CURRENT THOUGHTS IN PEDIATRIC REFRACTIVE SURGERY

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ABSTRACT

The goal of this article is to review current literature regarding the emerging field of pediatric refractive surgery. This encompasses current thought in adult refractive surgery, published literature in pediatric refractive surgery, and future possibilities for refractive technology in the pediatric population. This study includes a comprehensive review of literature in the general refractive surgery, cornea, and pediatric literature. [J Pediatr Ophthalmol Strabismus 2008;45:331-337.]

EDUCATIONAL OBJECTIVES

1. To compare surgical and conventional treatment options for children with unilateral and bilateral large refractive errors.
2. To identify the challenges of performing refractive surgery in children.
3. To evaluate the benefits of early refractive surgery in certain pediatric populations.

INTRODUCTION

The arena of adult refractive surgery is a fluid environment with rapidly changing technology, techniques, and advances during the past 35 years. As procedures have come into and fallen out of favor, a rapid evolution of refractive technologies and techniques has occurred. With this evolution, a vast body of knowledge covering the various procedures in adult refractive surgery has developed and the breadth of knowledge accumulated from these endeavors is applicable to the emerging field of pediatric refractive surgery. With greater experience of refractive surgery in the adult population, the pediatric community has begun to show special interest in these techniques to help a new population of patients. As clinicians are performing refractive surgery procedures in the pediatric population, they report on many of the challenges, adaptations, and concerns about this emerging practice. In addition, it is possible to look at the refractive technologies of today and potential devices for the future and envision expanded patient populations and indications for refractive surgery in children.

HISTORICAL PERSPECTIVE

The seeds of modern refractive surgery were planted in 1950 when Columbian ophthalmologist Jose Barraquer developed an instrument to create a corneal flap for the purpose of correcting refractive errors. From this point, there was the introduction of radial keratotomy by Svyatoslav Fyodorov and the concurrent development of excimer laser technology. Excimer laser was first proposed for the treatment of corneal refractive errors by U.S. ophthalmologist Stephen Trokel in 1983. Laser technology evolved rapidly and photorefractive keratectomy (PRK) was first performed on humans in the mid 1980s by Theo Seiler. As a melding of PRK and Dr. Barraquer’s early thoughts on keratomileusis, laser-assisted in-situ keratomileusis (LASIK) was first performed in 1990 by Lucio Burrato and Ioannis Pallikaris.
Since the first laser refractive procedure in the early 1980s, millions of refractive procedures have been performed worldwide. In this vast experience, much has been learned about corneal properties, including healing, haze formation, biomechanics, and stability. Concurrently, the laser manufacturers have advanced the software, hardware, speed, precision, and accuracy of the instruments.

When the first lasers were introduced, the obvious initial candidates for treatment were those with large, often debilitating refractive errors. These people were often contact lens intolerant, hindered by poor optical quality in spectacles, and willing to accept new treatment modalities. After initial success with the treatment of high refractive errors, clinicians began to note complications with haze, excessive corneal thinning, and scarring in some patients. By this point, laser vision correction was becoming more common for lower refractive errors and patients and clinicians alike were satisfied with the outcomes in this population. Researchers began to look for alternative technology for the treatment of high refractive errors and reserved laser technology for low to moderate refractive errors.

The first intraocular lens (IOL) was conceptualized and implanted by Sir Harold Ridley in 1949 for the treatment of aphakia after cataract surgery. Because IOL materials and technology advancement have been driven by cataract surgeons and patients, this technology was proposed for use as a refractive technology in phakic patients. The first phakic IOL was implanted and studied in 1990 for the treatment of high myopia. This surgery placed the phakic IOL in the anterior chamber without disruption of the crystalline lens. An additional lens design was proposed that was implanted anterior to the crystalline lens in the posterior chamber. Multiple designs for phakic IOL insertion both anterior and posterior to the iris diaphragm have been studied since the initial lens implantation. Further studies have shown that the phakic IOL technologies provided excellent optical outcomes in patients with high refractive errors. Because this technology is more invasive than surface refractive procedures, concern has arisen regarding endothelial cell effects, cataract formation, risk for retinal detachment, and the generally increased risk of intraocular surgery.

Another treatment modality that has evolved for large refractive errors is lensectomy with or without implantation of a low-power or plano IOL. This technique, also termed refractive lens exchange, has been used for patients with large refractive errors and those desiring multifocal IOLs to treat presbyopia and refractive error in one procedure.

As the understanding of the capabilities and limitations of the different refractive procedures has grown, clinicians have also found the ability to combine procedures to be a useful tool in the refractive arsenal. This combining technique, known as biopics, often combines IOL implantation with corneal surface laser techniques to treat a complex refractive error.

**CURRENT ADULT REFRACTIVE SURGERY**

The field of refractive surgery is a booming commercial and technological entity, as evidenced by the rapid emergence of new technologies and techniques. Preferred procedures and technologies vary greatly between clinicians both inside and outside of the United States. The technology available to U.S. clinicians is limited to those approved by the U.S. Food and Drug Administration (FDA), whereas international physicians have access to a wider variety of treatment options. This discussion will focus on the technologies available to the U.S. market.

**Low to Moderate Myopia and Low Hyperopia**

After determination that the patient is a suitable candidate for refractive surgery (adequate corneal thickness, normal corneal architecture, absence of other pathology, and realistic expectations), the majority of these low to moderate myopes and hyperopes will be excellent excimer laser candidates. Daniel Durrie, a U.S. refractive surgeon, reported that laser correction (either LASIK or PRK) is the procedure of choice for refractions ranging from approximately +3.00 to -8.00 D, depending on many factors identified in the preoperative visit (personal communication, Daniel Durrie, MD, December 10, 2007). This is the range where this clinician finds maximization of refractive outcomes, stability, and patient satisfaction with laser surgery.

**High Myopia**

Decisions about treatment options for moderate to high myopia often hinge on age and refractive error. In young patients with myopia of greater than -8.00 D, laser treatments are sometimes an option when the patient has adequate corneal thickness. If there is a concern about corneal thickness, young myopic patients are often better candidates for pha-
pheric IOL implantation. A highly myopic patient 50 years or older would also be offered the option of a refractive lens exchange with the implantation of a single vision or multifocal IOL. In an eye with high myopia of greater than -20.0 D, a biopic treatment with a phakic IOL combined with surface laser treatment for full correction would be a potential option.

**Moderate to High Hyperopia**

Because there is no FDA-approved phakic IOL for the treatment of hyperopia, highly hyperopic patients have more limited surgical options. Excimer laser treatments are most effective up to +4.00 D. The discrepancy between the limits for hyperopic and myopic treatment results from the relative ease in flattening the central cornea (myopic treatment) contrasted with the difficulty in achieving a satisfactory optical result with steepening the central cornea (hyperopic treatment). Hyperopic patients outside the range of excimer laser treatments have the option of a refractive lens exchange with single vision or multifocal IOL implantation.

**CHALLENGES OF PEDIATRIC REFRACTIVE SURGERY**

As in most aspects of medicine, children are not just small adults when considering refractive surgical procedures. There are many unique challenges that arise when considering refractive surgery for the pediatric population.

**Patient Cooperation**

Adult laser and intraocular refractive surgeries are mostly outpatient procedures that require using only topical anesthesia. The patient is instructed to fixate on the operating light or laser target to center the treatment and assist in surgical manipulation. When dealing with a pediatric population, the cooperation of the patient is much more variable. Adolescent subjects will often be able to lie still and self-fixate, but in surgery performed to prevent amblyopia the children will often be much too young and require sedation. In the United States, studies have reported brief general anesthesia for sedation during excimer laser procedures. Intraocular surgeries have been performed with general anesthesia in a similar manner to pediatric cataract surgeries.

Another challenge arises when considering the logistics for administering anesthesia during excimer laser treatments. Excimer lasers are cumbersome pieces of equipment and are for the most part immobile. They are usually located in outpatient surgery centers or in the office of refractive surgeons—far from the pediatric anesthesiology needed to perform sedation. Excimer laser technology is also costly, with a laser price of $300,000 and greater. For the most part, this problem has been solved by bringing the laser into a pediatric hospital setting, which is a solution not available to every clinician.

A final challenge of patient cooperation with pediatric refractive surgery is the potential for flap (LASIK) or epithelial (PRK) complications in the immediate postoperative period. Adult patients can be trusted not to rub or manipulate their eye in the healing stages postoperatively. Children, especially young children, may manipulate the eye and cause a flap slip after LASIK that requires additional surgery. After PRK, epithelial disruption from manual manipulation may cause delayed healing, subsequently increasing the risk for haze formation.

**Long-Term Risks for Corneal Changes**

The biomechanical changes in the postoperative adult cornea are starting to be elucidated but are not yet fully understood. A more thorough understanding of maximal tissue ablation and limits to keratorefractive surgery has been explored but is still the topic of many avenues of research in adult refractive surgery. When considering intraocular or cornea-based refractive surgery in children, it is also necessary to carefully consider these issues. It is known that pediatric eyes have a greater propensity toward the development of postoperative inflammation. Due to this difference, special concern exists for the development of haze and regression in pediatric treatments.

**Desired Postoperative Correction**

Planning for refractive surgery in the adult population consists of targeting a plano or monovision refraction depending on the age or activities of the patient. Planning intended treatment and postoperative refraction in pediatric surgery is a more challenging and complicated endeavor. For the younger pediatric population undergoing surgery to prevent or treat amblyopia, most surgeons would consider the desired postoperative refraction to be plano.
cases of anisometropia, the treatment goal is often to match the refraction in the other eye. For older children, the ideal postoperative refraction has not been established. Because most children can tolerate a mild degree of hyperopia, a mildly hyperopic target may be appropriate in older children who will continue to have a natural myopic progression with growth. Although population studies have examined the growth of the eye and changes in refraction, it cannot be calculated for an individual eye at this time.16 The key to these calculations is to keep in mind that the refractive error of the child will change with age and the refractive surgeon must have future options available to handle future refractive needs. Options for future treatments include lift-flap retreatment after LASIK, surface retreatment after PRK, phakic IOL exchange, piggyback IOL implantation, contact lenses as the child matures, and future LASIK after previous IOL implantation.

More Challenging Refractive Errors

As discussed in the historical section, it was discovered that using an excimer laser to treat high refractive errors often led to inferior optical and safety outcomes. The problem arises with pediatric refractive surgery in that the patients brought to the attention of refractive surgeons are often those with severe refractive errors. Many of these errors fall outside of the range of treatments accepted for laser refractive procedures. With the larger refractive corrections, it is necessary to look to alternative procedures such as phakic IOLs, lensectomy, refractive lens exchange, and bioptics.

**Pediatric Refractive Surgery Today**

There are many companies that manufacture excimer lasers worldwide, and a smaller number of these have pursued the FDA approval process and are approved for use in the United States. For all models, excimer laser technology is approved for treatment of refractive errors in individuals older than 18 years with documented stability in refraction. The individual clinician has the authority to use these lasers on patients younger than 18 years with special informed consent and patient and parent notification of the off-label use of the technology. Both phakic IOLs currently FDA-approved are indicated for patients aged 21 years or older and fall under the same regulations as for off-label use.

There is growing literature about the use of various refractive technologies in the pediatric population. The most common indications for pediatric refractive surgery today are unilateral anisometropic amblyopia,17-19 bilateral high myopia,20 and refractive accommodative esotropia.21 The majority of patients undergoing refractive surgery have failed traditional treatments such as occlusion therapy, glasses, and contact lenses. In some studies, the authors identify neurobehavioral disorders as a secondary cause for the intolerance of traditional therapies.

**Surgical Techniques**

Excimer laser therapies include surface treatments with PRK and laser-assisted subepithelial keratomileusis (LASEK), as well as flap-based treatments with LASIK and sub-Bowman’s keratomileusis. The advantages of surface treatments (PRK/LASEK) are the elimination of potential flap complications and the possibility of increased long-term corneal stability due to the minimization of stromal disruption. It has been theorized that the creation of the LASIK flap destabilizes the cornea due to the cutting of stromal fibers.22 The disadvantages of surface treatments are the increased discomfort, increased healing time, and potential for haze formation. With LASIK surgery or sub-Bowman’s keratomileusis, which is a modern thin flap variant of LASIK, the advantages are decreased healing time and increased comfort. The disadvantages are potential flap complications or flap dislocation in the future.23

Intraocular techniques have been discussed previously and include phakic IOL implantation, lensectomy without IOL implantation, and refractive lens exchange. One benefit of these procedures is improved optics over spectacle, contact lens, or laser correction. They are also often the only option for correcting high refractive errors. The potential disadvantages to these procedures are the usual risks associated with intraocular surgery and an increased risk for retinal detachment due to high myopia. Specific risks associated with lensectomy or refractive lens exchange are a need for anterior vitrectomy and posterior capsulotomy, aphakia (if left aphakic), and loss of accommodation. Additional disadvantages with phakic IOLs include the potential for endothelial cell loss, angle damage, UGH syndrome, and catact formation.

**Current Literature**

A literature search found 41 articles reporting on technologies and techniques in pediatric refractive
surgery. The majority of articles reported on methods of treating anisometropic amblyopia, with a few articles reporting on bilateral high myopia and refractive accommodative esotropia. A review article of the early literature published from 1995 to 2003 showed that initial studies often used laser procedures to treat high refractive errors. Also of note was that many studies included subjects in their early teenage years and well out of the amblyogenic period. This factor made data analysis difficult due to the low probability for vision improvement despite refractive correction. Mirroring the evolution with treatment of refractive errors in the adult population, more recent literature shows a trend toward treating lower refractive errors. Tychsen et al. suggests that -12 D should be the upper limit for excimer laser treatment due to the increased likelihood of haze formation. Additionally, more recent studies are tending to treat children at a younger age in an attempt to prevent the onset of dense amblyopia.

Paysse et al. published a small study of anisometropic amblyopic patients undergoing PRK. They found negligible haze formation, an increase in visual acuity and stereopsis, and an improvement in refractive correction compared with controls at 3 years postoperatively. Astle et al. recently reported a study investigating 1-year data on anisometric amblyopic patients undergoing the LASEK procedure. They found a significant improvement in best spectacle-corrected visual acuity and stereopsis postoperatively. Nucci et al. performed bilateral PRK for the treatment of refractive accommodative esotropia on 8 patients. Postoperatively, the patients were all orthophoric with a residual refractive error of less than ± 0.375 D.

There are few case reports of phakic IOL implantation in the pediatric population. Assil reported a case of Verisyse anterior chamber IOL implantation in a 3-year-old anisometric amblyopic patient who had improvement in visual acuity and stereopsis without complications at 4 years postoperatively. Ben Ezra et al. reported that 3 older children with dense anisometric amblyopia who underwent implantation of the Visian posterior chamber IOL had no complications or decrease in endothelial cell count. Tychsen et al. also reported a series of 13 children treated for high myopia with bilateral lensectomy or refractive lens exchange and found an increase in functional vision and an improvement in behavior after the treatment. Complications included posterior capsular opacification and 2 cases of retinal detachment in the follow-up period.

**FUTURE ROLE OF REFRACTIVE TECHNOLOGY IN CHILDREN**

Refractive Surgery in the Adolescent Population

Mathers et al. postulated that refractive surgery was safer than contact lenses. Through comparison of studies estimating the risk of vision loss from contact lens wear compared to laser vision correction, they concluded that laser surgery is safer than contact lens wear. Although this assertion has been widely disputed and debated, it raises concerns about the safety of long-term contact lens wear. There is also growing concern about the safety of contact lens use in the preteen and adolescent populations. These children are more likely to take risks with the care, use, and hygiene of their lenses and products. It is a possibility that in the future, instead of waiting until the child is 18 years old, laser correction may be used at an earlier age. It would be anticipated that a retreatment would be necessary as the individual achieves full maturity, but a large amount of the refractive error could be neutralized at an earlier age.

Identifying and Treating Highly Anisometric Eyes Earlier

One of the greatest hurdles to the early treatment of anisometropia and subsequent amblyopia is the problem of identifying these children at a young age. This condition is often not discovered until routine grade school vision screening when the child is nearing the age of visual maturation. When discovered and treated before visual maturation, anisometropia can be successfully treated with traditional forms of therapy including spectacles, contact lenses, and occlusion therapy. Unsuccessful visual rehabilitation with these patients frequently stems from noncompliance with traditional treatments, astigmatism greater than 1.50 D, and age older than 6 years.

Many current studies evaluating refractive surgery for anisometropic amblyopia include patients who have failed conventional treatment for many years. It has been suggested that the inability to improve visual acuity in these patients may be accounted for by the dense amblyopia developed during failure of conventional interventions. Future movement in pediatric ophthalmology may be to
find modalities of identifying anisometropic children at an earlier age. Pediatric refractive surgeons may also step in earlier on cases with children who appear to be intolerant of conventional therapies and are not showing signs of improvement. It is even possible that as the techniques, technology, and experience with these surgical procedures expand, refractive surgery will be considered in certain cases at the time of diagnosis.

Accommodating and Multifocal IOLs

The rapidly progressing field of presbyopia correction has produced new technology that may be effective in treating special situations in the pediatric population. At this date, the only FDA-approved accommodating IOL is the Crystalens (Eyeconics, Aliso Viejo, CA). This is a three-piece posterior chamber lens that has a modified plate haptic lens with hinges across the plates adjacent to the optic. The hinges enable anterior movement of the lens during accommodating effort, allowing for improvement in near vision. Multifocal IOLs are also used in the adult cataract surgery market for improvement in near acuity while preserving distance vision. These lenses use different optical techniques to vary the power or shape of the IOL surface to allow for focusing ability at near and distance simultaneously.

These new lens technologies would have the potential for use in both pediatric cataract patients and patients undergoing lensectomy for high refractive errors. The use of these technologies would only be necessary in bilateral cases and may allow the child to function for most tasks without the need for bifocals or reading glasses. The lenses currently approved in both the accommodating and multifocal versions are not perfect solutions for the loss of near vision after lens extraction. Many patients complain of glare and halo with the multifocal IOLs and are often disappointed by the inability to achieve full-time independence from reading glasses with the accommodating IOL.33 Undoubtedly, there will be a continued progression to improve these technologies as driven by the cataract population. In the future, the ability to correct near and distance vision in children undergoing lensectomy may be a plausible alternative.

DISCUSSION

The emerging field of pediatric refractive surgery is an interesting marriage of the rapidly progressing field of refractive surgery and the traditionally ultra-conservative field of pediatric ophthalmology. The refractive side offers its advanced technologies and the pediatric group is charged with making conscientious and practical decisions regarding their use in children. In cases of anisometropic amblyopia, bilateral high myopia, and refractive accommodative esotropia, surgeons have found clinical situations in which refractive surgery has been effective, safe, and beneficial.

Looking into the future of applying refractive technologies to children and adolescents, many research areas need to be explored. One potential study would be a large study evaluating the safety and efficacy of traditionally treated anisometropic amblyopes versus those treated shortly after diagnosis with refractive surgery. Another study would be to evaluate the adolescent population for a comparison between the long-term safety profiles of contact lens use versus refractive surgery. Further study also needs to be pursued in the area of excimer laser effects on corneal biomechanics and healing in pediatric and adolescent eyes. These studies will be important in evaluating the long-term effects of refractive surgery in the pediatric population.

Overall, the field of pediatric refractive surgery shows great promise in its ability to help a small segment of the pediatric population. Maximizing visual potential in these patients who have often failed traditional therapies is the ultimate goal of these endeavors. Emerging techniques and technology may bring even more possibilities for benefit in an expanded population of infants, children, and adolescents.

REFERENCES

Responses to Last Issue’s E-Consults Case

In our last issue, we asked readers for their suggestions regarding the treatment of a 62-year-old man with symptomatic vertical diplopia that began 9 months after a retinal cryotherapy in the superior nasal quadrant of the right eye.

Many respondents note that Brown’s syndrome is extremely unusual following cryotherapy. Despite this, almost all respondents went on to recommend that some form of forced ductions be performed as a first step to rule out superior oblique involvement. All respondents agree that if the forced ductions are negative, the diagnosis is most certainly a left inferior oblique paresis or palsy.

Although there was general agreement on the diagnosis, this was not so with the treatment. Approximately 75% of those responding suggested a left superior rectus recession with or without an adjustable suture. The remainder said that because of the presence of torsional diplopia they would suggest a right superior oblique weakening procedure (partial tenotomy or expander).

We have had responses from Korea and the United States. Thank you all.