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Corneal biomechanical changes following small incision lenticule extraction (SMILE) with variable cap thickness in management of mild to moderate myopia

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Abstract
Background: The emergence of CorVis ST® as a non-invasive method enables *in vivo* studying of the corneal biomechanical properties as the cornea is inevitably altered biomechanically following any kind of refractive surgery including SMILE. While many research has investigated as well as compared the corneal biomechanical response following SMILE as opposed to other laser refractive procedures utilizing flaps, few research have specifically focused on the corneal cap thickness's effect on postoperative biomechanical strength.
Objective: To compare the impact of applying different cap thicknesses (100 µm & 120 µm) on the corneal biomechanical properties following (SMILE) while management of mild to moderate myopia.
Patients and Methods: A prospective, comparative, interventional, randomized study was conducted on 40 eyes (of 20 cases) with mild to moderate myopia with or without astigmatism. They went through an equal and random categorization into two groups underwent SMILE where group A operated with 100 µm and group B operated with 120 µm cap thickness. They were compared pre- and 3 months postoperatively regarding visual outcomes, topographical outcomes using Pentacam®, and biomechanical outcomes as evaluated by CorVis ST®.
Results: A statistically significant difference was documented among both groups as regard the deformation amplitude ratio (DA ratio). Moreover, a negative statistical correlation between the preoperative central corneal thickness (CCT) and postoperative corneal biomechanical index (CBI) was demonstrated. Nevertheless, no statistically significant variations were documented regarding other corneal biomechanical parameters, topographic parameters, or the visual outcomes.
Conclusion: Three months after the surgery, corneal biomechanics-deformation amplitude in particular- were marginally less altered in group A operated with a 100 µm cap thickness (thinner cap) in comparison with group B operated with 120 µm (thicker cap). Both groups exhibited similar visual and topographical outcomes.

Keywords: Corneal biomechanics, CorVis ST, small incision lenticule extraction, smile, cap thickness, myopia

Introduction
Uncorrected refractive error is the primary etiology for vision impairment worldwide, with myopia representing the predominant refractive error [1, 2]. Approximately 1.5 billion individuals, accounting for 22% of the global population, are believed to have myopia. Its prevalence often varies considerably throughout various regions of the globe [3, 4]. Among adults, its occurrence rates fall between 15% and 49% [5, 6].
The myopic degree is quantified by the power of the ideal correction, measured in diopters. Additionally, myopia is designated with a minus sign [7]. It is categorized based on dioptric power into: Mild myopia often refers to a degree falling between - 0.50 and - 3.00 diopters, Moderate refers to a degree above -3.00 yet less than - 6.00 diopters, while High myopia typically refers to a degree of - 6.00 or above [8].
The primary corneal refractive surgeries utilized when correcting myopia and myopic astigmatism are excimer laser ablation and femtosecond laser-assisted lenticule extraction. The (SMILE) represents a surgical procedure involving a stromal lenticule creation then removing it via a small incision ranging from 2.0 to 4.0 mm located on the lenticule's edge. SMILE has been well established as a favorable approach as opposed to prior laser surgical

procedures utilizing flaps due to its ability to maintain more sub-basal corneal nerves along with minimizing the corneal biomechanical strength damage [9-11]. The standard cap thickness would be preserved at a range of 110 and 120 µm. Theoretically, a higher cap thickness would be anticipated to preserve more anterior stroma as well as corneal nerve fibers, thus strengthening corneal rigidity along with rapid ocular surface function recovery [12].

The cornea exhibits an intricate biomechanical structure, controlling its response under stress conditions [13]. At present, ophthalmologists exhibit a strong interest in precisely defining the corneal biomechanical characteristics in various ocular diseases as well as following refractive surgeries [14].

The CorVis ST represents an innovative non-contact tonometer utilizing dynamic corneal deformation information for corneal biomechanics' analysis. It is capable of capturing a series of horizontal Scheimpflug images through a high-speed camera recording 4,300 frames per second in a 100 (ms) timeframe [13-17].

Thus, our research was aimed at evaluating the corneal biomechanical alterations following (SMILE) with variable cap thickness (100 µm versus 120 µm) in management of mild to moderate myopia with/without astigmatism.

Patients and Methods

Study design

A prospective, comparative, interventional, randomized study, involving 40 eyes of 20 participants having mild to moderate myopia with or without astigmatism. Participants were recruited from El-Nokhba Ophthalmology Center in Tanta, Gharbia governorate, Egypt in coordination with Tanta University Ophthalmology Hospital in the period from June 2022 to June 2023. Our study was approved by the Institutional Research Ethics Committee of the Faculty of Medicine, Tanta University (Approval code: 35458/4/22). All participants were asked to fill an informed consent. Additionally, there were adequate provisions to ensure all participants privacy and confidentiality of the data will be preserved. They were randomly distributed into two groups 20 eyes each. All eyes were operated with SMILE by the same surgeon (Group A with 100 µm cap thickness while group B with 120 µm cap thickness).

Inclusion Criteria

1. Individuals with mild to moderate myopia (between -2 and -6 Diopters) with/without astigmatism (between 0 to -4 Diopters).
2. Stable manifest refraction (changes within +/- 0.5 D over a period of one year preoperatively).
3. Central corneal thickness (CCT) more than 500 µm.
4. Ages above eighteen years.

Exclusion Criteria

1. Those younger than eighteen years.
2. Individuals with previous ocular surgical interventions or ocular trauma.
3. Patients with active ocular pathology e.g. active uveitis.
4. Patients with any corneal topographic abnormalities, corneal ectasia suspects or with a central corneal thickness less than 500 µm.
5. Patients with associated systemic diseases (e.g. collagen disorders).
6. Patients with posterior segment pathologies.
7. Participants with intraoperative and⁄or postoperative complications were excluded from the statistical analysis of this study.

The included participants were subjected to the following

1. Complete ocular medical and surgical history taking.
2. Comprehensive ophthalmological examination:

- Uncorrected (UDVA) as well as Corrected Distant Visual Acuity (CDVA) assessment utilizing Snellen's chart and expressed in decimal notation.
- Manifest and cycloplegic refraction.
- Anterior segment examination using slit-lamp.
- I.O.P. measurement by Goldmann's applanation tonometer (GAT).
- Posterior segment examination using +90D auxiliary lens and indirect ophthalmoscope.

Investigations

All participants were subjected to evaluation of corneal topography using Scheimpflug corneal tomography (Pentacam; Oculus GmbH, Wetzlar, Germany) & corneal biomechanics by utilizing Corvis ST non-contact tonometer (Oculus, Wetzlar, Germany, Type 7200) preoperatively. The following parameters as shown in Vinciguerra screening report display were included in the statistical analysis:

1. Deformation amplitude ratio (DA ratio).
2. Integrated radius of curvature.
3. Ambrossio's relational thickness horizontal (ARTh).
4. Stiffness parameter at 1st applanation (SP-A1).
5. Corneal biomechanical index (CBI).

Operative technique

Each FemtoSMILE operation was performed utilizing The VisuMax 500 femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) with established and standard technique by the same surgeon. All participants in Group A had SMILE with 100 µm cap thickness versus 120 µm cap thickness in group B.

Postoperative treatment

All participant received topical antibiotic eyedrop (Moxifloxacin hydrochloride 0.5% -Vigamox® - by Alcon® company, Geneva, Switzerland) 5 times / day along with a topical corticosteroid eyedrop (prednisolone acetate 1.0% suspension -Econopred plus®- by Alcon® company, Geneva, Switzerland) 5 times / day for 1 week then gradually tapered over a period of 2 weeks. Also, preservative free artificial tears (-Systane Ultra®- by Alcon® company, Geneva, Switzerland) also 5 times / day for a period of one month.

Postoperative follow up

All participants underwent a postoperative follow-up at 1 day, 1 week, 1 month as well as 3 months postoperatively including:

1. Uncorrected (UDVA) and Corrected Distant Visual Acuity (CDVA) assessment.
2. Evaluation of corneal topography using corneal tomography (Pentacam) & corneal biomechanics by using CorVis ST non-contact tonometer were performed three months postoperatively.

Statistical Analysis

The data went through a statistical analysis utilizing SPSS

V20, for windows. Following normality testing utilizing Kolmogrov-Smirnov test, Qualitative data were displayed as numbers as well as percentages, while Quantitative data were displayed as median for nonparametric data as well as Mean ± SD for parametric data. Student t-Test was utilized for comparing normally distributed quantitative variables among two groups, Paired t-Test was utilized for comparing normally distributed quantitative variables within the same group, Chi-square was utilized for comparing not normally distributed variables, and Pearson Linear Correlation Coefficient was applied. The significance was deemed to be at $p \leq 0.05$.

Results

Demographic data

No statistically significant difference was documented between both groups regarding age (P= 0.211) and the gender (P= 0.376) as shown in table 1.

UDVA and CDVA (in decimal notation

In both groups a statistically significant improvement was documented regarding both postoperative UDVA as well as postoperative CDVA ($p< 0.001$) as compared to the preoperative UDVA and preoperative CDVA respectively. Nevertheless, no statistically significant variation was documented between both groups as regards both postoperative UDVA as well as postoperative CDVA as shown in table 2 and table 3.

Efficacy and safety indices

Efficacy index (postoperative UDVA / preoperative CDVA) was 1.05 ± 0.09 in group A and 1.07±0.13 in group B. while the safety index (postoperative CDVA / preoperative CDVA) was 1.08±0.13 in group A and 1.12±0.11 in group B as shown in table 4 and table 5.

Manifest Refraction, Spherical Equivalent (SE)

A statistically significant improvement ($p< 0.001$) was addressed regarding the postoperative SE as opposed to the preoperative values within each group. A statistically significant difference (P= 0.038) was documented between both groups as regards preoperative SE. However, postoperatively there was no statistically significant difference documented between both groups as shown in table 6.

Corneal topography

1. **Central corneal thickness (CCT) in μm:** No statistically significant differences were documented between both groups regarding preoperative as well as postoperative CCT values. However, a statistically significant reduction ($p< 0.001$) was documented in the postoperative CCT compared to the preoperative CCT in each group as shown in table 7.
2. **K-mean (Km) in diopters:** No statistically significant differences were documented between both groups regarding preoperative as well as postoperative Km values. Nevertheless, a statistically significant reduction ($p< 0.001$) was documented in the postoperative Km compared to the preoperative Km in each group as shown in table 8.

Corneal biomechanics

1. **DA ratio:** No statistically significant difference was documented regarding the preoperative DA ratio between both groups. A statistically significant rise ($p< 0.001$) was documented regarding the postoperative DA ratio as compared to preoperative DA ratio in each group, However, a statistically significant difference (P= 0.033) was observed in the postoperative DA ratio values in group B as compared to group A as shown in table 9.
2. **Integrated radius of curvature:** A statistically significant variation (P= 0.020) was documented regarding the preoperative Integ. Radius values between both groups. However, no statistically significant variation was documented regarding the postoperative Integ. Radius values between both groups. A statistically significant rise ($p< 0.001$) was observed regarding the postoperative Integ. Radius as compared to preoperative Integ. Radius in each group as shown in table 10.
3. **Ambrósio relational thickness (ARTh):** No statistically significant differences were documented between both groups regarding preoperative as well as postoperative ARTh values. However, a statistically significance decrease ($p< 0.001$) was documented within the postoperative ARTh as compared to the preoperative ARTh in each group as shown in Table 11.
4. **Stiffness parameter at P1 (SP-A1):** No statistically significant differences were documented between both groups regarding preoperative as well as postoperative SP-A1 values. However, a statistically significance decrease ($p< 0.001$) was observed within the postoperative SP-A1 as compared to the preoperative SP-A1 in each group as shown in Table 12.
5. **Corneal biomechanical index (CBI):** No statistically significant differences were documented between both groups regarding preoperative as well as postoperative CBI values. However, a statistically significance rise ($p< 0.001$) was observed within the postoperative CBI as compared to the preoperative CBI in each group as shown in Table 13.

Statistical correlation

A negative statistical correlations were shown between postoperative (CBI) and preoperative (CCT) in group A (r= - 0.462 \ P= 0.040) (Graph 1) and group B (r= - 0.578 \ P= 0.008) (Graph 2), as well as between postoperative (CBI) and postoperative (CCT) in group A (r= - 0.763 \ P= <0.001) (Graph 3) and group B (r= - 0.640 \ P= 0.002) (Graph 4).

Discussion

Corneal biomechanics is an important concern to be considered when planning any kind of refractive surgery, since the cornea undergoes inevitable biomechanical alterations during surgical procedures, which might potentially result in corneal ectasia following the treatment. Non-invasive techniques for analyzing biomechanical alterations following these treatments remain valuable while comparing various approaches for refractive surgeries. The SMILE represents a non-flap based technique, preserving the anterior cornea without a flap, which makes it more effective as opposed to LASIK in maintaining the corneal biomechanical stability, especially for those having greater myopic degree [18].

While many research has investigated as well as compared

the corneal biomechanical response following SMILE as opposed to other laser refractive procedures utilizing flaps, few research have specifically focused on the corneal cap thickness's effect on postoperative biomechanical strength [19].

Hence, our research was aimed at evaluating the corneal biomechanical characteristics using the CorVis ST (Oculus, Wetzlar, Germany) in individuals with mild to moderate myopia with or without astigmatism who underwent FemtoSMILE with two different cap thickness.

Our research involved forty eyes of twenty participants sought refractive surgery. Preoperative confounding epidemiological-demographic factors as age, sex distribution, as well as the corneal topographic parameters including CCT, the thinnest location, and the K-mean (Km) exhibited no statistical variation among both groups. Thus, we could analyze corneal deformation parameters independent of these confounders.

Moreover, both groups did not exhibit statistically significant variations as regard to the preoperative corneal biomechanical parameters evaluated utilizing CorVis ST including (DA ratio), the (ARTh), the (SP-A1), as well as the (CBI). However, the integrated radius of curvature was the only one exhibiting a statistically significant difference with its values being greater within group A as opposed to group B.

Studied participants underwent FemtoSMILE surgery performed utilizing the VisuMax 500 femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) through an established and standard technique, by the same surgeon and with fixed treatment data with the cap thickness being the only changeable factor (Group A with 100 µm versus Group B with 120 µm cap thickness).

Postoperative evaluation of the previously mentioned corneal topographical and biomechanical parameters 3 months after FemtoSMILE was conducted and did not exhibit statistically significant variations between both groups. Only the deformation amplitude ratio (DA ratio) showed a statistically significant difference with its value being higher in group B compared to group A postoperatively.

Results of this study coincide with the results of Wu *et al*. (2019) who performed a contralateral eye comparison between 2 cap thicknesses (110 µm within an eye Versus 140 µm on the other one) where they addressed non-significant between-group variation regarding UDVA or manifest refraction spherical equivalent (MRSE) postoperatively. However, DA ratio, integrated inverse radius, time of 1st applanation (A1T), and time of 2nd applanation (A2T) were significantly increased postoperatively, but alterations regarding A2T, DA ratio as well as integrated inverse radius were significantly less within 110-µm group [20].

Also, similar to our research, Jun *et al*. (2021) conducted a prospective study that was aimed at comparing the clinical outcomes as well as corneal biomechanical alterations utilizing Corvis ST following FemtoSMILE. They involved participants who underwent FemtoSMILE with two different cap thicknesses: 120-µm within one group versus 140-µm within another group. They addressed, the mean UDVA, safety, efficacy indices, as well as refractive predictability exhibited similar outcomes in both groups. Nevertheless, with the exception of (bIOP), all the corneal biomechanical parameters analyzed exhibited significant alterations following the surgery. Postoperatively a significant rise regarding the DA ratio as well as integrated inverse radius was documented. Additionally, there was a significant drop regarding SP-A1, ARTh via the horizontal meridian, and stress strain index (SSI), suggesting a significant reduction in corneal stiffness along with its deformation resistance ability postoperatively. Significant variations found regarding pre and postoperative values of DA ratio as well as integrated inverse radius in the two groups suggest that the corneal weakening was less pronounced within 120-µm group. This could be attributed to the fact that a thicker lenticule was needed in the 140-µm group to achieve a similar refractive outcome, thus leading to a thinner residual stromal bed after the surgery. This residual stromal bed thickness difference explains the variation regarding the DA ratio as well as integrated inverse radius changes between both groups [21].

In contrast, Lv *et al*. (2023) conducted a prospective comparative study to examine the corneal biomechanical characteristics following SMILE for myopia as well as astigmatism, utilizing three various cap thicknesses (110, 120, and 130 µm). The corneal biomechanical parameters went through assessment before the surgery as well as at 1 week, 1, 3, and 6 months postoperatively. The findings exhibited that at the 1-month mark following the surgical procedure, the IR along with DA ratio 2mm were significantly greater within both 120 µm as well as 130 µm groups as opposed to the 110 µm group. However, there were no significant variations observed at other time points. The ARTh exhibited a significant rise within the 120-µm as well as 130 µm groups as opposed to the 110 µm one, yet only at the 6-month mark following the surgery. Regarding SP-A1, SSI, bIOP, as well as CCT, all of these parameters significantly higher within the thicker cap groups (130 µm group, 120 µm group, and 110 µm group, respectively) at both 3 months as well as 6 months following the surgical procedure. However, there were no significant variations seen across the groups in subsequent follow-ups. Furthermore, the Corvis biomechanical index-laser vision correction (CBI-LVC) did not exhibit any significant variations either among various groups or at different postoperative follow-up intervals. The research addressed that the corneal stiffness was highest after FemtoSMILE within a 130 µm cap, then a 120 µm cap, and finally a 110 µm cap in a decreasing order. Additionally, the 130 µm cap could exhibit benefits in relation to corneal biomechanics along with retreatment possibility [22]. These advantages might be linked to the implementation of a longer timeframe (Up to 6 months after the surgery) for evaluating corneal biomechanical parameters.

Regarding the findings achieved by EL-Massry *et al*. (2015) [23] also disagreed with ours since they conducted a contralateral eye comparison between femtosecond SMILE at 100 µm depths (Within the right eyes) as well as 160 µm (within the left ones). They addressed, the refractive lenticule creation at 160 µm depth in SMILE exhibited less impact on the corneal biomechanics regarding corneal hysteresis (CH) as well as corneal resistance factor (CRF) when compared to a lenticule at 100 µm depth as evaluated utilizing ocular response analyzer (ORA). At 1-month following the surgery, both CH as well as CRF exhibited statistically significant greater values within the left eyes (lenticule at a of 160 µm depth). Non-significant variation was documented among the right or left eyes as regards

manifest refraction, UDVA, as well as total high order aberrations (THOA) [23]. This could be attributed to the comparison between a higher cap thickness of 160 µm versus 100 µm and also the use of a different method (Ocular response analyzer) for assessment of corneal biomechanical stability as early as one month postoperatively.

Table 1: Epidemiological-demographic characteristics of the studied groups

		Cap thickness (µm)				Student t-Test	
		Group A		Group B		t	P-value
Age	Range	19 - 34		19 - 32		1.273	0.211
	Mean ±SD	25.10 ± 5.52		23.00 ± 4.90			
						Chi-Square	
		N	%	N	%	X^2	P-value
Sex	Male	2	10.00	4	20.00	0.784	0.376
	Female	18	90.00	16	80.00		
Eye	OD	10	50.00	10	50.00	0.000	1.000
	OS	10	50.00	10	50.00		

N: number, OD: right eye, OS: left eye

Table 2: UDVA data (In decimal notation)

UDVA		Cap thickness (µm)		Student t-Test	
		Group A	Group B	t	P-value
Pre	Range	0.05-0.2	0.05-0.15	3.240	0.002*
	Mean ± SD	0.13±0.07	0.08±0.03		
Post	Range	0.8-1	0.7-1	1.437	0.159
	Mean ± SD	0.98±0.06	0.94±0.09		
Differences		-0.85±0.06	-0.87±0.08		
Paired t-Test		<0.001*	<0.001*		

UDVA: Uncorrected distant visual acuity (pre- and post-operative).

Table 3: CDVA data (In decimal notation)

CDVA		Cap thickness (µm)		Student t-Test	
		Group A	Group B	t	P-value
Pre	Range	0.7-1	0.7-1	1.611	0.115
	Mean ± SD	0.94±0.10	0.89±0.10		
Post	Range	1-1	0.9-1	1.453	0.154
	Mean ± SD	1.00±0.00	0.99±0.03		
Differences		-0.06±0.10	-0.10±0.08		
Paired t-Test		0.014*	<0.001*		

CDVA: Corrected distant visual acuity (pre- and post-operative).

Table 4: Efficacy index

Efficacy	Cap thickness (µm)		Student t-Test	
	Group A	Group B	t	P-value
Range	0.9-1.25	0.88-1.29	-0.543	0.590
Mean ± SD	1.05±0.09	1.07±0.13		

Efficacy index = postoperative UDVA / preoperative CDVA

Table 5: Safety index

Safety	Cap thickness (µm)		Student t-Test	
	Group A	Group B	t	P-value
Range	1-1.43	1-1.29	-1.219	0.230
Mean ± SD	1.08±0.13	1.12±0.11		

Safety index = postoperative CDVA / preoperative CDVA

Table 6: MRSE data (In diopters)

SE		Cap thickness (µm)		Student t-Test	
		Group A	Group B	t	P-value
Pre	Range	-6.75-2.00	-6.63-2.25	2.147	0.038*
	Mean ± SD	-3.61±1.45	-4.61±1.51		
Post	Range	-0.88-0.75	-0.63-0.25	-1.975	0.056
	Mean ± SD	-0.38±0.46	-0.14±0.27		
Differences		-3.23±1.58	-4.48±1.46		
Paired t-Test		<0.001*	<0.001*		

MRSE: Manifest refraction spherical equivalent.

Table 7: CCT data (in µm)

CCT		Cap thickness (µm)		Student t-Test	
		Group A	Group B	t	P-value
Pre	Range	513-593	520-602	0.077	0.939
	Mean ± SD	557.75±26.84	557.10±6.59		
Post	Range	419-548	435-517	0.445	0.659
	Mean ± SD	468.50±41.25	463.50±28.60		
Differences		89.25±27.47	93.60±23.45		
Paired t-Test		<0.001*	<0.001*		

CCT: Central corneal thickness.

Table 8: Km data (In diopters)

Km		Cap thickness (µm)		Student t-Test	
		Group A	Group B	t	P-value
Pre	Range	42.7-47.1	43.1-45.1	-0.830	0.412
	Mean ± SD	43.85±1.16	44.11±0.78		
Post	Range	38.8-40.8	37.2-41	1.853	0.072
	Mean ± SD	40.27±0.64	39.59±1.51		
Differences		3.58±1.30	4.52±1.65		
Paired t-Test		<0.001*	<0.001*		

Km: K-mean.

Table 9: DA ratio data

DA ratio		Cap thickness (µm)		Student t-Test	
		Group A	Group B	t	P-value
Pre	Range	3.8-4.7	3.8-4.6	0.469	0.642
	Mean ± SD	4.32±0.27	4.28±0.19		
Post	Range	4.7-6	5.3-6	-2.209	0.033*
	Mean ± SD	5.42±0.45	5.66±0.22		
Differences		-1.10±0.30	-1.38±0.22		
Paired t-Test		<0.001*	<0.001*		

DA ratio: deformation amplitude ratio.

Table 10: Integrated radius of curvature data

Integrated Radius		Cap thickness (µm)		Student t-Test	
		Group A	Group B	t	P-value
Pre	Range	5.8-8.5	5.6-7.6	2.427	0.020*
	Mean ± SD	7.08±0.82	6.53±0.58		
Post	Range	7.5-10.8	8.2-9.5	-0.822	0.416
	Mean ± SD	8.81±1.03	9.01±0.42		
Differences		-1.73±0.78	-2.48±0.49		
Paired t-Test		<0.001*	<0.001*		

Table 11: ARTh data

ARTh		Cap thickness (µm)		Student t-Test	
		Group A	Group B	t	P-value
Pre	Range	309.3-574.6	360.8-905.6	0.100	0.921
	Mean ± SD	460.13±94.32	456.02±156.58		
Post	Range	125.4-345.5	121.5-236.1	1.716	0.094
	Mean ± SD	214.24±70.65	183.08±40.02		
Differences		245.89±90.62	272.94±163.03		
Paired t-Test		<0.001*	<0.001*		

ARTh: Ambrósio relational thickness -horizontally.

Table 12: SP-A1 data

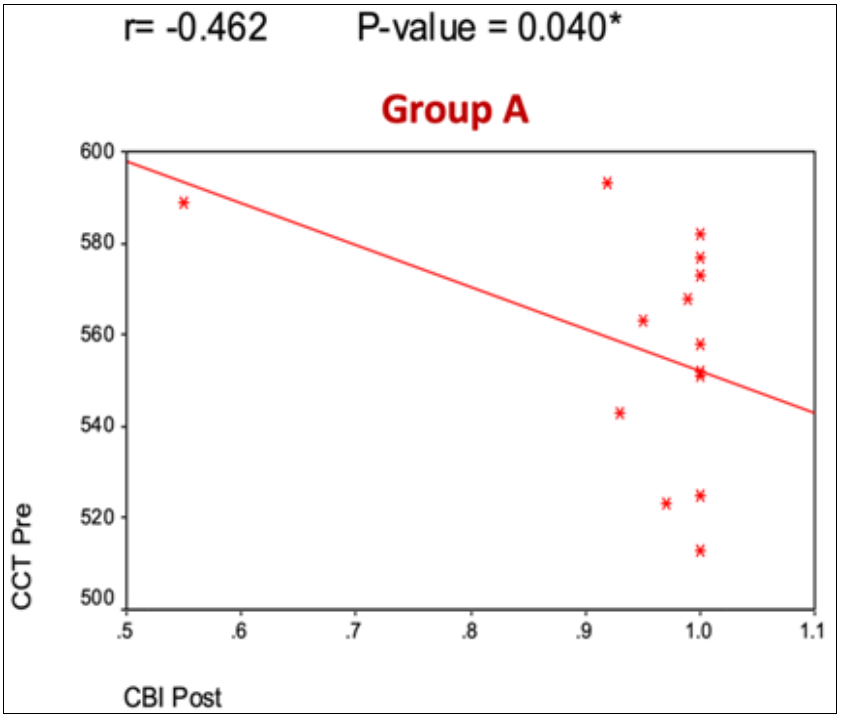
SP-A1		Cap thickness (µm)		Student t-Test	
		Group A	Group B	t	P-value
Pre	Range	84.1-145.8	82.9-142.9	-1.153	0.256
	Mean ± SD	107.37±16.38	113.76±18.63		
Post	Range	51.9-106.6	56.7-90.5	1.750	0.088
	Mean ± SD	79.58±16.60	71.48±12.37		
Differences		27.79±15.98	42.28±22.50		
Paired t-Test		<0.001*	<0.001*		

SP-A1: stiffness parameter at first applanation.

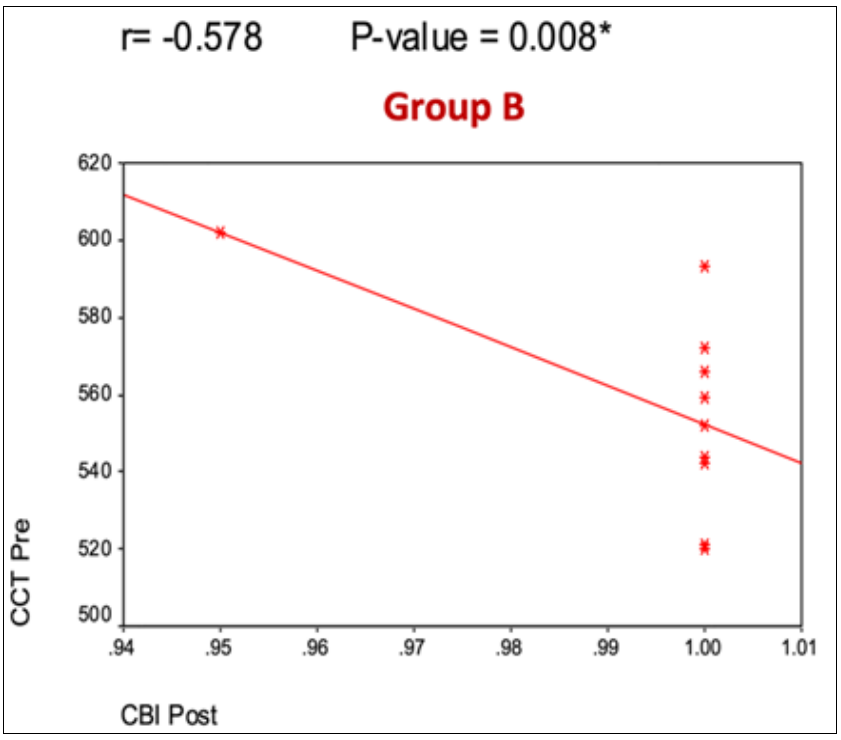
Table 13: Corneal biomechanical index (CBI) data

CBI		Cap thickness (µm)		Student t-Test	
		Group A	Group B	t	P-value
Pre	Range	0-0.22	0-0.6	-1.465	0.151
	Mean ± SD	0.04±0.07	0.10±0.18		
Post	Range	0.55-1	0.95-1	-1.829	0.075
	Mean ± SD	0.94±0.14	0.10±0.02		
Differences		-0.904±0.141	-0.90±0.18		
Paired t-Test		<0.001*	<0.001*		

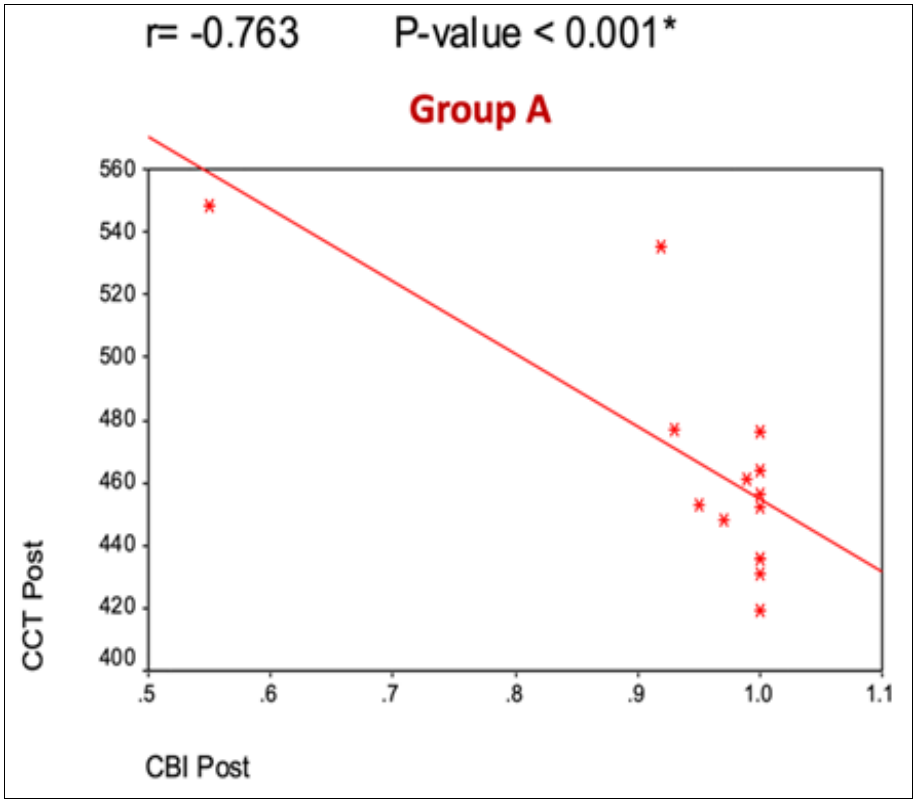
CBI: corneal biomechanical index.



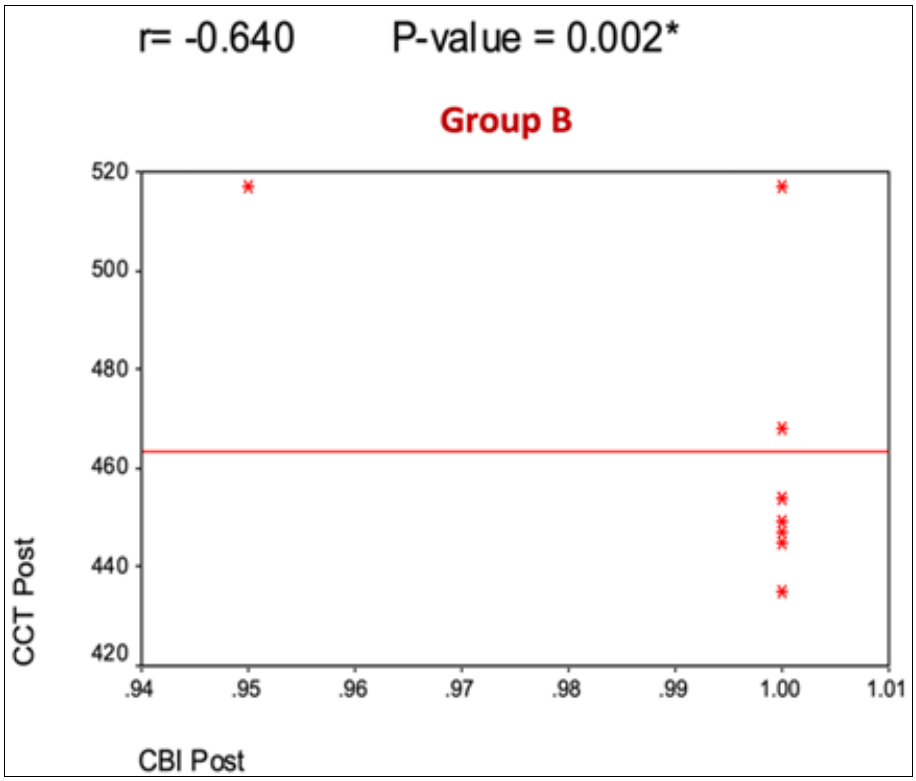
Graph 1: Illustrating the negative statistical correlation between the postoperative corneal biomechanical index (CBI) and preoperative central corneal thickness (CCT) in group A



Graph 2: Illustrating the negative statistical correlation between the postoperative corneal biomechanical index (CBI) and preoperative central corneal thickness (CCT) in group B



Graph 3: Illustrating the negative statistical correlation between the postoperative corneal biomechanical index (CBI) and postoperative central corneal thickness (CCT) in group A



Graph 4: Illustrating the negative statistical correlation between the postoperative corneal biomechanical index (CBI) and postoperative central corneal thickness (CCT) in group B

Conclusion

FemtoSMILE for treating myopia with or without astigmatism represents efficient, safe approach that yields highly predictable outcomes along with high degree of patient satisfaction. Nevertheless, it is crucial to develop as well as implement various nomograms based on cap thickness in order to get excellent results. A thicker lenticule, necessary for a thick cap, could lead to greater corneal biomechanical alterations, which in turn is linked to a thinner residual stromal bed. Furthermore, future research is required to fully grasp the cap thickness impact on clinical results, corneal biomechanics, as well as the

interface between the cap and stromal bed. This will help determine the optimal parameters, involving cap thickness, depending on the patient's ocular condition.

Thus, our recommendation for future studies is to continue this work on a larger number of participants, more different cap thicknesses, and a longer follow up postoperatively.

Conflict of Interest
Not available

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Not available

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