

Refractive surgeries in children: Debunking the controversy and assessing the safety and efficacy

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Abstract:

New innovations in adults' refractive surgeries have revolutionized the field, offering improved outcomes and enhanced patient experiences. While traditionally considered contraindicated in pediatric populations, emerging research suggests that this notion may not always hold true. Challenges, indications, safety, and other topics will be addressed in this review article.

Keywords:

Amblyopia, anisometropia, pediatric, refractive surgery

INTRODUCTION

Glass compliance is critical in the treatment of amblyopia. One-third of children with amblyopia do not wear their glasses as recommended, which is by far the most common reason of treatment failure.^[1] This has sparked increased interest in the use of refractive surgery in children, particularly in cases where other treatments have been unsuccessful. There are dozens of papers published in PubMed that investigate refractive surgeries in children since 1995. These papers cover a wide range of topics, including the safety and efficacy of different refractive surgery procedures in children, the long-term outcomes, and the psychological and social impact of refractive surgery on children.

CHILDREN ARE NOT YOUNG ADULTS

Performing refractive surgery in children is similar to aiming at a moving target. As a result, understanding the evolution of refractive errors in children is vital, and the two key players here are axial length and corneal properties. According to various regression models, the most substantial gains in axial length occur during the first 10 months of life, after which axial length continues to rise, albeit at a slower

pace, until the age of 7 years.^[2] In pediatric cataract for example, patients who underwent cataract surgery at a younger age had a greater average myopic shift in postoperative refraction of approximately 6.00 D when compared to those who had cataract surgery at an older age and part of this was attributed to the changes to the increase in the axial length.^[3] On the other hand, children with myopia tend to have longer axial lengths than children without myopia, and the rate of axial length elongation is faster in children who develop myopia.^[4]

The cornea is the next key aspect to consider, and there are two significant variances: first the changes in the corneal curvature and second the biomechanical nature of the cornea in children. Generally, the cornea is flatter in children than in adults, and its curvature increases with age.^[5] The thickness of the cornea also tends to increase with age. This is partly due to the accumulation of extracellular matrix material in the stroma, the middle layer of the cornea. While there is limited research on the biomechanics of the cornea in children specifically, some studies have suggested that the cornea in children may have different biomechanical properties than in adults. One study measured the corneal hysteresis and corneal resistance factor in children and adults using a noncontact tonometer. The study found that the corneal hysteresis and resistance factor were lower in children than in adults, suggesting that

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the cornea in children may be more compliant and less resistant to deformation than in adults.^[6] These measures are currently used in adults to identify patients at higher risk of developing postoperative complications after refractive surgeries.^[7]

The final significant distinction in pediatric eyes is the immunological response to ocular surgery. Studies suggest that children may have a more robust immune response following cataract surgery than adults, with higher levels of inflammatory cytokines in the aqueous humor.^[8] This is likely to apply to refractive surgery too, and this will have implications for the postoperative care and management of pediatric patients.

POTENTIAL CANDIDATES

Anisometropia

Nucci was among the first to study the effectiveness of refractive surgery in children with refractive amblyopia secondary to high unilateral myopia. The study included 14 children with an average age of 12 years. The findings of this study were promising for mildly amblyopic children.^[9] This study was limited by the sample number; however, it opened the door for more studies. The prior study prompted researchers to look into a younger population, in a series of 11 patients with anisometropia amblyopia aged 2 and 11 years, uncorrected visual acuity improved by 2 or more lines in 75% following photorefractive keratectomy (PRK).^[10] According to a recent analysis of the literature, effective outcomes (residual refractive error of 1 diopter or less) ranged from 38% to 87%. However, the evidence for improved amblyopia was ambiguous, and long-term safety trials were insufficient.^[11] On the other hand, Utine *et al.* reported the outcomes of laser-assisted *in situ* keratomileusis (LASIK) for hyperopia in children with amblyopia, which was found to be effective and safe, resulting in improved visual acuity and decreased anisometropia in the treated eyes.^[12]

Ali *et al.* investigated another strategy to treating unilateral high myopia and discovered that unilateral clear lens extraction (CLE) is an effective way to improve vision in children with high myopia who are beyond the range of excimer laser correction.^[13] More recently, studies on the role of femtosecond laser small incision lenticule extraction (SMILE) and posterior chamber phakic intraocular lens (PC-pIOL) for unilateral myopic anisometropia in children demonstrated significant improvements in postoperative corrected distance visual acuity.^[13-16]

Neurobehavioral disorders

A subset of children with high myopia and neurobehavioral problems is resistant to spectacle wear and unsuitable for contact lens correction. Tyachsen *et al.* conducted two studies that included children with neurobehavioral disorder to evaluate the role of CLE and LASEK. The studies found both procedures to be a safe procedure in this group of children.^[17,18] More recently, implantation of phakic IOLs in children was also suggested as an effective method for correcting high myopia in spectacle noncompliant children.^[19]

In a prospective case series, PRK was performed on 16 children (aged 2–8 years) with severe isoametropia and intellectual disability. After 6 months, the developmental quotient (DQ) showed a significant improvement in expressive communication, interpersonal relationships, and coping. At the 12-month follow-up, significant improvements in DQ were observed for receptive communication, written communication, and domestic skills.^[20]

PROCEDURES

Photorefractive keratectomy

The effectiveness and safety of PRK in children have been investigated in several studies. These studies have generally yielded favorable results in terms of improved visual acuity and refractive error. One study documented a mean postoperative refractive error reduction from $-13.70\text{ D} (\pm 3.77)$ (myopic group) and from $+4.75\text{ D} (\pm 0.50)$ (hyperopic group) at a mean follow-up of 31 months. In that study, the refractive regressions were minimal ($0.50 \pm 1.41\text{ D}$ for myopes, $0.60 \pm 0.57\text{ D}$ for hyperopes), and the final visual acuity and refractive error of the PRK group were significantly better than those of the control groups.^[21] In 2011, a meta-analysis study included 15 articles with a total of 213 amblyopic eyes, and the results showed a significant increase in both uncorrected and corrected distance visual acuities after surgery. Additionally, the study found a correlation between age and preoperative visual acuity, as well as the change in visual acuity after surgery. It also revealed that surface ablation resulted in a significantly superior improvement in uncorrected visual acuity compared to LASIK.^[22]

Generally, a low rate of short-term complications including corneal haze and corneal epithelial defects has been documented. For instance, a study conducted by Alió *et al.* examined the outcomes of PRK in 6 children with amblyopic myopic anisometropia in whom conventional amblyopia treatments have failed, and reported only one experienced a significant complication in the form of severe haze, and no other significant complications were reported.^[23] In another study conducted by Astle *et al.*, corneal haze was absent in 59.5% of eyes, while three eyes initially had 3+ haze, with two requiring repeat PRK for significant haze reduction.^[24] In ten patients between 3 and 10 years of age, the mean healing time was 3.5 days. Patients experienced mild discomfort on the day of surgery and the 1st postoperative day but minimal pain on day 2. After day 2, no patient reported pain or other discomforts.^[25]

While the available studies suggest positive outcomes, it is important to consider the risks and potential complications associated with PRK in children. Complications such as delayed epithelial healing, corneal haze, regression of the correction, and glare or halos in low-light conditions have been reported in some cases. Therefore, careful patient selection and counseling are crucial in determining the appropriateness of PRK for children. Additionally, long-term stability and the

impact on visual development in growing children require further investigation. Ongoing monitoring and adherence to postoperative care are essential to minimize risks.

Laser-assisted *in situ* keratomileusis

While PRK involves directly removing the thin outer layer of the cornea before reshaping, LASIK involves creating a corneal flap and reshaping the underlying tissue. Research on the role of LASIK in children is limited. Some studies and case reports have provided insights into its outcomes. A study included 14 pediatric patients with myopic anisometropia and amblyopia who underwent LASIK. One year after the procedure, the best-corrected visual acuity improved in all eyes, with 42.9% achieving a postoperative visual acuity of 20/20. The study reported no significant complications.^[26] Another group reported the results of LASIK for hyperopia in 32 pediatric eyes with amblyopia caused by anisometropia, with a mean follow-up period of 20.1 months. The mean spherical equivalent refraction decreased from +5.17 diopters preoperatively to +1.39 diopters postoperatively. The majority of eyes gained lines of visual acuity, with some achieving substantial gains of 4 or more lines. Complications were minimal, with only one eye experiencing a slight loss of visual acuity due to haze.^[12] Long-term follow-up of two pediatric patients who underwent LASIK for anisometropic amblyopia showed stable visual acuity, balanced refraction, improved stereopsis, and good quality of life after 16 years. Corneal topography revealed a mildly decentered ablation bed with no signs of ectasia.^[27]

Although most of these studies reported positive outcomes in terms of improved visual acuity and decreased anisometropia, there are several limitations that warrant criticism. First, there are the small sample sizes, which might not give an accurate representation of the pediatric population. Additionally, the follow-up period varied widely among participants. Additionally, the absence of control groups for comparison makes it challenging to determine the real efficacy of LASIK. Moreover, none of the studies provided information on potential adverse effects beyond flap complications, such as long-term stability, regression, or the occurrence of other visual symptoms. Therefore, further research with larger sample sizes, longer follow-up periods, and appropriate control groups is necessary to establish the safety and efficacy of LASIK for this specific condition in pediatric patients.

Laser-assisted subepithelial keratectomy

Studies exploring the efficacy and safety of LASEK in pediatric populations are scarce. However, research on LASEK in adult populations can provide some insights into its potential role in children. LASEK has been primarily studied and applied in adults as an alternative to LASIK, especially in cases where the cornea is deemed too thin for flap creation. The procedure involves loosening the corneal epithelium, reshaping the underlying cornea with an excimer laser, and repositioning the epithelium. The available evidence suggests that LASEK can be effective in correcting refractive errors in adults, with

favorable outcomes in terms of visual acuity and refractive correction.^[28]

Astle *et al.* conducted the largest retrospective study to evaluate the outcomes of LASEK in children with bilateral hyperopia or hyperopic anisometropic amblyopia. The study included 72 hyperopic eyes (47 patients) and found that the mean spherical equivalent improved from +3.42 D preoperatively to +0.59 D at 1 year postoperatively. For the hyperopic anisometropic amblyopia subgroup (18 eyes, 10 patients), the mean anisometropic difference improved from 4.39 D preoperatively to +0.51 D at 1 year. An improvement in best-corrected distance visual acuity was observed in 41.7% of hyperopic eyes and 64.7% of anisometropic eyes. While this study provides some positive outcomes regarding visual acuity improvement and reduction of anisometropic difference after LASEK in pediatric hyperopia and hyperopic anisometropic amblyopia, several limitations should be considered. Firstly, the study's sample size is relatively small, which may limit the generalizability of the results. Additionally, the follow-up duration of 1 year may not provide a comprehensive understanding of the long-term stability and efficacy of the procedure.^[29]

While direct studies on LASEK in children are limited, some research on PRK can provide insights as both have similar principles in terms of epithelial removal and corneal reshaping, albeit with slight technical differences.

Small incision lenticule extraction

A study on femtosecond laser SMILE for unilateral myopic anisometropia in children demonstrated significant improvements in postoperative corrected distance visual acuity, indicating the safety of the procedure. Notably, 23% of cases showed an improvement of one or more lines at the 3-month follow-up, while only 2% experienced a decline of one line. The study also reported favorable postoperative uncorrected distance visual acuity and achieved good refractive results with a high percentage of cases within ± 0.50 diopters of the intended correction. Although the study did not specifically mention an improvement in stereopsis, the positive outcomes in corrected visual acuity and refractive correction suggest the potential for overall improvement in stereopsis and vision in patients who undergo SMILE for myopic anisometropic amblyopia.^[14] However, further studies with larger sample sizes and longer follow-up periods are necessary to evaluate the long-term effects of SMILE.

Clear lens extraction

CLE, also known as refractive lens exchange, involves the removal of the natural lens and replacing it with an artificial intraocular lens (IOL) to correct refractive errors. Before diving into this method, keep in mind that key negatives include loss of accommodation and an increased chance of retinal detachment. Like other techniques, research on CLE in pediatric populations is scarce. A study was conducted to evaluate the safety and efficacy of CLE with IOL implantation in children with high myopia who are noncompliant with spectacle wear. The study included 13 children (mean age: 10.4 years) with myopia

ranging from -14.25 to -26.00 D. At 12-month follow-up, the mean spherical equivalent refraction was $+0.9$ D and all patients achieved functional vision with uncorrected distance visual acuity of 20/40 or better.^[17] One of the complications reported in the study was focal retinal detachment in one eye with cicatricial retinopathy of prematurity, and capsular regrowth and/or opacification in 50% of the eyes.^[17] Another study examined the outcomes of refractive surgery of CLE in children with neurobehavioral disorders and anisometropic myopia. The average preoperative refractive error in the study ranged from -11.9 to -24.5 D, with a mean of -16.7 D. The results showed successful correction of high myopia, with 86% of eyes achieving a refractive correction within ± 3 D of the goal refraction. Postoperatively, there was an improvement in uncorrected visual acuity, although modestly, and no cases of retinal detachment were reported during the follow-up period.^[13] Although both studies highlight the good outcome from CLE, there is still a need for further research to determine the long-term safety of these procedures in similar pediatric populations and to assess potential complications such as capsular opacification necessitating additional intervention.

Phakic intraocular lens (posterior chamber-phakic intraocular lens)

PC-pIOLs are placed in front of or behind the natural lens of the eye and do not require the removal of the natural lens. PC-pIOLs are an alternative to refractive surgery, such as LASIK and PRK, for people who are not good candidates for these procedures. PC-pIOLs have been used in adults for many years, but their use in children is more controversial. In a study by BenEzra *et al.*, PC-pIOLs were implanted in three children with anisometropic amblyopia and myopia ranging from -6 to -16 D. Follow-up over a 9-month period showed a significant improvement in visual acuity and binocular function. No change in endothelial cell count was observed during the follow-up.^[30]

Lesueur and Arne reported the results of PC-pIOL insertion in five eyes of children aged 3–16 years with amblyopic high myopia. The mean preoperative spherical equivalent was -12.8 D. There were no complications reported from the study, and all parents reported an improvement in their child's quality of life. Two patients achieved a gain of 3 or more Snellen lines and recovered binocular vision. In a follow-up study, outcomes of PC-pIOLs to correct high myopia and amblyopia were reported in 12 eyes of children aged 3–16 years. These children had a mean preoperative spherical equivalent of -12.7 D and were followed up for a period of 20.5 months. Six patients recovered binocular vision and showed an improvement in quality of life. No complications were reported.^[31] Alió *et al.* reported the longest follow-up period of 5 years after PC-pIOL implantation in a child with high anisometropic amblyopia. An improvement in visual acuity of one logMAR line was reported, and no complications were seen.^[32]

It is important to note that potential complications of PC-pIOLs include cataract formation, pupillary block glaucoma, posterior

dislocation into the vitreous cavity, and retinal detachment. Reports of complications in the pediatric population are rare; however, this may be attributed to the limited number of PC-pIOL procedures performed in children.

DISCUSSION

Glasses and contact lenses are typically the primary treatment choices for children with refractive errors. These nonsurgical methods offer the flexibility to adjust prescriptions as the child's eyes continue to develop. Refractive surgery can be regarded as a viable choice rather than a last resort in rare circumstances where other treatments have failed or are inappropriate. The spectrum of refractive errors that each procedure may correct largely overlaps, therefore additional factors including the age of the child, the surgeon's experience, and the refractive state of the second eye in anisometropic patients should also be taken into account.

When considering refractive surgery in children, several special considerations come into play. Firstly, children's eyes are still in the process of growth and development, which can affect their refractive errors. Children also may exhibit a stronger immune response following ocular surgery, which necessitates careful consideration in the postoperative care and management of pediatric patients. Therefore, more frequent postoperative follow-up and monitoring are vital for children who undergo refractive surgery to ensure proper healing, and track visual development. Potential development of complications such as haze, regression, and ectasia has been documented. Haze formation is more common in pediatric excimer laser cases. On the other hand, the possibility of long-term corneal endothelial cell loss with phakic IOLs is especially concerning in the pediatric population, which is influenced by factors such as the child's long life expectancy and the possibility of eye rubbing.

Another significant point to emphasize is that performing refractive surgery on pediatric patients involves different obstacles than on adults. Adult surgeries are often performed as outpatient procedures with topical anesthetic; however, pediatric patients require sedation. Because the technology is immobile and expensive, administering anesthesia during refractive surgeries can be difficult logistically, necessitating the relocation of lasers to pediatric hospital settings.

Finally, parent counseling is critical due to the potential risks and long-term implications of refractive surgery. Parents need to be fully informed about the benefits, risks, and alternatives, and actively participate in the decision-making process regarding their child's eye health.

CONCLUSION

The field of pediatric refractive surgery represents a fascinating combination of the rapidly evolving field of refractive surgery and the traditionally cautious realm of pediatric ophthalmology. By harnessing advanced technologies, refractive surgery

brings new possibilities, while the pediatric ophthalmology community carefully evaluates and makes responsible decisions regarding their application in children. We believe that when traditional therapy reaches a point of clear failure, it may be prudent to redirect efforts toward considering the possibility of refractive surgeries, which have shown encouraging results.

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Conflicts of interest

There are no conflicts of interest.

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