Dry Eye After Femtosmile Versus Femtolasik

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Abstract

Objective: To compare the incidence of dry eye after Femtosmile versus Femtolasik.

Patients and Methods: In this study we selected 100 eyes of 50 patients divided into two equal groups: group (1); 50 eyes in which Femtosmile (FS) was performed and group (2); 50 eyes in which Femtolasik (FL) was performed. Comparison of the outcomes within 2 weeks, 1, 3, 6 and 12 months postoperatively.

Results: There is evidence of dry eye symptoms in both groups after surgery as proved by Schirmer's test, tear meniscus height (TMH) and tear break-up time (TBUT). There is reduction in all of them in both groups. However, these signs and symptoms of dry eye were mostly transient. It returns to near normal values with 3 months and maximum 12 months. It was observed that FS eyes showed less reduction in tear parameters than eyes in FL group with statistically significant difference ($p < 0.05$).

Conclusion: Both FS and FL induce transient dry eye symptoms postoperatively. The evidence is mixed and changes after Lasik is controversy between studies, but most of them support dry eye parameters and recovery in corneal sensitivity after FS. FS shows better recovery than FL in the short-term follow-up.

Keywords: Dry eye, Femtosmile, Femtolasik.

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Introduction

Dry eyes is one of the most frequent complications of refractive surgery **[1]**. In FL 28% without previous dry eye symptoms developed new symptoms 3 months after surgery **[2]**.

FS offers a novel and minimal invasive technique of using femtosecond laser to create an intrastromal lenticule that can be removed through a small incision of 3 to 4 mm, which is smaller than a standard 8- to 9-mm diameter FL flap. Involvement of the anterior cornea is spared in FS. With the absence of corneal flap and a smaller incision site, there is less damage to the sub-basal nerve plexus and corneal stromal nerves. This could partially account for the higher levels of corneal sensitivity after FS, and theoretically reduce the incidence of dry eye after the procedure **[3,4]**.

Dry eye after FS and FL procedures have been compared in several studies. Overall, it has been found that FS induces less postoperative dry eye compared to FL. FS is a flapless procedure with a smaller corneal incision, resulting in less corneal denervation and better corneal sensitivity compared to LASIK **[3]**.

Meta-analysis results also support these findings, showing a significant reduction in tear break-up time (TBUT) and tear production with FL, while FS had a nonsignificant reduction in these parameters **[5]**.

Additionally, FS has been shown to have a less pronounced impact on the ocular surface and corneal innervation compared to FL, leading to a lower incidence of dry eye disease and better quality of life after surgery **[6]**. Therefore, FS may be a better option for patients concerned about dry eye after refractive surgery. In the current study, compared both refractive techniques regarding the incidence of dry eye after surgery.

Patients:

This is a comparative trial conducted between March 2021 and November 2022 at the Airforce Specialized Hospital, Egypt. The study protocol was done and approved by our institute that was adhered to the tenets of the Declaration of Helsinki, and written informed consent was obtained from all participants before participation.

It involved 100 eyes of 50 adult patients were enrolled in the study and provided informed consent. All patients included patients were eligible for refractive surgery. Patients had clear cornea and intact anterior chamber with central corneal thickness (CCT) more than 500 µm. However, patients with elevated intraocular pressure (IOP), corneal diseases (e.g., keratoconus, pterygium, ulcer, opacity, dystrophy, … etc), symblepharon or conjunctival scar, previous trauma or surgery, posterior segment diseases such as vitreo macular traction or dense sub-foveal hard exudates, diabetic retinopathy (DR), epiretinal membrane, and previous laser surgery or CCT less than 500 µm were excluded.

Patients classified into two equal groups each of 50 eyes; the first group had FS technique and the second group performed FL technique. Both groups were age and sex matched.

Methods:

History and clinical ophthalmic examination including uncorrected and corrected visual acuity, refraction by autorefractometer, anterior chamber (AC) examination by slit-lamp biomicroscopy, IOP measurement, and fundus examination by indirect +28 & +90 ophthalmoscopy.

Pentacam was done for all patients before surgery to determine the anterior and posterior elevations, CCT, ACD, K1, K2, K-avg and Belin curves for determination of any keratoconus.

Examination of dry eye was done including Schirmer's test, examination of tear floaters, Meibomian gland, tear break-up time (TBUT) and tear meniscus height (TMH) were performed before and after the procedure.

Schirmer Test involves measuring the amount of wetting of a special filter paper, 5 mm wide and 35 mm long. The test can be performed with or without topical anaesthesia. In theory, when performed with an anaesthetic (Schirmer 2) basic secretion is measured and without anaesthetic (Schirmer 1) it measures maximum basic plus reflex secretion. In practice, however, topical anaesthesia cannot abolish all sensory and psychological stimuli for reflex secretion. In this study Schirmer test without anaesthesia (Schirmer 1 test) was used. The test was performed as follows: The filter paper was folded 5 mm from one end and inserted at the junction of the middle and outer third of the lower lid, taking care not to touch the cornea or lashes**.** The patient was asked to keep the eyes gently closed. After 5 minutes the filter paper was removed and the amount of wetting from the fold was measured.

TBUT describes the stability of the tear film. Fluorescein was instilled into the patient's tear film using a fluorescein strip and the patient was asked not to blink while the tear film was observed under a slit lamp broad beam of cobalt blue illumination. The TBUT was recorded as the number of seconds that elapse between the last blink and the appearance of the first dry spot in the tear film.

Tear meniscus variables, such as height, width, cross-sectional area, and meniscus curvature, have been reported to be of value in the diagnosis of dry eye. Tear meniscus height has been confirmed to have good reliability and accuracy in detecting tear meniscus volume. TMH can be measured by a slit lamp using cobalt blue light after fluorescein instillation.

At follow-up period, patients of both groups were examined postoperatively after 2 weeks, 1 month, 2 months, 3 months, 6 months and 12 months from the beginning of therapy. Main outcome measures were visual outcomes and tears parameters were recorded, tabulated and statistically analyzed.

Statistical analysis

Statistical analyses were performed using SPSS v23 statistical software (SPSS, Inc, Chicago, Illinois). Descriptive statistics (means correlation standard deviations) were calculated for quantitative variables. Two-sided Chi-square, student-t and ANOVA test were used as appropriate for parametric data, and Mann-Whitney U and Kruskal Wallis tests were employed for non-parametric variables. The significance level was calculated and $P \leq 0.05$ was considered statistically significant, while $P > 0.05$ was considered statistically non-significant.

Results

This study involved two equal groups each of 50 eyes of 25 patients referred for refractive surgery of total 100 eyes of 50 patients. They were 12 males (48%) and 13 females (52%) in group (1) and 13 males (52%) and 12 females (48%) in group (2). The mean age was 21.5 ± 2.18 years of group (1) and 22.2 ± 3.31 years of group (2). The mean intraocular pressure (IOP) was 15.3 ± 3.52 mmHg and 14.9 ± 3.64 mmHg in group (1) and (2), respectively. The mean CCT was 536 ± 16.7 µm and 532 ± 19.2 µm, and the mean ACD was 3.21 ± 0.51 and 3.15 ± 0.38, respectively, while the average keratometry (K-avg) was 43.5 ± 1.27 mm and 43.7 ± 1.38 mm, respectively. The two groups were matched regarding all those parameters with non-significant difference between them (table 1).

In FS group (1), the mean LogMAR BCVA was improved from 1.21 ± 0.11 at baseline to 0.25 ± 0.08, 0.2 ± 0.09, 0.15 ± 0.07, 0.12 ± 0.06 and 0.13 ± 0.06 at 2 weeks, 1, 3, 6 and 12 months, respectively, while in FL group (2), the mean LogMAR BCVA was improved from 1.15 ± 0.12 at baseline to 0.27 ± 0.12, 0.21 ± 0.08, 0.18 ± 0.06, 0.15 ± 0.05 and 0.14 ± 0.06 at 2 weeks, 1, 3, 6 and 12 months, respectively. There is non-significant difference ($p > 0.05$) in comparison between the two groups regarding visual acuity improvement during the follow-up period (table 2).

Schirmer's test was performed for all patients. In group (1), it was decreased from 11.15 ± 1.864 mm at baseline to 8.925 ± 1.596 mm, 8.075 ± 1.467 mm, 8.616 ± 1.644 mm, 9.751 ± 1.342 mm and 10.64 ± 1.524 mm, at 2 weeks, 1, 3, 6 and 12 months after surgery, respectively while in group (2), it was decreased from 10.89 ± 1.862 mm at baseline to 7.735 ± 2.731 mm, 7.147 ± 1.844 mm, 7.945 ± 1.765 mm, 8.162 ± 1.538 mm and 9.084 ± 1.327 mm, at 2 weeks, 1, 3, 6 and 12 months after surgery, respectively. The differences between the two groups showed statistically significant difference ($P<0.05$) after surgery (table 3).

Tear meniscus height (TMH) was measured for all patients. In group (1), it was reduced from 0.262 ± 0.054 mm at baseline to 0.185 ± 0.058 mm, 0.184 ± 0.061 mm, 0.208 ± 0.053 mm, 0.239 ± 0.052 mm and 0.257 ± 0.055 mm, at 2 weeks, 1, 3, 6 and 12 months after surgery, respectively while in group (2), it was reduced from 0.264 ± 0.062 mm at baseline to 0.167 ± 0.064 mm, 0.165 ± 0.113 mm, 0.173 ± 0.099 mm, 0.177 ± 0.106 mm and 0.183 ± 0.097 mm, at 2 weeks, 1, 3, 6 and 12 months after surgery, respectively. The differences between the two groups showed statistically significant difference ($P<0.05$) after surgery (table 4).

Also, tear break-up time (TBUT) was done for all patients. In group (1), it was decreased from 11.12 ± 1.82 sec at baseline to 9.185 ± 1.82 sec, 9.177 ± 2.19 sec, 9.537 ± 1.83 sec, 10.23 ± 1.85 sec and 10.94 ± 1.82 sec, at 2 weeks, 1, 3, 6 and 12 months postoperatively, respectively while in group (2), it was decreased from 11.23 ± 2.12 sec at baseline to 7.36 ± 2.23 sec, 7.65 ± 2.05 sec, 8.12 ± 1.98 sec, 8.73 ± 1.63 sec and 8.85 ± 1.59 sec, at 2 weeks, 1, 3, 6 and 12 months after surgery, respectively. The differences between the two groups showed statistically significant difference ($P<0.05$) after surgery (table 5).

It was observed that Schirmer's test, TNH and TBUT showed deterioration 2 weeks after surgery up to one month, then return gradually to near normal baseline values from 3 months to one year.

Discussion

Small incision lenticule extraction (SMILE) is a novel all-in-one procedure that can be used in the surgical correction of myopia without the creation of a corneal flap. This technique makes it possible for FS patients to have lower risks of development of dry eye and decreased corneal sensation after surgery. A previous study reported the changes in corneal sensation before and after FS surgery in a 3-month follow-up period **[7]**. But there was only one study **[8]** that reported the changes in dry eye symptoms and signs before and after SF surgery. In the present study, we describe a prospective study to investigate the changes in post-surgical dry eye symptoms and clinical signs following FS surgery by comparing them with patients who had undergone femto-LASIK (FL).

Both dry eye symptoms and corneal sensation reduction are common after all types of corneal refractive surgeries **[8]**. Dry eye could negatively affect the daily activities of patients, and the morbidity of dry eye increases with symptom severity **[9]**.

In this study, we found that there is reduction in tears after surgery by Schirmer's test, TMH and TBUT in both groups but these showed short-term changes that returned to near normal values within 3 to 12 months after surgery, however we found that there are better results in FS than FL with statistically significant difference. Several studies compared the short-term results of dry eyes after FS and FL at different postoperative times with varying results.

In agreement with the current study, several studies reported better results in FS **[8,10-13]**. **Li et al.[8]** in 2013 conducted a nonrandomized, prospective study on 71 eyes of 71 patients in China undergoing FS and FL. Ocular surface disease index (OSDI) in both groups showed significant increase at 1 week (FS 23.95 vs FL 18.78) after surgery comparing to baseline ($P<0.0001$ and $P=0.010$, respectively), but returned to normal at 1 month. No significant difference was found between both groups at 1 week, 1 month, and 3 months. However, FS group has better results in TBUT and corneal staining. Decreased TBUT at 1 week, 1 month, and 3 months was reported after FS compared with baseline [FS: 4.32, 5.68, 5.03 sec and FL: 4.70, 3.77, 4.43 sec, respectively ($P\leq0.001$ for all)]. These results returned to the baseline level at postoperative 6 months ($P=0.08$), but TBUT remained decreased after FL throughout the study period at 1 week, 1 month, 3 months, and 6 months ($P\leq0.002$). After 6 months, there was a significant difference in TBUT scores between FS (7.06 sec) and FL (4.97 sec) groups ($P=0.030$). Compared with patients undergoing FL, patients undergoing FS were less likely to have corneal staining (odd ratio 0.50, $P=0.030$).

Xu et al. [12] in 2014 compared FS with FL in a prospective nonrandomized study of 338 eyes in 176 patients in China. Both groups had significant lower TBUT at 1 month (6.79 vs 6.41 sec, respectively) and 3 months (5.79 vs 5.67 sec, respectively), with a modest improvement by 6 months postoperatively (7.39 vs 7.13 sec). McMonnies questionnaire scores from both groups increased significantly at 1 month as compared with baseline (FS: 9.09–12.75 and FL 8.60–12.48, $P<0.010$ for both). However, FS group took 3 months ($P=0.080$), whereas FL group took 6 months ($P=0.170$) to return to preoperative value.

Ganesh and Gupta [13] in India performed a single-center, randomized, prospective study in 50 patients undergoing bilateral FS or FL in 2014. Three months after surgery as compared with the preoperative values, both groups demonstrated a reduction in Schirmer I test (FS: 33.04–31.94 mm, FS-LASIK: 33.96–26.84 mm), Schirmer II test (FS: 26.4–23.28 mm, FL: 27.14–15.82 mm), and TBUT (FS: 12.32–10.92 sec, FL: 12.5–8.54 sec). However, these postoperative values were significantly lower in FL group ($P<0.001$ for all parameters). Similarly, both groups showed increased tear osmolarity compared with baseline (FS: 300.3–314.67 mOsm/L and FL: 302.3–321.18 mOsm/L), but the increase was significantly higher in the FL group ($P<0.001$). Despite having a similar satisfactory score (an arbitrary score defined by the investigators) in patients with FS, patients in FL group had more dry eye complaints including eye pain, watering, pricking.

In contrast, **Demirok et al. [14]** reported similar results between FS and FL. Their study was conducted in Turkey in 2013 which compared FS and FL through a paired-eye study design, with 1 eye undergoing FS and the fellow eye undergoing FL in 28 patients. They reported no significant change from baseline and between both groups in terms of subjective symptoms, Schirmer II test, TBUT, and tear osmolarity after 1 week, 1 month, 3 months, and 6 months postoperatively.

Furthermore, **Denoyer et al. [11]** in 2015 conducted a similar but nonrandomized study with longer follow-up period on 30 patients in France. In addition, they performed corneal esthesiometry and in vivo confocal microscopy to correlate the function and structure of corneal innervation to the severity of postoperative dry eyes symptoms. One month after surgery, FL group had a significantly higher incidence of mild-to-moderate dry eye disease, which remained similar after 6 months. 80% of FS patients versus 57% of FL patients remained artificial tear-free. Among those requiring lubricants, 20% of FL patients but none in FS group required daily or frequent use of lubricants after surgery. FL group also had higher tear osmolarity 1 month after surgery, significantly high OSDI score, TBUT, and tear osmolarity 6 months after surgery. Corneal sensitivity was found to be negatively correlated to dry eye corneal staining ($R^2=0.48$, $P<0.010$). Long finer nerve density was reported to be independently correlated with OSDI score ($R^2=0.50$, $P<0.010$) and Schirmer test ($R^2=0.21$, $P<0.010$) 6 months after surgery.

Xia et al.[10] in 2016 performed a larger study in China involving 128 eyes in 65 patients which showed favorable results toward FS. Decreased Schirmer test, TBUT, and higher OSDI were observed in both FS and

FL groups at 1 week, 1 month, 3 months, and 6 months. However, FS-LASIK group showed lower Schirmer test value (1 week: 5.6 vs 9.1 mm; 1 month: 7.6 vs 9.7 mm; 3 months: 10.4 vs 12.6 mm; 6 months: 9.3 vs 9.5 mm; $P=0.016$), reduced TBUT (1 week: 4.5 vs 6.4 seconds; 1 month: 4.2 vs 9.7 seconds; 3 months: 5.1 vs 6.0 seconds; 6 months: 6.6 vs 6.3 seconds; $P<0.001$), and higher OSDI (1 month: 26.03 vs 20.34; 3 months: 20.63 vs 14.91; 6 months: 16.00 vs 12.11; $P<0.001$) than FS group.

On a long-term follow-up study, comparing the dry eye parameters >6 months postoperatively. **Elmohamady et al.[15]** compared 35 eyes after FS and 35 eyes after FL in Egypt with a follow-up period up to 3 years. By comparing their preoperative values, both groups had transient worsening in dry eye parameters including higher OSDI score and reduction in TBUT starting from the first month. FS took 3 months and 6 months, whereas FL needed 6 months and 12 months for recovery from dry eye symptoms and TBUT reductions, respectively. No recurrence of dry eye was seen from 12 months onwards to 3 years among the groups.

The influence of incision size on dry eyes in FS also warrants further evaluation. **Cetinkaya et al. [16]** evaluated the influence of incision size (2 mm, 3 mm, or 4 mm) on dry eye symptoms in FS with a decrease in incision size during the course of the surgeon's learning curve. All 3 groups had a similar trend with early deterioration followed by improvement in dry eye parameters during the 6 months' follow-up. For all 3 groups, TBUT and Schirmer test reached their preoperative values 1 month after FS, whereas OSDI and corneal staining score returned to their preoperative level after 3 months. No significant differences among the different incision size groups with respect to OSDI scores, TBUT, Schirmer test, and staining grade values were observed. These results signify that the variation in incision size between 2 and 4 mm in FS does not influence the dry eye parameters after FS. Therefore, larger incision sites can facilitate the procedure for the beginning surgeons during their learning curve **[3]**.

The mechanism for the dry eye syndrome after corneal refractive surgery is multifactorial: decreased trophic influence on the corneal epithelium, impaired corneal sensation affecting blink reflex, damage to the limbal goblet cells during suction, inflammation, and the side effects of medication **[6]**. Disruption of corneal innervation plays an important role in post-refractive surgery dry eye. The corneal nerve bundles enter from the periphery toward the center in a radial fashion to form a subepithelial nerve plexus beneath the Bowman membrane. The nerve bundles penetrate the Bowman membrane to form a sub-basal nerve plexus, giving rise to the terminal nerves in the deep epithelium. The vertical incision in LASIK transects the sub-basal nerve plexus beneath the corneal epithelium except for those at the hinge. LASIK damages both the dense sub-basal nerve plexus and corneal stromal nerves in the creation of the anterior stromal flap and excimer laser photoablation, which could result in corneal and conjunctival hypersensitivity **[17]**. This is known as neuropathic dry eyes with disproportionate dry eye sensation yet minimal clinical signs **[18]**.

Corneal nerve damage also affects the cornea-blink reflex and tear production reflex loop, leading to a reduction in tear secretion and tear film instability **[19]**. **Lee et al. [20]** reported that the number of reinnervated corneal fibers at 1-year post-LASIK remains at less than half of the baseline value. Contrary to LASIK, the all-in-one FS no longer requires the use of excimer laser or a large flap cut. The smaller incision length in FS theoretically better preserves the sub-basal nerve compared with FL **[3]**.

In conclusion, both FS and FL induce transient dry eye symptoms postoperatively. The evidence is mixed and changes after Lasik is controversy between studies, but most of them support dry eye parameters and recovery in corneal sensitivity after FS. FS shows better recovery than FL in the short-term follow-up.

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Table (1): Baseline characteristics of the studied groups.

Item	FS Group (1)		FL Group (2)		Significance	
	No.	%	No.	%	χ^2	P
Gender: Males: 1 Females: 2 13	48 52		13 12	52 48	0.041	0.523
Total (N = 50)	25	50	25	50		
	Mean	± SD	Mean	± SD	t	P
Age (years)	21.5	2.18	22.2	3.31	0.045	0.789
IOP (mmHg)	15.3	3.52	14.9	3.64	0.011	0.912
CCT (µm)	536	16.7	532	19.2	0.021	0.848
ACD (mm)	3.21	0.51	3.15	0.38	0.013	0.897
K-Avg (D)	43.5	1.27	43.7	1.38	0.015	0.924

χ^2: Chi square, t: unpaired t-test, P >0.05: non-significant. IOP: intraocular pressure, CCT: central corneal thickness, ACD: anterior chamber depth, K-avg: average keratometry.

Table (2): Best corrected visual acuities of patients before and after treatment.

BCVA (LogMAR)	Group (1)		Group (2)		Significance	
	Mean	± SD	Mean	± SD	t	P
Before treatment	1.21	0.11	1.25	0.12	0.013	0.891
2 weeks post-treatment	0.25	0.08	0.27	0.12	0.251	0.259
1-month post-treatment	0.20	0.09	0.21	0.08	0.091	0.485
3 months post-treatment	0.15	0.07	0.18	0.06	0.344	0.163
6 months post-treatment	0.12	0.06	0.15	0.05	0.402	0.124
12 months post-treatment	0.13	0.06	0.14	0.06	0.412	0.421

t: unpaired t-test, * P <0.05: significant. BCVA: Best corrected visual acuity.

Table (3): Comparison of Schirmer's test in the two studied groups.

Schirmer's test (mm)	FS Group (1)		FL Group (2)		Significance	
	Mean	± SD	Mean	± SD	t	P
Before treatment	11.15	1.864	10.89	1.862	0.042	0.794
2 weeks post-treatment	8.925	1.596	7.735	2.731	0.998	0.041*
1-month post-treatment	8.075	1.467	7.147	1.844	1.015	0.045*
3 months post-treatment	8.616	1.644	7.945	1.765	1.019	0.048*
6 months post-treatment	9.751	1.342	8.162	1.538	1.020	0.049*
12 months post-treatment	10.64	1.524	9.084	1.327	1.019	0.048*

t: unpaired t-test, * P <0.05: significant.

Table (4): Tear meniscus height of patients before and after treatment in both groups.

TMH (mm)	FS Group (1)		FL Group (2)		Significance	
	Mean	± SD	Mean	± SD	t	P
Before treatment	0.262	0.054	0.264	0.062	0.019	0.0862
2 weeks post-treatment	0.185	0.058	0.167	0.064	1.013	0.043*
1-month post-treatment	0.184	0.061	0.165	0.113	1.012	0.042*
3 months post-treatment	0.208	0.053	0.173	0.099	1.326	0.025*
6 months post-treatment	0.239	0.052	0.177	0.106	1.394	0.019*
12 months post-treatment	0.257	0.055	0.183	0.097	1.789	0.009*

t: unpaired t-test, * P <0.05: significant. IOP: Intraocular pressure.

Table (5): Tear break-up time of patients before and after treatment in both groups.

TBUT (sec)	FS Group (1)		FL Group (2)		Significance	
	Mean	± SD	Mean	± SD	t	P
Before treatment	11.12	1.82	11.23	2.12	0.002	0.935
2 weeks post-treatment	9.185	2.19	7.36	2.23	1.011	0.039*
1-month post-treatment	9.177	1.86	7.65	2.05	0.998	0.041*
3 months post-treatment	9.537	1.83	8.12	1.98	1.016	0.037*
6 months post-treatment	10.23	1.85	8.37	1.63	1.194	0.033*
12 months post-treatment	10.94	1.82	8.85	1.59	1.206	0.031*

t: unpaired t-test, * P <0.05: significant. IOP: Intraocular pressure.