Pediatric phakic intraocular lens surgery: review of clinical studies

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Purpose of review

To report on the accumulating peer-reviewed data of phakic intraocular lens (pIOL) implantation in the pediatric population. I evaluate and compare the published peer-reviewed articles for the reported efficacy and complications of phakic intraocular lens implantations in children for correction of clinically significant high refractive errors.

Recent findings

Multiple studies have shown the relevancy and effectiveness of pIOL implantation as an alternative surgical management for highly significant pediatric ametropia in selective patients who are noncompliant with medical treatment.

Summary

In the management of clinically significant severe pediatric ametropic and/or anisometropic myopia or hyperopia and in the event of nonadherence to traditional medical treatment, phakic anterior chamber IOL implantation is currently considered an effective modality of treatment. Long-term follow-up of pediatric patients following pIOL implantation is necessary. Future clinical trials should focus on children of various age groups to assess the variables of visual acuity gain or loss, stereopsis, contrast sensitivity, high-order aberrations, corneal physiology, and long-term complications to accurately and properly address the safety and efficacy of the type of and the best time for pIOL implantation in treatment and/or prevention of amblyopia in children.

Keywords

amblyopia, ametropia, anisometropia, children, myopia, pediatric, phakic intraocular lens, refractive surgery

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Introduction and background on phakic intraocular lens

Currently, there are three models of phakic intraocular lens (pIOL) available for implantation in the market: iris-supported/fixated anterior chamber (AC-pIOL), ciliary sulcus-supported posterior chamber (PC-pIOL), and angle-supported anterior chamber (AS-pIOL).

The AC-pIOL was first conceived by Professor Jan G.F. Worst in The Netherlands and was subsequently introduced by Ophtec (Boca Raton, Florida, USA) in 1978 for the correction of aphakia. The lens was redesigned by Ophtec and entered the market as the Worst myopia claw lens in 1991. Currently, Ophtec distributes and markets seven individual models of Artisan (A-pIOL, a PMMA CA-UV optic, 6/5 mm optic size) for correction of myopia (−1.00 to −23.00 D) and hyperopia (+1.00 to +12.00 D) and Artiflex, a foldable polysiloxane 6.0 mm optic. The first AC-pIOL in the USA was approved in 2004 as the Verisyse phakic IOL (v-pIOL) under Advanced Medical Optics (Santa Ana, California, USA). The first posterior chamber pIOL in the USA was approved as the Visian Implantable Collamer, ICL (a single-piece porcine collagen/HEMA copolymer optic, size 4.8–5.5 mm) distributed by STAAR surgical (Monrovia, California, USA) for correction of myopia of −3.00 to −20.00 D. Other posterior chamber pIOLs such as the ChironAdatomed lens (ChironAdatomed GmbH, Munich, Germany) as well as angle-supported pIOLs, although available in international markets, are yet to be approved in the USA. Alcon (Fort Worth, Texas, USA) had released foldable AcrySof phakic lens in international markets for correction of myopia (−6.0 to −16.50 D) in 2008 and is currently undergoing FDA clinical trials in the USA.

In this article, I will attempt to review all the previously published single case studies, case reports, and case series on indications, outcomes, and complications of pIOL implantation in children. I will also report on the relevant data from the adult pIOL implantation studies on the related topics to be considered in correlation to pediatric pIOL implantation, so that pertinent application of such

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findings may open up a roadmap into future clinical trials required on this subject.

As a result of a comprehensive review of the peer-reviewed journal, I have found no more than 15 peer-reviewed articles on the topic of 'pediatric pIOL' implantation, the first of which was published in 1998. They are single case studies, case reports, and/or small case series. In the review of literature, no comparative and/or randomized case–control series or trials on pIOL implantation in children could be found. There are over 3756 peer-reviewed articles in PubMed on 'refractive surgery in children' from periods of 1951 to 2009. However, there are only eight peer-reviewed articles on 'pediatric pIOL' during the period of 2007–2009 in PubMed, four of which are comments and/or reviews.

History of pediatric phakic intraocular lens surgery

The first reported pIOL implantation in a child was with a STAAR ICL in 1998 by Lesueur *et al.* [1] for the purpose of high anisometropic myopia treatment. Lesueur *et al.* reported successful implantation of the PC-pIOL in a selective group of five children who were noncompliant to spectacle and contact lens therapy [1]. Subsequent to the positive result of this study, the anterior and posterior chamber pIOL implantations were undertaken for similar purposes of collapsing high anisometropia and/or bilateral high ametropia in similar groups of patients with the ultimate goal of treating refractive-induced amblyopia through restoration of emmetropia.

Indication of phakic intraocular lens implantation in children

pIOL implantation in the pediatric population, although a form of refractive surgery, is deemed necessary and essential in a particular subpopulation of children who have highly significant anisometropia or bilateral ametropia and who are simultaneously noncompliant to traditional treatment of spectacle wear or contact lens therapy (Table 1), hence improving the prospect of achieving a normal state of binocular function, binocular fusion, stereopsis, and overall visual function. I will summarize all previously published trials on pediatric pIOL surgery, detailing the risks and benefits associated with each class of pIOL implant.

Table 1 Reported indications for pediatric phakic intraocular lens implantation

1	High anisometropia, myopia or hyperopia in noncompliant to medical treatment
2	Bilateral high ametropia in noncompliant to medical treatment
3	Secondary high-refractive amblyopia in neurobehavioral-disorder children

Review of pediatric phakic intraocular lens studies: case reports and case series

This section will review the three types of pIOLs that are currently available on the market.

Posterior chamber phakic intraocular lens

There are three peer-reviewed pediatric PC-pIOL case studies in the published literature, first of which by Lesueur *et al.* [1] reports the first pediatric PC-pIOL implantation in 1999. Lesueur *et al.* implanted five eyes with the Visian ICL for treatment of severe anisometropia in children of ages 3–16 years. The mean preoperative spherical equivalent was −12.8 D and the best spectacle-corrected visual acuity (BSCVA) was count-fingers to 20/200. The mean follow-up was 11.8 months (range 4–21 months). Gain of three or more snellen lines of visual acuity as well as recovery of binocular vision was observed in two patients. Three patients achieved orthophoria. All parents reported an improvement in their children's quality of life. No complications were noted in the study.

In their follow-up study, Lesueur *et al.* reported on the anatomical and functional outcomes of PC-pIOL (Visian ICL) implantation for correction of high myopia and amblyopia in the 12 eyes of noncompliant children of ages 3–16 years [2]. Mean preoperative spherical equivalent refraction was −12.70 D (range −8.00 to −18.00 D) and the BSCVA ranged from count-fingers to 20/63. Mean follow-up was 20.5 months. Mean postoperative BSCVA was 20/63. Six patients showed improvement in quality of life as well as recovery of binocular vision. Seven patients achieved orthotropic alignment. No complication was reported.

BenEzra *et al.* [3] reported on the potential visual benefits of PC-pIOLs (Visian ICL) in the eyes of three female children (ages 9–18) with anisometropic amblyopia and myopia of −6 to −16 D. The study showed significant improvement in visual acuity and binocular function with no change in corneal endothelial cell count (ECC) during the 9 months of follow-up. Despite no reported complication, pigment dispersion on the IOLs was observed without any clinical significance (Table 2).

In a related study of prospective randomized comparative trial of Visian toric ICL (TICL) vs. photorefractive keratectomy (PRK) for moderate to high myopic astigmatism in the adult population, Schallhorn *et al.* [4] showed the toric ICL to have better predictability, safety, efficacy, and stability than PRK. The study showed 7% of patients losing one line of BSCVA in the PRK group compared with 0% in the TICL group at the end of 1 year of follow-up. This result is a pertinent finding to take into account when considering corneal laser ablative

Table 2 Pediatric posterior chamber phakic intraocular lens studies (implantable collamer)

Series	Patients (age)	Pre/SE	Post/SE	F/u	Complication
Lesueur and Arne [1], ICL	5 (3–16)	−12.70	+0.5	11.8	None
BenEzra *et al.* [3], ICL	3 (9–18)	−12.5	−1.0	9	Pigment dispersion
Chipont *et al.* [14], Artisan	1 (6)	−15.5	−4.0	18	None
Saxena *et al.* [15]	1 (4)	−12.5	−2.5	36	Endothelial cell loss

procedure for treatment of high myopia of more than −10 D in children. Reported adverse events in the pediatric PC-pIOL implantation have been rare in the literature. By and large, this is due to low overall number of PC-pIOL implantations in children. A number of potential complications have been attributed to implantation of PC-pIOLs in adult population, which clinicians will likely encounter with increasing number of pediatric PC-pIOL implantations such as cataract formation (9.6% in PC-pIOL vs. 1.11% in AC-pIOL over 3–7 years of follow-up), pupillary-block glaucoma, spontaneous dislocation of pIOL into the vitreous cavity, and retinal detachment [5–10]. The most significant risk and concern for pediatric PC-pIOL implantation stems from the development of visually significant anterior subcapsular cataract by the mechanism of direct plate-crystalline lens contact due to a shallower posterior chamber depth in children. A way to prevent and/or lower such a risk is to more accurately assess for proper IOL size and for the projected postoperative PC-pIOL position through use of ultrasound biomicroscopy for white-to-white measurements rather than calipers [11]. A relative retinal detachment rate of 2.07% has been observed over 64 months of follow-up in a selected group of adult patients with mean preoperative spherical equivalent of -17.3 ± 2.47 D [12]. Retinal detachment occurred from 1 to 70 months after PC-pIOL implantation, with a mean of 29.12 months following surgery. The retinal detachment rate may be even higher in children who have a higher life-long predisposition to spontaneous trauma.

Anterior chamber iris-enclavation phakic intraocular lens

In 1997, the iris-claw intraocular lens implantation in children was first reported for treatment of aphakia. In a series of 27 children and 38 eyes, treatment with iris-fixated one-piece iris-claw intraocular lenses showed comparable visual acuity results with other clinical series [13]. The authors concluded that the lens could be removed and exchanged at a later date with minimal surgical trauma for growing eyes in children. Chipont *et al.* [14] expanded the clinical indication of iris-fixated phakic anterior chamber intraocular lenses by implanting an Artisan pIOL in an 8-year-old anisometropic–amblyopic child, achieving best corrected visual of 20/25 in the surgical eye at 6 months after surgery with stable visual acuity at 18 months following implantation without any complication. Although preoperative ECCs were assessed, no postoperative measurements were reported in this study. Similar findings were reported once again by Saxena *et al.* [15], who showed an improvement of visual acuity to 20/20 in a 4-year-old child following implantation of Artisan pIOL for correction of highly myopic ansiometropia. Although no complications were noted at the 3-year follow-up, the authors reported a significant postoperative endothelial cell loss of 11.9% in the operated eyes as well as a difference of 17% in ECC between the two eyes by the end of the third year of follow-up. Lifshitz and Levy [16] reported improved visual acuity and stable refractive error of −3.25 D following a single case of Artisan pIOL implantation in a 14-month-old pseudo-phakic child over 9 months of follow-up time with no complications. In the first US pilot study of the Verisyse pIOL (5/5.5 mm optic) implantation in children with noncompliance to spectacle/contact lens wear, we showed positive efficacy of Verisyse implantation in treatment of highly significant anisometropic myopia in five children with a follow-up time of 6 months [17]. In a larger case series of 12 children (mean age, 10.1 years; 4–17 years) with neurobehavioral disorders, high ametropia and poor compliance to spectacles, Tychsen *et al.* [18] showed Verisyse pIOL (5 mm optic) implantation to substantially improve the visual function in this subset of children. The study included 18 eyes with myopia (−10.00 to −22.75 D) and two eyes with hyperopia (+10.25 to +10.75). The mean follow-up time was 9.1 months (3–15 months). All children had anterior chamber depth of more than 3.2 mm. Corneal pachymetry was performed in all children, although endothelial cell density (ECD) measurements were obtained only in a subset of cooperative children. Clinically nonsignificant refractive shift was noted. Uncorrected visual acuity improved by 60-fold, central corneal thickness remained stable, and one patient required IOL exchange (IOLE) due to de-enclavation and subsequent damage during surgical manipulation. Of three eyes in which ECD were properly assessed, two showed an average of 2% loss during 6 months. Visual function scores improved by an average of 73% in bilateral ametropic patients and by an average of 58% in anisometropic patients. Assil *et al.* [19] reported an excellent refractive outcome in a 3-year-old highly myopic anisometropic child (−17.00 D) over a 4-year follow-up following Verisyse pIOL implantation and concluded that the Verisyse pIOL may be a treatment option for prevention of highly anisometropic myopic induced amblyopia. The ECCs were similar between the operated and

Table 3 Pediatric anterior chamber phakic intraocular lens studies (Artisan/Verisyse)

Author	Age	Refractive error	Follow-up	Number	Complications
Saxena *et al.* [15]	4	$-14.00+3.00\times115$	3 years	1	ECC 11.9%
Assil *et al.* [19]	3	$-17.00-1.00\times180$	4 years	1	None-ECC stable
Chipont *et al.* [14]	8	$-14.00-3.00\times100$	18 months	1	None
Lifshitz and Levy [16]	14 months	−16.00 D	9 months	1	None
Pirouzian *et al.* [21••]	5–11	−14.20 SE	6 months	6	None
Tychsen *et al.* [18]	4–17	−10 to −22/+10.00	9 months	12	IOLE × change

nonoperated eye, with final visual acuity of 20/30 in the anisometropic eye over the follow-up period. Brown [20] reported successful implantation of the Verisyse pIOL in a child with anisometropic amblyopia. We reported, in a more comprehensive format, our experience with Verisyse pIOL implantation in six noncompliant children ages 5–11 years with high anisometropic myopia (mean −14.33 SE). During the 6 months of follow-up, mean visual acuity (BCVA) improved from 20/500 to 20/70. Refractive error remained stable, postoperative ECD declined by 3.0–6.7% over the 6 months of follow-up time [21••]. In a follow-up to our first study, our mid-term data of seven noncompliant children of the same age group showed an improvement of mean best corrected visual acuity (log-MAR) from 1.18 to 0.3, with an excellent refractive stability, improved stereo-acuity from a mean zero seconds-arc to a mean of 185 s-arc without an evidence of postoperative complications over the follow-up period (3 years) [22]. No patient lost any lines of visual acuity. Rate of ECD loss ranged from 6.5 to 15.2%; however, they remained stable from the second to the third year in four of the seven patients (Table 3). Reported adverse events following implantation of AC-pIOL in pediatric patients remain scant in the literature due to a limited number of surgical cases already performed. In comparison, traumatic aniridia, cataract development, iritis, pigment dispersion, Urrets-Zavalia syndrome, cyclodialysis cleft formation, traumatic dislocation, endophthalmitis, and toxic anterior segment syndrome have been reported following Artisan and/or Artiflex pIOL implantation in adult population [23–32]. The most significant concern for pediatric AC-pIOL implantation is long-term corneal endothelial cell loss, which may ultimately lead to corneal decompensation. In a series of adult ECD studies, Saxena *et al.* [33] reported an average of 8.3% of ECD loss over 5 years in 318 patients following AC-pIOL implantation in the adult population, and the ECD loss was negatively correlated to the anterior chamber depth (ACD). In the FDA clinical trial, the mean change in ECD from baseline to 3 years was $-4.8\pm-7.8\%$, with a 2.4% loss between years 2 and 3 [34]. In yet another study by Budo *et al.* [35], the rate of ECD loss following Artisan pIOL implantation was 4.8% at 6 months postoperatively and dropped to 0.7% at 3 years. In comparison, reduction of ECD ranged from 7.5 to 23% 1 year following lensectomy with IOL implantation in children ages 9–12 [36–37].

Anterior chamber angle-supported phakic intraocular lens

Angle-supported AC-pIOL has not been studied in the pediatric population. In series of adult patients, clinical trials of ZSAIL-4 and AcrySof angle-supported (Alcon) pIOL implantations are ongoing with mixed results [38,39].

Comments and discussion

In final analysis, iris-fixated anterior chamber pIOLs seem to be the preferred choice of pIOLs for surgical management of severe ametropia and/or anisometropia in children. The advantages of iris-fixated pIOL implantation in comparison with PC-pIOLs and/or corneal laser ablative procedures for treatment of high ametropia are numerous, including relative stability of contrast sensitivity (HOAs) following pIOL implantation (Tables 4 and 5) [40–43]. It is imperative for visual function in children to be studied in terms of visual quantity (acuity) and quality (contrast) lost or gained. To date, no pediatric pIOL study as well as corneal laser ablative trial has accomplished such a task [44,45,46•,47•].

Proper preoperative assessment and over-time monitoring of ECD following pediatric pIOL implantation is equally important and strongly encouraged, as children are at higher risk of ECD loss due to recurrent eye-rubbing and trauma, although a recent report showed minimal ECD loss after traumatic dislocation and repositioning of the Artisan pIOL over the span of 4 years [48]. Selection of proper optic size in pIOL implantation in correlation to the anterior chamber depth is equally vital, as it may also play a critical factor in ECD loss over time

Table 4 Advantages of phakic intraocular lenses

1	Reversibility
2	Predictability
3	High optical quality
4	Potential gains in best corrected visual acuity due to retinal magnification in myopic eyes
5	Preservation of corneal architecture
6	Preservation of natural accommodative state
7	Maintaining normal contrast sensitivity from lack of postoperative HOA induction
8	Lack of clinically significant regression over early years after surgery

Table 5 Advantage of pediatric phakic intraocular lenses vs. pediatric corneal refractive laser surgery

1	Preservation of corneal architecture and integrity
	Lack of corneal scar induction
	Lack of late corneal ectasia induction
2	Maintaining normal contrast sensitivity from lack of postoperative HOA induction
	Lack of off-axis laser ablation
	Lack of cyclotorsional-induced laser ablation
3	Reversibility and exchange of IOLs in future

IOL, intraocular lens.

Table 6 Proper anterior chamber phakic intraocular lens optic size selection

Anterior chamber depth (mm)	
<3.0	Defer implantation
3.0–3.20	5.0 mm optic
>3.20	5.0 or 5.50

Data from [45].

in children (Table 6). Central corneal thickness (CCT) measurements cannot determine the ongoing cell loss until a critical threshold of loss may have been reached.

Despite the multiple advantages of pIOL for treatment of severe anisometropic myopia or high ametropia, clinicians must carefully weigh the risks, benefits, and alternatives as well as the necessity for long-term follow-up prior to advocating pIOL implantation in children noncompliant to spectacle and/or contact lens wear. Lack of achievement in gaining a normal 20/20 visual acuity following pIOL eyes may stem from a number of factors including intractable amblyopia due to late therapeutic intervention, foveopathies, retinopathies, ocular motor misalignments, and so on.

Comments and future road to clinical research and exploration

In view of the impending approval of Veriflex and toric Veriflex IOLs in the USA, the future advantages of such lenses in simultaneous reduction of astigmatic errors and induction of higher aberrations depends on the smaller incisions required for implantation of such lenses [49–53]. Future advances in pIOL technology in pediatric patients will likely incorporate intraoperative ORange wavefront aberrometry (WaveTec Vision, Aliso Viejo, California, USA) and anterior segment OCT to further define and address additional visual function parameters in children following refractive procedures.

Conclusion

Large prospective randomized multicentered clinical trials as well as comparative controlled trials of refractive lens exchange, clear lens extraction, and corneal laser ablative procedures would be of great value to assess the true efficacy of pIOL implantation in the pediatric population. Upcoming technology and advances in pediatric refractive pIOL surgery hold great promise in surgical management of high refractive errors in children.

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A.P. as the principal author takes responsibility for the integrity of the data and the accuracy of the data analysis.

References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:

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Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 322).

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This review summarizes the evolution of the treatment of pediatric refractive errors, with an emphasis on recent advancements in the use of refractive surgery to treat children from 1950 to 2007. A thorough review of variously published reports on pediatric PRK, LASK, Phakic IOLs, clear lens extraction were analyzed and reported. The study reports corneal haze and myopic regression are the main complications in PRK treatment group especially in very high myopia (>12 diopters). The report concludes by stating that refractive surgery is appropriate in children with severe anisometropia or bilateral high ametropia resistant to conventional therapy.

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This correspondence appropriately points out to the readers that all the previously published reports/trials on pediatric refractive surgery have simply studied the visual function by visual acuity. The article suggests future pediatric refractive trials should study visual function both in terms of visual acuity and visual quality (through contrast and/or HOA) lost or gained.

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