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Comparison of Changes in Corneal Biomechanical Properties before and After Photorefractive Keratectomy and Small Incision Lenticule Extraction

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Background: Corneal biomechanics is the study of the mechanical properties and responses of the cornea to external forces. Two devices are currently available for characterizing the corneal biomechanical properties in a clinical setting; Ocular Response Analyzer (ORA) (Reichert, Buffalo, New York, USA) based on bidirectional applanation tonometry and Corvis -ST (Oculus Optikgeräte GmbH, Wetzlar, Germany) based on corneal deformation estimation using Scheimpflug imaging. Ocular response analyzer was used to assess corneal hysteresis (CH) and corneal resistance factor (CRF) to characterize changes in corneal biomechanics.
The other device is Corvis –ST which produces air pulse on the cornea then measures and records the movements using a high-speed Scheimpflug video camera in real time. It is highly sensitive and specific to differentiate healthy cornea from keratoconic one.
Aim: The aim of our study is to compare the changes in corneal biomechanical properties before and after PRK and SMILE.

Patients and Methods: This is a prospective comparative study and included 20 patients who had undergone PRK by Allegretto wave eye-Q device & 20 patients who had undergone SMILE by Visumax Ziess device.
Results: The significant difference between two groups at 6 months after surgery considering IOPb=0.027*. Integ. Radius=0.001*. SPA1=0.003*. This difference makes Femto SMILE better than PRK procedure for more stability of the corneal biomechanics and possibly lowers the incidence of postoperative ectasia.
Conclusion: According to CORVIS-ST for corneal biomechanical evaluation, the significant difference between two groups at 6 months after surgery considering IOPb=0.027*. Integ. Radius=0.001*. SPA1=0.003*. This difference makes SMILE better than PRK procedure for more stability of the corneal biomechanics and possibly lowers the incidence of postoperative ectasia.

Keywords: Corneal biomechanical properties; changes; photorefractive keratectomy; small incision lenticule extraction.

1. INTRODUCTION

With the rapid and extensive development of modern refractive surgery of the cornea, related technologies have been promoted to develop a new surgical procedure [1]. Surgical correction of refractive errors is becoming progressively popular, quick and effective for correction of myopia, hyperopia and astigmatism [2,3]. Photo refractive keratectomy (PRK) has been administered effectively and reliably for many years in the treatment of myopia [4]. In PRK, the laser is applied directly to the anterior corneal stroma without creating a flap. It is one of the developing procedures that have been engaging to avoid flap creation [4,5].

Recently, SMILE has been established as a flapless procedure. It has been reported since 2011 for the treatment of myopia and astigmatism [6,7]. An intra-stromal lenticule is cut by a femto second laser and manually extracted via a peripheral tunnel incision in the cornea leaving the stroma overlying the lenticule intact [8,9].

Corneal biomechanics is the study of the mechanical properties and response of the cornea. This study used the Corvis that measures in-vivo biomechanical corneal property [10,11].

The Corvis is based on corneal thickness profile and deformation parameters, and is considered as a non-contact tonometer that monitors the response of the cornea to an air pressure pulse using an ultra-high Scheimpflug camera and uses the captured image sequence to produce estimates of intraocular pressure and deformation response parameters [11,12].

2. PATIENT AND METHODS

This was a prospective comparative study involving 20 patients who had undergone PRK by Allegretto wave eye-Q device and 20 patients who had undergone SMILE by Visumax Ziess device.

2.1 Inclusion Criteria

1. Age: 18- 40 years.
2. Myopia (-2 to -6) diopters.
3. Astigmatism up to (2) diopters.
4. Clear and healthy cornea.
5. Stable refraction.

2.2 Exclusion Criteria

1. Systemic disease interfering with healing of the cornea.
2. Ocular disease such as Dry Eye Syndrome, keratoconus, glaucoma, retinal diseases and lens opacity.
3. Ocular trauma.
4. Pregnancy and lactation.

2.3 Medical Ethics

- An informed consent was obtained from all participants in the research.
- We respect our patient privacy by using coded numbers for their data files instead of names.
- The surgeries were carried out in an operation theater under complete sterilization.
- The adverse effects of different surgical procedures were discussed with the patient.
  - Patients were evaluated preoperatively: this included history taking, slit lamp

examination, fundus examination and intraocular pressure measurement, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) using glasses, and cycloplegic refraction. The CORVIS-ST was used to assess the corneal biomechanics. Patients were evaluated at one month after surgery using CORVIS-ST to assess corneal biomechanics and Pentacam, also after 6 months patients were evaluated using CORVIS-ST and Pentacam.

2.4 Operative Technique of PRK

1. Accurate cleaning of the eyelid skin with betadine, sterile adhesive strips were applied followed by the eyelid speculum to expose the cornea correctly.
2. The patient received topical anaesthetic drops.
3. The epithelium was removed by instillation of an alcohol solution (25% ethanol for 20 seconds) and removed with a sponge tip procedure
4. By (Allegretto Wave Eye-Q Lasers) excimer laser platform, treatment was centered on the patient’s visual axis, and the eye-tracker was activated following the ablation. Mitommycin C was applied to the cornea (mitomycin c is an alkylating antibiotic with anti-fibroblastic properties that induces keratocytes apoptosis and reduces anterior stromal keratocytes density after surface excimer laser ablation. Many studies found that there was no significant change in corneal biomechanics parameters with using this substance however its impact in the long term on corneal biomechanics remains unknown).
5. A contact lens was placed over the cornea, as this encourages re-epithelialization

2.5 The Surgical Procedure Operative Technique of SMILE

1. Accurate cleaning of the eyelid skin with betadine, sterile adhesive strips were applied followed by the eyelid speculum to expose the cornea correctly.
2. The patient received topical anaesthetic drops.? name
3. Once centration was adequate (ring of touch zone concentric with a margin of the cone and near pupil center), suction was applied.
4. With the Visumax platform (Carl Zeiss Meditec AG), the posterior surface of the lenticule was created from periphery to center (optical zone of 6.5 mm) followed by a transition into the peripheral optical zone, with the anterior surface of the lenticule created from the center to the periphery.
5. After that creation of a 2.0 mm peripheral incision with 30 degrees of angle for posterior lenticule extraction; laser configuration parameters with a repetition rate of 500 kHz, spot size of 4.50 mm for the lenticule and 2.0 mm for its border, and pulse energy of 150 nJ.
6. After laser treatment, the patient was moved to the surgical microscope for the second part of the procedure in which the front and back lenticule surfaces were delineated and then separated by moving the SMILE dissector back and forth with a blunt circular tip.
7. The lenticule was extracted with a SMILE lenticule removal forceps.

3. RESULTS

3.1 Intraocular Pressure Corrected Biomechanically (IOPb) (Table 1)

In group A with PRK, the pre-operative range of IOPb was 12.6 – 19.4 mmHg with a mean 16.26 ± 2.16 mmHg. After the 1-month post-operative, IOPb ranged between 11.5 – 17.6 mmHg with a mean of 14.05 ±1.77 mmHg, and after 6months IOPb ranged between11.1 – 17.2 mmHg with a mean of 13.62 ± 1.60 mmHg. IOPb was decreased with a statistically significant difference from pre-operative time to 6 months post-operative (p=0.001*).

In group B with SMILE, the pre-operative range was 12.4 – 20.5mmHg with a mean of 16.26 ± 2.07mmHg. After the 1-month post-operative IOPb ranged between 11.1 – 20 mmHg with a mean of 15.79 ± 2.94mmHg and after 6 months the IOPb ranged between11.5 – 19.5 mmHg with a mean of 15.27 ± 2.78mmHg. IOPb was decreased with no significant difference from pre-operative to 6months post-operative (p=0.238). There was no statistically significant difference between the two groups pre-operatively (t=0.013, p=0.990), however; there was significant difference between the two groups at 1 and 6 months postop (t=2.275, P=0.029*and t=2.293, p=0.027* respectively).

Table 1. Intraocular Pressure Corrected Biomechanically (IOPb)

IOPb		PRK	Smile	t. test	p. value
Pre	Range	12.6 – 19.4	12.4 – 20.5	0.013	0.990
	Mean ± S. D	16.26 ± 2.16	16.26 ± 2.07		
Post 3 m.	Range	11.5 – 17.6	11.1 – 20	2.275	0.029*
	Mean ± S. D	14.05 ± 1.77	15.79 ± 2.94		
Post 6 m.	Range	11.1 – 17.2	11.5 – 19.5	2.293	0.027*
	Mean ± S. D	13.62 ± 1.60	15.27 ± 2.78		
F. test		11.665	0.713		
p. value		0.001*	0.495		
P1		0.001*	0.578		
P2		0.001*	0.238		
P3		0.473	0.529		

3.2 Integrated Concave Radius (Table 2)

In group A (PRK group), the pre-operative range of integrated concave radius was 4.7 – 7.6 msxmm^{-1} with a mean of 6.34 ± 0.82 msxmm^{-1}. One month post-operatively, the integrated radius ranged between 5 and 9 msxmm^{-1} with a mean of 7.18 ± 0.97 msxmm^{-1} and after 6 months integrated radius ranged between 6.5 and 9.8 msxmm^{-1} with a mean of 8.27 ± 0.84 msxmm^{-1}. Integrated radius was increased with a statistically significant difference from preop to 6months post-operatively msxmm1 (p=0.001*).

In group B (SMILE group), the pre-operative range was 5 – 8.52 msxmm^{-1} with a mean of 6.75 ± 1.08 msxmm-1. At the 1-month post-operative, Integ. radius ranged between 8 and 9.3 msxmm-1 with a mean of 8.70 ± 0.39 msxmm-1 and after 6 months integrated radius ranged between 8.4 and 10 msxmm^{-1} with a mean of 9.21 ± 0.51msxmm^{-1}. Integrated radius was increased with a statistically significant difference from preop to 6 months post-operatively (p=0.001*). There was no statistically significant difference between the two groups pre-operatively (t=1.334, p=0.190), however, there was a significant difference one and 6months postoperatively (t=6.505, p=0.001* and t=4.313, p= 0.001* respectively).

3.3 Stiffness Parameter A1(SPA1) (Table 3)

In group A (PRK), the pre-operative range of stiffness parameter A1 was 90 – 130 mmHg/mm with a mean of 112.16 ± 11.67 mmHg/mm. One month post-operatively, the SPA1 ranged between 85 – 106.3 mmHg/mm with a mean of 94.64 ± 7.58mmHg/mm; and after 6 months SPA1 ranged between 72.6 – 100 mmHg/mm with a mean of 86.33 ± 7.46. SPA1 showed a decrease with a significant difference from preop to 6 months postoperative (p<0.001*).

In group B (SMILE), the pre-operative range was 78.5 – 129.1mmHg/mm with a mean of 110.34 ± 12.58mmHg/mm. At the 1-month post-operative, SPA1 ranged between 87.5 – 126.5mmHg/mm with mean of 108.38 ± 11.92 mmHg/mm; and after 6 months SPA1 ranged between 80.5 – 170.7mmHg/mm a mean of 100.74 ± 19.05. SPA1 showed a decrease from preop to 6 months post-operative but this was not statistically significant (p=0.064).

Table 2. Integrated Concave Radius (Integrated Radius)

Integrated Radius		PRK	Smile	t. test	p. value
Pre	Range	4.7 – 7.6	5 – 8.52	1.334	0.190
	Mean ± S. D	6.34 ± 0.82	6.75 ± 1.08		
Post 1 m.	Range	5 – 9	8 – 9.3	6.505	0.001*
	Mean ± S. D	7.18 ± 0.97	8.70 ± 0.39		
Post 6 m.	Range	6.5 – 9.8	8.4 – 10	4.313	0.001*
	Mean ± S. D	8.27 ± 0.84	9.21 ± 0.51		
F. test		24.148	64.027		
p. value		0.001*	0.001*		
P1		0.004*	0.001*		
P2		0.001*	0.001*		
P3		0.001*	0.029*		

Table 3. Stiffness Parameter A1 (SPA-1)

SPA – 1		PRK	Smile	t. test	p. value
Pre	Range	90 – 130	78.5 – 129.1	0.473	0.639
	Mean ± S. D	112.16 ± 11.67	110.34 ± 12.58		
Post 1 m.	Range	85 – 106.3	87.5 – 126.5	4.350	0.001*
	Mean ± S. D	94.64 ± 7.58	108.38 ± 11.92		
Post 6 m.	Range	72.6 – 100	80.5 – 170.7	3.151	0.003*
	Mean ± S. D	86.33 ± 7.46	100.74 ± 19.05		
F. test		41.882	2.330		
p. value		0.001*	0.107		
P1		0.001*	0.678		
P2		0.001*	0.064		
P3		0.006*	0.110		

Table 4. Corvis Biomechanical Index (CBI)

CBI		PRK	Smile	t. test	p. value
Pre	Range	0 – 0.33	0 – 0.36	0.454	0.504
	Mean ± S. D	0.12 ± 0.21	0.16 ± 0.22		
Post 1 m.	Range	0 – 1	0 – 0.75	2.932	0.006*
	Mean ± S. D	0.64 ± 0.37	0.32 ± 0.31		
Post 6 m.	Range	0 – 1	0 – 0.63	4.842	0.001*
	Mean ± S. D	0.69 ± 0.37	0.21 ± 0.26		
F. test		18.226	1.974		
p. value		0.001*	0.148		
P1		0.001*	0.057		
P2		0.001*	0.540		
P3		0.749	0.189		

There was no statistically significant difference between the two groups pre-operative (t=0.473, p=0.639) however; after 1 and 6months there was a statistically significant difference between the two groups (t=4.350, p=0.001* and t=3.151, p=0.003* respectively).

3.4 Corvis Biomechanical Index (CBI) (Table 4)

In group A (PRK), the pre-operative range of CBI was 0 –0.53 with a mean of 0.12 ± 0.21. One month post-operatively, the CBI ranged between 0and 1 with a mean of 0.64 ± 0.37; and after 6 months CBI ranged between 0 and 1 with a mean of 0.69 ± 0.37. CBI Showed an increase with a statistically significant difference from preop to 6months post-operatively (p<0.001*).

In group B (SMILE), the pre-operative range of CBI was 0 – 0.56 with a mean of 0.16 ± 0.22. At the 1-month post-operative, CBI ranged between 0 – 0.75 with a mean of 0.32 ± 0.31 and after 6 months CBI ranged between 0 – 0.63 with a mean of 0.21 ± 0.26. Corvis biomechanical index showed an increase with no significant difference from preop to 6 months post-operative (p=0.540).

There was no statistically significant difference between the two groups pre-operatively (t=0.454, p=0.504), however, after 1 and 6months, there was statistically significant difference between the two groups (t=2. 932, p<0.006* and t=4. 842, p=0.001* respectively).

4. DISCUSSION

In this study, it was found that changes in IOP have no statistically significant difference recorded between the two groups pre-operatively (t=0.013, p=0.990), however there was significant difference between the two groups 1 and 6 months postoperative (t=2.275, P=0.029*and t=2.293, p=0.027* respectively).

Dou et al., [13] found that corneal compensated IOP after surgery were significantly lower than the preoperative values (P < 0.05). In our study IOPb was decreased with a significant difference from preop to 6 months post-operatively (p <0.001*) in group A, but Chow et al., reported no significant difference in IOPb measured by Corvis ST in post PRK eyes when compared with the baseline (p=0,101) [14].

In group B (SMILE), IOPb was decreased with no statistically significant difference from preop to 6months post-operative (p=0.238). Fernandez et al., demonstrated that IOPb showed a significant difference after SMILE. IOPb showed a smaller reduction when compared with conventional IOP measured with dynamic Scheimpflug analyser [15].

Integrated concave radius in group A was 4.7 – 7.6 msxmm-1 with a mean 6.34 ± 0.82 msxmm-1 pre-operatively, and between 5 and 9 msxmm-1 with a mean - 7.18 ± 0.97 msxmm-1 one month postoperatively. After 6 months, the integrated radius ranged between 6.5 and 9.8msxmm-1 with a mean of 8.27 ± 0.84 msxmm-1. Integrated radius was increased with a statistically significant difference from preop to 6months post-operatively (p=0.001*). Hassan et al., also found a significant difference in the integrated radius one month post PRK eyes compared with preoperative baseline figures [16].

In group B, pre-operatively range was 5 – 8.52 msxmm-1 with a mean of 6.75 ± 1.08 msxmm-1, 1 months post-operatively Integrated radius ranged between 8 and 9.3 msxmm-1 with a mean -8.70 ± 0.39 msxmm-1 and after 6 months Integ radius ranged between 8.4 and 10 msxmm-1 with a mean 9.21 ± 0.51msxmm-1 Integ radius was increased with a statistically significant difference from pre to 6 months post-operatively (p=0.001*) There was no statistically significant difference between two groups pre-operatively (t=1.334, p=0.190) however post 1, 6 months was significant (t=6.505, p=0.001* and t=4.313, p= 0.001*respectively).

Stiffness parameter A1(SPA1) In groupA pre-operatively range was 90 – 130 mmHg/mm with a mean112.16 ± 11.67 mmHg/mm, 1 months post-operatively SP A1 ranged between 85 – 106.3 mmHg/mm with a mean 94.64 ± 7.58 mmHg/mm and after 6 months SP A1 ranged between 72.6 – 100 mmHg/mm with a mean 86.33 ± 7.46. SPA1 showed decrease with a significant difference from pre to 6months postoperatively (p<0.001*).

in group Bpre-operatively range was 78.5 – 129.1mmHg/mm with a mean 110.34 ± 12.58mmHg/mm, 1 months post-operatively SPA1 ranged between 87.5 – 126.5mmHg/mm with mean 108.38 ± 11.92 mmHg/mm and after 6months SP A1 ranged between 80.5 – 170.7mmHg/mm a mean100.74 ± 19.05. SPA1 showed decrease with a statistically insignificant difference from pre to 6months post-operatively (p=0.064).

There was no statistical difference between two groups pre-operative (t=0.473, p=0.639) however after 1 and 6 months there was a statistically significant difference between two groups (t=4.350, p=0.001* and t=3.151, p=0.003* respectively). Roberts et al., [17] found that SPA1 shows a greater separation between keratoconic and normal eyes, Also Zhao et al study showed that there was a significant decrease in corneal stiffness in keratoconic eyes compared with the normal eyes [18].

Corvis Biomechanical Index (CBI) was introduced by Vinciguerra et al., as highly sensitive and specificto separate healthy from non-healthy cornea. CBI value of 0.5 and higher indicates an increase in the possibility of corneal ectasia for the patient under study [10].

According to CBI in our study In group A pre-operatively range was 0 –0.53 with a mean 0.12 ± 0.21, 1 months post-operatively CBI ranged between 0 and 1 with mean 0.64 ± 0.37 and after 6 months CBI ranged between 0 and 1 with a mean 0.69 ± 0.37.

CBI showed an increase with a statistically significant difference from pre to 6months post-operatively (p=0.001*).

In group B pre-operatively range was 0 – 0.56 with a mean0.16 ± 0.22, 1 months post-operatively CBI ranged between 0 – 0.75 with a mean0.32 ± 0.31 and after6 months CBI ranged between with 0 – 0.63 a mean 0.21 ± 0.26.

CBI Showed an increase with no significant difference from pre to 6 months post-operatively. (p=0.540).

There was no statistical difference between two groups pre-operative (t=0.454, p=0.504) however after 1 and 6 months there was highly significant difference between two groups (t=2. 932, p<0.006* and t=4. 842, p=0.001* respectively).

Yang et al. admitted these new parameters had detectability for distinguishing keratoconus eyes from normal eyes and diagnostic ability of these parameters in detecting keratoconus from normal eyes. [19].

There was statistically significant difference between the two groups at 6 months postop

(IOPb=0.027*; Integrated radius=0.001*; SPA1=0.003* and CBI = 0.001*). This difference makes Femto SMILE better than PRK procedure for more stability of the corneal biomechanics and possibly lowers the incidence of postoperative ectasia.

5. LIMITATIONS

The small sample size of this study requires further researches to be conducted with larger samples.

6. RECOMMENDATION

1. Although corneal topography is the most widely used diagnostic method for screening refractive surgery patients, further work is needed to determine whether the combination of topography with the new CORVIS can assist the refractive surgeon in diagnosing subtle corneal abnormalities and ultimately allow improved exclusion criteria of patients at risk for postsurgical ectasia.
2. We found that all the parameters were significantly correlated with the residual CCT except the stiffness parameter at the first applanation (SPA1) and intra ocular pressure corrected biomechanically in both groups. This indicates that this parameter would be an indicator to predict the biomechanical properties of the cornea independent of the tissue volume.
3. Further studies with longer follow-up duration are needed for evaluating stability of corneal biomechanical changes.

7. CONCLUSION

According to CORVIS-ST for corneal biomechanical evaluation, there was a significant difference between the two groups at 6 months postop considering IOPb=0.027*; integrated radius=0.001*; and SPA1=0.003*. This difference makes SMILE better than PRK for more stability of the corneal biomechanics and possibly lowers the incidence of postoperative ectasia.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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