Refractive Outcomes of Femtosecond LASIK for Myopic Correction at Siriraj Hospital, Thailand

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Objective: *To evaluate refractive outcomes of myopic femtosecond LASIK at Siriraj Hospital, Thailand.*
Material and Method: *A retrospective study of patients who underwent femtosecond LASIK at SiLASIK center, Siriraj hospital, Mahidol University, Thailand, from April 2009 to April 2010 was conducted. All patients had completely normal pre-operative eye examination. All LASIK procedures were performed using Intralase® femtosecond laser (Abbott Medical Optics Inc (AMO)) and VISX® star S4 excimer laser (AMO). Postoperative follow-up included visual acuity (ETDRS chart) and manifest refraction at 1 day, 1 week, 1 month and 3 months. The flap thickness was evaluated at 3 months using Visante® optical coherence tomography (OCT, Carl Zeiss Meditec).*
Results: *One hundred and twenty eight eyes of 64 patients were included in the study. Mean preoperative manifest refraction spherical equivalent (MRSE) was -5.47 ± 2.28 diopters (range, -1.88 to -12.63 diopters). At 3 months post-operation, the MRSE was -0.26 ± 0.39 diopters (range, + 0.25 to -2.00 diopters) and 95.31% were within ± 1.00 diopter of intended correction. There was 98% of eyes achieved uncorrected distance visual acuity (UDVA) 20/40 or better and 73% achieved UDVA 20/20 or better. There was 31% of eyes gained one line and 15% lost 1 line of corrected distance visual acuity (CDVA). The mean error of flap thickness (difference between actual and intended central flap thickness) was + 0.23 ± 1.77 μm for 120 μm flap setting and + 0.22 ± 0.97 μm for 110 μm flap setting. The flap morphology was planar configuration.*
Conclusion: *Myopic femtosecond LASIK at Siriraj Hospital provided satisfactory refractive outcomes and high accuracy of the flap thickness.*

Keywords: *Refractive outcome, Myopia, Femtosecond LASIK, Thailand*

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Laser in situ keratomileusis (LASIK) is the most popular laser corneal refractive surgery nowadays[1,2]. The benefit of treatment in myopic patients has been well documented[3]. There are several methods to create the corneal flap before reshaping the cornea. Among them, femtosecond laser is one of the latest flap cutting technologies. Femtosecond laser is a near infrared laser which has the wavelength of 1,053 nanometer and pulse duration of 10^{-15} second (femtosecond). The laser-tissue interaction is similar to Nd: YAG laser (photodisruption), which creates plasma cavity and acoustic shock wave to separate the surrounding tissue[4,5]. It has been used to create corneal flap in LASIK surgery since 2002[4]. From the previous study, the flap created by femtosecond laser has been shown to have some advantages over the flap created by a microkeratome. By using femtosecond laser, uniform and smooth flap surface was achieved, which results in less flap- related complication, more safety and efficacy and better visual outcome[6-8]. Nevertheless, no such reports are available to evaluate this new technology in Thailand. The present study was conducted to evaluate the efficacy, safety, stability of the treatment and the accuracy of the flap thickness created by femtosecond laser in situ keratomileusis for myopic correction in Thai patients.

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Material and Method

All data of the patients who visited SiLASIK center, Siriraj Hospital, Mahidol University, Thailand

from April 2009 to April 2010 were reviewed. Patients who were eligible for LASIK surgery were included in the present study. Preoperative evaluation was done including complete eye examination, tonometry, manifest and cycloplegic refraction, corneal thickness and Orbscan® corneal topograghy (Bausch & Lomb, Inc). All procedures were performed under topical anesthesia. The corneal flap was created using Intralase® femtosecond laser (AMO). The flap thickness was set at 110 or 120 micrometer (μm), according to the corneal thickness of the patient. Laser ablation was performed using VISX® star S4 excimer laser (AMO). The ablation setting was customized according to the manifest refraction. Postoperative topical antibiotics, topical steroid and artificial tears were administered. Postoperative examination was performed at 1 day, 1 week, 1 month and 3 months post-operation. Manifest refraction, uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) was recorded using ETDRS chart. The flap thickness was evaluated at 3 months post-operation using Visante® OCT (Carl Zeiss Meditec). Statistical analysis was calculated using Microsoft Excel 2007. The present study was conducted under the approval of the institutional's ethics committees.

Refractive outcomes were reported as recommended by the Journal of Refractive Surgery using the standard graphs for reporting refractive surgery[9]. Efficacy of the treatment was defined as 20/40 or better of UDVA. Safety of the treatment was measured by loss of CDVA and would be considered significant if there was more than 1 CDVA line loss. Accuracy of the treatment was evaluated using attempted vs. achieved refraction scatter plot, residual post-operative manifest refraction spherical equivalent (MRSE) and residual refractive astigmatism. Stability of the treatment was assessed by MRSE over time.

Results

One hundred and twenty eight eyes of 64 patients were included in the present study. Mean age of the patients was 31.49 years (range, 18-54 years). Mean preoperative MRSE was -5.47 ± 2.28 diopters (range, -1.88 to -12.63 diopters).

Efficacy

Efficacy of the treatment at 3 months post-operation is shown in Fig. 1. There was 98% of eyes which achieved UDVA of 20/40 or better and 73% achieved UDVA of 20/20 or better. Post-operative spherical equivalent refraction at 3 months is shown in Fig. 2. There was 95.31% of eyes which achieved within ± 1.00 diopter of intended correction and 86% achieved within ± 0.50 diopter of intended correction. Six eyes (4.69%) had under-correction of more than 1.00 diopter of target refraction. Residual refractive astigmatism at 3 months post-operation is shown in Fig. 3. There was

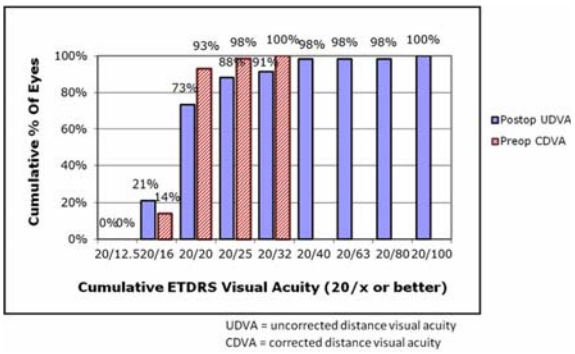

Fig. 1 Percentage of eyes achieving cumulative uncorrected distant visual acuity (UDVA) at 3 months post-operation

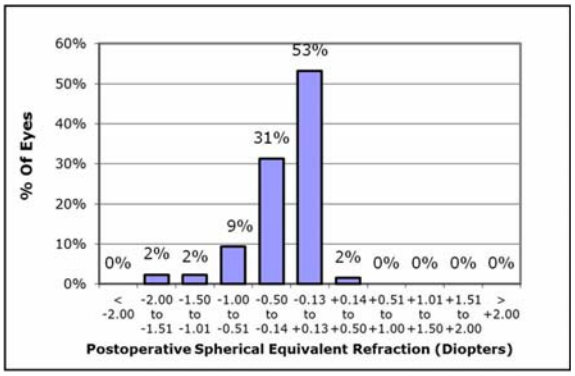

Fig. 2 Post-operative spherical equivalent refraction (Diopters) at 3 months

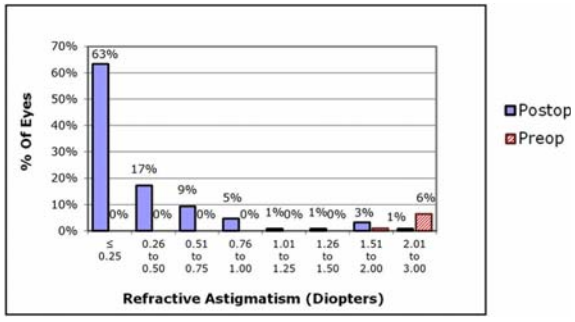

Fig. 3 Post-operative refractive astigmatism (Diopters) at 3 months

80% of eyes that had residual refractive astigmatism of + 0.50 diopter or less and 95% that had a value of + 1.00 diopter or less. At 3 months after surgery, the MRSE was -0.26 ± 0.39 diopter (range, + 0.25 to -2.00 diopters).

Stability

The stability of the treatment over the 3 months post-operation is shown in Fig. 4. Preoperatively, the mean MRSE was -5.47 ± 2.28 diopters. After surgery, mean MRSE at 1 week (0.3 month), 1 month, and 3 months was -0.27 ± 0.39 diopter, -0.25 ± 0.49 diopter and -0.26 ± 0.39 diopter, respectively. The graph shows minimal change of post-operative refraction towards 3 months. There was 6% of eyes that had a mean MRSE change more than ± 0.50 diopter over 3 months.

Predictability

The predictability of the treatment is shown by attempted versus achieved correction graph in Fig. 5. The mean pre-operative MRSE (-5.47 ± 2.28 diopters (range, -1.88 to -12.63 diopters)), was the attempted value of correction as all eyes were targeted at full myopic correction. At 3 months post-operation, the achieved spherical equivalent refraction was compared with the attempted spherical equivalent refraction. Strong correlation and predictability of the treatment was shown with the coefficient of determination (r^2) of 0.97. There was slightly undercorrection in high myopic patients.

Safety

Safety of the treatment is shown in Fig. 6. There was 31% of eyes which gained one line and 15% lost 1 line of CDVA acuity. No eye lost more than 1 line of CDVA.

There was no flap-related complication resulting in abortion of the procedure. Intra-operatively, there were 2 eyes (1.4%) that had the vertical gas breakthrough and 1 eye (0.7%) had air bubble in the anterior chamber. The operations went successfully in all of these eyes without any complications with the CDVA of 20/20 at 1 week post-operation.

Corneal flap

In the present study, the corneal flaps were created using 120 µm thickness setting in 54 eyes and 110 µm thickness setting in 74 eyes. There was no statistically significant difference in all refractive outcomes between the 120 µm and 110 µm flap setting.

The corneal flap was evaluated at three months after surgery. The flap accuracy was evaluated by measuring the flap thickness from center to periphery, at every 1 cm width, along 4 axes (0,45,135,180 degree). Mean ± SD of actual flap thickness for 120 µm

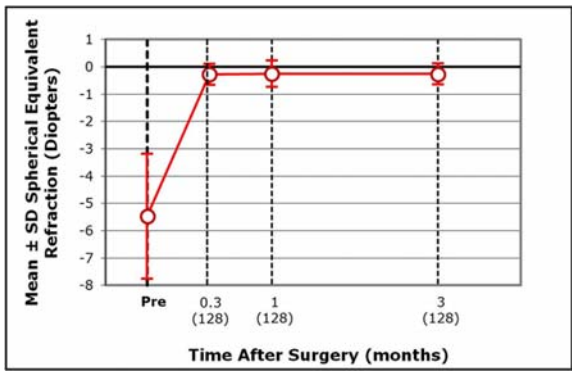

Fig. 4 Stability of refraction towards 3 months post-operation

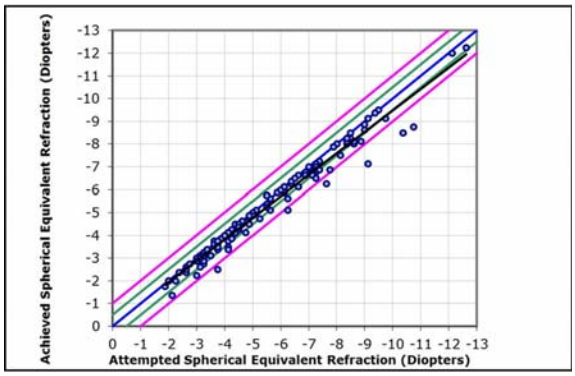

Fig. 5 Predictability of the treatment (attempted versus achieved refraction)

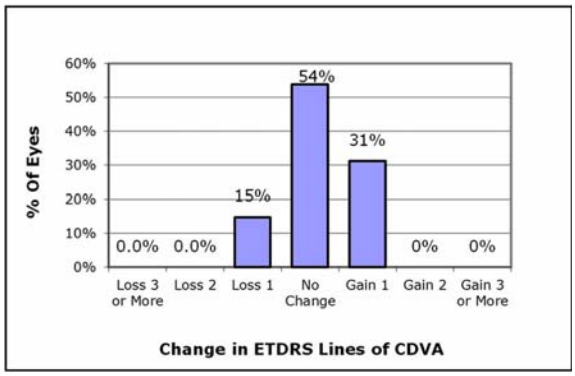

Fig. 6 Three-month safety of the treatment (corrected distance visual acuity (CDVA) line loss)

and 110 μm setting is shown in Fig. 7. The error of the flap thickness (the difference between actual central flap thickness and intended flap thickness) was + 0.23 ± 1.77 μm (range, -5 to +3 μm) for the setting of 120 μm and + 0.22 ± 0.97 μm (range, -2 to + 2 μm) for the setting of 110 μm.

The flap morphology was evaluated by comparing the difference between peripheral flap thickness and the central flap thickness (peripheral-central). The positive value means the flap is thicker in the periphery than the center and vice versa. The morphology for 120 μm and 110 μm flap setting is shown in Fig. 8. The maximum difference from peripheral to central flap was + 2.26 μm in 120 μm flap setting, while the maximum difference was + 0.74 μm in 110 μm flap setting. The achieved corneal flap shows planar flap configuration (Fig. 9).

Fig. 7 Mean ± SD (μm) of actual flap thickness for 120 μm and 110 μm setting

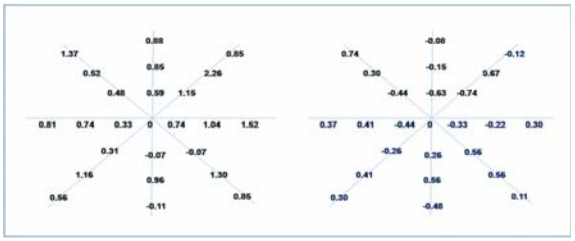

Fig. 8 Morphology of 120 μm and 110 μm flap setting (comparing the difference between peripheral flap thickness and the central flap thickness (μm) (peripheral-central)). The positive value means the flap is thicker in the periphery than in the center. The negative value means the flap is thinner in the periphery than in the center

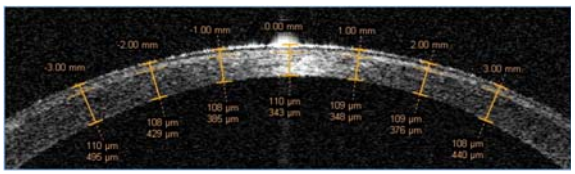

Fig. 9 Horizontal cross-sectional optical coherence tomography image of the cornea at 110 μm flap thickness setting. The image of the femtosecond laser flap shows flat and planar morphology

Discussion

The advantages of femtosecond laser in LASIK flap creation has been well established[6-8]. Among other benefits which made femtosecond laser become popular, one extraordinary benefit is the higher flap accuracy compared to conventional microkeratome. Moreover, the corneal flap has excellent structure, uniform thickness and smooth surface. This flap architecture results in increasing the safety and improving the efficacy of the treatment[10]. The femtosecond laser's ability to create the thinner flap with high accuracy yields several advantages. It improves the safety of the procedures, which leads to better visual outcome. It also helps the surgeon to extend range of treatment in the patient who was previously unsafe for LASIK. The ultra-thin flap made by femtosecond laser gives more stromal bed for the myopic laser treatment in the patient with high myopia or thin cornea. This method could help to reduce postoperative complication, such as corneal ectasia.

The SiLASIK center, Siriraj Hospital, has been using femtosecond laser for LASIK surgery since April 2009. This is the first report of the results of femtosecond LASIK in Thailand. The present study was conducted in order to evaluate the refractive outcomes, complications and the flap architecture, which was done by femtosecond LASIK. The refractive outcomes of myopic femtosecond LASIK shown in the present study were better than the authors' previous reports using mechanical microkeratome[15,16].

The efficacy of the treatment was high, as well as the safety. No eyes in the present study lost more than 1 line of ETDRS CDVA acuity, while 31% gained 1 line. Those who lost 1 line (15%) were carefully reviewed and found that 12.5% lost CDVA from 20/16 to 20/20. This could be due to the method of measuring the visual acuity that the patient had not been instructed to read further down when they reached 20/20 line. The attempted versus achieved correction graph showed good correlation and predictability. However, slight under-correction was found in the high myopic treatment. The stability graph also showed good result toward 3 months.

One of the major misleading interpretations in refractive surgery is using MRSE (sphere + cylinder/2) alone to report refractive outcome[17]. The value can be

zero despite the high magnitude of sphere and cylinder due to the difference in the sign of the cylinder and sphere. Therefore, refractive astigmatism or defocus equivalent (MRSE added to one-half of the cylinder, ignoring the sign) was proposed to solve this problem[17]. In the present study, 95% of eyes had a refractive astigmatism of + 1.0 diopter or less. Those who had high residual refractive astigmatism were the eyes that had the high preoperative refractive error.

Complications such as vertical gas breakthrough and air in anterior chamber have been reported in femtosecond LASIK surgery[11-13]. However, this neither effected the operation nor the treatment outcome in the present study. All 3 eyes had CDVA of 20/20 at 1 week post-operation.

The femtosecond laser flap thickness in the present study showed excellent accuracy. Earlier reports showed the standard deviation of flap thickness using mechanical microkeratome range between 24.9-29 μm[7,18]. The result found in the present study was much lower (1.77 and 0.97 μm for 120 and 110 μm flap setting). Also the error of the central flap thickness was very low for both 120 μm and 110 μm flap setting (within the range of 5 microns). There was a slight difference between the peripheral and central flap thickness. This difference was minimal and did not have an influence on the flap shape. The morphology of the flap created by the femtosecond laser showed to have a regular planar shape (Fig. 9), in contrast with morphology of microkeratome flap[14], which had the meniscus shaped (the flap-thickness measurement were thinnest in the center and increased toward the periphery).

In conclusion, these results of LASIK using the femtosecond laser was shown to be safe, effective and stable in Thai myopic patients. However, there was a slightly under-correction in high myopic patients. Normogram adjustment is required in order to improve the efficacy of the treatment.

Potential conflicts of interest

None.

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การศึกษาผลการรักษาภาวะสายตาสั้นด้วยวิธี Femtosecond LASIK ณ โรงพยาบาลศิริราช

สบง ศรีวรรณบูรณ์, ภรณ์ลดา ศัลกวิเศษ, พนิดา โกสียรักษ์วงศ์, ภิญนิตา ประภาสะวัต, วิภาวี บูรณพงศ์, สุขศรี โชติกวณิชย์, วศิน โพธิ์งาม

วัตถุประสงค์*: เพื่อศึกษาผลการรักษาภาวะสายตาสั้นด้วยวิธี Femtosecond LASIK ณ โรงพยาบาลศิริราช*

วัสดุและวิธีการ*: ศึกษาผู้ที่มีภาวะสายตาสั้นที่เข้ารับการรักษาด้วยวิธี Femtosecond LASIK โดยใช้ Intralase® femtosecond laser (Abbott Medical Optics Inc. (AMO)) และ VISX® star S4 excimer laser (AMO) ที่ศูนย์รักษาสายตา โรงพยาบาลศิริราช ตั้งแต่เดือนเมษายน พ.ศ. 2552 ถึงเดือนเมษายน พ.ศ. 2553 ทำการเก็บข้อมูลก่อนการรักษาและผลหลังการรักษา ได้แก่ ค่าสายตา (ETDRS) ที่ระยะเวลา 1 วัน, 1 สัปดาห์, 1 เดือน และ 3 เดือนหลังการรักษา และค่าความหนาของชั้นกระจกตาที่ 3 เดือนหลังการรักษาโดย Visante® optical coherence tomography (OCT, Carl Zeiss Meditec) และประเมินผลการรักษาที่ 3 เดือนหลังรักษา*

ผลการศึกษา*: ผู้ที่มีภาวะสายตาสั้นที่เข้ารับการรักษาด้วยวิธี Femtosecond LASIK จำนวน 64 คน 128 ตา พบว่าค่าสายตาเฉลี่ย manifest refraction spherical equivalent (MRSE) ก่อนเข้ารับการรักษาคือ -5.47 $\pm$ 2.28 diopters (ช่วงระหว่าง -1.88 ถึง -12.63 diopters) ผลการศึกษาที่ 3 เดือนหลังการรักษาพบว่าค่าสายตาเฉลี่ย MRSE คือ -0.26 $\pm$ 0.39 diopters (ช่วงระหว่าง +0.25 ถึง -2.00 diopters) ค่าสายตาเฉลี่ย MRSE ภายใน $\pm$ 1.00 diopter พบร้อยละ 95.31 ค่าสายตา uncorrected distance visual acuity (UDVA) ที่มีค่า 20/40 หรือดีกว่าพบร้อยละ 98 ค่าสายตา UDVA ที่มีค่า 20/20 หรือดีกว่าพบร้อยละ 73 ค่าสายตา corrected distance visual acuity (CDVA) ที่มีจำนวนเพิ่มขึ้น 1 แถวเทียบกับก่อนเข้ารับการรักษาพบร้อยละ 31 และค่าสายตาCDVA ที่ลดลง 1 แถวพบร้อยละ 15 ค่าความคลาดเคลื่อนของชั้นกระจกตาที่แยกได้จริงเมื่อเทียบกับค่าที่ต้องการมีค่า +0.23 $\pm$ 1.77 μm ในการแยกชั้นกระจกตาที่ความหนา 120 μm และมีค่า +0.22 $\pm$ 0.97 μm ในการแยกชั้นกระจกตาที่ความหนา110 μm การศึกษารูปร่างชั้นกระจกตาที่ได้พบว่ามีรูปร่างเรียบสม่ำเสมอ*

สรุป*: การรักษาภาวะสายตาสั้นด้วยวิธี Femtosecond LASIK ณ โรงพยาบาลศิริราชได้ผลดี Femtosecond laser มีความแม่นยำสูงในการแยกชั้นกระจกตา*