 1 month. Corticosteroid dosage after the completion of the third month was at the discretion of the individual surgeon based on the patient's refraction and degree of corneal haze.

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Data Analysis

Definitions of Principal Outcomes. Outcomes studied included (1) uncorrected visual acuity of 20/40 or better at 2 years; (2) predictability of postoperative refraction within 1.0 D of attempted correction at 2 years; (3) stability of the postoperative refraction, assessed by comparing the refractive spherical equivalent at 12 versus 24 months and considering a refraction to be stable if there was 1 0 D or less change in spherical equivalent between these two visits. All visual acuity measurements were reported on the logMAR scale [10]

Characteristics Assessed. Preoperative patient characteristics and surgical variables were analyzed for possible associations with each of the principal outcomes The patient characteristics studied included age, sex, medical history, biomicroscopic findings of the anterior segment, measures of visual acuity, refraction, astigmatism, average corneal power as assessed by mean keratometry readings, and intraocular pressure. Surgical characteristics analyzed included the attempted correction, optical zone size, treatment center, total PRK time, and the time from epithelial removal to laser treatment.

Statistical Analysis

Data were entered from uniform study forms submitted from each investigational site Bivariate analyses were performed initially to test for individual associations between the preoperative and surgical characteristics and the outcomes measured. Contingency tables were constructed for categorical variables. For continuous variables, mean values were compared across groups A significance level of 0.05 was used for subsequent inclusion in the multivariate models Multivariate models were constructed using the variables found to be significant in the bivariate analyses ($P \leq 0.05$) and additional variables thought to be of demographic or clinical significance such as treatment center or optical zone size. Odds ratios, indicating the strength of the independent association were calculated and are presented with their 95% confidence intervals (CIs) Statistical analysis was performed using the Statistical Analysis System 6.07 (SAS Institute, Inc, Cary, NC).

Results

A total of 701 patients entered the study cohort Clinical data were available on 612 patients (87%) 2 years after PRK. Comparing those patients lost to follow-up with the study cohort, there were no differences at baseline in age, sex, or manifest spherical equivalent. The mean age of the 612 patients followed was 38 years, and 55% were male. Treatment zone size was 4.5 mm in 198 (32 3%) and 5.0 mm in 414 (67.6%) of the 612 patients.

Characteristics Associated with Uncorrected Visual Acuity

Overall, for the 612 patients analyzed in this study, 563 (92%) achieved a postoperative uncorrected visual acuity of 20/40 or better at the 2-year follow-up visit. Bivariate analyses indicated possible associations of uncorrected visual acuity of 20/40 or better with preoperative age, contact lens use, refractive cylinder, attempted correction, intraocular pressure, and total PRK time. Table 1 presents the multiple logistic regression model of preoperative and surgical characteristics associated with uncorrected visual acuity worse than 20/40 at the 2-year follow-up visit This analysis indicates independent associations of age, attempted correction, and intraocular pressure with uncorrected visual acuity.

The effect of age was large; an individual's relative likelihood of having uncorrected visual acuity of 20/40 or better decreases by approximately 8% with every additional year of age. For instance, more than 95% of patients between 21 and 40 years of age achieved 20/40 or better visual acuity compared with 76% of those between 51 and 60 years of age (Table 2).

Similarly, attempted correction (i e., the correction programmed into the laser) was found to be associated with lesser likelihood of achieving 20/40 or better uncorrected visual acuity. Table 3 shows patients stratified to 0.5-D increments of attempted correction. Patients with less attempted correction fared the best. Compared with

Table 1. Multiple Logistic Regression Model of Preoperative and Operative Characteristics Associated with Uncorrected Visual Acuity <20/40 2 Years after Photoreactive Keratectomy (n = 611)

Characteristic	Odds Ratio	95% CI
Age (1-yr increment)*	1.08	1 04–1 12
Attempted correction*		
<2.5 D	0 34	0.04–2 87
2 5–<3 5 D	1 00	—
3 5–<5.5 D*	2 78	1.18–6.75
≥5 5 D*	4 19	1.66–10.58
Intraocular pressure (1-mm increment)*	0 85	0.75–0 96
Total PRK time (1-min increment)	0 96	0.68–1 36
Optical zone <5.0 mm	1 26	0.62–2.56
Study center		
1	0 89	0.23–3 38
2	0 79	0.23–2.76
3	0 70	0.16–3 03
4†	1 00	—
5	1 07	0.28–4.14
6	0 26	0 05–1 53
7	0.28	0 03–2.81
8	0.36	0 03–3.85
9	1.16	0 29–4.60
10	0.21	0 02–1 97

CI = confidence interval; D = diopter; PRK = photorefractive keratectomy

* Statistically significant

† Reference: center with percent uncorrected visual acuity 20/40 or better closest to the overall mean

Table 2. Patient Age and Uncorrected Visual Acuity after Photorefractive Keratectomy

Age (yrs)	No.	% of Patients with UCVA ≥ 20/40
21–30	140	95 7
31–40	241	95 4
41–50	179	89.4
51–60	41	75.6
>60	9	88 9

UCVA = uncorrected visual acuity.

those with attempted correction of 2.5 to 3.5 D, those with attempted corrections of 3.5 to 5 5 D had approximately a threefold greater likelihood of not achieving 20/40 or better uncorrected visual acuity and those with corrections of 5.5 D or more had over a fourfold greater risk of having uncorrected visual acuity worse than 20/40.

Conversely, those patients with higher intraocular pressures were less likely to have an uncorrected visual acuity worse than 20/40 No independent effects of other preoperative and surgical characteristics, including optical zone size, study center, and total PRK time, were seen.

Characteristics Associated with Procedure Predictability

Overall, for the 612 patients analyzed in this study, 78% achieved a refractive change within 1.0 D of the attempted correction at the 2-year follow-up visit. Bivariate analyses indicated possible associations of a number of preoperative and surgical characteristics, including patient age, attempted correction, study center, refractive astigmatism, optical zone size, presence of lens opacities, and the time from the start of epithelium removal to laser ablation

Table 4 shows the multiple logistic regression model of preoperative and surgical characteristics associated with

Table 3. Attempted Correction and Uncorrected Visual Acuity after Photorefractive Keratectomy (n = 612)

Attempted Correction (D)	No.	UCVA ≥ 20/40 (%)
1 5–<2 0	16	93 8
2 0–2 5	40	100 0
2.5–3 0	55	98.2
3.0–3 5	73	97 3
3 5–4.0	81	92 6
4 0–4 5	86	89 5
4.5–5 0	69	92.8
5.0–5 5	65	89.2
5 5–6.0	60	88 3
6 0	67	85 1

D = diopter; UCVA = uncorrected visual acuity

Table 4. Multiple Logistic Regression Model of Preoperative and Surgical Characteristics Associated with Predictability Outside ± 1.0 Diopter 2 Years after Photorefractive Keratectomy (n = 612)

Characteristic	Odds Ratio	95% CI
Age (1-yr increment)*	1.05	1.04–1.07
Attempted correction*		
<2.5 D	0 74	0 29–1 85
2.5–<3.5 D	1 00	—
3 5–<5.5 D*	1.72	1.05–2 85
≥5.5 D*	2 95	1 65–5 26
Total PRK time (1-min increment)	0 89	0 72–1 10
Optical zone <5 0 mm	1 18	0 75–1 87
Iris color*		
Dark and medium	1.00	—
Light	2 03	1 33–3 09
Study center		
1	0.93	0.44–1.98
2†	1.00	—
3	1 89	0 78–4 62
4	1 02	0 41–2 53
5	0 78	0.37–1 64
6	0.49	0.19–1.26
7	1 99	0 79–4.97
8	2 05	0 76–5 54
9	1 92	0 83–4 45
10	1.59	0.71–3 58

CI = confidence interval; D = diopter.

* Statistically significant

† Reference: center with percent predictability closest to the overall mean

predictability outside ±1.0 D at the 2-year follow-up visit. As with the analysis of uncorrected visual acuity, significant and comparable independent effects were seen for age and attempted correction An independent association also was seen for iris color; individuals with light irides had fewer predictable outcomes No association was seen for intraocular pressure, optical zone size, total PRK time, or study center.

With each 1-year increment in age, there was an approximately 5% decreased relative likelihood of achieving within 1 0 D of attempted correction. A second regression analysis was performed, separating those individuals who were overcorrected from those who were undercorrected. This analysis indicated that age was associated specifically with overcorrections (but not undercorrections) of more than 1 0 D (odds ratio = 1 09 for each yearly increment, 95% CI = 1.06–1 12). Table 5 illustrates predictability stratified by decade of life, demonstrating the association of increasing age with lesser predictability as well as overcorrection. For example, more than 82% of patients between 21 and 40 years of age achieved within 1.0 D of attempted correction compared with 59% of those between 51 and 60 years of age

Table 6 shows predictability stratified to 0.5-D increments of attempted correction As can be seen, propor-

Table 5. Stratified Age Groups and Predictability Outcome

Age (yrs)	No.	±1.0 D (%)	Overcorrection >1.0 D (%)	Undercorrection >1.0 D (%)
21–30	140	83.6	4.3	12.1
31–40	241	82.4	8.7	8.7
41–50	179	71.0	19.6	9.5
51–60	41	58.5	29.3	12.2
>60	9	77.8	11.1	11.1

D = diopter.

tionately fewer patients with higher attempted corrections achieved this success outcome. Compared with those patients with attempted correction of 2.5 to 3.5 D, those with attempted corrections of 3.5 to 5.5 D had approximately a twofold greater likelihood of not achieving within ±1.0 D of attempted correction, and those with corrections of ≥5.5 D had nearly a threefold greater risk of not achieving within 1.0 D of attempted correction (Table 4). When the analysis was repeated, separating those patients who were undercorrected and those who were overcorrected, the association between attempted correction and predictability was found specifically for undercorrections (but not overcorrections) of more than 1.0 diopter. Compared with those patients with attempted corrections of 2.5 to 3.5 D, those with attempted corrections of 3.5 to 5.5 D had 3.32 times (95% CI = 1.42–7.73) greater odds of being undercorrected by 1.0 D or more; those with attempted correction of 5.5 or more D had a 7.88-fold (95% CI = 3.22–19.24) excess risk of being undercorrected.

Characteristics Associated with Stability of Refraction

Table 7 shows the proportion of patients stable within 1.0 D between 12 and 24 months, stratified by preoperative spherical equivalent. Over this time interval, visual acuity of 89.9% of patients overall was stable within 1.0 D. There appeared to be a greater tendency toward myopic shifts with higher degrees of correction. Table 8 shows the multiple logistic regression model of characteristics associated with changes of more than 1.0 D between the 12- and 24-month examinations. There was no significant effect of age on stability. A large independent effect was seen for attempted correction; higher refractive corrections were associated with less likelihood of refractive stability. Those patients with attempted corrections of 5.0 D or greater were more than three times more likely to be less stable (within ±1.0 D) between 1 and 2 years.

One study center had a lesser likelihood of refractive stability. This center was not associated with any variation in either predictability or the proportion of patients achieving uncorrected visual acuity of 20/40 or better. Otherwise, no independent effects of optical zone size or other characteristics could be demonstrated.

Discussion

To date, patients undergoing excimer laser PRK generally have received treatment based solely on refractive error without regard to individual patient characteristics. This "one-size-fits-all" approach has, thus far, led to encouraging results in numerous clinical trials.[1–4,11–13] The identification of preoperative and intraoperative characteristics influencing outcomes of PRK, however, should improve future results both by clarifying patient selection and suggesting changes in treatment algorithms. In our study of 612 patients in a rigorous multicenter trial, we have identified a number of preoperative and intraoperative characteristics independently associated with specific important clinical outcomes of PRK.

Effect of Patient Age

In this study, older patients had a decreased chance of achieving 20/40 or better uncorrected visual acuity compared with younger patients; each 1-year increment in age was associated with a decreased relative likelihood of

Table 6. Attempted Correction and Predictability of Photorefractive Keratectomy

Attempted Correction (D)	No.	±1.0 D (%)	Overcorrection (%)	Undercorrection (%)
1.5–<2.0	16	75.0	25.0	0.0
2.0–2.5	40	92.5	5.0	2.5
2.5–3.0	55	89.1	9.1	1.8
3.0–3.5	73	79.9	15.1	5.5
3.5–4.0	81	81.5	13.6	4.9
4.0–4.5	86	77.9	11.6	10.5
4.5–5.0	69	71.0	18.8	10.1
5.0–5.5	65	76.9	12.3	10.8
5.5–6.0	60	73.3	5.0	21.7
6.0	67	65.7	11.9	22.4

D = diopter.

Table 7. Stability of Refraction between 12 and 24 Months Stratified to Refractive Error*

	Overall	Preoperative Spherical Equivalent (D)					
		<2.0	2.0–2.9	3.0–3.9	4.0–4.9	5.0–5.9	≥6.0
Hyperopic shift >1.0 D	3.2	0.0	5.2	0.7	3.5	5.0	3.0
Stable ±1.0 D	89.9	100.0	93.5	94.9	89.4	86.7	80.0
Myopic shift >1.0 D	6.8	0.0	1.3	4.4	7.0	8.3	16.7

D = diopter

* Values are percentages

approximately 8% of achieving 20/40 or better visual acuity. Older patients were also less likely to achieve within 1.0 D of attempted correction and were more likely to be overcorrected. Regarding this latter finding, it is possible that accommodation in younger patients may have led to underestimation of hyperopic refractions, thus augmenting the age differences found in this study.

Photorefractive keratectomy in general may be associated with an early overcorrection which diminishes over time with expected stromal wound healing.[12,14–16] In the older patient, therefore, the relative tendency toward overcorrection could be secondary to a diminished stromal wound-healing response, with more patients retaining the initial overcorrection seen in the early postoperative period. This may be analogous to the increased correction seen in older patients who have undergone radial keratotomy, where diminished healing and contraction of the incisions leads to a greater refractive response to surgery.[17] Age, in contrast, was not associated with stability of refractive correction from the 1- to 2-year examination. This implies that the interaction between age and wound healing, which causes a tendency toward undercorrection, occurs in the first year; the refraction, thereafter, remains equally stable as for the younger patient.

Given this finding of increased overcorrection in older patients, the decreased likelihood of uncorrected visual acuity of 20/40 or better found in older patients could, in part, be a result of the inability of patients with presbyopia who are hyperopic postoperatively to focus to good-distance visual acuity. Moreover, the novel optics of the cornea resulting from the change in normal asphericity[18] and topography[8] induced by PRK may interact with other aging changes of the eye, thus potentially resulting in the negative relation of age to uncorrected vision found in this study (i.e., optical aberrations after PRK could possibly decrease visual acuity in the aging eye more than in the young eye).[19] However, actual aging changes such as cataract and age-related macular degeneration were not found on examination of the patients enrolled in this study. Furthermore, no age effect on topography classification or corneal surface irregularity was found in previous studies of a subset of this patient cohort.[8,20] Such interactions between the optics of the cornea after PRK and the aging eye thus remain speculative.

Table 8. Multiple Logistic Regression Model of Preoperative and Surgical Characteristics Associated with Changes of >1.0 Diopter in Manifest Spherical Equivalent Refraction between 12 and 24 Months after Photorefractive Keratectomy (n = 555)

Characteristic	Odds Ratio	95% CI
Age (1-yr increment)	1.02	0.99–1.05
Attempted correction*		
<3.0 D	1.00	—
3.0–<5.0 D	1.56	0.60–4.0
≥5.0 D*	3.46	1.32–9.11
Total PRK time (1-min increment)	0.91	0.66–1.26
Optical zone <5.0 mm	0.59	0.32–1.10
Intraocular pressure (1-mm increment)	0.99	0.89–1.10
Study center		
1	0.38	0.09–1.86
2†	1.00	—
3	0.56	0.11–2.86
4	1.86	0.60–5.79
5	0.88	0.28–2.79
6*	2.90	1.08–7.80
7	1.04	0.21–5.19
8	0.90	0.17–4.70
9	1.70	0.55–5.25
10	2.60	0.92–7.37

CI = confidence interval; D = diopter; PRK = photorefractive keratectomy

* Statistically significant.

† Refrence: center with percent stability in manifest refraction spherical equivalent closest to the overall mean.

Effect of Attempted Correction

Attempted refractive correction also was independently associated with postoperative uncorrected visual acuity; patients with higher attempted corrections had a lesser likelihood of achieving 20/40 or better visual acuity. This finding may be related to the greater likelihood of undercorrection with higher attempted corrections. Moreover, other sequelae causing optical aberrations, such as treatment zone edge effects,[20,21] decentration,[10] and corneal asphericity,[18,22] also could be increased with higher corrections and possibly lead to a diminished likelihood of good uncorrected vision after PRK.

While, in general, there was less likelihood of achieving within 1.0 D of attempted correction with higher attempted corrections, patients undergoing higher attempted corrections were specifically more likely to be undercorrected by more than 1.0 D. For patients in whom 5.5 D or more of correction were attempted, the odds of being undercorrected were nearly eightfold greater than patients in whom attempted correction was less than 3.5 D; more than 20% of patients with attempted corrections of 5.5 D or greater were undercorrected by more than 1.0 D.

The algorithm governing ablation of a spherical tissue lens by the excimer laser is theoretically correct[6,7]; therefore, explanations for these findings must rest either in the laser–tissue interaction itself[23–25] or subsequent corneal wound healing.[26] The laser–tissue interaction may be affected by corneal hydration during the procedure, possibly with increases in stromal hydration secondary to shock-wave phenomena during the procedure, leading to a decreasing ablation rate as lasing proceeds. In particular, shock-wave phenomena could drive water into the ablation zone, thus decreasing the ablation rate and removing less stromal tissue than anticipated, with a consequent tendency toward undercorrection.[8,27,28] More likely, corneal epithelial or stromal wound healing may play a role in the decreased predictability of patients undergoing higher refractive ablations. Relatively increased wound healing and stromal remodeling with higher corrections could lead to greater "fill-in" of the ablation zone with resulting decreased achieved correction. Patients in this trial had optical zones of 4.5 or 5.0 mm. Larger optical zones or bevelled transition zones might moderate corneal healing and lead to increased predictability for higher attempted corrections.[28,29]

Postoperative refractive stability was inversely associated with the patient's refractive error. Patients with myopia of 5.0 D or more were more than threefold more likely to have a change of refraction of more than 1.0 D between the 1- and 2-year examinations. Whereas 93.5% to 100% of patients with a preoperative myopia of less than 4.0 D were stable over this 1-year period, only 80% to 89.4% of those with 4.0 D or more met the stability outcome. Again, corneal wound healing is an important factor in stability; those patients with greater ablations may undergo more substantial and lengthy wound remodeling.[26] Clinically, this may help to determine the timing of treatment of the fellow eye. To allow the first eye to stabilize, a longer time lag between treatments should be planned for eyes undergoing high attempted corrections.

Other Factors Associated with Outcomes of Photorefractive Keratectomy

Treatment zone diameters in this study were either 4.5 or 5.0 mm. Although size of the treatment zone was not associated with postoperative uncorrected visual acuity or overall predictability, patients with the smaller diameter were more likely to be undercorrected. One possible explanation is that the distance from the edge of the ablation to the center of the optical zone modulates overall wound healing, larger zones tending to regress less than smaller zones.[30]

No center effect was found for the outcomes analyzed in this study, although one center did show less refractive stability than the others. This one finding may possibly be associated with measurement error because no variation in any of the other principal outcomes was found. All surgeons received similar training and conformed to standard surgical and perioperative protocols. When PRK is in more widespread use at multiple sites with numerous lasers and surgeons, it will be important to re-examine the possibility of an effect of treatment center on outcomes.

The tendency of higher intraocular pressure to be independently associated with lower odds of not achieving 20/40 or better uncorrected visual acuity is difficult to explain. Similarly, the finding of an effect of iris color on predictability was unanticipated. Finally, the finding that average preoperative keratometry readings (i.e., average corneal power) did not influence outcomes of best visual acuity or predictability was expected based on theoretical optics of the PRK procedure.[7,22]

Conclusions

Photorefractive keratectomy algorithms may need to be modified to account for predictive characteristics such as age and attempted correction. For instance, using the excimer laser system in this study, procedure predictability probably could have been improved by intentionally undercorrecting older patients. Moreover, increasing the nominal attempted correction in the case of higher desired corrections, especially for younger patients may improve the results in this subset of patients. It must be emphasized that the specific results presented in this study can be attributed only to the specific laser system, configuration, and optical zone diameter used for these patient treatments. Although our findings may be representative of PRK in general, similar analyses should be performed before modifying patient treatments using a 6.0-mm treatment zone or other laser systems. However, knowledge of the influence of individual patient and surgical variables should be an important addition to patient treatments as the PRK procedure continues to develop.

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Appendix

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