A 10-Year Prospective Audit of LASIK Outcomes for Myopia in 37 932 Eyes at a Single Institution in Asia

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Purpose: This study evaluates the efficacy, predictability and safety of LASIK surgery as a treatment for myopia performed as part of a large-scale, prospective clinical audit spanning 10 years in an Asian study population and to evaluate the outcomes and trends.

Design: Prospective, nonrandomized, single-center, multisurgeon study.

Participants: We included 37 932 eyes of 19 753 patients that underwent myopic LASIK at the Singapore National Eye Centre between 1998 and 2007.

Methods: All eyes underwent LASIK as a treatment for myopia. Pre- and postoperative refractions, uncorrected visual acuity (UCVA), and best-corrected visual acuity (BCVA) were documented.

Main Outcomes Measures: Safety, efficacy, refractive predictability, treatment trends, retreatment rates, and complications for mild, moderate, and high myopia according to spherical equivalence (SE) of less than −5.00 diopters (D), −5.00 D or more to less than −10.0 D, and −10.00 D or more, respectively.

Results: Patients' median age was 32 years (mean, 33.0±7.9 years); there were 6832 males (34.6%) and 12 921 females included. Patients were predominantly ethnic Chinese (90.5%). Mean follow-up time was 68.8 days. The mean spherical error corrected was −5.90±2.57 D (median, −5.625 D), and outcomes were categorized into low, moderate, or high myopia. The UCVA achieving ≥20/40 has been consistently above 90% since 2000, with 72.8% achieving ≥20/20. More than 93.0% of eyes achieved within ±1.00 D target in the last 4 years. An improvement in safety was observed since the start of the study, with the best outcomes observed in 2007; loss of 1 and 2 Snellen line BCVA postoperatively was 2.4% and 0.1%, respectively. The overall retreatment rate was 3.8%; 91% of retreated eyes achieved UCVA of ≥20/30. Between 1998 and 2007, there was a significant improvement in postoperative UCVA and BCVA ($P<0.001$).

Conclusions: Myopic LASIK performed in Asian eyes within a comprehensive LASIK clinical program with appropriate clinical audit governance can be safe and effective, with high refractive predictability. Improvements in the nomograms to prevent undercorrection and to compensate for myopic regression have led to better efficacy after LASIK, with an increasing percentage of patients achieving 20/15 visual acuity postoperatively.

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LASIK is among most common ophthalmic procedures in the world. Reasons for its popularity lie in its safety, efficacy, quick visual recovery, and minimal patient discomfort.[1–5] As a result, millions of patients worldwide undergo this procedure each year, making the safety and efficacy of LASIK a significant public health interest.[5]

LASIK results have been audited at Singapore National Eye Centre (SNEC) since 1998, at a similar time when the first excimer laser was approved by the United States Food and Drug Administration (FDA) for use in LASIK eye surgery.[6] The aim of this study was to evaluate refractive outcomes and trends on safety, efficacy, and predictability of myopic LASIK in Singapore spanning 10 years with a complete 100% data capture. To our knowledge this is the largest refractive series reported in the literature.

Materials and Methods

Patient Population

In this prospective study, informed consent was obtained from 19 753 patients after they received a detailed description of LASIK and a thorough review of its known risks. All patients underwent myopic LASIK at the Singapore National Eye Centre (SNEC) between February 14, 1998, and December 31, 2007. Patients returned for 1 day, 1 week, 1 month, and 3 month follow-up after the initial procedure. Patient demographics are given in Table 1. A

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Table 1. Annual Breakdown of Race, Gender, and Age for Patients Who Underwent Myopic LASIK

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	Total	
Race												
Chinese	258	866	1252	1408	1457	1447	2487	3302	3377	2013	17867	90.50%
Malay	5	17	16	16	24	22	29	75	72	49	325	1.60%
Indian	5	18	19	20	13	20	41	55	85	78	354	1.80%
Others	7	45	89	91	114	94	135	196	237	199	1207	6.10%
Total	275	946	1376	1535	1608	1583	2692	3628	3771	2339	19753	
Gender												
Male	97	312	478	549	578	575	930	1306	1228	779	6832	34.60%
Female	178	634	898	986	1030	1008	1762	2322	2543	1560	12921	65.40%
Total	275	946	1376	1535	1608	1583	2692	3628	3771	2339	19753	
Age												
Mean	33±8	34±8	34±8	33±8	33±8	33±7	33±7	33±7	32±7	33±7	33±8	
Median	32	34	34	33	32	32	33	32	31	31	32	
Range	21–53	19–75	20–70	20–56	16–63	21–62	19–61	20–69	20–64	19–62	16–75	

comprehensive 100% clinical audit of all LASIK cases in SNEC was performed independently by our Clinical Audit Department.

Inclusion criteria for surgery were no soft contact lens wear for 1 week before surgery and rigid contact lens wear for 3 weeks prior; stable refractive error for 12 months before surgery; normal peripheral retina or after prophylactic treatment with photocoagulation; no previous ocular surgery, no corneal diseases, no glaucoma; and no history of ocular trauma. Exclusion criteria for LASIK were keratoconus or forme fruste as evidenced by corneal topography, active ocular or systemic disease likely to affect corneal wound healing, calculated postoperative corneal residual bed thickness of <250 μm, pregnant, or nursing.

Surgical Technique

There were mild variations in technique between surgeons. In general, after 1 drop of local anesthetic (tetracaine hydrochloride 0.5%; Minims, Chauvin Pharmaceuticals Ltd, Surrey, England) was applied, the eyelashes of the upper and lower lids were isolated from the surgical field using a surgical drape. A lid speculum was used to retract the eyelids, and polyvinyl acetate surgical spears (Ivalon, New London, CT) were used to dry the conjunctival fornices. The cornea was marked with a Hoffman or Bansal corneal marker that was coated with ink from a surgical marker. A superiorly hinged 160/180-μm thick flap was created with a B&L Hansatome (Bausch & Lomb Surgical, Inc., Rochester, NY), or 120/140-μm thick flap using the B&L XP microkeratome (Bausch & Lomb Surgical, Inc.) or the IntraLase femtosecond laser (AMO, Santa Ana, CA). Excimer laser ablation was then performed either with a Technolas 117c, 217c, 217z, or a 217z100 excimer laser system (Bausch & Lomb Surgical, Inc.) or LADARVision 4000 excimer laser system (Alcon, Fort Worth, TX). After ablation, the flap was carefully repositioned, and postoperative medications were commenced. In the initial years a combination medication, Tobradex (tobramycin 0.3%, dexamethasone 0.1% ophthalmic suspension; Alcon) was used after surgery. From 2007, separate medications using Maxidex (dexamethasone 0.1%; Alcon) and Vigamox (0.5% moxifloxacin ophthalmic solution, Alcon) or Pred Mild (0.12% ophthalmic suspension; Allergan, Irvine, CA) and Zymar (0.3% gatifloxacin ophthalmic solution; Allergan) combinations used every 2 hours, then 4 times daily for 1 week. Artificial tears were used every hour for the first day and on an as-required basis afterwards for a month. LASIK was performed separately in each eye on different days or sequentially bilateral on the same day—for the latter, only senior LASIK surgeons of senior consultant grade were permitted to perform bilateral surgery only for cases with moderate myopia with spherical equivalence (SE) below -7 diopters (D) in either eye.

In addition, various algorithms were adopted by each surgeon according to the treatments used, e.g. wavefront guided treatment (range, 0.1%–17.8% of total cases per year), aspheric (range, 0.5%–8.3% of total cases per year), and tissue saving treatment (0.2% of total cases in 2007); this was, however, not differentiated in this study to provide an all-inclusive picture of the trend over the 10-year period.

Postoperative Evaluation

All patients underwent postoperative examinations at 1 day, 1 week, 1 month, and 3 months after the initial procedure, which included uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA) using a standard Snellen acuity chart at 6 meters, manifest refraction, slit-lamp biomicroscopy, fundoscopy, and cycloplegic refraction. If the patient defaulted at the 3-month visit (e.g., work commitments), then the last follow-up data were recorded. The mean follow-up time was 68.8±43.4 days (median, 58). Patients' vision was examined and evaluated by independent examiners at each follow-up. Safety index = $\mathrm{BCVA}_{\mathrm{postoperative}}/\mathrm{BCVA}_{\mathrm{preoperative}}$; Efficacy index = $\mathrm{UCVA}_{\mathrm{postoperative}}/\mathrm{BCVA}_{\mathrm{preoperative}}$. All complications were documented.

For visual analysis we excluded all monovision cases, therapeutic treatments (e.g., postpenetrating keratoplasty refractive correction) and retreatments. Retreatments were analyzed separately and outcomes are also presented in this paper.

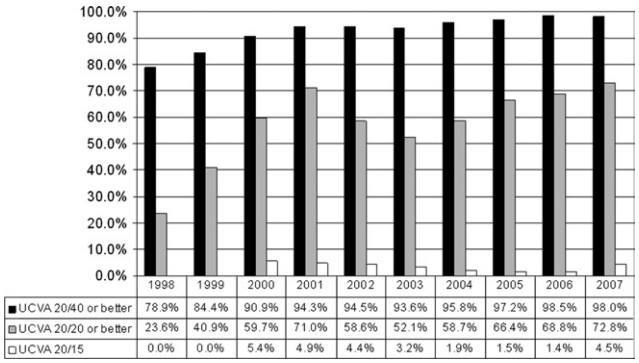
Cases in this study were categorized into low (SE $<$ 5.00 D), moderate (SE ≥ -5.00 D and < -10.00 D), or high myopia (SE > -10.00 D).

Statistical Methods

Statistical analysis was performed by Stata (StataCorp LP, College Station, TX) and Microsoft Excel software (Microsoft, Redmond, WA). Parametric and nonparametric tests were used to compare continuous variables according to data distribution. Student *t*-tests and analysis of variance were used to determine the statistical difference for BCVA and UCVA between the years. $P<0.01$ was considered significant.

Results

Between 1998 and 2007, 37 932 eyes of 19 753 patients underwent myopic LASIK. The median age was 32 years, and mean age was



	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
UCVA 20/40 or better	78.9%	84.4%	90.9%	94.3%	94.5%	93.6%	95.8%	97.2%	98.5%	98.0%
UCVA 20/20 or better	23.6%	40.9%	59.7%	71.0%	58.6%	52.1%	58.7%	66.4%	68.8%	72.8%
UCVA 20/15	0.0%	0.0%	5.4%	4.9%	4.4%	3.2%	1.9%	1.5%	1.4%	4.5%

Figure 1. Overall efficacy of myopic LASIK from 1998 to 2007: percentage of eyes achieving uncorrected visual acuity (UCVA) of ≥20/40, ≥20/20, and 20/15.

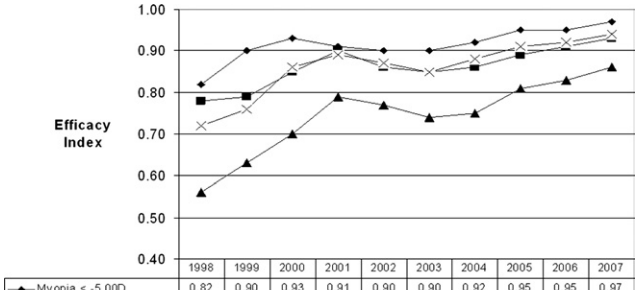
33.0±7.9 years; there were 6832 males (34.6%) and 12 921 females. Patients were mostly Asian, and predominantly ethnic Chinese (90.5%). Table 1 shows the annual breakdown of ethnicity, gender, and age of patients who underwent myopic LASIK from 1998 to 2007. The mean spherical error corrected was −5.90±2.57 D (median, −5.625 D).

Efficacy

The overall UCVA for Snellen visual acuity of ≥20/40 postoperatively has been consistently above 90% since 2000, with a positive trend achieving 98.0% in 2007. The UCVA for Snellen visual acuity of ≥20/20 postoperatively improved for 5 consecutive years to 72.8% in 2007. In 2007, 4.5% achieved 20/15, which was the highest for the preceding 5 years (Fig 1). The absolute number of eyes achieving 20/15 postoperatively was also highest in 2007. The overall efficacy indices have been consistently higher than 0.85 since 2000, improving to 0.94 in 2007 (Fig 2). An upward trend in efficacy indices over all 3 grades of myopia can also be observed.

Safety

There was an improvement in overall safety postoperatively with the best safety index in 2007 for the categories: loss of 1 and 2 Snellen lines of BCVA (Fig 3). The safety indices over time have been consistent, overall ranging between 1.00 and 1.04 (Fig 4). Figure 5 shows the percentage of eyes with BCVA Snellen lines lost or gained postoperatively.



	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Myopia < -5.00D	0.82	0.90	0.93	0.91	0.90	0.90	0.92	0.95	0.95	0.97
Myopia ≥ -5.00D & <-10D	0.78	0.79	0.85	0.90	0.86	0.85	0.86	0.89	0.91	0.93
Myopia ≥ -10D	0.56	0.63	0.70	0.79	0.77	0.74	0.75	0.81	0.83	0.86
Overall	0.72	0.76	0.86	0.89	0.87	0.85	0.88	0.91	0.92	0.94

Figure 2. Efficacy indices of LASIK treatment for the 3 myopic categories in diopters (D) and overall efficacy index from 1998 to 2007.

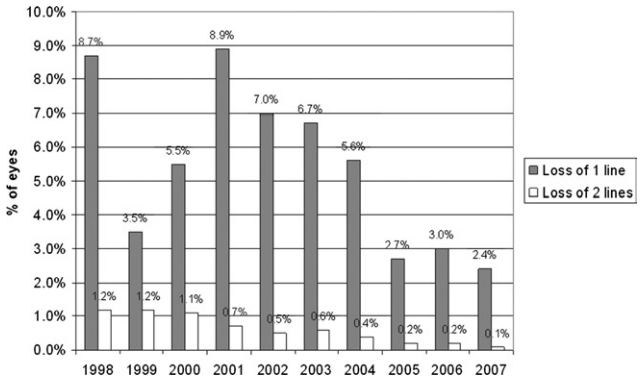


Figure 3. Overall safety of myopic LASIK: percentage of eyes with loss of 1 line and 2 lines of best spectacle-corrected visual acuity.

Predictability

The overall refractive predictability postoperatively ranged from between 78.2% and 96.7% in the last 10 years, with the last 4 years consistently above 93.0% within ±1.0 D from target (Fig 6). The overall values over 10 years ranged from between 56.4% to 83.0% for ±0.50 D from the target; the last 7 years being consistently >70% (Fig 6). As expected, a lower refractive predictability was observed with increased degrees of myopia treated.

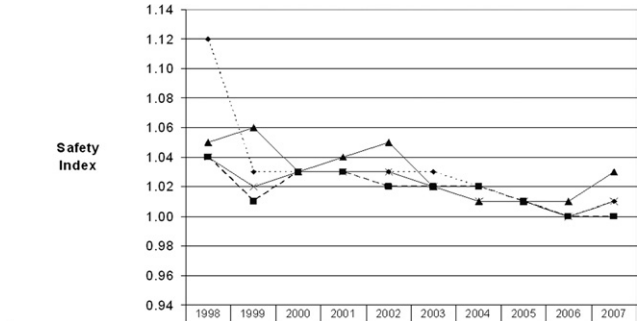
Treatment and Outcome Trends

In the initial 2 years of its inception, LASIK was reserved for treating eyes with a SE of −6.0 D or worse, whereas PRK was reserved for lower SE to avoid postoperative haze (Fig 7). As LASIK became more popular and proven safe for lower myopia, lower SE were eventually treated. There was also a trend where 3 months' postoperative outcomes tended toward mild hyperopia (Fig 8).

Year-on-year improvements for BCVA and UCVA were significant between 1998 and 2001. Overall there has been an improvement in BCVA and UCVA; however, in some years this was not significant. The BCVA has reached a consistent 20/20 vision since 2005. The UCVA has also reached a plateau since 2003, achieving an equivalent of $20/20^{-2}$ vision (Table 2).

Retreatment Rates

Overall there has been a 2.2%–6.2% retreatment rate, ranging between a 0% and 0.5% retreatment rate in the moderate to high



	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Myopia < -5.00D	1.12	1.03	1.03	1.03	1.03	1.03	1.02	1.01	1.00	1.01
Myopia ≥ -5.00D & <-10D	1.04	1.01	1.03	1.03	1.02	1.02	1.02	1.01	1.00	1.00
Myopia ≥ -10D	1.05	1.06	1.03	1.04	1.05	1.02	1.01	1.01	1.01	1.03
Overall	1.04	1.02	1.03	1.03	1.03	1.02	1.01	1.01	1.00	1.01

Figure 4. Safety index of myopic LASIK for the 3 myopic categories in diopters (D). (Note that safety index on the *y*-axis starts from 0.94 for clarification and to reduce crowding of the trend lines).

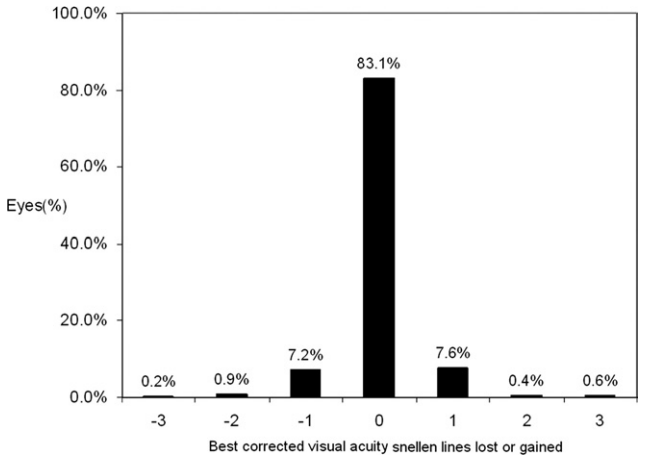


Figure 5. Safety of myopic LASIK: percentage of eyes with best-corrected visual acuity Snellen lines lost or gained postoperatively.

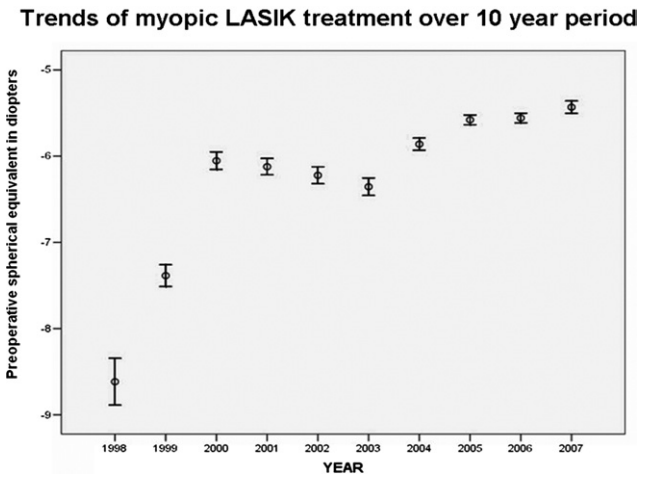


Figure 7. Preoperative trends: higher myopic manifest refractive spherical equivalent in diopters treated in the initial 2 years associated with treatment policies with LASIK, with gradually lesser myopia treated in the more recent 5 years.

myopic group over the last 7 years. Most retreatments were done in the first 3 years of the study (1998–2000) in the low myopic group. After retreatment, 91.6% of eyes achieved a UCVA of ≥20/30 and 59.6% achieved ≥20/20 (Fig 9). Table 3 shows the preoperative SE, attempted SE, and postoperative outcomes for eyes that underwent retreatment.

Complications

Intraoperative problems were divided into flap complications (incomplete, dislodged, eccentric, button hole), decentered ablation zones, and loose epithelium. These accounted for between 0.3% and 0.7% of total complications annually over the 10 years.

Postoperative complications include flap striae, epithelial ingrowth, infection, diffuse lamellar keratitis (DLK), and debris at the interface (Table 4). There were only 3 confirmed cases of infection throughout the 10-year period (0.008%). The complication rate in 2007 was higher owing to DLK. This was identified as an outbreak secondary to use of a gentian violet ink marker pen (Codman Marker; Johnson & Johnson, New Brunswick, NJ),

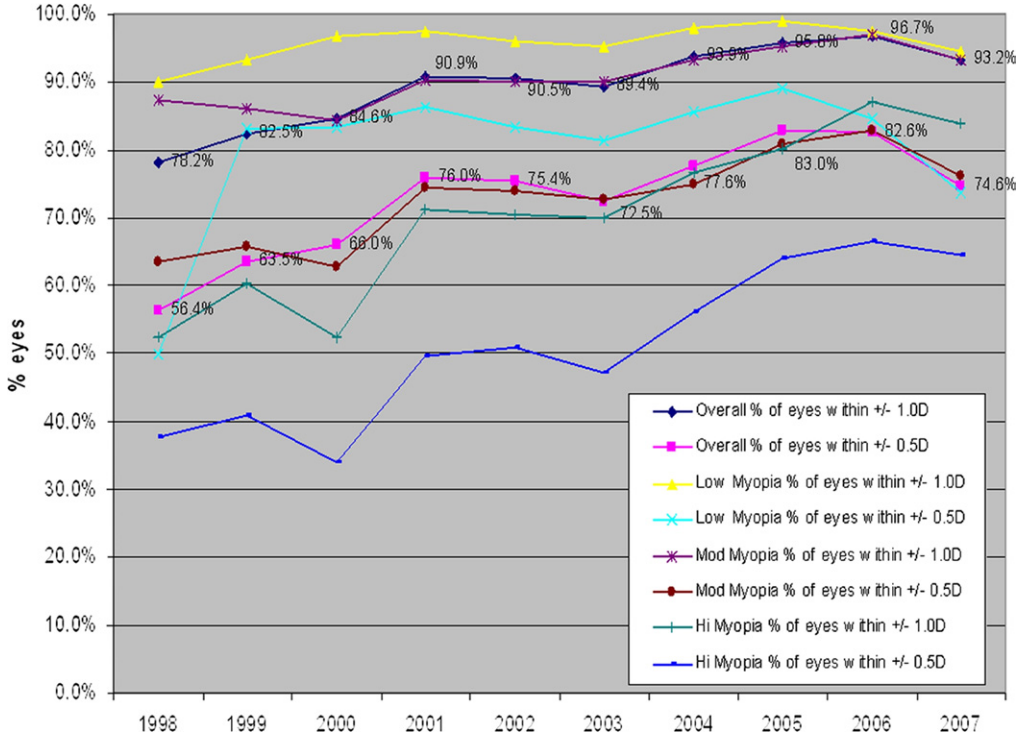


Figure 6. Refractive predictability of myopic LASIK: percentage of eyes within ±0.5 and ±1.0 diopters (D) of target postoperative in low, moderate, and high myopia groups according to spherical equivalence (less than −5.00 D, −5.00 to less than −10.0 D, and −10.00 D or greater, respectively). Hi = high; Mod = moderate.

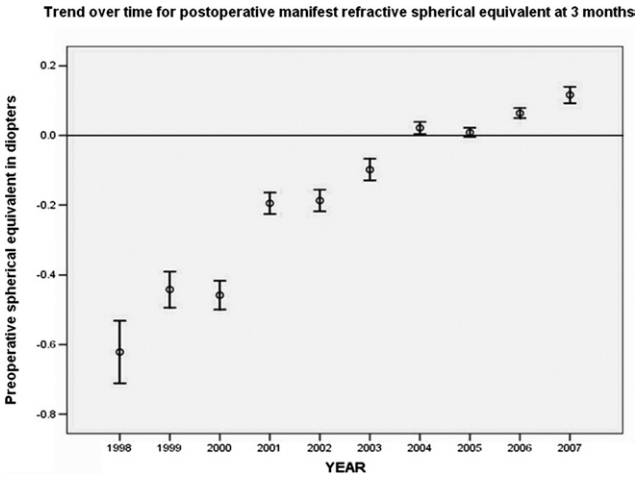


Figure 8. Postoperative trends: manifest refractive spherical equivalent at 3 months showing a tendency toward a target of mild hyperopia.

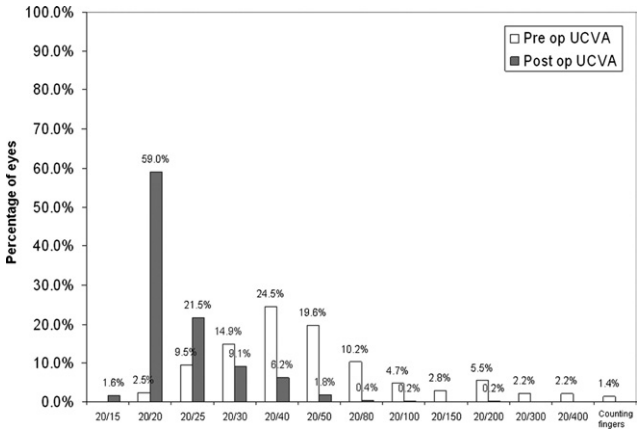


Figure 9. Retreatment outcomes: uncorrected visual acuity (UCVA) before retreatment and at 3 months postoperatively showing a high percentage achieving ≥20/25. PreOp = preoperative; PostOp = postoperative.

which was promptly identified, controlled, and treated.[7] The complication rate without DLK was 1.19%, which is consistent with previous years. Table 4 shows a breakdown of complications over the years into intraoperative and postoperative categories. It is also worth noting that over the 10-year period, there were only 8 known cases (0.02%) of post-LASIK ectasia that presented at varying time points after surgery.

Discussion

This study represents a comprehensive, long-term, prospective audit of a large cohort of LASIK surgeries performed for myopia in an Asian population, and to our knowledge is the largest series of its kind to be reported. It enables validation of the true efficacy, safety, and predictability of LASIK surgery when performed in a single, high-volume, clinical institution.

Efficacy results from this study are comparable to those conducted by the FDA[4,6] and other large studies for myopic LASIK[5,8–10] with 97% achieving postoperative UCVA of ≥20/40, and 62% of eyes achieving 20/20 UCVA. Results from SNEC showed similar outcomes in 2007 with 98% achieving UCVA of ≥20/40 and 72.8% of ≥20/20. Over the 10-year period at SNEC, the mean UCVA achieved was 92.6% for ≥20/40 and 57.3% for ≥20/20, with lower percentages observed from the first 3 years (1998–2000). This is attributed to an initial learning curve as well as improvements in the lasers and ablation nomograms which resulted in better results in the latter years.

In the low myopia category (defined as less than −6.0 D), eyes treated with conventional LASIK in FDA clinical trials reported that 67%–86% of eyes achieved UCVA of ≥20/20 and 93%–100% achieved ≥20/40. Although our cutoff was not identical (low myopia group defined as less than −5.0 D), similar results were attained, 82.6% achieved UCVA of ≥20/20 and 99.4% achieved ≥20/40 in 2007. Over the 10-year period, the mean achieved UCVA was 68.1% for ≥20/20 and 98.0% for ≥20/40; again, the lower percentages tended to be in the first 3 years (1998–2000).

In the moderate myopia group (defined as –6.0 to –12.0 D), results from large, published series[11,12] and FDA trials report that 26%–71% of eyes achieved an UCVA of ≥20/20. At SNEC, again although our cutoffs are not identical (moderate myopia defined as SE between −5.0 and less than −10.0 D), similar results were attained, with 68.9% achieving an UCVA of ≥20/20 and 97.9% achieving ≥20/40 for 2007. Overall, the mean was 55.7% who

Table 2. Postoperative Logarithm of Minimal Angle of Resolution (logMAR) Best-Corrected Visual Acuity (BCVA) and Uncorrected Visual Acuity Comparing Year-on-Year Performance

Year	Mean logMAR BCVA	Mean Difference (year on year)	*P*	Mean logMAR Uncorrected Visual Acuity	Mean Difference (year on year)	*P*
1998	0.0212	—	—	0.2232	—	—
1999	0.0089	0.0123	0.002	0.1685	0.0547	<0.001
2000	−0.0106	0.0195	<0.001	0.0987	0.0698	<0.001
2001	−0.0183	0.0077	<0.001	0.0633	0.0354	<0.001
2002	−0.0132	−0.0051	0.02	0.0804	−0.0171	0.005
2003	−0.0052	−0.008	<0.001	0.0752	0.0052	>0.05
2004	−0.0037	−0.0015	>0.05	0.0579	0.0173	<0.001
2005	0.0009	−0.0046	<0.001	0.0498	0.0081	>0.05
2006	0.0012	−0.0003	>0.05	0.0412	0.0086	>0.05
2007	0.0009	0.0003	>0.05	0.0691	−0.0279	>0.05
Mean	−0.0018	0.0023		0.0927	0.0171	

Table 3. Preoperative Manifest Refractive Spherical Equivalent in Diopters and Retreatment Trends between 1998 and 2007

Year	Pre-retreatment Manifest Refractive Spherical Equivalent	Retreatment Attempted (D)	3 Months Postretreatment (D)	No. of Eyes (% of total)
1998	−2.41±1.37	−2.64±0.88	−0.73±0.60	10 (2.2)
1999	−1.78±0.79	−1.84±0.71	−0.41±0.60	90 (5.3)
2000	−1.66±0.88	−1.80±0.76	−0.37±0.51	161 (6.2)
2001	−1.53±1.00	−1.59±0.60	−0.11±0.43	133 (4.6)
2002	−1.52±1.00	−1.61±0.87	−0.34±0.60	102 (3.3)
2003	−1.08±0.63	−1.41±0.59	−0.01±0.40	151 (5.0)
2004	−1.00±0.95	−1.27±0.86	0.06±0.43	154 (3.0)
2005	−1.06±0.75	−1.43±0.74	0.09±0.51	214 (3.0)
2006	−0.90±0.69	−1.24±0.71	0.11±0.41	171 (2.3)
2007	−0.97±0.85	−1.38±0.91	0.19±0.45	153 (3.4)

D = diopters.

achieved UCVA ≥20/20 and 93.7% achieved ≥20/40. Percentages were again lower in the first 3 years (1998–2000).

In the highest myopia group (defined as −10.0 D or higher), the results were predictably less favorable in efficacy, safety, and refractive predictability. This may be attributed to increased central corneal ablation compared with midperipheral cornea,[4] higher variability relating to wound healing and myopic regression with greater ablation, and nomogram adjustment with surgeons electing to undercorrect, especially when faced with limits imposed by corneal thickness. In 2007, 49.1% achieved an UCVA of ≥20/20, with 90.3% achieving ≥20/40. Over the 10-year period, the mean was 30.1% for ≥20/20, with 79.2% achieving ≥20/40; the percentages improving steadily over the last 5 years.

The overall efficacy index at SNEC was 0.86, comparable with 0.88 in a large, long-term study.[13] Our efficacy index was consistently >0.90 in the last 3 years. Improvements in the nomograms and lasers to prevent undercorrection and to compensate for myopic regression have led to better efficacy after LASIK with time. Of note is that the mean spherical error corrected at SNEC was −5.90±2.57 D (median, −5.625; range, −5.43 to −8.74; Table 5), which is slightly higher than the FDA studies[14] and that may underestimate our efficacy indices.

Table 5. Preoperative Manifest Refractive Spherical Equivalent and Treatment Trends for Myopic LASIK

Year	Preoperative Manifest Refractive Spherical Equivalent (D)	Treatment Attempted (D)	3 Months Postoperatively (D)
1998	−8.74±2.61	−8.71±2.42	−0.72±1.00
1999	−7.39±2.56	−7.44±2.40	−0.44±0.92
2000	−6.05±2.54	−7.30±2.35	−0.46±0.88
2001	−6.12±2.54	−6.18±2.35	−0.20±0.72
2002	−6.22±2.72	−6.07±2.42	−0.19±0.73
2003	−6.35±2.77	−6.37±2.55	−0.10±0.68
2004	−5.86±2.57	−5.95±2.35	0.02±0.58
2005	−5.58±2.39	−5.83±2.24	0.01±0.49
2006	−5.54±2.39	−5.87±2.27	0.08±0.48
2007	−5.43±2.42	−5.90±2.35	0.12±0.64

D = diopters.

There was a low rate of loss of BCVA in the FDA trials (from 1993 to 2002), with a range of 0% and 4.5% of eyes losing ≥2 lines of BCVA.[4,7] At SNEC, the mean percentage losing ≥2 lines of BCVA was 0.6% (10-year range, 0.1%–1.2%), which is comparable with postmillennium FDA trials of 0.61%.[15] The poorer outcomes at SNEC were observed in the earlier years (1998–2000) during the initial learning period. The safety index ranged from 1.00 to 1.04 over 10 years, which is comparable with the safety index of 1.08 in a large, long-term study.[13]

In terms of refractive predictability, data from FDA trials showed that 72% of eyes resulted in a refractive error of ±0.50 D of the intended correction and 90% of eyes within

Table 4. Breakdown of Intra- and Postoperative Complications

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Intraoperative										
Incomplete flap	2	1	6	2	2	2	6	12	12	12
Dislodged flap	—	5	3	7	13	6	9	13	9	7
Eccentric flap	1	3	2	1	—	—	1	—	—	1
Decentered ablation zone	1	—	1	—	—	—	1	1	—	—
Loose epithelium	—	—	1	5	7	1		2	1	—
Button hole	—	—	2	—	—	3	2	—	—	1
Postoperative										
Significant flap striae	2	1	3	—	5	4	25	32	39	24
Epithelial ingrowth	2	3	12	4	1	2	8	8	18	2
Infective keratitis	—	—	—	—	1	—	—	1	1	—
Diffuse lamellar keratitis	—	—	2	2	1	2	2	3	2	76*
Debris at interface	—	—	—	—	—	—	—	6	3	6
Others	—	—	1	1	2	—	—	1	1	1
Total complication cases	8	13	33	22	32	20	54	79	86	130
Total LASIK cases	446	1692	2582	2906	3081	3028	5214	7139	7310	4534
Overall complication rate (%)	1.79	0.77	1.28	0.76	1.01	0.66	1.04	1.11	1.16	2.8*

*Without deep lamellar keratitis, the overall complication rate in 2007 is 1.19%.

±1.00 D of the target.[4,7] Over the 10-year period, the average was 72.8% achieving ±0.50 D of target, and 89.6% achieving ±1.0 D of target; the lower percentages tended to be in the first 3 years. In 2007, 74.6% achieved ±0.50 D of target and 93.2% achieved ±1.0 D of target in 2007.

In the low myopia group, other studies reported a manifest refraction SE within ±1.0 D target in 94%–100% of eyes in the early postoperative period.[4] At SNEC over a period of 10 years, 95.8% achieved within ±1.0 D target. In 2005, 99.0% achieved within ±1.0 D target. There was a lower attainment of refractive predictability in the higher myopic treatment group.

The postoperative manifest refraction SE in the latter years tended to be slightly hyperopic, and may have accounted for the increased incidence of UCVA of 20/15 Snellen acuity postoperatively over the last 3 years, particularly in 2007. This may have been due to improvements in the nomograms to prevent undercorrection and to compensate for myopic regression, especially for moderate myopes that constituted the greatest portion of the eyes. This was preferred by most surgeons especially for treating young patients and low myopic corrections.

The main reasons for retreatment were patient dissatisfaction with the visual result, UCVA of ≤20/30, or a manifest SE of −0.75 D or more. The overall retreatment rate was 3.8%, which is significantly lower than similar reports of laser refractive surgery for moderate myopia,[16–21] which found a retreatment rate of 20%–30% after LASIK or PRK. The majority of retreatments were performed in the mild myopia group in the first 3 years of this study, ranging from 16.8% to 43.8%; however, subsequent years dropped to 5.9% from 13.8% in this group. Watson et al[15] explained that their low retreatment rate (4.9%) was because of higher refractive errors being treated. Interestingly, in our study, the moderate to high myopic group had minimal retreatments in the last 7 years (0%–0.5%). Alio et al[13] reported a significant correlation between myopic regression and the achieved correction, implying that myopic regression increases with higher corrections. We, however, did not find a symptomatic increase in myopic regression to warrant a higher retreatment rate in the high myopic group. The lower retreatment rates in high myopes may be limited by the lack of residual stroma; however, these data were not captured and we are unable to confirm this. Another reason for lower retreatment rates in higher myopes is that they may be generally satisfied with a large improvement in their refractive errors and functional vision. Figure 7 shows the pre- and post-retreatment UCVA, with 91% achieving ≥20/30 and 2% achieving 20/15. Three months postoperative outcomes suggest that LASIK retreatments are safe and effective.

In 2007, there was an increased incidence of DLK due to an outbreak, the etiology identified as surgical marker pens.[7] The median time follow-up after treatment for this subgroup was 29 days (range, 2–55). After treatment using steroid drops, irrigation, or both, 58.1% achieved an UCVA of ≥20/20 and 92.1% achieved ≥20/40 Snellen acuity. For BCVA, 82.3% achieved ≥20/2 and 98.4% achieved ≥20/40. All patients had a mean of 1 month follow-up. At the time of writing, there have only been 3 cases of DLK in 2008.

There were 7 complications recorded as "others," which included machine and technician-dependent complications. There were 3 confirmed cases (0.008%) of infectious keratitis, which warranted flap lift and antibiotic washout, all of which generally recovered with good BCVA without resorting to corneal transplantation. Select cases included a complicated femtosecond laser created flap that was difficult to lift; the hinge tore off on manipulation. Subsequently, a bandage contact lens was inserted and the procedure was repeated successfully at a later date. This was the only complication using the femtosecond laser for flap creation. There was 1 case of programming error where the contralateral eye's refraction was input for treatment. This was explained to the patient and no further treatment was warranted. One case stopped prematurely when the excimer machine stopped at 70% ablation without any known cause.

Over the 10-year period, there were only 8 confirmed cases (0.02%) of post-LASIK ectasia. All cases were done between 2000 and 2002 using a microkeratome, with a flap thickness of 160 or 180 microns. Preoperative Orbscans did not show signs of forme fruste keratoconus in these eyes, and a residual stromal bed of 250 microns rule was adhered to in all these cases. One patient developed bilateral keratectasia 2 years after myopic LASIK despite a deliberate undercorrection (to ensure a 250-micron residual stromal bed). Another patient developed ectasia 2 years after enhancement surgery (again respecting the 250-micron rule) and subsequently underwent successfully an automated lamellar therapeutic keratoplasty procedure.

Randleman et al[22] estimate the incidence to be approximately 1 in 2500 cases (0.04%). A possible reason for the low rate of keratectasia despite our higher myopic corrections (SE between −5.43 and −8.74 D), is our careful observation of topography to exclude forme fruste keratoconus as well as adhering to a strict, 250-micron residual stromal bed rule.[22] However, we recognize that there may have been patients who developed later onset keratectasia who did not return to us for identification. Anecdotally, there may be a higher corneal rigidity in Chinese eyes, hence the seemingly lower prevalence of keratoconus in this population.[23,24]

One of the limitations with this study include a short follow-up time; therefore, we are unable to conclude on refractive stability. However, long-term studies have shown that treatment effects for laser refractive surgery generally stabilize after 3 months,[13] the mean corneal power slightly increasing (0.44 D) and topographic cylinder slightly decreasing (0.15 D) between 3 months and 10 years. This was evident and supported by corneal topography.[15] The same authors also reported minimal regression from 3 months to 10 years (−1.04±1.73 D, equating to −0.10±0.18 D per year), which was not significant in the retreatment versus retreatment group, supporting that 3 months' follow-up time may provide a fair estimation of the final visual outcome at 10 years. Liu et al[16] also showed a postoperative mean manifest refraction SE of 0.29 D at 1 year and 0.24 D at 7 years, showing no significance. Six-month and 1-year follow-up after PRK and LASEK provided similar out-

comes in visual outcome and refraction.[23,24] Furthermore, it can be anticipated that a longer follow-up may include physiologic development of cataract and macular disease, or the development of other ocular disease, which may not be related to LASIK and would affect visual outcomes and results. Three months' follow-up may therefore provide a practical time frame for evaluating outcomes while capturing a complete sample size.

We compared our outcomes with other large, well-controlled, international studies and found that our results were comparable, or even slightly better. Smaller studies on safety, predictability, and efficacy may have better outcomes; however, it is still worth noting that these trials were carried out independently at each center and that there are protocol differences that could affect surgical outcomes.[6] For example, there were differences in flap creation technique, excimer laser platforms used, the amount of preoperative myopia that was treated (myopic categorical definitions, for instance, were different), and postoperative management. We have thus compared myopic category as closely as possible, and plan to make the reader aware of the ranges of outcomes from these studies when possible.

In summary, this large-scale study provides evidence to suggest that visual acuity and the refractive predictability outcomes appear to have improved over the 10-year period of assessment, and this may be attributed to experience, better laser technologies, and nomogram adjustments. Our data suggest that LASIK is safe and effective, and anticipated to remain as the mainstay of laser refractive surgery, even as phakic intraocular lenses and surface ablation techniques assume a larger share of refractive surgery.[5] Our center's 100% clinical audit of all LASIK surgery has and will continue to provide valuable data that will complement other studies evaluating quality of life, satisfaction surveys, and other studies evaluating adverse symptoms such as dryness and night vision complaints that are currently being evaluated by the FDA. This study serves as a useful assessment of the evolution of LASIK treatment within 1 center over a decade's experience, and provides encouraging reassurance that our LASIK outcomes remain highly satisfactory and may continue to improve with advances in laser refractive technologies. Furthermore, it acts as a baseline to compare data for annual auditing, as well as for prospective laser refractive surgery studies, especially in East Asian eyes within the Chinese diaspora (China, Korea, Japan, Southeast Asia) in which the prevalence of myopia is significantly higher than other ethnic groups. Myopic LASIK eye surgery stands out in that technological advances have occurred at a rapid pace and that safety and efficacy outcomes are anticipated to continually improve.

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