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·Clinical Research·

Visual performance with accommodating and multifocal intraocular lenses

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Abstract
● **AIM: To compare the visual functional outcomes with accommodating and multifocal intraocular lenses (IOLs).**

● **METHODS: Our retrospective comparative study included 51 patients (60 eyes) received implantation of an accommodating IOL (Tetraflex; 16 patients, 20 eyes), a refractive multifocal IOL (ReZoom; 18 patients, 20 eyes), or a diffractive multifocal IOL (ZMA00; 17 patients, 20 eyes). Subjective refraction, visual acuity, contrast sensitivity (CS), intraocular aberration, and subjective photic phenomena were detected at 3mo after surgery.**

● **RESULTS: The spherical equivalent in the three groups was -0.38±0.54 D, 0.14±0.56 D, and 0.35±0.41 D, respectively. No statistically significant differences were found in uncorrected and corrected distance visual acuity and uncorrected intermediate visual acuity among the groups (*P*=0.39). The ReZoom group had significantly better distance-corrected intermediate visual acuity than the ZMA00 group (*P*=0.003). The ZMA00 group had significantly better near visual acuity than the other groups (*P*<0.05). Better contrast sensitivity values were observed in the Tetraflex group under most of the spatial frequencies conditions (*P*=0.025). The total aberration was lowest in the ZMA00 group (*P*=0.000), and the spherical aberration was highest in the Tetraflex group (*P*=0.000). The three groups had similar frequency of ghosting and glare, and the Tetraflex group had a low rate of halos (*P*=0.01).**

● **CONCLUSION: Both accommodating and multifocal IOLs can successfully restore distance and uncorrected intermediate visual acuities. Tetraflex accommodating IOLs perform better in CS and with less halos of photic phenomena. ReZoom refractive multifocal IOLs have better performance in distance-corrected intermediate visual acuity than ZMA00 diffractive multifocal IOLs, and the latter achieved better near visual acuity and efficiently decreased the optical aberration.**

● **KEYWORDS:** intraocular lens; accommodating; multifocal; visual performance

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INTRODUCTION

Visual performance is crucial to daily life. After cataract surgery with traditional monofocal intraocular lens (IOL) implantation, this ability usually declines in near visual acuity for the lack of accommodation. At present, the ultimate postoperative goal is to acquire the whole range of visual acuity with better visual quality. Many sophisticated IOL designs have been introduced to clinical practice, like multifocal and accommodating IOLs, to restore functional vision at the near distance. Multifocal IOLs, which involve refractive or diffractive techniques, have been demonstrated to provide good vision without the use of spectacles. However, optical side effects, including decreased contrast sensitivity, glare disability, and halos, have also been reported[1]. Accommodating IOLs have fewer optical problems, but do not restore the crisp level of near visual acuity that can be found with multifocal IOLs and thus provide a real near focus[2].

One type of accommodating IOLs (Tetraflex) and two types of multifocal IOLs (ReZoom and ZMA00) are used for the treatment of cataract at the Qingdao Eye Hospital, Shandong Eye Institute. The single-piece Tetraflex (Lenstec Inc, St Petersburg, Florida, USA) accommodating posterior chamber IOL, manufactured completely from medical grade hydroxyethylmethacrylate (HEMA, 26% water content), possesses highly flexible, 5° anteriorly angulated "closed loop" haptics, and a 5.75-mm optic with square edges designed to prevent glare effects and reduce the risk of posterior capsular opacification. The lens is inserted through a commercially available 2.2-mm cartridge using standard posterior chamber IOL insertion techniques, which allow for insertion through a small (2.5 to 3.0 mm) clear corneal incision. The originally proposed principal action is an anterior shift in the capsular bag on contraction of the ciliary muscle and/or change of vitreous pressure, which could supply 2 to 3 diopter (D) of accommodation ability[3-5]. The ReZoom (Advanced Medical Optics, Santa Clara, California, USA) refractive multifocal IOL is comprised of a hydrophobic acrylic material with angulated, modified C polymethylmethacrylate monofilament haptics. It has five concentric refractive zones alternating for distance and near vision, with aspheric transitions that allow for intermediate vision. Zones 2 and 4 are near dominant and provide 3.5 D near add power at the IOL plane and 2.57 D at the spectacle plane. The distribution of light is dependent on pupil size. With a 2-mm pupil, approximately 83% of light is directed to the distant focus and 17% to the intermediate focus; with a 5-mm pupil, approximately 60% of light is directed to the distance focus, 30% is directed to the near focus, and 10% is directed to the intermediate focus. The optical part of the Tecnis ZMA00 (Advanced Medical Optics, Santa Clara, California, USA) diffractive multifocal lens is made from hydrophobic acrylic with a refractive index of 1.47, which is a three-piece IOL with a biconvex design. The anterior surface is a wavefront aspheric design, whereas the posterior surface is diffractive with 29 concentric circles. The light entering the IOL is split equally into a distance and near focus (4.00 D add, approximately 3.00 D at the spectacle plane) independent of pupil size. All of the three IOLs block ultraviolet radiation but allow the passage of blue light, which is fundamental to good scotopic sensitivity[6].

The aim of this study was to evaluate and compare the clinical performance of the three kinds of IOLs in presbyopic patients by examining subjective refraction, visual acuity, CS, intraocular aberrations and subjective photic phenomena.

SUBJECTS AND METHODS

This retrospective, comparative study was approved by the Ethics Committee of Shandong Eye Institute and conformed to the tenets of the Helsinki Declaration. Fifty-one patients (60 eyes) with visually significant cataracts treated by cataract surgery and IOL implantation at our institution were collected in this study. The exclusion criteria included corneal astigmatism over 1.0 D, ocular pathologies such as amblyopia, corneal dystrophy, keratoconus, retinopathy, glaucoma, ocular atrophy, iris atrophy, uveitis, retinal dystrophy, and conditions after retinal detachment, and previous ocular surgery. The operations were performed under local anesthesia by one experienced surgeon. A 2.8-mm clear corneal incision was placed temporally, paranasally or near the axis of corneal astigmatism, after a continuous and intact circular-tear capsulorrhexis, not larger than 5.5 mm in diameter, was made. Irrigation and aspiration of the cortex and IOL implantation in the capsular bag were performed. Patients with complications like capsular rupture, zonulysis, and obvious posterior capsule opacification during the follow-up were also excluded. The patients were divided into 3 groups according to the types of their implanted IOLs. As a retrospective study, the grouping procedure was non-randomized. In group A, 16 patients (20 eyes) received implantation of an accommodating IOL (Tetraflex, model KH-3500), with the postoperative refraction targeted as 0 to -0.50 D according to the IOL manufacturer's recommendations. In group B, 18 patients (20 eyes) received implantation of a refractive multifocal IOL (ReZoom, model NXG1). In group C, 17 patients (20 eyes) were implanted with a diffractive multifocal IOL (Tecnis, model ZMA00). The postoperative refraction target in these two groups was 0 to +0.25 D, following the manufacturer's recommendations.

The follow-up was more than 3mo. All examinations were carried out under photopic light conditions. The distance manifest refraction was measured by an auto refractometer (Canon R-50, Canon, Tokyo, Japan). The uncorrected and best corrected distance visual acuities were measured by a phoropter (Topcon ACP-8, Tokyo, Japan).

Monocular photopic and mesopic contrast sensitivities (CS) were measured with best distance correction. CS function was measured using the functional acuity contrast test, under two illumination conditions (photopic and mesopic). The chart luminance was 85 cd/m^2 (photopic, the luminance recommended in the manufacturer's guidelines) and 5 cd/m^2 (mesopic) room illumination with or without glare which included 4 conditions altogether. Patients were allowed to adapt to each level for 5min before the testing. Wavefront measurements were performed with the Zywave aberrometer (Bausch & Lomb, Rochester, NY, USA) under about 6 mm pupil diameter to evaluate total, high-order, and spherical aberration.

Subjective visual quality was evaluated based on Miguel's questionnaire[7]. We estimated the presence and frequency of undesirable photic phenomena such as ghosting around letters, glare, and halos.

Statistical Analysis Data analysis was performed using SPSS statistical package (version 17.0). Categorical variables (sex construction and subjective visual quality) were compared with the χ^2 test. Individual logarithms of the minimum angle of resolution (logMAR) visual acuities were statistically averaged. Normality of all data samples was evaluated by means of the Kolmogorov-Smirnov test. When parametric analysis was possible and variances were homogeneous (checked by the Levene test), the one-way analysis of variance (ANOVA) with Bonferroni post-hoc comparison was used among the groups. If variances were neither normal nor homogeneous, the Kruskal-Wallis test with Mann-Whitney post-hoc comparison was used to compare the analyzed parameters among the groups. Results were expressed as mean±standard deviation (SD), and a P value less than 0.05 was considered statistically

Table 1 Demography and postoperative outcomes at 3mo after cataract surgery in patients who underwent IOL implantation

Demography /postoperative visual acuity	Tetraflex group	ReZoom group	ZMA00 group	*P*
Ratio (male/female)	11/5	12/6	13/4	0.80
Age (a)	54.00±10.96	52.53±11.38	53.90±13.00	0.86
Sphere (D)	-0.15±0.65	0.36±0.65	0.58±0.27	0.002[a]
Cylinder (D)	-0.49±0.58	-0.41±0.47	-0.45±0.89	0.64
Spherical equivalent (D)	-0.38±0.54	0.14±0.56	0.35±0.41	0.000[a]
UDVA (logMAR)	0.06±0.06	0.03±0.10	0.04±0.10	0.53
CDVA (logMAR)	-0.07±0.07	-0.06±0.09	-0.08±0.09	0.70
UIVA (logMAR)	0.33±0.16	0.30±0.10	0.35±0.13	0.39
DCIVA (logMAR)	0.33±0.14	0.29±0.09	0.42±0.11	0.004[a]
UNVA (logMAR)	0.40±0.10	0.35±0.11	0.05±0.15	0.000[a]
DCNVA (logMAR)	0.40±0.10	0.31±0.10	0.02±0.09	0.000[a]
CNVA (logMAR)	0.03±0.11	-0.02±0.11	-0.05±0.10	0.049[a]

UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; UIVA: Uncorrected intermediate visual acuity; DCIVA: Distance-corrected intermediate visual acuity; UNVA: Uncorrected near visual acuity; DCNVA: Distance-corrected near visual acuity; CNVA: Corrected near visual acuity. [a]$P<0.05$.

significant. When the multiple comparisons were carried out by Mann-Whitney test, using the same level of significance (α=0.05) directly may result in too high type I error probability. To avoid it, Bonferroni adjustment method was used to adjust α level. In this report, the significance level should have been α/3 (α/number of compare times) as 0.017 in subgroup comparisons.

RESULTS

General Information and Visual Outcomes The patients were followed for 5.26±1.69mo (range, 3.2 to 10.4mo). No statistically significant differences in male versus female ratio (Chi-square, *P*=0.80) and age (one-way ANOVA, *P*=0.86) were present among the three groups. Table 1 summarizes the demography and postoperative conditions of the eyes implanted with different IOLs. The sphere (Mann-Whitney with Bonferroni correction, *P*=0.008, 0.002) and spherical equivalent (Bonferroni, *P*=0.007, 0.000) in the Tetraflex group were statistically lower than the other groups, but the cylinder was not significantly different (Kruskal-Wallis, *P*=0.64). Regarding the visual data, no statistically significant differences were found in uncorrected and corrected distance visual acuity and uncorrected intermediate visual acuity among the groups (one-way ANOVA, *P*=0.53, *P*=0.70, *P*=0.39). The intermediate acuity (uncorrected and best distance corrected) at 60 cm and the near acuity (uncorrected, best distance corrected, and best corrected) were measured by the 40 cm visual acuity chart (Cardiff Acuity Chart). Transferred denominator of Snellen visual acuity at a distance =[the chart distance from patient's eye (cm)/40]×the denominator of Snellen visual acuity line identified at the 40 cm chart. In distance-corrected intermediate visual acuity (DCIVA), uncorrected near visual acuity (UNVA), distance-corrected near visual acuity (DCNVA) and corrected near vision acuity (CNVA), significant differences were found (one-way ANOVA, *P*=0.004, *P*=0.000, *P*=0.000, *P*=0.049) among the 3 groups. DCIVA in eyes implanted with the ReZoom IOL was significantly better than those with the ZMA00 IOL (Bonferroni, *P*=0.003). UNVA in eyes implanted with the ZMA00 IOL was significantly better than those with Tetraflex IOL (Bonferroni, *P*=0.000) and those with ReZoom IOL (Bonferroni, *P*=0.000). DCNVA was improved in all eyes, most significantly in eyes with ZMA00 IOL and least significantly in eyes with Tetraflex IOL (Bonferroni, Tetraflex group *vs* ReZoom group, *P*=0.015, ReZoom group *vs* ZMA00 group, *P*=0.000, and Tetraflex group *vs* ZMA00 group, *P*=0.000). And CNVA in eyes implanted with the ZMA00 IOL was significantly better than those with the Tetraflex IOL (Bonferroni, *P*=0.046).

Contrast Sensitivity Outcomes The CS values are plotted as the form of lgCS in Figure 1, showing distance CS functions at the 2 luminance levels. No statistically significant differences were found in the groups for the spatial frequency of 1.5 cycles/degree (c/d) in photopic without glare (one-way ANOVA, *P*=0.057), and the spatial frequency of 1.5, 3, 18 c/d in mesopic with glare condition (one-way ANOVA, *P*=0.31, *P*=0.25; Kruskal-Wallis, *P*=0.10). A trend toward better CS values was observed for those eyes implanted with the Tetraflex IOL for the spatial frequency of 3, 6, 18 c/d in photopic without glare, 12, 18 c/d in photopic with glare, 1.5, 3, 6, 12, 18 c/d (all of the spatial frequencies) in mesopic without glare, and 12 c/d in mesopic with glare conditions (Bonferroni, Mann-Whitney with Bonferroni correction, *P*=0.025). Another trend toward worse CS values was also observed for those eyes implanted with the ZMA00 IOL for the spatial frequency of the rest conditions (Mann-Whitney with Bonferroni correction, *P*=0.043).

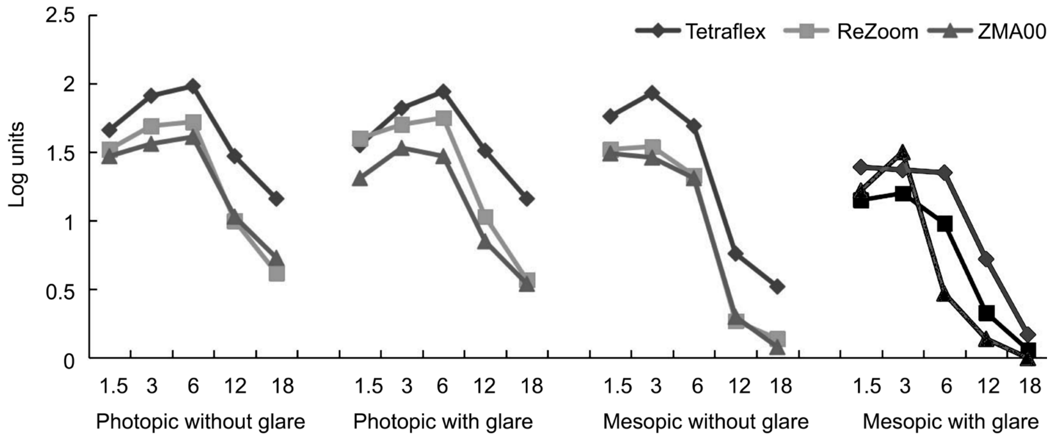

Figure 1 Contrast sensitivity showed as the mean of lgCS in photopic and mesopic with/without glare conditions.

Table 2 Results of wavefront errors

Aberrations	Tetraflex group	ReZoom group	ZMA00 group	*P*
Total aberrations RMS (μm)	2.10±0.59	1.99±0.56	1.33±0.31	0.000[a]
High-order aberrations RMS (μm)	0.93±0.29	0.81±0.31	0.74±0.25	0.11
Spherical aberrations RMS (μm)	0.40±0.15	0.16±0.10	0.14±0.13	0.000[a]

RMS: Root-mean-square. [a]$P<0.05$.

Intraocular Aberrations Table 2 shows the total aberration, high order aberrations, and spherical aberrations results of eyes in the three groups. The total aberration of the ZMA00 group was statistically lower than the other groups (Mann-Whitney with Bonferroni correction, ZMA00 group *vs* Tetraflex group, *P*=0.000; ZMA00 group *vs* ReZoom group, *P*=0.000). The spherical aberration in the Tetraflex group was statistically highest (Bonferroni, Tetraflex group *vs* ReZoom group, *P*=0.000; Tetraflex group *vs* ZMA00 group, *P*=0.000). However, a trend toward lower high-order aberrations was observed with the ZMA00 IOL, but no statistically significant differences were found due to the significant variability observed in the outcomes (one-way ANOVA, *P*=0.11).

Subjective Visual Quality The items of subjective visual qualities are listed in Table 3. There was no statistically significance between the three groups in ghosting (*P*=0.46) and glare (*P*=0.76), whereas statistically significant difference was found in halos (*P*=0.01). Sixty-five percent (13/20) of patients in the Tetraflex group did not suffer the problem of halos, which compared with 30% (6/20) in the ReZoom group and 20% (4/20) in the ZMA00 group. Further pairwise comparison revealed statistically significant differences between the Tetraflex and ReZoom groups (*P*=0.04) and the Tetraflex and ZMA00 groups (*P*=0.00) in terms of halos.

Table 3 Postoperative subjective visual quality *n*

Items	Tetraflex group	ReZoom group	ZMA00 group	*P*
Ghosting around letters				0.46
None	14	10	11	
Sometimes	5	6	4	
Often	1	3	2	
Always	0	1	3	
Glare				0.76
None	8	11	7	
Sometimes	8	5	11	
Often	3	2	2	
Always	1	2	0	
Halos				0.01[a]
None	13	6	4	
Sometimes	3	11	15	
Often	3	3	1	
Always	1	0	0	

[a]$P<0.05$.

DISCUSSION

Patients usually have a variety of preferences and needs with regard to their daily life. As conventional monofocal IOLs fail to supply enough postoperative near visual acuity, they have to rely on reading spectacles or magnifying glass which could make the near-seeing easier. Refractive and diffractive technologies have been introduced into IOL production to provide multiple focuses for restoring near visual acuity. By this means the new multifocal IOLs could increase the depth of field in the eye and have better near vision performance even intermediate vision[8-10]. Yet many deficiencies such as the induction of halos and glare and the decline of CS[11-13] caused by a simultaneous superimposition of images on the retina remain to be made up. There is a great interest among ophthalmologists to provide cataract surgical candidates with the option of an IOL that can offer clear vision at the full range with higher CS. Therefore, besides the multifocal IOL, the accommodative IOL with proposed principal action as an anterior shift on contraction of the ciliary muscle[14] has been designed to match that demands. It was reported that this IOL can improve the whole range vision and CS simultaneously[15-16].

As reported in previous studies[5,17-18], a significant improvement in visual performance was observed with the three IOL models. In this study the three groups had similar performances in distance and some part of intermediate visual acuities, and DCIVA performed statistically worse in the ZMA00 group than in the ReZoom group, revealing little near-add and refractive design may be useful in promoting intermediate visual acuity. Near visual acuity was better in the ZMA00 IOL with statistical significance than the other IOLs, also revealing more near-add and diffractive design may be useful in promoting near visual acuity. Sanders[5] listed that the Tetraflex accommodative IOL could restore functional near vision while giving the patient high-quality intermediate and distance vision. Muñoz[19] summarized photopic visual acuity reported by different authors and did some tests, which showed better near vision with diffractive designs than with the refractive ReZoom IOL, but better intermediate vision with the ReZoom IOL, which was the unique characteristics inherent to each of the three presbyopia-correcting IOL implants.

Because of dividing light power for 2 or more foci[20-21], multifocal IOLs have lower sensitivity contrast compared with accommodating IOLs, which with an optic shift mechanism provide the whole range vision with no light distribution as only 1 optical focus simultaneously[15,22-23]. In our study, the eyes with Tetraflex IOLs showed statistically higher scores than those with the two kinds of multifocal IOLs at most spatial frequencies. The ZMA00 diffractive multifocal IOL showed lower scores, which might be concerned with more light power distribution. So the results reported here for the multifocal IOL agreed with this statement. The similar results could be found in the study of Pepose *et al*[24], which were considered to be attributed to the simultaneous distribution of light energy between near and far, with some loss to higher diffraction orders with the apodized diffractive IOL and a distribution of the light energy continuum between near, intermediate, and far with the zonal refractive multifocal IOL. Given the multifocal IOL is pupil dependent, Muñoz *et al*[19] considered that the role of pupil size was significant in the visual performance of multifocal IOLs, and the increase in pupil size under mesopic conditions worsened distant CS as more light was focused through the near-distance zones.

According to the previous studies[25-26], the diffractive multifocal IOLs could induce less spherical aberrations which would increase depth of focus compared to other monofocal IOLs. Kim *et al*[27] found great changes of the ReZoom refractive multifocal IOL in spherical aberration as the pupil size changed and large amounts of higher-order spherical aberrations (8th and 10th orders), which were the results of the optical design of this multifocal IOL by alternating distance and near refractive zones along with intermediate transitional zones. Total root-mean-square (RMS) and higher-order RMS, mainly coma and spherical aberrations were considerably higher with the refractive multifocal IOL compared to a diffractive model in a report by Zelichowska *et al*[28]. Santhiago *et al*[29] reported similar values of high-order aberrations, coma, and SA to those found in the present study on a large sample of eyes implanted with the ReZoom IOL; these values were also higher than those obtained in eyes with diffractive multifocal IOLs, which displayed significantly higher modulation transfer function (MTF) values than the ReZoom for a 5-mm pupil diameter. Wolffsohn *et al*[30] found the pupil size decreased and ocular aberrations changed with increased accommodative demand. The results in our current study were consistent with the previous reports. Moreover, a higher value of spherical aberration at 6.0 mm was achieved in this study demonstrating the greater sphericity of the peripheral part of the IOL compared with the central apodized diffractive part. The discrepancy from the reports may be due to measurement variability, differences in manufacturing error and pupil diameter.

Visual quality can be increased in patients implanted with accommodating or multifocal IOLs. However, photic phenomena are often observed. Previous studies showed a higher rate of incidence in refractive multifocal IOLs[7,30] in comparison with our series. This may be explained by the benefits of more concentric refractive zones and aspheric design in this new generation refractive IOLs. Moreover, halos were more frequent in multifocal IOLs, which may be caused by the distribution of light energy.

In summary, compared to different multifocal IOLs, patients implanted with accommodating IOL may have similar distance and intermediate visual acuities. But the ZMA00 diffractive multifocal IOL performs better in near visual acuity, and the ReZoom refractive multifocal IOL shows statistically better DCIVA than the ZMA00 diffractive multifocal IOL. The Tetraflex accommodating IOL has an obviously high score in sensitivity contrast and fewer postoperative halos, and the ZMA00 diffractive multifocal IOL can reduce total RMS.

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