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Corneal biomechanical properties comparison after laser-assisted in situ keratomileusis and refractive lenticular extraction

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Abstract

Background: Corneal biomechanical properties are a measure of corneal structural integrity and stiffness. Corneal refractive surgery can cause substantial changes in these properties and the extent of the effect is determined by the type of technique used.

Objective: To compare the change in the biomechanics of the cornea after Laser-Assisted in Situ Keratomileusis (LASIK) and Small Incision Lenticule Extraction (SMILE).

Methodology: The study was a prospective cohort study carried out at AL Yamama Eye Center, Baghdad, Iraq. Sixty patients with myopia and myopic astigmatism (mean age 26.6 ± 7.3 years) were randomly recruited and stratified into two groups: LASIK group (mean spherical equivalent -3.1 ± 2.3 D) and SMILE group (mean spherical equivalent -3.5 ± 1.0 D). Every patient was subjected to complete corneal biomechanical analysis with the Corvis ST (Scheimpflug Technology) before operation and at 2 weeks and 2 months after operation. The main outcomes measures were deformation amplitude at 2 mm above the apex (DA 2mm), integrated radius (IR), and stiffness parameter at first applanation (SP-A1).

Results: Surgical groups showed significant Decrease of corneal biomechanical properties at 2 weeks and 2 months after surgery by reducing central corneal thickness, stiffness parameter at initial applanation, increasing deformation amplitude at 2 mm, and increasing integrated radius (all $p < 0.05$). The results of intergroup comparison showed that there was no significant difference in the corneal stiffness at 2 weeks after the operation ($p > 0.05$). At 2 months follow-up, however, the LASIK group had considerably more corneal stiffness reduction than the SMILE group ($p < 0.05$).

Conclusion: Both LASIK and SMILE operations result in the significant change of corneal biomechanical properties, though LASIK showed a higher level of corneal stiffness change than SMILE. These results indicate that SMILE can provide a better maintenance of corneal biomechanical integrity in the correction of myopia and myopic astigmatism.

Keywords: Biomechanics of the cornea, Corvis ST, SMILE, LASIK, stiffness of the cornea, refractive surgery

1. Introduction

Human cornea is the transparent anterior organ of the eye, which acts as a protective barrier as well as the main refractive element of the visual system ^[1, 2]. The basis of its biomechanical integrity is its special architectural organization, especially in stromal layer, which constitutes most of the corneal thickness. Corneal mechanical properties show considerable depth-related change, the Bowman layer and anterior stroma are stiffer than are the posterior stroma ^[3]. The corneal stroma helical collagenous structure which starts with tropocollagen molecules (1 nm) which crosslink into collagen fibrils (50-100 nm), which in turn form collagen fibres or corneal lamellae (500-1000 nm) ^[4]. These collagen fibrils are immobilized in a hydrated mesh of proteoglycans and interstitial fluid with a significant role of proteoglycans in ensuring the transparency of the cornea by ensuring an irregular spacing of interfibrillar space ^[5]. This change in stiffness is a result of differences in collagen fiber organization: the anterior cornea is characterized by an isotropic arrangement of collagen fibres with steep fiber angulation and arcuate spring-like extensions of the collagen fibre into Bowman membrane ^[6], whereas collagen organization gives the anterior stroma a huge degree of rigidity and a low degree of flexibility in comparison to the middle and posterior stroma ^[7]. There are preferential orientations of the middle and posterior cornea along the nasotemporal and inferosuperior axis, and the density of collagen fibers decreases with depth and the fibers reorganize based on increases in filling pressure in the middle and posterior cornea ^[8].

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The development of sophisticated diagnostic methods has led to accurate measurements of the biomechanical characteristics of the corneas *in vivo*. One such development is the introduction of the Corneal Visualization Scheimpflug Technology (CorVis ST; Oculus, Wetzlar, Germany) in 2010, which was a breakthrough in corneal biomechanics and measurement of intraocular pressure^[9]. The device uses a high-speed Scheimpflug camera that can record more than 4,300 frames per second and at the same time use a controlled air puff with a maximum internal pump pressure of 25 kPa. The system uses a blue light-emitting diode (455 nm wavelength, free of ultraviolet) to capture 140 sequential digital images at 576 measurement points, capturing the corneal deformation in its natural convex form in the maximum concavity and then the recovery^[10]. The CorVis ST produces various biomechanical parameters which have been medically tested to evaluate the structural integrity of the cornea. The critical parameters are the stiffness parameter at first applanation (SP-A1), which is the ratio of adjusted air puff pressure, less biomechanically corrected intraocular pressure to the amplitude of deflection at first applanation, the integrated inverse radius (IR), which is the sum of inverse concave radii between the first and second applanation, and the deformation amplitude at 2 mm peripheral (DA 2mm), which is the ratio of deformation amplitude 2 mm peripheral to the apex to apical deformation^[11].

Corneal refractive surgery is one of the most popular types of elective surgeries of the eye. Nevertheless, the biomechanical effects of such interventions have become a vital factor in the planning of the surgery and the evaluation of postoperative outcomes^[12, 13]. Small incision lenticule extraction (SMILE) is considered to have a negligible effect on cornea biomechanics in relation to other refractive surgery methods^[14, 15]. Laser-assisted in situ keratomileusis (LASIK) is the most common of the two because of its quick painless restoration of vision^[16]. SMILE uses the purely femtosecond laser based method to form an intrastromal refractive lenticule^[17]. Early results of ocular response analyzer and dynamic Scheimpflug imaging experiments indicate that SMILE can provide improved protection of corneal biomechanical functions than LASIK^[18, 19]. LASIK refers to a procedure where an anterior corneal opening is created by the use of a femtosecond laser or microkeratome and then stromal photoablation with excimer laser is done to correct a refractive error and the anterior corneal opening is repositioned^[20]. Conversely, SMILE entails dissection and mechanical excision of the lenticule with a small arcuate side incision thus preserving the integrity of the anterior corneal architecture and no flap is created^[21]. With the inherent nature of corneal biomechanical stability as a crucial baseline to long-term refractive performance and structural safety, the ability to clarify the difference in biomechanical effect of these surgical methods is of the paramount clinical importance to ophthalmologists in enhancing patient selection and surgery mode.

2. Methodology

2.1 Study Design and Setting

This is a prospective cohort study that was undertaken during five months between September 1, 2022, and January 1, 2023, at AL Yamama Eye Center, Baghdad, Iraq. The patients used in the study included 30 patients (60 eyes) with myopia and myopic astigmatism that had undergone corneal refractive surgery.

2.2 Study Population

The study sample included patients diagnosed with myopia and myopic astigmatism with an average age of 26.6 ± 7.3 years and who reported to AL Yamama Eye Center and expressed interest in refractive surgery within the study time frame.

2.3 Eligibility Criteria

Inclusion Criteria

All patients who had myopia with a range of -1.0 to -6.0 diopters sphere (DS) and myopic astigmatism with a range of -3.0 to -6.0 diopters cylinder (DC) were included.

Exclusion Criteria

Patients with mixed astigmatism or hypermetropia were excluded from the study.

2.4 Sampling and Participant Allocation

Sixty eyes were recruited through convenience sampling and stratified in two groups according to patient choice to complete the LASIK group with a mean spherical equivalent of (-3.1 ± 2.3) D (30 eyes) and SMILE group with a mean spherical equivalent of (-3.5 ± 1.0) D (30 eyes). To ensure minimization of confounding variables, two groups were matched on the baseline characteristics such as age, central corneal thickness, refractive error, and intraocular pressure.

2.5 Data Collection

Each participant was gathered on comprehensive demographic and clinical information, such as age, sex, past medical history, past surgical history, ophthalmic history, and type of surgical procedure performed. The ophthalmic parameters were evaluated at three points namely; preoperative (baseline), two weeks after operation (when the Cornea is still during the inflammatory healing phase) and two months after operation (when the healing process is complete). At every visit, the following parameters were monitored: uncorrected visual acuity (UCVA), Best corrected visual acuity, refractive error, spherical equivalent, central corneal thickness (CCT), deformation amplitude at 2 mm of apex (DA 2mm), integrated radius (IR), stiffness parameter at first applanation (SP-A1), biomechanically corrected intraocular pressure (bIOP) and CorVis Biomechanical Index (CBI).

2.6 Outcome Assessment

The main findings were the corneal biomechanical measurement in both surgical groups by CorVis ST device (Corneal Visualization Scheimpflug Technology; Oculus, Wetzlar, Germany). The biomechanical assessment was done at three points namely; preoperative, after two weeks after surgery (when the inflammatory healing process takes place) and after two months (when the healing process is complete) postoperative. The most important biomechanical parameters were evaluated, which were deformation amplitude at 2 mm (DA 2mm), integrated radius (IR), and stiffness parameter at first applanation (SP-A1).

2.7 Statistical Analysis

Normality of data distribution was tested and the continuous variables were represented by means as standard deviations of normally distributed data or by median and range in skewed data. Frequencies and percentages were used to give the categorical variables. Welch two-sample t-test of

normally distributed continuous variables, in independent samples was used to make statistical comparisons between groups. The chi-square test and the exact test, which were developed by Pearson and Fisher respectively, were used to test associations between categorical variables. Repeated measures analysis of variance (ANOVA) was applied to detect the changes in continuous variables at several time points in the same sample, and the post hoc testing was made to identify specific pairwise differences between time points. The correlation coefficient of Pearson product-moment was used to test the relationships of continuous variables. A p-value under 0.05 was taken to be statistically significant. R software 4.2.2 (R Foundation for Statistical Computing, Vienna, Austria) with specific packages such as dplyr, gtsummary, and ggplot2 were used to do all data

processing, management, and statistical analysis.

2.8 Ethical Considerations

This study was ethically and scientifically approved by the Scientific Committee of the Department of Ophthalmology, Iraqi Board of Medical Specializations. Any study that involved human subjects was performed in compliance with the ethical principles of the institutional and national research committees and was carried out at the time of the 1964 Declaration of Helsinki and its further amendments. Informed consent was taken in writing among all the participants before the study commenced after a thorough explanation of the aims of the study and assurance of data confidentiality.

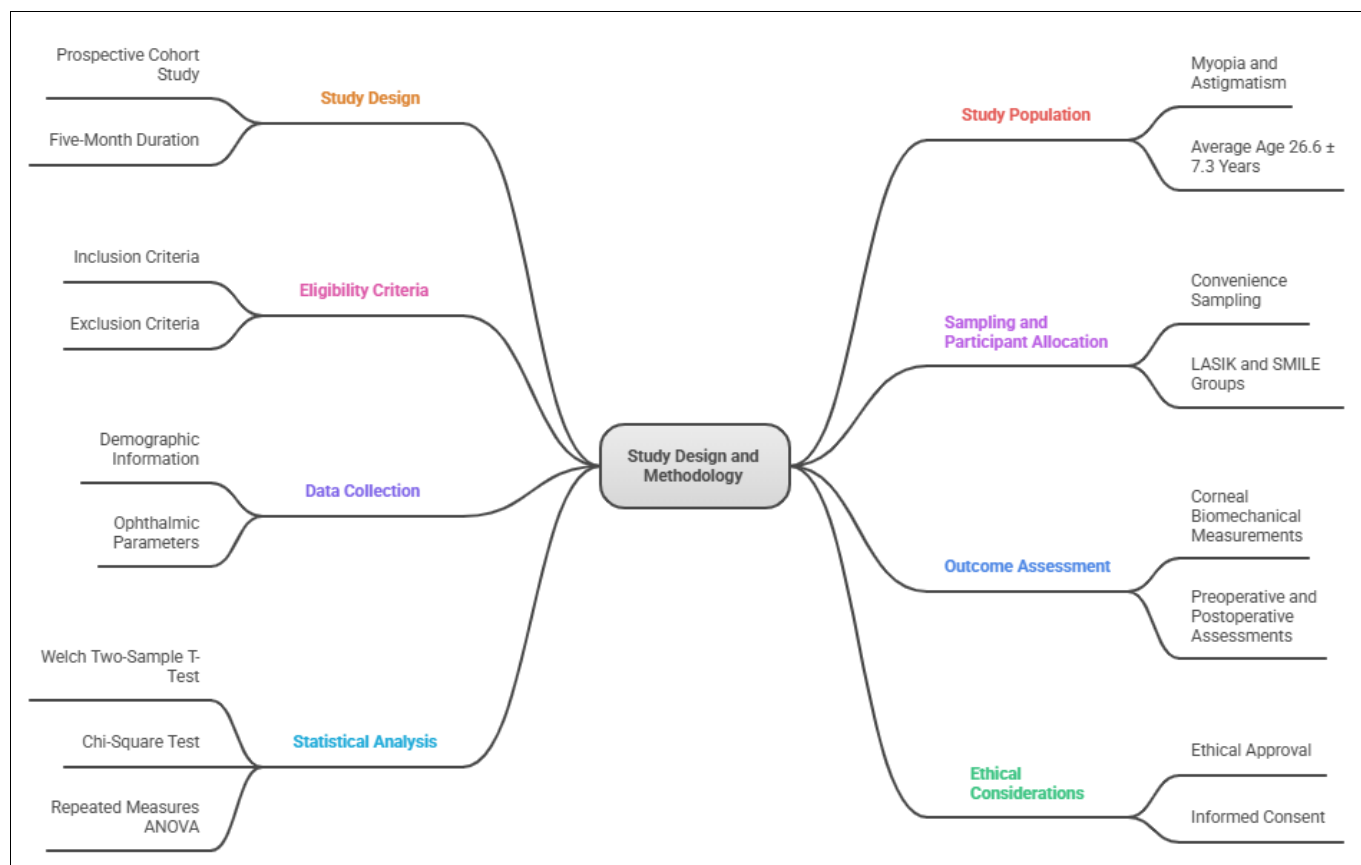


Fig 1: Study design and methodology framework.

3.Results

3.1 Patient Demographics

The number of patients in this study was 30 with 60 eyes (30 eyes were subjected to LASIK and 30 eyes were subjected to SMILE procedures). The mean age of the study subjects was 26.62 years. The surgical groups were well matched with the LASIK group with mean age of 28.3 with SD of 9.2 years and the SMILE group of 24.8 with SD of

4.0 years and there was no statistically significant difference ($p=0.062$). The sample size used in the study was mainly female (76.7%), and male (23.3). The distribution of sex in the two surgical groups was even ($p=0.5$). All participants with no past medical and ophthalmological history, which made the clinical profile in both groups similar.

Table 1: Description of Patient's demographics

Characteristics	Overall, N = 60 ¹	LASIK, N=30 ¹	SMILE, N=30 ¹	P-value ²
Age, years	26.6±7.3	28.3±9.2	24.8±4.0	0.062
Sex				
Females	46 (76.7%)	22 (73.3%)	24 (80.0%)	0.5
Male	14 (23.3%)	8 (26.7%)	6 (20.0%)	

¹Mean±SD; n (%)

²Welch Two Sample t-test; Pearson's Chi-squared test

3.2 LASIK Group

The LASIK group's ophthalmological parameters were subjected to repeated measures analysis, which was undertaken at three different time intervals: before the surgery, two weeks after the procedure, and two months after the operation. The results of this study indicated that there were statistically significant changes in a number of metrics. All of the following parameters exhibited significant changes: the spherical equivalent ($p<0.001$), the

central corneal thickness ($p<0.001$), the amplitude of deformation at 2 mm ($p<0.001$), the integrated radius ($p<0.001$), the stiffness parameter at first applanation (SP-A1) ($p=0.021$), the biomechanically corrected intraocular pressure (bIOP) ($p<0.001$), and the CorVis Biomechanical Index (CBI) ($p<0.001$). In terms of the other metrics that were being evaluated, there was no difference between the two periods of time that were being compared that was statistically significant.

Table 2: Repeated measures of study characteristics in the LASIK group, N=30.

Characteristics	Pre-operative ¹	After 2 weeks ¹	After 2 months ¹	p-value ²
Spherical equivalent	-3.1±2.3	-0.1±0.4	-0.2±0.3	<0.001
Central corneal thickness (micron)	548.8±22.2	528.4±41.1	519.8±37.3	<0.001
deformation amplitude	4.6±0.5	5.3±0.7	5.5±1.1	<0.001
integrated radius	8.5±1.0	10.2±1.1	10.6±2.3	<0.001
SP-1A	111.3±17.3	106.6±20.3	99.4±22.2	0.021
Biomechanical corrected IOP	16.6±1.9	17.2±2.5	15.7±2.5	0.0004
CorVis Biomechanical Index	0.3±0.3	0.6±0.2	0.7±0.3	<0.001

¹Mean±SD; n (%)

²Repeated Measure ANOVA (type III tests with auto correction)

Abbreviations, SP-1A: stiffness parameter at first applanation

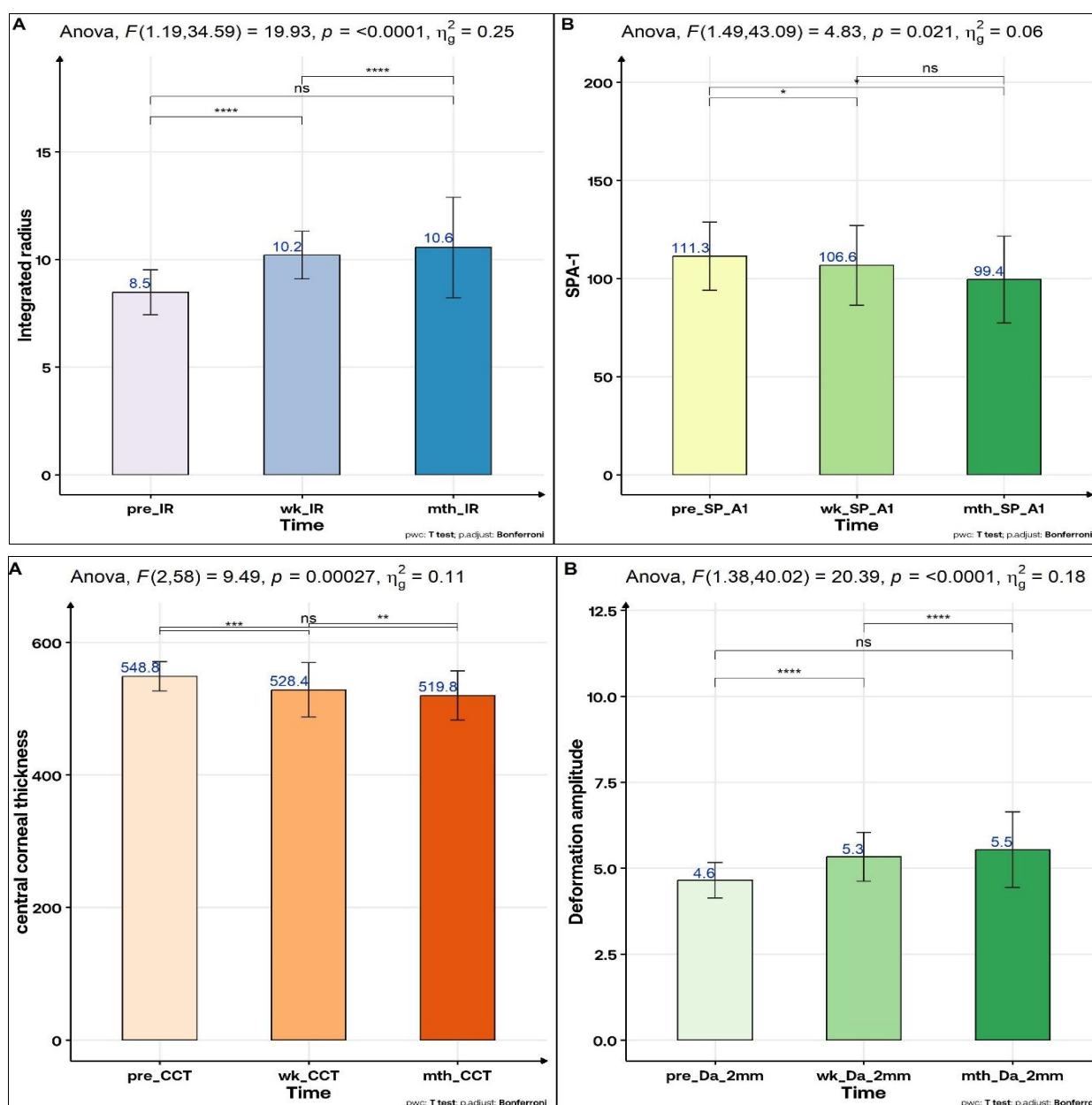


Fig 2: post-hoc test for repeated measurement in the LASIK group, preoperatively, after 2 week and after 2 months

3.3 SMILE Group

Ophthalmological parameter changes at three time points (preoperatively, 2 weeks postoperatively, and 2 months postoperatively) in the SMILE group were statistically significant in a number of parameters. There were significant changes in spherical equivalent ($p<0.001$), central corneal thickness ($p<0.001$), deformation amplitude

at 2 mm ($p<0.001$), integrated radius ($p<0.001$), stiffness parameter at first applanation (SP-A1) ($p=0.001$) and CorVis Biomechanical Index (CBI) ($p<0.001$). The rest of the parameters did not show statistically significant differences between the analyzed time points.

Table 3: Repeated measures of study characteristics in the SMILE group, N = 30.

Characteristics	Pre-operative ¹	After 2 weeks ¹	After 2 months ¹	p-value ²
Spherical equivalent	-3.5±1.0	0.2±0.4	-0.2±0.3	<0.001
Central corneal thickness (micron)	553.0±31.7	520.1±44.9	517.3±30.5	<0.001
deformation amplitude	4.6±0.6	5.1±0.5	5.0±0.7	<0.001
integrated radius	8.5±1.1	9.7±1.0	9.2±1.1	<0.001
SP-1A	116.1±27.8	99.3±19.5	105.2±17.1	<0.001
Biomechanical corrected IOP	16.9±2.5	17.3±2.4	16.3±2.0	0.13
CorVis Biomechanical Index	0.2±0.4	0.7±0.3	0.8±0.5	<0.001

¹Mean±SD; n (%)

²Repeated Measure ANOVA (type III tests with auto correction)

Abbreviations, SP-1A: stiffness parameter at first applanation

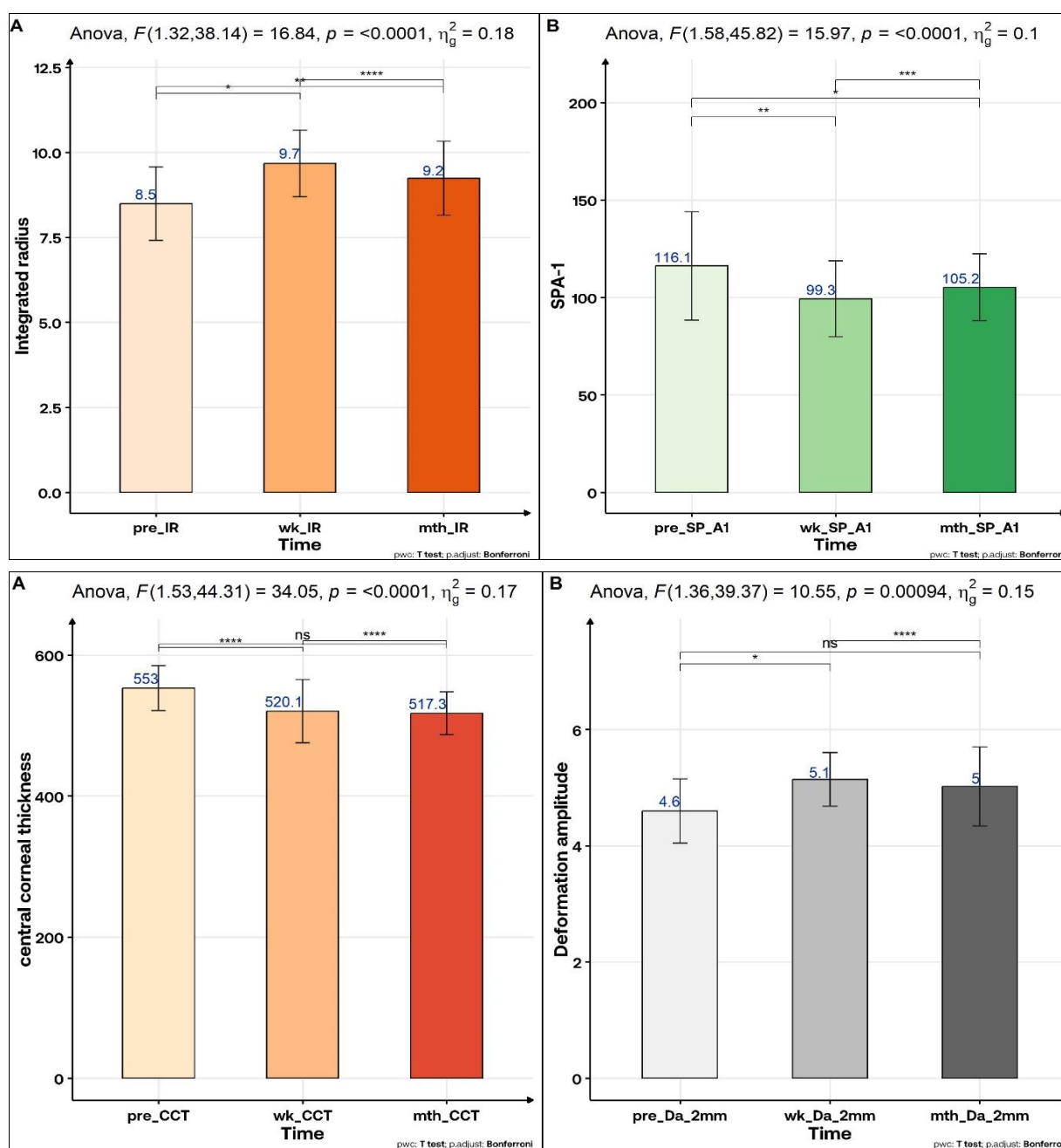


Fig 3: Post-hoc test for repeated measurement in the SMILE group, preoperatively, after 2 week and after 2 months.

3.4 Comparison Between Groups at Two Weeks Postoperatively

Comparative analysis between the LASIK and SMILE groups at two weeks postoperatively revealed a statistically significant difference in ablation/lenticule thickness, with

the LASIK group demonstrating a mean of $53.2 \pm 22.4 \mu\text{m}$ compared to $64.5 \pm 18.6 \mu\text{m}$ in the SMILE group ($p=0.038$). No statistically significant differences were observed between the two groups for other ophthalmological and biomechanical parameters at this time point.

Table 4: Comparison between LASIK and SMILE procedures after two weeks

Characteristics	LASIK, N=30 ¹	SMILE, N=30 ¹	P-value ²
Spherical equivalent	-0.1±0.4	-0.2±0.4	0.13
Ablation/lenticular thickness	53.2±22.4	64.5±18.6	0.038
Central corneal thickness (CCT)	528.4±41.1	520.1±44.9	0.5
Deformation amplitude	5.3±0.7	5.1±0.5	0.2
Integrated radius	10.2±1.1	9.7±1.0	0.057
SP-1A	106.6±20.3	99.3±19.5	0.2
Biomechanical corrected IOP	17.2±2.5	17.3±2.4	0.9
CorVis Biomechanical Index (CBI)	0.7±0.4	0.7±0.3	0.8

¹Mean±SD; n (%)

²Welch Two Sample t-test; Pearson's Chi-squared test; Fisher's exact test

Abbreviations, SP-1A: stiffness parameter at first applanation

3.5 Comparison Between Groups at Two Months Postoperatively

A comparative analysis of both the LASIK and SMILE groups two months after surgery showed that there was a statistically significant difference in three parameters. There was still a significant difference in ablation/lenticule thickness between groups ($p=0.038$) as found in the two-week experiment. It is notable that biomechanical

parameters were also significantly different across groups at this time and that, deformation amplitude at 2 mm was found to have a significant intergroup difference ($p=0.035$) whereas the integrated radius had a highly significant difference ($p=0.008$). The remaining ophthalmological and biomechanical parameters at two months after surgery did not achieve statistically significant differences in the two groups.

Table 2: Comparison between LASIK and SMILE procedures after two months.

Characteristics	LASIK, N=30 ¹	SMILE, N=30 ¹	P-value ²
Spherical equivalent	-0.2±0.3	-0.2±0.3	0.5
Ablation/lenticular thickness	53.2±22.4	64.5±18.6	0.038
Central corneal thickness	519.8±37.3	517.3±30.5	0.8
Deformation amplitude	5.5±1.1	5.0±0.7	0.035
Integrated radius	10.6±2.3	9.2±1.1	0.008
Stiffness parameter at first applanation (SP-1A)	99.4±22.2	105.2±17.1	0.3
Biomechanical corrected IOP	15.7±2.5	16.3±2.0	0.3
CorVis Biomechanical Index	0.7±0.3	0.8±0.5	0.8

¹Mean±SD; n (%)

²Welch Two Sample t-test; Pearson's Chi-squared test

Abbreviations, SP-1A: stiffness parameter at first applanation

We correlate the central corneal thickness (CCT), and other ophthalmological parameters after 2 weeks correlation between CCT and other parameters, showed a positive correlation between CCT and SP-1A, ($r = 0.5$, $P\text{-value} < 0.001$), and a negative correlation between CCT and deformation amplitude, ($r = -0.44$, $P\text{-value} = 0.0004$), also, there was a negative correlation between CCT and CorVis Biomechanical Index, ($r = -0.64$, $P\text{-value} < 0.001$). While

after two months of the procedures, there was a positive correlation between CCT and SP-1A, ($r = 0.66$, $P\text{-value} < 0.001$), also, there was a positive correlation between CCT and Biomechanical corrected IOP, ($r = 0.26$, $P\text{-value} = 0.049$), but there was a negative correlation between CCT and CorVis biomechanical index, ($r = -0.26$, $P\text{-value} = 0.046$).

Table 3: Correlation between central corneal thickness (CCT) and other ophthalmological parameters after 2 months from the procedures.

Characteristics	Correlation coefficient (R)	P-value ¹
Spherical equivalent	-0.12	0.38
Ablation/lenticular thickness	-0.17	0.18
Deformation amplitude	-0.20	0.12
Integrated radius	0.19	0.14
SP-1A	0.66	<0.001
Biomechanical corrected IOP	0.26	0.049
CorVis Biomechanical Index	-0.26	0.046

¹Pearson product moment correlation

Abbreviations, SP-1A: stiffness parameter at first applanation

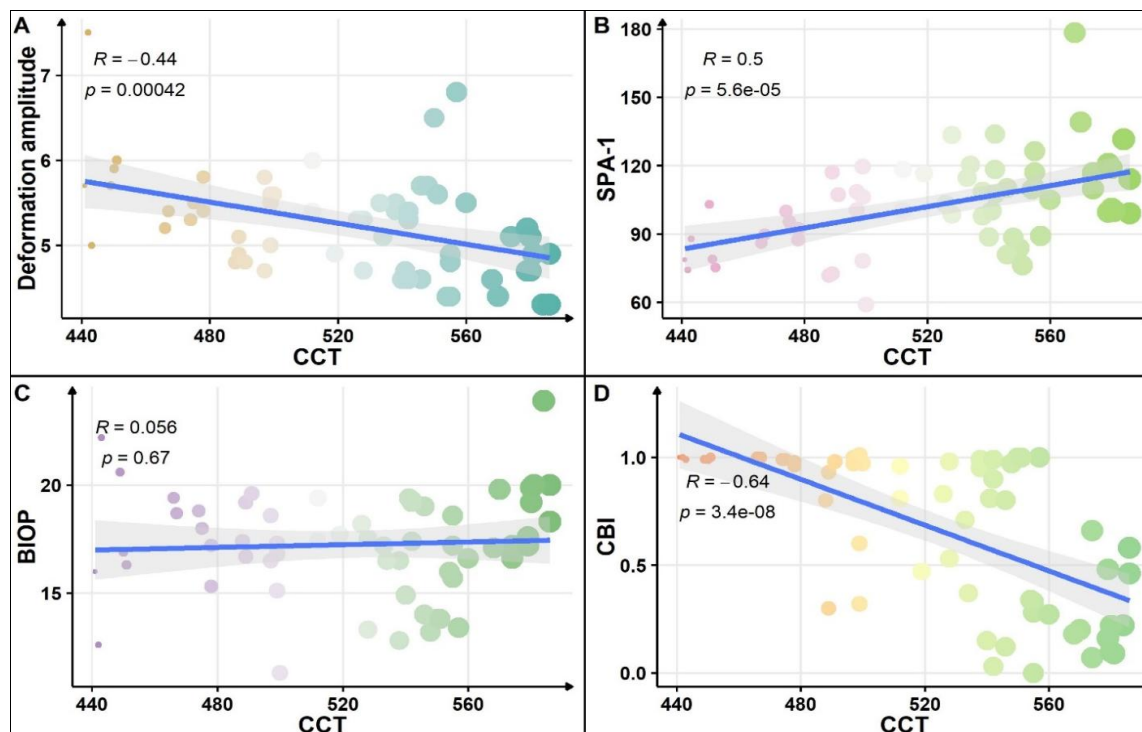


Fig 3: Correlation between Central corneal thickness, and BIOP, CBI, and SP-1A after two weeks.

4. Discussion

A comparative analysis of both the LASIK and SMILE groups two months after surgery showed that there was a statistically significant difference in three parameters. There was still a significant difference in ablation/lenticule thickness between groups ($p=0.038$) as found in the two-week experiment. It is notable that biomechanical parameters were also significantly different across groups at this time and that, deformation amplitude at 2 mm was found to have a significant intergroup difference ($p=0.035$) whereas the integrated radius had a highly significant difference ($p=0.008$). The remaining ophthalmological and biomechanical parameters at two months after surgery did not achieve statistically significant differences in the two groups.

In the current study, a strictly controlled design was used to compare the different biomechanical outcomes in these two techniques of surgery. Baseline characters such as age, spherical equivalent, central corneal thickness, and intracorneal pressure were carefully matched between the participants having myopia and myopic astigmatism. Every single procedure was carried out in one center by one surgeon to avoid inter-surgeon and inter-institutional variability. The CorVis ST dynamic Scheimpflug analyzer was used to test the corneal biomechanical data, that is, preoperative measurements, 2 weeks postoperative (when the wound is actively healing), and two months postoperative (when the wound has healed completely). The parameters were evaluated on verified biomechanical factors such as deformation amplitude at 2 mm (DA 2mm), stiffness parameter at first applanation (SP-A1), and integrated radius (IR) to fully describe the structural changes in the corneal arrangement after surgery.

We showed that corneal biomechanical properties were significantly reduced in both surgical groups at two weeks and two months after surgery. The worsening was demonstrated by a reduction in central corneal thickness, a drop in the stiffness parameter of the first applanation, an increase of deformation amplitude at 2 mm and an increase of the integrated radius (p less than 0.05). Interestingly, two

weeks after surgery, no significant difference between groups in corneal stiffness ($p > 0.05$) was found, which can probably be explained by the fact that the inflammatory healing process is still going on and may temporarily suppress biomechanical differences. Nonetheless, the LASIK group expressed a greater decrease in corneal hardness than the SMILE group at two months postoperative when the wound healing was complete ($p<0.05$) and validated the fact that SMILE is superior in terms of biomechanical preservation.

These results are consistent with the findings of Abd El-Fatah *et al.* (2021), who found that, in terms of biomechanically corrected intraocular pressure (bIOP, $p=0.001$), integrated radius (IR, $p=0.026$), stiffness parameter at first applanation (SP-A1, $p=0.013$), and CorVis Biomechanical Index (CBI, $p<0.001$), postoperative outcomes were significantly different between the femtosecond SMILE (On the same note Xin *et al.* (2022) concluded that there was a significant variation in corneal biomechanical reaction to LASIK and SMILE with the femtosecond LASIK (FS-LASIK) resulting in greater reduction in overall corneal stiffness relative to SMILE even though the loss of corneal thickness was similar^[23]. This underlines how biomechanical compromise is not determined purely by tissue excision but rather, it is highly determined by the surgical technique and maintenance of anterior stromal structure.

On the other hand, our findings do not support the results of Ibrahim *et al.* (2022), who noted reduced corneal biomechanical properties after both LASIK and SMILE surgeries but did not find any significant difference among groups^[24]. This variation can be explained by disparities in the follow-up period, size of the sample, inclusion criteria of patients or differences in the procedure and equipment used. The single-surgeon, single-center design of our study was standardized, which was complemented by trial balance parameters and a long-term two-month follow-up, and possibly offered a closer evaluation of long-term biomechanical outcomes.

The clinical implications of these results are huge. Improved

retention of corneal biomechanical integrity using SMILE could be translated into a decreased risk of long-term outcome in terms of post-refractive ectasia, higher refractive stability, and structural safety in eyes with borderline preoperative biomechanical parameters. These findings justify the favorable treatment of SMILE as compared to LASIK in the right candidates, particularly the one with Thin Cornea or low preoperative biomechanical indices. These findings should be supported by further long-term research with more participants to confirm them and draw clear clinical recommendations on the choice of procedure depending on personal biomechanical risk profiles.

5. Conclusion

The corneal biomechanical properties change after LASIK and SMILE, but higher reduction of corneal stiffness in LASIK group than SMILE group.

6. Acknowledgement

Not available

7. Author's Contribution

Not available

8. Conflict of Interest

Not available

9. Financial Support

Not available

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