Original Article

Central Asian Journal of Medical Sciences
CAJMS

Cent Asian J Med Sci. 2023 Sept;9(3): 125-130 https://doi.org/10.24079/CAJMS.2023.09.003

Assessment of Laser in Situ Keratomileusis Flap Predictability by Laser and Moria Microkeratome

Tsetsegjargal Baasanjav [1], Uranchimeg Davaatseren[1], Davaalkham Dambadarjaa[2], Baasankhuu Jamyanjav[3]

[1]Department of Ophthalmology, School of Medicine, Mongolian National University of Medical Sciences, Ulaanbaatar, Mongolia;
[2]Department of Epidemiology and Biostatistics, School of Public Health, Mongolian National University of Medical Sciences, Ulaanbaatar, Mongolia;
[3]Bolor Melmii Hospital, Ulaanbaatar, Mongolia.

Submitted: June 12, 2023
Revised: August 22, 2023
Accepted: September 08, 2023

Corresponding Author
Tsetsegjargal Baasanjav (M.D)
Department of Ophthalmology,
School of Medicine,
Mongolian National University of Medical Sciences, Ulaanbaatar,
Mongolia.

Tel: +976-99056585
E-mail: baasanjavtsetsegjargal@gmail.com
ORCID: https://orcid.org/0009-0001-9843-1428

Objective: In the present study, we compared LASIK flap thickness predictability created by a FS laser versus a Moria microkeratome in Mongolian patients. **Methods:** A total of ninety-six candidates for the LASIK procedure were stratified into two groups: FS laser-assisted and MK flap creation. Flap thickness was determined at five points. The side-cut angle was measured in three directions at the margin interface. LASIK flap assessment was performed one month postoperatively by Spectralis anterior segment optical coherence tomography. **Results:** Ninety-five participants (190 eyes) were recruited; 190 eyes were stratified to the FS group and 78 eyes to the MK group. The FS group had relatively even flap configurations, and the MK group had meniscus-shaped flaps. Regarding CR-sphere and cylinder, there was significant difference between 2 groups. The mean cylinder was -1.216 ± 0.924 in FS group while it was -0.730 ± 0.738 in MK group. Similarly, the mean sphere was -3.635 ± 2.031 in FS-LASIK group and -2.984 ± 1.502 in MK-LASIK group. The side-cut architecture varied among the two groups. OCT-C and OCT1Temporal values were significantly different between two groups. **Conclusion:** Improving the predictability of LASIK flap thickness and morphology is significantly important.
Keywords: Coherence Tomography, Optical, Keratomileusis, Laser Therapy

Introduction

Laser in situ keratomileusis (LASIK) is most popular corneal refractive procedure in the world with fast-growing updates in operative techniques, devices as well as instrumentation [1-3]. The surgical outcome of the LASIK highly depends on the consistency and predictability of the corneal flap thickness. There are two flap creation procedure for LASIK [4-8]. Moria microkeratome is based on the oscillating blade principle. However, there are several challenges in this procedure such as free caps, button holes, incomplete cuts [9, 10]. Another one is femtosecond (FS)-assisted flap creation. Here, the cleavage line is created through the cornea at a predetermined depth by photo-ionization of optically transparent tissues with a resultant acoustic shock wave and gas bubble formation, disrupting treated tissues. Currently, there are many FS-laser systems (IntraLase, VisuMax, Femto LDV) for measuring postoperative flap thickness

depending on subtraction from the preoperative planned residual stromal bed. It has been reported also that FS-LASIK has lower incidence of complications and greater options in flap thickness as well as better contrast sensitivity. For example, in the study of Issa et al, FS-LASIK was performed at 98 patients and resulted with no complication and high level of safety [11]. On the other hand, there are some reports indicated diffuse lamellar keratitis after FS-LASIK [12].

Improving the predictability of LASIK flap thickness and morphology is significantly important, because above mentioned measurements are rough and mostly inaccurate. Xia et al compared FS-LASIK with mechanical microkeratome for myopia and astigmatism. This non-randomized study included 120 eyes and flap thickness, visual acuity, manifest refraction, contrast sensitivity function (CSF) curves and other parameters were measured at 1wk; 1, 3, 6mo after surgery. The authors concluded that both procedures were safe and effective to correct myopia, with no statistically significant difference in the UDVA, CDVA during 6mo follow-up [13]. Another comparing study of Moshirfar et al revealed, on the other hand, that the total complication rates between the 2 groups were similar. Moreover, microkeratome group had significantly more epithelial defects intraoperatively while FS-LASIK group had significantly more diffuse lamellar keratitis cases postoperatively [14].

As mentioned above, the outcome of FS-LASIK and microkeratome procedures are reported contrarily in many studies and reason is still unclear till today. Therefore, in the current study, we aimed to assess LASIK flap thickness predictability created by a FS laser versus a Moria microkeratome in Mongolian patients.

Materials and Methods

Subjects and Study design

We conducted the hospital based cross-sectional study. A total of 95 participants (13 men and 81 women) who underwent conventional LASIK for the correction of myopia and myopic astigmatism, and who regularly returned for postoperative examination were included in this retrospective study design. The sample size in the study offered 90.1% statistical power at the 5% level in order to detect a 0.10 difference in the logarithm of the minimal angle of resolution (Decimal) of visual acuity, when the standard deviation (SD) of the mean difference was 0.25, and offered 98.1% statistical power at the 5% level in order to detect a 0.5 D-difference, when the SD of the mean difference was 1.0 D. Patients who had following criteria had included: unsatisfactory correction with spectacles or contact lenses, sufficient corneal thickness, endothelial cell density ≥ 1800 cell/mm^2, no history of ocular surgery, severe dry eye, progressive corneal degeneration, cataract, glaucoma.

LASIK was performed on both eyes of each patient successively using an identical method. The corneal flap was created using an M2 (Moria; 2 eyes), MI 7 (Med- Logics, Inc) microkeratome. After the flap was created Laser ablation was then performed using Visx Star S4 (AMO) excimer laser. The interface between the flap and stromal bed was irrigated with balanced salt solution containing 0.6-mg/ml gentamicin and 0.4-mg/ml dexametazone. After surgery, low-dose steroid (0.1% Flumetholone) 3 weeks, antibiotic (Gatifloxacin 0.5%) 5 days, and 0.3% hyaluronic acid (Hyalein, Santen) eyedrops were prescribed postoperatively.

Postoperative examinations were performed 1 day; 1 week; 1, 3, and 6 months; 1 year; and every year after that up to 5 years after surgery. Uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), manifest refraction, cycloplegic refraction measured by Autorefractometer Tomey. After surgery, low-dose steroid (0.1% Flumetholone,) 3 weeks, antibiotic (Gatifloxacin 0.5%) 5 days, and 0.3% hyaluronic acid (Hyalein, Santen) eyedrops were prescribed postoperatively.

Statistical Analysis

For comparing proportion of categorical variables, chi-square and Fisher exact tests were used. The normality of all data samples was checked by the Kolmogorov-Smirnov test. For mean value between two-groups, unpaired t-test was carried out. The results are expressed as mean and standard deviation (SD). The value of $p < 0.05$ was considered statistically significant. The statistical analysis was done in STATA 14 software.

Ethical Statements

The study protocol was approved by the Ethical Committee of the Mongolian National University of Medical Sciences (No: 2021/3-06).

Results

Study participants baseline characteristics are showing in Table 1. This study included 190 eyes of 95 participants. FS-assisted LASIK surgery was done in 190 eyes of 95 participants (13 males and 81 females). There were no statistically significant differences between the two groups with respect to age.

Table 1. General characteristics of study participants.

Variables	FS-LASIK	MK-LASIK	Total	P-value
	n = 49 (98 eyes)	n = 46 (92 eyes)	n = 95 (190 eyes)	
	Mean ± SD	Mean ± SD	Mean ± SD	
Age, years	30.31 ± 6.32	32.16 ± 6.20	31.19 ± 6.30	0.155
Age group	N (%)	N (%)	N (%)	
20-29	23 (46.9)	14 (31.1)	37 (39.4)	0.164
30-39	26 (53.1)	31 (68.9)	57 (60.6)	
Gender				
Male	4 (8.2)	9 (20.0)	13 (13.8)	0.173*
Female	45 (91.8)	36 (80.0)	81 (86.1)	

*Fisher's exact test

Table 2 demonstrates planned and actual flap thickness in both femtosecond laser-assisted LASIK and microkeratome-assisted LASIK. In the FS-assisted LASIK group, mean UCVA was 0.110 ± 0.074, while it was 0.144 ± 0.090 in MK-LASIK group. The mean CCT was 517.56 ± 28.81 and 537.6 ± 23.59 µm in the FS and MK groups, respectively. The mean preIOP was similar between two groups (13.45 ± 2.58 mmHg in the FS; 13.61 ± 2.49 mmHg in the MK group). Regarding CR-sphere and cylinder, there was significant difference between 2 groups. The mean cylinder was -1.216 ± 0.924 in FS group while it was -0.730 ± 0.738 in MK group. Similarly, the mean sphere was -3.635 ± 2.031 in FS-LASIK group and -2.984 ± 1.502 in MK-LASIK group.

Table 2. Planned and actual flap thickness in both femtosecond laser-assisted LASIK and microkeratome-assisted LASIK

Variables	FS-LASIK	MK-LASIK	Total	P-value
	n = 49 (98 eyes)	n = 46 (92 eyes)	n = 95 (190 eyes)	
	Mean ± SD	Mean ± SD	Mean ± SD	
UCVA	0.110 ± 0.074	0.144 ± 0.090	0.127 ± 0.083	0.005
BCVA	0.897 ± 0.123	0.959 ± 0.087	0.927 ± 0.118	0.000
MR sphere	-4.09 ± 1.89	-3.39 ± 1.52	-3.75 ± 1.75	0.005
Cylinder	-1.127 ± 0.958	-0.671 ± 0.688	-0.907 ± 0.867	0.000
CR sphere	-3.635 ± 2.031	-2.984 ± 1.502	-3.32 ± 1.819	0.012
CR cylinder	-1.216 ± 0.924	-0.730 ± 0.738	-0.98 ± 0.871	0.000
CCT	517.56 ± 28.81	537.6 ± 23.59	527.26 ± 28.19	0.000
IOP	13.45 ± 2.58	13.61 ± 2.49	13.53 ± 2.53	0.689

UCVA-Uncorrected Visual Acuity; BCVA-Best Corrected Visual Acuity; MR-Manifest Refraction; CR- Cycloplegic Refraction; CCT Central Corneal Thickness; IOP-Intra-ocular Pressure

The actual flap thickness in five locations across the horizontal meridian in FS-LASIK and MK-LASIK groups was given in Table 3. In FS-LASIK group, the postoperative mean manifest sphere (PO1msph) was 0.161 ± 0.460, while in MS-LASIK group it was 0.188 ± 0.412. The difference in postoperative sphere between the two groups was statistically insignificant (p value =0.673). On the other hand, the postoperative cylinder was -0.443 ± 0.439 in FS-LASIK group while in MS-LASIK group it was to -0.296 ± 0.367. The difference in postoperative cylinder between the two groups was statistically significant (p value =0.013). When comparing two groups, OCT-C and OCT1Temporal values were significantly different. In FS-LASIK group, OCT-C was 118.33 ± 10.98 while in MS-LASIK group it was 124.09 ± 13.08 p value =0.001).

Table 3. Actual flap thickness in five locations across the horizontal meridian in FS-LASIK and MK-LASIK groups

Variables	FS-LASIK	MK-LASIK	Total	P-value
	n = 49 (98 eyes) Mean ± SD	n = 46 (92 eyes) Mean ± SD	n = 95 (190 eyes) Mean ± SD	
PO1 VA	0.908 ± 0.151	0.934 ± 0.099	0.92 ± 0.129	0.169
PO1 sphere	0.442 ± 0.479	0.521 ± 0.447	0.48 ± 0.464	0.243
PO1 cylinder	-0.443 ± 0.439	-0.296 ± 0.367	-0.37 ± 0.411	0.013
PO1 IOP	9.29 ± 1.68	9.47 ± 1.43	9.38 ± 1.56	0.464
PO1 VA	0.954 ± 0.116	0.981 ± 0.062	0.97 ± 0.095	0.095
PO1 sphere	0.161 ± 0.460	0.188 ± 0.412	0.173 ± 0.428	0.673
PO1 IOP	9.11 ± 1.58	9.42 ± 1.30	9.27 ± 1.45	0.141
OCT-C	118.33 ± 10.98	124.09 ± 13.08	121.15 ± 12.36	0.001
OCT1 Temporal	115.83 ± 10.33	118.95 ± 9.86	117.36 ± 10.20	0.035
OCT2 Temporal	113.71 ± 12.29	115.87 ± 7.76	114.77 ± 10.36	0.149
OCT1 Nasal	115.75 ± 17.26	116.56 ± 7.60	116.15 ± 13.41	0.673
OCT2 Nasal	115.58 ± 15.71	118.61 ± 10.24	117.06 ± 13.37	0.118

PO1-Post Operative Day 1; VA- Visual Acuity; OCT-C Ocular Computer Tomography-Central

Discussion

Laser in situ keratomileusis (LASIK) is the most common corneal refractive procedure. During LASIK eye surgery, flap creation is the most critical step, because the precise creation of the corneal flap is mandatory for successful LASIK. If the flap is too thin, then there may have complications such as a free or buttonhole flap. In opposite, if flap is too thick then it may result in iatrogenic keratectasia and refractive regression.

In Moria microkeratome-assisted flap creation, an oscillating blade is used to create corneal flaps. However, this procedure has been considered to have a low level of precision in creating corneal flaps. Clinical studies revealed that a standard deviation of flap thickness between 18 and 24 μm [15]. On the other hand, in the FS-LASIK procedure, it has been showed that a standard deviation of flap thickness is within ±20 μm of the intended result [16, 17].

There are numerous studies that highlighted the utility of optical coherence tomography (OCT) in the valuation of LASIK flaps created by either MK or FS laser [18, 19]. Consequently, variable results have been obtained when comparing the clinical outcomes of patients who underwent FS-LASIK or MK-LASIK [20-22]. In this prospective study, we have been investigated the predictability of flap thickness and its configuration by two different methods. We analyzed LASIK flap characteristics and measurements by optical coherence tomography (OCT). Regarding to the UCVA, in the FS-assisted LASIK group, mean UCVA was 0.110 ± 0.074, while it was 0.144 ± 0.090 in MK-LASIK group (p>0.005). The mean CCT was 517.56 ± 28.81 and 537.6 ± 23.59 μm in the FS and MK groups, respectively (p=0.000). The mean preIOP was similar between two groups (13.45 ± 2.58 mmHg in the FS; 13.61 ± 2.49 mmHg in the MK

group). Regarding CR-sphere and cylinder, there was significant difference between 2 groups. The mean cylinder was -1.216 ± 0.924 in FS group while it was -0.730 ± 0.738 in MK group. Similarly, the mean sphere was -3.635 ± 2.031 in FS-LASIK group and -2.984 ± 1.502 in MK-LASIK group. Moreover, the postoperative cylinder was -0.443 ± 0.439 in FS-LASIK group while in MS-LASIK group it was to -0.296 ± 0.367. The difference in postoperative cylinder between the two groups was statistically significant (p value =0.013).

Furthermore, the side-cut architecture varied among the two groups. When comparing two groups, OCT-C and OCT1Temporal values were significantly different. In FS-LASIK group, OCT-C was 118.33 ± 10.98 while in MS-LASIK group it was 124.09 ± 13.08 p value =0.001).

There are numerous studies emphasized the difference in flap morphology between FS- and MK-assisted LASIK. The architecture of FS-assisted flaps is uniform despite the difference of the FS machines, while MK-assisted LASIK flaps yield a meniscus-shaped architecture.

The limitations of the current study include the relatively small number of enrolled patients. Second, the present study is single-centered retrospective study, thus probably had a selection bias due to the place of sampling. Further study of flap thickness predictability, contrast sensitivity as well as the postoperative visual fluctuations on a larger number of patients are required to corroborate the present findings.

Conclusion

Improving the predictability of LASIK flap thickness and morphology is significantly important. In the present study, we compared LASIK flap thickness predictability created by a FS laser versus a Moria microkeratome in Mongolian patients. Regarding CR-sphere and cylinder, there was significant difference between 2 groups. The mean cylinder was -1.216± 0.924 in FS group while it was -0.730 ± 0.738 in MK group. Similarly, the mean sphere was -3.635±2.031 in FS-LASIK group and -2.984±1.502 in MK-LASIK group. The side-cut architecture varied among the two groups. OCT-C and OCT1Temporal values were significantly different between two groups.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

References

1. Reinstein DZ, Archer TJ, Gobbe M. The history of LASIK. *J Refract Surg*. 2012 Apr;28(4):291-8. https://doi.org/10.3928/1081597X-20120229-01.
2. Bashir ZS, Ali MH, Anwar A, et al. Femto-lasik. The recent innovation in laser assisted refractive surgery. *J Pak Med Assoc.* 2017;67:609-15. https://pubmed.ncbi.nlm.nih.gov/28420926/
3. López-Montemayor P, Valdez-García JE, Loya-García D, et al. Safety, efficacy and refractive outcomes of LASIK surgery in patients aged 65 or older. *Int Ophthalmol*. 2018 Aug;38(4):1515-20. https://doi.org/10.1007/s10792-017-0614-3
4. Stonecipher K, Ignacio TS, Stonecipher M. Advances in refractive surgery: microkeratome and femtosecond laser flap creation in relation to safety, efficacy, predictability, and biomechanical stability. *Curr Opin Ophthalmol.* 2006 Aug;17(4):368-72. https://doi.org/10.1097/01.icu.0000233957.88509.2d
5. Kymionis GD, Portaliou DM, Tsiklis NS, et al. Thin LASIK flap creation using the SCHWIND Carriazo-Pendular microkeratome. *J Refract Surg.* 2009 Jan;25(1):33-6. https://doi.org/10.3928/1081597X-20090101-06.
6. Ambrósio R Jr, Wilson S. LASIK vs LASEK vs PRK: advantages and indications. *Semin Ophthalmol.* 2003; 18: 2-10. https://doi.org/10.1076/soph.18.1.2.14074.
7. Pajic B, Vastardis I, Pajic-Eggspuehler B, et al. Femtosecond laser versus mechanical microkeratome-assisted flap creation for LASIK: a prospective, randomized, paired-eye study. *Clin Ophthalmol.* 2014 Sep 22;8:1883-9. https://doi.org/10.2147/OPTH.S68124
8. Fang L, Wang Y, Yang R, et al. Effects of the LASIK flap thickness on corneal biomechanical behavior: a finite element analysis. *BMC Ophthalmol.* 2020 Feb 24;20(1):67.

https://doi.org/10.1186/s12886-020-01338-8.
9. Knorz MC. Flap and interface complications in LASIK. *Curr Opin Ophthalmol*. 2002 Aug;13(4):242-5. https://doi:10.1097/00055735-200208000-00010
10. Ambrósio R Jr, Wilson SE. Complications of laser in situ keratomileusis: etiology, prevention, and treatment. *J Refract Surg.* 2001 May-Jun;17(3):350-79. https://doi.org/10.3928/1081-597X-20010501-09
11. Issa A, Hassany U. Femtosecond laser flap parameters and visual outcomes in laser in situ keratomileusis. *J Cataract Refract Surg*. 2011; 37: 665-74. https://doi.org/10.1016/j.jcrs.2010.10.049
12. Paula FH, Khairallah CG, Niziol LM, et al. Diffuse lamellar keratitis after laser in situ keratomileusis with femtosecond laser flap creation. *J Cataract Refract Surg.* 2012;38:1014-9. https://doi.org/10.1016/j.jcrs.2011.12.030
13. Xia LK, Yu J, Chai GR, et al. Comparison of the femtosecond laser and mechanical microkeratome for flap cutting in LASIK. *Int J Ophthalmol.* 2015;8:784-90. https://doi.org/10.3980/j.issn.2222-3959.2015.04.25
14. 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: 1925-33. https://doi.org/10.1016/j.jcrs.2010.05.027.
15. Torky MA, Al Zafiri YA, Khattab AM. Visumaxfemtolasik versus Moria M2 microkeratome in mild to moderate myopia: efficacy, safety, predictability, aberrometric changes and flap thickness predictability. *BMC Ophthalmol* 2017;17:125-7. https://doi.org/10.1186/s12886-017-0520-5
16. Salomão MQ, Wilson SE. Femtosecond laser in laser in situ keratomileusis. *J Cataract Refract Surg*. 2010 Jun;36(6):1024-32. https://doi.org/10.1016/j.jcrs.2010.03.025/
17. Kim JH, Lee D, Rhee KI. Flap thickness reproducibility in laser in situ keratomileusis with a femtosecond laser: optical coherence tomography measurement. *J Cataract Refract Surg.* 2008 Jan;34(1):132-6. https://doi.org/10.1016/j.jcrs.2007.08.036
18. Parafita-Fernández A, Teus M. Femtosecond laser in situ keratomileusis flap creation. *J Cataract Refract Surg.* 2018 Oct;44(10):1297. https://doi.org/10.1016/j.jcrs.2010.03.025
19. Ju WK, Lee JH, Chung TY, et al. Reproducibility of LASIK flap thickness using the zeiss femtosecond laser measured postoperatively by optical coherence tomography. *J Refract Surg*. 2011 Feb;27(2):106-10. https://doi.org/10.3928/1081597X-20100428-04
20. Zhang J, Zhou Y, Zhai C, et al. Comparison of 2 femtosecond lasers for laser in situ keratomileusis flap creation. *J Cataract Refract Surg*. 2013 Jun;39(6):922-7. https://doi.org/10.1016/j.jcrs.2013.01.042
21. Rush SW, Rush RB. Optical Coherence Tomography-Guided Femtosecond LASIK in the Setting of Corneal Scarring. *Clin Ophthalmol.* 2021 Apr 20;15:1601-6. https://doi.org/10.2147/OPTH.S307191
22. Murakami Y, Manche EE. Comparison of intraoperative subtraction pachymetry and postoperative anterior segment optical coherence tomography of laser in situ keratomileusis flaps. *J Cataract Refract Surg.* 2011 Oct;37(10):1879-83. https://doi.org/10.1016/j.jcrs.2011.05.024