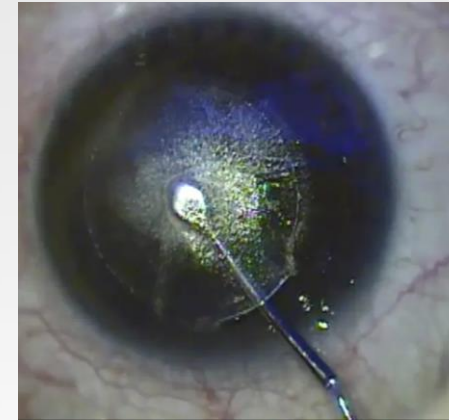


ASSESSMENT OF THE TEAR FILM AND CORNEAL STABILITY IN PATIENTS WITH VARIOUS DEGREES OF MYOPIA FOLLOWING SMALL INCISION LENTICULE EXTRACTION

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Introduction

SMALL INCISION LENTICULE EXTRACTION –SMILE:

- Technique for correcting myopia and myopic astigmatism. It involves cutting of the intra-stromal lenticule using a femtosecond laser, followed by manual extraction through a peripheral corneal tunnel incision
- This minimally invasive approach preserves corneal nerves more successfully and is reported to result in lower incidence of dry eye

Introduction

The main concern for refractive surgeons and patients undergoing corneal refractive surgery are the:

- Predictability and long-term stability of attempted correction
- The quality of the visual outcome
- Safety of the procedure
- Less postoperative dryness
- Long-term corneal bio-mechanical stability
- Minimization of intra and postoperative complications

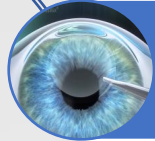
Objective of the Study


To evaluate the changes of:


- Lipid layer thickness (LLT)
- Non-invasive tear break-up time (NITBUT)
- Median Corneal curvature (Km) $Km=(K1+K2)/2$
- Central corneal thickness (CCT)

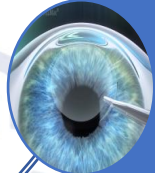
In patients with different myopia degrees 6 months postoperative after small-incision lenticule extraction (SMILE)

LIPID LAYER TEAR FILM (LLT)

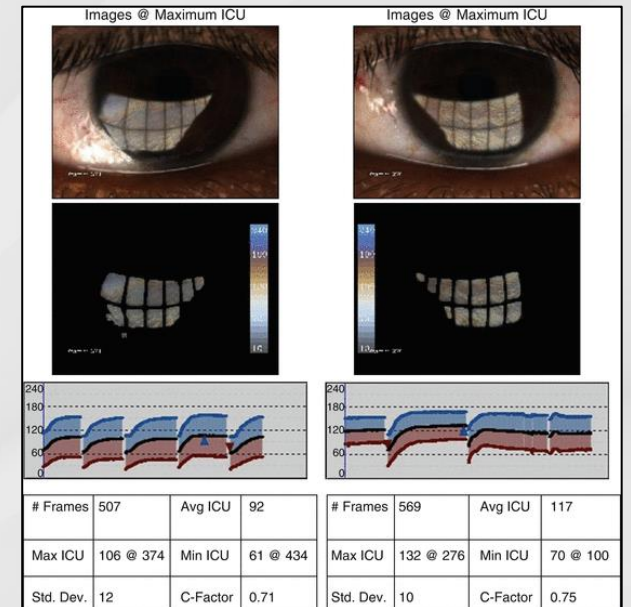
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Lipid layer has been found to play an important role in the maintenance of **tear film stability**
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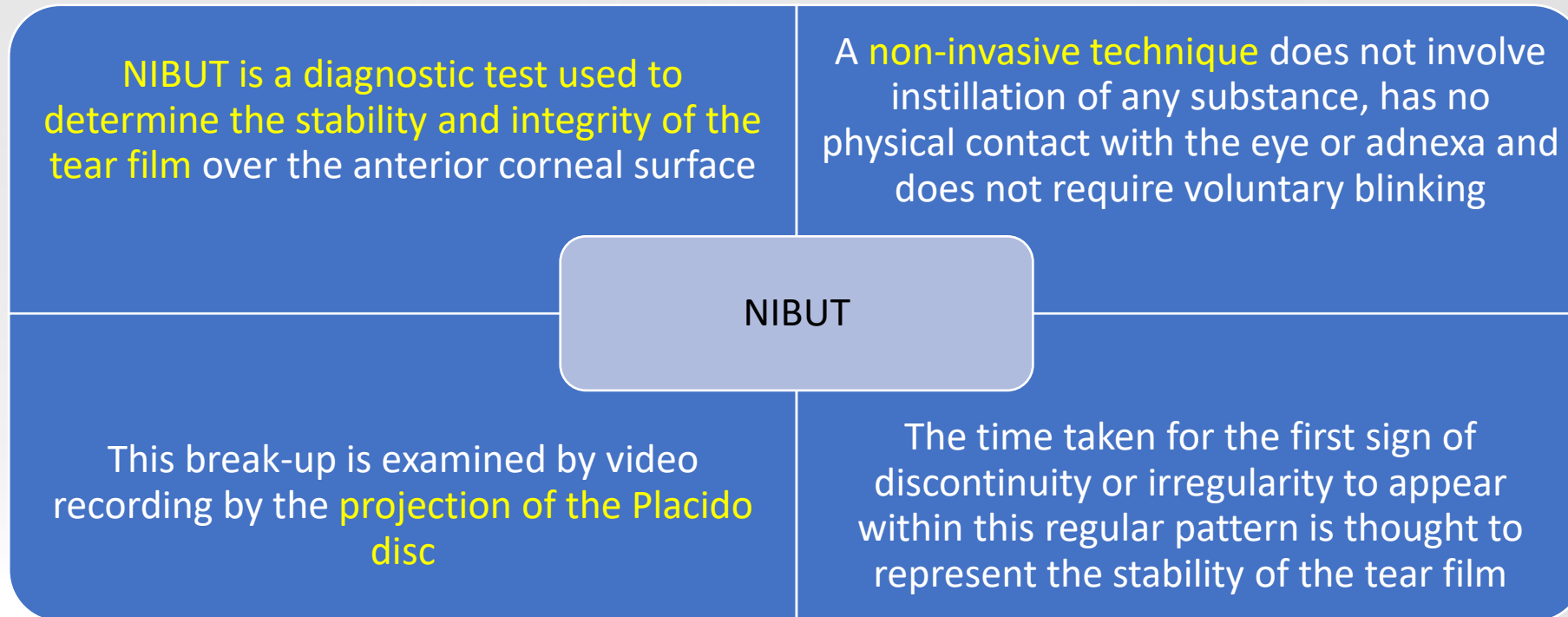
We evaluated the changes in LLT after SMILE and the effects on dry eye syndrome with ocular surface interferometry
- 

Lipiview interferometer is a **noninvasive method** that can quantitatively measure the average lipid layer thickness
- 

LLT serves many functions, including promotion of rapid spreading and redistribution of aqueous tear fluid after blinking, stabilization of the tear film surface, and suppression of excessive evaporation of tear fluid

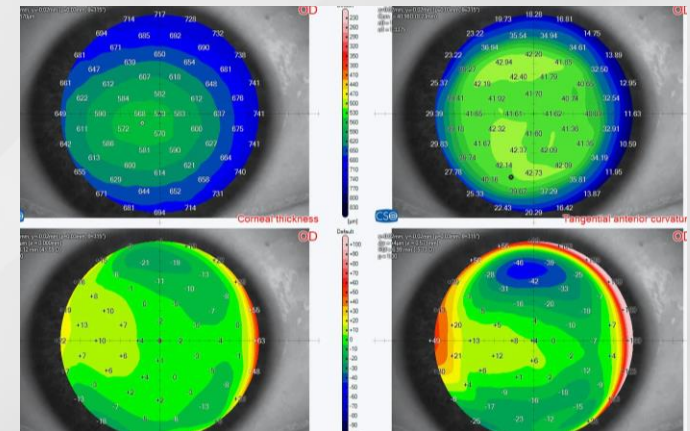


NON-INVASIVE TEAR BREAK-UP TIME (NIBUT)

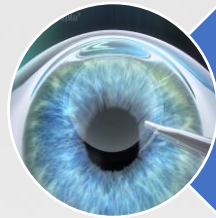


KERATOMETRY (Km) CENTRAL CORNEAL THICKNESS (CCT)

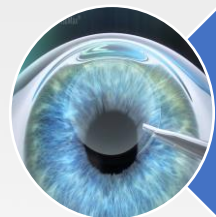
- Accurate analysis of the cornea is important for preoperative risk assessment and early detection of postrefractive surgery ectasia
- Evaluated parameters such as Km and CCT were obtained with Sirius tomography system
- Our aim was to quantify the effect of SMILE on the corneal biomechanical stability
- The same mechanisms responsible for preserving ocular integrity can undermine the goals of achieving predictable and stable visual outcomes after refractive surgery



Material & Methods



Prospective, interventional, non-case control study was carried out in a tertiary eye care center in Kuwait



We enrolled **266 eyes of 133** patients, treated with SMILE refractive surgery from March 2019 to August 2019

Material & Methods

Patients were divided into 3 groups according to the degree of spherical refraction:

Low myopia group

LMG: spherical refraction ≤ -3.00 D,
35 patients; 70 eyes

Moderate-myopia group

MMG; -spherical refraction from -3.00 to -6.00 D, 52 patients; 104 eyes

High-myopia group

HMG; spherical refraction ≥ -6.00 D,
46 patients; 92 eyes

Material & Methods



Inclusion criteria: Minimum age of 18 years, preoperative myopic spherical refraction from -1.0 D to -10,0 D, cylindrical refraction up to -3,50 D, best corrected visual acuity (BCVA) of 20/30 or better, and minimum calculated postoperative residual stromal bed of 350 μm



Exclusion criteria: Annual refractive changes more than -0.50 D, history of corticosteroids and antiglaucoma drugs, dry eye syndrome, corneal pathology, active disease in the eye and eye adnexa, progressive retinal changes, autoimmune or other systemic disease, pregnancy and lactation

Material & Methods



LLT film measurements were done with **Lipiview II** ocular surface interferometer (TearScience Inc, Morrisville, North Carolina, USA)



The LLT is presented in **interferometric color units (ICU)**, where 1 ICU corresponds to approximately 1 nm



LipiView II interferometer displays a maximum of 100 nm



NIBUT, Km and CCT were obtained with **Sirius corneal topography** (Costruzioni Strumenti Oftalmici, Italy)



Corneal curvature recorded by Sirrus topography system was taken as median K (Km).
 $Km = (K1 + K2) / 2$, K1 represents the keratometry value for the flat meridian, K2 represents the keratometry value for the steep meridian

Material & Methods

For **SMILE procedure VisuMax 500-kHz femtosecond laser** (Carl Zeiss Meditec AG, Jena, Germany) was used

The following examinations were performed at follow up visits:

UCVA, BCVA,
auto-refractometry,
K1 and K2 readings,
Lipiview interferometer,
intraocular pressure, corneal topography,
slit lamp examination, fundus examination



Main outcome measured were the change in average

LLT,
NIBUT,
K readings
corneal thickness

at 6 months after SMILE and its statistical significance.

Result:

All the parameters were matched preoperatively in all three myopia groups.

Kruskal-Wallis test was used for inter group comparison with significance level set at a value $p > 0.05$.

	Low Myopia Group	Medium Myopia group	High Myopia group	P value
Numbers	35	52	46	
Gender				
Male	14 (40%)	19 (36.5%)	17 (36.9%)	
Female	21 (60%)	33 (63.5%)	29 (63.1%)	
Age	23 (+/- 3.39)	23.21 (+/-3.02)	23.76 (+/- 3.54)	P .64863.
LLT				
Right eye	61.08 (+/-9.99)	59.55 (+/-8.47)	59.65 (+/-8.87)	P 0.80143
Left eye	61.17 (+/-9.00)	61.07 (+/-8.35)	62.95 (+/-7.80)	P 0.52427
TBUT (av)				
Right eye	12.69 (+/-1.08)	12.77 (+/-0.96)	12.58 (+/-0.97)	P 0.554
Left eye	13.16 (+/-1.04)	13.25 (+/-1.10)	13.08 (+/-1.33)	P 0.836
Corneal thickness				
Right eye	541.08 (+/- 15.21)	543.32 (+/- 13.42)	543.02 (+/-11.13)	P .84906
Left eye	541.22 (+/- 14.25)	541.34 (+/- 18.81)	543.17 (+/-10.85)	P .82052
K_m				
Right Eye	43.14 (+/-0.830)	43.44 (+/-0.643)	43.21 (+/-0.819)	.12924
Left Eye	43.45 (+/-0.987)	43.93 (+/-0.633)	43.87 (+/-0.709)	.09254

Result:

Comparative analysis
of all 4 parameters

Preoperative
Vs
6 months post-
operative

	Preoperative				Postoperative 6 months			
	LMG	MMG	HMG	p-value	LMG	MMG	HMG	p-value
LLT								
Right eye	61.08	59.55	(+/- 59.65	0.801	59.22	58.55	58.13	0.845
Left eye	(+/-9.99)	8.47)	(+/-8.87)		(+/-8.64)	(+/-7.46)	(+/-6.82)	
	61.17	61.07	(+/- 62.95	0.524	59.82	59.17	59.47	0.924
	(+/-9.00)	8.35)	(+/-7.80)		(+/-7.52)	(6.61)	(+/-6.65)	
TBUT (av)								
Right eye	12.69	12.77	(+/- 12.58	0.554	12.59	13.01	12.71	0.036
Left eye	(+/-1.08)	0.96)	0.97)	0.836	(+/-0.77)	(+/-0.73)	(+/-0.88)	
	13.16	13.25	(+/- 13.08		13.14	13.04	13.46	0.206
	(+/-1.04)	1.10)	1.33)		(+/-0.56)	(+/-0.92)	(+/-0.70)	
Corneal thickness								
Right eye	541.08	543.32	(+/- 543.02	0.849	500.88	494.32	479.69	<0.00001
Left eye	(+/-15.21)	13.42)	11.13)	0.820	(+/-15.97)	(+/-13.17)	(+/-11.57)	
	541.22	541.34	(+/- 543.17		501.22	492.13	478.91	
	(+/- 14.25)	18.81)	10.85)		(+/-14.46)	(+/-11.38)	(+/-11.01)	<0.00001
K_m								
Right Eye	43.14	43.44	(+/- 43.21	0.129	39.02	37.47	35.52	<0.00001
Left Eye	(+/-0.830)	0.643)	(+/-0.819)	0.092	(+/-0.86)	(+/-0.83)	(+/-0.95)	
	43.45	43.93	(+/- 43.87					
	(+/-0.987)	0.633)	(+/-0.709)		39.06	37.23	35.51	<0.00001
					(+/-0.66)	(+/-0.67)	(0.86)	

Result:

Results

Post **SMILE data** showed that both **LLT and NITBUT** values changes were **not statistically significant**

The changes in the **corneal thickness and median keratometric** values were **statistically significant** in all myopia groups

Overall corneal thickness changes were statistically significant at $p < 0.00001$

Median keratometric values also showed statistically significant changes after SMILE procedure when compared to baseline values ($p < 0.00001$), showing that the corneal meridians became more flat

Median keratometry (Km) value decreased by **4.12 diopters - LMG, 5.97 diopters - MMG and by 7.74 diopters - high myopia group**

Discussion



SMILE ensures maintenance of anatomical structures and biomechanical properties



No statically significant changes were seen postoperatively in **LLT values**.

However, Although LLT was higher in the HMG at 6 month postoperatively than in the other two groups, **there was no significant difference between any of the three groups after adjusting the P value**



There are some **limitations** of this study.

The statistical deviation caused by the limited number of low-myopia patients may have affected the accuracy of the results. We only studied the effect of LLT on tear film stability, the role of tear film composition and distribution after SMILE needs to be further studied

Discussion



Our study showed that NITBUT in the HMG was significantly lower than that in the LMG and the MMG at 1 week and 1 month postoperatively, but at the final analysis at 6 months the NITBUT time was not statically significant between the three myopia degree groups



In our study we documented the decrease in central corneal thickness in 3 different myopia groups according to the degree. The changes in the corneal thickness and median keratometric values were statistically significant



Keratometry values after SMILE showed differences according to the dioptric degrees preoperative

Conclusion



- Our study demonstrated that SMILE was beneficial in all measures of **safety, efficacy, predictability and stability** for the correction of myopia and myopic astigmatism throughout the 6 months follow-up period



- There **was no statistically significant change in LLT and NIBUT** after the procedure and between the three groups



- There was **significant change in Km and CCT in different myopia groups** when compared to the baseline levels and intergroup analysis (low myopia group showing lesser changes than higher myopia groups)



THANK YOU

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