# Outcomes of LASIK for Myopia With FDA-Approved Lasers

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**Purpose:** To report expected outcomes of laser in situ keratomileusis (LASIK) for myopia and myopic astigmatism from existing US Food and Drug Administration (FDA) data.

**Methods:** Data from *Summaries of Safety and Effectiveness* for each of the 12 lasers approved by the FDA for LASIK for myopia or myopic astigmatism between 1998 and 2004 were recorded from the FDA Web site. The Cochran–Armitage test for trend was used to determine whether improvements in outcomes occurred with laser technology changes.

**Results:** For all patients, there was a statistically significant trend toward improvement with improved laser technology in the proportion of patients with uncorrected visual acuity (UCVA) of 20/20 or better, UCVA of 20/40 or better, results within ±0.50 D of intended correction, results within ±1.00 D of the intended correction, and night vision symptoms (all $P < 0.0002$). Because there were preoperative differences across laser types, subgroup analyses were also completed. The results for subgroup analyses (high myopia, low to moderate myopia, spherical myopia, and myopic astigmatism) for visual acuity and refractive error outcomes were similar to results for analyses for all groups combined. Conversely, there was no difference across laser types in the proportion of patients who experienced dry eye symptoms or for the proportion of patients with low to moderate myopia who experienced night vision symptoms that were worse or significantly worse than before LASIK.

**Conclusions:** LASIK provides excellent visual acuity and refractive error outcomes. Night vision and dryness symptoms still occur in a significant proportion of patients. Future studies should seek to determine whether additional changes in technology, patient selection criteria, or postoperative treatment could reduce or eliminate these symptoms.

**Key Words:** LASIK, FDA, visual acuity, night vision symptoms, dry eye, outcomes, wavefront-guided

(*Cornea* 2007;26:246–254)

Received for publication October 25, 2005; revision received October 6, 2006; accepted October 11, 2006.

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Supported by NIH/NEI Grant T32-EY013359 and American Optometric Foundation William C. Ezell Fellowships (CIBA Vision and the AAO Section on Cornea and Contact Lenses).

Presented at the 2004 Annual Meeting for the Association for Research in Vision and Ophthalmology (ARVO), April 25–29, 2004, Fort Lauderdale, FL.

The authors state that they have no proprietary interest in the products named in this article.

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Laser in situ keratomileusis (LASIK) is one of many procedures that have been developed within the last few decades for the surgical correction of myopia and myopic astigmatism. The first excimer laser was approved for use in LASIK eye surgery on July 30, 1998. Since that time, millions of patients have undergone this surgical procedure each year, making the safety and efficacy of LASIK a significant public-health interest.

*Summaries of the Safety and Effectiveness* data for each of the lasers approved by the US Food and Drug Administration (FDA) for use in LASIK are readily available on the Internet.[1] Although many of the studies conducted for FDA approval of lasers remain unpublished, data contained within the summaries of safety and efficacy on the FDA's Web site have served as a source of information on LASIK outcomes that is available publicly for patients and eye care practitioners to evaluate. For this study, we analyzed these datasets to summarize expected outcomes of LASIK eye surgery for all lasers that have received premarket approval by the FDA for LASIK.

## MATERIALS AND METHODS

### Data Source

The *Summary of Safety and Effectiveness* data for each of the ophthalmic excimer laser systems approved by the FDA for LASIK were downloaded from the FDA's Web site.[1] For simplification during data presentation and analysis, each device was assigned numbers 1–12 in temporal order of approval (Table 1). Lasers were classified as 1 of 5 types: Broad Beam, Scanning Spot, Scanning Slit, Scanning with Eye Tracker, or Wavefront Guided. Variables were recorded for 5 categories of eyes: the entire cohort, high myopia, low to moderate myopia, eyes receiving spherical-only ablations, and eyes receiving spherocylindrical ablations. All data presented are 6-month outcomes.

The summary reports for laser numbers 1, 4, and 6 categorized high myopia as those eyes with spherical equivalent corrections equal to or more myopic than −7.00 D and low to moderate myopia as those eyes with corrections less myopic than −7.00 D. The summary reports for laser numbers 2, 3, 5, and 7 categorized high myopia as more myopic than −7.00 D and low to moderate myopia as equal to or less myopic than −7.00 D. At the time of data analysis, only a small percentage of eyes with higher levels of myopia were included in the studies for approval of lasers 8, 9, 10, and 12 (Table 1); thus, we were not able to evaluate differences among levels of myopia for these lasers.



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**TABLE 1.** Excimer Lasers Approved by the FDA for LASIK

| No. | Excimer Laser Trade Name | Applicant Name | Date of FDA Approval | Date of Summary Download | Technology Classification | Patients With High Myopia (%) |
|---|---|---|---|---|---|---|
| 1 | Kremer Excimer Laser | Photomed, Inc. | 07/30/1998 | 04/30/2003 | Broad Beam | 188/665 (28) |
| 2 | SVS Apex Plus Excimer Laser Workstation | Summit Technology, Inc. | 10/21/1999 | 04/30/2003 | Broad Beam | 404/1013 (40) |
| 3 | VISX STAR S2 Excimer Laser System | CRS Clinical Research, Inc. | 11/19/1999 | 04/30/2003 | Broad Beam | 424/1276 (33) |
| 4 | Dishler Excimer Laser System | Jon G. Dishler, MD, FACS | 12/16/1999 | 04/30/2003 | Broad Beam | 231/810 (29) |
| 5 | TECHNOLAS 217A Excimer Laser System | Bausch & Lomb Surgical, Inc. | 02/23/2000 05/17/2002* | 04/30/2003 | Scanning Spot | 263/624 (42) |
| 6 | LADARVision Excimer Laser System | Autonomous Technologies Corporation | 05/09/2000 | 04/30/2003 | Scanning with Eye Tracker | 57/327 (17) |
| 7 | Nidek EC-5000 Excimer Laser System | Nidek Technologies, Inc. | 04/19/2000 | 04/30/2003 | Scanning Slit | 425/758 (56) |
| 8 | LaserSight LaserScan LSX Excimer Laser System | LaserSight Technologies, Inc. | 09/28/2001 | 04/30/2003 | Scanning Spot | 10/204 (5) |
| 9 | LADARVision 4000 Excimer Laser System | Alcon | 10/18/2002 | 04/30/2003 | Wavefront guided | 90/757 (4) |
| 10 | VISX STAR S4 Excimer Laser System and WaveScan WaveFront System | VISX, Incorporated | 05/23/2003 | 11/24/2003 | Wavefront guided | 0/351 (0) |
| 11 | WaveLight ALLEGRETTO WAVE Excimer Laser System | SurgiVision Refractive Consultants, LLC | 10/7/2003 | 11/24/2003 | Scanning with Eye Tracker | 124/901 (14) |
| 12 | Bausch & Lomb 217z Zyoptix System for Personalized Vision Correction | Bausch & Lomb Incorporated | 10/10/2003 | 06/28/2004 | Wavefront guided | 1/340 (0.3) |

*Approval for high-myopia cohort.

For laser number 7, it was not possible to make the division between high myopia and low to moderate myopia at −7.00 D for the following variables: uncorrected visual acuity (UCVA) of 20/20 or better, UCVA of 20/40 or better, best spectacle-corrected visual acuity (BSCVA) worse than 20/40, or loss of >2 lines of BSCVA. These variables were reported in categories, one of which grouped eyes between −6.00 and −7.99 D in 1 group. We had no way of determining how many of the eyes would have been categorized at or above −7.00 D; therefore, high myopia was categorized as all eyes with spherical equivalent refractive error equal to or more myopic than −6.00 D. Low to moderate myopia was categorized as eyes with spherical equivalent refractive error less myopic than −6.00 D.

Data regarding patient symptoms (eg, glare, dryness) were included when reported in individual summaries. Unlike refractive error and visual acuity outcomes, these data were reported for each patient rather than by eye. Some questionnaires used by laser companies asked patients to compare their current symptoms to symptoms before surgery, whereas others just queried patients about the severity of their postoperative symptoms. For the overall summary of symptoms for each laser type, the proportion of subjects for each laser who experienced glare, halos, night driving problems, or dryness was defined as the number of subjects who said these symptoms were either worse than before surgery, much worse than before surgery, moderately severe, or severe. For analyses comparing laser types, however, lasers were included in the analysis only if the patients were surveyed before and after surgery. For these analyses, we compared the proportion of subjects who reported postoperative symptoms that were worse or much worse than the preoperative report of the same symptom.

## Data Entry and Analysis

Data from each summary were entered into a Microsoft Excel spreadsheet. All variables (Tables 2–4) were extracted from the summaries as proportions, recording both the numerator and denominator for data analysis. The Cochran–Armitage test for trend was used to compare laser types for each of the variables.[2] The analyses were performed for all 5 categories of eyes (the entire cohort, high myopia, low to moderate myopia, eyes receiving spherical-only ablations, and eyes receiving spherocylindrical ablations). The Cochran–Armitage test for trend was chosen because the data were available only in the form of binomial proportions.[2] (The null hypothesis for this test is that no trend exists across levels of the explanatory variable.)

Comparisons of 2 individual laser types, Scanning with Eye Tracker and Wavefront Guided, were made to test for improvements in outcomes between these 2 most recent technological developments. These comparisons were made using $\chi^2$ tests. We were unable, however, to compare Scanning with Eye Tracker lasers to Wavefront-Guided lasers for eyes with high myopia because few eyes with high myopia were included in studies evaluating wavefront-guided LASIK. For both the Cochran–Armitage test for trend and $\chi^2$ tests, $P < 0.001$ was

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**TABLE 2.** Proportion of All Eyes Achieving Each Visual Acuity Outcome Measure With Reference to Preoperative Levels of Refractive Error

| | Laser Categories | | | | | |
|---|---|---|---|---|---|---|
| Measurement | Broad Beam (%) | Scanning Spot (%) | Scanning Slit (%) | Scanning with Eye Tracker (%) | Wavefront Guided (%) | Total (%) |
| Proportion of eyes with preoperative high myopia | 1247/3764 (33.1) | 273/828 (33.0) | 425/758 (56) | 181/1228 (14.7) | 91/1448 (6.3) | 2217/8026 (27.6) |
| Proportion of eyes with ≥1.00 D of preoperative astigmatism* | 61/461 (13.2) | 127/843 (15.1) | 0/0 (0.0) | 161/1248 (12.9) | 115/1397 (8.2) | 464/3949 (11.7) |
| UCVA of 20/20 or better | 1328/2716 (48.9) | 493/712 (69.2) | 359/758 (47.4) | 851/1083 (78.6) | 875/981 (89.2) | 3906/6250 (62.5) |
| UCVA of 20/40 or better | 2488/2716 (91.6) | 679/712 (95.4) | 640/758 (84.4) | 1043/1083 (96.3) | 977/988 (98.9) | 5827/6257 (93.1) |
| Loss of >2 lines of BSCVA | 29/2266 (1.3) | 0/747 (0) | 5/752 (0.7) | 0/327 (0) | 0/1372 (0) | 34/5464 (0.6) |
| Loss of ≥2 lines of BSCVA | 19/2416 (0.8) | 8/747 (1.1) | 11/752 (1.5) | 10/1145 (0.9) | 5/1372 (0.4) | 53/6432 (0.8) |
| BSCVA worse than 20/40 | 12/3081 (0.4) | 1/747 (0.1) | 1/754 (0.1) | 0/1128 (0) | 0/1372 (0) | 14/7082 (0.2) |
| BSCVA worse than 20/25 | 56/2832 (2.0) | 2/710 (0.3) | 5/752 (0.7) | 3/1089 (0.3) | 1/1356 (0.1) | 67/6739 (1.0) |

*The denominator for the proportion is the number of patients who received astigmatic treatments. Some patients with small amounts of astigmatism received spherical ablations.

considered statistically significant after adjustment for multiple comparisons.

Because we did not have individual patient data for use in statistical analyses, we were unable to control for differences in refractive error, age, sex, etc, across the different studies or across the different laser types included in our analyses. To address this limitation in the analyses, we compared the preoperative spherical equivalent refractive error and cylinder power distributions for each laser type. Decisions as to which laser types were included in subsequent analyses were from the results of this comparison. Spherical equivalent refractive error was divided into 2.00-D steps, and cylinder power was divided into 1.00-D steps. The percentage of eyes within each step was compared across laser types. Because of the large number of eyes included in these analyses, we were able to detect differences of just a few percent. To address this, clinically meaningful differences were defined as a difference of >10% between 2 laser types.

# RESULTS

## Summary of All Studies

The mean age of subjects across all studies of LASIK for FDA approval ranged from 34 to 43 years old. A total of 9192 eyes were initially enrolled in these studies, with data reported for 7266 (79%) eyes 6 months after the initial LASIK procedure. Fifty-three percent (4116/7804) of the subjects were women. Tables 2–4 summarize major visual acuity (Table 2), refractive error (Table 3), and symptom (Table 4) outcomes. See the differences in the proportion of eyes with high myopia and higher levels of astigmatism treated with each of the laser types (Table 2, rows 1 and 2). In summary, most eyes achieved UCVA of 20/20 or better, and the vast majority of eyes achieved UCVA of 20/40 or better. Postoperative spherical equivalent refractive error was within ±0.50 D of the intended correction for most patients. Overall, ~20% of patients experienced night vision or dryness symptoms after LASIK.

## Trends in Visual Acuity and Refractive Error Outcomes

Graphs were constructed of the distribution of spherical equivalent refractive error and cylinder power for each of the laser types (Figs. 1A, B). When evaluating the distributions of spherical equivalent refractive error, 2 laser types had clinically meaningful differences. The distribution of spherical equivalent refractive error for the scanning slit laser category was skewed toward higher levels of myopia, and the distribution of the wavefront-guided lasers was skewed toward

**TABLE 3.** Proportion of All Eyes Achieving Each Refractive Error Outcome Measure

| | Laser Categories | | | | | |
|---|---|---|---|---|---|---|
| Refractive Error Outcome Measurements | Broad Beam (%) | Scanning Spot (%) | Scanning Slit (%) | Scanning with Eye Tracker (%) | Wavefront Guided (%) | Total (%) |
| Within ±0.50 D of intended correction | 2045/3069 (66.6) | 546/735 (74.3) | 455/755 (60.3) | 948/1145 (82.8) | 798/988 (80.8) | 4792/6692 (71.6) |
| Within ±1.00 D of intended correction | 2645/3069 (86.2) | 672/735 (91.4) | 643/755 (85.2) | 1099/1145 (96.0) | 940/988 (95.1) | 5999/6692 (89.6) |
| Within ±2.00 D of intended correction | 2997/3069 (97.7) | 723/735 (98.4) | 733/755 (97.1) | 1139/1145 (99.5) | 277/277 (100) | 5869/5981 (98.1) |
| Change in spherical equivalent of <1.00 D from 3 to 6 months | 1856/1975 (94.0) | 652/669 (97.5) | 590/612 (96.4) | 1011/1019 (99.2) | 979/986 (99.3) | 5088/5261 (96.7) |
| Increase of >2.00 D cylinder | 5/1444 (0.4) | 0/283 (0) | 2/755 (0.3) | 0/569 (0) | 0/943 (0) | 7/3999 (0.2) |


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**TABLE 4.** Proportion of All Patients Reporting Each Postoperative Symptom*

| Postoperative Symptom | Laser Categories | | | | | |
|---|---|---|---|---|---|---|
| | Broad Beam (%) | Scanning Spot (%) | Scanning Slit | Scanning with Eye Tracker (%) | Wavefront Guided (%) | Total (%) |
| Glare | 137/1259 (10.9) | 103/572 (18.0) | NA | 429/1171 (36.6) | 114/966 (11.8) | 783/3968 (19.7) |
| Halos | 130/1259 (10.3) | 165/651 (25.4) | | 286/1171 (24.4) | 125/966 (12.9) | 706/4047 (17.5) |
| Night driving problems | 7/661 (1.1) | 145/651 (22.3) | | 407/1171 (34.8) | 108/966 (11.2) | 667/3449 (19.3) |
| Dryness | NA | 107/572 (18.7) | | 82/339 (24.2) | 206/966 (21.3) | 395/1877 (21.0) |

*Recorded as worse than before surgery, much worse than before surgery, moderately severe after surgery, or severe after surgery.
NA, not available.

lower levels of myopia. There were 2 ways that we accounted for these skewed distributions in our subsequent analyses. First, the scanning slit laser type was excluded from subsequent analyses because of its skewed distribution and because it was the only laser category that included 1 laser only. Second, analyses were also completed for 2 subgroups: low to moderate myopia only and high myopia only. When graphs were constructed for the distribution of low to moderate myopia (Fig. 2A) and high myopia (Fig. 2B) separately for the remaining 4 laser types (Broad Beam, Scanning Spot, Scanning with Eye Tracker, and Wavefront Guided), no clinically meaningful differences among the laser types remained; thus, the wavefront-guided lasers were included only in the analyses for low to moderate myopia and were excluded from analyses for high myopia.

When evaluating the distribution of cylinder power for the remaining 4 types of lasers (Fig. 1B), the only meaningful difference clinically was that the broad beam lasers were skewed slightly toward higher levels of cylinder power. Because the skewed distribution did not affect the highest levels of cylinder power (ie, differences in cylinder power ≥2.00 D across laser types were all 5% or less and not

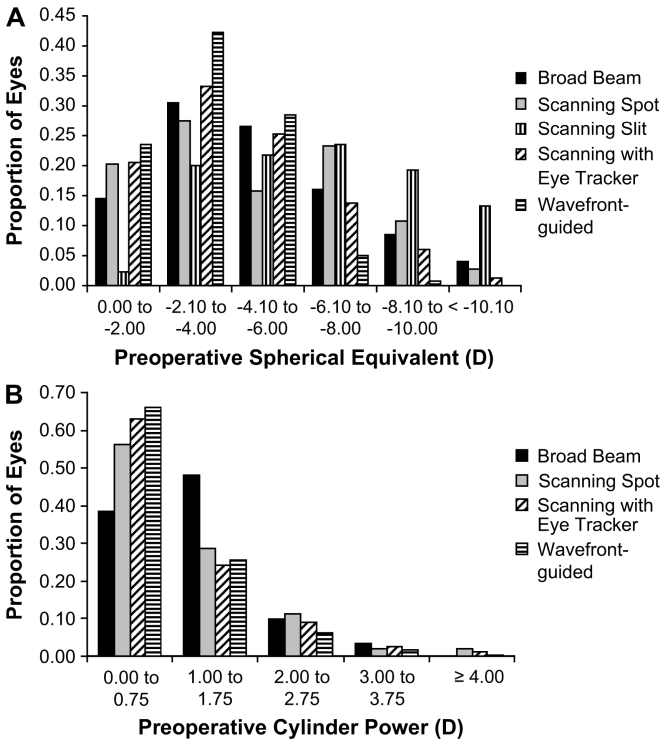


**FIGURE 1.** A, Proportion of all eyes at each level of preoperative spherical equivalent (D) refractive error for each laser group. B, Proportion of eyes with each level of preoperative cylinder power (D) for each laser group.

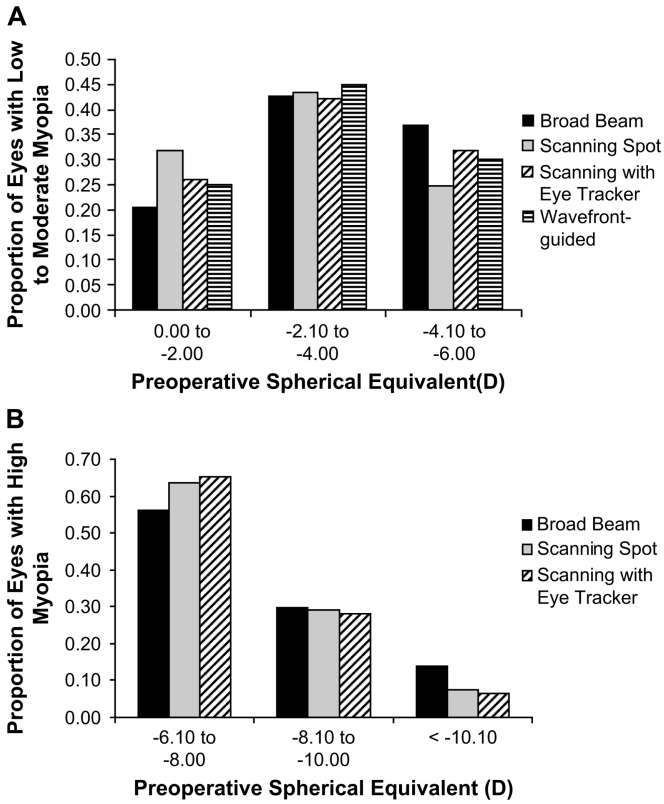


**FIGURE 2.** A, Proportion of eyes at each level of preoperative spherical equivalent refractive error for all laser categories in the analyses including eyes with low to moderate myopia. B, Proportion of eyes at each level of preoperative spherical equivalent refractive error for all laser categories in the analyses including eyes with high myopia.

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meaningful clinically), the broad beam lasers were not excluded from analyses comparing eyes receiving correction for myopic astigmatism across laser types. Nonetheless, the slightly skewed cylinder power distribution of the broad beam lasers should be considered when evaluating the data analyses below.

Statistically significant differences across laser types were found for multiple variables listed in Tables 2–4. Nonetheless, many of these comparisons were not meaningful clinically, because the largest proportion of eyes/patients with or without each event was almost always <5%. Thus, our report of statistical analyses focuses on those outcomes that occurred in >5% of eyes/patients. For the percentage of eyes with UCVA of 20/20 or better, trends for improvement were found for all 5 groups of eyes (low to moderate myopia, high myopia, spherical myopia only, myopic astigmatism, and the entire cohort: all $P < 0.0001$; Figs. 3A, B). Further comparison of only the scanning with eye tracker category and the wavefront-guided category showed that these 2 categories of lasers are different significantly for the 4 groups of eyes for which data were available (low to moderate myopia, spherical myopia only, myopic astigmatism, and the entire

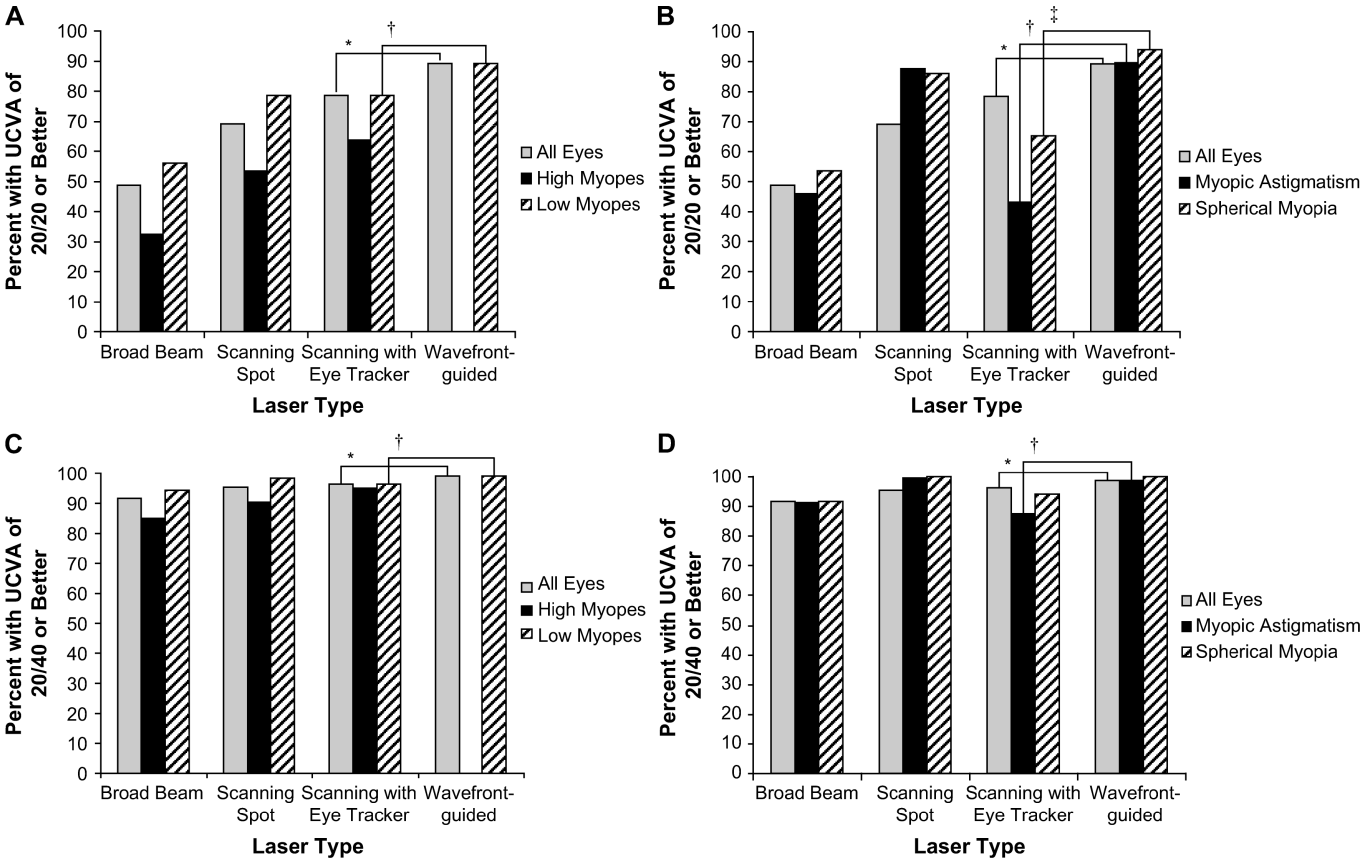


**FIGURE 3.** A, Percentage of all eyes, eyes with high myopia, and eyes with low to moderate myopia achieving Snellen visual acuity of 20/20 or better for each laser type. There was a statistically significant trend across groups for all eyes ($Z = 25.0$, $P < 0.0001$), eyes with low to moderate myopia ($Z = 19.0$, $P < 0.0001$), and eyes with high myopia ($Z = 8.2$, $P < 0.0001$). *Statistically significant difference (78.6% vs. 89.2%, $\chi^2 = 42.4$, $P < 0.0001$). †Statistically significant difference (78.6% vs. 89.2%, $\chi^2 = 41.9$, $P < 0.0001$). B, Percentage of all eyes, eyes with spherical myopia only, and eyes with myopic astigmatism achieving Snellen visual acuity of 20/20 or better for each laser type. There was a statistically significant trend across laser categories for all eyes ($Z = 25.0$, $P < 0.0001$), patients with spherical myopia ($Z = 8.0$, $P < 0.0001$), and eyes with myopic astigmatism ($Z = 17.6$, $P < 0.0001$). *Statistically significant difference (78.6% vs. 89.2%, $\chi^2 = 42.4$, $P < 0.0001$). †Scanning with Eye Tracker category includes only laser 6. Statistically significant difference (43.4% vs. 89.6%, $\chi^2 = 165.1$, $P < 0.0001$). ‡Statistically significant difference (65.2% vs. 94.0%, $\chi^2 = 32.0$, $P < 0.0001$). C, Percentage of all eyes, eyes with low to moderate myopia, and eyes with high myopia achieving Snellen visual acuity of 20/40 or better for each laser type. There was a statistically significant trend across groups for all eyes ($Z = 8.9$, $P < 0.0001$), eyes with low to moderate myopia ($Z = 5.3$, $P < 0.0001$), and eyes with high myopia ($Z = 3.8$, $P < 0.0001$). *Statistically significant difference (96.3% vs. 98.9%, $\chi^2 = 14.3$, $P = 0.0002$). †Statistically significant difference (96.3% vs. 98.9%, $\chi^2 = 13.8$, $P = 0.0002$). D, Percentage of all eyes, eyes with spherical myopia only, and eyes with myopic astigmatism achieving Snellen visual acuity of 20/40 or better for each laser type. There was a statistically significant trend across categories of lasers for all eyes ($Z = 8.9$, $P < 0.0001$), eyes with spherical myopia ($Z = 3.3$, $P = 0.0005$), and eyes with myopic astigmatism ($Z = 5.4$, $P < 0.0001$). *Statistically significant difference (96.3% vs. 98.9%, $\chi^2 = 14.3$, $P = 0.0002$). †Scanning with Eye Tracker category includes only laser 6. Statistically significant difference (87.4% vs. 98.6%, $\chi^2 = 45.7$, $P < 0.0001$).


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cohort; all $P < 0.0001$). Similarly, trends for improvement were found for all 5 groups for the proportion of eyes who had UCVA of 20/40 or better (Figs. 3C, D; all $P \leq 0.0005$). Further comparison of only the scanning with eye tracker category and the wavefront-guided category showed that these 2 categories of lasers were different significantly for 3 of the 4 groups of eyes (all $P \leq 0.0002$), the exception being eyes receiving spherical-only ablations (after adjusting for multiple comparisons, $\chi^2 = 6.9$, $P = 0.01$).

There was a statistically significant trend across laser types for all groups (all $P \leq 0.0001$) for the proportion of eyes within ±0.50 D (Figs. 4A, B). Differences between scanning with eye tracker lasers and wavefront-guided lasers were not found for any category of eyes (all $P > 0.01$) This outcome indicates that, although there is a trend for improvement over time in the proportion of eyes who were within ±0.50 D of the intended correction, this trend for improvement reached a plateau before the advent of lasers that use scanning with eye trackers or wavefront-guided technology.

Statistically significant trends were present across laser types for all groups for the proportion of eyes within ±1.00 D of the intended correction (Figs. 2C, D; all $P \leq 0.0002$). There were no differences, however, between scanning with eye tracker and wavefront-guided lasers for the proportion of eyes within ±1.00 D of the intended correction (all $P > 0.03$). Once again, this result indicates that the trend for improvement

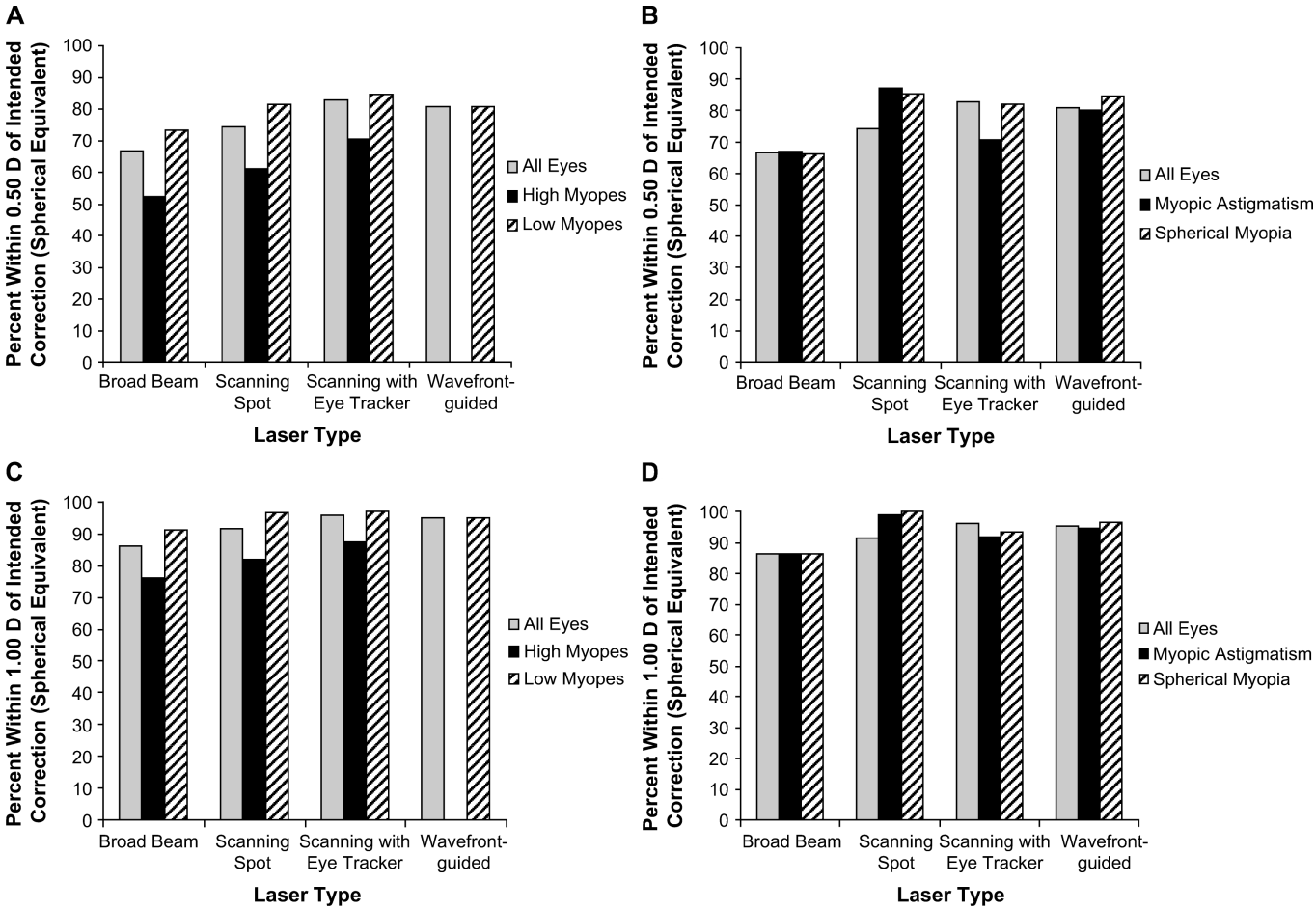


**FIGURE 4.** A, Percentage of all eyes, eyes with low to moderate myopia, and eyes with high myopia having spherical equivalent refractive error within ±0.50 D of the intended correction for each laser type. There was a statistically significant trend across groups for all eyes (Z = 11.7, $P < 0.0001$), eyes with low to moderate myopia (Z = 6.3, $P < 0.0001$), and eyes with high myopia (Z = 4.8, $P < 0.0001$). B, Percentage of all eyes, eyes with spherical myopia only, and eyes with myopic astigmatism having spherical equivalent refractive error within ±0.50 D of intended correction for each laser type. There was a statistically significant trend across laser categories for all eyes (Z = 11.7, $P < 0.0001$), eyes with spherical myopia (Z = 5.8, $P < 0.0001$), and eyes with myopic astigmatism (Z = 6.2, $P = 0.0001$). C, Percentage of all eyes, eyes with low to moderate myopia, and eyes with high myopia having spherical equivalent refractive error within ±1.00 D of the intended correction for each laser type. There was a statistically significant trend across groups for all eyes (Z = 10.8, $P < 0.0001$), eyes with low to moderate myopia (Z = 5.8, $P < 0.0001$), and eyes with high myopia (Z = 3.6, $P = 0.0002$). D, Percentage of all eyes, eyes with spherical myopia only, and eyes with myopic astigmatism having spherical equivalent refractive error within ±1.00 D of the intended correction for each laser type. There was a statistically significant trend across laser categories for all eyes (Z = 10.8, $P < 0.0001$), eyes with spherical myopia (Z = 4.4, $P < 0.0001$), and for eyes with myopic astigmatism (Z = 6.0, $P < 0.0001$).

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reached a plateau with the scanning with eye tracker lasers and did not improve with wavefront-guided technology.

To determine whether changes in technology have affected patient symptoms, we compared symptoms across laser types. Analyses included only symptom data from studies that compared preoperative symptoms to postoperative symptoms. A significant trend across laser types was found for halos, but not for glare, night driving problems, or dryness symptoms when the data were analyzed for all patients (Table 5). When the analyses were repeated for low to moderate myopes only, no significant trends were found across laser types for any symptoms (Table 6). The proportion of patients experiencing each symptom in the wavefront-guided category in Table 5 is identical to the proportion of patients experiencing each of the symptoms in Table 6; this outcome reflects the fact that data for higher myopes were not included in reports for the wavefront-guided lasers. Also, comparisons could not be made across lasers for high myopes, patients undergoing spherocylindrical ablations, or patients undergoing spherical ablations because symptom data were not available for these categories.

## DISCUSSION

*Summaries of Safety and Effectiveness* has proven to be an invaluable source of data for comprehensive evaluations of ophthalmic medical devices.[3–5] Although this data source can provide a wealth of information to the vision care community, when evaluating the results of this study, the reader should still consider the fact that these trials are carried out independently at each center and that there may be protocol differences that could affect surgery outcomes. For example, there were substantial differences from laser to laser in the amount of preoperative myopia that was treated. Although the statistical analyses used in this study attempted to account for these differences, the reader should consider these data as a source for direction of future, carefully controlled, prospective studies in the field and not as a definitive statement regarding the effects of technological advancements on LASIK outcomes.

For the thousands of eyes that have been evaluated in FDA studies of LASIK, LASIK was capable of providing UCVA of 20/40 or better for most (97%) eyes, and 62% of eyes achieved 20/20 UCVA after LASIK. Significant loss of BSCVA was extremely rare. In addition, most eyes received an accurate refractive error correction, with 72% of eyes receiving a refractive error correction within $\pm 0.50$ D of the intended correction and 90% of eyes receiving a refractive error correction within $\pm 1.00$ D of the intended correction.

In addition to objective measurements such as visual acuity and refractive error, these studies also assessed adverse symptoms such as night vision complaints and dry eye complaints. Because the FDA does not require manufacturers to use a specific symptom questionnaire, providing an overall estimate of the percentage of patients who experience night vision or dryness symptoms is more complicated. Some patients may have experienced these symptoms before having LASIK, making it difficult to determine if the symptoms should be attributed to LASIK eye surgery. To address this issue, comparisons across laser types were made only when data were available to indicate that the symptoms were worse, or significantly worse, than the preoperative condition. In these studies, ~15% of patients experienced night vision symptoms that were worse or significantly worse than preoperative night vision symptoms. Approximately 20% of patients experienced dryness symptoms that were worse or significantly worse than preoperative dryness.

LASIK eye surgery stands out in that technological advances have occurred at a rapid pace; thus, overall summaries of visual acuity outcomes, refractive error outcomes, and symptoms may not truly reflect what a patient who had LASIK today might expect his or her results to be. From analyses of FDA refractive error and visual acuity data after LASIK, increases in the proportion of subjects with 20/20 and/or 20/40 UCVA have occurred with changes in laser technology (Fig. 3). These trends were statistically significant and present for analyses including the entire cohort of eyes. There were, however, noteworthy differences across laser types in the preoperative level of myopia that was treated; therefore, we also completed analyses for subgroups of refractive error so that we would be comparing eyes with similar preoperative refractive error when comparing laser types. There were data from so few eyes with higher levels of myopia in the reports for wavefront-guided lasers included in this study that we were unable to include that laser type in high-myopia subgroup analyses. In these subgroup analyses, we found increases in the proportion of subjects with 20/20 and/or 20/40 UCVA with changes in laser technology for eyes with low to moderate myopia, high myopia, spherical myopia only, and myopic astigmatism. When comparing only the 2 most recent types of lasers, scanning with eye tracker and wavefront-guided lasers, we still found statistically significant differences between these 2 groups for the proportion of patients with postoperative UCVA of 20/20 and/or 20/40. This result was statistically significant for all eyes, as well as analyses including eyes with low to moderate myopia, spherical myopia, and myopic astigmatism.

Similarly, there were statistically significant trends for all groups of subjects for an increasingly higher proportion of eyes receiving their intended postoperative refractive error correction (Fig. 4; all $P < 0.0002$). Nonetheless, improvements in the proportion of eyes receiving the intended refractive error correction reached a plateau with scanning lasers with eye trackers, with no additional improvement in the proportion of eyes who are within $\pm 0.50$ D with wavefront-guided technology. This plateau occurs when we compare all eyes, even though there were a higher proportion of eyes with high myopia treated with the scanning with eye tracker lasers than the wavefront-guided lasers, and the plateau also occurs when comparing eyes with low to moderate myopia, spherical myopia, and myopic astigmatism.

It is curious that the proportion of eyes achieving UCVA of either 20/20 or 20/40 continued to improve across laser categories but that there was no statistically significant difference in the proportion of eyes within $\pm 0.50$ D of their intended correction between the scanning with eye tracker and wavefront-guided laser categories. One might have expected that an improvement in UCVA would have a corresponding improvement in refractive error. This discrepancy might


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**TABLE 5.** Proportion of All Eyes in Each Category of Laser With Postoperative Symptoms That Were Worse or Significantly Worse Than the Preoperative Condition

| | Laser Categories | | |
|---|---|---|---|
| Symptom | Scanning Spot (%) | Scanning with Eye Tracker (%) | Wavefront Guided (%) |
| Glare* | 103/572 (18.0) | 429/1171 (36.6) | 103/708 (14.6) |
| Halos† | 160/572 (28.0) | 286/1171 (24.4) | 107/708 (15.1) |
| Night driving problems* | 122/572 (21.3) | 407/1171 (34.8) | 85/708 (12.0) |
| Dryness* | 107/572 (18.7) | 82/339 (24.2) | 182/708 (25.7) |

*Test for trend across laser types is not statistically significant (glare: Z = 0.42, $P = 0.3$; night driving problems: Z = –2.1, $P = 0.02$; dryness: Z = –3.0, $P = 0.001$).
†Statistically significant trend across laser types (halos: Z = –5.1, $P < 0.0001$).

**TABLE 6.** Proportion of Eyes With Low to Moderate Myopia in Each Category of Laser With Postoperative Symptoms That Were Worse or Significantly Worse Than the Preoperative Condition

| | Laser Categories* | |
|---|---|---|
| Symptom | Scanning Spot (%) | Wavefront Guided (%) |
| Glare | 36/348 (10.3) | 103/708 (14.6) |
| Halos | 64/348 (18.4) | 107/708 (15.1) |
| Night driving problems | 40/348 (11.5) | 85/708 (12.0) |
| Dryness | 59/348 (17.0) | 182/708 (25.7) |

Tests for trend across laser types were not statistically significant (glare: Z = –1.9, $P = 0.03$; halos: Z = –1.4, $P = 0.09$; night driving problems: Z = 0.24, $P = 0.4$; dry eye: Z = 3.2, $P = 0.001$).
*Data were not available for other laser categories for eyes with low to moderate myopia only. Most applications did not report symptoms for patients with low to moderate or high levels of myopia separately.

indicate that earlier laser technology was capable of providing an adequate correction of the lower-order aberrations of the eye (ie, most eyes were within ±0.50 D of their intended correction) but that the wavefront-guided laser technology induced fewer higher-order aberrations and ultimately provided eyes with better overall quality of vision and better UCVA. In fact, 2 of the 3 wavefront-guided laser summaries (lasers 9 and 12) included data showing that the wavefront-guided treatments induced fewer higher-order aberrations than conventional treatments. (Note: subjects were not randomly assigned to wavefront-guided or conventional lasers.) In the LADARVision 4000 Excimer Laser System summary, conventional LASIK patients experienced more higher-order aberrations than custom LASIK patients. Vision simulations showed this difference in higher-order aberrations to correspond to conventional LASIK patients experiencing ~0.2 D more blur.

It is also possible that the wavefront-guided LASIK eyes had less residual postoperative astigmatism. With a careful examination of Figure 3, one can see that the most dramatic difference between the scanning with eye tracker and wavefront-guided laser types is found in the myopic astigmatism subgroup. The exact amount of residual postoperative astigmatism was not available in many of the summaries to make such a comparison, but one could see where residual astigmatism might be a factor when considering the results for eyes with myopic astigmatism in Figure 3B. Small differences in residual astigmatism could explain why the scanning with eye tracker groups and the wavefront-guided groups would have similar proportions of eyes with postoperative spherical equivalent refractive error within ±0.50 D of the intended correction but different proportions of eyes with 20/20 or 20/40 UCVA. On the basis of the comparisons of preoperative spherical equivalent refractive error (Fig. 1) and cylinder power (Fig. 2) across laser types, it does not seem that any preoperative differences between the scanning with eye tracker and the wavefront-guided groups would have resulted in the observed postoperative differences in visual acuity. Other explanations for this discrepancy include issues related to the nature of these data (ie, differences across studies in visual acuity protocols and/or the inherent variability of subjective refraction).[6]

In addition to obvious changes in technology that have occurred with each new generation of lasers (ie, eye trackers or wavefront-guided technology), there have also been changes in the ablation diameter used in LASIK procedures over time. We were unable to complete analyses comparing lasers by ablation zone diameters, however, because some of the laser manufacturers did not report this information and because the ablation zone diameter was not the same for all levels of myopia. Nonetheless, the ablation zone diameter ranged from 6.0 mm in many of the broad beam lasers to 6.5 or 7.0 mm with transition zones in the scanning, scanning with eye tracker, and wavefront-guided lasers. In addition, the minimum diameter in the oval astigmatic ablation zone has also increased with advances in technology. Thus, the enlarging ablation zone diameter should also be considered as a reason for improving outcomes over time.

Although there seem to have been improvements in visual acuity outcomes with changes in technology, there were few trends showing improvements in the proportion of patients whose symptoms were worse or much worse than before LASIK. When comparisons were made across laser categories for the entire cohort, there was a significant declining trend for the proportion of patients who had halos that were worse or significantly worse than before LASIK. No differences were found for any other symptoms. When the analyses were repeated for patients with only low to moderate myopia, however, there were no statistically significant differences in the proportion of patients who had glare, halos, or night driving problems between scanning lasers and wavefront-guided lasers. This important difference in patient demographics may indicate that the trend for improvement in halos found for all patients was driven by differences among laser types in the mean amount of preoperative myopia; almost all patients in the wavefront-guided laser category had preoperative myopia of less than −7.00 D. Night vision symptoms in general have been attributed to the higher-order aberrations that are induced by conventional LASIK procedures.[7] The fact that there was no significant trend for improvement in night vision symptoms with changes in laser technology suggests that further study of the association between higher-order aberrations and night vision symptoms is needed.

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No trends for improvement in the proportion of patients experiencing dryness were found for either all patients or low to moderate myopes only. The percentage of patients experiencing this symptom was consistently ~20%. This result was expected. Lamellar flaps were cut during the LASIK procedure for all 4 types of laser, and the changes in technology that were implemented across laser types were not intended or purported to improve symptoms of dryness. This consistency in dry eye symptoms may also indicate that large differences in study subjects do not exist among the various FDA trials. If there were large differences in the subjects selected for earlier trials versus later trials, one would have expected rates for dry eye symptoms to have declined in later trials as the refractive surgery community learned more about the risk factors for postoperative dry eye symptoms.

Studies that are retrospective or comparative but not randomized have important limitations. Limitations to this study include the use of binomial proportions for each laser instead of individual patient data; therefore, it is impossible to control for differences in patient selection criteria across studies, such as the level of preoperative myopia. Also, the results of this study are limited by our assumption that data reported in the summaries of safety and efficacy for each laser are accurate. We were also limited by the data available. For example, few of the summaries included measurements of contrast sensitivity and/or low-contrast visual acuity, either of which would have provided a more objective measurement of quality of vision than was obtained from patient-reported symptoms. Also, one does not usually consider a large sample size as a study limitation, but given the large sample of eyes included in these analyses, be aware of the magnitude of the differences between laser types in addition to the significance of the *P* value; in this study, our sample size allowed us to detect small differences between groups that the reader may or may not consider to be meaningful.

Another important limitation to this study is the fact that the eyes in each laser category were not randomly assigned to that category of laser. We compared data collected over several years, and our comparison of laser types may be confounded by several different variables (ie, changes in patient selection criteria, surgeon experience, new knowledge regarding the biomechanics of the cornea). Nonetheless, the unique nature of any FDA clinical study offers us some assurances as to the quality of these data. This level of quality, consistency across studies, and the extraordinarily large sample size is not usually available for meta-analysis studies of published literature, so this dataset provided us with an opportunity to examine the relationship between changes in laser technology and LASIK outcomes without the expense and time involved with a randomized clinical trial. In addition, this opportunity may be rare because it is unlikely that anyone would conduct, fund, or enroll as a subject in a trial of technology that the refractive surgery community believes is out of date.

In summary, there is evidence to suggest that visual acuity and the accuracy of the refractive error correction have improved with changes in laser technology. In our analyses, wavefront-guided LASIK provided an additional improvement in the proportion of patients who had postoperative UCVA of 20/20 or better; however, there were differences across laser types in the preoperative levels of refractive error that were treated, so future studies of higher myopes are needed to determine whether these patients have improvements in UCVA, night vision symptoms, and low-contrast visual acuity with wavefront-guided technology compared with conventional LASIK. Further study is also required to evaluate the effect of LASIK on patient symptoms. How are higher-order aberrations and night vision symptoms related? What can be done to prevent ~20% of patients who have had LASIK from experiencing dryness symptoms that are worse or significantly worse than before LASIK? Changes in technology, patient selection criteria, and postoperative treatment routines should be considered when addressing these 2 questions.

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