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ORIGINAL RESEARCH

Phakic anterior chamber intraocular lens (Verisyse™) implantation in children for treatment of severe ansiometropia myopia and amblyopia: Six-month pilot clincial trial and review of literature

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Purpose: The current study aims to evaluate both safety and efficacy of Verisyse™ (AMO, Irvine, CA) phakic anterior chamber intraocular lens (IOL) in the reduction of clinically significant (>–8 D) myopic anisometropia in children who are noncompliant to traditional medical treatment including spectacle correction or contact lenses.

Design: Retrospective interventional case series.

Methods: Six anisometropic myopic pediatric patients in one practice were identified through chart-review. None of the patients were compliant with specatacle correction or contact lens wear and as a result had dense amblyopia of less than 20/400 by Snellen or Allen visual acuity (mean <20/400). All patients underwent Verisyse™ phakic IOL implantation in the more myopic eye by one surgeon (AP). Pre- and post-operative visual acuity, anterior/posterior segment examination, stereoacuity, axial biometry measurements, cycloplegic refraction, and endothelial cell counts were performed in all patients whenever feasible.

Results: The age of patients ranged from 5–11 years. The mean post-operative follow-up time was six months from the time of IOL insertion. Improvement in visual acuity >6 lines was achieved in four patients (mean visual acuity of 20/70 at six months). Improvement in stereoacuity was noted in all six patients (from total mean zero seconds-arc to six-months post-operative mean of 500 seconds-arc by randot stereoacuity testing). Improvement of >2 lines of visual acuity lines was achieved in the other two patients. No patient lost any lines of visual acuity. Enhanced physical activity, coordination, and improved social interaction were noted in patients and were reported by the parents. No intra/post-operative complications were noted.

Discussion: Irreversible or intractable amblyopia secondary to severe anisometropic myopia is a serious medical concern in the pediatric population. Failure of compliance with contact lens therapy consistently leads to visual loss. Anterior chamber phakic IOLs may provide a safe alternative in treatment of noncompliant anisometropic myopic patients who do not accept spectacle wear or contact lens therapy.

Conclusion: To reduce or eliminate highly significant anisometropic myopia in children who are noncompliant with traditional medical treatment, phakic anterior chamber IOL implantation may be considered as an alternative modality of treatment.

Keywords: amblyopia, anisometropia, myopia, intraocular lens implant

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Introduction

The prevalence of myopia has been reported to be one in three in the US, affecting some seventy million people.[1] Unilteral myopia, or anisometropia, starts early in life.[2] If severe (anisometropic myopia >6–8 Diopters) and left untreated, anisometropia may not only lead

to visual loss but it may as well lead to the disruption of binocular fusion. Hence, strict compliance with spectacle correction or contact lens therapy is essential for the amblyopia treatment to be successful, restoring binocular fusion and stereopsis.

In high pediatric anisometropic ametropia of >10 D, spectacle correction may not be the most desirable medical therapeutic option due to induction of aniseikonia and secondary loss of binocular fusion.[3,4] Therefore, contact lens wear for treatment of anisometropia may seem to be the best preferred method of intervention.[3] However, many children resist contact lens wear and a number of parents find placement of contact lenses in toddlers to be extremely challenging, difficult, and unrewarding. As a result, some authors have advocated surgical methods ranging from clear lens extraction and refractive lens exchange to corneal refractive laser ablations.[5,6] Yet these procedures may carry serious short- or long-term post-operative side effects including increased risks for central corneal-opacification and/or off-visual axis laser-ablation patterns.[5]

More recently, a few individual case reports set outside the US have been published for both phakic anterior chamber (AC) and posterior chamber (PC) intraocular lens implantation for the treatment of severe anisometropia myopia.[6–9] Implantation of phakic AC intraocular lens without removal of natural lens is an innovative approach in treatment of high anisometropia as the method will have reversibility and potentially fewer side effects in comparison to other currently existing and proposed surgical techniques such as corneal laser procedures or clear lens extraction in terms of reduced risk for retinal detachment and/or corneal haze/scar.

In this retrospective pilot study, we attempt to investigate post-operative outcome and side effects of Verisyse™ phakic IOL (Abbott Medical Optics, Inc., Irvine, CA) for the treatment of severe anisometropic myopia (>–8) in early childhood where the traditional medical treatment has been employed and failed.

Design and methods

Six anisometropic myopic pediatric patients (aged 5–11) in one practice were identified through retrospective chart review. All surgeries were done during 2005–2006. Four male and two female patients were identified. None of the patients were compliant with spectacle wear and contact lens therapy despite strong medical counseling and support. All patients suffered from dense amblyopia. Comprehensive discussion with parenst was thoroughly undertaken pre-operatively and informed consent with Food and Drug Administration (FDA) off-label use (of this form of IOL) was carefully obtained by all parents. All patients underwent Verisyse™ phakic IOL implantation in the more myopic eye by one surgeon (AP). Pre- and post-operative (on days 1, 3, 7, 30 and at 2, 4, and 6 months) visual acuity, anterior/posterior segment examination, stereoacuity, axial biometry measurements, cycloplegic refraction, and endothelial cell counts (ECC) were performed in all patients whenever feasible during office visits or at examinations under anesthesia. Part-time occlusion treatment of two hours/day was initiated two weeks subsequent to IOL insertion in all patients for a period of 12 weeks. Further part-time occlusion treatment was adjusted based on the visual acuity response of each patient.

Surgical technique

Verisyse™ phakic IOL implantation was performed by a single surgeon (AP). Surgical technique followed the procedural implantation described by the Abbott Medical Optics (AMO) guidelines (Abbott Medical Optics, Inc., Irvine, CA). The superior incisions were carried as clear corneal. Choice of Verisyse™ phakic IOL optic size was determined based on the anterior chamber depth. In the eyes with anterior chamber depth of greater than 3.20 mm, 5.5 mm optic-size implant was selected (Table 2). Four 10-vicreyl (Ethicon, West Somerville, NJ) sutures were used to close the wound at the conclusion of the procedures. Subconjunctival injections of marcaine, dexamethesone, and ancef® into inferior fornix were done at the conclusion of the procedures. Post-operative medical regimen included administration of topical Pred Forte® and Tobradex® ointment alternating every two hours for the first two weeks. After two weeks, tobradex ointment was discontinued and the Pred Forte was gradually tapered over the following four weeks.

Results

Six patients ranging in age from 5–11 years had a mean pre-operative visual acuity of 20/400 or worse. Four male and two female were included in this study. Mean post-operative follow-up time was six months following AC-IOL implantation. Improvement of visual acuity (>6 lines of Allen/Snellen) in four patients. All patients gained gross stereoacuity. Two other patients displayed improvement of >4 lines of visual acuity. No patients lost any line of visual acuity (Tables 1 and 2). Pre and post-operative cycloplegic refraction and visual acuity are summarized in (Tables 4 and 5).

All patients showed enhanced physical activity, improved coordination and social interaction, which were reported by all parents through direct questinaoire about eight weeks from the surgery and remained so until the end of the six-months study period. No intra/post-operative serious or vision-threatening side effects were noted. Retrospectively, one

Table 1 Review of patients' pre-/post-op visual and stereoacuity

Patient #	Eye	Age yr	Pre-op VA (cc best)	Pre-op SA	Post-op VA (6-months) sc	Post-op SA	Complications (post-operative)
1-M	OD	10	20/200	0	20/80	800	None
2-M	OD	11	20/400	0	20/50	400	None
3-F	OS	6	20/200	0	20/80	400	None
4-M	OS	10	20/400	0	20/50	400	None
5-M	OD	6	CF	0	20/100	800	None
6-F	OD	5	20/400	0	20/60	200	None

Abbreviations: SA, stereoacuity; VA, visual acuity.

patient with an intra-operative cyclotorsion showed phakic IOL-claws to be at 10 and 4 o'clock post-operatively.

Post-operative direct clinical assessment of anterior chamber showed mean of 1 + cell/flare inflammation on day 1 for all patients and it subsided to trace cell by the end of first week. By the second week, no cells or active inflammation was observed in any of our patients.

Although one patient acquired oblique corneal astigmatism, which gradually decreased over a six-month period, visual acuity was still better by two lines at the end of our follow-up period. At the end of the six-month follow-up period, all patients showed a 3%–7% endothelial cell loss in the phakic IOL eye; however, the rate of cell loss had stabilized in three patients from the three- to six-month examinations. All patients were strongly urged and instructed to avoid eye-rubbing. The greatest rate of endothelial cell loss had occurred during the first three post-operative months (Table 3). No patient required re-operation or IOL-explantation. Patients' parents were all pleased with the outcome of surgery. They pointed to lack of further requirement for contact lens wear, improved vision, and enhanced physical coordination as their main subjective satisfaction points.

Discussion

Intractable amblyopia secondary to severe long-term untreated anisometropic myopia is a serious medical concern in the pediatric population. Failure of compliance with contact lens therapy or spectacle correction may lead to permanent long-term visual loss with tremendous negative social and financial impact on both the society and the individual families. A variety of surgical options have been advocated for the treatment of severe anisometropic myopia including lensectomy, clear lens extraction, and more recently corneal laser ablative procedures with the ultimate measure of success representing improvement of visual acuity in the absence of adverse outcomes or side effects.[10] Despite the profound success of refractive laser surgery in adults, significant challenges persist in treatment of pediatric patients with refractive corneal laser surgery ranging from higher rate of best corrected visual acuity loss from corneal haze formation or off-center visual axis treatment to requirement for general anesthesia in the laser suite, and the meticulous post-operative cooperation of the patient to avoid eye rubbing to reduce incidence of flap displacement in LASIK-treated patients.[6] Long-term myopic regression has also been observed.[6] Such disadvantages have led to exploration for alternative surgical techniques for treatment of high myopic anisometropia in children. The clinical application of phakic IOL for treatment of severe anisometropia was first described by Lesueur and colleagues with the use of ICL STAAR.[6] Long-term follow up of such patients have shown substantial functional improvement in this group. Currently there are only a handful of peer-reviewed published studies in the literature on the subject of phakic IOL implantation for treatment of high anisometropia myopia in children.[6–12] As far as we are aware there has been only two other published

Table 2 Patients' pre- and post-anterior chamber depth and axial length and IOL size

Patient	Eye	Anterior	Chamber depth	Axial	Length	P-IOL
#		OD	OS	OD	OS	Optic size
1	OD	3.20	3.38	26.32	22.00	5.5
2	OD	3.00	3.21	27.22	22.42	5.0
3	OS	3.00	3.20	23.86	25.66	5.5
4	OS	2.92	3.18	21.78	24.34	5.0
5	OD	2.83	3.00	24.56	21.91	5.0
6	OD	3.00	3.22	24.62	21.65	5.0

Abbreviation: IOL, intraocular lens.

Table 3 Pre- and post-operative ECC in surgical eye (±200c)

Eye	Pre-	Post-1-mo	Post-3-mo	% loss 3-m	Post-6-mo	% loss 6-mo
OD	3300	3200	3200	3.1%	3100	6.1%
OD	3000	2900	2800	6.7%	2800	6.7%
OS	3100	3000	2900	6.5%	2900	6.5%
OS	3300	3200	3200	3.1%	3100	6.1%
OD	3100	3000	3000	3.3%	2900	6.5%
OD	3500	3400	3400	2.9%	3300	5.7%
OS	3400	3300	3300	3.0%	3300	3.0%

Abbreviations: ECC, endothelial cell counts; mo, months.

studies in the US on the investigation of anterior chamber phakic IOL for the treatment pediatric myopic anisomteropic ametropia.[11,12] We additionally believe that there are significant advantages in using anterior chamber phakic IOLs for treatment of severe anisometropic myopia in the pediatric patients as potential side effects of this procedure may be less than the refractive laser corneal-ablative procedures currently available for the treatment of myopia >10 D.

An advantage of anterior chamber phakic IOL (AC-pIOL) includes the farther distance of its sitting optic from the natural crystalline lens in comparison to posterior-phakic IOLs (PC-pIOL) hence reducing the risk of early or late onset lenticular-opacification. A disadvantage of AC-pIOL includes an ongoing corneal endothelial cell loss potentially attributing to the eventual corneal decompensation. Furthermore, although anterior chamber phakic-IOL (AC-pIOL) has firm iris enclavation at the end-haptics, there is a potential risk for traumatic iris-haptic de-enclavation, hence a possibility for spontaneous lens dislocation.[11]

A few advantages of PC-pIOLs, on the other hand, include reduced risk for endothelial cell loss, a smaller corneal incision entry site for delivery into the anterior chamber, and no requirement for iris-haptic enclavation.[13] The disadvantages of PC-pIOLs include increased risk for lenticular opacification due to inadvertent lenticular touch during the implantation and/or due to childhood eye rubbing.[13] Other potential complications of PC-pIOLs, including papillary-block glaucoma and posterior dislocation of IOL, have also been reported in an European Clinical Trial with PRL group and other studies.[15–17]

Our study has been one of the first and largest pilot clinical series in the US to thoroughly investigate the variables of risks and benefits of anterior chamber phakic IOL in treatment of high anisometropic myopia in children.[6–12] We also believe phakic IOL implantation employs several inherent properties which makes it ideal for treatment of high anisometropia myopia in comparison to corneal laser surgeries. Technique though distinct due to necessity of enclavation of haptics to iris is somewhat similar to IOL placement following cataract extraction and many pediatric ophthalmologists are already familiar with this form of surgery. Conscious central fixation is not necessary in phakic IOL implantation as is in laser ablative procedures. The technique is reversible and in the cases of rapidly progressive myopia, phakic IOL exchange with a higher power IOL could be considered.

Despite the many advantages of phakic IOL, an essential similarity with clear lens extraction or corneal ablative procedures still exists which is the need for occlusion therapy. A very deliberate and careful selection process of patients with appropriate anterior chamber depth is a key factor in potentially reducing rate of ECC loss following the phakic anterior chamber IOL implantation. Patients need to be instructed as well to avoid any eye rubbing post-operatively. In cases where ECC cannot be determined and/or endothelial cell loss is disproportionally progressing, explantation of phakic IOL could be considered once a child reaches post-amblyopic age and is no longer at risk for visual loss.

We believe eliminating the underlying anisometropic refractive error by placement of phakic IOL is the direct etiology for gradual improvement of best-uncorrected visual acuity in our pediatric patients over the six-month period of

Table 4 Post-operative refraction (cycloplegic)

Patient #	Pre-op Refraction (SE)	Cycloplegic	Post-op refraction (Six months) p-IOL	Target operative Eye refraction
	OD	OS		
1	−16.50	−1.50	−0.50 + 0.50 × 100	Plano
2	−17.00	−1.00	Plano	Plano
3	+1.25	−13.50	−3.50 + 3.50 × 150	Plano
4	−1.50	−13.00	Plano + 1.00 × 90	Plano
5	−12.50	+2.00	−1.50 sph	Plano
6	−13.50	+1.00	−0.50 + 1.00 × 90	Plano

Abbreviations: IOL, intraocular lens; SE, spherical equivalent.

Table 5 Mean preoperative and postoperative refraction and visual acuity pre-op and six months post-op

Pre-op best VA	Pre-op refraction	Post-op sc	Post-op refraction
Mean	Mean and range	VA mean	Mean (SE)
20/500	−14.33 ± 2.5	20/70	−0.50 ± −1.25

Abbreviations: SE, spherical equivalent; VA, visual acuity.

this study. Two other independent studies have proven by eliminating anisometropia solely with spectacle correction would improve the visual acuity in amblyopic children, hence supporting our theory.[18,19] Furthermore, we feel our lack of ability to achieve a better visual acuity gain is related to the long-standing pre-existing amblyopia in our patients' population. We deem further studies are needed to assess whether a better visual acuity improvement could be attained if phakic IOL implantation is performed at an earlier age in an uncooperative child prior to the onset of amblyopia.

Therefore, at this point we advocate larger prospective clinical trials with longer follow-up time to conclusively demonstrate the efficacy of phakic IOL as an effective alternative method of treatment for non-compliant to medical treatment in severe anisometropic myopic pediatric patients. Anterior chamber phakic intraocular lens implantation without removal of the natural lens of children could ultimately become an ideal alternative treatment of high anisometropia in noncompliant to contact lens patients. The method will have reversibility as well as stability and may have fewest side effects in comparison to other currently proposed and existing surgical techniques.

Conclusion

To reduce or eliminate highly significant anisometropic myopia (>−8 D) in young children with secondary amblyopia who have failed the conventional medical treatment with contact lenses or spectacle correction with binocular fusional loss, AC-pIOL implantation may be considered as an alternative form of treatment.

Disclosure

The authors have no financial interest in any product investigated in this study. No grants have been received for this study. No potential conflict of interest exists for the authors.

References

1. Kempen JH, Mitchell P, Lee KE, et al; Eye Diseases Prevalence Research Group. The prevalence of refractive errors among adults in the United States, Western Europe, and Australia. *Arch Ophthalmol*. 2004;122:495–505
2. Kleinstein RN, Jones LA, Hullett S, et al; Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error Study Group. Refractive error and ethnicity in children. *Arch Ophthalmol.* 2004;121:1141–1147.
3. Winn B, Ackerley RG, Brown CA, et al. Reduced aniseikonia in axial anisometropia with contact lens correction. *Ophthalmic Physiol Opt.* 1988;8:341–344.
4. Lubkin V, Kramer P, Meininger D, et al. Aniseikonia in relation to strabismus, anisometropia and amblyopia. *Binocul Vis Strabismus Q*. 1999;14:203–207.
5. Paysse EA, Coats DK, Hussein MA, et al. Long-term outcomes of photorefractive keratectomy for anisometropic amblyopia in children. *Ophthalmology*. 2006;113:169–176.
6. Lesueur LC, Arne JL. Phakic posterior chamber lens implantation in children with high myopia. *J Cataract Refract Surg*. 1999;25:1571–1575.
7. Lesueur LC, Arne JL. Phakic intraocular lens to correct high myopia amblyopia in children. *J Refract Surg*. 2002;18:519–523.
8. Chipont EM, Garcia-Hermosa P, Alió JL. Reversal of myopic anisometropic amblyopia with phakic intraocular lens implantation. *J Refract Surg*. 2001;17:460–462.
9. Saxena R, van Minderhout HM, Luyten GP. Anterior chamber iris-fixated phakic intraocular lens for anisometrpic amblyopia. *J Cataract Refract Surg*. 2003;29:835–838.
10. Tychsen L. Refractive surgery for children: excimer laser, phakic intraocular lens, and clear lens extraction. *Curr Opin Ophthalmol*. 2008;19:342–348.
11. Tychsen L, Hoekel J, Ghasia F, et al. Phakic intraocular lens correction of high ametropia in children with neurobehavioral disorders. *J AAPOS*. 2008;12:282–289.
12. Pirouzian A, Bansal P, O'Halloran H. Phakic IOL in children. *Ophthalmology*. 2007;114:194–195.
13. BenEzra D, Cohen E, Karshai I. Phakic posterior chamber intraocular lens for the correction of anisometropia and treatment of amblyopia. *Am J Ophthalmol*. 130:292–296.
14. Fink AM, Gore C, Rosen E. Cataract development after implantation of the Staar Collamer posterior chamber phakic lens. *J Cataract Refract Surg*. 1999;25:278–282.
15. Eleftheriadis H. Potential complications of phakic IOLs. *Br J Ophthalmol*. 2004;88:1480–1481.
16. Eleftheriadis H, Amoros S, Bilbao R, et al. Spontaneous dislocation of a phakic refrafractive lens into the vitreous cavity. *J Cataract Refract Surg*. 2004;30:2013–2016.
17. Rosen E, Gore C. Staar Collamer posterior chamber phakic intraocular lens to correct myopia and hyperopia. *J Cataract Refract Surg*. 1998;24:596–606.
18. Cotter SA; Pediatric Eye Disease Investigator Group. Treatment of anisometropic amblyopia in children with refractive correction. *Ophthalmology*. 2006;113:895–903.
19. Phillips CI. Treatment of bilateral refractive amblyopia in children three to less than 10 years of age. *Am J Ophthalmol.* 2008;145(3):588; author reply 588.