Hyper Oxygen-Permeable Rigid Contact Lenses as an Alternative for the Treatment of Pediatric Aphakia

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Purpose. To establish the safety and efficacy of a hyper-oxygen-permeable rigid contact lens material, Menicon Z, for the fitting of aphakic infant eyes. Methods. A prospective study was performed on 16 eyes of 10 newly aphakic infants. Aphakic fittings were performed postoperatively with the Dyna Z intralimbal design of lenses, made exclusively from Menicon Z material for this study. Examinations were performed at 1 day, 1 week, 1 month, 3 months, and 6 months, during which the lenses were used on a 1-week extended-wear basis. The following outcome measures were evaluated at each visit: Fit Characteristics, Ocular Integrity, Usability, and Contact Lens Integrity. Results. When used for the treatment of pediatric aphakia, the Menicon Z material provided excellent Fit Characteristics, was not damaging to the ocular structures, was relatively easy to manipulate for caregivers, and maintained its integrity well throughout the course of the study. Because there were no observable increases in the rate of microbial infection during the course of the study, the hyper oxygen-permeable nature of the Menicon Z material seems to provide adequate corneal oxygenation for aphakic children when used on a 1-week extended-wear basis. Conclusions. The Menicon Z contact lens material provides a safe and effective alternative for the treatment of infants and children requiring aphakic correction. This hyper oxygen-permeable material offers sufficient corneal oxygenation at the lens powers and thicknesses demanded by newly aphakic eyes combined with a low risk for associated complications. Key Words: Contact lenses—Menicon Z—Pediatric aphakia.

Newly aphakic eyes require optical correction in the form of glasses or contact lenses to replace the function of the human lens that was removed during cataract surgery. Providing a clearly defined vision is critical in order to allow children to move about and participate in daily activities. The need for optical correction is primarily for their optical superiority at high refractive powers such as those necessitated by aphakia. Other more practical reasons for preferring contact lenses to glasses include improved comfort, fit, and cosmesis thereby promoting more consistent wearing time and the potential for better visual outcomes.

The choice of contact lenses for pediatric use is limited because of the technical difficulties involved in producing high-powered lenses that are highly oxygen-permeable and therefore safe for the infant eye. Lenses that are approved for extended-wear use are the preferred wearing modality by parents and doctors. Parents appreciate the convenience of weekly rather than daily insertion and removal of the lens, and doctors prefer the high level of oxygen delivery to the cornea at all hours, including during sleep. Currently, there is only one contact lens on the market that is approved by the Food and Drug Administration for extended wear for the treatment of pediatric aphakia, the Silsoft lens from Bausch & Lomb (Rochester, NY). The safety profile and usefulness of this lens are well established, and in general, it is considered by many pediatric eye doctors to be the first choice for pediatric aphakia. Clinically, its usefulness has been observed, but some limitations, including power and base curve restrictions, poor deposit resistance, and cost, have been discovered. In some instances, a satisfactory fit has not been possible with hydrogel or silicone hydrogel lenses, and other products that are only approved for daily wear must be relied on.

The Menicon Z lens (Menicon Company, Nagoya, Japan) is a rigid gas-permeable (RGP) contact lens approved for extended-wear use in adults. This study investigated the usefulness of this lens for fitting aphakic children, primarily for three reasons. First, gas-permeable materials are optically superior to soft lenses (i.e., hydrogel or silicone hydrogel), especially at the high powers required by aphakic eyes. Second, the Menicon Z product is constructed from a lens material categorized as hyper oxygen-permeable, and is approved by the Food and Drug Administration for extended wear, and therefore has a proven safety profile. Third, like any RGP lens, the manufacturing of this lens allows for flexibility in design and permits the use of tailor-made lenses for optimal comfort, fit, and vision.

MATERIALS AND METHODS

Study Design

This study was an observational study involving clinical analysis through objective and subjective measures of lens wear and performance. This study was not a comparative analysis, and therefore, randomization into experimental and control groups was not a requirement.
Sixteen eyes of 10 patients (six boys and four girls) were enrolled in the 6-month study. Six children were bilateral aphakes and four were unilateral aphakes, ranging in age from 3 weeks to 2 years at the time of their first contact lens evaluation. Although eligibility guidelines did not exclude established aphakic patients deemed to benefit from a change in current lens modality, all the patients enrolled were new aphakes without a history of contact lens wear. All children underwent uncomplicated anterior capsulotomy and extracapsular cataract extraction at Cincinnati Children’s Medical Center by any one of four pediatric ophthalmologists (Table 1).

One of the major outcome measures of this study included the presence or absence of a clear, undamaged, and otherwise healthy cornea after 6 months of lens wear. Therefore, any infant with a preexisting corneal condition resulting in suboptimal corneal integrity at the outset was excluded from the study. Excluded also was any child with a condition that had the potential to affect corneal health during the study, namely congenital or aphakic glaucoma.

Short-term postoperative treatment for uncomplicated cataract surgery usually involves the use of topical pharmaceuticals, so study patients were permitted to continue their use as instructed by their surgeon. Normal complications of cataract surgery, such as peripheral corneal scars and irregular astigmatism, were similarly not a reason for exclusion from the study. Because visual acuity was not a final outcome measure of this study, the presence of posterior segment conditions, such as retinopathy of prematurity, proliferative vitreoretinopathy, posterior hyperplastic primary vitreous, or macular dysfunction, was not a reason for exclusion. Related or unrelated systemic conditions, including developmental delay, were similarly not a reason for exclusion unless they rendered the patient intolerable to contact lens wear or if it was against the recommendation of the patient’s attending physician. This study was approved by the Institutional Review Board of Cincinnati Children’s Medical Center.

Initial Examination

Newly aphakic children were scheduled for a contact lenses fitting from 2 days to 2 weeks after their surgery. At initial examination, parents were given the option of study participation. Informed consent was obtained from one parent or both after the nature and possible consequences of the study were outlined and all questions were answered. It was made clear that pediatric aphakia is not a use approved by the Food and Drug Administration for the Menicon Z lens.

Initial examination included a diagnostic lens fitting of Menicon Z trial lenses to determine proper base curve, diameter, and power. The Dyna Z intralimbal lens design (Lens Dynamics, Golden, CO) was exclusively used in this study. Optimal fit was based on empirical evaluation of the cornea-to-lens relationship by using conventional fluorescein pattern analysis of the tear layer. Proper lens power was determined by performing a contact lens over-refraction by using standard streak retinoscopy and hand-held trial lenses. Insertion, removal, and cleaning techniques were taught at the follow-up.

Follow-up

Children were examined at 1 day, 1 week, 1 month, 3 months, and 6 months, which marked the end of the study. The following outcome measures were individually considered at each follow-up appointment: Fit Characteristics, Ocular Integrity, Usability, and Contact Lens Integrity. A standard follow-up evaluation form (Table 2) that included these outcome measures was used at each visit to track and monitor the progress of each patient. In the case of an infant wearing a contact lens in both eyes, an evaluation form was used for each eye.

Parents were instructed to use the lens on an extended-wear basis for 1-week intervals. After 1 week of continuous wear, they were instructed to clean and soak the lens for a minimum of 6 hours or overnight in Clari's solution (Advanced Medical Optics, Inc., Santa Ana, CA) before reinserting the lens. Lenses were rinsed and conditioned in Boston conditioning solution (Bausch & Lomb, Inc., Rochester, NY) before reinsertion.

If at any point in the study, a satisfactory fit was not attainable or if it were noted that the Menicon Z lens in any way damaged the cornea, the subject was discontinued from the study and a different lens or treatment was selected. Financial compensation was provided for study participation.

Method of Data Analysis

Since this was not a comparative study, the overall efficacy of the lens was graded by objectively evaluating lens performance as it pertained to each of the four outcome measures listed earlier. At each appointment, each of these measures was evaluated indepen-
RESULTS

When used in an aphakic design, the Menicon Z material was found to provide excellent fitting qualities for most (8 of 10) patients in this study. Once customized to suit the individual, these lenses are stable on the eye, are resistant to deposits, are easy to use, and did not show signs of increased risk for microbial infection during the course of a 1-week extended-wear regimen. A summary evaluation of lens performance is shown in Figures 1–4 in terms of each of the four outcome measures.

TABLE 2. Follow-up Evaluation Form

<table>
<thead>
<tr>
<th>Fit characteristics</th>
<th>Poor</th>
<th>Adequate</th>
<th>Ideal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Movement with blink and gaze change</td>
<td>Lens appears to be adhering to cornea</td>
<td>Lens moves with blink, but only minimally</td>
<td>Lens moves appropriately and recenters with each blink</td>
</tr>
<tr>
<td>Corneal-lens relationship and fluorescein pattern</td>
<td>Significant bearing on the cornea and or poor edge lift</td>
<td>Adequate alignment pattern and sufficient edge lift</td>
<td>Excellent alignment pattern and edge lift</td>
</tr>
<tr>
<td>Overall positioning of lens</td>
<td>Poorly centered</td>
<td>Adequately centered</td>
<td>Perfectly centered</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ocular integrity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal punctate staining</td>
<td>Present in no more than one quadrant</td>
<td>Present between one and 4 quadrants</td>
<td>Diffuse; present in at least four quadrants</td>
</tr>
<tr>
<td>Corneal abrasion</td>
<td>&lt;1 mm in diameter</td>
<td>Between 1 and 2 mm in diameter</td>
<td>&gt;2 mm in diameter</td>
</tr>
<tr>
<td>Corneal edema</td>
<td>Corneal haze that is visually insignificant</td>
<td>Corneal haze that has the potential to affect vision</td>
<td>Enough corneal haze to warrant lens</td>
</tr>
<tr>
<td>Corneal neovascularization</td>
<td>Vessel penetration &lt;1 mm in a single quadrant</td>
<td>Vessel penetration &gt;1 mm in a single quadrant</td>
<td>Vessel penetration &gt;1 mm in multiple quadrants</td>
</tr>
<tr>
<td>Corneal ulceration or infiltrate</td>
<td>Single infiltrate present</td>
<td>More than one infiltrate present</td>
<td>One or more infiltrates present with associated signs or symptoms of infection\a</td>
</tr>
<tr>
<td>Conjunctival irritation</td>
<td>Conjunctival vessels minimally injected (eye looks pink)</td>
<td>Conjunctival vessels significantly injected (eye looks red)</td>
<td>Conjunctival vessels injected and eye watering (lens to be removed)</td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>Conjunctival injection and papillae without discharge or irritation</td>
<td>Conjunctival injection and papillae with discharge, irritation, or both</td>
<td>Conjunctival injection and papillae with significant discharge and irritation</td>
</tr>
<tr>
<td>Usability</td>
<td>Success on first attempt</td>
<td>Successful with three or fewer attempts</td>
<td>Unsuccessful or successful with three or more attempts</td>
</tr>
<tr>
<td></td>
<td>Easy to understand and perform regimen</td>
<td>Caretaker not completely comfortable with regimen</td>
<td>Difficult to understand and perform proper regimen</td>
</tr>
<tr>
<td>Contact Lens Integrity</td>
<td>Low or absent</td>
<td>Average</td>
<td>High or present</td>
</tr>
<tr>
<td>Presence of deposits</td>
<td>Fewer than three surface deposits</td>
<td>More than three surface deposits</td>
<td>More than three surface deposits obscuring vision</td>
</tr>
<tr>
<td>Rate of loss or replacement</td>
<td>Happens no more than once every 3 months</td>
<td>Happens once per month</td>
<td>Happens more than once per month</td>
</tr>
<tr>
<td>Rate of displacement</td>
<td>Happens no more than once per month (rarely)</td>
<td>Happens once or twice per week</td>
<td>Happens more than twice per week</td>
</tr>
<tr>
<td>Lens cracks, breaks, or chips</td>
<td>Absent</td>
<td>Present</td>
<td></td>
</tr>
</tbody>
</table>

\aMay include red eye, tearing, or mucous discharge.

DISCUSSION

The goal in treating infants with contact lenses after cataract extraction is to provide the child with a clear, well-focused image that supports normal ocular growth and nondelayed development of the visual system. The potential benefits of this optical rehabilitation cannot be overstated since its aim is to prevent amblyopia and severe vision loss. In doing so, contact lens treatment promotes optimal visual acuity and binocularity, which are highly associated with depth perception, fine motor skills, and coordination.

The ability to fit a child with a contact lens that is approved for extended-wear use in adults has definite advantages. Considering the number of hours newborns spend with their eyes closed, the increased risk of infection after surgery, and the obvious stress and anxiety that many babies and parents initially experience during daily lens insertion and removal,\textsuperscript{18,19} having a contact lens with a proven extended-wear safety profile is appealing and is partially what led to the consideration of the Menicon Z material as a treatment option. Furthermore, when compared to soft hydrogel or soft silicone hydrogel materials, contact lenses made of RGP material offer the extra advantages of improved tear exchange, higher oxygen permeability, lesser rates of infection, superb optics, and decreased cost.\textsuperscript{11,20}

Other investigators have not attempted to specifically show the usefulness of the Menicon Z lens for the treatment of pediatric...
FIG. 1. Fit Characteristics of the lenses, as rated by the primary examiner, were deemed adequate to ideal throughout the study. Initial fitting success (1-day and 1-week) could be attributed to the fitting preferences of the primary examiner, because no child was sent home with lenses unless a satisfactory fit was achieved. By the study end, most fits were deemed ideal because ample time was provided to customize the initial lens to reflect a more preferred fitting pattern.
FIG. 2. Ocular integrity was essentially uncompromised throughout the study. Mild conjunctival irritation (i.e., redness) and some epithelial staining were the most significant complications and were easily remedied through lens modification, reinstruction of proper cleaning techniques, or the addition of rewetting drops in most cases. By the study end, all eyes of every subject were free of any sign of contact lens-related complications.
In terms of Usability, ease of insertion and removal was considered the most difficult task at the study outset. On further questioning, most families felt that insertion of the lens was simple and that removal of the lens was itself the more difficult task. Difficulty with lens removal is what accounts for more subjects reporting Manageable or Difficult throughout the first month of the study. Nevertheless, by the study end, most families had acquired the appropriate skills to perform insertion and removal more efficiently. Understanding and performing the cleaning and disinfection regimen was never a significant concern.

FIG. 3.
aphakia, but studies have shown the usefulness of RGP lenses on an extended-wear basis for the treatment of adult and pediatric eye conditions, including aphakia. An earlier study involving adult aphakic patients showed the Menicon EX lens, a precursor to the current Menicon Z, to be advantageous in its ability to reduce the incidence of corneal neovascularization and excess mucus secre-

FIG. 4. Contact Lens Integrity was well maintained for all patients throughout the course of the study. Frequent lens displacement was the most cited complaint by the middle of the study, but the level of deposits, lens loss, cracks, breaks, and chips was minimal throughout the study.
tion when used on an extended-wear basis.21 Another adult study, which involved two children aged 4 and 6 years, examined the usefulness of extended wear RGP lenses in 186 aphakic patients.7 Using the Boston or Paraperm lens, one third of patients in this study removed their lenses weekly, another third monthly, and most others were able to postpone lens removal for intervals up to 6 months without complications, emphasizing the safety profile of RGP lenses. Amos et al.20 examined the usefulness of the Fluoroperm 92 RGP lens in fitting 10 consecutive aphakic infants. Although the lenses were fitted primarily on a daily-wear basis, the authors reported negligible complications, with the lens being well-tolerated by the infants and accepted by parents primarily for its ease in handling.

As with any contact lens wear modality, however, the potential risk for infection is always a factor to be considered as it relates to corneal oxygen deprivation. This possibility is especially true when fitting infants on an extended-wear basis.

The extended-wear modality has been shown to place the eye at a higher risk for associated complications in comparison to daily-wear lenses.22,23 Although these studies report a 10- to 15-fold higher incidence of infection among extended-wear lens users, they are in specific reference to soft hydrogel contact lenses, which are limited by the permeability of water to oxygen. Because the Menicon Z lens is made of an RGP polymer, it benefits from much better oxygen delivery to the cornea, through the lens and around the edges of the lens as a result of better tear exchange owing to its rigidity and movement. A limited number of studies have also specifically examined the safety profile of the Menicon Z lens in adult extended wear.15–17,24 These studies all show the Menicon product to be a safe and effective option providing adequate corneal oxygenation when used on an extended-wear basis, hence providing further support for the author’s decision to use the Menicon Z lens for his pediatric aphakic population.

The Menicon Z material is classified as a hyper oxygen-permeable material with an oxygen permeability (Dk) value of 189 (Fatt). Because most traditional RGP contact lenses have a Dk value of less than 100,13 the Menicon Z product is therefore considered capable of providing adequate oxygenation. With aphakic contact lenses, however, center thicknesses can be more than 1 mm, so oxygen transmissibility becomes the more important variable to consider.

Figure 5 shows the average oxygen transmissibility for lenses ranging in base curve from 7.9 to 7.5 and in power from +23 to +32 diopters respectively. Although neither the Silsoft nor the Menicon Z is a hydrogel lens, the Holden and Mertz study25 on the minimal oxygen requirements to avoid corneal edema when using hydrogel lenses provides an interesting comparison for the purposes of this discussion. Their study determined that the critical lens oxygen transmissibility for hydrogel lenses necessary to limit overnight corneal edema to less than 4% was 87.0 ± 3.3 × 10⁻⁹. Because hydrogel technologies at the time of publication could not provide this level of transmissibility, Holden and Mertz proposed a more forgiving value, the level of transmissibility required to allow overnight swelling to exceed 4% but allow the cornea to return to normal thickness soon after eye opening. This value, 34.3 ± 5.2 × 10⁻⁹, is shown in Figure 5 (labeled Extended Wear). Also shown is the critical transmissibility value to prevent corneal edema under daily-wear conditions, 24.1 ± 2.7 × 10⁻⁹ (labeled Daily Wear).

At first glance, it would appear that neither of the lenses in question satisfies the minimal oxygen requirement for overnight wear (i.e., 87 × 10⁻⁹), not even the Silsoft with its Dk of 340. However, the Silsoft lens meets the minimal extended-wear transmissibility requirement of 34 × 10⁻⁹ and the daily-wear requirement of 24 × 10⁻⁹ at the thicknesses studied. The Menicon Z (Dk

![Figure 5](image-url)
of 189 and 163) appears not to be able to provide the minimal corneal oxygenation for daily- or extended-wear modalities at the lens thicknesses described. Only when rated with a Dk of 250 does the Menicon Z start to provide acceptable oxygen transmissibility values. The author has been using the Menicon Z lens on a 1-week extended wear basis in children for more than 3 years and has yet to encounter a case of corneal edema or associated microbial keratitis. How can this seemingly inadequate transmissibility of high plus lenses be explained?

First, Holden and Mertz clearly pointed out that using the center thickness of the lens to define oxygen transmissibility provides a misrepresentation of oxygen delivery throughout the entire lens and that oxygen transmissibility based on average thickness across the lens provides a more valid and accurate predictor of true transmissibility.25 Figure 5 is based on center thickness readings only, and therefore, it should be stated that these transmissibility calculations are probably skewed to reflect much poorer lens performance than is actual. However, one must also keep in mind that lenses soil during the course of a 1-week continuous-wear schedule, and what effect it may play on in vivo oxygen permeability and delivery to the cornea is not known and likely different for every patient.

According to their studies on human subjects, Gardner et al.26 concluded that contact lens materials of higher oxygen transmissibility offer the ability to design thicker lenses without significant compromise to corneal oxygen uptake. In other words, high- or hyper-Dk lenses offer the advantage of allowing for a thicker lens design without the expected decrease in oxygen transmissibility.27 Although much thicker lens designs were used than those in the aforementioned studies, this may provide some further insight as to why the current thick lenses did not induce any clinically significant signs of corneal hypoxia. Soft hydrogel or silicone hydrogel lenses do not follow the same permeability principles as hard lenses and must overlap the limbus when fit properly. It is therefore not surprising that these lenses must have much higher Dk values to be safely used for aphakic designs (e.g., Silsoft Dk of 340).

The author believes that the success of the Menicon Z lens (Dk of 189) as an extended-wear product is not only attributable to its hyper oxygen permeability rating but, as with any lens, is also a function of choosing the proper lens design while paying close attention to fitting characteristics. This study strictly incorporated the Dyna Z intralimbal design from Lens Dynamics. The author finds that it is well suited for the purposes of pediatric aphakia, mostly for its large diameter and therefore overall stability and comfort on the infant eye. The design uses a spherical, single-cut, central optic zone, a blended multicurve peripheral system, and a larger overall diameter than most typical RGP lenses.

In addition to lens permeability and thickness profile, good tear exchange, which happens around the edges of the lens, is considered as an equally important component of proper lens design when trying to ensure adequate corneal oxygenation with high plus lenses. This is especially prudent in infants because it does not take a baby long to soil a lens that is being worn on a 1-week continuous-wear basis. Removal of the lens after just 48 to 72 hours of wear can show significant lipid or protein deposition, associated with infant contact lens insertion and removal can safely benefit from the use of this hyper oxygen-permeable material on an extended-wear basis, and doctors can remain comfortable knowing that their patients are fitted with a lens that allows for sufficient corneal oxygenation and a low risk of associated complications.

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REFERENCES