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Corneal Biomechanical Properties after SMILE and Femto-LASIK Procedures (Comparative Study)

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ABSTRACT

Background: Small-incision lenticule extraction (SMILE) and femtosecond laser-assisted LASIK (FS-LASIK) are the most recent vision correction techniques. In SMILE procedures a stromal lentiform slice is designed by femtosecond laser then extracted manually. Theoretically SMILE safeguards the corneal biomechanics more than FS-LASIK due to its smaller incisions and reservation of anterior corneal stromal collagen.

Aim of The Work: To compare the corneal biomechanical changes induced by FS-LASIK and SMILE procedures using dynamic Scheimpflug imaging (Corvis-ST).

Patients and Methods: This was a prospective comparative observational study, with 80 eyes were included. 40 eyes were subjected to FS-LASIK procedures and 40 eyes were subjected to SMILE procedures. We analyzed the preoperative and the postoperative Corvis ST parameters for both groups over a period of one year in the IFLC in Cairo.

Results: The two studied groups were comparable in respect to the first and second applanation parameters showing no significant difference. Also, both groups were comparable in respect to changes in mean deformation, peak distance and radius after one year follow up.

Conclusion: Corneal biomechanical properties were substantially decreased after both procedures as regarding preoperative and postoperative data, with no significant difference between both groups.

Keywords: *SMILE; FS-LASIK; Corvis ST; corneal biomechanics.*

INTRODUCTION

The cornea is a dome-shaped, clear, avascular tissue that clearly focuses light rays on the retina, forming a protective and impermeable layer against infectious pathogens and mechanical damage. The cornea must be smooth and transparent and must have a constant arch surface for proper refraction. In contrast, strong and elastic components are needed to support intraocular pressure and maintain regenerative biological protection.[1]

Biomechanics is the study of mechanical laws determined by the structural elements of an organism or object. It helps to characterize function and understand the factors that affect pathophysiology. Corneal biomechanics study has been an interesting research matter and a focus of attention for many years. [2]

This has led to the development of several methods of measuring ex vivo and in vivo corneal biomechanics. Current technology includes an imaging system combined with a non-contact air-puff tonometer, as in the Corvis ST (Oculus Optikgerate GmbH, Germany) and Ocular Response Analyzer (ORA, Reichert Ophthalmic Instruments, Buffalo, NY). Further techniques include Brillouin spectroscopy and optical coherence elastography. [3]

The results of ORA may not directly explain the corneal mechanical behavior. Optical coherence tomography (OCT) or Scheimpflug imaging techniques can now directly measure corneal deformation. [4]

Corvis ST and ORA are non-contact devices, both based on the use of an air-puff system. However, the parameters determined by both devices cannot be compared to each other, and there are some differences. The maximum pressure of the air puff is variable in ORA (depending on P1) and constant in Corvis ST. Also Corvis ST gives much more information regarding corneal deformation than ORA. Lastly the main parameters of ORA are based on applanation pressures P1 and P2, but Corvis ST depends on the dynamic corneal response (DCR). [3]

The Corvis ST device takes 140 Scheimpflug images in a time of only 30 milliseconds (4,330 images per second). It focuses on the central corneal eight mm in a single horizontal meridian. It uses a 455 nm wavelength, UV-free blue LED. This device produces an air jet with a pressure up to 25 kilopascals. The cornea undergoes a well-characterized flattening cycle (applanation) until it is completely deformed, followed by a second flattening state to achieve a complete reformation. Immediately after the measurement, a quality score is available to assess the reliability of the measurement. The device is CE marked on all measurements, but can only be used in the United States to measure IOPs and CCTs. [5]

The common refractive surgeries nowadays include photorefractive keratectomy, laser-assisted in situ keratomileusis and SMILE. [6]

The femtosecond laser produces corneal flaps that are safer and more predictable in thickness than those produced by microkeratomes. In addition, flap adhesions are stronger and less susceptible to traum. Femtolasik also provides higher contrast sensitivity, less dry eye, and lower epithelial ingrowth rates. In addition, femtoseconds reduce the incidence of short flaps, buttonhole perforations, epithelial abrasions and blade marks. Although it is more likely to develop corneal haze, photosensitivity and rainbow glare after FS-LASIK. [7]

SMILE was approved by the U.S. Food and Drug Administration in 2016 for the correction of nearsightedness with or without astigmatism as a "flapless" refraction correction laser technology using a single femtosecond laser system. [8]

Utmost of the anterior stromal corneal lamellae are kept untouched in SMILE, it has been hypothesized that the biomechanical influence in SMILE is lower than in other laser vision correction procedures, implying that it may be secure for modulation of high refractive defects with a lower risk of ectasia. [9]

In this study, we evaluated and compared the biomechanical behavior of the cornea after SMILE and FS-LASIK procedures to check the theoretical advantage of SMILE over FS-LASIK.

PATIENTS AND METHODS

This was a prospective comparative observational study. The study was carried out on forty eyes underwent SMILE procedures and other forty eyes underwent Femto-LASIK procedure. The study was carried out in the International Femto-LASIK Center (New Cairo).

All patients provided written informed consent after the nature of the procedure was explained in addition to the benefits and possible risks explained.

Both groups were subjected to detailed clinical assessment including assessment of unaided and best aided visual acuity, manifest and after cycloplegic drops refraction, Slit-lamp biomicroscopy to assess anterior segment, ocular fundus examination, intraocular pressure measurement: obtained by the Corvis ST system (biomechanically corrected IOP), corneal topography with Pentacam system(Oculus gmbh, Wetzlar, Germany) and measuring corneal biomechanical parameters with the Corvis ST preoperatively and postoperatively (at day one, three months and one year after the procedure). All participants were informed about the indications & the hazards of the procedures and signed a written informed consent.

We included candidates who were 18 years old or older, any sex is accepted, patients who had myopia or compound myopic astigmatism excluding those with hypermetropia or mixed astigmatism. All patients had stable refraction in the previous 2 years and had normal corneal morphology with normal corneal tomography. Contact lenses wear was prevented at least 2 weeks before surgery.

We excluded those with any corneal disease or had a previous ocular operation, those who had Keratoconus or suspected keratoconus, patients with previous ocular trauma, patients developed post-operative complications, females had pregnancy or lactation at time of follow-up and patients who had systemic disorders as diabetes.

Surgical techniques:

Topical anesthesia:

Multiple drops of Benoxinate hydrochloride 0.4% were used.

FS-LASIK procedure:

a flap was generated using a VisuMax femtosecond laser (Carl Zeiss Meditec®, Germany), the flap thickness was 110 µm and its diameter ranged from 7.9 to 9.0 mm. After flap creation and elevation, photoablation correction was applied in a diameter of 5.8 to 6.9 optical zone with a MEL-80 Excimer laser (Carl Zeiss Meditec®, Germany); then the flap was repositioned.

SMILE Procedures: The VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Germany) was employed to design the corneal stromal lenticule, the laser pulse frequency was 500 kHz and pulse energy ranged from 130 to 160 nJ. The cap thickness designed to be between 110 and 120 µm, the diameter of the lenticule varied from 6.0 to 7.0 mm, and the corneal cap diameter designed to be 1.0 mm larger than the lenticule. A blunt spatula was used to first the front surface of the lenticule and then it's back surface. After that the surgeon manually brought out the lenticule through a tiny opening (Figure 1).

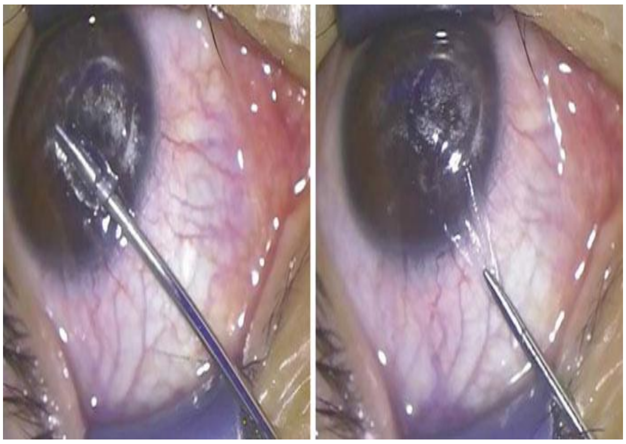

Fig. 1: extraction of the lenticule through small incision

Postoperative medications:

We used topical 0.5% gatifloxacin q.i.d for one week, 1% prednisolone acetate t.i.d for one week and one tears substitute containing carboxy methyl cellulose sodium 0.5% for three months.

Assessment of corneal biomechanical parameters:

We used Corvis ST machine (software version Recalc 1.2b1036 RC) for measurement of corneal biomechanical parameters, IOP, CCT, and Scheimpflug video capture of the corneal deformation (Figure 2). The accepted videos only showed a smooth progression with no disturbances from eyelash or eyelid obstruction. If the video indicated an error, or the biomechanical parameters revealed a blank value, then up to 3 more attempts were performed in an effort to get a valid reading.

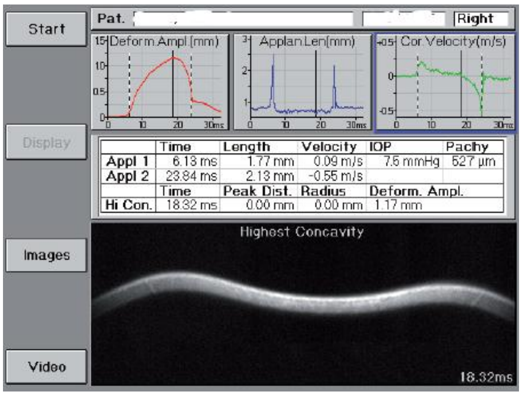

Fig. 2: video capture of corneal deformation parameters.

RESULTS

The collected data was tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 26.0, Microsoft Excel 2016 and MedCalC program software version 19.1. Descriptive statistics were performed for numerical parametric data as mean ± SD (standard deviation) and minimum & maximum of the range and for numerical non parametric data as median and 1st & 3rd inter-quartile range.

At the first follow up, assessment of Ocular Biomechanics revealed that the two studied groups were also comparable in respect to A1 length, A2 length, A1 velocity and A2 velocity showing no significant difference (p= 0.554, 0.221, 296 & 0.123 respectively). Also, there was no statistically significant difference between both groups regarding change in mean deformation, peak distance and radius (p= 0.079, 0.861 & 0.210 respectively) (table 1).

	SMILE group (n = 44)	Femto-LASIK group (n = 44)	Test value	P-value
		bIOP		
Mean± SD	22.87± 5.59	19.75± 4.11		
Median	21.45	19.25	Z_{MWU}=2.88	**0.004**
Range	11.70 – 39.50	11.70 – 35.20		
		CCT		
Mean± SD	421.17± 32.0	445.00± 39.78		
Median	418.0	434.0	Z_{MWU}=2.52	**0.012**
Range	358.0 – 499.0	391.0 – 523.0		
		A1 length		
Mean± SD	1.80±0.37	1.76± 0.26		
Median	1.80	1.79	T=0.594	**0.554**
Range	1.22 –3.14	1.22 – 2.40		
		A1 velocity		
Mean± SD	0.15± 0.03	0.16± 0.03		
Median	0.16	0.16	Z_{MWU}=1.23	**0.221**
Range	0.09 – 0.21	0.11 – 0.22		
		A2 length		
Mean± SD	1.35± 0.42	1.42± 0.40		
Median	1.26	1.31	Z_{MWU}=1.05	**0.296**
Range	0.59 – 2.56	0.79 – 2.12		
		A2 velocity		
Mean± SD	-0.31± 0.12	-0.34± 0.12		
Median	-0.28	-0.31	Z_{MWU}=1.54	**0.123**
Range	(-0.63) – (-0.14)	(-0.63) – (-0.20)		
		Deformation amplitude		
Mean± SD	1.07± 0.17	1.14± 0.14		
Median	1.07	1.10	Z_{MWU}=1.79	**0.074**
Range	0.64 – 1.38	0.91 – 1.61		
		Peak distance		
Mean± SD	4.85± 0.78	4.84± 0.87		
Median	5.01	5.10	Z_{MWU}=0.175	**0.861**
Range	2.57 – 5.76	2.51 – 5.66		
		Radius		
Mean± SD	5.74± 0.61	5.93± 0.69		
Median	5.69	5.87	T=1.27	**0.210**
Range	**4.66 – 7.66**	**4.66 – 7.66**		

Table 1: Comparison between the studied groups regarding Ocular Biomechanics at first follow up.

At the second follow up, the two studied groups were also comparable in respect to A1 length, A2 length, A1 velocity and A2 velocity showing no significant difference (p= 0.430, 0.882, 1.0 & 0.491 respectively). Also, there was no statistically significant difference between the two groups regarding change in mean deformation, peak distance and radius (p= 0.831, 0.880 & 0.195 respectively) (table 2).

	SMILE group (n = 44)	Femto-LASIK group (n = 44)	Test value	P-value
bIOP				
Mean± SD	19.68± 4.19	18.71± 3.52	T=1.14	**0.265**
Median	20.05	18.80		
Range	12.60 – 37.0	12.50 – 25.10		
CCT				
Mean± SD	431.93± 34.20	445.08± 43.74	Z_{MWU}=1.28	**0.200**
Median	427.0	441.5		
Range	386.0 – 502.0	386.0 – 516.0		
A1 length				
Mean± SD	1.86± 0.28	1.82± 0.28	Z_{MWU}=0.790	**0.430**
Median	1.87	1.83		
Range	1.32 – 2.45	1.21 – 2.44		
A1 velocity				
Mean± SD	0.17± 0.04	0.17± 0.03	Z_{MWU}=0.148	**0.882**
Median	0.18	0.17		
Range	0.04 – 0.23	0.04 – 0.23		
A2 length				
Mean± SD	1.48± 0.46	1.47± 0.42	Z_{MWU}=0.001	**1.00**
Median	1.31	1.35		
Range	0.86 – 2.34	0.86 – 2.32		
A2 velocity				
Mean± SD	-0.30± 0.07	-0.30± 0.06	Z_{MWU}=0.690	**0.491**
Median	-0.31	-0.30		
Range	(-0.38) – (-0.06)	(-0.50) – (-0.06)		
Deformation amplitude				
Mean± SD	1.16± 0.18	1.16± 0.09	Z_{MWU}=0.213	**0.831**
Median	1.15	1.15		
Range	0.54 – 1.78	1.00 – 1.39		
Peak distance				
Mean± SD	5.22± 0.40	5.20± 0.52	Z_{MWU}=0.151	**0.880**
Median	5.33	5.33		
Range	3.50 – 5.59	2.42 – 5.66		
Radius				
Mean± SD	5.82± 0.63	5.98± 0.67	Z_{MWU}=1.29	**0.195**
Median	5.69	5.91		
Range	**4.77 – 7.94**	**4.77 – 7.94**		

Table 2: Comparison between the studied groups regarding Ocular biomechanics at second follow up.

At the third follow up, the two studied groups were also comparable in respect to A1 length, A2 length, A1 velocity and A2 velocity showing no significant difference (p= 0.223, 0.895, 0.529 & 0.781 respectively). Also, there was no statistically significant difference between the two groups regarding change in mean deformation, peak distance and radius (p= 0.895, 0.263 & 0.455 respectively) (table 3).

	SMILE group (n = 44)	Femto-LASIK group(n = 44)	Test value	P-value
bIOP				
Mean± SD	18.96± 3.22	18.61± 2.50	Z_{MWU}=0.515	**0.529**
Median	19.70	19.00		
Range	13.70 – 23.80	13.70 – 23.10		
CCT				
Mean± SD	437.18± 32.53	439.56± 25.57	T=0.243	**0.809**
Median	437.5	438.50		
Range	368.0 – 505.0	397.0 – 496.0		
A1 length				
Mean± SD	1.76± 0.26	1.85± 0.23	Z_{MWU}=0.214	**0.223**
Median	1.81	1.90		
Range	1.28 – 2.21	1.40 – 2.21		
A1 velocity				
Mean± SD	0.18± 0.02	0.18± 0.02		

Median	0.18	0.18	Z_{MWU}=0.892	**0.895**
Range	0.15 – 0.21	0.16 – 0.21		
		A2 length		
Mean± SD	1.37± 0.37	1.35± 0.39		
Median	1.31	1.15	Z_{MWU}=0.524	**0.529**
Range	0.72 – 2.10	0.99 – 2.17		
		A2 velocity		
Mean± SD	-0.31± 0.02	-0.31± 0.03		
Median	-0.30	-0.30	Z_{MWU}=0.775	**0.781**
Range	(-0.35) – (-0.27)	(-0.38) – (-0.27)		
		Deformation amplitude		
Mean± SD	1.18± 0.08	1.19± 0.10		
Median	1.17	1.17	Z_{MWU}=0.894	**0.895**
Range	1.06 – 1.32	1.06 – 1.42		
		Peak distance		
Mean± SD	5.33± 0.30	5.22± 0.29		
Median	5.40	5.23	T=1.14	**0.263**
Range	4.68 – 5.76	4.68 – 5.59		
		Radius		
Mean± SD	5.89± 0.82	5.68± 0.29		
Median	5.84	5.76	Z_{MWU}=0.451	**0.455**
Range	**4.55 – 8.82**	**4.55 – 6.66**		

Table 3: Comparison between the studied groups regarding Ocular biomechanics at third follow up.

Variation from preoperative values of the DCR and all time of follow- up of the SMILE group showed a statistically significant difference (reduction) as regard radius of curvature (p<0.001) and a statistically significant difference (increase) (p<0.001) as regard A1 velocity, deformation amplitude and peak distance (table 4).

		SMILE group		Testvalue	P- value
		Mean	**SD**		
IOP	**Preoperative**	16.46	2.75		
	At 1st follow up	21.35	5.14		
	At 2nd follow up	19.21	3.89	21.11	**<0.001**
	At 3rd follow up	18.82	2.91		
CCT	**Preoperative**	530.55	27.32		
	At 1st follow up	432.64	37.69		
	At 2nd follow up	438.18	39.33	39.6	**<0.001**
	At 3rd follow up	438.18	29.45		
A1 length	**Preoperative**	1.97	0.37		
	At 1st follow up	1.78	0.32		
	At 2nd follow up	1.84	0.28	7.26	**0.064**
	At 3rd follow up	1.80	0.25		
A1 velocity	**Preoperative**	0.16	0.02	18.21	**<0.001**
	At 1st follow up	0.16	0.03		
	At 2nd follow up	0.17	0.04		
	At 3rd follow up	018	0.02		
A2 length	**Preoperative**	1.65	0.43		
	At 1st follow up	1.38	0.41		
	At 2nd follow up	1.47	0.44	5.49	**0.139**
	At 3rd follow up	1.36	0.37		
A2 velocity	**Preoperative**	-0.33-	0.10		
	At 1st follow up	-0.32-	0.12		
	At 2nd follow up	-0.30-	0.06	2.25	**0.522**
	At 3rd follow up	-0.31-	0.02		
Deformation amplitude	**Preoperative**	1.09	0.12		
	At 1st follow up	1.10	0.16		
	At 2nd follow up	1.16	0.14	19.67	**<0.001**
	At 3rd follow up	1.19	0.09		
Peak distance	**Preoperative**	4.73	0.91		
	At 1st follow up	4.84	0.82		
	At 2nd follow up	5.21	0.46	19.86	**<0.001**

	At 3rd follow up	5.28	0.30		
	Preoperative	6.75	0.69		
	At 1st follow up	5.83	0.66		
Radius	**At 2nd follow up**	5.90	0.65	18.87	**<0.001**
	At 3rd follow up	**5.80**	**0.71**		

Table 4: Difference between parameters during follow up in SMILE group

Variation from preoperative values of the DCR and all time of follow- up of the FS-LASIK group showed a statistically significant difference (reduction) as regard A1 length (p<0.001) and non-statistically significant difference (reduction) as regard radius of curvature and a statistically significant difference (increase) (p<0.001) as regard deformation amplitude (table 5).

		FS-LASIK group		Testvalue	P- value
		Mean	**SD**		
IOP	**Preoperative**	16.46	2.75		
	At 1st follow up	21.35	5.14	6.20	**0.102**
	At 2nd follow up	19.21	3.89		
	At 3rd follow up	18.82	2.91		
CCT	**Preoperative**	530.55	27.32	14.0	**0.003**
	At 1st follow up	432.64	37.69		
	At 2nd follow up	438.18	39.33		
	At 3rd follow up	438.18	29.45		
A1 length	**Preoperative**	1.97	0.37		
	At 1st follow up	1.78	0.32	8.40	**0.038**
	At 2nd follow up	1.84	0.28		
	At 3rd follow up	1.80	0.25		
A1 velocity	**Preoperative**	.16	0.02		
	At 1st follow up	.16	0.03	7.66	**0.054**
	At 2nd follow up	.17	0.04		
	At 3rd follow up	.18	0.02		
A2 length	**Preoperative**	1.65	0.43		
	At 1st follow up	1.38	0.41	3.71	**0.294**
	At 2nd follow up	1.47	0.44		
	At 3rd follow up	1.36	0.37		
A2 velocity	**Preoperative**	-.33-	0.10		
	At 1st follow up	-.32-	0.12	2.04	**0.564**
	At 2nd follow up	-.30-	0.06		
	At 3rd follow up	-.31-	0.02		
Deformation amplitude	**Preoperative**	1.09	0.12	8.56	**0.036**
	At 1st follow up	1.10	0.16		
	At 2nd follow up	1.16	0.14		
	At 3rd follow up	**1.19**	**0.09**		

Table 5: Difference between parameters during follow up in Femto- LASIK group

DISCUSSION

Theoretically, the cornea should be more mechanically stronger following SMILE surgery than after femto LASIK since SMILE damages less collagen lamellae, resulting in milder changes in biomechanical properties than Femto-LASIK. However, due to the rearrangement of the corneal collagen lamellae, the anterior stroma may have no contribution to the biomechanical strength.

Multiple studies were done to compare corneal biomechanical strength after smile and other refractive procedures, some of them showed a stronger cornea after SMILE procedures. On the contrary, other studies have shown comparable effects after SMILE and other refractive procedures.

Our study involved 80 eyes of persons were seeking laser vision correction surgery. The potentially confusing factors like age, sex distribution preoperative CCT, IOP, and manifest spherical equivalent were not statistically different between the two groups. Thus, we could test corneal biomechanical parameters independent of these factors.

CCT and IOP were considered because these parameters are already known by scientific literatures to be fundamental in corneal biomechanical behaviour and could influence the Corvis ST biomechanical values.

The assessment of Ocular Biomechanics by Corvis ST revealed that there was no statistically significant difference between both groups preoperatively and postoperatively as regards IOP and CCT.

In the first, second and third follow up visits, assessment of dynamic corneal response revealed that there was no statistically significant difference between both groups.

In fact, softer corneas will have longer applanation time because when it is exposed to a load force, its corresponding response force will be reduced. Also the amplitude of deformation will be augmented by increasing the corneal thinning.

Our results coincide with the results of Shen et al. [(10)] who retrospectively reported the biomechanical outcomes after LASIK and SMILE using the Corvis ST. They found no significant differences in any of the evaluated parameters three months after surgery.

Our results also coincide with the results of Sefat et al. [11] who reported similar biomechanical responses after LASIK and SMILE with the Corvis ST in a subgroup matched for age, preoperative CCT, IOP and preoperative spherical equivalent.

Our results do not coincide with the results of Osman et al., [12]. they compared the percentage of change in preoperative and postoperative measurements in a comparative study of LASIK and SMILE treated patients. They found significant difference between SMILE and LASIK, which may reflect a less compliant cornea after the flap-free procedure.

Our results also do not coincide with the results of a retrospective study by Pedersen et al., [13] who examined only the A1 deflection length and HC deflection 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 which supported the hypothesis of a more compliant cornea after LASIK compared with SMILE.

The limitations of the current study include the use of in vivo assessment of corneal biomechanics which is relatively a recent approach with multiple limitations. First, we don't currently have a biomechanical model that characterises the "normal" cornea. The embrassing influence of age, IOP, CCT and K reading, among other things, is another essential constraint to consider. Although we tried to rule out the effect of some of these intrinsic characteristics.

Other external factors, such as ocular hydration, may also alter biomechanical assessment. Aside from dry eye, investigations have shown changes in biomechanics with the presence of hypertension, diabetes, contact lens wear, and myopia degree. It will be crucial to understand the relationship between these parameters and biomechanical instability in order to improve screening processes and methods.

A contralateral eye comparison study, we feel, would yield more trustworthy results and allow us to quantify corneal deformation characteristics without being influenced by confounders.

CONCLUSION

In conclusion, regarding Corvis ST outcomes, SMILE and FS-LASIK decreased the corneal biomechanical strength with no significant differences between both procedures, despite the fact that SMILE retains the corneal biomechanical power better. It seems possible that the anterior cap after SMILE does not take part to the corneal solidity due to a wrinkled configuration of the collagen lamellae.

Conflict of interest : none

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