Original article

Evaluation of tear film stability before and after laser in situ keratomileusis

Shrestha GS[1], Wagh S[2] , Darak A[3]
[1]B.P. Koirala Lions Centre for Ophthalmic Studies
Institute of Medicine, Tribhuvan University, Maharajgunj, Kathmandu, Nepal
[2]Bharati Vidyapeeth University
School of Optometry, Katraj, Pune, India
[2]Consultant Ophthalmologist, Wagh Eye Clinic, Shivajinagar, Pune, India
[3]Conultant Ophthlamologist and Lasik Surgeon, Zy- vision, 101 Trikaya house, Deendayal Hospital Lane, FC Road, Pune 411 004, India

Abstract

Objective: The study was conducted to evaluate tear film stability and tear secretion before and after laser in situ keratomileusis.

Materials and methods: It was a prospective, longitudinal and non-comparative analysis of clinical data of 20 consecutive myopic patients (40 eyes) collected before and after laser in situ keratomileusis. Assessments included tear secretion (Schirmer I and II), fluorescein tear break up time and ocular surface staining.

Statistics: The statistical package for social science (SPSS 10.0) was used for data analysis. The parameters of tear secretion and tear stability were analyzed using the paired and unpaired Student t-tests.

Results: Schirmer II was reduced at seven days (9.5 ± 4.30 mm) and one month (10.3 ± 3.06 mm, p = 0.001) after operation from the pre-operative value of 16.12 ± 3.90 mm. Tear film stability significantly decreased at seven days (6.79 ± 3.05 sec, p < 0.001) and one month (8.03 ± 2.81secs, p< 0.001) from its pre-operative value (12.68 ± 2.69 secs). 87.5% had tear film instability (FBUT < 10secs) seven days after surgery; it was reduced to 75 % at one month and 27.5 % at three months. It was 7.5 % before surgery. Corneal staining score was increased significantly at seven days (1.42 ± 1. 58, p < 0.01) and one month (0.95 ± 1.41, p = 0.02), from the pre-operative score of 0.17 ± 0.44.

Conclusion: Laser in situ keratomileusis significantly alters the tear film stability, Schirmer values and corneal staining at least for three months.

Key words: Dry eye, LASIK, Schirmer test, tear film stability

Introduction

Laser in situ keratomileusis (LASIK) is the refractive procedure for permanent correction of vision. According to Sridhar et al (2002), despite low post-operative complications, Alan et al (2002) reported dry eye as one of the major side effect of LASIK (Ang et al 2001). Albietz et al (2004) estimated the persistence of dry eye from a few weeks up to six months and in 48 % of cases. Incidence of dry eye

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Address for correspondence: Gauri Shankar Shrestha
B.P. Koirala Lions Centre for Ophthalmic Studies, Maharajgunj, Kathmandu
Phone numbers: 00977-016915588, 9841019594; Fax: 00977-1-4720142
E-mail: gs101lg@hotmail.com; gaurishshrestha@yahoo.com

among patients undergoing LASIK is particularly higher among women, contact lens wearers, systemic medicine users and older patients (Albert et al 2004). Julie (2005) and Benitez-del-Castillo (2001) cautioned that preexisting conditions like meibomitis, blepharitis, low blink rate, low corneal sensation or low hormone levels are risk factors. This study was conducted to evaluate tear secretion, tear film stability and corneal staining among the patients undergoing LASIK.

Materials and methods

The study was a prospective, longitudinal and non-comparative analysis of 20 consecutive patients who underwent LASIK for correction of myopia and myopic astigmatism at ZY Vision, Trikaya house, FC Road Lane, Deccan, Pune, India. All the subjects who were enrolled in the study had stable refraction, keratometry and pachymetry at least for 12 months. Patients with re-operation of LASIK, under treatment for dry eye, preoperative medications other than those prescribed, active diseases of ocular surface and adnexa were excluded from the study. All the patients received a detailed explanation of the procedures involved in the study and provided written informed consent.

Intervention

All lasik procedures were performed by a co-author using surgeon-adjusted ablation nomogram. The lamellar flaps were created using Hansatom microkeratome (Bausch & Lomb surgicals, Munich Germany). The flaps were 8.5/9.5 mm wide and 120 to 160 micron thick with the optic zone diameter of 6 mm. Excimer laser (Fluorine Neon gas, spectral gases GMBH, Germany) was used to perform the stromal ablations. Surgeries were performed using Bausch and Lomb Technolas 217 Z (Technolas GmBh; Ophthalmologische system, Hana – Riedi - Str. 9, D - 85622, Feldkirchen, Germany). All eyes received the standard treatment of Moxifloxacin hydrochloride 0.5% w/v for ten days, Prednisolone acetate 1%, for 15 days, preservative free tear drops (Carboxymethyl cellulose IP 5mg stabilized oxychlocomplex 0.005% w/v) for one month.

Assessment

Assessment included visual acuity in internally-illuminated Snellen visual acuity chart at six meter distance, subjective refractive error, best spectacle-corrected vision pre-LASIK and uncorrected visual acuities post-LASIK. The subjects' preoperative variables (corneal power, corneal astigmatism, corneal thickness) were obtained through corneal topography (Orbscan ^{tm} IIz, Bausch and Lomb, A/N SLC 01027, S/N 0905 14262).

Tear secretion was measured as Schirmer I and Schirmer II (Proparacain hydrochloride 0.5 %,) using A 35 mm x 5 mm size pre-packaged sterile mm scale imprinted filter paper strips (Avesta, Sun pharmaceutical Industries LTD). Wetting less than 10 mm of the filter paper in 5 minutes was considered as a probable aqueous tear deficiency (ATD). Tear stability was assessed as fluorescein-break up time (FBUT) using sterile fluorescein sodium impregnated strips USP 1 mg and was observed under cobalt-blue filtered light on the slit lamp microscope (Topcon Slit lamp SL-1E S/N 1110995, Tokyo, Japan) under 16X magnification. FBUT of less than 10 seconds was considered that the tear film was unstable. Following measurement of FBUT, corneal staining was evaluated using a contact lens visual scale. Each zone was graded independent of one another on a 0 to 4 grading scale. A cumulative score of > 4 (> 20 %) in the worse eye denoted probably dry eye surface compromise. These assessments were performed on each patient one or two days before LASIK and then one week, one month and three months after LASIK.

Statistical analysis

All the data were evaluated using the statistical package for social science (SPSS 10.0). Tear

secretion (Schirmer I and II) and tear stability were analyzed through parametric paired student t- test for the mean in the same group and unpaired t test for unmatched groups. Other ocular variables were analyzed using Mann-Whitney U test for two different unmatched subject groups and Pearson chi-square test for comparisons between groups and between variables. The confidential interval was considered at 95 % level.

Results

Among 20 patients enrolled in the study, the mean age was 23.8 ± 3.77 years (range 18 - 36 years), male 35 % and female 65 %. The mean spherical equivalent refraction (Table 1) was 6.15 ± 2.25D (range 2.0 to 12.0D).

Schirmer I was found to be reduced statistically at all the time post-operatively; clinically, it was normal (Table 2). Schirmer II test was normal at three months (15.17 ± 4.77mm) post-LASIK compared to the pre-operative score (16.12 ± 3.90 mm). FBUT was significantly decreased and staining scores were significantly increased post-LASIK as compared to the pre-LASIK values, but they were clinically normal at three months follow-up.

Pre-operative Schirmer I and II were significantly higher preoperative in females (Schirmer I: 28.23 ± 4.99 mm, p = 0.01; Schirmer II: 17.11 ± 3.49 mm, p<0.001) than in males (Schirmer I: 26.28 ± 5.12 mm; Schirmer II: 14.28 ± 4.08 mm). In females, Schirmer I was significantly reduced one month (19.38 ± 7.92mm, p = 0.002) and 3 months (25.23 ± 7.13 mm, p = 0.007) and Schirmer II in one month (9.84 ± 3.37 mm, p = 0.007) after LASIK (Table 3). Tear secretion (Schirmer I: 27.92 ± 4.58 mm; Schirmer II: 15 ± 3.72 mm), tear break up (12.94 ± 4.12sec) and corneal staining (0.14 ± 0.36) returned to pre-LASIK values in males during the three-month follow- up, whereas they did not do so during the same period in females. Corneal staining score significantly increased in females than in males in all follow- up post operatively (Table 3).

Table 1

Patients' overall pre-LASIK demographic variables

SN	Variables	Value
1.	Age ± SD	23.8 ± 3.77 years
2.	Attempted spherical equivalent correction ± SD	6.15 ± 2.25 DS
3.	Attempted spherical correction ± SD	5.73 ± 2.16 DS
4.	Attempted cylinder correction ± SD	1.00 ± 0.80 D cyl
5.	Ablation depth ± SD	94.45 ± 31.20µm
6.	Mean pre-op keratometry ± SD	44.30 ± 1.78D
7.	Mean pre-op Sim K ± SD	1.05 ± 0.69 D cyl
8.	% reduced tear secretion (Schirmer II)	5 %
9.	% teat film Instability (FBUT)	7.5%
DS = dioptres spherical, D cyl =dioptres cylinder, µm= micrometer		

Table 2

Comparison of tear function assessments before and after myopic LASIK surgery

Tear function assessments	Time from surgery	N = 40	P value
Schirmer I (mm) ± SD	Pre-op	27.55 ± 5.05	
	7 days	18.8 ± 7.46	< 0.001
	1 month	20.72 ± 7.79	< 0.001
	3 months	26.17 ± 6.42	0.01
Schirmer II (mm) ± SD	Pre-op	16.12 ± 3.90	
	7 days	9.5 ± 4.30	< 0.001
	1 month	10.3 ± 3.06	< 0.001
	3 months	15.17 ± 4.77	NS
FBUT (seconds) ± SD	Pre-op	12.68 ± 2.69	
	7 days	6.79 ± 3.05	< 0.001
	1 month	8.03 ± 2.81	< 0.001
	3 months	11.82 ± 3.99	= 0.01
Corneal staining ± SD	Pre-op	0.17 ± 0.44	
	7 days	1.42 ± 1.58	< 0.01
	1 month	0.95 ± 1.41	< 0.02
	3 months	0.72 ± 1.28	< 0.05

Table 3

Comparison of tear function in male and female before and after myopic LASIK

Tear function assessments	Time from surgery	Male	Female	P(§)
Schirmer I (mm)	Pre-operative	26.28 ± 5.12	28.23 ± 4.99	p = 0.01
	7 days	19.5 ± 9.88**	18.04± 5.48**	NS
	1 month	23.21 ±7.17**	19.38± 7.92**	P = 0.002
	3 months	27.92 ± 4.58	25.23± 7.13**	P = 0.007
Schirmer II (mm)	Pre-operative	14.28 ± 4.08	17.11 ± 3.49	P < 0.001
	7 days	9.92 ± 5.49 **	9.26 ± 3.61**	NS
	1 month	11.14 ± 2.24**	9.84 ± 3.37**	P = 0.007
	3 months	15 ± 3.72	15.26± 5.31**	NS
FBUT (seconds)	Pre-operative	12.41 ± 3.60	12.83 ± 2.12	NS
	7 days	7.24 ± 4.59**	6.55 ± 1.82**	NS
	1 month	7.55 ± 2.70**	8.28 ± 2.88**	NS
	3 months	12.94 ± 4.12	11.21± 3.86**	P = 0.005
Corneal staining	Pre-operative	0.14 ± 0.36	0.19 ± 0.49	NS
	7 days	0.92 ± 1.54#	1.69 ± 1.56#	0.002
	1 month	0.5 ± 0.85#	1.24 ± 1.61#	0.001
	3 months	0.14 ± 0.36	0.96 ± 1.34#	<0.001

§ Based on comparison between male and female
NS = not significant at 5 % level
** Significantly decreased (at 5% level) from pre-operative value
# Significantly increased (at 5% level) from pre-operative value

Discussion and conclusion

This study demonstrates significant decrease in tear secretion and tear film stability and increase in staining scores at seven days after surgery with gradual recovery later on. Schirmer I was significantly decreased in seven days ($p < 0.001$), one month ($p < 0.001$) and three months ($p = 0.01$) post-LASIK, from the pre-LASIK score. Schirmer I test results were also lower at 1 week and 3 months ($P < 0.05$) post-LASIK in the study by Yang B et al (2002). Michaeli et al (2004) reported a non-statistical reduction in the Schirmer values immediately post-LASIK, which returned to a slightly lower than baseline level by three months. In the study by Edward et al (2000), Schirmer test value was increased at Day 1 ($P = 0.25$) and subsequently decreased at 1 week ($P = 0.05$) and at 1 month ($P = 0.03$). In a study by Siganos DS et al (2002), Schirmer I was decreased at one month, three months and six months post-LASIK. Though all of the reports suggested that tear secretion decrease post-LASIK, Kallarackal et al (2002) noticed that the variation in outcomes and stability could be due to its poor reproducibility and poor sensitivity. The pre-operative mean value for Schirmer II decreased at one month and returned to normal between three months and six months in the Siganos et al (2002) study. Edward et al (2000) observed that basal tear secretion test value decreased at one day ($P = 0.05$), at one week ($P = 0.005$), and at one month ($P = 0.007$). We also observed a similar result in the Schirmer II value in our study, which decreased at seven days ($p < 0.001$) and one month ($p = 0.001$) post-LASIK from its pre-LASIK value. It was severely reduced at seven days (Table 2) post-LASIK and recovered gradually on due course to normal in three months. 57.5 % (23 eyes) had decreased tear secretion at

seven days, below 10mm, as indicated by the Schirmer II value, which was only 30 % (12 eyes) at one month and 10 % (4 eyes) at three months. Only 5 % (2 eyes) had tear secretion below 10 mm pre-LASIK. According to Aras et al (2000), tear secretion decreased following LASIK probably due to a decrease in corneal sensitivity.

Shoja et al (2007) observed obvious decrease in TBUT at one, three, and six months post-LASIK relative to pre-LASIK level ($p < 0.05$). Toda et al (2001) and Siganos et al (2002) also supported the view that break-up time decreased until three months post-LASIK but it recovered to preoperative levels thereafter. Our study showed similar results to that of the study of Yang et al (2002). In his study, decreases in BUT were noticed at one day, one week, one month and three months post-LASIK relative to the pre-LASIK level ($P < 0.05$). And in our study, tear stability decreased significantly at seven days ($p < 0.001$); one month ($p < 0.001$) and three months ($p = 0.01$) from its pre-LASIK scores. 87.5 % (35 eyes) have reduced tear stability (below 10 seconds) seven days post-LASIK, which was 75 % (30 eyes) at one month and 27.5% (11 eyes) at three months. Pre-LASIK, 7.5 % (3 eyes) had FBUT below ten seconds. Linna et al (2000) and Battat et al (2001) suggested that loss of sensory innervations had been identified as one of the leading causes of tear film and ocular surface anomalies post-LASIK surgery. Other suggestions are differences in lid anatomy in Hong Kong Chinese and their interaction with tear film (Julie et al, 2005) and abnormal blink rate in a Japanese subject group (Toda et al, 2001).

Though corneal staining score was increased significantly at seven days ($p < 0.01$), one month ($p = 0.02$) and three months ($p = 0.05$) post-LASIK in our study, clinically it was normal at three months follow-up. 28.57 % (6 eyes) had a staining score of > 4 at seven days post-LASIK, which decreased to 26.66 % (4 eyes) at one month, but none had a score of more than four pre-LASIK.

There was no complication with suction ring placement and flap cutting in those subjects. But Lenton (2005) suggested that LASIK could add to intra-operative damage to the ocular surface, the limbal goblet cell loss and be a contributing factor to the high degree of ocular surface staining seen after lasik. The study by Battat et al (2001) also reported a significant increase in punctate corneal fluorescein staining at one week postoperatively ($P < 0.001$), but staining returned to baseline by 12 months. In the study by Yang et al (2002), staining was observed more concentrated during one day and one week post-LASIK and decreased during the one-month and three-month follow -ups.

In males tear secretion and tear film stability returned to normal post-LASIK at three months and Schirmer II was even clinically normal after one month (Table 3). In females, tear secretion for Schirmer II reduced post-LASIK even after three months. Schirmer I decreased significantly in females than in males despite no clinical significance. Tear film stability decreased even during the three-month follow- up in females and suggested delay in recovery. Males had a normal FBUT at three months but females had an abnormal FBUT even at three months. Shoja et al (2007) has also indicated that women are at a higher risk than men in developing dry eye related problem.

This study was carried out in a small sample of people undergoing Lasik. The number was small due to the few attendees of Lasik surgery, poor compliance to follow-ups, and the short period of study duration. Though this finding can't be generalized to the general population in terms of the probability of dry eye occurring in patients undergoing LASIK, it can be inferred that dry eye is an inevitable complication which needs thorough dry eye evaluation. Schirmer - I is the least sensitive tool to rule out clinical significance of dry eye. The complete assessment of dry eye warrants assessment of blink rates, completeness of blinking and corneal sensation, apart from routine dry eye assessment.

Conclusion

Laser in situ keratomileusis significantly alters the tear film stability, Schirmer values and corneal staining at least for three months. Tear film stability decreases more in females than in males.

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