

Comparison on dry eye symptoms and stability of tear film after correction of myopia by LASIK versus LASEK with the use of artificial tears

Shu-Yue Zheng^{1,2}, Qi Li²

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¹Chongqing Medical University, Chongqing 400016, China

²Department of Ophthalmology, the First Affiliated Hospital of Chongqing Medical University, Chongqing 400010, China

Correspondence to: Qi Li. Department of Ophthalmology, the First Affiliated Hospital of Chongqing Medical University, Chongqing 400010, China. 1986572259@qq.com

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人工泪液对LASIK与LASEK术后干眼症状及泪膜稳定性的影响

郑淑月^{1,2},李琦²

作者单位:¹(400016)中国重庆市,重庆医科大学;²(400010)中国重庆市,重庆医科大学附属第一医院眼科

作者简介:郑淑月,重庆医科大学在读硕士研究生,研究方向:屈光。

通讯作者:李琦,毕业于重庆医科大学,博士,副主任医师,研究方向:屈光. 1986572259@qq.com

摘要

目的:探究激光辅助原位角膜磨镶术(LASIK)和激光上皮角膜磨镶术(LASEK)术后配合0.1%玻璃酸钠(HA)治疗对于干眼症状及泪膜稳定性的影响。

方法:将2017-02/2017-12纳入的230例460眼近视患者分为LASIK组和LASEK组,然后将每个治疗组随机分为0.1% HA治疗亚组和无HA亚组,两个亚组均在角膜屈光手术后应用0.3%加替沙星和0.5%氯替泼诺。观察各组患者不同时间点干眼症状评分、角膜知觉反应、角膜荧光染色(FL)、基本泪液分泌试验(S I t)和泪膜破裂时间(BUT)的变化。

结果:LASIK和LASEK患者术后1wk, 1,3,6mo, 0.1% HA治疗组与无HA组的FL、干眼症状评分和角膜知觉反应均存在显著差异($P<0.05$)。各组术后1wk BUT均较术前明显下降。术后其他观察时间点BUT及各时间点术后S I t水平虽低于术前水平,但仍在正常范围内。LASEK术后患者的干眼主观症状、泪膜稳定性和角膜表面知觉优于LASIK患者,尤其是在术后1wk, 1,3mo。

结论:两种屈光手术可引起不同程度的干眼症状,LASEK组干眼症状在术后早期较LASIK组轻。早期足量使用不含防腐剂的0.1% HA可有效促进角膜修复,对术后干眼症状有很大帮助。

关键词:激光辅助原位角膜磨镶术;激光上皮角膜磨镶术;干眼;玻璃酸钠

Abstract

• **AIM:** To investigate the dry eye symptoms and the stability changes of tear film after correction of myopia by laser-assisted *in situ* keratomileusis (LASIK) and laser epithelial keratomileusis (LASEK) with the use of 0.1% sodium hyaluronate (HA).

• **METHODS:** A total of 230 myopia patients (460 eyes) were divided into LASIK group and LASEK group from February 2017 to December 2017. Each operation group was randomly assigned to 0.1% HA treatment subgroup and HA-free subgroup. Both subgroups were instructed to apply gatifloxacin (0.3%) and loteprednol (0.5%) after the corneal refractive surgery. The changes of dry eye symptom score, corneal perceptual reaction, corneal fluorescein staining (FL), basic Schirmer I test (S I t) and tear film break-up time (BUT) were observed in different time points.

• **RESULTS:** There were significant differences in FL, dry eye symptom score and corneal perceptual response between the 0.1% HA treatment group and HA-free group at 1wk, 1, 3 and 6mo after operation both in LASIK and LASEK patients ($P<0.05$). BUT after operation in each group was significantly decreased at 1wk compared with preoperative level. Other observation time points after surgery of BUT and each postoperative level of S I t were still within the normal range although lower than the preoperative levels. The subjective symptoms of dry eyes, tear film stability and corneal surface perception of LASEK patients were better than LASIK patients especially at 1wk, 1 and 3mo after surgery.

• **CONCLUSION:** These two kinds of refractive surgery may cause different degrees of dry eye symptoms. These symptoms in the LASEK group were lighter than that in the LASIK group in the early postoperative period. The early adequate use of preservative-free 0.1% HA could effectively promote the corneal repair and be greatly helpful for postoperative dry eye symptoms.

• **KEYWORDS:** laser-assisted *in situ* keratomileusis; laser epithelial keratomileusis; dry eyes; sodium hyaluronate

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INTRODUCTION

Corneal refractive surgery is an effective method for the treatment of myopia. Laser-assisted *in situ* keratomileusis (LASIK) and laser epithelial keratomileusis (LASEK) are two kinds of classic refractive surgeries^[1-2]. LASEK, a relatively new laser surgical procedure for the correction of the myopia, combines certain elements of LASIK and photorefractive keratectomy (PRK)^[3]. Although both methods of operation could be accurate, safe and effective for correcting the ametropia, the dry eye symptoms that are caused by surgery could not be ignored. The dry eye symptoms are fairly common among postoperative patients in the ophthalmic clinic and have a negative impact on the daily routines and social lives of the patients. Corneal refractive surgery could directly affect the health of the ocular surface by reducing corneal sensation, tear secretion, conjunctival goblet cell density and corneal and conjunctival epithelial integrity^[4]. These alterations break the stability of tear film and lead to postoperative dry eye symptoms^[5-7].

Sodium hyaluronate (HA), composed of b-1, 3-N-acetyl glucosamine and b-1, 4-glucuronic acid repeating disaccharide units found in the vitreous body and in the inter-fibrillar space of cross-linked collagen matrix in the cornea, has emerged as one of the most common water solution artificial tears^[8]. HA has been shown good biocompatibility, viscoelastic properties, and strong water retention, which could stabilize the tear film and relieve dry eye symptoms such as ocular irritation and burning. In addition, HA has also been found for ocular surface wound healing especially due to its positive biological functions on corneal epithelial cells in recent researches^[8-9]. In view of the important effect of artificial tears on the improvement of corneal injury, we performed a randomized controlled analysis to compare the recovery time of cornea and dry eye symptoms of the myopia patients after LASIK and LASEK with continuous use of 0.1% HA [(C₁₄H₂₀NNaO₁₁)_n, 2-3 × 10⁶ Daltons, no preservatives, EUSAN GmbH, Germany] eye drops for 3mo immediately after surgery in Chinese myopia patients.

SUBJECTS AND METHODS

Patients This prospective, single-site, randomized and comparative clinical study was conducted at the Department of Ophthalmology, the First Affiliated Hospital of Chongqing Medical University (Chongqing, China) from February 2017 to December 2017. A total of 230 patients (460 eyes) diagnosed with myopia underwent corneal refractive surgery in this study. They were divided into LASIK group (230 eyes) and LASEK group (230 eyes). Each operation group was then randomly assigned to 0.1% HA treatment subgroup (115 eyes) and HA-free subgroup (115 eyes). Both subgroups were instructed to apply gatifloxacin (0.3%) and loteprednol (0.5%) after the corneal refractive surgery. Eligible participants consisted of myopia patients aged ≥18 years with refractive correction range of -2.0 D to -9.25 D. Meanwhile, these patients had the corneal thickness ≥ 470 μm and annual change of degree within 0.5 D in the past two years.

The major exclusion criteria, including ocular and systemic factors were as follows: 1) inflammation or active infection in the eyes; 2) abnormal or serious dry eyes such as eyelid defects, incomplete closure, high intraocular pressure, keratoconus and fundus diseases; 3) severe connective tissue diseases and abnormal autoimmune function; 4) severe hyperthyroidism exophthalmia and mental illness such as depression, anxiety and so on. This study was reviewed by the Ethics Committee of Chongqing Medical University, and all investigated subjects provided informed consent before treatment. All procedures conformed to the tenets of the Declaration of Helsinki.

Study Protocol For the LASIK technique, a corneal lamellar knife (MORIA, French) was used to create a corneal flap pedicle in the 12 o'clock position with the negative pressure suction ring of 9 mm diameter. For the LASEK technique, a corneal epithelial saw with a diameter of 8 mm was used on the surface of cornea. A 20% ethanol solution was infused into the corneal surface for 20-22s. Then the ethanol was absorbed with dry sponge, and the conjunctival capsule and corneal tissue were carefully washed with balanced salt solution. The corneal epithelial area exposed for laser was carefully separated with a scraper. Finally, the excimer laser system (Allegretto wave EYE-Q, USA) was used for diopter treatment in these two groups. The optical treatment area cut by laser was 6.0 mm × 6.5 mm, the temperature of operating room was controlled at 22 °C - 24 °C, and the humidity was 45%-50%. All of the operations were performed by the same experienced ophthalmologist. The patients in both operation groups were instructed to apply gatifloxacin (0.3%) and loteprednol (0.5%) four times a day, then tapering over 1mo. The sodium hyaluronate eye drops (0.1%) was used three times a day for 3mo. The HA subgroup was additionally treated with 0.1% HA (EUSAN GmbH, Germany) four times a day for 3mo.

The patients in both groups were examined before operation, and 1wk, 1, 3, 6mo after operation. The observation indexes included: 1) routine ophthalmology examination: uncorrected visual acuity, the best corrected visual acuity (BCVA), cornea, diopter and intraocular pressure. BCVA was measured in decimal values and converted to LogMAR scores for all patients at every visit; 2) corneal fluorescein staining (FL): the cornea was divided into four quadrants. No corneal fluorescein staining was recorded as 0 points. The presence of scattered fluorescein staining was recorded as 1 point. The dense fluorescein staining point or flake staining was recorded as 2 points, and the block or fusion fluorescein staining area was recorded as 3 points; 3) Schirmer I test (S I t) without corneal anesthesia; 4) tear film break-up time (BUT) was performed using a fluorescein strip (invasive); 5) dry eye symptoms score: whether the subjects had eye dryness, burning sensation and foreign body sensation. Those who always had symptoms were recorded as 3 points, those who had intermittent symptoms were scored as 2 points, and those who occasionally had symptoms were scored as 1 point. Score 0

Table 1 Clinical features of study participants in two groups

Parameters	LASIK group	LASEK group
Eyes (patients)	230 (115)	230 (115)
Age (y)	22.0±5.30 (18–39)	23.7±5.44 (18–38)
Gender (M/F, patients)	63/52	61/54
Postoperative visual acuity	1.0 or better	1.0 or better
Spherical equivalent refraction (D)	-4.58±1.61	-4.87±1.58
Corneal thickness (µm)	558±27	524±28
Keratometry (D)		
K1	42.4±2.87	42.8±1.54
K2	43.8±1.46	43.9±3.03
Anterior chamber depth (mm)	47.6±14.0	49.7±12.2

K1: Flat meridian corneal refractive power; K2: Steep meridian corneal refractive power.

Table 2 Comparison of corneal FL in patients before and after the surgery (LASIK and LASEK groups) point

Groups	Preoperative	Postoperative			
		1wk	1mo	3mo	6mo
LASIK	1.33±1.01	4.29±2.16 ^a	2.98±1.65 ^a	2.27±1.36 ^a	1.77±1.19 ^a
LASIK-HA	1.43±1.11	3.3±2.09 ^a	1.9±1.27 ^a	1.71±1.08 ^a	1.41±0.95
<i>P</i>	0.51	<0.01	<0.01	0.001	0.011
LASEK	1.36±0.87	3.97±2.27 ^a	2.62±1.69 ^a	2.13±1.34 ^a	1.54±1.03
LASEK-HA	1.32±1	2.71±1.49 ^a	1.93±1.25 ^a	1.4±0.97	1.35±0.98
<i>P</i>	0.778	<0.01	0.001	<0.01	0.17

FL: Fluorescein staining; ^a*P*<0.05 vs preoperative.

Table 3 Comparison of the tear film BUT in patients before and after the surgery (LASIK and LASEK groups) s

Group	Preoperative	Postoperative			
		1wk	1mo	3mo	6mo
LASIK	15.3±4.2	8.4±2.67 ^a	10.8±2.15 ^a	11.2±2.14 ^a	12.1±2.24 ^a
LASIK-HA	15.8±3.72	9.5±2.46 ^a	11.9±5.11 ^a	12.2±2.57 ^a	13.2±3.06 ^a
<i>P</i>	0.349	0.001	0.023	0.003	0.002
LASEK	15.0±4.18	9.84±2.8 ^a	11.3±2.09 ^a	11.8±1.97 ^a	12.7±2.56 ^a
LASEK-HA	15.2±3.27	10.8±3.03 ^a	12.7±3.35 ^a	13.2±2.82 ^a	13.6±3.29 ^a
<i>P</i>	0.661	0.015	<0.01	<0.01	0.025

BUT: Break-up time; ^a*P*<0.05 vs preoperative.

for those who do not complain of discomfort; 6) corneal sentience: repeated tests 3 times, record the average. The criteria of judgment are divided into three grades; normal, declining and disappearing.

Statistical Analysis SPSS 17.0 software (Chicago, IL, USA) was used for statistical analysis. A *P* values <0.05 were considered statistically significant. The data were presented as mean±standard deviation ($\bar{x}\pm s$). Independent-samples *t*-test was used for comparison between groups, and repeated measure ANOVA was used for comparison at different time points before and after refractive surgery. Rank sum test was used to compare the counting data.

RESULTS

There were 230 eyes (from 115 patients) in each surgical group. The mean age of the patients comprising 124 men (54%) and 106 women (46%), age 22.8±5.43 (range: 18–39) years. The preoperative equivalent spherical mirror of LASIK group and LASEK group were -4.58±1.61 D and -4.87± 1.58 D, respectively, showing no statistical

difference. Detailed clinical findings for the enrolled patients of both surgical groups were presented in Table 1.

There was significant difference in corneal FL at each time point after operation both in the LASIK and LASEK groups compared with that before operation (Table 2). With the use of 0.1% HA eye drops, the FL at 1wk, 1mo and 3mo were significantly lighter compared with the HA-free groups. The patients gradually recovered to the preoperative level at 6mo after operation in LASIK-HA group and three months earlier in LASEK-HA group (1.41±0.95 and 1.4±0.97, respectively) (*P*>0.05).

Before surgery, the average level of BUT were more than 15s both in the LASIK and LASEK group (Table 3). The BUT changed immediately after either LASIK or LASEK operation (*P*<0.05). Postoperative BUT was markedly decreased at 1wk, 1, 3 and 6mo after LASIK and LASEK compared with that at the preoperative baseline. For comparison between HA treated and HA-free eyes; there were statistically significant differences in BUT at each time-point after operation. HA

Table 4 Comparison of corneal perceptual reaction in patients before and after the surgery (LASIK and LASEK groups)

Parameters	LASIK				LASIK-HA				P
	Grade 1	Grade 2	Grade 3	P ₁	Grade 1	Grade 2	Grade 3	P ₂	
Preoperative	100	15	0		103	12	0		0.54
Postoperative									
1wk	16	70	29	<0.0125	39	54	22	<0.0125	0.003
1mo	29	68	18	<0.0125	52	50	13	<0.0125	0.004
3mo	56	45	14	<0.0125	78	31	6	<0.0125	0.002
6mo	80	32	3	<0.0125	98	15	2	>0.0125	0.001

Parameters	LASIK				LASEK-HA				P
	Grade 1	Grade 2	Grade 3	P ₁	Grade 1	Grade 2	Grade 3	P ₂	
Preoperative	99	15	1		101	14	0		0.679
Postoperative									
1wk	31	63	21	<0.0125	60	35	20	<0.0125	0.003
1mo	54	45	16	<0.0125	77	28	10	<0.0125	0.003
3mo	80	29	6	<0.0125	97	16	2	>0.0125	0.007
6mo	91	22	2	>0.0125	98	17	0	>0.0125	0.07

P₁, P₂: Compared with preoperative. For intra-group comparison (comparison between different time points after surgery and before surgery), the test level was redefined as $\alpha' = \alpha / (k - 1)$, ($\alpha = 0.05$, $k = 5$), and $\alpha' = 0.0125$.

treated eyes had a longer BUT than that HA-free eyes either in LASIK group or in LASEK group ($P < 0.05$).

The corneal perceptual reaction of patients was significantly reduced at each observation point after HA-free LASIK operation ($P < 0.0125$). In LASIK-HA group, this change has improved at every point time compared to the LASIK group. The corneal perceptual reaction basically returned to the preoperative level at 6mo after operation (Table 4). In LASEK group, it was significantly lower at 1wk, 1 and 3mo after surgery compared with preoperation level ($P < 0.0125$), and the corneal perceptual reaction returned to the preoperative level at 6mo ($P > 0.0125$). The recovery time of corneal perceptual reaction was effectively shortened after administration of 0.1% HA in the LASEK-HA group. There was no statistical difference from 3mo after LASEK surgery compared with preoperative level. For comparison of LASEK and LASEK-HA groups, the decline of corneal perceptual reaction was more significant on patients who were not receiving the HA eye drops.

The S I t in LASIK group was lower at each postoperative time point than preoperative level, but it was still in the normal range (Figure 1). The HA-treated LASIK eyes showed slight improvement at 3 and 6mo after operation. There was no significant difference at each postoperative time point in the LASEK group ($P > 0.05$), and also between LASEK and LASEK-HA groups ($P > 0.05$).

The subjective symptoms assessments mainly include the eye dryness, burning sensation and foreign body sensation. The subjective symptom of HA treated eyes at 1wk, 1 and 3mo after operation were significantly alleviated comparing with HA-free eyes both in the LASIK group and LASEK group (Figure 2). In the LASIK group, the subjective symptom score has not been restored to the preoperative level until half a year. In the LASEK group, the level returned to the

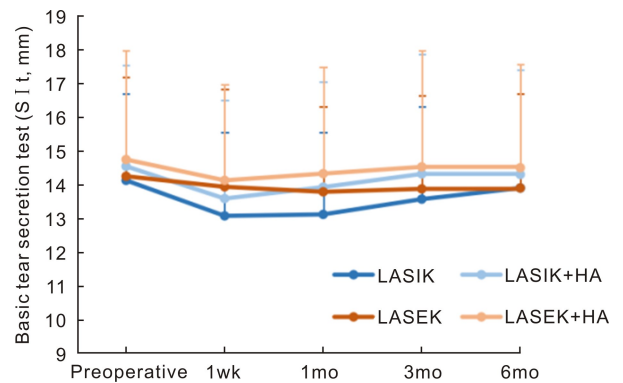


Figure 1 Comparison of basic tear secretion test (S I t) in patients before and after the surgery (LASIK and LASEK groups).

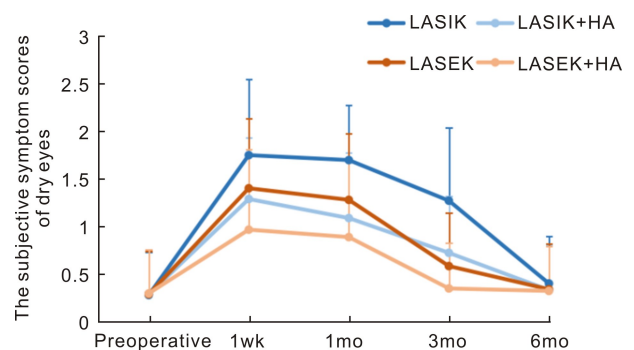


Figure 2 The subjective symptom scores of dry eyes in patients before and after the surgery (LASIK and LASEK groups).

preoperative scores at 6mo after operation. HA treated eyes in LASIK group and LASEK group recovered faster than those who were not treated with 0.1% HA ($P < 0.05$).

DISCUSSION

LASIK and LASEK surgery have been recognized by the ophthalmology community and the majority of patients because of good stability, effectiveness, predictability and safety. These two kinds of refractive surgeries are the main methods of

excimer laser refractive surgery in China^[10-11]. However, since both surgeries are carried out on a healthy cornea, the corneal tissue will be cut and damaged, and the nerve fibers of the cornea will be destroyed to varying degrees. Consequently, patients often have symptoms such as dryness, eye fatigue, photophobia, or accompanied by obvious foreign body sensation, burning feeling and other discomfort. Dry eye symptoms have become the common complication after the excimer refractive surgery^[12-13]. HA is a high molecular weight polysaccharide. Compared to other artificial tears, it not only has the ability to relieve dry eye symptoms but also has found to contribute to the wound healing of ocular surface^[14-15]. Due to the different ways for making the corneal flap in LASIK and LASEK, it is of great significance to observe and compare the recovery of cornea after these two operations with the use of artificial tears. In the present study, we investigated the role of 0.1% HA in these two kinds of refractive surgeries. Compared with other clinical reports comparing the dry eye symptoms after LASIK and LASEK, we focus on the role of HA in corneal recovery after surgery, which proves the important role of HA in corneal recovery after corneal refractive surgery. The results showed that the subjective symptoms of dry eye, the stability of the tear film and the corneal perceptual response of the groups with HA treatment were obviously improved after operation with the use of 0.1% HA eye drops.

In the LASIK group, the subjective symptoms of dry eyes, S I t, corneal FL and corneal perceptual reaction were gradually improved at 6mo after operation, but were still lower than those before surgery. In the LASEK group, the subjective symptoms, corneal FL and corneal perceptual reaction were basically restored to preoperative level at 6mo after operation. These results indicated that both LASIK and LASEK could lead to different degrees of dry eye symptoms and the decrease of tear film stability in the short term. This is consistent with other clinical reports that excimer laser therapy for myopia would cause different degrees of dry eye symptoms^[16-17]. The mechanisms involved in post-LASIK and post-LASEK dry eye are complex and not completely understood. Firstly, the intracorneal nerve is disrupted by corneal flap creation and directly cutting on corneal basement layer. As we known, the corneal nerve originates from the long nasociliary nerve and passes through the eyeball through the superior choroid cavity, then emits branches into the cornea with the highest density of nerve fibers in the central area of cornea^[18]. Surgical cutting could lead to the break-up of corneal nerve fibers and the decrease of corneal sensitivity. The nerve impulse of the cornea transmitted to the brain system through the reflex arc is then reduced by the decrease of corneal perception, resulting in a corresponding decrease of the lacrimal gland secretion and dry eye symptoms. The regeneration of nerve fibers usually occurred within 3-6mo after refractive surgery through the observation by a confocal microscope^[6]. The recovery time of our study was consistent with this conclusion. Secondly, the stability of tear film declined after refractive surgery. After the

refractive surgery, the regularity of corneal surface decreased, the epithelial cells of eye surface were damaged, mucin could not be adsorbed, and the stability of tear film decreased. In addition to the reduction of corneal perception after operation, the blink movement was reduced accordingly, which further affected the reconstruction of tear membrane^[19-20]. Besides, the different drug types, doses and frequency of postoperative drugs in different patients also directly affect the recovery of corneal function and the degree of dry eye condition.

The early adequate use of 0.1% HA eye drops continuously for 3mo in LASIK and LASEK patients could both significantly reduce the corneal recovery time. Our results revealed that the subjective symptoms, corneal FL and corneal perceptual reaction in LASIK-HA and LASEK-HA groups were restored to preoperative level about 3mo earlier than the HA-free groups. These findings indicated that 0.1% HA could effectively improve the postoperative dry eye symptoms and accelerate the repair of corneal epithelium. The corneal epithelium healing is a complex process involving intercellular signaling, interactions between cells and the extracellular matrix, proteases, growth factors, and epithelial and stromal cytokines^[21-22]. HA, as a major component of the extracellular matrix, has been shown to reduce the tear evaporation rate, increase tear film stability and accelerate ocular surface wound healing^[23]. The wound healing effect of HA are not merely depend on its mechanical protective role of water retention and viscoelasticity, but also on its positive biological functions involved in cell adhesion and locomotion^[9]. Researchers have found that HA could stimulate corneal epithelial migration independent of fibronectin and epidermal growth factor *in vitro*^[24]. The hyaluronan in the culture medium could increase the length of the path of the corneal epithelial layer^[24]. This effect of HA on cell behavior and intracellular signaling is mediated by binding to specific cell-surface receptors and the activation of these receptors modulate cell proliferation and migration. In addition, studies also have shown that BUT after operation in each group was significantly decreased at 1wk compared with preoperative level. Other observation time points after surgery of BUT and each postoperative level of S I t were still within the normal range although lower than the preoperative levels. This may be due to the decrease of corneal sensitivity^[25].

This study also found that although LASIK and LASEK had different degrees of dry eye in the early postoperative period at distinct observation points, the subjective symptoms of dry eyes, tear film stability and corneal surface perception of LASEK patients were better than LASIK patients especially at 1wk, 1 and 3mo after surgery. This may be due to the differences in the principles of these two types of surgery. LASIK used a corneal lamellar knife to make a pedicled corneal epithelial combined partial corneal stroma flap at 12 o'clock position. The deep corneal matrix bed was then cut by excimer laser. Since the corneal nerve is most densely located in the central horizontal position, the cutting process will directly cause a large range of damage on the corneal

epithelial and stromal layer. Most of the nerve fibers that pass through the cornea beyond the pedicle are cut off, leaving only the upper pedicle connected to the flap. At the same time, laser may damage corneal plexus to some extent in the process of cutting deep corneal stroma bed. The gradual recovery of cornea in LASIK group is mainly due to the corneal flap connecting with the peripheral cornea through the pedicle after corneal refractive surgery. The nerve fibers from the pedicle into the corneal flap can be preserved, and the broken ends of the nerves regenerate and send branches to participate in nerve repair^[26]. However, LASEK used alcohol to separate the surface tissue of cornea and made an upper corneal flap with a corneal epithelial knife. The corneal flap did not reach the stromal layer of the nerve trunk distribution, thus the damage to the epithelial basal nerve plexus was more mild. Current studies have also shown that corneal sensory loss is related to the cutting depth^[27].

There are several limitations in the present study. Since the dry eye symptoms of most patients could basically recover in half a year after surgery, we just followed up the postoperative level for 6mo. More prospective studies with a longer period for these different operations are needed to compare the dry eye symptoms and stability of tear film.

In conclusion, LASEK and LASIK could both cause the injury of ocular surface tissue and the destruction of corneal nerve fibers, resulting in a certain degree of dry eye symptoms and decreased tear film stability. Early adequate use of preservative-free 0.1% HA eye drops could effectively promote the corneal repair and be greatly helpful for postoperative dry eye symptoms.

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