AMERICAN ACADEMY OF OPHTHALMOLOGY®

Ophthalmic Technology Assessment

Contact Lens Correction of Aphakia in Children

A Report by the American Academy of Ophthalmology

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Purpose: To review the published literature to assess the visual outcomes and adverse events associated with the 2 most commonly used contact lenses for treating aphakia in children: silicone elastomer (SE) and rigid gas permeable (RGP).

Methods: Literature searches were last conducted in January 2018 in the PubMed, Cochrane Library, and ClinicalTrials.gov databases with no date or language restrictions. These combined searches yielded 167 citations, 27 of which were reviewed in full text. Of these, 10 articles were deemed appropriate for inclusion in this assessment and subsequently assigned a level of evidence rating by the panel methodologist.

Results: The literature search identified 4 level II studies and 6 level III studies. There were insufficient data to compare visual outcomes for eyes treated using SE lenses versus RGP lenses. Silicone elastomer lenses have the advantage that they can be worn on an extended-wear basis, but they were associated with more adverse events than RGP lenses. These adverse events included microbial keratitis, corneal infiltrates, corneal edema, corneal scars, lenses adhering to the cornea, superficial punctate keratopathy, lid swelling, and conjunctival hyperemia. The lens replacement rate was approximately 50% higher for RGP lenses in the only study that directly compared SE and RGP lenses.

Conclusions: Limited evidence was found in the literature on this topic. Silicone elastomer and RGP contact lenses were found to be effective for treating aphakia in children. Silicone elastomer lenses are easier to fit and may be worn on an extended-wear basis. Rigid gas permeable lenses must be removed every night and require a more customized fit, but they are associated with fewer adverse events. The choice of which lens a practitioner prescribes should be based on the particular needs of each patient. *Ophthalmology 2018;■:1–7 © 2018 by the American Academy of Ophthalmology*

The American Academy of Ophthalmology prepares Ophthalmic Technology Assessments to evaluate new and existing procedures, drugs, and diagnostic and screening tests. The goal of an Ophthalmic Technology Assessment is to review systematically the available research for clinical efficacy, effectiveness, and safety. After review by members of the Ophthalmic Technology Assessment Committee, other Academy committees, relevant subspecialty societies, and legal counsel assessments are submitted to the Academy's Board of Trustees for consideration as official Academy statements. The purpose of this assessment by the Ophthalmic Technology Assessment Committee Pediatric Ophthalmology/Strabismus Panel is to review the published literature on the efficacy and safety of silicone elastomer (SE) or rigid gas permeable (RGP) contact lenses in aphakic children.

Background

Contact lenses have been used since the 1950s for optical correction in children after cataract surgery.[1] They are particularly useful for children with monocular aphakia because of the marked aniseikonia induced by spectacles. Originally, contact lenses were made of polymethylmethacrylate or hydrogel, which have low oxygen permeability. In the 1970s, a major advance occurred with the introduction of contact lenses made of SE that had a higher oxygen permeability. Subsequently, RGP and silicone hydrogel contact lenses became commercially available; both also have increased oxygen permeability. Because silicone hydrogel lenses have only recently become available in the powers required to

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correct pediatric aphakia, this review will focus on SE and RGP lenses.

In the United States, the most commonly used contact lens to correct pediatric aphakia is an SE lens—the SilSoft Super Plus (Bausch & Lomb, Rochester, NY).[2] It has a high oxygen permeability (Dk = 340) and oxygen transmissibility with high plus powers (Dk/t = 71)[3] that allow it to be worn on an extended-wear basis. (The manufacturer recommends that the lens be removed for cleaning and disinfection at least once every 30 days and then left out of the eye overnight.) This wearing schedule is advantageous for young children, who often have a low tolerance for the insertion and removal of contact lenses. Silicone elastomer lenses are manufactured in a limited range of powers (+23, +26, +29, +32 diopters [D]), 3 base curves (7.5, 7.7, 7.9 mm), and only 1 diameter (11.30 mm). Most aphakic infants are initially fitted with lenses that have a base curve of 7.5 mm. Lower-power SE contact lenses (SilSoft Aphakic, Bausch & Lomb) are available in 1 D increments (+11.50 D to +20.00 D), 5 base curves (7.5 to 8.3 mm), and 2 diameters (11.30, 12.50 mm). Some young children require powers higher than are available with the SE lens.

The hydrophilic surface coating on SE lenses deteriorates over time, allowing its underlying hydrophobic surface to be exposed, which results in reduced wettability and mucus buildup on its anterior surface.[4,5] This is a particular problem in children 3 years of age and older and necessitates frequent lens replacement.[6] In addition, SE lenses have a limited capacity to correct corneal-induced astigmatism that exceeds 2 D in magnitude.

In contrast to SE lenses, RGP lenses can be customized to achieve virtually any power, base curve, or diameter. For the high plus powers needed to correct pediatric aphakia, RGP lenses are commonly made from Menicon Z (Menicon, Nagoya, Japan) with a Dk = 189 or hexafocon B (Bausch & Lomb) with a Dk = 141.[2,7] The advantages of RGP lenses include availability in a wider range of powers, increased ability to correct corneal astigmatism (up to 6 D), better durability, and lower cost. The primary disadvantage of RGP lenses is that for the high plus powers needed to correct pediatric aphakia, their effective oxygen permeability is not optimal for extended wear.

Beginning in the 1990s, there was an increasing trend to implant intraocular lenses to optically correct for pediatric aphakia.[8] However, subsequent clinical studies have shown that intraocular lens implantation during early infancy is not associated with an improved visual outcome, and it increases the incidence of adverse events and additional intraocular surgeries.[9–11] As a result, ophthalmologists generally leave infants aphakic after cataract surgery and then optically correct them with aphakic contact lenses or spectacles.[12] In the United States, SE and RGP lenses are the most commonly used contact lenses used to optically correct aphakic eyes during early childhood.

Resource Requirement

In 2017, the current estimated wholesale price is approximately $150 for an SE lens, $110 for a custom silicone hydrogel lens, and $40 for an RGP lens (design dependent). Less-expensive silicone hydrogel lenses are available up to a power of +15 D, but with a single base curve and diameter. Soft hydrogel lenses are available in powers up to +20 D.

Description of the Treatment

To optically correct aphakic children with contact lenses after cataract surgery.

Questions for Assessment

The focus of this assessment is to address the following questions: (1) Does the rate of adverse events differ between SE and RGP contact lenses? (2) Does the visual outcome vary when using these 2 types of contact lenses in aphakic children?

Description of Evidence

Literature searches were last conducted in the PubMed, Cochrane Library, and ClinicalTrials.gov databases in January 2018, without date or language restrictions. The search strategy used the following MeSH terms and text words: *aphakia*[MeSH], *cataract extraction*[MeSH], *aphakia*, *postcataract*[MeSH] *Aphakia*, *postcataract/therapy*[MeSH], *lensectomy, aphakia, aphakic, Silsoft, silicone, rigid permeable gas, RGP, GP, hydrogel, rigid gas permeable, rigid gas permeable CL, rigid gas permeable CLS, rigid gas permeable contact, rigid gas permeable contact lens, hydrogel silicone lens, optical correction, rigid lens, hydrogel lens, optical rehabilitation,* and *silicone elastomer*.

A total of 161 unique citations were identified, and 27 of them were reviewed in full text with respect to the inclusion criteria, which specified that the primary objective of the study was to evaluate visual outcomes and adverse events associated with SE or RGP contact lenses in aphakic children, the research was original, the follow-up was 6 months or longer, and at least 10 patients were enrolled in the series.

Of these 27 articles, 10 were deemed appropriate for inclusion in this assessment, and each was then assigned a level of evidence rating by the panel methodologist (R.T.K.) based on a rating scale developed by the Oxford Centre for Evidence-Based Medicine.[13] A level I rating was assigned to well-designed and well-conducted randomized clinical trials, a level II rating was assigned to individual cohort studies with well-defined outcomes, and a level III rating was assigned to lower-quality cohort studies or small case series. Of note, no studies met level I criteria, 4 studies met level II criteria, and 6 studies met level III criteria.

Published Results

Visual Outcomes

A summary of the visual outcomes for level II studies is presented in Table 1. Aasuri et al[14] reported treating a large