·Clinical Research·

Effect of femtosecond and microkeratome flaps creation on the cornea biomechanics during laser *in situ* keratomileusis: one year follow-up

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Abstract

• AIM: To compare the corneal biomechanical outcomes at one year after laser *in situ* keratomileusis (LASIK) with the flaps created by Ziemer and Moria M2 microkeratome with 110 head and -20 blade.

• METHODS: Totally 100 eyes of 50 consecutive patients were enrolled in this prospective study and divided into two groups for corneal flaps created by ZiemerFemto LDV and Moria M2 microkeratome with 110 head and -20 blade. Corneal biomechanical properties including cornea resistance factor (CRF) and cornea hysteresis (CH) were measured before and 1, 3, 6, 12mo after surgery by ocular response analyzer. Central cornea thickness and corneal flap thickness were measured by optical coherence tomography.

• RESULTS: The ablation depth (*P*=0.693), residual corneal thickness (*P*=0.453), and postoperative corneal curvature (*P*=0.264) were not significant different between Ziemer group and Moria 110-20 group after surgery. The residual stromal bed thickness, corneal flap thickness, CH and CRF at 12mo after surgery were significant different between Ziemer group and Moria 110-20 group (*P*<0.01); Ziemer group gained better corneal biomechanical results. The CRF and CH increased gradually from 1 to 12mo after surgery in Ziemer group, increased from 1 to 6mo but decreased from 6 to 12mo in Moria 110-20 group. Both CRF and CH at one year after surgery increased with the increasing of residual cornea thickness; pre-LASIK CRF, CRF also increased with residual stromal bed thickness, while CH decreased with the increasing of pre-LASIK intraocular pressure and cornea flap thickness (*P*<0.01).

• CONCLUSION: In one year follow-up, femtosecond laser can provide better cornea flaps with stable cornea biomechanics than mechanical microkeratome.

• KEYWORDS: femtosecond; microkeratome; biomechanics; keratomileusis
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INTRODUCTION

In the recent 10y, the femtosecond laser became available for laser *in situ* keratomileusis (LASIK) flap formation other than mechanical microkeratome. Refractive surgery altered the biomechanical properties of the cornea [1], which were thought to play an important role in affecting treatment outcome[2]. There was growing evidence that it was different in the wound-healing response and biomechanical effects on the cornea depending on whether a flap was created by a microkeratome or femtosecond laser[3-4]. Recently, the Ocular Response Analyzer (ORA; Reichert Ophthalmic Instruments, Depew, NY, USA) has enabled us to quantitatively assess the biomechanical parameters of the cornea *in vivo*[5]. In this prospective study ZiemerFemto LDV (Ziemer Ophthalmic group, Port, Switzerland) which is characterized by low pulse energy and high pulse frequency [6], and Moria M2 microkeratome (Moria, Antony, France) equipped with a 110 head and -20 calibrated-LASIK blade (Med- Logics Inc, Laguna Hills, California, USA) were applied to create the cornea flaps.

The aim of this study was to investigate the biomechanical properties of the cornea and their relationship with the central corneal radius of curvature, the central corneal thickness (CCT), corneal flap thickness (CFT), refraction, age and intraocular pressure (IOP). In the meantime, this study also compared the biomechanical properties before and after LASIK with different methods of cornea flap formation.

SUBJECTS AND METHODS

This study was approved by the Ethic Committee at Beijing Tongren Hospital, Capital Medical University, Beijing, China, and all the investigations were conducted in accordance with the principles of the Declaration of Helsinki. The files of patients who had myopic LASIK at Beijing Tongren Ophthalmic Center of Capital Medical University (Beijing, China) from March to September 2013 were selected. The informed consent was obtained from each subject participating in this study. Patients enrolled received an extensive preoperative examination to determine candidacy for the procedure. This included corneal topography (TOMEY, Japan) and anterior segment optical coherence tomography (OCT, OPTOVUE, USA) to exclude patients with topographic evidence of keratoconus or thin/asymmetric pachymetric profile. Patients were excluded from the study if they did not have all required preoperative parameters measurements, or did not have postoperative follow-up of 1y with all parameters recorded.

Fifty patients with 100 eyes (ranged from 18 to 42 years old, 26.7 years old in average) were enrolled in this study, 17 male and 33 female. The refractive diopter (D) of all the patients remained stable for at least 2y. Neither did those patients have any history of wearing contact lens nor did they use soft contact lens, rigid gas permeable contact lens or the orthokeratology contact lens for at least 2, 3wk and 6mo respectively. All the patients had no history of eye surgery, trauma, or any serious eye diseases such as dry eye syndrome, glaucoma, amblyopia, keratoconus, retinal detachment or cornea dystrophy *etc.* Besides, some specific systemic diseases such as diabetes, collagen disease, drug addiction, mental disease or scar diathesis were the exclusion criteria.

Based on different flap formation, cases were divided into two groups: Ziemer group, corneal flap completed by ZiemerFemto LDV (50 eyes, 25 patients); and Moria 110-20 group, corneal flap completed by Moria M2 microkeratome with 110 head and Med Logic -20 blade (50 eyes, 25 patients).

For each eye, uncorrected visual acuity (UCVA), spherical refraction, cylinder refraction, manifest refraction spherical equivalent (MRSE), corneal thickness, and corneal curvature were measured before and after surgery. The preoperative CCT and postoperative residual corneal thickness (RCT) were measured by ultrasound before and one year after surgery. CFT was measured by the anterior segment OCT one week after surgery. Ablation depth (AD) was the result of CCT minus RCT. Residual stromal bed thickness (RSBT) was the outcome of RCT minus CFT.

In early period after LASIK surgery, the intersection of corneal flap and corneal stromal bed could be clearly manifested through OCT. A week after surgery, including the apex point on vertical and transverse section, the CFT of all the participants at 10 points was recorded by the particular technician (Zhang J). Their average values represented the overall CFT. This method took the difference between the central and peripheral CFT into consideration, which therefore better than only measuring the central CFT by ultrasound during surgery.

The corneal biomechanical properties measured by the ORA are corneal hysteresis (CH) and corneal resistance factor (CRF). According to the manufacturer of the ORA, CH is a measure of viscous damping in the corneal tissue, or the energy absorption capability of the cornea. The CRF parameter is a measure of the cumulative effects of both the viscous damping and elastic resistance of the cornea. The CH and CRF parameters vary from person to person, providing distinct biomechanical information [7]. The ORA measures two different pressure values: the Goldmann-correlated intraocular pressure (IOPg) and the corneal-compensated intraocular pressure (IOPcc). The IOPg is the average of the P1 and P2 applanation pressures and the IOPcc is a value that compensates for the corneal biomechanical properties [8]. Every recorded outcomes of these parameters was the average value of the four measurements carried out on each eye by two doctors (Sun Q or Deng ZZ).

The same experienced surgeon (Zhou YH) performed all LASIK surgeries. The thickness of flap in Ziemer group was set at 110 μm and the diameter of suction ring was 8.5 mm, while all the hinges of the flaps were at superior. The Moria M2 microkeratome with a 110 head and Med Logic -20 blade was used to create a corneal flap with a superior hinge in Moria 110-20 group. The ablations were performed by the Visx S4 excimer laser (VISX Inc, Santa Clara, California, USA) with a 6.0 mm optical zone and 0.5 mm transition zone.

Statistical Analysis Data were expressed as mean±standard deviation (SD) andanalyzed with SPSS 17.0 software (SPSS Inc, Chicago, Illinois, USA). Independent-samples t-test was used to compare the mean values of each parameter between the two groups. Multiple linear step wise regression was used to evaluate influencing factors of corneal biomechanics. $P<0.05$ was considered statistically significant.

RESULTS

Preoperative patient data were shown in Table 1. No significant difference was shown between the two groups by t-test.

The parameters relevant to operation were shown in Table 2. The CFT of each eye in the two groups was directly shown in Figure 1. The difference of AD, RCT and postoperative corneal curvature were not significant between Ziemer group and Moria 110-20 group (P=0.693, P=0.453 and P=0.264) by t-test. The RSBT, and CFT were significant different between Ziemer group and Moria 110-20 group ($P<0.01$) by t-test.

The preoperative biomechanical parameters measured by ORA were shown in Table 3. The difference of CRF and CH value were not significant between the two groups (t-test, P= 0.097 and P=0.218).

Table 1 Preoperative basic data $\bar{x} \pm s$

Group	Ziemer	Moria 110-20	*P*
No. of eyes	50	50	
Age (range)	26.80±4.37 (18 to 36)	26.28±5.54 (18 to 42)	0.426
Male/Female	8/17	9/16	1.000
Spherical refraction (range, D)	-5.81±1.76 (-2.25 to -9.0)	-5.40±2.06 (-1.50 to -10.0)	0.393
Cylinder refraction (range, D)	-0.57±0.52 (0 to -2.0)	-0.60±0.48 (0.5 to -2.0)	0.182
Spherical equivalent (range, D)	-6.09±1.79 (-2.25 to -9.38)	-5.70±2.12 (-1.5 to -10.50)	0.338
Corneal thickness (range, μm)	537.38±28.39 (500 to 604)	539.58±20.84 (498 to 585)	0.375
Corneal curvature (range, D)	43.86±1.55 (40.57 to 46.55)	43.93±1.18 (41.71 to 46.05)	0.064

Table 2 Parameters relevant to operation in two groups $\bar{x} \pm s$

Group	Ziemer	Moria 110-20	*P*
Ablation depth (μm)	73.3±20.2	72.9±21.9	0.693
Residual corneal thickness (μm)	464.6±33.5	460.4±20.5	0.453
Corneal flap thickness (μm)	108.9±5.0	116.7±12.9	<0.01
Residual stromal bed thickness (μm)	360.7±24.6	339.7±26.2	<0.01
Postoperative corneal curvature (D)	38.3±2.4	37.6±2.0	0.264

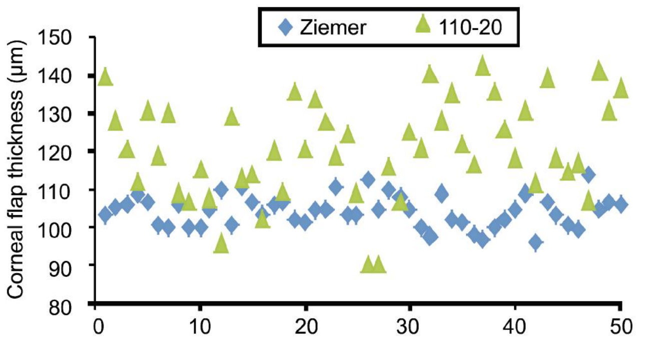

Figure 1 The corneal flap thickness of each eye in the two groups.

Table 3 Preoperative biomechanical parameters $\bar{x} \pm s$ (mm Hg)

Group	Ziemer	Moria 110-20	*P*
IOPg	16.7±2.9	17.1±2.5	0.679
IOPcc	17.5±3.0	17.9±2.7	0.284
CRF	10.3±1.4	10.6±1.0	0.097
CH	9.8±1.4	9.9±1.1	0.218

IOPg: Goldmann-correlated intraocular pressure; IOPcc: Corneal-compensated intraocular pressure; CRF: Corneal resistance factor; CH: Corneal hysteresis.

Table 4 Refractive outcomes at 12mo after surgery $\bar{x} \pm s$ (D)

Group	Ziemer	Moria 110-20	*P*
DS12mo	-0.15±0.41	-0.20±0.41	0.598
DC12mo	-0.12±0.33	-0.18±0.42	0.338
SE12mo	-0.21±0.41	-0.30±0.35	0.540

DS: Diopters sphere; DC: Diopters cylinder; SE: Spherical equivalent.

Table 5 Postoperative biomechanical parameters and basic corneal characters at 12mo $\bar{x} \pm s$

Group	Ziemer	Moria 110-20	*P*
CRF1mo (mm Hg)	6.9±1.06	6.95±.88	0.734
CH1mo (mm Hg)	7.47±1.31	7.45±0.96	0.801
CRF12mo (mm Hg)	7.34±1.50	7.04±1.41	<0.01
CH12mo (mm Hg)	8.15±1.64	7.78±1.18	<0.01
RCT (μm)	464.6±33.5	460.4±20.5	0.453
RSBT (μm)	360.7±24.6	339.7±26.2	<0.01
CFT (μm)	108.9±5.0	116.7±12.9	<0.01
Cur12mo (D)	38.3±2.4	37.6±2.0	0.264
IOPg12mo (mm Hg)	9.74±1.54	9.56±2.10	0.267
IOPcc12mo (mm Hg)	13.85±1.93	13.95±1.78	0.280

CRF: Corneal resistance factor; CH: Cornea hysteresis; RCT: Residual cornea thickness; Cur: Cornea curvature; IOPcc: Corneal-compensated intraocular pressure; IOPg: Goldmann-correlated intraocular pressure.

The refractive outcomes at one year after surgery were shown in Table 4. No significant difference were observed between the two groups (*t*-test, $P>0.05$).

The postoperative biomechanical parameters and basic corneal characters at 12mo were shown in Table 5. The *P* values displayed in the table were obtained by *t*-test.

In the two surgery groups the pre-LASIK CRF and CH were compared with post-LASIK CRF and CH at 1, 6, 12mo after surgery. The strong significant differences were found in the comparison of CRF at 1mo with 6mo, 6mo with 12mo, and 1mo with 12mo in the Ziemer group, the value of CRF increased gradually after operation. The significant difference in the comparison of CRF was found at 1mo with 6mo and 6mo with 12mo in the Moria 110-20 group, but the mean value increased from 1mo to 6mo, decreased from 6mo to 12mo, while no significant difference was found between 1mo and 12mo. The strong significant difference in the comparison of CH was found at 1mo with 6mo and 1mo with 12mo in the Ziemer group, the significant difference was found at 1mo with 6mo and 1mo with 12mo in the Moria 110-20 group (Table 6).

The results of correlation analysis of postoperative cornea biomechanical parameters were shown in Table 7. CRF12mo was positively correlated with RCT, CRF, CCT, RSBT, CH, and was negatively correlated with AD, CFT. CH12mo was

Table 6 Comparison of cornea biomechanical parameters at different stages after operation $\bar{x} \pm s$ (mm Hg)

Postoperation stage		Post-LASIK			*P*		
		1mo	6mo	12mo	1mo *vs* 6mo	6mo *vs* 12mo	1mo *vs* 12mo
Ziemer	CRF	6.90±1.06	7.14±1.32	7.34±1.50	<0.05	<0.05	<0.01
	CH	7.47±1.31	8.1±1.67	8.15±1.64	<0.01	0.305	<0.01
Moria 110-20	CRF	6.95±.88	7.26±0.72	7.04±1.41	<0.05	<0.05	0.718
	CH	7.45±0.96	7.93±0.85	7.78±1.18	<0.05	0.266	<0.05

CRF: Corneal resistance factor; CH: Cornea hysteresis.

Table 7 Correlation analysis of CRF12mo and CH12mo

Parameters		CRF	CH	AD	Cur	CCT	RCT	IOPcc	CFT	RSBT
CRF12mo	*r*	0.494[a]	0.378[a]	-0.332[a]	-0.046	0.423[a]	0.554[a]	0.117	-0.418[a]	0.410[a]
	P	<0.01	<0.01	<0.01	0.504	<0.01	<0.01	0.089	<0.01	<0.01
CH12mo	*r*	0.477[a]	0.505[a]	-0.388[a]	-0.026	0.422[a]	0.590[a]	-0.116	-0.471[a]	0.422[a]
	P	<0.01	<0.01	<0.01	0.711	<0.01	<0.01	0.090	<0.01	<0.01

AD: Ablation depth; Cur: Cornea curvature; CCT: Central cornea thickness; RCT: Residual cornea thickness; IOPcc: Corneal-compensated intraocular pressure; IOPg: Goldmann-correlated intraocular pressure. [a]The result is statistically significant, $P<0.05$.

Table 8 The multiple linear stepwise regression of pre and post-LASIK CRF and CH

Parameters	Regression function	*F* value	*P*
CRF	CRF=-21.038+0.337×CCT+0.257×Cur	92.460	<0.01
CH	CH=-11.31-0.242×IOPcc+0.230×CCT+0.210×Cur	94.285	<0.01
CRF12mo	CRF12m=-1.735+0.023×RCT+0.350×CRF+0.644×RSBT	37.427	<0.01
CH12mo	CH12m=3.891+0.021×RCT-0.212×IOPcc+0.289×CRF-0.064×CFT	55.303	<0.01

positively correlated with RCT, CH, CCT, RSBT, CRF, and was negatively correlated with AD, CFT.

The multiple linear stepwise regression of cornea biomechanical parameters were shown in Table 8.

DISCUSSION

LASIK is the mainstream surgery to correct the refraction errors nowadays, which is proved to be safe, effective and well predicable. The critical step of LASIK is to make a thin and uniform lamellar cornea flap. Studies [9] had shown that femtosecond laser flaps were uniform thickness and planar-shape, however some microkeratome created flaps, which were not uniform but meniscus-shaped. The flaps made by femtosecond laser were proved to be more precise, more even, and better predictable than the flaps made by microkeratome [10-11]. In this study, the CFT of each eye in Ziemer group was much more concentrated than the Moria 110-20 group (Figure 1). This outcome revealed that Ziemer LDV femtosecond laser can provide thinner and better predictable cornea flaps compared to the mechanical microkeratome.

In this study, the value of SE12mo, DS12mo and DC12mo in the two groups were not significant different, which implied that successful cornea flaps can help to avoid the iatrogenic astigmatism or the refractive regression.

According to the one year follow-up, CRF1mo, CH1mo, Cur12mo and RCT between the two groups had no significant difference by *t*-test, while CRF12mo, CH12mo, RSBT and CFT were significant different between the two groups. Although all the other parameters of ORA (IOPg, CRF, CH) except IOPcc are affected by the CCT [12], CH12mo or CRF12mo were significant different between the two groups while the RCT was not significant different. In the meantime the RSBT was significant different between the two groups, which means RSBT would influence the post-operational corneal biomechanical parameters rather than RCT do. The Ziemer group provided thinner corneal flaps and remained thicker corneal stroma compared with the Moria 110-20 group, therefore better performance of corneal biomechanics was gained in the Ziemer group. Based on the previous researches [12-13], sufficient RCT is the guarantee of the post-operational corneal biomechanics, the conclusion could be drawn that the RSBT is the main influencing factor on the corneal biomechanics under the condition of the same RCT. This outcome indicated that with the premise of the same RCT, the different way of flap formation had notable influence on the cornea biomechanical parameters including CRF and CH one year after surgery. Our study was coincide with the previous research [14]. Femtosecond flaps and microkeratome flaps were different in the flap depth, shape, architecture, and biomechanical parameters.

The values of CRF and CH were tested at 1, 3, 6 and 12mo after surgery in two groups. The values of CRF and CH increased gradually and significantly in Ziemer group, however only significant increase of CH in Moria 110-20 group were obtained between the early stages and one year after surgery. It is noticeable that there was significant decrease of CRF from 6 to 12mo in the Moria 110-20 group. This outcome means the Ziemer group has better long-term effect on cornea biomechanics than the Moria 110-20 group. The impact of the flap is needed equal emphasis compared with the impact of AD on the cornea biomechanics. Although iatrogenic post-LASIK ectasia is reported in the patients whose residue cornea were thicker than 250 μm, reserving enough RCT was still the most important way to avoid post-LASIK ectasia [15-18]. Based on the result of this research, in the premise of same RCT, thick RSBT means better corneal biomechanical parameters. Since the delayed-onset keratectasia had been documented [19-21], the observation of cornea biomechanics after surgery should be as long as possible, and this is a one year follow-up study which provided the longest and intact observation of cornea biomechanics. The flaps made by the Ziemer LDV femtosecond laser were moreuniform and accurate thanthose created by the Moria M2 microkeratome[22]. Furthermore, the greater inflammatory response and biomechanical stability of the femtosecond flap was reported by Dawson *et al* [23] and Netto *et al* [24], as proved by Kim *et al* [4] the femtosecond flaps were more strong and unlikely to shift or have a crease. It would be a wise choice to use femtosecond flaps for those patients with high myopia and corresponding thicker AD, because the influence of flap is reduced.

In the multiple linear regression analysis of the pre-LASIK CRF and CH value, we found that CRF and CH value increased with the increasing of CCT and the curvature of the cornea, while CH value decreased with the increasing of IOPcc. Cornea thickness was the main effective factor of cornea biomechanics, we found that cornea curvature had some influence on the CH value, which was proved by other research [25]. The relationship between the cornea curvature and the biomechanical parameters indicated that cornea with high refractive power might need more strength to gain applanation, so the IOP would be higher than actual. Hence, when the myopia eyes were taken the IOP test, not only the cornea thickness but also the cornea curvature should be taken into account.

In the multiple linear regression analysis of the post-LASIK CRF and CH, we found that CRF12mo increased with the increasing of RCT, pre-LASIK CRF and RSBT, while CH12mo increased with the increasing of RCT or pre-LASIK CRF and decreased with the increasing of pre-LASIK IOP or CFT. This result indicated that post-LASIK cornea biomechanical parameters (CRF and CH) correlate not only with the RCT but also with the inherited physical and physiological characters of the operated eyes. In the multiple linear regression analysis about the post-LASIK CH, CFT was introduced into the regression equation, which indicated that CFT had influence on the corneal biomechanics. The influence might due to that the corneal flaps with different thickness would induce different histological repair reaction to the injury. Corneal flaps at different depth in the cornea might activate the keratocytes in different level, which would lead to the different effect in injury repair. Some early research proceeded by confocal microscope showed that keratocytes were more active under the thinner corneal flaps, so did the global healing reaction of the cornea [26-28]. The corneal healing reaction observed by confocal microscope between the corneal flap and the residual stromal bed were stronger in femtosecond group than in microkeratome group, reported by Netto *et al* [24]. At cellular level, the wound healing and the biomechanics of cornea might variable based on the different way of corneal flaps formation.

The Ziemer group got better corneal biomechanical performance one year after surgery than the Moria 110-20 group in this study, therefore the conclusion could be drawn that Ziemer LDV femtosecond laser can offer more stable biomechanical effect than microkeratome do. In the meantime femtosecond laser provide thinner and better cornea flaps, and remain thicker RSBT, which are proved to be the guarantee of better corneal biomechanical performance in this study as well as RCT.

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