A Long Term Follow Up of Posterior Chamber Phakic Intraocular Lenses for Correcting Intractable Pediatric Myopic Anisometropic Amblyopia

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Abstract

Background

Pediatric myopic anisometropic amblyopia is one of the most challenging clinical situations that can face an ophthalmologist. Conventional correction modalities for myopic anisometropic amblyopia, using spectacles, contact lenses, and/or occlusion therapy, may not be suitable for some pediatric patients or for some ocular conditions. This may lead to the development of amblyopia and loss of binocular vision. The aim of the present study was to evaluate the visual and refractive efficacy, safety, and stability of Posterior Chamber Phakic Intraocular Lenses (PC-pIOLs) for correcting pediatric myopic anisometropic amblyopia.

Methods

This case series, prospective, interventional study was conducted at Watany Eye Hospital, Cairo, Egypt. It comprised 42 eyes of 42 children with myopic anisometropic amblyopia and unsuccessful conventional therapy. After implantation of Intraocular Collamer Lenses “ICLs” (Visian ICL, Model V4c, STAAR Surgical, Monrovia, California, USA), postoperative follow up visits were scheduled, with subjective refraction and Pentacam imaging performed.

Results

The patients’ age range was 3 to 18 years (mean ± SD = 10.58 years ± 4.23). The mean preoperative SE was − 12.54 D ± 2.93. The results declared a significant improvement in the postoperative CDVA (P value < 0.01) and SE (P value < 0.01). The efficacy index had a value of 1.18 ± 0.3 and the safety index was 1.09 ± 0.24. The follow up visits had a mean ± SD of 14.67 months ± 16.56 (range of 1 to 54 months). The results showed a refractive stability, with slight (statistically insignificant) improvements in the subjective refraction between the first postoperative and the follow up visits. No postoperative complications were encountered.

Conclusions

The present study, with the longest reported follow up range, declared the long-term efficacy, safety, and stability of Visian ICLs for correcting pediatric myopic anisometropic amblyopia. The reported non-compliance with occlusion therapy validates the early implantation of Visian ICLs in cases of failed conventional therapy to guard against anisometropic amblyopia.

Background

Pediatric amblyopia is one of the most challenging situations that can face an ophthalmologist. Its prevention and correction require proper cooperation of the child and his/her guardians, which is difficult to achieve in many instances.[1] Anisometropic amblyopia is a common amblyopic form which leads to aniseikonia and unilateral image blur, with a consequent suppression of this blurred image by the brain.[2] The conventional correction of anisometropia using spectacles remains the gold standard that is adopted by many pediatric ophthalmologists. Children can, in many instances, tolerate glasses while having large refractive differences between both eyes. This is mainly encountered with axial rather than refractive myopia, assuming Knapps’ law of visual optics. However, literature has demonstrated an induced stretching of the retina with significantly long globes that can be a primary cause of reduced spatial resolution in the peripheral field.[3] This renders the glasses an inconvenient corrective modality in a major portion of myopes with high errors or those having refractive rather than axial myopia. Besides, if anisometropic amblyopia develops, occlusion or penalization of the fellow eye can be challenging and difficult to implement.[4] Contact lenses (CLs) are another available option for correcting anisometropia. Nonetheless, intolerance to their use and poor compliance, especially with younger age groups, can lead to treatment failure.[5] Furthermore, visual rehabilitation using either spectacles or CLs cannot be properly secured in cases of neurobehavioral-disorder children.[6]

When spectacles and CLs fail to guarantee the desired visual acuity for the pediatric age group, other treatment modalities should be addressed to prevent amblyopia. Corneal excimer laser ablative procedures are an available alternative. Yet, the risks of flap related complications, postoperative corneal haze, and the possible development of corneal ectasia are higher among the pediatric patients.[7–9] Another refractive correction modality for amblyopia with higher values of refractive errors is refractive lens exchange. Such procedures however carry major disadvantages, the most prominent of which are the greater risks of retinal detachments and the permanent loss of the accommodative power.[10]

The use of phakic intraocular lenses (pIOLs) has been proposed as an effective modality for correcting intractable anisometropic amblyopia in children.[11] The major advantages of using pIOLs include their predictability, high optical quality, preservation of the child’s accommodative power, and avoiding the hazards of corneal ablative procedures.[12,13,14] Though previous studies reported that both iris-fixated pIOLs and posterior chamber pIOLs (PC-pIOLs) have equally satisfactory postoperative visual outcomes, implantation of iris-fixated pIOLs carries a higher risk of endothelial cell loss and intraocular inflammation in adulthood. On the other side, PC-pIOLs have a significantly lower risk of such complications.[11] Though the implantation of a PC-pIOL in a child seems more convenient than an iris fixated pIOL, it can induce other complications that usually arise from preoperative miscalculations or mispositioning of the IOL, including mainly anterior subcapsular cataract formation and shallow anterior chamber.[15] Though reports of such

complications in the pediatric population are few, this may be attributed to the paucity of studies on this age range, especially for long follow up intervals.[11]

The aim of the present study was to evaluate the refractive efficacy, safety, and stability of PC-pIOLs (Visian Intraocular Collamer Lenses " ICLs") in a pediatric cohort with myopic anisometropic amblyopia. Long follow up intervals in the study aimed to detect the long-term stability and the possible long-term complications.

Patients And Methods

This is a prospective, non-randomized, non-controlled, interventional, case series study that was performed on a pediatric group of patients (aged 3 to 18 years) who sought medical advice at Watany Eye Hospital, Cairo, Egypt. All the recruited patients performed the surgical procedure in the period from January 2016 to July 2020. The study adhered to the tenets of the Declaration of Helsinki and was conducted in compliance with the Ethical Standards set by the Institutional Review Board of the Watany Research and Development Center (the registration code is REF-2016-002). The guardians of the participating children and teenagers signed preoperative informed consents and were counselled about the nature of the surgical technique and the possible postoperative outcomes.

The exclusion criteria included pediatric patients with previous ocular trauma or surgeries, corneal pathologies (mainly corneal dystrophies or ectatic conditions), angle anomalies, congenital glaucoma, any lenticular abnormalities [including abnormal lenticular shapes (mainly spherophakia and microspherophakia), abnormal lens positions (ectopia lentis), and lenses with cataractous changes], Anterior Chamber Depth (ACD) less than 2.8 mm, and any posterior segment abnormalities. Besides, cases with high cylindrical errors (either exceeding 3 D in the operated eye or having a difference in the cylindrical component between both eyes of more than 2 D) were excluded from the selected candidates.

The study enrolled 42 eyes of 42 children with myopic anisometropic amblyopia and unsuccessful conventional amblyopic therapy (using spectacles, contact lenses, and/or occlusion therapy). Other than analyzing the results for the whole pediatric cohort, a subgrouping was performed for the enrolled participants based on the refractive condition of the other eye; group 1 included 17 eyes of 17 pediatric patients with low myopia (more than 1 diopter "D" and less than 6 D), while group 2 comprised 25 eyes of 25 patients with myopia of less than 1 D or emmetropia. Both groups were compared regarding the visual performance (Unaided Distance Visual Acuity "UDVA", Corrected Distance Visual Acuity "CDVA", and Spherical Equivalent "SE") of the eye with the pediatric ICL implantation.

For all candidates of the case series, a baseline ophthalmological examination was performed before the surgical intervention. This included subjective refraction (which was performed under complete cycloplegia with cyclopentolate 1%) including UDVA, CDVA, and SE. Furthermore, slit lamp examination, intraocular pressure (IOP) measurement using air puff tonometer, and fundus examination by indirect ophthalmoscopy were done for all participants. The visual acuity was performed using the Snellen scoring, which was converted to LogMAR for the statistical analysis.

Prior to the selection of the suitable candidates, good quality scans of the Pentacam HR, branded as Allegro Oculyzer II (WaveLight, Erlangen, Germany, software version 1.20r20) were captured for all the patients to rule out corneal ectatic conditions and to measure the ICL vault. Essential biometric measurements were performed, including the ACD, central corneal thickness, keratometric values, and measuring the white-to white (WTW) diameter. To ensure the proper sizing of the ICL and for calculation of its suitable power as well as validation of the WTW and ACD measurements, the values obtained from the Pentacam HR were also confirmed by capturing good quality scans from the IOL Master 500 (Carl Zeiss Meditec, Germany) for all the enrolled participants. The ACD values in all patients exceeded 2.8mm, which was measured from the anterior lens surface to the corneal endothelium.

Surgical Technique

The surgical technique was performed for all the cases by the same experienced surgeon (F.F.M). All the surgeries were carried out under general anesthesia due to the young age group. Proper draping of the eye and the lashes and sterilization of the surgical field using betadine 5% were performed. Following pupillary dilatation, a 1.2 mm superior slanting paracentesis was incised using a clear cut blade (ALCON - USA), and a dispersive viscoelastic material (Methylcellulose) was injected into the anterior chamber. The holes of the Visian ICL (Model V4c, STAAR Surgical, Monrovia, California, USA) were checked under the operating microscope for reassuring the correct antero-posterior orientation. The ICL was then properly loaded within its cartridge (with the aid of a McPherson forceps) and implanted through a 3.0 mm temporal corneal incision. A second slanting paracentesis was performed to allow easier positioning of the ICL haptics in the ciliary sulcus. The haptics were gently pushed behind the edge of the iris using a blunt spatula through one of the paracenteses, and the ICL was properly centralized. Meticulous irrigation of the viscoelastic material was then performed by a Simcoe Cannula. Afterwards, the temporal corneal incision was sutured using a single 10-0 Nylon suture. The surgery was ended by stromal hydration closure of the two paracenteses.

Postoperative management

Postoperatively, eyedrops containing a steroid/antibiotic combination were prescribed 4 times daily and tapered out weekly for 1 month. The suture was removed two weeks after surgery. Subjective refraction, slit lamp examination, IOP measurement using air puff tonometry, and Pentacam HR were performed for all the participating pediatrics along the follow up visits. The Pentacam images were evaluated to document the ICL stability, the value of the anterior ICL vault, and any detectable postoperative complications. Occlusion of the fellow eye during the day was prescribed for at least 3 hours, combined with one hour of near visual activities,[16] along the first month following surgery. The occlusion therapy was prescribed thereafter if necessary.

Statistical analysis

Data analysis was performed using IBM SPSS Statistics for Windows (Version 25.0. Armonk, NY: IBM Corp.). The one-sample Kolmogorov-Smirnov test was used to test for normality. Quantitative data were presented as mean and standard deviation (SD). Sex differences were evaluated by the chi-squared test. Comparisons between the preoperative, postoperative, and follow up visits were performed using the independent-T test. P-values < 0.05 were considered statistically significant. Both the efficacy and the safety indices for the ICL implantation were calculated for the recruited cohort, where the cut-off level of the efficacy index was set to 0.80 and that of the safety index was set to 0.85.

Results

The present study was conducted on 42 eyes of 42 children with unilateral high myopia or myopic anisometropic amblyopia, where the ICL was implanted in the more ametropic eye. The age range of the recruited pediatric cohort was 3 to 18 years, with a mean ± SD of 10.58 years ± 4.23. The female to male percentage was 39.2–60.8%. Twenty-three eyes were right while 20 eyes were left. The mean preoperative SE was − 12.54 D ± 2.93 (range of -19.00: -6.00 D), the mean preoperative cylindrical error was − 1.82 D ± 1.1, while the mean Visian ICL power was − 12.70 D ± 2.39 (range of -18.00: -9.00 D). The follow up visits had a mean ± SD of 14.67 months ± 16.56 (range of 1 to 54 months).

Table 1 shows the mean values of the patients' subjective refraction on each of the preoperative visit, the first postoperative visit, and the follow up visit. The results declared statistically significant differences between the values of the preoperative and the first postoperative visit, with a significant improvement in each of the postoperative UDVA (P value < 0.01), CDVA (P value < 0.01, with a mean improvement of 0.2 LogMAR ± 0.3), and SE (P value < 0.01, with mean improvement of -11.32 D ± 2.41). Moreover, the results obviously showed refractive stability among the participating patients, as there was a slight (statistically insignificant) improvement in all the mean values of the patients' subjective refraction between the first postoperative and the follow up visit. The values of both the efficacy and the safety indices for the enrolled patients were determined and showed remarkably high values of 1.18 ± 0.3 and 1.09 ± 0.24, respectively.

Table 1
The mean values, standard deviations and ranges of the patients' subjective refraction on each of the preoperative visit, the first postoperative visit, and the follow up visit.

Variable	Mean	SD	Range
Age (Years)	10.58	4.23	3: 18
Follow up period (Months)	14.67	16.56	1: 54
Preoperative UDVA* (LogMAR, Snellen)	1.33 (20/400)	0.53	0.04: 2
Preoperative CDVA* (LogMAR, Snellen)	1.06 (20/250)	0.55	0.18: 2
Preoperative Spherical Equivalent (Diopters)	-12.54	2.93	-19.00: -6.00
ICL* Power (Diopters)	-12.70	2.39	-18.00: -9.00
ICL* Diameter (mm)	12.86	0.41	12.1: 13.7
1st Postoperative UDVA* (LogMAR, Snellen)	0.56 (20/80)	0.40	0.00: 1.52
1st Postoperative CDVA* (LogMAR, Snellen)	0.42 (20/50)	0.34	0.04: 1.52
1st Postoperative Spherical Equivalent (Diopters)	-1.98	1.4	-2.50: +1.63
2nd Postoperative UDVA* (LogMAR, Snellen)	0.41 (20/50)	0.33	0.00: 1.3
2nd Postoperative CDVA* (LogMAR, Snellen)	0.22, 20/32	0.21	0.0: 0.7
2nd Postoperative Spherical Equivalent (Diopters)	-0.65	1.54	-2.00: +2.13
*UDVA: Unaided Distance Visual Acuity, CDVA: Corrected Distance Visual Acuity, ICL: Intraocular Collamer Lens.			

The slit lamp examination during the first postoperative and the follow up visits showed clear corneas, quiet anterior chamber (AC) with no detected inflammatory reactions or pigmentary deposits, and a centralized ICL. The Pentacam images during the follow up visits confirmed the stability of the ICL in place, with no detected obstruction of the AC angle, and a sufficient space between the ICL and the crystalline lens. The anterior ICL vaulting had a mean and SD of 490 um ± 4.23.

As regards to the IOP measurements and the fundus examination of the participants, the findings were unremarkable before and after the surgical performance and during the follow up visits.

A significant portion of the children's guardians (80%) reported poor compliance with the prescribed occlusion therapy, despite strict instructions that were given to abide by it. Yet, the parents of all the children reported enhanced physical activities and improved social intermingling for all the participating patients within a short time interval of performing the surgical intervention.

As regards to the subgrouping that was based on the refractive status of the fellow eye, group 1 patients had a spherical equivalent that ranged between − 1.25 and − 4.75 D. The results declared no statistically significant differences between the two groups regarding the visual performance of the eye that performed the pediatric ICL implantation.

Discussion

This prospective case series study showed the efficacy (efficacy index value of 1.18 ± 0.3), safety (safety index value of 1.09 ± 0.24), and long term stability of Visian ICLs for correcting pediatric myopic anisometropic amblyopia in cases of unilateral high myopia and non-compliance with the conventional treatment modalities. To date, the present study comprised the largest number of pediatric patients who implanted an ICL for correcting anisometropic amblyopia, and it is also the first study to document this long follow up interval that reached up to 54 months. Thus, the present report validates the use of Visian ICLs in young children and teenagers without concerns about their long-term refractive stability or about the development of long-term complications.

Our studied population included cases of unilateral high myopia. This population was shown to be more prone to develop anisometropic amblyopia, even with trials of conventional treatments with spectacles, contact lenses, and occlusion therapy.[17]

For all candidates included in the present study, the cylindrical component did not exceed 3 D in the operated eye and the difference in the cylindrical component between both eyes was no more than 2 D. We excluded patients having higher cylindrical errors that would require toric ICLs for correcting this high astigmatism, assuming that the corneal toricity will change along the time and thus implanting a toric ICL at this young age would possibly require a secondary exchange within few years. Even though our enrolled patients had relatively low cylindrical values, the patients who were left postoperatively with a visually-significant cylinder were corrected by spectacles, especially that this study aimed at correcting the anisometropic amblyopia rather than attaining glass independence for the candidates.

Implantation of PC-pIOLs in children for preventing and treating anisometropic amblyopia can be considered as a preferable technique by many surgeons, and also, after proper counselling, by many parents. This can be attributed to the efficacy and safety of the procedure in restoring the visual performance, the lack of post-operative noxious precautions which are encountered with the corneal refractive surgeries (especially with the younger ages), the significantly lower risk of endothelial cell loss than the AC-IOLs (especially with the inevitable eye rubbing in children), the unbreaching of the corneal architecture (allowing for future successful corneal refractive surgeries if needed), and the reversible nature of the technique (if needed).[18]

The enrolled pediatric cohort in the present study did not experience post-operative complications. Lack of surgical experience and an improper vault size are the two main reported risk factors for a higher incidence of developing pediatric secondary cataract (in cases with low vaults) or pupillary block glaucoma (with high vault values) following the surgical intervention.[18] Yet, it is noteworthy that the complications related to the improper ICL vault were more frequently encountered with the older ICL models. The newer model ICLs (V4c used in this study as well as the newer model V5) include a central port which greatly minimizes the risk of either cataract development or pupillary block.[19] The absence of the two aforementioned risk factors in our study may clearly explain the absence of post-operative complications in our recruited patients.

In our studied pediatric population, the mean vault value was within the normal ranges and towards the higher normal values. A relatively higher value for the pediatric ICL vault has been advocated, considering the expected progressive reduction of the central vault over time with the slow (yet steady) axial growth of the crystalline lens over the years. That is why higher vault values (within the normal ranges) can be more preferable for younger age groups.[20]

Worthy of mention is that the compliance with the occlusion therapy was poor for most of the pediatric cohort, which has also been reported in previous studies.[21,22] This can be attributed to many factors, including mainly skin irritation, poor cosmetic appearance, lengthy treatment periods, and the stress suffered by the child and his parents. These factors make the occlusion therapy difficult to achieve and more likely to be abandoned or applied considerably less than required. This validates the use of the ICLs at an early phase if the conventional therapy is ineffective, so as to avoid the occurrence of anisometropic amblyopia.

The parents of the pediatric cohort reported improved physical and social activities within a short period of the ICL implantation. These short-term enhancements cannot be attributed to simple maturation of the children that requires longer time intervals, so we can attribute these improvements to the better visual performance following the ICL implantation.

Previous studies reported the outcomes of implanting iris-fixated ICLs for correcting pediatric anisometropic amblyopia. Though the visual outcomes were satisfactory, some complications were documented, including progressive endothelial cell loss with eye rubbing (that is mostly uncontrollable with younger ages) and iris chaffing. Furthermore, the relatively short follow up intervals render the results of these studies unreliable for the true evaluation of the possible consequent complications.[20,23–28]

To the authors' knowledge, few case series studies were conducted on implanting PC-pICLs for myopic anisometropic children. All these studies recruited a fewer number of children than the present study, and the follow up ranges were shorter. Table 2 displays the clinically relevant results of these studies, which are collectively in accordance with our study results in validating the stability and the absence of significant complications after implanting PC-pICLs.[29–33]

Table 2
Summary of the clinically-relevant data of the previous studies performed on the implantation of Posterior Chamber Visian Intraocular Collamer Lenses (ICL) for pediatric cohorts.

Authors	Year	Number of eyes	Range (mean) of age (years)	Mean Preoperative Unaided Distance Visual Acuity	Mean Preoperative Corrected Distance Visual Acuity	Mean Preoperative Spherical Equivalent	Mean ICL power	Mean Post-operative Unaided Distance Visual Acuity	Mean Post-operative Corrected Distance Visual Acuity	Mean Post-operative Spherical Equivalent	Follow Up Period (months)
Elmassry et al.	2017	12	2–15 (8)	0.9	0.4	-11.28	-	0.0.3	0.1	-1.82	12
Zhang et al.	2016	11	5–17 (11)	2.15	1.5	-15.34	-	0.95	0.75	-0.92	8
Lesueur and Arne	1999	5	3–16 (9)	-	-	–12.8	-15.5	All gained lines	All gained lines	+ 0.5	11.8
Alio et al.	2011	11	2–15 (8)	1.1	0.84	-10.14	-	0.65	0.36	-1.16	60
TYCHSEN et al.	2016	40	2–17 (10)	1.72	-	-9.2	-	0.48	-	+ 0.56	15.1
BenEzra et al.	2000	3	Reported as individual cases (9,14, and 18 years old), and all showed improvements in the visual performance.								

We also performed a subgrouping for the enrolled cohort that was based on the refractive condition of the fellow eye. This aimed to declare whether the eyes with low myopia in the fellow eye had a more favorable visual prognosis along the follow up visits than those with emmetropia in the fellow eye, assuming that the amblyopic eye will be favored from the refractive aspect after the ICL implantation. Although our study did not show significant differences between the two groups, we believe that these results should be negated or reinforced by future studies performed on larger cohorts and having a more equivocal number of patients in both groups (as the eyes in group 1 with low myopia in the fellow eye represented 39.5% only of the enrolled patients).

In our studied cohort, specular microscopy was not performed for the patients. Previous reports have documented that PC-pICLs are much safer on the corneal endothelium than AC-IOLs.[18] Even though we do not expect a significant compromise for the corneal endothelium by the implanted ICLs, further studies may reassure this by performing specular microscopy along the follow up periods. Moreover, future longitudinal studies for even longer follow up intervals are advocated to more robustly declare the refractive stability and the safety of the Visian ICLs. Besides, highlighting the impact of improving the visual performance on the binocular vision is recommended in the upcoming studies.

Conclusions

In conclusion, the present study declared the long term visual and refractive efficacy, safety, and stability of the Visian ICL for correcting myopic anisometropic amblyopia in a pediatric cohort with a mean preoperative SE of -12.54 D ± 2.93 and a range of -19.00 to -6.00 D. Based on our study results, the implantation of Visian ICLs for cases of unilateral high myopia with intractable anisometropic amblyopia results in a long-term visual and refractive stability, and can also be gauged as a low risk procedure, evidenced by the long-term absence of reported complications. Furthermore, the reported non-compliance with occlusion therapy validates the early implantation of Visian ICLs in cases of failure of the conventional conservative correction and occlusion therapy to guard against anisometropic amblyopia.

Abbreviations

- Contact lenses (CLs)
- phakic intraocular lenses (pIOLs)
- posterior chamber pIOLs (PC-pIOLs)
- Intraocular Collamer Lenses (ICLs)
- Anterior Chamber Depth (ACD)
- diopter (D)
- Unaided Distance Visual Acuity (UDVA)
- Corrected Distance Visual Acuity (CDVA)
- Spherical Equivalent (SE)
- intraocular pressure (IOP)
- white-to white (WTW)
- standard deviation (SD)

- anterior chamber (AC)

Declarations

- **Ethics approval and consent to participate:** The study was conducted in compliance with the Ethical Standards set by the Institutional Review Board of the Watany Research and Development Center (the registration code is REF-2016-002). The guardians of the participating children and teenagers signed preoperative informed consents and were counselled about the nature of the surgical technique and the possible postoperative outcomes.
- **Consent for publication:** Not applicable.
- **Availability of data and materials:** The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
- **Competing interests:** The authors declare that they have no competing interests.
- **Funding:** Nothing to be declared.
- **Authors' contributions:** FFM plotted the study design, examined the patients, and supervised the manuscript along its whole stages, NFF assisted in patients' selections and examinations and aided in the manuscript drafting, MB retrieved the data and performed the statistical analysis, NF assisted in data retrieval and manuscript drafting, and RS shared in the study design, drafted the manuscript, and prepared it for publication.
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