Original Article

Surgical Outcomes of Photorefractive Keratectomy, Femtosecond-LASIK, and SMILE for Myopia and Myopic Astigmatism: A Comparative Study in Babylon, Iraq

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Mustafa Tawfeeq Halboos[1], Marrwan Hisham Mohammed[2], Ziyad Kamel Al-Jenabi[3], Noor Khamees Hamad[4], Noor Muzahim Abdelhaleem[5]

[1,3]Department of Surgery College of Medicine, Babylon University, Babylon, Iraq [2,4]Optics Techniques Department, College of Health and Medical Techniques, Al-Mustaqbal University, Hillah 51001, Iraq.

[5]Department of Optical Techniques, College of Health and Medical Techniques, Middle Technical University, Baghdad, Iraq

ABSTRACT

Purpose: To compare the surgical outcomes of Photorefractive Keratectomy (PRK), Femtosecond-LASIK (FSL), and Small Incision Lenticule Extraction (SMILE) in patients with myopia and myopic astigmatism.

Study Design: Retrospective chart analysis.

Place and Duration of Study: This study was conducted with a retrospective cohort design in myopia and myopic astigmatism patients from two clinics in Babylon, Iraq between February 2021 and March 2023.

Method: Retrospective analysis of patients with myopia and myopic astigmatism who underwent kerato-refractive surgery were evaluated for pre-operative and post-operative refraction, corneal topography, and contrast sensitivity. Standardized laser protocols were used for surgery, with follow-ups at 30 days, 90 days, and 6 months.

Results: This study included 217 eyes from 109 patients who had PRK, SMILE, and FSL. The patients in FS-LASIK group were older than other groups ($p = 0.013$), while gender showed insignificant difference among the three methods ($P = 0.480$). No statistically significant differences were observed in preoperative visual acuity ($P = 0.083$), sphere ($P = 0.206$), cylinder ($P = 0.278$), or spherical equivalent ($P = 0.232$) among the groups. After the surgery, all three groups showed significant improvements in best corrected visual acuity, spherical error, cylindrical error, and spherical equivalent ($P < 0.001$). Keratometry values and central corneal thickness significantly decreased in all groups ($P < 0.001$) after the surgery. Contrast sensitivity decline done month after the surgery but improved significantly by 6 months ($P < 0.001$).

Conclusion: PRK, Femto-LASIK, and SMILE are all effective in managing myopia and myopic astigmatism, with significant improvements in visual acuity, refractive errors, and keratometry values across all groups.

Keywords: Refractive Surgery, Photorefractive Keratectomy, Femtosecond LASIK, Small Incision Lenticule Extraction, Visual Acuity.

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Correspondence: Marrwan Hisham Mohammed
Department of Optical Techniques, Al-Mustaqbal University, 51001 Hillah, Babylon, Iraq
Email: marrwan.hisham@uomus.edu.iq

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INTRODUCTION

Refractive error (RE) is one of the commonest causes of visual abnormalities in the world. The prevalence of RE has increased during the last 30 years from 24.32% in 1990 to 35.81% in 2023 and it is expected to be about 40% in 2050.[1] Various methods are used for correcting visual impairment. Eyeglasses constitute the commonest remedy in the low and middle income countries due to their cost-effectiveness and accessibility.[2]Photorefractive keratectomy (PRK) was the first laser eye surgery that was used to correct refractive errors. corneal abnormalities.[3]Since 1980s, studies have shown that PRK is a safe and effective treatment for mild to moderate myopia, hyperopia, and astigmatism. However, it can cause complications such as pain, discomfort, and dry eye syndrome.[4-5] Refractive surgery, such as laser-assisted in situ keratomileusis (LASIK), is an advanced method for correcting myopia and astigmatism. More recently, femtosecond LASIK (FS-LASIK) has emerged as one of the latest innovations in corneal refractive surgery.[6] This method received a high acceptance rate over other refractive surgical options since it had some advantages including high precision, consistency, absence of postoperative symptoms, and reduced rate of dryness.[7] Small incision lenticule extraction (SMILE) is another advancement in refractive correction.[8] The technique was initially introduced in 2011 for correcting myopia and received approval by the US Food and Drug Administration (FDA).[9] The side effects of this method after surgery such as dry eye symptoms and maintaining the biomechanical stability of the cornea are low.[10]

Selecting the appropriate surgical method requires careful consideration of the advantages and disadvantages of each technique for individual patients. One of the most important goals in refractive error (RE) treatment is to achieve optimal refractive correction with high visual quality. While some studies have reported the superiority of certain techniques over others, other reports have found no significant differences in effectiveness among the methods used for managing myopia and astigmatism.[11,12] Previous studies have shown inconsistencies in their findings. Moreover, factors such as the availability of medical resources, the experience of the surgical team, the specific techniques employed, and the quality of postoperative care may all influence the effectiveness of refractive surgical methods.[13] This study was conducted to compare the outcomes of PRK, FSL, and SMILE for myopia and myopic astigmatism patients in Iraq.

METHODS

It was a retrospective study to determine and compare the surgical outcomes of myopia and myopic astigmatism after PRK, FSL, and SMILE. This study was conducted in two separate clinics including the Department of Ophthalmology of Surgery Hilla Hospital, Babylon, Iraq, and the privet Clinic of Optical Techniques, Al-Mustaqbal University. These are referral clinics and most of the Babylon population refer to these clinics. Hence the included population is representative of the general population. The timeline of the study was between February 2021 to March 2023. The study was approved by the Institutional review board/Ethical review board **(OPT 1/2025)**.

Participants with age between 18 and 42 years, a confirmed diagnosis of myopia or myopic astigmatism, a spherical equivalent (SE) refractive error ranging from -1.00 D to -9.00 D, stable refractive error for a minimum of 12 months before the surgery, minimum central corneal thickness of at least 440 µm and no history of trauma or previous ocular surgeries were included. Patients with corneal ecstatic disorders such as keratoconus, ocular pathologies including glaucoma, cataracts, or retinal diseases, systemic conditions affecting wound healing, pregnancy or lactation during the study period, and poor ocular surface health or significant dry eye disease, were excluded from the study.

All patients were advised to discontinue contact lens use at least two weeks prior to ocular assessments for soft lenses and three weeks for hard lenses. Both preoperative and postoperative examinations included manifest refraction measured by an auto-refractokeratometer (ARK/510A; Nidek, Gamagori, Japan), slit-lamp biomicroscopy, and anterior segment analysis using the Pentacam HR (Oculus, Wetzlar, Germany) and Galilei system (Ziemer Ophthalmic Systems, Port, Switzerland). Uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (BCVA) were assessed using Snellen charts. The ocular examination also included tear film evaluation using Schirmer's test and contrast sensitivity assessment with the Pelli-Robson chart.

The surgeries were conducted by skilled surgeons (M.T. and Z.K.). Proparacaine 0.5% eye drops (Alcaine; Alcon-Couvreur, Puur, Belgium) were

instilled. For PRK and FSL, the Custom Ablation Manager protocol was applied. The VisuMax Femtosecond Laser System (Carl Zeiss Meditec AG, Jena, Germany; Standard, Version 2.1) was used to create flaps for FS-LASIK, with superior hinges, with a flap thickness ranging from 90 to 100 μm, and diameters measuring 7.90 mm. For ablation, the AMARIS 750S excimer laser, developed by SCHWIND eye-tech solutions (Kleinostheim, Germany), was used to treat an optical zone between 6.0 mm and 6.8 mm. Following the procedure, a bandage contact lens (Pure Vision™ Bausch & Lomb, Rochester, NY, USA) was applied to the treated area. The SMILE surgery was performed by using the VisuMax femtosecond laser system (Carl Zeiss Meditec AG) with a repetition rate of 500 kHz.[14] During each surgical procedure, a small, curved interface cone was utilized. An outward spiral design was used for the incision on the anterior surface of the lens, while an inward spiral design was applied to the posterior surface. The selected energy value and spot distances for lens shaping were 140 nm and 4.5 μm, respectively. The femtosecond laser included a lens diameter of 6.0–6.5 mm, a flap thickness of 110 μm, a 4 mm hinge positioned at 120° for lens extraction, and a flap diameter ranging from 7.5 mm to 7.6 mm, with a lateral cut angle of 90°. A spoon-like instrument was introduced through the lateral incision above the refractive lens to separate this layer, providing access to the lens base. The lens was then extracted using modified McPherson forceps (Geuder GmbH, Heidelberg, Germany).Postoperative assessments were carried out at30 days, 90 days, and 6 months to assess visual acuity, refractive results, and contrast sensitivity. The gathered data was retrospectively analyzed to compare the efficacy, safety, and visual results of the three surgical techniques.

Quantitative variables were presented as mean ± standard deviation (SD), while categorical variables were expressed as frequencies and percentages. A paired t-test was performed to compare between continuous variables before and after treatment within each group. One-way ANOVA was used to compare differences among the three surgical groups, and Tukey's conducted as the post hoc test for pairwise comparisons. Repeated measures ANOVA were performed to evaluate changes over time within each surgical group that were assessed more than 2 times. The trend analysis was conducted by ANOVA and a line graph was drawn to report the trend of contrast sensitivity over time. Data analysis was performed using SPSS software version 26, with a p-value of less than 0.05 as statistically significant.

The minimum required sample size of the study was calculated with the aim of detecting a minimum difference of 10% in outcomes among PRK, FS-LASIK, and SMILE. The calculation was performed with 80% power ($\beta = 0.20$) and 95% ($\alpha = 0.05$) confidence interval. Based on these parameters, the estimated sample size for each group was 71 patients.
The study protocol was approved by the Institutional Review Board (IRB) of Al-Mustaqbal University and received an ethical number (approval number: Optic 01/2025). Written informed consent was obtained from all participants. Data were gathered anonymously and utilized exclusively for research purposes.

RESULTS

This study involved 217 eyes of 109 patients who underwent either PRK, FS-LASIK, or SMILE. Patients' characteristics are shown in Table 1. The mean age in FS-LASIK group was greater than PRK group (27.79 ± 6.26 vs 24.72 ± 5.54, p=0.013). While the difference of gender distribution among these groups was insignificant (p=0.480). The mean planned optical zone was significantly larger in the SMILE group (6.41 ± 0.25 mm) compared to the PRK(6.24 ± 0.25 mm) and FS-LASIK (6.21 ± 0.27 mm) groups (p< 0.001). There were no significant differences in the visual acuity (0.083), sphere (0.206), cylinder (0.278), and spherical equivalent (0.232) (Table 1).

Visual acuity, spherical, cylinder, and spherical equivalent outcomes showed significant improvement after treatment. The BCVA of patients in the PRK group (0.67 ± 0.15 to 0.04 ± 0.11,p< 0.001), FS-LASIK group, (0.37 ± 0.13 to 0.007 ± 0.03, p = 0.023), and in the SMILE group (0.23 ± 0.05 to 0.01 ± 0.03, P = 0.003) had significantly improved. The spherical error changes in the PRK, FS-LASIK and SMILE group were statistically significant (Table 1). Similarly, cylindrical error changes among the three groups showed significant improvement. The spherical equivalent was also improved in the three groups (Table 1).

In addition, flat keratometry and steep keratometry readings showed significant reductions in all the three groups (Table 2). Similarly, maximum keratometry values and central corneal thickness (CCT) also showed significant reductions(Table 2).

Table 1: *Comparative Analysis of Visual and Refractive Parameters Among PRK, Femto-LASIK, and SMILE Techniques.*

Characteristics		*PRK group*** *(n=72)* Mean± SD / n %	*FS-LASIK Group*** *(n=75)*	*SMILE***Group (n=70)*	P-value
Age (years)		24.72± 5.54	27.79± 6.26	25.79± 7.18	**0.013***
Male/Female		32/40 (44.4%/55.6%)	30/45 (40%/60%)	35/35 (50%/ 50%)	**0.480**
Planned optical zones		6.24± 0.25	6.21± 0.27	6.41± 0.25	**<0.001***
Visual Acuity	Pre-BCVA**	0.67± 0.15	0.37±0.13	0.23±0.05	0.083
	Post-BCVA	0.04± 0.11	0.007±0.03	0.01± 0.03	0.083
	P-value	<0.001	0.023	0.003	
Sphere	Pre	-2.85± 1.68	-2.69±1.33	-3.14± 1.59	0.206
	Post	-0.15± 0.27	-0.13±0.29	-0.09± 0.26	0.515
	P-value	<0.001	<0.001	<0.001	
Cylinder	Pre	-0.95 ± 0.94	-1.24±1.28	-1.11± 1.05	0.278
	Post	-0.14± 0.28	-0.20±0.39	-0.10± 0.24	0.154
	P-value	<0.001	<0.001	<0.001	
Spherical Equivalent	Pre	-3.32± 1.65	-3.31±1.38	-3.69± 1.59	0.248
	Post	-0.22± 0.32	-0.23±0.33	-0.15± 0.27	0.232
	P-value	<0.001	<0.001	<0.001	

*Paired Samples Test.**PRK-Lasik: Photorefractive keratectomy, FS-Lasik: femtosecond laser, SMIL: Small incision lens extraction, SD: standard deviation, BCVA: best corrected visual acuity.

Table 2: *Comparing the tomographic index before and after surgery in PRK, femto-LASIK and SMILE surgery methods.*

Characteristics		*PRK Group*** *(n=72)* (Mean±SD)	*FS-LASIK Group*** *(n=75)* (Mean±SD)	*SMILE***Group (n=70)* (Mean±SD)	P-value
Flat Keratometry	Pre-surgery	42.76± 1.68	42.83± 1.26	42.50± 4.55	0.768
	Post-surgery	39.71± 2.16	39.77± 2.11	39.75± 2.15	0.986
	P-value	<0.001	<0.001	<0.001	
Steep Keratometry	Pre-surgery	44.25± 1.59	44.49± 1.30	44.43± 1.31	0.557
	Post-surgery	41.11± 1.92	41.27± 1.84	40.68± 1.81	0.140
	P-value	<0.001	<0.001	<0.001	
Maximum Keratometry	Pre-surgery	44.02± 1.65	43.26± 1.25	43.65± 1.64	0.011
	Post-surgery	40.89± 2.09	40.61± 1.94	40.21± 1.82	0.115
	P-value	<0.001	<0.001	<0.001	
Central corneal thickness	Pre-surgery	530.04± 26.12	536.52± 27.78	537.85± 29.80	0.203
	Post-surgery	473.69±48.12	454.89± 39.18	458.35± 46.89	0.028
	P-value	<0.001	<0.001	<0.001	

*Paired Samples Test, PRK-Lasik: Photorefractive keratectomy, FS-Lasik: femtosecond laser, SMIL: Small incision lens extraction, SD: standard deviation.

Table 3: *Longitudinal analysis of contrast sensitivity changes after surgery.*

Within-Subjects Effect	df	Mean Square	F	P-value
Mauchly's value	3	2.353	282.007	<0.001
Greenhouse-Geisser	1.322	5.338	282.007	<0.001
Huynh-Feldt	1.327	5.318	282.007	<0.001
Linear	1	1.512	153.071	<0.001
Quadratic	1	5.296	404.696	<0.001

* df: Degree of Freedom,

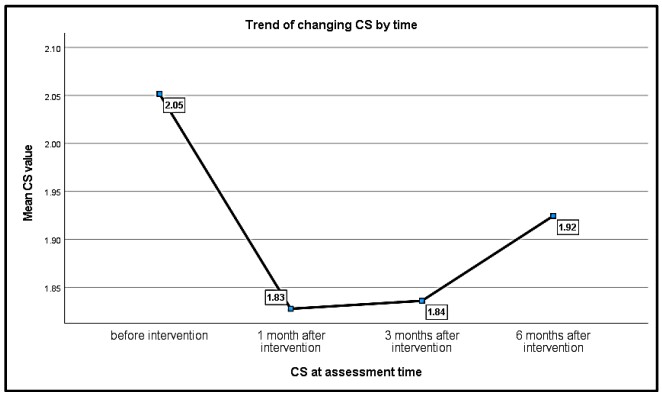
Table 4: *Pairwise comparisons of contrast sensitivity changes over time.*

Time of Assessment (x-y)	Mean Difference (time x-y)	Std. Error	P-value	95% Confidence Interval
1-2	0.224	0.012	<0.001	(0.20, 0.25)
1-3	0.216	0.012	<0.001	(0.19, 0.24)
1-4	0.127	0.010	<0.001	(0.11, 0.15)
2-3	-0.008	0.002	<0.001	(-0.01, -0.01)
2-4	-0.097	0.005	<0.001	(-0.11, -0.09)
3-4	-0.088	0.005	<0.001	(-0.10, -0.08)

Descriptive statistics for contrast sensitivity (CS) are shown in Graph 1. The mean contrast sensitivity decreased from the preoperative measurement of 2.05±0.237 to 1.83±0.318 at one month post-operatively. However, there was a slight improvement at 3 months (1.84±0.311) and a further increase at 6

months after procedure (1.92±0.291) as shown in Table 3.

Analysis of trends depicted that within-subjects contrasts showed a linear trend (F= 153.071, p <0.001). Within-subjects effect assessment showed a significant difference in the trend of CS value (Greenhouse-Geisser P-value<0.001, Huynh-Feldt P-value<0.001). In other words, the CS value was changed significantly during that time (Table 3).



Graph 1: Trend of contrast sensitivity changes over after refractive surgery (CS: Contrast Sensitivity).

Pairwise comparisons showed that the differences were statistically significant (p <0.001), which suggests that the CS changed significantly between each time of assessment. The highest decrease was reported between preoperative and 1-monthpost-operative measurements (Mean Difference= 0.224, p <0.001). At 3-months of assessment and after that, the CS value improved significantly between 3-month and 6-month postoperative values (Mean Difference = 0.088, p <0.001)as shown in Table 4.

DISCUSSION

The results of this study demonstrated significant improvements in UCVA, CE, SE and BCVA across all the three surgical groups. These findings provide evidence-based support to assist both clinicians and patients in making informed decisions regarding refractive surgical options. In addition, the improvement of RE and BCVA among these three groups was not statistically significant suggesting viable options for patients who need refractive surgery.

Our findings are consistent with previous literature that reported significant improvements in visual acuity, and RE across these treatments. A comparative study by Piao et al, reported that all the three surgical methods effectively corrected REs, with SMILE and FS-LASIK showing superior efficacy compared with Trans-PRK in the early postoperative period.[15]Another study by Chang et al, showed that SMILE had fewer complications, faster intermediate vision recovery and better biomechanics, compared to Trans-PRK and LASIK.16In addition, a study by Balgos et al, evaluated the cost-effectiveness of these procedures and reported that SMILE had the lowest cost-effectiveness, following FS-LASIK and PRK.[17]

Our study showed changes in flat keratometry, steep keratometry, maximum keratometry, and CCT across all three surgical groups. The decrease in keratometry values showed effective corneal reshaping, that caused improved refractive outcomes. In addition, a significant reduction in CCT in all the procedures suggests the expected structural changes post-surgery. A significant reduction in keratometric values suggests a uniform flattening of the cornea, which is expected in successful myopic correction.[18] The significant decrease in central corneal thickness (CCT) is an expected outcome following tissue ablation or lenticule removal.[19] The results across the three surgical methods demonstrated comparable efficacy, although some variation was observed in patient outcomes among the procedures.

Another study reported that both SMILE and LASIK were relatively safe and effective procedures; however, dry eye symptoms were less frequently observed with the SMILE technique.[20] In addition, a comparative study by Sekundo et al, found that SMILE is associated with the absence of flap-related complications and provides moderate recovery time and greater biomechanical stability compared to Trans-PRK and LASIK.[21]

The study revealed a significant change in CS over time after surgery. The mean CS decreased from preoperative levels to one month postoperatively. However, improvement occurred at three months after surgery and further at six months after operation. The within-subjects contrast comparisons showed a statistically significant trend and reported CS values changed by linear pattern in the postoperative recovery period.

These findings reported new insight into corneal biomechanical changes following refractive surgery. These results help ophthalmologists in prescribing surgical methods and patient counselling. The

significant reductions in keratometry values confirm the comparable success rate and precision of these techniques and suggest their relatively similar effectiveness for myopia correction. However, the reduction in CCT confirms the importance of preoperative screening to identify patients at risk of postoperative ectasia.

The significant initial decline in contrast sensitivity one month after surgery is consistent with the expected temporary reduction in visual function because of corneal healing, inflammatory responses, and neural adaptation. In addition, subsequent improvement that was reported at three and six months after surgery may be due to corneal stabilization and neuroadaptation over time. These findings showed the importance of patient counseling after surgery. The initial decline in CS suggests the need for cautious postoperative visual assessments. These findings can be used to understand patient cure expectations and improve postoperative care strategies. These findings are consistent with previous studies that reported a temporary reduction in CS following refractive surgery. Montes-Micó et al, reported that CS decreased in the early month after surgery due to corneal haze and wound healing responses.[22] Shen et al, compared CS changes among SMILE, FS-LASIK, and PRK. They found that in all the procedures had an initial decline in CS, but patients in the SMILE category had faster recovery.[23] Zhao et al, reported the improvements in CS correlating with stabilization of the ocular surface and corneal healing rates.[24] In addition, Panigrahi et al, reported that CS was dependent on surgical technique and preoperative corneal parameters.[25]

Our results suggest that the effectiveness of surgery methods is not significantly different hence, factors such as success rate, patient comfort, usability, cost, and potential side effects should be considered when choosing a treatment method. Decision-making between the doctor and patient should be conducted based on an overall evaluation of the patient's eye condition, lifestyle, and treatment goals. A shared decision approach for surgery methods may cause to selection of the method according to both medical recommendations and patient preferences.

One of the limitations of this study is the sample size of participants. The sample size may affect the generalizability and reliability of the finding. In addition, the follow-up time was limited, and a month's follow-up may not cover long-term changes. In addition, some factors such as cost, patient experience, postoperative care quality, quality of vision, night vision disturbances, and symptoms such as dry eye symptoms were not assessed in this study.

CONCLUSION

This study showed that PRK, Femto-LASIK, and SMILE are all effective in managing myopia and myopic astigmatism, with significant improvements in visual acuity, REs, and keratometry values across all groups. Due to the effectiveness of these procedures, treatment selection should be based on a comprehensive evaluation of the patient's condition, lifestyle, cost, and potential risks, with shared decision-making.

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Authors Designation and Contribution

Mustafa Tawfeeq Halboos; Teacher: *Literature Search, Data Acquisition, Manuscript Review.*

Marrwan Hisham Mohammed; Teacher: *Design, Statistical Analysis, Manuscript Preparation, Manuscript Editing.*

Ziyad Kamel Al-Jenabi; Teacher: *Data Acquisition.*

Noor Khamees Hamad; Teacher: *Data Analysis, Manuscript Editing.*

Noor Muzahim Abdelhaleem; Teacher: *Data Analysis.*