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Comparison of clinical outcomes of implantable collamer lens versus femtosecond-laser *in situ* keratomileusis and small incision lenticule extraction for moderate-to-high myopia and myopic astigmatism correction

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Abstract

Purpose: *To compare safety, efficacy, stability, and predictability of implantable collamer lens (ICL) with femtosecond-laser in situ keratomileusis (FS-LASIK) or small incision lenticule extraction (SMILE) for the correction of moderate-to-high myopia/myopic astigmatism.*

Study design: *We retrospectively collected data from patients with moderate-to-high myopia/myopic astigmatism (spherical equivalent [SE] ≥ −3.00 diopters [D]) who underwent ICL (48 eyes), FS-LASIK (36 eyes), or SMILE (86 eyes) at Hai Yen Eye Center from October 2016 to February 2018.*

Materials and methods: *The Wilcoxon Mann-Whitney U test was used to compare pre- and postoperative patients' characteristics of ICL with SMILE or FS-LASIK. Generalized linear models with unstructured correlation matrix and robust standard errors were used to analyze efficacy and safety indices; logistic regression was used for cylinder predictability.*

Results: *After controlling for age, preoperative SE, and preoperative corrected distance visual acuity (pCDVA), SMILE had significantly lower safety indices (Coefficient = −0.04, 95% CI = −0.07–−0.01) and efficacy indices (Coefficient = −0.10, 95% CI = −0.20–−0.01) than did ICL, while FS-LASIK was not significantly different from ICL (Coefficient = −0.02, 95% CI = −0.06–0.02 and Coefficient = −0.01, 95% CI= −0.10–0.09, respectively). ICL SEs were stable over 12 months after surgery. However, in FS-LASIK and SMILE, SEs significantly decreased at 12 months compared with 6 months after surgery. The percentage*

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of eyes that underwent FS-LASIK and had target SEs within ±0.5 D at 12 months was significantly lower than those that underwent ICL (OR = 0.14, 95% CI = 0.02–0.85), after controlling for age, preoperative SE, and pCDVA.
Conclusions: *For the correction of moderate-to-high myopia/myopic astigmatism, ICL seems to perform better than SMILE and FS-LASIK.*

Keywords: *femtosecond-laser in situ keratomileusis, implantable collamer lens, myopia, myopic astigmatism, small incision lenticule extraction*

Introduction

Three main surgical options to treat refractive errors are corneal reshaping, lens replacement, and intraocular lens (IOL) implantation. In femtosecond-laser in situ keratomileusis (FS-LASIK), the cornea is reshaped by using an excimer laser to ablate the corneal stroma. The main step of this surgery is to create a flap with minimal tissue damage by using ultra-short infrared laser pulses of a femtosecond laser. In contrast, small incision lenticule extraction (SMILE) is a flapless corneal refractive surgery. Instead of creating a flap, this procedure uses a femtosecond laser to create a lenticule inside the corneal stroma and a small incision through which a whole lenticule is extracted. The incision size in SMILE is approximately 2–3 mm, 7–10 times shorter than the incision used in FS-LASIK (20–22 mm).[1] Another option for correcting refractive errors is to implant a collamer lens between the crystalline lens and the iris. The STAAR Surgical Co. (Monrovia, CA, USA) Visian implantable collamer lens (ICL) is currently the only posterior-chamber phakic IOL approved for use in the United States.[2]

All of these refractive surgeries can be used to correct myopia with or without astigmatism. Many studies have confirmed the safety and effectiveness of ICL in correcting low-moderate-to-high myopia and myopic astigmatism.[3-5] Several studies have compared refractive outcomes between FS-LASIK and SMILE among different populations.[6-9] However, few studies have compared ICL with FS-LASIK or SMILE,[10] and most of these studies were conducted on Caucasian populations, who may have different ocular characteristics to those of Asian populations.[11,12] One study in India showed that ICL had higher safety and efficacy indices than did FS-LASIK and SMILE for myopic astigmatism correction 1 year after surgery.[10] However, the authors did not examine these differences longitudinally. The present study aimed to compare the safety, efficacy, stability, and predictability between ICL and SMILE and between ICL and FS-LASIK for the correction of moderate-to-high myopia and myopic astigmatism among southern Vietnamese patients. Results from our research will contribute to the findings regarding three different refractive surgeries among a South East Asian population.

Methods

A retrospective cohort study was used to compare data of patients with moderate-to-high myopia and myopic astigmatism who underwent ICL, FS-LASIK, or SMILE. Different surgeons with minor variations in their techniques performed procedures from February 2016 to February 2018 at three clinics: Hai Yen Eye Center, An Sinh Hitec Eye Center, and 304 Hitec Eye Center. All patients had a bilateral procedure on the same day (SMILE and FS- LASIK) or within 1 week (ICL). Moderate-to-high myopia and myopic astigmatism were defined as having preoperative spherical equivalent (SE) worse than −3.00 diopters (D). No potentially identifiable information was collected. Only patients with available uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), spherical error, and cylindrical error before and after the surgery at 1 month, 6 months, and 12 months were included. Patients who had a history of other refractive surgery were excluded. We performed corneal topography, which was measured with the Pentacam (Oculus Optikgerate GmbH, Wetzlar, Germany), for all patients prior to surgery. The study protocol was approved by the Ethical Review Committee of the An Sinh Hospital (1062-18/AS-QD).

Surgical procedures

ICL

We used V4c Visian ICL (Staar Surgical AG, Nidau, Switzerland) with central hole. Toric ICL was used for suitable patients whose cylindrical errors were worse than −0.50 D. Posterior chamber IOL size and power calculation were performed with the software provided by the manufacturer (Online Calculation & Ordering System). Manifest refraction, white-to-white corneal diameter, and anterior chamber depth were measured to determine the appropriate size and refractive power of the V4c-ICL. White-to-white diameter and anterior chamber depth were measured with the Park1 and Pentacam (Oculus Optikgerate). Before surgery, cycloplegic and phenylephrine eye drops were applied. Peribulbar anesthesia was achieved using lidocaine 2%. After making a 3-mm temporal clear corneal incision, the viscoelastic material (hydroxypropyl methylcellulose) was placed into the anterior chamber. The viscoelastic material was completely washed out at the end of the surgery. Then, a surgeon used an ICL injector and manipulator to insert the lens into the posterior chamber.

After surgery, moxifloxacin and dexamethasone 0.1% eye drops were applied 4–6 times daily for 4 weeks. Surgery was performed on the second eye during the first postoperative week after surgery on the first eye.

FS-LASIK and SMILE

We used 0.5% proparacaine as a topical anesthetic. In the FS-LASIK procedure, a 500-kHz VisuMax femtosecond laser (Carl Zeiss Meditec AG, Jena, Germany) was used to create a flap (8.1-mm diameter and 110-μm thickness) with 59° hinges (4.20 mm length) and 45° side-cut angles. A pulse energy of 185 nJ was used to create lamellar and side cuts. We used a MEL-80 (Carl Zeiss Meditec) excimer laser with a frequency of 250 Hz to perform stromal tissue ablation using a 6.5-mm optical zone in all cases. In the SMILE procedure, the VisuMax femtosecond laser system was employed using femtosecond lasers with a frequency of 500 kHz and pulse energy of 130 nJ. Spot distance and track distance of lenticule and cap cut were 4.5 μm. Lenticule side and cap side-cut were 2.5 μm and 2.0 μm, respectively. The treatment parameters were set at a cap thickness of 120 μm, an incision width range of 2–4 mm, a lenticule diameter of 6.5 mm, and a lenticule side-cut angle of 90°. Immediately after surgery, patients received moxifloxacin and dexamethasone 0.1% eye drops. Patients applied moxifloxacin and dexamethasone 0.1% eye drops four times a day for 1 week. In addition, patients administered sodium hyaluronate 0.18% eye drops four times a day, beginning at 1 day after surgery and continuing for 6 months.

Measurement

The efficacy index was determined as a ratio between postoperative UCVA and preoperative CDVA. The safety index was measured by a ratio between postoperative CDVA and preoperative CDVA. The percentages of gain of 1, 2, or > 2 lines or loss of 1, 2, or > 2 lines of postoperative CDVA were compared with preoperative CDVA based on LogMAR values. Stability was measured by a change in the mean SE and cylindrical errors over 12 months after surgery. SE was calculated by adding spherical errors to half of cylindrical errors. Predictability was measured by percentage of eyes within ±0.5 D of target SE at 12 months after surgery.

Data analyses

Analyses were performed with Stata version 13 (StataCorp LP, College Station, TX, USA). Mean, standard deviation, frequencies, and percentages were used to describe the efficacy index, the safety index, and other characteristics. We used the Wilcoxon Mann-Whitney rank test to compare patients' pre- and postoperative characteristics between surgeries. Variables associated with type of surgery with $p < 0.25$ were included in the multivariate models. Generalized linear models with unstructured correlation matrix and robust standard errors were used to compare efficacy and safety indices longitudinally between ICL and SMILE or between ICL and FS-LASIK, controlling for other factors. We used multivariate logistic regression to compare cylinder predictability between

groups. The final model was selected if it had the least likelihood ratio score. A two-sided $p < 0.05$ was considered statistically significant.

Results

Our analyses included 170 eyes that underwent ICL (48 eyes), FS-LASIK (36 eyes), or SMILE (86 eyes). Table 1 provides patients' pre-operative demographics and refractive errors. The mean age was 23.35 years (*SD* = 3.55) in the ICL group, 26.78 years (*SD* = 6.29) in the FS-LASIK group, and 24.95 years (*SD* = 5.27) in the SMILE group. The mean preoperative SE was −10.46 ± 3.10 (*SD*) D in the ICL group, −6.12 ± 2.46 (*SD*) D in the FS-LASIK group, and −5.69 ± 1.58 (*SD*) D in the SMILE group. There were significant differences in terms of age and preoperative UDVA, CDVA, spherical errors, cylindrical errors, SE, and central corneal thickness (CCT) in the ICL group, compared with the FS-LASIK group or with the SMILE group (Wilcoxon Mann Whitney rank test, all $p < 0.05$). There was a statistically insignificant difference between these groups regarding intraocular pressure.

Table 2 shows the comparison of clinical outcomes between ICL, FS-LASIK, and SMILE. The mean efficacy indices of ICL were significantly higher at 1 month (0.98 ± 0.16), 6 months (0.98 ± 0.18), and 12 months (0.96 ± 0.18) after surgery than in SMILE (0.89 ± 0.20, 0.92 ± 0.17, and 0.86 ± 0.18, respectively). The ICL indices were lower than the FS-LASIK indices (1.00 ± 0.16, 0.98 ± 0.15, and 0.94 ± 0.16, respectively), but this difference was not statistically significant. Percentages of eyes were comparable among the three surgery types over the three time points. At 12 months, the percentages of ICL, FS-LASIK, and SMILE recipients with UCVA ≥ 5/10 were 97.92%, 94.44%, and 95.35%, respectively (Fig. 1). However, more eyes that had undergone FS-LASIK had UCVA ≥ 8/10 and ≥ 10/10 than eyes that had undergone ICL or SMILE; at 12 months after surgery, 41.67% of eyes that underwent ICL had UCVA ≥ 10/10, compared with 69.44% of eyes that underwent FS-LASIK and 36.05% of eyes that underwent SMILE.

The mean safety indices of the ICL group were 1.08 ± 0.13, 1.08 ± 0.14, and 1.07 ± 0.12 at the 1-, 6-, and 12-month follow-ups, respectively. These indices were significantly better than those of SMILE (1.01 ± 0.07, 1.01 ± 0.08, and 1.00 ± 0.05, respectively) at three time points, but only significantly better at the 12-month follow-up for the FS-LASIK group (1.03 ± 0.10, 1.04 ± 0.09, and 1.04 ± 0.16, respectively) (Table 2). At 6 months after ICL, 39 eyes (81.25%) showed no change in CDVA, 5 eyes (10.42%) gained 1 line, 4 eyes (8.33%) gained 2 lines, and 0 eyes lost 1 line or 2 lines. At the same time point after FS-LASIK, 30 eyes (83.33%) showed no change in CDVA, 6 eyes (16.67%) gained 1 line, 0 eyes (0.00%) gained 2 lines, and 0 eyes (0.00%) lost 1 line or 2 lines. Finally, 6 months after SMILE, 78 eyes (90.70%) showed no change in CDVA, 6 eyes (6.98%) gained 1 line, 0 eyes (0.00%) gained 2 lines, 1 eye (1.16%) lost 1 line, and 1 eye (1.16%) lost 2 lines (Fig. 2). At

Table 1. Preoperative demographic and clinical characteristics of patients who underwent ICL, FS-LASIK, or SMILE

Characteristics	ICL (*N* = 48 eyes)		FS- LASIK (*N* = 36 eyes)			SMILE (*N* = 86 eyes)		
	Mean ± SD	Range (Min, Max)	Mean ± SD	Range (Min, Max)	*p*-value*	Mean ± SD	Range (Min, Max)	*p*-value*
Age, years	23.35 ± 3.55	(18, 33)	26.78 ± 6.29	(20, 41)	0.007	24.95 ± 5.27	(18, 38)	0.164
CDVA, LogMAR	0.042 ± 0.087	(0.00,0.52)	0.015 ± 0.052	(0.00, 0.22)	0.001	0.003 ± 0.010	(0.00, 0.04)	< 0.0001
CDVA, Decimal	0.92 ± 0.13	(0.3, 1.0)	0.97 ± 0.10	(0.6, 1.0)	0.001	0.99 ± 0.02	(0.9, 1.0)	< 0.0001
Spherical errors, D	−9.52 ± 3.26	(−18.25, −0.75)	−5.73 ± 2.24	(−10.75, −2.75)	< 0.0001	−5.18 ± 1.45	(−8.50, −2.50)	< 0.0001
Cylindrical errors, D	−1.87 ± 1.27	(−6.00, 0.00)	−0.77 ± 0.64	(−2.25, 0.00)	< 0.0001	−1.01 ± 1.01	(−5.00, 0.00)	< 0.0001
SE, D	−10.46 ± 3.10	(−18.50, −3.00)	−6.12 ± 2.46	(−11.625, −3.00)	< 0.0001	−5.69 ± 1.58	(−9.50, −3.00)	< 0.0001
Intraocular pressure, mmHg	15.82 ± 1.90	(12, 19)	16.44 ± 2.99	(11, 23)	0.530	16.28 ± 2.29	(10, 20)	0.201
Central corneal thickness, mm	523.17 ± 42.95	(466, 663)	542.17 ± 21.96	(487, 586)	0.003	542.47 ± 34.58	(454, 638)	0.002

CDVA: corrected distance visual acuity; D: diopter; FS-LASIK: femtosecond-laser in situ keratomileusis; ICL: implantable collamer lens; LogMAR: logarithm of the minimum angle of resolution; SE: spherical equivalent; SMILE: small incision lenticule extraction; UDVA: uncorrected distance visual acuity
***Wilcoxon Mann Whitney rank test results between FS-LASIK and ICL, or between SMILE and ICL.**

Table 2. Summary of clinical outcomes comparing ICL with FS-LASIK or SMILE

Clinical outcomes	ICL	FS-LASIK		SMILE	
	Mean ± *SD*	Mean ± *SD*	*p*-value*	Mean ± *SD*	*p*-value*
UDVA, LogMAR					
1 month after surgery	0.06 ± 0.09	0.02 ± 0.10	0.005	0.07 ± 0.13	0.562
6 months after surgery	0.06 ± 0.10	0.03 ± 0.11	0.030	0.05 ± 0.10	0.676
12 months after surgery	0.07 ± 0.10	0.05 ± 0.11	0.037	0.08 ± 0.12	0. 557
CDVA, LogMAR					
1 month after surgery	0.010 ± 0.067	0.003 ± 0.069	0.120	-0.001 ± 0.031	0.217
6 months after surgery	0.011 ± 0.052	-0.001 ± 0.050	0.019	-0.001 ± 0.038	0.010
12 months after surgery	0.013 ± 0.066	0.002 ± 0.035	0.236	0.003 ± 0.018	0.681
Spherical errors, D					
1 month after surgery	0.35 ± 0.30	0.11 ± 0.30	0.001	-0.12 ± 0.33	< 0.0001
6 months after surgery	0.34 ± 0.29	0.15 ± 0.31	0.005	-0.06 ± 0.29	< 0.0001
12 months after surgery	0.16 ± 0.38	-0.03 ± 0.37	0.011	-0.11 ± 0.30	< 0.0001
Cylindrical errors, D					
1 month after surgery	-0.75 ± 0.54	-0.20 ± 0.26	< 0.0001	-0.29 ± 0.26	< 0.0001
6 months after surgery	-0.71 ± 0.59	-0.28 ± 0.32	0.0002	-0.27 ± 0.27	< 0.0001
12 months after surgery	-0.61 ± 0.59	-0.19 ± 0.28	0.0003	-0.28 ± 0.27	0.0007
Spherical equivalent, D					
1 month after surgery	-0.02 ± 0.38	0.01 ± 0.34	0.536	-0.26 ± 0.35	0.0006
6 months after surgery	-0.02 ± 0.32	0.01 ± 0.31	0.810	-0.19 ± 0.31	0.004
12 months after surgery	-0.14 ± 0.40	-0.13 ± 0.45	0.926	-0.25 ± 0.31	0.010
Within ±0.5 D of target SE at 12 months after surgery (SE predictability)			0.627**		0.555**
No	5 (10.42%)	5 (13.89%)		12 (13.95%)	
Yes	43 (89.58%)	31 (86.11%)		74 (86.05%)	
Efficacy index					
1 month after surgery	0.98 ± 0.16	1.00 ± 0.16	0.529	0.89 ± 0.20	0.007
6 months after surgery	0.98 ± 0.18	0.98 ± 0.15	0.676	0.92 ± 0.17	0.011
12 months after surgery	0.96 ± 0.18	0.94 ± 0.16	0.556	0.86 ± 0.18	0.0009
Safety index					
1 month after surgery	1.08 ± 0.13	1.03 ± 0.10	0.055	1.01 ± 0.07	0.0001
6 months after surgery	1.08 ± 0.14	1.04 ± 0.09	0.072	1.01 ± 0.08	< 0.0001
12 months after surgery	1.07 ± 0.12	1.04 ± 0.16	0.042	1.00 ± 0.05	< 0.0001

CDVA: corrected distance visual acuity; D: diopter; FS-LASIK: femtosecond-laser in situ keratomileusis; ICL: implantable collamer lens; LogMAR: logarithm of the minimum angle of resolution; SE: spherical equivalent; SMILE: small incision lenticule extraction; UDVA: uncorrected distance visual acuity

***Wilcoxon Mann Whitney rank test results between FS-LASIK and ICL or between SMILE and ICL.**

****Chi-squared test between FS-LASIK and ICL or between SMILE and ICL.**

Table 3. Multivariate analyses for selected clinical outcomes

Variables	Efficacy index			Safety index			SE predictability		
	Coef.	95% CI	*p*-value*	Coef.	95% CI	*p*-value*	OR	95% CI	*p*-value**
Age	−0.01	(−0.01–−0.00)	0.027	0.00	(−0.00–0.00)	0.826	0.92	(0.84–1.00)	0.062
Surgery type									
ICL	1			1			1		
FS-LASIK	−0.01	(−0.10–0.09)	0.889	−0.02	(−0.06–0.02)	0.275	0.26	(0.05–1.38)	0.112
SMILE	−0.10	(−0.20–−0.01)	0.048	−0.04	(−0.07–−0.01)	0.005	0.14	(0.02–0.85)	0.033
Preoperative spherical error									
−3.0 D– −5.9 D	1			1			1		
−6.0 D–−8.9 D	−0.05	(−0.11–−0.01)	0.082	−0.01	(−0.03–0.00)	0.126	0.60	(0.19-1.89)	0.385
≤ −9.0 D	−0.09	(−0.19–−0.01)	0.086	−0.02	(−0.06–0.02)	0.368	0.10	(0.02-0.60)	0.011
Preoperative CDVA	0.81	(0.41-1.21)	<0.0001	1.12	(0.33–1.91)	0.006	0.15	(0.00-156.82)	0.593

CDVA: corrected distance visual acuity; Coef: regression coefficient; D: diopter; FS-LASIK: femtosecond-laser in situ keratomileusis; ICL: implantable collamer lens; LogMAR: logarithm of the minimum angle of resolution; OR: odds ratio; SE: spherical equivalent; SMILE: small incision lenticule extraction; UDVA: uncorrected distance visual acuity

***Generalized linear model with unstructured correlation matrix and robust standard errors**

****Logistic regression**

12 months after ICL, 39 eyes (81.25%) showed no change in CDVA, 7 eyes gained 1 line (14.58%), and 2 eyes gained 2 lines (4.17%). At the same time point after FS-LASIK, 27 eyes (75.00%) showed no change in CDVA, 7 eyes (11.11%) gained 1 line, and 2 eyes (5.56%) gained 2 lines. Finally, at 12 months after SMILE, 84 eyes (97.67%) showed no change in CDVA, 2 eyes (2.33%) gained 1 line, and 0 eyes (0.00%) gained 2 lines (Fig. 2). However, there were 3 eyes that lost 1 line at the 12-month follow-up after FS-LASIK (8.33%).

The mean change in SE over time for the three surgical types is depicted in Fig. 3 and Table 2. The differences in SE between ICL and FS-LASIK at 1, 6, and 12 months after surgery were not statistically significant (p = 0.536, 0.810, and 0.926, respectively). However, the differences in SE between ICL and SMILE at 1, 6, and 12 months after surgery were significant, with p = 0.0006, 0.004, and 0.010, respectively.

Stability of cylindrical error and SE of the three surgery types are shown in Fig. 3. Before surgery, the ICL group had higher SE and cylindrical error than did the FS-LASIK and SMILE groups. Cylindrical error remained higher in the ICL group after surgery. Comparisons of SE between 6 months and 1 month or between 12 months and 6 months in the ICL group showed no significant difference (p = 0.945 and 0.110, respectively) (data not shown). For both the FS-LASIK and SMILE groups, although there was no significant difference in SE at 6 months and 1 month (p = 0.778 and 0.075, respectively), SE at 12 months significantly increased compared with SE at 6 months (p = 0.010 and 0.018, respectively).

SE predictability at 12 months after surgery was within ±0.5 D in 89.58% of eyes in the ICL group compared with 86.11% of eyes in the FS-LASIK group and 86.05% of eyes in the SMILE group. However, there were no significant differences between eyes in the ICL and FS-LASIK groups or between eyes in the ICL and SMILE groups (Table 2). The percentage of eyes that had target SEs within ±1.0 D was higher in the ICL (95.83%) group than in the FS-LASIK (91.67%) group, but lower than in the SMILE (97.67%) group (Fig. 4).

Table 3 presents the results of the longitudinal multivariate analyses. Variables were selected for the multivariate model if they had $p < 0.25$ in our univariate analyses. Although CCT was significantly associated in the univariate analyses ($p <$ 0.05), it was not significantly different among these surgery types in the multivariate analyses. In addition, the multivariate model with CCT had lower goodness of fit than did the model without CCT. So, this variable was removed from the final model. The final model showed that ICL had significantly better safety and efficacy indices than did SMILE over 12 months (Coefficient = −0.04, 95% CI = −0.07−−0.01 and Coefficient= −0.10, 95% CI= −0.20−−0.01, respectively), after controlling for age, preoperative SE, and preoperative CDVA. The percentage of eyes that underwent ICL and had target SEs within ±0.5 D at 12 months was

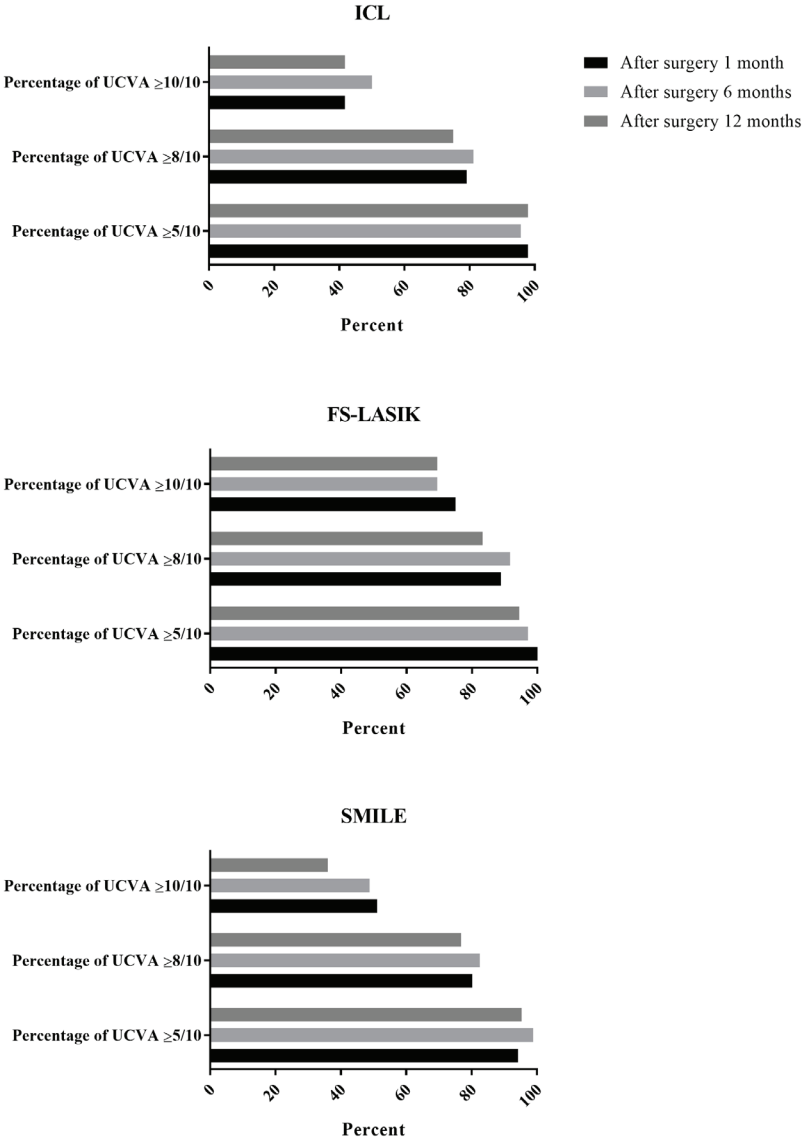
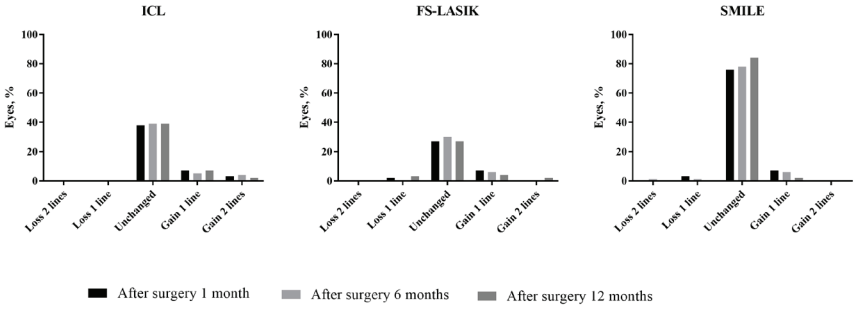


Fig. 1. Percentage of uncorrected distance visual acuity (UCVA) ≥ 5/10, 8/10, and 10/10 at each time point, by surgery type.



	After surgery 1 month			After surgery 6 months			After surgery 12 months		
	ICL	FS-LASIK	SMILE	ICL	FS-LASIK	SMILE	ICL	FS-LASIK	SMILE
Loss 2 lines	0.00%	0.00%	0.00%	0.00%	0.00%	1.16%	0.00%	0.00%	0.00%
Loss 1 line	0.00%	5.56%	3.49%	0.00%	0.00%	1.16%	0.00%	8.33%	0.00%
Unchanged	79.17%	75.00%	88.37%	81.25%	83.33%	90.70%	81.25%	75.00%	97.67%
Gain 1 line	14.58%	19.44%	8.14%	10.42%	16.67%	6.98%	14.58%	11.11%	2.33%
Gain 2 lines	6.25%	0.00%	0.00%	8.33%	0.00%	0.00%	4.17%	5.56%	0.00%

Fig. 2. Changes in corrected distance visual acuity (CDVA) at each time point, by surgery type.

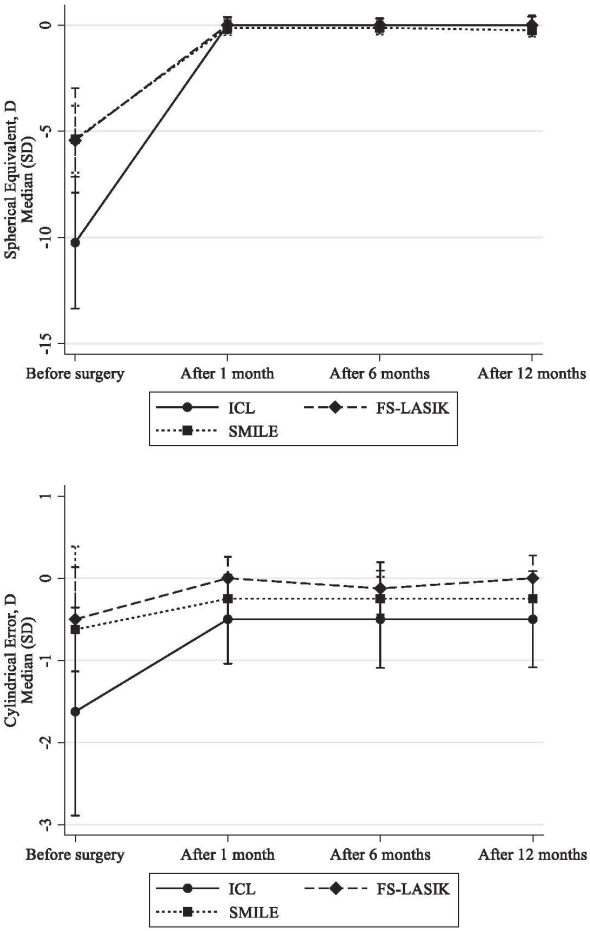
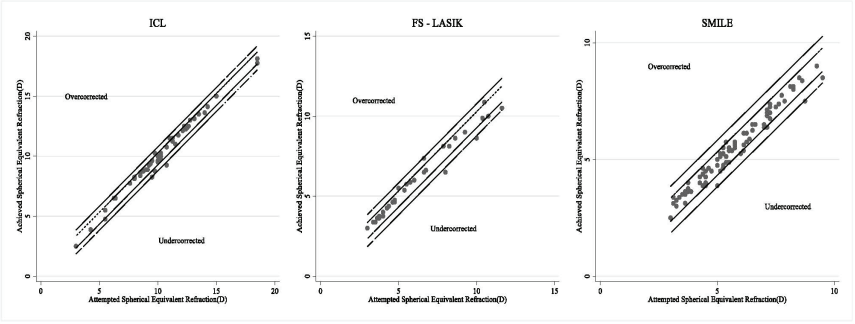


Fig. 3. Stability of spherical equivalent and cylindrical error at each time point, by surgery type.



SE predictability at 12 months after surgery

	N	Target SE within ± 0.25 D *n* (%)	Target SE within ± 0.5 D *n* (%)	Target SE within ± 1 D *n* (%)
ICL	48	33 (68.75%)	43 (89.58%)	46 (95.83%)
FS-LASIK	36	28 (77.78%)	31 (86.11%)	33 (91.67%)
SMILE	86	57 (66.28%)	74 (86.05%)	84 (97.67%)

Fig. 4. Scattergram of attempted versus achieved spherical errors (SE) by surgery type at 12 months after surgery.

significantly seven times higher than that of eyes that underwent SMILE (OR = 0.14, 95% CI = 0.02–0.85), after controlling for age, preoperative SE, and preoperative CDVA.

Discussion

Our results showed that ICL had favorable outcomes compared with FS-LASIK and SMILE in terms of efficacy, safety, stability, and predictability throughout 12 months after surgery to correct moderate-to-high myopia and myopic astigmatism. Our findings are consistent with those of the study of an Indian population by Ganesh *et al.*[10] However, the safety and efficacy indices in our three groups were lower than those in the Ganesh study. This discrepancy might be due to a different preoperative SE range and our larger sample size. Our patients had SEs higher than −9 D, while patients in the Ganesh *et al.* study had SEs in the range of −3 to −8 D.

Before surgery, the mean SE among our ICL group (−10.46 ± 3.10) was significantly higher than that among the FS-LASIK (−6.12 ± 2.46) and SMILE groups (−5.69 ± 1.58). At 1-, 6-, and 12-month follow-ups, the SE means (−0.02 ± 0.38, −0.02 ± 0.32, and −0.14 ± 0.40, respectively) of the ICL group were significantly lower than those of the SMILE group (−0.26 ± 0.35, −0.19 ± 0.31, and −0.25 ± 0.31, respectively) and were comparable to those of the FS-LASIK group (0.01 ± 0.34, 0.01 ± 0.31, and −0.13 ± 0.45, respectively). Eyes that received ICL showed no loss of lines at 1, 6, and 12 months after surgery. These findings suggest that ICL

had better efficacy and safety than did FS-LASIK and SMILE in correcting moderate-to-high myopia and myopic astigmatism. This result was confirmed again in our longitudinal multivariate analysis, which showed that after controlling for age, preoperative SE, and preoperative CDVA, ICL had higher efficacy and safety indices than did SMILE (p =0.048 and 0.005, respectively) and FS-LASIK (p = 0.889 and 0.275, respectively). However, other studies with larger sample size and with prospective follow-up are needed to reinforce the result.

With regard to stability and predictability, ICL scored better than did either FS-LASIK or SMILE. The refractive regression was observed after both types of laser vision correction, while ICL implantation showed stable results throughout 12 months after surgery. This finding may be due to the small corneal incision (3 mm) and no need for removal of corneal tissue during ICL, which induces fewer corneal wound healing responses and fewer changes in corneal biomechanics.[13] The percentage of SE predictability within ±0.5 D at 12 months was higher in the ICL group than in the FS-LASIK and SMILE groups.

Our study had some advantages. First, to our knowledge, the current study was one of the few studies comparing the efficacy and safety indexes and the stability of ICL to those of FS-LASIK or to those of SMILE in an Asian population.[10] Ocular characteristics of Caucasians are different from those of Asian populations,[11,12] which may influence evaluation of refraction surgery outcomes. Second, instead of matching some preoperative patient characteristics, which might cause selection bias, we used multivariate analyses to control for the confounding factors. In order to longitudinally analyze repeated refractive outcomes over time, the generalization estimate equation was employed. Finally, our sufficient sample size assisted us in detecting significant results.

However, this study had some limitations. First, the study was retrospectively conducted, which may decrease the quality of evidence. Although this is a multicenter study with a large cohort of patients, a prospective randomized control trial would be ideal to confirm our results. Second, only patients who had available refractive errors at 1-, 6-, and 12- months after surgery were included. This approach might cause selection bias. Third, ICL, FS-LASIK, and SMILE were performed by different experienced surgeons. Variations in surgical technique may have influenced our results. However, according to Yo and colleagues, results of refractive surgery between surgeons are comparable under standardized surgical techniques.[14]

Overall, our results favored ICL over SMILE and FS-LASIK for the treatment of moderate-to-high myopia and myopic astigmatism. However, the appropriate surgical procedure should be chosen based on preoperative parameters and patient preferences.

Declarations

Ethics approval and consent to participate

This retrospective study was approved by the Ethical Review Committee of the An Sinh Hospital (1062-18/AS-QD).

Competing interests

None to declare.

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None to declare.

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