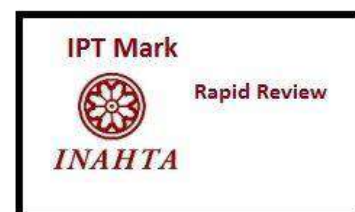




INFORMATION BRIEF (RAPID REVIEW)

iLASIK Procedure

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
010/2024



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TITLE: iLASIK Procedure

PURPOSE

To provide scientific evidence on the effectiveness, safety, and cost-effectiveness of iLASIK following the request by the Director of Medical Practice Division, Ministry of Health, Malaysia as this procedure is currently not listed under the 13th Schedule of Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) (Amendment) Order 2013.

BACKGROUND

A variety of refractive surgery techniques, which reshape the corneal stroma using laser energy, have been marketed as simple and safe alternatives to glasses or contact lenses. LASIK (Laser-Assisted In Situ Keratomileusis) has been recognised as a surgical method for correcting refractive errors such as myopia, hyperopia, and astigmatism. There are several types of LASIK and related laser eye surgeries designed to correct refractive errors (Table 1):¹

Table 1: Types of Refractive Surgery. ¹

Category	Procedure	Description
Surface Ablation	PRK (photorefractive keratectomy)	Corneal epithelium is removed, and an excimer laser is used to reshape the underlying corneal stroma.
	LASEK (laser-assisted subepithelial keratectomy)	Alcohol is used to loosen the corneal epithelium, which is pushed aside as a sheet. An excimer laser is then used to reshape the underlying corneal stroma. The epithelial layer is repositioned.
Stromal Flap	LASIK (laser-assisted in situ keratomileusis)	Corneal flap is created, and an excimer laser is used to reshape the underlying corneal stroma.
Lenticule Extraction	SMILE (small incision lenticule extraction)	A femtosecond laser is used to create a lenticule within the cornea, which is then removed through a small corneal incision.

Recent advancements in LASIK technology (iLASIK) have focused on improving precision, safety, and customisation through the integration of femtosecond and excimer lasers.²

The iLASIK combines the most advanced measurement technology and two of the most advanced computer-guided laser procedure. It is classified as the pinnacle of blade-free, fully customised laser vision correction, and is the premium laser solution available today. The systems in use today have been around for years. It is the first vision correction technique that is completely customised to each eye's particular features.² The FDA approved IntraLase for laser-assisted creation of a corneal flap in 2001 and approved wavefront-guided LASIK for custom correction in 2002.⁶ The two most advanced laser techniques available are combined in iLASIK:¹

1. Bladeless Femtosecond Laser

- Replaces the mechanical microkeratome for corneal flap creation.
- Offers high precision and safety by producing uniform, predictable flaps while minimizing blade-related complications.

2. Excimer Laser for Ablation

- Operates with high pulse repetition rates (400+ Hz) for faster and more efficient procedures.
- Features scanning spot technology for precise tissue ablation.
- Enables customized treatments, including aspheric, wavefront-guided, and topography-guided ablation profiles, addressing higher-order aberrations and unique corneal shapes.

These innovations have been claimed to improved LASIK's efficacy, decreased complications, and customised treatments for each patient, thereby securing its place as the industry standard for vision correction.²

A number of brands have released the analyser using this cutting-edge technique, including the [REDACTED]



Figure 1: Example of analysers for iLASIK procedure.³

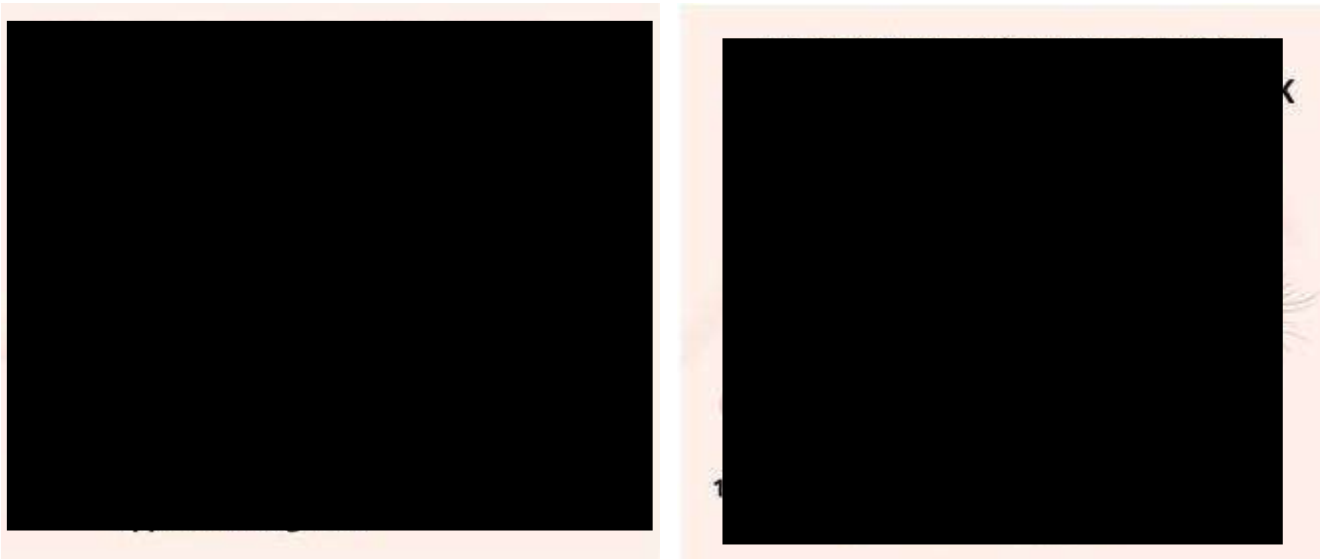


Figure 2: Two type of LASIK eye surgery.¹¹

Steps involved in the iLasik procedure are as follows:⁴

i. Wavefront Analysis

The LASIK procedure starts with a wavefront analysis of the patient's eyes. A WaveScan Wavefront system directs light into the eye, which reflects off the retina. This reflection is captured and analysed using Hartmann-Shack technology and Fourier analysis. The outcome is a customized treatment based on the total ocular aberrations identified in the eye.

ii. Creation of the Corneal Flap

Next, a corneal flap is created using the IntraLase FS or iFS femtosecond laser. The flap parameters, such as depth and diameter, are customised to the patient's needs. The laser emits focused pulses in a precise pattern to create a resection plane. Pulses are arranged vertically or at angles up to 150° to form the flap edge. The flap is manually lifted to reveal a smooth lamellar bed for treatment, with minimal energy use, reducing inflammation, procedure time, and improving healing.

iii. Wavefront-Guided Treatment

The wavefront-guided treatment profile is aligned under the excimer laser using iris registration to ensure accuracy. Pupils may constrict unevenly under the laser, but iris registration prevents misalignment. The Star S4 IR excimer laser uses variable spot scanning to reshape corneal tissue and correct aberrations.

iv. Completion

After laser ablation, the LASIK flap is placed back on the cornea, completing the procedure.

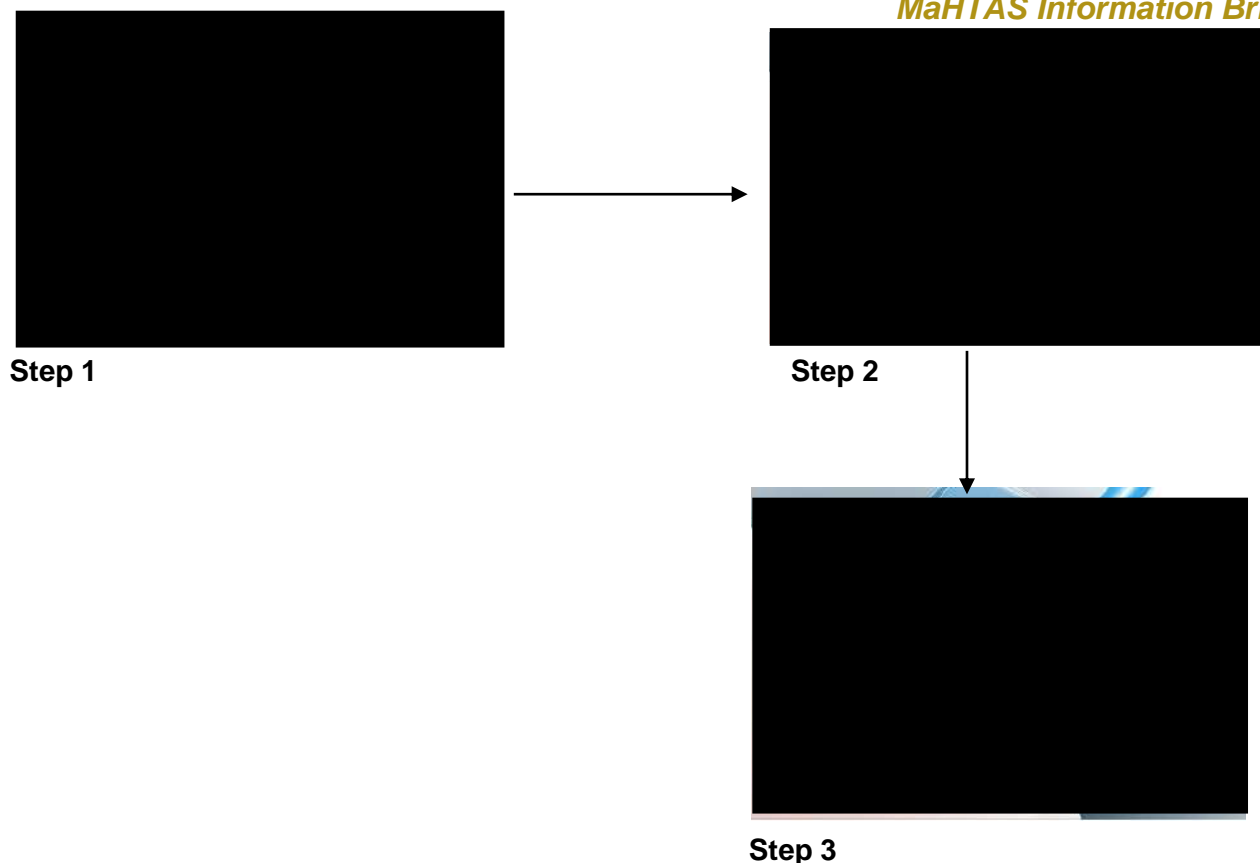


Figure 3: Example of illustration step by step for iLASIK procedure. ¹¹

EVIDENCE SUMMARY

Three hundred and sixty-seven articles were retrieved from scientific databases of Ovid-EBM, Medline, PubMed, Embase, Cochrane Library, general search engine (Google Scholar) and reference list on iLASIK procedure using the following search terms “*refractive errors, laser in situ keratomileusis, intralase lasik and ilasik*”. The last search was done on 30th December 2024. Five studies were included in this review which consisted of one randomised controlled trial, two observational studies and two case series.

EFFICACY/ EFFECTIVENESS

A randomised controlled trial by Zhang YL et al (2013) compared the uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), refractive errors, and aberrations in patients who have different sizes of corneal flap implanted in both eyes during the LASIK procedure. Forty patients who underwent intralase femtosecond LASIK (iLASIK) from April 2011 to December 2011 were included in this study. Prior to surgery, patients underwent comprehensive ophthalmologic exams, including uncorrected distance visual acuity (UCVA), best-corrected distance visual acuity (BCVA), corneal topography, and wavefront analysis. All procedures were performed on the right eye first, with corneal flap diameters set between 8.0-9.0mm. The small flap was designed to be 8.1mm to minimize the effects of the flap hinge and apparatus error, while the 8.6mm flap was designated as the big flap. One eye was randomly assigned to the small flap group, and the other to the big flap group, with patients

blinded to the flap used. After flap creation, a 15-minute delay was followed by excimer laser ablation using the VISX S4. Postoperative examinations were conducted at one week, one month, and three months. Visual acuity (UCVA and BCVA) was recorded in 5-logMAR format, and each eye underwent three wavefront analyses. Higher-order aberrations (HOAs), including trefoil, coma, and spherical aberration, were measured using the WaveScan aberrometer. In the study, 40 patients (19 men, 21 women with mean age 23.55 ± 4.05 years) underwent LASIK with either small or large corneal flaps. All surgeries were successful without complications. There were no significant differences in preoperative measurements (sphere, astigmatism, spherical equivalent, UCVA, BCVA) between the two groups. The UCVA improved significantly at week one, month one, and three postoperatively ($p = 0.001$), but no differences were found between the small and large flap groups. Visual acuity remained stable, and there were no significant differences in residual sphere or cylinder. Both groups showed increased higher-order aberrations (HO-RMS), particularly spherical aberration (Z12) and vertical coma (Z7), but no significant differences in HO-RMS between the two groups at any time point during follow-up. The author concluded that both small and large corneal flaps are safe and effective for correcting myopia, as long as the exposed stroma is adequate for excimer laser ablation. Personalized corneal flap sizes are feasible, as the flap diameter can be designed based on the principle that it should be equal to or greater than the sum of the maximum ablation diameter and any potential apparatus error.⁵

Another study on iLASIK procedure is from alMahmoud T et al (2011). This study aimed to evaluate changes in wavefront (ocular) and corneal higher-order aberrations (HOAs) and visual acuity (VA) outcomes following wavefront-guided advanced surface ablation (ASA) techniques and IntraLase femtosecond LASIK (iLASIK) for myopia treatment. The study included 378 eyes, with 240 eyes undergoing four ASA techniques (Epi-LASIK, LASEK, Epi-PRK, AA-PRK) and 138 eyes treated with iLASIK. The spherical correction range was -1.00 to -8.25 D for ASA and -1.00 to -9.5 D for iLASIK. Preoperative and 3-month postoperative ocular wavefront aberrations and corneal topography were assessed using WaveScan and Pentacam systems. Surgical procedures were performed under topical anesthesia, with customized treatment using excimer and femtosecond lasers. Postoperative care included medications, bandage contact lenses for ASA patients, and scheduled follow-up visits. The study found no significant differences between the flap-on, flap-off ASA, and iLASIK groups regarding preoperative refractive spherical equivalent (-4.06 ± 1.93 D, -4.02 ± 1.98 D, and -3.79 ± 1.95 D, respectively), preoperative refractive cylinder power (0.50 ± 0.54 D, 0.61 ± 0.50 D, and 0.69 ± 0.66 D, respectively), or mean age (34 ± 8.7 years, 34 ± 9 years, and 40 ± 9.0 years, respectively). The mean preoperative uncorrected distance visual acuity (UDVA) was 20/320 for both flap-on and flap-off ASA groups, and 20/250-2 for the iLASIK group (logMAR 1.13 ± 0.52 vs. 1.20 ± 0.44). At 3 months, 70% of the flap-on group, 67% of the flap-off group, and 68% of the iLASIK group achieved UDVA of 20/20 or better, with 11% of iLASIK eyes reaching 20/12.5 or better. The mean postoperative corrected distance visual acuity (CDVA) was 20/20+2 for flap-on and 20/16-2 for both flap-off and iLASIK groups, with no significant differences between them. Regarding mean refractive spherical equivalent (MRSE) at three months, 95% of eyes in the flap-on group, 98% in the flap-off group, and 86% in the iLASIK group had MRSE within ± 0.50 D. The iLASIK group showed MRSE closer to emmetropia with a tighter standard deviation (-0.14 ± 0.43 D for iLASIK vs. -0.62 ± 0.97 D for flap-on ASA and -0.53 ± 0.81 D for flap-off ASA, $p < 0.001$). In terms of wavefront (ocular) HOAs, both flap-on and flap-off groups showed significant increases in HOAs, spherical aberration (SA), and coma ($p < 0.001$), whereas iLASIK showed a significant increase only in SA ($p < 0.001$). Pairwise comparisons revealed iLASIK induced significantly lower HOAs and SA than both ASA groups ($p < 0.001$). At three months, all groups showed a significant

increase in corneal HOAs compared to preoperative values ($p < 0.001$). The iLASIK induced significantly fewer corneal HOAs and SA compared to ASA groups ($p < 0.001$). Furthermore, iLASIK induced more coma than flap-on ASA ($p = 0.017$). Correlations between changes in aberrations and postoperative CDVA were significant in the flap-off ASA group (HOA: $r = -0.371$, $p < 0.0001$; SA: $r = -0.309$, $P = 0.0007$; coma: $r = -0.182$, $p = 0.049$), but not in iLASIK, which only showed a correlation between SA and CDVA ($r = -0.194$, $p = 0.025$). The author concluded that both ASA techniques and iLASIK are effective for myopia, with comparable 20/20 UDVA outcomes. The iLASIK was superior for achieving 20/12.5 or better vision. All treatments caused increases in HOAs and SA, but the flap-off ASA group showed a negative correlation between corrected aberrations and CDVA, suggesting that modifying the ablation pattern could improve visual outcomes.⁷

A prospective, open-label, noncomparative, multicenter study by Maloney RK et al (2021) evaluated visual, refractive, aberrometric, and patient-reported outcomes of wavefront-guided (WFG) myopic laser in situ keratomileusis (LASIK) using a high-resolution Hartmann-Shack aberrometer (iDesign Advanced WaveScan system) with a new nomogram and to determine whether the new nomogram resolved the mild undercorrection that occurs with the manufacturer's default settings. This study included 190 eyes of 95 patients with myopia or myopic astigmatism, conducted at three U.S. centers. Patients aged 18 years and above with refractive goals of emmetropia were enrolled, excluding those with certain ocular conditions or health issues. Preoperative and follow-up evaluations (one day, one month, three months, and six months) included visual acuity measurements and wavefront, corneal topography, and ocular aberrometry assessments using the iDesign Advanced WaveScan system. Patient satisfaction and photic phenomena were assessed via a modified NEI-RQL-42 questionnaire at baseline and six months. The wavefront map generated by the iDesign system was used to create an excimer laser treatment pattern. A "sphere adjustment" allows modification of this correction by ± 0.75 D. This is calculated by adjusting the manifest refraction sphere to an infinite lens length, subtracting the iDesign sphere correction, and entering the resulting value. Cylinder correction is not adjusted, and if the sphere adjustment falls outside the ± 0.75 D range, the patient is excluded. Using this nomogram adjustment is off-label. The iLASIK procedure used the iLASIK suite, including the iDesign Advanced WaveScan aberrometer, iFS femtosecond laser, and Star S4 IR excimer laser. Surgery was performed under topical anaesthesia by experienced LASIK surgeons. Corneal flaps were created with a femtosecond laser, with a thickness of 90-120 μm and a diameter of 8.0-9.0 mm. Wavefront-guided laser ablation was performed with XYZ tracking for all eyes and torsional tracking based on iris registration when possible. The treatments were programmed for a 6.0 mm wavefront correction zone and an 8.0 mm ablation zone, targeting emmetropia for all eyes. At three months postoperatively, 78% of eyes achieved 20/16 or better, and 97% achieved 20/20 or better, with these results remaining stable at six months (77% and 96%, respectively). All patients had binocular uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) of 20/20 or better at six months. Additionally, 53% of eyes gained one or more lines of CDVA at three months, and 49% at six months, with no patient losing more than one line of CDVA during follow-up. Refractive outcomes showed that 98.3% of eyes were within ± 0.50 diopters (D) of emmetropia at three months, and 97.6% at six months. The mean manifest refractive spherical equivalent (MRSE) improved from -3.83 D preoperatively to -0.01 D at six months, with minimal regression observed between one to three months (0.04 D) and three to six months (0.06 D). For astigmatism, 94% of eyes had residual refractive cylinder of 0.50 D or less at three months, and 92% at six months. Aberrometry outcomes showed a small but statistically significant increase in higher-order

aberrations (HOAs) from preoperatively to six months ($p < 0.001$) for both 4 mm and 5 mm pupils, though mean CDVA improved, suggesting minimal impact on visual performance.⁸

A prospective study by Uceda-Montañés A et al (2020) evaluated three-month post-operative visual, refractive, and optical outcomes in 100 eyes (50 patients; 28 female and 22 male) with low-to-moderate myopia and varying astigmatism. Patients, aged 21 to 41 years, underwent topography-integrated wavefront-guided (TI-WFG) LASIK at Optilase Eye Clinic, Ireland, using the STAR S4IR excimer laser and iDesign system. Preoperative and postoperative assessments included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), refraction, corneal topography, aberrometry, and optical quality. Follow-ups were conducted at one day, one week, one month, and three months. Surgeries, performed by a single experienced surgeon, utilized femtosecond laser flaps and customized ablation profiles. The mean ablation depth was 60.88 μm , and the mean flap diameter was 8.97 mm. The outcomes summarize in Table 2, 3 and 4.⁹

Table 2: Summary for Visual and refractive outcomes.

Visual and refractive outcomes		
Outcome	Result	P-value
Refractive Outcomes	Significant reduction in sphere and cylinder at one day post-surgery	<0.001
	Significant improvement in UDVA and CDVA at one day post-surgery	<0.001
	Additional improvement in UDVA and CDVA during follow-up	<0.001
Refractive Parameters	Significant changes in refractive parameters during follow-up (excluding J0 and J45)	≤ 0.014
J ₀	No significant change	0.071
J ₄₅	No significant change	0.684
Spherical Equivalent (at 90 days)	Eyes within ± 0.50 D	91.1% (82/90)
	Eyes within ± 1.00 D	98.9% (89/90)
UDVA (at 90 days)	Eyes achieving 20/16 or better	93.3% (84/90)
	Eyes achieving 20/20 or better	98.9% (89/90)
	Eyes achieving 20/25 or better	100% (90/90)
CDVA (at end of follow-up)	All eyes achieved 20/20 or better	100% (90/90)
Safety (at 90 days)	No eye lost 2 lines or more of CDVA	0%
	Eyes that gained 1 line of CDVA	50.0% (45/90)

The given refractive error and J₀ and J₄₅ are the two Jackson crossed cylinders equivalent to the conventional cylinder.

Table 3: Summary of the vector analysis of astigmatic changes observed in the study, including the relevant statistical significance.

Vector Analysis of Astigmatic Changes		
Parameter	Result	P-value
Mean Spherical Equivalent (ME)	No significant changes, mean value: -0.04 D at 90 days	0.005
Surgically Induced Astigmatism (SIA)	No significant changes, mean value: 0.65 D at 90 days	N/A
Correction Index (CI)	No significant changes, mean value: 1.01 at 90 days	N/A
Vector Difference (DV)	Small but statistically significant increase	0.005
Axis Error (AE)	Significant reduction, mean value: 0.17° at 90 days	N/A

Table 4: Summary of the optical quality outcomes, including significant changes in high-order aberrations, coma, and the ocular scattering index after surgery

Ocular Optical Quality Outcomes		
Parameter	Result	P-value
High-Order Aberration (HOA) RMS	Small but statistically significant increase	<0.001
Spherical Aberration Zernike Term	Small but statistically significant increase	<0.001
Percentage of Eyes with HOA > 0.50 μ m	7.8% (7/90) of eyes	N/A
Percentage of Eyes with Spherical Aberration > 0.50 μ m	0% (0/90) of eyes	N/A
Coma Aberration (Vertical)	Small significant increase	<0.001
Coma Aberration (Horizontal)	Small significant increase	0.007
Ocular Scattering Index (OSI)	Mean postoperative value: 0.71 (SD: 0.44; Median: 0.60; Range: 0.30 to 3.60)	N/A

In another case series, Kanellopoulos AJ et al (2013) evaluated the safety, efficacy, and long-term stability of myopic and myopic astigmatism corrective LASIK procedures utilizing the WaveLight® FS200 femtosecond and EX500 excimer laser refractive surgery platform. This study evaluated 109 consecutive patients undergoing uncomplicated primary bilateral LASIK, performed by a single surgeon (AJK) using the WaveLight FS200 Femtosecond Laser and WaveLight EX500 Excimer Laser platform (Alcon Laboratories) between September 2009 and September 2010. Preoperative spherical equivalents ranged from 0.00 to –8.00 diopters (D) with up to 4.25 D of cylinder refractive error. The average flap thickness (planned 110 μ m) was 107 ± 5 μ m, and the average flap diameter (planned 8.00 mm) was 7.95 ± 0.05 mm, measured using the integrated diagnostic and surgical platform. Preoperative evaluations included best corrected distance visual acuity (CDVA), wavefront analysis, pupillometry, and contrast sensitivity, while postoperative assessments involved uncorrected distance visual acuity (UDVA), refraction, tonometry, and corneal tomography. Follow-up examinations at one week, three months, six months, and one year. A total of 190 eyes were evaluated, with 96 (50.5%) right eyes and 94 (49.5%) left eyes. Among these, 86 eyes (45.3%) were from female patients, and 104 eyes (54.7%) were male. The mean patient age was 28.8 ± 7.8 years (range 17–52). Preoperative UDVA averaged 0.04 ± 0.17 (decimal), ranging from 0.001 to 0.8. The preoperative refractive error averaged -5.29 ± 2.39 D (range –8.00 to 0.50), improving postoperatively to -0.27 ± 0.09 D at three months, -0.27 ± 0.10 D at six months, and -0.39 ± 0.08 D at one year. Preoperative refractive astigmatism averaged

-1.07 ± 0.91 D (range -4.25 to 0 D) and improved to -0.14 ± 0.04 D at three months, -0.15 ± 0.04 D at six months, and -0.16 ± 0.04 D at one year visit. Postoperative monocular uncorrected distance visual acuity (UDVA) improved significantly, with 94.7% of eyes achieving unaided visual acuity better than 1.0 (decimal) at three months, and this level of visual acuity remained stable over the one-year follow-up period. The refractive stability is demonstrated by the SE correction, at the 12-month postoperative visit. Defocus equivalent results are presented in Figure 4. Predictability is demonstrated in Figure 5, where the achieved SE versus attempted SE (in D) was plotted, for gate = 0.5 D. Of the 190 eyes shown, one eye (0.5%) is marked with red, indicating overcorrection, 180 (95%) are marked with green (indicating individual outcomes where the achieved spherical correction was within the gate, that is, 0.5 D of the attempted correction), and nine eyes (5%) are marked with blue, indicating undercorrection. The data have a linearity $a = 1.00$, with bias $b = -0.16$, and the regression coefficient (r) = 0.98. Likewise, in the six-month follow-up visit, the linearity was 1.02, and for the 12-month postoperatively follow-up visit, the linearity was 0.99. Besides, the comparison between postoperative and preoperative refractive astigmatism is demonstrated by the percentage of eyes within 0.25 D of postoperative refractive astigmatism. Postoperative refractive astigmatism reported has improved significantly, with 94.7% of eyes achieving astigmatism less than 0.25 D at the three-month visit, and 97.9% achieving less than 0.5 D at the 12-month visit. Keratometric stability was evaluated by monitoring K-flat (Kf) and K-steep (Ks) values at one, three, six, and 12 months. A $+0.1$ D increased in keratometric power was observed over one year, indicating a slight steepening of the cornea postoperatively. According to the author, this suggests that corneal stiffening through cross-linking might be beneficial for all LASIK cases to enhance long-term stability. (Figure 6) ¹⁰

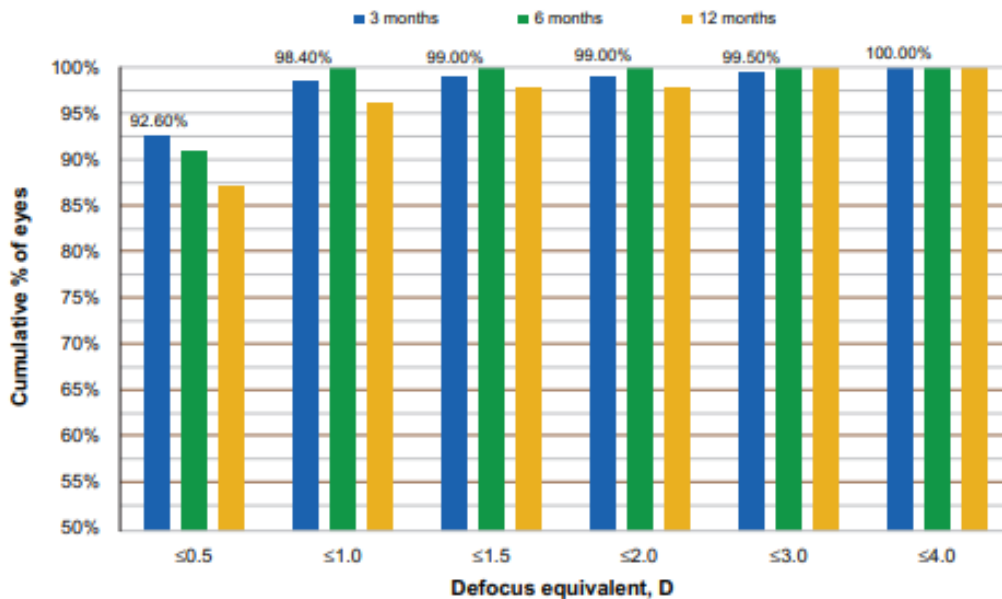


Figure 4: Defocus equivalent results at the 3-, 6-, and 12-month visits.
Abbreviation: D, diopter

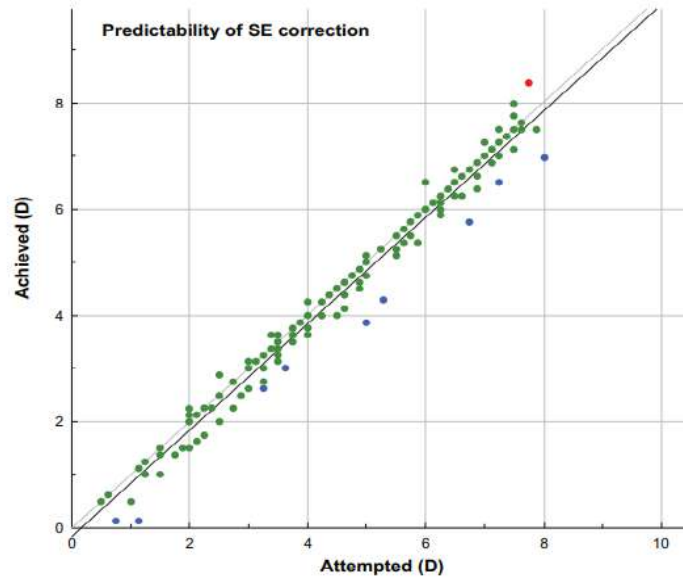


Figure 5: Predictability of spherical equivalent (SE) correction, showing achieved SE versus attempted SE

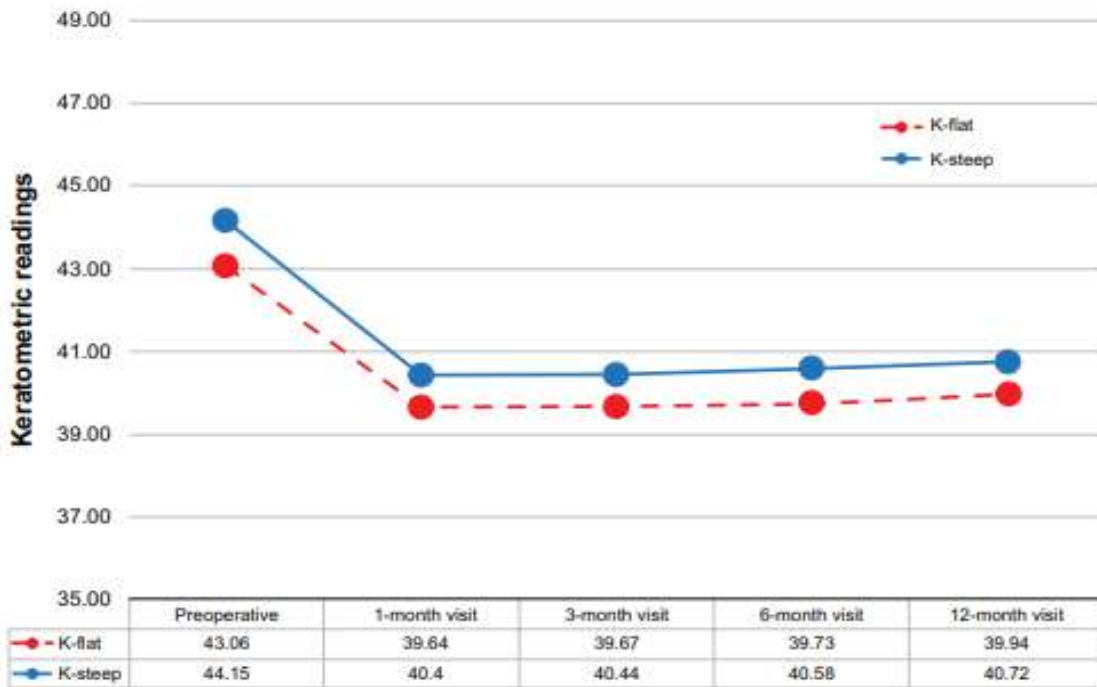


Figure 6: Keratometric readings for up to 12 months of follow-up.

SAFETY

According to the United States Food and Drug Administration, the iDESIGN Refractive Studio and the [REDACTED] incorporated were included in the list of FDA-approved lasers for iLASIK procedure and have undergone several updates to their approval. The most recent approval for the [REDACTED] was granted on 9th August 2024, reflecting compliance with regulatory standards and advancements in laser-assisted vision correction technology. The [REDACTED]

██████████ as approved by Medical Device Authority, Ministry of Health Malaysia with registration number GC94069603818. ^{13,14}

In the study conducted by Uceda-Montañés A et al (2020), patient satisfaction outcomes were exceptionally positive. Of the 50 patients, 88.0% (44/50) participated in the satisfaction survey, and all respondents (100%, 44/44) reported being satisfied with the final outcomes. Additionally, they indicated they would choose to undergo the same surgical procedure again if needed and would recommend it to friends and family.⁹

The RCT study by Zhang YL et al (2013) found no safety concerns, as all surgeries were successful without flap-related complications. There was no release of vacuum during flap creation, and no flap decentrations occurred. Both the small and big flap groups showed similar postoperative inflammation, and no complications were observed at any point during the treatment. The results highlight that both procedures were safe with no significant safety-related issues. ⁵

Maloney RK et al (2021) found no intraoperative complications or serious adverse events were reported, ensuring the safety of the procedure. At six months, 96% of patients expressed extreme satisfaction or satisfaction with their vision postoperatively, without the need for spectacles or contact lenses. The safety index at six months was 1.12, and the efficacy index was 1.09, indicating excellent safety and effectiveness. Patient-reported outcomes revealed a significant decrease in symptoms related to dryness, with reductions in soreness/irritation ($p < 0.001$) and burning/stinging ($p = 0.021$). Regarding quality of life, 96% of patients reported improvement postoperatively, with no patients indicating a worse quality of life. Additionally, no significant increase in glare, halos, starburst, or ghosting/double vision was observed at six months compared to preoperative levels. The author also reported that the latest wavefront-guided (WFG) system, the iDesign system, was approved by the U.S. Food and Drug Administration (FDA) with manufacturers default settings that produced a consistent undercorrection, resulting in only 83% of eyes achieving 20/20 or better vision in the U.S. FDA study. ⁸

According to the study conducted by Kanellopoulos AJ et al (2013), the safety of corrected distance visual acuity (CDVA) was evaluated by comparing preoperative best-corrected CDVA with postoperative uncorrected distance visual acuity (UDVA) at three months. This study reported that 33.3% of eyes remained unchanged, 59.2% gained one Snellen line, and 6.4% gained two or more Snellen lines. Less than 2% of eyes lost one Snellen line, and a similarly small proportion lost two Snellen lines. ¹⁰

COST-EFFECTIVENESS

There was no evidence retrieved on cost effectiveness of iLASIK procedure. The price of the procedure found in ██████████ and ██████████ for conventional lasik offered including surgeon's fees and hospital medical services and medications ██████████ ^{11,12}

CONCLUSION

Based on the above review, the iLASIK procedure is effective in correcting refractive errors, improving the uncorrected and corrected distance visual acuity (UDVA and CDVA), with many patients attaining 20/20 vision or better and stable corneal curvature changes up to one-year post-operation. Evidence demonstrated its safety with no significant complications and high patient satisfaction was reported. Femtosecond laser and excimer laser have obtained regulatory approvals from the FDA and Malaysia Medical Device Authority. There was no evidence retrieved on the cost-effectiveness study of iLASIK procedure.

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