Hydrophilic Acrylic versus PMMA Intraocular Lens Implantation in Pediatric Cataract Surgery

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Purpose: To compare primary implantation of foldable hydrophilic acrylic with polymethylmethacrylate (PMMA) intraocular lenses (IOLs) in pediatric cataract surgery in terms of short-term complications and visual outcomes.

Methods: This randomized clinical trial included 40 eyes of 31 consecutive pediatric patients aged 1 to 6 years with unilateral or bilateral congenital cataracts undergoing cataract surgery with primary IOL implantation. Two types of IOLs including foldable hydrophilic acrylic and rigid PMMA were randomly implanted in the capsular bag during surgery. Primary posterior capsulotomy and anterior vitrectomy were performed in all eyes. Patients were followed for at least 1 year. Intra- and postoperative complications, visual outcomes and refractive errors were compared between the study groups.

Results: Mean age was 3.2±1.8 years in the hydrophilic acrylic group and 3.7±1.3 years in the PMMA group. Mean follow-up period was 19.6±5 (12-29) months. No intraoperative complication occurred in any group. Postoperative uveitis was seen in 2 (10%) eyes in the acrylic group versus 5 (25%) eyes in the PMMA group (P=0.40). Other postoperative complications including pigment deposition (30%), iridocorneal adhesions (10%) and posterior synechiae formation (10%), were seen only in the PMMA group. The visual axis remained completely clear and visual outcomes were generally favorable and comparable in the study groups.

Conclusion: In pediatric eyes undergoing lensectomy with primary posterior capsulotomy and anterior vitrectomy, hydrophilic acrylic IOLs are comparable to PMMA IOLs in terms of biocompatibility and visual axis clarity, and seem to entail less frequent postoperative complications.

Key words: Cataract; Lenses, Intraocular; Polymethylmethacrylate (PMMA)

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INTRODUCTION

Modern surgical techniques and correction of aphakia with intraocular lens (IOL) implantation have improved the standard of care for children with cataracts.[1] Use of automated vitrectomy equipment, development of techniques for primary anterior and posterior capsulotomy,[1] and effective anterior vitrectomy procedures have promoted maintenance of a clear visual axis.[2] Improved intracameral agents have made implant surgery easier and safer in younger eyes; however, IOL implantation during infancy remains controversial.[3]

Hydrophilic foldable IOLs have excellent uveal biocompatibility, are resistant to surface alterations or damage during folding and insertion, and have low potential to damage corneal

endothelial cells in case of contact.[4] However, according to the 2001 pediatric cataract surgery and IOL survey of ASCRS and AAPOS members, this type of IOL was preferred by only 2.4% and 1% of the responders, respectively.[5] Lack of enthusiasm for hydrophilic acrylic IOLs may be due to lower capsular biocompatibility in comparison to other biomaterials; this type of IOLs are associated with higher rates of lens epithelial cell (LEC) outgrowth, anterior capsule contracture, posterior capsule opacification (PCO) and surface calcification as experienced in adult cataract surgery.[6-8] The latter complication can be severe enough to necessitate IOL explantation in some patients.[6,7,9]

Primary posterior capsulotomy and anterior vitrectomy are components of standard pediatric cataract surgery; they eliminate the scaffold for LEC outgrowth and visual axis opacification which seems unrelated to the type of IOL in pediatric eyes. In this trial we compared primary implantation of foldable hydrophilic acrylic with polymethylmethacrylate (PMMA) IOLs in pediatric eyes in terms of postoperative complications and visual outcomes.

METHODS

This randomized clinical trial included 40 eyes of 31 consecutive patients aged 1 to 6 years with unilateral or bilateral congenital or developmental cataracts. As it was difficult to establish the age of onset of cataracts with certainty, we did not attempt to distinguish developmental from congenital cataracts. The eyes were randomly assigned to two groups (20 eyes each) to undergo implantation of a foldable hydrophilic acrylic IOL (Corneal ACR6 DES, Paris, France) with 6 mm optic and overall diameter of 12 mm, or a single piece PMMA IOL (Corneal CP65 TH, Paris, France) with 6.5 mm optic and overall diameter of 13 mm. Exclusion criteria consisted of monocular patients and cataracts associated with ocular abnormalities (microphthalmos, microcornea, glaucoma, uveitis, posterior lenticonus, and colobomas) or systemic diseases, and traumatic or complicated cataracts. Patients were followed for a minimum period of 12 months.

All patients underwent a detailed preoperative evaluation. Visual acuity was determined using standard E-chart when feasible; fixation patterns were noted in preverbal/uncooperative children. Special attention was paid to the presence of nystagmus, amblyopia or strabismus. When necessary, an examination under general anesthesia was carried out. Intraocular pressure (IOP) was measured in all patients with either the Perkins applanation tonometer (Clement Clarke International Ltd, Harlow, UK) or the Schiotz hand-held tonometer (Medton 1483, Germany). To increase accuracy, biometric measurements were performed twice in all eyes; first with the IOL master (Carl Zeiss, Jena, Germany), followed by conventional keratometry. Axial length was measured via a standard contact technique using Compuscan LT A-scan ultrasonography (Storz Instruments Co., St. Louis, USA) under general anesthesia, preoperatively. IOL power calculations were performed using the SRKII formula[10] in all cases. The IOL power was adjusted according to patient age (Table 1) to achieve postoperative hypermetropia in order to counterbalance the myopic shift in pseudophakic pediatric eyes.[11] Other routine ocular examinations included assessment of pupil dilatation, funduscopy and B-scan ultrasonography if necessary.

Table 1 Age-adjusted target hypermetropia

Age (yr)	Target hypermetropia
1-3	5 Diopter
3-5	3.5 Diopter
> 5	2 Diopter

Surgical Technique

All operations were performed under general anesthesia using a standard technique by one of two experienced anterior segment surgeons (MRP and MZ). A wire lid speculum was inserted. For the PMMA group, a 6-0 silk superior rectus bridle suture was passed using a tapered needle. The conjunctiva was opened at the limbus for 3 clock hours superiorly. A partial thickness scleral groove 6.5 mm in length was made 2 mm posterior to the limbus.

A blade was used to create a scleral tunnel anteriorly until clear cornea was reached. A microvitreoretinal blade was used to enter the anterior chamber in the center of the tunnel. A paracentesis site was also fashioned in the tunnel 3 clock hours apart to permit insertion of a 23-gauge butterfly needle for infusion of balanced salt solution. For the acrylic IOL group, a temporal clear corneal tunnel incision was made with a 3.2 mm keratome and a paracentesis site was made 3 clock hours apart.

In younger patients (1-4 years, 24 eyes), anterior capsulotomy was performed using an automated vitrector in circular motion to create a 4-5 mm opening; in older children (16 eyes), a bent-tip #27 needle and capsular forceps were used under viscoelastic support to create a 4-5 mm anterior continuous curvilinear capsulorrhexis. After performing anterior capsulotomy, an automated irrigation/aspiration handpiece was used to remove cortical and nuclear materials. Viscel 2% (Corneal, Paris, France) was used to inflate the capsular bag and fill the anterior chamber. Posterior capsulotomy at least 4 mm in diameter and adequate anterior vitrectomy were performed in all subjects.

The foldable acrylic hydrophilic IOL was folded longitudinally with forceps and implanted into the capsular bag. After IOL implantation, viscoelastic material was carefully removed from the anterior chamber and the capsular bag. The clear corneal incision was closed using 2 separate 10/0 nylon sutures. In the PMMA group, the limbal groove was opened with corneal scissors and the IOL was inserted within the capsular bag. After complete removal of viscoelastic material, the limbal incision was closed using 4 to 5 separate 10/0 nylon sutures.

Postoperatively, all patients received a standard regimen of 1% prednisolone acetate eye drops every 2 hours which was tapered off weekly over one month and 0.5% chloramphenicol eye drops every 6 hours for 5 days. Patients were examined 1 and 3 days, 1 week and 1, 3 and 6 months postoperatively, and every 6 months thereafter. Anterior segment examination, tonometery and dilated ophthalmoscopy were performed under general anesthesia one month postoperatively. Refractive error was also measured with retinoscopy and corrected with spectacles when all sutures had been removed. In all postoperative examinations, palpebral and conjunctival inflammation, suture condition, corneal clarity, anterior chamber depth and inflammation, pupil shape and reactivity, synechiae formation, IOL position, pigment deposition on the IOL, visual axis opacification (VAO), IOP and refractive errors were recorded. Statistical analysis was performed using Fisher exact or Chi-square tests to compare frequency values, and *t*-test for comparing mean values between the study groups with significance set at $P<0.05$.

RESULTS

Overall 40 eyes of 31 patients including 18 (58%) male and 13 (42%) female subjects with mean age of 40.8±19.2 (range 12-72) months were operated. Twenty-two (70.9%) patients had unilateral cataracts. The two groups were comparable in terms of age at the time of surgery and follow-up period. Table 2 shows preoperative characteristics of the patients.

None of the patients were excluded due to intraoperative complications which were practically nil. Preoperatively, best-corrected visual acuity (BCVA) ranged from fixing but not following light, and fixing and following light to 20/200 in both groups (Fig. 1, Table 3). Postoperatively, 18 (90%) eyes in the acrylic group had BCVA better than 20/200, of which 16 (80%) had BCVA better than 20/60. Corresponding values in the PMMA group were 17 (85%) and 16 (80%), respectively (P=0.83), (Fig. 2 and Table 3).

Mean postoperative spherical refractive error was +4.22±2.53 diopter (D) in the acrylic group and +3.38±2.79 D in the PMMA group (P=0.2). The corresponding figures for cylindrical error were 1.03±0.84 and 1.58±1.10 D in the two groups respectively (P=0.2).

Table 4 summarizes postoperative complications. Inflammation was noted in 5 (25%) eyes in the PMMA group and 2 (10%) eyes in the acrylic group (P=0.407). The inflammation subsided by increasing the frequency of steroid drops and use of mydriatic-cycloplegic eye drops in all 7 eyes.

Table 2 Demographic and clinical characteristics of the study groups

	Acrylic group (N= 20 eyes)	PMMA group (N= 20 eyes)	P value**
Male/Female	13/7	10/10	0.337
Age (yr): 1-2	8	4	
2-5	8	12	0.20
>5	4	4	
Age at surgery (yrs)*	3.2±1.8	3.7±1.3	0.20
Right/Left eye	14/6	12/8	0.507
Amblyopia/No amblyopia	6/14	8/12	0.507
Positive/Negative family history	6/14	7/13	0.736
Cataract type: Mature	4	5	
Lamellar	6	8	
Nuclear	4	3	0.50
Posterior subcapsular	3	3	
Anterior polar	3	1	

*Mean ± standard deviation. **t-test for mean values and Chi-square (or Fisher exact) test for frequency values.

Table 3 Pre- and postoperative visual acuity in the study groups

	Acrylic group	PMMA group	P value**
Preoperative			
BCVA (logMAR)*	1.18±0.15 (13 eyes)	1.13±0.15 (11 eyes)	0.453
Fixing and following light	4	3	0.677
Fixing but not following light	3	6	0.256
Postoperative			
BCVA (logMAR)	0.42±0.16 (18 eyes)	0.41±0.13 (17 eyes)	0.836
Fixing and following light	2	2	1
Fixing but not following light	0	1	0.311

BCVA, best-corrected visual acuity.
*mean ± standard deviation **t-test for mean values and Chi-square (or Fisher exact) test for frequency values.

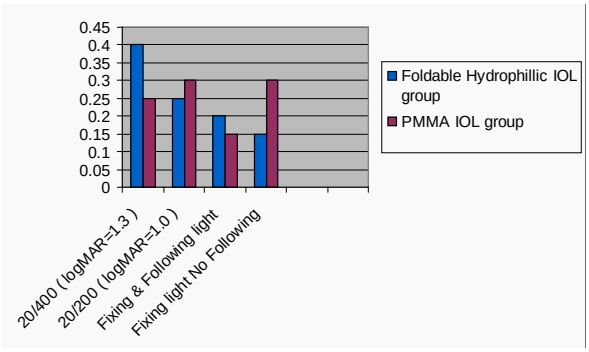

Figure 1 Preoperative visual acuity in the study groups.

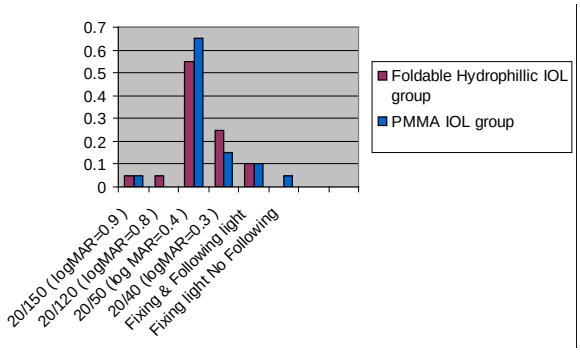

Figure 2 Postoperative visual acuity in the study groups.

Table 4 Postoperative complications in the study groups

	Acrylic group	PMMA group	P value*
Uveitis	2	5	0.40
Corneal edema	4	1	0.34
Iridocorneal adhesions	0	2	0.48
Distorted pupil	0	5	0.04
Posterior synechiae	0	2	0.48
Traumatic wound dehiscence	0	2	0.48
Iris capture	0	1	1
Pigment deposit	0	6	0.02

*Fisher exact test.

DISCUSSION

Hydrophilic acrylic IOLs are composed of a hydroxyethylmethacrylate (poly–HEMA) backbone and hydrophilic acrylic monomers. These lenses belong to the family of acrylic-methacrylic polymers similar to PMMA which is an acrylic biomaterial made from only one type of monomer. Hydrophilic acrylic IOLs are soft and have excellent biocompatibility because of their hydrophilic surface and 18%-38% water content. These IOLs show little or no surface alterations or damage from folding because of their soft flexible surface.[4] Low surface energy and hydrophilic nature are major reasons for good uveal biocompatibility. They also have low potential to cause damage when touching corneal endothelial cells. However, hydrogel IOLs seem to have lower capsular biocompatibility as compared to other biomaterials, resulting in more LEC outgrowth, anterior capsule contracture and PCO formation following adult cataract surgery.[12] Fortunately, when Nd:YAG capsulotomy is necessary, these lenses have a high threshold for laser induced damage.[13] Furthermore, the hydrophilic properties of these lenses including low surface energy, cause minimal adherence to silicone oil in patients requiring vitreoretinal surgery.[14]

Due to the greater inflammatory response, the risk of postoperative complications in pediatric cataract surgery is higher than adults. In very young children, VAO is virtually inevitable and rapidly develops following surgery when the posterior capsule is left intact.[15] VAO requiring secondary intervention is the most common complication of pediatric cataract surgery with IOL implantation. Despite performing primary posterior capsulotomy and vitrectomy, a second procedure was required in as many as 80% of eyes operated in the first 6 months of life.[15,16] Therefore we decided to include only subjects older than 1 year in this study.

Posterior capsule and anterior vitreous management greatly influences visual axis clarity and final visual outcomes in children regardless of IOL material. Ram and coworkers[17] evaluated the effect of primary posterior capsulotomy with anterior vitrectomy and various IOL materials in 64 eyes of 52 children aged 3 months to 12 years in terms of development of PCO at least 2 years after cataract surgery. They used the Acrysof acrylic IOL in one group and a single-piece PMMA IOL in the other, each including 32 eyes. Within each group, 16 eyes underwent posterior capsulotomy and vitrectomy however the posterior capsule was left intact in the other 16 eyes. Postoperatively, 12 eyes with acrylic and 13 eyes with PMMA IOLs and an intact posterior capsule, versus only 2 eyes with acrylic and 3 eye with PMMA IOLs in the posterior capsulotomy and anterior vitrectomy subgroup developed PCO ($P<0.05$).

Vasavada et al[18] evaluated VAO and need for a second procedure after Acrysof IOL implantation in 103 eyes of 72 consecutive children with congenital cataracts. The patients were divided into two groups based on age at the time of surgery; younger than 2 years (group 1) and 2 years or more (group 2). All eyes in group 1 (n=37) underwent primary posterior continuous curvilinear capsulorrhexis (PCCC) and anterior vitrectomy. Management of the posterior capsule in group 2 (n=66) was randomly assigned to no PCCC (group 2A, n= 37) or PCCC (group 2B, n=29). The latter group was further randomized into 2 subgroups: no vitrectomy (group 2BN, n=14) or vitrectomy (group 2BV, n=15). After a mean follow-up of 2.3±0.9 years, 4 (10.8%) eyes in group 1 and 31 (83.8%) eyes in group 2A developed PCO, of which 3 eyes in group 1 and 10 eyes in group 2A required a second intervention. The rate of PCO formation was significantly higher in children aged less than 8 years at the time of surgery as compared to older children (P=0.01). Five (37.5%) eyes in group 2BN had opacification of the anterior vitreous face, one of which required a second procedure. The authors concluded that Acrysof IOL implantation with appropriate management of the posterior capsule provided a clear visual axis in pediatric cataract surgery.

Ahmadieh et al,[2] in a prospective study on 38 eyes in two equal groups with bilateral developmental and unilateral traumatic cataract, compared two different techniques: limbal versus pars plana lensectomy, primary posterior capsulotomy and anterior vitrectomy. They im-

planted a single-piece PMMA IOL in the capsular bag in all cases. The visual axis remained clear in all eyes in both groups during the follow-up period. In one eye with inadequate capsulotomy (smaller than 3 mm), postoperative refraction was difficult, but this did not affect vision. In our study, primary posterior capsulotomy (at least 4 mm in diameter) and anterior vitrectomy was performed in all cases; mild peripheral PCO was seen in two eyes but VAO did not occur with mean follow-up of 19.6±5 month in any case irrespective of IOL material. Visual axis clarity in our series is comparable to the study by Ram[17], group 1 in the study by Vasavada et al[18] who underwent posterior capsulotomy and anterior vitrectomy, as well as with the study by Ahmadieh et al.[2]

Fibrinous uveitis due to increased tissue reactivity is a common complication during the early postoperative period in pediatric cataract surgery.[15] Kuchle et al[19] reported that postoperative fibrin formation was less frequent in eyes with Acrysof IOL as compared to PMMA IOL. In our study, although non-significant, the incidence of postoperative uveitis was higher with PMMA IOLs (25%) as compared to acrylic IOLs (10%). The lower incidence of anterior uveitis with hydrophilic IOLs may be attributed to higher biocompatibility, less iris manipulation and trauma during IOL implantation, and good positioning of the IOL within the capsular bag.

Kuchle et al[19] reported posterior synechiae formation in none of 10 eyes with Acrysof acrylic IOLs versus 6 of 20 eyes with PMMA IOLs. Wilson et al[15] noted posterior synechiae in 4.5% of cases following Acrysof lens implantation versus 19.2% in the PMMA group. In our study we encountered no case of iridocorneal adhesions or posterior synechiae in the acrylic group, but iridocorneal adhesions were seen in 2 cases with traumatic wound dehiscence, and posterior synechiae were detected in 2 other eyes in the PMMA group at the last visit (P=0.14).

Precipitations on the IOL surface are composed of pigment, inflammatory cells, fibrin, blood breakdown products, and other elements; they are often seen during the immediate postoperative period. This complication is much more common in children with dark irides but is usually not visually significant. In a retrospective study, Wilson et al[15] reported IOL deposits in 6.4% of hydrophobic acrylic lenses as compared to 21.75% of PMMA IOLs. Deposits have been reported from 24.1% to 35.9% in other studies.[15,16,18,21] In the current study we found no instance of pigment deposition on hydrophilic acrylic IOLs, but 30% of eyes in the PMMA group had pigment deposition on the optic (P=0.008).

The incidence of iris capture following pediatric cataract surgery has been reported 8.5% by Basti et al[22] and 33% by Vasavada and Chouhan[23]; this condition occurs most often in children younger than 2 years, when the IOL optic is smaller than 6 mm and it is implanted in the ciliary sulcus. In our study however, only one eye with a PMMA IOL developed pupil capture.

In our series, none of the eyes developed IOP rise, glaucomatous changes in the optic disc, clinical cystoid macular edema, retinal detachment or endophthalmitis. Considering the low rate of postoperative complications in eyes with foldable hydrophilic acrylic IOL in our study and despite the low acceptability of this type of IOL among ASCRS and AAPOS members;[5] it seems that these IOLs have good uveal biocompatibility and are suitable for implantation in pediatric cataract surgery. The major problem with hydrophilic IOLs is the low capsular biocompatibility, but with appropriate posterior capsule management (performing at least 4 mm posterior capsulotomy) and limited anterior vitrectomy, we encountered no case of VAO.

Although pediatric cataracts represent a treatable cause of lifelong visual impairment, good long-term visual outcomes depend on many factors such as age of onset, cataract density, surgical technique, control of postoperative inflammation, and finally continuous refractive correction and visual rehabilitation. Our results showed that hydrophilic acrylic IOLs are as effective as PMMA IOLs in terms of short- to intermediate-term outcomes following surgery for congenital and developmental cataracts.

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