

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

Daniele P. Saltarelli, O.D.

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 focused retinal image soon after surgery is essential to preventing permanent vision loss related to deprivational amblyopia.[1–3] For this reason, aphakic correction is a critical medical necessity. Contact lenses are the preferred therapy, as opposed to glasses, primarily for their optical superiority at high refractive powers such as those necessitated by aphakia.[2,4] 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.[5]

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.[6,7] 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,[6,8,9] 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.[10–12] Second, the Menicon Z product is constructed from a lens material categorized as hyper oxygen-permeable,[13,14] is approved by the Food and Drug Administration for adult extended wear, and therefore has a proven safety profile.[15–17] 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.

From the Division of Ophthalmology/Abrahamson Pediatric Eye Institute, Cincinnati Children's Medical Center, Cincinnati, OH; and the Department of Ophthalmology, University of Cincinnati College of Medicine, Cincinnati, OH.

Supported in part by an unrestricted grant from Research to Prevent Blindness, Inc., New York, New York, presented to the Department of Ophthalmology, University of Cincinnati College of Medicine, Cincinnati, Ohio (James J. Augsburger, M.D., Chairman).

Address correspondence and reprint requests to Dr. D.P. Saltarelli, Division of Pediatric Ophthalmology Abrahamson Pediatric Eye Institute, 3333 Burnet Avenue, Cincinnati, OH 45229-3039; e-mail: daniele.saltarelli@cchmc.org

Accepted May 15, 2007.

DOI: 10.1097/ICL.0b013e31811eadaa

TABLE 1. *Patient Demographics*

Patient	Diagnosis	Age at 1st contact lens visit	Postoperative complications
S.G.	Congenital cataract in OU with microophthalmia	3 weeks	None
E.B.	Congenital cataract in the OD with hydrocephalus	17 weeks	Glaucoma
C.S.	Congenital cataract in OU	15 weeks	None
K.H.	Congenital cataract in the OS	2 years, 4 months	None
P.B.	Congenital cataract in OU	12 weeks	None
G.F.	Congenital cataract and posterior hyperplastic primary vitreous in the OS	14 weeks	None
S.L.	Congenital cataract in OU	48 weeks	None
A.S.	Congenital cataract in the OS	20 weeks	Secondary membrane
D.T.	Congenital cataract in OU with microophthalmia	4 weeks	Secondary membrane in the OD
A.R.	Congenital cataract in OU with nystagmus and microophthalmia	8 weeks	None

OD, right eye; OS, left eye; OU, both eyes.
Patient E.B. dropped out of the study because of complications related to aphakic glaucoma.
Patient C.S. was discontinued from the study because a satisfactory fit could not be achieved as a result of steep corneas. Menicon Z and Silsoft lenses were attempted, as were other hard and soft designs. The result was aphakic spectacles.

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 overrefraction 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 Claris 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-

TABLE 2. *Follow-up Evaluation Form*

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

[a]May include red eye, tearing, or mucous discharge.

dently by placing a check in the appropriate box on the follow-up evaluation form. Under the heading of Fit Characteristics, cornea-to-lens fit and performance were evaluated by fluorescein pattern analysis with the slitlamp if possible, but because of patient age and size, doing so typically was accomplished through gross examination with a powerful hand-held cobalt blue illuminating device. Ocular Integrity was similarly assessed by fluorescein analysis of the eye after lens removal. Usability was assessed by way of questioning the primary caregiver, and Contact Lens Integrity was assessed by questioning and by examining the lens itself under high magnification. At the study end, the results were tabulated for all 10 patients and summarized into 1-day, 1-week, 1-month, 3-month, and 6-month findings (Figs. 1–4).

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.

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,[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.[11,20]

Other investigators have not attempted to specifically show the usefulness of the Menicon Z lens for the treatment of pediatric

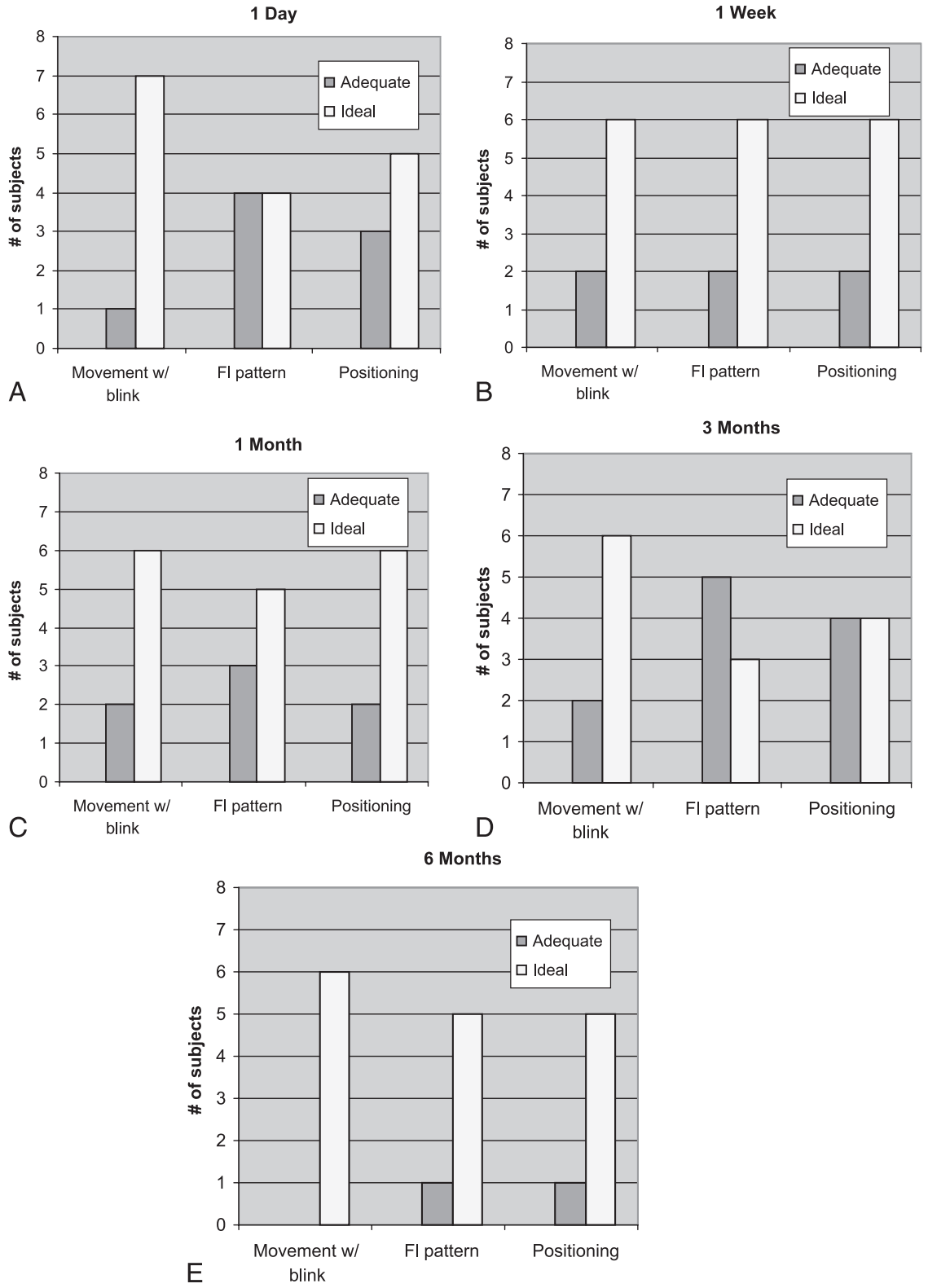

FIG. 1. Fit Characteristics of the lenses, as rated by the primary examiner, were deemed adequate to ideal throughout the study. Initial fitting success (1-day and 1-week) could be attributed to the fitting preferences of the primary examiner, because no child was sent home with lenses unless a satisfactory 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.

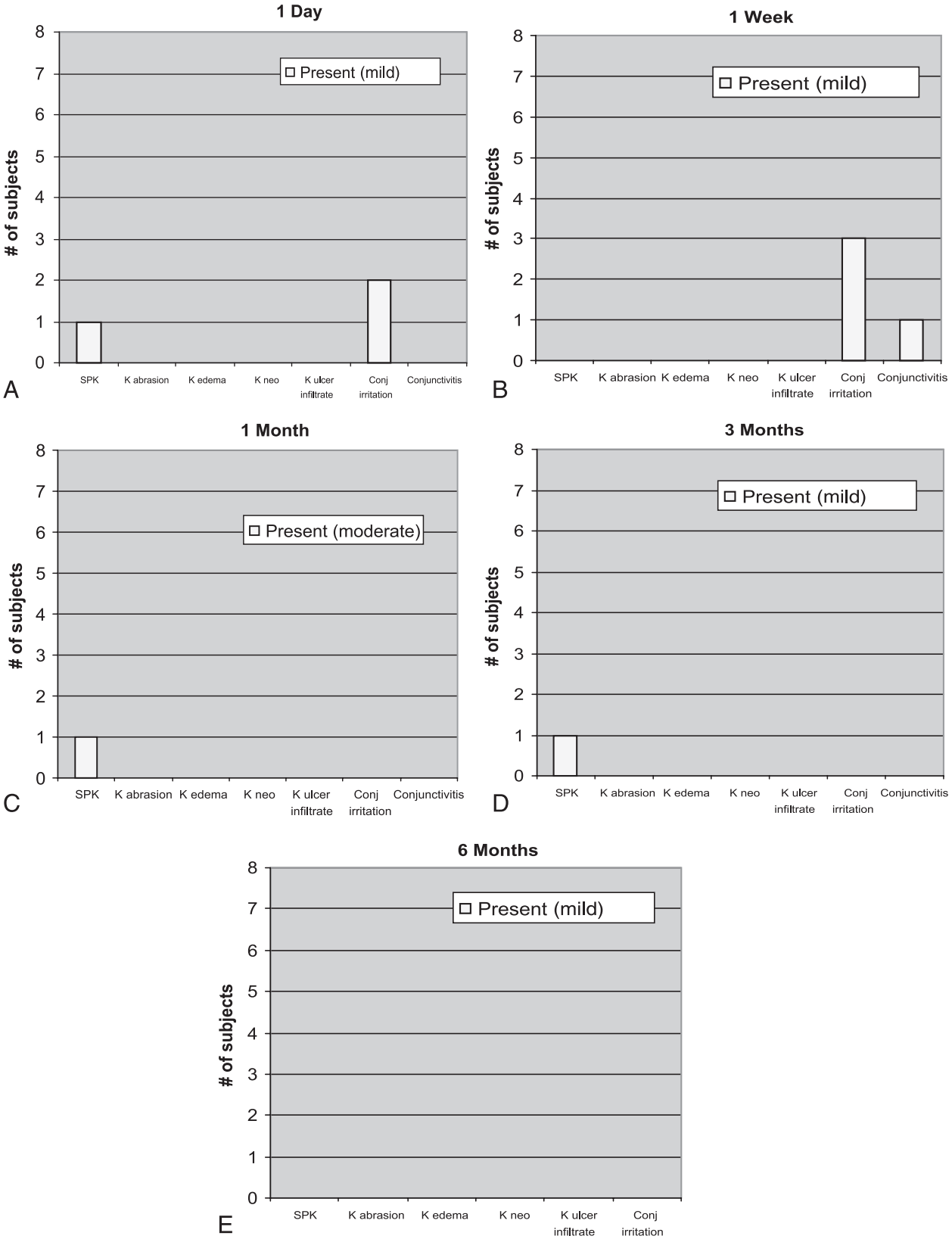

FIG. 2. Ocular Integrity was essentially uncompromised throughout the study. Mild conjunctival irritation (i.e., redness) and some epithelial staining were the most significant complications and were easily remedied through lens modification, reinstruction of proper cleaning techniques, or the addition 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.

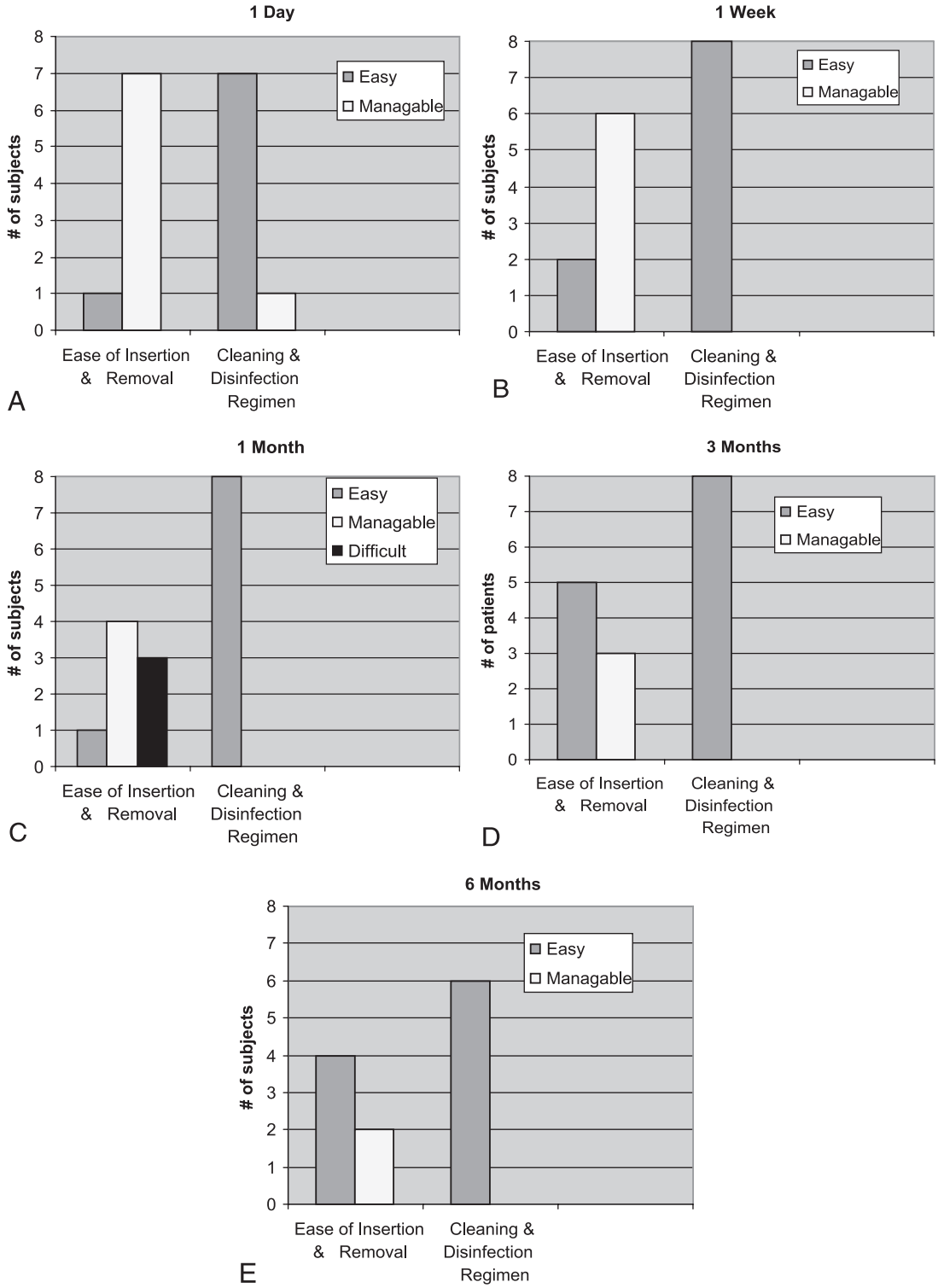

FIG. 3. In terms of Usability, ease of insertion and removal was considered the most difficult task at the study outset. On further questioning, most families felt that insertion of the lens was simple and that removal of the lens was itself the more difficult task. Difficulty with lens removal is what 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.

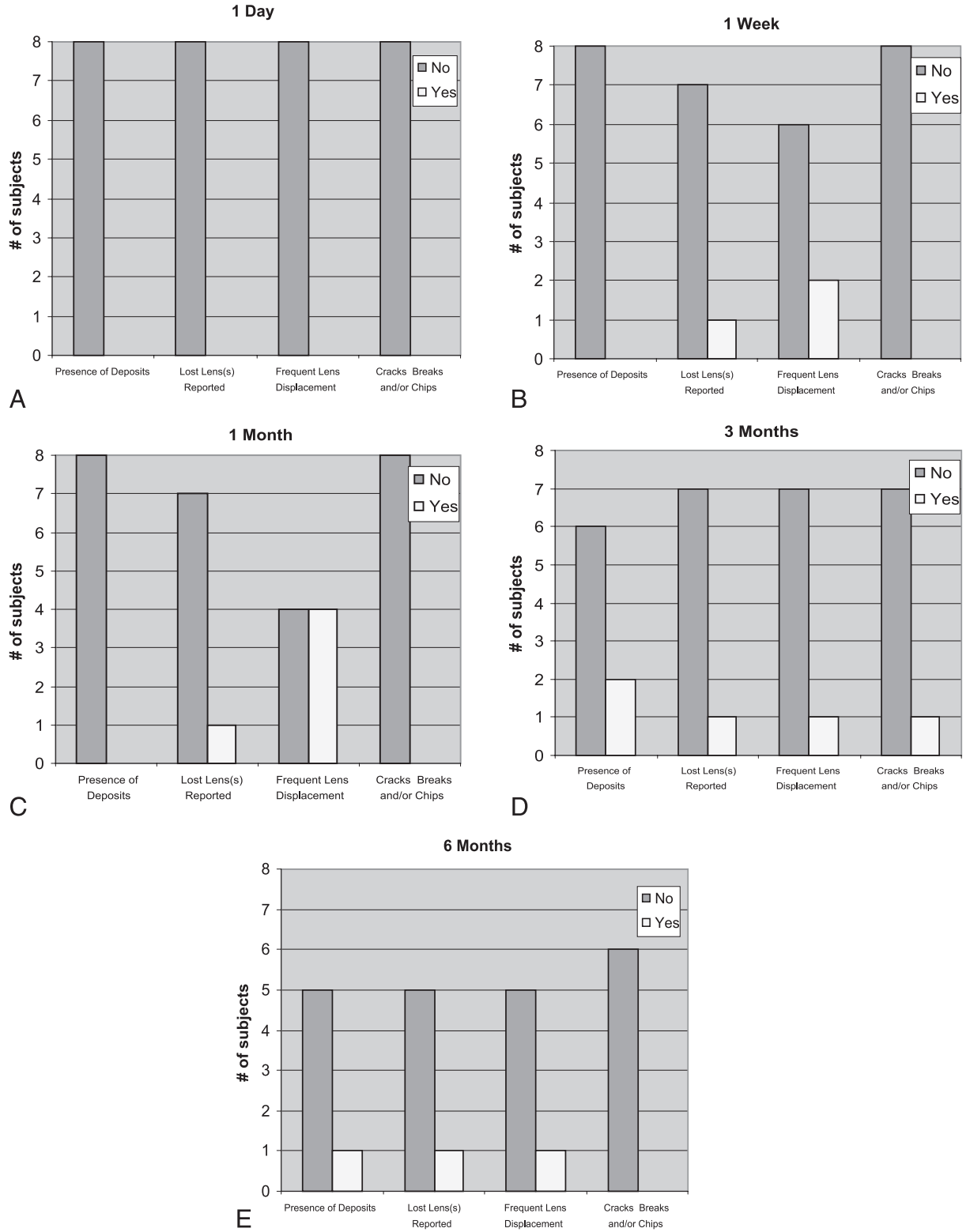

FIG. 4. Contact Lens Integrity was well maintained for all patients throughout the course of the study. Frequent lens displacement was the most cited complaint by the middle of the study, but the level of deposits, lens loss, cracks, breaks, and chips was minimal throughout the study.

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-

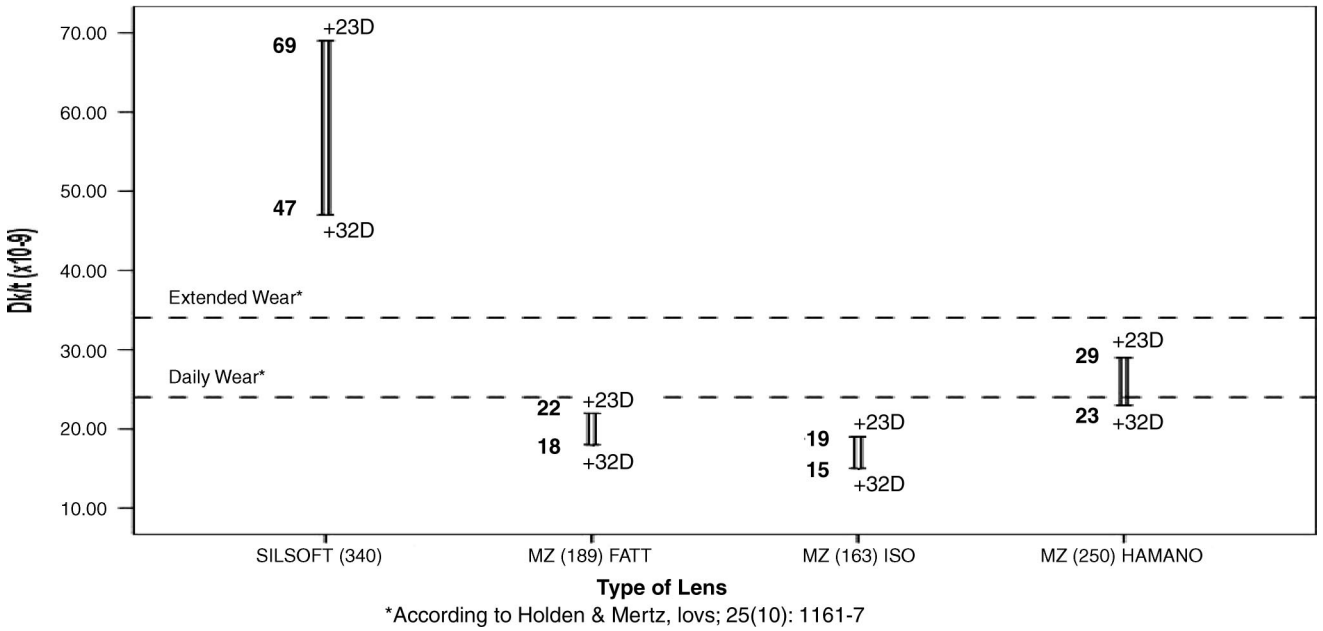

FIG. 5. Average oxygen transmissibility for lenses ranging in base curve from 7.9 to 7.5 and in power from +23 to +32 diopters respectively.

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. These values were chosen because they are a good reflection of the lens parameters used in the aphakic population. A comparison is made between Silsoft (Dk of 340), the current market leader for pediatric aphakia, and Menicon Z (Dk of 189, 163, or 250, depending on the method used to rate Dk).

Although neither the Silsoft nor the Menicon Z is a hydrogel lens, the Holden and Mertz study[25] 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 $87.0 \pm 3.3 \times 10^{-9}$. 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, $34.3 \pm 5.2 \times 10^{-9}$, is shown in Figure 5 (labeled Extended Wear). Also shown is the critical transmissibility value to prevent corneal edema under daily-wear conditions, $24.1 \pm 2.7 \times 10^{-9}$ (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

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, depending on the lens material used, thus making one question the level of oxygen delivery that is truly afforded to the cornea in the in vivo situation. The Dyna Z intralimbal design offers the option of flattening the edge profile in a stepwise fashion if needed to make adequate lens movement and good tear exchange easily achievable.

The large diameter of the Dyna Z intralimbal lens deserves particular mention because several families regarded it to be favorable when it came to lens insertion (Fig. 3). The author has found that families prefer the size and rigidity of the Dyna Z intralimbal design as compared to smaller rigid designs or silicone hydrogel lenses, the latter of which can fold and bend on themselves during insertion and removal. Removal of the lens was always the most difficult task for families to perform in the current study, but this is true regardless of the lens size or rigidity.

Also noteworthy is the impeccable contact lens integrity maintained throughout the course of extended-wear use with the combination Menicon Z lens material and Dyna Z design. Even with the high plus and thin edge design required by aphakic lenses, rarely did any of the patients experience a crack, break, or edge chip despite 6 months of use and sometimes forceful insertion and removal techniques by parents. Furthermore, the level of lens surface deposits was negligible (Fig. 4), even after a full week of extended wear. Only by the 3- to 6-month visit did some lenses start to show minimal surface buildup despite weekly cleaning.

In summary, it is hoped that this study has shown the usefulness of the Menicon Z contact lens as a safe and effective contact lens material for the treatment of infants and children requiring aphakic correction. Coupled with proper lens design, this hyper oxygen-permeable material offers all the advantages implicit with rigid lens wear while simultaneously providing sufficient corneal oxygenation at the lens powers and thicknesses demanded by newly aphakic eyes. Parents faced with the anxieties and difficulties 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.

Acknowledgements

The author thanks Al Vaske, NCLE and Ray McWherter of Lens Dynamics, Inc. for their contributions in the lens design and manufacture. Also, Randy Sakamoto, O.D., Ph.D. and Menicon Co., Ltd. are thanked for financing the cost of lenses for families. Michael B. Yang, M.D. is thanked for his helpful comments regarding data analysis and Stephanie Visjager, RN for her assistance in coordinating care for study participants.

REFERENCES

1. Drummond GT, Scott WE, Keech RV. Management of monocular congenital cataracts. *Arch Ophthalmol* 1989;107:45–51.
2. Ozbek Z, Durak I, Tulin BA. Contact lenses in the correction of childhood aphakia. *CLAO J* 2002;28:28–30.
3. Davis LJ. Complex refractive errors in pediatric patients: Cause management and criteria for success. *Optom Vis Sci* 1998;75:493–499.
4. Levin AV, Edmonds SA, Nelson LB, et al. Extended-wear contact lenses for the treatment of pediatric aphakia. *Ophthalmology* 1988;95: 1107–1113.
5. Newmann D, Weissman BA, Isenberg SJ, et al. The effectiveness of daily wear contact lenses for the correction if infantile aphakia. *Arch Ophthalmol* 1993;111:927–930.
6. Cutler SI, Nelson LB, Calhoun JH. Extended wear contact lenses in pediatric aphakia. *J Pediatr Ophthalmol Strabismus* 1985;22:86–91.
7. Garcia GE, Aucoin J, Gladstone G. Extended wear rigid gas permeable lenses used for correction of aphakia. *CLAO J* 1990;16:195–199.

8. Aasuri MK, Venkata N, Preetam P, et al. Management of pediatric aphakia with Silsoft contact lenses. *CLAO J* 1999;25:209–212.
9. Nelson LB, Cutler SI, Calhous JH, et al. Silsoft extended wear contact lenses in pediatric aphakia. *Ophthalmology* 1985;92:1529–1531.
10. Hong X, Himebaugh N, Thibos LN. On-eye evaluation of optical performance of rigid and soft contact lenses. *Optom Vis Sci* 2001;78:872–880.
11. Shaughnessy MP, Ellis FJ, Jeffery AR, et al. Rigid gas-permeable contact lenses are a safe and effective means of treating refractive abnormalities in the pediatric population. *CLAO J* 2001;27:195–201.
12. Dorronsoro C, Barbero S, Llorente L, et al. On-eye measurement of optical performance of rigid gas permeable contact lenses based on ocular and corneal aberrometrg. *Optom Vis Sci* 2003;80:115–125.
13. Benjamin WJ, Cappelli QA. Oxygen permeability (Dk) of thirty-seven rigid contact lens materials. *Optom Vis Sci* 2002;79:103–111.
14. Ichijima H, Imayasu M, Tanaka H, et al. Effects of RGP lens extended wear on glucose-lactate metabolism and stromal swelling in the rabbit cornea. *CLAO J* 2000;26:30–36.
15. Barr JT, Pall B, Szczotka LB, et al. Corneal endothelial morphology results in the Menicon Z 30-day continuous-wear contact lens clinical trial. *Eye Contact Lens* 2003;29:14–16.
16. Pall B, Barr JT, Szczotka LB, et al. Corneal thickness results in Menicon Z 30-day continuous wear and ACUVUE 7-day extended-wear contact lens clinical trial. *Eye Contact Lens* 2003;29:10–13.
17. Gleason W, Tanaka H, Albright RA, et al. A 1-year prospective clinical trial of Menicon Z (tisilfocon A) rigid gas-permeable contact lenses worn on a 30-day continuous wear schedule. *Eye Contact Lens* 2003;29:2–9.
18. Franzco AC, Johnson K, Martin F. Use of contact lenses to correct aphakia in children. *Clin Exp Ophthalmol* 2002;30:252–255.
19. Ma JJ, Morad Y, Mau E, et al. Contact lenses for the treatment of pediatric cataracts. *Ophthalmol* 2003;110:299–305.
20. Amos CF, Lambert SR, Ward MA. Rigid gas permeable contact lens correction of aphakia following congenital cataract removal during infancy. *J Pediatr Ophthalmol Strabismus* 1992;29:243–245.
21. Elie G. Gas permeable extended wear lenses: An excellent solution of aphakic patients. *CLAO J* 1986;12:51–53.
22. Poggio EC, Glynn RJ, Schein OD, et al. The incidence of ulcerative keratitis among users of daily-wear and extended-wear lenses. *N Engl J Med* 1989;321:779–783.
23. Schein OD, Glynn RJ, Poggio EC, et al. The relative risk of ulcerative keratitis among users of daily-wear and extended-wear soft contact lenses: A case control study. *N Engl J Med* 1989;321:773–778.
24. Pall B, Szczotka LB, Barr JT, et al. Comparing corneal thickness changes in 30-day continuous wear with the Menicon Z rigid gas permeable lens versus 7-day extended wear with the Acuvue hydrogel contact lens. *Invest Ophthalmol Vis Sci* 2001;42:S594.
25. Holden BA, Mertz GW. Critical oxygen levels to avoid corneal edema for daily and extended wear contact lenses. *Invest Ophthalmol Vis Sci* 1984;25:1161–1167.
26. Gardner HP, Fink BA, Mitchell LG, et al. The effects of high-Dk rigid contact lens center thickness, material permeability, and blinking on the oxygen uptake of the human cornea. *Optom Vis Sci* 2005;82:459–466.
27. Fink B, Smith B, Hill RM, et al. High Dk lowers risk of thickness. *Contact Lens Spectrum* 1995;10:23–24.