

Visual Performance Following Bilateral Implantation of Refractive Rotationally Asymmetric Bifocal Intraocular Lens (LS-313 MF30) or Apodized Diffractive Bifocal Intraocular Lens (ReSTOR SN6AD1)

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Purpose: This study compared the clinical outcomes after cataract surgery with implantation of refractive rotationally asymmetric bifocal intraocular lens (IOL) (LS-313 MF30) and apodized diffractive bifocal IOL (ReSTOR SN6AD1).

Methods: This was a prospective, non-randomized, controlled study, where patients diagnosed with age-related cataracts were selected for phacoemulsification combined with bilateral IOL implantation. Based on the type of IOL voluntarily implanted, the patients were divided into two groups, ie, refractive and diffractive groups. In total, 30 cases (60 eyes) were in a refractive group, while 30 cases (60 eyes) were in diffractive group. Three months after surgery, we examined the uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA), uncorrected near visual acuity (UNVA), defocus curve, objective visual quality, and subjective questionnaire.

Results: Three months after surgery, the UIVA of the refractive group (0.18 ± 0.08) logMAR was better than that of the diffractive group (0.29 ± 0.16) logMAR ($P < 0.05$). No significant difference in UDVA and UNVA was noted between the two groups. For a 4mm pupil diameter, the intraocular and total eye aberration, higher-order aberration (HOA), coma, spherical aberration, and trefoil in the refractive group were significantly higher than those in diffractive group ($P < 0.05$). The intraocular modulation transfer function (MTF), intraocular strehl ratio (SR), total eye MTF, and total eye SR in the refractive group were lower than those in diffractive group ($P < 0.05$). No significant difference in glare incidence, spectacle independence rate, and patient satisfaction was observed between the two groups ($P > 0.05$). The halos incidence in the refractive group was lower than the diffractive group ($P < 0.05$).

Conclusion: Both bifocal IOLs obtained satisfactory UDVA and UNVA, with higher patient satisfaction. Unlike the apodized diffractive bifocal IOL, the refractive rotationally asymmetric bifocal IOL yielded slightly better UIVA, lower halos incidence, whereas the apodized diffractive bifocal IOL showed a better objective visual quality.

Keywords: refractive rotationally asymmetric, apodized diffractive, intraocular lens, visual quality

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Introduction

With the continuous advancement of phacoemulsification technology, cataract surgery has gradually developed to refractive surgery. Traditional monofocal IOL has

only one fixed focus, causing the loss of accommodation after implantation.¹ Based on different optical principles, different multifocal intraocular lens (MIOL) are designed, which are primarily divided into refractive MIOL, diffractive MIOL, and diffractive refractive MIOL. MIOL provides a clear vision at different distances and a better near vision than single focus IOL with significant success in clinical practice.² Nonetheless, the decreased contrast sensitivity of MIOL and the high incidence of photic phenomena including halos and glare potentially influence visual quality and patient satisfaction after MIOL.³

Refractive rotationally asymmetric MIOL is a novel type of MIOL, with a rotational asymmetric design. IOL combines distant vision provided by the larger fan-shaped area above and near vision provided by the smaller +3D sector-shaped refractive surface below with a smooth transition between the two areas. Theoretically, refractive rotationally asymmetric MIOL lacks a concentric ring for refraction or diffraction, and the light passing through the transition region is reflected to the area far away from the optical axis. Therefore, the occurrence of photic phenomena including glare and halos can be minimized.^{4,5} To our knowledge, the visual performance of refractive rotationally asymmetric MIOL (LS-313 MF30) and apodized diffractive MIOL (ReSTOR SN6AD1) has not been compared.

This paper aims to compare the clinical efficacy of the two types of MIOL to provide clinical guidance for the selection of MIOL.

Patients and Methods

A prospective, non-randomized, controlled study was conducted on patients with age-related cataracts treated in Qingdao Eye Hospital between June 2019 and September 2020. The characteristics of MIOL were comprehensively introduced to the patients. Based on the type of IOL voluntarily implanted, the patients were subdivided into two groups including refractive and diffractive groups. This study followed the principles of the Helsinki Declaration and was approved by the Ethics Committee of Qingdao Eye Hospital. All patients signed the informed consent form to the treatment plan with a clinical trial registration number of ChiCTR1900022818.

The inclusion criteria included (1) axial length (AL) ≥ 22 mm and ≤ 26 mm; (2) preoperative corneal astigmatism ≤ 1.0 D; and (3) 4 mm pupil diameter total HOA $< 0.3 \mu\text{m}$.

Meanwhile, the exclusion criteria included (1) previous history of ophthalmic surgery; (2) amblyopia; (3) chronic or recurrent uveitis; (4) progressive retinopathy; (5)

glaucoma; (6) corneal disease; (7) maculopathy (based on optical coherence tomography).

Intraocular Lens

LS-313 MF30 (Oculentis Co., Germany) adopted a one-piece plate loop bifocal IOL design with a total length of 11.0mm and optical diameter of 6mm. Unlike the previous concentric circular multifocal intraocular lens, its optical region exhibited two sector-shaped regions, ie, the larger region was the far-sighted region while the smaller area was the near-sighted region with additional + 3D, and a transition zone between them. Through the spectroscopic principle, the light was divided into two focal points to see far and near (Figure 1A).

Restor SN6AD1 (Alcon Co., USA) aspheric apodized diffractive bifocal IOL with +3.0 D near addition power, which uses the principle of Huygens-Fresnel diffraction and refraction had an optical diameter of 6mm. The diameter of the central diffraction region was 3.6mm comprising nine concentric micro-slope rings. The height decreased step by step from the middle to the periphery, the width gradually narrowed, while the periphery gradually changed into a refractive zone. The higher part of the slope ring focused on the light to the near focus. The lower part focused on the light to the far focus and the separation of the far (Figure 1B).

Preoperative Examination

All patients underwent comprehensive preoperative ophthalmological examination, including UDVA, axial length, anterior chamber depth, corneal curvature, measured by optical biometric instrument (OA-2000, Tomey Co., Japan), slit-lamp examination, intraocular pressure, funduscopy, corneal endothelial count, optical coherence tomography, Pentacam (Oculus Co., Germany). The power of IOL was calculated using Barrett Universal II, the target refractive state was emmetropia, while the degree of IOL was in the range of ± 0.25 D.

Surgical Procedures

The standard phacoemulsification was performed by one experienced operator (WXM) in both groups. The incision was 2.2mm transparent corneal incision, the diameter of the capsulorhexis was 5.0–5.5 mm, phacoemulsification, the residual cortex was removed by I/A, IOL was placed in the capsule bag, and the near-sighted region of LS-313 MF30 was placed below.

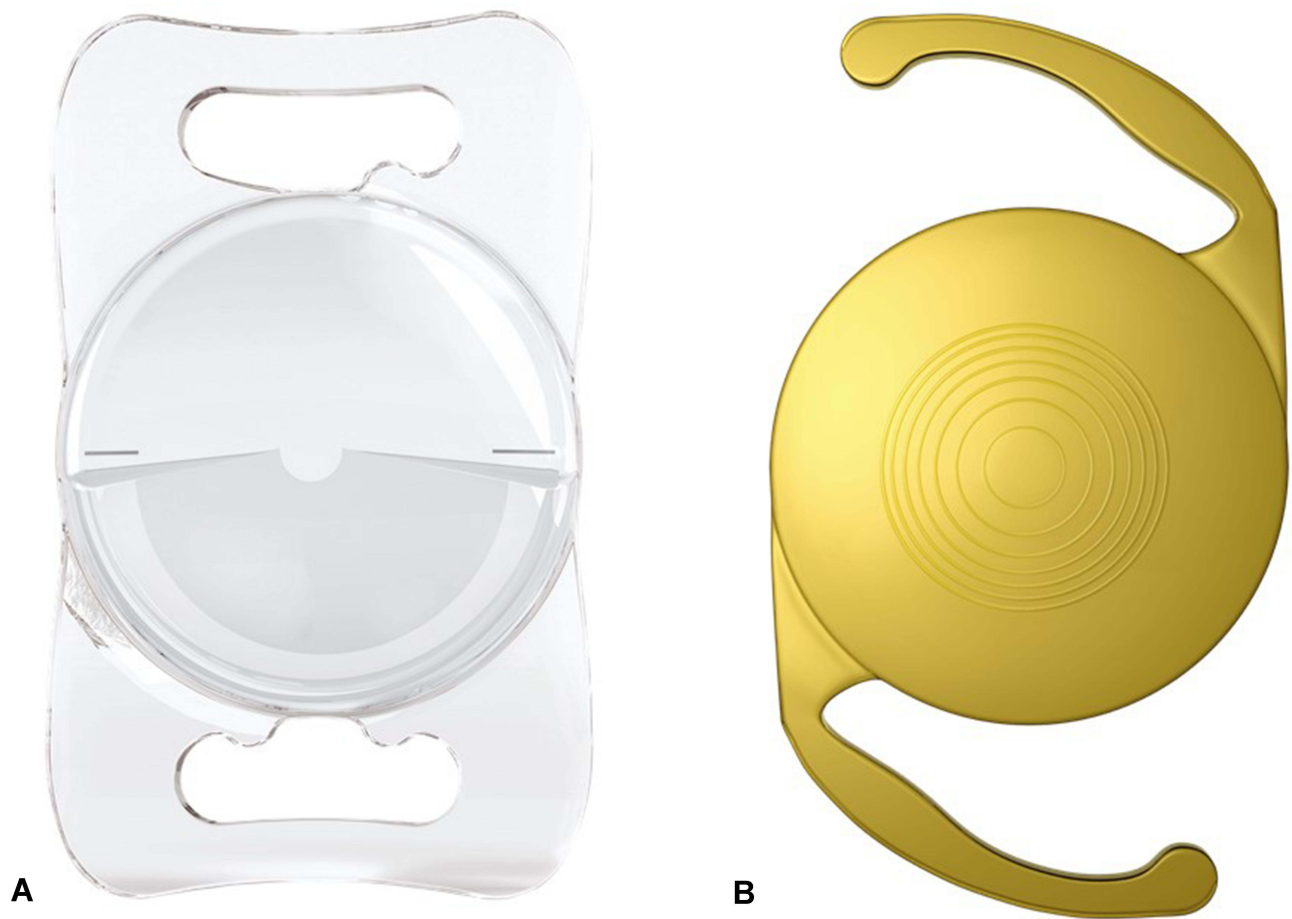


Figure 1 Two models of multifocal intraocular lens. (A) Refractive rotationally asymmetric bifocal intraocular lens (LS-313 MF30); (B) Apodized diffractive bifocal intraocular lens (ReSTOR SN6AD1).

Postoperative Examination

Three months after surgery, the UDVA, UIVA, and UNVA of the patients were examined, where the examination distance of UDVA, UIVA, and UNVA was 4m, 80cm, and 40cm, respectively. Refraction, defocus curve, objective visual quality and subjective questionnaire including Visual Functioning Questionnaire-14⁶ were examined and objective visual quality were measured by iTrace (Tracey Company, USA). All the postoperative examinations were performed by the same person and the examiner did not know the type of IOL implanted in the patient.

Data Analysis

SPSS (version 22.0; SPSS, Inc., Chicago, IL) statistical software was used for data analysis. The data between the two groups were compared, where the chi-square test was used for classified data, Kruskal–Wallis test was used for measurement data to check whether the data conformed to a normal distribution, while independent sample *t*-test was used if normal

distribution was satisfied; otherwise, Mann–Whitney *U*-test was used. $P < 0.05$ was considered statistically significant.

Results

In total, 30 cases (60 eyes) were implanted with LS-313 MF30, while 30 cases (60 eyes) were implanted with Restor SN6AD1. No intraoperative and postoperative complications were reported. Moreover, no significant difference in age, gender, laterality, preoperative CDVA, corneal curvature, axial length, anterior chamber depth, and power of IOL implantation was noted between the two groups ($P > 0.05$) (Table 1).

Visual and Refractive Outcomes

Three months after surgery, no significant difference in sphere, cylinder, and spherical equivalent was found between the two groups, and no significant difference in UDVA, UNVA, and CDVA was observed between the two groups ($P > 0.05$). The UIVA of the refractive group was

Table 1 Preoperative Conditions of the 2 Groups of Eyes

	Refractive	Diffraction	P value
Patients/Eyes(n)	30/60	30/60	–
Male/Female(n)	14/16	13/17	>0.99+
Age (years)	59.41±7.04	58.25±8.79	0.60*
UDVA(logMAR)	0.53±0.24	0.62±0.31	0.35**
AL(mm)	23.73±0.94	23.89±0.94	0.48**
K1	43.94±1.17	43.4±1.23	0.15**
K2	44.52±1.08	44.1±1.34	0.19**
ACD	3.25±0.29	3.35±0.44	0.19**
IOL power	19.22±2.67	19.85±2.88	0.66**

Notes: + χ^2 test; *t-test; **Mann-Whitney U-test.

Abbreviations: UDVA, uncorrected distance visual acuity; AL, axial length; ACD, anterior chamber depth; IOL, intraocular lens.

0.18 ±0.08, while that of the diffractive group was 0.29 ±0.16. Notably, the UIVA of the refractive group was better than that of the diffractive group (Table 2). Figure 2 shows the percentage of eyes with a UDVA, UNVA, and UIVA of 0.3 logMAR or better between the two groups. Diffractive group had a limitation in UIVA.

Defocus Curve

Three months after surgery, the wave peaks of the eyes in the refractive group appeared at 0D and -3D, stable in the range between 0D and -3D, and slightly decreased in the range from -3.0D to -5.0D. The peaks in the diffractive group appeared at 0D and -3D, and the fluctuation in the range from 0D to -3D in the apodized diffractive group was more apparent than that in the refractive group. The curve decreased rapidly in the range of -3.0D to -5.0D (Figure 3).

Objective Visual Quality

For a 4mm pupil diameter, the intraocular and total eye aberration, HOA, coma, spherical aberration, and trefoil in

Table 2 Postoperative Visual and Refractive Outcomes in the 2 Groups

	Refractive	Diffraction	P value
Sphere (D)	-0.25±0.16	-0.13±0.12	0.63**
Cylinder (D)	-0.31±0.2	-0.11±0.16	0.12**
SE (D)	-0.41±0.15	-0.28±0.14	0.15**
UDVA (logMAR)	0.07±0.08	0.04±0.06	0.36**
CDVA (logMAR)	0.02±0.06	0.01±0.05	0.58**
UIVA (logMAR)	0.18±0.08	0.29±0.16	0.02**
UNVA (logMAR)	0.13±0.08	0.17±0.09	0.11**

Note: **Mann-Whitney U-test.

Abbreviations: UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity; SE, spherical equivalent; D, diopter.

the refractive group were significantly higher than those in diffractive group ($P < 0.05$) (Figure 4). The intraocular MTF, intraocular SR, total eye MTF, and total eye SR in the refractive group were lower than those in diffractive group ($P < 0.05$) (Figure 5) (Table 3).

Subjective Questionnaire Survey

In the refractive group, 36.67% of the eyes showed glare compared to 43.33% in the diffractive group ($P=0.79$). The halos were present in 36.67% of the eyes with a refractive rotationally asymmetric IOL and 66.67% of the eyes with an apodized diffractive IOL ($P=0.04$). The halos were more frequent than glare in diffractive groups (Figure 6).

In the refractive group, 96.67% reported no need of spectacles for far distance compared to 96.67% in the diffractive group ($P=0.99$), 63.33% for intermediate distance compared to 40.0% in the diffractive group ($P=0.12$) and 86.67% for near distance compared to 83.33% in the diffractive group ($P=0.99$) (Figure 7).

The Visual Functioning Questionnaire-14 for evaluation of the difficulty in performing vision-related activities demonstrated no significant difference in any parameter between the two groups ($P > 0.05$) (Table 4). 93.33% of the patients with refractive rotationally asymmetric IOL were satisfied, compared to 90% of the patients with apodized diffractive IOL ($P=0.99$).

Discussion

The primary purpose of MIOL is to obtain ideal clinical efficacy after cataract surgery, achieving satisfactory distance, intermediate, and near vision. At present, two types of MIOL are used clinically, ie, rotational symmetrical MIOL and rotational asymmetric MIOL. Rotational symmetric MIOL has been widely investigated and evaluated, however, the resulting visual interference limits its application.^{7,8} For instance, patients with diffractive MIOL implantation might have many types of photic phenomena, including decreased contrast sensitivity, glare, or halos.⁹ By comparing the clinical visual effects of different models of MIOL, it may be helpful for ophthalmologist to select the appropriate IOL according to the needs of the patients. Herein, subjective and objective visual quality were compared between refractive rotationally asymmetric bifocal IOL (LS-313 MF30) and apodized diffractive bifocal IOL (ReSTOR SN6AD1). We found that refractive rotationally asymmetric bifocal IOL had better UIVA, lower halos incidence, whereas the apodized diffractive bifocal IOL showed a better objective visual quality.

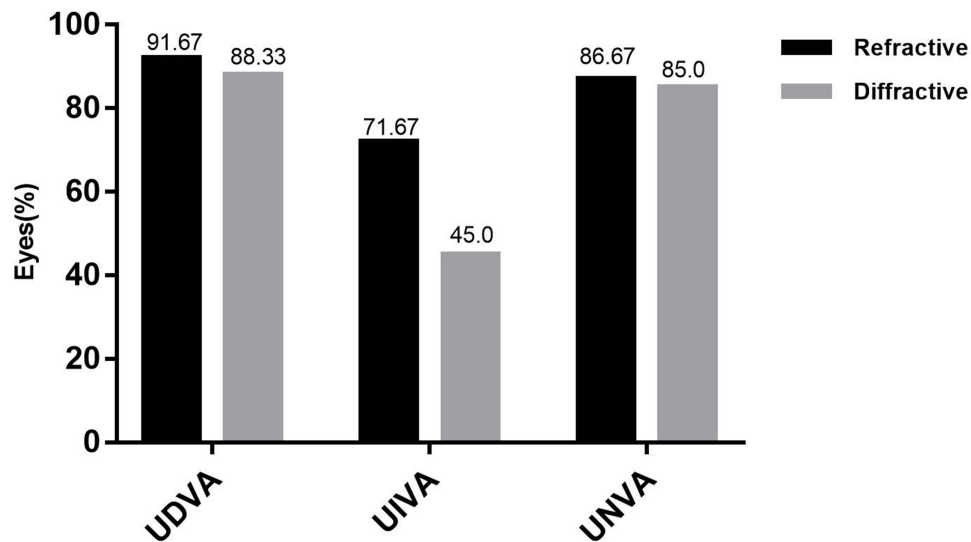


Figure 2 Percentage of eyes with a postoperative UDVA, UNVA, and UIVA of 0.3 logMAR or better by group.

Abbreviations: UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity.

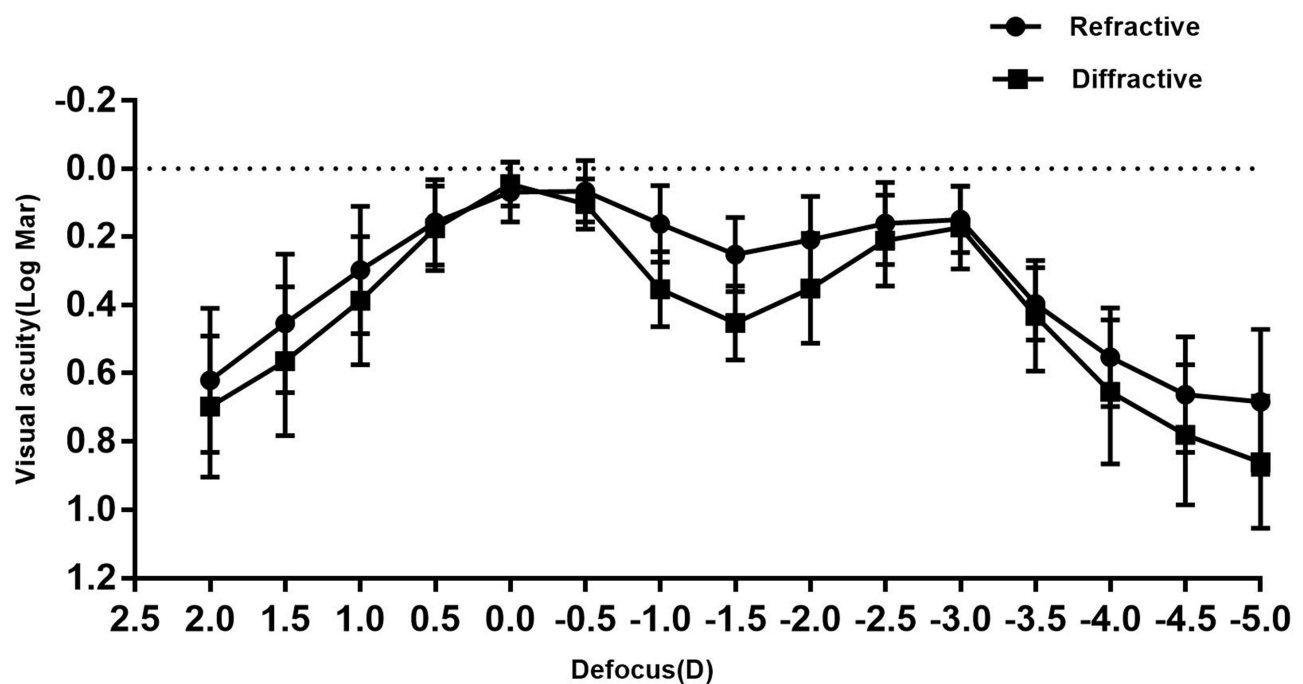


Figure 3 Mean defocus curve in the 2 groups of eyes 3 months after cataract surgery.

Refractive group showed slightly better UIVA than diffractive group. LogMAR value of the refractive group (0.18 ± 0.08) was significantly lower than that of the diffractive group (0.29 ± 0.16), confirming that the refractive rotationally asymmetric bifocal IOL provides a better UIVA than the apodized diffractive bifocal IOL. The

results were consistent with the previous findings of rotationally asymmetric and diffractive MIOL.^{10–12} Wang et al¹⁰ reported that rotationally asymmetric MIOL (SBL-3) provided better UIVA and wider range of intermediate vision than apodized diffractive MIOL (SN6AD1). Alio et al¹¹ also found that refractive MIOL (Lentis Mplus LS-

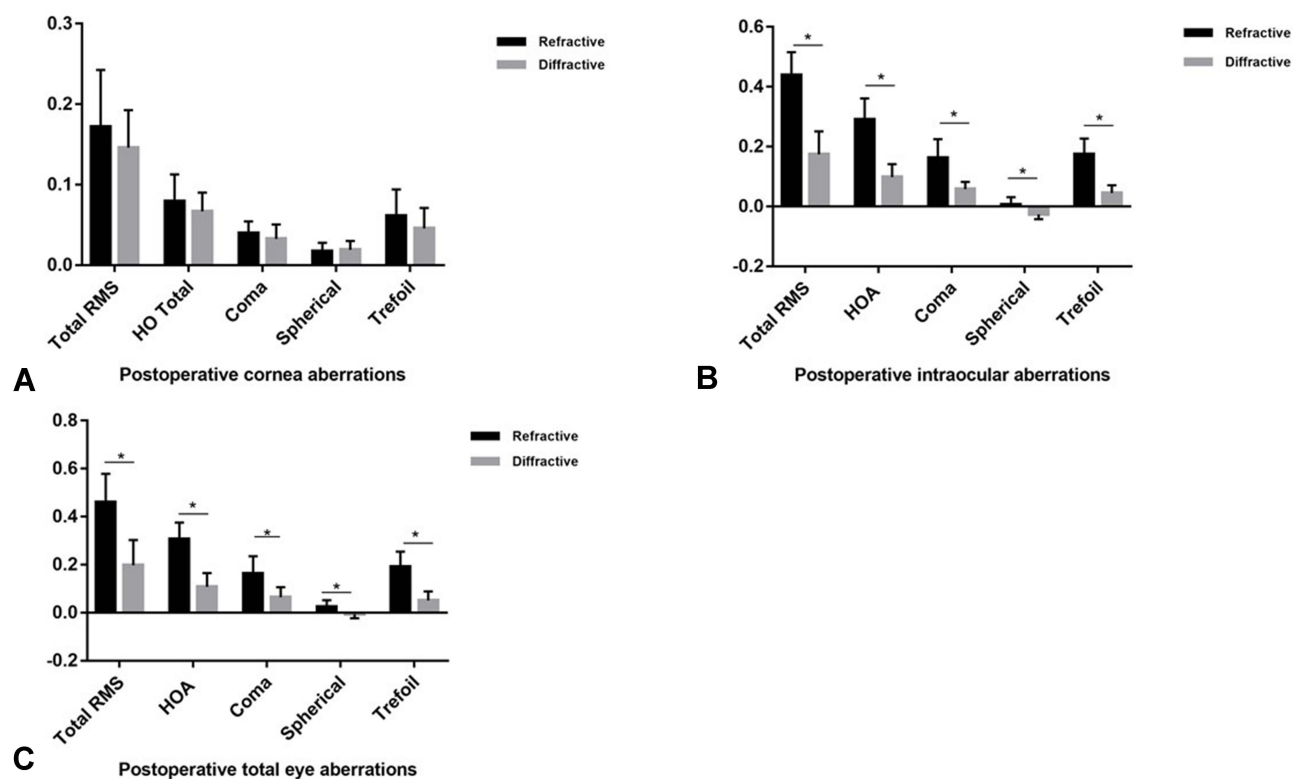


Figure 4 Postoperative aberrations in the 2 groups of eyes 3 months after cataract surgery (* $P < 0.05$). (A) Postoperative cornea aberrations; (B) Postoperative intraocular aberrations; (C) Postoperative total eye aberrations.

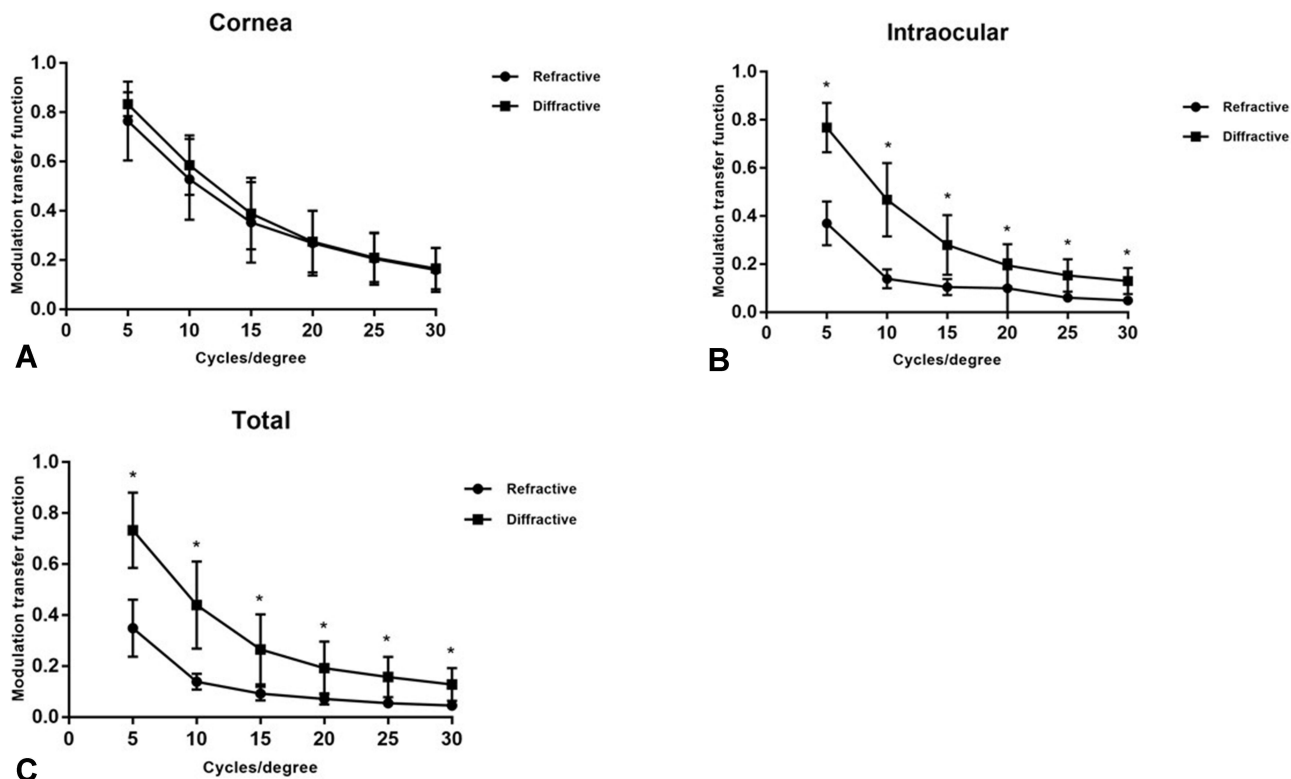


Figure 5 Postoperative modulation transfer function in the 2 groups of eyes 3 months after cataract surgery (* $P < 0.05$). (A) Postoperative cornea modulation transfer function; (B) Postoperative intraocular modulation transfer function; (C) Postoperative total eye modulation transfer function.

Table 3 Postoperative SR in the 2 Groups

	Refractive	Diffraction	P-value
Cornea SR	0.23±0.16	0.24±0.15	0.67**
Intraocular SR	0.05±0.02	0.19±0.09	≤0.001**
Total eye SR	0.05±0.01	0.16±0.09	≤0.001**

Note: **Mann–Whitney U-test.

Abbreviation: SR, strehl ratio.

312) provided better intermediate vision than diffractive MIOL (Acri.Lisa 366D). Although there was a statistical difference between the two groups in UIVA, the slight

advantage of average 0.11 logMAR value (approximately 1 logMAR line) was limited in refractive group. In our study, the spectacle independence rate, especially in intermediate distance, did not differ between the two groups. This illustrated that the slightly better UIVA in refractive group might not have a meaningful effect on the spectacle independence rate in intermediate distance. Perhaps, only patients who had a higher demand of intermediate visual acuity might benefit more from refractive bifocal IOL compared with diffractive bifocal IOL.

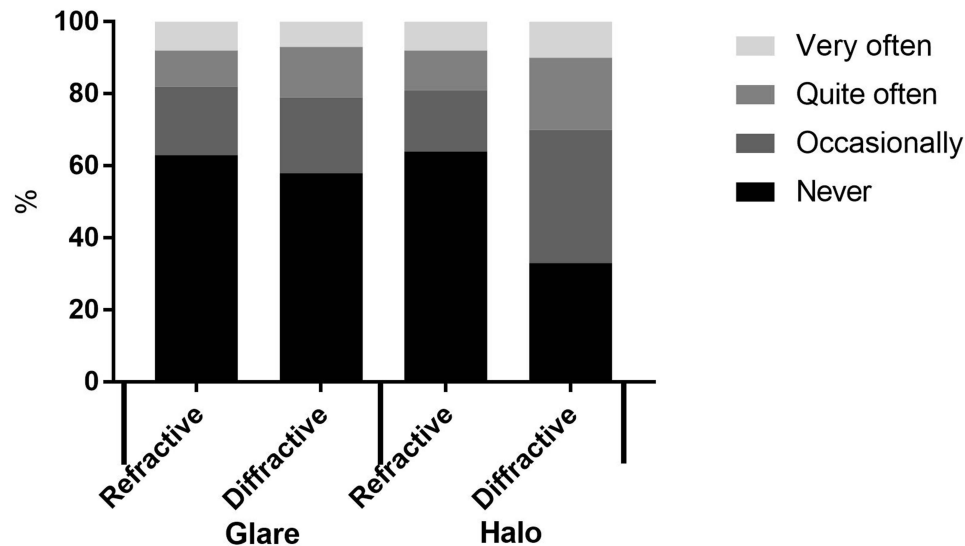
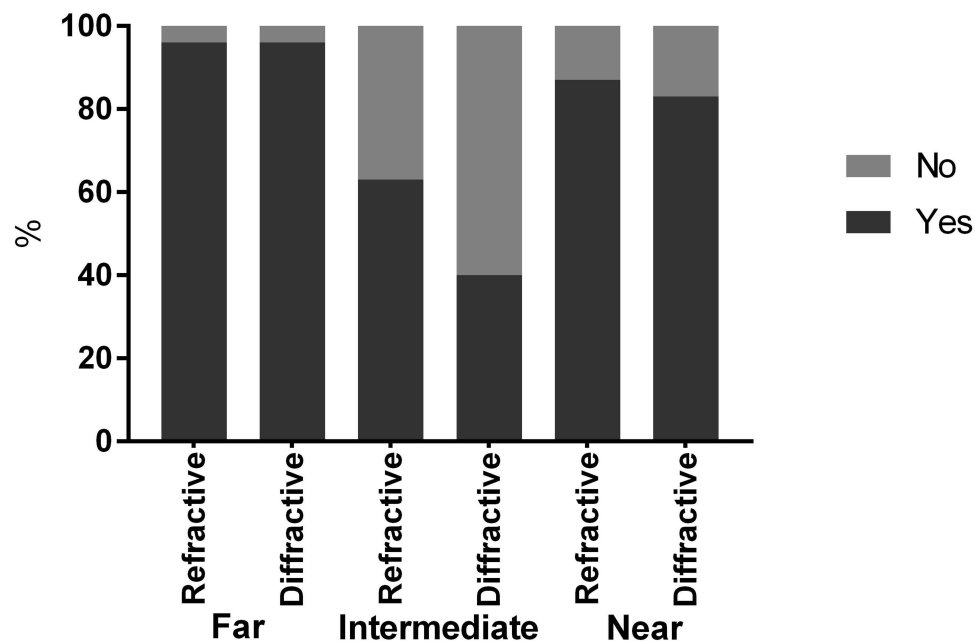
**Figure 6** Frequencies of halos and glare cataract surgery.**Figure 7** Rates of spectacle independence at far, intermediate and near distance.

Table 4 National Eye Institute Visual Functioning Questionnaire-I4

	Refractive	Diffraction	P-value*
Reading small print	0.27±0.70	0.33±0.55	0.25
Reading a newspaper or book	0.13±0.59	0.27±0.55	0.33
Reading a large-print book or newspaper or the numbers on a telephone	0.2±0.32	0.33±0.27	0.23
Recognizing people when they are close to you	0.17±0.59	0	0.21
Seeing steps, stairs, or curbs	0	0.07±0.21	0.26
Reading traffic signs, street signs, or store signs	0.27±0.30	0.23±0.15	0.35
Doing fine handwork like sewing, knitting, crocheting, or carpentry	0.63±0.87	0.78±0.87	0.13
Writing checks or filling out forms	0.07±0.19	0.10±0.29	0.41
Playing games such as bingo, dominos, card games, or mahjong	0.13±0.21	0.23±0.3	0.37
Taking part in sports like bowling, handball, tennis, or golf	0	0.07±0.21	0.26
Cooking	0.13±0.59	0.27±0.55	0.18
Watching television	0.23±0.42	0.2±0.5	0.55
Driving during the day	0.17±0.22	0.27±0.35	0.43
Driving at night	0.15±0.36	0.29±0.55	0.4

Notes: *Mann–Whitney test; Scale is from 0 = no difficulty to 4 = unable to do.

Defocus curve is an effective method to evaluate the whole visual acuity of MIOL, showing a visual acuity of different defocus levels, with the result being equivalent to the visual acuity of different viewing distances. The mid-range visual acuity in the refractive group was better than diffractive group, as confirmed by the results of the defocus curve. Both groups provided two peaks of vision of -3D and 0.0D, with a slight decrease between 0.0D and -3D. This decrease was not apparent on the defocus curve of the refractive group; hence, the defocus curve effect of the refractive group was better than that of the diffractive group. This was consistent with previous studies reporting that refractive rotationally asymmetric bifocal IOL exhibits a satisfactory visual range of intermediate visual acuity.^{12–14}

Apodized diffractive bifocal IOL showed a better objective visual quality. The intraocular and total eye aberration, HOAs, coma, spherical aberration, and trefoil in the refractive group under 4mm pupil diameter were higher than those in the diffractive group. This was similar to a previous study where the HOAs and coma of rotationally asymmetric MIOL were higher than those of diffractive MIOL.^{11,12} This might be related to the asymmetric design of rotationally asymmetric MIOL because of a gradual transition between the two regions from far vision to near.¹⁴ Higher coma harms vision because of visual interference, which might reduce the objective optical quality of refractive rotationally asymmetric MIOL.¹⁵ However, the increased intraocular aberration of rotationally asymmetric MIOL potentially extended the focal depth, ie, its advantage in UIVA compared with diffractive bifocal IOL.^{10,16} It was believed that the presence of this optical defect allowed an extended depth of focus that would grant adequate vision at

various distances. We also reported significant differences in 5c/d, 10c/d, 15c/d, 20c/d, 25c/d, and 30c/d in intraocular and total eye MTF between the two groups. The value of MTF represents the contrast ratio of the retinal image to the actual object in different spatial frequencies, and the higher the value, the better the contrast of the image. We found that the value of apodized diffractive MIOL MTF was better than that of refractive rotationally asymmetric MIOL. Previous studies showed that asymmetric MIOL exhibited a better contrast sensitivity than rotationally symmetrical diffractive MIOL.^{11,17} Nevertheless, the introduction of intraocular aberration potentially reduces the retinal image quality of rotationally asymmetric MIOL.¹⁰ Similarly, Nio et al¹⁸ discovered that HOA increases the depth of focus and decreases the MTF value at higher spatial frequency. Therefore, we concluded that the increase of intraocular aberration might decrease the MTF value. Besides, we evaluated SR as a parameter to compare the objective visual quality between MIOLs provided by iTrace. SR is a parameter used to estimate the overall optical quality, defined as the peak intensity ratio of the image formed by the aberration optical system to the intensity of the aberration-free system. The higher the value, the better the visual quality.¹⁹ The SR value showed that the objective visual quality of the refractive group was better than that of the diffractive group, consistent with previous research findings.¹⁰

De Vries et al⁸ reported that 38.2% of dissatisfied patients after MIOL implantation complained primarily of optical phenomena-glare and halos. Therefore, the phenomenon of optical interference after operation is a primary concern of ophthalmologists. There was a trend toward a lower incidence of halos perception in eyes with the refractive

rotationally asymmetric MIOL ($P=0.04$). This trend may be related to the rotational asymmetric design in optical performance with the refractive rotationally asymmetric MIOL. Just as Montés-Micó et al⁹ reported, patients with diffractive MIOL implantation might have more photic phenomena, including glare, or halos. This difference may also be related to the concentric rings design in optical performance with the diffractive IOL.^{20–22} Although refractive rotationally asymmetric bifocal IOL might have less photic phenomena, its objective visual quality was not as good as that of diffractive bifocal IOL. It was reported that because of the vertical asymmetric optical geometry of refractive rotationally asymmetric MIOL, the direct application of conventional wavefront sensors cannot precisely evaluate the aberrations.²³ Objective aberration measurements may be inaccurate in refractive group. This suggested that subjective feelings of patients were an indispensable part of our evaluation of visual performance of the two MIOLs. A topic that should be addressed in future studies with larger samples.

No significant difference in UDVA and UNVA was found between the two groups, corroborating with previous findings.^{11,12} More than 83.33% of patients in both groups reported spectacle independence at far and near distance. In general, most of the patients in both groups revealed an extremely high spectacle independence rate and satisfaction, corroborating with the previous research findings.^{5,12,13,22,24,25} We administered a Visual Functioning Questionnaire-14 to assess postoperative patient satisfaction. This questionnaire evaluated the patient's ability to perform daily activities. We have not found significant differences in any parameter. Although 40.0% spectacle independence for intermediate distance and 45% eyes of 0.3 logMAR or better for UIVA was relatively lower and a higher incidence of halos perception in diffractive group, the Visual Functioning Questionnaire-14 parameters between the 2 groups exhibited no significant difference, especially when intermediate distance vision was required for fine handwork, cooking, and card games. The level of overall satisfaction was high. The reason may be that the slightly better intermediate visual acuity in refractive group was not enough to affect postoperative patient satisfaction between the 2 groups. This may also be a reflection of adequate preoperative communication, careful patient selection, and less expense.

Previous studies showed that because of the process of neuroadaptation, difficulties with photopic phenomena might decrease over time.^{26,27} The evaluation of these parameters requires a larger study population (at least 50 cases in each group) and a longer follow-up period (≥ 6 months). In future studies, we will continue to follow up

the study to expand the sample size and extend the follow-up time. Additionally, because we hope to offer patients a personalized choice prior to surgery, patients were assigned to different groups according to their requirement for intermediate vision and the price of IOLs. The lack of randomization could have affected the generalizability of the findings. In future studies, it is necessary to confirm this finding providing a more accurate assessment.

In conclusion, to our knowledge, this was the first study to compare the visual acuity, optical quality, and satisfaction of patients between a refractive rotationally asymmetric bifocal IOL (LS-313 MF30) and an apodized diffractive bifocal IOL (ReSTOR SN6AD1). Both IOLs could effectively restore visual function after cataract surgery up to 3 months. However, eyes with LS-313 MF30 showed better UDVA, UIVA and lower halos incidence, and eyes with ReSTOR SN6AD1 showed significantly lower HOAs. Therefore, the rotationally asymmetric bifocal IOL seems to be a promising alternative for MIOL implantation because it provides a wide range of visual acuity and a more physiologic defocus curve. When patients choose an IOL, it is necessary to fully inform them of the advantages and disadvantages of both IOL models to improve postoperative satisfaction.

Disclosure

The authors declare that they have no conflicts of interest for this work.

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