Original Article

Central Asian Journal of Medical Sciences
CAJMS

Cent Asian J Med Sci. 2023 Mar;9(1): 51-56 https://doi.org/10.24079/CAJMS.2023.03.007

Laser in Situ Keratomileusis for Moderate to High Myopia in Mongolians

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Submitted: December 27, 2022
Revised: February 7, 2023
Accepted: March 14, 2023

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Objectives: To compare the pre and post-operative outcomes of Mongolian patients who had LASIK surgery.

Methods: We conducted hospital based prospective study. A total of 176 consecutive patients who underwent conventional LASIK were examined for the correction of myopia. Study participants were followed for 5 years after surgery.

Results: The mean age was 29.89 ± 6.42 years. 145 patients were female and 31 were male. The mean UCVA was 0.10 ± 0.09 Decimal and the mean BCVA was 0.81 ± 0.16 Decimal. Preoperative analysis showed that UCVA and BCVA were significantly different in mild, moderate, and high myopia groups. Especially, patients with mild myopia had higher acuity compared to other groups (0.21 ± 0.13 and 0.86 ± 0.12, respectively). Moreover, the manifest spherical equivalent the of mild myopia group also had significantly lower compared to the other two groups (-1.73 ± 1.17).

Conclusions: Our results support the view that preoperative clinical examination is an extremely important part of the LASIK procedure to improve refractive predictability.

Keywords: Eye Diseases, Refractive Errors, Myopias, Situ, Keratomileusis

Introduction

Laser-assisted in situ keratomileusis (LASIK) is the most common ophthalmologic surgery to correct myopia [1-4]. Over thirty years, tremendous studies have been conducted and revealed that 99% of patients could achieve better than 20/40 uncorrected visual acuity after the surgical procedure. A meta-analysis of 97 relevant studies conducted by Sandoval et al demonstrated that 99.5% (59 503/59 825 eyes) achieved uncorrected distance visual acuity better than 20/40. Moreover, it has been shown that only 1.2% of the patients had dissatisfaction with LASIK [5]. The 18-year clinical audit of LASIK outcome in the Chinese population evaluated the safety, efficacy as well as retreatment rates, and complication rates. The overall efficacy index was 0.91 with >99% of eyes achieving UCVA of ≥20/40 and >70% achieving 20/20. The retreatment rate was 2.55%, and after retreatment, 98.4% of eyes achieved ≥20/40 UCVA and the annual complication rate has been <0.8% [6].

The overall success of the LASIK procedure highly depends on thorough preoperative examination and selection of the patients [7]. The prospective study of Chan et al evaluated the effect of preoperative pupil size on the quality of vision after

wavefront-guided LASIK. Mesopic pupil size and preoperative and postoperative variables were evaluated using an analysis of variance. At the 12-month postoperative visit, patients with medium pupils experienced less glare at night than small pupils, and also this group of patients had less halos than small or large pupils [8]. Another retrospective study also estimated the effect of preoperative keratometric value on the corneal flap dimensions of 45 patients who had LASIK. Eyes with keratometric values lower than 42.5 D resulted in a corneal flap with 116.70+/-12.6 micron thickness and 7.65 mm diameter flap in corneas compared with patients who had keratometric values above 44.5 D (102.16+/-13.41 micron thickness and 8.05+/-0.37 mm diameter flap in corneas) [9]. Smadja et al used the percentage of tissue altered (PTA) calculation as part of the planning strategy for myopic laser in situ keratomileusis (LASIK). It has been concluded that the mean difference between the estimated and achieved PTA was 0.451 ± 3.45% ($P < .001$) (95% CI: 0.3708 to 0.5322) with a preoperative and postoperative mean PTA of 31.07 ± 4.07% and 31.52 ± 5.78%, respectively. The PTA value (less than 1%) was clinically non-significant and indicated a highly reliable metric for preoperative refractive surgery planning [10].

According to the above-mentioned studies, preoperative clinical examination has been described as an extremely important part of the LASIK procedure to improve refractive predictability. However, other studies argue that the effect of the evidence for pre-operative examination to LASIK outcome is weak. For example, Kato et al described that the frequency of additional laser ablation showed no correlation with severity of the preoperative refractive error [11]. Authors indicated that this result is probably because eyes with high myopia tended to have less thickness of the residual corneal stroma for additional ablation. Another study of Lopez et al also indicated that central corneal thickness by the preoperative examination should not be considered a determinant factor during screening for candidates for LASIK surgery [12]. In this way, most related literatures on LASIK procedure, as well as several multivariate analyses of high myopia have not described clearly about the importance of the studying preoperative patient data and visual quality. Moreover, the studies that included preoperative data and corneal ablation measurements are still controversial and remain to be clarified. Thus, in the present study, we evaluated the preoperative outcomes of Mongolian patients who had LASIK surgery. The objective of the study was toevaluate the preoperative outcomes of Mongolian patients who had LASIK surgery.

Material and Methods

Subjects and Study design

We conducted the hospital based prospective study. A total of 176 patients (31 men and 145 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. 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/mm2, 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 test was used. The normality of all data samples was checked

by the Kolmogorov-Smirnov test. One-way analysis of variance (ANOVA) was used for the analysis of the time course of changes, the Tukey test being employed for multiple comparisons. The mixed effect two-way ANOVA was carried out to compare the difference between study groups and repeated-measures. The results are expressed as mean and standard deviation (SD). Myopic regression with the changes in central corneal thickness or mean keratometric reading was in linear regression analysis. The value of $p < 0.05$ was considered statistically significant. The statistical analysis was done in STATA 14 software.

Ethics

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

Results

The preoperative demographics of the study population are shown in Table 1. The mean age was 29.89 ± 6.42 years. 145 patients were female and 31 were male.

Table 1. Preoperative demographics of the study population undergoing conventional laser in situ keratomileusis (n=176).

Variables	Myopia (gradOD3)				
	Mild n = 36	Moderate n = 90	High n = 50	Total n = 176	P-value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Age, years	28.89 ± 5.74	30.16 ± 6.34	30.12 ± 7.04	29.89 ± 6.42	*0.422
Age group	N (%)	N (%)	N (%)	N (%)	
18-26	13 (36.1)	30 (33.3)	17 (34.0)	60 (34.1)	0.835
27-35	18 (50.0)	39 (43.3)	22 (44.0)	79 (44.9)	
36 <	5 (13.9)	21 (23.3)	11 (22.0)	37 (21.0)	
Gender					
Female	11 (30.6)	12 (13.3)	8 (16.0)	145 (82.4)	0.048
Male	25 (69.4)	78 (86.7)	42 (84.0)	31 (17.6)	
Surgery complication					
1-2	2 (25.0)	10 (55.6)	10 (58.8)	22 (51.2)	
3<	6 (75.0)	8 (44.4)	7 (41.2)	21 (48.8)	
Repetitive surgery	2 (1.14)	2 (1.14)	2 (1.14)	6 (3.42)	

*One-way-ANOVA The mean UCVA was 0.10 ± 0.09 Decimal and the mean BCVA was 0.81 ± 0.16 Decimal. The right eye's mean corneal thickness were 533.6 ± 27.12 µm while the left eye's corneal thickness were 529 ± 45.11 µm. Six patients had a history of repetitive surgery.
*One-way-ANOVA, multiple comparison (Tukey): Mild vs. High, P-value 0.014

Table 2. Preoperative outcomes of cylinder and keratometer as well as spherical equivalent.

Variables	Myopia				
	Mild n = 36	Moderate n = 90	High n = 50	Total n = 176	*p-value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Cylinder (D)	1.52 ± 1.64	1.14 ± 1.12	1.28 ± 0.80	1.26 ± 1.64	0.452
Corneal thickness	533.05 ± 28.62	528.69 ± 26.01	539.32 ± 27.12	532.60 ± 27.11	0.202
Manifest spherical equivalent (D)[a]	-1.73 ± 1.17	-4.26 ± 0.85	-7.18 ± 2.47	-4.58 ± 2.45	0.000
Intraocular pressure (mmHg)	15.83 ± 2.25	15.07 ± 2.37	16.4 ± 2.34	15.60 ± 2.40	0.154

In Table 2, we show preoperative outcomes. Based on the degree of myopia, we divided them into three groups: mild, moderate, and high myopia group. The mean age of the mild myopia group was 28.88 ± 5.74, whilst it was 30.16 ± 6.34 for the moderate myopia group and 30.12 ± 7.04 for the high myopia group.

Table 3. Vision acuity before and after operation.

Vision acuity (Decimal)	Myopia				
	Mild[a, b, c] n=36	Moderate[d, e] n=90	High[f, g] n=50	Total n=176	*p-value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
BCVA (Decimal)	0.86 ± 0.12	0.83 ± 0.16	0.75 ± 0.17	0.81 ± 0.16	0.001
First day	0.93 ± 0.19	0.90 ± 0.24	0.81 ± 0.20	0.88 ± 0.22	0.011
1 month	0.95 ± 0.20	0.94 ± 0.21	0.86 ± 0.18	0.92 ± 0.20	0.020
3 months	0.97 ± 19.7	0.96 ± 0.21	0.87 ± 0.17	0.94 ± 0.19	0.015
6 months	0.97 ± 0.18	0.95 ± 0.18	0.88 ± 0.18	0.93 ± 0.19	0.023
1 year	0.97 ± 0.13	0.95 ± 0.18	0.88 ± 0.19	0.93 ± 0.18	0.026
2 years	0.97 ± 0.14	0.95 ± 0.16	0.86 ± 0.17	0.93 ± 0.16	0.001
3 years	0.97 ± 0.15	0.93 ± 0.16	0.87 ± 0.17	0.92 ± 0.16	0.003
4 years	0.96 ± 0.14	0.92 ± 0.16	0.84 ± 0.19	0.90 ± 0.17	0.001
5 years	0.95 ± 0.14	0.92 ± 0.15	0.83 ± 0.22	0.89 ± 0.18	0.002

Two-way mixed ANOVA results: Interaction of time and diagnosis F (1.816, 413.11) = 18.231, p < 0.071; Main effect of time F (1.013, 291.11) = 125.24, p < 0.092; Main effect of diagnosis F (1,931) = 0.932, p = 0.322; *One-way ANOVA; Paired t-test: aFirst day1 vs. 6 months, p=0.041, bFirst day vs. 1 year, p=0.035, c1 month vs. 1 year, p=0.046 in Mild; dFirst day vs.1 month, p=0.010, eFirst day vs. 3 months, p=0.009 in Moderate; fFirst day vs. 1 month, p=0.003, gFirst day vs. 6 months, p=0.008 in High.

In table 3, BCVA were significantly different in each group. Especially, patients with mild myopia had higher acuity compared to other groups (0.86 ± 0.12, respectively) (p <0.000).

Table 4. Multiple linear regression results.

Dependent variables	Factors	β	95% CI	SE	t	p-value
Cylinder (D)						
	Age	-0.018	-0.044 -0.008	0.0133	-1.36	0.177
	Gender	-0.311	-0.764 – 0.142	0.2298	-1.35	0.178
Corneal thickness						
	Age	-0.104	-0.736-0.527	0.3201	-0.33	0.745
	Gender	-16.49	-26.823-6.170	5.2321	-3.15	0.002
Spherical equivalent						
	Age	-0.023	-0.080-0.033	0.0288	-0.80	0.426
	Gender	-0.505	-1.461-0.451	0.4844	-1.04	0.299
Intraocular pressure (mmHg)						
	Age	-0.013	-0.068-0.043	0.0283	-0.44	0.664
	Gender	-0.482	-1.429-0.454	0.4744	-1.02	0.310

R-square: 0.039, F=1.034

Moreover, the manifest spherical equivalent the of mild myopia group also had significantly lower compared to the other two groups (-1.73 ± 1.17). In the linear regression analysis, there was statistically significant relationship between corneal thickness and gender (p <0.002) (Table 4).

Discussion

LASIK surgery is being performed for more than 30 years and numerous studies demonstrated that this procedure is the safest and most favorable option for vision correction in myopic eyes [13-15]. Only 0.1% of the patients had been reported to have a loss of the best corrected visual acuity. It also has been reported that the rate of severe complication is up to 0.6% and the rate of recurrent corneal erosions is up to 0.08. Post-operative UCVA of 20/20 was reported in 70% whilst 20/40 acuity was reported in 95% [16-18]. There are significantly few studies investigating the predictive factors for the safety and efficacy of LASIK. A retrospective cohort study of Gomel et al showed that 91.9% and 86.0% of all evaluated eyes were above the safety and efficacy cut-off levels, respectively. Younger age was significantly correlated with safety and efficacy indices above the cut-off levels ($p<0.001$). Male gender was significantly correlated with efficacy above the cut-off level ($p<0.001$) [19]. The non-randomized, cohort study of Garcia-Gonzalez showed a significant correlation between age and the postoperative spherical equivalent (SE; r2=0.004, P=0.006), efficacy (r2=0.006, P=0.001), and safety indexes (r2=0.05, P=0.0001) in the mechanical LASIK group [20]. A retrospective analysis including 1659 consecutive eyes of 895 patients also concluded that the preoperative sphere was strongly correlated with visual outcomes. Higher levels of correction were associated with a greater loss of best spectacle-corrected visual acuity (BSCVA), a lower percentage of eyes achieving 20/20 BSCVA, and a lower percentage of eyes achieving 20/20 uncorrected visual acuity [21]. In the present study, our results showed that UCVA and BCVA were significantly different in each group. Especially, patients with mild myopia had higher acuity compared to other groups (0.21 ± 0.13 and 0.86 ± 0.12, respectively). Moreover, the manifest spherical equivalent the of mild myopia group also had significantly lower compared to the other two groups (-1.73 ± 1.17). In the study of de Benito et al, residual spherical equivalent (SE) were -4.59 diopters (D) +/- 2.80 (SD) (range -0.25 to -13.00 D) and the mean keratometry, 44.20 +/- 1.60 D (range 39.00 to 49.00 D). Three months postoperatively, the mean SE was +0.05 +/- 0.50 D. There was a significant ($P = .04$), although weak ($r2 = 0.003$), correlation between the mean preoperative keratometry and residual SE [22]. Another study of Ditzen et al revealed that preoperative corneal radius appeared to be an important factor in eyes with high hyperopia [23]. The retrospective study comparing the average preoperative keratometry values between 39.9 and 42.0 diopters (96 eyes) and between 46.0 and 47.2 D (103 eyes) that underwent LASIK for moderate myopia revealed that significant differences were found at 6 months postoperatively between these groups. Moderately myopic eyes with flatter corneas preoperatively have better visual prognosis following LASIK compared with moderately myopic eyes with steeper corneas [24]. Aaron et al measured high contrast BCVA before and 3 months after custom LASIK in one eye of 79 individuals. Preoperative spherical equivalent refractive error ranged between −1.00 and −10.38 D. It has been concluded that dividing the sample into two subsamples based on preoperative acuity confirmed the common clinical observation that eyes with better-than-average acuity tend to stay the same or lose acuity whereas eyes with worse-than-average acuity tend to gain acuity [25]. Our study had the following limitations. Our present study included both eyes of each patient undergoing LASIK surgery. We have not performed a statistical analysis of one eye per patient. Moreover, the sample size was relatively small. Thus, further research is required to determine which treatment is optimal for specific patient groups and can create the least myopic regression.

Conclusion

LASIK is a safe surgical option for such patients in a clinical setting. Our results support the view that preoperative clinical examination is an extremely important part of the LASIK procedure to improve refractive predictability. In the present study, we evaluated the preoperative outcomes of Mongolian patients who had LASIK surgery.

Conflicts of Interest

Non conflicts of interest.

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