Lenticulorhexis versus Traditional SMILE

AHMED G. E. MOHAMED, M.D.[*]; MOHSEN EMADELDIN SALEM, M.D.; AHMED HASSANEIN, M.D.; RAMY RIAD FIKRY, M.D.

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Abstract

Background: Small incision lenticule extraction or SMILE is a novel form of 'flapless' corneal refractive surgery that was adapted from refractive lenticule extraction (ReLEx), **Aim:**The aim of this study is to evaluate whether SMILE is non-inferior to LASIK in terms of refractive outcomes**. Methods:** this was a randomized clinical trial, had included 60 eyes of 31 patients in the study undergoing SMILE for correction of myopia between July 2016 and July 2019. They were divided into two groups: 30 eyes for continuous curvilinear lenticulerrhexis (CCL) technique (group A), and 30 eyes for traditional technique group (group B). **Results:** Mean BLM at 1 day postoperatively were 3.73 and 6.6 in groups A and B, respectively. Statistically significant difference was found between the two groups (P = 0.01). Mean BLM at 3 months postoperatively were 3.00 and 4.73 in groups A and B, respectively. No statistically significant difference was found between the two groups (P = 0.06). **Conclusion:**This novel trial will provide information on whether SMILE has comparable, if not superior, refractive outcomes compared to the established LASIK for myopia, thus providing evidence for translation into clinical practice.

Keywords: Refractive surgery, Laser in situ keratomileusis, small incision lenticule extraction.

The Department of Ophthalmology, Faculty of Medicine, Cairo University
[*]**Corresponding Email:**ahmedishaak@gmail.com

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Introduction

Refractive errors have traditionally been corrected by spectacles and contact lenses. Despite their long- standing use, there are some disadvantages in both forms of optical correction. Image magnification/minification, discomfort and inconvenience are some of the issues with glasses **(1).**

An increased number of incisions induced greater refractive effects up to approximately 16 incisions, with a greater number of incisions found to provide no additional effect and potentially an opposing effect. Most performers used four or eight incisions, depending on the refractive error for the correction of up to 6.00 D of myopia.Using 16 incisions over eight incisions had only a 5–10% further effect. The radial keratotomy incisions result in peripheral elevation, which in turn causes central corneal flattening **(2)**.

Keratomileusis originates from the Greek words keras meaning cornea and mileusis meaning carving or sculpting. The first attempts at corneal carving started in 1963 in the Ignacio Barraquer clinic in Bogota, Colombia. But the initial surgical maneuvers were imprecise **(3).**

Laser (light amplification by stimulated emission of radiation) is a method for emitting electromagnetic (EM) radiation via stimulated emission.In 1960 Theodore Maiman developed the first laser following the earlier work of Schawlow and Townes. The emitted EM radiation is usually spatially coherent, monochromatic and of low-divergence, enabling it to be manipulated. This means that the emitted EM radiation is in waves of one wavelength, equal frequency and phase, which can be easily re-directed **(4).**

In 1981, the first reports of the use of excimer lasers with the eye emerged from Taboada, Mikesell and Reed from the Laser Effects branch of the Radiation Sciences Division, US Air Force School of Aerospace Medicine. This study involved the exposure of a rabbit cornea to a 248 nm krypton laser causing either opacification or de-epithelialisation to that area of the cornea **(5).**

Treatment planning involves accurate entry of the treatment data which includes the lenticule and cap parameters. Lenticule dimensions mainly depend on the manifest refraction, optical zone (OZ) diameter, transition zone (TZ) and minimum lenticule thickness predefined. Cap parameters that need to be entered in the graphic-user interface during treatment planning include the keratometry and the thinnest corneal thickness measured as shown in table 2.1**(6).**

In this study we aimed to demonstrate that SMILE is just as good in terms of visual outcome in this randomized non-inferiority trial.

Materials and Methods:

We have included 60 eyes of 31 patients in the study undergoing SMILE for correction of myopia between July 2016 and July 2019. They were divided into two groups: 30 eyes for continuous curvilinear lenticulerrhexis (CCL) technique (group A), and 30 eyes for traditional technique group (group B).

Inclusion criteria: Age over 18, stable refraction, normal pentacam, patients undergoing SMILE for correction of myopia between -3.00D and -10.00D and residual stromal thickness more than 250 μm.

Exclusion criteria: Patients with hypermetropia, patients with myopia less than -3D, patients with myopia more than -10D, patients with astigmatism more than 5D, other ocular diseases and previous ocular surgeries.

All patients received a comprehensive preoperative examination that measured uncorrected and corrected distance visual acuity (UDVA and CDVA, respectively) and intraocular pressure, slit-lamp examination, Pentacam imaging.

The VisuMax femtosecond laser system, with a fixed repetition rate of 500 kHz, was used for all SMILE procedures. Benoxinate hydrochloride 0.4% was instilled as a topical anesthesia before surgery. The intended thickness of the cap was set to 110 μm and its diameter ranged from 7.3 to 7.5 mm. The optical zone (lenticule diameter) varied between 6.3 and 6.5 mm. A 2-mm side cut for the extraction of the lenticule was created at the 12-o'clock position. The new CCL technique was used in the first group and the traditional lenticule dissection method was used in the second group. All surgeries were performed by the same surgeon (AG).

The CCL technique included the following procedures: a spatula (Castroviejo spatula, model No. G-15485; Geuder) separated the cap–lenticule interface through the 2-mm incision at the 12-o'clock position, then separated 0.3 mm of the superior margin of the lenticule from the stromal bed near the cap incision. The microforceps (multifunction microforceps, model No.G-32932; Geuder) was inserted to grasp the margin of lenticule, by which the lenticule could be pulled clockwise in a continuous, circumferential manner. The separation was performed only between the cap and anterior surface of the lenticule. The lenticule was then extracted in a clockwise motion using CCL.

In the traditional group, both the anterior and posterior surfaces of the lenticule were separated prior to removal. The lenticule was carefully observed in vitro for its integrity as soon as it was extracted for both techniques.

Postoperative ophthalmologic examinations included measurements of UDVA and CDVA and looking for epithelial defects, the presence of diffuse lamellar keratitis, contrast and sensitivity using Cambridge contrast chart (Clement Clarke, UK), and microdistortions in Bowman's layer by the swept source OCT (Topcon Inc., Tokyo, Japan), evaluated at 1 day and 3 months postoperatively.

To measure the Bowman's layer microdistortions four images were taken along the 0°, 45°, 90°, and 135° meridians to constitute a complete measurement of the cornea. Microdistortions were depicted as irregular, twisted sections of Bowman's layer. The number of the peaks in the central 6-mm region was counted in each image. The total number of microfolds in the four images was added together. All measurements were taken by the same operator and calculated by another masked experimenter.

To measure the duration of lenticule extraction; a stop watch was used and the result was rounded to one decimal place.

Primary outcomes: Comparing Bowman's layer microdistorsions in SMILE procedure between the 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 outcome parameters: Uncorrected and corrected distance visual acuity, manifest refraction, and the duration of the extraction procedure were evaluated at 1 day and 3 months postoperatively.Any adverse events were noticed.

Statistical analysis: All data was collected on standardized study spreadsheets and entered into Excel 2007 (Microsoft, Inc., Redmond, WA) for further statistical analysis. Data analysis was performed 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 median and range while categorical 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 correlation analysis was performed between continuous variables; controlled for the two techniques of SMILE procedure. A P value of less than 0.05 was considered statistically significant.

Results

Table 1: socio demographic data of studied cases

	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 (%).

Mean age was 35.13 in group A and 29.33 in group B. Statistically significant difference was found between the two groups (P = 0.02). 18 eyes (60%) of male patients and 12 eyes (40%) of female patients were found in group A, while 17 eyes (56.7%) of male patients and 13 eyes (43.3%) of female patients were found in group B. No statistically significant difference was found between the two groups (P = 0.79).

Mean pre-operative spherical equivalent (SE) was -4.75 in group A and -4.78 in group B. No statistically significant difference was found between the two groups (P = 0.52). Mean pre-operative uncorrected distance visual acuity (UDVA) was 0.15 and 0.16 in groups A and B, respectively. No statistically significant difference was found between the two groups (P = 0.86). Mean pre-operative corrected distance visual acuity was 1.11 in group A and 1.06 in group B. No statistically significant difference was found between the two groups (P = 0.18).

Table 2: Microdistortions in Bowman's layer between the two groups

	Group	N	Mean	Median	Range	P
BLM at 1 day 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	

Mean BLM at 1 day postoperatively were 3.73 and 6.6 in groups A and B, respectively. Statistically significant difference was found between the two groups (P = 0.01). Mean BLM at 3 months postoperatively were 3.00 and 4.73 in groups A and B, respectively. No statistically significant difference was found between the two groups (P = 0.06).

Table 3: Visual Outcomes

		Group	N	Percentage	P
At 1 day postoperatively	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%	
At 3 months postoperatively	UDVA of 0.8 or better	A	30	100%	0.69
		B	30	100%	
	UDVA of 1.0 or better	A	27	90.0%	0.69
		B	26	86.7%	

At 1 day postoperatively, 96.7% (29 of 30) of treated eyes in group A and 86.7% (26 of 30) in group B had a UDVA of 0.8 or better. No statistically significant difference was found between the two groups (P = 0.16). 83.3% (25 of 30) of treated eyes in group A and 66.7% (20 of 30) in group B had a UDVA of 1.0 or better. No statistically significant difference was found between the two groups (P = 0.14). At 3 months postoperatively, 100% (30 of 30) of treated eyes in group A and 100% (30 of 30) in group B had a UDVA of 0.8 or better. No statistically significant difference was found between the two groups (P =

0.69). 90% (27 of 30) of treated eyes in group A and 86.7% (26 of 30) in group B had a UDVA of 1.0 or better. No statistically significant difference was found between the two groups (P = 0.69).

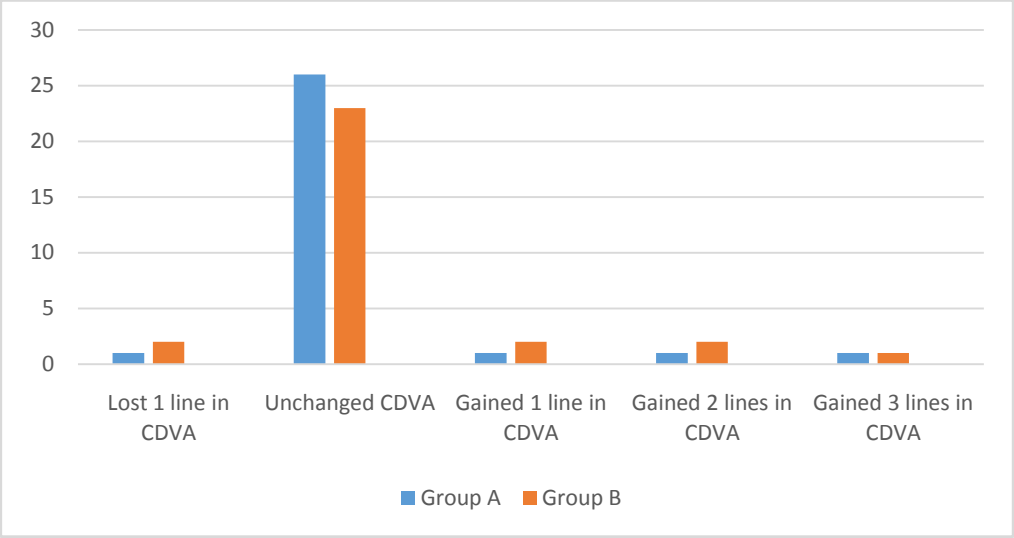

Fig. 1: Number of eyes in relation to change in CDVA difference postoperatively and preoperatively (procedure safety)

Table 4: Duration of lenticule extraction

	Group	N	Mean	Median	Range	P
Duration of lenticule extraction	A	30	78.4	71	59.5 to 124.5	0.25
	B	30	74.3	69	52 to 102	

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 traditional group. No statistically significant difference was found between the two groups (P = 0.25).

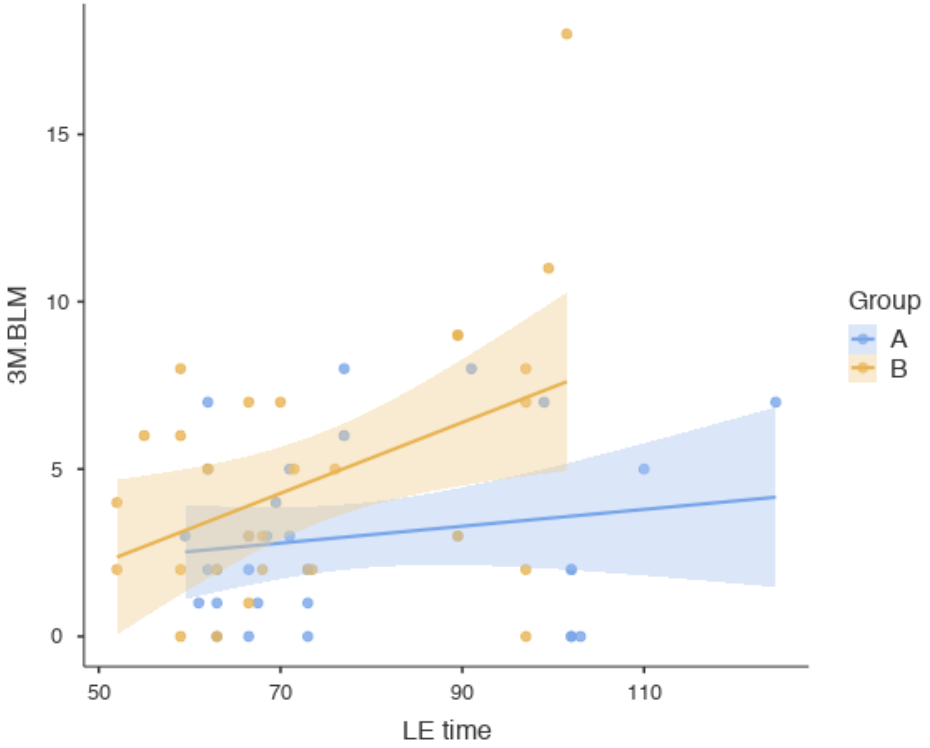

Fig. 2: Correlation between BLM at 3 months postoperatively (3M.BLM) and duration of lenticule extraction (LE), (P = 0.02).

No statistically significant difference was found between the two groups (P = 0.18). Additionally, Correlation between BLM at 3 months postoperatively (3M.BLM) and duration of lenticule extraction (LE) were analysed. 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).

Discussion

In particular, we analyzed the differences in microdistortions in Bowman's layer between the two techniques (group A: CCL technique, Group B: traditional technique); (fig. 3). Mechanical disturbances to the corneal cap during the manual lenticule extraction and a surgeon's surgical experience contribute to the development of microdistortions. Therefore, the amount of microdistortions in Bowman's layer was expected to be less in CCL-treated eyes than those that were treated traditionally**(7).**

Statistical difference was found between the two groups in the current study at 1 day postoperatively, However, no statistical difference was found between the two groups at 3 months postoperatively suggesting that CCL technique may have be less traumatizing effect and results in faster healing process. In comparison, Zhao et al compared the microdistortion in both groups and found no statistical difference between the two groups but they mentioned that their study was limited by the small sample size (31 eyes of which 16 eyes of CCL technique) **(8).**

Another study has compared a similar parameter (interface quality), as assessed with dilated clinical photographs in retroillumination using a slit-lamp camera on the first postoperative day with this technique was seen to be smoother when compared to the conventional dissection technique, which was more rough and corrugated (fig. 6.2). Also, the eye that had the conventional dissection technique showed the prominence of the anterior cap edge, suggesting stress to the Bowman's membrane. This would possibly translate into better quality of vision and faster visual recovery after SMILE using the no dissection or lenticuloschisis technique **(9).**

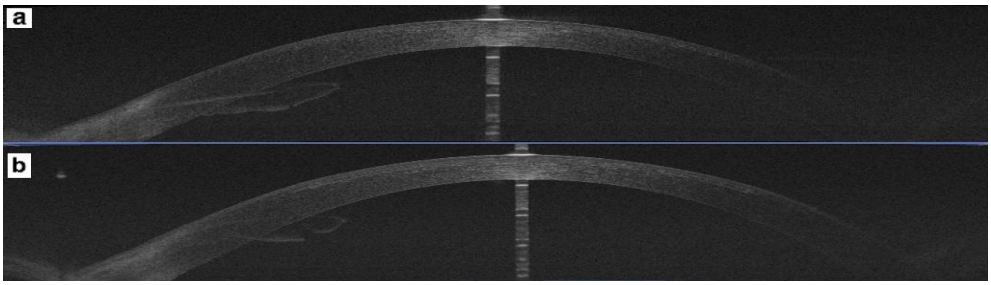

Fig. 3: The swept source optical coherence tomography image of one eye 3 months after SMILE in the (a) continuous curvilinear lenticulerrhexis and (b) traditional groups.

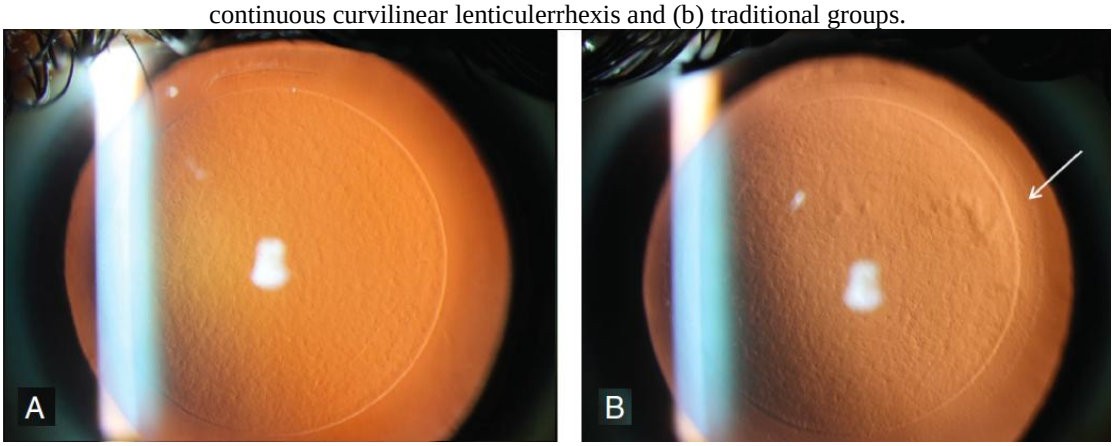

Fig. 6.2. Clinical photographs of the corneal interface in retroillumination after dilatation on the first postoperative day in a patient who underwent (A) SMILE with no dissection or lenticuloschisis technique in the right eye; the corneal interface showed smoother interface than the conventional technique and (B) SMILE with conventional dissection technique in the contralateral eye by the same surgeon in the same sitting for a similar degree of myopia (-4.00 diopters both eyes) showingmore roughness in the eye with dissection and showed prominence of the cap edge (white arrow) **(9).**

To our knowledge, no previous articles compared contrast and sensitivity (C&S) between the CCL and traditional techniques. No statistical difference was found between the two groups in the current study at 1 day, neither at 3 months postoperatively. A weak negative correlation was found between BLM and C&S at 1 day postoperatively indicating that BLM may have an early negative effect on C&S.

In the current study, all eyes in both group had a successful lenticule extraction, with all lenticules being intact and complete. Regarding UDVA at 1 day postoperatively, we have noticed that the percentage of better UDVA was higher in the CCL group. However, no statistical difference was found between both groups. At 3 months postoperatively, all eyes in the CCL group had an UDVA of 0.8 or better and the safety and efficacy indices were both about 1.01, which is consistent with previous studies **(10; 8)**, suggesting that CCL is as safe and efficient as other corneal refractive techniques. Furthermore, we have found strong negative correlation between BLM and UDVA at 1 day and 3 months postoperatively suggesting that BLM may have a direct negative impact on the UDVA postoperatively.

Our team didn't find statistical difference between the duration of extraction in the two groups was found, it is possible that with an improvement in surgical skill, use of CCL could make operative times shorter. Additionally, weak correlation was found between BLM and the duration of extraction at 3 months postoperatively.

There are limitations to this study. The sample size is relatively small, which may limit the precision of the results. We will try to observe the microdistortions in Bowman's layer in a larger sample size in the future. It would be best if CCL was performed on 1 eye and the traditional method was performed on the contralateral eye. In addition, corneal changes, such as inflammatory responses and interface haze, were not evaluated under confocal microscopy.

Conclusion

Low-degree myopia was not included in the current study because a very thin lenticule may increase the difficulty of CCL. It is important for surgeons to master the traditional method before using CCL. CCL facilitates lenticule extraction in SMILE procedures and results in fewer surgical steps and better lenticule quality. It is reasonable to believe that CCL is a promising new technique that may become the primary technique of lenticule extraction in SMILE.

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