

Comparing Femtosecond Lenticule Extraction (FLE_x) and Femtosecond Laser In-situ Keratomileusis (LASIK) for Myopia and Astigmatism

Tina Marie Saban-Roa, MD,¹ Irwin Cua, MD,^{1,2} and Ruben Lim Bon Siong, MD^{1,2,3}

¹ St. Luke's Medical Center - Quezon City
Quezon City, Philippines

² St. Luke's Medical Center - Global City
Taguig City, Philippines

³ Philippine General Hospital, University of the Philippines Manila
Taft Avenue, Manila, Philippines

Correspondence: Tina Marie Saban-Roa, MD
St. Luke's Medical Center, 279 E Rodriguez Sr. Blvd
Quezon City, 1102, Philippines
Tel. no.: +632-7275546
Email: tinsaban@gmail.com

Disclosure: No financial assistance was received for this study. The authors have no proprietary interest in any product used or cited in this study.

ABSTRACT

Objective: To compare the efficacy, safety, predictability, stability, contrast sensitivity, and higher-order aberration (HOA) of patients who had femtosecond lenticule extraction (FLE_x) and femtosecond laser in-situ keratomileusis (LASIK) for the correction of moderate myopia and astigmatism.

Method: A retrospective review of charts was conducted at the Vision Laser Center of the St. Luke's Medical Center-Global City. All patients that underwent FLE_x from November 2011 to June 2012, with adequate follow-up, were included in the study. Age-matched and refraction-matched patients, who underwent femtosecond LASIK in the same review period, were chosen as comparators. Uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BCVA), attempted refraction versus achieved refraction, contrast sensitivity, HOA, and adverse events were compared preoperatively and one-day, one-week, one-month, and three-month postoperatively in both groups.

Results: Twenty-six eyes of 13 patients who underwent FLE_x and 22 eyes of 11 patients who underwent femto-LASIK were included in the study. The preoperative mean spherical equivalent were -4.61 ± 1.17 D (range -2.50 D to -6.75 D) and -5.30 ± 1.14 D (range -2.63 to -6.88) for the FLE_x and the femto-LASIK groups respectively. At 1-day postoperatively, 12% and 100% achieved UCVA of 20/30 or better in the FLE_x and femto-LASIK groups respectively. At 3 months follow-up, 96% achieved UCVA of 20/32 or better in the FLE_x group and 3% lost >2 lines and 23% lost 1 line of BCVA. None in the femto-LASIK group lost any line of BCVA. Mean

spherical equivalent after 3 months was $+0.06 \pm 0.21$ D in the FLEEx and -0.44 ± 0.35 D in the femto-LASIK groups ($p < 0.001$). HOA, analyzed as root mean square (RMS), were similar preoperatively and postoperatively in both groups. Contrast sensitivity increased postoperatively in the lower spatial frequencies for both groups but were similar in the higher spatial frequencies. No adverse events were noted in either group.

Conclusion: FLEEx was comparable to femtosecond LASIK in terms of visual outcomes in the treatment of moderate myopia and astigmatism. The FLEEx group showed better accuracy and stability within the three-month follow-up period. However, delayed visual improvement and loss of BCVA were noted.

Keywords: Femtosecond lenticule extraction, femtosecond LASIK, myopia, astigmatism

Correction of myopia by corneal cutting was introduced in 1996 by Barraquer and Ruiz¹. It involved surgical removal of the corneal stroma by a microkeratome. The technique was later improved by Buratto and Pallikaris where the microkeratome was used to create a corneal flap, and then an excimer laser performed the in-situ keratomileusis (LASIK) for refractive correction on the corneal stroma. This produced a more accurate and predictable visual outcome.

Femtosecond laser is a major advancement in corneal refractive surgery. It is a near-infrared neodymium-doped yttrium aluminum garnet (Nd:YAG) laser that is based on nonlinear absorption of light and subsequent disruption of the corneal tissue.²⁻⁴ It was introduced several years ago to reduce microkeratome-related complications in conjunction with the corneal flap creation. The femtosecond laser was used to create the corneal flap, while the refractive procedure was performed using the excimer laser. This procedure is known as femtosecond laser in-situ keratomileusis or femto-LASIK.

Femto-LASIK has been the preferred laser refractive procedure worldwide since its introduction because of improved safety, reproducibility, planar flap thickness, and versatility.²⁻⁵ Its advantages over microkeratome-LASIK are better flap predictability, less flap-related complications, creation of thinner flaps allowing LASIK to be performed in thinner corneas and/or in higher refractive errors, better stromal bed quality, faster visual recovery, fewer induced higher-order aberration, better contrast sensitivity, and lesser degree of dry eye.²⁻¹¹

Since then, the use of the femtosecond laser have expanded to other ophthalmologic procedures, such as intrastromal corneal ring segment (ICRS) insertion, astigmatic keratotomies, penetrating keratoplasty, femtosecond lenticule extraction (FLEEx), and small

incision lenticule extraction (SMILE).⁵ Femtosecond lenticule extraction (FLEEx) involved using the femtosecond laser in a one-step refractive procedure.¹²⁻¹⁴ Instead of using the excimer laser for corneal stromal ablation, the femtosecond laser creates a flap and a refractive lenticule that corresponds to the patient's refractive correction. The surgeon lifts the flap, removes the lenticule, and repositions the flap. The corneal tissue is removed, not ablated. Initial studies on FLEEx demonstrated it to be a safe and effective refractive procedure.¹²⁻¹⁵

As a new procedure, there are few studies comparing FLEEx to a standard corneal refractive procedure such as femto-LASIK. Hence, we compared the efficacy, safety, predictability, stability, contrast sensitivity, and higher-order aberration of FLEEx and femtosecond-LASIK in the treatment of moderate myopia and astigmatism.

METHODOLOGY

A retrospective chart review of FLEEx and femto-LASIK procedures performed from November 2011 to June 2012 at the Vision Laser Center (VLC) of St. Luke's Medical Center-Global City (SLMC-GC) was conducted. Included were those with myopia or myopic astigmatism and a spherical equivalent of -3.00 D to -8.00 D, preoperative best spectacle-corrected visual acuity (BCVA) of 20/25 or better, target refraction of emmetropia, and at least 18 years of age. Excluded were eyes with targeted refraction for monovision or with inadequate follow-up data of less than 3 months.

All eyes underwent corneal flap creation by VisumaxTM femtosecond system (Carl Zeiss Meditec, Jena, Germany) at the same time period so that calibration and nomograms used were the same. The core refractive surgeons of St. Luke's Medical Center-Global City performed all the procedures.

Preoperative and postoperative data gathered included UCVA, BCVA, manifest refraction in spherical equivalent, contrast sensitivity, and higher-order aberration. Visual acuity and contrast sensitivity were measured using the SmartChart™ visual acuity system (OptoGlobal, South Australia, Australia) with a standard test distance for all patients. Both the Snellen fraction and the decimal value of visual acuity were obtained. Higher-order aberration was measured using the WASCA wavefront analyzer (Carl Zeiss Meditec, Jena, Germany) where the root-mean-square for higher-order aberration was obtained. All FLEX procedures and flap creation in the femto-LASIK were done using Visumax™ femtosecond system (Carl Zeiss Meditec, Jena, Germany). Laser ablation for the femto-LASIK was done using the MEL 80™ excimer laser (Carl Zeiss Meditec, Jena, Germany). Postoperative medications were the same in both groups.

RESULTS

A total of 26 eyes of 13 patients were included in the FLEX group and 22 eyes of 11 patients in the femto-LASIK group. The mean age of the FLEX group was 33.23 years (range 24-45 years), and for the femto-LASIK group 33.36 years (range 24-51 years). There were no differences in age, preoperative UCVA, and preoperative BCVA between the 2 groups. Preoperative spherical equivalent was significantly different, with higher myopia in the femto-LASIK. (Table 1).

Efficacy

The mean UCVA at 1-day follow-up was 0.43 ± 0.11 and 0.99 ± 0.12 for the FLEX and femto-LASIK

groups respectively ($p < 0.001$). UCVA at 1-week follow-up for the FLEX (0.66 ± 0.19) was still different ($p < 0.001$) from the femto-LASIK group (0.98 ± 0.09). The mean UCVA at 1-month follow-up was 0.83 ± 0.16 and 0.97 ± 0.17 , respectively ($p < 0.001$). The UCVA at 3-month follow-up was similar between the 2 groups ($p = 0.56$): 0.87 ± 0.15 for the FLEX and 0.89 ± 0.13 for the femto-LASIK (Figure 1).

UCVA of 20/40 or better was achieved in 42% and 20/32 or better in 12% of the FLEX at 1 day postoperatively. At 1 week, 84% was seeing 20/40 or better and 12% 20/20. At 1 month, 100% was 20/40 or better and 35% 20/20 or better. At 3 months, 100% was 20/40 or better and 46% 20/20 or better (Figure 2).

UCVA of 20/25 or better and 20/20 or better were achieved in 100% and 82% of the femto-LASIK at 1 day postoperatively. At 1 week, 100% was 20/25 or better and 82% 20/20. At 1 month, 100% was 20/25 or better and 65% 20/20 or better. At 3 months, 100% was 20/32 or better and 55% 20/20 or better (Figure 2).

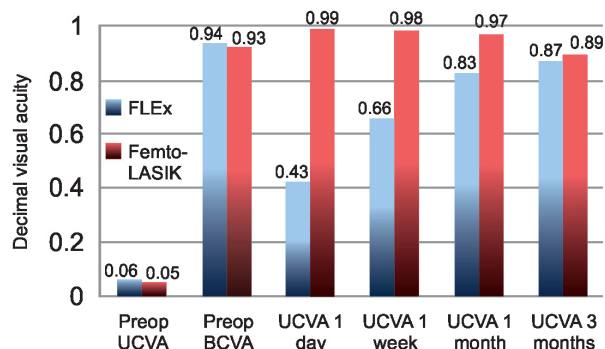


Figure 1. Mean uncorrected visual acuity (UCVA) in the FLEX and femto-LASIK groups before and after refractive surgery.

Table 1. Patient characteristics.

	FLEX group (n=26) (Mean ± SD)	Femto-LASIK (n=22) (Mean ± SD)	p value
Age (years)	33.23 ± 6.08	33.36 ± 8.12	0.96
M:F ratio	4:22	3:19	
Spherical Equivalent	-4.61 ± 1.17	-5.30 ± 1.14	0.05
UCVA	0.06 ± 0.03	0.05 ± 0.03	0.34
BCVA	0.94 ± 0.10	0.93 ± 0.10	0.69

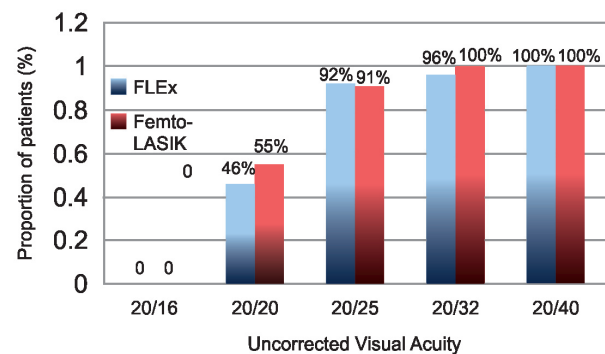


Figure 2. Uncorrected visual acuity in the FLEX and femto-LASIK groups 3 months after refractive surgery.

Safety

In the FLEEx group, 1 patient lost more than 2 lines of BCVA, 6 lost 1 line, 15 remained unchanged, and 4 gained 1 line 3 months after surgery. In the femto-LASIK group, none of the eyes lost any line; 14 remained unchanged and 8 gained 1 line of BCVA (Figure 3).

Predictability

The mean postoperative spherical equivalent was $+0.06 \pm 0.22$ and -0.44 ± 0.35 for the FLEEx and femto-LASIK groups respectively at 3 months follow-up. All eyes were within ± 1.0 D of attempted refraction (Figure 4). 100% from the FLEEx and 68% from the femto-LASIK were within ± 0.50 D of target refraction. The FLEEx group showed a tendency towards hyperopia (overcorrection) and the femto-LASIK myopia (undercorrection) (Figure 4).

Stability

The FLEEx group showed a tendency for overcorrection on the first postoperative day but the refraction stabilized after 1 week. There was no difference ($p=0.45$) in the mean spherical equivalent at 1 month (0.09 ± 0.31) and at 3 months follow-up (0.06 ± 0.22). The femto-LASIK group showed early achieved target for emmetropia and a regression to slight myopia at 1-month and 3-month follow-ups. The refraction at 1 month (-0.24 ± 0.27) and at 3 months (-0.44 ± 0.35) were significantly different ($p < 0.001$). At 3 months, 100% of the FLEEx group were within ± 0.5 of target refraction and 68% and 100% of the femto-LASIK were within ± 0.5 and ± 1.00 D of intended refraction (Figure 5).

Wavefront Analysis

The preoperative root mean square (RMS) was $0.40 \pm 0.16 \mu\text{m}$ and $0.50 \pm 0.22 \mu\text{m}$ for the FLEEx and femto-LASIK groups respectively ($p=0.08$). Pupil size at the time of examination ranged from 4-7.5 mm. There was no significant increase in RMS in the FLEEx ($p=0.49$) and femto-LASIK ($p=0.33$) groups at 3 months follow-up.

Contrast Sensitivity

There was an increase in contrast sensitivity in the low spatial frequencies for both groups after surgery (Figure 6). The FLEEx had a significant increase in the 1.5 spatial frequency ($p=0.03$) while the femto-LASIK

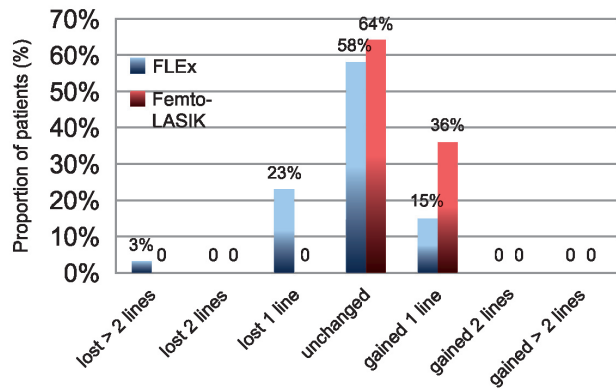


Figure 3. Change in best spectacle-corrected visual acuity in the FLEEx and femto-LASIK groups 3 months after refractive surgery.

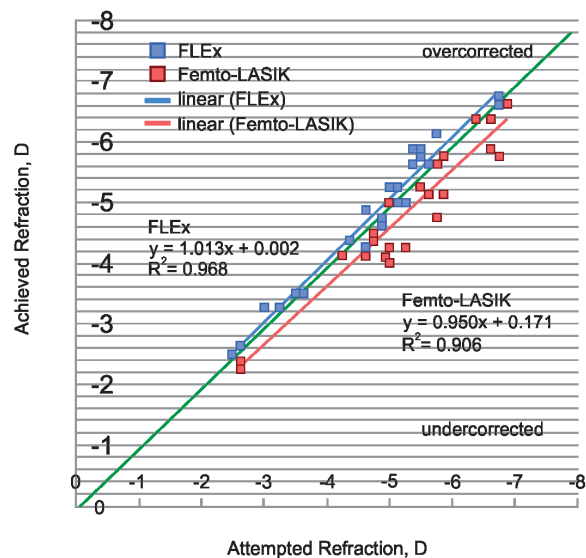


Figure 4. Attempted vs achieved refraction in the FLEEx and femto-LASIK groups at 4 months follow-up.

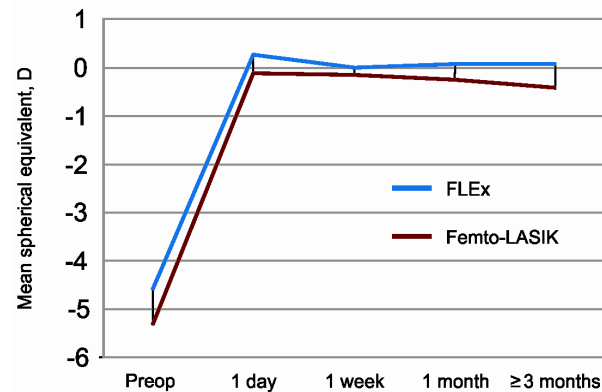


Figure 5. Mean spherical equivalent plotted as a function of time in the FLEEx and femto-LASIK groups.

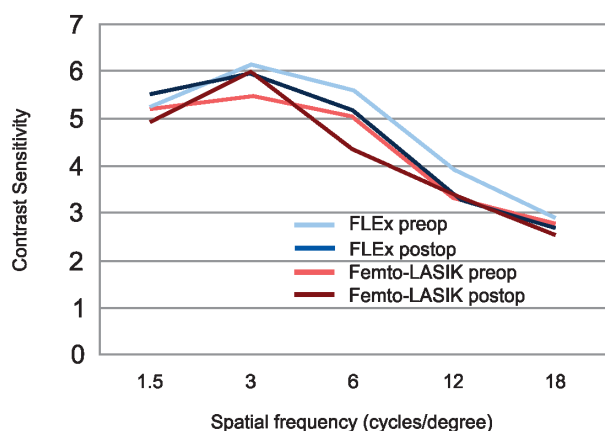


Figure 6. Contrast sensitivity before and after FLEEx and femto-LASIK.

had a significant increase in the 3 spatial frequency ($p=0.04$).

Adverse Events

During the follow-up periods for both groups, there were no postoperative complications noted. None of the patients needed re-lift or flap wash.

DISCUSSION

Visual outcomes of FLEEx appeared to be comparable to femto-LASIK. Our results showed that there was no significant difference between the mean UCVA at 3 months follow-up. 92% of the FLEEx and 91% of the femto-LASIK achieved 20/25 or better vision at 3 months, comparable to earlier studies on FLEEx that reported UCVA of 20/25 or better in 87-90% of cases.^{12-13,15} The FLEEx group, however, had delayed improvement in visual acuity in the early follow-up period, also observed in several studies.^{12,15}

One patient lost more than 2 lines of BCVA and 6 patients lost 1 line, despite the achievement of emmetropia with low residual errors of refraction in the FLEEx group. In other studies,^{13,15} a small percentage also lost at least 1 line of BCVA that decreased at the 6-month follow-up period. Thus, patients may still improve on subsequent follow-ups.

Refraction was stable at 1 week to 3 months of follow-up in the FLEEx group. Initial overcorrection seen at 1 day postoperatively (Figure 5) may be due

to corneal flap edema. In contrast, the femto-LASIK group was near emmetropia at one day and one week postoperatively, but regressed at one- and three-month follow-up periods.

In our study, the FLEEx group showed a tendency for overcorrection in higher degrees of myopia. In contrast, Sekundo observed overcorrection in eyes with low myopia and undercorrection in eyes with high myopia.^{12,13} Residual refraction in the FLEEx group had a tendency towards hyperopia, while the femto-LASIK had a tendency towards myopia. Although the FLEEx group had a lower final residual refraction than the femto-LASIK, the BCVA at the third month was higher in the femto-LASIK, which was 20/20 for all patients. There may be other factors besides refraction that caused the less than perfect vision in the FLEEx group.

Several authors reported that LASIK, in general, increases higher order aberrations,⁶⁻¹¹ leading to reduced quality of vision, such as glare, haloes, and night-vision problems despite excellent UCVA. Factors identified to increase corneal aberrations were flap creation, corneal lamellar ablation resulting in asymmetric anterior surface flattening, decentration of laser ablation, and wound healing defects.⁶ In this study, the preoperative and postoperative HOA RMS for both groups did not differ significantly. One limitation was the pupil size determination which was not uniform in the pre- and postoperative HOA measurements of both groups. Thus, further studies measuring the induced HOA after refractive lenticule extraction should be conducted.

Several studies showed a decrease in contrast sensitivity after LASIK surgery.¹⁰ The change in contrast sensitivity may further affect the quality of vision, especially night vision.^{7,10} In this study, however, both groups showed increased contrast sensitivity in the low spatial frequencies, but a decrease in the higher spatial frequencies. The difference between the 2 groups was not statistically significant.

The population in the FLEEx group represented the first cases of refractive lenticule extraction in the Philippines and the outcomes might have been influenced by the learning curve of the multiple refractive surgeons. Longer follow-ups with a larger sample and followed prospectively will provide a better picture of the safety, efficacy, and predictability of FLEEx.

In conclusion, our study showed that FLEx was comparable to femtosecond LASIK in terms of visual outcomes in the treatment of moderate myopia and astigmatism. The FLEx group showed better accuracy and stability at the three-month follow-up period. However, delayed visual improvement and loss of BCVA were noted in some.

ACKNOWLEDGEMENT

Special thanks is given to Dr. Walter Sekundo for sending the full text FLEx articles and to Mr. Janus Relos for the statistical analysis.

REFERENCES

1. Barraquer JI. The history and evolution of keratomileusis. *Int Ophthalmol Clin* 1996;36:1-7.
2. Tanna M, Schallhorn SC, Hettinger KA. Femtosecond laser versus mechanical microkeratome: a retrospective comparison of visual outcomes at 3 months. *J Refract Surg* 2009;25(Suppl):S668-S671.
3. Li H, Sun T, Wang M, et al. Safety and effectiveness of thin-flap LASIK using a femtosecond laser and microkeratome in the correction of high myopia in Chinese patients. *J Refract Surg* 2010;26:99-106.
4. Moshirfar M, Gardiner JP, Schliesser JA, et al. Laser in-situ keratomileusis flap complications using mechanical microkeratome versus femtosecond laser: retrospective comparison. *J Cataract Refract Surg* 2010;36:1925-1933.
5. Kim P, Sutton GL, Rootman DS. Applications of the femtosecond laser in corneal refractive surgery. *Curr Opin Ophthalmol* 2011;22:238-244.
6. Du CX, Shen Y, Wang Y. Comparison of higher order aberration after conventional and customized ablation in myopic LASIK in different eyes of the same patient. *J Zhejiang Univ Sci B* 2007;8:177-180.
7. Moshirfar M, Betts BS, Churgin DS, et al. A prospective, randomized, fellow eye comparison of WaveLight® Allegretto Wave® Eye-Q versus VISX CustomVue™ STAR S4 IR™ in laser-in-situ keratomileusis (LASIK): analysis of visual outcomes and higher order aberrations. *Clin Ophthalmol* 2011;5:1339-1347.
8. Padmanabhan P, Basuthkar SS, Joseph R. Ocular aberrations after wavefront optimized LASIK for myopia. *Indian J Ophthalmol* 2010;58:307-312.
9. Moreno-Barriuso E, Lloves JM, Marcos S, et al. Ocular aberrations before and after myopic corneal refraction surgery: LASIK-induced changes measured with laser ray tracing. *Invest Ophthalmol Vis Sci* 2001;42:1396-1403.
10. Yamane N, Miyata K, Samejima T, et al. Aberrations and contrast sensitivity after conventional laser-in-situ keratomileusis. *Invest Ophthalmol Vis Sci* 2004;45:3986-3990.
11. Calvo R, McClaren JW, Hodge DO, et al. Corneal aberrations and visual acuity after LASIK: femtosecond laser versus mechanical microkeratome. *Am J Ophthalmol* 2010;149:785-793.
12. Sekundo W, Kunert K, Russmann C, et al. First efficacy and safety study of the femtosecond lenticule extraction for the correction of myopia. *J Cataract Refract Surg* 2008;34:1513-1520.
13. Blum M, Kunert K, Schröder M, et al. Femtosecond lenticule extraction for the correction of myopia: preliminary 6-month results. *Graefes Arch Clin Exp Ophthalmol* 2010;248:1019-27.
14. Kunert KS, Blum M, Duncker GI, et al. Surface quality of human corneal lenticules after femtosecond laser surgery for myopia comparing different laser parameters. *Graefes Arch Clin Exp Ophthalmol* 2011;249:1417-1424.
15. Ang M, Chaurasia SS, Angunawela RI, et al. Femtosecond lenticule extraction (FLEx): clinical results, interface evaluation, intraocular pressure variation. *Invest Ophthalmol Vis Sci* 2012;53:1414-21.