THE STABILITY OF DRYNESS SYMPTOMS WITH SILICONE HYDROGEL CONTACT LENSES OVER 3 YEARS

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ABSTRACT

Purpose: To assess the stability of dryness symptoms among patients refit from low Dk/t hydrogels to silicone hydrogel (SiHy) contact lenses in a 3year study. A second purpose was to determine if early dryness symptoms with SiHy lenses were predictive of retention in the study.

Methods: 278 hydrogel lens wearers were dispensed in the 3 year study to wear lotrafilcon A (NIGHT & DAY, CIBA Vision, Duluth, GA) SiHy contact lenses for continuous wear of up to 30 nights. Data from questionnaires at baseline, 1 week and 3 years captured the frequency and intensity of dryness symptoms during and at the end of the wearing day. Responses of subjects at 1 week and 3 years were compared to their baseline response by Bowker's test of symmetry and the median change in response was tested with Wilcoxon Sign Rank test. The proportion of subjects with frequency > "sometimes" and severity > "mild" is shown for descriptive purposes.

Results: There was a significant decrease in the frequency of dryness during the day from baseline to 1 week and 3 years from 57.2% to 33.1% after 1 week and to 28.8% after 3 years (p=<0.0001, Wilcoxon all comparisons). Frequency of end of the day dryness also decreased significantly from 61.1% at baseline to 41.0% after 1 week and 35.9% after 3 years (p<0.0001, Wilcoxon all comparisons). After the improvement from baseline to 1 week, the proportion of subjects with dryness symptoms was stable throughout the 3-year study. Frequency and severity of dryness at the 1 week visit were significantly associated with discontinuation from the study (during the day: frequency p=0.007, severity p=0.017; end-of-day frequency p=0.002, severity 0.003, Chi-square).

Conclusions: Dryness symptoms improved after 1 week of refitting with lotrafilcon A and remained substantially improved through 3 years. The continued presence of dryness symptoms at 1 week was associated with discontinuation from the study. In many lens wearers, refitting with SiHy lenses reduced the frequency and severity of dryness symptoms that were present during low Dk/t hydrogel lens wear.

<u>INTRODUCTION</u>

At the 2003 AAO Annual Meeting, results of post hoc analysis through 6 months from this 3 year, prospective trial showed that there were short term improvements in the frequency (p<0.0001, Wilcoxon sign test) and severity (p<0.0001, Wilcoxon sign test) of dryness symptoms among adapted HEMA wearers who changed to lotrafilcon A silicone hydrogel lenses.1 The findings also reported that patients with less severe symptoms of dryness during the day had higher levels of overall satisfaction (p<0.0001, Kruskal-Wallis test) and comfort (p<0.0001, Kruskal-Wallis test). Since that time, post hoc analyses of several trials with lotrafilcon A and B lenses from up to 30 night continuous wear and daily wear consistently show short term improvement in dryness during the day and at the end of the day for adapted HEMA wearers who change to either material.²

	Visits	Dryness Symptoms		Wilcox on Signed-
Trial & Polymer	A nalyzed	Analyzed	N	R ank R esults
3 Year US Trial	Baseline &	During the day	292	p<0.0001
Lotrafilcon A	1 M onth	At end of day	292	p=0.0020)
1 Month Asian DW US Trial	Baseline &	During the day	81	p<0.001
Lotrafilcon A	1 M onth	At end of day	81	p=0.0017
1 M onth Italy DW Trial	Baseline &	During the day	60	p<0.0001
Lotrafilcon A	1 M onth	At end of day	60	p<0.0001
1 Month Nordic DW Trial	Baseline &	During the day	96	p<0.0001
Lotrafilcon A	1 M onth	At end of day	96	p<0.0001
2 Week DW US Trial	Baseline &	During the day	750	p<0.0001
Lotrafilcon B	2 Weeks	At end of day	750	p<0.0001
Pooled		During the day	1279	p<0.0001
		At end of day	1279	p<0.0001

With the completion of the 3 year trial, the data were re-analyzed to examine the long term stability of dryness symptoms and to determine if early symptoms that persisted when patients were changed to lotrafilcon A might be a predictor of discontinuation.

<u>SUBJECTS</u>

317 subjects were enrolled with informed consent for this 3 year trial. Two hundred seventy eight (278) were adapted, HEMA wearers who were refitted and dispensed to wear lotrafilcon A (NIGHT & DAY®, CIBA Vision Corp., Duluth, GA, USA) silicone hydrogel contact lenses in this 3 year trial. The profile of enrolled subjects is shown in Table 1.

Table 1. Profile of Adapted HEMA Wearers **Enrolled in 3 Year Trial** Gender 185 (67%) 93 (33%) **Age (years)** Mean ± SD 37.4 ± 10.9 Minimum - Maximum 13 - 72 **Years of Lens Wear** 14.8 ± 8.0 Mean ± SD 0.75 - 39 Minimum - Maximum Spectacle Refraction 5% Mean Spherical Equivalent -3.69 ± 2.52 DS OD: Mean Sph ± SD -3.80 ± 2.57 DS OS: Mean Sph ± SD Smoker 29 (10%) 249 (90%)

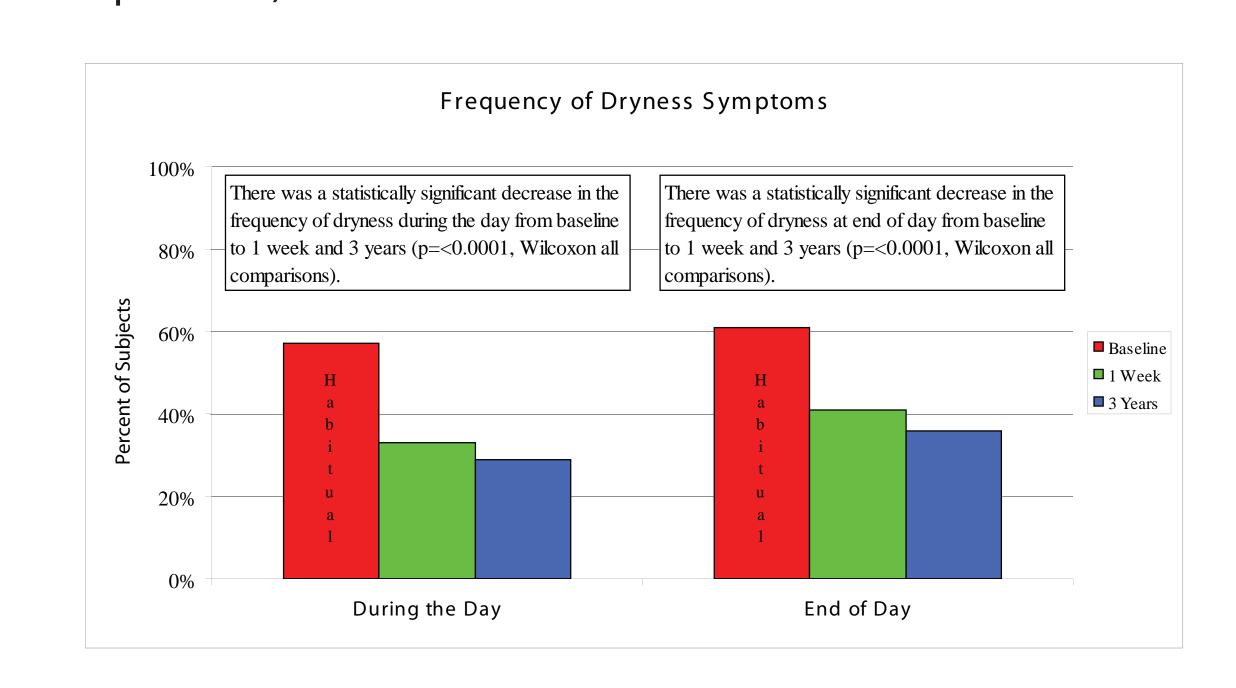
SUBJECT DATA

Subjects attending scheduled follow-up visits completed selfadministered questionnaires with a profile of symptoms that include frequency and intensity of dryness during the day and at the end of day. The symptoms were scored using ordinal scales as summarized in Table 2.

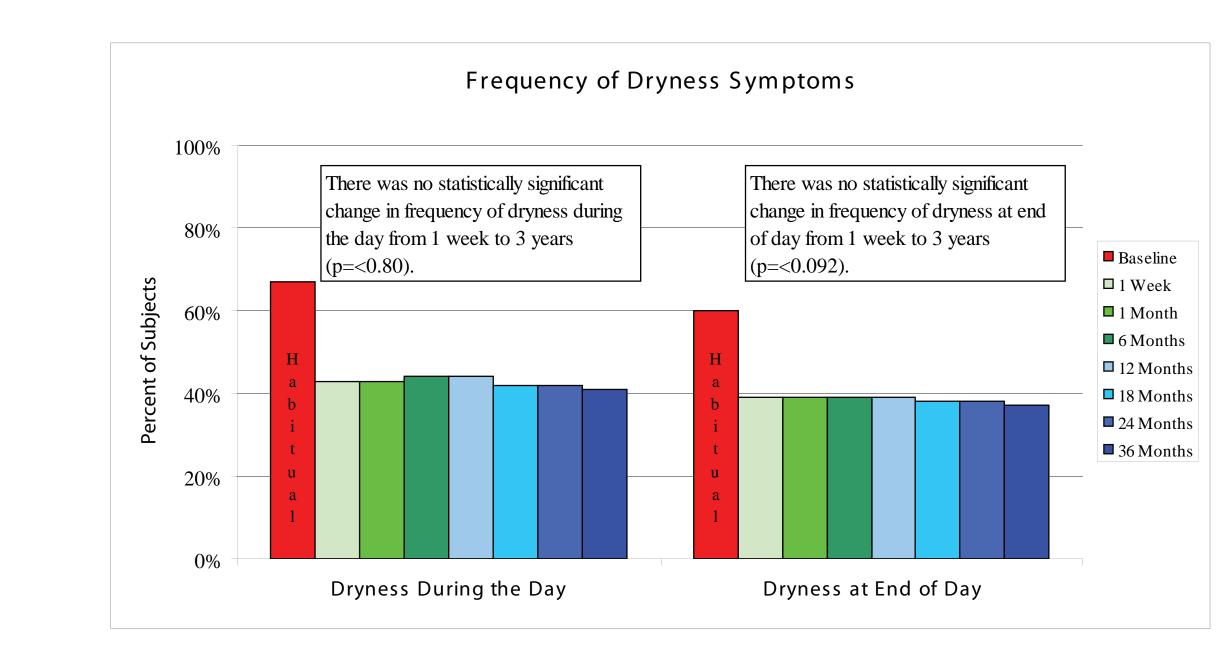
Frequency		Intensity		
Response	Score	Response	Score	
None	0	None	0	
Sometimes	1	Mild	1	
Often	2	Moderate	2	
Everyday	3	Severe	3	

RESULTS

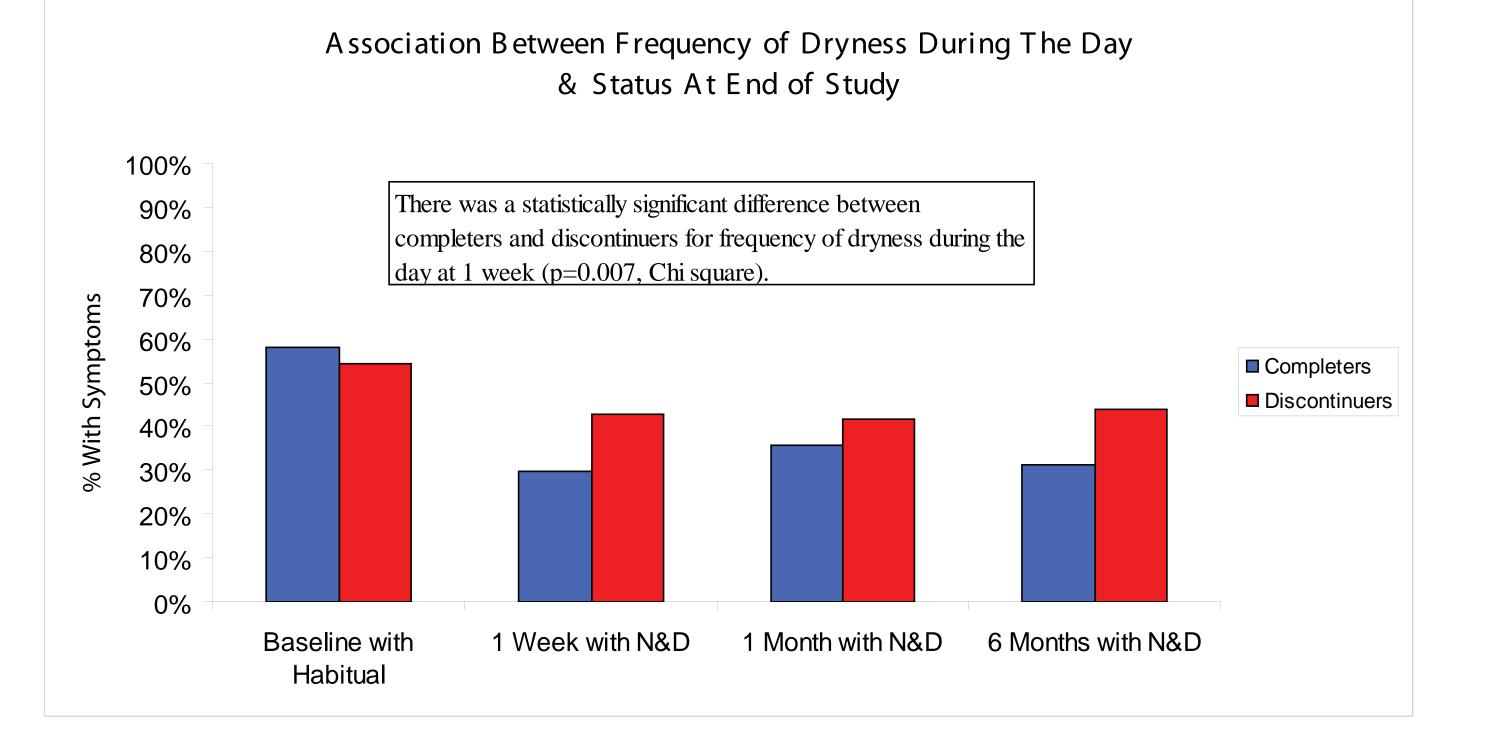
- There was a statistically significant decrease in the reported frequency of dryness during the day from baseline to 1 week and 3 years from 57.2% to 33.1% after 1 week and to 28.8% after 3 years (p=<0.0001, Wilcoxon all comparisons).
- There was also a statistically significant decrease in the reported frequency of end of the day dryness from 61.1% at baseline to 41.0% after 1 week and 35.9% after 3 years (p<0.0001, Wilcoxon all comparisons).

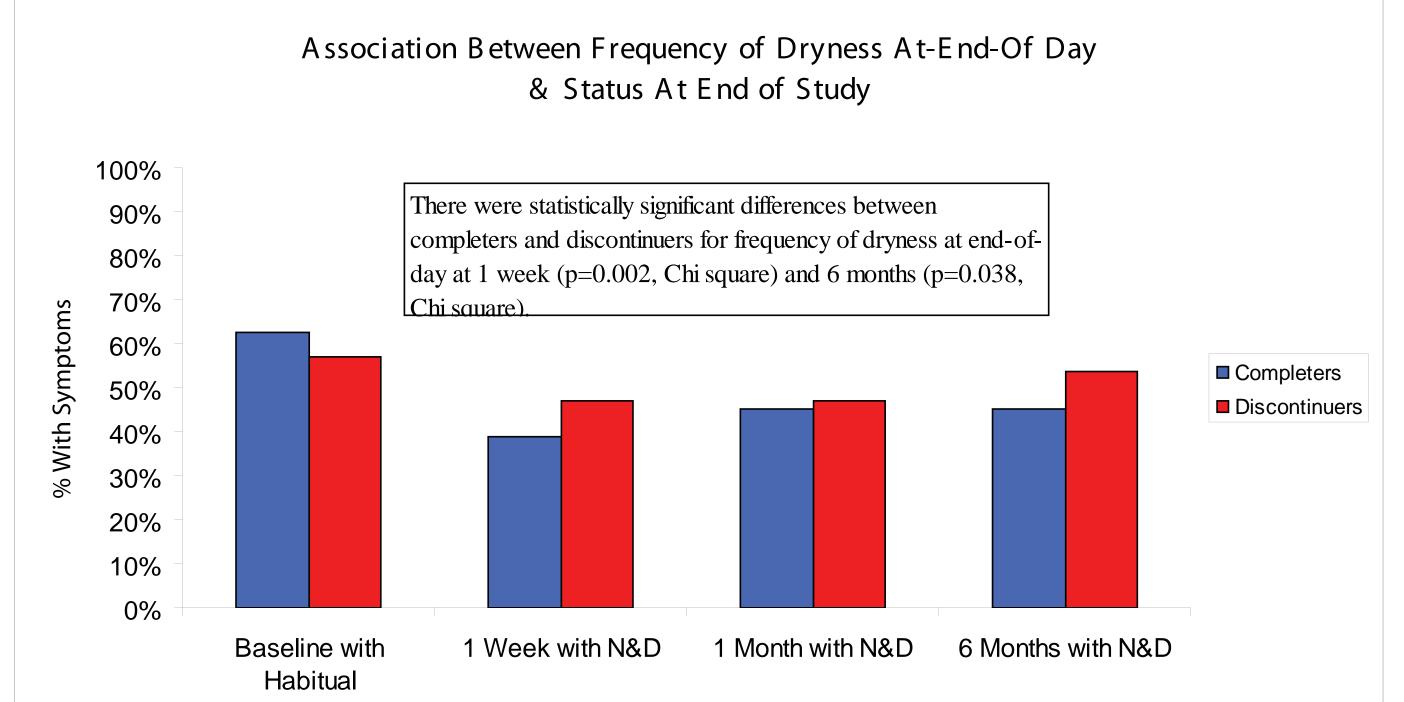


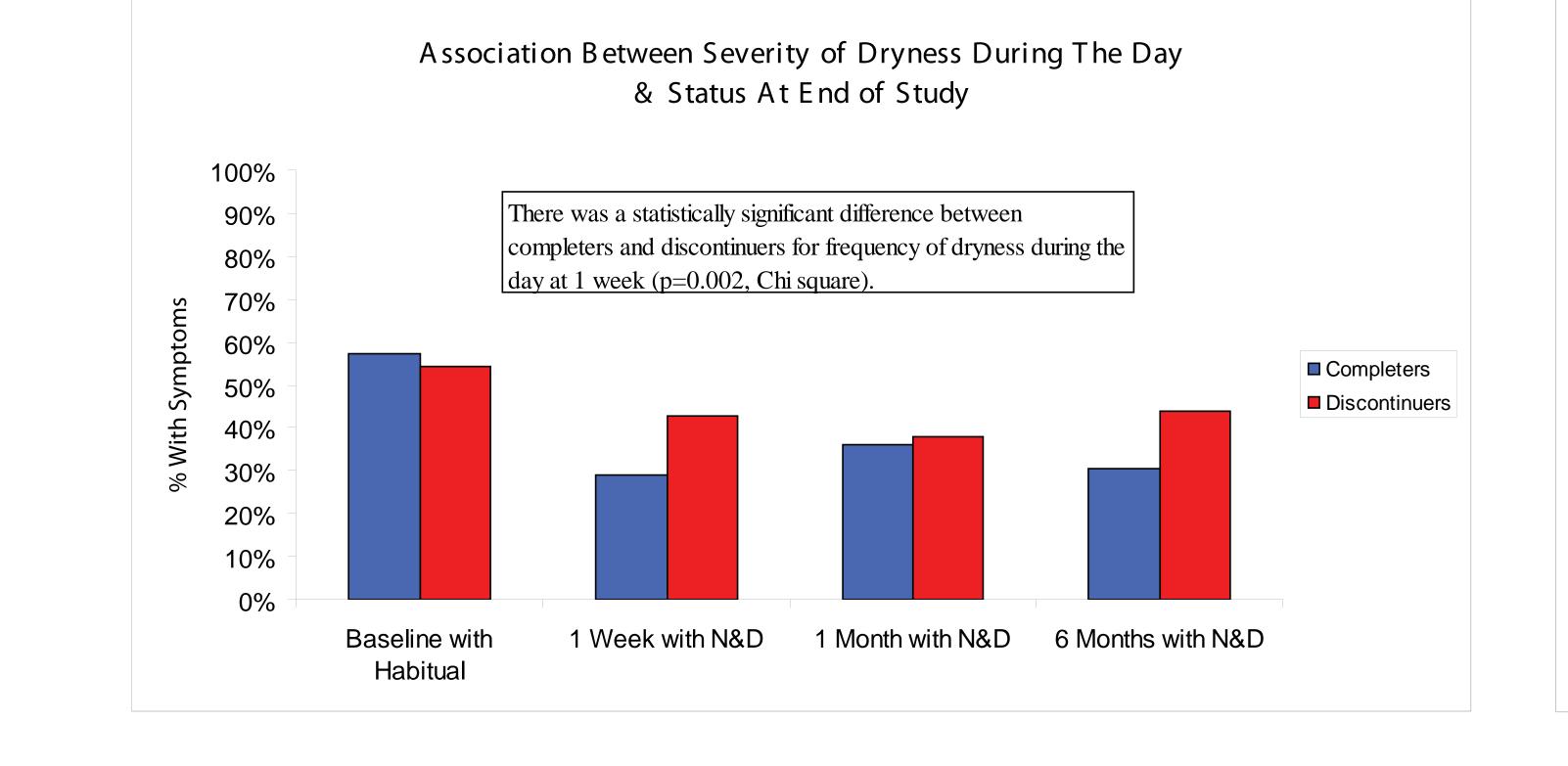
 After the improvement from baseline to 1 week, the proportion of subjects with dryness symptoms was stable throughout the 3-year

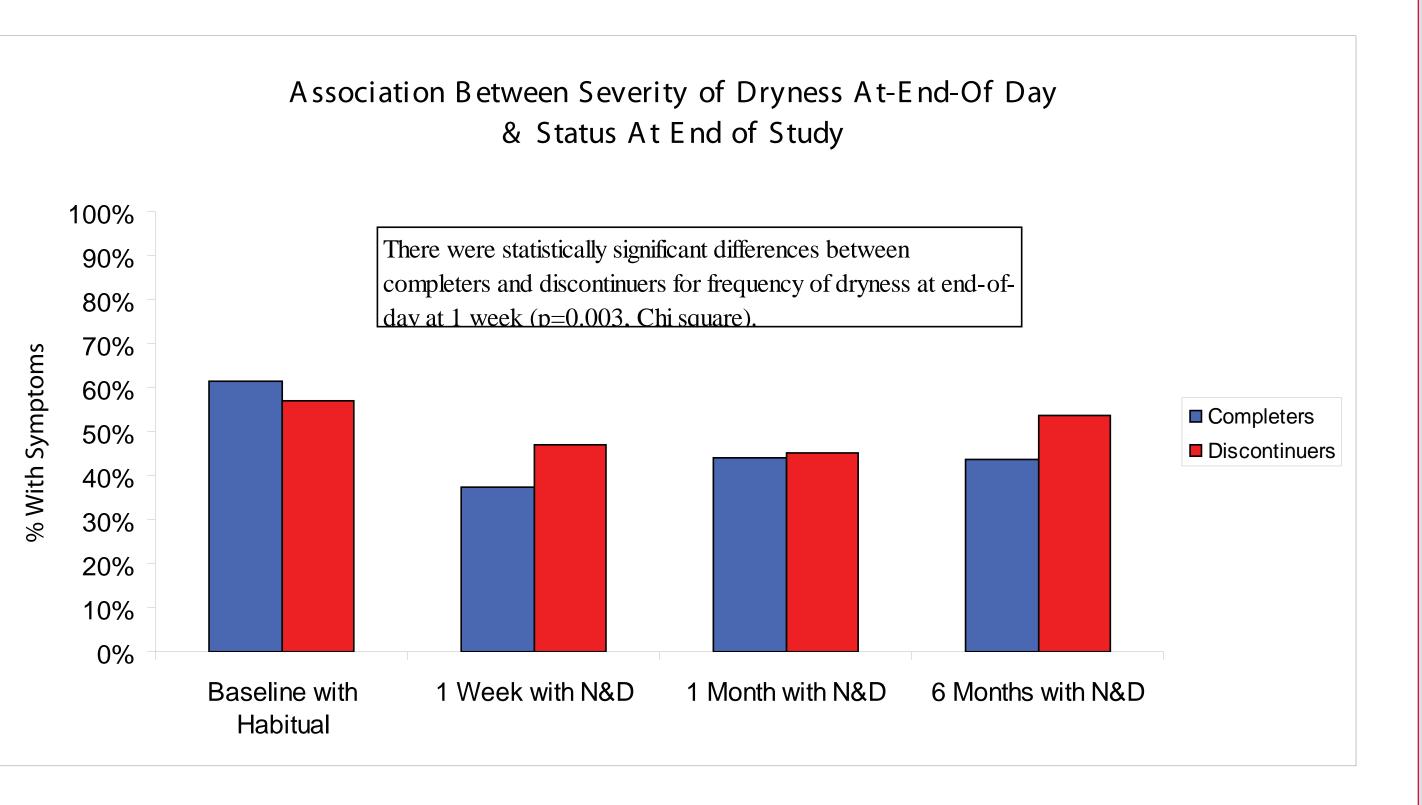


• Frequency and severity of dryness at the 1 week visit were significantly associated with discontinuation from the study (during the day: frequency p=0.007, severity p=0.017; end-of-day frequency p=0.002, severity 0.003, Chi-square).









ANALYSIS

- Symptom scores at 1 week, and 3 years were compared to their baseline response by Bowker's test of symmetry and the change in response was tested with the Wilcoxon Sign Rank test.
- Post-hoc comparisons were applied to test the stability of the dryness symptoms by excluding baseline reports and testing for
- significant changes in the mean overall score of DD and EOD (product of frequency X severity) across the remaining study visits.
- The influence of baseline reports of dryness and dryness reported at early visits on discontinuation from the study was conducted by testing the frequency and intensity of dryness responses by study status (completer vs. discontinued subject) using Chi-square analyses.

CONCLUSIONS

- In this large group of subjects, dryness symptoms that were present with their hydrogel lenses improved after 1 week of refitting with lotrafilcon A and that improvement was maintained through 3 years of lens wear.
- The continued presence of dryness symptoms at 1 week was significantly associated with discontinuation from the study.
- In many lens wearers, refitting with silicone hydrogel lenses reduced the frequency and severity of dryness symptoms that were present during hydrogel lens wear.

REFERENCES

- 1. Schafer J, Barr JT, Mack C: A Characterization of Dryness Symptoms with Silicone Hydrogel Contact Lenses. Optometry and Vision Science 80 (12S), 2003, p 87.
- 2. Long B, Dillehay SM, McNally J, Barr JT, Bergenske P, Donshik P, Secor G, Yoakum J. Improvement in subjective dryness among adapted soft contact lens wearers when dispensed in a lotrafilcon soft contact lens. British Contact Lens Association Clinical Conference & Exhibition 2006, p 81.