

Multifocal versus Monofocal Intraocular Lens Implantation in Children with Cataracts

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Highlight

Visual function was significantly improved after multifocal IOL optic implantation in Berger space in unilateral and bilateral pediatric patients and the incidence of complications was low.

Journal Pre-proof

Multifocal versus Monofocal Intraocular Lens Implantation in Children with Cataracts

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Abstract

Purpose: To evaluate the efficacy and safety of multifocal versus monofocal intraocular lens (IOL) implantation in children with cataracts in a real-world setting.

Design: Prospective, non-randomized comparative clinical study.

Methods: Pediatric patients who underwent cataract surgery with multifocal IOL optic implantation in Berger space or monofocal IOL implantation with primary posterior capsulorhexis (PCCC) and anterior vitrectomy (AV) were recruited for this study. The efficacy outcome was postoperative visual acuity (corrected distance visual acuity (CDVA), distance-corrected intermediate visual acuity (DCIVA), and distance-corrected near visual acuity (DCNVA)), modulation transfer function (MTF), Strehl ratio (SR), ocular scatter index (OSI) and stereopsis. The safety outcomes were postoperative complications.

Results: A total of 571 eyes of 402 children were included in our study. Multifocal IOLs were implanted in 219 children (311 eyes) and monofocal IOLs in 183 children (260 eyes).

Visual results in bilateral or unilateral patients were better after multifocal IOL implantation than after monofocal IOL implantation, regardless of CDVA and DCNVA ($P < 0.05$). More patients developed postoperative Titmus stereopsis ≤ 100 arcseconds after multifocal IOL

implantation compared to monofocal IOL implantation (both $P < 0.05$). The MTF and SR values showed a significant increase, and the OSI values showed a significant decrease after surgery (both $P < 0.001$). MTF cut-off, Strehl ratio, and OSI values showed no significant differences between unilateral and bilateral patients with multifocal or monofocal IOLs ($P > 0.05$). Multifocal IOL patients achieved higher spectacle independence than monofocal IOL patients (51.67% vs 37.31%, $P = 0.033$). IOL optic implantation in Berger space was achieved in 93.25% of the eyes with the multifocal IOL implantation (290/311). After surgery, the incidences of corneal edema, transient intraocular hypertension and visual axis opacification (VAO) of children after multifocal IOL implantation in Berger space were lower (2.28% vs. 9.84%, $P = 0.017$; 2.28% vs. 12.02%, $P = 0.006$; 0% vs. 6.56%, $P = 0.014$).

Conclusions: During the follow-up period of this study, multifocal intraocular lens optic implantation in Berger space demonstrated favorable safety and efficacy in improving visual function for rigorously screened pediatric cataract patients.

Introduction

Pediatric cataract in children is a major blinding eye disease in childhood, and the worldwide incidence of childhood cataract is estimated to be 1.8–3.6 per 10,000 children per year. ¹There are two main scientific issues in pediatric cataract surgery. First, reducing or avoiding surgical complications, especially for visual axis opacification (VAO).

²Second, improving visual quality as much as possible (including full range vision, stereopsis, and reducing dependence on glasses).

Pediatric cataracts should be treated with surgery as early as possible, and optical correction and amblyopia training should be carried out after surgery. ³Primary intraocular lens (IOL) implantation can help improve visual outcomes for these children. The main cause of a decline in vision after surgery is VAO. To decrease the risk for VAO, anterior vitrectomy is often routinely performed in pediatric cataract surgery. ^{4,5}There are currently two surgical techniques that can avoid VAO without anterior vitrectomy. Firstly, the BIL(bag-in-the-lens) IOL implantation technique appears to be safe and can provide a clear visual axis for early visual rehabilitation of the child's eye. ⁶Secondly, according to previous reports and our experience, IOL optic implantation in Berger space technique can successfully reduce the risk of VAO after surgery and can avoid anterior vitrectomy.

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Currently, the goal of cataract surgery in adults is "refractive cataract surgery", which involves the implantation of various premium intraocular lenses. ¹⁰Pediatric cataract surgery solves lifelong problems and is more important than cataract surgery in adults; therefore, the concept of "refractive pediatric cataract surgery" should be proposed. Just as multifocal IOLs can provide clear images at both near and distance for adults, pediatric patients may also benefit from this technology. However, the use of multifocal IOLs in children remains controversial among surgeons. ¹¹Some surgeons contend that potential adverse effects—such as glare, halos, and loss of contrast sensitivity—could be detrimental to a child's visual development. They also point out that surgical complications like

posterior synechiae, posterior capsule opacification, and anterior capsule fibrosis may occur. Nevertheless, others think multiple images produced by the multifocal IOL may reduce amblyopia by giving the child a choice of clear images from which to choose. And by reserving mild hyperopia before multifocal IOL surgery, some children may not be able to get rid of their glasses, but it can reduce their dependence on them. These controversies make sense. Recent clinical studies on multifocal IOL implantation in pediatric patients demonstrate satisfactory distance and near visual outcomes with improved stereopsis. The main surgical complications are VAO, IOL decentration, and IOL flicker, with no increase in incidence compared to monofocal IOL optic implantation.¹²⁻¹⁵

In previous years, we conducted a small sample study to evaluate binocular visual function and influencing factors after multifocal IOL optic implantation in Berger space in children with congenital cataracts.^{9,16,17} Multifocal IOL implantation could obtain relatively satisfactory binocular visual function in children with a low rate of complications. The objective of this study was to evaluate the preoperative versus postoperative changes in visual function, including visual acuity (distance visual acuity, intermediate visual acuity, near visual acuity), stereopsis, modulation transfer function (MTF), Strehl ratio (SR), ocular scatter index (OSI), in children with multifocal or monofocal IOL implantation based on real-world data. The intraoperative and postoperative complications were also recorded.

Methods

Study Population

Prospective enrollment was performed for children with cataract treated at our institution between January 15, 2019 and December 15, 2024. Following the principles of the Declaration of Helsinki and registered on the Chinese Clinical Trial Registry (ChiCTR identifier: 1900023155), the study was performed with approval from the Ethics Committee of the Qingdao Eye Hospital of Shandong First Medical University and informed consent from the parents of all involved pediatric patients.

Patients who had serious ocular diseases (retinopathy of prematurity, retinoblastoma, congenital glaucoma, retinal detachment) other than pediatric cataracts or could not cooperate with the examinations were excluded. The indication for surgery in all patients was significantly deteriorated visual function due to dense opacity of the lens without persistent fetal vasculature (PFV) or severe nystagmus. Amblyopia therapy included refractive correction, with or without patching. The children with residual refractive errors, including those with intentional undercorrection, were prescribed single-vision or bifocal spectacles at 4 to 6 weeks postoperatively. The duration of occlusion therapy was determined based on the corrected distance visual acuity (CDVA) of the children after surgery, and it was adjusted according to the changes in visual acuity after surgery. All surgeries was performed by two experienced cataract surgeons and followed up at the Pediatric Eye Center after the surgery.

Preoperative Examination

Detailed ophthalmic examinations were performed preoperatively, including detailed history-taking, visual acuity assessment, intraocular pressure (IOP) measurement (Canon TX-20 noncontact tonometer), eye position, slit lamp examination, and fundus

examination. Manifest and cycloplegic refraction were assessed using logMAR units. The axial length and keratometry parameters were measured with an IOLMaster 700 (Carl Zeiss Meditec AG) or an ophthalmic A-type ultrasonic diagnostic apparatus (MD-2300) in all patients. Holladay2, SRK/T, Hoffer Q, and Haigis formulas were used to calculate IOL power. ¹⁶Considering the possibility of myopic shift, mild hyperopia was reserved on the basis of age when an IOL was selected: Ages 3 to 3.9 years: +2.50 to +3.00 D, Ages 4 to 4.9 years: +2.00 to +2.50 D, Ages 5 to 5.9 years: +1.50 to +2.00 D, Ages 6 to 7.9 years: +1.00 to +1.50 D, Ages 8 years or older: +0.50 D. ¹⁸For unilateral cataract, the IOL power was calculated on the basis of the refraction in the contralateral eye. Multifocal IOLs used included ZFR00V IOLs (Johnson & Johnson Vision), AM4UH IOLs (Eyebright Medical Technology Co., Ltd), Tecnis ZMB00 IOLs (Abbott Medical Optics) and DiffaAy IOLs (Human Optics Holding AG). Monofocal IOLs include A1UL22 IOLs (Eyebright Medical Technology Co., Ltd), iSert 251 IOLs(Hoya Corp), SOFTEC HD IOLs(Lenstec, Inc.), Tecnis ZCB IOLs(Abbott Medical Optics), AQBH IOLs (Eyebright Medical Technology Co., Ltd), AR40e IOLs (Johnson & Johnson Vision) and Akreos™ Adapt AO IOLs (Bausch + Lomb). Detailed information and characterization of IOLs was explained to the parents of all participants before surgery.

Visual Function Evaluation before and after surgery

Examinations of visual function were performed preoperatively and at least 3 months postoperatively. These assessments included visual acuity, stereopsis, MTF, SR and OSI. Visual acuity assessment consisted of uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA; 80 cm), uncorrected near visual acuity

(UNVA; 40 cm), CDVA, distance-corrected intermediate visual acuity (DCIVA) and distance-corrected near visual acuity (DCNVA). Optical quality was evaluated with the Optical Quality Analysis System (OQAS) (Visiometrics SL). The primary parameters were the MTF cut-off frequency (cycles per degree, c/deg), SR and OSI. Stereopsis was determined with the best correction for distance vision at the last visit using the Titmus stereotest (Vectograph [Stereo Optical] cards dissociating the eyes optically), the Lang stereotests I and II (Lang-Stereotest AG) (random-dot stereograms with panographic presentation) and the TNO stereotest (randomdot stereograms).¹⁹

Lang I is a stereo test based on the dom-dot technique, consisting of a card that contains pictures of a cat, a star, and a car, which represent stereopsis of 1,200, 600, and 550 seconds of arc, respectively. The test is administered at a distance of 40 cm; it does not require red/green or cross-polarized filters. The Lang II stereo test differs from the other test in that it contains pictures of an elephant, a car, and the moon, which represent stereopsis of 600, 400, and 200 seconds of arc, respectively.

In the Titmus stereo test, we used only the circles and animals part, with a disparity ranging from 800 to 40 seconds of arc. The test requires cross-polarized filters (worn over prescription glasses). If a child was unable to identify the first circle part (800 seconds of arc) or animal A, B, or C, he or she was considered stereopsis non-existent.

The TNO stereo test was based on the random-dot technique. The first three plates are simple test plates with a retinal disparity of 1,900 seconds of arc. The test requires red/green filters worn over prescription glasses. Failure to identify just one of the hidden objects in each plate was considered a failure.

Surgical Technique

Cataract surgeries were performed under general anesthesia by two experienced surgeons (YH and LX). All children used antibiotic eye drops before surgery. Patients were categorized into four groups based on the type of IOL selected through joint decision-making by doctors and patients' families. Group A: 92 patients with bilateral cataracts had multifocal IOL implantation, group B: 127 patients with unilateral cataracts had multifocal IOL implantation, group C: 77 patients with bilateral cataracts had monofocal IOL implantation, group D: 106 patients with unilateral cataracts had monofocal IOL implantation. The procedure was cataract extraction and multifocal IOL optic implantation in Berger space (group A and B, video 1) or monofocal IOL implantation with primary posterior capsulorhexis (PCCC) and anterior vitrectomy (AV) (group C and D). During surgery for multifocal IOL optic implantation in Berger space, after multifocal IOL implantation and PCCC, a lens hook was used to push the IOL optic to slide posteriorly through the opening with the haptics in the capsular bag to achieve IOL implantation with optic capture in Berger space.⁸ During surgery for monofocal IOL implantation, after monofocal IOL implantation, dry pars plana posterior capsulotomy combined with anterior vitrectomy was performed with a 25-gauge cutter.^{20,21} All children used antibiotics, nonsteroidal anti-inflammatory, topical steroid eye drops and topical steroid eye ointment after surgery. The postoperative topical medication regimen required the use of antibiotic eye drops and topical steroid eye drops four times a day for 2 week, bromfenac sodium eye drops twice a day for 8 weeks and topical steroid eye ointment once daily for 1 weeks. After surgery, the follow-up visit included visual function examinations, IOP, conditions of

the anterior segment (including anterior chamber depth, aqueous flare, pupillary diameter, and pupillary adhesion), and conditions of the ocular fundus. The ocular fundus was observed with a Spectral Optical Coherence Tomographer (RTVue 100-2, America).

Statistical Analysis

The data were statistically analyzed using SPSS 22.0 software (SPSS, Inc.) and expressed as the mean \pm standard deviation. The paired t-tests was used to compare preoperative and postoperative visual outcomes, OSI, MTF cut-off, and SR within the same eyes. The results of tests for stereoacuity and complications were compared using chi-square analysis. A *P* value less than 0.05 was considered statistically significant.

Results

BASELINE CHARACTERISTIC: A total of 571 eyes of 402 children (191 females and 211 males) were included in our study. Two hundred and nineteen children (311 eyes) were implanted with multifocal IOLs and 183 children (260 eyes) were implanted with monofocal IOLs. Cataracts were unilateral in 233 patients and bilateral in the other 169 patients. Among bilateral cataract patients, 92 patients underwent implantation of multifocal IOLs and 77 patients underwent implantation of monofocal IOLs. Among unilateral cataract patients, 127 patients underwent implantation of multifocal IOLs and 106 patients underwent implantation of monofocal IOLs. No differences in the preoperative characteristics were noted between patients who received monofocal or multifocal IOLs ($P > 0.05$; Table 1). The ages of the four groups were respectively: $6.45 \pm$

3.58, 5.80 ± 2.81 , 5.50 ± 4.48 , 5.34 ± 3.20 years ($P > 0.05$). Table 1 summarizes the preoperative characteristics of the patients.

EFFICACY:

The mean CDVA improved from 0.90 ± 0.58 logMAR preoperatively to 0.20 ± 0.32 logMAR after multifocal IOL implantation postoperatively ($P < 0.05$). The mean CDVA improved from 0.94 ± 0.53 logMAR preoperatively to 0.47 ± 0.49 logMAR after monofocal IOL implantation postoperatively ($P < 0.05$). The mean postoperative CDVA, DCIVA and DCNVA in group A were 0.14 ± 0.26 , 0.23 ± 0.23 and 0.23 ± 0.23 logMAR, respectively. The mean postoperative CDVA, DCIVA, and DCNVA in group B were 0.34 ± 0.39 , 0.44 ± 0.23 and 0.48 ± 0.29 logMAR, respectively. The mean postoperative CDVA, DCIVA and DCNVA in group C were 0.36 ± 0.41 , 0.43 ± 0.12 and 0.59 ± 0.10 logMAR, respectively. The mean postoperative CDVA, DCIVA and DCNVA in group D were 0.60 ± 0.56 , 0.60 ± 0.26 and 0.72 ± 0.09 logMAR, respectively. Visual results in bilateral patients were better after multifocal IOL implantation than after monofocal IOL implantation, specifically in terms of CDVA and DCNVA ($P = 0.005$, $P = 0.001$, Table 2). Visual results in unilateral patients were better after multifocal IOL implantation than after monofocal IOL implantation, regardless of CDVA and DCNVA ($P = 0.025$, $P = 0.033$, Table 2). Figure 1A-B shows the distribution of final visual acuity among the children with multifocal and monofocal IOL implantation. Visual progress in bilateral cataract was better than in unilateral cataract regardless of multifocal IOL implantation or monofocal IOL implantation (Figure 1A-B).

DCIVA in patients were better after Extended Depth of Focus (EDOF) IOL implantation than after Bifocal IOL implantation, but no significant difference was observed between CDVA and DCNVA ($P = 0.046$, $P = 0.083$, $P = 0.157$, Supplementary Table1).

In group A, 54.7% of eyes achieved their targeted postoperative spherical equivalent refraction ± 1.00 D, and 30.8% achieved the targeted spherical equivalent refraction within ± 0.50 D. Thirty-nine point seven percent, 30.9% and 40.7% achieved the targeted spherical equivalent refraction within ± 0.50 D in group B, C and D, respectively. The postoperative refractive outcomes are shown in Figure 1C and 1D. The spectacle independence rate in patients implanted with multifocal IOLs is higher than in those implanted with monofocal IOLs (51.67% vs. 37.31%, $P = 0.033$).

Three hundred fifty-two children cooperated with the stereopsis examination preoperatively. In bilateral patients after multifocal and monofocal IOL implantation, 70% patients in group A and 40% patients in group C developed titmus stereopsis ≤ 100 arcseconds postoperatively ($P = 0.006$, Figure 2). In unilateral patients after multifocal and monofocal IOL implantation, 59% and 38% patients developed titmus stereopsis ≤ 100 arcseconds postoperatively in group B and D ($P = 0.003$, Figure 2).

The MTF cutoff frequency, SR and the OSI value were available in 483 eyes. The MTF cutoff frequency and SR values showed a significant increase after cataract surgery ($P < 0.001$, Table 3); the OSI values showed a significant decrease after cataract surgery ($P < 0.001$, Table 3). For the MTF cut-off, Strehl ratio and OSI values, there were no significant differences between unilateral and bilateral patients for multifocal and monofocal intraocular lens implantation ($P > 0.05$) (Figure 3).

SAFETY: The intraoperative, early, and late postoperative complications are shown in Table 4. IOL optic implantation in Berger space was achieved in 93.25% of the eyes with the multifocal IOL implantation (290/311). The main reason for unsuccessful optic capture was unplanned anterior vitrectomy, and the optic was implanted within the bag. In the monofocal IOL group, monofocal IOL implantation with PCCC and AV, ciliary sulcus fixation of the IOL with anterior vitrectomy were performed in 248 eyes (95.38%), 12 eyes (4.62%) respectively. Compared with the monofocal IOL implantation group, the rates of corneal edema and transient intraocular hypertension in the short term after surgery of children after multifocal IOL implantation in Berger space were lower (2.28% vs. 9.84%, $P = 0.017$; 2.28% vs. 12.02%, $P = 0.006$). The visual axis remained clear in 100% of eyes after multifocal IOL implantation during the follow-up period (Figure 4, Supplementary Figure 1). At the last follow-up, the incidence of VAO of children after multifocal IOL implantation in Berger space were lower (0% vs. 6.56%, $P = 0.014$). Mild IOL decentration was found in one child seven months after multifocal IOL implantation, which could have something to do with eye-rubbing, but the child still had a visual acuity of logMAR 0. There was no retinal detachment or cystoid macular edema during the follow-up period.

Discussion

In the present study, visual results in bilateral or unilateral patients were better after multifocal IOL implantation than after monofocal IOL implantation, in terms of both CDVA and DCNVA. Visual progress in bilateral cataract was better than in unilateral cataract regardless of multifocal IOL implantation or monofocal IOL implantation. After surgery, the

incidences of corneal edema, transient intraocular hypertension and visual axis opacification of children after multifocal IOL implantation in Berger space were lower.

There was no retinal detachment or cystoid macular edema during the follow-up period.

This study is currently the largest research sample comparing multifocal and monofocal IOL implantation in children with cataract. Our study found that multifocal IOL

implantations demonstrated significant improvements in visual acuity, which is similar to other findings.^{12-14,22,23} Cristobal et al. have shown satisfactory results using multifocal

IOLs in children with unilateral cataract.²² Hana Abouzeid evaluated the visual outcomes of multifocal IOL implantation in pediatric patients. CNVA and CDVA improved significantly in 100% of eyes, and CDVA was above 0.8 in 31.25% of bilateral cases.

¹²Some studies have shown that there is no significant difference in CDVA between multifocal and monofocal IOL implantation, which differs from our findings.^{13,24} In our

study, patients who received multifocal IOLs achieved better visual outcomes in both CDVA and DCNVA following implantation. We considered whether the differences in

distance vision after multifocal and monofocal IOL implantation in this study resulted from the non-randomized design of the research or from the fact that children with preoperative

mild nystagmus or posterior capsular abnormalities were more likely to receive monofocal IOLs. In our study, we found that visual progress in bilateral cataract was better than in

unilateral cataract regardless of multifocal IOL implantation or monofocal IOL implantation.

Hana Abouzeid and Vera also reported that the improvement in vision was significantly higher for bilateral cases than for unilateral cases, which is similar to our report.^{12,25} In

general, visual results in bilateral or unilateral patients were better after multifocal IOL

implantation than after monofocal IOL implantation, in terms of both CDVA and DCNVA.

Under ideal conditions, trifocal IOLs are more advantageous for improving intermediate vision. For children with cataracts and astigmatism, we had conducted another prospective study using multifocal toric IOL optic implantation in Berger space.

Stereopsis is an independent advanced visual function, and its development starts from 3-4 months after birth and ends by the age of six.²⁶ Three different stereoacuity tests were used in this study: the Titmus, Lang and TNO. Titmus is the most classic graphic stereoacuity test, and TNO is the internationally recognized representative of the Randot stereoacuity test. Although these three methods are skilled in clinical application, they still require the cooperation of children. The three methods of stereoscopic measurement are different, and children need to have a strong experience of "floating" the target in the titmus test. The Lang and TNO stereoacuity tests use matching graphics in design, which is more easily accepted by children. Some younger children cannot complete the test owing to a lack of understanding of the test. The postoperative vision of children is the most important factor affecting stereopsis.^{27,28} In our study, more patients developed postoperative Titmus stereopsis ≤ 100 arcseconds after multifocal IOL implantation compared to monofocal IOL implantation. We believe that by providing improved distance and near vision simultaneously, multifocal IOLs play an important role in helping patients reestablish stereoscopic function, which is the foundation for maintaining good stereopsis after cataract surgery. Jagat Ram evaluated visual function results after bilateral implantation of multifocal versus monofocal IOLs in children above five years of age, and stereopsis was slightly better in the multifocal IOL group (125.71 arc-sec vs. 140 arc-sec).

¹³Hana Abouzeid analyzed the changes in stereopsis after multifocal IOL implantation and found that only binocular patients had significant improvement in stereopsis after surgery.

¹²However, in our study, stereopsis in children with unilateral cataract was also significantly improved, which may be related to the fact that children with serious ocular abnormalities, such as serious nystagmus, retinoblastoma, maculopathy, iris melanoma, and high myopia with macular retinal pigment epithelium modifications, were not included in our study.

Similar to the stereopsis result, we demonstrated that the optical quality parameter, namely, the MTF cutoff frequency and Strehl ratio values, showed a significant increase after cataract surgery. For the MTF cut-off, Strehl ratio and OSI values, there were no significant differences between unilateral and bilateral patients for multifocal and monofocal intraocular lens implantation. Optical quality is not only an important parameter for decision-making before cataract surgery but also an important indicator of visual function evaluation in children with cataract after surgery, and MTF is an important parameter of optical quality. ²⁹The OQAS, which has been used in a number of studies, ^{30,31} has higher correlations with visual performance. ³² However, few studies studying the optical quality after implantation of multifocal IOLs in children using the OQAS system have been published. Wan Chen found that the MTF cutoff values showed a significant increase after cataract surgery (10.6 before surgery vs. 22.7 after surgery). ³⁰ Our results are comparable to those reported by Wan Chen, indicating that optical quality improved after surgery.

VAO is the most common complication after cataract surgery in children, and the

incidence rate is up to 100% when the posterior capsule remains intact.³³Therefore, different and adapted surgical techniques are needed to prevent the occurrence of VAO. The rate of secondary VAO depends on the surgical methods and IOL type.³⁴Optical capture is a safe and effective surgical method that can significantly reduce VAO.³⁵Under ideal conditions, we hope to achieve multifocal IOL optic implantation in Berger space without the need for anterior vitrectomy.^{15,16}First, this surgical method can maintain vitreous integrity and reduce the incidence of VAO. Second, it can decrease hyperopic defocus and may be a protective factor against myopic shift in pediatric cataract patients. Some studies found that the incidence of VAO in children after implantation of multifocal IOL was approximately 11%, 35.7%, and 46%, the follow-up periods for these studies were 25.73, 12 and 27.1 months, respectively.^{12,13,19}In our study, the visual axis remained clear in 100% of multifocal IOL eyes during the follow-up period (29.1 ± 15.4 months) and the incidences of VAO of children after multifocal IOL implantation in Berger space were lower, which confirmed that IOL optic implantation in Berger space without vitrectomy was adequate for the prevention of visual axis re proliferation. The observed difference in VAO incidence in this study directly stems from the distinct IOL implantation positions (multifocal IOLs in Berger's space versus monofocal IOLs in the capsular bag/ciliary sulcus), rather than the multifocal design.

Multifocal IOL implantation can obtain satisfactory distance and intermediate and near visual acuity. Compared with monofocal IOL, multifocal IOLs can obtain better uncorrected visual acuity at a range of distances, and the proportion of patients with spectacle independence is higher after surgery.^{36,37} In our study, 51.6% of children were

independent of additional spectacles after multifocal IOL implantation, and the other 48.4% of children needed only distance correction in their spectacles because of residual refractive errors. The spectacle independence rate in patients implanted with multifocal IOLs is higher than in those implanted with monofocal IOLs. One study has shown that patients with multifocal IOL have better near visual acuity and faster reading speed, which is an obvious advantage for children who need to read often.³⁸ Moreover, the advantages of these IOLs include better CDVA, CDIVA, and CDNVA, reduced higher-order aberrations and spherical aberrations, improved binocularity, especially in unilateral cataracts, and improved quality of life in children.^{39,40} There was no significant reduction in contrast sensitivity after implantation of the multifocal IOL.⁴¹ Despite good visual outcomes and spectacle independence achieved with multifocal IOLs, there are some disadvantages. For example, more adult patients complain about halo and glare after implantation of multifocal IOL.⁴² Clinical studies indicate an 18.20% incidence of glare in Chinese adults following multifocals IOL implantation.⁴³ However, in our pediatric cohort, such subjective complaints were rare, which is likely attributable to children's stronger neural adaptability. A total of five children (2.28%) reported experiencing glare after multifocal IOL implantation. However, all achieved a BCVA of 0.8 or better, with no cases of amblyopia observed during the follow-up period. In addition, if IOL decentration and tilt occur after surgery, the visual function of children will be affected. There are many influencing factors, including IOL design, iris adhesion, capsular fibrosis, bag mechanization, and posterior capsular opacification.^{44,45} It is necessary to monitor the IOL position for a longer period of time. Another unpublished, separate article by our research team discusses the results

of decentration and tilt in multifocal IOL implantation.

The results of this study should be interpreted in the context of several limitations. First, the follow-up time was not long enough, and we did not evaluate the impact of multifocal IOL on myopia drift in children, but our research team is working on that topic. Second, the measurements of optical quality and stereopsis before surgery were not available in some younger children with obvious lens opacity, which may limit the detection of positive results. Third, this study was a single center study. Fourthly, Prior to surgery, the advantages and disadvantages of multifocal and monofocal IOLs were thoroughly discussed with the patient's family, enabling joint decision-making with both surgeons and families regarding the type of IOL to be implanted. This is a prospective, non-randomized comparative clinical study, and IOL selection was jointly decided by surgeons and families, there is potential for selection bias. Fifth, considering the technical complexity of the surgical procedure, and the high level of expertise required for implanting multifocal IOLs in Berger space, these two factors may present a significant technical challenge, which could potentially limit the generalizability of the results.

Despite these limitations, our study is the largest sample size to date comparing multifocal and monofocal IOL implantation in children. During the follow-up period of this study, multifocal intraocular lens optic implantation in Berger space demonstrated favorable safety and efficacy in improving visual function for rigorously screened pediatric cataract patients. However, it is important to emphasize that these conclusions are limited by the following factors: the non-randomized controlled study design, wide variation in follow-up duration, and a certain rate of loss to follow-up. These findings require corroboration

through longer-term randomized controlled multicenter studies.

Author contributions: All authors attest that they meet ICMJE criteria for Authorship.

Yichao Ding: Conceptualization, Software, Formal Analysis, Investigation, Data Curation, Writing-Original Draft ; Xiaomei Wan: Conceptualization, Software, Formal Analysis, Investigation, Data Curation; Ling Kong: Software, Validation, Formal Analysis, Investigation, Data Curation; Qiuxuan Du: Software, Validation, Formal Analysis, Investigation; Mingming Jiang: Validation, Formal Analysis, Investigation; Feijia Xie: Formal Analysis, Investigation; Yi Pang: Formal Analysis, Investigation; Wenjie Su: Formal Analysis, Investigation; Jing Zhang: Formal Analysis, Investigation; Yusen Huang: Conceptualization, Validation, Formal Analysis, Investigation, Writing-Original Draft, Supervision, Surgery, Fund.

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Figure Legends:

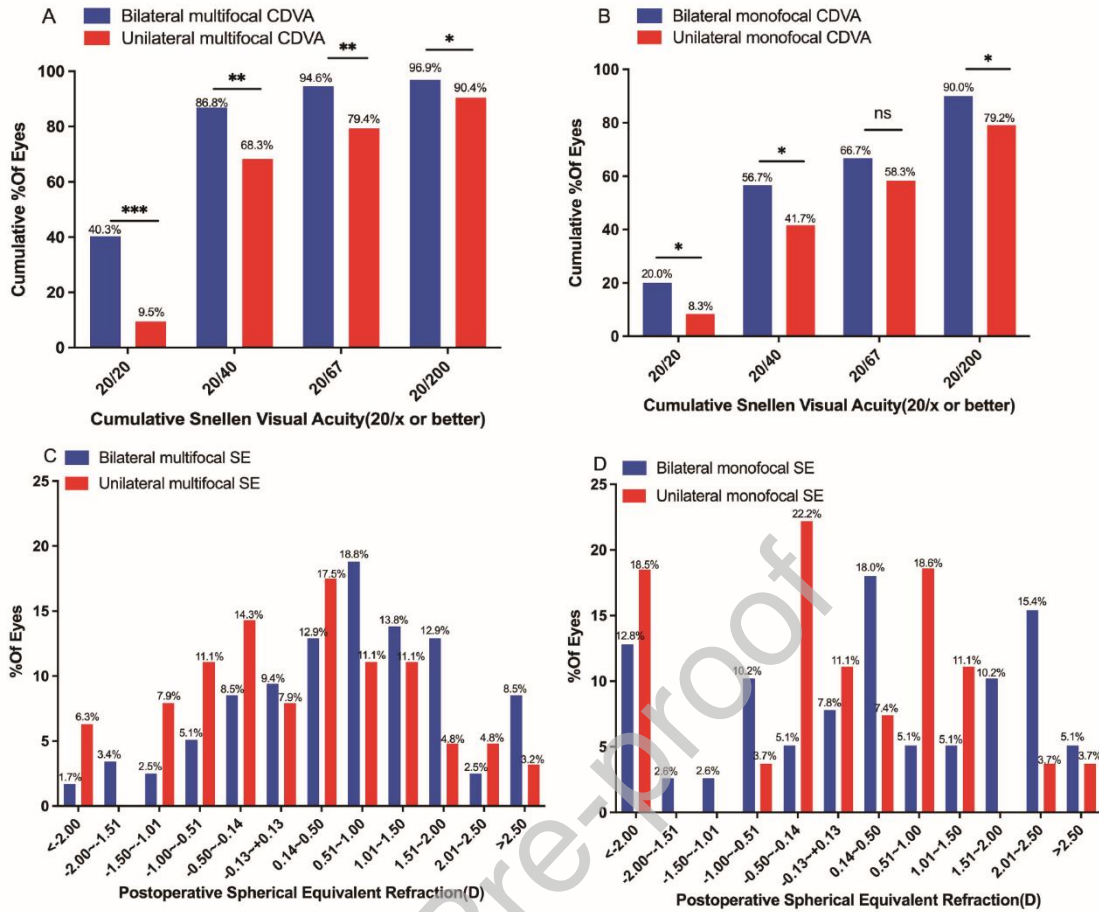


Figure 1. Graphs of refractive outcomes for multifocal and monofocal IOL implantation. (A) Bilateral multifocal CDVA and unilateral multifocal CDVA. (B) Bilateral monofocal CDVA and unilateral monofocal CDVA. (C) Bilateral multifocal SE and unilateral multifocal SE. (D) Bilateral monofocal SE and unilateral monofocal SE. SE = spherical equivalent refraction, D = diopters. Statistically significant, *p value <0.05; **p value <0.01; ***p value <0.001.

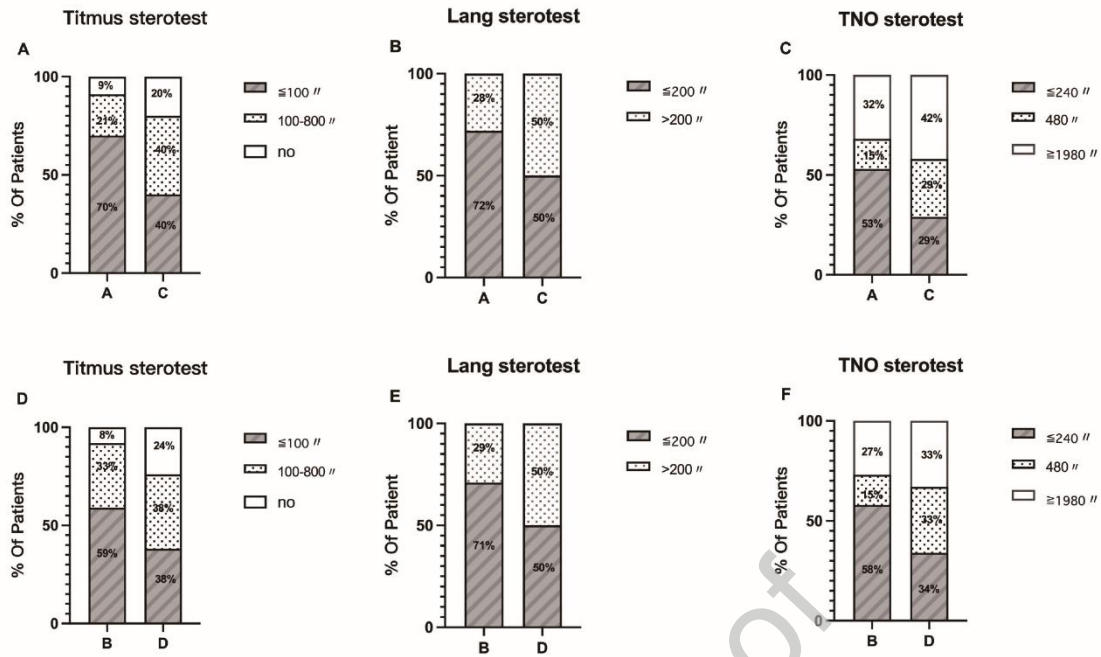


Figure 2. Graphs of stereopsis outcomes of unilateral and bilateral patients for multifocal and monofocal intraocular lens implantation. (A-C) Titmus test, The Lang Randot test and TNO test in bilateral patients with multifocal and monofocal intraocular lens implantation. (D-F) Titmus test, The Lang Randot test and TNO test in unilateral patients with multifocal and monofocal intraocular lens implantation.

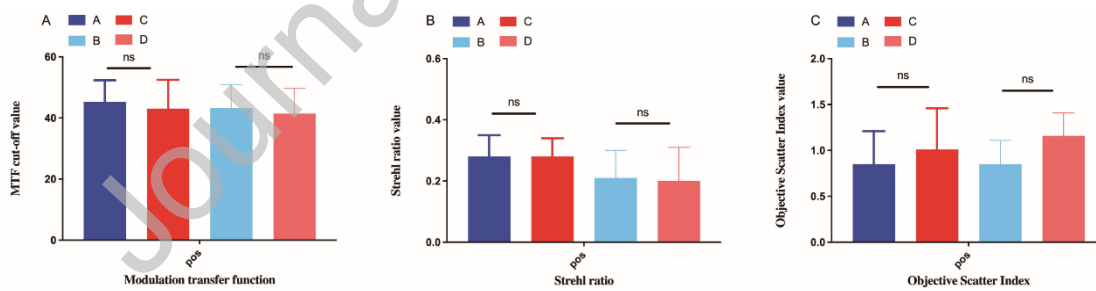


Figure 3. Graphs of visual quality outcomes of unilateral and bilateral patients after multifocal and monofocal intraocular lens implantation. (A) Modulation transfer function. (B) Strehl ratio. (C) Objective Scatter Index.

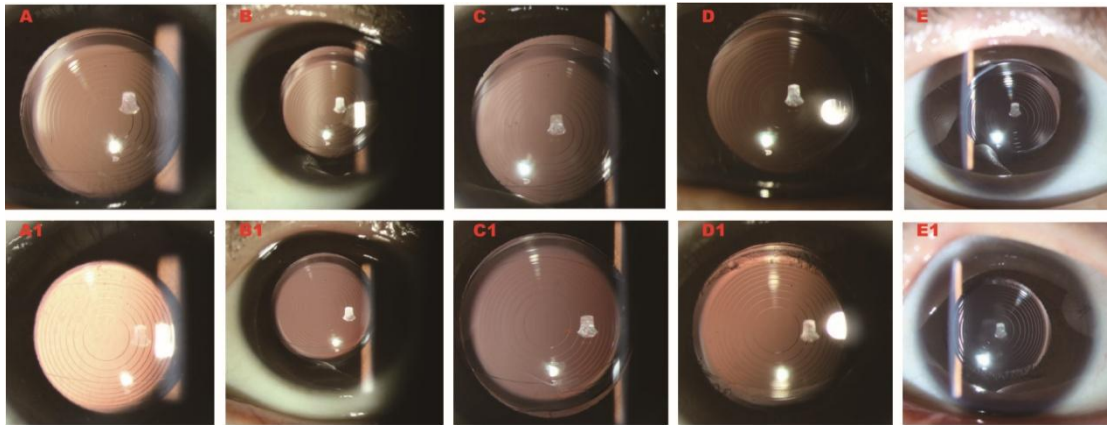


Figure 4. Images of a clear visual axis after multifocal IOL optic implantation in Berger space in a six-year-old child with bilateral cataract. A, A1: At 1 week. B, B1: At 6 months. C, C1: At 1 year. D, D1: At 2 years. E, E1: At 3 years. (A-E: right eye, A1-E1: left eye)

TABLE 1. The preoperative characteristics of the study subjects.

Parameter	multifocal IOL	monofocal IOL	P Value
Basic information			
Eyes/patients, (n/n)	311/219	260/183	NA
Gender (Male/Female, n/n)	118/101	93/90	0.540
Surgery age (Mean \pm SD)	5.89 \pm 2.95	5.85 \pm 3.65	0.666
Follow-up period (months)	29.1 \pm 15.4	35.3 \pm 23.6	0.275
Cataract type			
Nuclear cataract (eyes)	138	97	0.088
Cortical cataract (eyes)	96	90	0.341
posterior subcapsular cataract (eyes)	42	34	0.881
Posterior or polar cataract (eyes)	35	39	0.184
Preoperative CDVA, (logMAR, Mean \pm SD)	0.90 \pm 0.58	0.94 \pm 0.53	0.298
The development of eye			
AL, mm (Mean \pm SD)	22.41 \pm 1.49	22.18 \pm 2.10	0.375
Central corneal thickness (μ m)	535.64 \pm 61.73	522.33 \pm 40.90	0.339
Average corneal curvature (D)	43.72 \pm 1.85	43.77 \pm 2.33	0.861

Abbreviations: SD = standard deviation; CDVA = corrected distance visual acuity; AL = axial length; NA

= not available.

TABLE 2. Visual acuity results in patients after multifocal and monofocal IOL implantation.

Visual acuity	A	C	B	D
Post CDVA(logMAR)	0.14±0.26	0.36±0.41	0.34±0.39	0.60±0.56
<i>P</i> Value	0.005**		0.025*	
Post DCIVA	0.23±0.23	0.43±0.12	0.44±0.23	0.60±0.26
<i>P</i> Value	0.052		0.178	
Post DCNVA	0.23±0.23	0.59±0.10	0.48±0.29	0.72±0.09
<i>P</i> Value	0.001**		0.033*	

Statistically significant, **p* value <0.05; ***p* value <0.01; ****p* value <0.001.

Abbreviations: CDVA = corrected distance visual acuity, DCIVA = distance-corrected intermediate visual acuity, DCNVA = distance-corrected near visual acuity, Pre = Preoperative, Pos = Postoperative, A = group A, B= group B, C= group C, D= group D.

TABLE 3. Preoperative and postoperative optical quality in four group

Parameter	A		B		C		D	
	Pre	Pos	Pre	Pos	Pre	Pos	Pre	Pos
MTF cut-off	11.82±8.80	45.22±7.14	7.93±4.97	43.26±7.65	10.37±7.80	43.02±9.44	9.26±7.11	41.43±8.23
<i>P</i> Value	<0.001***		<0.001***		<0.001***		<0.001***	
SR	0.08±0.04	0.28±0.07	0.06±0.02	0.28±0.06	0.07±0.02	0.21±0.09	0.07±0.04	0.20±0.11
<i>P</i> Value	<0.001***		<0.001***		<0.001***		<0.001***	
OSI	5.94±3.21	0.85±0.36	6.71±3.65	0.85±0.26	6.35±3.41	1.01±0.45	6.87±3.35	1.16±0.25
<i>P</i> Value	<0.001***		<0.001***		<0.001***		<0.001***	

Statistically significant, **p* value <0.05; ***p* value <0.01; ****p* value <0.001.

Abbreviations: MTF = modulation transfer function (refers to the frequency at which the MTF reaches 1% contrast); SR = Strehl ratio (describes the ratio of central maximum of the illuminance of the point spread function in the aberrated eye to the central maximum of the aberration-free system—the closer it is to 1, the smaller the aberration of the eye); OSI = Objective Scatter Index (an index of intraocular scattered light, equal to the amount of light outside the double-pass retinal intensity point-spread function image in relation to the amount of light on the center). Pre=Preoperative, Pos=Postoperative, A = group A, B= group B, C= group C, D= group D.

TABLE 4. The intraoperative, early and late postoperative complications after multifocal and monofocal IOL implantation.

Complications	multifocal IOL	monofocal IOL	P Value
Intraoperative complications			
Intraoperative lens dislocation	0(0%)	0(0%)	NA
Posterior capsules rupture	2(0.91%)	6(2.74%)	0.312
Postoperative complications-early stage			
Corneal edema	5(2.28%)	18(9.84%)	0.017*
Transient intraocular hypertension	5(2.28%)	22(12.02%)	0.006**
Anterior chamber hyphema	0(0%)	0(0%)	NA
Choroidal effusion	0(0%)	0(0%)	NA
Postoperative complications-late-stage			
IOL decentration	1(0.45%)	5(2.73%)	0.081
Glaucoma	0(0%)	2(1.09%)	0.316
VAO	0(0%)	12(6.56%)	0.014*

Statistically significant, *p value <0.05; **p value <0.01; ***p value <0.001.

Abbreviations: VAO = visual axis opacification.

Contents Statement

During the follow-up period, visual function was significantly improved after multifocal IOL optic implantation in Berger space in pediatric patients and the incidence of complications was low. This will provide new insights and guidance for more pediatricians.

Declaration of interests

Yichao Ding: I have nothing to declare.

Xiaomei Wan: I have nothing to declare.

Ling Kong: I have nothing to declare.

Qiuxuan Du: I have nothing to declare.

Mingming Jiang: I have nothing to declare.

Feijia Xie: I have nothing to declare.

Yi Pang: I have nothing to declare.

Wenjie Su: I have nothing to declare.

Jing Zhang: I have nothing to declare.

Lixin Xie: I have nothing to declare.

Yusen Huang: I have nothing to declare.