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Myopia Progression over Three Years of Soft Contact Lens Wear

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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 was 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 ($F = 78.2$, $p < 0.001$, $R^2 = 0.218$) and subject age ($F = 13.1.2$, $p < 0.001$, $R^2 = 0.319$), but not baseline refractive error ($F = 2.56$, $p = 0.11$, $R^2 = 0.009$). 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.

Keywords

myopia progression; silicone hydrogels; lotrafilcon A

For decades myopia progression has been reported in adult low Dk/t hydrogel contact lenses wearers [1–3] and to a lesser degree in adults wearing silicone hydrogel lenses. [4–6] In a five-year retrospective study of 291 contact lens wearers aged 20 to 40 years, Bullimore and co-workers reported a mean progression of −0.44 ± 0.60 D during the 5 year period, but found a

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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 and co-workers 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 transmissibililty 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 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 contact lens material also affects myopic progression, although the relative contribution of physical (lens modulus) versus 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.

Since 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. In order to accomplish this, the data from the 3-year study [6] 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 6, [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 following 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.

Over 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 years 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 ($F = 13.1.2$, $p < 0.001$, $R^2 = 0.319$), with younger subjects increasing more during the study (Figure 1). Univariate analysis demonstrated that refractive error changes were significantly affected by lens type ($F = 78.2$, $p < 0.001$, $R^2 = 0.218$) but not baseline refractive error ($F = 2.56$, $p = 0.11$, $R^2 = 0.009$). Interactions between refractive error (as a continuous variable) and lens type were investigated and found to be non-significant ($p > 0.10$).

Table 2 shows the results of the first multivariate analysis treating age as a continuous variable. In this first multivariate model, lens type and age both had a significant effect on change in refractive error, but baseline refractive error did not. There was no interaction between age and lens type. The R^2 value for this model is 0.376 and the age-adjusted refractive error changes are +0.02 D for the silicone hydrogel lens wearers and −0.41 D for the low Dk/t hydrogel wearers.

Table 3 shows the results of the second multivariate analysis treating age (in decades) as a categorical variable. Lens type and age were again both significant and baseline refractive error was not. There was no interaction between age and lens type. The R^2 value for this model is 0.322.

The final series of multivariate analyses that stratify patients by decade are shown in Table 4. Lens type had a significant effect on refractive error changes in the youngest two age groups and approached significance in the third age group. In the group of 10–19 year old patients, the adjusted refractive error change was −0.35D for the silicone hydrogel lens wearers and −1.05D for the low Dk/t hydrogel wearers. Among the 20–29 and 30–39 year old patients, there was little refractive error change among the silicone hydrogel lens wearers (−0.05D and −0.01D respectively). In contrast, the adjusted change for low Dk/t lens wearers remained near half a diopter in both age subgroups (−0.46D and −0.45D). Interestingly, baseline refractive error had a significant effect on refractive error changes in the 30–39 year olds and age had a significant effect on refractive error changes in the over 40 year old group, with myopic regression in silicone hydrogel wearers over age 40. As would be expected with the onset of presbyopia, the adjusted refractive error change in the oldest age subgroup was in a hyperopic direction regardless of lens type. Older silicone hydrogel contact lens wearers adjusted change was +0.28D while it was +0.12 D for low Dk/t lens wearers over age 40.

DISCUSSION

In this study that compared continuous wear of up to 30 nights of high Dk/t lotrafilcon A silicone hydrogel lenses versus daily wear of 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 more than 1.00 D were observed in the teenage low Dk/t lens wearers and these changes remained high at nearly 0.50D through age 39.

The lower rate of myopia progression associated with silicone hydrogel contact lens use compared to use of low Dk/t hydrogel lenses in this study is consistent with previous reports. In a nine-month randomized clinical trial, Dumbleton and co-workers compared refractive error changes in patients at least 18 years of age 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 six months of a twelvemonth overnight wear comparison study, Jalbert found a significant myopic shift in eyes wearing low Dk/t hydrogel lenses on a 6 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, 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 wear basis.[9] Bergenske and co-workers have also demonstrated change in curvature after just one night of overnight wear with both inverted and normally inserted lenses.[10]

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 (Figure 1) is remarkably similar to the cohort of soft contact lens wearers studied for 3 years by Horner and co-workers, who showed a 1 diopter change in spherical component during that time period.[11] Between groups who wore the different lens types in this study, the difference in the increase in myopia over 3 years was 0.75D, an amount that is certainly of clinical significance. Another study of adolescents showed an increase of 0.75 D myopia in one year of daily hydrogel contact lens wear compared to an annual 0.25 D increase in myopia for teenaged spectacle wearers that was attributed primarily to a change in corneal curvature.[12]

Another group of United Kingdom subjects aged 18 to 25 were studied by Santodomingo-Rubido and co-workers.[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 over 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 years 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. Though prospective in nature, the study was not a randomized clinical trial, but rather a post-market 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. Likewise 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.[3]

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 whjen controlling for initial refractive error and age were controlled in the data analysis. Lotrafilcon A silicone appear to have little or no effect on the normal development of refractive error.

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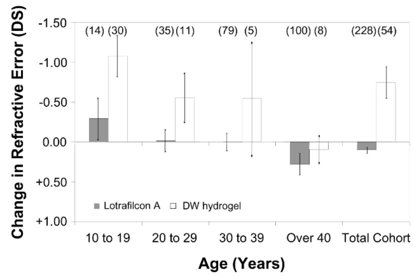

Figure 1.

Mean change in refractive error in 3 years by age. 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.

Table 1

The characteristics of the patients completing the three-year study.

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

Table 2

Multivariate analysis of the possible factors affecting refractive error changes treating age as a continuous variable (R^2 = 0.376).

Variable	F	P
Baseline age (years)	**70.18**	**<0.001**
Baseline refractive error	2.10	0.15
Lens Type	**18.82**	**<0.001**

Bold indicates significant associations.

Table 3

Multivariate analysis of the possible factors affecting refractive error changes treating age as a categorical variable ($R^2 = 0.322$).

Variable	F	P
Baseline age (decade)	**14.03**	**<0.001**
Baseline refractive error	0.51	0.47
Lens Type	**21.57**	**<0.001**

Bold indicates significant associations.

Table 4

Multivariate analyses of the possible factors affecting refractive error changes, stratifying patients by decade.

Decade	Variable	F	P	R^2
10–19 years	Age	3.02	0.090	0.325
	Baseline refractive error	1.67	0.204	
	Lens type	**7.19**	**0.011**	
20–29 years	Age	0.14	0.706	0.272
	Baseline refractive error	2.90	0.096	
	Lens type	**5.42**	**0.025**	
30–39 years	Age	2.64	0.108	0.180
	Baseline refractive error	**9.84**	**0.002**	
	Lens type	3.77	0.056	
40 years or older	**Age**	**26.30**	**<0.001**	0.207
	Baseline refractive error	0.50	0.481	
	Lens type	0.49	0.485	

Bold indicates significant associations.