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Lenticulorhexis Versus Traditional SMILE

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ABSTRACT

Background: Surgical treatment modalities for refractive errors include Laser Assisted In-situ Keratomileusis (LASIK), radial keratotomy, intrastromal corneal ring segments, lenticular extraction, etc. Later, Femtosecond Lenticule Extraction (FLEx) was designed for the treatment of severe myopic patients. With the arrival of the Visumax femtosecond laser and technique refinement by creating 2-3 mm small incisions, small incision lenticule extraction (SMILE) became an increasingly popular refractive surgery, which was approved in 2012 by the food and drug administration (FDA), and since then there have been numerous international research were conducted on determining its efficacy and visual outcomes.

Aim of Study: To evaluate the effectiveness of two different approaches to the SMILE technique (traditional verses lenticulerrhexis) in myopic patients.

Material and Methods: This study included 60 eyes (n=31 patients) that underwent SMILE for correction of myopia between July 2016 and July 2019. The subjects' eyes were randomly divided into two groups of 30 eyes. Group A eyes underwent lenticulerrhexis (CCL), and group B underwent the conventional myopic correction procedure. A comprehensive preoperative examination was done for all subjects, which included slit lamp examination, Pentacam imaging, measuring intraocular pressure (IOP), and uncorrected/ corrected distance visual acuity measurements were recorded. Postoperative follow-up was performed on day one and three-months. Primary Outcomes included Bowman's layer micro-distortions and contrast and sensitivity test, while secondary outcomes included corrected and uncorrected distance visual acuity, lenticule extraction duration, manifest refraction, and adverse events.

Results: No significance (p=0.52) was demonstrated between group A and B regarding mean pre-operative spherical equivalent (SE), the SE was –4.75 for group A and –4.78 in group B. Bowman's Layer distortions were 3.73, 6.6, and 3.00,

4.73 in group A and B at day one and three-months postoperatively, respectively (p=0.06). Mean contrast and sensitivity was 281, 277, and 317, 320 in groups A and B respectively, at day one and three-months postoperatively, respectively (p=0.38, p=0.52 - Day one and three months postop.). A UDVA of 0.8 or better was demonstrated in 96.7% (29 of 30) for group A and 86.7% (26 of 30) of group B, and no difference between both groups (p=0.16). Sphere equiva- lence mean was –0.16 diopters for group A and –0.27 diopters for group B (p=0.41). The mean length of time of lenticule extraction was 78.4 seconds (range: 59.5 to 124.5 seconds) in group A and 74.3 seconds (range: 52 to 102 seconds) in the conventional group.

Conclusion: The CCL technique is an excellent, repro- ducible, less manipulative, and efficient technique of SMILE surgery, that may result in better early corneal healing and visual outcomes compared to the conventional SMILE tech- nique. It is a promising technique that deserve further research and evaluation.

Keywords: *Myopia – Small incision lenticule extraction – Bowman's layer micro-distortions – Contrast and Sensitivity.*

1. INTRODUCTION

THERE are various methods to correct refractive errors including contact lenses and spectacles. Although these methods are cost effective and efficient, they do have considerable downsides including discomfort, image magnification / mini- fication defects, and irritation of ocular surfaces in contact lens wearers. Since the cornea is easily surgically accessible, various operative approaches have been developed to treat refractive errors, and the majority have concentrated their efforts on altering cornel power [1].

Predominant ophthalmological surgeries are those designed to treat refractive errors, since refractive errors are the most common ocular dis- order causing visual impairment and the second most common cause of blindness worldwide.

Surgical treatment modalities for refractive errors include Laser Assisted In-situ Keratomileusis (LASIK), radial keratotomy, intrastromal corneal ring segments, lenticular extraction, etc. Later, Femtosecond Lenticule Extraction (FLEx) was designed for the treatment of severe myopic pa-tients. With the arrival of the Visumax femtosecond laser and technique refinement by creating 2-3mm small incisions, small incision lenticule extraction (SMILE) became an increasingly popular refractive surgery, which was approved in 2012 by the food and drug administration (FDA) [2], and since then there have been numerous international research were conducted on determining its efficacy and visual outcomes [3].

Since the acceptance of SMILE, various mod- ifications have been made to the technique which aimed at easing the extraction of the lenticule and reducing complications. Various SMILE surgical techniques have been evaluated in terms of effec-tiveness and safety by many studies [4]. Treatment planning involves accurate entry of the treatment data which includes the lenticule and cap parame- ters. Lenticule dimensions mainly depend on the manifest refraction, optical zone (OZ) diameter, transition zone (TZ), and minimum lenticule thick- ness predefined. Cap parameters that need to be entered in the graphic-user interface during treat- ment planning include the keratometry and the thinnest corneal thickness measured [4].

SMILE takes place under mild suction without an eye tracking system. Accurate centralization of the treatment zone is crucial to achieve satisfactory visual outcomes, especially in refractive procedures like SMILE [5]. After the suction is applied, a posterior and anterior surface is created for the lenticule using incisions from different angles, and subsequently the laser treatment is applied [6]. SMILE intended for myopia correction is contrain- dicated in patients with a residual stromal bed thickness that is less than 250 microns from the corneal endothelium, keratoconus and keratoconus suspects and other abnormal corneal topographic findings, ophthalmoscopic signs of progressive or unstable myopia, irregular or unstable corneal mires on central keratometry images, severe dry eye, active eye infection or inflammation, and uncontrolled diabetes or glaucoma.

Aim of the study:

This research evaluates the effectiveness of two different approaches to the SMILE technique (traditional verses lenticulerrhexis) in myopic patients in terms of contrast, sensitivity, micro- distortions in Bowman's capsule, safety, and un-corrected/corrected distance visual acuity values.

2. MATERIAL AND METHODS

A Randomized Prospective Interventional Study that included 60 eyes of 31 patients) who underwentSMILE for correction of myopia between July 2016 and July 2019. The subjects' eyes were ran- domly divided into two groups of 30 eyes. Group A eyes underwent lenticulerrhexis (CCL), and group B underwent the conventional myopic cor- rection procedure. Randomization of patients was using a simple draw that contained patients that were either selected into group A or B.

All patients were explained the procedures in detail and all the relevant associated examinations regarding the procedure. An informed consent was taken from each of the subjects prior to study. This study is in accordance with the declaration of Helsinki.

Inclusion criteria: Patients that were over the age of 18 years, had stable refraction with normal Pentacam, had myopia between –3.00D and – 10.00D, and had a residual stromal thickness of more than 250 m were included in this study.

Exclusion criteria: Patients who had other ocular pathologies and previous ophthalmological surgeries/interventions were excluded from this study. Also, hypermetropic patients or those who had myopia less than –3D or more than –10D, and those with astigmatism of more than 5D were excluded.

Preoperative examination: A comprehensive preop examination was performed on all subjects, which included a slit lamp examination, Pentacam imaging, measuring intraocular pressure (IOP), and uncorrected/corrected distance visual acuity (UDVA and CDVA, respectively) measurements were recorded.

Surgical details: All patients were operated on using topical anesthesia (Benoxinate hydrochloride 0.4%). For all smile procedures, the VisuMax femtosecond laser system was used at a stable repetition rate of 500kHz. The cap thickness was set to 110 m and its diameter ranged from 7.3 to

7.5mm. The diameter of the lenticule ranged be- tween 6.3 and 6.5mm. Prior to lenticule extraction, a two-millimeter incision was made the 12 o'clock position. Group A underwent the new CCL tech- nique, while group B underwent the traditional lenticule dissection. One surgeon (A.G) performed all the surgeries.

For group A (CCL technique): The Castroviejo spatula (model No. G-15485; Geuder) was placed at through the two-millimeter incision mentioned before in order to separate the cap-lenticule inter- face, then separated 0.3mm at the superior margin

of the lenticule via the stromal bed close to the cap incision. Micro-forceps (multifunction micro- forceps, model No. G-32932; Geuder) were insert- ed, and used to hold on to the lenticule margin, which was continuously pulled clockwise in a circumferential manner. The cap was separated from the anterior surface of the lenticle, and the lenticule was then extracted in a clockwise motion using CCL. For group B: Anterior and posterior lenticular surfaces were separated prior to extrac- tion. Observation of the lenticular integrity in vitro was performed following the extraction for both techniques.

Postoperative examinations: These examina- tions included UDVA and CDVA measurements, epithelial analysis (for identification of defects, diffuse lamellar keratitis, etc.), contrast and sensi- tivity via the Cambridge contrast chart (Clement Clarke, UK), and Bowman's layer micro-distortions by the swept source OCT (Topcon Inc., Tokyo, Japan). Postoperative follow-up was done at day one and three months. To fully identify the bow- man's layer distortions, four images were taken along the 0□, 45□, 90□, and 135□ meridians to constitute a complete measurement of the cornea. A distortion was considered when irregular, twisted sections of Bowman's layer were demonstrated. For each image, the number of peaks within the central six-millimeter region was counted. The total number of microfolds in all four images were added together. For accuracy, all measurements were taken by the same experimenter, while calcu- lations were performed by a different masked experimenter. Contrast and sensitivity test was performed using Cambridge contrast chart (Clement Clarke, UK), at day one and three-months postop- eratively. To perform the test, the gratings' booklet is hung on a wall at a distance of six meters. The pages are presented in pairs one above the other. One page in each pair contains gratings and the other is blank but have the mean reflectance. The subject is simply required to choose which page in each pair contains the gratings. The pages are shown in order of descending contrast and told to stop when the first error is made. Four descending series are shown separately to each eye. When no error is made at plate 10, then a score of 11 is given. Depending on the total score of the patient from the four series, the contrast sensitivity is noted. To measure the duration of lenticule extrac- tion; a stopwatch was used, and the result was rounded to one decimal place.

Primary outcomes: Comparing Bowman's layer micro-distortions in SMILE procedure betweenthe CCL technique and the traditional technique using swept source optical coherence tomography (Topcon Inc., Tokyo, Japan), and contrast and sensitivity test using Cambridge contrast chart (Clement Clarke, UK), at 1 day and 3 months postoperatively.

Secondary outcomes: Uncorrected/corrected distance visual acuity, duration of the extraction procedure, manifest refraction was evaluated at day one and three months postoperatively. Any adverse events were noticed.

Statistical analysis: Data was collected on a spreadsheet and entered in Excel 2007 (Microsoft, Inc., Redmond, WA) for further analysis. Analysis was conducted using the Statistical Package for the Social Sciences 23.0 statistical package for Windows (SPSS Inc., Chicago). All variables were tested for normality using Kolmogorov-Smirnov test, which was significant, so the non-normality of the data was accepted. All continuous variables were presented as range and median, while cate- gorical data were presented as number (percentage). Chi-square test was used to compare categorical variables, while Mann-Whitney test was used to compare continuous variables. Spearman's corre- lation analysis was performed between continuous variables; controlled for the two techniques of SMILE procedure. Outcomes with $p<0.05$ were significant.

3. RESULTS

Mean age was 35.13 and 29.33 in group A and B, respectively (p=0.02). Sixty percent (n=18 eyes) and 40% (n=12 eyes) of male and female patients were in group A respectively, while 56.7% (n=17 eyes) and 43.3% (n=13 eyes) of male and female patients were in group B respectively (Table 1).

No significance (p=0.52) was demonstrated between group A and B regarding mean pre- operative spherical equivalent (SE), but the SE was –4.75 for group A and –4.78 in group B. Mean pre- operative uncorrected distance visual acuity (UDVA) was 0.15 and 0.16 in groups A and B, respectively, with no compelling difference between the groups (p=0.86). In group A, the mean pre- operative corrected distance visual acuity (CDVA) was 1.11, while in group B it was 1.06, with no statistical difference between both groups (p=0.18).

Primary outcomes (Table 2):

Micro-distortions in Bowman's Layer (BLM): At day one postoperative follow-up, mean BLM was 3.73 and 6.6 in groups A and B respectively, and a statistical significance was demonstrated between both groups (p=0.01). Mean BLM follow- ing three months was 3.00 and 4.73 in groups A and B respectively, with no significant difference (p=0.06).

Contrast and sensitivity: At day one postoper- ative follow-up, the mean C and S was 281 and 277 in groups A and B respectively, which demon- strated no statistically significant difference be- tween both groups (p=0.38). At three-months post- operatively, C and S was 317 and 320 in groups A and B, respectively (p=0.52).

Visual and refractive outcomes:

An UDVA of 0.8 or better was demonstrated in 96.7% (29 of 30) for group A and 86.7% (26 of 30) of group B on the first

postoperative day with no significant difference between both groups (p=0.16). A UDVA of 1.0 or greater was seen in 83.3% (25 of 30) group A eyes and 66.7% (20 of 30) in group B patients, with no statistically sig- nificant difference between the two groups (p=0.14).

Three months postoperatively, 100% (30 of 30) eyes in group A and 100% (30 of 30) of the eyes in group B had a UDVA of 0.8 or better, with no significant difference (p=0.69). Ninety percent (27 of 30) of group A patients and 86.7% (26 of 30) of group B had a UDVA of 1.0 or better, with no statistical difference (p=0.69).

Regarding the spherical equivalent, the mean postoperative SE was –0.16 diopters for group A and –0.27 diopters for group B, with no significant difference (p=0.41) on the first postoperative day. Three months postoperatively, the mean SE was -

0.12 diopters for group A and –0.14 diopters for group B, with no significant difference (p=0.81).

Safety and efficacy (Table 4, Fig. 1):

Regarding procedure safety, 86.67% (n=26) of group A and 76.67% (n=23) of group B had an unchanged CDVA difference postop and preop. In group A, 0.03% (n=1) gained one line, while in group B 0.07% (n=2) gained one line. The same number of patients in each group also gained two lines respectively. One of thirty patients in group A and 0.03% (n=1) in group B gained three lines, while and 0.03% (n=1) in group A and 0.07% (n=2) in group B lost one line. There were no eyes that lost two lines in either group.

Safety indices was 1.01 (range: 0.89 to 1.25) and

1.02 (range: 0.9 to 1.25) for groups A and B respectively, with no significant difference between them (p=0.74). The efficacy indices (the ratio between UDVA at three months and the corresponding preoperative CDVA) were 1.01 (range: 0.89 to 1.25) and 1.02 (0.9 to 1.25) for groups A and B, respectively, with no statistical difference (p=0.77), with 100% of the eyes in groups had a postoperative UDVA 0.5 or more.

Lenticule quality:

For both groups, all lenticular extractions went smoothly, and all the lenticules were intact and had round margins.

Lenticule extraction duration (Table 4):

The mean lenticule extraction time was 78.4 seconds (range: 59.5 to 124.5 seconds) in group A and 74.3 seconds (range: 52 to 102 seconds) in group B, with no significance between the groups (p=0.25).

Absence of micro-distortions in Bowman's layer (BLM) (Table 4):

Twenty percent (n=6) in group A and 10% (n=3) in group B had no BLM at day one postoperatively. No statistically significant difference was found between the two groups (p=0.28). Twenty percent (n=6) in group A and 10% (n=3) in group B had no BLM at 3 months postoperatively. No statisti- cally significant difference was found between the two groups (p=0.28).

Micro-distortions in Bowman's Layer (BML) in relation to duration of lenticule extraction (Fig. 2):

Correlation between BLM and lenticule extrac- tion (LE) duration at postop day one was analyzed. No correlation (r=0.03) and no statistically signif- icant difference were found between both variables (p=0.84). No statistically significant difference was found between the two groups (p=0.18). Ad- ditionally, Correlation between BLM at three months postoperatively (3M.BLM) and duration of lenticule extraction (LE) were analyzed. Weak correlation (r=0.14) and no statistically significant difference were found between both variables (p= 0.28). Statistically significant difference was found between the two groups (p=0.02).

Micro-distortions in Bowman's Layer (BML) in relation to UDVA postoperatively (Fig. 3):

Correlation between BLM and uncorrected distance visual acuity at day one postoperatively (1D. PO UDVA) was analyzed. A strong negative correlation (r=–0.63) and statistically significant difference were found between both variables (p= 0.01). Statistically significant difference was found between the two groups (p=0.01). Additionally, Correlation between BLM at three months postop- eratively (3M.BLM) and uncorrected distance visual acuity at three months postoperatively (3M. PO UDVA) were analyzed. A strong negative cor- relation (r=–0.54) and statistically significant difference were found between both variables (p= 0.01). Statistically significant difference was found between the two groups (p=0.01).

Micro-distortions in Bowman's Layer (BML) in relation to contrast and sensitivity (C&S):

Correlation between BLM and C&S at day one postoperatively was analyzed. A weak negative correlation (r=–0.2) and no statistically significant difference were found between both variables (p=.13). No statistically significant difference was found between the two groups (p=0.12). Addition- ally, Correlation between BLM and C&S at three months postoperatively (LE) were analyzed. No correlation (r=–0.1) and statistically significant difference were found between both variables (p= 0.45). No statistically significant difference was found between the two groups (p=0.41).

Adverse events:

None of the eyes in this study demonstrated infections, epithelial defects, corneal haze, diffuse lamellar keratitis, or other severe complications. Two eyes of different patients in group B witnessed suction loss and they were excluded.

Table (1)

	Group	N	Mean	Median	Range	*p*
Age	A	30	35.13	30	24-56	0.02
	B	30	29.33	27	22-40	
Sex (male)*	A	30	18 (60%)			0.79
	B	30	17 (56.7%)			
Pre-operative SE	A	30	–4.75	–4	–3.25 to –8.75	0.52
	B	30	–4.78	–4	–3 to –8.50	
Pre-operative UDVA	A	30	0.15	0.16	0.05 to 0.3	0.86
	B	30	0.16	0.16	0.05 to 0.3	
Pre-operative CDVA	A	30	1.11	1.2	0.8 to 1.5	0.18
	B	30	1.06	1	0.8 to 1.2	

*Number (%), uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), spherical equivalent (SE).

Table (2): Primary Outcomes (micro-distortions in the Bowman's layer and contrast and sensitivity) of both groups.

	Group	N	Mean	Median	Range	*p*
1- *BML distortions:*						
BLM at day one postoperatively	A	30	3.73	2.5	0-11	0.01
	B	30	6.6	6.5	0-21	
BLM at 3 months postoperatively	A	30	3	2	0-8	0.06
	B	30	4.73	3.5	0-18	
2- *Contrast and Sensitivity:*						
C & S at day one postoperatively	A	30	281	290	230-310	0.38
	B	30	277	270	230-310	
C & S at 3 months postoperatively	A	30	317	310	250-340	0.52
	B	30	320	340	250-340	

Table (3): The visual and refractive data of the 2 groups.

Day one post-op:						
UDVA of 0.8 or better		A	29	96.7%		0.16
		B	26	86.7%		
UDVA of 1.0 or better		A	25	83.3%		0.14
		B	20	66.7%		
3 months post-op:						
UDVA of 0.8 or better		A	30	100%		0.69
		B	30	100%		
UDVA of 0.1 or better		A	27	90.0%		0.69
		B	26	86.7%		
1- Spherical Equivalent	Group	N	Mean	Median	Range	*p*
SE day one post-op	A	30	–0.16	–0.25	–1 to +0.5	0.41
	B	30	–0.27	–0.25	–1.25 to +0.75	
SE day three months post-op	A	30	–0.12	–0.19	–0.75 to +0.5	0.81
	B	30	–0.14	–0.12	–0.62 to +0.37	

Number (%), uncorrected distance visual acuity (UDVA), spherical equivalent (SE).

Table (4): Safety and Efficacy Indices, duration of lenticule extraction, and absence of Bowman's layer micro-distortions in both groups.

	Group	N	Mean	Median	Range	*p*
1- *Safety and Efficacy:*						
The Safety Indices	A	30	1.01	1	0.89 to 1.25	0.74
	B	30	1.02	1	0.9 to 1.25	
The Efficacy indices	A	30	1.01	1	0.89 to 1.25	0.77
	B	30	1.02	1	0.9 to 1.25	
2- *Extraction Duration:*						
Duration of lenticule extraction	A	30	78.4	71	59.5 to 124.5	0.25
	B	30	74.3	69	52 to 102	
3- *BLM absence:* Group		No.		Percentage		*p*
No BLM at day one postop.	A	6 of 30		20%		0.28
	B	3 of 30		10%		
No BLM at 3 months postop.	A	6 of 30		20%		0.28
	B	30 of 30		10%		

*BLM – Bowman's layer Micro-distortions.

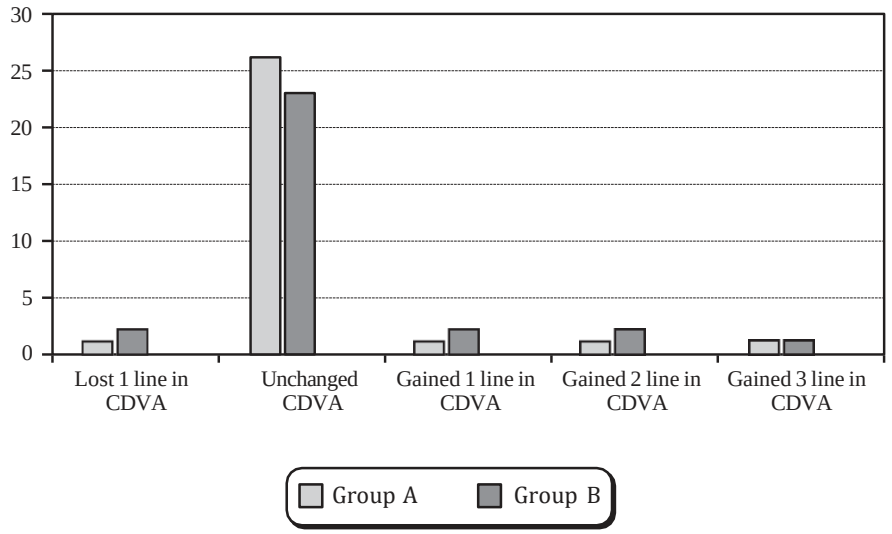

Fig. (1): Number of eyes in relation to change in corrected distance visual acuity difference preoperatively and postoperatively (procedure safety).

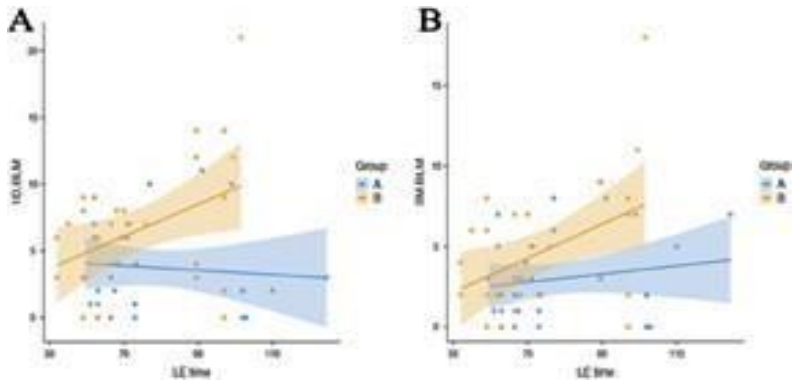

Fig. (2): (A) Correlation between BLM at day one postoperatively (1D.BLM) and duration of lenticule extraction (LE), (p=0.18), (B) Correlation between BLM at 3 months postoper- atively (3M. BLM) and duration of lenticule extraction (LE), (p=0.02).

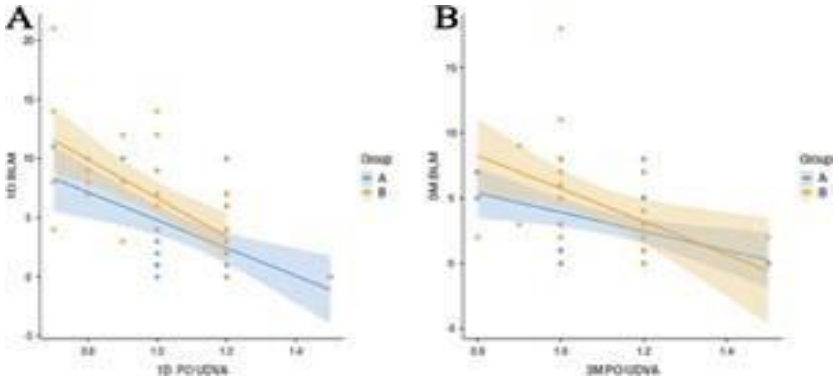

Fig. (3): (A) Correlation between BLM at day one postoperatively (1D. BLM) and uncorrected distance visual acuity at day one postoperatively (1D. POUDVA), (p=0.01), (B) Correlation between BLM at 3 months postoperatively (3M. BLM) and uncorrected distance visual acuity at 3 months postoperatively (3M. POUDVA), (p=0.01).

4. DISCUSSION

With regards to the treatment of astigmatism and myopia, SMILE has demonstrated great progress and efficacy, especially since it has elim- inated the need for a flap making it easier and safer, thereby gaining popularity within the field of refractive surgery [7].

SMILE demonstrated predictable and stable corrections in patients with moderate to high my- opia but no significant changes in SE postopera- tively (one month to a four-year follow-up) were seen in the study by Han et al. [8].

LASIK vision threatening complications arising from incomplete flap, flap loss, or traumatic flap dislocation are avoided by the SMILE techniquethat does not require a flap, and it is not required to change patients from femtosecond to excimer platform (which happens during LASIK) during SMILE which reduces patient anxiety and surgical time, therefore giving SMILE the upper hand in surgical repair of refractive surgeries [9,10].

In the current study, we analyzed micro- distortions of the Bowman's layer (BML) among both intervention groups. In group A, 20% of patients did show any BML micro-distortions, 10% of group B had no BML micro-distortions three months post-operatively, and a significant differ- ence was demonstrated between both groups (p= 0.01). Bowman's layer distortions were attributed to the mechanical disturbance that happens to the corneal cap during lenticule extraction as well as

the experience of the surgeon according to Miao et al., who reported higher micro-distortions in patients treated with the traditional technique verses CCL- treated eyes [11].

Zhao et al., found no significant difference between both groups in terms of micro-distortions but mentioned that significance of the study would have been limited by their small sample size (31 eyes of which 16 eyes of CCL technique) [10].

Garnesh and Brar assessed a similar parameter, interface quality, which was found to be smoother for the CCl-treated eyes on day one postoperatively compared to the conventional technique (rougher and corrugated). The conventional technique dem- onstrated prominence of the anterior cap edge, which suggests a form of stress on the BML. They concluded that, a better visual quality and faster recovery was associated with the no dissection/ lenticuloschisis SMILE technique 12. With regards to contrast and sensitivity (C and S), there are no none published articles comparing it for both SMILE techniques. In our study, the mean C and S were 281 and 277 in groups A and B respectively at day one postoperatively, with no significant difference between both groups (p=0.38).

All eyes had a successful lenticule extraction (complete and intact extraction). Extraction duration showed no significant difference was found be- tween both groups in our study (p=0.25). A weak non-statistically significant correlation was noticed between BML and extraction duration (r=0.14). Regarding UDVA at day one postoperatively, we noticed a higher UDVA percentage in the CCL group, but no statistical difference between both groups. At three months postop, the CCL-treated eyes demonstrated a UDVA of 0.8 or better, better safety and efficacy indices (approximately 1.01), which is consistent with previous studies 10, 11. This suggests that CCL is an efficient and safer alternative to other corneal refractive surgeries. Furthermore, we noticed a strong negative corre- lation between BLM and UDVA at day one and three months postoperatively, which suggests that BLM might have a direct negative effect on UDVA postoperatively.

A limitation of this study is its small sample size. Changes in the cornea like interface haze, confocal microscopy, and inflammatory responses were not evaluated in this study but should be evaluated in future studies.

5. CONCLUSION

The CCL technique is an excellent, reproduci- ble, less manipulative, and efficient technique of SMILE surgery, that may result in better early corneal healing and visual outcomes compared to the conventional SMILE technique. It is a promis- ing technique that deserve further research and evaluation.

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