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Diopter errors and safety of secondary intraocular lens implantation in the ciliary sulcus using a modified incision procedure in children with bilateral aphakia

Ma Zicheng, Zhu Siquan

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Department of Ophthalmology, Beijing Anzhen Hospital, Capital Medical University, Beijing 100029, China

Correspondence to: Zhu Siquan. Department of Ophthalmology, Beijing Anzhen Hospital, Capital Medical University, Beijing 100029, China. siquanzhu@qq.com

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双侧无晶状体患儿采用改良切口Ⅱ期睫状沟 IOL 植入术后的屈光度误差及安全性评估

马子程,朱思泉

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作者单位:(100029)中国北京市,首都医科大学附属北京安贞医院眼科

作者简介:马子程,毕业于首都医科大学,硕士,主治医师,教学秘书,研究方向:白内障。

通讯作者:朱思泉,毕业于首都医科大学,博士,主任医师,教授,研究方向:白内障、屈光. siquanzhu@qq.com

摘要

目的:评估双侧无晶状体儿童采用改良切口Ⅱ期睫状沟人工晶状体(IOL)植入术的屈光度误差及安全性。

方法:回顾性分析 2020/2021 接受改良切口Ⅱ期睫状沟折叠式 IOL 植入术的 12 例 24 眼双侧无晶状体儿童资料。分析术中、术后 1 d 及术后 1 mo 切口相关并发症的发生情况,记录最佳矫正视力(BCVA),眼轴长度(AL),水平角膜直径(WTW),以及术前预留屈光度(PRD)和实际等效球镜屈光度(AESD)的屈光结果。将患者按年龄(≤7 岁和>7 岁)、AL(<23 和≥23 mm)和 WTW(≤11.5 和>11.5 mm)分为两组,比较根据测量结果预测的 AESD 和 PRD 之间屈光度误差。

结果:在所有患儿中,男孩 9 例(75%),女孩 3 例(25%),其中 2 例(17%)为前囊下白内障,4 例(33%)为后极性白内障,6 例(50%)为核性白内障。白内障摘除时的平均年龄为 6.4±1.61(3.4-8.9)mo,白内障摘除至Ⅱ期 IOL 植入术的平均时间间隔为 6.8±1.82(4.4-11.5) a。术前平均 BCVA 为 0.49±0.33(1.0-0.1) LogMAR,术后平均 BCVA 为 0.38±0.32(1.0-0.0) LogMAR。平均 AL 为 23.56±1.96(19.00-26.38) mm,平均 WTW 为 11.5±0.92(9.3-13.9) mm,平均 PRD 为 1.57±0.60(0.73-2.77) D,平均 AESD 为 0.57±0.55(-0.50-1.75)D,AESD 与 PRD 的平均差值为-0.99±0.52(-2.22-0.32)D。按年龄、AL、WTW 分组的 AESD、PRD 差异无统计学意义(P=0.59、0.56、0.53)。

结论:无晶状体儿童采用改良切口Ⅱ期睫状沟 IOL 植入安全可行。在睫状沟植入 IOL 时,需要从公式选择的 IOL 度数中减去约 1 D。年龄、AL 和 WTW 对差异无显著影响。

关键词:先天性白内障;Ⅱ期人工晶状体植入术;改良切口;屈光度误差

Abstract

• AIM: To evaluate the diopter errors and safety of secondary intraocular lens (IOL) implantation in the ciliary sulcus using a modified incision procedure in children with bilateral aphakia.

• METHODS: The data of 12 children (24 eyes) with bilateral aphakia who had undergone secondary foldable IOL implantation in the ciliary sulcus using a modified incision procedure from 2020 to 2021 were retrospectively reviewed. Incision-related complications were analyzed intraoperatively and at 1 d and 1 mo postoperatively. Best-corrected visual acuity (BCVA), axial length (AL), white-to-white (WTW), and refractive outcomes in terms of preoperative reserved diopters (PRD) and actual equivalent spherical diopters (AESD). The patients were divided into two groups by age (≤7 and >7 a), AL (<23 and ≥23 mm) and WTW (≤11.5 and >11.5mm), and the diopter errors between their AESD and PRD predicted based on the measurement results were compared.

• RESULTS: The patients comprised 9 (75%) boys and 3 (25%) girls. Two (17%) patients had anterior subcapsular cataracts, 4 (33%) had posterior polar cataracts, and 6 (50%) had nuclear cataracts. The mean age at cataract extraction was 6.4±1.61 (3.4-8.9) mo. The mean interval between cataract extraction and secondary IOL implantation was 6.8±1.82 (4.4-11.5) a. The mean preoperative BCVA was 0.49±0.33 (1.0-0.1) LogMAR. The mean postoperative BCVA was 0.38±0.32 (1.0-0.0) LogMAR. The mean AL was 23.56±1.96 (19.00-26.38) mm, and the mean WTW was 11.5±0.92 (9.3-13.9) mm. The mean PRD was 1.57±0.60 (0.73-2.77) D, the mean AESD was 0.57±0.55 (-0.50 to 1.75) D, and the mean difference between the AESD and PRD was −0.99±0.52 (−2.22 to 0.32) D. The differences in the AESD and PRD between the groups according to age, AL and WTW were not statistically significant (P = 0.59, 0.56, and 0.53, respectively).

• CONCLUSION: IOL implantation in the ciliary sulcus after a modified incision is safe and feasible for children with aphakia. It is necessary to subtract approximately 1 D of IOL power from the formula-selected power when implanting an IOL in the ciliary sulcus. Age, AL, and WTW do not significantly affect the difference.

• KEYWORDS: congenital cataract; secondary intraocular lens implantation; modified incision; diopter errors
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INTRODUCTION

Congenital cataract is one of the leading causes of visual loss in children[1]. As the main cause of childhood blindness worldwide, congenital cataract has a variable prevalence of 0.6 to 9.3 per 10 000 live births, and it is approximately equally divided between bilateral and unilateral cases[2]. Despite the potentially significant risks of cataract surgery in the youngest infants, delaying or foregoing surgery leads to irreversible deprivation amblyopia[3]. Therefore, early surgical treatment of congenital cataract is an important means to treat this disease[1,4].

Secondary intraocular lens (IOL) implantation, as an ideal correction method for refractive error, is vital for vision reconstruction after cataract extraction[5]. However, because of many challenges involved in choosing the IOL power and difficulties in predicting postoperative diopters, secondary IOL implantation remains controversial[6-7].

Sulcus IOL implantation is widely performed for patients in whom the residual capsule cannot be successfully reopened during secondary IOL implantation[8]. Because of the imperfect IOL position, these patients' postoperative diopters are significantly different from those in patients who have been treated with in-the-bag IOL implantation[8-9].

The traditional surgical incision for IOL implantation is the scleral tunnel incision, which requires opening the conjunctiva and using a scleral tunneling knife[10]. This incision method is a cumbersome process and more damaging to the ocular tissues; additionally, the postoperative suture causes more corneal astigmatism, which will affect the outcome of the surgery.

Therefore, we devised an improved surgical incision in which the number of steps and severity of tissue damage are reduced than conventional incision methods[10-11]. In the present study, we used this modified incision for secondary IOL ciliary sulcus implantation in children with bilateral aphakia and analyzed the incision-related surgical safety and postoperative refractive outcomes.

SUBJECTS AND METHODS

Ethical Approval The Ethics Committee of Beijing Anzhen Hospital approved this study (No.2023213X). All relevant tenets of the Declaration of Helsinki were followed throughout. Written informed consent was obtained from all participants prior to inclusion of patient data as well as the surgery.

This retrospective study involved 19 bilateral aphakia patients who underwent secondary IOL implantation in the ciliary sulcus from 2020 to 2021 at Capital Medical University Affiliated to Beijing Anzhen Hospital in China. The reason for implantation in the sulcus in all patients was difficulty in capsule reopening. All patients who underwent implantation met the following surgical indications: age of ≤14 years, a history of bilateral cataract extraction at <1 year of age during the initial cataract removal surgery, and confirmation of the IOL in a satisfactory position at the observation time point following the second-phase IOL implantation.

We prefer to leave a certain degree of hyperopia in infants, mainly according to their age. Specifically, we have a postoperative refractive goal of +4.00 D for children aged <2 years, +3.00 D for children aged 2 to 4 years, +2.00 D for children aged 4 to 6 years, +1.00 D for children aged 6 to 8 years, and plano for children aged >8 years. In addition to age, we also adjust the degree of reservation according to the axial length (AL) to a certain extent. Specifically, for children with an excessively long AL, the reservation should be reduced accordingly to allow for better adaptation; by contrast, for children with a shorter AL, the reservation is appropriately increased. Ciliary sulcus implantation causes the IOL to move forward to a certain extent; therefore, in this study, we left an additional +1 D to +1.5 D for each patient[12].

Four formulas (Sanders, Retzlaff, and Kraff/Theoretical [SRK/T] formula; Hoffer Q formula; Barrett formula; and Haigis formula) were used to choose the IOL power. The SRK/T and Hoffer Q formulas were used for patients with an AL of ≤21 mm, and the Barrett and Haigis formulas were used for those with an AL of >21 mm[13].

Surgical Procedure Data regarding the patients' clinical characteristics was extracted from the case records. Before surgery, we obtained the patients' history of primary cataract removal surgery and performed detailed examinations including visual acuity measurement, intraocular pressure measurement, slit lamp examination, retinoscopy, and B-scan ultrasound. The Zeiss IOLMaster 700 (Carl Zeiss Meditec, Jena, Germany) was used to calculate the IOL power.

All surgeries were performed by two experienced surgeons (Zhu and Ma) with the patients under general anesthesia after 3 days of treatment with Levofloxacin eye drops. Tropicamide phenylephrine eye drops were used four times within 1 h prior to surgery. A 3.0-mm conjunctival-scleral incision was made for each patient, 2.0 mm behind the corneal limbus and 1 mm inside the limbus into the anterior chamber (Figure 1). After separating the pupillary adhesions, the capsule was examined in detail. The vitreous body that affected the implantation of the IOL was cleaned. In all patients, a single-piece, single-focal foldable IOL was implanted by ejector in the sulcus because of difficulty reopening the capsule. The procedure was completed by creating a secure and well-sealed 3.0-mm incision, followed by aspiration of the viscoelastic material from the anterior chamber. Postoperative tobramycin and dexamethasone eye drops and recombinant bovine basic fibroblast growth factor eye drops were administered six times a day for 2 wk, and then reduced to four times a day for 2 wk. During the surgery and/or 1 d after the surgery, the patients were examined for incision-related complications such as conjunctival hemorrhage, hyphema, iris prolapse, capsular tear, preexisting posterior capsule defect, IOL implantation difficulty, and failed incision closure. On the first day after surgery, the incision was stained with sodium fluorescein staining paper to record the leakage. Late incision-related complications such as iris insertion and hypotony were recorded at the 30-day postoperative visit.

The patients' actual diopters were determined by optometry 1 mo after surgery and compared with the preoperative reserved diopters (PRD).

Statistical Analysis All results were analyzed using SPSS version 22.0 (IBM Corp., Armonk, NY, USA). Frequency and percentage were recorded for categorical variables, while mean±standard deviation and median (range) were calculated for continuous variables. Analysis of variance or the Mann-Whitney *U* test was employed to compare the mean difference in diopters between different groups (age, AL, white-to-white measurement) depending on the normality of the analyzed variables. $P < 0.05$ was considered statistically significant.

RESULTS

From 2020 to 2021, 19 pediatric patients with aphakia who underwent secondary IOL implantation because of congenital cataracts were included in the evaluation. A total of 5 patients were excluded because of the need for suture fixation of one or both eyes during secondary IOL implantation. We also excluded 1 patient who developed partial IOL displacement within 1 month of surgery. One child with a missed follow-up visit was also excluded. Therefore, 12 patients (24 aphakic eyes) were eligible for inclusion and analyzed. All included patients were diagnosed with bilateral congenital cataracts and underwent bilateral cataract extraction within 1 year of age. Data on their clinical characteristics are summarized in Table 1. The patients comprised 9 (75%) boys and 3 (25%) girls. A total of 6 (25%) patients had anterior subcapsular cataracts, 7 (29%) had posterior polar cataracts, and 11 (46%) had nuclear cataracts (Figure 2). The mean age at cataract extraction was 6.4±1.61 (3.4-8.9) mo. The mean interval between cataract extraction and secondary IOL implantation was 6.8±1.82 (4.4-11.5) years. The mean preoperative best-corrected visual acuity (BCVA) was 0.49±0.33 (1.0-0.1) LogMAR. The mean postoperative BCVA was 0.38±0.32 (1.0-0.0) LogMAR. The mean follow-up was 33.25±4.09 (29-42) d (Figure 3).

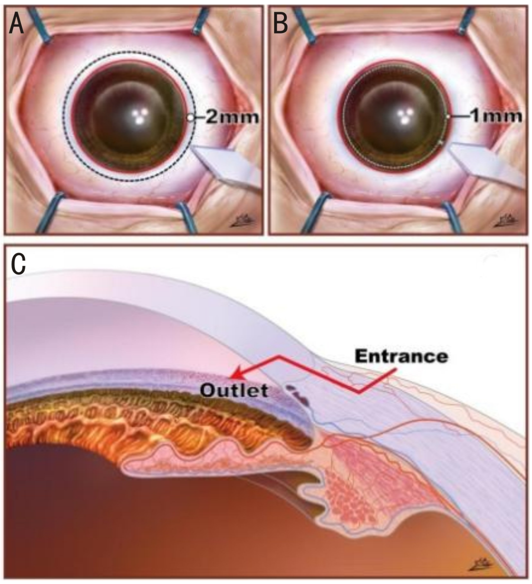

Figure 1 The diagram of the modified incision procedure. A: The entrance location of the incision, 2 mm outside the limbus of the cornea, directly through the conjunctiva into the sclera; B: The incision into the anterior chamber from a position of 1 mm within the limbus of the cornea; C: The path of the incision in conjunctival, sclera and corneal tissue.

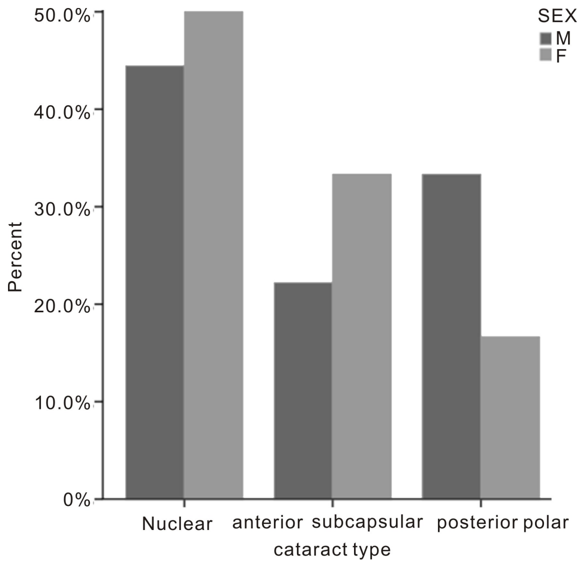

Figure 2 The ratio of cataract types and the proportion of male and female with different types of cataracts. The cataract types of the patients included in this trial were centered on nuclear, posterior polar, and anterior subcapsular, with a proportion of 46%, 29% and 25%. M: Male; F: Female.

We analyzed the basic results of ocular measurements in all patients. The mean AL was 23.56±1.96 (19.00-26.38) mm, and the mean white-to-white was 11.5±0.92 (9.3-13.9) mm.

All patients had conjunctival bleeding of different severities during performance of the incision. After application of pressure using cotton swabs and other hemostatic methods, the

Table 1 Basic information of the 12 enrollees, including gender, age, cataract type, time of extraction, interval time between cataract extraction and duration of follow-up

No.	Sex	Age (year)	Cataract type	Extraction age (mo)	Interval time (a)	Follow-up time (d)
1	M	7	nuclear	3.40	6.80	32
		7	anterior subcapsular	3.40	6.80	32
2	M	7	posterior polar	4.20	6.70	35
		7	nuclear	4.20	6.70	35
3	M	7	posterior polar	5.20	6.60	39
		7	posterior polar	5.20	6.60	39
4	M	12	anterior subcapsular	6.60	11.50	42
		12	posterior polar	6.60	11.50	42
5	M	8	nuclear	7.70	7.40	31
		8	nuclear	7.70	7.40	31
6	F	7	nuclear	5.60	6.60	36
		7	nuclear	5.60	6.60	36
7	M	10	nuclear	6.90	9.40	30
		10	posterior polar	6.90	9.40	30
8	M	7	posterior polar	8.90	7.30	29
		7	anterior subcapsular	8.90	6.30	29
9	M	5	nuclear	7.70	4.40	31
		5	anterior subcapsular	7.70	4.40	31
10	F	6	posterior polar	6.40	5.50	29
		6	anterior subcapsular	6.40	5.50	29
11	F	9	anterior subcapsular	5.90	8.50	30
		9	nuclear	5.90	8.50	30
12	M	9	nuclear	8.30	8.30	35
		9	nuclear	8.30	8.30	35

M:Male; F:Female.

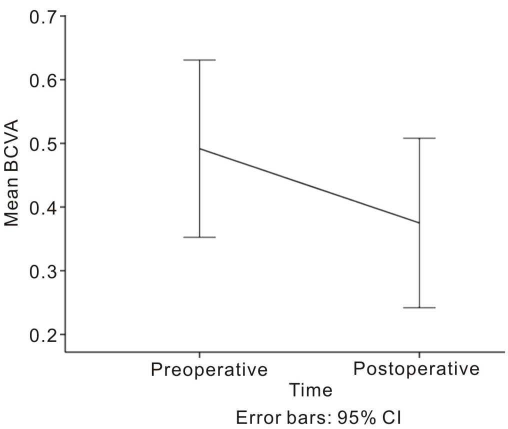

Figure 3 Significant improvement in the preoperative and postoperative best - corrected visual acuity (LogMAR) comparisons for all included patients. BCVA: Best corrected visual acuity.

conjunctival bleeding had disappeared by the end of the operation. Intraoperative hyphema occurred in 2 (8%) eyes and was effectively controlled by irrigation with perfusion fluid. No new hyphema was observed at either 1 d or 1 mo after surgery. Iris prolapse was not observed in any patients during or after the surgery. At the end of the operation, the incision was well sealed, and the anterior chamber and intraocular pressures were good. On the first day after surgery, the incisions were observed with fluorescein sodium staining, and no signs of leakage (stream sign) were observed at the incisions in all patients. The intraocular pressure did not indicate hypotony.

We compared the patients' PRD with the actual equivalent spherical diopters (AESD) after surgery. The mean PRD was 1.57±0.60 (0.73-2.77) D, and the mean AESD was 0.57±0.55 (-0.5 to 1.75) D (Figure 4). The mean difference between the AESD and PRD was -0.99±0.52 (-2.22 to 0.32) D (Figure 5).

In addition, we divided all the patients into two groups according to their age (≤7 *vs*>7 years) and compared the difference between their AESD and PRD predicted based on the measurement results. The comparison between the two groups showed no significant difference (P=0.59). We also grouped the patients according to the actual AL of the eye (<23 *vs* ≥23 mm), and the difference between the two groups was not statistically significant (P=0.56). Finally, we compared the actual refractive error values of the larger and smaller groups using a white-to-white measurement cut-off of 11.5 mm, and again the results were not statistically significant (P=0.53; Figure 6).

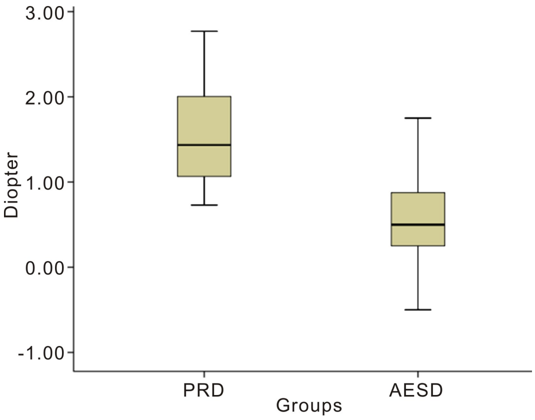

Figure 4 The comparison between the preoperative reserved diopter and the postoperative actual equivalent spherical diopters. It can be clearly seen that the postoperative actual equivalent spherical diopters is significantly smaller than the preoperative reserved diopter. PRD: Preoperative reserved diopter; AESD: Actual equivalent spherical diopters.

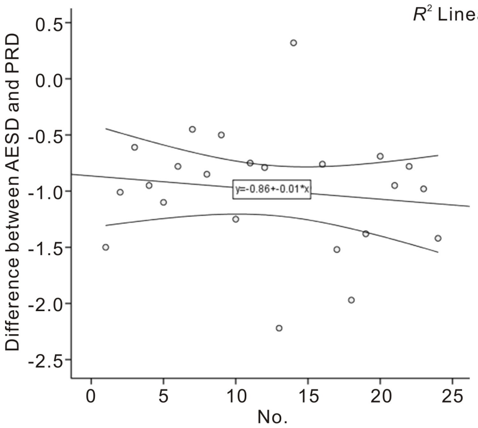

Figure 5 A scatterplot as well as a linear regression trendline for the difference between the preoperative reserved diopter and the actual equivalent spherical diopters. The mean difference between the AESD and the PRD was −0.99±0.52 (−2.22−0.32) D. PRD: Preoperative reserved diopter; AESD: Actual equivalent spherical diopters.

DISCUSSION

Sen *et al*[14-15] compared the safety, feasibility, and outcome of clear corneal cataract surgery with or without sutures in children aged 2 to 8 years with congenital or developmental cataracts and found that sutureless incisions were not inferior to sutured incisions. A clear corneal incision is the least invasive incision choice in intraocular surgery[16]. Although the tissue elasticity of children is weak, cataract phacoemulsification combined with IOL implantation is relatively simple. Many studies have confirmed the good effect of corneal or scleral incision on pediatric cataract combined with IOL implantation[15,17-18]. However, secondary IOL implantation in children often requires separation of the heavily adherent iris, making the operation more complex and

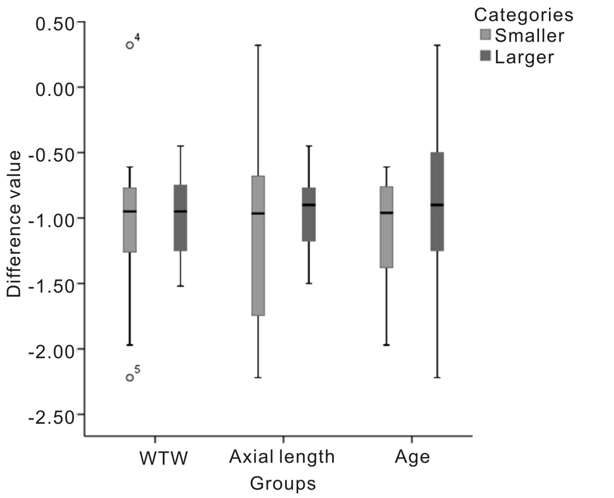

Figure 6 Mean difference of the three larger-value groups compared with the smaller-value group for the dividing line of white-to-white (11.5 mm), axial length (23 mm), and age (7 years). Although the results are not statistically significant, it can be clearly seen that the data of each group is basically around −1.0 D. WTW: White-to-white.

disrupting the iris more[19]. Iris prolapse is more likely to occur in such cases; therefore, a clear corneal incision is not a good option for secondary IOL implantation. Gangrade *et al*[20] conducted a 5-year retrospective study (2014-2019) of 138 eyes that had been treated by superior manual small-incision cataract surgery and found that this procedure resulted in minimal intraoperative complications and satisfactory visual and surgical outcomes for pediatric cataracts. Manual small-incision cataract surgery is the traditional surgical technique in pediatric cataract surgery, and its safety has been recognized; however, persistent problems include difficulty in creating a scleral tunnel and thin flap as well as buttonhole formation[20-22]. Few studies have focused on the choice of incision for secondary IOL surgery. Gupta *et al*[11] reported a modified scleral incision technique in which they first fabricated a conjunctival flap and then a scleral tunnel superiorly. A 3.2-mm partial-thickness scleral groove was made, and a tunnel was constructed using a 2.2-mm bevel-up crescent blade. The tunnel dissection was carried out 1 mm into the clear cornea. Anterior chamber entry was achieved using a 3.2-mm bevel-up keratome (Alcon, Geneva, Switzerland). The conjunctival-scleral tunnel dissection in this study was similar to that performed by Gupta *et al*[11]. However, we did not make a conjunctival flap and did not need to construct the tunnel with a 2.2-mm blade, making the procedure relatively simple. We integrated the advantages of traditional scleral tunnel dissection, ensuring effective closure, while minimizing the damage associated with traditional large tunnels. The results of our study also showed good surgical outcomes.

Measuring and selecting the IOL degree for secondary IOL implantation in children has always been a difficult issue in the field of pediatric cataract treatment[23]. Especially when the lens capsular bag cannot be opened and the IOL must be implanted into the ciliary sulcus, the complexity of the IOL position and thus the uncertainty of the actual postoperative refractive error increases[24-25]. Jafarinasab *et al*[26] used two formulas based on the aphakic refraction (Ianchulev and Leccisotti formulas). Unlike our technique in the present study, they calculated the mean absolute error and median absolute error differences between the true and calculated IOL power and found that these values were −0.9±2 and −1.1, respectively. This is in general agreement with the results of our study, which showed a difference of −0.99±0.52. In contrast to Jafarinasab *et al*[26], however, we chose commonly used formulas (SRK/T, Hoffer Q, Barrett, and Haigis formulas) and adjusted these formulas for different ALs (Hoffer Q for patients with AL of ≤21 mm, Barrett and Haigis for those with AL of >21 mm). The conclusion was consistent, indicating that the traditional formula for calculating the IOL power remains stable for secondary IOL implantation in children. Liu *et al*[27] compared the accuracy of IOL power calculations between intracapsular bag implantation and ciliary sulcus implantation in children and recommended that the power of a sulcus-implanted IOL should be reduced by 0.50 D to 2.50 D accordingly. This is a relatively wide range. Based on our research findings, we recommend that clinicians give more priority to a decrease of +1 D in the clinical setting, which is more conducive to clinicians' choice. Fossati *et al*[28] assessed the refractive outcomes of patients who underwent sulcus implantation of the Camellens FIL622-1 IOL (Soleko, Pontecorvo, Lazio, Italy) after posterior capsular rupture. They also optimized the A-constant suggested by the manufacturer. The A-constant recommended by the manufacturer of 118.8 was optimized to 117.5 (optimized by −1.3), which is also in general agreement with the results of our experiment. The ciliary sulcus structure in children with aphakia is more complex, and it is hoped that a more reliable A-constant optimization strategy can be derived in the future.

However, few reports have focused on whether different ALs, white-to-white, or ages affect differences of +1 D. Our comparisons of children grouped according to these three factors showed no statistically significant differences. Notably, a limitation of this study is its small sample size; whether increasing the sample size will lead to different results remains to be determined.

No standardized criteria have been established for the age at which secondary IOL implantation should be performed after removal of congenital cataracts in children. In children with bilateral congenital cataracts, implantation of the IOL at preschool age is frequently recommended to avoid myopic drift, at least to some extent[29]. However, among the patients in the present study, some of the younger patients had poorer corrected visual acuity because of poor wearing of frame glasses or corneal contact lenses, or their guardians were unable to ensure regular optometry visits and timely replacement of glasses or contact lenses in the children. We prefer to perform second-stage IOL implantation earlier in children, and this observation has been previously reported as well[30].

Surgical treatment of congenital cataracts in children is more challenging than that in adults. In this study, we analyzed the safety of a modified incision for secondary IOL ciliary sulcus implantation in children with bilateral congenital cataracts and investigated the preoperative and postoperative changes in the refractive status of these children. Our aim is to provide a reference for IOL degree selection.

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