Although congenital cataract in children is a rare disorder, it is considered to be the most common cause of treatable blindness worldwide. The prevalence in newborns is approximately 1 to 13 cases in every 10,000 births.\textsuperscript{1,2} Accurate diagnosis, ideal intervention timing, and treatment choice are extremely important to ensure visual rehabilitation, avoid amblyopia, and minimize the risk of complications.

One of the most crucial decisions when performing pediatric cataract surgery is the choice between aphakia or IOL implantation. The type of IOL to implant and the dioptric power of the IOL used are critical to avoid extreme refractive surprises postoperatively. The concept of a multi-component adjustable IOL (InfiniteVision Optics, Strasbourg, France) offers a new perspective in the future management of infantile cataracts. Patients who have not yet completed their biological ocular growth may still have the possibility of enhancement surgery, allowing for short-term and long-term refractive adjustments, as they are required, as the patient matures.

ABSTRACT

\textbf{PURPOSE:} The multi-component intraocular lens (IOL) (IVO; SAS, Strasbourg, France) is a novel approach to the treatment of pediatric cataract. Because the refractive requirements for pediatric eyes often change over time, current IOL technology does not easily allow refractive adjustments after the primary surgical intervention. The multi-component IOL concept allows easy, surgical refractive adjustments to the initial surgical implantation at any postoperative time period. Thus, both surgical implantation and enhancement surgery have been successfully accomplished in adult patients.

\textbf{METHODS:} A novel surgical approach to pediatric cataract surgery is described. At the time of the primary surgery, a two component IOL was implanted. At any postoperative time period, the front lens component, located in front of the capsular bag, could be easily surgically exchanged because the dioptric power requirements of the pediatric eye changed over time.

\textbf{RESULTS:} Both primary and enhancement surgeries have been done in adult patients with good results. Implantations have occurred uneventfully in all cases with no intraoperative or postoperative complications. There was no statistically significant difference in the endothelial cell density, anterior chamber depth, and pachymetry readings preoperatively and 2 years postoperatively. There was no interlenticular fibrosis present.

\textbf{CONCLUSION:} The multi-component IOL should provide a unique and greatly needed surgically adjustable approach to the treatment of pediatric cataract.

\cite{J Refract Surg. 20XX;XX(X):XX-XX.]

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\textbf{IOL IMPLANTATION: CURRENT STATUS}

The available options when performing cataract surgery in children are aphakia followed by immediate contact lens fitting versus primary IOL implantation. IOL implantation is the preferred approach in children who have completed their second year of life, but surgeons remain hesitant to implant an IOL in infants and children younger than 2 years. The advantages of IOL implantation include amblyopia prevention, lower rate of certain complications, and higher compliance if contact lens fitting is impossible. Ledoux et al.\textsuperscript{3} conducted a 14-year retrospective study of children with unilateral or
bilateral cataract who underwent IOL implantation, in which approximately 75% of children achieved 20/40 or better visual acuity postoperatively.

Despite the advantages, deciding on the IOL type and power remains challenging because the anatomy of children’s eyes is unique in certain aspects. A child’s ocular system is characterized by steeper corneas, shallower anterior chamber depth, and shorter axial length, making correct biometry and accurate IOL calculations almost impossible. In a study by Moore et al., the difference between predicted refraction with the usual biometry calculating formulas (Holladay I, SRK II, SRK/T) and actual postoperative refraction was found to be 1.08 ± 0.93 diopters. Children younger than 2 years had the greatest discrepancy of results. Trivedi et al. and Kekunnaya et al. conducted studies comparing different IOL power calculation formulas in children to enhance the accuracy of the IOL dioptic power chosen. Trivedi et al. concluded that even when preoperative refraction data are not available, the Holladay 2 formula has the least prediction error and absolute prediction error.

It seems that immersion A-scan biometry provides greater accuracy in axial length measurement in children than contact biometry. Both the IOLMaster (Carl Zeiss Meditec, Jena, Germany) and Lenstar (Haag-Streit AG, Koeniz, Switzerland) have been used in children, but their use is limited due to poor cooperation. Also, these biometric devices are not useful in the measurement of dense cataracts more commonly encountered in children.

McClatchey evaluated a computer program to predict the pseudophakic refraction of a child at any age. A computer program written for Windows 95 calculated the initial postoperative pseudophakic refraction of a child using Holladay’s formula, given the axial length and keratometry readings. The logarithmic model was used to predict the ultimate refraction at age 20 years and chart the predicted curve of refractive error with standard deviations. Despite the relative accuracy of this model, the need for a special pediatric IOL formula is evident and remains to be discovered. Also, because the refraction changes over time, the primary issue is to establish a clear focus at all times. This requires occasional changes in the optical system irrespective of accuracy at any given time. Also, these small adjustments tend to be accurate based on refractive measures.

Predicting the refractive change of a patient over time is another challenge for pediatric ophthalmologists. Trivedi and Wilson concluded that there is a continuous myopic shift in refraction as age advances. The higher difference in axial length occurs during the first 2 years of life. In particular, there is rapid growth of 0.62 mm/month during the first 6 months and sequentially 0.19 mm/month in the time frame between the 6th and 18th month of life. The growth continues with a much lower rate (0.01 mm/month) until adulthood. Of course, these general rules do not always apply because the natural variance in growth of the eye is unpredictable. Astle et al. demonstrated in a retrospective review that myopic shift in refraction can be as high as -10.0 to -12.0 D in children younger than 4 years, making IOL power calculation in infants a difficult task. Most surgeons aim for remaining hyperopia when implanting an IOL, expecting a myopic shift during the growth process that will lead to emmetropia by the age of 18 years. Others aim for a slight myopia that will facilitate children’s near vision and possibly prevent amblyopia.

The type of IOL to implant is an important issue. In-the-bag implantation is preferable and both polymethylmethacrylate (PMMA) and acrylic hydrophobic lenses are considered materials of choice. Wilson et al. believed the single-piece Acrysof SA (Alcon Laboratories, Fort Worth, TX) series was the best option available at the moment for in-the-bag implantation in children. Gupta et al. reported a retrospective study of primary IOL implantation after congenital cataract surgery with the use of the SRK II formula and implantation of either rigid PMMA non-foldable lenses (Ocular Vision SF 102; Eye Care, Vadodara, India) or acrylic hydrophobic foldable lenses (Acrysof SA60 AT, MA60AC, or SN60WF; Alcon Laboratories) with a low rate of manageable complications (such as opacification of the visual axis and decentration of the IOL) and no reports of glaucoma, endophthalmitis, or retinal detachment at the last follow-up.

Certain investigators have debated the use of multifocal IOLs in children. Multifocal IOLs can give the opportunity of spectacle independence in all distances, but at the same time their use remains problematic because accurate biometry calculations are a prerequisite to avoid halos and preserve near visual acuity benefit.

Tassignon et al. reported the outcome of a surgical procedure called ‘bag-in-the-lens’ in pediatric cataractous eyes. With this technique, the anterior and posterior capsules are placed in the groove of a specially designed IOL after a capsulorhexis of the same size is created in both capsules. The principle behind this IOL design is to ensure a clear visual axis by mechanically tucking the two capsules into the IOL, thereby preventing any migration of proliferating lens epithelial cells. In theory, this technique could be adapted to the multi-component lens system to isolate the vitreous (to simplify potential enhancement procedures), thus allowing easy access to the front lens.
The possibility of an adjustable lens represents a solution for many of the refractive difficulties that arise during IOL implantation in pediatric cataract surgery. The InfiniteVision Optics lens is an acrylic foldable posterior chamber optical system that enables customized correction of all degrees of sphere and cylinder in the primary surgery. This lens allows for continual correction of all residual refractive errors postoperatively with the surgical exchange of one of the lens components. The use of a multifocal lens front component is also possible.

The InfiniteVision Optics lens ocular system consists of two components. The base lens or posterior component has a plate-haptic configuration, contains only spherical correction, and can be implanted in the capsular bag, analogous to a conventional posterior chamber IOL. The front lens assembly has two haptics extending off of the optic. These haptics are designed to fit into the two small bridges that project off the anterior surface of the base lens to secure the front lens assembly to the base lens (Figure 1). In case of posterior capsule opacification, which is rather common in pediatric cataract surgery, YAG laser can be performed without compromising the safety of an enhancement surgery if it is judged as necessary. It is highly desirable to house the base lens in the capsular bag and allow capsule fibrosis to surround the base lens peripherally. When fibrosis is occurring, if the central area of the posterior capsule is involved, a small central capsular opening can be made, still allowing isolation of the vitreous body behind the base lens. This ensures that repeated vitreous surgery would not be required if a front lens exchange is necessary at some time point in the future. The front lens assembly allows for spherical, cylindrical, and multifocal primary corrections for immediate and long-term adjustments. Implantation of the two components can be effected through a 1.8- to 2.8-mm incision, with ease of assembly inside the eye.

The base lens component is first implanted and then rotated 90° so that the attachment openings are perpendicular to the insertion point. The front lens assembly is then inserted through the same incision into the anterior chamber and also rotated by 90°. The haptics of the front lens are then inserted into the bridge capture openings of the base lens. A technique called capsule capture is an important step of the surgical procedure, in which the haptics of the front lens are placed in front of the peripheral anterior capsule, capturing the capsule between the haptics of the front lens and the plate-haptic of the base lens. This surgical maneuver places the front lens component in front of the capsule so that when capsule fibrosis occurs it will only affect the base lens because the front lens is outside the capsular bag. Without the occurrence of fibrosis, the front component can be easily removed or exchanged surgically if necessary. Capsule capture of the base lens is important, but assembly and disassembly of the lenses can be performed even if proper capsule capture is not achieved in the primary surgery.

This multi-component lens is of great use in case of undercorrections or overcorrections after cataract extraction and IOL implantation because the front lens is easily surgically exchangeable.

The 2-year follow-up of the initial clinical evaluation of the InfiniteVision Optics multi-component IOL included 6 eyes of 6 patients with a mean age of 63.3 ± 12.7 years (range: 49 to 82 years) that underwent cataract surgery and multi-component IOL implanta-
The aim of this feasibility study was to evaluate the manufacturing expediency of the lens, the ease of the surgical implantation technique, the incidence of interlenticular fibrosis, and the rate of complications. All surgeries were uneventful and no complications occurred. At 2 years postoperatively, interlenticular fibrosis had not developed and there was no statistically significant difference in the endothelial cell density, anterior chamber depth, and pachymetry readings compared to preoperative values. Mean uncorrected and corrected distance visual acuity (UDVA and CDVA) improved significantly ($P < .01$) from $0.11 \pm 0.06$ (range: 0.05 to 0.2) (decimal scale) to $0.68 \pm 0.11$ (range: 0.5 to 0.8) and from $0.28 \pm 0.13$ (range: 0.1 to 0.5) to $0.83 \pm 0.16$ (range: 0.6 to 1), respectively. No patient lost lines of CDVA during the follow-up period. The study concluded that multi-component IOL implantations were easy and safe to perform without the risk of intraoperative or postoperative complications (Figure 2).

DISCUSSION

Predicting the axial growth and the refractive change that accompanies it remains one of the key challenges in the follow-up of pediatric cataract surgery. The multi-component IOL lens concept can facilitate pediatric ophthalmologists by customizing the primary surgery, by allowing a small variety of lenses in their inventory to cover a large refractive range of sphere and cylinder, and by easing the burden of IOL choice.

The multi-component IOL in pediatric cataract surgery should be designed with a smaller diameter to fit in a child’s capsular bag and to avoid anterior chamber shallowing and glaucoma development.

A case report of an enhancement performed with the multi-component lens system has been previously described (Gianluca Rubiollini, personal communication, Milan, Italy, 2009). The 78-year-old patient in question had a postoperative residual refractive error of 2.25 diopters (due to a biometry error) following routine cataract surgery and multi-component IOL implantation even though the target refraction was emmetropia. The patient underwent a minimally invasive enhancement surgery 9 months after the primary surgery by removal and exchange of the front lens assembly. Using the same incisions created in the primary surgery, the front lens assembly haptics were detached from the bridges of the base lens and the front lens was removed. Then another front lens was inserted in the anterior chamber and attached to the small bridges that project off the anterior surface of the base lens. This resulted in a final refraction of $+0.25$ with a final UDVA of 1.0 at 1 week after the enhancement procedure.

Clearly this case demonstrates the feasibility and safety of such a procedure, backing up the proof of the enhancement concept, which is so essential for the pediatric cataract population. Repeated surgeries can
worsen the prognosis, but enhancement surgery is a minimally invasive procedure in which the refractive benefit for the patient far outweighs the risk taken.

Pediatric cataract surgery is essentially different from adult cataract surgery. In pediatric cataract surgery, additional risks are present and postoperative complications may jeopardize an otherwise successful surgical intervention. One of the main considerations is the ongoing postoperative evolution of the power of IOL needed to correct children’s eyes. A solution to the problem is provided by the development of the new, innovative, multi-component InfiniteVision Optics IOL that will allow postoperative adjustments for postoperative changes in refraction.

AUTHOR CONTRIBUTIONS
Study concept and design (DMP, IGP, GDK); drafting of the manuscript (DMP); critical revision of the manuscript (IGP, GDK); supervision (IGP, GDK)

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