Myopia Progression During Three Years of Soft Contact Lens Wear

Adam Blacker*, G. Lynn Mitchell†, Mark. A. Bullimore‡, Bill Long§, Joseph T. Barr¶, Sally M. Dillehay**, Peter Bergenske††, Peter Donshik‡‡, Glenda Secor††, John Yoakum§§, and Robin L. Chalmers††

ABSTRACT

Purpose. To analyze the effect of lens material alone on myopia progression in a multi-center non-randomized prospective study of daily wear hydrogel and continuous wear silicone hydrogel contact lenses.

Methods. Refractive error data from completing subjects were collected during a 3-year study of 54 subjects wearing low-Dk/t hydrogel contact lenses for daily wear and 230 wearing silicone hydrogel contact lenses for up to 30 nights continuous wear. Univariate analysis of refractive error changes was first conducted on factors of lens type, age at baseline, and baseline refractive error. Multivariate analysis was then performed to control for potential confounders of age (categorical by decade and continuous), and baseline refractive error.

Results. Multivariate analysis showed that refractive error changes were significantly affected by lens type ($F_{11005}=78.2$, $p<0.001$, $R^2=0.218$) and subject age ($F_{11005}=131.2$, $p<0.001$, $R^2=0.319$) but not baseline refractive error ($F_{11005}=2.56$, $p=0.11$, $R^2=0.009$). The model's overall $R^2$ value is 0.376; the age-adjusted refractive error changes are $0.02$ D for the silicone hydrogel contact lens wearers and $-0.41$ D for the hydrogel contact lenses for the 3-year follow-up period.

Conclusions. Subject age and lens type significantly influenced the degree of myopic progression, with younger subjects and low-Dk/t hydrogel contact lens wearers increasing more during the study. The Lotrafilcon A silicone hydrogel lens material may contribute to less myopia progression in adult contact lens wearers.

(Optom Vis Sci 2009;86:1150–1153)

Key Words: myopia progression, silicone hydrogels, lotrafilcon A

For decades, myopia progression has been reported in adult low-Dk/t hydrogel contact lenses wearers1–3 and to a lesser degree in adults wearing silicone hydrogel lenses.4–6 In a 5-year retrospective study of 291 contact lens wearers aged 20 to 40 years, Bullimore et al. reported a mean progression of $-0.44 \pm 0.60$ D during the 5-year period, but found a range from $+1.88$ to $-2.75$ D, indicating a high degree of individual variability. In that study, myopic progression was greater in younger adult contact lens wearers and for those who began wearing spectacles at a later age.3 This and other studies also showed that the degree of myopia at baseline was not a contributing factor to the amount of myopic progression. Dumbleton et al. studied young adults primarily in their 20s for 9 months after initiation of extended wear and found that lower myopes showed significantly more myopic progression with extended wear of low transmissibility hydrogel contact lenses compared with those with higher refractive error.5 Clearly, quantifying the role of factors such as lens wearing schedule (daily or extended wear), lens material, subject age, and refractive status will help the research community to determine the importance of each in the changing refractive error of contact lens wearers.

The studies comparing myopic progression among low-Dk/t hydrogel and silicone hydrogel lens wearers have shown that the contact lens material also affects myopic progression, although the relative contribution of physical (lens modulus) vs. physiological (corneal oxygen supply) effects are not fully understood.4–7 The most recent of these studies, a 3-year non-randomized, prospective clinical study, compared clinical signs and symptoms in patients wearing lotrafilcon A silicone hydrogel contact lenses up to 30 nights at a time with those wearing low-Dk/t hydrogel contact lenses on a daily wear basis.6 Among the reported findings was a
comparison of change in refractive error. Because of a substantial difference in the mean baseline age of the groups wearing silicone hydrogel contact lenses and hydrogel contact lenses (38 vs. 23 years), the investigators elected to select two age-matched subsets, each of 36 patients (mean age of 27.9 years each). The age-matched subjects were selected by a masked investigator from among the lens wearers who completed the study. Consistent with other reports among randomized subjects that did not differ in age,5-7 the age-matched silicone hydrogel contact lens subset had an increase in myopia of −0.03 D, whereas the low-Dk/t hydrogel group increased in myopia by −0.40 D in the 3-year study (p = 0.007). Unfortunately, the two subgroups differed significantly in mean baseline refractive error as well, with the silicone hydrogel contact lens wearers entering the study with a refractive error of −3.59 ± 1.99 D compared with −2.10 ± 1.78 D for the low-Dk/t hydrogel contact lens wearers.

Because degree of myopia has been shown in some studies to affect myopia progression in adult contact lens wearers, an analysis is required to determine the role of lens material alone. To accomplish this, the data from the 3-year study6 were reanalyzed using strategies that allowed both age and baseline refractive error to be controlled. By using a multivariate analysis, data from all subjects in the study could be used, and not just a limited subset.

METHODS

Details of the conduct of the study have previously been described in detail.8 Briefly, in a non-randomized, prospective clinical study, 19 clinical sites in the United States enrolled a total of 398 subjects, of whom 284 completed the 3-year study. Each site had a target of 15 subjects to wear silicone hydrogel contact lenses (lotrafilcon A, CIBA Vision, Duluth, GA) for up to 30 nights (monthly replacement) and five subjects each to wear any low-transmissibility (Dk/t) hydrogel contact lenses replaced every 2 weeks, but worn on a daily wear basis. Subjects were not randomized to treatment groups, rather investigators were instructed to select patients for each group based on their usual and customary practices. Subjects completed informed consent documents and were then examined and refitted with either type of contact lenses with the intention of observing them up for 3 years.

At the dispensing visit and at each follow-up visit, biomicroscopy signs and symptoms were recorded. Refractive error was measured at baseline and annually for 3 years using standard clinical techniques and without cycloplegia.

Data Analysis

Refractive error changes were first analyzed as a factor of lens type, age at baseline, and baseline refractive error using univariate analysis. Refractive error changes were then analyzed using multivariate analysis to control for potential confounding factors of age and baseline refractive error. Age was analyzed as a continuous variable and as a categorical variable by decade of life in two separate analyses. Finally, subjects were stratified by decade and refractive error changes analyzed again using multivariate analysis.

RESULTS

A total of 398 subjects were enrolled for this study, with silicone hydrogel group comprising 317 subjects and 81 subjects in the low-Dk/t daily-wear group. The characteristics of the 284 subjects (71.4%) who completed the 3-year study are summarized in Table 1.

During the course of the study, the silicone hydrogel wearers had a mean reduction in myopic refractive error of +0.10 ± 0.60 D compared with a mean myopia progression of −0.75 ± 0.76 D in the low-Dk/t hydrogel wearers. The silicone hydrogel wearers were, on average, 15-year older than the low-Dk/t hydrogel group (38 ± 11 vs. 23 ± 12 years) and had more myopia at baseline (−3.36 ± 2.71 vs. −1.79 ± 1.74 D). Subject age significantly influenced the degree of myopic progression (F = 131.2, p < 0.001, R2 = 0.319), with younger subjects increasing more during the study (Fig. 1). Univariate analysis demonstrated that refractive error changes were significantly affected by lens type (F = 78.2, p < 0.001, R2 = 0.218) but not baseline refractive error (F = 2.56, p = 0.11, R2 = 0.009). Interactions between refractive error (as a continuous variable) and lens type were investigated and found to be non-significant (p > 0.10).

TABLE 1.
The characteristics of the patients completing the 3-year study

<table>
<thead>
<tr>
<th></th>
<th>Silicone hydrogel lens wearers</th>
<th>Low-Dk/t lens wearers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects completing study</td>
<td>230</td>
<td>54</td>
</tr>
<tr>
<td>Baseline age (years)</td>
<td>38 ± 11</td>
<td>23 ± 12</td>
</tr>
<tr>
<td>Baseline age (decades)</td>
<td></td>
<td></td>
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<tr>
<td>10–19 years</td>
<td>13 (5.6%)</td>
<td>30 (55.6%)</td>
</tr>
<tr>
<td>20–29 years</td>
<td>32 (13.9%)</td>
<td>11 (20.4%)</td>
</tr>
<tr>
<td>30–39 years</td>
<td>82 (35.7%)</td>
<td>5 (9.3%)</td>
</tr>
<tr>
<td>&gt;40 years</td>
<td>103 (44.8%)</td>
<td>8 (14.8%)</td>
</tr>
<tr>
<td>Baseline refractive error (spherical equivalent in D)</td>
<td>−3.36 ± 2.71</td>
<td>−1.79 ± 1.74</td>
</tr>
<tr>
<td>Mean change in refractive error (spherical equivalent in D)</td>
<td>+0.10 ± 0.60</td>
<td>−0.75 ± 0.76</td>
</tr>
</tbody>
</table>

FIGURE 1.
Mean change in refractive error in 3 years. Error bars show the 95% confidence interval (±1.96 × standard error of the mean) in each group and the number of subjects is shown in parentheses at the top.
low-Dk hydrogel lenses, subjects wearing lotrafilcon A silicone hydrogel lenses for up to 30 night continuous wear had significantly less myopic progression than in those wearing low-Dk/t hydrogel lenses on a daily wear basis, even after controlling for baseline refractive error and age. Controlling for age and baseline refractive error resulted in a difference in refractive error change of 0.42 D between the two groups across 3 years of follow-up. The higher myopic shifts in silicone hydrogel lens wearers were observed in subjects in their teens. Myopic changes of > 1.00 D were observed in the teenage low-Dk/t lens wearers, and these changes remained high at nearly 0.50 D through age 39.

The lower rate of myopia progression associated with silicone hydrogel contact lens use compared with use of low-Dk/t hydrogel lenses in this study is consistent with previous reports. In a 9-month randomized clinical trial, Dumbleton et al. compared refractive error changes in patients at least 18 years wearing lotrafilcon A silicone hydrogel lenses for up to 30 nights with those wearing low-Dk/t lenses for up to 6 nights. The extended wear low-Dk/t group demonstrated an increase in myopia of −0.30 D in 9 months compared with no change in the silicone hydrogel group who wore lenses for up to 30 nights. The larger change in refractive error with low-Dk/t lenses in that 9-month study may be due to the overnight wear schedule. It is possible that the 0.42 D increase in myopia among the low-Dk/t lens wearers in the current study may have taken place early in the 3-year period. In the initial 6 months of a 12-month overnight wear comparison study, Jalbert et al. found a significant myopic shift in eyes wearing low-Dk/t hydrogel lenses on a six night extended wear basis (mean = −0.23 ± 0.36 D) compared with a significant hyperopic shift in eyes wearing silicone hydrogel lenses for up to 30 nights (mean = +0.18 ± 0.33 D). The refractive error changes were associated with corresponding changes in corneal curvature in that study, and the authors speculated that the flattening of corneal curvature may be due to mechanical effects such as may be seen with rigid lenses. Other support for the role of mechanical flattening can be found in a report by Mountford,9 in which significant changes in refractive error and corneal topography were noted in a large group of hyperopic patients wearing silicone hydrogel lenses on an extended

**DISCUSSION**

In this study, that compared continuous wear of up to 30 nights of high-Dk/t lotrafilcon A silicone hydrogel lenses vs. daily wear of
wear basis. Bergenske et al.\textsuperscript{10} have also demonstrated change in curvature after just one night of overnight wear with both inverted and normally inserted lenses.

When the response to lens wear is stratified by age group, we also find similar results to earlier studies of low-Dk/t hydrogel lenses. The approximate 1 diopter increase in myopic refractive error among the small group of teens wearing low-Dk/t lenses in this study (Fig. 1) is remarkably similar to the cohort of soft contact lens wearers studied for 3 years by Horner et al.,\textsuperscript{11} who showed a 1 diopter change in spherical component during that time period. Between groups who wore the different lens types in this study, the difference in the increase in myopia during 3 years was 0.75 D, an amount that is certainly of clinical significance. Another study of adolescents showed an increase of 0.75 D myopia in 1 year of daily hydrogel contact lens wear compared with an annual 0.25 D increase in myopia for teenaged spectacle wearers that was attributed primarily to a change in corneal curvature.\textsuperscript{12}

Another group of United Kingdom subjects aged 18 to 25 were studied by Santodomingo-Rubido et al.\textsuperscript{4} In that study, the 45 young adults wore silicone hydrogel lenses for 18 months in daily or continuous wear and their myopia increased significantly during time, with no significant differences between lens types or wear regimen. The continuous wear silicone hydrogel wearers in that study increased in myopia by an average of approximately 0.20 D; slightly higher than the increase in the current study for the group aged from 20- to 29-year old, most likely due to the young age of the subjects in the UK study.

There are a number of limitations to the current study. It was not designed specifically to compare refractive error changes between users of continuous wear silicone hydrogel lenses and daily wear hydrogel lenses. Although prospective in nature, the study was not a randomized clinical trial, but rather a postmarket clinical study. As a result, the two lens groups differed significantly in age and refractive error, with older contact lens wearers with higher refractive error being fit with silicone hydrogel lenses. This is likely due to patient selection on the part of the practitioners, who may be more likely to consider silicone hydrogel lens for continuous wear in older adults or among patients who have been wearing low-Dk/t hydrogel lenses for many years. They may also have considered that the benefit of higher oxygen supply was greater for patients with higher lens prescriptions. In addition, patients with higher refractive errors may be more interested in continuous wear lenses and more likely to request them. The non-random nature of assigning patients to contact lens may have also introduced other biases, which were not measured and, therefore, cannot be quantified. The refractive error measurements were not made under cycloplegia and a range of objective and subjective techniques may have been employed by the clinical investigators. Similarly, ocular components were not measured, notably axial length. Finally, there were relatively few patients in the daily wear hydrogel group, although the progression is similar to that reported in a larger sample of adult hydrogel lens wearers.\textsuperscript{8}

CONCLUSIONS

In a reanalysis of a 3-year study data, continuous wear of lotrafilcon A lenses for up to 30 nights resulted in significantly less myopia progression as compared to daily wear of low-Dk/t hydrogel lenses when controlling for initial refractive error and age. Lotrafilcon A silicone hydrogel lenses appear to have little or no effect on the normal development of refractive error.

ACKNOWLEDGMENTS

This work was supported by CIBA Vision, a Novartis company. Additional analysis supported in part by grants T35-EY07151; R01-EY012598; and R24-EY014792 from the National Eye Institute, National Institutes of Health, Bethesda, MD.

Received February 5, 2008; accepted May 29, 2009.

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Mark A. Bullimore
The Ohio State University
College of Optometry
338 W 10th Avenue
Columbus, Ohio 43210
e-mail: bullimore.1@osu.edu