ORIGINAL ARTICLE

Myopic Regression After Phakic Intraocular Lens Implantation and LASIK

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ABSTRACT

Purpose. In myopia, biometry including the axial length is important, along with the refractive data. We compared the rates of myopic regression 3 years after phakic intraocular lens (pIOL) implantation and laser *in situ* keratomileusis (LASIK) after matching the preoperative axial length in highly myopic eyes of Japanese patients.

Methods. This retrospective nonrandomized study included 133 eyes of 84 patients with myopia exceeding -6.00 diopters (D) who underwent implantation of two iris-fixated pIOLs (pIOL group, 66 eyes/46 patients) or myopic LASIK (LASIK group, 67 eyes/38 patients) who were followed for more than 3 years postoperatively. The patient age, preoperative refraction, and preoperative axial length were matched between the study groups.

Results. There were no significant differences preoperatively between the groups in age, intraocular pressure, refraction, keratometry, or axial length. The mean regression values after 3 years compared with the 1-month postoperative refractions were -0.12 ± 0.47 (SD) D in the pIOL group and -0.82 ± 0.69 D in the LASIK group (p < 0.001). The differences in the mean regression rates between 1 and 12 months, 12 and 24 months, and 24 and 36 months of follow-up were, respectively, 0.09 ± 0.38 D, -0.11 ± 0.35 D, and -0.11 ± 0.30 D in the pIOL group and -0.57 ± 0.84 D, -0.24 ± 0.47 D, and 0.00 ± 0.53 D in the LASIK group (p < 0.001, p = 0.07, p = 0.15, respectively).

Conclusions. There was a significant difference in myopic regression 3 years postoperatively between the groups matched for preoperative axial length in Japanese patients. This result has the potential to elucidate myopia in the future. (Optom Vis Sci 2014;91:00–00)

Key Words: refractive change, myopia, myopic regression, phakic intraocular lens, LASIK

mplantation of phakic intraocular lenses (pIOLs) generally has been accepted as a treatment to correct moderate and high myopia. ^{1,2} Several pIOL designs have been developed, including angle-supported anterior chamber pIOLs, posterior chamber pIOLs, and iris-fixated pIOLs. Among them, long-term results have been published for the iris-fixated pIOLs Artisan (Ophtec BV, Groningen, Netherlands) and foldable Artiflex (Ophtec BV). ^{1,3–6} Most studies have reported the safety, efficacy, ^{1,3,6–8} and long-term refractive stability of this pIOL design. ^{1,6,9,10} The mean myopic regression is low (within -0.2 diopter [D]/year) during the first postoperative year, ^{1,11,12} and the regression is not problematic even for the long-term in highly myopic eyes implanted with a pIOL.

Regression is common especially in highly myopic eyes that have undergone LASIK. ^{17,19–21}

Although only one retrospective comparative study of myopic regression between pIOL and LASIK has been published, ²² no study has addressed the preoperative axial length despite the importance of measuring the axial length in myopia. Furthermore, although the refractive state has been discussed, the race and the

preoperative patient background, including the preoperative axial

length, were not considered in a previous study.²²

Laser in situ keratomileusis (LASIK), one of the most common

surgeries performed worldwide to correct myopia, 13-16 is effective

and safe for correcting low-to-moderate myopia^{17,18}; however, the results of LASIK for treating high myopia are less impressive.^{19,20}

Several investigators have reported a high mean myopic regression

rate (more than -1.00 D/year) during the first postoperative year. 20,21

The purpose of the current retrospective study was to compare the rates of myopic regression for 3 years after currently available pIOLs were implanted and LASIK was performed in highly myopic eyes of Japanese patients matched for preoperative background characteristics including race and axial length.

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Patient Profiles

This retrospective study included 133 eyes of 84 Japanese patients with myopia exceeding -6.00 D. The patients were divided into two groups: group 1, the pIOL group with 66 eyes of 46 patients (age range, 19 to 48 years; mean age, 35.0 ± 6.1 [SD] years) who were implanted with iris-fixated pIOLs from December 1, 2004, to December 31, 2007; and group 2, the LASIK group with 67 eyes of 38 patients (age range, 18 to 48 years; mean age, 33.8 \pm 7.4 years) who underwent myopic LASIK from June 1, 1999, to March 31, 2008. This retrospective study was performed at the Department of Ophthalmology, Keio University School of Medicine, Tokyo, Japan, and the Minato Mirai Eye Clinic, Yokohama, Japan. All patients provided written informed consent after receiving a preoperative explanation of the risk and benefits of the procedures. The Keio University School of Medicine Ethics Committee and Minato Mirai Eye Clinic Ethics Committee approved this study. All procedures involving human subjects were conducted in accordance with the tenets of the Declaration of Helsinki.

The inclusion criteria for both groups were a minimal age of 18 years with myopia exceeding -6.00 D; a refractive error that was stable for at least 6 months preoperatively; a normal retina or one treated with photocoagulation when necessary; and no previous ocular surgery, uveitis, cataracts, diabetic retinopathy, corneal diseases, glaucoma, or a history of ocular trauma. The inclusion criteria for pIOL implantation was a sufficiently deep anterior chamber (2.8 mm or more for the Artisan pIOL and 3.2 mm or more for the Artiflex pIOL) and an adequate endothelial cell count (2000 cells/mm² or higher).

The exclusion criteria for both groups were the presence of keratoconus or suspicion of keratoconus based on corneal topography, active ocular or systemic disease likely to affect wound healing, pregnancy, and nursing mothers. No intraoperative or postoperative complications developed, and no enhancements were performed.

Surgical Technique

Four experienced surgeons performed all pIOL implantations and LASIK procedures using the same techniques and protocol. All patients underwent a complete preoperative assessment, and none had pathology or intraoperative or postoperative complications. The target refraction was between emmetropia and -0.5 D in all cases.

We used the Artisan and Artiflex iris-fixated pIOLs. The preoperative treatment included instillation of 0.5% levofloxacin eye drops (Cravit; Santen Pharmaceutical Co., Osaka, Japan) three times daily for 3 days. The pupils were constricted with pilocarpine 2% preoperatively. A 3.2- or 6.5-mm sclerocorneal tunnel was made at the 12-o'clock position under topical and sub-Tenon anesthesia. Anesthesia was induced using 4% lidocaine hydrochloride eyedrops followed by a sub-Tenon injection with about 1 mL of 2% lidocaine hydrochloride. All Artisan pIOLs were implanted through a 6.5-mm sclerocorneal incision using forceps; all Artiflex pIOLs were implanted using an injector (OD110 Artiflex Disposable Insertion Spatula, Ophtec BV) through a 3.2-mm sclerocorneal incision. The anterior chamber was filled with sodium hyaluronate 3.0%, chondroitin sulfate 4.0% (Viscoat; Alcon, Fort Worth, TX), and sodium

hyaluronate 2.3% (Healon 5; Abbott Medical Optics, Abbott Park, IL). The pIOL was inserted into the anterior chamber, rotated inside the eye, and fixated to the iris using an OD125 Artisan and Artiflex Enclavation Needle (Ophtec BV). A peripheral iridectomy was performed at the 12-o'clock position after the pIOL was fixated. After removal of the ophthalmic viscosurgical devices, the 6.5-mm wound was closed with 10-0 nylon sutures; the 3.2-mm wound was self-sealing without sutures. Balanced saline solution (BSS Plus; Alcon Japan, Tokyo, Japan) was used as irrigation fluid.

The patients who underwent LASIK did not receive preoperative treatment. Anesthesia was administered using 4% lidocaine hydrochloride eye drops. The LASIK flaps were created using a MK-2000 microkeratome (Nidek Co., Aichi, Japan). All laser ablations with a 6.0-mm optical zone and a 7.0-mm transition zone were performed using the EC-5000 scanning excimer laser system (Nidek Co.).

Phakic Intraocular Lens

The Artisan (models 204 and 206) pIOL has a convex-concave polymethyl methacrylate (PMMA) optic with a 5.0- or 6.0-mm optical zone and PMMA haptics. The Artiflex (model 401) pIOL has a convex-concave silicone optic with a 6.0-mm optical zone and PMMA haptics. The pIOL powers were determined between emmetropia and -0.5 D according to power calculations using the Van Der Heijde formula.²³

Postoperative Treatment

For the eyes implanted with a pIOL, 0.5% levofloxacin eye drops (Cravit), 0.1% diclofenac sodium (Diclod; Wakamoto Co., Tokyo, Japan), and 0.1% betamethasone sodium (Sanbetason; Santen Pharmaceutical Co.) were administered five times daily for a maximum of 4 weeks based on the degree of inflammation and IOP. The steroid dose was tapered gradually.

For eyes treated with LASIK, 0.5% levofloxacin eye drops (Cravit), 0.1% sodium hyaluronate (Hyalein; Santen Pharmaceutical Co.), and 0.1% betamethasone sodium (Sanbetason) were used five times daily during the first postoperative week.

Outcome Measures

All patients were followed for more than 3 years postoperatively and evaluated preoperatively and at 1, 3, and 6 months and 1, 2, and 3 years postoperatively. The main outcome measure was the difference in myopic regression, defined as the change in SE between the postoperative time points, between the two groups. We also assessed the refraction (SE), uncorrected and best-corrected visual acuities (UCVA and BCVA), efficacy index, safety index, IOP, keratometry, and central corneal thickness. The efficacy index was defined as the ratio of the postoperative UCVA to the preoperative BCVA. The safety index was defined as the ratio of the postoperative BCVA to the preoperative BCVA.

Objective refraction and keratometry were measured by autorefractometry (ARK-700A; Nidek Co.). Axial length and corneal thickness were measured by biometry and pachymetry (AL-2000; Tomey Co., Aichi, Japan). The IOP was measured using a noncontact tonometer (NT-3000; Nidek Co.). The corneal endothelial cell density was measured using a specular microscope (EM-3000; Tomey Co.). We did not evaluate the corneal endothelial cell count

in the LASIK group postoperatively because the endothelial cell losses in the LASIK group likely were within the range resulting from physiologic age-related loss.^{24,25}

Statistical Analysis

To identify the factors affecting regression after pIOL implantation and LASIK, we performed multiple regression analysis (stepwise variable selection for regression). The outcome was the change in the spherical equivalent (SE) at 3 years minus 1 month. The covariates were age, sex, type of surgery (LASIK or pIOL), preoperative refraction, intraocular pressure (IOP), keratometry, corneal thickness, and axial length. Multicollinearity was not a factor.

The Mann-Whitney U test was used to compare data between the two groups. The paired t test with Bonferroni correction was used to evaluate the significance of within-group differences. A value of p < 0.05 was considered significant. All statistical analyses were performed using SPSS version 19.0 software (SPSS, Inc., Chicago, IL).

RESULTS

Patient Profile

The preoperative data are shown in Table 1. There were no significant differences in patient age, SE, axial length, UCVA, BCVA, IOP, keratometry, or corneal endothelial cell count between the groups. There was a significant (p < 0.001) difference in the corneal thicknesses between the groups.

Visual and Refractive Data and Surgical Outcomes

Table 2 shows the visual and refractive data and surgical outcomes in both groups 3 years postoperatively. There were no significant differences in the UCVA, BCVA, or efficacy index between the

groups. The SE in the LASIK group was significantly (p < 0.001) more myopic than in the pIOL group. The IOP and safety index in the pIOL group were significantly (p < 0.001 and p = 0.02, respectively) higher than those in the LASIK group.

The BCVA was better than 20/32 preoperatively and 1, 3, and 6 months and 1, 2, and 3 years postoperatively in all eyes.

The mean endothelial cell count 3 years postoperatively in the pIOL group was $2755 \pm 244 \text{ cells/mm}^2$, and the mean percentage of central endothelial cellular loss in the pIOL group at 3 years after surgery was $4.5 \pm 8.3\%$.

Refraction

The SE improved immediately after LASIK and pIOL implantation, and minimal regression was seen from 1 month postoperatively in the LASIK group. The SE values did not differ significantly between the LASIK and pIOL groups 1 month postoperatively.

In the pIOL group, the SE values at 3 months postoperatively were significantly (p = 0.01) more hyperopic than the SE values at 1 month postoperatively, and there were no significant differences between 1 month postoperatively and any postoperative point except for 3 months. The changes in the SE in the pIOL group stabilized after 3 months postoperatively.

The LASIK group had significant differences in the changes in the SE between 1 month postoperatively and all postoperative points (p < 0.001, for all comparisons) and between 1 and 2 years postoperatively (p < 0.001). The changes in the SE in the LASIK group stabilized 2 years postoperatively. The SE values in all patients in the LASIK group were significantly (p = 0.008, p < 0.001, p < 0.001, p < 0.001, and p < 0.001, respectively) more myopic than in the pIOL group at all times points after 3 months postoperatively (Fig. 1). In young patients (aged 18 to 25 years), the SE values in the LASIK group were significantly (p = 0.01, p = 0.04, and p = 0.01,

TABLE 1. Patient preoperative data

Parameter	LASIK group	pIOL group	р —	
No. eyes/patients	67/38	66/46		
Age, years	33.8 ± 7.4	35.0 ± 6.1	0.45	
	(18~48)	(19~48)		
SE, D	-10.39 ± 1.46	-10.80 ± 1.84	0.16	
	(-8.13 to -14.00)	(-6.13 to -13.38)		
Axial length, mm	27.26 ± 0.94	27.31 ± 1.05	0.82	
	(25.36~29.33)	(23.95~29.13)		
UCVA, logMAR	1.57 ± 0.24	1.57 ± 0.19	0.90	
	$(0.52\sim2.00)$	$(0.82\sim2.00)$		
BCVA, logMAR	-0.14 ± 0.07	-0.12 ± 0.08	0.12	
	$(-0.30 \sim 0.16)$	$(-0.30 \sim 0.05)$		
IOP, mm Hg	13.5 ± 2.4	13.6 ± 2.7	0.79	
	(8.7~19.0)	(8.0~18.7)		
Keratometry, D	43.88 ± 1.34	43.95 ± 1.25	0.75	
	(39.63~47.13)	(41.00~47.13)		
Corneal thickness, mm	542.8 ± 27.6	508.8 ± 29.9	< 0.001	
	(495~613)	(436~581)		
Corneal endothelial cell count, cells/mm ²	2789 ± 276	2875 ± 298	0.09	
	(1848~3278)	(2320~3546)		

The values are expressed as the mean \pm SD (range).

TABLE 2.Visual and refractive data and surgical outcomes in both groups 3 years postoperatively

Parameter	LASIK group	pIOL group	р
SE, D	-1.30 ± 0.83	-0.74 ± 0.64	< 0.001
UCVA, logMAR	-0.04 ± 0.22	-0.08 ± 0.14	0.16
BCVA, logMAR	-0.17 ± 0.09	-0.18 ± 0.09	0.49
IOP, mm Hg	7.6 ± 1.5	13.7 ± 2.5	< 0.001
Safety index	1.09 ± 0.21	1.21 ± 0.32	0.02
Efficacy index	0.88 ± 0.21	0.96 ± 0.30	0.10

The data are expressed as the mean \pm SD.

respectively) more myopic than those of the pIOL group at 1 month and 1 and 2 years after surgery (Fig. 2A). In older patients (aged 26 to 43 years), the SE values in the LASIK group were significantly (p = 0.008, p = 0.004, p < 0.001, p < 0.001, and p < 0.001, respectively) more myopic than those of the pIOL group at 3 and 6 months and 1, 2, and 3 years after surgery (Fig. 2B). In the oldest patients (aged 44 to 48 years), there were no significant differences in the SE values between the two groups at all times points (Fig. 2C).

The mean regression values after 3 years compared with the 1-month postoperative refractions were -0.12 ± 0.47 D in the pIOL group and -0.82 ± 0.69 D in the LASIK group (p < 0.001). The changes in the SE are shown in Table 3. There were significant (p < 0.001) differences between the groups at 3 months minus 1 month.

Multiple Regression Analysis

Y, year.

The following multiple regression equation was used:

Changes in SE = $5.357 - 0.609 \times \text{type}$ of surgery (LASIK or pIOL) $-0.180 \times \text{axial length}$ ($R^2 = 0.253$)

The results of the multiple regression equation showed that the type of surgery (p < 0.001) and the preoperative axial length

(p = 0.007) were associated with myopic regression, with the type of surgery being more relevant.

Keratometry

The postoperative keratometry was significantly (p < 0.001 for all comparisons) higher in the pIOL group in all patients and in each age group than in the LASIK group at all postoperative points (Figs. 3; 4A to C). There were no significant differences between preoperatively and at any postoperative time point in the pIOL group in all patients and in each age group (Figs. 3; 4A to C). However, in all patients in the LASIK group, there were significant (p = 0.002, p < 0.001, p < 0.001, and p < 0.001, respectively)differences between 1 month postoperatively and all other postoperative time points except 3 months postoperatively (p = 0.14) (Fig. 3). In young patients (aged 18 to 25 years), there were no significant differences between 1 month postoperatively and all other postoperative time points in the LASIK group (Fig. 4A). In older patients (aged 26 to 43 years), there were significant (p = 0.02, p < 0.001, p < 0.001, and p < 0.001, respectively) differences between 1 month postoperatively and all other postoperative time points except 3 months postoperatively (p = 0.10) (Fig. 4B). In the oldest patients (aged 44 to 48 years), there were significant (p = 0.04 and p = 0.02, respectively) differences between 1 month postoperatively and 2 and 3 years postoperatively (Fig. 4C).

Myopic Regression and Changes in Keratometric Values in the LASIK Group

There was a significant (Pearson correlation coefficient, r = -0.509, p = 0.001) correlation between the myopic regression (SE at 3 years minus 1 month) and the postoperative increase in keratometric value (keratometry at 3 years minus 1 month) after LASIK in all patients. There was a significant (Pearson correlation coefficient, r = -0.732, p = 0.039) correlation between the myopic regression and the postoperative increase in the

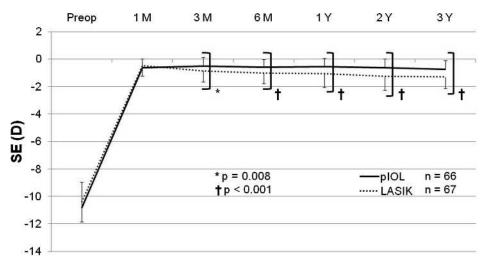


FIGURE 1.

Changes in the SE in all patients over time. The SE values in the LASIK group are significantly (p = 0.008, p < 0.001, p < 0.001, p < 0.001, and p < 0.001, respectively) more myopic than those of the pIOL group at 3 and 6 months and 1, 2, and 3 years after surgery. D, diopters; M, month; Preop, preoperatively;

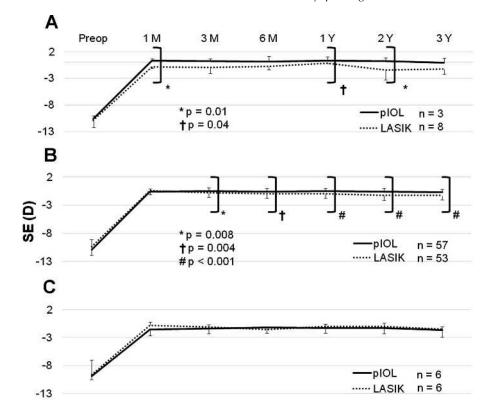


FIGURE 2.

Changes in the SE by age group over time. Preoperative age groups: 18 to 25 years (A), 26 to 43 years (B), and 44 to 48 years (C). M, month; Preop, preoperatively; Y, year. (A) The SE values in the LASIK group are significantly (p = 0.01, p = 0.04, and p = 0.01, respectively) more myopic than those of the pIOL group at 1 month and 1 and 2 years after surgery. (B) The SE values in the LASIK group are significantly (p = 0.008, p = 0.004, p < 0.001, p < 0.001, and p < 0.001, respectively) more myopic than those of the pIOL group at 3 and 6 months and 1, 2, and 3 years after surgery. (C) There are no significant differences in the SE values between the two groups at all times points.

keratometric values after LASIK in the young patients (aged 18 to 25 years, n = 8) (Fig. 5A). There was a significant (Pearson correlation coefficient, r = -0.446, p = 0.001) correlation between the myopic regression and the postoperative increase in the keratometric values after LASIK in the older patients (aged 26 to 43 years, n = 53) (Fig. 5B). There was no significant (Pearson correlation coefficient, r = -0.739, p = 0.093) correlation between the myopic regression and the postoperative increase in keratometric values after LASIK in the oldest patients (aged 44 to 48 years, n = 6) (Fig. 5C).

DISCUSSION

The current results showed that the type of surgery and the preoperative axial length were associated with myopic regression. To the best of our knowledge, except for one study²⁶ that compared the clinical results between LASIK and the Artiflex pIOL for high myopia, few previous studies²² on this topic have been published. No study has compared myopic regression between the current types of pIOL and LASIK, and the preoperative patient backgrounds including race and the axial lengths were matched in a search of PubMed.

The reason we included the IOP in our multiple regression analysis is that Qi et al.²⁷ reported a relationship between myopic regression after LASIK and the preoperative IOP. The current results did not confirm that relationship.

Laser in situ keratomileusis is the procedure of choice to treat mainly myopia below -10.00 D and pIOLs have been implanted

to treat myopia exceeding -10.00 D²² because the candidates for the two surgeries generally differ. Therefore, only one study²² compared the refractive outcomes of LASIK with those of pIOLs for treating almost the same degree of high myopia (Table 4).

Previous studies generally have reported that the long-term refraction is stable after pIOL implantation. 1,6,9,10 Myopic regression achieved by subtracting the mean SE was less than -0.10 D annually with the Artisan pIOL^{6,9,10} and the Artiflex pIOL. In the current study, the myopic regression in the pIOL group was $-0.12 \pm$ 0.47 D between 1 month and 3 years postoperatively, which was consistent with previous studies.

Meanwhile, several reports have been published on myopic regression after LASIK for high myopia¹⁹⁻²¹; the mean myopic regression associated with LASIK for high myopia ranged from -0.93 D for 9 months to -1.07 D for 3 months.

TABLE 3. Changes in the SE over time in both study groups

Time	LASIK group	pIOL group	р
3 M, 1 M	-0.35 ± 0.59	0.12 ± 0.38	< 0.001
6 M, 3 M	-0.10 ± 0.48	-0.07 ± 0.36	0.65
1 Y, 6 M	-0.08 ± 0.76	0.02 ± 0.28	0.33
2 Y, 1 Y	-0.24 ± 0.47	-0.11 ± 0.35	0.07
3 Y, 2 Y	0.00 ± 0.53	-0.11 ± 0.30	0.15

The data are expressed as the mean \pm SD.

M, month; Y, year.

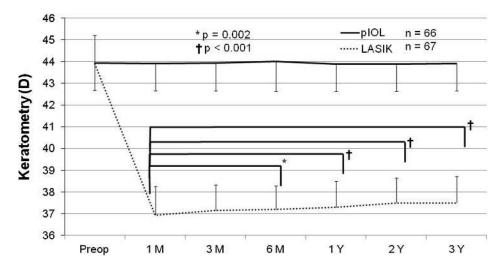


FIGURE 3.

Changes in the keratometry in all patients over time. There are no significant differences between preoperatively and any postoperative time point in the pIOL group. In the LASIK group, there are significant (p = 0.002, p < 0.001, p < 0.001, and p < 0.001, respectively) differences between 1 month postoperatively and all other postoperative time points except 3 months postoperatively (p = 0.14). The keratometry values gradually increase after 1 month postoperatively in the LASIK group. M, month; Preop, preoperatively; Y, year.

Myopic regression after LASIK for high myopia stabilizes between 3 months and 5 years ^{17,19,21,28,29} postoperatively. Variations in postoperative refractions have been attributed to the preoperative refraction, the amount of tissue ablated, postoperative treatment

protocols, and individual responses to stromal and epithelial wound healing.²⁸ In the current study, the annual regression in the LASIK group gradually decreased postoperatively and stabilized 2 years postoperatively.

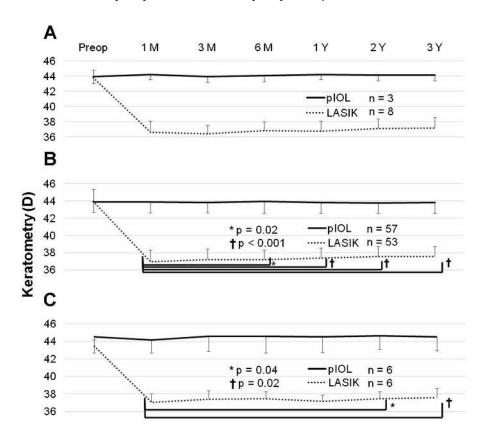


FIGURE 4.

Changes in the keratometry by age group over time. Preoperative age groups: 18 to 25 years (A), 26 to 43 years (B), and 44 to 48 years (C). There are no significant differences between preoperatively and any postoperative time point in the pIOL group in all age groups (A, B, C). M, month; Preoperatively; Y, year. (A), There are no significant differences between 1 month postoperatively and all other postoperative time points in the LASIK group. (B), There are significant (p = 0.02, p < 0.001, p < 0.001, and p < 0.001, respectively) differences between 1 month postoperatively and all other postoperatively in the LASIK group. (C), There are significant (p = 0.04 and p = 0.02, respectively) differences between 1 month postoperatively and 2 and 3 years postoperatively.

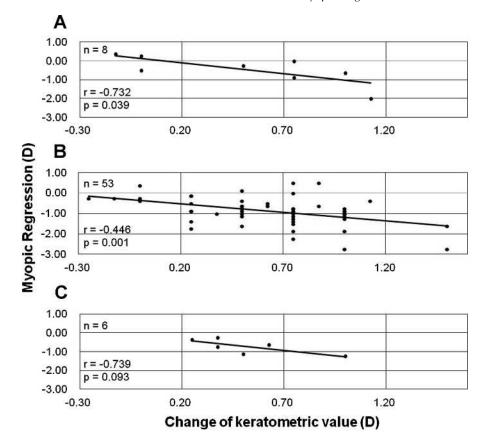


FIGURE 5.

Correlation between myopic regression (SE at 3 years minus 1 month) and the change of keratometric value (keratometry at 3 years minus 1 month) in the LASIK group. Preoperative age groups: 18 to 25 years (A), 26 to 43 years (B), and 44 to 48 years (C). There is a significant (Pearson correlation coefficient, r = -0.732, p = 0.039) correlation (A), a significant (Pearson correlation coefficient, r = -0.446, p = 0.001) correlation (B), and no significant (Pearson correlation coefficient, r = -0.446, p = 0.001) correlation (B), and no significant (Pearson correlation coefficient, r = -0.446, p = 0.001) correlation (B), and no significant (Pearson correlation coefficient, r = -0.446, p = 0.001) correlation (B), and no significant (Pearson correlation coefficient, r = -0.446, p = 0.001) correlation (B), and no significant (Pearson correlation coefficient) coefficient (Pearson correlation coefficient) coefficient (Pearson coefficient) coeffi tion coefficient, r = -0.739, p = 0.093) correlation (C) between the myopic regression and the postoperative increase in keratometric value after LASIK.

Keratometry showed gradual increases throughout 3 years in the LASIK group that were correlated with myopic regression (Fig. 3), as reported previously.²¹ In the current study, there were some differences in the changes in the SE and keratometry among age groups over time (Figs. 2A to C; 4A to C). There were significant (p < 0.05) correlations between the changes in refractive error and keratometry in the young and older patients (aged 18 to 25 years and aged 26 to 43 years) (Fig. 5A, B), although there was no significant correlation between the changes in refractive error and keratometry in the oldest patients (aged 44 to 48 years) (Fig. 5C).

TABLE 4. Studies comparing myopic regression after LASIK and pIOL implantation

Author journal year	No. preoperative SE range	LASIK group, D	pIOL group, D	Follow-up duration, p	plOL	Study design
Rosman et al. ²² J Ref Surg 2011	178 eyes -10.00 D to 19.50 D	-1.86	-0.19	10 years (10 Y-3 M) p = 0.24	ZB5M	Retrospective Preoperative ALs of study groups did not match. ZB5M pIOL is no longer in use. The races of the patients are unknown.
Current study	133 eyes/84 patients -6.00 D to 13.50 D	-0.82	-0.12	3 years (3 Y-1 M) p < 0.001	Artisan, Artiflex	Retrospective Preoperative ALs of study groups matched. Artisan and Artiflex pIOLs are in use currently. Only Japanese patients included.

AL, axial length; M, month; Preop, preoperatively; Y, year.

Corneal steepening during the long-term after LASIK30 and a hyperopic shift in the refractive error because of shifts in the refractive index of the crystalline lens in all individuals between the ages of 45 and 55 years³¹ have been reported previously. Considering these reports, the myopic shift in the cornea over time might be cancelled out by a hyperopic shift in the lens in old patients. This was the main reason why there were no significant differences in the SE values in the oldest patients between the LASIK and pIOL groups at all times points (Fig. 2C) despite the significant increase in the keratometric values in the oldest patients in the LASIK group (Fig. 4C). The small numbers of eyes in the young and the oldest age groups was a limitation (n = 8 and n = 6, respectively); a larger number of eyes should be evaluated in future studies.

The current study was limited in that we did not measure the axial length postoperatively and did not evaluate the axial elongation. Daoud et al.³² reported that myopic regression after corneal refractive surgery occurred in about 50% of children at an average rate of 1 to 1.7 D annually and that myopic regression primarily results from further axial elongation in growing pediatric eyes. This warrants further investigation to compare the differences in myopic regression between the pIOL and LASIK groups in adults.

In conclusion, our results showed a significant difference in myopic regression postoperatively between the study groups. This result has the potential to elucidate myopia in the future.

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REFERENCES

- 1. Dick HB, Budo C, Malecaze F, Guell JL, Marinho AA, Nuijts RM, Luyten GP, Menezo JL, Kohnen T. Foldable Artiflex phakic intraocular lens for the correction of myopia: two-year follow-up results of a prospective European multicenter study. Ophthalmology 2009; 116:671-7.
- 2. Huang D, Schallhorn SC, Sugar A, Farjo AA, Majmudar PA, Trattler WB, Tanzer DJ. Phakic intraocular lens implantation for the correction of myopia: a report by the American Academy of Ophthalmology. Ophthalmology 2009;116:2244-58.
- 3. Coullet J, Guell JL, Fournie P, Grandjean H, Gaytan J, Arne JL, Malecaze F. Iris-supported phakic lenses (rigid vs foldable version) for treating moderately high myopia: randomized paired eye comparison. Am J Ophthalmol 2006;142:909-16.
- 4. Benedetti S, Casamenti V, Benedetti M. Long-term endothelial changes in phakic eyes after Artisan intraocular lens implantation to correct myopia: five-year study. J Cataract Refract Surg 2007;33:784-90.
- 5. Stulting RD, John ME, Maloney RK, Assil KK, Arrowsmith PN, Thompson VM, , Group USVS. Three-year results of Artisan/ Verisyse phakic intraocular lens implantation. Results of the United States Food And Drug Administration clinical trial. Ophthalmology 2008;115:464-72.e1.
- 6. Tahzib NG, Nuijts RM, Wu WY, Budo CJ. Long-term study of Artisan phakic intraocular lens implantation for the correction of moderate to high myopia: ten-year follow-up results. Ophthalmology 2007;114:1133-42.

- 7. Tahzib NG, Eggink FA, Frederik PM, Nuijts RM. Recurrent intraocular inflammation after implantation of the Artiflex phakic intraocular lens for the correction of high myopia. J Cataract Refract Surg 2006;32:1388-91.
- 8. Torii H, Negishi K, Dogru M, Saiki M, Yamaguchi T, Watanabe K, Kato N, Tsubota K. Inflammation after phakic implants. Ophthalmology 2011;118:2518.e1-2.
- 9. Silva RA, Jain A, Manche EE. Prospective long-term evaluation of the efficacy, safety, and stability of the phakic intraocular lens for high myopia. Arch Ophthalmol 2008;126:775-81.
- 10. Guell JL, Morral M, Gris O, Gaytan J, Sisquella M, Manero F. Five-year follow-up of 399 phakic Artisan-Verisyse implantation for myopia, hyperopia, and/or astigmatism. Ophthalmology 2008;115:1002-12.
- 11. Malecaze FJ, Hulin H, Bierer P, Fournie P, Grandjean H, Thalamas C, Guell JL. A randomized paired eye comparison of two techniques for treating moderately high myopia: LASIK and artisan phakic lens. Ophthalmology 2002;109:1622-30.
- 12. El Danasoury MA, El Maghraby A, Gamali TO. Comparison of irisfixed Artisan lens implantation with excimer laser in situ keratomileusis in correcting myopia between -9.00 and -19.50 diopters: a randomized study. Ophthalmology 2002;109:955-64.
- 13. Sekundo W, Bonicke K, Mattausch P, Wiegand W. Six-year followup of laser in situ keratomileusis for moderate and extreme myopia using a first-generation excimer laser and microkeratome. J Cataract Refract Surg 2003;29:1152-8.
- 14. O'Doherty M, O'Keeffe M, Kelleher C. Five year follow up of laser in situ keratomileusis for all levels of myopia. Br J Ophthalmol 2006;90:20-3.
- 15. Solomon KD, Fernandez de Castro LE, Sandoval HP, Biber JM, Groat B, Neff KD, Ying MS, French JW, Donnenfeld ED, Lindstrom RL, Joint LSTF. LASIK world literature review: quality of life and patient satisfaction. Ophthalmology 2009;116:691-701.
- 16. Yuen LH, Chan WK, Koh J, Mehta JS, Tan DT, SingLasik Research G. A 10-year prospective audit of LASIK outcomes for myopia in 37,932 eyes at a single institution in Asia. Ophthalmology 2010;117:1236-44.e1.
- 17. Alió JL, Muftuoglu O, Ortiz D, Perez-Santonja JJ, Artola A, Ayala MJ, Garcia MJ, de Luna GC. Ten-year follow-up of laser in situ keratomileusis for myopia of up to −10 diopters. Am J Ophthalmol 2008;145:46-54.
- 18. Lin JM, Tsai YY. Laser in situ keratomileusis for different degrees of myopia. Acta Ophthalmol Scand 2005;83:40-5.
- 19. Alió JL, Muftuoglu O, Ortiz D, Perez-Santonja JJ, Artola A, Ayala MJ, Garcia MJ, de Luna GC. Ten-year follow-up of laser in situ keratomileusis for high myopia. Am J Ophthalmol 2008; 145:55-64.
- 20. Dada T, Sudan R, Sinha R, Ray M, Sethi H, Vajpayee RB. Results of laser in situ keratomileusis for myopia of -10 to -19 diopters with a Technolas 217 laser. J Refract Surg 2003;19:44-7.
- 21. Chayet AS, Assil KK, Montes M, Espinosa-Lagana M, Castellanos A, Tsioulias G. Regression and its mechanisms after laser in situ keratomileusis in moderate and high myopia. Ophthalmology 1998; 105:1194-9.
- 22. Rosman M, Alio JL, Ortiz D, Perez-Santonja JJ. Refractive stability of LASIK with the Visx 20/20 excimer laser vs ZB5m phakic iol implantation in patients with high myopia (>-10.00 d): a 10-year retrospective study. J Refract Surg 2011;27:279-86.
- 23. van der Heijde G. Some optical aspects of implantation of an IOL in a myopic eye. Eur J Implant Refract Surg 1989;1:245-8.
- 24. Kato N, Toda I, Hori-Komai Y, Sakai C, Tsubota K. Five-year outcome of LASIK for myopia. Ophthalmology 2008;115:839-44.e2.

- 25. Patel SV, Bourne WM. Corneal endothelial cell loss 9 years after excimer laser keratorefractive surgery. Arch Ophthalmol 2009;127:1423-7.
- 26. Albarran-Diego C, Munoz G, Ferrer-Blasco T, Garcia-Lazaro S, Belda-Salmeron L. Foldable iris-fixated phakic intraocular lens vs femtosecond laser-assisted LASIK for myopia between -6.00 and -.00 diopters. J Refract Surg 2012;28:380-6.
- 27. Qi H, Hao Y, Xia Y, Chen Y. Regression-related factors before and after laser in situ keratomileusis. Ophthalmologica 2006;220:272-6.
- 28. Kozak I, Hornak M, Juhas T, Shah A, Rawlings EF. Changes in central corneal thickness after laser in situ keratomileusis and photorefractive keratectomy. J Refract Surg 2003;19:149-53.
- 29. Guell JL, Muller A. Laser in situ keratomileusis (LASIK) for myopia from -7 to -18 diopters. J Refract Surg 1996;12:222-8.
- 30. Ivarsen A, Hjortdal J. Seven-year changes in corneal power and aberrations after PRK or LASIK. Invest Ophthalmol Vis Sci 2012; 53:6011-6.

- 31. Jones CE, Atchison DA, Meder R, Pope JM. Refractive index distribution and optical properties of the isolated human lens measured using magnetic resonance imaging (MRI). Vision Res 2005; 45:2352-66.
- 32. Daoud YJ, Hutchinson A, Wallace DK, Song J, Kim T. Refractive surgery in children: treatment options, outcomes, and controversies. Am J Ophthalmol 2009;147:573-82.e2.

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