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## Evaluation of tear film stability and visual outcomes among different refractive surgery techniques in myopia

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### Abstract

**Purpose:** To evaluate and compare the tear film stability and visual outcomes in patients with low to moderate myopia undergoing Femto-LASIK and SMILE refractive surgeries.

**Methods:** This prospective comparative study was conducted at the cornea department of M.M. Joshi Eye Institute, Hubli. This study was designed to evaluate and compare the tear film stability and corneal outcomes of two refractive surgeries—FEMTO-LASIK and SMILE. A total of 120 patients above 18 years of age were included, with 60 patients undergoing SMILE surgery and 60 patients undergoing FEMTO-LASIK. All patients provided informed consent. And were Preoperatively assessed for visual acuity (UCVA), contrast sensitivity & tear film stability. Postoperative evaluations at one week & one month assessed changes in visual acuity, contrast sensitivity & dry eye symptoms.

**Result:** Both SMILE and Femto-LASIK surgeries produced excellent visual and refractive outcomes. However, Smile patients demonstrated significantly better tear production, suggesting a lower risk of dry eye symptoms. Other parameters like visual acuity, contrast sensitivity, were comparable between groups. Visual Acuity: Significant improvement for SMILE at 1 month ( $p=0.048$ ). Contrast Sensitivity: Minor significant drop for SMILE at 1 week ( $p=0.013$ ); Femto improved at 1 month ( $p=0.011$ ). Schirmer's Test: Significant decrease in both groups at 1 week and still significant at 1 month ( $p<0.001$ ). NIBUT test: Significantly better tear film stability in SMILE vs. FEMTO at 1-week post-surgery ( $p<0.001$ ). SMILE maintains slightly better NIBUT values at 1 month.

**Conclusion:** while both SMILE and FEMTO-LASIK effectively correct low to moderate myopia, SMILE offers improved contrast sensitivity, & greater tear film stability, leading to enhanced comfort and visual quality. Therefore, SMILE is a better option in surgical techniques."

**Keywords:** Smile, femto-Lasik, tear film stability, Schirmer-1test, contrast sensitivity

### Introduction

Refractive error is a common vision condition caused by the eye's shape, resulting in blurred vision. It is one of the most prevalent ocular problems globally, particularly affecting children and adolescents, with myopia showing a significant increase in both incidence and earlier onset [1-3]. Myopia is commonly corrected using concave lenses or contact lenses, which have a negative refractive power to shift the focal point onto the retina. Refractive surgeries such as LASIK and SMILE are alternative methods that reshape the cornea, enhancing visual acuity by modifying its curvature and biomechanical properties [3, 5]. Uncorrected refractive errors are the second leading cause of global blindness, with myopia being the most frequent subtype [2]. With the global rise in myopia cases, preoperative assessment of uncorrected visual acuity (UCVA) and central corneal thickness (CCT) has become crucial, as CCT significantly influences the safety and effectiveness of refractive procedures [2]. Contrast sensitivity (CS) is another vital parameter in visual assessment, reflecting the visual system's ability to detect luminance differences between an object and its background. Unlike standard acuity tests, CS offers a more realistic evaluation of functional vision in everyday settings [4]. Dry eye disease (DED) is the most frequent postoperative complication of corneal refractive surgeries like LASIK, SMILE, and PRK. It can lead to discomfort and serious vision-threatening issues such as flap misalignment, refractive regression, and microbial keratitis [7]. Among these, LASIK remains the most

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widely performed technique for correcting myopia and astigmatism [8]. Small Incision Lenticule Extraction (SMILE) and Femtosecond Laser-Assisted In Situ Keratomileusis (FS-LASIK) are two widely accepted laser-based surgeries for correcting myopia and myopic astigmatism. SMILE involves creating and removing a corneal lenticule through a small incision, eliminating the need for a large corneal flap. FS-LASIK, in contrast, uses a femtosecond laser to create a corneal flap, followed by stromal ablation using an excimer laser [6,8]. Both methods offer high precision, short procedure time, minimal trauma, faster recovery, and fewer complications. The femtosecond laser, with its ultrafast pulses, has significantly enhanced the safety and accuracy of LASIK procedures. Unlike traditional microkeratomes, femtosecond lasers create uniform, precise corneal flaps, preserving corneal architecture and improving long-term structural stability. This results in fewer biomechanical disruptions and reduced postoperative complications [9].

## Materials and Methods

This prospective, hospital-based comparative study was conducted between September 2024 and June 2025 at a tertiary eye care center in Hubli, Karnataka, to evaluate and compare tear film stability and visual outcomes following two refractive surgical procedures: Small Incision Lenticule Extraction (SMILE) and Femtosecond Laser-Assisted In Situ Keratomileusis (Femto-LASIK). The study received prior approval from the Institutional Ethics Committee, and informed written consent was obtained from all participants before any study-related procedures were performed.

A total of 120 patients, aged 18 years and above, were enrolled and equally divided into two groups: 60 underwent SMILE and 60 underwent Femto-LASIK. Inclusion criteria included age  $\geq 18$  years, stable vision for at least six months, best corrected visual acuity (BCVA) of 0.00 LogMAR, central corneal thickness greater than 500  $\mu\text{m}$ , myopia ranging from  $-1.00\text{D}$  to  $-6.00\text{D}$ , and a mesopic pupil size between 6.0 and 6.5 mm. Patients were excluded if they had thin corneas ( $<500 \mu\text{m}$ ), unstable refractive errors, ocular pathologies such as keratoconus, cataract, glaucoma, or retinal disorders, systemic illnesses affecting ocular health, a history of ocular trauma or surgery, or signs or symptoms of dry eye disease.

All subjects underwent a standardized preoperative ophthalmic evaluation. Distance visual acuity was measured using a LogMAR chart and near visual acuity using a Reduced Snellen chart. Contrast sensitivity was assessed using the Pelli-Robson chart, and objective refraction was performed using a Welch Allyn 3.5V streak retinoscope and a trial lens set. Corneal thickness and curvature were evaluated using a Schwind Sirius topographer. Tear film assessment included the Schirmer I test, using sterile Schirmer strips without anesthesia to measure tear production over five minutes, and non-invasive tear break-up time (NIBUT) was evaluated using the IDRA Dry Eye Analyzer. Anterior segment evaluation was conducted with a slit lamp biomicroscope (ZEISS).

All surgeries were performed by experienced refractive surgeons following standardized protocols. The SMILE procedure involved the creation and removal of a stromal lenticule through a small corneal incision, while Femto-LASIK involved the creation of a corneal flap using a femtosecond laser followed by stromal ablation using an

excimer laser. Both groups were evaluated postoperatively at one week and one month to assess uncorrected distance visual acuity (UCVA), contrast sensitivity, and dry eye parameters.

The collected data were tabulated and analyzed using the Statistical Package for Social Sciences (SPSS) version 22.0. Graphs and tables were generated using GraphPad Prism version 5.03. Paired t-tests were used for within-group comparisons, while independent t-tests and ANOVA were employed for between-group analyses. A p-value of less than 0.05 was considered statistically significant.

## Results

The study comprised of two group of participants, Participants who underwent SMILE surgery for refractive correction was considered as SMILE group with participants having mean age of 24.5 years with 28 males and 32 females. Group 2 was termed as FEMTO group had participants who underwent FEMTO surgery, it had 60 participants with mean age of 24.67 years. Out of 60 participants, 27 were males and 33 females.

**Table 1:** Demographic information

Group	Mean	Gender distrubution (M/F)
Smile	24.53	28/32
Femto- lasik	24.67	27/33

**Table 2.** Base line comparison

Parameters	Smile mean SD	Femto- mean SD	P value
Visual acuity (decimal)	0.92 $\pm$ 0.18	0.95 $\pm$ 0.12	0.372
Contrast sensitivity	2.06 $\pm$ 0.07	2.06 $\pm$ 0.08	0.758
Schirmer's test 1	27.52 $\pm$ 6.66	30.10 $\pm$ 4.11	0.019
NIBUT	12.55 $\pm$ 1.64	12.67 $\pm$ 1.73	0.719

Both groups were comparable at baseline across most parameters. Only Schirmer's Test showed a significant difference.

**Table 3:** 1-week comparison

Parameters	Smile mean $\pm$ SD	Femto Mean $\pm$ SD	P- value
Visual acuity	0.71 $\pm$ 0.19	0.83 $\pm$ 0.23	0.584
Contrast sensitivity	2.03 $\pm$ 0.13	2.04 $\pm$ 0.09	0.530
Schirmer's test -1	11.85 $\pm$ 4.97	11.30 $\pm$ 3.80	0.526
NIBUT test	9.35 $\pm$ 2.19	7.45 $\pm$ 2.02	<0.001

At 1 Week, Significant reduction in NIBUT values in both groups compared to baseline. SMILE group maintained significantly higher NIBUT values compared to Femto-LASIK (9.35 vs. 7.45 seconds,  $p < 0.001$ )

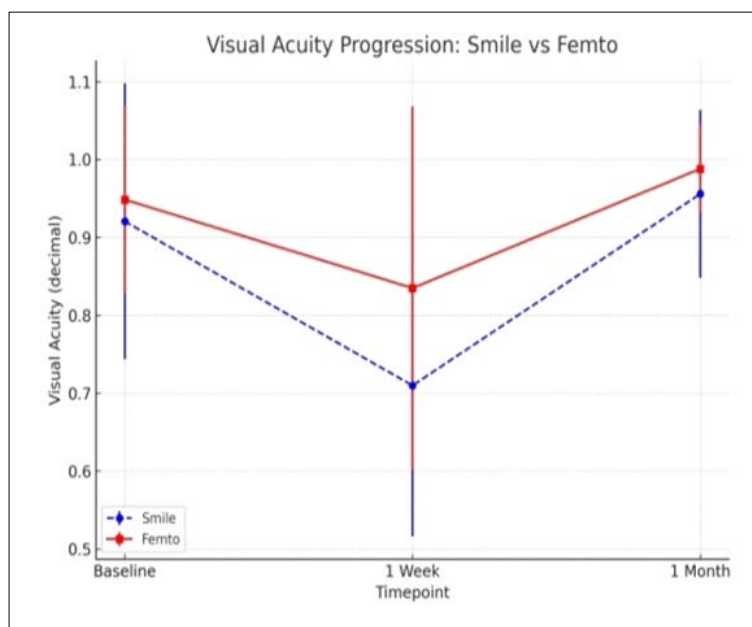
**Table 4:** 1-month comparison

Parameters	Smile mean $\pm$ SD	Femto Mean $\pm$ SD	P- value
Visual acuity	0.96 $\pm$ 0.11	0.99 $\pm$ 0.06	0.083
Contrast sensitivity	2.07 $\pm$ 0.07	2.08 $\pm$ 0.05	0.228
Schirmer's test -1	16.36 $\pm$ 7.37	12.73 $\pm$ 3.31	0.002
NIBUT	8.87 $\pm$ 2.38	8.20 $\pm$ 2.11	0.126

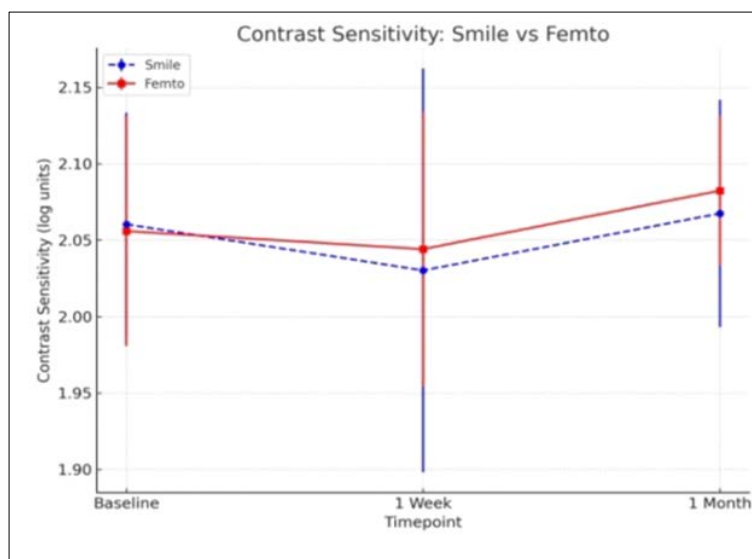
At 1 Month, Schirmer's Test remained significantly higher in Smile patients ( $p = 0.002$ ), both groups showed partial recovery in NIBUT values compared to 1 week, indicating better tear production compared to Femto. Paired comparison of (preoperative and postoperative)

**Table 5:** PaireT- Test (Smile and femto group)

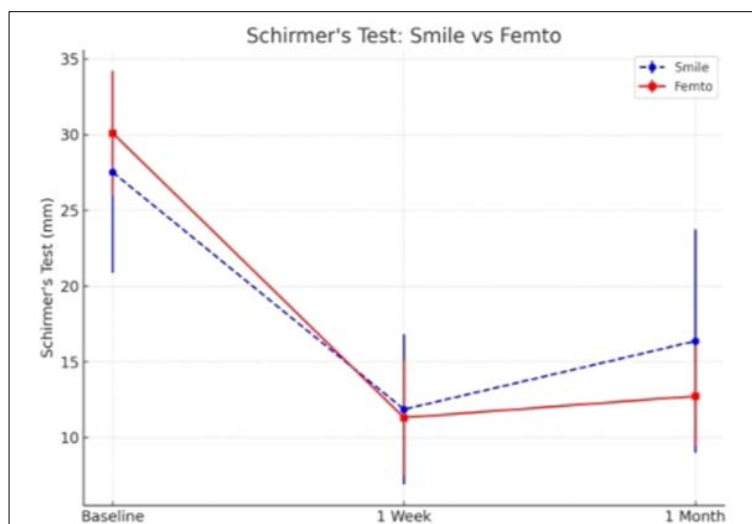
Baseline mean± SD	1 week mean	P-value (baselinevs1 week)	1month mean	P- value
0.82±0.35	0.72±0.21	0.337	0.96±0.11	0.048
2.06±0.07	2.03±0.13	0.013	2.07±0.07	0.358
27.52±6.66	11.85±4.97	<0.001	16.36±7.37	<0.001
12.55±1.64	9.35±2.19	<0.001	8.87±2.38	<0.001
1.00±NA	1.00±NA	Nan	0.99±0.06	0.051
2.06±0.08	2.04±0.09	0.103	2.08±0.05	0.011
30.10±4.11	11.30±3.80	<0.001	12.73±3.31	<0.001
12.67 ±1.73	7.45±2.02	<0.001	8.87±2.38	<0.001

**Graph 1** Visual Acuity

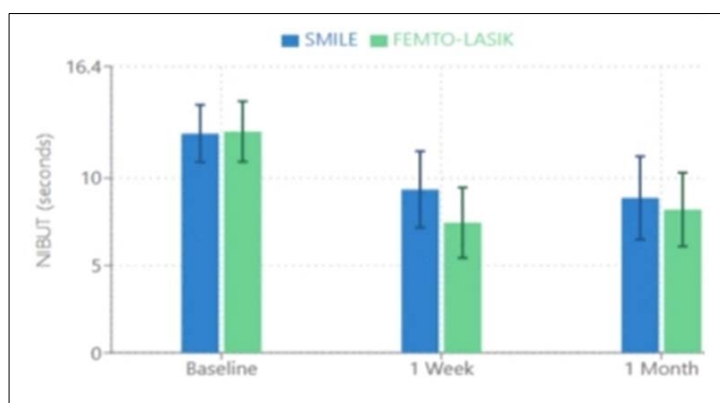
Smile showed a steady improvement from Baseline (0.92) to 1 Month (0.96). Femto showed slightly higher VA at all time points but without significant difference.

**Graph 2:** Contrast Sensitivity

Smile and femto maintained high contrast sensitivity postoperatively. No statistically significant differences at any time point.

**Graph 3:** Schirmer's Test-1

Smile group maintained better tear production (higher Schirmer values) at 1 Month. Statistically significant at both Baseline and 1 Month ( $p < 0.05$ ).

**Graph 4:** Nibut Test

Comparable baseline values between both procedures. Significantly better tear film stability in SMILE vs. FEMTO at 1-week post-surgery ( $p < 0.001$ ). SMILE maintains slightly better NIBUT values at 1 month. Both SMILE and Femto-LASIK surgeries produced excellent visual and refractive outcomes. However, Smile patients demonstrated significantly better tear production, suggesting a lower risk of dry eye symptoms. Cornea. Other parameters like visual acuity, contrast sensitivity, were comparable between groups. Visual Acuity: Significant improvement for SMILE at 1 month ( $p = 0.048$ ). Contrast Sensitivity: Minor significant drop for SMILE at 1 week ( $p = 0.013$ ); Femto improved at 1 month ( $p = 0.011$ ). Schirmer's Test: Significant decrease (dry eye symptoms) in both groups at 1 week and still significant at 1 month ( $p < 0.001$ ). NIBUT test: Significantly better tear film stability in SMILE vs. FEMTO at 1-week post-surgery ( $p < 0.001$ ). SMILE maintains slightly better NIBUT values at 1 month.

### Discussion

This prospective comparative study assessed outcomes such as visual acuity, contrast sensitivity, and tear film stability in myopic patients who underwent SMILE and Femto-LASIK procedures, with evaluations conducted at one week and one-month post-surgery. Findings indicate that both surgical methods result in notable enhancements in uncorrected

distance visual acuity and contrast sensitivity. However, SMILE demonstrated a modest advantage in maintaining tear film stability over Femto-LASIK. At the one-month follow-up, contrast sensitivity in the SMILE cohort remained slightly elevated compared to the Femto LASIK group. This observation aligns with previous research by Shri Ganesh *et al.* and Joshi Shivani *et al.*, who noted reduced postoperative dry eye symptoms [7-8], enhanced visual quality, and greater patient satisfaction following SMILE procedures [7]. "The Schirmer I and Non-Invasive Break-Up Time (NIBUT) test results also demonstrated a clear advantage in favor of the SMILE procedure, showing significantly higher tear production levels in the postoperative period. This suggests a comparatively lesser impact on corneal innervation when compared to other refractive surgeries. This favorable outcome can likely be attributed to the minimally invasive nature of the lenticule extraction technique employed in SMILE, which strategically avoids large corneal flaps and instead preserves a greater portion of the sub basal nerve plexus. As a result, SMILE appears to contribute to a reduced incidence and severity of postoperative dry eye symptoms by maintaining more of the eye's natural neural architecture and supporting a healthier ocular surface environment [11]. These findings carry significant clinical value for refractive surgeons in guiding patient decisions. Although both procedures deliver

outstanding visual outcomes, SMILE present advantages in terms of postoperative comfort—especially for individuals with pre-existing dry eye conditions or naturally thinner corneas. This suggests that SMILE could be a more suitable option for patients prioritizing ocular surface stability and long-term comfort. One of the notable strengths of this study is the uniform application of assessment techniques and the structured comparative approach implemented across various time intervals. However, the research is constrained by certain limitations, including a comparatively modest participant pool and a limited follow-up period. Additionally, the study did not incorporate subjective, patient-reported indicators such as perceived visual quality and overall satisfaction, which represent important aspects for future exploration.

## Conclusion

“While both SMILE and FEMTO-LASIK effectively correct low to moderate myopia, SMILE offers improved contrast sensitivity, & greater tear film stability, leading to enhanced comfort and visual quality. Therefore, SMILE is a better option in surgical techniques.”

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