

Comparison of clinical outcomes after femtosecond laser *in situ* keratomileusis in eyes with low or high myopia

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Abstract

• **AIM:** To compare the clinical results of femtosecond (FS) laser *in situ* keratomileusis (LASIK) in high myopic patients and low myopic patients.

• **METHODS:** This study included 212 myopic eyes undergoing LASIK using a VisuMax 500kHz FS laser. All treated eyes were assigned to one of two groups according to preoperative manifest spherical refraction: low myopia group (A, >−4.0 D) and high myopia group (B, ≤−4.0 D). Uncorrected and corrected distance visual acuity (UDVA, CDVA), refractive errors, and higher-order aberrations (HOAs) were measured preoperatively and 1wk, 1, 3 and 6mo postoperatively.

• **RESULTS:** At 6mo of follow-up, 92% and 76% had a UDVA of 20/20 or better in group A and B, respectively ($P=0.037$) and UDVA was significantly different between two groups ($P=0.042$). Six and seven percentage lost one line of CDVA in group A and B, respectively ($P=0.572$) and no eyes in both groups lost more than two lines. Each group had 87% and 76% of treated eyes within ± 0.5 D of

the intended correction ($P=0.186$), and 13% and 43% with a change of >0.50 D in spherical equivalent from 1wk to 6mo postoperatively ($P=0.005$). In terms of postoperative astigmatism, each group had 89.1% and 76.6% within ± 0.50 D, respectively and there was significant difference ($P=0.006$). Group A tends to induce smaller HOAs than group B.

• **CONCLUSION:** FS LASIK is effective and safe for correcting high myopia as well as low myopia. However, high myopic eyes showed more postoperative astigmatism and HOAs which affect visual acuity.

• **KEYWORDS:** femtosecond laser; LASIK; myopia

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INTRODUCTION

Laser-assisted *in situ* keratomileusis (LASIK) is the most common refractive surgery. LASIK consists of two main steps, corneal flap creation and stromal photoablation^[1]. The first step which has been performed by mechanical microkeratomers traditionally is very important because most of complications such as irregular cuts, free caps, and buttonholes occur during this procedure^[2]. Recently femtosecond (FS) laser has been used to make corneal flaps to reduce these problems. FS laser is an infrared laser using a 1053-nm wavelength and produces photoionization or photodisruption of the optically transparent tissue^[3]. These effects result in the formation of micro cavitation bubbles, thereby creating cleavage planes on the cornea. FS laser created flaps provide the accurate and customized flap diameter, thickness, hinge position, side-cut angle, and length, making LASIK safer and more predictable^[4]. Furthermore, FS laser created flaps can reduce not only intraoperative complications, but also postoperative myopic regression by epithelial hyperplasia^[5].

Recent articles reported that overall FS LASIK were predictable and safe^[6]. However, most of studies included

Table 1 Baseline characteristics of two groups

Parameters	Group A	Group B	mean±SD <i>P</i>
Age (y)	30±7 (19 to 45)	28±7 (19 to 47)	0.220
Sex (M:F)	24:40	11:31	
IOP (mm Hg)	15.69±2.58 (8 to 21)	16.65±2.46 (10 to 22)	0.091
Mean corneal power (D)	44.23±1.52 (40.25 to 47.12)	44.50±1.63 (39.75 to 47.62)	0.087
MR sphere (D)	-2.23±0.72 (-3.75 to -1.00)	-5.92±1.32 (-8.50 to -4.00)	<0.001
MR cylinder (D)	-0.77±0.60 (-2.75 to 0.00)	-1.21±0.68 (-2.75 to 0.00)	<0.001
MR SE (D)	-2.61±0.78 (-5.13 to -1.00)	-6.52±1.34 (-9.25 to -4.50)	<0.001
UDVA (logMAR)	1.48±0.22 (1 to 2)	1.57±0.23 (0.8 to 2)	0.047
CDVA (logMAR)	-0.053±0.037 (-0.1 to 0)	-0.045±0.041 (-0.1 to 0)	0.082
CCT (μm)	520.5±28.9 (458 to 583)	525±31.5 (462 to 607)	0.058

CCT: Central corneal thickness; CDVA: Corrected distance visual acuity; D: Diopter; logMAR: Logarithm of the minimal angle; MR: Manifest refraction; SE: Spherical equivalent; UDVA: Uncorrected distance visual acuity.

various range of refractive errors in their studies, and few studies have compared the results of FS LASIK depending on the degree of myopia. Therefore, we tried to compare the efficacy, safety, predictability, stability, astigmatism and higher-order aberrations (HOAs) between low and high myopia group.

SUBJECTS AND METHODS

Ethical Approval This study was approved by an Institutional Review Board (Pusan National University Hospital IRB, No. 05-2016-117). All process was performed according to the tenets of the Declaration of Helsinki and all patients were provided written informed consent.

Patients FS LASIK was performed at the BalGunNun Eye Hospital from May 2016 to May 2018. We evaluated the clinical records of patients who underwent FS LASIK and postoperative examinations regularly at least 6mo. Inclusion criteria were: age ≥18y; corrected distance visual acuity (CDVA) of 20/20 or better; spherical myopia >-10.0 D; myopic astigmatism >-3.0 D; and stable refraction for 2y. Exclusion criteria were: a history of ocular disease other than myopia or astigmatism; a history of ocular trauma or surgery; and patients with systemic diseases. All patients were assigned to one of two groups according to the degree of their preoperative manifest spherical refraction: group A, comprising low myopia eyes (>-4.0 D), and group B, comprising high myopia eyes (≤-4.0 D). The main outcome measures were efficacy, safety, predictability, stability, refractive astigmatism and HOAs in both groups.

Preoperative Assessments All patients underwent full ophthalmologic examinations preoperatively including uncorrected distance visual acuity (UDVA) and CDVA, manifest and cycloplegic refractions, slit-lamp microscopy, tonometry (TX-F; Canon, Tokyo, Japan), corneal pachymetry (Sp-100; Tomey, Nagoya, Japan), keratometry (KR 9900; Topcon, Tokyo, Japan), corneal topography and aberration (Pentacam; Oculus, Wetzlar, Germany) and fundus examination.

Surgical Procedures The FS LASIK was performed by one surgeon (Kim YH) with the VisuMax FS laser system (Carl Zeiss Meditec AG; Jena, Germany) using the repetition rate of 500 kHz for the creation of corneal flaps. The intended flap diameter and thickness were 8.1-8.5 mm and 90-100 μm, respectively. The position and angle of the hinge were set at 90° and 55°. The track and spot distances were set as 4.0 mm for flap creation and 1.5 mm for making the flap side cut. After lifting the flap, the excimer laser was used for stromal ablation and the flap was carefully repositioned over the stroma.

Postoperative Evaluations All patients were routinely examined at postoperative 1wk, and 1, 3 and 6mo. At every visit, UDVA, CDVA, keratometry, manifest and objective refractions, corneal topography and aberration, and slit-lamp examination were performed.

Astigmatic Analysis The target induced astigmatism (TIA) is defined as the astigmatic change the surgery was intended to induce, and it was same as preoperative astigmatism in this study because the target was emmetropia. The surgically induced astigmatism (SIA) is defined as the amount and axis of astigmatic change the surgery induced. Correction index (CI) is calculated by determining the SIA-to-TIA ratio by dividing SIA by TIA.

Statistical Analysis All data were statistically analyzed using SPSS Statistics 19.0 (SPSS Inc, Chicago, IL, USA). The Kolmogorov-Smirnov test was used to test for normality. Independent *t*-tests were used to analyze the data between two groups. To compare proportions, Chi-squared test was used. Statistical significance was considered as *P*<0.05.

RESULTS

Patients and Preoperative Demographics This study included total of 212 eyes of 106 patients. Table 1 summarizes the preoperative demographics. Groups A and B included 128 and 84 eyes, respectively. The two groups showed significant differences in mean manifest refraction (MR) of sphere,

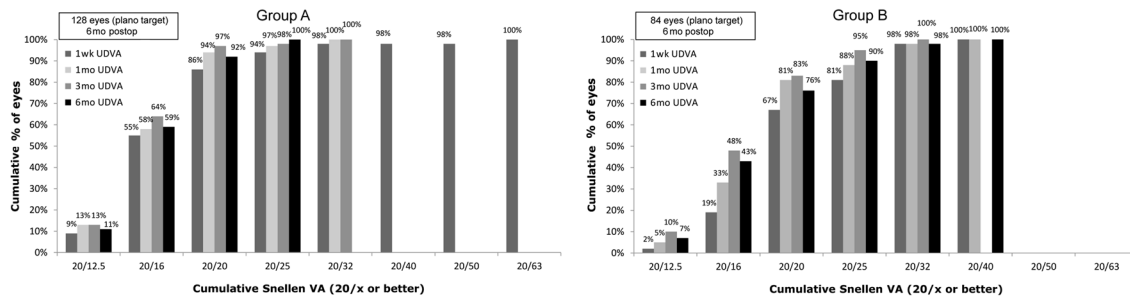


Figure 1 Comparison of postoperative cumulative UDVA during 6mo postoperatively The proportion of eyes achieving UDVA ≥ 20/20 at 6mo postoperatively was 92% in group A and 76% in group B (P=0.037).

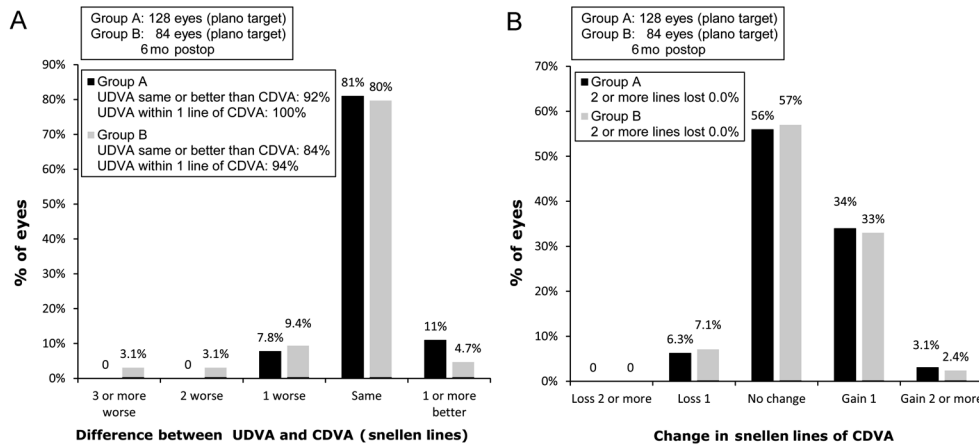


Figure 2 The difference between UDVA and CDVA and the changes in Snellen lines of CDVA A: Difference between UDVA and CDVA at postoperative 6mo showed that group A had higher proportion of better results, but no significant difference was observed; B: Changes in Snellen lines of CDVA showed that no eyes lost two or more lines in both groups 6mo after surgery.

Table 2 UDVA and CDVA changes in two groups

Parameters	UDVA logMAR		P	CDVA logMAR		P
	Group A	Group B		Group A	Group B	
1wk	0.02±0.10	0.05±0.13	0.563	-0.01±0.08	-0.00±0.09	0.154
1mo	-0.02±0.08	0.02±0.09	0.089	-0.08±0.06	-0.07±0.06	0.317
3mo	-0.08±0.09	-0.03±0.09	0.115	-0.10±0.07	-0.08±0.03	0.531
6mo	-0.09±0.09	-0.04±0.08	0.042	-0.13±0.06	-0.10±0.05	0.141

cylinder, and spherical equivalent (SE) and logMAR UDVA except age, sex, intraocular pressure (IOP), logMAR CDVA and central corneal thickness (CCT).

Efficacy At postoperative 1wk, and 1, 3 and 6mo, the proportion of eyes achieving UDVA ≥ 20/20 was 86%, 94%, 97%, and 92% in the group A and 67%, 81%, 83%, and 76% in the group B, respectively (Figure 1). Two groups showed significant differences at 6mo (P=0.037). There was also statistically significant difference for UDVA only at 6 month after surgery (P=0.042; Table 2). The efficacy indices were 1.05±0.18 and 1.01±0.15 in groups A and B, respectively, showing no significant differences between the groups (P=0.152).

Safety CDVA at 6mo postoperatively was used to evaluate the safety outcomes. Six percentage in group A and 7% in group B lost 1 line (P=0.572), and 37% in group A and 35% in group

B gained more than 1 line (P=0.413). No eyes lost two lines of CDVA in either group (Figure 2). The safety index was 1.18±0.17 in group A and 1.15±0.20 in group B (P=0.312).

Predictability Scatterplots of the attempted SE versus achieved SE and distribution of postoperative SE at 6mo are shown in Figure 3. The coefficient of determination (R²) was 0.980 for group A and 0.994 for group B at 6mo. The proportions of eyes within ±0.5 D and ±1.0 D of the attempted correction were 87% and 100%, respectively, in group A and 76% and 95%, respectively, in group B (P=0.186 for ±0.5 D and P=0.155 for ±1.0 D). MR sphere and MR SE showed statistically significant differences between groups at postoperative 1wk (P<0.001 and P<0.001, respectively), however, these differences were not continued until last follow up visit (P=0.752 and P=0.521 at 6mo postoperatively,

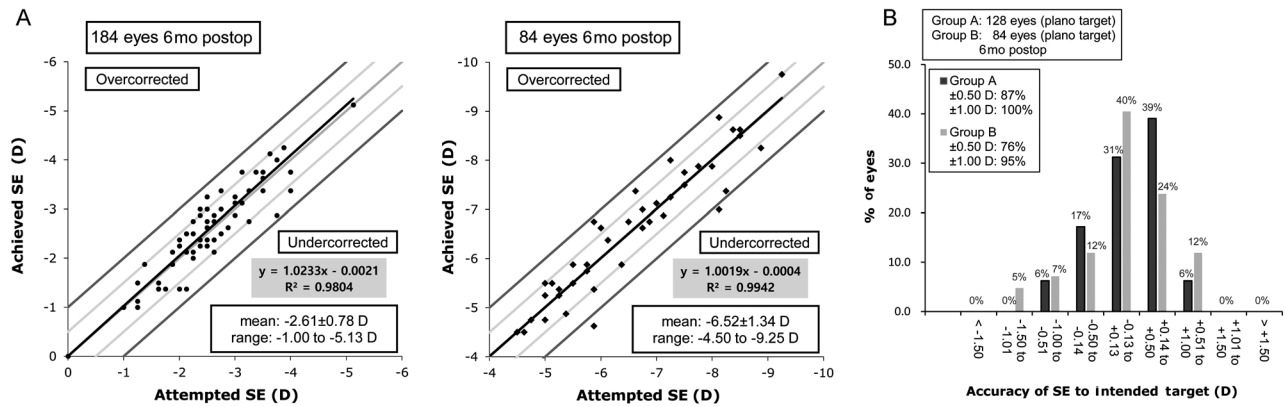


Figure 3 SE attempted versus achieved and distribution of postoperative SE at last visit after FS LASIK A: The coefficient of determination (R^2) was 0.980 for group A and 0.994 for group B at 6mo; B: In groups A and B, 87% and 76% of eyes, respectively, are within ± 0.5 D of the target refractive correction ($P=0.186$), and 100% and 95% of eyes, respectively, are within ± 1.0 D of the target refractive correction ($P=0.155$).

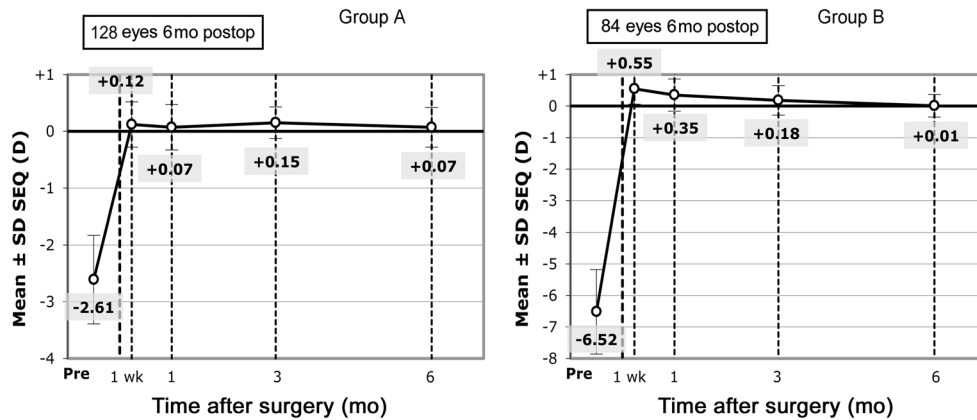


Figure 4 The mean SE over time The mean changes in SE were -0.05 ± 0.44 D in group A ($P=0.544$) and -0.53 ± 0.43 D in group B ($P<0.001$) from 1wk to 6mo postoperatively. No significant difference in SE was shown between two groups after 6mo ($P=0.495$).

respectively). In contrast, MR cylinder didn't show statistically significant difference between groups at postoperative 1wk ($P=0.061$), which finally showed a significant difference ($P=0.010$ at 6mo postoperatively; Table 3).

Stability The postoperative SE change is shown in Figure 4. Significant difference in SE between two groups was shown up to 1mo ($P<0.001$ at 1wk and $P=0.003$ at 1mo postoperatively), but not after 3mo ($P=0.679$ at 3mo and $P=0.521$ at 6mo postoperatively). The proportion of eyes with SE change over 0.50 D from 1wk to 6mo postoperatively was 12.5% in group A and 42.9% in group B ($P=0.005$). The mean changes in SE were -0.05 ± 0.44 D (-1.87 to +0.75 D) in group A ($P=0.544$) and -0.53 ± 0.43 D (-1.5 to +0.25 D) in group B ($P<0.001$) from 1wk to 6mo postoperatively.

Astigmatism The Alpíns vector method was used to determine vector analysis of the astigmatic changes^[7]. Scatterplots of TIA versus SIA and distribution of postoperative astigmatism at 6mo were shown in Figure 5. The mean TIA, SIA, and CI were 0.77 ± 0.60 D, 0.76 ± 0.54 D, and 0.96 ± 0.36 , respectively, in group A and 1.21 ± 0.68 D ($P=0.001$), 1.29 ± 0.74 D ($P<0.001$),

Parameters	Group A	Group B	mean±SD	P
MR sphere (D)				
1wk	0.25±0.40	0.73±0.57		<0.001
1mo	0.19±0.42	0.55±0.53		<0.001
3mo	0.23±0.28	0.39±0.56		0.093
6mo	0.19±0.35	0.22±0.52		0.752
MR cylinder (D)				
1wk	-0.25±0.27	-0.37±0.40		0.061
1mo	-0.23±0.26	-0.40±0.30		0.004
3mo	-0.18±0.18	-0.43±0.37		0.001
6mo	-0.24±0.27	-0.41±0.35		0.010
MR SE (D)				
1wk	0.12±0.40	0.55±0.49		<0.001
1mo	0.07±0.40	0.35±0.51		0.003
3mo	0.15±0.28	0.18±0.47		0.679
6mo	0.07±0.35	0.01±0.48		0.521

MR: Manifest refraction; SE: Spherical equivalent.

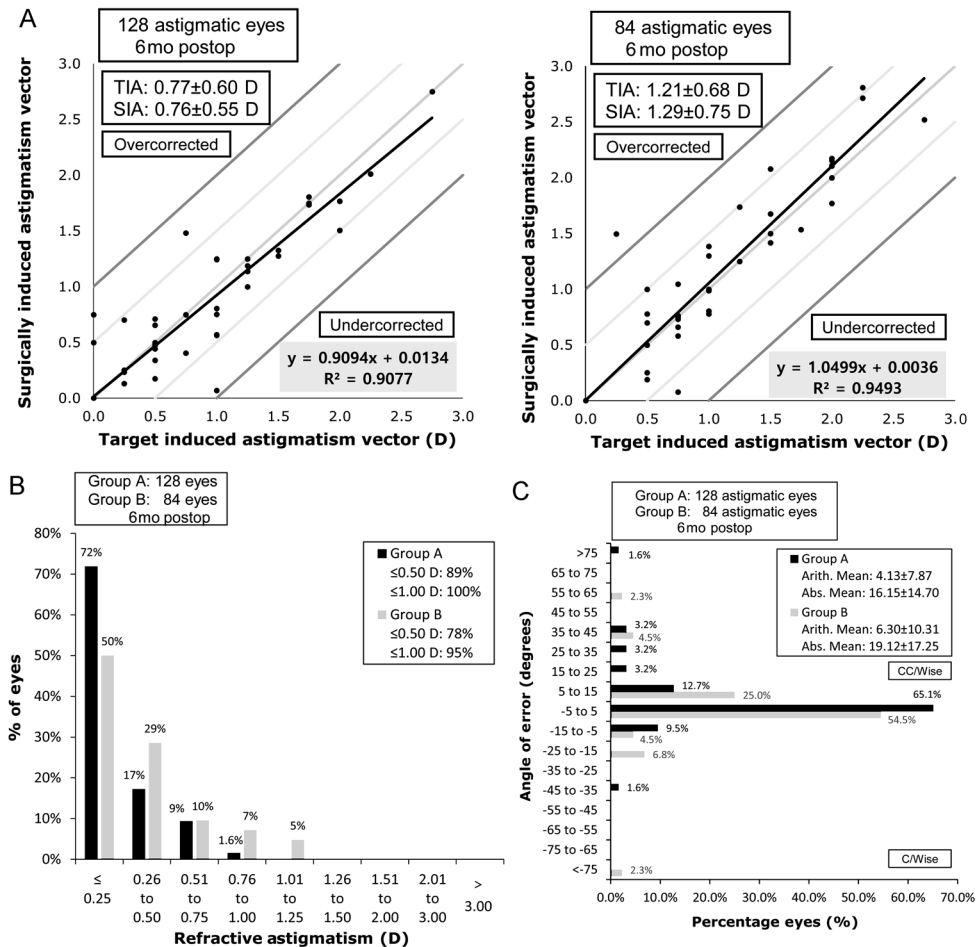


Figure 5 Postoperative astigmatism outcomes at 6mo postoperatively A: The means of target induced astigmatism (TIA) vector and surgically induced astigmatism (SIA) vector were 0.77±0.60 D and 1.21±0.68 D ($P=0.001$) in group A, and 0.76±0.54 D and 1.29±0.74 D ($P<0.001$) in group B, respectively. Scatterplots of TIA versus SIA showed undercorrection in group A and overcorrection in group B; B: Distribution of postoperative astigmatism showed that 89.1% of eyes in group A and 77.6% of eyes in group were within ±0.5 D of the attempted cylindrical correction; C: The refractive astigmatism angle of error showed no difference between the groups ($P=0.157$).

and 1.16±0.83 ($P=0.167$), respectively, in group B. At 6mo postoperatively, 114 eyes (89.1%) in group A and 74 eyes (77.6%) in group B were within ±0.50 D of the attempted cylindrical correction ($P=0.006$), and all eyes (100%) in group A and 80 eyes (95.2%) in group B were within ±1.00 D ($P=0.155$). The refractive astigmatism angle of error showed no difference between the groups ($P=0.157$).

Wavefront Aberrations

Changes in total, front and posterior corneal HOAs postoperatively HOAs (coma, trefoil, spherical, secondary astigmatism, tetrafoil) of total and front cornea tend to increase postoperatively (Figure 6). In group A, secondary astigmatism ($P=0.006$) of total cornea and total HOAs ($P=0.012$), coma ($P=0.042$), and secondary astigmatism ($P=0.08$) of front cornea increased significantly. In group B, all values of total ($P<0.001$ for total HOAs, $P<0.001$ for coma, $P=0.024$ for spherical, $P<0.001$ for secondary astigmatism, and $P=0.039$ for tetrafoil) and front ($P<0.001$ for total HOAs, $P<0.001$ for coma, $P=0.032$ for spherical, $P<0.001$ for secondary astigmatism,

and $P=0.013$ for tetrafoil) cornea except trefoil increased significantly. HOAs of the posterior corneal surface in group A tend to decrease postoperatively except for spherical and secondary astigmatism. There was not significantly different higher-order change in the HOAs of the posterior corneal surface postoperatively in group B.

Comparison of the surgically induced total, front and posterior corneal HOAs after surgery Most of HOAs in group A showed lower values than group B, postoperatively (Figure 7). There were significant differences between groups in total HOAs, coma, spherical, and tetrafoil of total cornea ($P<0.001$, $P=0.004$, $P=0.015$, and $P=0.009$, respectively), total HOAs, spherical, and tetrafoil of front cornea ($P=0.007$, $P=0.011$, and $P=0.009$, respectively), and trefoil of posterior cornea ($P=0.013$).

DISCUSSION

LASIK is a widely used refractive surgery with excellent safety and rapid visual recovery. FS laser is a new technique replacing the traditional microkeratomes to create corneal flap

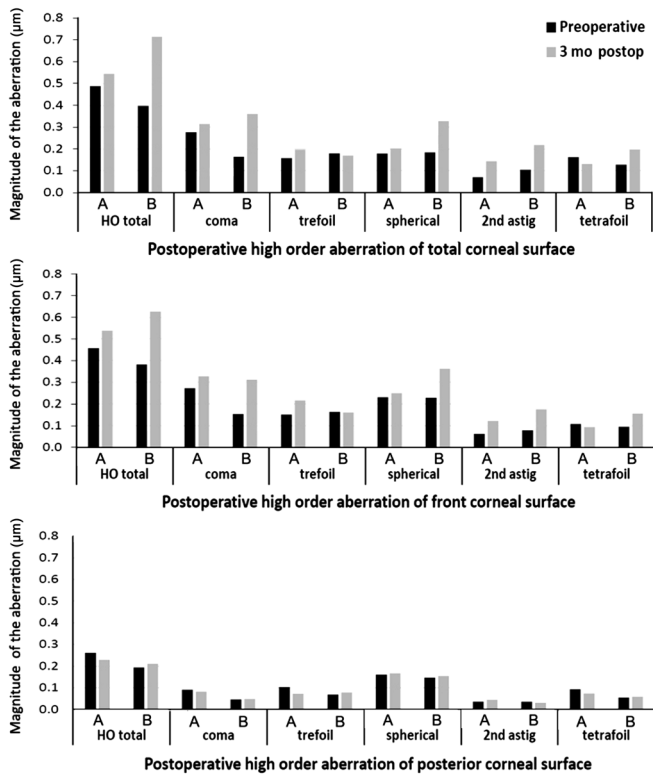


Figure 6 Changes in total, anterior and posterior corneal HOAs postoperatively HOAs of total and anterior cornea showed tendency to increase postoperatively, whereas there were no significant changes in posterior cornea.

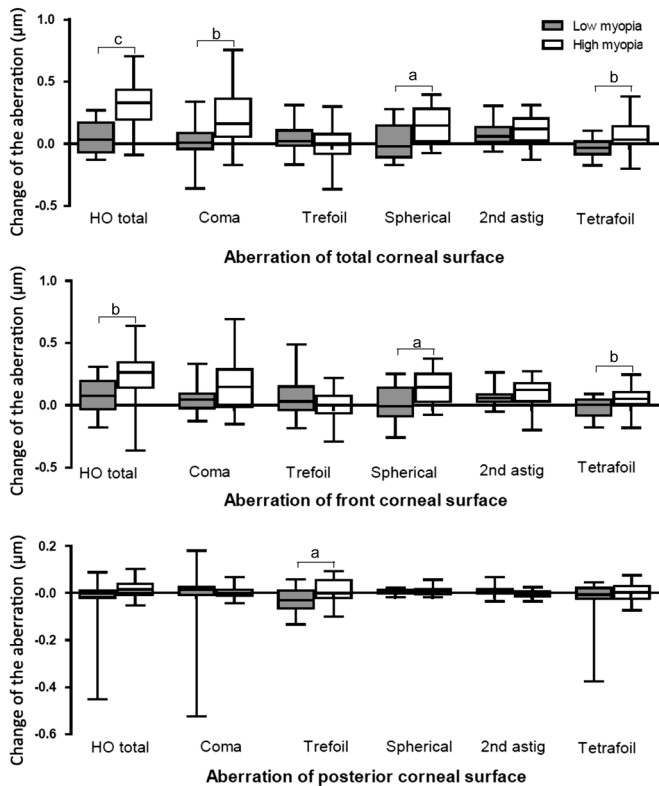


Figure 7 Comparison of the surgically induced HOAs at 6mo postoperatively Most of HOAs in group A showed lower values than in group B, especially HOAs of total and anterior cornea. There were significant differences between two groups (^a $P<0.05$; ^b $P<0.01$; ^c $P<0.001$).

and it was reported that FS laser created flaps had more regular and accurate architecture^[8]. Therefore, it contributes to safer and more predictable results than traditional methods.

Many studies have been reported regarding the visual outcomes of FS lasers used in LASIK procedures^[6,9-11]. Recent Meta-analysis reported that the overall efficacy, predictability, safety for Visumax was 79.1%, 87.1%, 0.48%, respectively^[6]. There have been few studies addressing the outcomes of FS LASIK in relation to the degree of myopia. Therefore, we analyzed the outcomes of FS LASIK according to degree of myopia in this study (between low and high myopia group), focusing on the efficacy, safety, predictability, stability, astigmatism, and HOAs.

In comparison with the proportion of eyes with a UDVA 20/20 or better between the groups through 6mo follow-up period, the results tend to be better in group A than group B and statistical difference was observed at 6mo postoperatively. We suggest that the difference of UDVA between groups could be due to the postoperative refractive change as well as residual astigmatism after FS LASIK which will be discussed. Meta-analysis study regardless of the degree of myopia reported that more than 88% of eyes achieved a UDVA of 20/20 or better^[6]. In terms of low myopia, Agarwal *et al*^[9] has reported that 96.1% achieved a UDVA of 20/20 or better at 3mo after FS LASIK in their low myopic patients (>-4.0 D). For patients with high myopia, it was reported that postoperative UDVA of 20/20 or better ranged from 58.8% to 89%^[10-12]. Although the criteria of high myopia are various depending on the studies, the results of group A (92%) and B (76%) were similar to that of previous studies.

Changes in CDVA were excellent in both groups with no eyes losing more than two lines. The result was similar to recent studies that the proportion of eyes losing two or more Snellen lines of CDVA was zero or close to zero^[6,9-10,12]. This study can infer that FS LASIK is an effective and safe procedure regardless of the degree of myopia. Recent Meta-analysis study reported that the average predictability for Visumax was 87.1% which was similar to the result of group A (87%)^[6]. Other studies for high myopia showed low predictability ranged from 55% to 56% within ± 0.5 D of the target refractive correction and 83% to 85% within ± 1.0 D^[12-13]. Our study showed relatively higher predictability in group B (76% for within ± 0.5 D and 95% for within ± 1.0 D) because our study included less myopic eyes (-6.0 to -8.0 D) than other studies (-8.0 to -14.5 D and -5.0 to -10.0 D). Although the previous studies included various range of myopia, our results of both groups are similar with the previous results and the result of high myopia tends to be better.

In terms of the stability, MR SE in group A showed no significant changes throughout the follow-up period, whereas

MR SE in group B tended to decrease from mild hyperopia to the intended refraction. Initial hyperopia in group B was possibly due to the calculated laser nomograms that anticipate natural regression effect because more myopic eyes preoperatively have more myopic regression postoperatively^[14]. The eyes in group B showed myopic regression of about 0.5 D and the SE approached emmetropia at last visit. Although the changes were observed only for 6mo, there might be no significant changes after the last visit because refractive changes became stable around 3 to 6mo after LASIK^[15-17].

Group B showed significantly higher preoperative astigmatism and it might be related to more myopic eyes in group B. Kaye and Patterson^[18] reported that the total amount of astigmatism in the myopic eye is proportional to the degree of myopia. Fluton *et al*^[19] suggested uncorrected astigmatism could cause myopic progression. Kim *et al*^[20] reported the change in astigmatism during childhood was significantly greater in the myopia group. Because the postoperative target was emmetropia, astigmatism did not show statistically significant difference between groups at postoperative 1wk, but it finally showed a significant difference and TIA and SIA were naturally higher in group B at postoperative 6mo. Undercorrection of astigmatism in group A and overcorrection in group B were shown at postoperative 6mo. However, CI showed no significant difference. It is important that residual astigmatism between two groups was significantly different from postoperative 1mo onward. These residual astigmatism after LASIK can cause decreased UDVA or monocular diplopia even if the degree of astigmatism is less than 1 D^[21-22]. We can explain the difference of postoperative UDVA between both groups based on the postoperative refractive change. Although postoperative SE in group B was more hyperopic up to 3mo postoperatively, there was no significant difference in UDVA. It seemed that residual astigmatism compensated initial spherical hyperopia to maintain good visual acuity. However, the compensation didn't last until 6mo postoperatively because residual astigmatism didn't change while hyperopic sphere decreased. Finally, SE in group B approached emmetropia at 6mo postoperatively, however, UDVA in group B was significantly worse because of residual astigmatism. This difference disappeared by correcting residual refractive errors and there was no significant difference in CDVA between two groups.

In this study, it was showed that corneal HOAs increased postoperatively in two groups and low myopia group had significantly lower HOAs than high myopia group. This result is consistent with previous studies which reported that induced HOAs have correlations with SE correction^[23-24]. Because these corneal HOAs can cause glare, halo and decreased visual quality, it is important to minimize postoperative HOAs^[25].

FS laser flap creation is one of the methods to reduce HOAs compared to conventional manual microkeratomes^[26-27]. Additional surgical techniques such as wavefront-guided LASIK may be necessary for high myopic patients who require larger amounts of laser correction^[28]. Meanwhile, the increase of HOAs in this study occurred only at total and anterior cornea, not posterior cornea in both groups. Recent studies found that posterior corneal HOAs were relatively unchanged in FS LASIK^[29-30], and our study suggests that FS LASIK may not influence the posterior cornea regardless of the degree of myopia.

In conclusion, our results indicate that FS LASIK is an effective and safe surgical procedure for correcting myopic refractive error, especially in low myopia. In the cases of high myopia, it is still effective and safe, however, larger amount of residual astigmatism and induced HOAs were shown postoperatively. Therefore, we recommend that surgeons consider preoperative refractive astigmatism in high myopia and inform the patients in advance that postoperative expectations may be worse than general.

The short follow up period of 6mo is the limitation of this study. Long-term follow up studies may be necessary to observe changes in refractive power, visual acuity, and quality of life. If advanced techniques to improve the accuracy of the surgery will be developed or further studies that can predict the postoperative results more accurately are performed, it will be helpful for patients to gain better visual acuity and quality of life.

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