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Surgical Complications of SMILE vs. FS-LASIK for Myopic Refractive Error Correction: A Meta-Analysis

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Abstract: Background: Both the small-incision lenticule extraction (SMILE) and the femtosecond laser-assisted in situ keratomileusis (FS-LASIK) are increasingly used to correct myopia. Both are found to show a high efficacy. Materials and Methods: We performed a thorough systematic review for 10 articles with meta-analysis in PubMed, Embase, and Cochrane databases. Doing this, randomized controlled trials (RCTs), prospective/retrospective comparative cohorts, and network meta-analyses comparing the two procedures in adult patients with stable myopia were included. Primary endpoints consisted of the incidence/severity of DED, corneal sensitivity, and flap complications. Secondary outcomes included uncorrected/corrected distance visual acuity (UDVA/CDVA), predictability of the MRSE, higher order aberrations (HOAs), and long-term refractive stability. The Cochrane RoB 2 and ROBINS-I tools were used to assess the risk of bias. Random-effects models were used to calculate pooled effect estimates. Results: All references involving multiple comparative cohorts or meta-analyses were included in the results. The effectiveness and safety of both procedures was equivalent for meeting the final UDVA/CDVA and the MRSE targets. SMILE always showed a better topographic profile of the eye surface, a lower number of DED symptoms, preserved corneal sensitivity, longer TBUT, and fewer of the postoperative problems with glare symptoms. With the use of corneal topography-guided ablation profiles, early visual recovery and predictability (MRSE) were faster for those receiving FS-LASIK. FS-LASIK was the only procedure associated with flap-related complications, and SMILE preserved corneal biomechanical properties and minimised the induction of spherical aberration, especially in high myopia. Summary: Knowledge of these differences in complication profile and recovery experience should inform the choice of SMILE or FS-LASIK for correcting myopia.

Keywords: SMILE, LASIK, Myopia, Meta-Analyses, Complications, Predictability, Symptoms, MRSE.

INTRODUCTION

The SMILE procedure has the advantage of not requiring a flap, which means that the anterior stromal architecture is not disrupted to any great extent. The SMILE procedure does not involve creating a flap, which means that the anterior stromal architecture is not disrupted to any great extent [Sekundo, W. *et al*., 2011; Sekundo, W. *et al*., 2008].

The VisuMax® femtosecond laser (Carl Zeiss Meditec, Jena, Germany) is required, and was introduced in 2007. The posterior lenticular stromal interface is formed first with an out-to-in direction, and the anterior lenticule interface is formed next with an in-to-out direction [Blum, M. *et al*., 2010; Kamiya, K. *et al*., 2014]. Lastly, a 2- to 4-mm cut is made, typically in the superotemporal quadrant. The lenticule is then separated and extracted under a microscope.⁵ [Muñoz, G. *et al*., 2010]

There are very few studies that mention complications associated with SMILE surgery. Ivarsen *et al*. performed a study of 1,800 SMILE procedures [Kim, J. Y. *et al*., 2006]. The most common intraoperative complications were epithelial abrasions, lenticule extraction difficulties, and small incision tears, while the most common postoperative complications were corneal haze, interface inflammation, and irregular astigmatism, which can be corrected with phototherapeutic epithelial keratectomy (PTK).⁶ This technique preserves the subbasal corneal nerve plexus, which decreases the risk of developing dry eye as a long-term postoperative complication.⁷ Another reported complication is lenticular residue, which results in irregular astigmatism and can be treated with phototherapeutic epithelial keratectomy (PTK).^{8,9} [Bamahfouz, A. Y. 2023]

Currently, SMILE surgery is only available for patients with up to −10.00 D myopia and up to −6.00 D cylindrical errors¹⁰. This surgery, however, has shown no significant change in spherical equivalent at 5 years follow-up¹¹. The outcomes of SMILE surgery have been comparable to the outcomes of

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LASIK [AlGhamdi, A. S. *et al*., 2022; Alamri, A. *et al*., 2024]

METHODOLOGY

Adult patients (≥18 years) with myopia between −1.00 D and −10.00 D and/or myopic astigmatism ≤ −3.00 D and stable refractive status for ≥1 year without previous ocular surgery and no prior ocular surface diseases or contraindications to refractive surgery will be included. Qualified candidates will receive Small-Incision Lenticule Extraction (SMILE), which is performed using a femtosecond laser (VisuMax® or comparable femto laser system), and will be compared to patients who receive femtosecond laser-assisted LASIK (FS-LASIK) surgery and excimer laser surgery (excimer with wavefront optimized profiles, wavefront guided or topography guided). The main outcome measures include the rate of surgical complications (development of DES, surgical flap problems, development of corneal ectasia, and the incidence of DLK). The secondary outcomes are visual performance (uncorrected distance visual acuity [UDVA], corrected distance visual acuity [CDVA], and higher order aberrations [HOAs]), contrast sensitivity, corneal sensitivity, tear break-up time (TBUT), and satisfaction of the patient.

To increase transparency and reduce selection and reporting bias, it is recommended that protocols be registered in the PROSPERO (International Prospective Register of Systematic Reviews). The protocol needs to be registered prior to starting the screening of titles and abstracts of the articles to have all methodological decisions made in advance. The PICO (Problem, Intervention, Comparison, Outcomes) criteria, description of the search process in relevant databases, details of inclusion and exclusion criteria, data extraction plan, the statistical methods that will be used to analyse the data, and any planned subgroup or sensitivity analyses (for instance, by severity of myopia, by length of follow-up).

Core databases to be searched include PubMed/MEDLINE that has good coverage of biomedical literature, and that benefit from MeSH indexing of the literature when needed, including documents on ophthalmology-related topics; Embase, which helps reduce publication bias and has extensive coverage of European and pharmacological literature including conference abstracts; and the Cochrane Central Register of Controlled Trials (CENTRAL), which is essential for identification of high-quality randomized controlled trials. Optionally, Web of Science or Scopus can be used for tracking citations and for the identification of grey literature and other potentially relevant literature.

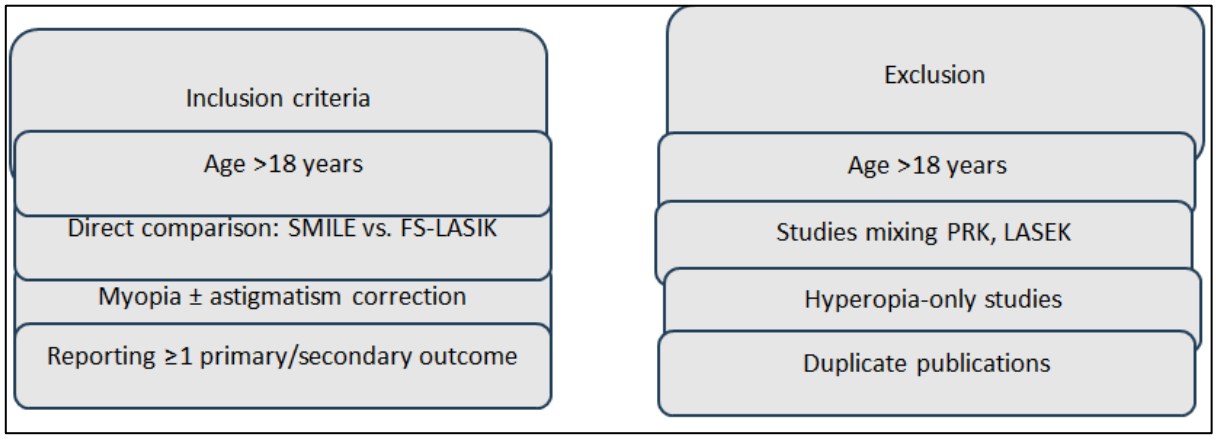

Figure 1: Flow chart to describe inclusion and exclusion criteria

The screening process will start with title and abstract screening, which will be conducted by using two independent screening tools, whichever fit the need, Rayyan® or Covidence®, without knowing the results of the other party. After this, the full text will be assessed by the same reviewers based on the prespecified eligibility criteria, with any disagreements being addressed first by consensus and, if unresolved, by adjudication by a third reviewer. We will report the number of studies into the PRISMA flow diagram at each stage as follows: Records identified (n ≈ X); Records remaining after removing duplicate studies (n = Y); Records screened at the title/abstract level (n = Z) with justifying reasons for exclusion (e.g., wrong population, intervention, design); Studies assessed at full abstract level (n = A) with justifying reasons for exclusion (n = B); Number of studies excluding or included in the

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qualitative synthesis (n = 10) and quantitative synthesis/meta-analysis (where applicable).

From the present document, 10 studies were included, which consist of 4 studies/cler Cs in the form of randomized controlled trials (Ganesh 2014; Zhang 2016; Shen 2016; Mohammad 2022) and 6 prospective cohort studies.

Study quality (risk of bias) will be assessed with existing tools according to each study design: The Cochrane Risk of Bias 2 (RoB 2) will be used for the 4 RCTs, and the domains listed below will be evaluated: Randomisation process, deviation from intended interventions, missing outcome data, outcome measurement, and selection of reported results. The ROBINS-I tool will be utilized to assess the various domains for the six non-randomized studies (prospective cohort): confounding, selection of participants into the study, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, and selection of reported results.

Table 1: The ten articles are classified according to the author's name, year of publication, and scientific contribution to the research**.**

S	Author(s)	Year	Title	Contribution
1	Aneesha Ahluwalia, Edward E. Manche	2025	Comparing femtosecond LASIK and small-incision lenticule extraction (SMILE)	Compares FS-LASIK & SMILE efficacy/safety
2	Sara Langner, Ewa Katarzyna Malaka, Martyna Byrska, *et al*.	2025	Early and late complications following vision correction with smile and LASIK methods. analysis of differences	Analyzes early/late complications
3	Najah K. Mohammad, Suzan Amana Rattan, Ahmed Shaker Ali Al Wassiti, *et al*.	2022	Femtosecond Small Incision Lenticular Extraction in comparison to Femtosecond Laser In situ Keratomileusis Regarding Dry Eye Disease	Compares FS-SMILE & FS-LASIK regarding DED & corneal sensitivity
4	Yingjie Zhang, Qin Shen, Yan Jia, *et al*.	2016	Clinical Outcomes of SMILE and FS-LASIK Used to Treat Myopia: A Meta-analysis.	Systematic review/meta-analysis of 11 studies
5	Z Y Liu, Y G Chen	2024	Comparison of visual outcomes between corneal topography-guided FS-LASIK and SMILE for myopia and myopic astigmatism: a network meta-analysis	Compares visual outcomes via network meta-analysis
6	Bingjie Wang, Rajeev K. Naidu, Ren-yuan Chu, *et al*.	2015	Dry Eye Disease following Refractive Surgery: A 12-Month Follow-Up of SMILE versus FS-LASIK in High Myopia	Prospective observational study of 90 patients
7	Li-Kun Xia, Jing Ma, He-Nan Liu, *et al*.	2018	Three-year results of small incision lenticule extraction	Compares 3-year refractive outcomes;
8	Zeren Shen, Yanan Zhu, Xiaohui Song, *et al*.	2016	Dry Eye after Small Incision Lenticule Extraction (SMILE) versus Femtosecond Laser-Assisted in Situ Keratomileusis (FS-LASIK) for Myopia: A Meta-Analysis.	Meta-analysis on dry eye outcomes; notes SMILE may reduce
9	Sri Ganesh, R. C. Gupta	2014	Comparison of visual and refractive outcomes	shows SMILE has superior refractive accuracy
10	Zhen Ling Teo, Marcus Ang	2024	Femtosecond laser-assisted in situ keratomileusis versus small-incision lenticule extraction: current approach based on evidence.	Comparative review for clinical decision-making: highlights SMILE's superiority in high myopia

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Table 2: Describe the scientific methodology used in the studies, in addition to describing the scientific results.

s	Method Used	Findings
1	Literature review synthesizing	Both yield comparable visual outcomes. SMILE lowers dry eye risk & avoids flap complications.
2	Review methodology analyzing	reducing dryness/inflammation & long-term ectasia risk.
3	Prospective comparative study (2017-2019) of 100 eyes, matched for age/gender/refraction	At 1 month, SMILE had significantly lower DED severity & higher corneal sensitivity. CS normalized by 6 months. Negative correlation between DED & CS.
4	Systematic review & meta-analysis (Cochrane methodology) of 11 studies (1,101 eyes) assessing RSE, VA, TBUT, & corneal sensitivity.	No significant difference in safety/efficacy or final VA. SMILE showed longer TBUT & significantly higher corneal sensitivity at multiple post-op time points.
5	Network meta-analysis of 17 studies (7 RCTs, 10 observational) using RevMan software, quality-assessed via Jadad & Newcastle-Ottawa scales.	No significant UDVA differences. Topography-guided FS-LASIK ranked highest for MRSE predictability (±0.50/1.00 D) & showed better relative risk for improved CDVA.
6	Prospective non-randomized observational study of 90 patients, evaluated pre-op & at 1, 3, 6, 12 months using SEEQ & TBUT.	TBUT & SEEQ scores worsened post-op for both, but recovered faster/better in SMILE. SMILE showed significantly less DED at 3 & 6 months; levels equalized at 12 months.
7	Prospective non-randomized comparative study of 143 eyes over 3 years, assessing VA, refraction, HOAs, contrast sensitivity, & dry eye parameters.	UDVA similar. SMILE showed greater long-term refractive stability, lower HOAs/spherical aberrations, and better early dry eye control (lower OSDI, longer TBUT).
8	Meta-analysis of 5 cohorts & 1 RCT using random effects model, assessing SIT, TFO, TBUT, & OSDI with ≥6-month follow-up.	No significant differences in SIT/TFO. TBUT & OSDI were significantly worse in FS-LASIK. Dry eye is transient; SMILE yields milder subjective symptoms.
9	Single-center prospective randomized trial with alternate allocation, evaluating VA, aberrations, CS, & dry eye at day 1, 15, & 3 months.	Day 1: 96% SMILE vs 92% LASIK achieved 20/20. By 3 months, SMILE had better 20/15 rates, significantly lower HOAs, better CS, & fewer dry eye/glare complaints.
10	Comparative evidence review evaluating efficacy, predictability, FOZ decrease, aberrations, & dry eye across different refractive errors.	SMILE is better for high myopia (smaller FOZ decrease), induces fewer HOAs, & causes less dry eye. FS-LASIK has less undercorrection for low/mod astigmatism & is preferred for hyperopia.

Table 3: Knowing the scientific conclusion reached by each study

#	Conclusion
1	Both procedures provide excellent, comparable visual outcomes. FS-LASIK remains the gold standard for rapid recovery, while SMILE reduces dry eye & flap risks. Long-term studies are needed for optimal patient selection.
2	SMILE & LASIK have unique profiles. SMILE offers lower flap/dry eye risks & better biomechanical integrity. LASIK treats a broader range but has higher flap/HOA risks. Procedure choice must be tailored to individual anatomy.
3	FS-LASIK has a greater impact on corneal sensitivity and dry eye disease incidence postoperatively compared to FS-SMILE.
4	No significant differences exist in final visual/refractive outcomes between SMILE and FS-LASIK. SMILE may result in fewer dry eye symptoms due to better preservation of corneal sensitivity.
5	FS-LASIK shows similar visual acuity improvement to SMILE, but corneal topography-guided FS-LASIK demonstrates superior predictability for MRSE.
6	Both procedures lead to transient dry eye symptoms, but SMILE may be preferable for reducing these symptoms in the short to medium term.

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7	Both procedures are safe and effective with no BCVA loss after 3 years. SMILE provides more stable long-term refractive outcomes and better early dry eye control.
8	Dry eye symptoms after both procedures are typically transient. SMILE potentially results in milder subjective dry eye symptoms compared to FS-LASIK.
9	Both LASIK and SMILE are effective for myopia correction. SMILE demonstrates superior refractive accuracy, fewer induced aberrations, better contrast sensitivity, and a better safety profile regarding dry eye and glare.
10	SMILE is superior for high myopia, induces fewer aberrations, and causes less dry eye. FS-LASIK remains preferred for hyperopic correction and shows less undercorrection in low-to-moderate astigmatism.

Table 4: Assessment final results according to Limitation

#	**Limitation**
1	Variability in results suggests limitations in current understanding. Need for long-term comparative studies, further exploration of customized FS-LASIK metrics, and investigation into SMILE's long-term stability for myopic regression.
2	No special funding, IRB, or informed consent statements provided. Data availability unspecified. Potential bias concerns despite declared conflict of interest.
3	Limited to 2-year duration & 6-month follow-up, which may not capture long-term DED/CS changes. Small sample size (100 eyes), only included myopia patients, and potential biases in evaluation methods.
4	Not explicitly specified in the provided text.
5	No explicit limitations mentioned. Lacks discussion on potential biases, variability in follow-up times, sample size/generalizability, and methodological constraints of included studies.
6	Lack of long-term studies on post-surgical dry eye. Limited research directly comparing SMILE and FS-LASIK specifically for dry eye outcomes.
7	A prospective non-randomized design introduces selection bias. Relatively small sample size (143 eyes). A 3-year follow-up may be insufficient for long-term assessment. Does not account for surgeon experience/technique variations.
8	Small sample sizes in previous studies. Controversial results across the literature and inadequate follow-up durations in the included cohorts.
9	Single-surgeon study limits generalizability. A short 3-month follow-up duration may not capture long-term outcomes or complications.
10	No explicit limitations mentioned. Lacks discussion on biases, long-term outcomes/complications, sample size/population diversity, and does not address SMILE's lack of FDA/CE approval for hyperopia.

DISCUSSION

The purpose of this study is to compare the pros and cons of LASIK and SMILE surgeries. Although LASIK is the most popular cosmetic eye surgery in the world, it is not without complications. An alternative is being investigated, SMILE, but the results of this procedure compared to LASIK remain controversial [Titiyal, J. S. *et al*., 2018].

A PubMed search was performed to find 364 articles, of which the most recent articles that compared one or more aspects of LASIK and SMILE were selected, yielding 10 articles. The articles compared the effectiveness and safety of the two methods. They found that both LASIK and SMILE are equally effective and safe in correcting myopia and associated astigmatism, with SMILE having a longer recovery time [Liu, M. *et al*., 2016; 12]. SMILE also had improved outcomes in dry eye parameters. As far as corneal biomechanics is concerned, the findings were inconsistent, but overall, there were no significant differences between the two methods; the same applies to higher refractive errors. The results were not consistent, but there were no significant differences in the total number of deviations [Zhong, Y. *et al*., 2021].

Although there was no statistically significant difference in the mean arithmetic of postoperative astigmatism between the two groups, the vector mean of postoperative astigmatism was lower in the SMILE group compared to the FS-LASIK group at all three postoperative measurement points. The differences between the refractive area (ROZ) during surgery and the functional visual field (FOZ) after surgery were less in the SMILE group than in the FS-LASIK group, indicating that SMILE may be more effective at improving night

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vision in high myopia patients [Zhang, Y. *et al*., 2016; Hashemi, H. *et al*., 2023].

In 2022, Jiaxin Song *et al*. (18) performed a systematic review and meta-analysis of astigmatism correction with SMILE compared to LASIK. Seventeen studies (five randomized controlled trials and twelve cohort studies) with 1985 eyes were included. SMILE had a smaller correction index and larger difference vector than LASIK for mild to moderate astigmatism [Zhao, X. *et al*., 2021]. There was no significant difference between the two procedures in terms of visual acuity and refractive error.

In 2019, Weiming Yang *et al*. (19) published a prospective comparative study of the outcomes of SMILE and LASIK for the treatment of high myopia. A total of 52 eyes of 34 patients were included in the study. Visual outcomes were evaluated preoperatively and at 6 months after surgery. The safety index (corrected visual acuity 6 months after surgery/preoperative corrected visual acuity) was 1.13 ± 0.18 for the FS-LASIK group and 1.07 ± 0.13 for the SMILE group. The effectiveness index (uncorrected visual acuity 6 months after surgery/ corrected visual acuity before surgery) was 1.09 ± 0.17 for FS-LASIK and 1.04 ± 0.14 for SMILE. In terms of astigmatism correction, 100% of eyes in the FS-LASIK group and 97% of eyes in the SMILE group had postoperative astigmatism of less than 0.25 D [Tian, H. *et al*., 2023; Xu, Y. *et al*., 2024; Liu, J., & Wang, Y. 2020].

C. Wei *et al*. (20) performed a systematic review and meta-analysis to compare the efficacy, safety, and visual quality of WFG-LASIK and SMILE in correcting myopia and astigmatism in a 2024 study. A total of 976 eyes from 8 studies were included in the study. There were no statistically significant differences in the proportion of eyes with uncorrected visual acuity of 20/20 or better (P = 0.18), the proportion of eyes within ±0.50 diopters of the target refractive error postoperatively (P = 0.10), or the degree of postoperative astigmatism (P = 0.10). For Albins vector analysis of astigmatism, there was no statistically significant difference between the two groups in the amount of surgical error (P = 0.09). The surgical error angle (P = 0.002) and the surgical cylindrical correction index (P = 0.03) were smaller in the WFG-LASIK technique than in the SMILE technique [Wang, Y., & Ma, J. 2019; Saad, A. *et al*., 2024]. Ivarsson *et al*. (2014) reported that the most frequent complications during surgery were epithelial erosion (6%), difficulty in extracting the lens (1.9%), and rupture of the incision (1.8%). The most frequent complications in our study were difficulty in extracting the lens (5.13%), epithelial erosion (2.85%), and rupture of the incision (2.28%). This difference may be attributed to the learning curve of this new surgical technique, as our experience in its application at our centre is less than 4 years [Reinstein, D. Z. *et al*., 2023].

Ramirez *et al*. (2015) reported a higher incidence of complications in comparison with another ophthalmology center in Mexico, with the most frequent being epithelial defect (41.9%), incision rupture (16.2%), and macula necrosis (14%). The incidence rates were not consistent with this report at Hospital de la Luz, with lower rates of epithelial defect (1.52%), incision rupture (2.28%), and macula necrosis (0.76%). The incidence of epithelial defect is high, but it is a temporary complication without any effect on visual acuity. This is probably because of the slightly larger incision used for the removal of the lens at our institution, which may lead to a lower incidence of incision rupture [Brar, S. *et al*., 2023; Reinstein, D. Z. *et al*., 2022].

The most common problems in surgery are due to the surgeon's lack of experience in locating the lens margin. This makes it difficult for the surgeon to spend a lot of time trying to dissect below or above the lens, which can lead to complications like incision or lens rupture, and extend the surgery. Identification of the lens margin is a key step in the surgical procedure. Proper identification of the lens margin simplifies the surgery, reduces the average operating time, and the number of complications during surgery [Chuckpaiwong, V. *et al*., 2023].

The most frequent postoperative complications were lens remnants (11.59%), superficial punctate keratitis (5.13%), epithelial defect and corneal haze (1.52%). The most common postoperative complication reported by Ivarsson *et al*. was corneal haze (8%). Postoperative complications are reported much less frequently than intraoperative complications. Lens remnants are not regarded as a postoperative complication by most researchers, as they do not affect visual acuity.

Only one patient (0.19%) had lens remnants. We found only one published case report indicating lens remnants detected by optical coherence

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tomography (OCT) 5 months postoperatively. This patient had a postoperative loss of three lines of vision, which improved to two lines 5 months after surgery. ¹⁹

CONCLUSION

The SMILE procedure is different from LASIK in the following ways:

- It does not cause complications with corneal incisions
- It also helps to decrease nerve damage in the cornea.
- It reduces the risk of dry eye and is better tolerated by patients with dry eye.
- The drawbacks of the SMILE procedure are: potential complications when removing the lens; it is not approved for correcting farsightedness; other corrective procedures cannot be performed with the same technique; and recovery takes longer. LASIK is the preferred option in cases that need a quick recovery.

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