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Capsular Outcomes After Pediatric Cataract Surgery Without Intraocular Lens Implantation

Qualitative Classification and Quantitative Measurement

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Abstract: The objective of this study was to investigate capsular outcomes 12 months after pediatric cataract surgery without intraocular lens implantation via qualitative classification and quantitative measurement.

This study is a cross-sectional study that was approved by the institutional review board of Zhongshan Ophthalmic Center of Sun Yat-sen University in Guangzhou, China.

Digital coaxial retro-illumination photographs of 329 aphakic pediatric eyes were obtained 12 months after pediatric cataract surgery without intraocular lens implantation. Capsule digital coaxial retro-illumination photographs were divided as follows: anterior capsule opening area (ACOA), posterior capsule opening area (PCOA), and posterior capsule opening opacity (PCOO). Capsular outcomes were qualitatively classified into 3 types based on the PCOO: Type I—capsule with mild opacification but no invasion into the capsule opening; Type II—capsule with moderate opacification accompanied by contraction of the ACOA and invasion to the occluding part of the PCOA; and Type III—capsule with severe opacification accompanied by total occlusion of the PCOA. Software was developed to

quantitatively measure the ACOA, PCOA, and PCOO using standardized DCRPs. The relationships between the accurate intraoperative anterior and posterior capsulorhexis sizes and the qualitative capsular types were statistically analyzed.

The DCRPs of 315 aphakic eyes (95.8%) of 191 children were included. Capsular outcomes were classified into 3 types: Type I—120 eyes (38.1%); Type II—157 eyes (49.8%); Type III—38 eyes (12.1%). The scores of the capsular outcomes were negatively correlated with intraoperative anterior capsulorhexis size ($R = -0.572, P < 0.001$), but no significant correlation with intraoperative posterior capsulorhexis size ($R = -0.16, P = 0.122$) was observed. The ACOA significantly decreased from Type I to Type II to Type III, the PCOA increased in size from Type I to Type II, and the PCOO increased from Type II to Type III (all $P < 0.05$).

Capsular outcomes after pediatric cataract surgery can be qualitatively classified and quantitatively measured by acquisition, division, definition, and user-friendly software analyses of high-quality digital coaxial retro-illumination photographs.

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Abbreviations: ACOA = anterior capsule opening area, CCPMOH = Childhood Cataract Program of the Chinese Ministry of Health, DCRP = digital coaxial retro-illumination photograph, ECO = Evaluation of Capsular Outcomes, IOL = intraocular lens, LEC = lens epithelial cell, PCOA = posterior capsule opening area, PCOO = posterior capsule opening opacity, VAO = visual axis opacity, ZOC = Zhongshan Ophthalmic Center.

INTRODUCTION

Capsulorhexis is a core technique of modern cataract surgery; however, capsular outcomes substantially differ in pediatric patients compared with adult patients. Different capsular outcomes will induce various capsule-related complications, such as anterior capsulorhexis opening area (ACOA) contraction, posterior capsulorhexis opening area (PCOA) reclosure, posterior capsular opening opacity (PCOO), and capsular contraction, as well as an imbalance of capsular tension.¹ In pediatric cataract surgery, even with additional limited anterior vitrectomy, postoperative capsule-related complications are very common due to the high proliferative capacity of lens epithelial cells (LECs) and severe postoperative inflammation that occurs in both infants and young patients.^{1,2}

In infant cataract surgery, the issue regarding whether to implant an intraocular lens (IOL) at the time of surgery or leave the child aphakic with a secondary IOL implantation later in childhood is controversial. Recently, the Infant Aphakia Treatment Study demonstrated that cataract surgery without IOL implantation is optimal for infantile patients with a relatively

lower incidence of visual axis opacity (VAO) and the need for second interventions and decreasing costs.^{3,4} Thus, many surgeons choose to leave infantile cataract patients aphakic prior to the mature and stable development of the eye ball.

The aphakic eye represents a special situation for pediatric cataract treatment.⁵⁻⁷ Without an IOL, the anterior capsule and posterior capsule will adhere in aphakic eyes, and the size and shape of the ACOA and PCOA can change and even reclose due to capsular contraction and LEC proliferation.⁸⁻¹⁰ Many pediatric ophthalmologists have recognized that the ideal site for secondary IOL implantation is the capsular bag because in-the-bag implantation sequesters the IOL from the highly reactive uveal tissue and maintains better IOL centration,¹¹⁻¹³ especially for hyper-responsive infant patients.¹⁴ However, capsular contraction and an imbalance in capsular tension of aphakic eye are unfavorable outcomes for secondary in-the-bag IOL placement.^{8,15}

An increasing number of ophthalmologists have realized that capsular outcomes after pediatric cataract surgery are among the most important postoperative factors that determine the final visual prognosis. However, few studies regarding the types/forms of capsular outcomes after pediatric cataract extraction surgery as a result of cell proliferation, fibrosis, contraction, and/or ending PCOO have been published. The purpose of this cross-sectional study was to qualitatively classify the capsular outcomes in aphakic eyes 12 months after pediatric cataract surgery and to quantitatively measure the ACOA, PCOA, and PCOO using our self-developed computerized program, which was specifically developed for the evaluation of capsular outcomes.

SUBJECTS AND METHODS

This cross-sectional study was performed at the Zhongshan Ophthalmic Center (ZOC) at Sun Yat-sen University in Guangzhou, China, which is the location of the Childhood Cataract Program of the Chinese Ministry of Health (CCPMOH).¹⁶ All children registered with the CCPMOH were diagnosed using anterior segment photography to confirm the morphology, location, and degree of cataract after pupil dilation. From June 2012 to November 2013, a total of 217 pediatric cataract patients were selected 12 months after undergoing surgery at the CCPMOH, which is conducting a series of ongoing studies on the influence of early interventions on the long-term outcomes of pediatric cataract treatment. Only patients who were >2 years old were considered for this study.

Exclusion criteria included preterm birth, microphthalmia, micro-or megalocornea, keratoconus, glaucoma, traumatic or complicated cataracts, retinal disease, and additional surgeries during the first year after the first cataract surgery.

All study patients underwent surgery performed by 2 senior surgeons (YZL and WRC), which included an anterior central curvilinear capsulotomy with a diameter range of 4.5 to 5.5 mm, cataract extraction, a posterior central curvilinear capsulotomy with a diameter range of 3.0 to 3.5 mm and a limited anterior vitrectomy without IOL implantation at ZOC. The accurate sizes of the intraoperative anterior and posterior capsulorhexis were measured with a self-made calibrated needle with a laser marker (1-mm scale) (Xinkeling, Inc, Shanghai, China) and recorded in 95 eyes (Figure 1). Postoperatively, Tobradex eye drops (tobramycin 0.3%, dexamethasone 0.1%, Alcon Laboratories, Fort Worth, TX) were utilized 6 times per day, and Tobradex eye ointment (tobramycin 0.3%, dexamethasone 0.1%, Alcon Laboratories, Fort Worth, TX) was applied once per night for 2 weeks. From 2 weeks to 1 month postoperatively, the eye drops were administered 4 times per day. For the second postoperative month, the patient switched to the use of Pranoprofen eye drops 4 times per day (Senju Pharmaceutical Co, Ltd, Osaka, JP).

The study was approved by the institutional review board of Zhongshan Ophthalmic Center of Sun Yat-sen University (IRB-ZOC-SYSU) in Guangzhou, China. Written informed consent was obtained from at least 1 parent or guardian of each participating child, and the tenets of the Declaration of Helsinki were adhered to throughout this study. Figure 2 provides a flowchart that details the patient selection, examination, and analysis.

Slit-Lamp-Adapted Anterior Segment Photography

All eligible pediatric patients underwent pupil dilation with compound tropicamide eye drops 3 to 5 times (once every 10 minutes) until the pupil size was >6 mm. Then, the children underwent slit-lamp-adapted anterior segment photography (BX900, Haag-Streit AG, K oniz, Switzerland) at 16 \times magnification for each operated eye, including 1 digital coaxial retroillumination photograph (DCRP), 1 diffuse light photo, and 1 slit-light photo across the central visual axis. The photography was repeated several times until high-quality photos with high resolution were obtained. For uncooperative children, a set of assistance procedures for slit-lamp-adapted photography

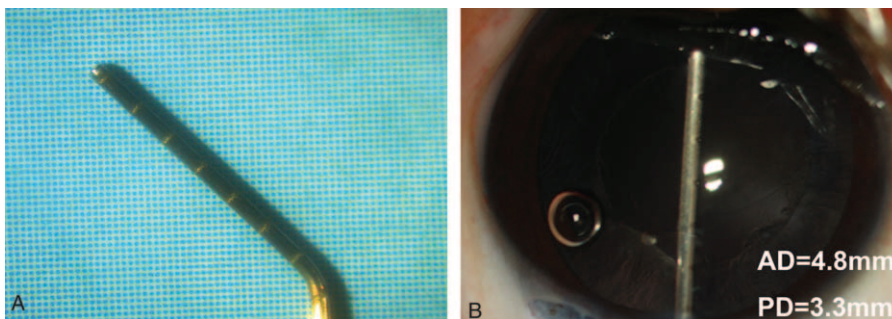


FIGURE 1. The self-made needle with laser markers (1-mm scale) used to measure the intraoperative anterior and posterior capsulorhexis diameter. (A) The 6 distinct laser markers (1-mm scale) on the needle. (B) A 4.8-mm anterior capsulorhexis and a 3.3-mm posterior capsulorhexis diameter were completed and measured with the laser-marker needle. AD=anterior capsulorhexis diameter, PD=posterior capsulorhexis diameter.

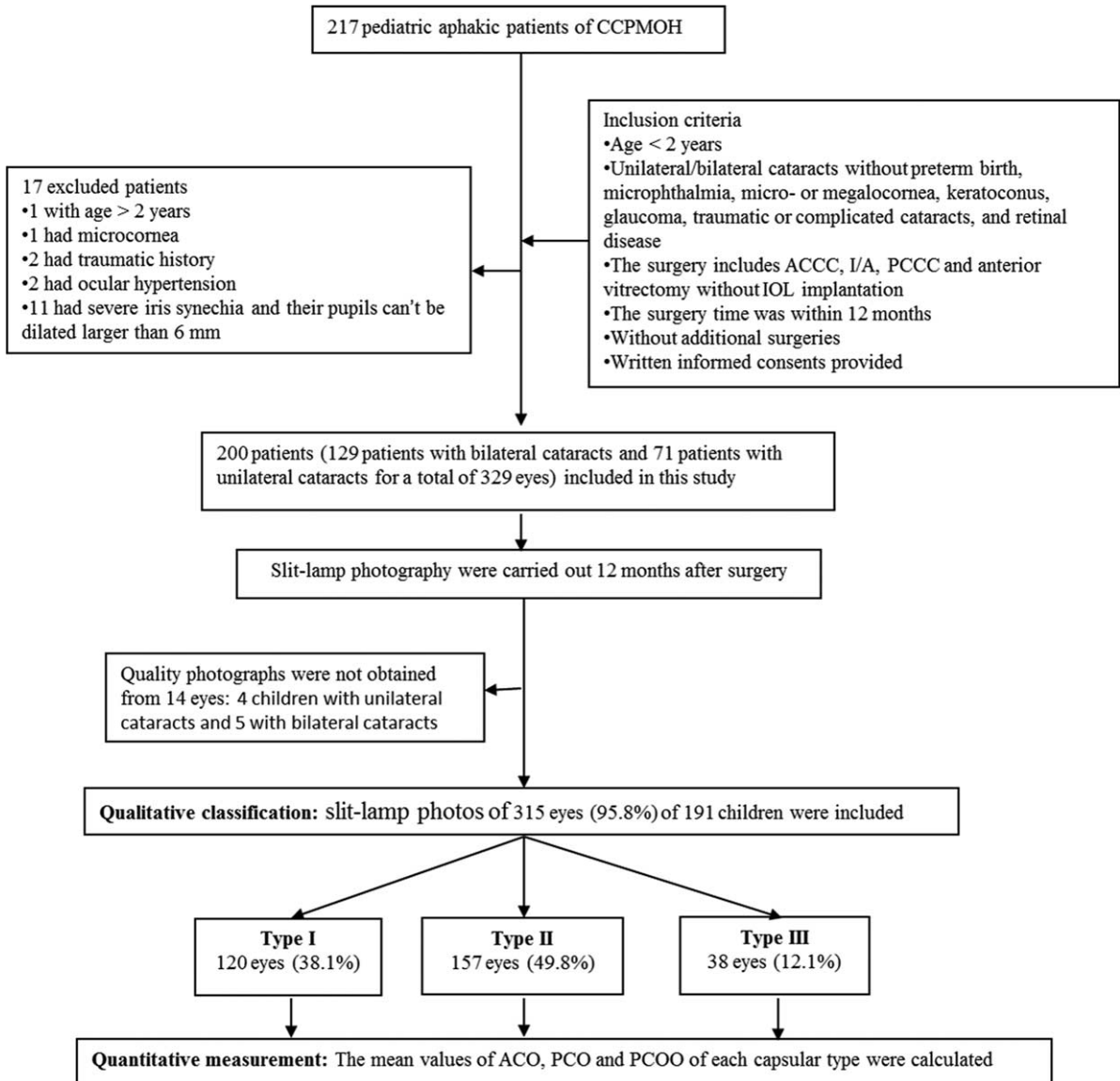


FIGURE 2. A flowchart of patient selection, examination, and analysis. ACCC = anterior central curvilinear capsulotomy, ACOA = anterior capsulorhexis opening area, CCPMOH = Childhood Cataract Program of the Chinese Ministry of Health, I/A = irrigation/aspiration, IOL = intraocular lens, PCCC = posterior central curvilinear capsulotomy, PCOA = posterior capsulorhexis opening area, PCOO = posterior capsular opening opacity.

was developed to instruct the parents to help prepare the child’s head position and to help the child open his or her eyes after administering chloral hydrate (10%, 0.5 mL/kg) as a sleep aid, as described in our previous studies.^{8,16,17} Written informed consent was obtained from at least 1 parent or guardian of each child for photography and/or chloral hydrate administration.

Division, Definition, and Qualitative Classification

The postoperative capsular DCRPs were divided and defined as follows: anterior capsule opening area (ACO), posterior capsule opening area (PCOA), and posterior capsule opening opacity (PCOO) (Figure 3A). The ACOA and PCOA are self-explanatory. The PCOO indicated lens epithelium

proliferation within the PCOA, which causes prominent opacity. Capsular outcomes were qualitatively classified into 3 types according to the degree and range of PCOO: Type I (Figure 4B)—capsule with mild cell proliferation and opacification around the ACOA and PCOA but no invasion into the capsule opening; Type II (Figure 4C)—capsule with moderate cell proliferation and opacification around the ACOA and PCOA accompanied by contraction of the ACOA and proliferative invasion to the occluding part of the PCOA (partial PCOO); and Type III (Figure 4D)—capsule with severe cell proliferation and opacification accompanied by total occlusion of the PCOA (total PCOO). Two researchers independently classified the capsular outcomes, and a third researcher was asked to determine when disagreement occurred between the first 2 researchers.

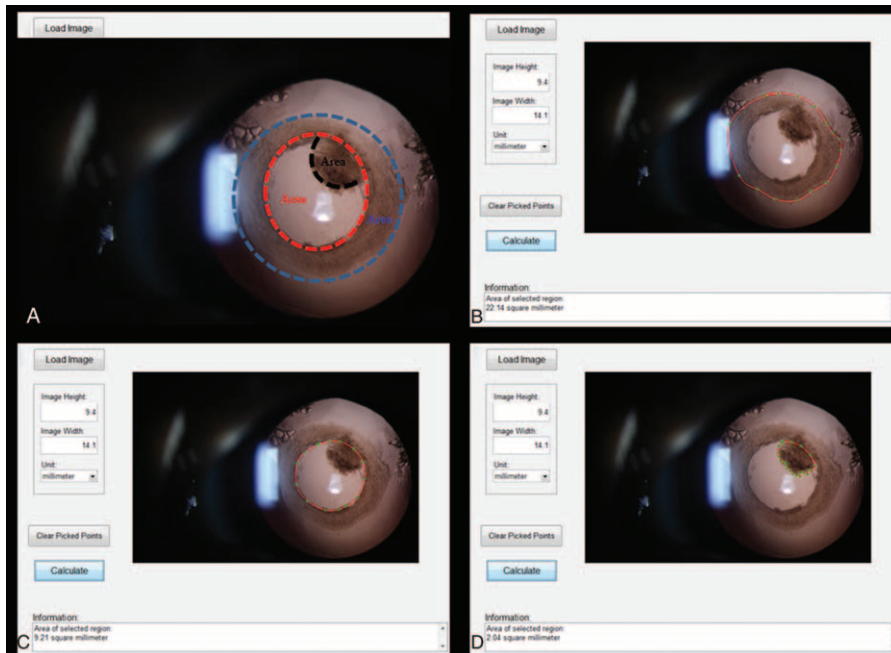


FIGURE 3. Division and definition of different capsule areas on standardized DCRPs. (A) Contour of different capsule areas in the retroillumination image, including the ACOA (blue area), PCOA (red area), and PCOO (black area). The ACOA (B), the PCOA (C), and PCOO (D) were traced by the ECO software. ACOA=anterior capsulorhexis opening area, ECO=evaluation of Capsular Outcomes, PCOA=posterior capsulorhexis opening area, PCOO=posterior capsular opening opacity.

Quantitative Measurement

The Evaluation of Capsular Outcomes (ECO) software, which is a custom image analysis algorithm developed by our team using MATLAB (The MathWorks Inc., Natick, MA), was applied to quantitatively measure the ACOA, PCOA, and PCOO (Figure 3B–D). The contours of the ACOA, PCOA, and PCOO were traced by hand using the ECO image processing software. Next, the capsule opening area, capsulorhexis diameter, and opacity area were measured by a computer. If multiple PCOOs existed, each opaque area was separately delineated and calculated by the program. Two researchers, who were masked to the qualitative classification of capsular outcomes, independently used the software to quantify the values of the ACOA, PCOA, and PCOO; the results are the mean values determined by the 2 researchers. The mean values of the ACOA, PCOA, and PCOO of each capsular type were calculated.

Statistical Analysis

Data for the numbers of different types and quantitative measurement indices were entered into a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, WA). Agreement between the readings, which was obtained by the 2 researchers, was calculated for each eye of each participant using the Bland–Altman limits of agreement. All measurements were determined to have normal distributions. The results are expressed as the means \pm 1 SD. An independent-sample test was conducted to assess the differences based on sex, and the Bonferroni test was utilized to compare the differences between any 2 types of capsules. Spearman correlation analysis was performed to assess the relationship between the types of capsular outcomes and the age at surgery,

the sex, the intraoperative anterior and posterior capsulorhexis size. A *P* value of < 0.05 was considered to be statistically significant and was adjusted for the effect of repeated measures on the same subject on sample size. All statistical analyses were performed using SPSS software, version 17 (SPSS Inc, Chicago, IL).

RESULTS

Of the 217 pediatric aphakic patients of the CCPMOH, 17 patients were excluded (Figure 2). The remaining 200 patients (329 eyes) were Han Chinese; 174 of these patients (62.7%) were men. The average age of the patients was 6.25 ± 2.03 months (range, 3–18 months) at surgery and 18.95 ± 4.55 months (range, 13–24 months) at photography. No differences in the age distribution were observed based on sex. A total of 129 patients (64.5%) had bilateral cataracts, and 71 patients (35.5%) had unilateral cataracts. However, quality photographs were not obtained for 4 children with unilateral cataracts and 5 children with bilateral cataracts; these photographs were excluded from the photo classification and objective quantitative measurements. Slit-lamp photos of 315 eyes (95.8%) of 191 children had sufficient quality to be included in our qualitative classification. A total of 158 children (82.7%) were administered chloral hydrate as a sleep aid due to noncooperation, and no complications occurred.

For the qualitative measurement (Figure 4), disagreement between the first 2 researchers was observed for the qualitative classifications of 7 eyes (2.2%), and a third researcher was asked to make a final choice. The capsular outcomes of all 315 aphakic eyes were ultimately classified into 3 defined types: Type I—120 eyes (38.1%), Type II—157 eyes (49.8%), and Type III—38 eyes (12.1%).

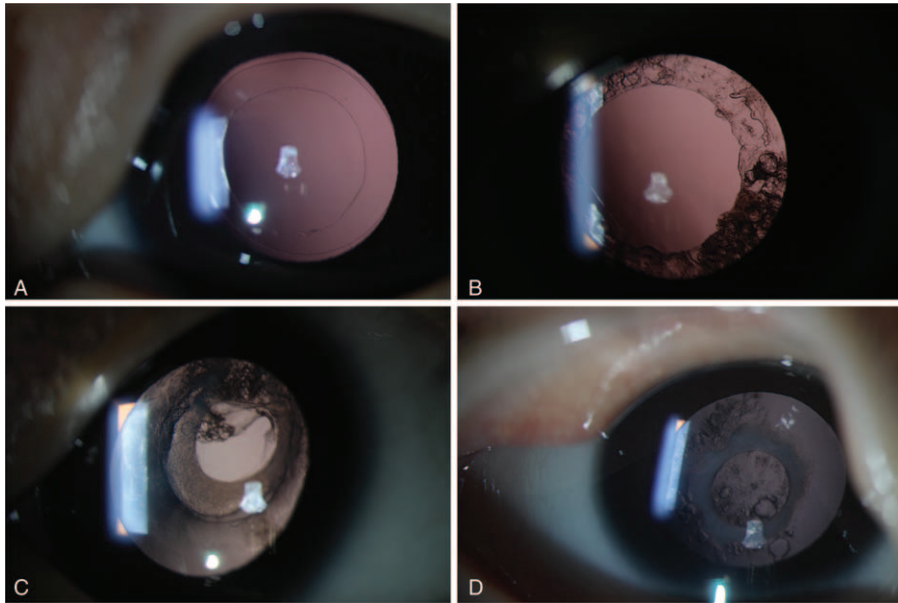


FIGURE 4. Qualitative classification of capsular outcomes. (A) Representative capsular outcome immediately after surgery without any proliferation or opacification. (B) Type I, mild cell proliferation and opacification around the ACOA and PCOA but no invasion into the capsule opening. (C) Type II, moderate cell proliferation and opacification around the ACOA and PCOA accompanied by contraction of the ACOA and proliferative invasion to the occluding part of the PCOA (partial PCOO). (D) Type III, severe cell proliferation and opacification accompanied by total occlusion of the PCOA (total PCOO). ACOA = anterior capsulorhexis opening area, PCOA = posterior capsulorhexis opening area, PCOO = posterior capsular opening opacification.

No significant correlation was observed between the types of capsular outcomes and the age at surgery or sex (all $P > 0.05$). Although we only had the accurate intraoperative anterior and posterior capsulorhexis size for 95 of the 315 aphakic eyes, the statistical analysis of the correlation between the types of capsular outcomes and the intraoperative capsulorhexis sizes was possible. We quantified Type I as 1, Type II as 2, and Type III as 3. The results showed that the scores of the capsular outcomes were negatively correlated with intraoperative anterior capsulorhexis size ($R = -0.572, P < 0.001$) but had no significant correlation with intraoperative posterior capsulorhexis size ($R = -0.16, P = 0.122$). The correlations between

the types of capsular outcomes and capsulorhexis size during surgery are presented in Figure 5.

Regarding the quantitative measurement (Figure 6) of Type I, the mean values of the ACOA, PCOA, and PCOO were $18.24 \pm 1.08, 7.45 \pm 1.12$ and 0 mm^2 , respectively; for Type II, the mean values of the ACOA, PCOA, and PCOO were $13.18 \pm 0.89, 9.05 \pm 1.12$, and $5.68 \pm 0.43 \text{ mm}^2$, respectively; and for Type III, the mean values were $11.16 \pm 0.45, 10.04 \pm 0.23$, and $10.04 \pm 0.23 \text{ mm}^2$, respectively. Statistically, the mean ACOA significantly decreased from Type I to Type II to Type III, whereas the PCOA increased in size from Type I to Type II and the PCOO increased from Type II to Type III (all

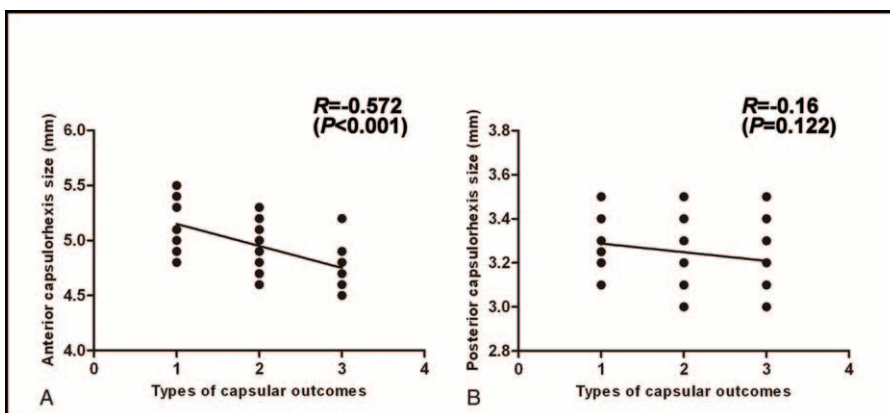


FIGURE 5. Correlation between types of capsular outcomes and intraoperative capsulorhexis size. The types of capsular outcomes are negatively correlated with intraoperative anterior capsulorhexis size (A) but had no significant correlation with intraoperative posterior capsulorhexis size (B).

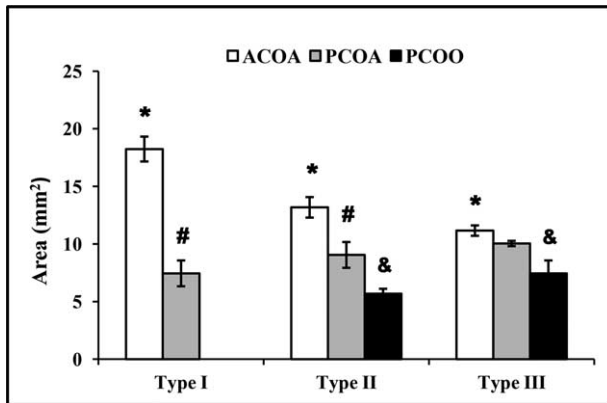


FIGURE 6. Quantitative measurement of capsular outcomes. The histogram demonstrates that the ACOA significantly decreased from Type I to Type II to Type III (* $P=0.016$, $P=0.038$), whereas the PCOA increased in size from Type I to Type II (# $P=0.025$) and the PCOO increased from Type II to Type III (& $P=0.012$). ACOA = anterior capsulorhexis opening area, PCOA = posterior capsulorhexis opening area, PCOO = posterior capsular opening opacity.

$P < 0.05$). No significant difference in PCOA was observed between Type II and Type III.

DISCUSSION

Capsule management is the key step in cataract surgery, and capsular outcomes are closely related to postoperative complications, such as visual axis opacification (defined as PCOO in this study), capsule block syndrome, capsule contraction syndrome, IOL eccentricity, IOL dislocation, IOL clamping, iris adhesion, and pupillary block, especially in pediatric patients.^{1,2,18–20} In this cross-sectional study, we first qualitatively classified the capsular outcomes in aphakic eyes 12 months after pediatric cataract surgery into 3 types based on the degree and range of PCOO. We discovered that the types (scores) of capsular outcomes were negatively correlated with intraoperative anterior capsulorhexis size but had no significant correlation with intraoperative posterior capsulorhexis size. We used a self-developed computer program to quantitatively measure the ACOA, PCOA, and PCOO, which also varied across the 3 types of capsular outcomes.

Objective qualitative classification and the quantification of capsular outcomes are gaining importance; these methods are primarily dependent on high-quality image acquisition.²¹ Pande et al²² developed a retro-illumination system with a coaxial optical path that produces homogeneous illumination over the entire region of interest and causes significantly smaller light reflections. The BX900 slit-lamp-adapted anterior segment photography system that was used in our study belongs to this advanced type; it provided excellent image quality and high reproducibility.¹⁶ In this study, we discovered that the DCRP method with the BX900 system was a simple and efficient method for documenting capsular outcomes in aphakic eyes after pediatric cataract surgery. The DCRPs of 315 (95.8%) of the 329 included eyes were of sufficient quality, including proper eye position and sufficiently high resolution, which forms the basis for our qualitative classification and objective quantification in the selected cases.

Although no studies have focused on the systematic classification of capsular outcomes in aphakic eyes after pediatric

cataract surgery, various posterior capsular complications (e.g., capsular opacification, capsule contraction, and capsule-iris adhesion) have been reported.²³ In our study, Type II constituted the largest proportion (49.8%), and Type III accounted for the smallest proportion (12.1%), which represented the total reclosure rate of primary PCOA in our series. Tassignon et al²⁴ reported that 12% of eyes with primary PCOA presented with total reclosure. This published study is the only study that focused on the PCOA reclosure rate in the human eye. Although the reclosure rates were similar, the participants in this previous study were patients with complicated ocular or systematic conditions that predisposed them to increased postoperative inflammation, whereas our participants were pediatric patients who are also prone to postoperative inflammation. Our study also demonstrated that types of capsular outcomes were correlated with intraoperative anterior capsulorhexis size and that the capsule with a small anterior capsulorhexis size is more likely to develop into Type III outcome. The reason is that a larger number of residual LECs in the capsule of a small capsulorhexis opening can proliferate, differentiate and migrate into the PCOA, which causes the occlusion of the PCOA. No significant correlations were identified between types of capsular outcomes and intraoperative posterior capsulorhexis size. It may be because the capsulorhexis size was limited to the small range of 3.0 to 3.5 mm.

Some systems and software programs, such as the Anterior Eye Segment Analysis System (EAS-1000; NIDEK),²⁵ the Evaluation of Posterior Capsular Opacification (EPCO) system,²⁶ automated computer-aided design (CAD) software,²⁷ FotoLook PS205 software²⁸ and London POCO and AQUA software,²⁹ are capable of measuring the ACOA, PCOA or PCOO after cataract surgery in adult patients.³⁰ However, no available user-friendly software has been reported as being specifically applicable for quantitatively measuring the ACOA, PCOA, and PCOO in pediatric aphakic eyes, as defined in our study. Therefore, with the help of a volunteer software engineer, we developed a custom image analysis algorithm software (ECO) using MATLAB and have determined that this technique was both successful and user-friendly. Using this self-developed imaging software, we measured the mean values of the ACOA, PCOA, and PCOO for the 3 different types of capsules. For the first time, we statistically demonstrated that the mean area of the ACO significantly decreased from Type I to Type II to Type III, whereas the PCO increased in size from Type I to Type II, and the PCOO increased from Type II to Type III.

Several limitations of this study should be considered. First, this study used a cross-sectional design, which was prone to selection and measurement biases.³¹ However, we excluded preterm births and other pathologies that may accompany eye conditions, which enabled us to precisely identify the types of patients to whom our results may be generalized (i.e., Chinese, full-term children with uncomplicated congenital/infantile cataracts and without other pathologic eye conditions). Second, all photos were obtained at only 12 months post-surgery; therefore, we could not evaluate dynamic variations in trends or demonstrate the postoperative evolution of the ACOA, PCOA, and PCOO. Third, we only recorded the intraoperative capsulorhexis size of 95 eyes; thus, the conclusion formed from the correlation analysis between types of capsular outcomes and intraoperative capsulorhexis size is likely to be slightly biased. Therefore, a prospective randomized controlled study is needed. Despite these limitations, this study was the first study to demonstrate the feasibility of the qualitative classification

and the quantitative measurement of capsular outcomes in aphakic eyes after pediatric cataract surgery by the acquisition, division, definition, and user-friendly imaging software analysis of high-quality retro-illumination ocular images.

In conclusion, our cross-sectional study of aphakic children at 12 months after pediatric cataract surgery demonstrated that capsular outcomes can be classified into 3 types according to the degree and range of PCOO. Our self-developed software was determined to be user-friendly and revealed different mean values of the ACOA, PCOA, and PCOO for the 3 types of postoperative capsules. Our study contributes to the knowledge and the evaluation of technology for the qualitative classification and quantitative measurement of capsular outcomes after pediatric cataract surgery.

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