One-month Outcomes of Wavefront-guided LASIK for Low to Moderate Myopia With the VISX STAR S4 Laser in 32,569 Eyes

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ABSTRACT

PURPOSE: To determine the safety and efficacy of wavefront-guided LASIK for the correction of low to moderate myopia, as performed by surgeons employed by Optical Express, a large corporate provider.

METHODS: Data were extracted from the Optical Express central database on 22,900 patients (42,143 eyes) who underwent primary LASIK to treat low to moderate myopia and/or astigmatism. All treatments used a wavefront-guided ablation profile and had a refractive target of emmetropia. Outcomes were evaluated using 1-month follow-up data, which were available for 32,569 eyes of 17,713 patients (77% follow-up). Complications were tabulated using all available data.

RESULTS: The mean manifest spherical equivalent (MSE) was reduced from −2.97±1.33 diopters (D) (range: −0.37 to −6.00 D) to −0.03±0.29 D (range: −3.50 to +4.50 D) 1 month after surgery. Ninety-four percent of eyes were within 0.50 D of the intended correction, and the correlation coefficient of the attempted versus achieved MSE was 0.96. Uncorrected visual acuity (UCVA) of 20/20 or better was achieved in 92% of eyes; 99% of eyes achieved UCVA of 20/40 or better. Among patients who had bilateral laser vision correction, 98% achieved 20/20 uncorrected binocular vision. Average best spectacle-corrected visual acuity (BSCVA) improved slightly 1 month after surgery (mean change: +0.01 logMAR). There were 210 (0.67%) eyes that lost 2 or more lines of BSCVA; however, all eyes were 20/40 or better. Intraoperative complications occurred in 25 eyes (0.06%; 1:1686), and postoperative complications occurred in 210 eyes (0.64%; 1:155). The most common complications were dry eye (n=58; 0.18%; 1:562) and mild diffuse lamellar keratitis (grade 1 or 2) (n=58; 0.18%; 1:562).

CONCLUSIONS: Wavefront-guided LASIK can safely and effectively correct low to moderate myopia, as demonstrated by 1-month postoperative visual outcomes from a large number of patients. [*J Refract Surg*. 2009;25: S634-S641.] doi:10.3928/1081597X-20090611-02

The quality of laser vision correction provided in corporate settings has been questioned by some, particularly with respect to the quality of outcomes and the safety of the procedures. However, the depth of resources provided by a large corporation and the potential advantages of a standardized patient care model may actually enhance the quality of care. To assess the safety and effectiveness of surgical outcomes in a large corporate practice, Optical Express conducted a retrospective review of early postoperative results following wavefront-guided LASIK treatment for low to moderate myopia.

Optical Express is Europe's largest provider of laser vision correction, employing over 3000 optometrists, surgeons, and support staff in the United Kingdom, Ireland, the Netherlands, Germany, France, Croatia, and the United States. Like many refractive surgery providers in the United States and elsewhere, Optical Express takes advantage of a coordinated, multidisciplinary model in which both optometrists and surgeons deliver patient care. In this model, optometrists and surgeons share responsibility for patient care, with additional support provided by nurses, surgical technicians, counselors, administrative personnel, and head office staff.

To ensure a positive patient experience with seamless provision of care, each patient follows a specific pathway through the refractive surgery process. For most patients, the clinical journey begins with a preoperative examination conducted by an optometrist, often with the assistance of a technician or counselor. During this evaluation, the optometrist collects all necessary clinical data and continues the informed consent process (which starts when the patient receives a surgical

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information package via mail and/or e-mail) by discussing lifestyle, motivation, risks, benefits, and alternatives to surgery.

After a complete review of clinical data, the surgeon meets with the patient. During this meeting, the surgeon examines the patient, performs any additional tests that may be needed, and completes the informed consent process. The surgery and perioperative care are then delivered by the surgeon.

Finally, postoperative examinations are conducted by the optometrist in close consultation with the surgeon. At the conclusion of the final postoperative follow-up examination, the patient exits the surgical care cycle, after which he or she receives routine annual vision care at an Optical Express clinic.

For patients who require an enhancement or secondary procedure following surgery, the optometrist works closely with the surgeon to provide the necessary care. If an enhancement is needed, the patient reenters the surgical care cycle and a second preoperative examination is conducted. In the instances when a patient experiences a complication, a complex case management program provides immediate, definitive clinical and surgical care.[1] This program also offers a communications and support structure for both clinicians and patients.

To facilitate efficient patient care across multiple locations, Optical Express uses an electronic medical records system to capture and store all relevant clinical information. Because information can be extracted from this database, the Optical Express biostatistics department has the data resources necessary to perform a range of large-scale patient outcomes analyses.[2] The data presented in this article represent one such endeavor.

PATIENTS AND METHODS

Patient records for wavefront-guided LASIK procedures were extracted from the Optical Express electronic medical records system if they met the following criteria: 1) preoperative low to moderate myopia (manifest spherical equivalent [MSE] ≤6.00 diopters [D]), 2) refractive target was emmetropia, 3) no prior refractive procedures, and 4) treated in 2008. This search yielded 42,143 eyes of 22,900 patients treated by 30 surgeons at 41 Optical Express centers. The size of the overall dataset and the extraction techniques are described in another article in this supplement.[2]

Indications for surgery were similar to the VISX Professional Use manual for CustomVue (Abbott Medical Optics [AMO], Santa Ana, Calif) treatments.[3] However, three exceptions were allowed: 1) the minimum age for treatment was 18 years, 2) the maximum preoperative cylinder was 6.00 D, and 3) patients with inactive or well-controlled and stable collagen vascular diseases could be treated if they had no ocular involvement and had received clearance from their primary care provider. There was no restriction on patients with large low-light pupil diameters as measured with an infrared pupillometer.

All treatments were performed using the STAR S4 IR excimer laser system (AMO) using a wavefront-guided ablation profile (Advanced CustomVue, AMO). First, an aberrometer (WaveScan, AMO) measured the wavefront of the eye under low-light conditions. Each capture was then assessed to determine the quality of the lenslet pattern as well as the disparity between the derived sphere and the manifest sphere; poor quality captures were repeated. If necessary, a physician adjustment was made to match the treatment sphere to within 0.50 D of the manifest sphere. The wavefront treatment profile was then transferred from the aberrometer to the excimer laser via a USB stick. All treatments were performed with a 6.0-mm optical zone and 8.0-mm transition zone.

Corneal flaps were created using either the IntraLase FS-60 (AMO) or the Moria Evo3 One Use-Plus microkeratome (Moria SA, Antony, France). The diameter of the femtosecond flaps ranged from 8.2 to 9.2 mm, and the programmed depth ranged from 100 to 120 µm. The 130-µm head was used for the mechanical keratome. Patient preference determined the method of flap creation.

Postoperative medications consisted of a commercially available third-generation fluoroquinolone and 1% prednisolone acetate, both of which were prescribed four times a day for 1 week after surgery. Patients were also instructed to use an artificial tear solution at least four times a day for 1 month after surgery.

Patients returned for follow-up at 1 day, 1 week, 1 month, 3 months, and 6 months postoperatively. At each examination, the manifest refraction was measured using a "push plus" technique, and uncorrected (UCVA) and best spectacle-corrected visual acuity (BSCVA) were measured with either a projected eye chart or an LCD wall-mounted display using logarithmically sized letters. All patients had both monocular and binocular UCVA documented. Beginning in the summer of 2008, patients also completed a postoperative patient experience questionnaire at select follow-up examinations; results of this survey are discussed in a separate article in this supplement.[4]

Data tabulation and statistical operations were performed with SAS 9.1 (SAS Institute Inc, Cary, NC) and Microsoft Office Excel 7.0 (Microsoft, Redmond, Wash).

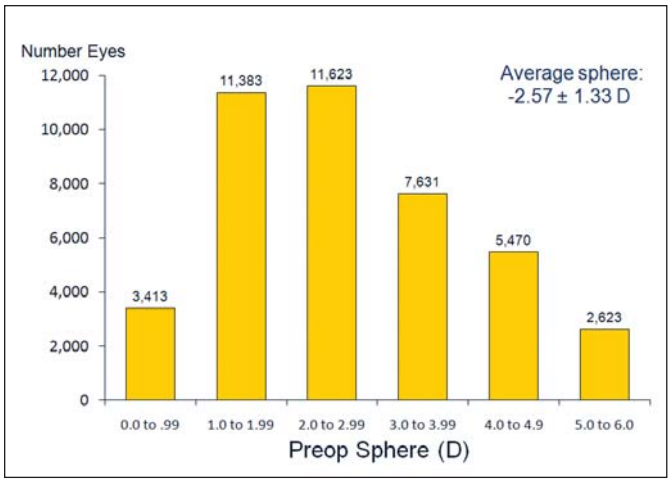

Figure 1. Preoperative sphere ranged from 0.0 to 6.00 D in 42,143 eyes that underwent LASIK.

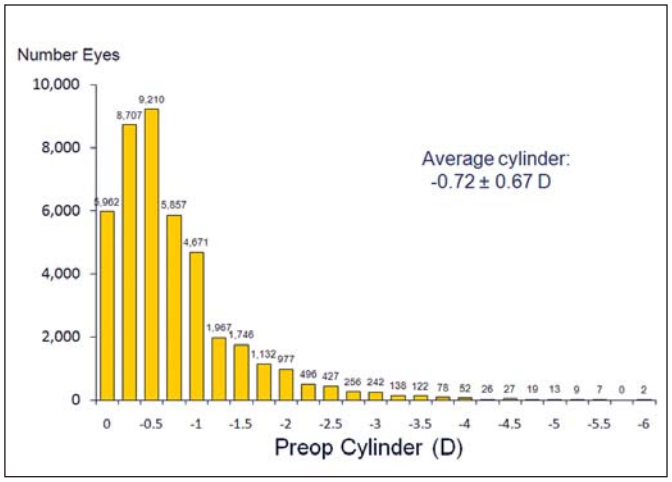

Figure 2. Preoperative cylinder ranged from 0.0 to −6.00 D in 42,143 eyes that underwent LASIK.

TABLE 1

Preoperative Comparison of Patients Who Did and Did Not Attend 1-month Follow-up

	1-month Follow-up	
	Attended	**Did Not Attend**
No. of eyes (patients)	32,569 (17,250)	9574 (5650)
Mean age (range) (y)	36.2 (18 to 69)	35.1 (18 to 68)
Male/female (%)	47.4/52.6	52.0/48.0
MSE (D)	−2.97±1.34	−2.93±1.35
FS laser/keratome (%)	76.6/23.4	73.5/26.5

MSE = manifest spherical equivalent

RESULTS

Patient Demographics

Of the 22,900 patients included in this study, 51.2% were female and 48.8% were male. Patients ranged in age from 18 to 69 years, with an average age of 35.6 years. The mean preoperative sphere was −2.57±1.33 D (range: −0.25 to −6.00 D) (Fig 1). The mean preoperative cylinder was −0.72±0.67 D (range: 0.00 to −6.00 D) (Fig 2). Preoperative cylinder >2.00 D was present in 1894 eyes. The average preoperative MSE was −2.93±1.34 D (range: −0.38 to −6.00 D). Most eyes (99.5%) had a BSCVA of 20/20 or better; all other eyes (329; 0.8%) had BSCVA between 20/20 and 20/32.

The majority of corneal flaps (75.7%) were created with the femtosecond laser, with the remainder created by the mechanical microkeratome.

One-month postoperative examination data were available for 32,569 eyes of 17,713 patients, representing a follow-up rate of 77.3%. A manifest refraction was recorded in 98% of these eyes (31,755 eyes of 17,348 patients), and BSCVA was documented in 97% (31,390 eyes of 17,187 patients). Almost all eyes (98.6%) that did not have a refraction and BSCVA had UCVA of 20/20 or better at their 1-month examination; the remaining 12 eyes had UCVA of 20/25.

A comparison of patients who completed 1-month examination and those who did not showed that the preoperative mean MSE was similar for both groups (−2.97 D and −2.93 D, respectively) (Table 1). However, patients who did not attend 1-month follow-up were slightly younger (35.1 vs 36.2 years), more likely to be male (52.0% vs 47.4%), and more likely to have had a corneal flap created using a mechanical keratome (26.5% vs 23.4%).

Refractive and Visual Acuity Outcomes

Mean MSE at 1-month follow-up was −0.03±0.29 D (range: −3.50 to +4.50 D). A linear regression of attempted versus achieved MSE yielded a slope of 0.96, an intercept of +0.08, and a correlation coefficient of 0.95 (Fig 3). Manifest spherical equivalent was within 0.50 D of target for 93.7% of eyes and within 1.00 D for 99.3% of eyes. Two hundred twenty-five eyes were >1.00 D from target; 49 (0.15%) eyes were overcorrected by >1.00 D MSE, and 176 (0.54%) eyes were undercorrected by >1.00 D.

The mean defocus equivalent at 1 month was 0.27±0.31 D (range: 0.00 to +5.25 D). Defocus equivalent was within 0.50 D of target in 88.6% of eyes and within 1.00 D in 98.2% of eyes.

The average manifest cylinder at 1 month was −0.17±0.26 D (range: 0.00 to −4.00 D), representing

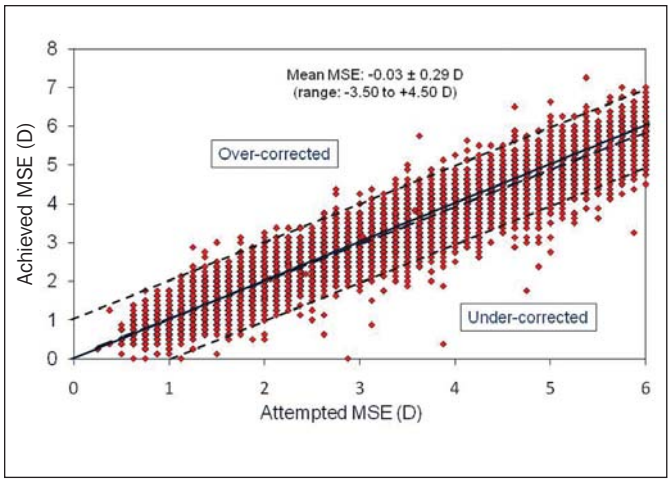

Figure 3. The linear regression of attempted versus achieved manifest spherical equivalent (MSE) 1 month after surgery in 31,755 eyes is displayed as a long-dashed line (slope 0.96 and intercept of +0.08) with a correlation coefficient of 0.95.

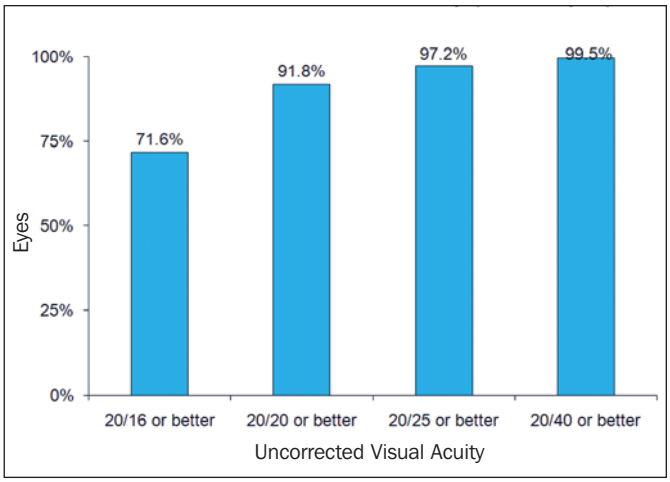

Figure 4. One month after surgery, the majority of eyes (97.2%, 31,657/32,569) had achieved at least 20/25 uncorrected visual acuity (UCVA).

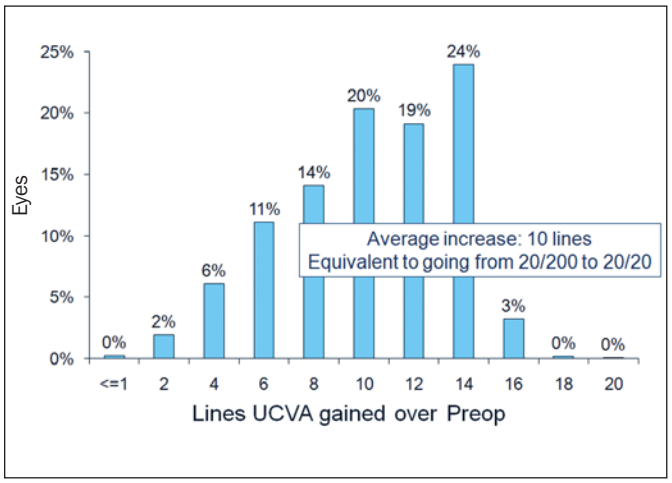

Figure 5. Compared to preoperative values, uncorrected visual acuity (UCVA) at 1 month in 32,569 eyes showed an average improvement of 10 lines.

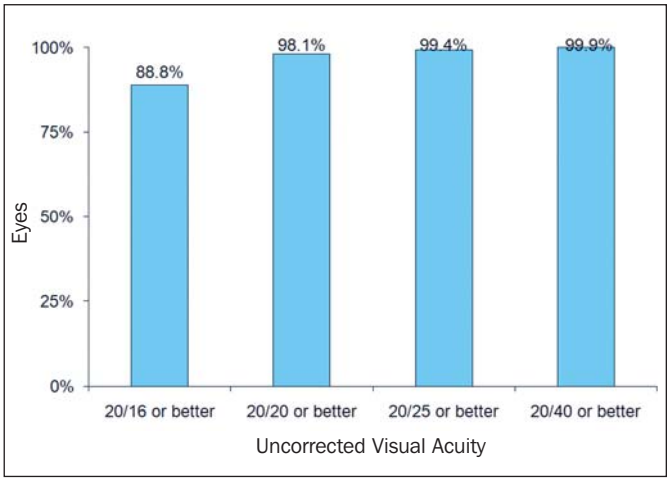

Figure 6. Of the 15,035 patients who underwent bilateral LASIK, the majority (98.1%) achieved binocular uncorrected visual acuity of 20/20.

a 76% mean reduction in absolute cylinder. In those eyes that had preoperative cylinder >2.00 D and a 1-month refractive examination (1504 eyes; mean preoperative cylinder: −2.87±0.68 D), an 81% reduction was noted in the absolute manifest cylinder at 1 month (mean: −0.51±0.46 D). Seven (0.02%) eyes had a postoperative manifest cylinder >2.00 D.

The majority of eyes (91.8%) achieved UCVA of at least 20/20 at 1 month, and 71.6% of eyes achieved 20/16 UCVA (Fig 4). Almost all eyes (99.5%) achieved 20/40 UCVA. The efficacy index for the procedure (mean postoperative UCVA/mean preoperative BSCVA) was 0.96. Compared to preoperative UCVA, treated eyes gained an average of 10 lines following surgery—equivalent to the change from 20/200 to 20/20 (Fig 5).

Among patients who had bilateral LASIK (30,070 eyes of 15,035 patients), 98.1% achieved 20/20 or better uncorrected binocular vision at 1 month (Fig 6).

Average BSCVA was slightly improved 1 month after surgery compared to preoperatively (mean change in BSCVA: 0.014 logMAR, 95% confidence interval [CI]: 0.013-0.014). The safety index for the procedure (mean postoperative BSCVA/mean preoperative BSCVA) was 1.02, and most eyes (98.3%) remained within 1 line of their preoperative BSCVA (Fig 7). There were 210 eyes (0.67%) that lost 2 or more lines of BSCVA. No eye had a BSCVA worse than 20/40, and 98.8% of eyes had BSCVA of 20/20 or better.

COMPLICATIONS

Both intra- and postoperative complications were assessed (Tables 2 and 3). Of the 42,143 eyes treated,

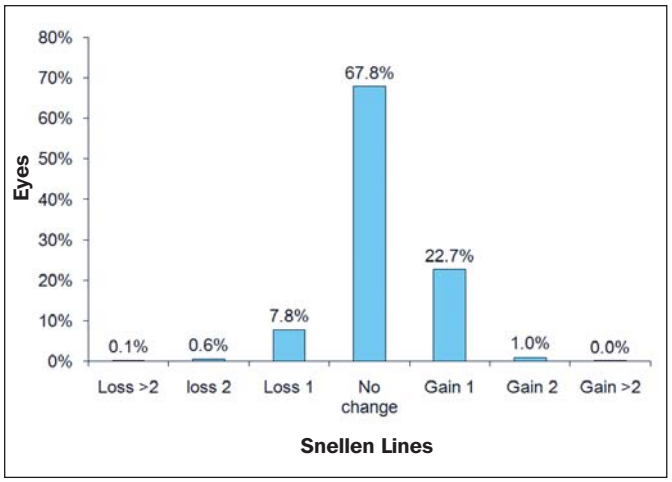

Figure 7. Most eyes (98.3%) were within one line of their preoperative best spectacle-corrected visual acuity.

25 (0.06%; 1:1686) experienced an intraoperative complication. The most common intraoperative complications were related to flap creation (n=22, 0.05%; 1:1916) and included epithelial abrasion as well as incomplete, buttonhole, and free flaps.

For postoperative complications, all available follow-up data were included in the analysis, and the incidence was computed based on the number of eyes evaluated at 1 month (32,569). There were 210 eyes that experienced a postoperative complication (0.64%; 1:155) between 1 day and 7 months after surgery.

Most of the common LASIK complications were observed, but many of these were transient and eventually resolved. The most common postoperative complications were dry eye (n=58; 0.18%; 1:562), mild diffuse lamellar keratitis (DLK, grade 1 or 2) (n=58; 0.18%; 1:562), and night vision symptoms (n=19, 0.06%; 1:1714). Thirteen eyes (0.04%; 1:2505) had flap striae that required flap lift and repositioning. Eight of these eyes had striae due to frank flap displacement caused by trauma; 7 (88%) of these 8 flaps were created with the mechanical keratome. When flaps required repositioning, this procedure was performed an average of 16 days (range: 1 to 127 days) following surgery.

In addition to these common complications, a few eyes experienced rare but serious complications. Six cases of microbial keratitis or presumed microbial keratitis were observed in the perioperative time period (0.018%; 1:5428). All cases were successfully treated with intense antibiotics, and 4 of these 6 eyes had a resultant BSCVA of 20/20 or better; the remaining 2 eyes had a BSCVA of 20/25 and 20/25^{-2}. Other serious complications included grade 3 or 4 DLK (8 eyes; 0.025%; 1:4071), crystalline lens changes noted 2 and 7 months following surgery (2 eyes; 0.006%; 1:16,285),

TABLE 2

Summary of Intraoperative Complications (N=42,143 Eyes)

Complication	n	Incidence (%)	1:___
Flap creation complication	22	0.052	1916
Incorrect treatment	2	0.005	21,072
Decentered ablation	1	0.002	42,143
Total	25	0.06	1686

TABLE 3

Summary of Postoperative Complications (n=32,569 eyes)

Complication	n	Incidence (%)	1:___
Dry eye	58	0.18	562
Mild DLK	58	0.18	562
Glare/halos	19	0.058	1714
Flap striae	13	0.040	2505
Delayed healing	9	0.028	3619
Grade 3/4 DLK	8	0.025	4071
Sterile infiltrates	8	0.025	4071
Postop cylinder >2.00 D	7	0.022	4653
Transient light sensitivity	6	0.018	5428
Microbial keratitis	6	0.018	5428
Significant haze	5	0.015	6514
Elevated IOP	4	0.012	8142
Recurrent erosions	3	0.009	10,856
Epithelial ingrowth	2	0.006	16,285
Crystalline lens changes	2	0.006	16,285
Ectasia	1	0.003	32,569
Retinal detachment	1	0.003	32,569
Total	210	0.64	155

DLK = diffuse lamellar keratitis, IOP = intraocular pressure

ectasia diagnosed 3 months after surgery (1 eye; 0.003%; 1:32,569), retinal detachment (1 eye; 0.003%; 1:32,569), and a decentered ablation (1 eye; 0.003%; 1:32,569).

DISCUSSION

The purpose of this study was to evaluate the early postoperative outcomes of wavefront-guided LASIK offered by a corporate provider for the treatment of low

to moderate myopia. The large study population was gender and age diverse (range: 18 to 69 years). A high percentage of patients achieved the refractive target (emmetropia) 1 month after surgery; 94% of eyes had a postoperative MSE within 0.50 D and 99% of eyes were within 1.00 D. Excellent refractive predictability was also demonstrated by the tight distribution of the postoperative MSE (standard deviation of 0.29 D) and the high correlation coefficient of the attempted versus achieved MSE (0.96).

Another measure of refractive accuracy is the defocus equivalent. Unlike MSE, this measure considers the defocus effect of both residual sphere and residual cylinder without allowing opposite signs of sphere and cylinder to cancel each other. As a result, defocus equivalent has only positive values. In this study, 89% of eyes were within 0.50 D of the defocus equivalent target (0.0 D).

In terms of UCVA, most eyes achieved 20/16 or 20/20 vision (71.6% and 91.8%, respectively). The efficacy score was 0.96—the ratio of mean postoperative UCVA to the mean preoperative BSCVA. Although not commonly reported, binocular acuity may also be a useful metric of functional vision, and almost all patients (98.1%) who underwent bilateral LASIK (15,035 patients) achieved 20/20 bilateral UCVA.

The safety of the procedure was assessed by the postoperative and pre- to postoperative change in BSCVA. All eyes had a BSCVA of 20/40 or better 1 month after surgery, and almost all eyes (98.8%) were 20/20 or better. A slight improvement in the mean BSCVA occurred in this study, which is commonly observed when treating myopia. A small number of eyes lost 2 or more lines of BSCVA (210 eyes, 0.67%) at 1 month postoperative. However, visual improvement can occur for several months after LASIK.[5,6] Visual results may improve in the later postoperative period.

Large, multicenter studies that are not part of a US Food and Drug Administration (FDA) clinical trial are uncommon in the literature. To the authors' knowledge, this study represents the largest study to report on the safety and effectiveness of LASIK.

The largest series previously published reported 34,099 eyes of 17,388 patients who underwent LASIK performed by 48 surgeons in 15 centers.[7] However, these authors only evaluated intraoperative complications, not postoperative outcomes.

Another large series reported 1-month data on 10,052 eyes of 5081 patients treated at a hospital in China.[8] However, the study did not discuss refractive outcomes, change in BSCVA, or the percentage of eyes that achieved specific levels of UCVA.

Other studies that have evaluated the outcomes of wavefront-guided LASIK performed to treat low to moderate myopia have had much smaller sample sizes (range: 25 to 187 eyes) and varying lengths of follow-up (range: 1 to 6 months). Overall, these studies have reported mixed refractive and acuity results, with the percentage of eyes being within 0.50 D MSE ranging from 72% to 98%, and the percentage of eyes achieving UCVA of 20/20 ranging from 56% to 98%.[9-16]

The results of the current study are similar to the regulated and controlled premarket approval (PMA) FDA clinical trial reported in 2003, which was conducted by the manufacturer using the same laser platform and wavefront-guided treatment profile.[3] The same optical and transition zones were used in this trial and in the current study, and the refractive indications for both studies were similar, with the exception that the PMA study limited preoperative cylinder to 3.00 D, whereas this study included eyes with up to 6.00 D of cylinder. In fact, our study included 1504 eyes with >2.00 D of preoperative cylinder. Higher levels of cylinder can result in less predictable refractive and acuity outcomes.[9]

The PMA study reported 331 eyes with 1-month follow-up data, whereas our study had approximately 100 times that number of eyes (32,569). Despite the difference in sample size, the percentage of eyes with an MSE within 0.50 D at 1 month was similar for both studies (92.7% and 93.7% for the PMA and this study, respectively), and the percentage of patients who attained 20/20 UCVA was the same (91.8% for both). In the PMA study, no eye lost more than 2 lines of BSCVA; the 95% CI for this measure was 0 to 0.9%. The percent of eyes in this study that lost more than 2 lines of BSCVA (0.12%) was within this range.

In addition to visual outcomes, this study also provides data on LASIK complications. Many of the complications previously reported for LASIK were observed in this study, including dry eye, DLK, and loss of BSCVA.[17] Most of the observed complications—such as dry eye, DLK, flap striae, and transient light sensitivity—were treated successfully without sequelae or long-term visual effects. Rare but potentially vision-threatening complications were also observed, such as microbial keratitis and ectasia. Despite these complications, the worst BSCVA at 1 month after surgery was 20/40. The low overall rate of complications in this study (intraoperative: 0.06% and postoperative: 0.64%) also reflects the high level of safety that modern LASIK has achieved.

This complication rate is lower than the rate of intraoperative complications described in another large LASIK study. In a study of 34,099 eyes that were treated using a mechanical keratome (Moria LSK One man-

ual), Albelda-Vallés et al[7] observed that 1338 (3.92%) eyes experienced intraoperative complications, with the most common being a free cap (571 eyes, 1.67%) and epithelial abrasion (282 eyes, 0.82%). Part of the reason for the disparity in complication rates may be due to the fact that the majority of procedures in our study were created with the femtosecond laser (76%). A free cap from a femtosecond-created flap has not been reported. Also, because there is no movement of the keratome head over the cornea, the rate of epithelial abrasion with the femtosecond laser is believed to be lower than with a mechanical keratome.[18]

The most important limitation of the current study was the number of patients lost to follow-up. Of the original cohort of 22,900 patients, 5187 patients (22.7%) did not attend the 1-month examination. These patients tended to be younger (35.1 vs 36.2 years), more often male (52.0% vs 47.4%), and had a higher percentage of mechanical keratome flaps (26.5% vs 23.4%).

A literature review shows that the possible influence of these factors on refractive and acuity outcomes is mixed. Gender does not appear to be a predictor of LASIK outcomes. Some reports have found that age is a factor, with younger patients having better outcomes, but other studies have not found an association.[9,19,20] In addition, studies of the possible benefit of femtosecond-created LASIK flaps have shown both similar and improved outcomes compared to mechanical keratome-created flaps.[4,21-24] Given these mixed results, it is not known whether patients who did not attend the 1-month examination would have collectively done better, worse, or the same as the cohort who attended the 1-month examination.

In addition to some patients being lost to follow-up, another limitation of this study is that several factors could have resulted in an overestimation or underestimation of the complication rates reported. With only 77% follow-up at 1 month, some complications may have been missed; however, the ready access to care and the network of Optical Express clinics throughout the countries where the treatments were performed should help minimize such losses. It is also possible that patients who missed their 1-month examination may have been less likely to have a complication, resulting in an overestimation of the actual complication rate.

Also, while most complications after laser vision correction occur during the perioperative period, some complications can occur much later; ectasia has been reported to occur years after surgery.[25] Although one ectasia case was reported in this study (diagnosed 3 months after surgery), additional long-term follow-up could reveal other late complications.

Although the factors affecting complications were not analyzed in depth, flap-related complications appeared to be significantly more common in eyes treated with a mechanical keratome. Of eight traumatic flap dislocations, seven occurred with the mechanical keratome. Reflecting a growing public awareness of such advantages, most patients (76%) elected to have flaps created with the femtosecond laser, despite the significantly higher procedure fee (~$1200) associated with this option.

This study demonstrates that a large corporate provider employing a surgeon/optometrist comanagement model and using wavefront-guided and femtosecond/mechanical keratome technology can achieve excellent 1-month refractive surgery outcomes with a low complication rate, even when treating a large and diverse population. Because of this study's large sample size, these results also help further validate laser vision correction as a safe and effective method of correcting refractive errors in the general population.

AUTHOR CONTRIBUTIONS

Study concept and design (S.C.S., J.A.V.); data collection (S.C.S.); interpretation and analysis of data (S.C.S.); drafting of the manuscript (S.C.S.); critical revision of the manuscript (S.C.S., J.A.V.); statistical expertise (S.C.S.); administrative, technical, or material support (S.C.S.); supervision (S.C.S., J.A.V.)

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