KJO
pISSN: 1011-8942 eISSN: 2092-9382
Korean J Ophthalmol 2011;25(1):8-14
DOI: 10.3341/kjo.2011.25.1.8

Original Article

Factors Influencing Corneal Flap Thickness in Laser *In Situ* Keratomileusis with a Femtosecond Laser

Chan Young Kim, Ji Hye Song, Kyoung Sun Na, So-Hyang Chung, Choun-Ki Joo

Department of Ophthalmology and Visual Science, Seoul St. Mary's Hospital, The Catholic University of Korea School of Medicine, Seoul, Korea

Purpose: To evaluate factors responsible for the variability between intended and achieved corneal-flap thickness during femtosecond laser-assisted laser *in situ* keratomileusis (LASIK).

Methods: A prospective, nonrandomized, case study was performed on 35 eyes of 18 consecutive patients who underwent LASIK surgery using the 60 kHz femtosecond laser microkeratome. Eyes were assigned to three different thickness groups, with 110-, 120-, or 130-μm cut depths. Anterior segment optical coherence tomography was used to assess the morphology of 35 LASIK flaps at postoperative one week postoperatively. The flap thickness was assessed at seven measuring points across each flap. Patient age, preoperative spherical equivalent, manual keratometry, preoperative central pachymetry, and regional variability of the cornea were evaluated to determine where they influenced the achieved corneal flap thickness.

Results: Cuttings of all flaps were easily performed without any intraoperative complications. Flap-thickness measurements had a mean of 115.21 ± 4.98 μm (intended thickness, 110 μm), 121.90 ± 5.79 μm (intended, 120 μm), and 134.38 ± 5.04 μm (intended, 130 μm), respectively. There was no significant difference between the 110-μm and 120-μm groups when compared with the 130-μm group (one-way analysis of variance test, $p > 0.05$). Patients' age, preoperative spherical equivalent, manual keratometry, and preoperative central pachymetry did not affect the achieved flap thickness (Pearson correlations test, $p > 0.05$). The reproducibility of flap thickness in the central 1.5-mm radius area was more accurate than that in the peripheral 3.0 to 4.0-mm radius area (paired samples *t*-test, $p < 0.05$).

Conclusions: Femtosecond laser-assisted LASIK is likely to reproduce a reliable thickness of the corneal flap, which is independent of corneal shape factors or refractive status. Future studies should focus on variations in corneal biomechanical factors, which may also play an important role in determining flap thickness.

Key Words: Corneal flap thickness, Femtosecond laser, Laser *in situ* keratomileusis

Over the past decade, laser *in situ* keratomileusis (LASIK) has become the most common refractive procedure for the correction of refractive errors. Consistency and predictability of corneal flap thickness is crucial in both planning and in producing successful LASIK outcomes. Complications associated with thin flaps include flap slippage, striae, irregularity, astigmatism, buttonholes, free caps, and corneal haze. Thicker flaps cause decreased stromal-bed thickness, which increases the risk for biomechanical corneal changes and iatrogenic corneal ectasia [1-4].

Few studies have attempted to find a correlation between preoperative variables and corneal-flap thickness with the mechanical microkeratome. Yildirim et al. [5] found a low correlation with preoperative corneal thickness and no correlation with preoperative keratometry when using the mechanical microkeratome. Giledi et al. [6] reported a correlation between preoperative spherical-equivalent refraction and flap thickness, and a paradoxical finding of thinner flaps in patients with thicker corneas using the mechanical microkeratome. Current mechanical microkeratomes have a very good performance record; however, in a few cases, complications can occur during the microkeratome pass and flap cut. Femtosecond lasers offer an alternative to mechanical cutting and can pro-

Received: March 25, 2010 *Accepted*: September 3, 2010

Corresponding Author: Choun-Ki Joo, MD, PhD. Department of Ophthalmology, Seoul St. Mary's Hospital, The Catholic University of Korea School of Medicine, #505 Banpo-dong, Seocho-gu, Seoul 137-701, Korea. Tel: 82-2-2258-1188, Fax: 82-2-599-7405, E-mail: ckjoo@catholic.ac.kr

vide additional features that affect flap morphology. Studies by Krueger and Dupps [7] and Alió and Piñero [8] found a planar-flap profile for femtosecond-laser–created flaps versus a meniscus-flap profile for microkeratome flaps. A meniscus flap extends deeper in the periphery and is shallower in the center of the flap, while a planar flap has the same thickness across its entirety. Despite the improved flap-thickness predictability with the femtosecond lasers compared with the conventional microkeratome, unexpectedly thinner or thicker flaps sometimes occur with the femtosecond lasers and can lead to surgical complications [9]. The main aim of this study was to evaluate preoperative variables and flap thickness in eyes having flap creation with the femtosecond-laser-assisted LASIK.

Materials and Methods

Patient examinations and surgical technique

This prospective study included patients who had uneventful LASIK for myopia between November 2008 and Feburary 2009. The flap was created with a 60 kHz femtosecond laser (IntraLase; Abbott Medical Optics, Irvine, CA, USA). All patients had a full preoperative workup including topography (Orbscan; Bausch & Lomb, Rochester, NY, USA), and pachymetry. No patient had corneal abnormalities or contraindications to LASIK. All patients provided written informed consent.

The patients were divided into three groups. In 110-µm group, the intended corneal-flap thickness was 110 µm. The targeted corneal flap thickness was 120 µm for 120-µm group. 130-µm group, the intended corneal-flap thickness was 130 µm.

The same surgeon (CKJ) performed all the LASIK procedures. The femtosecond laser was programmed to a flap thickness of 110 µm to 130 µm and a flap diameter of 8.3 mm to 9.0 mm with a 90-degree angled side cut and a 55-degree hinge angle. The femtosecond laser's bed energy was 0.65 mJ, it's side cut energy was 0.8 mJ and it's repetition frequency was 60 kHz. The myopic stromal ablations were performed with a Visx Star S4 excimer laser (Wavescan; VISX, Sunnyvale, CA, USA).

Imaging and measurement of the LASIK flaps were performed by high-speed AS-optical coherence tomography (OCT) (Visante; Carl Zeiss-Meditec, Dublin, CA, USA). This noncontact system generates images of the complete flap cross-section with precise geometry and reduces movement artifacts and distortion [10,11]. Imaging is performed with the patient seated, and cross-sectional images of the anterior chamber and the cornea are generated. A horizontal OCT image of the cornea was taken by the same experienced examiner (YJL) at one week after surgery. The imaging and measurements were repeated three times per patient. Flap thickness was measured at seven points in each horizontal image (center, ±1.5 mm, ±3.0 mm, ±4.0 mm to the vertex) (Fig. 1).

Patients were examined before LASIK and also one week and one month after surgery. At each visit, the uncorrected visual acuity (UCVA) and best corrected visual acuity were measured using the Snellen visual-acuity test. Postoperative topical medication regimens were identical in all groups and consisted of gatifloxacin ophthalmic solution, diclofenac ophthalmic solution and fluorometholon 0.1% four times a day for seven days and then tapered over the next week.

Statistical analysis

The correlations between preoperative variables and corneal-flap thickness were analyzed using Pearson correlation statistics. A one-way analysis of variance test was used to compare differences in flap thickness among 110-µm, 120-µm and 130-µm groups. Data were analyzed using the Excel XP program (Microsoft Corp., Redmond, WA, USA) and the SPSS ver. 13.0 (SPSS Inc., Chicago, IL, USA). A *p*-value of 0.05 was considered to be statistically significant.

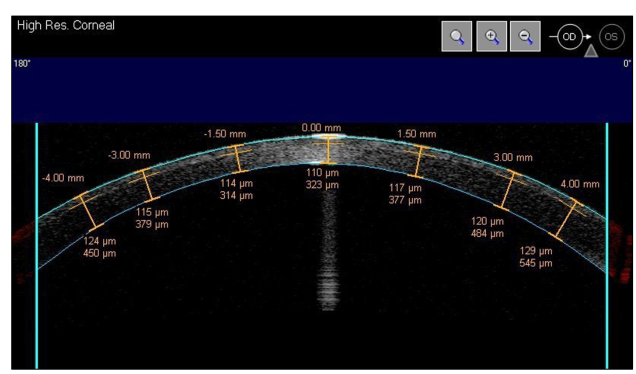

Fig. 1. Example of a horizontal cross-sectional optical coherence tomography image of the cornea. The calipers are located at the seven measurement points.

Table 1. Preoperative patient characteristics

Parameter	110-µm group	120-µm group	130-µm group	*p*-value
Mean age ± SD (yr)	25.30 ± 6.86	25.25 ± 4.65	27.60 ± 7.02	0.017
Mean SE ± SD (D)	-5.60 ± 2.47	-5.18 ± 2.08	-3.07 ± 1.12	0.009
Mean keratometry ± SD (D)	43.95 ± 1.00	43.14 ± 2.05	42.08 ± 1.20	0.082
Mean pachymetry ± SD (µm)	541.31 ± 22.16	554.86 ± 31.89	584.89 ± 33.38	0.030
Patients	10 (19 eyes)	4 (7 eyes)	5 (9 eyes)	

SD = standard deviation; SE = spherical equivalent; D = diopters.

Results

This prospective study included 35 eyes of 18 patients (5 males, 13 females) with a mean age of 26.20 ± 6.30 years (standard deviation, SD) (range, 19.0 to 40.0 years). The mean preoperative spherical equivalent (SE) was -4.86 ± 2.34 diopters (D). The mean preoperative corneal keratometry was 43.31 ± 1.50 D, and the mean preoperative corneal pachymetry on ultrasound was 557.40 ± 31.05 mm. Table 1 shows the preoperative demographics of the patients.

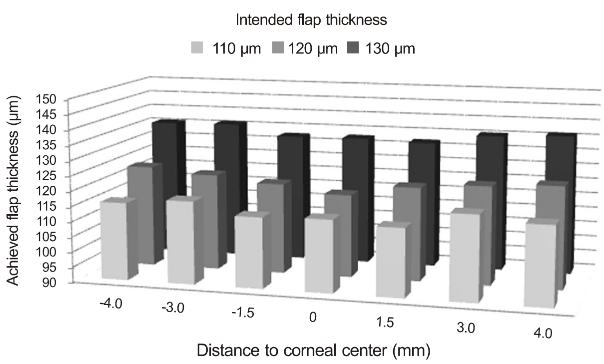

Fig. 2. Increasing the intended thickness by 10-μm increments increased the mean achieved thickness. The mean achieved flap thickness in the central 1.5-mm radius area was thicker than that in the peripheral 3.0 to 4.0-mm radius area.

Intended corneal flap thickness

Increasing the intended thickness by 10-mm increments increased the mean achieved thickness (Fig. 2). In addition, the mean achieved thickness exceeded the intended thickness by 1 μm to 6 μm (Table 2). We verified the correlation between the intended corneal-flap thickness and the achieved corneal flap thickness. There was no significant difference between the 110-μm and 120-μm groups when compared with the 130-μm group (one-way ANOVA test, $p > 0.05$).

Preoperative variables and corneal-flap thickness

No significant correlations were found between the residual of the achieved flap thickness and preoperative variables (Fig. 3). The Pearson correlation coefficient was less than 0.05 for all parameters. Table 3 shows the results of the correlation analysis.

Regional variability of the cornea

The periphery of the flaps showed higher variations in thickness and deviations from the intended flap thickness (Table 4). The mean achieved flap thickness in the central 1.5 mm radius area was thicker than that in the peripheral 3.0 to 4.0-mm radius area (paired-samples *t*-test; 110-μm group, $p = 0.001$; 120-μm group, $p = 0.004$; 130-μm group, $p = 0.014$) (Table 5 and Fig. 3).

Table 2. Detailed results of thickness measurements for the three investigated flap thickness groups (μm)

Intended flap thickness	Eyes (n)	Median	Mean	Standard deviation	Difference achieved-intended	Minimum	Maximum
110	19	115	115.21	4.98	5.21	104	128
120	7	121	121.90	5.79	1.90	109	130
130	9	134	134.38	5.04	4.38	123	147

Table 3. Bivariate correlation analyses for preoperative factors' influence on achieved flap thickness

Factor	r-value*	*p*-value*
Age	0.144	0.408
Preoperative spherical equivalent	0.192	0.270
Preoperative keratometry	-0.045	0.080
Preoperative pachymetry	-0.183	0.293

*Pearson correlation.

Table 4. Effect of regional variability of the cornea on flap thickness

Intended flap thickness (μm)	Region of cornea	Achieved-intended flap thickness (μm) % of total measurement points					
		≤-10	-10 to -6	-5 to -1	0 to 5	6 to 10	≥10
110	Central 1.5-mm radius area	0	5.3	24.5	38.7	26.2	3.6
	Peripheral 3.0-4.0-mm radius area	0	2.6	6.5	27.6	44.8	18.3
120	Central 1.5-mm radius area	4.8	33.4	28.6	19.1	14.3	0
	Peripheral 3.0-4.0-mm radius area	0	3.6	21.5	25	49.9	0
130	Central 1.5-mm radius area	0	3.7	22.2	40.7	29.6	0
	Peripheral 3.0-4.0-mm radius area	0	5.6	8.4	30.6	38.8	16.7

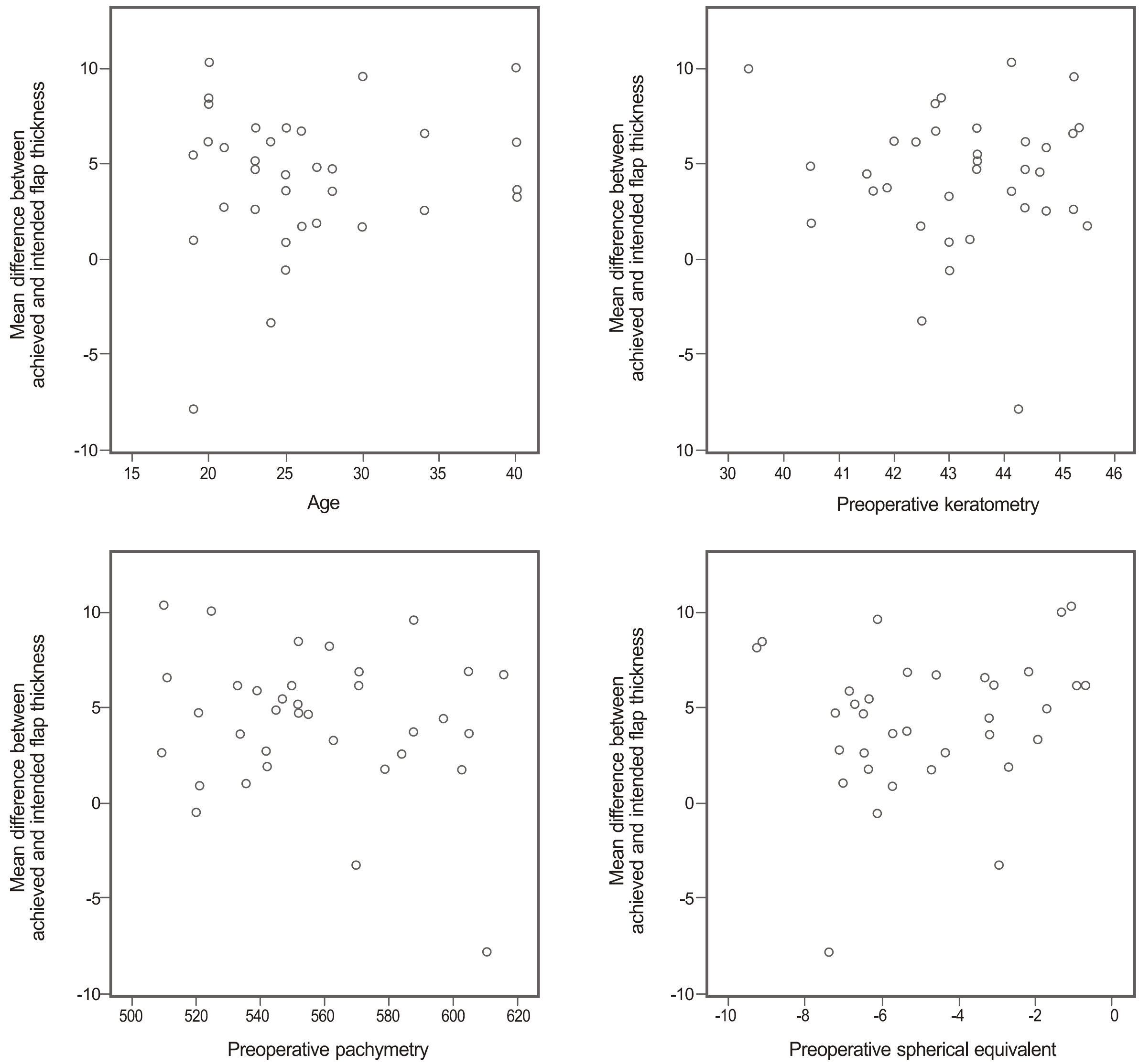

Fig. 3. Correlation of achieved flap thickness and age, preoperative spherical equivalent, keratometry, and pachymetry.

Table 5. Comparison of the mean achieved flap thickness between the central and peripheral area

Intended flap thickness (μm)	Achieved flap thickness (μm) Mean ± standard deviation		*p*-value*
	Central 1.5-mm radius area	Peripheral 3.0 – 4.0-mm radius area	
110	113.23 ± 4.50	116.71 ± 4.83	0.001
120	118.71 ± 5.79	124.29 ± 4.57	0.004
130	132.48 ± 4.10	135.81 ± 5.25	0.014

*Paired samples *t*-test.

Visual acuity and refractive error

Figs. 4-6 show the UCVA and spherical and cylinder refraction preoperatively and one month postoperatively. There were good visual outcomes in all groups, and there was no significant difference among any group for refractive error. No sight-threatening intraoperative or postoperative complications waere seen. No infection was noted.

Discussion

Since the initial LASIK procedures were performed in 1990 [12], multiple mechanical microkeratomes have been used to create the corneal flap [13-21]. The current microkeratomes have a very precise and reliable performance and show standard deviations in flap thickness between 15 and 35 μm [22]. However, the accuracy of mechanical micro-

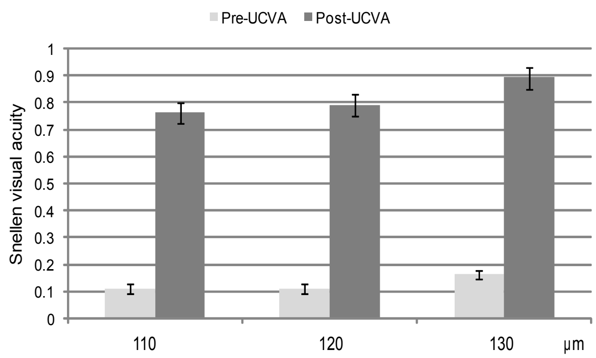

Fig. 4. Preoperative and one-month postoperative mean uncorrected visual acuity (UCVA).

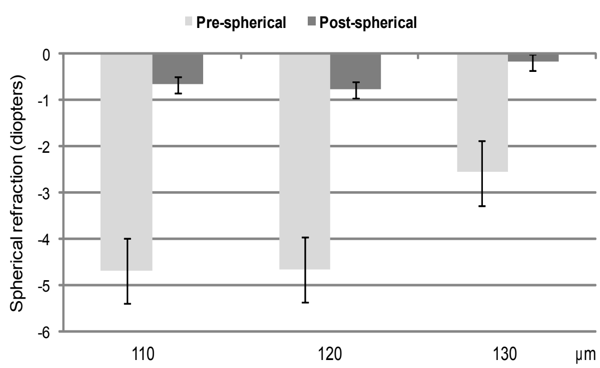

Fig. 5. Preoperative and one-month postoperative mean spherical refraction.

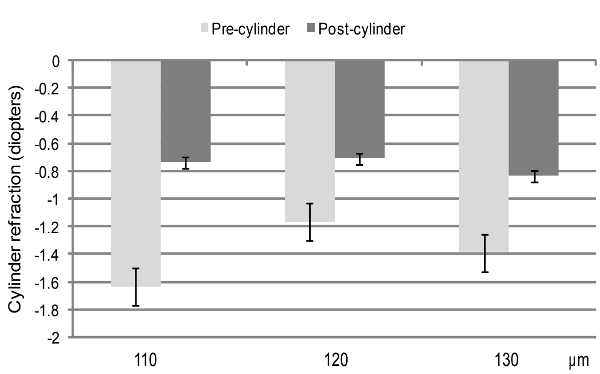

Fig. 6. Preoperative and one-month postoperative mean cylinder refraction.

keratomes is due to their specifications, and their method of cutting is limited. Therefore, they still can cause some complications during the cutting process. Among these are incomplete cuts, free caps, off centered flaps, button holes, inconsistent flap thickness, epithelial defects, induction of higher-order corneal aberrations, etc. [23,24]. A different approach to cutting corneal flaps is the use of laser energy. Ultrashort laser pulses such as those emitted by pico- and femtosecond lasers, have been tested, and femtosecond laser technology has shown the most promising results in flap separation [25]. The femtosecond laser is a focusable infrared laser, which uses pulses in the femtosecond (10^{-15} s) duration range. Contiguous pulses are placed at a precise depth within the cornea. The 1,053-nm wavelength of light used by the laser is transparent to the cornea, so it resects only targeted tissue while leaving the surrounding tissue unaltered. Because the energy and firing patterns are controlled by a computer, the laser is capable of cutting tissue at various depths and patterns, which produces minimal inflammation or collateral tissue damage [26-29]. Thermal damage to adjacent tissue in the cornea has been measured to be in a 1-mm radius [30]. The laser essentially vaporizes small volumes of tissue by photodisruption, producing plasma, a shock wave, cavitation, and gas (CO_2 and H_2O) bubbles. The femtosecond laser creates a resection plane for a lamellar cut using a spot size of 2.5 mm, a pulse-repetition rate of 15 to 60 kHz and a pulse width of 600 to 800 femtoseconds. The intensity of the laser energy can be varied at the operator's discretion. A side (trephination) cut can also be fashioned from the stroma to the surface of the cornea for anterior flaps in LASIK. The cut angle can be varied between 45° and 90°. The femtosecond laser is also capable of creating lamellar dissections ranging from 5 mm to 9.5 mm in diameter.

The femtosecond laser's range of achieved flap thickness is narrower than that created with conventional microkeratomes. This advantage translates into few thicker-than-expected flaps, which reduces the risk for ectasia, and very few thinner flaps, which reduces the risk for cap perforation and corneal striae. Mechanical microkeratomes tend to create meniscus-shaped corneal flaps that are thinner in the center and thicker in the periphery, whereas the femtosecond laser typically creates a more uniform planar flap. Alió and Piñero [8] found that the peripheral pachymetric values of the Moria M2 microkeratome flaps were always higher than those corresponding with the IntraLase flap.

The femtosecond laser is not perfect. Unexpectedly thinner or thicker flaps sometimes occur with the femtosecond laser and can lead to surgical complications [9]. Flap thickness has been an important measure of femtosecond-assisted LASIK safety. Pfaeffl et al. [31] found that the following factors had a low correlation with preoperative keratometry in predicting the variance of the achieved flap thickness, selection of the right suction ring, suction time, use of the pocket option, flap diameter, temperature, and humidity when using the femtosecond laser microkeratome. Binder [32] suggested that the femtosecond laser photodisrupts more deeply when set between 110 μm and 120 μm with an SD of 12 μm but dissects less deeply when set between 130 μm and 140 μm with an SD of 18.5 μm. Sutton and Hodge [33] reported no significant correlation in either group between keratometry and flap thickness, or between preoperative pachymetry and flap thickness. Additionally, 74.9% of patients treated with 15 kHz had a corneal flap within 20 μm of the intended location, which was increased to 97.9% with the 30-kHz laser [33].

In this study, the intended flap thickness was 110, 120 or 130 μm depending on the surgeon's preference. One week posteratively, the mean achieved flap thickness was 115.21 ± 4.98 µm (range, 104 to 128 µm) in the 110-µm group, 121.90 ± 5.79 µm (range, 109 to 130 µm) in the 120-µm group and 134.38 ± 5.04 µm (range, 123 to 147 µm) in the 130-µm group. There was no significant difference between the 110-µm and the 120-µm groups when compared with the 130-µm group. No significant correlations were found between the residual of the achieved flap thickness and age, preoperative keratometry, pachymetry, or SE. In our study, the periphery of the flap showed higher variations in thickness and greater deviations from the intended flap thickness. The mean achieved flap thickness in the central 1.5-mm radius area was thicker than that in the peripheral 3.0 to 4.0-mm radius area. The difference of the mean achieved-flap thickness between the central and peripheral areas ranged from 3.33 µm to 5.58 µm (Table 5). Li et al. [34] reported that the repeatability of OCT corneal-thickness measurements was 2 µm. Other studies found that the mean femtosecond laser flap thickness increased slightly toward the periphery [35].

The possible factor is the biomechanical characteristics of the cornea. Dawson et al. [36] reported a difference in tensile strength between the central and peripheral cornea, with increasing tensile strength moving from the center to the periphery. However, when boundaries between the corneal flap and the stroma become ambiguous, especially in the central portion of the cornea, corneal-flap thickness measurements using OCT are not absolutely precise.

In conclusion, the ultimate goal of LASIK surgery is to provide patients with the best possible visual and refractive outcomes with the lowest risk of complications. Therefore flap thickness is an important indicator of LASIK safety because of the importance of stromal preservation. Sub-Bowman keratomileusis (SBK) is becoming a prominent procedure because SBK is said to combine the advantages of LASIK (i.e., low risk for haze and almost no pain) and classic photorefractive keratectomy in the hopes of maintaining better corneal strength. However, these newer excimer laser techniques still have disadvantages caused by an unstable corneal flap. Further randomized studies are required to evaluate factors affecting flap thickness.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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