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Trifocal Intraocular Lens Implantation to Treat Visual Demands in Mongolian Patients

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Objective: Intraocular lens (IOL) implants are artificial lenses which helps to clear up the vision after cataract surgery. In this work, we aimed to compare the monofocal and trifocal IOL implantation during phacoemulsification. **Methods:** 60 eyes of 60 patients were divided into 2 equal groups. Postoperative astigmatism and UCVA were measured and compared during week 1, week 2 and month. **Results:** The mean preoperative UCVA was 6.83 ± 4.61 in the monofocal IOL group, and 17.5 ± 17.55 in the trifocal IOL group. At the first week: The mean postoperative UCVA at one week was 35.46 ± 19.45 and 58.64 ± 20.77, in each group respectively. The mean postoperative BCVA in the first week was 42.71 ± 20.63 and 65.91 ± 20.85, in each group respectively. The mean postoperative UCVA at 1 month was 46.57 ± 24.37 and 76.36 ± 23.61, in each group, while BCVA was 63.14 ± 24.94 and 89.54 ± 14.63. There was a highly significant statistical difference between the result of UCVA preoperative and the results of UCVA at the early and last postoperative follow up. **Conclusion:** From our results, it is evident that post-operative near UCVA and BCVA was statistically significant at monofocal and trifocal groups.

Keywords: Lenses, Intraocular, Lens Implantation, Vision, Ophthalmologic Surgical Procedures

Introduction

Corneal opacity and cataract are the primary cause of decreasing visual acuity. Corneal opacity can be caused by ocular trauma or disease and can be unilateral or bilateral [1 - 3]. On the other hand, an estimated 95 million people worldwide are affected by cataract [4]. Depending on the case, cataracts can be classified according to age-related, pediatric and secondary. Among these groups, age related cataract is the most common type in adults, with the age between 45 to 50 years old [5]. Further, pediatric cataract is a leading cause of childhood blindness. It accounts for 7.4 %–15.3 % of pediatric blindness [6 - 8].

Nowadays, there are two main surgical treatments for patients with corneal opacity and cataract. One is to perform simultaneous penetrating keratoplasty, cataract extraction and intraocular lens (IOL) implantation [9], although it has some

disadvantages including expulsive hemorrhage, inadequate cortical cleaning as well as inaccuracy in IOL power calculation [10]. Another treatment is to postpone cataract surgery after penetrating keratoplasty (PKP) in order to attain refractive accuracy [11]. However, this method also has weaknesses including a delay in visual rehabilitation and the risk of endothelial loss [12]. Nevertheless, these surgery treatments in eyes can vary. During cataract surgery, astigmatism can be corrected by prescription glasses, contact lenses, astigmatic keratotomy, laser ablation or toric intraocular lens (IOL) implantation [13]. Among these, toric IOL implantation is the most consistent and effective method for correcting regular astigmatism during cataract surgery. Standard IOL is monofocal offering only fixed focal distance. Therefore, at the differently distanced objects, blur usually occurs [14]. On the other hand, multifocal IOL provides better near and intermediate visual acuity [15 - 16]. However, because of the difficulties related to the post-operative side effects in multifocal IOL implantation, surgeries such as corneal refractive surgery for the trifocal IOL is rare, even though the trifocal IOLs provide better intermediate visual acuity with equivalent distance and near visual acuity than bifocal IOLs [17 - 18]. Moreover, even for eyes undergoing implantation with a trifocal IOL, astigmatism correction may be performed to reduce the postoperative astigmatism. The effect of astigmatism on all-distance visual acuity in eyes with trifocal IOLs has not yet been examined, therefore, in the present study, we have aimed to compare the effect of monofocal and trifocal IOL outcomes of visual acuity in eyes of Mongolian patients.

Materials and Methods

Research design

This study was a retrospective exploratory study undertaken to evaluate the effect of residual refractive astigmatism on VA from far to near distances in eyes implanted with a trifocal IOL or a bifocal IOL.

Fifty-seven patients who underwent implantation of a trifocal IOL (PanOptix, model TFNT00; Alcon Laboratories, Ft. Worth, Texas) and 64 eyes of 57 patients who underwent implantation of a bifocal IOL (ReSTORþ3D, modelSA60D1; Alcon) at least 3 months previously and later were recruited for this study. Only the first-operated eye of each patient was selected. Preoperative exclusion criteria included 1) any pathology of the cornea, macula, or optic nerve; 2) opaque media other than cataract; 3) a history of inflammation or surgery of the eye; 4) corneal astigmatism that was assumed to be 1.0 D or more after surgery; 5) marked irregular corneal astigmatism; 6) corrected distance logarithm of minimal angle resolution (logMAR) VA better than 0.10; 7) patient refusal; and 8) any difficulty with the examinations. Intraoperative exclusion criteria included eventful surgery and the use of pupil expansion procedures for eyes with small pupils. Intraocular lens: Eyes in the trifocal group received the PanOptix trifocal IOL (TFNT00). The TFNT00 is a single-piece aspherical hydrophobic acrylic IOL with an optic diameter of 6.0 mm. The diffractive structure is located within the central 4.5 mm optic zone and consists of 15 concentric steps that divide the incoming light to attain 1.08 D distance, 2.17 D intermediate, and 3.25 D near addition points. Quadrifocal technology is used for this trifocal IOL, and the focal points are N, 1.2, 0.6, and 0.4 m. 7,23 because the light from the first focal point (1.2 m) is diffracted to the distance focal point (N m), however, this IOL acts as a trifocal IOL with distance, intermediate, and near focal points. The eyes in the bifocal group received the ReSTOR bifocal IOL with 3.0 D near addition power (SN6AD1). The SN6AD1 has the same IOL platform as the TFNT00. The diffractive structure is located within the central 3.6 - zone and contains 9 concentric steps of decreasing height, thereby creating bifocality from distance to near dimensions. The surgeons performed a 2.4 mm clear corneal incision or transconjunctival corneoscleral incision according to previously described procedures. A horizontal incision at the 180-degree meridian was made in eyes having against-the-rule and oblique astigmatism, whereas a vertical incision at the 908 meridians was made in eyes having with-the-rule astigmatism.

Statistical analysis

The normality of the data distribution was tested by inspecting a histogram. Categorical variables were compared using the chi-squared test or Fisher probability test where applicable. Comparing the mean of continuous variables between groups, unpaired t-test was carried out. The mean of UCVA, BCVA and visual acuity values for each group at each time were checked for outliers and missing data. 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. The Monofocal IOL and Trifocal IOL groups' differences at each time interval were tested using the independent t-tests. A Bonferroni-type correction was applied to all t-test results resulting in a significance level set at $p < 0.017$ ($p = 0.05/3$). 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

Baseline characteristics of the 57 patients in the phacoemulsification are shown in Table 1. Mean age was 39.26 ± 15.68 and 48.86 ± 20.55 in each group, respectively.

Preoperative uncorrected visual acuity was 6.83 ± 4.61 in monofocal and 17.5 ± 17.55 in trifocal IOL group (Table 2). The mean UCVA were significantly better in the trifocal group than monofocal group. The mean postoperative UCVA at 1 month was 76.36 ± 23.61 in trifocal group, whereas UCVA at the monofocal group was 46.57 ± 24.37.

Preoperative uncorrected visual acuity was 22.03 ± 17.59 in monofocal and 46.82 ± 18.36 in trifocal IOL group. The mean BCVA were significantly better in the trifocal group than monofocal group. The mean postoperative BCVA at 1 month was 89.54 ± 14.63 in trifocal group, whereas UCVA at the monofocal group was 63.14 ± 24.94 (Table 3).

Table 4 shows the visual acuity according to the treatment groups. There was a statistically significant difference between pre-operative and post-operative near BCVA in both groups. In the Trifocal IOL group, the significant difference was observed between pre and post-operative measurements ($p < 0.004$).

Table 1. General characteristics of the study participants.

Variables	Monofocal IOL (n = 35)	Trifocal IOL (n = 22)	Total (n = 57)	p-value
	Mean ± SD	Mean ± SD	Mean ± SD	
Age, year	39.26 ± 15.68	48.86 ± 20.55	42.96 ± 18.16	0.068
	N (%)	N (%)	N (%)	
Gender				
Male	12 (34.3)	7 (31.8)	19 (33.3)	0.731
Female	23 (65.7)	15 (68.2)	38 (66.7)	
Eye				
Right	16 (54.3)	8 (63.6)	33 (57.8)	0.674
Left	19 (45.7)	14 (36.4)	24 (42.2)	

Table 2. Uncorrected visual acuity (UCVA).

Variables	Monofocal IOL[a, b, c] (n = 35)	Trifocal IOL [d, e] (n = 22)	Total (n = 57)	p-value*
	Mean ± SD	Mean ± SD	Mean ± SD	
Pre-operative	6.83 ± 4.61	17.5 ± 17.55	10.94 ± 12.48	0.010
Day one	29.97 ± 18.74	46.82 ± 16.15	36.47 ± 19.48	0.000
First week	35.46 ± 19.45	58.64 ± 20.77	44.40 ± 22.82	0.000
Second week	39.43 ± 18.62	66.36 ± 23.21	49.82 ± 24.24	0.000
One month	46.57 ± 24.37	76.36 ± 23.61	58.07 ± 27.99	0.000

Two-way mixed ANOVA results: Interaction of time and diagnosis F (1.921, 335.36) = 23.182, $p < 0.006$; Main effect of time F (1.810, 319.21) = 321.13, $p < 0.013$; Main effect of diagnosis F(1,173) = 0.431, $p = 0.411$; *Independent t-test, Monofocal IOL vs. Trifocal IOL; Paired t-test: [a]Pre-operative vs. Second week, $p < 0.001$; [b]Day one vs. One month, $p < 0.013$; [c]First vs. One month, $p < 0.071$; [d]Pre-operative vs. One month, $p < 0.004$; [e]Day one vs. One month, $p < 0.001$.

Table 3. Best-corrected visual acuity (BCVA).

Variables	Monofocal IOL [a, b] (n = 35)	Trifocal IOL [c, d] (n = 22)	Total (n = 57)	p-value*
	Mean ± SD	Mean ± SD	Mean ± SD	
Pre-operative	22.03 ± 17.59	46.82 ± 18.36	31.59 ± 21	0.000
Day one	36.4 ± 22.32	58.18 ± 16.51	44.81 ± 22.78	0.000
First week	42.71 ± 20.63	65.91 ± 20.85	51.67 ± 23.48	0.001
Second week	54.00 ± 18.51	76.36 ± 22.79	62.63 ± 22.87	0.004
One month	63.14 ± 24.94	89.54 ± 14.63	73.33 ± 25.02	0.002

Two-way mixed ANOVA results: Interaction of time and diagnosis F (1.922, 341.14) = 21.191, $p < 0.001$; Main effect of time F (1.910, 317.24) = 317.11, $p < 0.015$; Main effect of diagnosis F (1,189) = 0.562, p = 0.562; *Independent t-test, Monofocal IOL vs. Trifocal IOL; Paired t-test: [a]Pre-operative vs. One month, $p < 0.000$; [b]Pre-operative vs. One month, $p < 0.004$; [c]First week vs. One month, $p < 0.000$; [d]Pre-operative vs. Second week, $p < 0.000$.

Table 4. Visual acuity.

Variables	Monofocal IOL [a] (n = 35)	Trifocal IOL [b, c] (n = 22)	Total (n = 57)	p-value*
Pre-operative	11.54 ± 4.19	40.68 ± 26.11	22.78 ± 21.70	0.003
Post-operative	38.00 ± 18.67	87.27 ± 11.20	57.02 ± 29.06	0.006
Post-operative Near BCVA	79.71 ± 17.74	90.91 ± 9.71	84.04 ± 16.02	0.004

Two-way mixed ANOVA results: Interaction of time and diagnosis F (1.834, 234.15) = 22.172, $p < 0.000$; Main effect of time F (1.640, 340.33) = 333.21, $p < 0.041$; Main effect of diagnosis F (1,274) = 0.091, p = 0.201; *Independent t-test, Monofocal IOL vs. Trifocal IOL; Paired t-test: [a]Pre-operative vs. Post-operative Near BCVA, $p < 0.000$; [b]Pre-operative vs. Post-operative, $p < 0.004$; [c]Pre-operative vs. Post-operative Near BCVA, $p < 0.002$.

Discussion

Visual impairments include low vision and blindness refer to any degree of impairment to a person's ability to see that affects his or her daily life. The symptoms occur when one or more eye structure is damaged. There can be reduced acuity, reduced visual fields, reduced ability to see color or contrast as well as difficulty with lighting and glare. Nowadays, there are two main surgical treatments for patients with corneal opacity and cataract. One is to perform simultaneous penetrating keratoplasty, cataract extraction and intraocular lens (IOL) implantation and other one is to postpone cataract surgery after PKP in order to attain refractive accuracy. However, the initiation of phacoemulsification, foldable intraocular lenses, IOL has decreased the incidence of surgically induced astigmatism in cataract patients, there are still 10 - 15 % patients who has more than 1.5 D of keratometric astigmatism or refractive astigmatism.

Phacoemulsification is the procedure where an anterior opening in the lens capsule or capsulorhexis is made, then the lens is emulsified by an ultrasonic hand piece and is then aspirated through a 2.2 – 3.2 mm incision, before an intraocular lens is implanted into the capsular bag. Compared with extracapsular cataract extraction, this procedure advances visual rehabilitation and reduces occurrence of surgical complications such as iris prolapse, or postoperative astigmatism. However, phacoemulsification cataract surgery requires the use of complex phaco machines. Some studies demonstrated that when there is an age-related cataract, complications such as ocular hemodynamics and blood rheology lesions can occure, which in turn shows that vision recovery of patients after cataract phacoemulsification is not ideally achieved. Slabaugh et al. demonstrated that the average preoperative IOP of 16.3 ± 3.6 mm Hg decreased to 14.5 ± 3.4 mm Hg at 1 year ($p < 0.001$). Sixty eyes (38 %) required additional medications or laser for IOP control within the first year postoperatively, or had a higher IOP at postoperative year 1 without medication change. Among eyes without postoperative medication changes (n = 102), higher preoperative IOP ($p < 0.001$), older age (p = 0.006), and deeper anterior chamber depth (p = 0.015) were associated with lower postoperative IOP. Phacoemulsification resulted in a small average decrease in IOP in patients with open-angle glaucoma [19]. Tham et al. also reported that combined phacotrabeculectomy with adjunctive mitomycin C resulted in 0.80 less topical glaucoma drugs ($p < 0.001$) in the 24-month postoperative period compared with phacoemulsification alone. The conclusion is that the combined phacotrabeculectomy

with adjunctive mitomycin C may be marginally more effective than phacoemulsification alone in controlling IOP in medically controlled chronic angle closure glaucoma eyes with coexisting cataract [20].

On the other hand, multifocal IOL results reduced dependency on eyeglasses after surgery. It has been demonstrated however that bifocal IOL cannot fully provides the range of vision and have a drop of visual acuity in the intermediate distance. Compared with bifocal, trifocal IOL provides good uncorrected distance and gives high rate of spectacle freedom. Voskresenskaya et al. presented that postoperatively, monocularly, the uncorrected (UDVA) and the corrected distance visual acuity (CDVA) were 0.74 +/- 0.21 and 0.86 +/- 0.23 respectively ($p < 0.05$). No differences were found between uncorrected (UNVA) - 0.85 +/- 0.13 and best distance-corrected near visual acuity (CNVA) 0.89 +/- 0.12 ($p > 0.05$). But in the case of diffractive trifocal IOL, the percentage of patients achieving spectacle freedom was 94 % and shows high patient satisfaction [18]. Another prospective, non-randomized study by Carballo-Alvarez et al. showed that bilateral trifocal IOL implant achieved a full range of adequate vision, satisfactory contrast sensitivity, and a lack of significant adverse photic phenomena [21].

The limitation of the present study was that the sample size was significantly small. Though, the effect of residual refractive astigmatism should be confirmed in actual postoperative eyes implanted with the trifocal IOL. Further studies are necessary to examine the effect of residual astigmatism on the performance of trifocal IOLs.

Conclusion

From our results, it is evident that post-operative near UCVA and BCVA was statistically significant at monofocal and trifocal groups.

Conflict of Interest

The authors declare that they have no conflict of interest concerning this study.

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