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Femtosecond LASIK Versus Microkeratome LASIK, A Comparative Study Of The Effect On Tear Film Stability

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Abstract: LASIK is the most common procedure used to correct refractive errors. Conventional LASIK depends on a microkeratome to create the corneal flap. Femto Lasik uses femtosecond laser to create that flap. Those procedures may cause tear film instability, therefore patients often complain of dryness. Dry eye disease can be problematic for some individuals, as it can affect their daily activities. Different tests are used to assess tear film stability and dry eye. One of the most recent tests is measurement of tear film stability by anterior segment Optical Coherence Tomography. 80 eyes of 40 patients were examined to compare between Femto LASIK and mechanical LASIK. Tear film stability was assessed by Tear Break-up Time Test, Schirmer's Test and basically in our study by Anterior Segment Optical Coherence Tomography. The data revealed decrease in tear film stability in the early postoperative period. The parameters measured were stabilized to near normal levels 3 months postoperatively. A slight difference was noticed between mechanical LASIK patients and Femto LASIK, although the difference was insignificant.
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Keywords: LASIK and Femtolasik; Tear film stability; Anterior segment OCT.

1. Introduction

Laser in situ keratomileusis (LASIK) is the most commonly performed corneal refractive surgery throughout the world (1). Among the complications of LASIK, dry eye is considered to be the most common complaint after surgery, and it frustrates both patients and surgeons. Dry eye may be associated with creation of the corneal flap and stromal ablation (2). During these procedures, the corneal afferent nerve fibers are transected, resulting in a decrease in the corneal reflexes and blinking rate and a disruption of the neurotrophic factors released from the corneal nerves. These factors are important for corneal epithelial cells (3).

Mechanical microkeratomes and femtosecond lasers are used to create corneal flaps during LASIK surgery. Compared with microkeratomes, femtosecond lasers provide better predictability of flap dimensions and improve the quality of the optical surfaces (4). These two factors may reduce the incidence of postoperative dry eye (5). However, whether the femtosecond laser reduces the incidence or decreases the severity of dry eye symptoms compared with the microkeratome is controversial (6).

Traditional dry eye evaluations, such as a dry eye questionnaire, Schirmer test, tear breakup time, and corneal fluorescein staining, which exhibit fairly good reliability in clinics, have been widely applied in previous studies (7). However, the conflicting results of these evaluations have been yielded because many factors exist that can influence the outcomes of these evaluations (8,9).

Dry eye symptoms are the most common consequence of laser in situ keratomileusis (LASIK). It has been proposed that subbasal and stromal corneal nerve damage by LASIK and the subsequent disturbance of the lacrimal functional unit and of corneal homeostasisis a causative factor in post-LASIK dry eye (10,11). Corneal nerve damage resulting from LASIK surgery is evidenced by decreased corneal sensitivity and sub-basal nerve fibre density (NFD). In order to address the role of reinnervation in post-LASIK dry eye, or in post-LASIK neuropathic dry eye, it is important to understand the mechanisms involved in enervation (12,13).

The three layered tear film creates a smooth ocular surface for passage of light through the eye, nourishes and provides protection from infection. Blinking initiates renewal of tear film to maintain the ocular surface integrity, clear vision and comfort (14,15). The balance of the system is affected by components such as tear secretion, spreading, evaporation and drainage (16). Tear meniscus refers to

the tears lying at the junction of the bulbar conjunctiva and both lid margins and it act as indicator of tear volume as it forms 75-90% of it (17,18).

Optical coherence tomography (OCT) is a noninvasive, high-resolution imaging technique that is based on low-coherence interferometry. It can provide in vivo cross-sectional images of tissue structure (19). Although OCT has been used predominantly for imaging of the posterior segment of the eye, recently it has been used to image the anterior segment as well. Evaluation of the tear film using OCT allows us to quantify tear meniscus dimensions, and it has a potential to measure tear film thickness (20).

2. Patients & Methods

Inclusion and exclusion criteria This study included 80 eyes of 40 healthy adults. Patients are between 20 and 40 years old and have a stable refractive error during the previous 6 months. They also have to have spherical equivalent (SE) refraction between −1.00 diopters and −8.00 diopters. They all had a stable refractive error during the previous 2 years (progressing by <0.5 diopters.

The exclusion criteria include:

Chronic systemic diseases like diabetes.

Immunological abnormalities.

Drugs affecting tear secretion.

Antiglaucoma medications.

Period and date:

Patients will be examined at 3 periods. Study will be at interval dates; preoperative, 1 month and three months postoperatively.

Examinations:

- visual acuity testing,
- manifest refraction,
- Slit-lamp bio-microscopy.
- Intraocular pressure measurement,
- posterior segment evaluation,
- TBUT,
- Schirmer’s test.
- OCT imaging (Anterior segment OCT).

Surgical methods:

Topical Anesthesia with benoxinate eye drops.

In Femtosecond LASIK, the corneal flap is created with femtosecond laser.

In conventional LASIK, that flap is created by mechanical microkeratome.

Reflection of the corneal flap.

Corneal stromal ablation.

The corneal flap is repositioned.

Topical medication.

Postoperative management:

In all patients, TBUT, Schirmer’s test, and the tear meniscus parameters were measured preoperatively, 1 month and 3 months postoperatively.

Comparison between the two LASIK groups is achieved by comparing the parameters of TBUT, Schirmer's test and the lower tear meniscus height. This is being done preoperatively, 1 month and 3 months postoperatively. Also, those parameters were studied in each group along the follow-up periods.

Measurement of the lower tear meniscus parameters was performed by AS- OCT. Application of the anterior segment line at 90 degree at junction of lower cornea with lower lid margin. The lower tear meniscus is being imaged. In the software of the OCT system there is a caliber. This caliber allows measurement of the lower meniscus height.

Tear meniscus makes most of exposed tear volume. It is the thin strip of fluid at the lower and also the upper eyelid margins with a concave surface. If this meniscus is absent, it indicates a state of dry eye.

Many techniques are in use to assess the tear meniscus, but, most of them entail invasive procedures. So that it may give rise to false-positive or false-negative results. Although measuring the tear meniscus by the slit lamp is non-invasive, it is usually difficult to assess the tear meniscus.

Anterior segment OCT allows for accurate imaging of anterior segment structure. Spectral domain gives high sensitive results. Those data correlate well with Schirmer's test and break up time test.

It is considered to be more accurate and sensitive to evaluate state o dry eye using anterior segment spectral domain OCT. The results are more relevant than those from conventional clinical tests. However, it is relatively of high cost.

By using anterior segment OCT we can get a valuable assessment of the tear film. It has the advantage of being a non-invasive technique. OCT imaging also has a good repeatability of tear meniscus measurements. It gives a quantitative assessment of tear film and meniscus. No need for dye instillation needed during the procedure. Also there is no contact with the ocular surface.

Oct Imaging Technique:

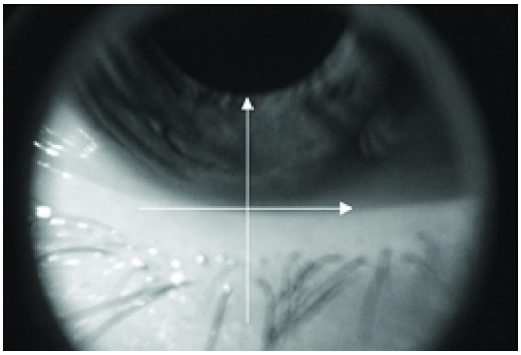
Imaging of the lower tear meniscus is performed by a scan of 6 mm vertical at the lower cornea eyelid junction. The test is being done in a dim light room with average humidity. All these precautions are in effect to avoid reflex tearing.

No use of any topical eye drops for 1 hour before testing. This is to negate the effect of any medication on tear film. Patients are instructed to look straight ahead at the fixation target within the OCT machine.

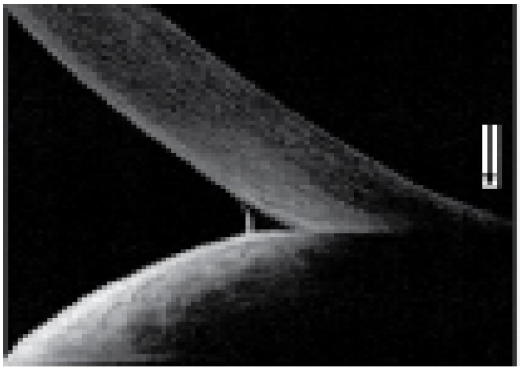
To avoid the effect of delayed blinking, the patient is asked to blink, and then measurements were taken immediately after blinking. The pattern used for scanning the inferior tear meniscus is CL-cross line.

The two lines were horizontal one on the lower lid margin and the other vertical line on inferior cornea at 6 o'clock hour.

Multiple images were taken to reach a high quality scan. The image is captured viewing the concave tear meniscus from lower lid margin to cornea interface.



Cross line with horizontal line on lower lid and vertical line on inferior cornea at 6'0 clock



Lower tear meniscus by AS-OCT

Statistical analysis:

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

- Independent-samples t-test of significance was used when comparing between two means.
- Paired sample t-test of significance was used when comparing between related samples.
- Chi-square (x^2) test of significance was used in order to compare proportions between qualitative parameters.
- The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:
- Probability (P-value)
  - P-value <0.05 was considered significant.
  - P-value <0.001 was considered as highly significant.
  - P-value >0.05 was considered insignificant.

3. Results

The results of the present study are demonstrated in the following tables and figures.

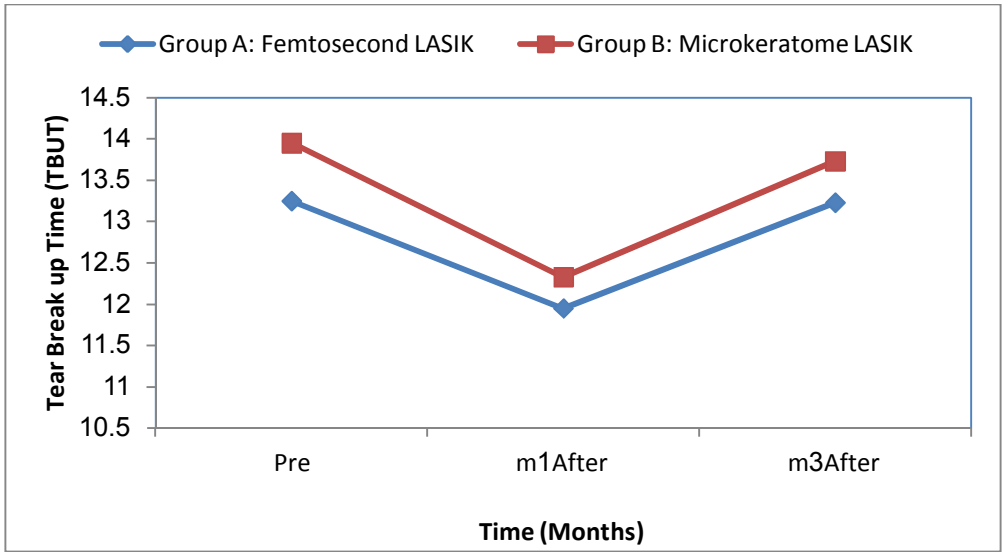


Fig. (1): Comparison between group A: Femtosecond LASIK and group B: Microkeratome LASIK according to tear break up time.

Table (1): Comparison between group A: Femtosecond LASIK and group B: Microkeratome LASIK according to tear break up time (TBUT).

Tear Break up Time (TBUT)	Group A: Femtosecond LASIK *(n=40)*	Group B: Microkeratome LASIK *(n=40)*	t-test	p-value
Pre Mean±SD Range	 13.25±1.30 11_15	 13.95±1.13 12_15	6.624	0.124
After 1m Mean±SD Range	 11.95±0.88 11_13	 12.33±0.83 11_13	3.871	0.093
After 3m Mean±SD Range	 13.23±1.21 11_15	 13.73±1.18 12_15	3.515	0.065
Change (Pre and after 1m) Mean±SD Range	 -1.30±0.88 -3_0	 -1.63±0.93 -4_0	2.584	0.112
Change (Pre and after 3m) Mean±SD Range	 -0.03±1.66 -3_3	 -0.23±1.54 -3_3	0.312	0.578
Change (After 1m and 3m) Mean±SD Range	 1.28±1.20 0_4	 1.40±1.13 0_4	0.231	0.632

t-Independent Sample t-test; p-value >0.05 NS

According to Break up Time Test, the mean range was 13.25 second and 13.95 second in the two groups preoperatively.

Decline in this time was noticed 1 month postoperatively. It reached 11.95 second and 12.33 in the two groups respectively.

It reaches near normal time 3 months postoperatively. TBUT was 13.23 with standard deviation 1.21 in the first group and 13.73 with standard deviation 1.18 in the second group.

This table shows no statistically significant difference between groups according to tear break up time (TBUT).

Table (2): Comparison between group A: Femtosecond LASIK and group B: Microkeratome LASIK according to schirmer's test (ST).

Schirmer's tests (ST)	Group A: Femtosecond LASIK *(n=40)*	Group B: Microkeratome LASIK *(n=40)*	t-test	p-value
Pre Mean±SD Range	 13.30±1.36 11_16	 13.43±1.03 12_16	0.213	0.645
After 1m Mean±SD Range	 11.08±1.31 9_14	 11.30±1.14 9_14	0.674	0.414
After 3m Mean±SD Range	 12.60±1.39 11_15	 12.58±1.30 11_15	0.007	0.934
Change (Pre and after 1m) Mean±SD Range	 -2.23±0.80 -4_-1	 -2.13±0.85 -4_-1	0.292	0.590
Change (Pre and after 3m) Mean±SD Range	 -0.70±0.94 -2_2	 -0.85±0.86 -2_1	0.553	0.459
Change (After 1m and 3m) Mean±SD Range	 1.53±1.11 0_4	 1.28±1.15 0_4	0.975	0.326

t-Independent Sample t-test; p-value >0.05 NS

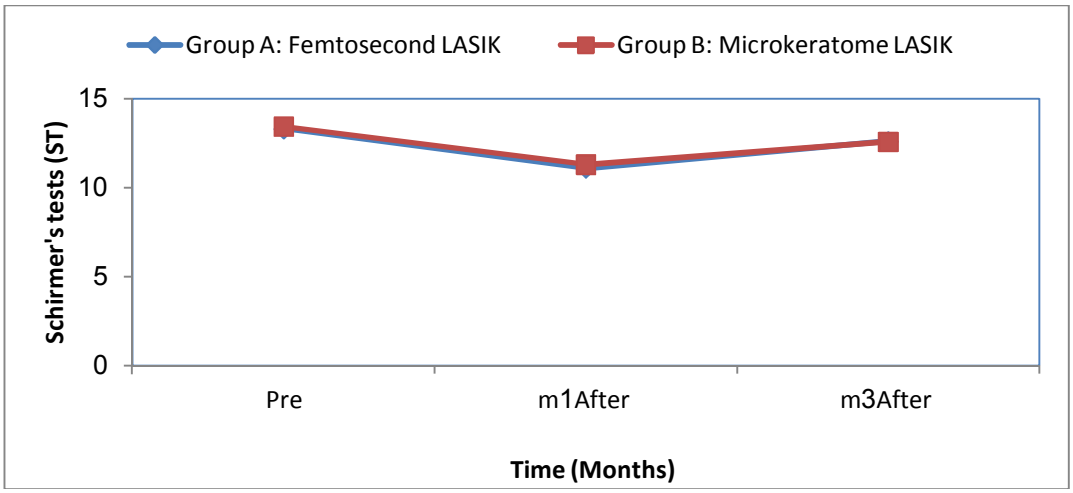


Fig. (2): Comparison between group A: Femtosecond LASIK and group B: Microkeratome LASIK according to schirmer's tests (ST).

In relation to Schirmer's test, the mean range was 13.30 ml in the Femtosecond group and 13.43 ml in the microkeratome group. Standard deviation was 1.36 and 1.03 in the two groups respectively.

1 month postoperatively this value was decreased to 11.08 and 11.30 ml. Schirmer's test was stabilized nearly by 3 months. It reached 12.60 in the Femtosecond group and 12.58 in the microkeratome group. No significant difference was noticed between the two subgroups.

This table shows no statistically significant difference between groups according to schirmer's tests (ST).

Table (3): Comparison between group A: Femtosecond LASIK and group B: Microkeratome LASIK according to tear meniscus height (TMH).

Tear Meniscus height (TMH)	Group A: Femtosecond LASIK *(n=40)*	Group B: Microkeratome LASIK *(n=40)*	t-test	p-value
Pre Mean±SD Range	 298.98±18.43 270_320	 289.98±18.54 270_320	1.742	0.097
After 1m Mean±SD Range	 287.93±17.06 265_309	 279.18±16.79 265_309	1.345	0.089
After 3m Mean±SD Range	 292.73±17.86 266_311	 283.18±18.38 264_311	1.055	0.060
Change (Pre and after 1m) Mean±SD Range	 -11.05±6.45 -25_-1	 -10.80±6.06 -25_-3	0.032	0.859
Change (Pre and after 3m) Mean±SD Range	 -6.25±4.34 -13_0	 -6.80±3.92 -13_-1	0.354	0.554
Change (After 1m and 3m) Mean±SD Range	 4.80±6.57 1_22	 4.00±5.74 -1_22	0.336	0.564

t-Independent Sample t-test; p-value >0.05 NS

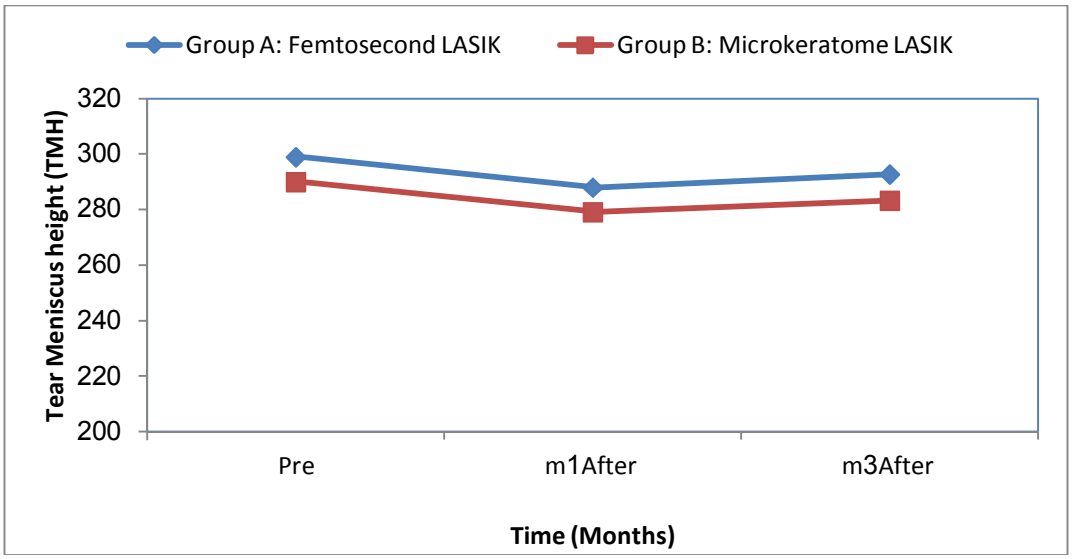


Fig. (3): Comparison between group A: Femtosecond LASIK and group B: Microkeratome LASIK according to tear meniscus height (TMH).

By using Anterior Segment OCT, the tear meniscus height could be assessed. The mean range was 298.98 micrometer with standard deviation 18.43 in the Femtosecond group. Tear Meniscus Height showed mean range of 289.98 micrometer in the microkeratome group with standard deviation 18.54.

That height was decreased 1 month postoperatively to reach 287.73 in the first group and 283.18 in the second group.

By 3 months Tear Meniscus Height was reaching 292.73 and 279.18 with a standard deviation 17.86 and 18.38 in both groups respectively.

This table shows no statistically significant difference between groups according to tear meniscus height (TMH).

4. Discussion

In our study we can notice the effect of age on tear film stability. By advancing age the tear parameters decline to an extent. The variables of tear film such as tear break-up time test and Schirmer's test are higher in younger age groups, as compare to older one. Also decrease in tear meniscus height is noticed.

The lower tear meniscus relates with the tear volume and stability. The tear film spreads over the ocular surface during blinking. So that, we need about 3 seconds before tear meniscus imaging. Also, Schirmer's test gives a reliable data in dry eye due to the suction effect of the meniscus that opposes the tears entry on to the Schirmer's strip.

Basically, the OCT device was designed first to capture retinal images. The new advances in the machine and software enable us from anterior segment imaging.

The tear meniscus shows insignificant difference between younger and older age groups. This is may be due to less sensitive methods that may lead to reflex tearing. But there was a significant correlation between tear break up time test and Schirmer's test.

Also there was a positive relation shown between tear meniscus height and Schirmer's test. This was consistent with other investigative findings. Also, a significant relation between tear meniscus area and height is observed that is consistent with other studies.

The tear break up time test is known to reflect tear film stability rather than tear fluid quantity. Also, use of fluorescein may change tear film condition.

On the other side, anterior segment OCT can image the tear meniscus in the natural condition. Also, slit lamp was used to assess tear meniscus height. There is a positive correlation between tear meniscus heights seen by the slit lamp with that obtained by OCT imaging.

Judgment of operators in detection of junctions may influence image processing. This can be decreased by automated image application into the OCT software. Also, repeatability of measurement with intra and inter observer fluctuation can be monitored. Other variable factors such as corneal curvature and lower eyelid length might not be ruled out in our study.

In corneal refractive surgeries, it is noticed that tear film stability may change. This is because nerve fibers injury along with surface epithelium injury often alters the tear condition.

Femtosecond LASIK and conventional LASIK are considered to be effective methods for correcting myopic patients. Meanwhile, dry eye disease often is a common complaint after refractive surgeries.

While conventional LASIK depends on mechanical microkeratome to create the corneal flap, Femtosecond LASIK depends on very high power infrared laser to do this function. The flap created by femtosecond laser is more predictable in dimensions and edges. This usually enhances the quality of optical surface.

In Femtosecond LASIK, the infrared laser produces pulses and micro bubbles. Those in large number will be connected to make a cutting effect.

Anterior Segment OCT is being confirmed to give a valuable assessment of the tear film. It is useful in quantitative measurements. Hence, it is a valuable procedure for diagnosis of dry eye disease.

Anterior segment OCT is highly specific and sensitive in dry eye diagnosis. It can detect early change in tear meniscus following refractive surgery. So that, it helps to enhance investigative assessment of dry eye all over the follow up period postoperatively.

The total tear volume might better be represented by inferior tear meniscus than the superior tear meniscus. Also, the change in lower meniscus height might be more informative than area change.

In multiple researches it has been found that tear film stability is altered after refractive surgeries. Some researches informed significant difference between Femtosecond LASIK and conventional LASIK. Other studies reported no significant difference between both groups.

In our study there was a significant difference in tear film parameters between preoperative period and 1 month postoperatively. These changes show effect in both femtosecond LASIK and conventional LASIK groups. But the difference between both groups was mild. It is noted that femtosecond LASIK may result in less dry eye severity and symptoms, especially at early postoperative stage.

One of the important factors affecting dry eye condition is the corneal flap. It is to be considered that uniform flap can enhance postoperative rehabilitation and dryness symptoms. Also, appropriate residual stroma together with minor change in the planned thickness of the corneal flap might result in better tear film stability.

Multiple variables may affect the research outcome when comparing between Femtosecond and conventional LASIK. Different surgeons handling may play a role. Also, ablation process often changes with different machines. The diagnostic procedures used can affect the results.

In comparison between tear film parameters preoperatively and 1 month postoperatively the difference was statistically significant. That difference is noted to be insignificant 3 months postoperatively. The tear film parameters were higher to an extent in the Femtosecond group while conventional LASIK showed lower parameters.

Conclusion

Dry eye can be assessed by anterior segment OCT. It provides a reproducible quantitative measurement of tear meniscus height and area. Those parameters can reflect the state of tear film stability.

Measurements showed that refractive surgeries affect tear film stability. No significant difference was noticed between LASIK and FemtoLASIK. Tear film parameters are reduced in the early postoperative period but stabilized mostly by 3 months.

Recommendations

Refractive surgery often results in dry eye condition. Femtolasik gives a fast recovery period with less dryness and more tear film stability.

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