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ORIGINAL RESEARCH

Residual stromal bed thickness correlates with regression of myopia after LASIK

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Purpose: The purpose of this study was to evaluate the correlation between residual stromal bed thickness (hereinafter bed thickness) and regression of myopia after LASIK, taking into consideration the long-term outcomes.
Subjects and methods: A total of 177 patients (309 eyes) and 41 patients (70 eyes) were retrospectively reviewed at 5 and 10 years after surgery, respectively. These patients were also continuously examined throughout the study. All patients underwent laser in situ keratomileusis (LASIK) for myopia in our clinic and scored at least 1.0 (0 logMAR) uncorrected distance visual acuity (UCVA) 1 month after surgery. Bonferroni–Dunn method and Student's *t*-test were used for statistical analyses.
Results: Cases with a refractive value (spherical equivalent) of less than −6.0 D (Group A) were compared to those with −6.1 D or higher (Group B). There was a statistically significant decrease in Group B UCVA of 0.04 logMAR and 0.12 logMAR at 5 and 10 years after surgery, respectively. With regard to the relationship between regression of myopia and bed thickness in the long-term, there was a significantly higher frequency of regression of myopia in cases with less than 350 μm bed thickness compared to those with 350 μm and more, in a surgical volume of more than −6.1 D (Group B).
Conclusion: The present study indicates that bed thickness correlates with regression of myopia after LASIK and enough bed thickness is important to maintain good UCVA in the long-term.
Keywords: LASIK, regression, residual stromal bed thickness

Introduction

Several retrospective studies have examined the long-term postoperative results of laser in situ keratomileusis (LASIK)[1–5] and proposed various mechanisms that could lead to a regression of myopia. These include changes in corneal refraction of the corneal anterior surface, anterior displacement of the posterior surface of the cornea,[6–9] higher degree of astigmatism,[10] axial length elongation during the long-term follow-up period, and hardening of lens nucleus by age.[11] However, there have not been any studies investigating the correlation between regression of myopia and residual stromal bed thickness (hereinafter bed thickness) more than 10 years after surgery. We have previously suggested the correlation between regression of myopia and bed thickness in a short-term study.[8] In the present study, we investigated the importance of bed thickness to maintain good uncorrected distance visual acuity (UCVA) after LASIK based on the long-term outcomes.

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Subjects and methods

Subjects

A total of 177 patients (309 eyes) and 41 patients (70 eyes) were retrospectively reviewed at 5 and 10 years after surgery, respectively. These patients were also

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continuously examined throughout the study. All the patients underwent LASIK for correction of myopia at our clinic from July 2001 and scored at least 1.0 (0 logMAR) UCVA 1 month after surgery. Details of the preoperative data and characteristics of subjects are summarized in Tables 1 and 2. Patients with postoperative complications and enhancement cases were not included in this study.

Surgical technique

In those cases analyzed for the present study, two surgeons performed LASIK using microkeratome MK-2000® (NIDEK Co., Ltd.) for all cases of corneal flap preparation, and the Excimer laser system EC-5000 (NIDEK Co., Ltd.) for laser ablation. Flap thickness of analysis cases in this study was 110.2±15 μm (mean ± standard deviation). Standard LASIK with an optical zone of 6 mm and transitional zone of 7 mm was performed. Corrected astigmatism was –0.71±0.8 D (mean ± standard deviation). Corneal shape analysis was carried out using Orbscan®. Corneal thickness was measured using pachymeter DGH-500® (DGH Co., Ltd.), preoperatively, intraoperatively, and postoperatively. Bed thickness was determined by subtracting the ablated volume of the cornea from the remaining value of corneal central thickness before intraoperative excimer laser ablation after flap reverse.

Methods

An examination is performed at our clinic on the day after surgery, followed by 1 week, 1 month, 3 months, 6 months, 1 year, and 2 years after surgery. Then, the patient is advised to return to the clinic once a year. Cases of noncompliance where subjects returned irregularly for follow-up examinations were excluded from the study. This study considered only those cases that could be continuously examined throughout the postoperative periods of 1 month, 6 months, 5 years, and 10 years after surgery.

Postoperative safety index, visual acuity, efficacy index, and corneal refraction were among the data collected. Postoperative change of corneal refraction in 5 and 10 years was evaluated by comparing with the keratometric value (diopter: hereinafter D) of 6 months after surgery. Furthermore, cases with a corrected refractive value (spherical equivalent) of less than –6.0 D (hereinafter referred to as Group A) were compared with cases with a corrected refractive value –6.1 D and higher (hereinafter referred to as Group B). In addition, long-term progression of vision and corneal refraction were considered with regard to bed thickness of more or less than 350 μm after LASIK. We described here the meaning of bed thickness 350 μm. When surgical ablation volume was set at refractive value of –6.0 D in cases of myopia correction by LASIK, ablation volume was ~90 μm. As average central corneal thickness of Japanese individual is around 540 μm, the value chosen to compare bed thickness was set at 350 μm, which is 540 μm minus 190 μm including flap thickness. An efficacy index (postoperative UCVA/preoperative corrected distance visual acuity) was used to evaluate the effectiveness of LASIK. A safety index (postoperative corrected distance visual acuity/preoperative corrected distance visual acuity) was used to evaluate the safety of the procedure. Regarding vision, the value of visual acuity fraction was converted to logMAR vision and set as the database.

With regard to statistical analysis, Bonferroni–Dunn method for multiple comparisons (Figures 1 and 2B) and Student's *t*-test for two groups (Figures 2A, 3, and 4) were used. The significance level of 5% was used.

Written informed consent was obtained from all the subjects. The study was conducted in accordance with the tenets of the Declaration of Helsinki and with the approval of the Ogasawara Eye Clinic's ethical review board.

Table 1 Details of preoperative data and characteristics of subjects in cases of 5 years after LASIK

Preoperative data and characteristics of subject	Group A		Group B	
	Male	Female	Male	Female
Eyes	182		127	
Number of patients	34	69	19	55
Mean age at surgery (years)	34.0	33.7	34.7	24.0
Refraction (spherical equivalent) (mean ± SD) (D)	–4.29±1.19		–8.22±1.75	

Abbreviations: LASIK, laser in situ keratomileusis; SD, standard deviation; D, diopter.

Table 2 Details of preoperative data and characteristics of subjects in cases of 10 years after LASIK

Preoperative data and characteristics of subjects	Group A		Group B	
	Male	Female	Male	Female
Eyes	38		32	
Number of patients	13	9	7	12
Mean age at surgery (years)	35.7	40.3	34.4	39.7
Mean refraction (spherical equivalent) (mean ± SD) (D)	–4.49±1.08		–8.63±2.00	

Abbreviations: LASIK, laser in situ keratomileusis; SD, standard deviation; D, diopter.

Results

Safety of LASIK

The overall safety index of all targeted cases at 5 and 10 years after surgery was 1.15 and 1.18, respectively. Moreover, good results of the efficacy index were obtained in both Group A (less than –6.0D) and Group B (–6.1D or higher). Thus, the efficacy

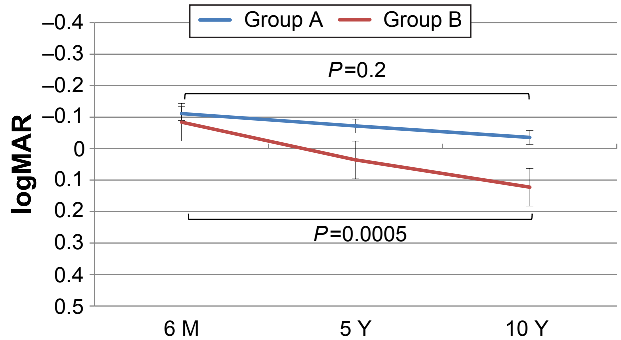

Figure 1 The time course and changes of UCVA in this study and comparison of UCVA in cases of Group A (corrected refractive value of less than –6.0 D) and Group B (corrected refractive value of higher than –6.1 D).
Note: There was a significant decrease of UCVA in Group B at 10 years after LASIK.
Abbreviations: UCVA, uncorrected distance visual acuity; LASIK, laser in situ keratomileusis; M, months; Y, years; D, diopter.

index of Group A and Group B was 1.18 and 1.15 at 5 years after surgery and 1.18 and 1.08 at 10 years after surgery.

Postoperative vision and effectiveness of LASIK

A statistically significant difference was observed in postoperative UCVA with an average value of –0.02 logMAR and 0.04 logMAR at 5 and 10 years after surgery, respectively, compared to –0.1 logMAR 6 months after surgery in all the cases. When compared with cases of Group A and Group B, there was a statistically significant decrease in Group B UCVA of 0.04 logMAR and 0.12 logMAR at 5 and 10 years after surgery, respectively (Figure 1). These results are reflected by the efficacy index where Group A and Group B scored 1.00 and 0.86 at 5 years after surgery and 0.94 and 0.68 at 10 years after surgery, respectively.

Changes in postoperative vision were verified by bed thickness. There was a trend toward a significant difference in UCVA between cases of bed thickness above 350 µm and those less than 350 µm at 10 years after surgery in Group B (Figure 2A). Furthermore, when the ablation volume by LASIK was set as 92–98 µm (approximately for –7.0 to –7.8 D) in cases of Group B with bed thickness of more than 350 µm and less than 350 µm, a more significant decrease in UCVA in cases with bed thickness of less than 350 µm after surgery was apparent (Figure 2B).

Corneal refraction

A change in the degree of corneal refraction is considered an important factor for a decreased postoperative UCVA in the long-term. With regard to the change in corneal refraction, a significant increase of keratometric value (D) was observed in Group B compared to Group A (Figure 3). Furthermore, when changes in keratometric value beyond 6 months after surgery were examined in the two groups (Group A and B), a significant increase in keratometric value was observed in both Group A (Figure 4A) and Group B (Figure 4B) with bed thickness of less than 350 µm from 0.34 D at 5 years to 0.54 D at 10 years, and with bed thickness of more than 350 µm from 0.41 D at 5 years to 0.70 D at 10 years, respectively. Conversely, among cases with bed thickness of more than 350 µm, a statistical difference of keratometric value was not observed in both Group A (Figure 4A) and Group B (Figure 4B).

Discussion

The fact that the safety index of all target cases at 5 and 10 years after surgery was 1.15 and 1.18, respectively confirmed the safety of LASIK.

Regarding UCVA after LASIK, the frequency of regression of myopia has been reported to be higher in cases with more surgical volume.[1,3,4] Consistent with these reports, our

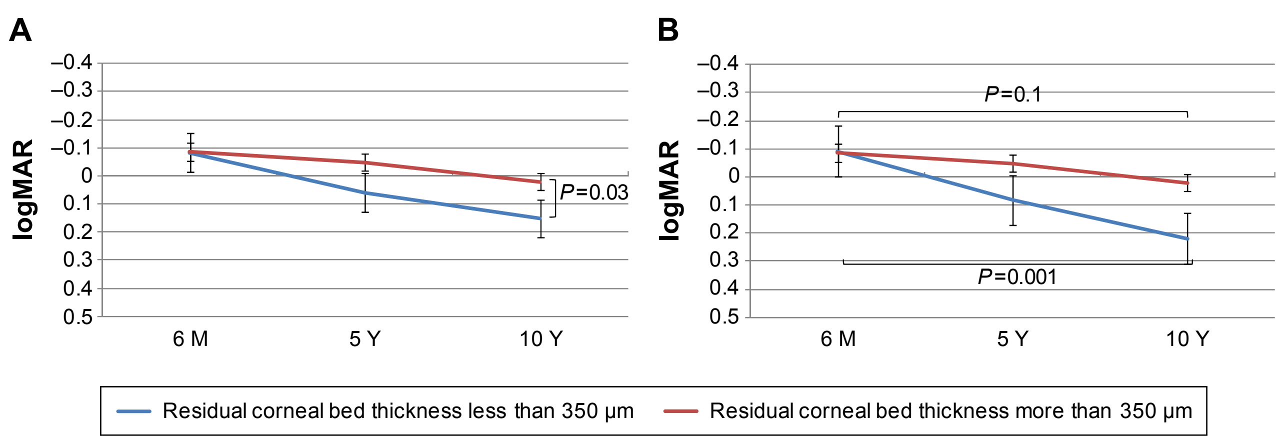

Figure 2 Changes of UCVA in verified bed thickness in Group B. Significant decrease of UCVA in cases of Group B with bed thickness of less than 350 µm compared to those with more than 350 µm at 10 years after LASIK was observed (**A**). When the ablation volume by LASIK was set as 92–98 µm (approximately for –7.0 to –7.8 D) in Group B, a more significant decrease in UCVA in cases with bed thickness of less than 350 µm after surgery was apparent (**B**).
Abbreviations: UCVA, uncorrected distance visual acuity; LASIK, laser in situ keratomileusis; M, months; Y, years; D, diopter.

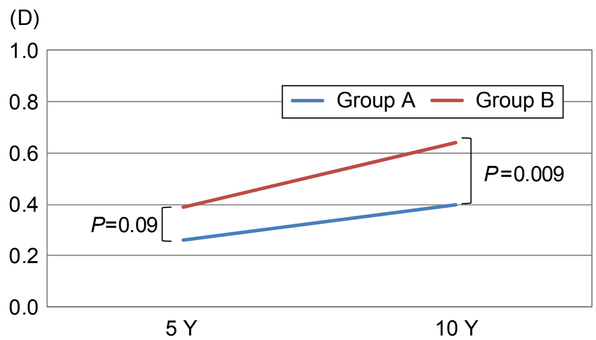

Figure 3 Difference in keratometric value (D) to show changing of corneal refraction in Group A and Group B. A significant increase of keratometric value was observed in Group B at 10 years after LASIK.
Abbreviations: LASIK, laser in situ keratomileusis; Y, years; D, diopter.

study observed a trend toward a decrease in UCVA over a longer term in Group B with a surgical volume of more than −6.1 D compared to Group A with a surgical volume of less than −6.0 D. When visual acuity was compared with that at 6 months after surgery, a significant decrease of UCVA was observed in Group B after surgery (Figure 1). This is reflected by the changes in efficacy index over time. A significant decrease in efficacy index was reported in Group B at 10 years after surgery. Conversely, no significant difference was observed in UCVA or efficacy index in Group A even after 5 and 10 years after LASIK.

We have previously reported evidence of a correlation between regression of myopia and bed thickness in the short-term.[8] In this study, we investigated regression of myopia in the long-term, comparing bed thickness of more than 350 µm with that of less than 350 µm. A trend toward a significant difference in UCVA was observed at 10 years after surgery. When comparing the correlation between bed thickness in Group A and Group B, no significant difference was observed in Group A for both cases with bed thickness of more or less than 350 µm. However, a significant difference was observed at 10 years after LASIK in Group B (Figure 2A). Furthermore, the data that a more significant decrease in UCVA with bed thickness of less than 350 µm at 10 years after surgery in Group B when the ablation volume by LASIK was set as 92–98 µm (approximately for −7.0 to −7.8 D) confirmed the importance of bed thickness in maintaining a good UCVA in high myopia (Figure 2B). Taken together, the data suggest the possibility of keeping good UCVA in the long-term after LASIK even in Group B, if the bed thickness is more than 350 µm. On the other hand, a significant decrease in vision was observed in Group B with a bed thickness of less than 350 µm.

With regard to the change in corneal refraction, Group A and Group B were compared as the number of cases with decreased UCVA after LASIK were found to be higher in Group B. A significant increase in keratometric value was observed in Group B compared to Group A (Figure 3). Moreover, in cases where bed thickness was less than 350 µm, the degree of changes in keratometric value increased over the years, when compared with cases where bed thickness was 350 µm or more (Figure 4), indicating a correlation in regression.

It is well established that the frequency of regression of myopia increases as the degree of refractive correction by LASIK.[1,3,4] However, there have not been any studies investigating the correlation between this regression and bed thickness. As such, our study provides novel and important data with regard to this relationship in the long-term. The present study is an indication of the limit of refractive surgical volume, so as to maintain UCVA in the long-term after LASIK surgery.

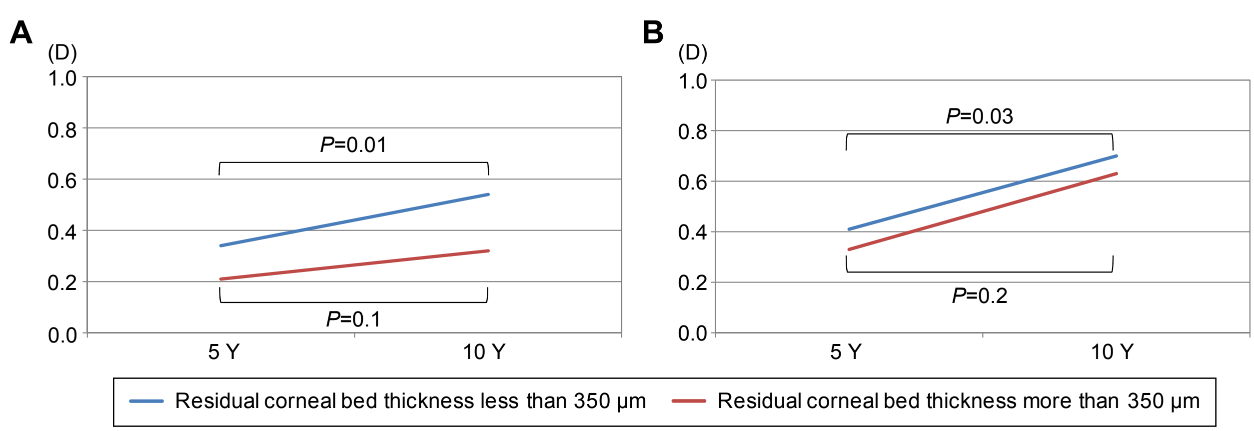

Figure 4 Changes of keratometric value (D) of Group A (**A**) and Group B (**B**). A significant increase of keratometric value was observed in cases with bed thickness of less than 350 µm at 10 years after LASIK in both Group A and Group B. Conversely, among cases with bed thickness of more than 350 µm, there was no statistically significant increase of keratometric value in both Group A and Group B.
Abbreviations: LASIK, laser in situ keratomileusis; Y, years; D, diopter.

Study limitations

We would like to mention here that the 10-year visit rate (17.4%) after LASIK in our clinic may be better than previous reports and the analysis cases were strictly selected and evaluated. However, the limitation of this study included the fact that it was performed in a retrospective manner and analysis cases in 10 years after surgery are relative small number. We also have to consider more sophisticated methods such as OCT and high-resolution ultrasound instrument to measure flap thickness. Furthermore, higher risk for myopic regression by LASIK with a mechanical microkeratome than with a femtosecond laser has been reported.[12] Prospective examinations in considerations of various factors of myopic regression after surgery will further clarify causes concerning regression of myopia after LASIK.

Disclosure

The authors report no conflicts of interest in this work.

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