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CORNEAL BIOMECHANICAL CHANGES POST-FLAPLESS FEMTO REFRACTIVE PROCEDURE VS FEMTO-LASIK IN MYOPIC EYES

By

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ABSTRACT

Background: Refractive errors are the most common ocular problem affecting all age groups. They are considered a public health challenge. Recent studies and WHO reports indicate that refractive errors are the first cause of visual impairment and the second cause of visual loss worldwide as 43% of visual impairments are attributed to refractive errors.

Objective: To evaluate and compare corneal deformation amplitude in patients prior to and following small incision lenticule extraction (SMILE), and femtosecond laser in situ keratomileusis (Femto-LASIK) using non-contact-tonometer with visualization, and measurement of the corneal deformation response to an air pulse with an ultra-high-speed scheimpflug camera (Corvis®ST).

Patients and Methods: The present study included 40 eyes of 20 patients randomly selected from outpatient clinic of Al-Azhar University Hospital and International Femto-Lasik Center from November 2018 till January 2021, divided into 2 equal groups: Group (1) for patients undergoing small incision lenticule extraction (SMILE), and Group (2) for patients undergoing Femtosecond laser in situ keratomileusis (Femto-LASIK).

Results: There was a highly statistically significant difference between pre-operative, post-operative 1 month, and Post-operative 3months regarding CCT (µm), MRSE (D), DA (mm), IOPg(mmHg), A1 length (mm), A2 length (mm), A1 time (ms), A2 time (ms), HC Time (ms), HC radius (mm), and Peak distance (mm) in Femto-LASIK, while there was a highly statistically significant difference found between pre-operative, post-operative 1 month, and post-operative 3 months regarding CCT (µm), MRSE (D), DA (mm), IOPg (mmHg), A1 length (mm), A2 length (mm), A1 time (ms), A2 time (ms), HC time (ms), HC radius (mm), and peak distance (mm) in SMILE.

Conclusion: Both Femto-LASIK, and SMILE substantially decreased the corneal biomechanical properties with less reduction in the SMILE group. SMILE was more effective, safe, and predictable manner as Fs-LASIK with better outcomes.

Keywords: Femto Refractive Procedure, Femto-LASIK, Myopic Eyes.

INTRODUCTION

Different refractive procedures are used to correct different refractive errors such as photorefractive keratectomy (PRK), laser assisted in situ keratomileusis (LASIK), Femtosecond Laser LASIK, and Small-incision lenticule extraction (SMILE) *(Ramirez-Miranda et al., 2013).*

Femtosecond Laser LASIK Procedure uses femtosecond laser system to create a 110 µm thickness, 7.9~8.0 mm diameters, standard 90° hinges, and 90° side-cut angles flap. Stromal tissue ablation was performed with excimer laser system *(Pajic et al., 2014).*

Small-incision lenticule extraction (SMILE) is used to treat myopia, with or without astigmatism. is relatively a new photo refractive procedure, was introduced as a third-generation laser refractive surgery procedure. The flap creation, and epithelial stripping was eliminated, and replaced with creation of a corneal pocket, achieving the desired refractive correction by creating an intra-stromal lenticule with a femtosecond laser, and removing the lenticule thereafter by a small incision made at the limbus 2-4 mm in width *(Reinstein et al., 2014).*

Corneal biomechanics is a branch of science that studies deformation, and equilibrium of corneal tissue under the application of any force. The structure, and hence the properties of a soft tissue, such as the cornea, are dependent on the biochemical, and physical nature of the components present, and their relative amounts. The mechanical properties of a tissue depend on how the fibers, cells, and ground substance are organized into a structure. Collagen, and elastin are responsible for the strength, and elasticity of a tissue, while the ground substance is responsible for the viscoelastic properties *(Nery et al., 2014).*

Two main corneal biomechanics are measured, Corneal Hysteresis (CH), and corneal resistance factor (CRF). CH represents the corneal absorption ability against external energy, while the CRF is an indicator of the total reaction of the cornea, incorporating corneal elastic resistance. Both CH, and the CRF, as inherent attributes of the cornea, can be used in the diagnosis of keratoconus *(Nery et al., 2014).*

The Corvis ST (CST) (Corneal Visualization Scheimpflug Technology, Oculus, Wetzlar, Germany) is a tool for measuring IOP, and corneal biomechanics. This device captures sequential horizontal Scheimpflug images using a high-speed camera during corneal deformation in response to a metered air puff. The machine takes more than 4300 frames per second with a fixed maximal internal pump pressure of 25 kpa *(Hong et al., 2013).*

The aim of this study was to evaluate, and compare corneal deformation amplitude in patients prior to, and following small incision lenticule extraction (SMILE), and femtosecond laser in situ keratomileusis (Femto-LASIK) using non-contact-tonometer with visualization, and measurement of the corneal deformation response to an air pulse with an ultra-high-speed scheimpflug camera (Corvis®ST).

PATIENTS AND METHODS

An interventional study was conducted on 40 eyes of 20 patients at Al-Azhar University Hospital, and International Femto-Lasik Center from November 2018 till January 2021. A written consent was taken from each patient.

As well as the permission of the ethical committee

Our study included 2 equal groups:

- **Group (1)** for patients undergoing small incision lenticule extraction (SMILE (
- **Group (2)** for patients undergoing femtosecond laser in situ keratomileusis (Femto-LASIK).

Inclusion Criteria:

- Myopic sphere range from -3.00 to-8.00 diopters (D), and myopic astigmatism range up to -2.00 (D) cylinder.
- Age group from 18 to 40 years old.
- Pre-operative central corneal thickness from 520 microns to 550 microns.

Exclusion Criteria:

- Patients not fulfilling the above criteria.
- Any other previous ophthalmic surgical interference.
- Keratoconus patient.
- Keratoconus suspect.
- Corneal opacity of any kind.
- Nursing or pregnant patients.
- Age over 40
- Background systemic diseases such as diabetes mellitus - collagen vascular disease.
- Severe dryness.

Systematic random sampling technique was used.

All patients were subjected to the following:

- Personal history: age, sex, presence of parental consanguinity, ethnicity.
- Objective refraction using automated refracto-meter
- Pentacam
- Corvis®ST.
- Corneal deformation amplitude prior to, and 3 months after corneal deformation using Corvis®ST. Preoperative corneal hysteresis was correlated with age, and preoperative central corneal thickness (CCT). Postoperative corneal hysteresis was correlated with postoperative CCT in both treatment groups. The correlations between postoperative change in hysteresis, and stromal ablation/removal depth, percentage of tissue ablated/removed, optical zone, and patient age.

Surgical technique:

All surgical procedures were performed by the same surgeon. After routine irrigation of the conjunctival sac, and periocular sterilization, topical anesthesia was applied with 2 to 3 drops of oxybuprocaine hydrochloride (Benox) twice before surgery, 5 minutes apart. In the SMILE group, the femtosecond laser system (VisuMax; Carl Zeiss Meditec AG, Germany) with a repetition rate of 500 kHz, and pulse energy of 115 to 130 nJ was used for the entire procedure. In the FEMTO LASEK group the corneal flap was made by IntraLase iFS 150 kHz (Advanced Medical Optics Inc, Santa Ana, CA) with a 9mm superior hinge, and 100-µm depth. Excimer photoablation (Allegretto 500, Alcon Laboratories, Fort Worth, TX) was performed for a 6.5 mm optical zone. An eye drops with 0, 3% tobramycin/0, 1% dexamethasone suspension (Tobradex®, Alcon

Laboratories) was administered 3 times a day for one week, and sodium hyaluronate 0.1% preservative free eye drops (Hylocomod, BrillPharma laboratories) was administered 5 times a day for 1 month. In both groups, preservative free artificial tears were then administered when needed. Briefly, for the eyes in the SMILE group, the corneal cap thickness was 110 mm, and the diameter was 7.2 mm. The diameter of the lenticule was 6.2 mm, the side-cut angles were all 90 degrees, and the spot distance was 2.0 mm. The femtosecond laser was activated for photodissection of the lenticule in the correct sequence, at the posterior surface of the lenticule, the edge, the anterior surface of the lenticule, and the incision. An incision with 2 to 5 mm width was made at the 12 o'clock position of the edge of the corneal cap. A basement of 10 to 15 mm for the lenticule was set to remove the lenticule successfully. After surgery, patients received prophylactic antibiotic treatment with 0.3% topical ofloxacin (Tarivid; Santen, Inc) applied 4 times daily for 1 or 2 days, and anti-inflammatory treatment with 0.1% fluorometholone (Flumetholon; Santen, Inc) applied 4 times daily for 2 weeks, which was then decreased to 1 time every 2 weeks.

CST:

The CST was used to measure the first applanation (A1) time, highest concavity (HC) time, second applanation (A2) time, A1, and A2 lengths, HC radius of curvature, peak distances, and deformation amplitude [Table 1] *(Ahmed et al., 2019).*

DA *(mm)*	Deformation amplitude
Radius *(mm)*	Radius of curvature at the time of highest concavity
A_1 length *(mm)*	Length of flattened cornea at the first applanation
A_2 length *(mm)*	Length of flattened cornea at the second applanation
A_1 velocity *(m/s)*	Speed of the corneal apex at the first applanation
A_2 velocity *(m/s)*	Speed of the corneal apex at the second applanation
Peak distance *(mm)*	Distance between the two apex of the cornea at the time of highest concavity
A_1 time *(ms)*	Time form starting until the first applanation
A_2 time *(ms)*	Time form starting until the second applanation
HC time *(ms)*	Time from starting until the highest concavity of cornea is reached
Pachy *(μm)*	Central corneal thickness

A1: First Applanation, A2: Second Applanation, DA: Deformation amplitude, HC: Highest Concavity.

Statistical analysis:

Data were collected, revised, coded, and entered to the Statistical Package for Social Science (IBM SPSS) version 20. The qualitative data were presented as number, and percentages while quantitative data were presented as mean, standard deviations, and ranges.

The comparisons between two groups with qualitative data were done by using Chi-square test.

The comparison between two independent groups with quantitative data, and parametric distribution was done by using Independent t-test or Mann-Whitney U test.

The comparison between paired groups with quantitative data, and parametric distribution were done by using Repeated measures ANOVA.

The confidence interval was set to 95%, and the margin of error accepted was set to 5%. So, the p-value was considered significant when P< 0.05.

RESULTS

There was no statistically significant difference found between two groups regarding age, and sex. **(Table 1)**.

Table (1): Comparison between Femto-LASIK, and SMILE Regarding Age, and Sex

		Femto-LASIK	**SMILE**	**P-value**
		No.= 20	**No.= 20**	
Age	Mean ± SD	28.1 ± 2.90	29.3 ± 2.95	>0.05
	Range	18 – 38	20 – 40	
Sex	Male	8 (40.0%)	9 (45.0%)	>0.05
	Female	12 (60.0%)	11 (55.0%)	

There was no statistically significant difference found between two groups regarding CCT (µm) Pre, CCT (µm) Post 1 months, and CCT (µm) Post 3 months. There was no statistically significant difference found between two groups regarding MRSE (D) Pre, MRSE (D) Post 1 months, and MRSE (D) Post 3 months. There was no statistically significant difference found between two groups regarding Ablation depth / lenticule thickness (µm), and Ablation depth / lenticule thickness (%). **(Table 2)**.

Table (1): Comparison between Femto-LASIK, and SMILE Regarding CCT (μm) and MRSE (D) Pre, Post 1 months, and Post 3 Months & Ablation depth / lenticule thickness (μm), and Ablation depth / lenticule thickness (%)

Parameters / Groups		Femto-LASIK No.= 20	SMILE No.= 20	P-value
CCT (μm)				
Pre	Mean ± SD	520.58 ± 31.49	528.14 ± 18.89	>0.05
	Range	506 – 567	513 – 603	
Post 1 months	Mean ± SD	488.84 ± 14.66	492 ± 18.3	>0.05
	Range	448 – 523	452 – 517	
Post 3 months	Mean ± SD	466.12 ± 11.52	470.58 ± 12.7	>0.05
	Range	440 – 520	450 – 500	
MRSE (D)				
Pre	Mean ± SD	-4.45 ± 0.09	-4.44 ± 0.1	>0.05
	Range	-4 – -7.75	-5.49 – 1.5	
Post 1 months	Mean ± SD	-2.99 ± 0.01	-3.01 ± 0.09	>0.05
	Range	-2 – --5.88	-3.49 – 0.99	
Post 3 months	Mean ± SD	0.1 ± 0.74	0.3 ± 0.8	>0.05
	Range	-0.5 – 0.75	-0.75 – 1	
Ablation depth / lenticule thickness (μm)	Mean ± SD	70.2 ± 22.3	73.1 ± 19.2	>0.05
	Range	41 – 89	52 – 98	
Ablation depth / lenticule thickness (%)	Mean ± SD	17.1 ± 4.2	18.9 ± 3.8	>0.05
	Range	7.1 – 23.3	7.4 – 24.8	

There was no statistically significant difference found between two groups regarding A1 length (mm) Pre, A1 length (mm) Post 1 months, and A1 length (mm) Post 3 months, regarding DA (mm) Pre, DA (mm) Post 1 months, and DA (mm) Post 3 months, regarding IOPg (mmHg) Pre, IOPg (mmHg) Post 1 months, and IOPg (mmHg) Post 3 months, regarding A2 length (mm) Pre, A2 length (mm) Post 1 months, and A2 length (mm) Post 3 months, regarding A1 time (ms) Pre, A1 time (ms) Post 1 months, and A1 time (ms) Post 3 months, regarding A2 time (ms) Pre, A2 time (ms) Post 1 months, and A2 time (ms) Post 3 months, regarding HC Time (ms) Pre, HC Time (ms) Post 1 months, and HC Time (ms) Post 3 months, regarding HC radius (mm) Pre, HC radius (mm) Post 1 months, and HC radius (mm) Post 3 months and regarding Peak distance (mm) Pre, Peak distance (mm) Post 1 months, and Peak distance (mm) Post 3 months. **(Table 3)**.

Table (2): Comparison between Femto-LASIK, and SMILE Pre, Post 1 months, and Post 3 Months

Parameters	Groups	Femto-LASIK No.= 20	SMILE No.= 20	P-value
DA (mm)				
Pre	Mean ± SD	0.99 ± 0.12	1.01 ± 0.06	>0.05
	Range	1.05 – 0.08	1.04 – 0.11	
Post 1 months	Mean ± SD	1.23 ± 0.9	1.12 ± 0.09	>0.05
	Range	1.11 – 0.17	0.99 – 1.30	
Post 3 months	Mean ± SD	1.42± 0.33	1.33 ± 0.03	>0.05
	Range	1.15 – 0.15	1.02 – 1.33	
IOPg (mmHg)				
Pre	Mean ± SD	15.99 ± 3.50	15.64 ± 2.04	>0.05
	Range	8.9 – 20	9.1 – 21	
Post 1 months	Mean ± SD	11.81 ± 1.89	11.66 ± 2.05	>0.05
	Range	8.0 – 18.1	8.7 – 18.5	
Post 3 months	Mean ± SD	9.33 ± 1.12	8.99 ± 2.5	>0.05
	Range	7.5 – 17.9	7.9 – 16.5	
A1 length (mm)				
Pre	Mean ± SD	1.78 ± 0.21	1.88 ± 0.22	>0.05
	Range	1.53 – 2.55	1.58 – 2.56	
Post 1 months	Mean ± SD	1.53 ± 0.11	1.60 ± 0.18	>0.05
	Range	1.88 – 2.77	0.31 – 1.83	
Post 3 months	Mean ± SD	1.36 ± 0.9	1.49 ± 0.10	>0.05
	Range	1.2 – 2.1	0.21 – 1.70	
A2 length (mm)				
Pre	Mean ± SD	1.90 ± 0.83	1.87 ± 0.48	>0.05
	Range	1.40 – 2.2	1.44 – 2.28	
Post 1 months	Mean ± SD	1.46 ± 0.53	1.49 ± 0.36	>0.05
	Range	1.37 – 2.0	1.41 – 2.21	
Post 3 months	Mean ± SD	1.35 ± 0.43	1.29 ± 0.25	>0.05
	Range	1.3 – 2.1	1.39 – 2.19	
A1 time (ms)				
Pre	Mean ± SD	6.48 ± 0.30	6.65 ± 0.39	>0.05
	Range	7.3 – 9.1	7.1 – 9.2	
Post 1 months	Mean ± SD	6.22 ± 0.31	6.25 ± 0.13	>0.05
	Range	6.7 – 8.7	6.9 – 8.9	
Post 3 months	Mean ± SD	5.99 ± 0.29	6.10 ± 0.9	>0.05
	Range	6.7 – 8.7	6.6 – 9.28.6	
A2 time (ms)				
Pre	Mean ± SD	20.99 ± 0.39	20.81 ± 0.60	>0.05
	Range	21.1 – 24.3	21.1 – 23.8	
Post 1 months	Mean ± SD	19.93 ± 0.32	19.89 ± 0.55	>0.05
	Range	19.2 – 24.1	20.6 – 23.8	
Post 3 months	Mean ± SD	19.88 ± 0.33	19.65 ± 0.48	>0.05
	Range	17.8 – 24.0	19.9 – 23.6	
HC Time (ms)				
Pre	Mean ± SD	16.63 ± 0.93	16.82 ± 1.15	>0.05
	Range	16.1 – 19.3	16.7 – 19.9	
Post 1 months	Mean ± SD	15.98 ± 0.88	16.10 ± 1.03	>0.05
	Range	14.8 – 18.8	15.9 – 19.3	
Post 3 months	Mean ± SD	15.88 ± 0.78	15.99 ± 0.99	>0.05
	Range	13.9 – 18.3	15.1 – 19.0	
HC radius (mm)				
Pre	Mean ± SD	9.88 ± 1.21	9.63 ± 0.82	>0.05
	Range	6.87 – 11.01	6.81 – 12.0	
Post 1 months	Mean ± SD	8.99 ± 0.77	8.55 ± 0.80	>0.05
	Range	5.9 – 10.22	5.7 – 10.4	
Post 3 months	Mean ± SD	9.01 ± 0.70	8.54 ± 0.79	>0.05
	Range	4.9 – 9.83	4.99 – 8.0	
Peak distance (mm)				
Pre	Mean ± SD	3.42 ± 0.74	3.55 ± 0.74	>0.05
	Range	3.7 – 5.2	3.7 – 5.3	
Post 1 months	Mean ± SD	4.19 ± 0.53	4.22 ± 0.83	>0.05
	Range	4.1 – 5.8	4.3 – 6.1	
Post 3 months	Mean ± SD	4.88 ± 0.50	4.98 ± 0.96	>0.05
	Range	4.0 – 6.1	4.8 – 6.5	

there was a highly statistically significant difference found between Pre, Post 1 months, and Post 3 months regarding CCT (µm), MRSE (D), DA (mm), IOPg(mmHg), A1 length (mm), A2 length (mm), A1 time (ms), A2 time (ms), HC Time (ms), HC radius (mm), and Peak distance (mm) in Femto-LASIK. **(Table 4)**.

Table (3): Comparison between Pre, Post 1 months, and Post 3 months Regarding CCT (µm), MRSE (D), DA (mm), IOPg(mmHg), A1 length (mm), A2 length (mm), A1 time (ms), A2 time (ms), HCC Time (ms), HC radius (mm), and Peak distance (mm) in Femto-LASIK

Femto-LASIK		Pre	Post 1 months	Post 3 months	P-value
CCT (µm)	Mean ± SD	520.58 ± 31.49	488.84 ± 14.66	466.12 ± 11.52	<0.001
	Range	506 – 567	448 – 523	440 – 520	
MRSE (D)	Mean ± SD	-4.45 ± 0.09	-2.99 ± 0.01	0.1 ± 0.74	<0.001
	Range	-4 – -7.75	-2 – --5.88	-0.5 – 0.75	
DA (mm)	Mean ± SD	0.99 ± 0.12	1.23 ± 0.9	1.42± 0.33	0.034
	Range	1.05 – 0.08	1.11 – 0.17	1.15 – 0.15	
IOPg(mmHg)	Mean ± SD	15.99 ± 3.50	11.81 ± 1.89	9.33 ± 1.12	<0.001
	Range	8.9 – 20	8.0 – 18.1	7.5 – 17.9	
A1 length (mm)	Mean ± SD	1.78 ± 0.21	1.53 ± 0.11	1.36 ± 0.9	0.043
	Range	1.53 – 2.55	1.88 – 2.77	1.2 – 2.1	
A2 length (mm)	Mean ± SD	1.88 ± 0.83	1.46 ± 0.53	1.35 ± 0.43	0.010
	Range	1.40 – 2.2	1.37 – 2.0	1.3 – 2.1	
A1 time (ms)	Mean ± SD	6.48 ± 0.30	6.22 ± 0.31	5.99 ± 0.29	<0.001
	Range	7.3 – 9.1	6.7 – 8.7	6.7 – 8.7	
A2 time (ms)	Mean ± SD	20.99 ± 0.39	19.93 ± 0.32	19.88 ± 0.33	<0.001
	Range	21.1 – 24.3	19.2 – 24.1	17.8 – 24.0	
HC Time (ms)	Mean ± SD	16.63 ± 0.93	15.98 ± 0.88	15.88 ± 0.78	0.011
	Range	16.1 – 19.3	14.8 – 18.8	13.9 – 18.3	
HC radius (mm)	Mean ± SD	9.88 ± 1.21	8.99 ± 0.77	9.01 ± 0.70	0.004
	Range	6.87 – 11.01	5.9 – 10.22	4.9 – 9.83	
Peak distance (mm)	Mean ± SD	3.42 ± 0.74	4.19 ± 0.53	4.88 ± 0.50	<0.001
	Range	3.7 – 5.2	4.1 – 5.8	4.0 – 6.1	

There was a highly statistically significant difference found between Pre, Post 1 months, and Post 3 months regarding CCT (µm), MRSE (D), DA (mm), IOPg(mmHg), A1 length (mm), A2 length (mm), A1 time (ms), A2 time (ms), HC Time (ms), HC radius (mm), and Peak distance (mm) in SMILE. **(Table 5)**.

Table (4): Comparison between Pre, Post 1 months, and Post 3 months Regarding CCT (µm), MRSE (D), DA (mm), IOPg(mmHg), A1 length (mm), A2 length (mm), A1 time (ms), A2 time (ms), HCC Time (ms), HC radius (mm), and Peak distance (mm) in SMILE

SMILE		Pre	Post 1 months	Post 3 months	P-value
CCT (µm)	Mean ± SD	528.14 ± 18.89	492 ± 18.3	470.58 ± 12.7	<0.001
	Range	513 – 603	452 – 517	450 – 500	
MRSE (D)	Mean ± SD	-4.44 ± 0.1	-3.01 ± 0.09	0.3 ± 0.8	<0.001
	Range	-5.49 – 1.5	-3.49 – 0.99	-0.75 – 1	
DA (mm)	Mean ± SD	1.01 ± 0.06	1.12 ± 0.09	1.33 ± 0.03	<0.001
	Range	1.04 – 0.11	0.99 – 1.30	1.02 – 1.33	
IOPg(mmHg)	Mean ± SD	15.64 ± 2.04	11.66 ± 2.05	8.99 ± 2.5	<0.001
	Range	9.1 – 21	8.7 – 18.5	7.9 – 16.5	
A1 length (mm)	Mean ± SD	1.88 ± 0.22	1.60 ± 0.18	1.49 ± 0.10	<0.001
	Range	1.58 – 2.56	0.31 – 1.83	0.21 – 1.70	
A2 length (mm)	Mean ± SD	1.87 ± 0.48	1.49 ± 0.36	1.29 ± 0.25	<0.001
	Range	1.44 – 2.28	1.41 – 2.21	1.39 – 2.19	
A1 time (ms)	Mean ± SD	6.65 ± 0.39	6.25 ± 0.13	6.10 ± 0.9	<0.001
	Range	7.1 – 9.2	6.9 – 8.9	6.6 – 9.28.6	
A2 time (ms)	Mean ± SD	20.81 ± 0.60	19.89 ± 0.55	19.65 ± 0.48	<0.001
	Range	21.1 – 23.8	20.6 – 23.8	19.9 – 23.6	
HC Time (ms)	Mean ± SD	16.82 ± 1.15	16.10 ± 1.03	15.99 ± 0.99	0.033
	Range	16.7 – 19.9	15.9 – 19.3	15.1 – 19.0	
HC radius (mm)	Mean ± SD	9.63 ± 0.82	8.55 ± 0.80	8.54 ± 0.79	<0.001
	Range	6.81 – 12.0	5.7 – 10.4	4.99 – 8.0	
Peak distance (mm)	Mean ± SD	3.55 ± 0.74	4.22 ± 0.83	4.98 ± 0.96	<0.001
	Range	3.7 – 5.3	4.3 – 6.1	4.8 – 6.5	

DISCUSSION

Refractive surgery is one of the commonest "cosmetic" procedures performed worldwide to get rid of the glasses by altering the corneal curvature *(Bashir et al., 2017)*. With the passage of time, more, and more new treatment options are becoming available in the market to meet, and satisfy peoples' needs who want to have spectacular unaided vision *(Tetlock, 2017)*.

Worldwide, femtosecond Laser Assisted In-situ Keratomileusis (LASIK) is a well-known, and commonly used refractive technique, although Small Incision Lenticule Extraction (SMILE) has become increasingly popular since it was introduced in 2011 *(Damgaard et al., 2018)*.

In LASIK, a corneal flap is cut with a micro keratome or femtosecond laser, followed by thinning of the stromal bed with excimer laser ablation, and in SMILE, a minor intrastromal lenticule is cut with a femtosecond laser, and subsequently removed through a small incision, leaving the anterior, and strongest part of the cornea almost intact *(Reinstein et al., 2013)*.

Both LASIK, and SMILE require cutting of corneal lamellae that may reduce the biomechanical stability of the cornea, with the potential risk of corneal iatrogenic ectasia as a severe complication. However, SMILE preserves the anterior corneal integrity, and may, in theory, better preserve the corneal biomechanical strength than LASIK after surgery *(Guo et al., 2019).*

Our study aimed to describe, and compare the corneal biomechanical properties after Laser Assisted In-situ Keratomileusis (LASIK), and Small Incision Lenticule Extraction (SMILE).

The present study included 40 eyes of 20 patients randomly selected from outpatient clinic of Al-Azhar University Hospital, and International Femto-Lasik Center, divided into 2 equal groups. Group (1) for patients undergoing small incision lenticule extraction (SMILE), and Group(2) for patients undergoing Femtosecond laser in situ keratomileusis (Femto-LASIK).

In our study, the average age of the patients was 28.1 ± 2.90 years (range: 18–38) in group I, and 29.3 ± 2.95 years (range: 20–40) in group II, and females showed high percentages in the two groups (26%), and (27%) in group I, and group II respectively.

The average of preoperative MRSE was -4.45 ± 0.09 (range: −4.0 to −7.75) diopter in group I, and the average of preoperative MRSE was -4.44 ± 0.1 (range: -5.49 – 1.5) diopter in group II.

The average preoperative central cornea thickness was 520.58 ± 31.49 (range: 506–567) µm in group I, and the average preoperative central cornea thickness was 528.14 ± 18.89 (range: 513–603) µm in group II, and the average tissue ablated was 70.2 ± 22.3 (range: 41–89) µm in group I, and the average lenticule thickness was 73.1 ± 19.2 (range: 52–98) µm in group II. The preoperative values of deformation amplitude were within normal ranges in all patients.

The CST showed no significant difference between the preoperative, and postoperative IOP in both groups, with the postoperative IOP being lower than the preoperative value, supporting findings in other studies by *Pedersen et al. (2014)* and *Shen et al. (2014).*

Our study showed that the average of DA (mm) in SMILE group was 0.99 ± 0.12 while in Femto-LASIK was 1.01 ± 0.06 with no statistically significant difference.

In contrast to our study, deformation amplitude by *Ahmed et al. (2019)* showed a significant increase from preoperative to postoperative values in both groups, and there was a nearly two-fold increase in the mean percentage of change of the deformation amplitude in the LASIK group, denoting much lower biomechanical change which also different from another study by *Osman et al. (2016)* who found a five-fold increase in the LASIK group).

In our study, the average of A1 time (ms) in SMILE group was 6.65 ± 0.39, and then decreased to 6.48 ± 0.30 in Femto-LASIK group which also showed no statistically significant difference with P-value = 0.131. Also, in this study the average of A2 time (ms) in SMILE group was 20.81 ± 0.60, and then increased to 20.99 ± 0.39 in Femto-LASIK group but with no statistically significant difference with P-value = 0.268, and the average of A1 length (mm) in SMILE group was 1.88 ± 0.22, and then decreased to 1.78 ± 0.21 in Femto-LASIK group, and also showed no statistically significant difference, and the average of A2 length (mm) in SMILE group was 1.67 ± 0.48, and then decreased to 1.66 ± 0.83 in Femto-LASIK group but with no significant difference.

The A1, and A2 lengths showed no significant postoperative decrease in both groups I, and II by *Ahmed et al. (2019)* who supports our results, and these results were consistent with *Pedersen et al. (2014)* and *Shen et al. (2014)* studies.

Shen et al. (2014) were the first to retrospectively report the biomechanical outcomes after Femto-LASIK, and SMILE using the Corvis ST as they found no significant differences in any of the evaluated parameters three months after surgery. However, only the postoperative values were described, whereas a comparison of the average change due to surgery would provide more information about the biomechanical impact following Femto-LASIK, and SMILE.

Both groups post-operatively had no significant change as regard the IOPcc, and significant change as regard the IOP by the CST, and that agrees with *Osman et al. (2016)*. This finding indicates that the ORA device does not completely compensate for the biomechanical properties of the cornea when measuring IOP. Also, IOP in all forms especially non-contact is largely dependent on corneal thickness. There is no statistically significant difference between the two groups either pre- or postoperatively.

Sefat et al. (2015) also reported similar biomechanical responses after LASIK, and SMILE with the Corvis ST in a subgroup matched for age, preoperative CCT, IOP, preoperative spherical equivalent, and CCT.

Osman et al. (2016) calculated, and compared the percentage of change in preoperative and postoperative measurements in a comparative study of 25 LASIK-, and 25 SMILE-treated patients. The authors found significant less reduction in A1 time, HC time, and A2 time after SMILE than LASIK, which may reflect a less compliant cornea after the flap-free procedure. Furthermore, the percentage of increase in deformation amplitude during highest concavity was significantly larger in LASIK than SMILE, suggesting a more severe inward deformation during the air pulse after LASIK, possibly due to a more compliant cornea.

When comparing the mean percentage of change of corneal biomechanics between both groups, we found significant difference regarding the CH, and CRF with greater reduction of the corneal biomechanics in the LASIK group *(Osman et al., 2016).*

Hence, a retrospective study by *Pedersen et al. (2014)* examined only the variables with a coefficient of variation <10% including A1 deflection length, and HC deflection length, which were not standard parameters in the initial Corvis ST software. It has previously been questioned if the repeatability and reproducibility of the Corvis ST parameters available with the first software version were acceptable *(Lopes et al., 2017).* After adjusting for postoperative CCT, IOP, and age, only HC Time was significantly shorter in LASIK than SMILE, suggesting that a LASIK- treated corneas reached their highest concavity at an earlier stage.

The LASIK group showed a significant reduction regarding the mean percentage of change of almost all the biomechanical data except for the IOP by the CST, and the A1 length. Of greater interest was the nearly fivefold increase in the mean percentage of change of the deformation amplitude in the LASIK group denoting much lower biomechanical change. These differences in the biomechanical behavior between both groups in our study can be explained by three factors. First, the microkeratome creates a meniscus flap extending deeper in the peripheral stronger corneal layers thus severing more biomechanically vital collagen bundles. Second, is the differential healing pattern perhaps with more inflammation with the femto SMILE group resulting in stronger fibrotic scarring as stated in previous studies. Third, was the difference of the flap to cap diameters as flaps tended to be bigger than the transition zones in the LASIK group (more than 8.5 mm) while the usual cap diameter in the femto SMILE cases was usually less than 8 mm thus also salvaging cutting the stronger peripheral collagen bundles *(Osman et al., 2016)*.

There were several previous attempts to evaluate the corneal biomechanical changes after refractive surgeries. *Sefat et al. (2015)* evaluated the changes in human corneas after femtosecond laser-assisted LASIK, and SMILE using Corvis ST. Corneal biomechanical parameters measured preoperatively with Corvis ST showed significant differences postoperatively in total, and in both groups. In subgroup analysis with homogenous groups, FS-LASIK showed no significant changes in biomechanical data measured with Corvis ST compared with SMILE. Also, *Mastropasqua et al. (2014)* evaluated corneal biomechanical properties modification after SMILE using Scheimpflug-based noncontact tonometer. No significant modifications in biomechanical properties were observed after SMILE so this procedure could induce only minimal transient alterations of corneal biomechanics. While *Shen et al. (2014)* evaluated changes in corneal deformation parameters after lenticule creation and extraction during SMILE procedure. There was a significant change in corneal deformation parameters following SMILE procedure. They suggested that the changes may be caused predominantly by stromal lenticule extraction, while lenticule creation with femtosecond laser may not have an obvious effect on corneal deformation properties. The current study combined two different tools to compare the corneal mechanical stability of the novel SMILE procedure to the standard LASIK procedure. To our knowledge, this is one of the first studies that measures the corneal biomechanics using two different machines in the same study, and on the same patients thus adding to the strength of the comparison, and hence the strength of the study.

Finally, in our study, there was a highly statistically significant difference between pre-operative, post-operative 1 month, and post-operative 3 months regarding CCT (μm), MRSE (D), DA (mm), IOPg(mmHg), A1 length (mm), A2 length (mm), A1 time (ms), A2 time (ms), HC time (ms), HC radius (mm), and Peak distance (mm) in Femto-LASIK while there was a highly statistically significant difference found between pre-operative, post-operative 1 month, and postoperative 3 months regarding CCT (µm), MRSE (D), DA (mm), IOPg(mmHg), A1 length (mm), A2 length (mm), A1 time (ms), A2 time (ms), HC time (ms), HC radius (mm), and peak distance (mm) in SMILE.

CONCLUSION

Both Femto LASIK, and SMILE substantially decreased the corneal biomechanical properties with less reduction in the SMILE group. SMILE was more effective, safe, and predictable manner as Fs-LASIK with better outcomes.

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التغيرات الحيوية الميكانيكية للقرنية ما بعد عملية تصحيح أبصار بالفيمتو ليزر بدون رقعة والفيمتو ليزك لمرضي قصر النظر

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خلفية البحث: في تقنية الفيمتو ليزك يتم استخدام شعاع الليزر لعمل قطع عرضي غير كامل بسمك ١١٠ مايكرومتر وقطر ٨ ميلليمتر في نسيج القرنية ثم يتم رفع النسيج واستخدام (الاكزيمر) ليزر لتصحيح الابصار بعكس تقنية (الفيمتو سمايل) التي لا تحتاج لرفع نسيج وانما يتم اصلاح عيوب الابصار عن طريق تفصيل جزء من نسيج القرنية يتم استبعاده من خلال فتحه لا تتجاوز ٤ ميلليمتر.

الهدف من البحث: تقييم ومقارنة سعة تشوه القرنية في المرضى قبل وبعد عملية استخراج ذائدة نسيجية صغيرة الشق (فيمتو سمايل) والليزر الفيمتوسكند ليزك باستخدام جهاز قياس عدم الاتصال - Tonometer مع التصوير بكاميرا فائقة السرعة (شيمفلج) وقياس استجابة تشوه القرنية لنبضات هوائية (جهاز الكورفس)

المرضى وطرق البحث: تم عمل الدراسة علي ٤٠ عينا ل ٢٠ مريضا سيتم اختيارهم بطريقة عشوائية من عيادات جامعة الازهر والمركز الدولي للفيمتو-ليزك وتم تقسيمهم الي مجموعتين مجموعة للفيمتو سمايل ومجموعة للفيمتوليزك في كل مجموعة تم عمل فحص لميكانيكا القرنية قبل العملية وبعدها بثلاثة اشهر باستخدام جهاز (كورفس) وتم ربط قيم ميكانيكا القرنية بالعمر وكذلك بسمك القرنية قبل وبعد العملية.

نتائج البحث:

- لا يوجد تغيير كبير في القيم بالنسبه لمعامل مقاومة القرنية وتباطئ القرنية بعد العملية الجراحية في مجموعة سمايل.
- هناك فرق كبير بين المجموعتين فيما يتعلق بتغيير السعة المشوهة في القرنية
- لا يوجد فرق كبير بين المجموعات التي شملتها الدراسة فيما يتعلق مرات التطبيق بعد الجراحة.
- هناك تغيّر كبير في أوقات التطبيق في مجموعة سمايل.
- أن هناك تغيرًا كبيرًا في قيم أوقات ما بعد الجراحة في مجموعة فيمتوليزك.

الاستنتاج: قلل كل من Femto-LASIK و SMILE بشكل كبير من الخصائص الميكانيكية الحيوية للقرنية مع انخفاض أقل في مجموعة سمايل. كان SMILE أكثر فعالية وأمانًا ويمكن التنبؤ به مثل Fs-LASIK مع نتائج أفضل.

الكلمات الدالة: إجراء الفيمتو الانكساري، الفيمتو ليزك، قصر النظر.