

# Eighteen-year prospective audit of LASIK outcomes for myopia in 53 731 eyes

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## ABSTRACT

**Background** To assess the outcomes of laser-assisted in situ keratomileusis (LASIK) performed for the treatment of myopia in terms of safety, efficacy and predictability in an 18-year clinical audit.

**Method** In this single-centre, prospective, non-randomised study, preoperative and postoperative refractions, uncorrected (UCVA), best-corrected Snellen visual acuity (BCVA) and complications of all eyes undergoing myopic LASIK were recorded. Safety, efficacy, refractive predictability, treatment trends, retreatment rates and complication rates were evaluated.

**Results** Between 1998 and 2015, 53 731 eyes of 27312 patients underwent myopic LASIK. Patients' median age was 31.6 years (mean, 32.6±7.3 years); there were 9703 males (35.5%). Patients were predominantly ethnic Chinese (87.4%). Mean follow-up time was 78±75.6 days (median, 86 days). Overall efficacy index was 0.91 with >99% of eyes achieving UCVA of ≥20/40 and >70% achieving 20/20 since 2010. 95.43% of eyes had no loss of vision postoperatively and 4.2% and 0.37% lost 1 and ≥2 lines BCVA, respectively. From 2010 the safety index has been >1.05. More than 94.0% of eyes achieved within ±1.0 D of target refraction and at least 70% achieved within ±0.50 D of target from 2010 onwards. Retreatment rate was 2.55% and after retreatment 98.4% of eyes achieved ≥20/40 UCVA and 63.5% achieved ≥20/20 UCVA. The overall complication rate is 0.98%, and since 2010, the annual complication rate has been <0.8%.

**Conclusions** Myopic LASIK performed in Asian eyes is safe and effective with high refractive predictability in a comprehensive LASIK programme with appropriate clinical audit.

and predictable flaps with less intraoperative flap complications.<sup>5–8</sup>

At the Singapore National Eye Centre (SNEC), all LASIK outcomes are audited since 1998 and a previous analysis of this data shows that LASIK is safe and efficacious and has high predictability and low complication rates.<sup>4</sup> Since then changes to the equipment and practice of LASIK in SNEC have occurred. These include the use of newer patient screening modalities, improved excimer lasers, updated laser algorithms and the use of FS lasers for flap creation. In this paper, we examine the overall trends and outcomes of myopic LASIK over an 18-year period in a single public institution.

## METHODS

General criteria for consideration of LASIK, which may vary in specifics from criteria used in other refractive practices, included age 21 years or older; stable refractive error for ≥12 months before surgery; normal ocular surface; absence of corneal abnormalities suggestive of keratoconus or other corneal ectatic diseases; normal peripheral retina or after prophylactic photocoagulation; absence of active ocular pathology or systemic disease; and absence of pregnancy or lactation. During the study period, any abnormal corneal topography findings that are risk factors for corneal ectatic disorders and ectasia after LASIK were excluded (central corneal thickness <480 µm, expected residual stromal bed <250 µm after LASIK, asymmetrical topography between eyes, asymmetric inferior corneal steepening or asymmetric bowtie topographic patterns with skewed steep radial axes above and below the horizontal meridian). We also assessed patients using ectasia risk indices such as the Pentacam Belin-Ambrósio deviation index (BAD-D) since June 2013 and the Orbscan Screening Corneal Objective Risk of Ectasia (SCORE) Analyzer since January 2014. Patients with clinically abnormal ocular surface and dry eye symptoms were first put on a trial of dry eye treatment. Non-response to treatment or those with severe dry eye symptoms, persistent corneal staining or decreased vision due to ocular surface disease were excluded.

We excluded from analysis therapeutic treatments (such as post-penetrating keratoplasty refractive correction), intended undercorrection for monovision and other modalities of myopic refractive surgery such as photorefractive keratectomy.

## INTRODUCTION

Laser-assisted in situ keratomileusis (LASIK) is the most commonly performed procedure for refractive correction, with >16 million LASIK procedures performed globally since being introduced in 1990.<sup>1</sup> The popularity of the procedure is due to its excellent efficacy, safety, stability and predictability in treating both myopia and hyperopia, with or without astigmatism and high patient satisfaction.<sup>2–4</sup> Over time, outcomes have improved with technological advancements.<sup>3,5</sup> Most notably, creation of the corneal flap has shifted from using the mechanical microkeratome (MK) to the femtosecond (FS) laser driven by the numerous advantages of FS laser flap creation over the MK, including the ability to create thinner yet more uniform, accurate



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### Surgical technique

This has been previously described.<sup>4</sup> The flaps were created using a microkeratome (B&L Hansatome or XP Microkeratome (Bausch & Lomb Surgical, Rochester, New York, USA)) or a FS laser (Intralase (Abbott Medical Optics, Santa Ana, California, USA), Visumax (Carl Zeiss Meditec, Jena, Germany) or the FEMTO LDV (Ziemer Ophthalmic Systems, Port, Switzerland)). Excimer laser ablation was performed using one of the following excimer laser systems: Chiron Technolas 117C, Technolas 217C, Technolas 217Z, Technolas 217Z 100 (Bausch & Lomb Surgical, Irvine, California, USA), LADARVision 4000 (Alcon, Fort Worth, Texas, USA), WaveLight Allegretto Wave Eye-Q 400 Hz or WaveLightEX500 (WaveLight, Alcon).

The various algorithms adopted by each surgeon such as wave-front-guided treatment, aspheric and tissue saving treatment were not differentiated in this study to provide an all-inclusive picture of the trends over the 18-year period.

### Postoperative evaluation

All patients underwent postoperative examinations at 1 day, 1 week, 1 month and 3 months. Postoperative evaluations by independent examiners at each visit included uncorrected Snellen visual acuity (UCVA), best-corrected visual acuity (BCVA) and slit-lamp biomicroscopy. Cases were categorised into low (spherical equivalent (SE) < -5.0 D), moderate (SE  $\geq$  -5.0 D and < -10.0 D) or high myopia (SE  $\geq$  -10.0 D) based on their preoperative refraction. All complications and retreatments were documented. Statistical analyses were performed using R V.3.3.3 (R Core Team; Vienna, Austria).

### RESULTS

Between 1998 and 2015, 53 731 eyes of 27 309 patients underwent myopic LASIK surgery at the SNEC by a total of 37 surgeons. In 2008, 30% of the flaps were created using the FS laser. This proportion increased to 86% in 2009 and to 100% in 2011 and thereafter. The median age was 31.6 years (mean, 32.6 $\pm$ 7.3 years); there were 9706 (35.5%) males and 17 606 (64.5%) females.

Patients were predominantly ethnic Chinese (87.4%). The mean follow-up time was 78 $\pm$ 75.6 days.

### Efficacy

Overall, 97.3% of eyes achieved UCVA of  $\geq$ 20/40 and 68.7% achieved UCVA of  $\geq$ 20/20, with an upward trend from 98.6% achieving UCVA of  $\geq$ 20/40 in 2006 to >99.0% since 2010. Similarly the percentage of eyes achieving  $\geq$ 20/20 also increased from 67.9% to >78.1%. In 2015, 80.1% achieved  $\geq$ 20/20 vision and 99.7% achieved UCVA  $\geq$ 20/40 (figure 1). Eyes in the low myopia group tend to have the highest efficacy with 79.6% achieving UCVA of  $\geq$ 20/20 and 99.2% achieving  $\geq$ 20/40 (figure 2).

### Safety

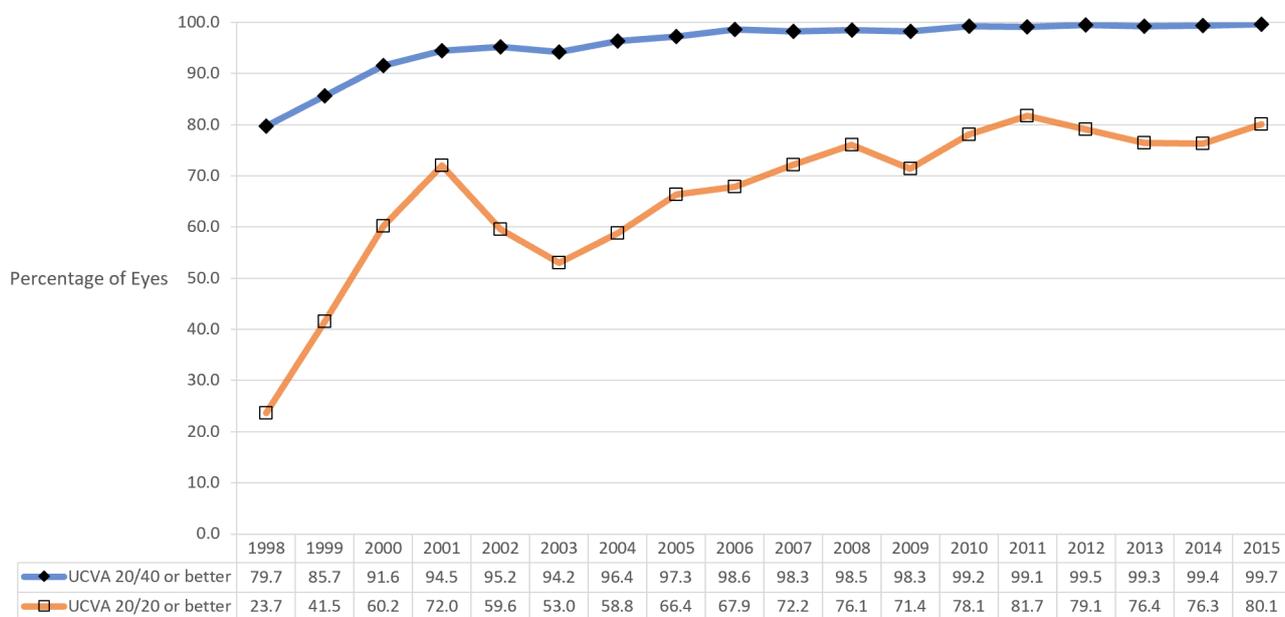
The overall percentage of eyes with no change or a gain in BCVA Snellen lines of vision is 95.43%. Less than 5% had loss of vision with 4.2% losing one line and 0.40% losing two or more lines of BCVA. From 2008, the percentage of patients with loss of two lines of vision was 0.4% or less (figure 3).

### Predictability

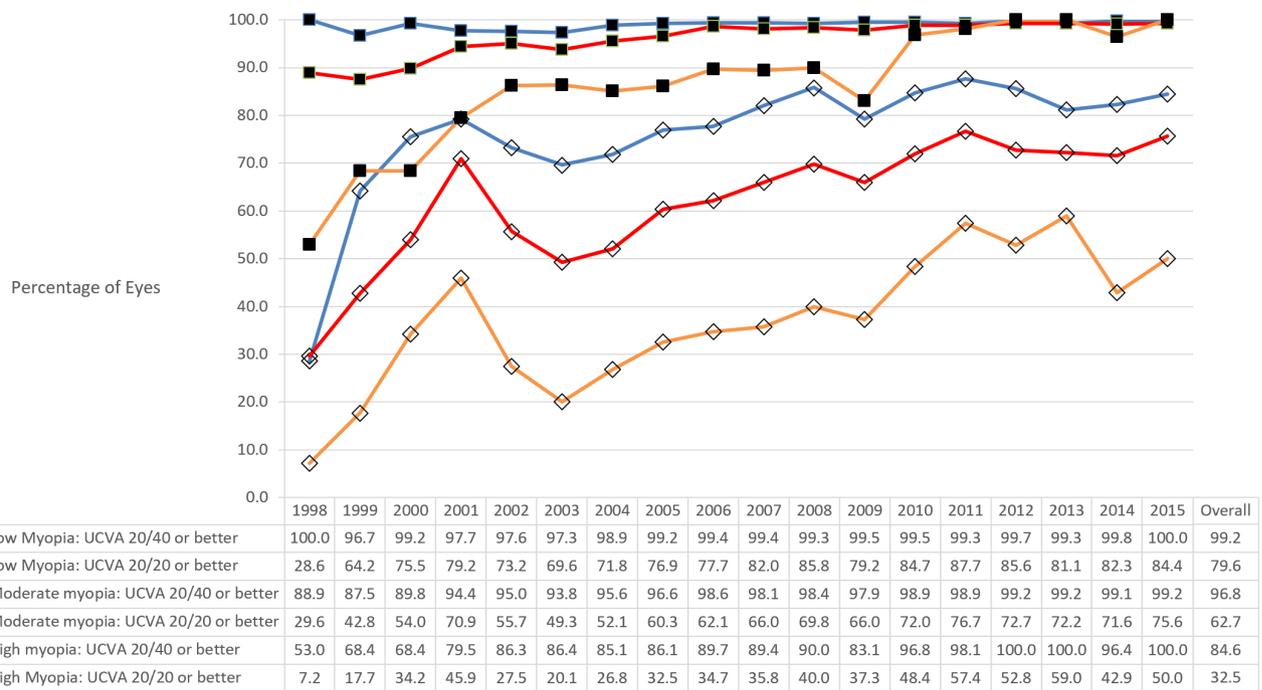
Overall, 90.4% of eyes achieved  $\pm$ 1.0 D of target refraction and 65.6% achieved  $\pm$ 0.50 D of target refraction. The refractive predictability showed an increasing trend with 92.5% in 2009 and 97.6% in 2015 achieving within  $\pm$ 1.0 D from target refraction postoperatively. During the same period, the percentage of eyes achieving within  $\pm$ 0.5 D of target refraction also improved from 67.1% to 74.8% (Figure 4). The low and moderate myopes tend to have better predictability than the high myopes (figure 5).

### Retreatment rates

The overall retreatment rate was 2.55% (1335 of 52 396 eyes) and has progressively decreased from >4% in the early years to <1.2% since 2010 (table 1). After retreatment, 98.4% of eyes achieved  $\geq$ 20/40 UCVA and 63.5% achieved  $\geq$ 20/20 UCVA. The main indications for retreatment were visual results-related dissatisfaction such as UCVA of  $\leq$ 20/30, or a manifest SE of  $\geq$  -0.75 D.



**Figure 1** Graph of overall efficacy of myopic laser-assisted in situ keratomileusis from 1998 to 2015 showing percentage of eyes achieving uncorrected visual acuity (UCVA) of  $\geq$ 20/40 and  $\geq$ 20/20.



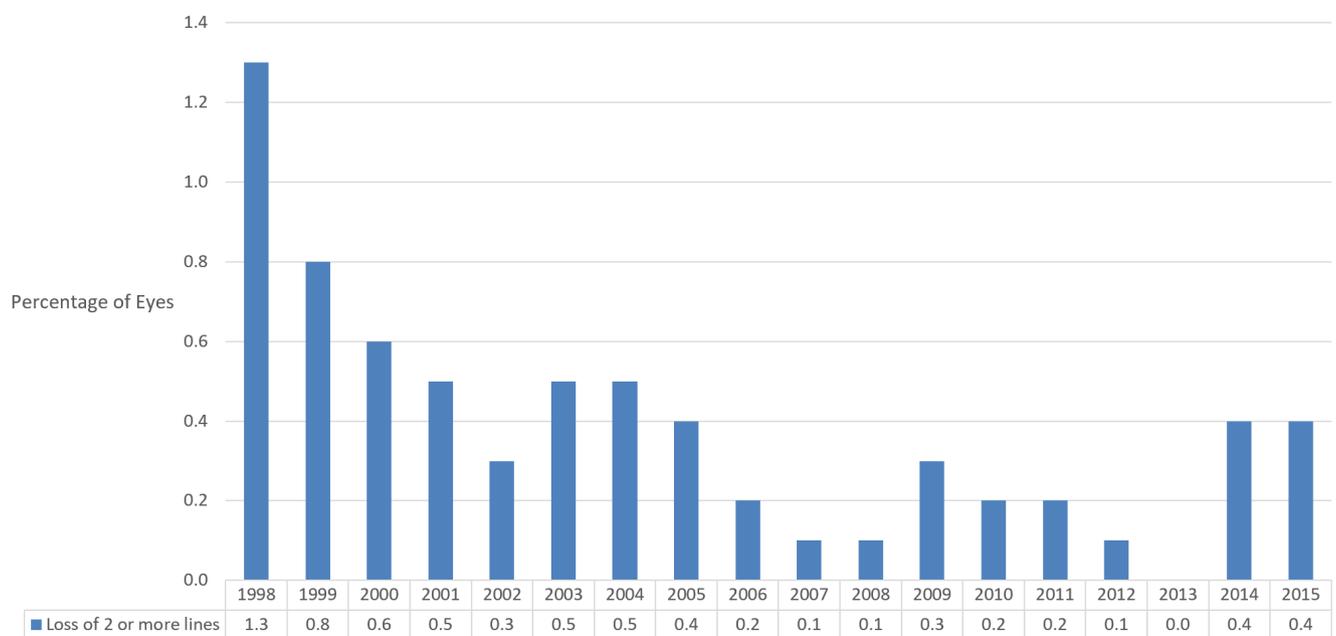
**Figure 2** Graph of efficacy of myopic laser-assisted in situ keratomileusis from 1998 to 2015 showing percentage of eyes achieving uncorrected visual acuity (UCVA) of  $\geq 20/40$  and  $\geq 20/20$  for the three categories of myopia. Low myopia=spherical equivalent (SE)  $< -5.0$  D; moderate myopia =SE  $\geq -5.0$  D and  $< -10.0$  D; high myopia = SE  $\geq -10.0$  D.

When the retreatment cases were stratified according to the preoperative refraction, there was one case each from the moderate and the high myopia category. The remaining retreatment cases were in the low myopia category.

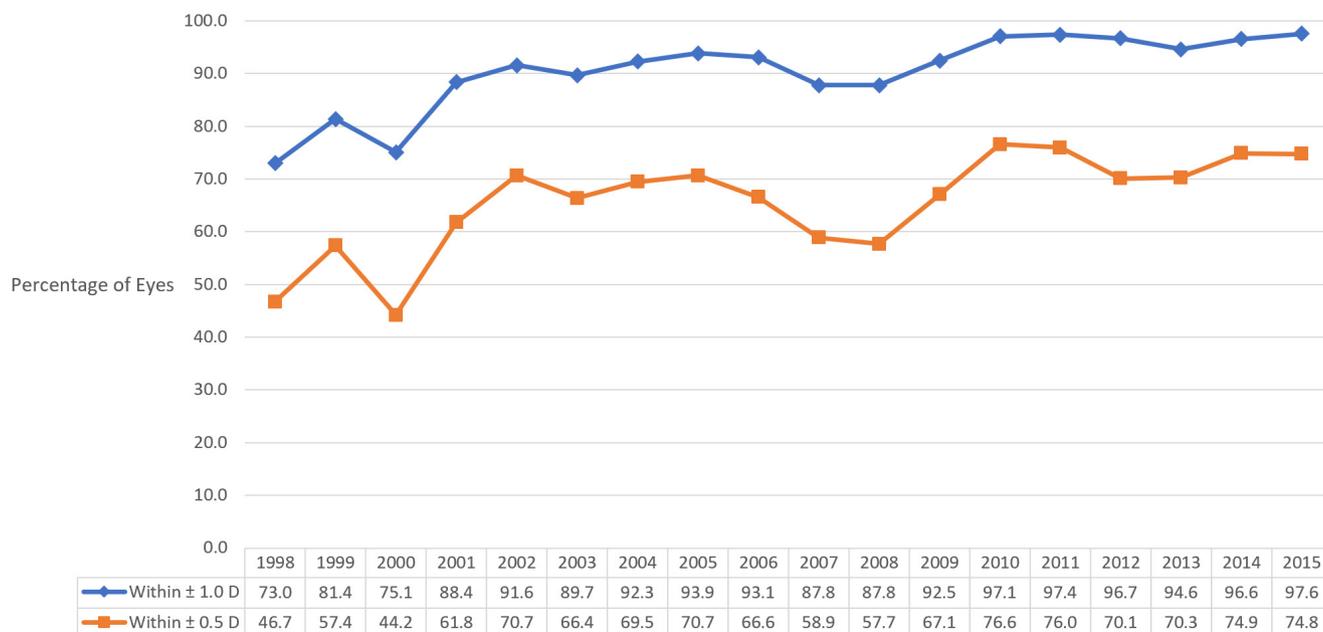
**Complications**

The overall complication rate is 0.98%, and since 2010, the annual complication rate has been  $< 0.8\%$ . In 2007, there was a surge in the number of complications from an epidemic of cases

of surgical markers related diffuse lamellar keratitis (DLK).<sup>9</sup> With the exclusion of these 67 cases of DLK, flap-related complications comprised the majority of complications both intraoperatively (103, 78.6%) and postoperatively (234, 66.9%). All cases of loose epithelium, buttonhole flap and eccentric flaps occurred in MK flaps and all the flap tears occurred in the FS laser flaps. There was only one case of dislodged flaps occurring in the FS LASIK cases (table 2). Other complications included various machine and



**Figure 3** Graph of safety of myopic laser-assisted in situ keratomileusis from 1998 to 2015 showing percentage of eyes losing two or more lines of best-corrected visual acuity.



**Figure 4** Graph of overall refractive predictability of myopic laser-assisted in situ keratomileusis showing percentage of eyes within  $\pm 0.5$  and  $\pm 1.0$  D of target refraction postoperatively.

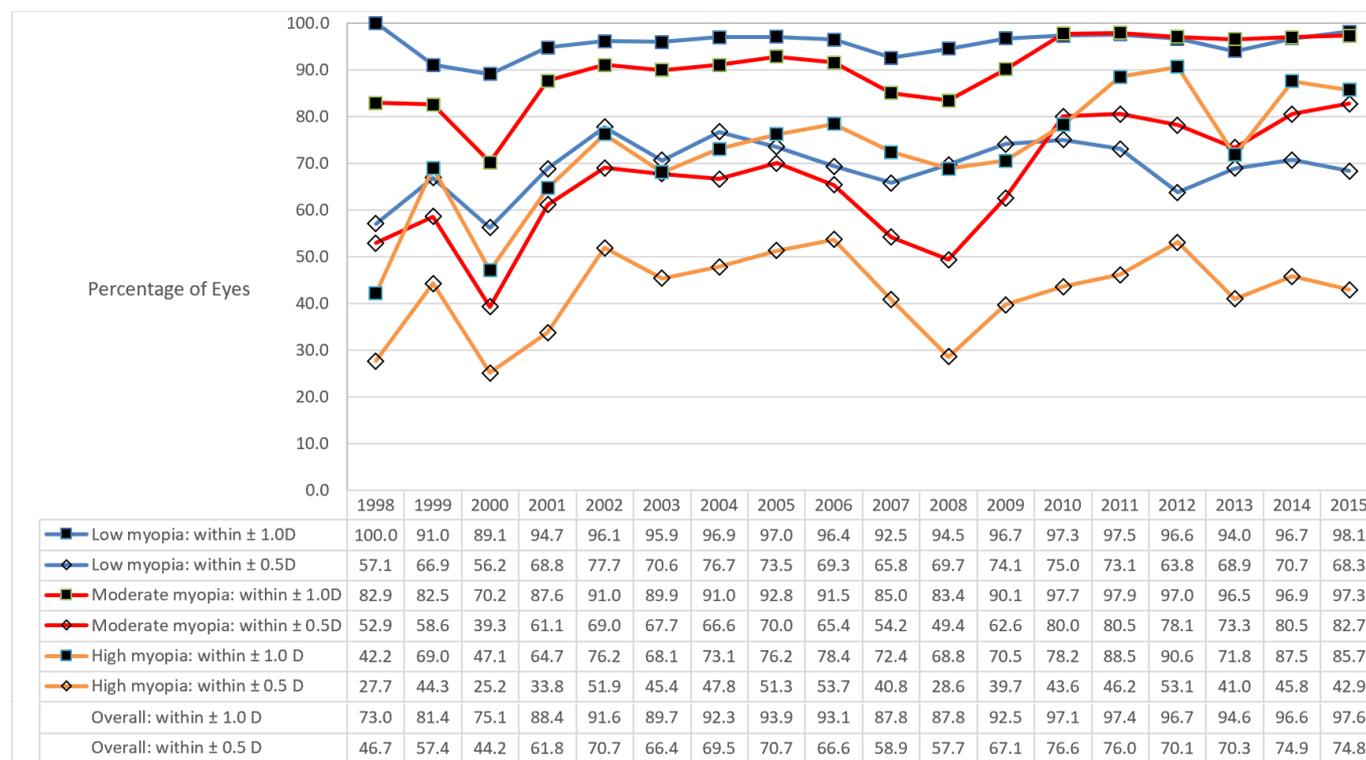
technician-related issues as suction loss. Due to limitations in the data collected, we could not stratify the complications in table 2 according to the preoperative myopia categories.

There were 12 cases of post-LASIK ectasia that presented at varying times points after surgery before 2007. When these cases were stratified according to the preoperative refraction, there was 1 case each from the low and the high myopia category and the

remaining 10 cases belonged to the moderate myopia category. All had received MK flaps.

**DISCUSSION**

Our study shows a consistent, progressive improvement in the efficacy of LASIK for myopia over time. Over the 18-year



**Figure 5** Graph of refractive predictability of myopic laser-assisted in situ keratomileusis showing percentage of eyes within  $\pm 0.5$  and  $\pm 1.0$  D of target refraction postoperatively for the three categories of myopia. Low myopia =spherical equivalent (SE)  $< -5.0$  D; moderate myopia = SE  $\geq -5.0$  D and  $< -10.0$  D; high myopia =SE  $\geq -10.0$  D.

**Table 1** Pre-retreatment manifest refractive spherical equivalent in dioptres and retreatment trends between 1998 and 2015

Year	Pre-retreatment manifest refractive spherical equivalent	Retreatment attempted (D)	3 months post-retreatment (D)	Eyes, n (% of total)
1998	-2.10±1.21	-2.38±0.57	-0.59±0.61	6 (1.4)
1999	-1.77±0.83	-1.82±0.74	-0.37±0.60	73 (4.5)
2000	-1.61±0.87	-1.78±0.83	-0.32±0.44	135 (5.6)
2001	-1.51±0.65	-1.58±0.56	-0.09±0.35	117 (4.3)
2002	-1.45±0.81	-1.58±0.69	-0.27±0.47	82 (2.9)
2003	-1.09±0.44	-1.45±0.44	-0.01±0.39	134 (4.7)
2004	-1.23±0.62	-1.49±0.57	0.09±0.38	114 (2.3)
2005	-1.20±0.61	-1.58±0.57	0.03±0.47	178 (2.5)
2006	-1.01±0.50	-1.37±0.53	0.05±0.35	143 (2.0)
2007	-1.20±1.30	-1.52±0.72	0.12±0.52	116 (2.6)
2008	-1.14±0.73	-1.58±0.74	0.03±0.44	108 (3.1)
2009	-1.42±0.70	-1.70±0.66	-0.04±0.38	48 (1.7)
2010	-1.33±0.87	-1.70±0.83	-0.02±0.29	21 (0.7)
2011	-1.07±0.57	-1.57±0.61	0.06±0.33	15 (0.6)
2012	-1.06±0.41	-1.56±0.39	0.28±0.38	20 (1.1)
2013	-1.28±0.66	-1.76±0.80	0.20±0.40	12 (0.7)
2014	-1.12±0.83	-1.63±0.75	0.05±0.20	11 (0.9)
2015	-1.38±0.53	-1.75±0.35	0.00±0.00	2 (0.2)

period, the mean UCVA achieved was 97.3% for  $\geq 20/40$  and 68.7% for  $\geq 20/20$ . These outcomes are comparable to other large studies for myopic LASIK with 97% achieving postoperative UCVA of  $\geq 20/40$  and 62% of eyes achieving  $\geq 20/20$  UCVA.<sup>3 10 11</sup> Although the myopia categories defined in our study and that in the US Food and Drug Administration (FDA) clinical trials were not identical (low myopia being  $< -6.0$  D, moderate myopia as  $-6.0$  D to  $< -12.0$  D and  $\geq -12.0$  D, respectively),<sup>10 12</sup> the efficacy between similar myopia categories was comparable. The FDA clinical trials reported that for the low myopia category 67%–86% of eyes achieved UCVA of  $\geq 20/20$  and 93%–100% achieved  $\geq 20/40$ . In our series, 79.6% achieved UCVA of  $\geq 20/20$  and 99.2% achieved UCVA of  $\geq 20/40$ . In the moderate myopia category, FDA trials reported that 26%–71% of eyes achieved an UCVA of  $\geq 20/20$  and our results showed that 62.7% achieved UCVA of  $\geq 20/20$  and 96.8% achieved UCVA of  $\geq 20/40$ . In the high myopia group, 32.5% achieved UCVA of  $\geq 20/20$  and 84.6% achieved UCVA of  $\geq 20/40$  which is again comparable to the FDA trials where eyes with  $\geq -10.0$  D of myopia 21.4%–92.0% achieved an UCVA of  $\geq 20/20$  and 78.1%–94.9% achieved an UCVA of  $\geq 20/40$ .<sup>12</sup>

The refractive predictability also showed an increasing trend with 97.6% being within  $\pm 1.0$  D of target refraction and 74.8% within  $\pm 0.5$  D in 2015. The average was 90.4% achieving  $\pm 1.0$  D of target, and 65.6% achieving  $\pm 0.50$  D of target. The mean percentage of eyes losing two or more lines of vision has been 0.40% or less since 2008. These results are comparable with the findings of Sandoval where 98.6% of eyes achieved postoperative refraction within  $\pm 1.0$  D of target refraction and 0.61% lost two or more lines of vision.<sup>3</sup>

In the high myopia category, although the results compared less favourably, steady improvement of outcomes with time in terms of efficacy, safety and refractive predictability have also been observed (figures 2 and 5). The lower outcomes compared with other myopia categories may be attributable to an increased central corneal ablation, a higher reported rate of myopic

regression in eyes with higher myopia corrections and nomogram adjustments with surgeons electing to undercorrect, especially when corneal thickness limits are encountered.<sup>4 10 13</sup>

The overall retreatment rate was 2.55%, which was lower than the rate of 3.8% previously reported<sup>4</sup> and comparable to similar reports of laser refractive surgery for myopia that saw a retreatment rate of 1.8%–6.85%.<sup>14 15</sup> This low retreatment rate may be attributed to increased surgeon experience, improved excimer laser systems and established ablation nomograms that prevents undercorrection.

The shift in flap creation from using a manual MK to the FS laser in the later part of the study is similar to what is seen in other centres despite the higher cost and space constraints associated with the use of a FS laser. The American Society of Cataract and Refractive Surgery surveys show an increase in the use of femtosecond laser for flap creation from about 21% in 2007 to 55% in 2009 while the 2015 International Society of Refractive Surgery indicate that about 75% use it today. This shift is driven by a number of factors including improved accuracy in flap creation, flexibility in flap design, reduction in flap-related complication such as epithelial defects, as well as increased patient comfort with the new high-speed lasers.

Excimer lasers systems used at SNEC have change considerably from the Chiron Technolas 117C (1998) to the current WaveLightEX500, in use since 2013. Among the many advances that occurred with the changes in the lasers are reductions in the spot size and increase in speed, from a 2 mm beam and a pulse repetition rate of about 25 Hz to a 0.68 mm spot size and repetition rate of 500 Hz, allowing treatment times of 1.4 s per dioptre. Improved eye trackers and pupil monitoring systems as well as better customisation profiles in these excimer laser systems have resulted in more accurate treatments with less induced postoperative higher-order aberrations.<sup>16–18</sup>

The complication rates have progressively reduced over time, except for a higher rate in 2007 due to an increased incidence of DLK. The occurrence of DLK in the early postoperative period has been associated which a number of factors including instrument sterilisation protocols, use of certain types of surgical gloves and surgical markers. In our series, it was traced to a certain brand of marker and subsequent to its removal, the complication rates showed a significant reduction from 2008 onwards to 0.57% in 2015.<sup>9</sup> The reduction in flap-related complication rates after 2007 was largely the result of transition to FS laser for corneal flap creation particularly with a reduction in the occurrence of dislodged flaps, with only one case occurring in the FS LASIK eyes. In eyes undergoing primary LASIK, flap dislodgement has been postulated to be less likely to occur in FS LASIK than in MK LASIK due to better flap morphology and adhesion strength of flap created with the femtosecond laser.<sup>19 20</sup> Most notably, there were no additional cases of infectious keratitis other than the three confirmed cases previously reported which generally recovered with good BCVA without resorting to corneal transplantation.<sup>4</sup>

There were a total of 12 cases of ectasia (0.02%). This is comparable to other studies with post-LASIK ectasia rates of 0.04%–0.57%.<sup>17 21–23</sup> All 12 cases had undergone LASIK surgery using a MK before 2007. None of these cases had preoperative corneal topography signs of forme fruste keratoconus and a residual stromal bed of 250  $\mu$ m rule was adhered to in all these cases. The low rates of keratectasia observed in our series can be attributed to a strict adherence to a  $>250$   $\mu$ m residual stromal bed rule and careful observation of the corneal topography combined with quantitative diagnostic indices such as using Scheimpflug-based corneal tomography (Pentacam with

**Table 2** Intraoperative and postoperative complications rate from 1998 to 2015

	All	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
<b>Intraoperative complications</b>																			
<b>Flap-related</b>																			
Button hole	9	-	-	4	-	-	2	2	-	-	1	-	-	-	-	-	-	-	-
Eccentric flap	9	1	3	2	1	-	-	1	-	-	1	-	-	-	-	-	-	-	-
Flap tear/ torn hinge	14	-	-	-	-	-	-	-	-	-	-	1	8	2	1	1	-	1	-
Incomplete flap	71	3	2	3	2	2	2	6	12	12	13	5	3	2	2	-	-	2	-
Decentered ablation zone	5	-	-	1	-	-	-	3	1	-	-	-	-	-	-	-	-	-	-
Loose epithelium/ defects	23	-	-	3	6	7	1	1	2	1	-	1	-	1	-	-	-	-	-
<b>Postoperative complications</b>																			
<b>Flap-related</b>																			
Dislodged flap	68	-	4	3	6	13	5	7	13	6	5	5	-	1	-	-	-	-	-
Significant flap striae	166	2	1	3	-	4	4	24	32	40	23	12	9	3	1	-	3	3	2
Diffuse lamellar keratitis	90	-	-	2	2	1	2	1	3	2	67	3	6	-	-	1	-	-	-
Infective keratitis	3	-	-	-	-	1	-	-	1	1	-	-	-	-	-	-	-	-	-
Epithelial ingrowth	66	2	3	9	4	1	1	9	9	15	2	3	3	1	-	1	2	1	-
Debris at interface	24	-	-	-	-	-	1	-	6	3	5	3	3	-	-	1	2	-	-
Others	44	-	-	1	1	2	-	-	1	1	1	2	4	10	5	7	5	1	3
Total complication cases	592	8	13	31	22	31	18	54	80	81	118	35	36	20	9	11	12	8	5
Total LASIK cases	53731	422	1615	2431	2697	2828	2879	4995	6993	7214	4399	3510	2749	2999	2381	1846	1671	1223	879
Overall complication rate (%)	1.10	1.90	0.80	1.28	0.82	1.10	0.63	1.08	1.14	1.12	2.68	1.00	1.31	0.67	0.38	0.60	0.72	0.65	0.57

Excluding diffuse lamellar keratitis cases in 2007, the overall complication rate in 2007 is 1.16%; the overall complication rate for 1998–2015 is 0.98%.

Belin/Ambrósio Enhanced Ectasia display, Oculus) and Placido-scanning slit system (Orbscan IZ Corneal Topography System with SCORE Analyzer, Bausch+Lomb Technolas) to exclude forme fruste keratoconus. This has improved our ability to identify unsuitable LASIK candidates who are at risk of post-LASIK keratectasia. We acknowledge that there may have been other patients who developed late onset keratectasia and who have not returned to us for identification and that there may be other cases that may present later. Hence the ectasia rate may be under-reported.

The limitations of this study include a short follow-up time (mean of  $78 \pm 75.6$  days) and the absence of data on post-LASIK dry eye. However, long-term studies show that the treatment effects stabilise generally after 3 months and the change in regression rates and postoperative mean manifest refraction between 3 months and 10 years was minimal.<sup>13 24</sup> Hence a 3-month follow-up time was chosen as an end point to provide a practical time frame for evaluating outcomes while capturing a complete sample size. As our study was designed to examine the effectiveness and safety of LASIK, formal assessment of dry eye post-LASIK was not performed postoperatively. As dry eye is one of the common complications reported after LASIK, further studies are required to assess post-LASIK dry eye based on clinical examination together with the Oxford Grading System and symptoms using the Ocular Surface Disease Index scores.<sup>2</sup>

The strengths of this study include the 100% clinical audit of all LASIK cases since the introduction of LASIK in 1998, and to our current knowledge, the largest series of its kind to be reported. This allows the examination of the overall outcomes and complications rate in a large, multisurgeon, single-centre practice which has adopted changes in pretreatment screening strategies, evolution of surgical techniques, refinements of ablation nomograms and laser machines over time.

In conclusion, we found that the outcomes of LASIK have continued to improve over the 18-year period with higher efficacy, refractive predictability and safety outcomes while maintaining a low rate of retreatment and complications and thus is a safe and effective modality which is anticipated to remain as a mainstay of laser refractive surgery.

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**Contributors** DC and RM were involved in study concept and design. DC, HHM and RM performed data analysis and interpretation. DC and RM drafted the manuscript. LL, CC, JSM, DT and RM helped revised the article. All authors have read and approved the final manuscript.

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**Competing interests** None declared.

**Patient consent** Not required.

**Ethics approval** This study adhered to the tenets of the Helsinki Declaration and the SingHealth Centralized Institutional Review Board ruled that approval was not required for this study.

**Provenance and peer review** Not commissioned; internally peer reviewed.

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