Incidence and Associations of Retreatment After LASIK

Peter S. Hersh, MD,[1,2,3] *Kristen L. Fry, OD,MS,*[1,2,3] *Douglas S. Bishop, BA*[3]

Purpose: To determine the incidence and risk factors for laser in situ keratomileusis (LASIK) retreatment and to present a novel retreatment technique.

Design: Retrospective noncomparative consecutive case series.

Participants: Two thousand four hundred eighty-five eyes (1306 patients) underwent LASIK surgery for myopia, hyperopia, or astigmatism using either the Summit Apex Plus or the Alcon LADARVision excimer laser systems. Only retreatments for residual refractive error were included.

Main Outcome Measures: Prevalence and incidence of retreatments were determined. Potential risk factors for retreatment, including age, gender, and attempted correction, were assessed. Refractive error and a ratio of residual sphere to cylinder in retreated eyes were also analyzed.

Results: Of the total cohort studied, 288 eyes of 233 patients underwent one retreatment, and 3 eyes of 3 patients required two retreatment procedures. The overall 1-year incidence of retreatment was 10.5%. The average length of time between initial treatment and enhancement was 7.3 ± 6.4 months; 85% of retreatments took place within 1 year. Two hundred eighty-five of the 288 retreatments were accomplished using a manual flap lift approach; 3 eyes required a repeat microkeratome cut. Higher initial corrections and residual astigmatism were associated with a significantly higher rate of retreatment. Patients older than 40 years were at greater risk for retreatment. There was no gender difference.

Conclusions: Higher initial corrections, astigmatism, and older age are risk factors for LASIK retreatment. Most LASIK flaps can be lifted using the manual technique described up to 3 years after initial surgery. *Ophthalmology 2003;110:748–754 © 2003 by the American Academy of Ophthalmology.*

Although laser in situ keratomileusis (LASIK) has experienced improvements in technique, safety, and efficacy, the incidence, risk factors, and techniques for retreatment remain considerably underexplored. Enhancements have been shown to be generally safe and effective for the treatment of residual visual complaints in myopic, hyperopic, and astigmatic patients,[1–14]as well as after photorefractive keratectomy.[15] Many factors, such as individual patient expectations, actual refractive result, and surgeon preference can lead patients to desire a retreatment procedure.[1–15] LASIK retreatment rates of between 5% and 28% have been reported.[1–14] This article presents the results of a large study designed to quantitate the incidence of LASIK retreatment and to further understand the preoperative characteristics leading to increased probability of enhancement surgery.

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[1] Department of Ophthalmology, UMDNJ-New Jersey Medical School, Newark, New Jersey.

[2] Hackensack University Medical Center, Hackensack, New Jersey.

[3] Cornea and Laser Eye Institute, Teaneck, New Jersey.

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Reprint requests to Peter S. Hersh, MD, Cornea and Laser Eye Institute, Hackensack University Medical Center/New Jersey Medical School, 300 Frank W. Burr Boulevard, Teaneck, NJ 07666.

Materials and Methods

Study Design

A retrospective study was carried out on 2485 eyes of 1306 patients. All procedures were performed by a single surgeon (PSH) at an academic cornea and refractive surgery subspecialty practice. One thousand eight hundred ninety-eight initial procedures were performed with the Summit Apex Plus excimer laser (Alcon Summit Autonomous, Fort Worth, TX), and 587 were performed with Autonomous LADARVision excimer laser (Alcon Laboratories, Fort Worth, TX).

All patients included in this study were 18 years of age or older. Because the goal of this investigation was to analyze the incidence and risk factors associated with LASIK retreatment for residual refractive error after uncomplicated surgery, eyes were excluded if a retreatment was required for a reason other than residual refractive error, such as epithelial ingrowth, flap striae, or diffuse lamellar keratitis. Moreover, all eyes with previous surgery other than LASIK were excluded. Because a major interest in this study was to assess the 1-year incidence of retreatment after LASIK, only eyes with at least 1-year follow-up were included.

Criteria for retreatment were residual, correctable refractive error causing subjective patient dissatisfaction with the uncorrected postoperative vision, as well as a stable postoperative refraction. Thus, patients who may have "required" retreatment on the basis of substantial refractive error may have deemed their initial correction to be satisfactory and have chosen not to pursue an enhancement procedure. On the contrary, patients with relatively good uncorrected visual acuity with small residual refractive corrections may have chosen to have a retreatment. Because pa-

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Table 1. Patient Demographics for Initial LASIK

	All Eyes	Myopia	Hyperopia
No. eyes	2016	1920	96
Males	933 (46.3%)	884 (46%)	47 (49%)
Females	1083 (53.7%)	1036 (54%)	49 (51%)
Mean age (yrs)	39.9	39.2	55.0
Age range (yrs)	18–78	18–78	23–74
Mean attempted MRSE ± SD (D)		−5.19 ± 2.61	+3.47 ± 1.26
Attempted range (D)		−0.50 to −14.00	+1.50 to +6.00

D = diopter; MRSE = manifest refraction spherical equivalent; SD = standard deviation.

tient satisfaction, not emmetropia per se, is the essential goal of any refractive surgery procedure, the criteria used in this study for retreatment reflect that likely used in common clinical practice today.

Previous studies have shown that patient prescriptions generally stabilize by 6 months after initial LASIK,[1–14,16,17] although regression can occur up to 1 to 2 years after surgery.[3] Therefore, in this study, we looked specifically at the incidence of retreatment during the year after initial surgery. In addition, we investigated characteristics associated with retreatment and trends in LASIK retreatment over time.

LASIK Retreatment Procedure

Primary LASIK procedures were performed with the Hansatome (Bausch & Lomb, Rochester, NY) or the Alcon SKBM microkeratome (Alcon Laboratories, Fort Worth, TX). The general LASIK technique was as previously reported.[17]

Retreatments in most cases were performed using a manual technique to elevate the original flap. The specific surgical protocol was as follows (Fig 1):

1. The edge of the flap is marked first at the slit lamp with a gentian violet marking pen to facilitate visualization at laser.
2. The cornea is marked with nonradial marks to facilitate flap repositioning (Fig 1A).
3. Using the edge of a spatula (Hersh LASIK retreatment spatula, ASICO, Westmont, IL), the epithelium is gently scratched down for approximately 1.0 mm in length to reveal the flap edge. In cases of retreatment soon after primary cutting of the flap, the edge might be more easily identified, making actual removal of the epithelium over the flap edge unnecessary.
4. The spatula is then placed tangential to the flap edge, and the flap-bed adhesion is broken (Fig 1B).
5. Using a tire iron technique, the spatula is used to break the adhesion for approximately 4 mm (Fig 1C).
6. Using double-pronged forceps with nonbiting tips (Hersh LASIK retreatment forceps, ASICO, Westmont, IL), the freed flap edge is gently grasped (Fig 1D).
7. The flap is then carefully peeled back with the retreatment forceps (Fig 1E).
8. Laser ablation is performed.
9. The epithelium is carefully pushed back from the flap bed edge (Fig 1F).
10. The flap is repositioned using standard techniques, ensuring that no epithelium is introduced into the interface (Fig 1G).
11. The edge epithelium is repositioned if necessary (Fig 1H).
12. A bandage soft contact lens is applied.

Data Analysis

Data were collected postoperatively and entered into an Excel spreadsheet for subsequent analysis (Microsoft, Inc., Seattle, WA). Data are reported as mean ± standard deviation. Statistical significance was determined using Student's *t* test for associations of patient age and refractive error with retreatment incidence. A *P* value of 0.05 was considered significant. Rates of retreatment were analyzed for significance using a chi-square test.

To investigate the influence of residual astigmatism on the incidence of retreatment, we created an astigmatism index, which was defined as the sphere component of the patient's remaining refraction after the initial treatment divided by the residual astigmatism (i.e., sphere/cylinder ratio). Thus, the lower this ratio, the greater was the relative cylindrical component of the retreatment.

Results

Study Group Characteristics and Retreatment Prevalence

Of the 2485 eyes initially treated, 2322 (93.4%) were for myopia and 163 (6.6%) for hyperopia. From this entire cohort, 292 (11.8%) of 233 patients underwent a LASIK retreatment for residual refractive error. Of the 2322 myopic and 163 hyperopic eyes treated, 282 (12.1%) and 10 (6.2%), respectively, were retreated. One hundred eighty-five of 1899 eyes (9.7%) initially treated using the Summit Apex Plus excimer laser underwent enhancement procedures. In comparison, 107 of 587 eyes (18.2%) treated with the Autonomous LADARVision laser had retreatment.

Retreatment Incidence

To more rigorously characterize the predicted need for retreatment in an individual patient, we looked specifically at the incidence of retreatment over 1 year after the primary procedure. Of the 2016 eyes in the study group falling into this cohort, 212 (10.5%) required an enhancement LASIK procedure within 1 year of primary surgery. One-year retreatment incidence was 10.8% and 6.0% for initially myopic and initially hyperopic eyes, respectively. Preoperative data for the 1-year incidence initial and retreatment cohorts are seen in Tables 1 and 2.

Effect of Initial Refraction on Retreatment Rate

Both higher degree of myopia ($P < 0.001$) and higher degree of astigmatism ($P = 0.013$) were independent predictors of the need for retreatment. For example, a patient with 10 diopters (D) of myopia had a retreatment incidence of approximately 14%,

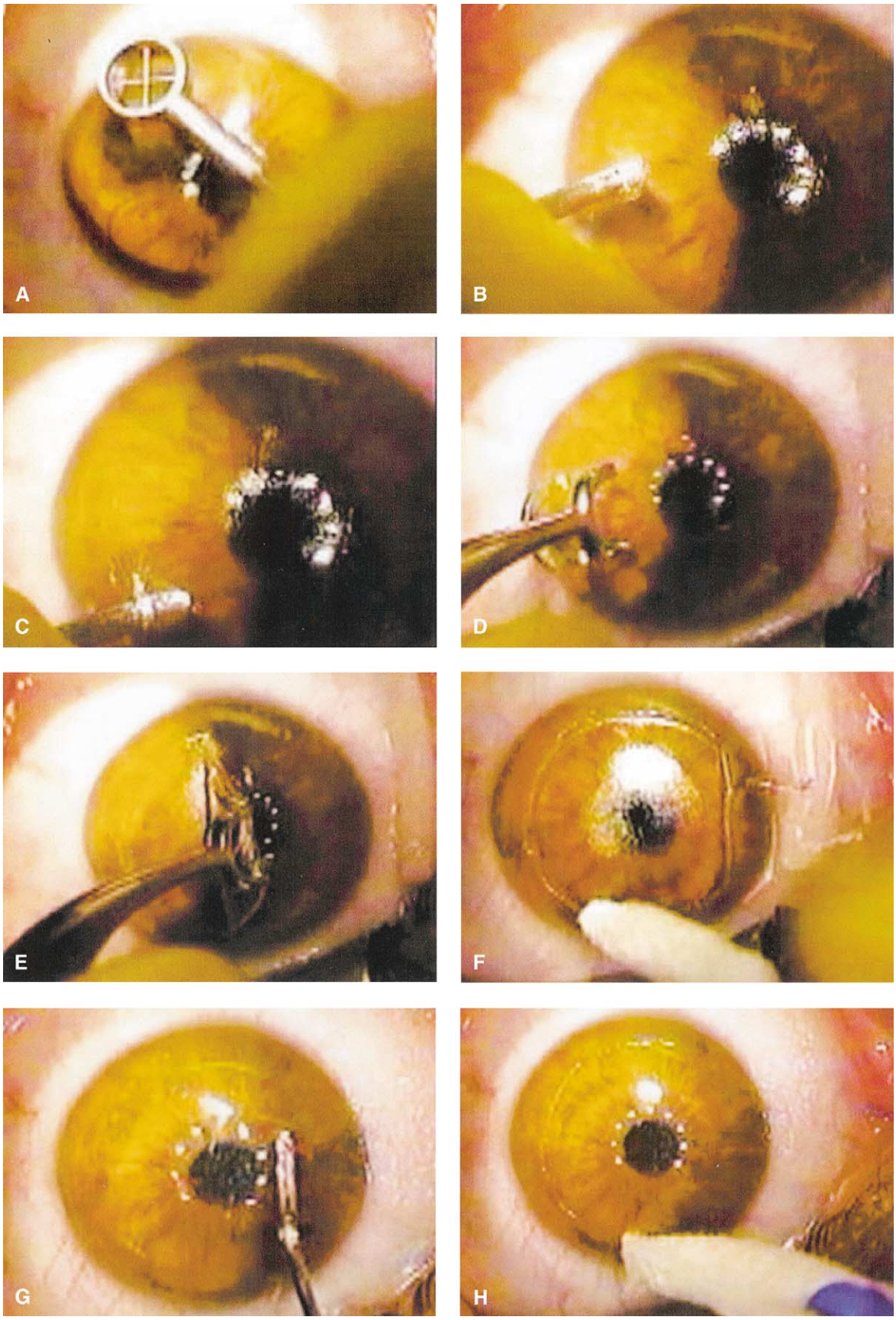

Figure 1. **A,** Cornea marked with two or more nonradial marks. **B,** The spatula is placed tangential to the flap edge, and the flap-bed adhesion is broken. **C,** Using a tire iron technique, the spatula is used to break the adhesion for approximately 4 mm. **D,** Using double-pronged forceps with nonbiting tips (Hersh LASIK retreatment forceps, ASICO, Westmont, IL), the freed flap edge is gently grasped. **E,** The flap is carefully peeled back with the retreatment forceps. **F,** After laser ablation, the epithelium is carefully peeled back from the flap bed edge. **G,** The flap is repositioned using standard techniques. **H,** The edge epithelium is repositioned if necessary.

Table 2. Patient Demographics for Retreatments

	All Eyes	Myopia	Hyperopia
No. eyes retreated	212 (10.50%)	206 (10.80%)	6 (6%)
Males	88 (41.5%)	85 (41.3%)	3 (50.0%)
Females	124 (58.5%)	121 (58.7%)	3 (50.0%)
Mean age (yrs)	42.8	42.4	56.3
Age range (yrs)	18–64	18–64	49–64
Mean initial attempted MRSE (D)		−6.23 ± 2.83	3.38 ± 0.80
Initial attempted range (D)		−0.88 to −14.00	+2.50 to +4.50
Mean retreatment attempted MRSE (D)		−1.14 ± 0.81	0.55 ± 2.32
Retreatment range (D)		−4.00 to +2.00	−1.60 to +4.50

D = diopter; MRSE = manifest refraction spherical equivalent.

whereas a patient with only 3 D of myopia had an approximately 7% chance of needing retreatment during the 1 year after initial surgery (Fig 2). Hyperopic patients requiring retreatments (n = 6) were not significantly different ($P > 0.05$) from the total hyperopic population with respect to their initial spherical equivalent refractions. However, the number of patients in this group was very small.

Of initial myopic refractions, 97.6% (206 eyes) were retreated for residual myopia. Two of 206 eyes (1.0%) required hyperopic correction, and three eyes (1.4%) had mixed astigmatism. Of the initial hyperopic eyes requiring retreatment, 4 of 6 eyes were retreated for myopia, 1 was retreated for residual hyperopia, and 1 had mixed astigmatism.

Effect of Residual Astigmatism on Retreatment Rate

The astigmatism index (sphere/cylinder ratio) was used to more carefully analyze the influence of residual astigmatism on the incidence of retreatment. Of 212 eyes needing retreatment, 86 (40.6%) were for spherical corrections. Sixty-two eyes (29.2%) were for residual astigmatism alone. Of the 64 (30.2%) spherocylindrical prescriptions retreated, there was a trend for a greater numbers of eyes with lower sphere/cylinder ratios, and thus relatively more residual astigmatism, to require retreatment (Fig 3).

Historical Trend in Magnitude of Attempted Retreatments

In the myopia group studied, analysis of both initial and retreatment corrections over time showed a trend toward decreasing amounts of correction by year of surgery (Fig 4). For each successive year, the mean initial attempted correction was less compared with the preceding years. A similar trend was observed in retreatment magnitude. For surgeries in 1997 to 1998, the retreatment manifest refraction spherical equivalent was significantly ($P = 0.04$) greater than amounts for later years. For instance, in 1997 to 1998, the mean retreatment attempted correction was 1.54 D, which by 2001 had fallen to 1.12 D. Eyes with residual hyperopia or mixed astigmatism were excluded from these calculations.

Relation of Patient Age and Gender to Retreatment Incidence

In the 1-year incidence patient cohort, a trend for a greater number of retreatments in older patients was observed (Fig 5). Patients older than 40 years had a significantly ($P < 0.001$) higher rate of retreatment than patients younger than 40 years. To rule out an influence of preoperative refraction, initial spherical equivalent refractions were compared between these age groups. No signifi-

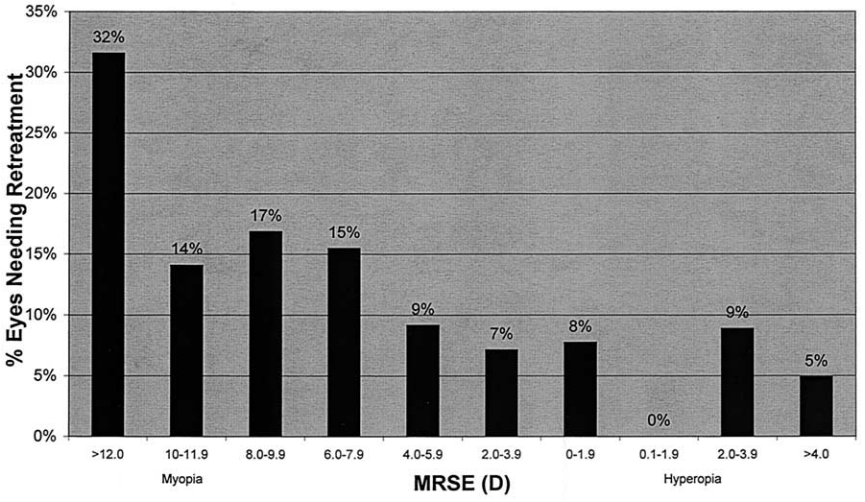

Figure 2. Retreatment incidence stratified by manifest refraction spherical equivalent (MRSE, 2.0 diopter subgroups) before the initial laser in situ keratomileusis surgery. Note increased retreatment incidence with higher initial MRSE.

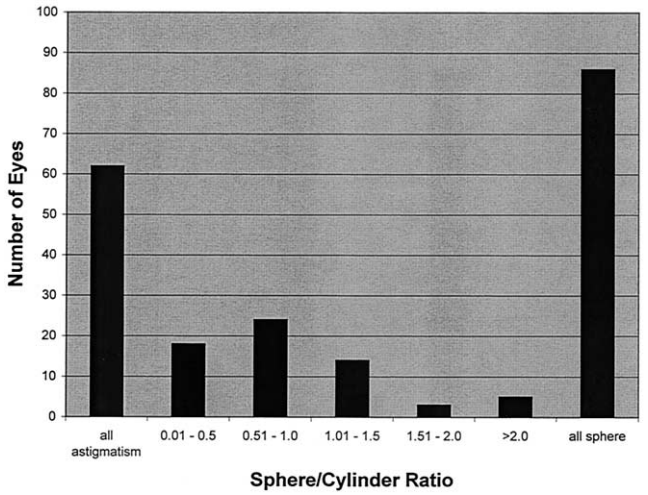

Figure 3. Number of eyes requiring retreatment stratified to astigmatism index. The astigmatism index was calculated as the ratio of the spherical component of the patient's initial prescription divided by amount of astigmatism.

cant difference was found in the magnitude of initial refractive error among patients older than 40 years old compared with patients younger than 40 years of age. In fact, an inverse relationship was seen in patients older than 50 years; these older patients had significantly lower initial attempted corrections (-5.46 ± 4.08 D) compared with patients younger than 50 years of age (-7.16 ± 3.38 D).

No gender difference in retreatment rate was observed. Of males, 9.4% (88 of 993) underwent retreatment compared with 11.4% (124 of 1083) of females. This result was not statistically significant.

Time Between Treatments

Approximately 85% of retreatments took place within 12 months of the initial LASIK procedure (Fig 6). Whereas the mean number of months between treatments was 7.3 ($\pm$ 6.4), the greatest number of retreatments (40.8%) took place between 3 and 6 months of initial surgery. The longest time elapsed before retreatment was approximately 3 years (1133 days).

Purposeful Undercorrection/Monovision

This article does not distinguish retreatments necessitated through purposeful undercorrections (i.e., monovision or staged procedures for high myopia). As in a recent retrospective study on monovision,[18] we define a purposeful undercorrection as any attempted correction that is more than 1 D less than the actual manifest refraction spherical equivalent. In our 1-year cohort, 362 planned undercorrections were performed, mostly for monovision. Of those, 62 eyes (17.1%) underwent retreatment.

Multiple Retreatments

Three eyes (1.0% of retreatment cohort, 0.1% overall) undergoing LASIK retreatment received an additional enhancement. All 3 were initially treated for myopia and subsequently underwent retreatment for undercorrection. The second retreatments were performed at 9, 13, and 21 months, respectively, after primary enhancement.

Aborted Manual Procedures

Of the 2485 eyes analyzed in this study, 3 had a planned retreatment procedure that was aborted as a result of the inability to manually lift the LASIK flap. The mean age of these patients was 30.7 years. On average, the retreatments were attempted more than 2 years (795 days) after the original procedure. Patient WZ was 39 years of age, and retreatment was attempted at 524 days. Patient RL was 30 years old when retreatment was attempted 900 days after the original surgery. The third patient, TF, was 23 years old and had a retreatment attempted at 961 days. All of these patients had uncomplicated initial surgery without postoperative diffuse lamellar keratitis or epithelial ingrowth. All other retreatment procedures were successfully performed using manual flap relifting.

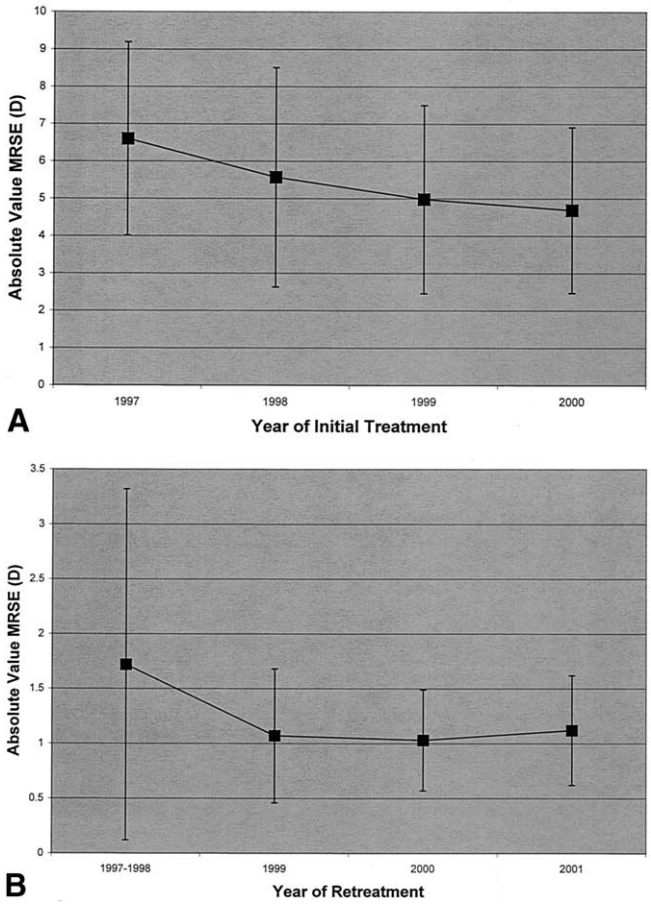

Figure 4. Mean attempted correction in patients with myopia by year of treatment for initial laser in situ keratomileusis **(A)** and retreatments **(B)**. Each black square represents the mean spherical equivalent refraction, and the vertical bars indicate the standard deviation.

Discussion

LASIK retreatments for residual refractive error can be necessitated for undercorrection or regression.[1–17,19,20] This study reports results of retreatments among 2485 eyes in an attempt to more comprehensively and accurately elicit retreatment incidence and risk factor data.

Our retreatment rate of 10.5% (Table 2) compares favorably with the literature reports, which range from 5.5% to 28%.[1–14] However, reported rates may not be comparable, based on a number of factors. Some articles report retreatment rate as the number of eyes needing any type of

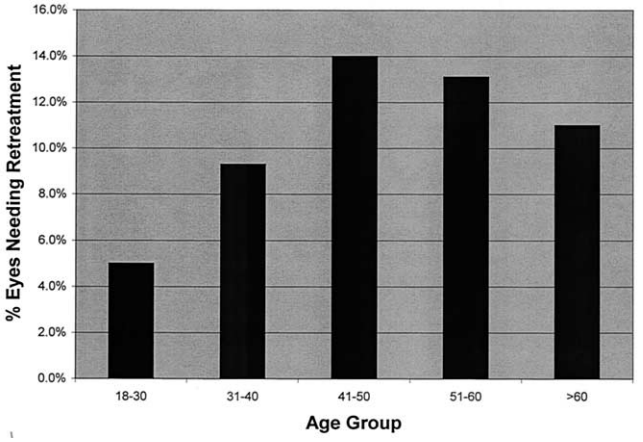

Figure 5. Incidence of retreatment stratified to patient age. Patients older than 40 years had a significantly higher rate of retreatment ($P = 0.03$).

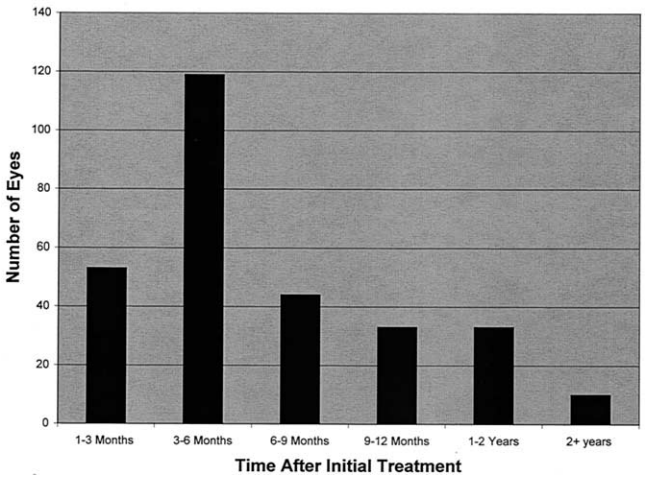

Figure 6. Retreatments by time after initial surgery.

retreatment procedure. Thus, they include, in addition to refractive enhancements, retreatments such as interface epithelium removal, diffuse lamellar Keratitis treatment, or flap repositioning. Other factors confounding the literature are issues of incidence versus prevalence reporting; the latter may not give a true picture of a patient's risk of retreatment over a specified interval. Differing nomograms and retreatment criteria by surgeon can also lead to difficult comparisons between rates.[8] In addition, the number of purposeful undercorrections can offer distorted views of retreatment figures. If, for instance, we were to exclude all purposeful undercorrections such as monovision from our analysis, our 1-year incidence of retreatment would fall to 8.4%. This article, however, focuses solely on the patient's individual prescriptive need for further laser refractive correction in an attempt to provide clinically meaningful and accurate retreatment rates to inform both patient and surgeon.

We analyzed a number of risk factors for retreatment, including amount of attempted correction, initial and residual astigmatism, age, and gender. There was a significant trend, confirming other published reports,[3,5,9] that patients with greater amounts of initial refractive error had higher retreatment rates (Fig 2). This in part may be attributed to the practice of purposefully undercorrecting eyes of extreme prescription to avoid an initial overcorrection. Certainly, however, decreased predictability of the procedure with higher degrees of correction generally would be expected to lead to a higher retreatment incidence.[21] Moreover, patients with greater astigmatism, both before the initial procedure and before retreatment, also had significantly greater rates of retreatment. In postoperative patients, analysis using the astigmatism index (sphere/cylinder) in this study demonstrated a trend of greater residual astigmatism compared with residual sphere leading to retreatment. This suggests that either current methods are not as predictable in correcting naturally occurring astigmatism as they are in correcting spherical ametropias or that patients postoperatively are more troubled by residual or induced astigmatism than by remaining spherical myopia or hyperopia.[22] Although not significant in this study, similar findings for hyperopia treatments would be expected. Further analysis of hyperopia with a larger number of patients is warranted.

Our data indicated significantly higher rates of retreatment for older patients (greater than 40 years old) compared with younger patients, without finding significant differences in the initial refractive error between the cohorts. These data are of particular interest, because they contradict our general clinical inclination to aim for mild undercorrection in older patients, assuming that they will tolerate more residual myopia after surgery. Because younger patients have the accommodative ability to see well despite residual hyperopia, it is possible that an increased retreatment rate for older patients would be a consequence of overcorrections requiring retreatment in the presbyopic age range. This theory is not supported by our data, however, because 98% of retreatment patients in the overall cohort were treated for residual myopia.

Looking at trends in retreatment over time, we have shown that patients who had undergone retreatment nearer to the time of this publication in general were treated for less residual refractive error than those treated in the more remote past. Although LASIK has experienced improvements over time in its technology, predictability, and efficacy, the public has met these successes with an ever-increasing expectation of visual result. It is possible that patients who were treated successfully by the standards at the time of their initial surgery may later return as anecdotal reports, word of mouth, or the media have informed them that it is now possible to "fix" the little prescription that remains. Indeed, patient expectations, in many cases, may be greater than the results the procedure can offer. Before surgery, therefore, the patient should be given an accurate prediction of their likelihood of needing a retreatment to provide full informed consent.

The change in average amount of retreatment correction over the years also may help to explain the difference in retreatment rate between the Summit Apex Plus and Alcon LADARVision lasers used in this study. Patients treated on the LADARVision laser had almost twice the rate of retreatment (18.2%) compared with the Summit Apex Plus

laser (9.7%). The Summit laser was in use from the beginning of the study throughout, whereas the LADARVision was introduced to the practice in January 2000. Thus, patient expectations and desire for enhancement may have been greater for the LADARVision group. Moreover, the difficulty of the initial procedures performed on the LADARVision laser, for example, higher degrees of astigmatism correction or mixed astigmatic corrections, compared with the Apex Plus laser, where more spherical myopic corrections were treated, may partially account for these findings. Our overall study findings suggest that these more complex prescriptions would have a greater likelihood of needing enhancement.

Finally, we found that most retreatments could be undertaken using the manual flap-lifting technique described. Only 3 flaps could not be successfully lifted. Such a manual technique precludes the potential complications inherent in using the microkeratome itself. In addition, a manual technique avoids trauma to the first flap when recutting a second flap with the microkeratome. These potentially include separation of the first flap from the second, especially at the edge, and a "double-cut" circumferential scar at the flap periphery. In addition, the original bed is ablated rather than another lamellar plane as would occur with a second flap. Certainly, a randomized trial comparing manual relifting to flap recutting would be necessary to ascertain the relative safety and efficacy of the two techniques. Specific outcomes results using our technique will be discussed in a forthcoming study.

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