

## Comparative Study between Femtosecond Laser Assisted In-Situ Keratomileusis and Femtosecond Small Incision Lenticule Extraction for Correction of Myopia and Myopic Astigmatism

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### Abstract

**Purpose:** To compare femto-LASIK with SMILE as regards the safety, efficacy, accuracy and post-operative complications with special emphasis on the post-operative dry eye, corneal sensation and corneal biomechanics in cases of myopia and myopic astigmatism.

**Patients and Methods:** The study was a prospective cohort study that was conducted in a private eye hospital on 60 eyes of 30 patients with myopia or myopic astigmatism. Each patient was fully assessed preoperatively including VA, refraction, TBUT, Schirmer test, corneal sensation and Ocular Response Analyzer®. Femto-LASIK was done to 15 patients and SMILE was done to 15 patients. Postoperative VA, refraction, TBUT, Schirmer test, corneal sensation at 1 month, 3 months and 6 months and Ocular Response Analyzer® at 6 months were done and data was retrieved and analyzed.

**Results:** Cylindrical error was higher in SMILE group at all postoperative points. TBUT was better in SMILE group in 1st month, but no significant difference in later follow ups. Corneal sensation was better in SMILE group in 1 month and 3 months, but this difference disappeared at 6 months. CH and CRF were significantly better in SMILE group.

**Conclusion:** Both techniques are safe and efficient. Femto-LASIK is more efficient in correcting cylindrical error. SMILE is better in early postoperative dry eye, corneal sensation and in corneal biomechanics.

**Keywords:** Femto-LASIK; SMILE; Dry Eye; Corneal Sensation; Corneal Biomechanics

### Introduction

The creation of a corneal flap is one of the fundamental steps in LASIK. A LASIK flap can be created with a mechanical microkeratome or femtosecond laser. Since the early femtosecond laser models were introduced, considerable progress has been made in improving flap geometry and limiting complications of LASIK performed with the laser. This has led to increasing popularity of LASIK performed with the femtosecond laser [1]. SMILE was first introduced in 2011 as a flap-free intrastromal laser assisted refractive surgery technique for the correction of myopia and myopic astigmatism with a reported high efficacy, predictability, stability, and safety for myopic treatments [2].

However, the lack of cyclotorsion control on the VisuMax (Carl Zeiss Meditec AG, Jena, Germany) and the complete surgeon-dependent centration of the treatment have raised some concerns regarding the capability of SMILE to properly correct moderate or high levels of myopic astigmatism with the current commercially available technology [3]. Theoretically, SMILE is a minimally invasive approach to cor-

neal refractive surgery because of the absence of flap cutting. According to recent studies, SMILE causes less damage to the corneal sub-basal nerves and has fewer effects on the ocular surface than does FS-LASIK [4]. LASIK alters corneal biomechanical properties that are thought to play an important role in the development of post-LASIK ectasia. SMILE may have biomechanical benefits over LASIK because it does not involve the creation of a flap and leaves the stroma over the lenticule untouched [5].

## **Patients and Methods**

### **Patients**

The study was conducted on 60 eyes of 30 patients. The study was done in accordance with the ethical standards of the institutional review board of the faculty of Medicine, Ain Shams University. All recruited patients signed the consent letter. They either received femto-LASIK (30 eyes of 15 patients) or SMILE (30 eyes of 15 patients). All surgeries were performed by the same surgeon (T.E.) following standard procedures at Subspecialty Eye Center (Cairo, Egypt). Inclusion Criteria were age from 21 to 40 years, spherical error from -4 to -8 D., cylindrical error from zero to 4 D., normal corneal topography, pachymetry  $\geq 500 \mu\text{m}$  and residual stromal bed after correction  $\geq 300 \mu\text{m}$ . Exclusion Criteria were previous corneal or ocular surgery, ocular disease other than myopia and astigmatism, moderate or severe dry eye, and systemic disease that may affect the wound healing.

Preoperative assessment included monocular uncorrected and corrected distance visual acuities (UDVA and CDVA), anterior segment examination by slit-lamp biomicroscopy, fundus examination, assessment of tear film using tear breakup time test (TBUT) and Schirmer test, corneal sensation using Cochet-Bonnet aesthesiometer (Luneau Ophthalmogica, Paris, France). Corneal tomography using Pentacam® (Oculus, Inc, Wetzlar, Germany) and measurement of corneal hysteresis (CH) and corneal resistance factor (CRF) using Ocular Response Analyzer® (ORA; Reichert Ophthalmic Instruments, Buffalo, NY, USA).

### **Surgical technique**

#### **Femto-LASIK procedure**

The thickness of the corneal flap was set to be  $110 \mu\text{m}$ . All flaps had a superior hinge with angle  $90^\circ$ , the flap diameter was set to be 9 mm, with a  $70^\circ$  angled side cut. Drying of the ocular surface using microsponges was done. Patient was asked to look directly at the light target. The suction ring was applied for eye fixation. Alcon/WaveLight® FS 200 1505 (Alcon Surgical, Fort Worth, Texas, USA) patient interface was used. Adjusting the flap centration was done before laser application. Canal was done to collect air bubbles out of the cornea, then Laser application to create the corneal flap and the side cut. After creating the corneal flaps in both eyes, patient's bed was then swung to the WaveLight® EX 500 excimer laser system for excimer laser application. The flap was gently dissected from the corneal stromal bed using a spatula and was gently raised. Patient was asked to look at the aiming beam green light. A micro sponge was used to protect the flap during the excimer laser application. Excimer laser application was done. Irrigation of the corneal stromal bed with Balanced Salt Solution (BSS®) was performed. The flap was floated back into position with a cannula. Drying the corneal surface was performed using disposable microsponges to ensure proper flap adherence.

#### **SMILE procedure**

The thickness of the corneal cap was set to  $100 \mu\text{m}$ , cap diameter was set to 7.5 mm, lenticule sidecut angle was set to  $90^\circ$ , lenticule diameter (optical zone) was set to 6.5 mm and wound was set to be 4 mm in the upper side. Drying of the ocular surface using microsponges was done. Visumax® S cone (Carl Zeiss Meditec AG, Jena, Germany) patient interface was used. The patient was raised to the contact glass of the femtosecond laser. Patient was asked to look directly at the green target. The corneal suction ports were activated for eye fixation and completion of docking. The lower interface of the intrastromal lenticule was created first using an out-to-in direction. The upper interface of the lenticule then was created using an in-to-out direction. Finally, 2 mm supero-temporal tunnel incision was created to link

the cap interface to the corneal surface. The patient was then moved to the surgical microscope. The small incision was opened and the upper and lower edges of the lenticule were delineated. The upper interface was dissected first using circular blunt dissector. The lower interface was then dissected using blunt spatula. Once both layers had been separated, the lenticule was removed from the cornea using micro-forceps. Wash of the interface with Balanced Salt Solution (BSS®) was performed. Drying the corneal surface was performed using disposable microsponges.

### **Post-operative assessment**

All patients were instructed to apply topical antibiotic-steroid drops (Tobradex eye drops, Tobramycin 3 mg, dexamethasone 1 mg, Alcon-Couvreur, Puurs, Belgium) 6 times daily for 7 days and preservative-free artificial tears (Systane ultra eye drops, Alcon Laboratories, Inc., Fort Worth, Texas, USA) 6 times daily for a month.

All patients underwent assessment at 1 month, 3 months and 6 months after procedure. - Tear breakup time test (TBUT): Usually associated with the stability of the tear film. A fluorescein impregnated strip was placed in the lower conjunctival sac, and the patient was asked to blink several times. Using slit-lamp biomicroscopy with a cobalt blue filter, the time that elapsed before the first observation of tear film breakup after a complete blink was recorded as the TBUT.

**Schirmer's test:** The Schirmer's test without anesthesia for tear secretion function was performed by inserting a 30-mm Schirmer tear test strip into the inferior fornix at the junction of the middle and lateral thirds of the lower eyelid margin. Schirmer test strips remained in place for 5 minutes with the eyes closed. The extent of wetting was subsequently measured according to the scale provided on the strip.

**Corneal sensation:** Corneal sensation was measured in the central cornea using a Cochet-Bonnet esthesiometer (Luneau Ophthalmogica, Paris, France). This instrument consists of a nylon monofilament that is 6.00 cm in length and with diameter of 0.12 mm. The patients were positioned on the ophthalmic chin and brow rest of a slit lamp, and the nylon monofilament was perpendicularly advanced to the central cornea. The filament was shortened in 0.50 cm increments if the patient did not feel the filament. If the patient felt the filament, the response was defined positive.

**Corneal biomechanics:** Were assessed preoperatively and 6 months after the procedure using Ocular Response Analyzer® (ORA; Reichert Ophthalmic Instruments, Buffalo, NY, USA). During the measurement procedure, a rapid air impulse is used to applanate the cornea. Using an electrooptical system, 2 applanation pressure measurements are recorded. The first measurement occurs when the cornea is flattened and moving inward and the other as the cornea flattens and is moving outward after moving through a concavity at maximum applanation. Due to its viscoelastic properties, the cornea resists the dynamic air puff differentially on the inward and outward applanation events, resulting in 2 different pressure values. Corneal hysteresis is defined as the difference between these 2 pressure values. Corneal hysteresis is thought to correlate with the amount of viscous dampening inherent to the cornea. The CH measurement also provides a basis for an additional parameter, the CRF. This measure appears to be an indicator of the overall mechanical resistance of the corneal tissue, including both viscous and elastic components, and is derived from specific combinations of the inward and outward applanation values using proprietary algorithms [6].

### **Statistical analysis**

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges. Also, qualitative variables were presented as number and percentages. The comparison between groups regarding qualitative data was done by using Chi-square test. The comparison between two independent groups with quantitative data and parametric distribution were done by using Independent t-test while non-parametric data were compared using Mann-Whitney test. The comparison between two paired groups with quantitative data and parametric distribution

were done by using Paired t-test while non-parametric data were compared using Wilcoxon Rank test. The comparison between more than two paired groups with quantitative data and parametric distribution were done by using Repeated Measures ANOVA while with non-parametric data were done by using Friedman test. 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:  $P > 0.05$ : Non-significant (NS),  $P < 0.05$ : Significant (S),  $P < 0.01$ : Highly significant (HS).

## Results

### Demographic data

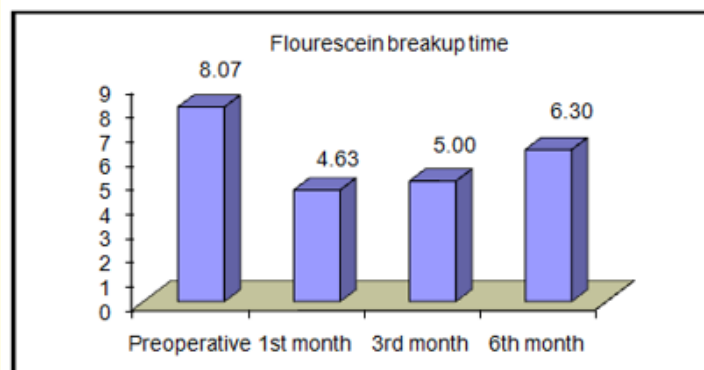
This study included sixty eyes of thirty patients with simple myopia or myopic astigmatism (simple and compound) prospectively recruited. These patients were randomly assigned into two equal groups: Group (A): the femto-LASIK group that included 30 eyes of 15 patients, and Group (B): the SMILE group that included 30 eyes of 15 patients.

The mean age in Group A was 24.0 years (range from 20 to 31 years old) and Group B was 23.73 years (range from 18 to 31 years old). Group A included 6 male patients and 9 female patients while Group B included 7 male patients and 8 female patients. There was no statistically significant difference between the two groups regarding the age (P value 0.825).

### Intragroup results

#### Group A

Comparison between preoperative BCVA and postoperative UCVA at 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month revealed no statistically significant difference, also comparison between UCVA at 1<sup>st</sup> month and at 6<sup>th</sup> month revealed no statistically significant difference which proves stability of VA. No eyes lost a line of BCVA. Also there was no significant change in spherical equivalent, spherical error and cylindrical error between 1<sup>st</sup> month and 6<sup>th</sup> month proving stability of results. TBU; T showed significant postoperative decrease at 1<sup>st</sup> month, no significant improvement at 3<sup>rd</sup> month. There was significant improvement at 6<sup>th</sup> month but values were statistically less than baseline values. Shirmers' test values showed significant postoperative decrease at 1<sup>st</sup> month, but there was highly significant improvement from 1<sup>st</sup> month to 3<sup>rd</sup> month, and highly significant improvement from 3<sup>rd</sup> month to 6<sup>th</sup> month but still remained significantly less than baseline values. Corneal sensation also showed significant decrease at 1<sup>st</sup> month, highly significant improvement from 1<sup>st</sup> to 3<sup>rd</sup> month and highly significant improvement from 3<sup>rd</sup> month to 6<sup>th</sup> month but remained less than baseline values. CH and CRF at 6<sup>th</sup> month showed highly significant decrease compared to baseline values.



**Figure 1:** TBUT results (preoperative, at 1st month, 3rd month and 6th month) in group A.

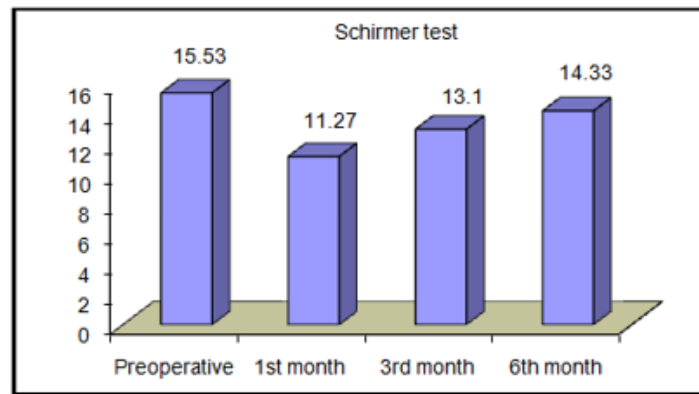


Figure 2: Schirmer's test results (preoperative, at 1st month, 3rd month and 6th month) in group A.

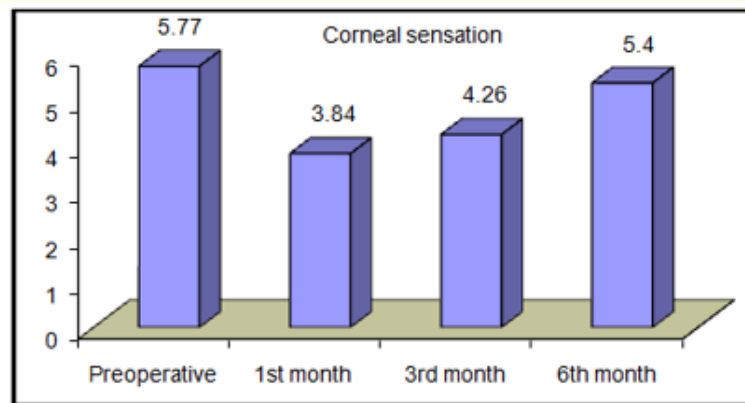


Figure 3: Corneal sensation results (preoperative, at 1st month, 3rd month and 6th month) in group A.

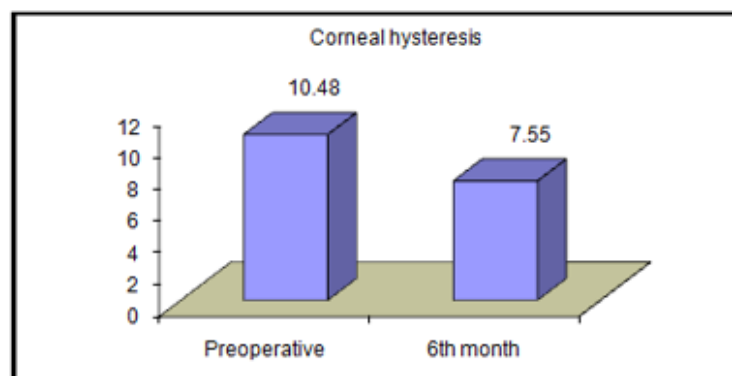


Figure 4: CH results (preoperative and at 6th month) in group A.

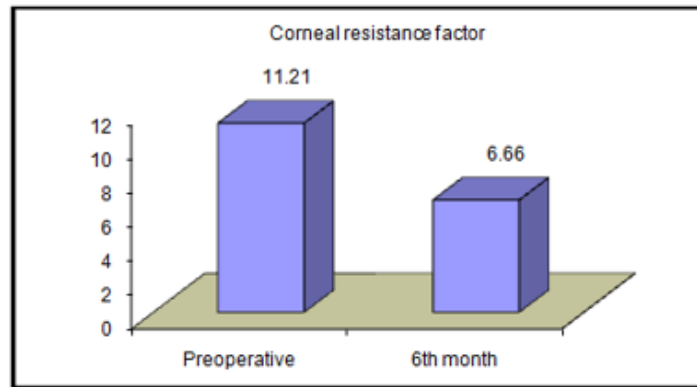


Figure 5: CRF results (preoperative and at 6th month) in group A.

### Group B

Comparison between preoperative BCVA and postoperative UCVA at 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month revealed no statistically significant difference, also comparison between UCVA at 1<sup>st</sup> month and at 6<sup>th</sup> month revealed no statistically significant difference which proves stability of VA. No eyes lost a line of BCVA. Also, there was no significant change in spherical equivalent, spherical error and cylindrical error between 1<sup>st</sup> month and 6<sup>th</sup> month proving stability of results. TBUT showed significant postoperative decrease at 1<sup>st</sup> month, highly significant improvement at 3<sup>rd</sup> month and highly significant improvement at 6<sup>th</sup> month but values were statistically less than baseline values. Shirmer’s test values showed significant postoperative decrease at 1<sup>st</sup> month. There was highly significant improvement from 1<sup>st</sup> month to 3<sup>rd</sup> month, but there was no significant improvement from 3<sup>rd</sup> month to 6<sup>th</sup> month. Values at 6<sup>th</sup> month still remained significantly less than baseline values. Corneal sensation also showed significant decrease at 1<sup>st</sup> month, highly significant improvement from 1<sup>st</sup> to 3<sup>rd</sup> month and highly significant improvement from 3<sup>rd</sup> month to 6<sup>th</sup> month but remained less than baseline values. CH & CRF at 6<sup>th</sup> month showed highly significant decrease compared to baseline values.

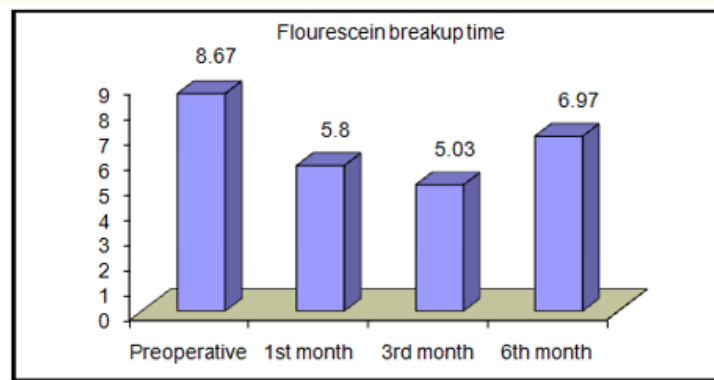


Figure 6: TBUT results (preoperative, at 1st month, 3rd month and 6th month) in group B.

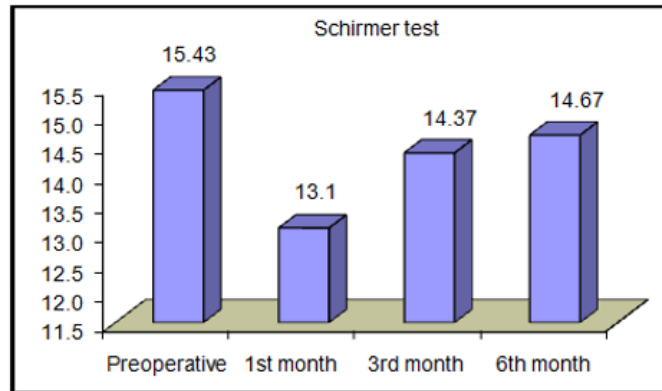


Figure 7: Schirmer's test results (preoperative, at 1st month, 3rd month and 6th month) in group B.

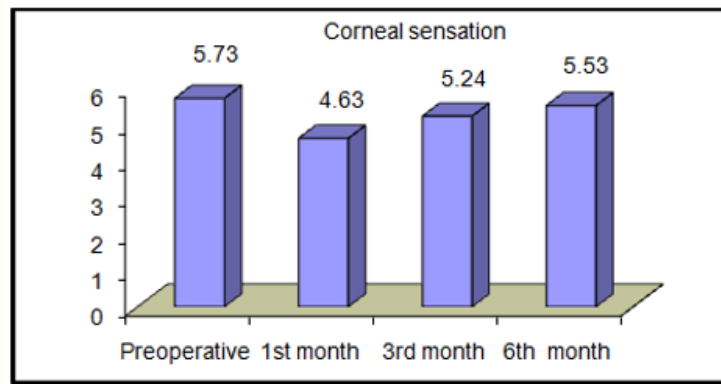


Figure 8: Corneal sensation results (preoperative, at 1st month, 3rd month and 6th month) in group B.

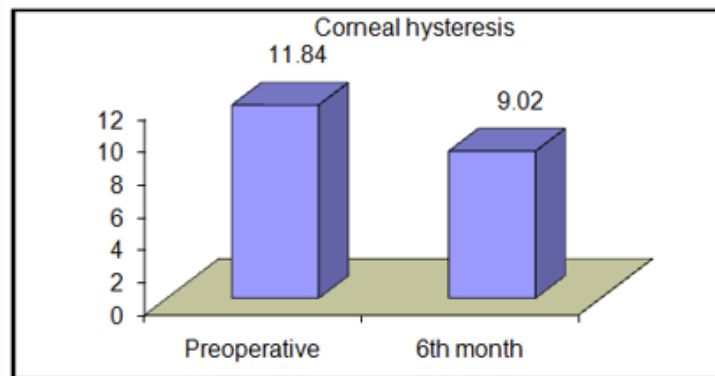


Figure 9: CH results (preoperative and at 6th month) in group B.

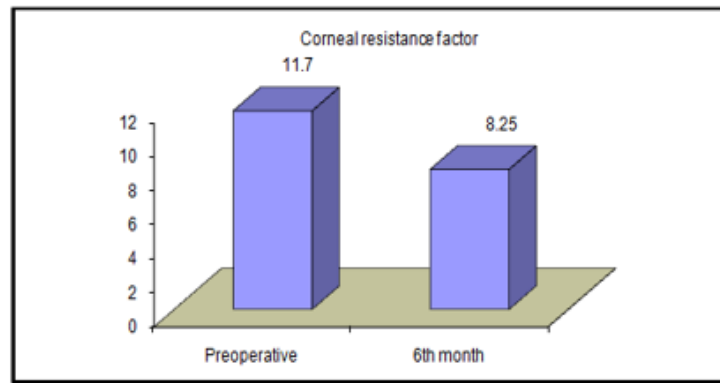


Figure 10: CRF results (preoperative and at 6<sup>th</sup> month) in group B.

### Intergroup comparison

There was no significant difference in preoperative UCVA, BCVA, spherical equivalent, spherical error, cylindrical error, TBUT, Schirmer test, corneal sensation, CH and CRF between both groups. Postoperatively, there was no significant difference between both groups in UCVA, BCVA, spherical equivalent and spherical error at any time point. Cylindrical error was significantly higher in SMILE group than femto-LASIK group at all time points. TBUT was significantly shorter in femto-LASIK group at 1<sup>st</sup> month, but there was no significant difference between both groups at 3<sup>rd</sup> and 6<sup>th</sup> months. Schirmer’s test results showed no significant difference between both groups at all time points. Corneal sensation was significantly better in SMILE group than in femto-LASIK group at 1<sup>st</sup> month and 3<sup>rd</sup> month, but this difference disappeared at 6<sup>th</sup> month. CH and CRF were significantly higher in SMILE group than in femto-LASIK group at 6<sup>th</sup> month.

	Group A	Group B	P-value
VA	0.97 ± 0.09 0.8 – 1.2	0.98 ± 0.09 0.8 – 1.2	0.574
Spherical equivalent	-0.03 ± 0.33 -0.75 – 0.63	-0.22 ± 0.43 -1 – 0.75	0.063
Spherical error	0.14 ± 0.33 -0.5 – 0.75	0.17 ± 0.54 -0.75 – 1.25	0.964
Cylindrical error	-0.37 ± 0.36 -1.25 – 0	-0.71 ± 0.55 -2 – 0	0.013
TBUT	4.63 ± 1.85 2 – 8	5.80 ± 2.27 2 – 10	0.033
Schirmer’s test	11.27 ± 3.88 5 – 19	13.10 ± 5.09 4 – 23	0.122
Corneal sensation	3.84 ± 0.86 2.5 – 5.25	4.63 ± 0.65 3.5 – 5.5	0.000

Table 1: Intergroup comparison at 1<sup>st</sup> month.



	Group A	Group B	P-value
VA	1.01 ± 0.09 0.8 – 1.2	0.98 ± 0.09 0.8 – 1.2	0.335
Spherical equivalent	-0.11 ± 0.31 -0.75 – 0.38	-0.24 ± 0.40 -0.88 – 0.75	0.100
Spherical error	0.09 ± 0.32 -0.5 – 0.5	0.13 ± 0.47 -0.5 – 1.25	0.860
Cylindrical error	-0.39 ± 0.33 -1.25 – 0	-0.73 ± 0.56 -2 – 0	0.019
TBUT	5.00 ± 2.23 3 – 12	5.03 ± 2.34 2 – 11	0.955
Schirmer's test	13.10 ± 3.52 8 – 20	14.37 ± 5.28 4 – 22	0.279
Corneal sensation	4.26 ± 1.00 2.75 – 6	5.24 ± 0.54 3.75 – 6	0.000

**Table 2:** Intergroup comparison at 3<sup>rd</sup> month.

	Group A	Group B	P-value
VA	0.99 ± 0.07 0.9 – 1.2	1.00 ± 0.08 0.9 – 1.2	0.335
Spherical equivalent	-0.08 ± 0.29 -0.63 – 0.5	-0.21 ± 0.32 -0.88 – 0.5	0.100
Spherical error	0.08 ± 0.38 -0.5 – 0.75	0.12 ± 0.41 -0.5 – 1	0.753
Cylindrical error	-0.29 ± 0.34 -1.25 – 0	-0.67 ± 0.57 -2 – 0	0.002
TBUT	6.30 ± 2.87 3 – 14	6.97 ± 2.65 3 – 12	0.955
Schirmer's test	14.33 ± 3.84 9 – 22	14.67 ± 4.52 5 – 23	0.279
Corneal sensation	5.40 ± 0.47 4 – 6	5.53 ± 0.38 4.57 – 6	0.000
CH	7.55 ± 1.64 5 – 11.2	9.02 ± 1.32 6.7 – 11.3	0.000
CRF	6.66 ± 1.14 5.2 – 8.9	8.25 ± 1.74 5.9 – 11.8	0.000

**Table 3:** Intergroup comparison at 6<sup>th</sup> month.

## Discussion

In this study, we investigated the efficacy, predictability and safety of femto-LASIK and SMILE through clinical evaluation of stability of VA, refraction and loss of best corrected VA. We also compared the effect of both techniques on dry eye, corneal sensation and corneal biomechanics.

In this study, the femto-LASIK group preoperative best corrected VA was  $0.99 \pm 0.07$ , and uncorrected VA at 6<sup>th</sup> postoperative month was  $0.99 \pm 0.07$ . This denotes the efficacy of femto-LASIK procedure. Uncorrected VA at 1<sup>st</sup> month was  $0.97 \pm 0.09$  and uncorrected VA at 6<sup>th</sup> month was  $0.99 \pm 0.07$ . This denotes stability of results of the procedure. No eye lost line in best corrected VA denoting safety of the procedure.

Our results were similar to Kymionis, *et al.* [7] study in 2013 which comprised 50 eyes of 25 patients undergoing LASIK with the FS200 femtosecond laser for flap creation. Mean preoperative corrected VA was  $1.02 \pm 0.06$ . Uncorrected VA at 6 months was  $1.01 \pm 0.09$ . Six months postoperatively, no eye lost lines of corrected VA in their study.

Spherical equivalent in femto-LASIK group was reduced from  $-6.37 \pm 1.65$  D. preoperatively to  $-0.08 \pm 0.29$  D. at 6<sup>th</sup> month. There was no significant change in spherical equivalent from 1<sup>st</sup> month to 6<sup>th</sup> month denoting stability of results. All treated eyes were within  $\pm 1.00$  D. and 28 of the 30 treated eyes were within  $\pm 0.50$  D. of the intended correction at 6<sup>th</sup> month. Spherical error also was reduced from  $-5.96 \pm 1.61$  D. preoperatively to  $0.08 \pm 0.38$  D. at 6<sup>th</sup> month. The results were stable with no significant change from 1<sup>st</sup> month to 6<sup>th</sup> month. Cylindrical error was reduced from  $-0.83 \pm 0.62$  D. preoperatively to  $-0.29 \pm 0.34$  D. at 6<sup>th</sup> month. The results were also stable with no significant change from 1<sup>st</sup> month to 6<sup>th</sup> month. Our results were similar to Winkler von Mohrenfels, *et al.* [8] study in 2012 in which spherical equivalent was reduced from  $-4.22 \pm 1.22$  D. to  $-0.15 \pm 0.16$  D. with 18 of the 20 treated eyes within  $\pm 0.5$  D., and all eyes were within  $\pm 1.0$  D. of the intended correction.

Significant reduction in TBUT was noticed after femto-LASIK in 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month, but there was significant improvement in TBUT from 3<sup>rd</sup> month to 6<sup>th</sup> month. Schirmer's test results also showed significant reduction in 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month, but there was significant improvement from 1<sup>st</sup> month to 3<sup>rd</sup> month and significant improvement from 3<sup>rd</sup> month to 6<sup>th</sup> month. Our results were not similar to Sun, *et al.* [9] results in 2013 that showed that there was no within-group differences in TBUT in femto-LASIK group postoperatively compared to baseline values. The mean Schirmer's test values were increased throughout the postoperative visits. The values of Schirmer's were significantly higher at months 1 and 6 in the femto-LASIK group compared with those at baseline values. This difference is mostly due to inferior punctal plug occlusions that were performed immediately after surgery in all of the patients in Sun, *et al.* study.

Corneal sensation was significantly reduced after femto-LASIK in 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month, but there was significant improvement in corneal sensation from 1<sup>st</sup> month to 3<sup>rd</sup> month and significant improvement from 3<sup>rd</sup> month to 6<sup>th</sup> month. Our results were similar to Sauvageot, *et al.* [10] study in 2017 in which femto-LASIK intragroup results showed significant reduction of corneal sensation after 3 months and after 6 months of the procedure.

Regarding corneal biomechanics, there was significant reduction in CH from  $10.48 \pm 1.26$  mmHg preoperatively to  $7.55 \pm 1.64$  mmHg 6 months after femto-LASIK, and there was significant reduction in CRF from  $11.21 \pm 1.26$  mmHg preoperatively to  $6.66 \pm 1.14$  mmHg 6 months after femto-LASIK. Our results were similar to Hamilton, *et al.* [11] results in 2008 in femto-LASIK group results which showed significant reduction in CH from  $10.7 \pm 1.3$  mmHg preoperatively to  $8.8 \pm 1.3$  mmHg postoperatively, and significant reduction in CRF from  $11.1 \pm 1.3$  mmHg preoperatively to  $7.6 \pm 1.3$  mmHg postoperatively.

In the SMILE group, preoperative best corrected VA was  $0.99 \pm 0.07$  and uncorrected VA at 6<sup>th</sup> postoperative month was  $1.00 \pm 0.08$ . This denotes the efficacy of SMILE procedure. Uncorrected VA at 1<sup>st</sup> month was  $0.98 \pm 0.09$ , and uncorrected VA at 6<sup>th</sup> month was  $1.00 \pm 0.08$ . This denotes stability of results of the procedure. No eye lost line in best corrected VA denoting safety of the procedure. Our results were similar to Ağca, *et al.* [12] study in 2014 that reported postoperative uncorrected VA at 1 year in SMILE group  $0.95 \pm 0.06$ . Mean best corrected VA didn't change significantly from preoperative to postoperative values and no eyes lost line in best corrected VA.

Spherical equivalent in SMILE group was reduced from  $-5.67 \pm 2.59$  D. preoperatively to  $-0.21 \pm 0.32$  D. at 6<sup>th</sup> month. There was no significant change in spherical equivalent from 1<sup>st</sup> month to 6<sup>th</sup> month denoting stability of results. All treated eyes were within  $\pm 1.00$  D.

and 26 of the 30 treated eyes were within  $\pm 0.50$  D. of the intended correction at 6<sup>th</sup> month. Spherical error also was reduced from  $-5.03 \pm 2.56$  D. preoperatively to  $0.12 \pm 0.41$  D. at 6<sup>th</sup> month. The results were stable with no significant change from 1<sup>st</sup> month to 6<sup>th</sup> month. Cylindrical error was reduced from  $-1.27 \pm 1.05$  D. preoperatively to  $-0.67 \pm 0.57$  D. at 6<sup>th</sup> month. The results were also stable with no significant change from 1<sup>st</sup> month to 6<sup>th</sup> month. Our results were similar to Moshirfar, *et al.* [13] results in 2018 regarding improvement of spherical equivalent from  $-5.16 \pm 1.34$  D. preoperatively to  $-0.26 \pm 0.53$  D. at 6 months postoperatively. With regards to predictability, the intended target refraction was within  $\pm 0.5$  D. and  $\pm 1.00$  D. in 80% and 93% of cases in their study. Regarding spherical error, they proved improvement from  $-5.05 \pm 1.32$  D. preoperatively to  $-0.01 \pm 0.58$  D. at 6 months postoperatively. Their results in cylindrical error showed induction of astigmatism with increased cylindrical error from  $-0.23 \pm 0.22$  preoperatively to  $-0.49 \pm 0.30$  postoperatively. They explained the induction of astigmatism according to current literature by lack of an automated cyclotorsion alignment in the Visumax<sup>®</sup> platform that can correct for any unintentional movement of the head and body under the laser; and lack of an automated centration control in the Visumax<sup>®</sup> platform by which small misalignments can lead to slight decentration and may impact astigmatism. This difference from our results may be due to very low preoperative cylinder in their study group.

Significant reduction in TBUT was noticed after SMILE in 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month, also there was significant reduction in TBUT from 1<sup>st</sup> month to 3<sup>rd</sup> month, but there was significant improvement from 3<sup>rd</sup> to 6<sup>th</sup> month. Schirmer test results also showed significant reduction in 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month, but there was significant improvement from 1<sup>st</sup> month to 3<sup>rd</sup> month. Our results were similar to Zhang and Wang [14] study in 2017 which showed that TBUT significantly decreased at both 1 and 6 months when compared with preoperative values, but our results were not similar to the same study regarding Schirmer test values as they reported that Schirmer test results significantly decreased by 1 month and recovered near to baseline at 6 months. This difference may be due to different racial groups as this study was conducted in China and our study was conducted in Egypt where trachoma is endemic and it results in altered tear secretion.

Corneal sensation was significantly reduced after SMILE from  $5.73 \pm 0.25$  cm preoperatively to  $4.63 \pm 0.65$  cm at 1<sup>st</sup> month,  $5.24 \pm 0.54$  cm at 3<sup>rd</sup> month and  $5.53 \pm 0.38$  cm at 6<sup>th</sup> month. There was significant improvement in corneal sensation from 1<sup>st</sup> month to 3<sup>rd</sup> month and significant improvement from 3<sup>rd</sup> month to 6<sup>th</sup> month. Our results were similar to Demirok, *et al.* [15] study in 2013 that showed significant reduction in central corneal sensation from  $5.68 \pm 0.47$  cm preoperatively to  $4.53 \pm 0.11$  cm at 1 month,  $4.93 \pm 0.99$  cm at 3 months and  $5.59 \pm 0.49$  cm at 6 months after SMILE.

Regarding corneal biomechanics, there was significant reduction in corneal hysteresis from  $11.84 \pm 1.35$  mmHg preoperatively to  $9.02 \pm 1.32$  mmHg 6 months after SMILE, and there was significant reduction in corneal resistance factor from  $11.70 \pm 0.77$  mmHg preoperatively to  $8.25 \pm 1.74$  mmHg 6 months after SMILE. Our results were comparable to Chen, *et al.* [16] results in 2016 in SMILE group that showed significant reduction of corneal hysteresis from  $10.4 \pm 1.7$  mmHg preoperatively to  $8.3 \pm 1.2$  mmHg postoperatively and significant reduction of corneal resistance factor from  $11.0 \pm 1.7$  mmHg preoperatively to  $7.0 \pm 1.2$  mmHg postoperatively.

Regarding comparison between both groups, our study showed no significant difference between both groups regarding visual acuity at 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month. This proves excellent and comparable effectiveness and stability of visual acuity of both techniques. Our results were similar to Liu, *et al.* [17] study in 2016 that showed no significant difference between SMILE group and FS-LASIK group in postoperative visual acuity at 1 month, 3 months and 6 months.

No significant difference was reported in our results between both techniques regarding correction of spherical equivalent and spherical error at 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month, but it showed superiority of femto-LASIK over SMILE in correcting cylindrical error with significant difference at all postoperative follow ups.

Our results were comparable to Liu, *et al.* [17] study in 2016 regarding correction of spherical error and spherical equivalent that showed absence of significant difference in manifest refraction between FS-LASIK group and SMILE group at all time points. Their results

regarding astigmatic correction were not comparable to our results as they reported that there were no significant differences between the SMILE and FS-LASIK surgeries in all parameters regarding refractive astigmatism. This difference may be due to difference in preoperative cylinder ( $-0.68 \pm 0.69$  D. in their study compared to  $-1.27 \pm 1.05$  D. in our study). Our results were comparable to Khalifa., *et al.* [18] study in 2017 that reported comparable predictability in correcting spherical error between FS-LASIK and SMILE, but the magnitude of postoperative manifest cylinder was significantly lower in the FS-LASIK group than in the SMILE group.

On comparing both groups for dry eye parameters, longer TBUT was seen in SMILE group more than femto-LASIK group at 1<sup>st</sup> month, but there was no significant difference between both groups at 3<sup>rd</sup> and 6<sup>th</sup> months. TBUT is used to assess tear stability. Schirmer test results showed no significant difference between both groups at all time points. Schirmer test is used to assess tear secretion function. These results prove superiority of SMILE group regarding dry eye in early postoperative period, but later this superiority disappears and both techniques become equal. Our results were comparable to Gao., *et al.* [19] in 2014 that showed a quicker TBUT recovery in SMILE than in FS-LASIK patients. The tear stability of SMILE patients was found to be superior to that of FS-LASIK patients at 1 month and 3 months postoperatively. Tear secretion of two groups assessed by Schirmer test was not significantly different at any follow-up time points.

Corneal sensation was significantly higher in SMILE group than femto-LASIK group at 1<sup>st</sup> month and 3<sup>rd</sup> month, but there was no significant difference between both groups at 6<sup>th</sup> month. This proves earlier recovery of corneal sensation after SMILE procedure than femto-LASIK procedure which is explained by absence of flap lifting in SMILE procedure so preserving more corneal nerves in the superficial stroma. Our results were comparable to Wei., *et al.* [20] study in 2013 and Gao., *et al.* [19] study in 2014 that reported better corneal sensation in SMILE group than FS-LASIK group at 1 month and 3 months which was the end of follow-up period.

On comparing biomechanical changes, our results showed that CH and CRF were significantly higher in SMILE group than femto-LASIK group at 6 months postoperatively. This proves higher biomechanical strength after SMILE than after femto-LASIK. This can be explained by flap creation resulting in cutting the collagen lamellae in the anterior stroma which is the most condensed part of stroma. Alternatively in SMILE, the lenticule is extracted through a small wound preserving structural integrity of the anterior stroma. Our results were comparable to Wu., *et al.* [21] study in 2014 that showed that both corneal hysteresis and corneal resistance factor were significantly higher in SMILE group than FS-LASIK group 6 months postoperatively.

## Conclusion

We concluded that both techniques are safe and efficient. Femto-LASIK is more efficient in correcting cylindrical error. SMILE is better in early postoperative dry eye, corneal sensation and in corneal biomechanics.

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