Clinical results of using a high-repetition-rate excimer laser with an optimized ablation profile for myopic correction in 10235 eyes

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PURPOSE: To evaluate the visual outcomes, safety, stability, efficacy, and predictability of laser in situ keratomileusis (LASIK) to correct myopia using a high-repetition-rate excimer laser with an optimized ablation profile.

SETTING: Private clinic, Tokyo, Japan.

DESIGN: Retrospective noncomparative study.

METHODS: In this study, patients had LASIK using the Schwind Amaris excimer laser for myopic correction.

RESULTS: The study comprised 10 235 eyes of 5191 patients. The patients' mean age was 33.9 years \pm 7.84 (SD) (range 18 to 56 years). The mean preoperative manifest refraction spherical equivalent (MRSE) was -5.02 ± 2.17 diopters (D) (range -2.75 to -11.50 D). Three months postoperatively, 82.0% of patients achieved an uncorrected distance visual acuity of $-0.18 \log$ MAR or better and 96.9% achieved 0.00 logMAR or better. The MRSE was within ± 0.50 D of the intended refractive target in 88.4% of eyes and within ± 1.00 D in 98.8%. Despite using the profile designed to minimize postoperative aberrations, the postoperative corneal and ocular higher-order aberrations increased.

CONCLUSION: Laser in situ keratomileusis using a high-repetition-rate excimer laser was a safe and effective procedure, yielding predictable results for a wide range of myopic patients.

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Since Pallikaris et al.¹ first reported performing laser in situ keratomileusis (LASIK) in human eyes, it has become widely accepted as a technique for correcting refractive errors.^{2–6} Since the first report, a variety of excimer lasers have been developed.

In this study, we evaluated the visual and refractive outcomes of LASIK in a large cohort using a highrepetition-rate excimer laser with an optimized ablation profile for refractive correction.

PATIENTS AND METHODS

In this retrospective noncomparative study, patients had LASIK between August 2009 and April 2010 at Shinagawa LASIK Center, Tokyo, Japan. Consecutively included were patients who met the following requirements: preoperative corrected distance visual acuity (CDVA) of 0.00 logMAR or better, myopia (manifest sphere ≤ -0.25 diopter [D]), and

© 2013 ASCRS and ESCRS Published by Elsevier Inc. attendance at all postoperative checkups at 1 day, 1 week, and 3 months. Exclusion criteria were abnormal topography including keratoconus, glaucoma, cataract, retinal disease, an expected residual bed thickness after LASIK of less than 300 μ m, expected total pachymetry after LASIK of less than 390 μ m, and previous eye surgery including refractive surgery.

Preoperative Assessment

The preoperative examinations included uncorrected distance visual acuity (UDVA), CDVA, manifest refraction, autorefraction, cycloplegic refraction, intraocular pressure (full auto tonometer TX-F, Topcon Corp.), ultrasonic pachymetry (Pachy Meter SP-3000, Tomey Corp.), endothelial cell density (Noncon Robo FA-3509, Konan Medical), Placido-based topography (TMS-4, Tomey Corp.; OPD-Scan II, Nidek Co., Ltd.), Scheimpflug tomography (Oculus Pentacam, Oculus Optikgeräte GmbH), and wavefront analysis (KR-9000PW, Topcon Corp.). The OPD-Scan II device was used to evaluate pupil diameter.

Excimer Laser

The Schwind Amaris excimer laser (Schwind Eye-Tech Solutions GmbH & Co. KG) was used in this study. Introduced in 2007, the excimer laser has a 500 Hz pulse rate and a 1050 Hz eye-tracking system. The eye tracker tracks the pupil and the limbus following linear movements along the *x*-axis and *y*-axis (first and second dimensions), rolling movements of vertical and horizontal rotation (third and fourth dimensions), and static and dynamic cyclotorsion movements (fifth dimension) with automatic pupil size control and pupil-center-shift compensation. The repetition rate is high with thermal effect controls; 1.00 D of correction is completed in 2 seconds.

Surgical Technique

After the preoperative slitlamp examination, 1 drop of oxybuprocaine hydrochloride 0.4% ophthalmic solution (Benoxil) was instilled followed by 1 drop of moxifloxacin hydrochloride 0.5% ophthalmic solution (Vigamox) and 1 drop of lidocaine 4.0% ophthalmic solution (Xylocaine). The Femto LDV femtosecond laser (Ziemer Ophthalmic Systems AG) was used for lamellar flap creation in all patients. The intended flap thickness was 90 µm, 100 µm, or 110 µm depending on the preoperative central corneal thickness and ablation depth. No patient had a surface procedure (eg, photorefractive keratectomy, laser-assisted subepithelial keratectomy). Femtosecond laser settings included a pulse energy of 20 to 100 nJ, a repetition rate of 1 MHz, and a spot size of less than 1 μ m. After the flap was created, excimer laser ablation was performed with an aberration-free program equipped with a 5-dimensional (5-D) eye tracker to correct the refractive error. Considering future regression of the patient's myopic condition, the attempted target was set to plano for eyes with low or moderate myopia (0.00 to -6.00 D) or to +0.25 D for eyes with high myopia (-6.01 D or higher) using the preoperative spherical equivalent (SE) measured with an autorefractometer. The surgeries were performed by 1 of 6 surgeons using similar techniques.

The following surgeons participated in this study: Tadayuki Nakamura, MD, Nobuo Nakamura, MD, PhD, Satoshi Yukawa, MD, Kiwa Sugawara, MD, PhD, and Toru Nakamura, MD.

Corresponding author: Minoru Tomita, MD, PhD, Shinagawa LASIK Center, Yurakucho ITOCiA 14F, 2-7-1 Yurakucho, Chiyoda-ku, Tokyo 100-0006, Japan. E-mail: tomita@shinagawa-lasik.com. After the procedure was completed, 1 drop of moxifloxacin hydrochloride, 1 drop of sodium hyaluronate 0.3% ophthalmic solution (Hyalein Mini), and 1 drop of dexamethasone sodium metasulfobenzoate 0.1% ophthalmic solution (DEX) were instilled. The patients were instructed to rest for 20 minutes before the postoperative examination, after which 1 drop of sodium hyaluronate ophthalmic solution was instilled.

Postoperative Regimen and Assessment

Patients were instructed to visit the clinic for postoperative examinations at 1 day, 1 week, and 3 months. On the day of surgery, patients were instructed to apply 1 drop of dexamethasone sodium metasulfobenzoate 0.1% ophthalmic solution, 1 drop of moxifloxacin hydrochloride 0.5% ophthalmic solution, and 1 drop of sodium hyaluronate 0.3% ophthalmic solution once every hour. One day postoperatively, patients were directed to instill these 3 eyedrops 5 times a day for 1 week.

Postoperative examinations included UDVA, CDVA, manifest refraction, corneal topography, and slitlamp evaluation.

Questionnaire

Three months after LASIK, patients were asked to answer questions to evaluate their level of satisfaction with the LASIK outcome as follows: (1) How satisfied are you with your LASIK outcome? (options: very satisfied, satisfied, less satisfied, and not satisfied). (2) Is your vision better now than when wearing glasses/contact lenses? (options: better, the same, slightly worse, and worse). (3) Did your visual results meet your preoperative expectations? (options: exceeded, met, and did not meet). (4) Did you experience halo/glare? (options: yes and no). The answers were studied and analyzed.

Data Analysis

The data were divided into low (-3.00 D and less), moderate (-3.01 to -6.00 D), high (-6.01 to -10.00 D), and very high (greater than -10.00 D) myopia according to the preoperative MRSE. Furthermore, the data were divided into age groups (by decade from 10s to 50s); the study evaluated whether the age group influenced predictability. The relationship between the preoperative MRSE and age and the postoperative errors from the attempted correction 3 months after LASIK were also analyzed. The corneal and ocular higher-order aberrations (HOAs) were measured at a 6.0 mm diameter with the apex of the cornea at its center under dim light. In addition, the relationship between changes in HOAs 3 months after LASIK and halos/glare was studied.

Statistical Analysis

For the statistical analysis, the paired t test, Mann-Whitney U test, and Pearson correlation coefficient (r) were used where applicable. A P value less than 0.05 was considered statistically significant.

RESULTS

The study comprised 10 235 eyes of 5191 patients (4787 eyes of 2428 men; 5448 eyes of 2763 women). The mean

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age of the patients was 33.9 years \pm 7.81 (SD) (men 33.9 \pm 7.78 years; women 33.9 \pm 7.84 years). The preoperative mean corneal thickness was 537.8 \pm 29.6 µm. The mean attempted correction was -5.21 ± 2.13 D.

Postoperatively, the mean flap thickness was 94.9 \pm 5.72 µm. The mean pupil diameter was 4.47 \pm 0.71 mm under photopic conditions and 6.34 \pm 0.77 mm under mesopic conditions.

Efficacy

The mean UDVA preoperatively and 1 day, 1 week, and 3 months postoperatively was 1.18 ± 0.26 log-MAR, -0.15 ± 0.09 logMAR, -0.18 ± 0.08 logMAR, and -0.18 ± 0.10 logMAR, respectively. The improvement in the mean UDVA was statistically significant 3 months postoperatively compared with preoperatively (P < .0001, paired *t* test). At 3 months, 9918 eyes (96.9%) achieved a UDVA of 0.00 logMAR or better (Figure 1). The efficacy index was 1.00.

Safety

The mean CDVA before LASIK and 1 day, 1 week, and 3 months postoperatively was -0.18 ± 0.06 log-MAR, -0.17 ± 0.08 logMAR, -0.20 ± 0.07 logMAR, and -0.20 ± 0.07 logMAR, respectively. The improvement in the mean CDVA was statistically significant 3 months postoperatively compared with the preoperative values (P < .0001, paired *t* test). Three months after LASIK, 10219 eyes (99.8%) achieved a CDVA of 0.00 logMAR or better. The safety index was 1.03.

The CDVA was worse than 0.00 logMAR in 16 eyes (0.16%) (men 8 eyes, women 8 eyes) 3 months postoperatively. The mean age in this group of 16 eyes was 38.1 ± 9.2 years (range 18 to 56 years), and the mean preoperative manifest refraction spherical equivalent (MRSE) was -5.80 ± 2.92 D (range -2.75 to -11.50 D). Fourteen of these eyes (87.5%) were

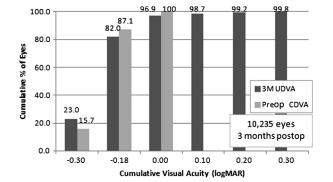


Figure 1. Cumulative logMAR UDVA 3 months after LASIK and preoperative CDVA (CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity).

diagnosed as dry eye and/or showing a symptom of superficial punctate keratitis. None of the eyes in this study had LASIK retreatment or intraoperative complications, such as suction loss or flap irregularities. Three months postoperatively, 1193 eyes (11.7%) lost 1 line of CDVA (Figure 2); however, 3 of the 1193 eyes (0.03% in 10 235 eyes) had a CDVA worse than 0.00 logMAR. At 3 months, 59 (0.6%) of the 10 235 eyes lost 2 or more lines of CDVA (Figure 2); 12 of the 59 eyes (0.1% in 10 235 eyes) had a CDVA of worse than 0.00 logMAR. In eyes that lost 1 or more lines (1252 eyes), the preoperative CDVA was -0.30 logMAR in 768 eyes (61.3%), -0.18 logMAR or better in 1210 eyes (96.6%), and -0.08 logMAR or better in 1251 eyes (99.9%).

Manifest Refraction

The mean MRSE preoperatively and 1 day, 1 week, and 3 months postoperatively was -5.02 ± 2.17 D (range -12.00 to -0.38 D), 0.17 ± 0.33 D (range -2.00 to 2.00 D), 0.17 ± 0.31 D (range -1.63 to 2.00 D), and 0.08 ± 0.31 D (range -2.75 to 2.00 D), respectively (Figure 3, *A*).

Three months postoperatively, the mean defocus equivalent refraction was 0.20 ± 0.32 D (range 0.00 to 3.50 D) (Figure 3, *B*). At 3 months, 9352 patients (91.4%) were within ± 0.50 D and 10090 patients (98.6%) were within ± 1.00 D of the mean defocus equivalent refraction.

The mean refractive cylinder preoperatively and 1 day, 1 week, and 3 months postoperatively was -1.01 ± 0.80 D (range -6.50 to 0.00 D), -0.02 ± 0.11 D (range -1.50 to 0.00 D), -0.03 ± 0.14 D (range -2.25 to 0.00 D), and -0.06 ± 0.20 D (range -2.00 to 0.00 D), respectively (Figure 4).

Predictability

Figure 5 shows a scattergram of the achieved SE refraction versus the attempted SE refraction 3 months

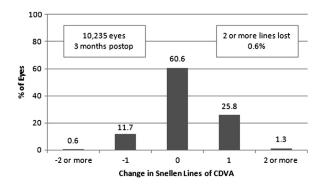


Figure 2. Change in CDVA (CDVA = corrected distance visual acuity).

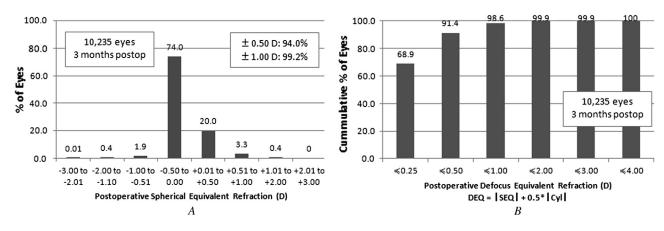


Figure 3. A: Spherical equivalent (SEQ) refractive accuracy. B: Defocus equivalent (DEQ) refraction.

after LASIK. Nine thousand forty-four eyes (88.4%) were within ± 0.50 D of the attempted correction and 10 113 eyes (98.8%) were within ± 1.00 D.

The correlation coefficient between the attempted correction and the achieved correction was 0.986 (P < .0001). For low, moderate, high, and very high myopia, the correlation coefficient between the attempted and achieved correction was correlated or highly correlated (r = 0.890, r = 0.928, r = 0.909, and r = 0.628, respectively; P < .0001). All age groups (10s, 20s, 30s, 40s, and 50s) had a very high correlation between the attempted and the achieved correction (r = 0.984, r = 0.986, r = 0.986, r = 0.986, andr = 0.984, respectively; P < .0001). The correlation coefficient between the preoperative MRSE and age and the postoperative errors from the attempted correction 3 months after LASIK was 0.178 and 0.094, respectively (P < .0001), showing little correlation between errors from the attempted correction and the 2 parameters studied.

Corneal and Ocular Aberrations

Table 1 shows the preoperative and 3-month postoperative aberrations measured at a 6.0 mm diameter.

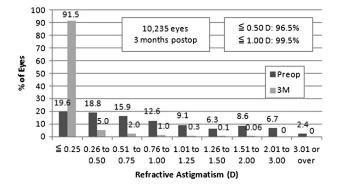


Figure 4. Refractive astigmatism.

Patient Satisfaction

Some patients did not complete the written questionnaire, and others submitted an invalid or missing answer to some questions. Three months after LASIK, of the 10 117 patients who submitted a valid response, 4625 (45.7%) were satisfied with their outcomes, 4554 (45.0%) were very satisfied, 809 (8.0%) were less satisfied, and 129 (1.3%) were dissatisfied. Furthermore, 9440 (93.4%) of the 10108 patients who submitted a valid response said they believed their vision was better than (6129 patients [60.6%]) or the same as (3311 patients [32.8%]) it was when they wore glasses/contact lenses and 536 patients (5.3%) and 132 patients (1.3%) said their vision was slightly worse or worse than when they worse glasses/contact lenses. Of the 10 118 patients who submitted a valid response,

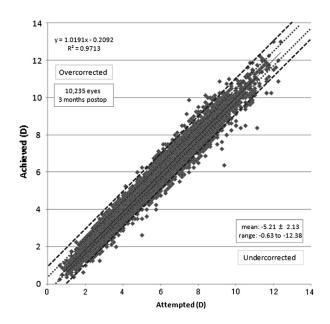


Figure 5. Spherical equivalent, attempted versus achieved.

	Preoperative		Postoperative		
	Mean RMS (μ m) \pm SD	Range	Mean RMS (μ m) \pm SD	Range	P Value*
Corneal					
Coma	0.255 ± 0.107	0.010, 1.097	0.416 ± 0.190	0.010, 2.199	<.0001
Spherical	0.213 ± 0.069	0.014, 1.170	0.527 ± 0.198	0.044, 2.171	<.0001
Total	0.348 ± 0.098	0.022, 1.575	0.704 ± 0.234	0.044, 3.301	<.0001
Ocular					
Coma	0.252 ± 0.115	0.013, 1.425	0.460 ± 0.235	0.005, 2.888	<.0001
Spherical	0.163 ± 0.080	0.012, 0.896	0.312 ± 0.166	0.017, 2.238	<.0001
Total	0.322 ± 0.118	0.016, 1.598	0.596 ± 0.262	0.060, 3.715	<.0001

9409 (93.0%) said they believed their outcome from LASIK met (6825 patients [67.5%]) or exceeded (2584 patients [25.5%]) their preoperative expectations; 709 patients (7.0%) said their outcome from LASIK was worse than preoperatively.

Furthermore, 362 (3.6%) of the 10148 patients who submitted a valid response developed a contrast issue, such as night-vision problems including halos and/or glare. The mean MRSE 3 months after LASIK in patients who experienced halos and/or glare and those who did not was 0.02 \pm 0.41 D and 0.08 \pm 0.31 D, respectively (P = .0013, Mann-Whitney U test). The mean change in corneal HOAs in patients who experienced halos/glare and those who did not was $0.452 \pm 0.267 \,\mu\text{m}$ and $0.353 \pm 0.241 \,\mu\text{m}$, respectively (P < .0001,Student *t* test). The mean increase in ocular HOAs in patients who experienced halos/glare and those who did not was 0.368 \pm 0.304 μm and $0.271 \pm 0.270 \ \mu\text{m}$, respectively (P < .0001, Student t test). No patient had extensive worsening of vision for daily-life activities such as driving.

DISCUSSION

As the excimer laser has developed over the past decade, many models have been introduced to the market. Each product has unique characteristics related to speed, eye-tracking ability, ablation pattern, ablation speed, ablation energy, and pulse size. In this study, we evaluated the use of the Schwind Amaris excimer laser for refractive correction. The objective of our study was to evaluate the visual and refractive outcomes of LASIK using this laser in a cohort with a broad range of myopia and age. To our knowledge, this is the largest report on the effectiveness of LASIK using this excimer laser.

We observed patient outcomes up to 3 months after LASIK. For UDVA and CDVA, 96.9% and 99.8% of the

eyes achieved 0.00 logMAR or better, respectively. One thousand two hundred fifty-eight eyes (12.3%) lost 1 or 2 lines or more of CDVA compared with preoperatively. The mean preoperative CDVA was excellent $(-0.18 \log MAR \text{ or better})$. Of eyes that lost 1 or 2 lines or more, 1237 (98.8%) maintained a CDVA of 0.00 logMAR or better. Because the preoperative CDVA was especially high in this cohort, most patients who lost lines maintained a safe CDVA of 0.00 logMAR or better. More than 99% of eyes were within ± 1.00 D of the MRSE 3 months after LASIK. Three months postoperatively, 98.6% of patients were within 1.00 D of the defocus equivalent refraction. Although some may contend that visual and refractive outcomes are not stable 3 months after LASIK, it has been reported that refractive results can be considered stable at this timepoint.⁷

In our study, patient satisfaction at 3 months in terms of the procedure meeting or exceeding expectations and when comparing postoperative vision with preoperative vision with glasses and/or contact lenses was very high (>90%). Despite the high number of patients who achieved the intended SE outcome, our patients' satisfaction rate is slightly lower than in other studies.8

At 3 months, 3.6% of the patients had contrast issues such as halo and/or glare. These symptoms were not severe enough to affect their daily-life activities, such as driving. It has been reported that halo and glare symptoms can be observed early in the postoperative period and that these conditions can lessen gradually over time.9 However, a previous study¹⁰ found that 50% of patients reported halo and 21.6% reported glare 6 months after LASIK. Our patients had a much lower rate of undesirable postoperative symptoms. We also found that the increase in HOAs may have been related to the reports of halos and glare. Further study is needed to determine whether this finding was influenced not only by the increase of HOAs but by other factors as well.

Our visual and refractive outcomes are similar to those in other studies of LASIK using different combinations of femtosecond lasers and excimer lasers.¹¹⁻¹³ There are several studies of the Schwind Amaris excimer laser in the literature. This laser uses an "aberration-free" profile, which aims to maintain the preoperative aberration profile and minimize contrast sensitivity loss postoperatively.^{7,14} With this profile, patients do not require a long time to adjust neurologically to their newly acquired aberration (increased or decreased) and their vision quickly recovers. Other studies of HOA changes using this excimer laser¹⁵⁻¹⁷ report a lower increase in HOAs than in our study. In 1 study,¹⁵ the preoperative and postoperative corneal HOAs were 6-month 0.33 \pm 0.15 μm and 0.34 \pm 0.14 μm , respectively. In another study,¹⁶ the preoperative and 3-month postoperative corneal HOAs were 0.347 \pm 0.060 μ m and $0.425 \pm 0.129 \,\mu\text{m}$, respectively. In our study, there was an increase in corneal HOAs of 0.356 \pm 0.243 μ m 3 months postoperatively compared with the preoperative value. However, the amount of refractive correction was higher in our study (preoperative mean -5.02 ± 2.17 D; range -12.00 to -0.38 D). We believe this may be the cause of the higher HOA changes we observed. A comparison of our Japanese cohort with white cohorts in another study¹⁷ showed that Japanese patients have a higher rate of high or very high myopia. Thus, the patients in our study required a deeper corneal ablation to correct their refractive error and this deeper ablation may have induced a higher rate of HOAs postoperatively.

In our study, the predictability of LASIK as a whole using the Schwind Amaris excimer laser was excellent, with a high correlation coefficient between the attempted correction and the achieved correction (r = 0.986). The correlation coefficient was high over all ranges of preoperative myopia, including in eyes with high myopia and very high myopia (r = 0.909 and r = 0.628, respectively). We found that the predictability of the procedure was not influenced by the amount of preoperative refractive error or by patient age. The 16 eyes (0.16% of eyes) that had a CDVA worse than 0.00 logMAR 3 months postoperatively had a slightly higher mean age and a higher preoperative MRSE; however, the differences were not statistically significant. Older patients and/or those with stronger refractive errors may have reduced effects from excimer lasers. However, no patient had a reoperation 3 months after LASIK in this study. It has been reported that the main factor affecting the retreatment rate is the preoperative MRSE.^{18,19} In our study, the predictability of the attempted versus achieved

correction was excellent and was not affected by the preoperative MRSE. Further long-term study is needed to make conclusive statements on the reoperation rate and to determine which factor(s) leads to increased retreatment rates using this excimer laser.

It has been reported that the change in hydration on the stromal surface caused by excimer lasers affects the visual outcomes.²⁰ Longer ablation times could dry the stromal surface and affect the patient's ability to fixate.²¹ It has been shown that high-repetitionrate (500 or 1000 Hz) excimer lasers have no obvious clinical side effects associated with the high repetition rates.^{22,23} The Schwind Amaris excimer laser delivers laser spots at 500 Hz with a thermal control system. Using this, the laser-pulse distribution is thermally optimized, which gives the individual positions on the cornea sufficient time to cool before a repeated pulse application to the same location. This thermal optimization combined with the fast ablation speed of the excimer laser may minimize the impact of thermal and hydration extremes during treatment. A study²⁴ found that the maximum temperature rise on the stromal surface during the ablation was 3.73°C, which is lower than other published values, and that the stromal surface temperature did not exceed 35°C. The temperature rise was not dependent on the amount of refractive correction or the treatment duration and did not cause corneal collagen denaturation.²⁴

Waring²⁵ examined the differences in the preciseness of the ablation patterns by comparing different speeds of eye trackers (60 Hz, 200 Hz, and 1000 Hz) as well as that of excimer lasers without eye trackers. The higher speed eye trackers had increased preciseness in terms of ablation spot placement.²⁵ In our study, the visual and refractive outcomes were excellent with very high predictability. The high-speed eye tracker (1050 Hz) of the Schwind Amaris excimer laser may increase the precision of the ablation pattern, which may lead to improved visual outcomes.

Some patients have difficulty fixating during LASIK. The eye tracker of the Schwind Amaris excimer laser tracks 5-D movements of the eye as well as pupil displacement. Static cyclotorsion may be compensated for using the static cyclotorsion compensation algorithm.²⁶ The optimized aspheric ablation profiles were used in conjunction with a 1050 Hz active eye tracker in all patients, which may have played a role in the excellent LASIK outcomes in this study.

In conclusion, we present the first large-scale study of the visual outcomes after LASIK performed using the Schwind Amaris excimer laser in more than 10 000 eyes. We found this laser to be safe and effective in a large sample size with a wide range of myopia. Longer-term follow-up study to confirm our findings as well as further evaluation of the various types of refractive errors are needed.

WHAT WAS KNOWN

• The Schwind Amaris excimer laser can be applied safely for the correction of refractive error.

WHAT THIS PAPER ADDS

 Despite seeing a slight increase in postoperative HOAs when compared with findings in other studies, results show that LASIK using the high-repetition-rate excimer laser is a safe and predictable procedure for a wide range of myopic patients.

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