Clear lens extraction and refractive lens exchange for the treatment of amblyopia

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Abstract:

Treatment of amblyopia typically involves spectacles or penalization of the nonamblyopic eye with occlusive patching or pharmacological penalization. However, these methods can be ineffective or difficult in certain children who may be unable to tolerate or are poorly compliant with such therapies. Untreated high refractive error can result in dense amblyopia, and thus, other treatment methods are necessary in this subset of children. With technological advances in ocular surgery, clear lens extraction (CLE) and refractive lens exchange (RLE) have emerged as popular alternative treatments for amblyopia, as they may avoid some of the challenges surrounding traditional methods. CLE involves lensectomy for refractive purposes in patients without cataracts, while RLE involves lensectomy followed by intraocular lens implantation. The purpose of this review was to summarize the use of CLE and RLE for the treatment of amblyopia in the pediatric population, discussing indications, techniques, treatment outcomes, safety, and potential complications.

Keywords:

Amblyopia, clear lens extraction, pediatrics, refractive lens exchange, refractive surgery

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Introduction

Amblyopia is one of the most common causes of pediatric visual impairment. It has a prevalence of 1%–4% of children and is typically diagnosed between the ages of 3 and 6 years.[1-6] Amblyopia can be caused by strabismus, refractive error, or visual deprivation that prevents the normal development of the visual system in the growing child.[7]

Several forms of refractive error can predispose children to develop amblyopia. Anisometropia is one of the leading causes of refractive amblyopia and occurs when there is an asymmetric refractive error between the two eyes.[8] Anisometropic amblyopia can occur in the setting of asymmetric myopia, hyperopia, or astigmatism, although the latter two are the most amblyogenic. Because of the unequal refractive error, the two eyes are presented with one focused and one unfocused image. One study even found that uncorrected anisomyopia of more than -6 D or anisohyperopia of more than +4 D caused amblyopia in 100% of the cases.[9] In general, >2 D of anisoastigmatism is considered amblyogenic.

In the past several years, many studies have emerged regarding the treatment of amblyopia. In particular, the amblyopia treatment studies (ATS) by the Pediatric Eye Disease Investigator Group (PEDIG) have played a large role in evaluating traditional treatment modalities for amblyopia. To date, PEDIG has 22 ATS with many studies including multiple phases, each studying optimal treatments for amblyopia from a range of causes in a variety of ages.

Treatment of amblyopia involves treating the underlying cause of the visual disturbance (i.e., removing visual obstructions, correcting refractive errors, and treating strabismus) and then encouraging the use of the amblyopic eye.[10] Spectacles are first-line therapy for the correction of refractive errors. Data from PEDIG ATS 5 examined the efficacy of spectacles alone in treating amblyopia. Spectacles were used to treat amblyopia in 84 children aged 3–<7 years with previously untreated anisometropic amblyopia. Upon up to 30 weeks of glasses use alone, they found that 77% of eyes were able to improve by two or more lines of vision, and 27% of children

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were able to achieve full resolution of amblyopia. They found better treatment outcomes in children with lesser amounts of baseline anisometropia, as most cases of resolution occurred in children with moderate (starting acuity of 20/40–20/100) amblyopia.[11]

Occlusive patching or pharmacologic penalization with atropine is employed to encourage the use of the amblyopic eye. For anisometropic amblyopia, there is currently some variability in practices, with some providers favoring starting spectacles first with the goal of adding patching when treatment effect stalls; whereas others start spectacles simultaneously with patching of the better-seeing eye hoping to see a more rapid resolution of amblyopia. A currently enrolling PEDIG study is investigating the efficacy of simultaneous versus sequential patching for the treatment of anisometropic amblyopia. Future studies from PEDIG and other investigators will continue to provide evidence-based treatment recommendations for amblyopia.

Treatment of amblyopia should be initiated as early as possible, as studies have shown improved long-term outcomes when treatment is started before the age of 7.[12-14] The success of these treatments ranged in the literature from 25% to 90% with most falling around 60%, depending on the initial degree of anisometropia and the definition of success.[15-17] ATS 3 evaluated the treatment of amblyopia with patching in children between the ages of 7 and 17, randomizing patients to either optical correction alone or optical correction with patching. Children between the ages of 7 and 12 were also treated with atropine. Upon follow-up, they found that patching with atropine was more effective than glasses alone in children aged 7–12 years. They recommended that children between the ages of 7 and 12 should be treated with 2–6 h a day of patching for near-vision activities with atropine. On the other hand, in children aged 13–17 years, they found no significant difference between optical correction and optical correction with patching, unless the patient had no history of previous treatment.[18]

Compliance with therapy is crucial for the successful treatment of amblyopia, yet several studies report poor compliance among children.[19-22] Compliance with amblyopia therapy is the most significant indicator of successful visual acuity outcomes, and a range of factors may limit adherence to physicians' recommendations. Spectacles may be unfavorable due to induced aniseikonia, distortion in the extremes of the field of vision, social discomfort, and may be frequently lost or broken.[23] Amblyopia is also associated with a myriad of neurodevelopmental conditions (e.g., Down Syndrome and autism spectrum disorder), and spectacle use may be more difficult in these populations.[24-26] Occlusion therapy with patching is often even more challenging to encourage compliance.[22] In addition, particularly in children with anisometropic amblyopia, who oftentimes have one good eye that does not require correction, the use of spectacles or patching may be perceived as unnecessary and further reduce compliance. Pharmacologic penalization using atropine may be better tolerated but may be less effective, especially when penalizing a myopic eye. There are other less common side effects of atropine such as light sensitivity, irritation, eye pain, and other anticholinergic side effects that may be intolerable for some patients.[22,23]

Contact lens correction has been explored as an alternative form of treatment for anisometropic amblyopia. The advantages of contact lens therapy include potentially improved contrast sensitivity and quality of vision in children.[27] However, contact lens therapy still relies on patient compliance. As with spectacles, contact lenses can be easily lost and can cause discomfort or total intolerance. In addition, parents are often required to assist with contact lens insertion and removal. Contact lenses may also not be covered on major insurance plans. All contact lens use carries with it a risk of corneal infection and neovascularization. In children who frequently rub their eyes, this risk may be increased.[27]

In recent years, advances in surgical treatments have led to the emergence of refractive surgery as a new potential treatment option for amblyopia. Nonincisional surgical procedures include advanced surface ablation and laser refractive surgery (i.e., photorefractive keratectomy, laser *in situ* keratomileusis, and laser-assisted subepithelial keratectomy), and these techniques have been used to effectively treat refractive error in children.[26,28] However, the maximum treatment of myopia and hyperopia correctable by laser refractive surgery is typically limited to -10 D to +4.5 D, due to the risk of corneal haze and treatment regression.[19,29,30]

Intraocular surgical procedures have also been used successfully in children, and include phakic intraocular lens (pIOLs), clear lens extraction (CLE), and refractive lens exchange (RLE).[31-33] pIOL implantation has been a popular form of refractive surgery, in which the natural lens of the eye is left in place, but an artificial lens is implanted to correct refractive error. As technologies have continued to advance, the removal of the lens for refractive purposes in patients without cataracts (CLE) and the insertion of another intraocular lens (IOL) (RLE) have emerged as popular alternatives.

Lens Removal for Refractive Correction

CLE involves lensectomy alone, while RLE involves lensectomy followed by the simultaneous implantation of an IOL.[34] The procedures are technically the same as those in pediatric cataract surgery; although in CLE and RLE, the lens is either removed or replaced due to a high refractive error as opposed to an opacification of the lens. Standard techniques used for pediatric lensectomy, posterior capsulotomy, and anterior vitrectomy are used.[26,34] Similar to pediatric cataract surgery, capsulectomy and anterior vitrectomy are advised for young children due to the relatively high rate of posterior capsule fibrosis that may occur if the capsule is preserved.[35] IOL selection for implantation is made in an identical fashion to that for cataract surgery. With the axial length and keratometry, lens power calculations can be made.[26]

Indications for Clear Lens Extraction and Refractive Lens Exchange

Anisometropia

Most commonly, CLE and RLE are used for the treatment of anisometropic amblyopia, the leading cause of amblyopia.[36] It is reasonable that children with anisometropic amblyopia who have poor compliance to spectacles or contact lenses be considered for CLE or RLE.[26] With increasing age and at higher levels of anisometropia, both the prevalence and depth of amblyopia increase.[37] While the majority of children with anisometropia are able to be effectively treated with spectacles or contact lenses, a significant subset of patients, usually with extremely high levels of anisomyopia or anisohyperopia, is unsuitable for such treatments. This includes anisometropic patients with neurobehavioral disorders and developmentally normal children who are unable to tolerate spectacles or contact lenses. For the subset of the latter where issues arise with compliance or with poor adaptation to spectacles or lenses due to aniseikonia, asthenopia, or diplopia, CLE or RLE may be the best treatment option.

Myopia

CLE and RLE may also be the most suitable solutions for children with extreme myopia (>−15.0 D). This is especially true for children with ametropia exceeding -20 D, as this is the upper limit for pIOL power.[35,36] Uncorrected myopia of this degree typically translates to a visual acuity of 20/200 or worse, qualifying as legal blindness. Removal of a highly myopic lens through CLE or RLE has the benefit of improving uncorrected visual acuity (UCVA). Furthermore, the removal of a spectacle lens that has a significant minification effect (especially at powers >-20 D) improves best-corrected visual acuity (BCVA) by 1–2 lines. This dual effect makes CLE and RLE very appealing treatment options for highly myopic eyes.

Hyperopia

A few studies have evaluated the use of CLE and RLE to treat hyperopia specifically in the pediatric population. However, CLE and RLE have been shown to be effective in correcting refractive error in older populations. CLE and RLE may, thus, be the only option for children with a shallow anterior chamber depth of <3.2 mm, as pIOL has requirements for minimum depth of the anterior chamber.[35,36] More research is needed to examine the efficacy and potential complications following CLE and/or RLE in children with hyperopia.

Special populations

Patients who fail traditional treatments such as spectacles and contact lenses, occlusion therapy, or medical management may be more suitable for CLE and RLE.[35,36] CLE and RLE have been well-studied in children with neurodevelopmental disorders, which may cause specific sensory sensitivities that prevent compliance with spectacles or contact lenses. Effective treatment is particularly crucial in this subset of patients, as uncorrected visual impairment caused by high refractive error can exacerbate the neurobehavioral disorders by further hindering social/environmental interactions and motor skills.[35] Contact lenses may prove an even larger challenge, as insertion and removal by family members may require bodily restraint. While nonsurgical treatments are first-line, with occupational therapy and desensitization protocols to help with glasses compliance, these surgical treatments are important tools in the pediatric ophthalmologist's toolbox. CLE and RLE may, thus, be a much better option in these populations. Studies have found that children with neurodevelopmental disorders benefit significantly from CLE and RLE, particularly after traditional therapies fail.[35,36]

Congenital lens abnormalities with associated refractive error can also be considered an indication for CLE and RLE. One case study by Bhattacharjee *et al*. described the use of bilateral RLE to treat a 19-year-old boy with bilateral microspherophakia, high myopia, and angle-closure glaucoma. Upon 1-year follow-up, his corrected distance visual acuity was 20/20 bilaterally with sustained normal intraocular pressure.[38]

Contraindications for Clear Lens Extraction and Refractive Lens Exchange

Contraindications for CLE and RLE include the presence of glaucoma, uveitis, endothelial dysfunction, a retinal tear, and untreated lattice degeneration.[35,36] As with all types of intraocular surgery, timely follow-up examinations are necessary to ensure good visual outcomes, and as such, patients with caregivers with a history of difficulty adhering to recommended follow-up may not be as suitable for surgery. Finally, self-injurious behavior is a relative contraindication given the risks associated with incision surgery.

Technique for Clear Lens Extraction and Refractive Lens Exchange

Before CLE or RLE, children are evaluated in office to obtain UCVA and BCVA, pupillary examination, sensorimotor examination, cycloplegic refractions, slit-lamp evaluation, indirect ophthalmoscopy, and intraocular pressure measurement. This allows for screening for lens abnormalities that may complicate surgery. Observation of significant blepharitis, eye rubbing, or contact lens-related corneal issues is also helpful. Biometry when possible is done in the clinic; however, there are those patients for whom these measurements must be obtained as a part of an examination under anesthesia (EUA). Postoperative refractive correction is typically planned to achieve emmetropia or mild hyperopia. The decision between CLE versus RLE is guided by biometry, which helps determine whether IOL implantation is necessary to achieve the refractive goal, as well as individual patient factors.

Before the primary procedure, a EUA is most often performed to obtain or confirm preoperative measurements. If the axial length exceeds 29 mm, barrier diode laser therapy may be considered, as this may reduce the risk of future retinal detachment following CLE or RLE, although this remains a topic of debate.[26,35]

The procedure is performed under general anesthesia. Two clear corneal incisions are created using standard pediatric cataract surgical techniques. Following this, a continuous curvilinear capsulorhexis is performed. Lens aspiration can be performed with a vitrector or irrigation/aspiration cannulas. Posterior capsulotomy and anterior vitrectomy are performed on a case-by-case basis, using surgeon discretion based on the age of the patient, ability to sit for an awake YAG capsulotomy, and risk for performing a vitrectomy. For RLE, an IOL is placed in the capsular bag. Incisions are closed with absorbable sutures, and standard antibiotics and steroids are applied. The eye is then patched with a shield.

CLE and RLE are typically performed outpatient, with most children discharged within 2 h of the procedure. Postoperative follow-up is typically at 1 day, 1 week, and then, after 1-, 3-, and 6-month intervals. Refraction and dilated fundus examination are important parts of the postoperative follow-up.

A full detailed description of the technique regarding CLE and RLE can be referenced in Tychsen *et al*. and Ali *et al*.[35,36]

Outcomes and Advantages of Clear Lens Extraction and Refractive Lens Exchange

CLE and RLE are effective, while clearly more invasive, means to improve refractive error for the treatment of amblyopia. Tychsen *et al*. examined the clinical outcomes of CLE and RLE performed in 13 children with high bilateral myopia, who had neurobehavioral disorders. CLE was performed in 12 of these eyes, while RLE was performed in 14 eyes. Indication for each surgery was made by the primary surgeon and was based on whether preoperative calculations indicated that aphakia would result in a residual refractive error outside of the goal refraction. Preoperative myopia was an average of −19.11 D (range: −14.25 to −26.00 D). The average amount of myopia corrected by the procedures was −19.9 D, and 81% of eyes were corrected to within ± 2D of their goal refraction (+1D). They also found substantial improvement in UCVA in all eyes, in addition to improvements in behavior and environmental visual interaction in 88% of children.[35]

In a similar study in 2007, Ali *et al*. examined unilateral CLE and RLE for the treatment of high spherical anisomyopia in a group of children and adolescents with neurobehavioral disorders. CLE was performed in five eyes, while RLE was performed in two eyes. Similarly, this study found that CLE and RLE accurately reduced high anisometropia and improved functional vision. Upon follow-up, they found that the average refractive correction by the procedures was 17.3 D, and 86% of eyes were corrected within ± 3 D of their goal refraction (0 to +4 D). In all eyes, UCVA improved.[36]

The efficacy of CLE and RLE in the treatment of hyperopic amblyopia is less well-studied in the pediatric population. In older populations, however, CLE and RLE have satisfactory treatment outcomes for hyperopia. One study by Siganos and Pallikaris examined the use of RLE for the treatment of 35 hyperopic eyes of 21 adult patients. After surgery, the average UCVA was 0.8, and refraction typically remained stable after 2 months of follow-up.[39] In a similar study, RLE was performed in six eyes with high hyperopia. Following RLE, all six eyes were able to achieve 20/40 or better UCVA.[40]

The main advantage of CLE and RLE is the removal of the issue of compliance that is associated with other treatment modalities for amblyopia. In theory, the procedures remove the future need for cataract surgery, although patients lose the ability to accommodate the removal of the crystalline lens. For this reason, a discussion of the use of bifocal correction or consideration of a refractive target mildly myopic is important. Oftentimes, the child’s visual demands can help guide these decisions. With the eliminated need for a high myopic lens, spectacle-induced minification of images is greatly reduced. Reduced peripheral vision can occur with high hyperopic correction, and CLE or RLE may improve the optics of spectacle correction.[41]

Safety and Complications

Studies have shown that CLE and RLE are relatively safe procedures. In the study by Tychsen *et al*., there was a low prevalence of sight-threatening complications: 1 (3%) eye lost best-corrected vision, and another eye required IOL explantation and exchange. However, the occurrence of posterior capsule opacification was relatively high (50%), and as such, the authors recommended that primary posterior capsulotomy and anterior vitrectomy be performed as a part of the primary surgery. In addition, 50% of eyes in the study required a secondary procedure (YAG laser capsulotomy) for significant posterior capsule opacification. The authors point out that IOL implantation does not appear to promote or impede capsule opacification, and warn that primary posterior capsulotomy and vitrectomy may not be able to prevent opacification.[35] In the study by Ali *et al*., no eyes lost best-corrected vision, and there were no cases of retinal detachment on follow-up. However, capsular opacification requiring YAG laser capsulotomy occurred in two eyes.[36] These two studies showed that myopic regression was −0.5 D/year, which is less than myopic regression seen after laser correction, which is −1 D/year. Myopic regression may be more apparent in younger patients.[19,35] It is important to note that regression seen in CLE and RLE is most often related to axial length changes related to the growth of an eye; whereas regression in laser refractive surgery often has additional changes in corneal contour.

In adults, hyperopic eyes with short axial lengths may have an increased risk of choroidal effusions. Furthermore, hyperopic eyes may be more predisposed to develop pupillary block or postoperative increases in intraocular pressure, due to the shallower anterior chamber.[42]

Other risks associated with CLE and RLE in pediatric patients include the risks of intraocular surgery. However, it is important to keep in mind that there may be prolonged recovery, as pediatric eyes are more prone to develop inflammation and corneal haze following surgery.[27] This problem may be exacerbated by digital manipulation of the eye in the postoperative period, which may occur at higher rates in children, particularly those with neurodevelopmental disorders.

The most serious concern for CLE and RLE is retinal detachment. The risk of retinal detachment increases three-fold following lens extraction.[43] It is estimated that in adults who undergo RLE, the prevalence of retinal detachment ranges from 0.26% to 2.2%.[44,45] In addition, patients with high myopia are at a higher risk of retinal detachment.[46] Tychsen *et al*. found that retinal detachment occurred in one eye following a severe contusion injury 9 months following the procedure, while Ali *et al*. did not have any case of retinal detachment.[35,36] Retinal detachment is a significant concern that must be balanced against the risk of dense amblyopia associated with uncorrected refractive error.

Studies examining CLE and RLE in adults have shown that in eyes with axial lengths that exceed 29 mm, barrier diode laser therapy may be performed prophylactically to reduce the risk of retinal detachment.[43,47,48] However, the value of doing so still remains highly controversial,[49-52] and is not well-studied in the pediatric population. Tychsen *et al*.[35] performed barrier diode laser therapy before CLE in two of the children for lattice degeneration.

A similar controversy surrounding prophylactic laser use exists in patients with Stickler syndrome. Several studies have examined the use of prophylactic laser photocoagulation in preventing retinal detachment in patients with Stickler syndrome. These studies have had promising results, with several findings that patients who received prophylactic laser photocoagulation had lower rates of retinal detachment.[53-57] Research on laser use in Stickler syndrome still lacks larger prospective studies that would provide more data on safety, efficacy, and long-term outcomes. While these studies may further support the use of prophylactic laser in patients with CLE and RLE, it remains uncertain whether these results may be applicable. Future studies are needed to determine the efficacy of prophylactic laser treatment for the potential prevention of retinal detachment in specifically CLE and RLE.

Conclusion

CLE and RLE may be useful alternatives for the treatment of amblyopia in children with high refractive errors who have definitively failed traditional treatments or who concurrently have neurodevelopmental disorders. While studies have shown promising results in improving visual outcomes in children with high refractive error with relatively low rates of complications, further research is needed to study the long-term safety and efficacy of CLE and RLE. Studies that compare the long-term outcomes and complications associated with CLE and RLE with traditional treatments will be necessary to guide treatment selection. A careful follow-up in patients who undergo CLE or RLE will be essential for maximizing visual potential in these patients. Overall, CLE and RLE show great promise to benefit this subset of the pediatric population. Clinicians will be required to carefully weigh the risks and benefits of CLE and RLE against the permanent visual impairment from amblyopia in the noncompliant child with high uncorrected refractive error.

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Conflicts of interest

There are no conflicts of interest.

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