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Comparison of Tear Film Stability After Laser in Situ Keratomileusis (LASIK) and Laser Sub Epithelial Keratomileusis (LASEK)

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ABSTRACT

Objectives : To compare tear film stability in two different types of refractive surgery, laser in situ keratomileusis (LASIK) and laser subepithelial keratomileusis (LASEK) for correction of myopia.

Materials and methods : This is a prospective, randomized, open labeled, single center clinical study comparing patients who underwent two refractive procedures :- 1. LASEK with Mitomycin-C (MMC) 0.002%, and, 2. LASIK with mechanical microkeratome, followed by excimer laser, in mild to moderate myopia (-1 to -6 D with or without astigmatism). 240 eyes of 120 patients were evaluated , and followed up for 6 months. 18 patients were lost to follow up; hence 204 eyes of 102 subjects were analyzed at the end of 6 months and included in the study. Tear breakup time (TBUT), for evaluation of tear film stability were conducted on 30 days, 90 days, and 180 days postoperatively.

Results :Post operatively mean TBUT (in second) value after LASEK on day 30 was 8.48sec, which was statistically ($P<0.05$) higher than mean TBUT (in second) after LASIK which was 6.41sec. After LASEK on day 90 mean TBUT (in second) was 10.79sec, which was statistically ($P<0.05$) higher than mean TBUT (in second) after LASIK which was 7.10sec. After LASEK on 180th day mean TBUT (in second) was 10.80sec which was not significantly ($P>0.05$) different from mean TBUT (in second) of 7.53sec after LASIK

Conclusion : LASIK significantly alters the tear film stability, at least for three months, compromised tear function statistically not significant with LASEK after six months of surgery.

KEYWORDS Laser in situ keratomileusis (LASIK), Laser subepithelial keratomileusis (LASEK), Mitomycin-C (MMC), Myopia , Tear breakup time (TBUT)

Introduction

Laser in situ keratomileusis (LASIK)[1,2,3] is safe, accurate, predictable form of refractive surgery that gives stable refractive results and produces minimal post operative discomfort. Laser subepithelial keratomileusis (LASEK)[4,5,6], produces similar results and can also be used for a particular set of patients with thinner and irregular cornea where LASIK is not recommended.

The concept of ablative surgery is that by modified / removing small amounts of tissue from the anterior surface of the cornea, a significant change of refraction can be attained.

Laser in situ keratomileusis is known as LASIK, a procedure that has had rapid growth and evolution in the last 20 years. The benefits of quick visual rehabilitation, minimal postoperative discomfort, reduced risk of postoperative corneal haze, improved stability and predictability are a few of the reasons for the continued increase in popularity of LASIK over other surgical refractive options.

Laser assisted sub epithelial keratomileusis (LASEK) was introduced by Massimo Cammellin in 1996. This is another approach to photorefractive keratectomy (PRK). In LASEK alcohol is use to remove corneal epithelium . It is a surgical procedure to treat myopia and able to reduce intraoperative and postoperative LASIK complications [7] but associated with more postoperative pain and late visual recovery, and corneal haze . LASEK can be performed in thin cornea where LASIK is contraindicated . The plane of separation of the epithelium in LASEK is important to haze formation .

One of the most common problems after surgery is LASIK-associated dry eye.[8,9,10] One condition that is thought to play an important role in dry eye after LASIK is LASIK-induced neurotrophic epitheliopathy (LINE), a term suggested by Wilson [8] and Ambrosio et al.[9] To describe the neurotrophic component of LASIK dry eye and that results from damage to the nerves during flap formation and stromal ablation.[8,9,10]

Materials and Methods

This was a interventional (randomized, comparative, and prospective type), longitudinal, one year duration study.

Comparison between the groups will be done on the basis of TBUT, postoperatively. Parameters were recorded on 1st month, 3rd months, 6th months respectively.

We included patients who has both eyes mild to moderate myopia. Patients who had high myopia in other eye were excluded from study. Both eyes of the patients included in the study were treated simultaneously.

240 eyes of 120 patients were evaluated , and followed up for 6 months. 18 patients were lost to follow up; hence 204 eyes of 102 subjects were analyzed at the end of 6 months and included in the study

Inclusion Criteria for patients was Myopia -1D to -6D (spherical equivalent), Stable refraction for 1 year, Age 18-40 year, keratometry value between 40-47D,Pachymetry value not less than 450 µ If patient using Contact lens, it should be stop for at least one month, No slit lamp evidence of corneal scarring.

Exclusion Criteria for patients was any corneal pathology like

dry eyes, previous keratitis, keratoconus , Evidence of corneal diseases in the eye like Herpes simplex keratitis, Glaucoma, Large pupil size (>6mm, mesopic), Unwilling to participate, inability to attend follow up appointments over a period of months, Systemic disease which may affect the cornea like DM, RA, Rosacea, Pregnancy or lactating women.

Examination protocol:
A comprehensive ocular and medical history was obtained; this included history of spectacles, contact lens history, history of atopy. Corneal tear film was assessed(1st , 3rd and 6th months) using Fluorescein stain on the basis of- Tear film breakup time (TBUT) in second. -The time required for dry spots to appear on the corneal surface after blinking. A method of determining the stability of the tear film and checking for evaporative dry eye.

All measurements were made in one room with relatively constant temperature and humidity. Five measurements were made for each subject (right eye 1st then left) and the average of three closest TBUT values was taken as the mean value. This procedure increases the reliability of the technique.

For the measurement of TBUT,11 the subject was seated comfortably on the slit lamp with chin on the chin rest and forehead on the headrest and asked to look downwards. The upper lid of the right eye was slightly lifted and the Fluorescein strip was then used to stain the eye.

Subject was asked to keep the eyes open while looking straight ahead. The stopwatch was started after the last blink and the appearance of dry sports on the corneal surface was observed with the blue light of the slit lamp. At the first appearance of the dry spots, the stopwatch was stopped. The time interval between the last blink and the first appearance of the dry spots was recorded in seconds as the TBUT. "Table :1" shows interpretation of TBUT12

Result
204 eyes of 102 subjects were analyzed at the end of 6 months . In which 50%right eyes and 50% left eyes because we include both eyes of same patient (Chi-square = 0.020 with 1 degree of freedom; P = 0.889). The majority of the patients were between, 21- 25 years, 62.75% of the subjects undergoing LASEK procedure, 49.02% undergoing LASIK. (Chi-square = 4.193 with 3 degrees of freedom; P = 0.324) All the age distribution groups (<20, 20-30, >30 years) showed female predisposition (Chi-square = 0.664 with 1 degree of freedom; P = 0.415).

" Table 2" shows that mean TBUT (in second) value after LASEK on day 30 was 8.48sec, which was statistically (P<0.05) higher than mean TBUT (in second) after LASIK which was 6.41sec. After LASEK on day 90 mean TBUT (in second) was 10.79sec, which was statistically (P<0.05) higher than mean TBUT (in second) after LASIK which was 7.10sec. After LASEK on 180th day mean TBUT (in second) was 10.80sec which was not significantly (P>0.05) different from mean TBUT (in second) of 7.53sec after LASIK

Discussion
Our data suggest that LASEK and LASIK in low to moderate myopic patients offer an excellent safety profile with predictable and stable refractive outcomes.

Tear film breakup time (TBUT) in second is note on follow up of 1, 3, and 6 month. All measurements were made in one room with relatively constant temperature and humidity. Five measurements were made for each subject (right eye 1ST then left eye) and the average of three closest TBUT values was taken as the mean value

After data analysis mean TBUT was in LASIK group (6.41sec, 7.10sec and 7.53sec)and in LASEK group (8.48sec, 10.79sec and 10.80sec) respectively at 1, 3, and 6 months "Figure: 1". We found that at all visit mean TBUT (seconds) was less in LASIK group and this was statistically significant (p<0.05) at 1 and 3 month of follow up. At 6 month follow up this difference was not statistically significant.

Our results are similar to study which is conducted by Toda I [13] Asano-Kato N, Komai-Hori Y, Tsubota K on dry eye after LASIK they reach at conclusion that break-up time were decreased until 1 month (tear function index) and 3 months (break-up time) after laser in situ keratomileusis but recovered to preoperative levels thereafter.

Yu EY [14] Leung A, Rao S, Lam DS done study "Effect of laser in situ keratomileusis on tear stability" follow up for one month and came on results that , Dry eye symptoms are common after myopic LASIK surgery. Laser in situ keratomileusis significantly altered the tear break-up time.

Conclusion
The results of this study indicate that both LASEK and LASIK for low to moderate myopia are safe procedures. However, LASIK significantly alters the tear film stability, at least for three months, compromised tear function statistically not significant with LASEK after six months of surgery.

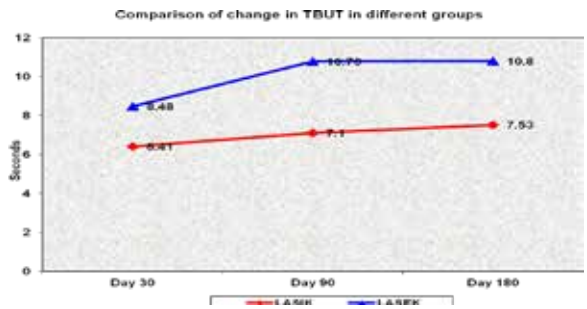

Table 1 : Tear film breakup time (TBUT) in second.	
<5 seconds	Dry eye syndrome
5-10 seconds	Dry eye syndrome if presence of symptoms and signs of dry eye
>10 seconds	Normal

Table 2 : Tear Film Breakup Time

(TBUT) in second	Group	N	Mean	Std. Deviation	'p' Value*
DAY 30	LASIK	102	6.41	2.18	<0.05
	LASEK	102	8.48	2.38	
DAY 90	LASIK	102	7.10	2.06	<0.05
	LASEK	102	10.79	3.30	
DAY 180	LASIK	102	7.53	2.21	0.577
	LASEK	102	10.80	3.19	

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