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## Comparison of SMILE and FS-LASIK procedures in terms of dry eye disease

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### Abstract

**Purpose:** To compare SMILE (Small Incision Lenticule Extraction) and FS-LASIK (Femtosecond Laser In Situ Keratomileusis) procedures in terms of dry eye disease.

**Material and Methods:** One hundred and six eyes of 53 patients with myopia and/or myopic astigmatism who had undergone SMILE procedure were compared with 106 eyes of 53 patients with myopia and/or myopic astigmatism who had undergone FS-LASIK procedure in terms of dry eye disease.

**Results:** The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month OSDI (Ocular Surface Disease Index) scores of the second group were significantly higher than those of the first group (p values, 0.000, 0.000 and 0.000 respectively). The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month TBUT (Tear break-up time) values of the second group were significantly lower than those of the first group (p values, 0.000, 0.000, 0.000, 0.003 and 0.003 respectively). The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month ST1 (Schirmer Test 1) values of the second group were significantly lower than those of the first group (p values, 0.000, 0.000, 0.000, 0.003 and 0.002 respectively). The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month staining values of the second group were significantly higher than those of the first group (p values, 0.007, 0.001, 0.000, 0.042 and 0.041 respectively). However, all postoperative dry eye tests of both groups returned to preoperative values after postoperative 3<sup>rd</sup> month.

**Conclusion:** The signs and symptoms of dry eye disease are fewer and last shorter in SMILE procedure, when compared with FS-LASIK procedure. But dry eye disease is transient after both procedures.

**Keywords:** Smile, FS-LASIK, Dry eye, OSDI, ST1, TBUT

### Introduction

Tear deficiency and overevaporation cause dry eye [1, 2]. It is a frequent and important disorder for ocular comfort and vision [3, 4]. Refractive surgeries have many benefits but also some complications like dry eye. The corneal nerves are cut during the flap creation and stromal ablation, which cause reduction in corneal sensitivity and tear production and induce evaporation [5, 6]. Intact corneal sensation is essential for blinking and production of tear [7]. Femtosecond laser-assisted LASIK provides more predictable flap thickness, diameter, and hinge width than microkeratomes and because of decreased neurotropic effects on the corneal nerves during flap formation, dry eye disease rate is decreased [8, 9].

SMILE is a less invasive and flapless method, in this technique, an intrastromal lenticule is extracted through a small incision, anterior cornea is left intact thus corneal biomechanical stability is protected and nerve fibers are preserved, that causes reduction in dry eye [10-13]. LASIK causes greater resection of corneal nerves, on the other hand, SMILE affects the posterior stromal bed with protection of subbasal nerve plexus [14-16].

In this study, we compared retrospectively, SMILE and FS-LASIK procedures in terms of dry eye.

### Material And Methods

The local ethics committee (Selcuk University, Faculty of Medicine Ethics Committee, Konya, Turkey) approved the study protocol. Before the surgery, patients read and signed an informed written consent. The study was conducted according to the principles of the Declaration of Helsinki.

One hundred and six eyes of 53 patients with myopia and/or myopic astigmatism who had undergone SMILE procedure between April 2017 and September 2017 comprised Group1.

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Twenty-five of them were males (47%) and 28 (53%) were females. One hundred and six eyes of 53 patients with myopia and/or myopic astigmatism who had undergone FS-LASIK procedure between April 2017 and September 2017 comprised Group 2. Their mean age was  $26.60 \pm 6.08$  (SD) (19-41) years. Twenty-six of them were males (49%) and 27 (51%) were females. All of the surgeries were performed by a single surgeon (MG). Patients did not have any ocular or systemic diseases like Diabetes Mellitus, Connective tissue diseases and chronic dry eye syndrome.

SMILE procedures were performed by Visumax femtosecond laser system (Carl Zeiss, Meditec AG, Jena, Germany). Under topical anesthesia, patient was focused on a target light, then corneal suction was commenced. Posterior and anterior surfaces of the lenticule were cut and separated, then the lenticule was extracted.

FS-LASIK procedures were performed by Visumax Femtosecond laser system (Carl Zeiss, Meditec AG, Jena, Germany) for creation of flap. The ablation was done by Wavelight EX500 (Alcon, USA) Laser system.

Postoperatively, patients used topical antibiotic (Moxifloxacin 0.5%, Vigamox, Alcon, USA) four times a day for a week, topical steroid (Dexamethasone Na Phosphate 0.1%, Dexa-sine, Liba, Turkey) four times a day for two weeks and a preservative-free topical lubricating drop (Na Hyaluronate 0.15%, Eystil, SIFI, Italy) six times a day for three months.

Follow-up examinations containing uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), intraocular pressure measurement, fundus examination, topographic measurements, fluorescein staining, TBUT, ST1 and OSDI questionnaire were applied preoperatively and 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month postoperatively.

For statistical analysis, SPSS version 22 programme was used. For comparison of percentages and means, Chi-square test, t-test and paired-t test were used. A p value smaller than 0.05 was accepted as significant statistically.

## Results

In respect to age and sex, there was no significant difference between the first (SMILE) and second (FS-LASIK) groups, (p values, 0.138 and 0.986, respectively).

The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week and 1<sup>st</sup> month OSDI scores of the second group were significantly higher than that of the first group, even though the mean postoperative 3<sup>rd</sup> month and 6<sup>th</sup> month scores of the second group were higher than those of the first group, these were not significant statistically (p values, 0.000, 0.000, 0.000, 0.228 and 0.087, respectively). The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week and 1<sup>st</sup> month scores of the first group were significantly higher than its mean preoperative score (p values 0.000, 0.000, 0.003, respectively) but the 1<sup>st</sup> month score was within the normal limits (0-25). The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week and 1<sup>st</sup> month scores of the second group were significantly higher than its mean preoperative score (p values, 0.000, 0.000 and 0.000, respectively). The OSDI scores of the patients are shown in Figure 1.

The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month TBUT values of the second group were significantly lower than those of the first group, however the 3<sup>rd</sup> and 6<sup>th</sup> month values of the second group were within the normal limits (>10 second), (p values,

0.000, 0.000, 0.000, 0.003 and 0.003 respectively). The 1<sup>st</sup> day and 1<sup>st</sup> week values of the first group were significantly lower than its preoperative value (p values, 0.002 and 0.002, respectively). The 1<sup>st</sup> day, 1<sup>st</sup> week and 1<sup>st</sup> month values of the second group were significantly lower than its preoperative value (p values, 0.000, 0.000 and 0.000, respectively). The TBUT values of the patients are shown in Figure 2.

The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month ST1 values of the second group were significantly lower than those of the first group, however the 3<sup>rd</sup> and 6<sup>th</sup> month values of the second group were within the normal limits (>10mm), (p values, 0.000, 0.000, 0.000, 0.003 and 0.002, respectively). The 1<sup>st</sup> day and 1<sup>st</sup> week values of the first group were significantly lower than its preoperative value (p values, 0.002 and 0.002, respectively). The 1<sup>st</sup> day, 1<sup>st</sup> week and 1<sup>st</sup> month values of the second group were significantly lower than its preoperative value (p values, 0.000, 0.000 and 0.000, respectively). The ST1 values of the patients are shown in Figure 3.

The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month staining values of the second group were significantly higher than those of the first group (p values, 0.007, 0.001, 0.000, 0.042 and 0.041, respectively), however, all values of the first and second groups were within the normal limits (<2). The 1<sup>st</sup> day and 1<sup>st</sup> week values of the first group were significantly higher than its preoperative value (p values, 0.000 and 0.001, respectively). The 1<sup>st</sup> day, 1<sup>st</sup> week and 1<sup>st</sup> month values of the second group were significantly higher than its preoperative value (p values, 0.000, 0.000 and 0.000, respectively). The staining values of the patients are shown in Figure 4.

## Discussion

Corneal nerves transmit stimuli to brain stem. The sympathetic and parasympathetic systems stimulate lacrimal gland for production and secretion of tear. For normal blinking and tearing, intact corneal innervation is essential. Destruction of this system lead to dry eye. Surgeries such as PRK, LASIK, SMILE, penetrating keratoplasty, extracapsular cataract extraction and phacoemulsification surgery inclining corneal denervation give rise to reduced blinking and decrease in tear production thus inducing increased epithelial permeability, decreased epithelial metabolic activity and corrupted epithelial wound healing. In healing process, neural growth factor is produced for regeneration of the subepithelial corneal axon, this process is finished in one month and this recovery of the nerves may express why dry eye signs and symptoms are marked early after the operation and improve later [17-20].

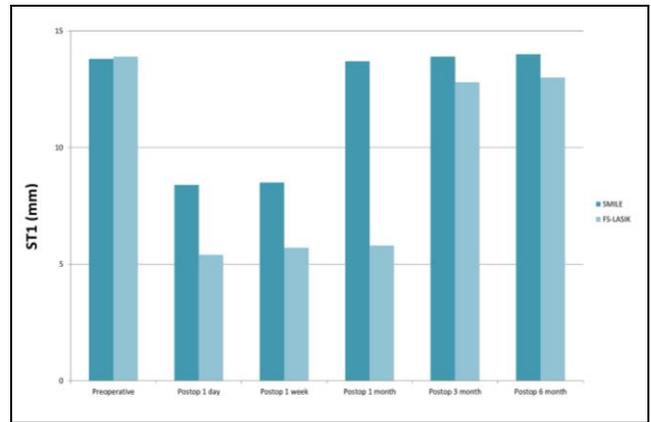
Many patients may be dissatisfied after refractive surgeries, because of dry eye syndrome. Several studies have stated that the rates and degree of dry eye are lower after SMILE than FS-LASIK. This is due to the small incision on the anterior stroma, which can reduce the destruction of tear film and nerve fibers [6, 21]. This is in accordance with our study. In our study, we found that the mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week and 1<sup>st</sup> month OSDI scores of FS-LASIK group were significantly higher than those of SMILE group. The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month TBUT values of FS-LASIK group were significantly lower than those of SMILE group. The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month ST1 values of FS-LASIK group were

significantly lower than those of SMILE group. The mean postoperative 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month staining values of FS-LASIK group were significantly higher than those of SMILE group. In SMILE group, OSDI scores, TBUT, ST1 and staining values returned to preoperative levels in 1<sup>st</sup> month, while in FS-LASIK group, they returned to preoperative levels in 3<sup>rd</sup> month.

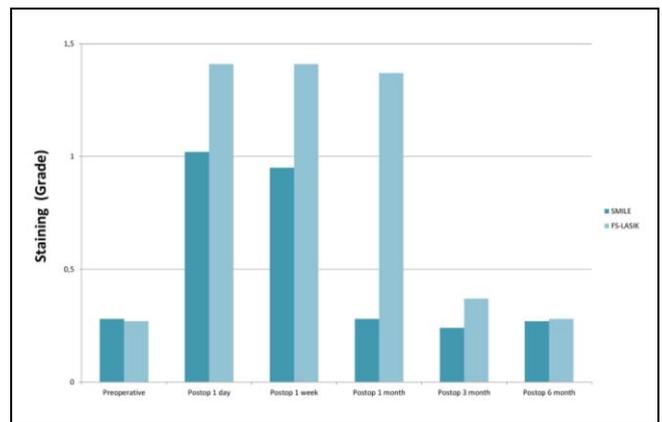
Kobashi *et al.* [22] reported that SMILE procedure has fewer negative impacts on the ocular surface and corneal innervation than does FS-LASIK. Furthermore, SMILE shows superiority over FS-LASIK by exhibiting a lower risk of postoperative dry eye. Denoyer *et al.* [14] reported that SMILE procedure has a less pronounced impact on the ocular surface and corneal innervation compared with LASIK, further reducing the incidence of dry eye disease and subsequent degradation in quality of life after refractive surgery.

Xu *et al.* [23] found that dry eye after corneal refractive surgery usually occurs transiently. The SMILE procedure had better dry eye parameters and relatively fewer subjective symptoms than LASIK. Zhang *et al.* [24] reported that SMILE may create fewer dry eye symptoms than FS-LASIK. Corneal sensitivity was greater after SMILE than FS-LASIK. Shen *et al.* [25] reported that dry eye symptoms and loss of corneal sensitivity may occur less frequently after SMILE than after FS-LASIK.

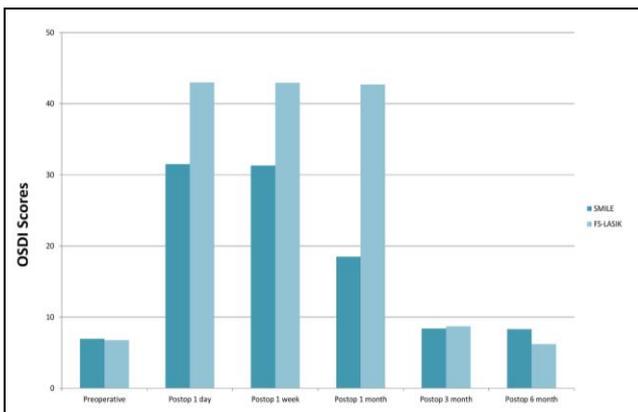
In conclusion, the signs and symptoms of dry eye disease are fewer and last shorter in SMILE procedure when compared with FS-LASIK procedure. But dry eye disease is transient after both procedures.



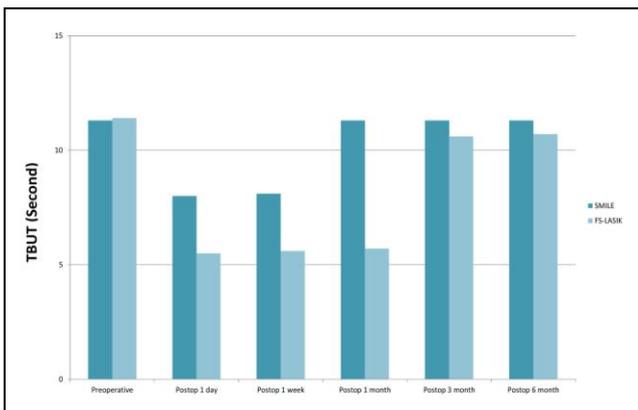
**Fig 3:** The preoperative and postoperative ST1 values of the patients



**Fig 4:** The preoperative and postoperative Staining values of the patients.



**Fig 1:** The preoperative and postoperative OSDI scores of the patients.



**Fig 2:** The preoperative and postoperative TBUT values of the patients.

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