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LASIK SURGERY
OUTCOMES, VOLUME AND RESOURCES

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I INTRODUCTION

LASIK stands for Laser-Assisted In Situ Keratomileusis and is a surgical procedure that permanently reshapes the cornea to correct focusing errors. It is commonly used to correct mild to moderate nearsightedness. This surgery is done in patients whose refraction has stabilised i.e., those whose prescription for spectacles/contact lenses has changed less than 50 degrees within the last year. For good outcome, patients need to satisfy certain criteria. Ophthalmologists would be able to advise patients on their suitability for the procedure.

2. Over the years, LASIK has become increasingly popular and the volume of LASIK procedures done in the Public and Private Hospitals here indicates an upward trend.

II Types of LASIK

3. LASIK procedure consists of three components;

i) A thin flap is cut through the top layer of the cornea, the clear surface of the eye above the iris;
ii) The flap is folded out of the way, and an excimer laser is used to remove parts of the corneal tissue underneath it;
iii) The flap is then replaced and left to heal naturally without stitches.

4. Based on these components, Table 1 shows the 4 types of LASIK procedures done in Singapore.

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Table 1: Types of LASIK Procedures

	Wavefront-guided[2]	
	No	Yes
Microkeratome (Knife)	Standard LASIK	Wavefront-guided with microkeratome flap
Laser (Bladeless)	Bladeless LASIK without wavefront evaluation	Wavefront-guided with bladeless flap

a) Standard LASIK – A microkeratome (knife) is used to make a hinged flap in the cornea. A pre-determined amount of corneal tissue is then removed based on the patient's refraction prior to the operation.

b) Wavefront-guided LASIK with microkeratome flap – A wavefront evaluation is first used to assess the entire optical characteristics of the eye before the treatment is customised to the eye. The corneal flap is made with a knife.

c) Bladeless LASIK without wavefront evaluation – The corneal flap is made with a laser, instead of a knife. Corneal tissue is removed depending on the pre-operative refractive error.

d) Wavefront-guided LASIK with bladeless flap – A wavefront evaluation is first used to assess the entire optical characteristics of the eye before the treatment is customised to the eye. The corneal flap is made with a laser (bladeless).

Complications

5. The more serious vision-threatening complications include infection and flap complications. There is also a slight possibility that the procedure or a complication arising from the procedure could cause vision to be blurred, doubled, distorted or to have halos. These may not be correctable with contact lenses or glasses. Medications and more surgery may be advised by the ophthalmologist. If the complication cannot be corrected by medications or more external surface corneal surgery, the only way of restoring vision may be a corneal transplant.

III VOLUME

6. MOH has invited centres providing LASIK surgery to participate in a study on its outcomes. The information is gathered from:

1. National University Hospital (NUH)
2. Singapore National Eye Centre (SNEC)
3. Tan Tock Seng Hospital (TTSH)
4. Jerry Tan Eye Surgery (JTES)

[2] A wavefront evaluation is done to diagnose existing imperfections in order to enable the surgeon to build a unique map of the individual eye which is used to guide the removal of corneal tissue below the flap that is customised to the eye.

7. ***This study on outcomes is based on patients operated on in 2005 at the 4 centres and were followed up for at least 3 months. The outcome information on success and predictability is based on patients with mild to moderate myopia and without co-morbidity. With regards to safety outcome, the analysis is based on <u>all</u> LASIK surgery patients.***

8. Table 2 shows the annual volume of LASIK surgery by the participating centres from January to December, 2005.

Table 2: Volume of LASIK surgery (2005)

Institution	Volume	No. of Doctors	Number of surgeries per doctor (50^{th} percentile)	Number of surgeries per doctor (75^{th} percentile)
NUH	262	7	22	40.5
SNEC	7183	18	285	841
TTSH	2284	4	290	969
JTES	665	1	not applicable as this is a solo practice	
Total	10392			

IV COST

9. The cost of LASIK surgery varies by the type of LASIK and the tables below list the fees for single eye and double eye surgery. The fees comprise procedure, facility and doctor's charges and do not include costs of pre-surgical evaluation, post-operative visits and medications.

Table 3 (a): Fees For *Standard LASIK*

Institution	Procedure Fee + Facility and Doctor's Fees (single eye)	Procedure Fee + Facility and Doctor's Fees (double eyes)
NUH	$1,275	$2,550
SNEC	$1,320- $2,230	$2,640 - $4,460
TTSH	$1,280 - $1,590	$2,560 - $3,180
JTES	service not provided	

Table 3 (b): Fees for *Wavefront-guided LASIK with microkeratome flap*

Institution	Procedure Fee + Facility and Doctor's Fees (single eye)	Procedure Fee + Facility and Doctor's Fees (double eyes)
NUH	$1,720 - $1,820	$3,440 - $3,640
SNEC	$1,520 - $2,430	$3,040 - $4,860
TTSH	$1,470 - $1,780	$2,940 - $3,560
JTES	$2,200 - $2,800	$4,400 - $5,600

Table 3 (c): Fees for *Wavefront-guided LASIK with bladeless flap*

Institution	Procedure Fee + Facility and Doctor's Fees (single eye)	Procedure Fee + Facility and Doctor's Fees (double eyes)
NUH	service not provided	
SNEC	service not provided	
TTSH	$1,970 - $2,280	$3,940 - $4,560
JTES	$2,800 - $3,400	$5,600 - $6,800

Table 3 (d): Fees for *Bladeless LASIK without wavefront evaluation*

Institution	Procedure Fee + Facility and Doctor's Fees (single eye)	Procedure Fee + Facility and Doctor's Fees (double eyes)
NUH	service not provided	
SNEC	service not provided	
TTSH	$1,780 - $2090	$3,560 - $4180
JTES	service not provided	

V OUTCOMES

10. LASIK surgery is effective, predictable and safe for patients with mild or moderate myopia (100 degrees to 600 degrees) while the outcome varies for patients with moderate to severe myopia (>600 degrees). Although LASIK has been performed for around 18 years,

the long term effects of the procedure are still relatively unknown.[3] There are not many studies on the long term effects of the procedure. In this study, we have focused on the shorter term outcomes of LASIK surgery in terms of success, predictability and safety.

Success

11. The criterion for success used in this study is the percentage of patients achieving unaided visual acuity of at least 6/12 or better at 3 months post-operatively. The percentage of those achieving 6/6 vision or better in clinical trials reported to FDA is more than 85%[4]. The percentage of those achieving 6/12 vision or better ranged from 96% to 100%. [4,5]

12. All four centres in our study achieved excellent results with success rates (vision better than 6/12) exceeding 98%. There was no significant difference in the success rate between the different types of LASIK.

Predictability

13. The criterion for predictability used here is the percentage of patients achieving final visual acuity to within 100 degrees of targeted refractive correction. In clinical trials reported to FDA, the percentage of those achieving correction to within 100 degrees of targeted correction is more than 97%. International studies reported rates ranging from 83% to 100%.[6,5]

14. The four centres achieved predictability rates exceeding 98%.

Safety

15. The criterion for safety used here is the percentage of all patients who had uneventful recovery. Surgeries with flap-related complications and post-operative corneal ulcers are considered eventful surgeries. The Council for Refractive Surgery Quality Assurance (CRSQA), which certifies refractive surgeons in America, requires its members to experience complications such as haze, haloes and glare in no more than 3% of their LASIK patients, and vision-threatening complications in no more than 0.5% of their LASIK patients. Other studies have reported safety rates between 95 % and 99.7 %. [6]

16. The four centres achieved safety rates exceeding 99%.

17. Outcomes for the four types of LASIK surgeries (standard LASIK, wavefront-guided LASIK with microkeratome flap, wavefront-guided LASIK with bladeless flap and bladeless LASIK without wavefront evaluation) performed in the four participating centres for the year 2005 are presented in Tables 4 (a) to (d).

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[3] National Institute of Clinical Excellence*. Interventional Procedures Programme. Interventional Procedures overview of laser in situ keratomileusis for the treatment of refractory errors*. May 2004

[4] US FDA *Outcomes after LASIK Surgery*, http://www.lasikmd.ca/results.html

[5] *Results of LASIK for low to moderate myopia* . Source: American Academy of Ophthalmology. *Preferred Practice Pattern on Refractive Errors. "Laser in situ keratomileusis for low myopia: safety and efficacy*. Ophthalmology 2002; 109: 175-87.

Table 4(a): *Volume and Outcomes of Standard LASIK*

Institution	Volume	Success	Predictability	Safety
NUH	232	98.86%	98.84%	100%
SNEC	6751	99.07%	98.66%	99.29%
TTSH	762	100.00%	99.73%	99.74%
JTES	service not provided			

Table 4(b): *Volume and Outcomes of Wavefront LASIK with microkeratome flap*

Institution	Volume	Success	Predictability	Safety
NUH	30	insufficient number to statistically analyse and report outcomes		
SNEC	432	99.25%	99.25%	99.31%
TTSH	599	100.00%	100.00%	99.83%
JTES	307	100.00%	100.00%	100.00%

Table 4(c): *Volume and Outcomes of Wavefront LASIK with bladeless flap*

Institution	Volume	Success	Predictability	Safety
NUH	service not provided			
SNEC	service not provided			
TTSH	694	100.00%	100.00%	100.00%
JTES	358	100.00%	100.00%	100.00%

Table 4(d): *Volume and Outcomes of Bladeless LASIK without wavefront evaluation*

Institution	Volume	Success	Predictability	Safety
NUH	service not provided			
SNEC	service not provided			
TTSH	232	100.00%	99.04%	100.00%
JTES	service not provided			

18. In interpreting outcome data it should be noted that:

- While we have tried to compare our local results with overseas studies, there may be differences in the reporting of complications between various studies.
- Although we have attempted comparability of patients across the 4 centres by including only patients without co-morbidities for success and predictability, the rates are not risk adjusted for other differences in patient profile.
- Loss to follow-up ranged from 4% to 16% at 3 months in overseas research studies. [6, 7,8] The losses to follow-up in the 4 centres in the study were: NUH – 40%, SNEC - 23%, TTSH - 32%, and JTES – 21%. The loss to follow-up is due to patients – both foreign and local – who did not return for the 3 month post-operation review. A future study on LASIK outcomes could look at the reasons for this loss to follow-up.
- Outcomes for JTES represent surgeries done by a single surgeon only. In contrast, outcomes from NUH, SNEC and TTSH represent aggregate outcomes of surgeries done by a number of surgeons with different levels of experience.

VI CONCLUSION

19. The success, predictability and safety rates of LASIK in the participating centres, in mild to moderate myopia patients, compare favourably with those achieved by established international benchmarks.

20. One important aspect of the outcome of LASIK surgery is the quality of vision. Some studies have reported less visual distortions, starbursts and glare, and better night vision i.e., better quality of vision with customized LASIK (i.e. Wavefront-guided LASIK and Bladeless LASIK). [9,10,11] However, there are no established objective measures to quantify the quality of vision which is very subjective.[12] Since our local centres do not have enough data on the quality of vision following LASIK surgery, this study is unable to present local experience on this outcome measure.

21. It is essential for patients to discuss thoroughly with their ophthalmologist the potential benefits, the expected refractive outcomes and possible risks of the procedure, and the type of LASIK procedure that is most suitable for them. This will enable the patient to make an informed decision. It is also important that patients comply with post-operative instructions and appointments.

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[6] Hersh PS, Brint SF et.al. *Photorefractive keratectomy versus laser in situ keratomileusis for moderate to high myopia*. Ophthal. 1998 Aug;105(8): 1512-22

[7] El Danasoury MA, el Maghraby A, Klyce SD, Mehrez K. *Comparison of photorefractive keratectomy with excimer laser in situ keratomileusis in correcting low myopia (from -2.00 to -5.50 dioptres). A randomized study*. Ophthal. 1999 Feb; 106(2): 411-20

[8] El-Maghraby A, Salah T et.al. *Randomised bilateral comparison of excimer laser in situ keratomileusis and photorefractive keratectomy for 2.5 to 8.0 dioptres of myopia.* Ophthal. 1999 Mar; 106(3): 447-57

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[11] Setlik DE, Fry KL, Hersh PS. *Comparison of visual outcomes of Wavefront guided and conventional LASIK*. Invest Ophthalmol Vis Sci 2005; 46:E-Abstract 4375

[12] Stephen D McLeod. *Beyond Snellen Acuity - The Assessment of Visual Function After Refractive Surgery*. Arch Ophthal. 2001; 119:1371-3