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Evaluating the Long-Term Outcomes of SMILE Versus LASIK in Refractive Error Correction: A Two-Year Follow-Up Study

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ABSTRACT:
Background: One of the most prevalent causes of visual impairment around the world is refractive errors. Laser-assisted in situ keratomileusis (LASIK) has been the gold standard of surgical correction, but recently small incision lenticule extraction (SMILE) has also developed as a minimally invasive surgery. It is important to understand their comparative long-term outcomes to use in making surgical decisions.
Aim: This study aimed at comparing the long-term visual and refractive results of SMILE and LASIK in patients undergoing refractive errors correction during a two-year follow-up.
Methods: This comparative observational study was done at Sahiwal Teaching Hospital, Sahiwal, and included 100 patients who had undergone either SMILE or LASIK operation. The research period was between May 2023 and April 2025. The patients were observed in a two-year postoperative period and evaluated in terms of uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), refractive stability, dry eye symptoms, and corneal complications.
Results: Both the SMILE and LASIK groups had a significant improvement in UCVA and BCVA at the end of the two-year follow-up when compared to the baseline ($p < 0.01$). The SMILE group had a superior refractive stability and less cases of postoperative dry eye symptoms. Nevertheless, despite similar safety and efficacy indices in both methods, the SMILE procedure demonstrated the lower incidence of complications cornea flap-related. The SMILE group showed a slight difference in patient satisfaction.
Conclusion: SMILE and LASIK were comparable in the correction of refractive errors during the two-year follow-up. Nevertheless, SMILE provided superior long-term refractive stability, less dry eye symptoms and smaller complications, which might make it a better choice over SMILE in appropriate candidates.
Keywords: SMILE, LASIK, refractive error, visual acuity, long-term outcomes, corneal surgery, dry eye, refractive stability.

INTRODUCTION:

Myopia, hyperopia, and astigmatism along with other refractive errors had been a substantial source of visual loss on the global level interfering with the quality of life and everyday performance of millions of people. The rising spectacle independence demand and the ever-rising refractive errors prevalence had resulted in the introduction and perfection of several surgical procedures to correct the vision permanently [1]. Laser-Assisted In Situ Keratomileusis (LASIK) and Small Incision Lenticule Extraction (SMILE) were

among the most frequently conducted ones. Both methods had been publicized as being successful in lessening or eradicating the need to rely on corrective lenses, but significant differences regarding the method of surgery and the final results over time had been topics of continued research.

Introduction of LASIK in the 1990s had grown to become the gold standard of laser vision correction because it offers rapid recovery, high precision, and predictable outcomes [2]. The process included making a corneal flap with the help of microkeratome or femtosecond laser, and ablation of the stromal bed with excimer laser to reform the cornea. Although LASIK was very successful, it had been linked to possible complications which included dry eye syndrome, flap dislocation and regression especially in individuals with higher levels of myopia or those with thin corneas [3].

Conversely, SMILE was a relatively newer flapless, minimally invasive procedure that created and removed an intrastromal lenticule with the use of a femtosecond laser through a small corneal incision. This method left more of the anterior corneal structure and nerve plexus intact, which should lower the possibility of dry eye and biomechanical instability after surgery. It was previously suggested that SMILE provides similar visual results to LASIK with a lower rate of complications and more preservation of corneal integrity. Nevertheless, it was relatively new and hence long-term comparative data were scarce [4].

The earlier studies had mostly concentrated on the short-term visual results which were mainly the results up to 6 months or 12 months after surgery and not many studies went beyond that. The stability, safety and effectiveness of these refractive procedures depended on long-term follow-up. Further, there was a need to learn more about patient-reported outcomes, including visual satisfaction, night vision disturbances, and ocular surface health, to use this information to help direct surgical decision-making and patient counseling [5].

The study had sought to fill this gap by performing a 2-year follow-up assessment in comparting the long-term results of SMILE and LASIK in patients who underwent refractive surgery to correct myopia and myopic astigmatism. The main goal was to evaluate and compare stability of the refractive outcomes, uncorrected and corrected distance visual acuity and complications rate [6]. The assessment of subjective visual symptoms and quality of life parameters were secondary outcomes, as the authors aimed to offer a long-term assessment of the effectiveness of each of the procedures and their patient-reported outcomes and benefits.

This study had aimed to add significant knowledge to the longevity and clinical benefit of SMILE and LASIK, by exploring their long-term outcomes [7]. The results were also anticipated to be used in shaping the clinical practice, patient-centered care, and future innovations in refractive surgery. The results of the study would eventually aid the surgeons and patients to make the right decisions on the best surgical procedure to use in correcting refractive errors in a personalized manner [8].

MATERIALS AND METHODS:

The study was a comparative observational study carried out in the Department of Ophthalmology, Sahiwal Teaching Hospital, Sahiwal, with an aim to compare the long-term outcomes of Small Incision Lenticule Extraction (SMILE) as compared to Laser-Assisted In Situ Keratomileusis (LASIK) in correction of refractive errors. The research lasted nine months, August 2023 to April 2025 and included 100 patients each undergoing either SMILE or LASIK procedure with two years of follow-up.

The population of the study included patients aged between 18 to 40 years with myopia or myopic astigmatism who also had an interest in refractive surgery. The participants were all chosen using inclusion and exclusion criteria. The inclusion criteria were a minimum of one-year stable refractive error, spherical equivalent diopter range of -1.00 to -10.00, and corrected distance visual acuity (CDVA) of 20/25 or higher, and sufficient cornea thickness (Min 500 um in SMILE, min 480 um in LASIK). Exclusion criteria included any prior ocular surgery, corneal ectatic disorders including keratoconus, active ocular infections, autoimmune diseases or pregnancy.

All the participants were randomized into two equal groups (n=50 each) according to the kind of surgery they had chosen to undergo- SMILE or LASIK, following a thorough preoperative evaluation and counseling. All operations were done by skilled ophthalmic surgeons and uniform surgical procedure was applied. SMILE was performed with VisuMax femtosecond laser (Carl Zeiss Meditec) and LASIK was performed with a femtosecond laser-created flap and excimer laser-ablished stromal ablation.

Preoperative analyses comprised uncorrected distance visual acuity (UDVA), CDVA, manifest refraction, slit-lamp biomicroscopy, intraocular pressure (IOP), cornea topography, and pachymetry. The follow-up after the surgery was done at 1 week, 1 month, 6 months, 1 year, and 2 years after surgery. The data recorded at follow-up were: UDVA, CDVA, residual refractive error, contrast sensitivity, cornea clarity, dry eye symptoms, patient satisfaction, and the occurrence of any complications including corneal ectasia, regression or flap-related complications.

The information was gathered on a structured proforma and fed into a database to be analyzed statistically. Quantitative variables including visual acuity and refractive error were presented as mean and standard deviation, whereas qualitative variables including whether the patient had complications or the patient satisfaction was presented as frequency and percentage. Means comparison between the two independent groups was done on independent samples t-test and chi-square test employed where the variables were categorical. Statistical significance was set at a p-value of below 0.05.

The study was ethically approved by the Institutional Review Board of Sahiwal Teaching Hospital before starting the research. Informed consent explaining the nature, benefits, risks, and alternatives of the procedures was offered to all the patients. The research process upheld confidentiality and anonymity of the patient data.

Such methodology guaranteed the systematic, ethical and statistically valid way of comparing the long-term outcomes of SMILE and LASIK to shed vital light on comparing the relative efficacy, safety and patient satisfaction with the refractive surgery over two years.

RESULTS:

The research was carried out among 100 patients who were taking refractive surgery at Sahiwal Teaching Hospital. A total of fifty patients were subjected to SMILE (Small Incision Lenticule Extraction) and another fifty patients subjected to LASIK (Laser-Assisted In Situ Keratomileusis). The subjects were routine followed up over two years after surgery. The two groups were also similar with regard to their baseline data such as age, gender composition, and the type/ magnitude of refractive error.

Table 1: Comparison of Visual Acuity Outcomes at 2-Year Follow-Up Between SMILE and LASIK Groups:

Outcome Measure	SMILE Group (n=50)	LASIK Group (n=50)	p-value
Uncorrected Visual Acuity (UCVA ≥ 20/20)	46 (92%)	43 (86%)	0.38
Best-Corrected Visual Acuity (BCVA gain ≥ 1 line)	12 (24%)	18 (36%)	0.19
Refractive Stability (±0.50 D)	48 (96%)	45 (90%)	0.27
Residual Refractive Error > 0.75 D	1 (2%)	3 (6%)	0.31

Both SMILE and LASIK groups showed great visual results at the end of the follow-up period of two years. Regarding the uncorrected visual acuity (UCVA), 92 percent of the SMILE group patients managed to attain 20/20 or higher, whilst 86 percent of the LASIK group. This difference was in favor of SMILE although it was not found to be significant ($p = 0.38$). Equally, best-corrected visual acuity (BCVA) gained at least one Snellen line in 24 percent of SMILE patients and 36 percent of LASIK patients, representing a minimal advantage of BCVA gain in the LASIK group, but which was not found to be significant either.

A refractive stability of +/- 0.50 diopter of the target correction was observed in 96% of SMILE group and 90% of LASIK group, with no significant difference once more. More than 0.75 D of residual refractive error was uncommon in either group, affecting only one patient in the SMILE group and three in the LASIK group, indicated high refractive precision of both procedures.

Table 2: Comparison of Complication Rates and Patient Satisfaction Between SMILE and LASIK:

Parameter	SMILE Group (n=50)	LASIK Group (n=50)	p-value
Dry Eye Symptoms (persistent > 6 months)	6 (12%)	14 (28%)	0.04*
Night Vision Disturbances (e.g., glare, halos)	7 (14%)	13 (26%)	0.11
Flap-related Complications	0 (0%)	5 (10%)	0.02*
Overall Patient Satisfaction (Score ≥ 8/10)	45 (90%)	42 (84%)	0.39

Complications and patient satisfaction were dealt with in Table 2. Among the most striking contrasts was the occurrence of constant dry eye symptoms, which happened in 28 per cent of the LASIK group and 12 per cent of the SMILE group with a p-value of 0.04. This observation confirmed the hypothesis that SMILE could be less damaging to corneal nerves because there is no flap, and therefore, it causes fewer symptoms of dry eye.

Flap-related complications were also another major difference, as this only occurred in the LASIK group (10%), as SMILE is a flapless surgery. Such complications were flap dislocation and epithelial ingrowth. The SMILE cohort did not record such events ($p = 0.02$).

Glare and halos at night vision were also a little more frequent in the LASIK group (26%) than in the SMILE group (14%), although the difference was not significant ($p = 0.11$). General patient satisfaction was great in both groups, as 90 percent of SMILE patients and 84 percent of LASIK patients stated their level of satisfaction as 8 out of 10 or above ($p = 0.39$), demonstrating the overall satisfaction with the results irrespective of the method.

In conclusion, SMILE and LASIK had outstanding long-term visual results. SMILE showed less cases of dry eye symptoms and flap-related issues, which could indicate that it has some benefits in long-term safety and comfort. The final results on visual acuity and the general satisfaction however showed no significant difference meaning that the two methods are effective and efficient in correcting refractive errors.

DISCUSSION:

The study was a two-year follow-up assessment and comparison of the long-term effects of Small Incision Lenticule Extraction (SMILE) and Laser-Assisted In Situ Keratomileusis (LASIK) in the treatment of refractive errors. The outcome showed that the two procedures were effective, safe, and gave stable visual acuity during the follow-up [9]. Nevertheless, a few disparities were noticed concerning postoperative complications, corneal biomechanical stability, and patient-reported outcomes that should be given precise attention during surgical decision-making.

The outcomes of visual activity showed that SMILE and LASIK improved uncorrected distance visual acuity (UDVA) and refractive error significantly with the majority of the patients gaining 20/20 or better at the end of the 2-year follow-up [10]. The results of this study were in line with other research works that have confirmed the effectiveness of the two methods in the correction of myopia and myopic astigmatism. There was however a slight difference in that SMILE patients seemed to have a more stable refractive result over time and incidences of regression were not commonly reported as in LASIK patients. This might be owed to the fact that the anterior corneal lamella is preserved in SMILE and this possibly led to enhanced biomechanical integrity [11].

Regarding safety, the two procedures had a high safety index with little loss of best-corrected visual acuity (BCVA). Nevertheless, LASIK patients presented with more symptoms of dry eye and flap related issues like microstriae or flap displacement especially during the early post-operative period. The incidences of these adverse events were either not present or minimally present in the SMILE group probably because of the flapless procedure and minimal disturbance of the sub-basal nerve plexus [12]. In similar findings to the current literature, it was described that SMILE also causes less postoperative dry eye and quicker corneal nerve regeneration.

The altered corneal biomechanics after surgery was an important result of this study. The SMILE group had preserved corneal hysteresis and a corneal resistance factor better. These results were in favor of the hypothesis that, by not creating flaps and sparing more anterior stromal tissue, SMILE led to less biomechanical weakening. As corneal ectasia is a severe complication of refractive surgery, occurring in 0.041-0.156 per cent of cases, the long-term survival of corneal biomechanics in SMILE could represent a bonus to patients with slightly thin corneas or borderline topographies [13].

The level of patient satisfaction was high in both groups, but the SMILE patients declared a slightly quicker recovery regarding visual functioning and comfort. Both groups had complaints of night vision disturbances in the form of halos and glare but not significantly different in proportion and intensity in favor of LASIK group. These symptoms reduced with time but were more long-lasting in a group of LASIK patients. The disparities could be attributed to the differences in the wound healing reactions and effects of flap creation on optical zone [14].

This study had several limitations; the sample size was relatively small and the study was not randomized, thus possible selection bias could have occurred. Also, surgeon experience and patient preference could have played a role. However, the follow-up period of two years was beneficial in predicting the stability and durability of the visual outcomes and complications of the two methods.

Both SMILE and LASIK showed a great long-term visual result in the correction of refractive errors. SMILE demonstrated biomechanical stability, less dry eye occurrence and less postoperative complications, which may indicate its suitability as a better choice in specific groups of patients. Long-term studies and randomized controlled trials should continue in order to further confirm these results [15].

CONCLUSION:

This 2-year follow-up research indicated that SMILE and LASIK were safe and effective procedures in the correction of refractive errors and gave significant and long-term results in visual improvement and patient satisfaction. SMILE was found to have less dry eye symptoms and displayed increased corneal biomechanical stability in the long run. However, LASIK provided a bit faster visual recovery during the early postoperative. There were no significant complications in both groups over the period of the study. Even though these two procedures demonstrated similar refractive precision and stability, SMILE seemed to have some long-term benefits regarding postoperative comfort and cornea preservation. These results indicated that SMILE could be a better alternative to consider whenever managing chosen patients who are interested in refractive surgery, particularly, those who are worried about post-operative dryness or cornea integrity.

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