·Clinical Research·

Comparative study of visual acuity and aberrations after intralase femtosecond LASIK: small corneal flap versus big corneal flap

Ya-Li Zhang[1,2], *Lei Liu*[2], *Chang-Xia Cui*[3], *Ming Hu*[2], *Zhao-Na Li*[2], *Li-Jun Cao*[2], *Xiu-Hua Jing*[2], *Guo-Ying Mu*[1]

[1]Department of Ophthalmology, Shandong Provincial Hospital Affiliated to Shandong University, No.324 Jingwuweiqi Road, Jinan 250021, Shandong Province, China
[2]Department of Ophthalmology, the Second People's Hospital of Jinan, 148 Jingyi Road, Jinan 250001, Shandong Province, China
[3]Department of Health Examination, Jinan Central Hospital Affiliated to Shandong University, No.105 Jiefang Road, Jinan 250013, Shandong Province, China
Correspondence to: Guo-Ying Mu. Department of Ophthalmology, Shandong Provincial Hospital Affiliated to Shandong University, No.324 Jingwuweiqi Road, Jinan 250021, Shandong Province, China. mgyeyes@yahoo.com.cn
Received: 2012-10-11 Accepted: 2013-7-24

Abstract

• AIM: To study the effects of different flap sizes on visual acuity, refractive outcomes, and aberrations after femtosecond laser for laser *in situ* keratomileusis (LASIK).

• METHODS: In each of the forty patients enrolled, 1 eye was randomly assigned to receive treatment with a 8.1mm diameter corneal flap, defined as the small flap, while the other eye was treated with a 8.6mm diameter corneal flap, defined as the big flap. Refractive errors, visual acuity, and higher-order aberrations were compared between the two groups at week 1, month 1 and 3 postoperatively.

• RESULTS: The postoperative refractive errors and visual acuity all conformed to the intended goal. Postoperative higher-order aberrations were increased, especially in spherical aberration (Z12) and vertical coma (Z7). There were no statistically significant differences between the two groups in terms of postoperative refractive errors, visual acuity, root mean square of total HOAs (HO-RMS), trefoil 30° (Z6), vertical coma (Z7), horizontal coma (Z8), trefoil 0° (Z9), and spherical aberration (Z12) at any point during the postoperative follow-up.

• CONCLUSION: Both the small and big flaps are safe and effective procedures to correct myopia, provided the exposure stroma meets the excimer laser ablations. The personalized size corneal flap is feasible, as we can design the size of corneal flap based on the principle that the corneal flap diameter should be equal to or greater than the sum of the maximum ablation diameter and apparatus error.

• **KEYWORDS:** femtosecond laser; laser *in situ* keratomileusis; refractive surgery; flap; visual acuity; aberration

DOI:10.3980/j.issn.2222-3959.2013.05.16

Zhang YL, Liu L, Cui CX, Hu M, Li ZN, Cao LJ, Jing XH, Mu GY. Comparative study of visual acuity and aberrations after intralase femtosecond LASIK: small corneal flap versus big corneal flap. *Int J Ophthalmol* 2013;6(5):641-645

INTRODUCTION

There is a variety of procedures available to correct myopia, such as photorefractive keratectomy (PRK), laser *in situ* keratomileusis (LASIK), epikeratome laser assisted *in situ* keratomileusis (Epi-LASIK), and phakic intraocular lens (PIOL) implantation *etc.* In particular, LASIK has become one of the most commonly performed refractive surgery procedures worldwide [1]. LASIK has been shown to be safe, effective and predictable in correcting different degrees of myopia[1-5].

A critical step in the LASIK procedure is the creation of the corneal flap. Flap-related complications occur in as many as 5% of the cases. Patient age, corneal thickness, corneal curvature, and the suction can influence the procedure. Studies have demonstrated the importance of the variability of the thickness not the size of the corneal flap on patient outcomes [6-8]. As technologies continue improving, femtosecond laser technology has emerged as an alternative way to create the corneal flap. Previous studies have demonstrated that the femtosecond laser can yield precise flap diameters, hinge location, and flap thickness with a narrow standard deviation[9,10].

Studies have evaluated postoperative vision function on different flap thickness, different ablation profile, and different methods in flap creation, but to the best of our knowledge, there is no study that compares postoperative vision function based on different sizes of corneal flap [11-13]. We know that the bigger flap is created, more wound is produced, and which may bring in more severe dry eye. In this study, we compare the uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), refractive errors, and aberrations in patients who have different sizes of corneal flap implanted in both eyes during the LASIK procedure.

SUBJECTS AND METHODS

Subjects Forty patients who underwent intralase femtosecond LASIK (iLASIK) from April 2011 to December 2011 were included in this study. When evaluated for surgery, the patients met the following criteria: 1) age > 18 years and with stable refraction within 2 years; 2) no systemic or ocular diseases; 3) contact lens discontinued for at least 2 weeks; 4) the differences between both eyes in spherical error and in astigmatism lower than 1.00D, and in the equivalent spherical error also lower than 1.00D; 5) both eyes have the same BCVA. Furthermore, the patients had to demonstrate successful treatment defined as both eyes retaining the corneal flap in the center of the cornea.

Methods All patients underwent a full ophthalmologic examination prior to surgery, consisting of measurements of UCVA, BCVA, slit-lamp biomicroscopy, tonometry, corneal pachymetry, corneal topography, aberration, and funduscopy. Each eye received 3 wavefront analysis using the VISX CustomVue WaveScan aberrometer without pharmacologic intervention, under mesopic conditions, and with a minimum pupil diameter of 6.0mm.

All femtosecond laser procedures were performed by a surgeon using Oxybuprocaine Hydrochloride Eye Drops (Santen Pharmaceutical, Japan) and the Intralase femtosecond laser (IntraLase Corp, Irvine, California, USA) with the 60kHz software. The laser had the following parameters: a raster pattern; a 70° side cut angle; a superior hinge; a hinge angle of 50°; and an attempted flap depth of 110μm.

All procedures were performed in the right eye first. The corneal flap diameter has typically been set as 8.0-9.0mm. We designed the small corneal flap diameter to be 8.1mm in order to eliminate the effect from both the flap hinge and apparatus error. And according to our experience, we named the 8.6mm diameter corneal flap as the big flap. One eye was randomly assigned to undergo the procedure with the small flap (small flap group), while the other eye was treated with the big flap (big flap group). The patients were blinded as to which flap was used in each eye.

After the corneal flaps were created, a 15-min delay was required. Then the excimer laser ablation was completed with VISX S4 [Abbott Medical Optics (AMO), Santa Ana, CA, USA]. In all cases, the ablation was central, with an optic zone of 6.00mm and the transition zone about 0.5mm. Postoperatively, patients received topical Fluorometholone 0.1% (Santen Pharmaceutical, Japan) 4 times daily for 1 week, followed by a reduced dosage of 3 times for 2 weeks, and Levofloxacin 0.3% (Bausch & Lomb Freda Inc, China) 3 times daily for 1 week, along with artificial tears as needed.

Table 1 Preoperative characteristics in the small and big flap groups

Variable	Small flap group	Big flap group
Sphere (D)	-7.46±4.82	-7.35±4.44
Astigmatism (D)	-0.82±0.57	-0.97±0.79
Spherical equivalent (D)	-7.87±4.83	-7.94±4.47
Pachymetry (μm)	554.52±22.77	553.76±21.06
UCVA	4.11±0.14	4.06±0.18
BCVA	5.07±0.11	5.06±0.18

UCVA: Uncorrected visual acuity; BCVA: Best corrected visual acuity.

Postoperative examinations occurred at week 1, month 1, and 3. Uncorrected and corrected distance visual acuity was recorded in 5-logMAR format. Each eye received 3 wavefront analysis. Higher-order aberrations (HOAs), including root mean square of total HOAs, trefoil 30° (Z6), vertical coma (Z7), horizontal coma (Z8), trefoil 0° (Z9), and spherical aberration (Z12) were measured by the WaveScan aberrometer.

Statistical Analysis Statistical analysis was performed using SPSS 16.0. Visual acuity outcomes in 5-logMAR notation were compared. The 2-paired samples test was used to detect the differences between small flap and big flap. Zernike coefficients were compared using nonparametric statistics with the Wilcoxon test. A P value less than 0.05 was considered statistically significant for all tests.

RESULTS

Of the 40 patients, 19 patients were men and 21 patients were women. The mean age was 23.55±4.05 years (mean± SD; range 18-32 years). Preoperative data are shown in Table 1.

All surgeries were successful, without flap-related complications. The vacuum was not released during flap creation. No flap decentrations occurred. In the small flap group, the hinge of the flap did not affect the laser ablation. Both groups showed almost the same inflammation postoperatively. There were no complications at any point during the treatment. There were no statistically significant differences between the 2 groups (P>0.05) in preoperative sphere, preoperative astigmatism, preoperative spherical equivalent, UCVA, and BCVA.

The UCVA increased at week 1, month 1 and 3 after LASIK (P=0.001, P=0.001, P=0.001, respectively). However, there were no significant differences between the small and big flap groups, at week 1, month 1 and 3 postoperatively. Visual acuity was stable at all times postoperatively as well. Furthermore, there was no significant difference in either the

Table 2 Postoperative visual acuity and refractive errors at week 1 week, month 1 and 3 $\bar{x}\pm s$ (range)

Parameter	Small flap	Big flap	*P*
1 week			
UCVA (5-LogMAR)	5.01±0.55 (4.9~5.1)	5.00±0.58 (4.9~5.1)	0.962
Sphere (D)	0.64±0.64 (-0.25~1.75)	0.76±0.67 (-0.50~1.75)	0.766
Cylinder (D)	-0.51±0.53 (-0.50~-1.50)	-0.39±0.30 (-0.50~-1.25)	0.572
1 month			
UCVA (5-logMAR)	5.01±0.63 (4.9~5.1)	5.01±0.48 (4.9~5.1)	0.906
Sphere (D)	0.32±0.68 (-0.25~1.25)	0.44±0.58 (-0.25~1.50)	0.841
Cylinder (D)	-0.30±0.54 (-0.25~-1.00)	-0.39±0.30 (-0.25~-1.25)	0.623
3 months			
UCVA (5-logMAR)	5.01±0.55 (4.9~5.1)	5.02±0.55 (4.9~5.1)	0.804
Sphere (D)	0.25±0.42 (-0.50~0.75)	0.32±0.48 (-0.25~0.75)	0.901
Cylinder (D)	-0.29±0.56 (-0.25~-1.00)	-0.11±0.39 (-0.25~-0.75)	0. 658

UCVA: Uncorrected visual acuity.

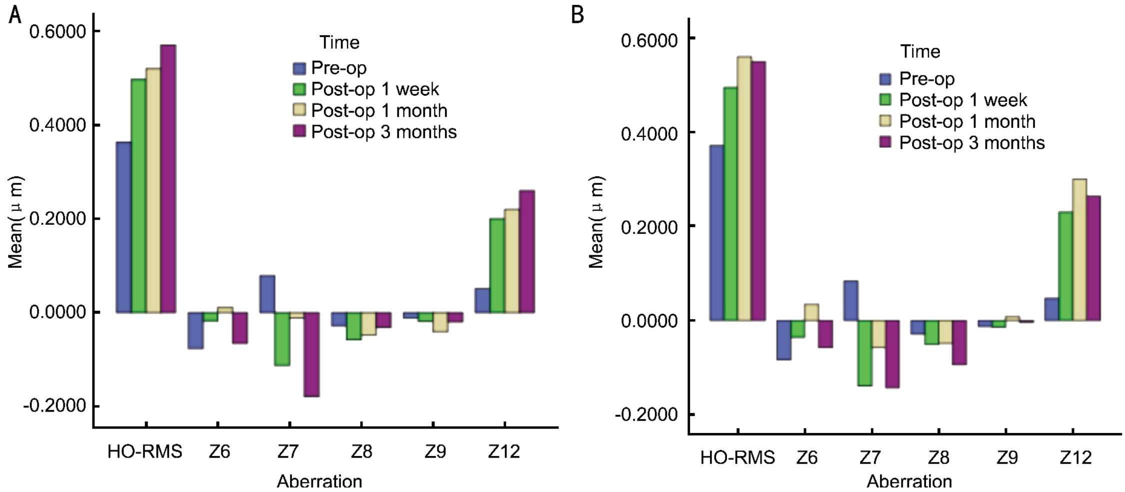

Figure 1 Aberrations in two groups preoperative and postoperative week 1, month 1 and 3 A: The small flap showed an increase in postoperative root mean square of higher-order aberrations (HO-RMS), especially the spherical aberration (Z12) and vertical coma (Z7); B: The big flap showed an increase in postoperative root mean square of higher-order aberrations (HO-RMS), especially the spherical aberration (Z12) and vertical coma (Z7).

residual sphere or the cylinder between the two groups at any time during the follow-up period (Table 2).

An increase in postoperative root mean square of higher-order aberrations (HO-RMS) in both groups, especially the spherical aberration (Z12) and vertical coma (Z7) was shown in Figure 1A and B. Table 3 shows that HO-RMS was similar between the 2 groups (P>0.05). At week 1, month 1 and 3, postoperatively, the HO-RMS values were increased. Postoperative HO-RMS values were similar at month 1 and 3. However, there were no statistically significant differences between the 2 groups at any point during the follow-up period.

DISCUSSION

The femtosecond laser yields precise flap dimensions with a narrow standard deviation and a high level of safety [9,10,13]. The mean flap diameter has been found to differ from the attempted diameter by less than 0.03μm in an attempted flap thickness of 110μm, 120μm, and 140μm [10]. And the standard deviation was 12μm in group 110μm [10]. The corneal flap diameter has typically been set as 8.0-9.0mm in IntraLase™ FS Laser. In our study, we designed the 8.1mm corneal flap to be the small flap, so the exposed area is enough to laser ablation in consideration of the effect of the flap hinge and apparatus error. And according to the corneal size of patients in our institution, if the corneal flap larger than 8.6mm, the bleeding in the corneal limbus would be happened in many patients. We named the 8.6mm corneal flap to be the big flap.

We found that both the small and big flaps are safe and effective in correcting myopia, with no significant differences in UCVA, refractive errors, and aberrations at any point during the follow-up period. Moreover, vision was not affected by the size of corneal flap, provided the corneal flap ensured adequate stromal exposure for the ablation. Therefore, we suggest that personalized corneal flaps can be designed, such as a small flap based on the ablation degrees.

Table 3 Aberrations of preoperative and postoperative week 1, month 1 and 3

Parameter(μm)	Small flap	Big flap	*P*
Preoperative			
HO-RMS	0.363±0.0381	0.3712±0.0432	0.816
Z6	-0.0769±0.041	-0.0839±0.0362	0.810
Z7	0.0786±0.0477	0.0835±0.0507	0.904
Z8	-0.0285±0.022	-0.029±0.029	0.559
Z9	-0.0117±0.022	-0.0128±0.0267	0.977
Z12	0.051±0.047	0.047±0.044	0.856
1 week postoperative			
HO-RMS	0.497±0.029	0.495±0.037	0.987
Z6	-0.018±0.036	-0.036±0.037	0.561
Z7	-0.113±0.052	-0.139±0.052	0.610
Z8	-0.058±0.062	-0.051±0.063	0.951
Z9	-0.019±0.024	-0.014±0.017	0.353
Z12	0.20±0.04	0.23±0.04	0.121
1 month postoperative			
HO-RMS	0.52±0.03	0.56±0.21	0.122
Z6	0.011±0.036	0.034±0.046	0.158
Z7	-0.0115±0.065	-0.058±0.063	0.676
Z8	-0.048±0.07	-0.049±0.07	0.967
Z9	-0.041±0.027	0.008±0.017	0.136
Z12	0.22±0.032	0.30±0.045	0.082
3 months postoperative			
HO-RMS	0.57±0.032	0.55±0.031	0.568
Z6	-0.066±0.031	-0.058±0.033	0.787
Z7	-0.179±0.044	-0.143±0.042	0.415
Z8	-0.032±0.063	-0.094±0.059	0. 492
Z9	-0.02±0.024	-0.004±0.019	0.952
Z12	0.260±0.029	0.264±0.033	0.912

For instance, if a patient has the maximum ablation diameter of 7.5mm, we can create a corneal flap with a diameter of 7.5mm+apparatus error, and the effect of the flap hinge should be considered. That is to say that we can design the size of corneal flap based on the principle that the corneal flap diameter should be equal to or greater than the sum of the maximum ablation diameter and apparatus error. Personalized corneal flaps may be preferable for the patients with corneal scars or pannus in the peripheral cornea but nevertheless would like to undergo iLASIK to correct myopia.

Studies have shown that the interlamellar branching in the peripheral cornea is more extensive and the lamellar and fibrillar distribution of collagen in the peripheral corneal stroma has higher cohesive tensile strength [14,15]. The mean adhesive strength in the peripheral cornea was approximately twice the mean central value [15]. Thus, more peripheral corneal tissue can be preserved in small corneal flaps than in big corneal flaps, which is benefit to patients. The stability of corneal biomechanics may be better in smaller flap after iLASIK, which need to further study.

In an early femtosecond study, Heisterkamp *et al* [16] found no significant wound healing reaction inside the corneal stroma and mild wound healing reaction at the flap-stroma interface. And another study, Lim *et al* [17] found that the femtosecond laser group had more postoperative inflammation than the mechanical microkeratome group. The incidence of diffuse lamellar keratitis (DLK) and flap-edge DLK had been noted. Our study also found that the wound healing of the flap periphery produced a healing line, which was clearly obvious on examination, but did not affect visual acuity and aberrations in both groups. The adhesion strength of the corneal flap may be evenly distributed in every direction of the cornea. The incidence of DLK was not different in small flap group and big flap group.

The mean postoperative refractive errors were similar between the 2 groups. We observed that the postoperative error was a slightly hyperopic trend for the 2 groups in moderate or high myopia, especially in the first postoperative week. Considering that most of the patients were young, some with high myopia, the large spot cutting mode of VISX 4, and more stromal inflammation of femtosecond laser, we revised the nomograph. So the postoperative achieved correction with hyperopic trend conformed to our intended correction. And we also found that the postoperative slight hyperopia did not affect visual acuity.

Due to the corneal curvature, the creation of the corneal flap, and the laser ablation, the surgery can induce astigmatism [18,19]. In this study, postoperative astigmatism was found; however, the degree of astigmatism was mild and not affected by the size of the corneal flap.

Our postoperative aberrations outcomes corroborate previous studies of myopic LASIK using a femtosecond laser for flap creation where higher-order aberrations were found to increase postoperatively [13,20]. In particular, spherical aberration (Z12) and vertical coma (Z7) were increased. The creation of corneal flap, the laser ablation, and the wound healing can affect the aberrations. In our study, the preoperative environment of the 2 groups was similar, apart from the size of the flap. Moreover, there were no statistically significant differences in higher-order aberrations, trefoil, spherical aberration, and coma between the 2 groups. Thus, the flap size and wound healing of the flap edge did not affect the aberration.

In this study, there are some limitations including the number of patients and the effect with apparatus error in corneal flap diameter. And this study mainly concerns on the visual function of the different flap sizes. Further studies concerning the corneal biomechanics and dry eyes are needed to demonstrate its safety.

REFERENCES

1 Sugar A, Rapuano CJ, Culbertson WW, Huang D, Varley GA, Agapitos PJ, de Luise VP, Koch DD. Laser *in situ* keratomileusis for myopia and astigmatism: safety and efficacy: a report by the American Academy of Ophthalmology. *Ophthalmology* 2002;109(1):175-187

2 Tomita M, Watabe M, Waring GO 4th, Durrie DS. Corneal endothelial cell

density after myopic intra-LASIK and the effect of AC gas bubbles on the corneal endothelium. *Eur J Ophthalmol* 2011;21(4):363-367
3 Lin JM, Tsai YY. Laser *in situ* keratomileusis for different degrees of myopia. *Acta Ophthalmol Scand* 2005;83(1):40-45
4 Vongthongsri A, Phusitphoykai N, Tungsiriput T. Laser *in situ* keratomileusis for high myopia using a small ablation zone and large aspheric transition zone. *J Refract Surg* 2004;20(5 Suppl):S669-673
5 Sánchez-Pina JM, Arranz-Márquez E, Gil Ciganda N, Román Guindo JM, Teus MA. LASIK results of IntraLase femtosecond laser to correct myopia: efficacy, security and predictability. *Arch Soc Esp Oftalmol* 2007;82(7):423-428
6 Gailitis RP, Lagzdins M. Factors that affect corneal flap thickness with the Hansatome microkeratome. *J Refract Surg* 2002;18(4):439-443
7 Paschalis EI, Labiris G, Aristeidou AP, Foudoulakis NC, Koukoula SC, Kozobolis VP. Laser *in situ* keratomileusis flap-thickness predictability with a pendular microkeratome. *J Cataract Refract Surg* 2011;37 (12):2160-2166
8 Du S, Lian J, Zhang L, Ye S, Dong S. Flap thickness variation with 3 types of microkeratome heads. *J Cataract Refract Surg* 2011;37 (1):144-148
9 Issa A, Al Hassany U. Femtosecond laser flap parameters and visual outcomes in laser *in situ* keratomileusis. *J Cataract Refract Surg* 2011;37 (4):665-674
10 Binder PS. Flap dimensions created with the IntraLase FS laser. *J Cataract Refract Surg* 2004;30(1):26-32
11 Bansal AS, Doherty T, Randleman JB, Stulting RD. Influence of flap thickness on visual and refractive outcomes after laser *in situ* keratomileusis performed with a mechanical keratome. *J Cataract Refract Surg* 2010;36(5):810-813
12 Anera RG, Castro JJ, Jiménez JR, Villa C, Alarcón A. Optical quality and visual discrimination capacity after myopic LASIK with a standard and aspheric ablation profile. *J Refract Surg* 2011;27(8):597-601
13 Kouassi FX, Blaizeau M, Buestel C, Schweitzer C, Gallois A, Colin J, Touboul D. Comparison of LASIK with femtosecond laser versus LASIK with mechanical microkeratome: predictability of flap depth, corneal biomechanical effects and optical aberrations. *J Fr Ophtalmol* 2012;35(1):2-8
14 Dupps WJ Jr, Wilson SE. Biomechanics and wound healing in the cornea. *Exp Eye Res* 2006;83(4):709-720
15 Smolek MK, McCarey BE. Interlamellar adhesive strength in human eyebank cornea. *Invest Ophthalmol Vis Sci* 1990;31(6):1087-1095
16 Heisterkamp A, Mamom T, Kermani O, Drommer W, Welling H, Ertmer W, Lubatschowski H. Intrastromal refractive surgery with ultrashort laser pulses: *in vivo* study on the rabbit eye. *Graefes Arch Clin Exp Ophthalmol* 2003;241(6):511-517
17 Lim T, Yang S, Kim M, Tchah H. Comparison of the IntraLase femtosecond laser and mechanical microkeratome for laser *in situ* keratomileusis. *Am J Ophthalmol* 2006;141(5):833-839
18 Huang D, Sur S, Seffo F Meisler DM, Krueger RR. Surgically-induced astigmatism after laser *in situ* keratomileusis for spherical myopia. *J Refract Surg* 2000;16(5):515-518
19 Sharma N, Pangtey MS, Vajpayee RB, Dada T, Aggarwal T, Dada VK, Pandey RM. Surgically induced astigmatism after laser *in situ* keratomileusis for spherical myopia. *J Refract Surg* 2002;18(3):239-244
20 Chen S, Feng Y, Stojanovic A, Jankov MR 2nd, Wang Q. IntraLase femtosecond laser *vs* mechanical microkeratomes in LASIK for myopia: a systematic review and meta-analysis. *J Refract Surg* 2012;28(1):15-24