

## Comparative Study of Visual Outcome between Femtosecond Lasik with Excimer Laser and All Femtosecond Relex Small Incision Lenticule Extraction (Smile)

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### Abstract

**Purpose:** To compare visual outcome between Femtosecond LASIK and ReLex SMILE in treatment of Myopia.

**Method:** A single center prospective randomized clinical study in which patients with Myopia +/- astigmatism were allocated to FemtoLASIK or SMILE group with 50 patients in each group. Main outcome measures were Visual acuity, safety and efficacy index; Contrast sensitivity; Aberrations; post-operative glare, patient satisfaction (quality of vision) and dry eye. Follow up visits were at day 1, day 15 and 3 months.

**Results:** Post operative visual acuity in SMILE group was significantly better ( $p = 0.033$ ) than FemtoLASIK group. The safety and efficacy index were similar in both groups. Contrast sensitivity showed more significant reduction ( $p < 0.001$ ) in FemtoLASIK group. There were more induced aberrations post FemtoLASIK ( $p = 0.004$ ) than post SMILE. Corneal topography showed more corneal flattening ( $p = 0.044$ ) post FemtoLASIK as compared to SMILE. There was lower incidence of dry eyes in SMILE group compared to FemtoLASIK group with  $p$  value  $< 0.001$ . 12% SMILE patients and 64% FemtoLASIK patients had mild glare post operatively and majority patients had good quality of vision in both groups.

**Conclusion:** In conclusion the visual outcome and patient comfort was better in SMILE group compared to FemtoLASIK group.

**Keywords:** Femtosecond Laser Assisted In Situ Keratomileusis (FSLASIK); Myopia; Refractive Lenticule Extraction (ReLex); Small incision lenticule extraction (SMILE)

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### I. Introduction

Femtosecond laser is the most recent development in refractive surgery. In Femtosecond assisted LASIK the flap is created using femtosecond laser and is more predictable; safer and relatively aberration neutral flaps than microkeratomes. But it requires two lasers to complete the procedure, namely, the femtosecond laser to make the flap and the excimer laser to perform the laser ablation of the stromal bed.<sup>(1)</sup>

Recently, a new corneal refractive procedure, refractive lenticule extraction to correct myopia, has emerged. Femtosecond laser is used to carve out a lenticule within the corneal stroma, the lenticule can then be extracted from within the corneal stroma, either by creating and lifting a hinged flap similar to LASIK or by extricating it using a small incision in the cornea. These techniques of femtosecond lenticule extraction are known as femtosecond lenticule extraction (FLEX) and small-incision lenticule extraction (SMILE), respectively. It is believed that SMILE is likely to provide better corneal biomechanical stability postoperatively. Both techniques represent all-in-one femtosecond laser refractive surgery because they represent novel integrated surgical techniques to perform corneal laser surgery in a single step and need only one laser to perform laser refractive surgery and have various clinical, practical, and economic advantages over the more traditional two-laser solution<sup>(2)</sup>

Studies have shown that the biomechanical stability and strength of cornea after SMILE is better than FSLASIK moreover SMILE being a flapless procedure the flap related complications are also eliminated.<sup>(3)</sup>

This study was conducted to evaluate and compare the visual and refractive outcome between SMILE and FSLASIK in terms of visual acuity, safety and efficacy index, aberrations, contrast sensitivity, dry eyes and patient satisfaction.

### II. Patients And Methods:

This Prospective Clinical study was performed at Nethradhama Superspeciality Eye Hospital, Bangalore from December 2012 to June 2014. The study was approved by the local ethics committee and performed with informed consent from all patients in accordance with the tenets of the Declaration of Helsinki. Patients were randomly allocated to FSLASIK and SMILE group.

### **2.1.1 Inclusion criteria:**

Single Surgeon, Myopia Between 1D To 10D Spherical Equivalent/Amount Of Astigmatism Less Than 5D, Age Above 21 Years And Less Than 40 Years, Stable Refraction For At least 6 months- 1 Year, Soft Contact Lens Discontinued For Minimum 1 Week And Rigid Gas Permeable Contact Lens Discontinued For Minimum 3 Weeks, Corneal Topography-Minimum Corneal Thickness 480 $\mu$  and Residual Corneal Thickness At least 250 $\mu$ /50% Of Original Thickness (Whichever Is Higher).

### **2.1.2 Exclusion Criteria:**

Evidence of ocular diseases like meibomian gland diseases, herpetic keratitis, uveitis, glaucoma, visually significant cataract, retinal diseases like retinal dystrophies or diabetic retinopathy, Progressive/unstable myopia and/or astigmatism, Any pathologies of cornea like corneal dystrophies including Keratoconus, any h/o corneal trauma or surgery within optical zone, Dry eye status- Schirmer's 2 test value less than 10 mm, Ocular medication like  $\beta$  blockers, Taking any systemic medication likely to affect wound healing like corticosteroids or antimetabolites, H/o immunocompromised state or pregnancy or nursing mothers.

Patient underwent thorough eye examination including Uncorrected distance visual acuity (UCVA), Corrected distance visual acuity (CDVA), manifest and cycloplegic refractions, IOP, Slitlamp microscopy, and dilated indirect Fundoscopy. The preoperative Keratometry and anterior and posterior corneal elevation were measured (Orbscan; Bausch & Lomb, Rochester, NY, and Pentacam; Oculus Optikgeräte GmbH, Wetzlar, Germany), Functional acuity contrast test (FACT chart), Schirmer's 1 and 2 tests, Tear break-up time (TBUT), and Aberrometry (iTrace; Tracey Technologies, Houston, TX).

Patients were given a Questionnaire on 1<sup>st</sup> postoperative day for assessment of pain, pricking sensation, watering and redness & on 15<sup>th</sup> postoperative day and at 3 months for assessment of glare and satisfaction in terms of quality of vision. Pain was assessed with Wong Baker Faces Pain rating scale (0-5), patient satisfaction was graded from 1 (excellent) to 4 (poor) and glare from 1 (no difficulty) to 5 (severe difficulty). {proforma attached}

## **III. Surgical Technique:**

All surgeries were performed by a single experienced surgeon.

The desired refractive change was entered directly into the laser machine. A VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany) was used for ReLEx treatments and FS-LASIK flaps. In FS-LASIK subsequent photoablation was done using excimer laser (SCHWIND AMARIS; SCHWIND eye-tech-solutions, Kleinostheim, Germany).

### **3.1 FS-LASIK:**

Docking was done and flap was created using femtosecond laser with parameter- Optical zone-6.3 mm, 90  $\mu$ m flap thickness, 8.5- to 8.8-mm flap diameter, 90° hinge position, 0.85- $\mu$ J bed energy, 1.0- $\mu$ J side-cut energy, and 6- $\mu$ m spot and track distance. After flap creation patient was shifted to excimer laser and stromal bed ablation was done depending on correction desired following which flap was repositioned and interface was dried.

### **3.2 SMILE:**

Docking was done with curved contact glass with the patient fixating on the blinking light, the femtosecond laser was used to cut first the posterior surface of the lenticule, followed by the side cut of the lenticule, then the anterior surface of the lenticule and finally, the side-cut incision of 2mm at 12 o'clock. Incision was opened and lenticule separated with thin blunt spatula and then extracted using forcep from the 2 mm incision. The corneal interface was then flushed with balanced salt solution; surface was dried.

Parameters used were- optical zone 6.5 mm, cap diameter 7.5 mm, cap thickness 100  $\mu$ , spot distance and tracking spacing 4.5- $\mu$ m, 35 to 37 (130 nJ) energy cut index. The lenticule thickness was variable depending on refractive error.

Post operatively patients were given steroids, antibiotic and lubricating eye drops for 1 month.

Follow up visits were at Day 1, Day 15 and 3 months post operatively. UCVA, subjective assessment of pain, pricking sensation, redness and watering was done at day 1. UCVA, CDVA, refraction, IOP, Corneal topography, Schirmer's 1 and 2 tests, TBUT, and FACT for contrast sensitivity were tested and subjective assessment of quality of vision and glare was done at day 15 and at 3 months and wavefront Aberrometry measurement (iTrace) was taken at 3 months.

#### **IV. Statistical Methods:**

Data analysis was done using Statistical software SAS 9.2, SPSS 15.0 for windows. A paired t test and Mann Whitney U test was used to test the significance of difference between quantitative variables and Chi-square test for qualitative variables. A P value of less than 0.05 denoted a significant relationship.

#### **V. Result:**

One hundred eyes of 50 patients underwent laser refractive surgery for correction of myopia, myopic astigmatism, or both. There were 50 eyes (25 patients) in the SMILE group and 50 eyes (25 patients) in the FSLASIK group. All patients were in the age group 20-40 years with a mean age of  $25.96 \pm 3.51$  in SMILE group and  $26.38 \pm 3.69$  in FSLASIK group. 19 patients were male (38%) and 31 were female (62%). The preoperative parameters were well matched between the two groups (**Table 1**)

##### **5.1 Refraction:**

The preoperative mean spherical equivalent in SMILE group was  $-4.15 \pm 1.53$  D (range: -1.0 to -7.00 D;  $P = .258$ ) and  $-3.80 \pm 1.57$  D (range: -1.0 to -7.00 D;  $P = .258$ ) in FSLASIK group. The postoperative mean spherical equivalent was  $-0.04 \pm 0.09$  D (range: -0.12 to -0.50 D) and  $-0.10 \pm 0.16$  D (range: -0.12 to -0.50 D) in the SMILE and FSLASIK groups, respectively ( $P = .024$ ). (**Figure 1 and 2**)

##### **5.2 Visual acuity:**

At day 1 postoperatively, 46 (92%) eyes in the SMILE group and 42 (84%) eyes in the FSLASIK group achieved a UCVA of 20/20; 4 (8%) eyes in the SMILE group and 8 (16%) eyes in the FSLASIK group achieved a UCVA of 20/25. At 3 months postoperatively, 48 (96%) eyes in SMILE group and 46 (92%) eyes in FSLASIK group achieved a UCVA of 20/20 (**Figure 3 and 4**), there was no loss of CDVA in any eye. Distribution of Preoperative UCVA was statistically similar in the two groups ( $p=0.668$ ). Both groups showed similar improvement in UCVA at postoperative day 1 and day 15 but at the end of 3 months the UCVA of SMILE group was better than FSLASIK group ( $p$  value of 0.033).

Safety and efficacy index in SMILE group was  $1.124 \pm 0.18$  and  $1.120 \pm 0.18$  respectively and in FSLASIK group it was  $1.000 \pm 0.12$  and  $1.070 \pm 0.12$  respectively. (**Figure 5**)

##### **5.3 Contrast Sensitivity:**

Contrast sensitivity reduced postoperatively in both groups at all spatial frequencies. By 3 months postoperatively, contrast sensitivity in the SMILE group was relatively better than the FSLASIK group at all spatial frequencies ( $p < 0.001$ ) (**Figure 6 and 7**)

##### **5.4 Corneal Topography:**

The mean mesopic pupil size was  $4.11 \pm 0.73$  mm in SMILE group and  $4.34 \pm 1.03$  mm in FSLASIK group. The preoperative CCT and Keratometric values were comparable between the two groups. There was a significant reduction in CCT after both the procedures at 15 and 90 days ( $p < 0.001$ ) and the difference between both the groups was not statistically significant.

There was significant reduction in Mean K values after both the procedures ( $p < 0.001$ ) due to corneal flattening. The reduction was more in FSLASIK group compared to SMILE group ( $p = 0.044$ ) at POD 90. (**Figure 8**)

##### **5.5 Wavefront Aberrometry:**

HOAs at the 5.0-mm analysis diameter increased in both groups postoperatively. The induced HOAs were significantly lower in the SMILE group than the FSLASIK group ( $p = 0.004$ ). (**Figure 9**)

##### **5.6 Tear Film Abnormalities:**

A reduction in Schirmer's 1 and 2 test values and TBUT was seen in both groups postoperatively. In SMILE group TBUT improved at 3 months post operatively compared to POD 15. Overall these postoperative values were significantly lower in the FSLASIK group than in the SMILE group ( $P < .001$ ). (**Figure 10**)

##### **5.7 Patient Questionnaire:**

18% FSLASIK patients complained of pricking sensation, no patient complained of redness, pain or watering in either group.

At 3 months post operatively 12% SMILE patients had glare and 60% FSLASIK patients had glare. The complaint was more persistent in FSLASIK group compared to SMILE group ( $p < 0.001$ .)

Majority patients in both the groups had good Quality Of Vision (QOV); with 24% eyes in SMILE group and 4% eyes in FSLASIK group having excellent QOV ( $p < 0.001$ ).

There were no complications following both the procedures.

## VI. Discussion

ReLEx SMILE and FemtoLASIK have good safety and efficacy for correction of myopia with or without astigmatism. The patients obtain a good visual outcome and quality of vision post procedure.

In a comparative study by **Hu et al.**<sup>(4)</sup> - 48 (out of 83) eyes in the SMILE group and 37(out of 94) eyes in the LASIK group showed a gain of one line. No patient in the SMILE group showed a loss of BCVA, whereas 1 eye in the LASIK group had a loss of BCVA by one line. **Vestergaard et al.**<sup>(5)</sup> showed that 95% of patients attained a UCVA of 20/40 or better 3 months following SMILE, whereas 2 eyes showed a gain of two lines of BCVA at 3 months. Similar results were found in a study by **Hjortdal et al.**<sup>(6)</sup> in which 97.2% of patients achieved a UCVA of 20/40 or better at 3 months following SMILE. **Vestergaard et al.**<sup>(7)</sup> in another study found that CDVA was better than 20/20 in 85% of eyes in the SMILE group and in 83% of eyes in the LASIK group postoperatively. However in another comparative study between SMILE and FS-LASIK, **Lin et al.**<sup>(8)</sup> found no significant difference between eyes attaining a UCVA of 20/20 in the two groups.

In our study, no eye had a loss of CDVA. Ninety-six percent of eyes in the SMILE group achieved a UCVA of 20/20, whereas 92% in the FSLASIK group achieved this benchmark at 3 months postoperatively ( $p=0.033$ ). Furthermore, the safety and predictability, as indicated by the gain in CDVA and postoperative residual error (spherical equivalent), was significantly better in the SMILE group than in the LASIK group ( $p=0.024$ ).

This can be explained by relatively less induction of higher order aberrations (HOAs) following SMILE than FSLASIK giving rise to a better visual outcome.

According to **Lin et al.**<sup>(8)</sup> the Higher-order aberrations and spherical aberration were found to be significantly lower in the SMILE group than the FS-LASIK group at 1 ( $P = .007$ ) and 3 ( $P = .006$ ) months of follow-up.

**Hjortdal et al.**<sup>(6)</sup> found that for a 6.0-mm pupil, corneal spherical aberrations increased significantly less in ReLEx than FS-LASIK eyes. A study done by **Gertnere et al.**<sup>(9)</sup> showed the induction of total HOA was significantly less for ReLEx than for LASIK ( $p=0.0023$ ; ReLEx: the RMS value increased from 0.15 to 0.275  $\mu\text{m}$ ; LASIK: the RMS value increased from 0.175 to 0.367  $\mu\text{m}$ ). **Shah et al.**<sup>(10)</sup> in their study on SMILE procedure found statistically significant ( $P<0.01$ ) increase in the root mean square (RMS) higher-order aberrations (HOAs) from preoperatively to 6 months postoperatively. **Sekundo et al.**<sup>(11)</sup> in their study on SMILE procedure found increase in the high-order aberrations (HOA) from 0.17 to 0.27  $\mu\text{m}$  postoperatively.

In our study- HOAs increased after both the procedures. However; the induction of HOA in SMILE group ( $0.23\pm 0.08$ - preoperative and  $0.26\pm 0.13$ - 3 months postoperatively) was less than FSLASIK group ( $0.21\pm 0.07$  and  $0.28\pm 0.14$ - preoperative and at 3 months postoperatively respectively).

Reason for less induced aberrations after ReLEx SMILE has to do with the elimination of flap creation. With ReLEx SMILE, there is only a small vertical cut and therefore minimal collapse or stromal damage while in LASIK the creation of flap causes irregularity and difference at the interface causing more aberrations. In SMILE the patient fixates on a light so the treatment zone correlates with visual axis and centration achieved is better than the LASIK which may also attribute to less induced aberrations.<sup>(16)</sup>

Also the wider transition zone in LASIK due to unequal laser delivery in centre and periphery of the prolate shaped cornea causes more induced HOAs.

In the current study, contrast sensitivity showed a decrease after both the procedures. Overall decrease was less in SMILE group compared to FSLASIK ( $p=0.001$ ). In another comparative study between SMILE and FS-LASIK, **Gertnere et al.**<sup>(9)</sup> found better mesopic contrast sensitivity in the ReLEx group than in the LASIK group. A study on SMILE procedure by **Sekundo et al.**<sup>(11)</sup> found no significant decrease in mesopic contrast postoperatively, and **Montés-Micó et al.**<sup>(12)</sup> found a statistically significant reduction ( $P < .01$ ) in contrast sensitivity at high spatial frequencies (12 and 18 cycles/degree) under mesopic conditions following LASIK. More HOAs induced following LASIK may be the reason for lower contrast sensitivity.

A comparative study by **Riau et al.**<sup>(13)</sup> showed a more significant corneal flattening after LASIK than after ReLEx as the degree of correction was increased ( $p = 0.916$  after -3.00D correction to  $p = 0.097$  after -9.00D correction). Our study also showed corneal flattening and decrease in thickness after both the procedures. The flattening caused in FSLASIK group ( $40.58\pm 1.80$ ) at 3 months postoperatively was more than SMILE group ( $41.32\pm 2.09$ ) compared to preoperative value of  $43.79\pm 1.40$  and  $44.01\pm 1.57$  respectively and this difference was statistically significant  $p=0.044$ .

The reason for this could be more ablation in centre and less in periphery due to unequal laser delivery in LASIK, because of normal prolate shape of cornea causing more corneal flattening while in SMILE the lenticule created is curved in accordance with curved contour of cornea leading to less flattening.

**Xu et al**<sup>(14)</sup> in a comparative study for dry eyes between SMILE and LASIK found that the SMILE procedure had better dry eye parameters and relatively fewer subjective symptoms than LASIK, also in both the groups the tear break-up time decreased significantly after surgery. **Li et al**<sup>(15)</sup> found that SMILE surgeries resulted in only a short-term increase in dry eye symptoms, tear film instability, and loss of corneal sensitivity compared to Femto-LASIK. Furthermore, SMILE surgeries have superiority over femto-LASIK in lower risk of postoperative corneal staining and less reduction of corneal sensation.

Our study demonstrated a significantly lower incidence of dry eyes in the SMILE group compared with the FSLASIK group. The TBUT decreased in SMILE group at POD 15 (preoperative value: 12.02±1.15 sec; value at POD 15: 10.80±0.95 sec) but stabilized at 3 months post operatively (11.58±0.99 sec) while in FSLASIK group it showed a significant reduction ( $p < 0.001$ ) than preoperative values (preoperative value: 12.42±1.44; at POD 15: 5.88±1.22; at POD 90: 8.86±1.53 sec)

The reason for this could be that during LASIK, sub-basal and superficial stromal nerve bundles get cut during flap creation and subsequent excimer ablation further severs stromal nerve fiber bundles, leading to decreased corneal sensations and increased dry eye symptoms.<sup>(15)</sup> In SMILE (a flapless procedure), the anterior stromal nerve plexus is disrupted significantly less than in FS-LASIK, resulting in fewer dry eye symptoms postoperatively. Moreover; there is a small 2mm incision located superiorly which preserves the nasal and temporal nerve arcades. The reason for dip in TBUT values post SMILE at 15 days could be due to corneal curvature changes which stabilises by 3<sup>rd</sup> month.

In study done by **Shah R et al**<sup>(10)</sup> an adverse event questionnaire was provided to all the study participants 3 months after ReLEx SMILE procedure. They found that a small percentage of patients complained of increased glare (13.9 %), mild pain (2.8%) 3 months after the procedure. But none of the patients complained of excessive tearing 3 months post procedure.

In our study, at 3 months post operatively 12% SMILE patients had mild glare and 60% FSLASIK patients had glare. This can be explained with relatively larger mesopic pupil size (4.34±1.03 mm) and smaller optical zone (6.3mm) in FSLASIK group compared to smaller mesopic pupil size (4.11±0.73 mm) and relatively larger optical zone (6.5mm) in SMILE treated eyes because of which LASIK patients had more glare compared to SMILE. The wider transition zone in LASIK due to unequal laser delivery in center and periphery may also contribute to increased glare.

## VII. Conclusion:

In conclusion both the procedures ReLEx SMILE and FemtoLASIK are very efficient procedures for correction of myopia with or without astigmatism. SMILE is evolving as a new procedure eliminating the side effects of LASIK (reduced corneal biomechanical strength, increased postoperative HOAs, low contrast sensitivity, and dry eyes). So being painless; flapless procedure with high refractive accuracy and predictability and faster recovery with good patient comfort SMILE has an edge over LASIK as a refractive procedure to correct myopia and myopic astigmatism.

## References

- [1]. LuciKaweri MD, RitikaSachdev MS, MahipalSachdev MD. ReLEx SMILE-Smiling All the Way. Times. 2014 Jan;19(7):19–23.
- [2]. Dong Z, Zhou X, Wu J, Zhang Z, Li T, Zhou Z, et al. Small incision lenticule extraction (SMILE) and femtosecond laser LASIK: comparison of corneal wound healing and inflammation. Br J Ophthalmol. 2013 Nov 13;bjophthalmol-2013-303415.
- [3]. Di Wu, PhD, Yan Wang, MD, PhD, Lin Zhang, MD, et al. Corneal biomechanical effects: Small-incision lenticule extraction versus femtosecond laser-assisted laser in situ Keratomileusis. J Cataract Refract Surg 2014; 40:954–962.
- [4]. Hu Y-K, Li W-J, Gao X-W, et al. Comparison of small incision lenticule extraction and femtosecond laser assisted LASIK for myopia. Int Eye Sci. 2013;13:2074-2077. - Google Search [Internet]. [cited 2014 Oct 17]. Available from: <https://www.google.co.in/search?q=Hu+Y-K%2C+Li+W-J%2C+Gao+X-W%2C+et+al.+Comparison+of+small+incision+lenticule+extraction+and+femtosecond+laser+assisted+LASIK+for+myopia.+Int+Eye+Sci.+2013%3B13%3A2074-2077>.
- [5]. Vestergaard A, Ivarsen AR, Asp S, Hjortdal JØ. Small-incision lenticule extraction for moderate to high myopia: Predictability, safety, and patient satisfaction. J Cataract Refract Surg. 2012 Nov;38(11):2003–10.
- [6]. Hjortdal JØ, Vestergaard AH, Ivarsen A, Ragnathan S, Asp S. Predictors for the Outcome of Small-incision Lenticule Extraction for Myopia. J Refract Surg. 2012 Dec 1;28(12):865–71.
- [7]. Vestergaard A, Ivarsen A, Asp S, Hjortdal JØ. Femtosecond laser vision correction procedure for moderate to high myopia: a prospective study of ReLEx FLEX and comparison with a retrospective study of FS-laser in situ keratomileusis. Acta Ophthalmol. 2013;91:355-362.
- [8]. Lin F, Xu Y, Yang Y. Comparison of the Visual Results After SMILE and Femtosecond Laser-Assisted LASIK for Myopia. J Refract Surg. 2014 Apr 1;30(4):248–54.
- [9]. Gertner J, Solomatin I, Sekundo W. Refractive lenticule extraction (ReLEx flex) and wavefront-optimized Femto-LASIK: comparison of contrast sensitivity and high-order aberrations at 1 year. Graefes Arch ClinExpOphthalmol. 2013 May 1;251(5):1437–42.
- [10]. Shah R, Shah S, Sengupta S. Results of small incision lenticule extraction: All-in-one femtosecond laser refractive surgery. J Cataract Refract Surg. 2011 Jan;37(1):127–37.
- [11]. Sekundo W, Gertner J, Bertelmann T, Solomatin I. One-year refractive results, contrast sensitivity, high-order aberrations and complications after myopic small-incision lenticule extraction (ReLEx SMILE). Graefes Arch ClinExpOphthalmol Albrecht Von Graefes Arch FürKlinExpOphthalmol. 2014 May;252(5):837–43.

- [12]. Montés-Micó R, España E, Menezo JL. Mesopic contrast sensitivity function after laser in situ keratomileusis. J Refract SurgThorofare NJ 1995. 2003 Jun;19(3):353–6.
- [13]. Riau AK, Angunawela RI, Chaurasia SS, Lee WS, Tan DT, Mehta JS. Early Corneal Wound Healing and Inflammatory Responses after Refractive Lenticule Extraction (ReLEx). Invest Ophthalmol Vis Sci. 2011 Aug 5;52(9):6213–21.
- [14]. Xu Y, Yang Y. Dry Eye After Small Incision Lenticule Extraction and LASIK for Myopia. J Refract Surg. 2014 Mar 1;30(3):186–90.
- [15]. Li M, Zhao J, Shen Y, Li T, He L, Xu H, et al. Comparison of dry eye and corneal sensitivity between small incision lenticule extraction and femtosecond LASIK for myopia. PloS One. 2013;8(10):e77797.
- [16]. Lazaridis A, Droustas K, Sekundo W. Topographic analysis of the centration of the treatment zone after SMILE for myopia and comparison to FS-LASIK: subjective versus objective alignment. J Refract SurgThorofare NJ 1995. 2014 Oct;30(10):680–6.

Table 1

Variable	SMILE (n=50)	FS-LASIK (n=50)	p
Sphere (D)	-3.63±1.57 (range: -0.25 to -5.5)	-3.15 ±1.84 (range: -0.25 to -6.25)	.0163
Cylinder (D)	-1.05 ± 1.07 (range: -0.25 to -4.0)	-1.30 ± 1.31 (range: -0.25 to -5.0)	.287
Spherical equivalent (D)	-4.15 ± 1.53 (range: -1.0 to -7.0)	-3.80 ± 1.57 (range: -1.0 to -7.0)	.258
RMS HOA total (µm)	0.23 ± 0.08 (range: 0.112 to 0.424)	0.21 ± 0.07 (range: 0.112 to 0.418)	.268
Schirmer’s 1 (mm)	33.04 ± 2.29 (range: 26 to 35)	33.96 ± 1.75 (range: 28 to 35)	.262
Schirmer’s 2 (mm)	25.76± 4.25 (range: 20 to 34)	27.20 ± 2.69 (range: 21 to 34)	.046
TBUT (sec)	12.02 ± 1.15 (range: 10 to 14)	12.42 ± 1.44 (range: 10 to 15)	.129
Mean K (D)	44.01± 1.57(range: 42.2 to 46.50)	43.79 ± 1.40(range: 42.0 to 46.10)	.449
FACT (log units)			
A	1.52 ± 0.09	1.54 ± 0.06	.358
B	1.78 ± 0.10	1.80 ± 0.07	.344
C	1.84 ± 0.09	1.85 ± 0.08	.471
D	1.50 ± 0.13	1.49 ± 0.03	.522
E	1.19 ± 0.19	1.19 ± 0.07	.944

SMILE = small-incision lenticule extraction; D = diopters; RMS = root mean square; HOA = higher-order aberration; TBUT = tear break-up time; FACT = functional acuity contrast test

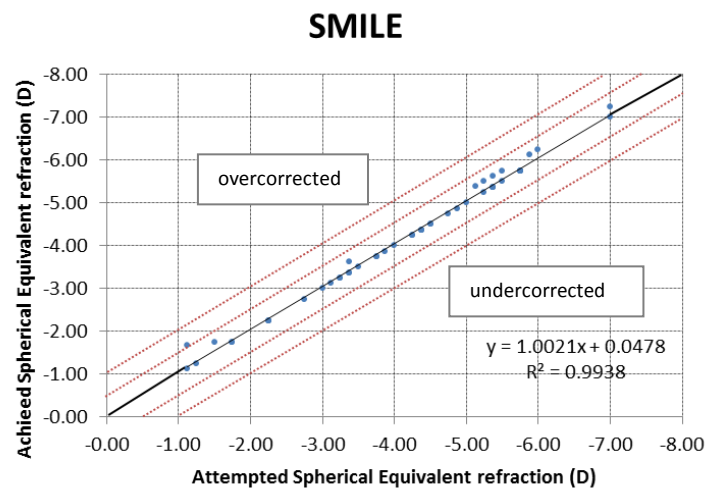


Figure 1

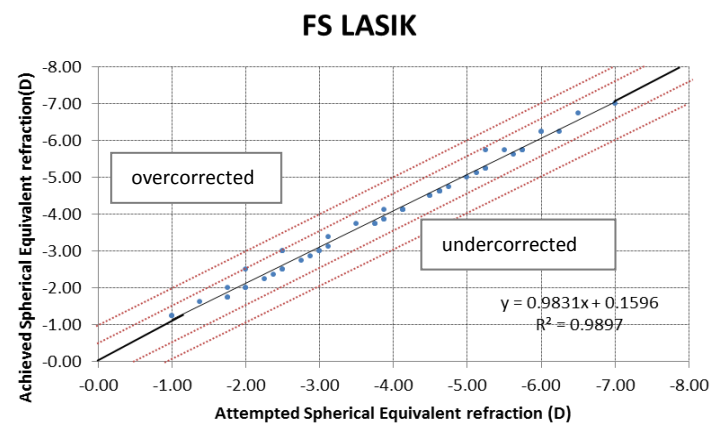


Figure 2

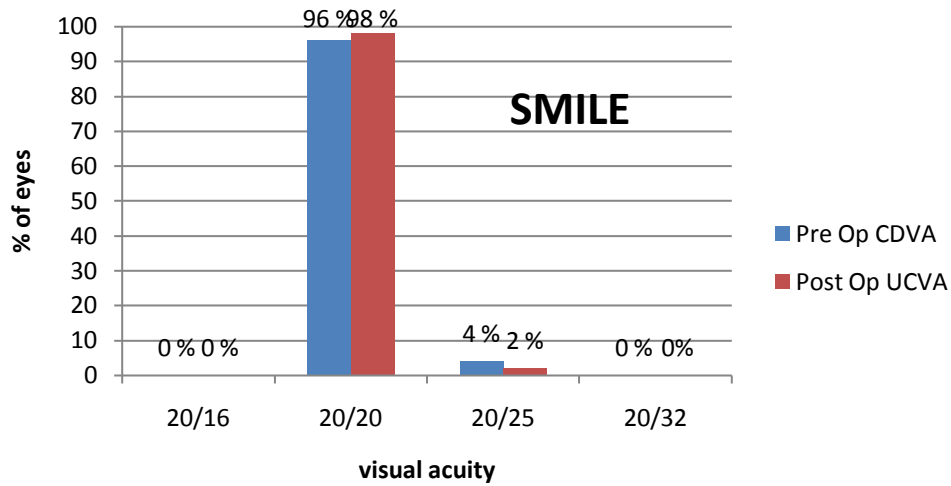


Figure 3

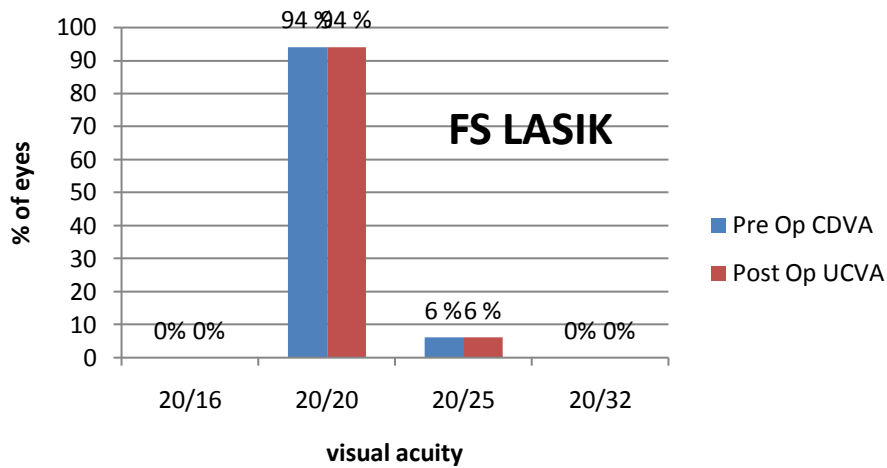


Figure 4

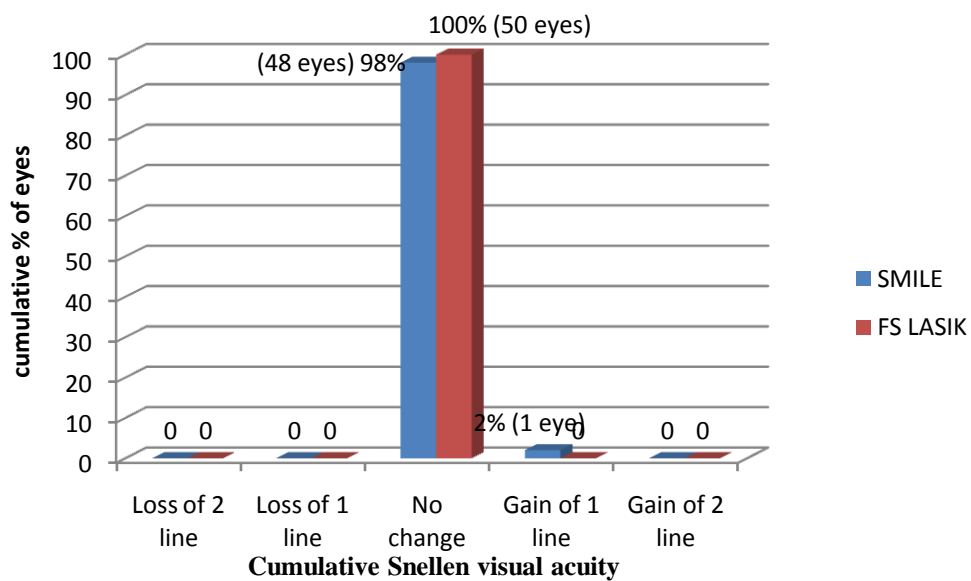


Figure 5

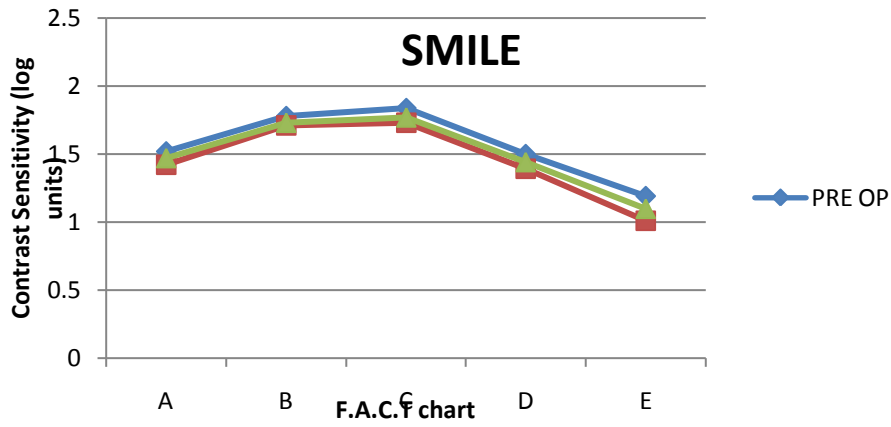


Figure 6

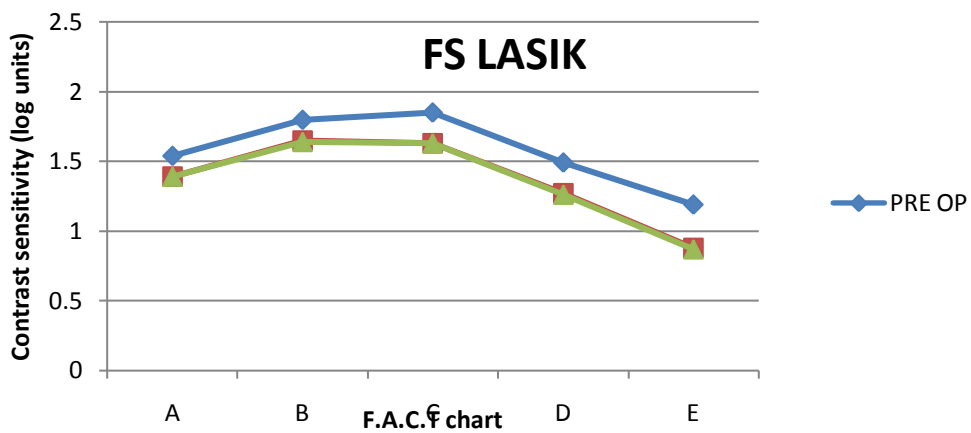


Figure 7

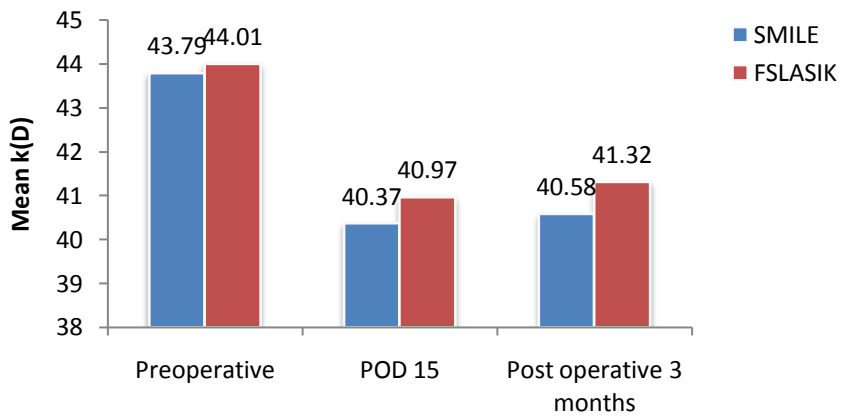


Figure 8



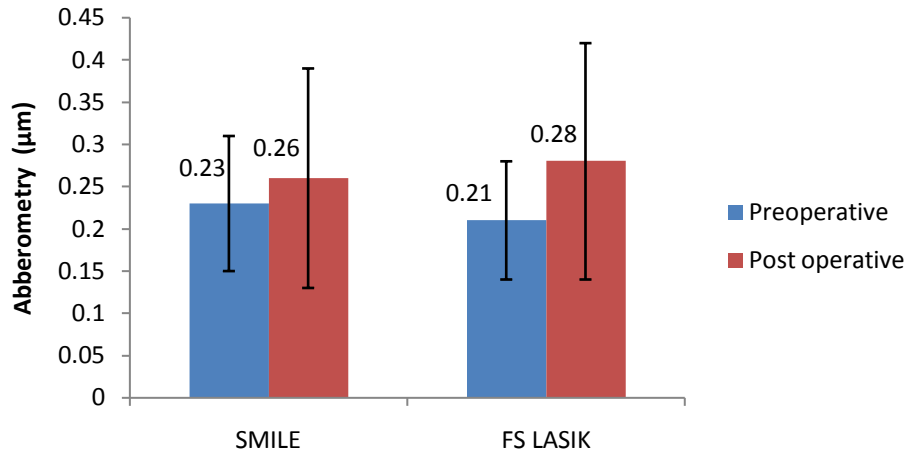


Figure 9

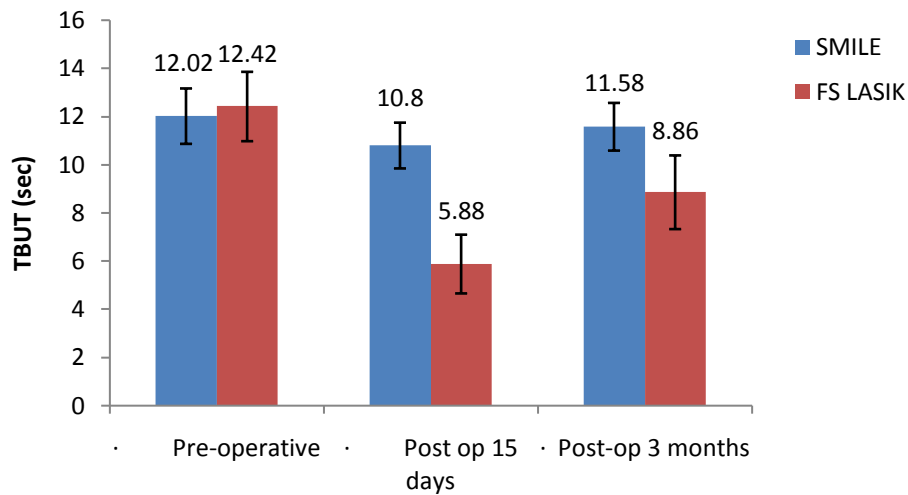


Figure 10

**Questionnaire given to the patients for subjective assessment on 1<sup>st</sup> day post-operative period.**

Patient: \_\_\_\_\_

Date: \_\_\_\_\_

Age: \_\_\_\_\_

Sex: \_\_\_\_\_

OP no.- \_\_\_\_\_

PARAMETER	RE	LE
Pain Score (FACES* pain scale)		
Pricking Sensation (Y/N)		
Watering (Y/N)		
Redness (Y/N)		

- \*FACES pain scale WITH 6 FACES GRADED 0 TO 5



**Wong-Baker Faces Pain Rating Scale**

Brief instructions: Ask the patient to choose face that best describes own pain and record the appropriate number.

From :Hockenberry MJ, Wilson D:Wong’s Essentials of Pediatric Nursing, 8<sup>th</sup> Edition. St. Louis:2009; Mosby.A7012-AS-6

**Questionnaire given to the patients for subjective assessment at 15 DAYS & 3 months of post-operative period**

Patient:

OP no.-

Age:

Sex:

	15th day		3 months	
	RE	LE	RE	LE
Patient’s satisfaction in terms of quality of vision**				
Glare***				

➤ **\*\*GRADING ACCORDING TO SATISFACTION OF PATIENT:**

- 1-EXCELLENT
- 2-GOOD
- 3-FAIR
- 4-POOR

● **\*\*\*GLARE is trouble seeing street signs due to bright light of oncoming headlights**

- **GRADING OF GLARE:**
  - 0: No difficulty
  - 1: Minimal difficulty
  - 2 and 3: Moderate difficulty
  - 4 and 5: Severe difficulty