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Comparison of Iris Calved IOL and LASIK Surgery Outcome in Mongolian Patients

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Keywords: Ophthalmologic Surgical Procedure, LASIK Surgery, Ocular Vision, Visual Acuity, Cornea Surgery

Introduction

Myopia is a very common eye condition where light focuses in front of, instead of on, the retina. It has been demonstrated that 1,4 billion people (22.9 % of the world population) has myopia and the population will be raised to 5 billion in 2050 [1 - 4]. There are several refractive surgery techniques including laser-assisted in situ keratomileusis (LASIK), photorefractive keratectomy as well as intraocular lens (IOL) implantation in order to correct spherical and cylindrical refractive errors in myopic patients [5 - 9]. LASIK is the most frequently performed procedure for refractive correction, with more than 16 million LASIK procedures performed globally since introduced first in 1990. It has been considered safe and stable procedure due to its excellent efficacy, predictability and high patient satisfaction in treating both myopia and hyperopia. Intraocular lens (IOL) implantation, on the other hand, is the standard for treating aphakia. About 10 million cataract surgeries are performed

globally each year. Angle-supported or iris-fixated anterior chamber IOL, posterior chamber (PC) trans-scleral sutured IOLs, PC iris-fixated IOL and trans-scleral sutured PCIOL are commonly used approaches [10 - 13].

Despite the low rates of surgical complications, the above-mentioned procedures have their own disadvantages. A retrospective study by Lin et al demonstrated the incidence of flap complications in LASIK surgery. Of the 1,019 eyes, 490 eyes underwent myopic keratomileusis in situ, and 529 eyes underwent laser in situ keratomileusis. Postoperative complications included displaced flaps that required repositioning in 20 eyes (2.0 %), folds in the flap that required repositioning in 11 eyes (1.1%), diffuse lamellar keratitis in 18 eyes (1.8%), infectious keratitis in one eye (0.1 %), and epithelial ingrowth that required removal in 22 eyes (2.2 %). The incidence of diffuse lamellar keratitis was 0.2 % in eyes that had undergone myopic keratomileusis in situ and 3.2 % in eyes treated by laser in situ keratomileusis [14]. Anatomic complications include corneal flap abnormalities, epithelial ingrowth, and corneal ectasia. Refractive complications include unexpected refractive outcomes, irregular astigmatism, decentration, visual aberrations, and loss of vision. Infectious keratitis, dry eyes, and diffuse lamellar keratitis may also occur following LASIK [15]. In a case of IOL, tilt and decentration have negative impact on visual performance by inducing optical aberrations and, in extreme cases, decreasing visual acuity [16]. Eum et al. presented that after a 6 - month follow-up period, postoperative complications occurred in 3 eyes in the IOL exchange group (17.6 %) and 2 eyes in the refixation group (11.8 %) [17].

There is very little research which has been done in order to make an accurate comparison between IOL and LASIK techniques. In the study of Malecaze et al. patient's eyes were treated with two different surgical techniques and outcomes were presented. One year after surgery, the mean spherical equivalent refraction was -0.74 ± 0.67 D for LASIK-treated eyes and -0.95 ± 0.45 D for Artisan-treated eyes, and the majority of LASIK-treated eyes (64 %) and Artisan-treated eyes (60 %) were within ± 1.00 D of the intended result. At 1 month, the mean spherical equivalent refraction was -0.28 ± 0.71 D for LASIK and -1.07 ± 0.59 D for Artisan (p < 0.01). The safety index was significantly better for Artisan (1.12 ± 0.21) than for LASIK (0.99 ± 0.17) at 1 year (p < 0.02) [18]. Kamiya et al. compared postoperative visual function after implantable collamer lens (ICL) implantation and after wavefront-guided laser in situ keratomileusis (LASIK) in eyes with low to moderate myopia. The postoperative area under the log contrast sensitivity function was significantly increased after ICL implantation (p < 0.001), whereas, after wavefront-guided LASIK, it was not significantly changed (p = 0.110). ICL implantation induces significantly fewer ocular HOAs than wavefront-guided LASIK. Moreover, CS was significantly improved after ICL implantation but unchanged after wavefront-guided LASIK in eyes with low to moderate myopia [27].

From the various aspects related to the above-mentioned procedures, one can be certain that both LASIK and IOL surgery have their own advantages and disadvantages. For example, LASIK is a more extraocular and irreversible procedure including permanent ablation of a few corneal tissues.

Moreover, it is less expensive in comparison to lens implants. On the other hand, IOL is an intraocular and more invasive procedure. It does not need to remove natural lens of the eye, so is entirely reversible. Normally, the implant procedure for each eye has to be done on different days due to intraocular infection. There are significantly few studies which has introduced the comparison IOL outcome with conventional phacoemulsification surgery. Therefore, we have aimed in the present study to determine the differences between IOL and LASIK surgery in Mongolian patients.

Materials and Methods

Research design

This study was a retrospective exploratory study undertaken to evaluate the effect of anterior chamber iris fixation intra ocular lens and LASIK surgery. To assess the improvement of the treatment over time in outcome variables, repeated-measures were done before surgery and post-operative day one and 1^{st} week as well as 2^{nd} weeks.

Sixty-seven patients participated in this study. Preoperative exclusion criteria included any pathology of the cornea, macula, or optic nerve and any history of inflammation or surgery of the eye. Inclusion criteria were eyes that underwent uncomplicated cataract surgery or refractive lens exchange (RLE) with either the PanOptix or PanOptix toric IOL, eyes that had previous myopic LASIK or PRK treatment, and patients highly motivated to increase spectacle independence. The surgeries took place between October 2016 and December 2018. All collected data consisted of preoperative and postoperative data on refractive error, prediction error, and visual acuity. Visual acuities were recorded in Snellen and converted to the equivalent log of the minimum angle of resolution (logMAR) notation for statistical analysis. Pre-LVC data was not known and was not collected.

Residual astigmatism, monocular uncorrected visual acuity at distance (UDVA; 4 m), intermediate (UIVA; 60 cm), and near (UNVA; 40 cm) and monocular best-corrected visual acuity at distance (BCVA; 4 m) was recorded. Postoperative spherical equivalent refraction (both actual and predicted) and the type and power of the IOL implanted (and suggested), determined by preoperative planning and IA, were taken from the AnalyzOR database and used to calculate prediction error. Comparisons were performed for absolute prediction errors between preoperative planning and IA.

Surgical procedures: The surgeons performed a 2.4 mm clear corneal incision or transconjunctival corneoscleral incision according to previously described procedures. 2 side ports were made with a 0.6 mm slit knife at approximately 110 and 90-degrees to the main incision. Afterward a continuous curvilinear capsulorrhexis using a bent needle was performed, the main incision was made with a 2.4 mm steel keratome.

Statistical analysis

The normality of the data distribution was tested by inspecting a histogram. The mean of UCVA, BCVA and visual acuity values for each group at each time were checked for outliers and missing data. Categorical variables were compared using the Chi-square test where applicable. Comparing the mean of continuous variables between AC IOL and LASIK surgery groups, unpaired t-test was carried out. For dependent groups, the mean of continuous variables were compared by using the paired t-test. The main effects of time, treatment type and their interaction were determined using a mixed two-way ANOVA with a Greenhouse-Geiser adjustment for lack of sphericity. The repeated measurements within subjects were then compared to the previous time interval using paired t-tests. A Bonferronitype correction was applied to all t-test results resulting in a significance level set at p < 0.017 (= 0.05/3). SPSS version 24 software (SPSS Inc., Chicago, IL, USA) was used for statistical analyses.

Ethical statement

The study was approved by the Research Ethics Committee of the Mongolian National University of Medical Sciences (No.2021/05/21). All patients provided written informed consent before participating in this study

Results

This study was conducted on 67 participants. Females comprised 58.8 % in the IOL patients and 72.0 % in the LASIK groups. The mean age of the participants was 32.06 \pm 9.29 in IOL and 29.4 \pm 6.59 in the LASIK (Table 1).

Pre-operative uncorrected visual activity (UCVA) was 7.94 \pm 6.56 in IOL patients, and 2 weeks after surgery, UCVA had increased to 61.18 \pm 21.18. In the case of LASIK, pre-operative UCVA was 20.56 \pm 17.20, and the value was 86.8 \pm 18.23 after surgery (Table 2).

AC IOL- Anterior Chamber Iris Fixated Intra Ocular Lens;

Best-corrected visual acuity (BCVA) was given in Table 3. Pre-operative BCVA of IOL and LASIK group were 37.65 ± 18.38 and 97.6 ± 4.31 , respectively. However, only IOL patients had significantly improved BCVA after surgery (71.76 \pm 22.97 at post-operative 2nd week).

Central corneal thickness (CCT) and axial length (AL) measurement was given in Table 4. The average CCT and AL were $539.92 \pm 22.66 \mu m$ and $28.21 \pm 2.20 mm$, respectively in IOL groups. While, the average CCT and AL of LASIK group were $529.74 \pm 28.22 \mu m$ and $26.94 \pm 1.54 mm$, respectively.

AC IOL- Anterior Chamber Iris Fixated Intra Ocular Lens;

We also measured pre- and post-operative near visual acuity of IOL patients. It improved from 40.29 \pm 21.10 to 83.53 \pm 19.98 in Table 5.

Mean endothelial cell count before and after IOL surgery is shown in Table 3. The preoperative IOL mean endothelial cell count was 2689.06 \pm 300.39. At post IOL it was found to be 2422.47 \pm 554.02. There is a less than 10 % loss in endothelial cell count before and after IOL surgery.

	Study Groups			
Variables	AC IOL (n = 17)	LASIK surgery (n = 50)	Total (n = 67)	p-value
	Mean ± SD	Mean ± SD	Mean ± SD	
Age, years	32.06 ± 9.29	29.4 ± 6.59	30.07 ± 7.39	0.287
Gender	N (%)	N (%)	N (%)	
Male	7 (41.2)	14 (28.0)	21 (31.3)	0.478
Female	10 (58.8)	36 (72.0)	46 (68.7)	
Eye				
Left	8 (47.1)	25 (50.0)	33 (49.3)	0.382
Right	9 (52.9)	25 (50.0)	34 (50.7)	
Glasses power, D				
Mild 1-3	-	19 (38.0)	19 (28.4)	
Moderate 3-6	-	21 (42.0)	21 (31.3)	
High 6 <	17 (100.0)	10 (20.0)	27 (40.3)	

Table 1. General characteristics.

Note: AC IOL- Anterior Chamber Iris Fixated Intra Ocular Lens

Table 2. Uncorrected visual acuity.

Study Groups				
Variables	AC IOL ^a (n = 17)	LASIK Surgery ^b (n = 50)	Total (n = 67)	p-value
	Mean ± SD	Mean ± SD	Mean ± SD	
Pre-operative	1.19 ± 0.36	0.80 ± 0.33	0.97 ± 0.34	0.000
Post operative day one	0.26 ± 0.14	0.13 ± 0.10	0.19 ± 0.13	0.006
Post operative 1 st week	0.22 ± 0.13	0.11 ± 0.03	0.16 ± 0.08	0.044
Post operative 2 nd week	0.23 ± 0.09	0.07 ± 0.01	0.14 ± 0.05	0.003

Two-way mixed ANOVA results: Interaction of time and treatment F(2.731, 584.59) = 24.195, p < 0.004; Main effect of time F(2.918, 487.16) = 412.23, p < 0.002; Main effect of treatment F(2,341) = 0.146, p = 0.781; paired t-test: ^apre-operative vs. post operative 1st week, p-value 0.049; ^bpre-operative vs. post operative day one, p-value 0.021.

Table 3. Best correction visual acuity.

Study Groups					
Variables	AC IOLª (n = 17)	LASIK Surgery (n = 50)	Total (n = 67)	p-value	
	Mean ± SD	Mean ± SD	$Mean \pm SD$		
Pre-operative	0.46 ± 0.12	0.02 ± 0.01	0.13 ± 0.10	0.000	
Post operative day one	0.24 ± 0.17	-	0.24 ± 0.17		
Post-operative 1st week	0.21 ± 0.09	0.05 ± 0.02	0.09 ± 0.04	0.003	
Post-operative 2 nd week	0.14 ± 0.07	0.02 ± 0.01	0.05 ± 0.02	0.016	

Two-way mixed ANOVA results: Interaction of time and treatment F(2.843, 514.46) = 21.285, p < 0.006; Main effect of time F (2.346, 316.12) = 384.14, p < 0.001; Main effect of treatment F(2,574) = 0.345, p = 0.091; paired t-test: ^apre-operative vs. post operative 2^{nd} week, p-value 0.052.

	Study	Groups		
Variables	AC IOL (n = 17)	LASIK Surgery (n = 50)	Total (n = 67)	p-value
	Mean ± SD	Mean ± SD	Mean ± SD	
Pachymeter	539.92 ± 22.66	529.74 ± 28.22	532.32 ± 27.12	0.143
Axial length	28.21 ± 2.20	26.94 ± 1.54	27.26 ± 1.80	0.038

Table 4. Pachymeter and axial length.

Table 5. Near visual acuity and endothelial cell count.

Variables	AC IOL (n = 17)		Total (n = 17)	p-value
	Preoperative	Postoperative		
	$Mean \pm SD$	Mean ± SD	Mean ± SD	
Near visual acuity	40.29 ± 21.10	83.53 ± 19.98	61.91 ± 20.54	0.081
Endothelial cell count	2689.06 ± 300.39	2422.47 ± 554.02	2555.76 ± 427.21	0.097

Discussion

Refractive surgeries can be broadly categorized into two classes: LASIK and IOL including phakic IOLS. LASIK is less invasive, but irreversible due to the removal of tissue from the cornea. The higher the correction, the more corneal tissue has to be removed. On the other hand, phakic IOL places a lens inside the eve thus does not require the removal of corneal tissue. IOL implantation can be used regardless of corneal thickness and topography, Numerous studies have demonstrated different advantages and surgical outcomes of these two procedures. Systematic review and meta-analysis by van Rijn et al revealed positive visual and refractive results after implantation and low complication rate. Moreover, endothelial cell loss appeared to be at an acceptable rate, although the range of endothelial cell change was too wide to draw firm conclusions [18]. V4c ICL implantation conducted by He et al resulted in improved optical quality under both bright and dark lighting conditions, and had an improved ability to reduce the extent of scattering in the dark. Further, patients with super high myopia (spherical equivalent greater than - 10 D) achieved greater improvement in visual quality [19].

Due to the site of implantation, IOL can be divided into 2 classes: iris-fixated pIOLs (posterior chamber lenses) and anterior chamber (AC) angle-supported lenses. Some studies reported that implantation of pIOLs is safe, efficient, and stable [20-22], however, other studies also showed increased astigmatism as well as corneal decompensation and rhegmatogenous retinal detachment in the immediate postoperative period [23]. On

the other hand, AC IOL has been used widely in the past two decades in phakic myopic eyes and in aphakic eyes after a cataract extraction procedure. This procedure has relatively high efficiency and simplicity of the operation. Akcay demonstrated that, at the 18-months follow up, uncorrected visual acuity improved to logMAR 0.37 \pm 0.23 from 1.60 \pm 0.10, and best spectacle corrected visual acuity improved to logMAR 0.36 \pm 0.14 [24].

In the present study, both AC IOLs and LASIK surgery outcomes were compared in Mongolian patients. Pre-operative uncorrected visual activity (UCVA) was 7.94 ± 6.56 in IOL patients, and 2 weeks after surgery, UCVA had increased to 61.18 ± 21.18 . In the case of LASIK, pre-operative UCVA was 20.56 \pm 17.20, and the value was 86.8 \pm 18.23 after surgery. Moreover, pre-operative BCVA of IOL and LASIK group were 37.65 ± 18.38 and 97.6 ± 4.31 , respectively. However, only IOL patients had significantly improved BCVA after surgery (71.76 \pm 22.97 at post-operative 2nd week). Al-Ageel et al. presented the comparison of CCT measurements taken with a Pentacam, noncontact specular microscope (NCSM), and ultrasound pachymetry (US) in normal and LASIK eyes. In normal eyes, the mean (± SD) CCT taken with Pentacam, NCSM, and US was 552.6 \pm 36.8 μ m, 511.9 \pm 38.6 μ m, and 533.3 \pm 37.9 μ m, respectively. The average values of CCT taken with the three instruments were significantly different. In post-LASIK eyes the mean CCT with Pentacam, NCSM, and US was 483.02 \pm 6.03 μ m, 450.7 \pm 5.3 μ m, and 469.5 \pm 5.8 μ m, respectively. In post-LASIK eyes, there was significant association between the

difference and the mean of the Pentacam and NCSM, and US and NCSM. Pentacam tends to give significantly thicker reading than ultrasound pachymetry. In our study, the postoperative average CCT and AL were 539.92 \pm 22.66 μ m and 28.21 \pm 2.20 mm, respectively in IOL groups.

Benedetti et al evaluated long-term endothelial cell changes in eyes that had implantation of an iris-fixated phakic Artisan intraocular lens (IOL) for moderate to high myopia. It was revealed that preoperative endothelial cell density was 2616 cells/mm (2) +/- 347 (SD) and the mean endothelial cell loss from preoperatively was 2.3 % at 4 months, 3.5 % at 12 months, 4.7% at 24 months, 6.7% at 3 years, 8.3% at 4 years, and 9.0 % at 5 years [24]. Moreover, in the study of Smith et al. the effect of femtosecond thin flap LASIK and photorefractive keratectomy (PRK) on postoperative endothelial cell density was compared. The average preoperative endothelial cell density was 3011+/-329 cells/mm (2), which decreased to 2951+/-327 cells/ mm (2) at 1 month (p = 0.573) and 2982+/-365 cells/mm (2) at 3 months (p = 0.651) in photorefractive keratectomy. In thin flap LASIK, the average preoperative endothelial cell density was 2995+/-325 cells/mm (2), which decreased to 2977+/-358 cells/mm (2) at 1 month (p = 0.575) and 2931+/-369 cells/mm (2) at 3 months (p = 0.410) [28]. However, in our study, mean endothelial cell count before IOL surgery was 2689.06 ± 300.39 and it was decreased to 2422.47 ± 554.02 . There was a less than 10 % loss in endothelial cell count before and after IOL surgery.

Our study had some limitations. The follow-up time was too short. We compared clinical outcomes between groups 2 weeks after surgery, but long-term follow-up is necessary in future studies. Another limitation is the small sample size. A larger number of eyes should form the basis of future studies. Moreover, some new methods which differ from the traditional principles, such as intraoperative aberrometry which allows both aphakic and pseudophakic refractive measurements and raytracing for calculating the IOL power in eyes should be applied in the future studies.

Conclusion

AC IOL placement and LASIK surgery was compared in this study. Pre-operative uncorrected visual activity (UCVA) was 7.94 \pm 6.56 in IOL patients, and 2 weeks after surgery, UCVA had

increased to 61.18 ± 21.18 . In the case of LASIK, pre-operative UCVA was 20.56 ± 17.20 , and the value was 86.8 ± 18.23 after surgery. Moreover, pre-operative BCVA of IOL and LASIK group were 37.65 ± 18.38 and 97.6 ± 4.31 , respectively. The techniques resulted in similar visual outcomes at minimum follow-up of 2 weeks after surgery.

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