

Comparison of the femtosecond Laser and mechanical microkeratome for flap cutting in LASIK

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Abstract

• **AIM:** To compare refractive results, higher-order aberrations (HOAs), contrast sensitivity and dry eye after laser *in situ* keratomileusis (LASIK) performed with a femtosecond laser versus a mechanical microkeratome for myopia and astigmatism.

• **METHODS:** In this prospective, non-randomized study, 120 eyes with myopia received a LASIK surgery with the VisuMax femtosecond laser for flap cutting, and 120 eyes received a conventional LASIK surgery with a mechanical microkeratome. Flap thickness, visual acuity, manifest refraction, contrast sensitivity function (CSF) curves, HOAs and dry-eye were measured at 1wk; 1, 3, 6mo after surgery.

• **RESULTS:** At 6mo postoperatively, the mean central flap thickness in femtosecond laser procedure was $113.05 \pm 5.89 \mu\text{m}$ (attempted thickness $110 \mu\text{m}$), and $148.36 \pm 21.24 \mu\text{m}$ (attempted thickness $140 \mu\text{m}$) in mechanical microkeratome procedure. An uncorrected distance visual acuity (UDVA) of 4.9 or better was obtained in more than 98% of eyes treated by both methods, a gain in logMAR lines of corrected distance visual acuity (CDVA) occurred in more than 70% of eyes treated by both methods, and no eye lost ≥ 1 lines of CDVA in both groups. The difference of the mean UDVA and CDVA between two groups at any time post-surgery were not statistically significant ($P > 0.05$). The postoperative changes of spherical equivalent occurred markedly during the first month in both groups. The total root mean square values of HOAs and spherical aberrations in the femtosecond treated eyes were markedly less than those in the microkeratome treated eyes during 6mo visit after surgery ($P < 0.01$). The CSF values of the femtosecond treated eyes were also higher

than those of the microkeratome treated eyes at all space frequency ($P < 0.01$). The mean ocular surface disease index scores in both groups were increased at 1wk, and recovered to preoperative level at 1mo after surgery. The mean tear breakup time (TBUT) of the femtosecond treated eyes were markedly longer than those of the microkeratome treated eyes at postoperative 1, 3mo ($P < 0.01$).

• **CONCLUSION:** Both the femtosecond laser and the mechanical microkeratome for LASIK flap cutting are safe and effective to correct myopia, with no statistically significant difference in the UDVA, CDVA during 6mo follow-up. Refractive results remained stable after 1mo post-operation for both groups. The femtosecond laser may have advantages over the microkeratome in the flap thickness predictability, fewer induced HOAs, better CSF, and longer TBUT.

• **KEYWORDS:** laser *in situ* keratomileusis; femtosecond laser; flap; visual acuity; higher-order aberrations; contrast sensitivity; dry eye

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INTRODUCTION

Approximately 10y ago, the first femtosecond laser was used in the corneal refractive surgery. Many studies have investigated the pros and cons between femtosecond laser and mechanical microkeratomers for creating flaps during laser *in situ* keratomileusis (LASIK) for myopia correction, and the results are hugely distinct^[1-4]. Some studies show that femtosecond laser seem to have advantages over mechanical devices in terms of quality of the corneal flap, such as uniform thickness across the flap, predictable hinge lengths with lamellar dissection under the hinge, and steep side-cuts for improved flap realignment^[5,6]. However, other studies show that femtosecond laser for creating flaps has specific complications, such as delayed-onset photophobia, increase in suction time, corneal folds, interface inflammation, and diffuse lamellar keratitis (DLK)^[7-10]. Several articles report that the femtosecond laser seem to

have better predictability of postoperative refraction, better uncorrected distance visual acuity (UDVA), and possible reduction in overall induced astigmatism^[2,11], whereas others report that no significant differences in efficacy, safety, and complication rates between the femtosecond laser and mechanical microkeratomes^[12,13]. Why the outcome so difference is still unclear till today. In the current study, we used the VisuMax femtosecond laser and mechanical microkeratome to fashion corneal flaps in LASIK, and investigated the differences of flap thickness, visual acuity, refractive results, aberrations, contrast sensitivity function (CSF) curves and dry eye between two methods.

SUBJECTS AND METHODS

Subjects In this prospective, non-randomized study, 120 patients with myopia or myopic astigmatism were enrolled in this trial from January 1, 2012 to January 1, 2013, and underwent evaluation at the Refractive Surgery Center of Shengjing Hospital, China Medical University. Written informed consent was obtained from all patients before surgery in accordance with the Declaration of Helsinki. Sixty patients (120 eyes) received a LASIK surgery with a 500-kHz femtosecond laser (Carl Zeiss Meditec VisuMax femtosecond laser system) for flap cutting, and 60 patients (120 eyes) received a conventional LASIK surgery with a mechanical microkeratome (Moria model 2, M2™). Inclusion criteria were patients with spherical myopia not more than 12.00 diopters (D), not more than 5.00 D of refractive astigmatism, stable refraction (<0.50 D of sphere or cylinder), discontinuation of soft contact wear at least 15d before the preoperative evaluation, age older than 18y, but no more than 45 years old and ability to participate in follow-up examinations for 6mo after LASIK. Patients having severe dry eye, severe blepharitis, keratoconus, and anterior segment abnormalities were excluded. The required residual stromal thickness limit was 300 μm for two groups.

The femtosecond group had a mean preoperative spherical refraction of -5.32 ± 1.65 D and a cylinder of -0.86 ± 0.52 D, whereas the microkeratome group had a mean preoperative spherical refraction of -5.41 ± 1.57 D and a cylinder of 0.93 ± 0.69 D. The mean age of the femtosecond group is 25.9 ± 8.9 y, and the microkeratome group is 26.1 ± 9.2 y. There were no statistically significant differences both in the mean age and preoperative mean refraction between the two groups.

Surgical procedure A drop of anesthetic was instilled in the eyes after the patients underwent sterile draping and preparation. In the femtosecond group, flaps were created with a 500-kHz VisuMax femtosecond laser. Femtosecond laser flaps were programmed with 110-μm thickness and 8.0-μm diameter, and 90° side cut angles. In the microkeratome group, the flaps were created by using an automated M2™ microkeratome with an intended flap

thickness of 140 μm and 9.0-μm diameter. All procedures were performed with nasal hinge flaps. Following the flap creation, the spherocylindrical refractive corrections were done with the Carl Zeiss Meditec MEL 80™ excimer laser system, which was a high-speed, flying spot scanning excimer laser with 0.7 mm Gaussian beam, 250 kHz repetition rate and eye registration and eye tracking capabilities.

Postoperative medication and follow-up As a routine, all patients received the administration of an ophthalmic solution of Levofloxacin 4 times per day for 7d, a 0.1% fluorometholone solution 4 to 1 times per day with a drop decrease per week for 1mo, and an artificial tear (Sodium Hyaluronate Eye Drops, Santen, Inc., Japan) 4 times per day for at least 3mo. Subsequent visiting were at 1wk; 1, 3 and 6mo after surgery. UDVA, corrected distance visual acuity (CDVA), objective and manifest refractions, corneal flap thickness (corneal Visante optical coherence tomography, Carl Zeiss Meditec AG), higher-order aberrations (HOAs, Carl Zeiss Meditec WASCA), CSF (Opetec 6500, Stero Optical) curves were gathered and analyzed.

Methods

Ocular surface disease index and tear breakup time

Ocular surface disease index (OSDI) questionnaire was used to quantify the dry eye symptoms. Subjects were asked questions regarding the dry eye symptoms that they had experienced during a 1wk recall period; the OSDI questions were drawn from 3 different subscales: ocular symptoms, vision-related functions, and environmental triggers. Each answer was scored on a 4-point scale from zero (indicating no problems) to four (indicating a significant problem). Responses to all of the questions were combined to generate a composite OSDI score that ranged from 0 to 100, with higher OSDI scores indicating more severe symptoms^[14,15]. Tear film stability was assessed based on tear breakup time (TBUT). A fluorescein impregnated strip (Jingming, Tianjin, China) that was wetted with non-preservative saline solution was placed in the lower conjunctival sac, and the patient was asked to blink several times. Using slit-lamp biomicroscopy with a cobalt blue filter, the time that elapsed before the first observation of tear film breakup after a complete blink was recorded as the TBUT. The test was repeated three times, and the average of the three measurements was calculated. Corneal fluorescein staining was graded as described by De Paiva and Pflugfelder^[16].

Statistical Analysis Statistical analysis was performed using SPSS 13.0 statistical analysis software. Visual acuity outcomes in 5-logMAR notation were compared. The comparison of two independent samples was performed with *t*-test. The difference was statistically significant when *P* value was <0.05.

Table 1 Mean UDVA (5-logMAR) after surgery

Parameters	Eyes	1wk	1mo	3mo	6mo
Femtosecond group	120	4.99±0.21 (4.7-5.2)	5.12±0.19 (4.9-5.2)	5.08±0.15 (4.9-5.2)	5.01±0.13 (4.9-5.2)
Microkeratome group	120	4.94±0.30 (4.7-5.2)	5.09±0.22 (4.9-5.2)	5.05±0.17 (4.8-5.2)	4.99±0.12 (4.8-5.2)
<i>t</i>		1.25	1.11	1.42	1.25

UDVA: Uncorrected distance visual acuity. The difference between two groups at 1wk; 1, 3, 6mo were not statistically significant ($P>0.05$).

RESULTS

Flap Thickness No complications occurred during surgery or the postoperative period in both groups. At 6mo postoperatively, the mean central flap thickness was 113.05±5.89 μm (range 107 to 116, attempted thickness 110 μm), and 148.36±21.24 μm (range 127 to 161, attempted thickness 140 μm) in the femtosecond group and the microkeratome group, respectively. The difference of flap thickness standard deviation between the femtosecond group (5.89) and the microkeratome group (21.24) indicates that the flap created by the femtosecond is more predictable and accurate than that by the mechanical microkeratome.

Refractive Outcome Findings of the UDVA at follow-up visits for two groups were summarized in Table 1 and Figure 1. At 6mo postoperatively, of the 120 femtosecond treated eyes, 90.8% (109 eyes) had an UDVA of 5.0 or better, 100% (120 eyes) had an UDVA of 4.9 or better (the mean UDVA was 5.01±0.13). Of the 120 microkeratome treated eyes, 90.0% (108 eyes) had an UDVA of 5.0 or better, 98.3% (118 eyes) had an UDVA of 4.9 or better, 100% (120 eyes) had an UDVA of 4.8 or better (the mean UDVA was 4.99±0.12). The difference of the mean UDVA between two groups at any time post-surgery were not statistically significant ($P>0.05$). The changes of CDVA pre- to post-surgery for two groups were shown in Figure 2. At 6mo postoperatively, of the 120 eyes treated with the femtosecond laser, 78.3% (94 eyes) gained one or two lines of CDVA, 21.7% (26 eyes) were unchanged post-surgery. Of the 120 eyes treated with the microkeratome, 73.3% (88 eyes) gained one or two lines of CDVA, 26.7% (32 eyes) were unchanged post-surgery. No eye lost ≥1 lines of CDVA in both groups. The results indicate that both the femtosecond and the microkeratome LASIK were effective and safe to correct myopia.

With regard to the changes of spherical equivalent (SE) from 1wk to 1mo after surgery, the mean SE in the femtosecond group changed from (+0.48±0.79) D to (0±0.76) D, and the microkeratome group from (+0.62±0.95) D to (0.05±0.82) D. The mean change was 0.48 D in the femtosecond treated eyes ($t=4.80, P<0.01$), and 0.57 D in the microkeratome treated eyes ($t=5.18, P<0.01$), demonstrating the instability of refractive results during the first month post-operation in both groups. However, the mean change of SE from 1 to 6mo post-operation was 0.01 D in the femtosecond treated eyes ($t=0.11, P>0.05$), and 0.15 D in the microkeratome treated eyes ($t=1.54, P>0.05$), demonstrating the stability of

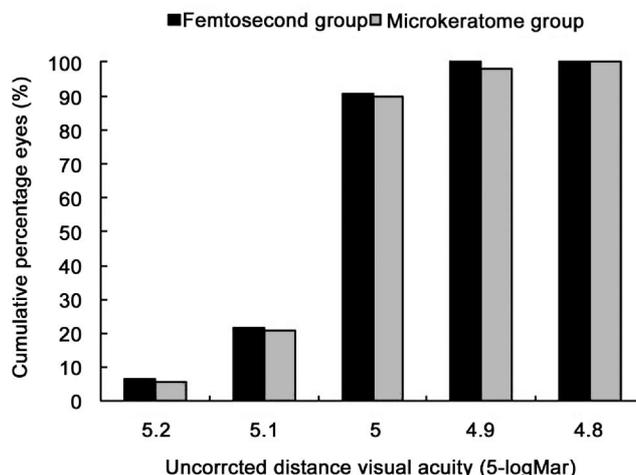


Figure 1 Cumulative percentage eyes of UDVA at 6mo after surgery for two groups.

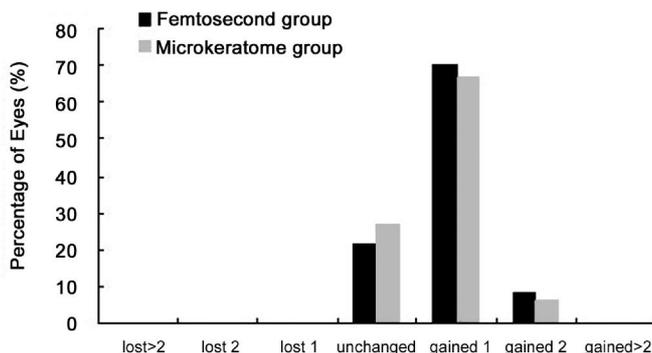


Figure 2 Percentage of eyes changes in CDVA at 6mo after surgery for two groups.

refractive results after 1mo post-operation in both groups (Figure 3).

Higher-order Aberrations With a 6.0-mm pupil diameter analysis, the preoperative root mean square (RMS) value of total HOAs was 0.27±0.12 μm in the femtosecond group and 0.29±0.11 μm in the microkeratome group. The preoperative RMS value of spherical aberrations was 0.07±0.09 μm in the femtosecond group and 0.06±0.10 μm in the microkeratome group. Preoperative total HOAs and spherical aberrations were similar between the two groups ($P>0.05$). The total RMS values of HOAs and spherical aberrations for both the femtosecond treated eyes and the microkeratome treated eyes were markedly increased at any time point after surgery compared to those preoperatively ($P<0.01$), and did not recover to preoperative levels until 6mo postoperatively. However, the total HOAs and spherical aberrations in the femtosecond treated eyes were markedly less than those in

Table 2 The comparisons of the RMS values of total HOAs for a 6-mm pupil between two groups (μm) $\bar{x} \pm s$

Parameters	Eyes	Before surgery	1wk post-surgery	1mo post-surgery	3mo post-surgery	6mo post-surgery
Femtosecond group	120	0.27±0.12	0.37±0.13 ^a	0.36±0.11 ^a	0.35±0.09 ^a	0.33±0.08 ^a
Microkeratome group	120	0.29±0.11	0.49±0.20 ^a	0.42±0.13 ^a	0.41±0.11 ^a	0.39±0.10 ^a
<i>t</i>		1.33	5.45	3.87	5.45	2.41
<i>P</i>		>0.05	<0.01	<0.01	<0.01	<0.01

RMS: Root mean square. ^a*P*<0.01, compared with pre-operation.

Table 3 The comparisons of the RMS values of spherical aberrations for a 6mm pupil between two groups (μm) $\bar{x} \pm s$

Parameters	Eyes	Before surgery	1wk post-surgery	1mo post-surgery	3mo post-surgery	6mo post-surgery
Femtosecond group	120	0.07±0.09	0.14±0.13 ^a	0.13±0.11 ^a	0.13±0.09 ^a	0.12±0.08 ^a
Microkeratome group	120	0.06±0.10	0.34±0.19 ^a	0.31±0.18 ^a	0.21±0.13 ^a	0.16±0.10 ^a
<i>t</i>		0.83	9.52	9.72	10.83	5.51
<i>P</i>		>0.05	<0.01	<0.01	<0.01	<0.01

RMS: Root mean square. ^a*P*<0.01, compared with pre-operation.

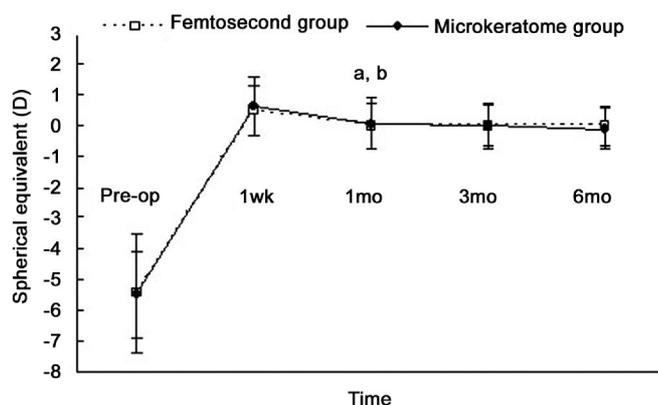


Figure 3 The changes of spherical equivalent (SE) from 1wk to 6mo after surgery for two groups ^aSignificantly changeable compared with 1wk post-surgery (femtosecond group, *P*<0.01); ^bSignificantly changeable compared with 1wk post-surgery (microkeratome group, *P*<0.01).

the microkeratome treated eyes during 6mo visit after surgery. The data were shown in Tables 2, 3.

Contrast Sensitivity Function At night environment (for a 5-mm pupil size condition), the CSF values between two groups at all spatial frequencies before surgery were not statistically significant (*P*>0.05, Figure 4), whereas at 6mo postoperatively, the CSF values for the femtosecond group were higher than those for the microkeratome group at 1.5, 3, 6, 12, 18 cpd space frequency (*P*<0.01, Figure 5).

Ocular Surface Disease Index The mean preoperative OSDI scores were 11.23±9.52 in the femtosecond group and 12.16±10.64 in the microkeratome group, and there was no significant difference between the two groups (*P*>0.05). The mean OSDI scores were 19.84±13.63 in the femtosecond group and 21.23±14.01 in the microkeratome group at 1wk after surgery, and were significantly higher than the preoperative level in both groups (*P*<0.01). The mean OSDI scores returned to preoperative level at 1mo after surgery for both groups (*P*>0.05). There was no significant difference in the mean OSDI scores at any time post-surgery between the two groups (*P*>0.05, Figure 6).

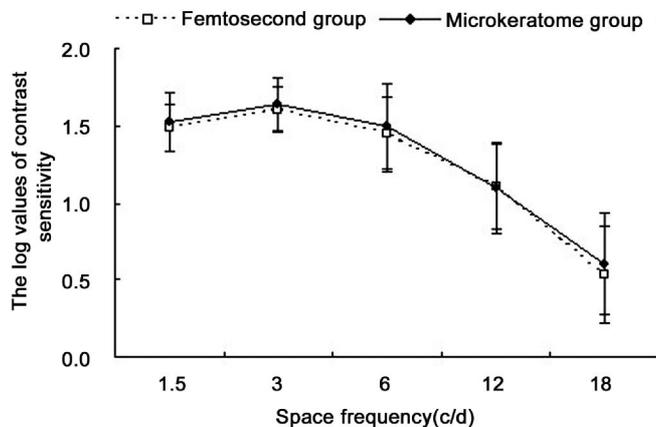


Figure 4 The comparison of contrast sensitivity between the femtosecond group and microkeratome group before surgery.

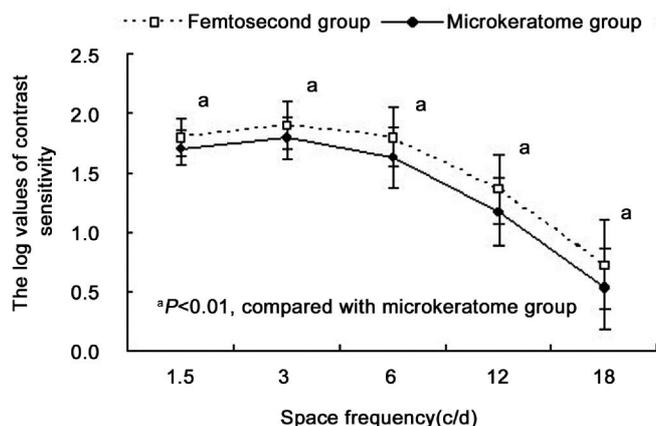


Figure 5 The comparison of contrast sensitivity between the femtosecond group and microkeratome group at 6mo after surgery.

Tear Breakup Time The mean TBUT were significantly shorter than the preoperative TBUT values at 1wk; 1, 3mo after surgery (*P*<0.01), and returned to the preoperative TBUT values at 6mo after surgery (*P*>0.05) for both groups. However, significant difference of the mean TBUT between the femtosecond group and the microkeratome group were found at postoperative 1 and 3mo, when the mean TBUT of the femtosecond treated eyes were markedly longer than those of the microkeratome treated eyes (*P*<0.01, Figure 7).

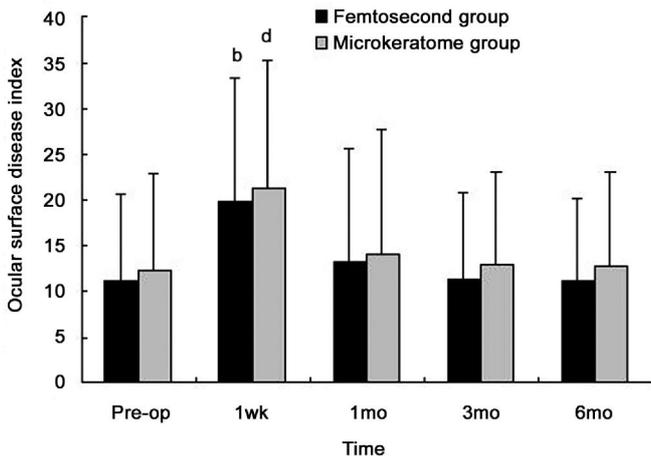


Figure 6 The changes of OSDI pre and post-surgery for two groups ^b $P < 0.01$, compared with the preoperative OSDI level in femtosecond group; ^d $P < 0.01$, compared with the preoperative OSDI level in microkeratome group.

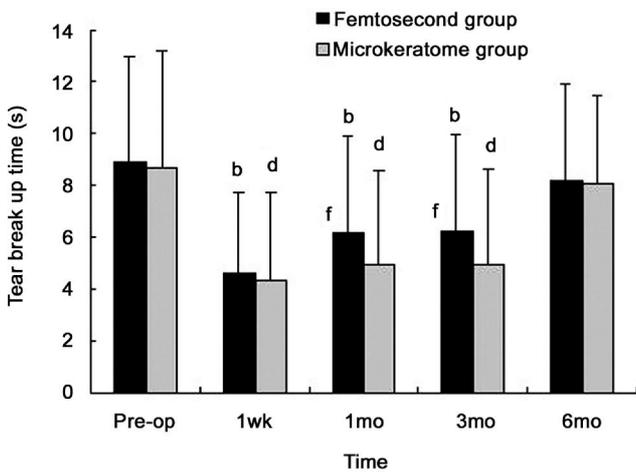


Figure 7 The changes of TBUT from 1wk to 6mo after surgery for two groups ^b $P < 0.01$, compared with the preoperative TBUT values in femtosecond group; ^d $P < 0.01$, compared with the preoperative TBUT values in microkeratome group; ^f $P < 0.01$, compared with the microkeratome group at 1 and 3mo post-surgery.

DISCUSSION

LASIK is the most common corneal refractive surgery for the correction of myopia, with excellent refractive outcomes. LASIK involves an anterior flap creation and photoablation of the corneal stroma deep. LASIK flap creation can be performed either by a mechanical microkeratome or a femtosecond laser. The complications of flap creation with a mechanical microkeratome include button-hole, epithelial abrasion, short flap, free cap, blade marks, and irregular cut, which often influence clinical outcomes. In contrast to the flap complications created with a mechanical microkeratome, femtosecond laser technology enables a large increase in the flap safety and flap thickness predictability^[5,6]. In this study, it was found that flap thickness was highly predictable with the VisuMax femtosecond laser: the mean achieved central flap

thickness was $113.05 \pm 5.89 \mu\text{m}$ for attempted flap thickness of $110 \mu\text{m}$, *i.e.* the variability of flap thickness was $3.05 \mu\text{m}$ with a narrow standard deviation (5.89), whereas the mean achieved central flap thickness with the mechanical microkeratome was $148.36 \pm 21.24 \mu\text{m}$ for intended flap thickness of $140 \mu\text{m}$, *i.e.* the variability of flap thickness was $8.36 \mu\text{m}$ with a wider standard deviation (21.24).

In the current study, we not only compared the difference of the flap thickness, but also analyzed refractive outcomes, CSF values, HOAs and the dry-eye symptom between the two methods. We found that an UDVA of 5.0 or better was obtained in 90% of eyes treated by both methods, an UDVA of 4.9 or better was obtained in more than 98% of eyes treated by both methods, a gain in logMAR lines of CDVA occurred in more than 70% of eyes treated by both groups, and no eye lost ≥ 1 lines of CDVA in both groups, which mean that both the femtosecond and the microkeratome LASIK were effective and safe to correct myopia. We also found that no statistically significant differences in the UDVA, CDVA during 6mo follow-up. Our results are similar to other comparative studies which also found no difference in visual acuity^[12,13]. With regard to the changes of spherical equivalent during 6mo follow-up period after the procedures, the marked changes of spherical equivalent occurred during the first month post-operation in both groups. However, spherical equivalent remained stable after 1mo post-operation in both groups.

It is well known that HOAs and especial spherical aberrations after LASIK are increased^[17], with some increases in aberrations being attributed to flap creation alone^[18,19]. The increase of aberrations is the main factor that influences the visual quality after surgery^[20]. Several studies have highlighted an association between aberrations and the femtosecond laser or microkeratome flaps. Calvo *et al*^[13] found that there were no differences in corneal total high-order aberrations, spherical aberration, coma or trefoil between methods of flap creation at any examination over 4 and 6 mm diameter pupils. However, Lim *et al*^[21] compared a series of eyes receiving either bladeless or microkeratome flaps and found that spherical aberration was higher in microkeratome flaps at 3mo, but total high-order aberrations did not differ. Similarly, Medeiros *et al*^[22] found that the increases in total high-order and spherical aberrations were lower after wavefront-guided LASIK with bladeless flaps that with microkeratome flaps. In myopic LASIK using a femtosecond laser for flap creation, Chen *et al*^[8] found that postoperative HOAs, in particular, spherical aberration (Z12) and vertical coma (Z7) were increased. In a non-randomized study, Buzzonetti *et al*^[23] found that corneal high-order aberrations were higher after LASIK with the flap created by

a microkeratome (Hansatome) than after LASIK with a femtosecond laser (IntraLase). In our study, the total RMS values of HOAs and spherical aberrations for both the femtosecond treated eyes and the microkeratome treated eyes were markedly increased after surgery, and did not recover to preoperative levels until 6mo postoperatively. However, the total HOAs and spherical aberrations in the femtosecond treated eyes were markedly less than those in the microkeratome treated eyes during 6-month visit after surgery. Our results were consistent with findings of Buzzonetti *et al* [23]. Moreover, we found that the CSF values of the femtosecond treated eyes were higher than those of the microkeratome treated eyes at all spatial frequencies at 6mo postoperatively.

One of the most dreaded and most frequent complications of LASIK is dry eye [24]. Dry eye is not only a simple disorder causing patients' discomfort with deteriorated quality of life, but also impairs visual function, CSF and ocular HOAs [25,26]. In our study, we observed an increase in postoperative OSDI scores in both femtosecond group and microkeratome group compared with their preoperative OSDI scores at 1wk after surgery, returned to preoperative level at 1mo after surgery for both groups; and there was no significant difference in the mean OSDI scores at any time post-surgery between the two groups, indicating that patients in both groups could recover quickly from subjective dry eye symptoms. We also observed that the TBUT values in both groups were reduced at 1wk; 1, 3mo after surgery relative to their preoperative scores, and returned to the preoperative TBUT values at 6mo. However, significant difference of the mean TBUT between the femtosecond group and the microkeratome group were found at postoperative 1, 3mo, when the mean TBUT of the femtosecond treated eyes were markedly longer than those of the microkeratome treated eyes. Our findings were consistent with the previous studies by Sun *et al* [27] who confirmed that TBUT was significantly higher in the femtosecond treated eyes than in the microkeratome treated eyes after surgery. The possible reason for this finding may be the different corneal flaps. The femtosecond lasers cut thinner and more regular flaps to avoid the damages of corneal deep nerves than the mechanical microkeratomes.

In conclusion, our study indicates that both the femtosecond and the microkeratome LASIK were effective and safe to correct myopia, with no statistically significant differences in the UDVA, CDVA during 6mo follow-up. Refractive results remained stable after 1mo post-operation for both groups. The femtosecond laser may have advantages over the microkeratome in the flap thickness predictability, fewer induced HOAs, better contrast sensitivity, and longer TBUT.

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Conflicts of Interest: Xia LK, None; Yu J, None; Chai GR, None; Wang D, None; Li Y, None.

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