

# Change in Myopia Over Three Years Among Wearers of Continuous Wear Silicone Hydrogel Lenses and Daily Wear Hydrogel Contact Lenses

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## Purpose:

Earlier studies with continuous wear (CW) of silicone hydrogel lenses showed that users had a lower rate of myopic progression compared to subjects who wore hydrogel lenses on a 6 night extended wear (EW) schedule. The purpose of this study was to compare the long-term results for lotrafilcon A CW lens wear compared to hydrogel daily wear (DW).

## Methods:

Subjects were enrolled in a 3-year non-randomized trial in which investigators could choose to place a subject in CW with lotrafilcon A lenses or 2 weekly replacement DW with hydrogel lenses. Age matched subsets were randomly selected by a masked investigator from among the CW and DW subjects who completed the study. Baseline and 3-year spectacle subjective refractive errors were compared to test whether there was a significant difference in the change in refractive error over time.

## Results:

36 CW subjects aged  $27.9 \pm 12.4$  years had baseline refractive error of  $-3.59 \pm 1.99$  DS. The 36 DW subjects were aged  $27.9 \pm 12.5$  years and had baseline refractive error of  $-2.10 \pm 1.78$  DS ( $p < 0.01$ ). CW subjects increased in myopia by 0.03 DS while DW subjects increased in myopia by 0.40 DS ( $p = 0.007$ ). There was no significant change in corneal curvature by keratometry for the CW subjects and there was slight but significant increase in the steepness of the steep K reading for the DW subjects ( $p < 0.05$ ). The proportion of CW subjects with presenting VA of 20/20 or better remained relatively stable, varying from 80 to 86% during the study, while the proportion for DW subjects ranged from 63% to 78% at follow-up visits through 36 months in the study.

## Conclusions:

Subjects with higher refractive errors were placed in the CW group by investigators in this study. Notwithstanding, there was a larger amount of myopic progression among the age matched users of DW hydrogel lens wearers that caused a portion of them to present with under-correction during scheduled annual visits. CW silicone hydrogel lenses maintained a more stable refractive error over the 3-year observation period in this study.

## Subject Profile:

317 patients were enrolled in the lotrafilcon A arm and 86 in the low Dk daily wear arm for this trial and followed through 36 months. Comparison of subject profiles at Enrollment between the groups found statistically significant differences in average age between the lotrafilcon A and low Dk daily wear arms.

Patient Profile at Enrollment / Dispensing		
	Lotrafilcon A Arm	Low Dk Daily Wear Arm
Gender distribution (n, %)		
Female	211, 67%	54, 63%
Male	106, 33%	30, 35%
Not reported	0, 0%	2, 2%
Age (years)		
Average $\pm$ sd	$37.6 \pm 11.1$	$22.7 \pm 11.7$
Maximum	72	54
Minimum	13	9
Spectacle refraction (average $\pm$ sd, max, min)		
Sphere power in diopters	$-3.36 \pm 2.71$ ; -10.75; +6.50	$-1.79 \pm 1.74$ ; -7.75; +2.75
Cylinder power in diopters	$-0.21 \pm 0.34$ ; -1.50; 0.00	$-0.39 \pm 0.36$ ; -2.25; 0.00
Axis in degrees	$64^\circ \pm 69^\circ$ ; 0°; 180°	$59^\circ \pm 61^\circ$ ; 0°; 180°
Keratometry (average $\pm$ sd, max, min)		
Horizontal power in diopters	$44.09 \pm 1.45$ ; 39.50; 49.13	$43.60 \pm 1.41$ ; 39.25; 47.00
Vertical power in diopters	$44.66 \pm 1.50$ ; 39.75; 49.62	$44.16 \pm 1.41$ ; 40.75; 47.75
Axis in degrees	$92^\circ \pm 37^\circ$ ; 0°; 180°	$91^\circ \pm 35^\circ$ ; 0°; 180°
Contact lens experience (n, %)		
Current SCL wearer	286, 90%	0
Former SCL wearer	26, 8%	15, 17%
New SCL wearer	5, 2%	71, 83%

\*Statistically significant difference,  $p < 0.0001$ , t-test.

230 patients in the lotrafilcon A arm and 54 in the low Dk daily wear arm completed the trial through 36 months. Comparison of subject profile data for these groups found that the difference in average age was 15.0 years.

Patients Completing Through 36 Months		
	Arm	
Data	Lotrafilcon A	Low Dk DW
n	230	54
Age (years)	38.1	23.1
Std Dev (years)	10.8	12.3
Maximum (years)	69.9	53.6
Minimum (years)	14.3	10.8

In order to compare the change in myopia between equal age and sex matched groups, an investigator (RLC) who was masked to treatment selected age and sex matched samples from each arm with results as follows:

Age & Sex Matched Set			
Arm	N	Sex	Age $\pm$ std; min - max
Lotrafilcon A	36	64% female	$27.9 \pm 12.4$ ; 14.3 - 54.0
Low Dk DW	36	64% female	$27.9 \pm 12.4$ ; 13.8 - 53.6

## Results:

From baseline to 36 months among age-matched patients, there was a change in average spherical power equivalent (SPE) of -0.03 diopters among patients in the lotrafilcon A arm and -0.40 diopters among patients in the low Dk daily wear arm. There was little change in cylinder, flat K, or steep K for either arm.

Parameter	Lotrafilcon A Arm			Low Dk DW Arm		
	Baseline	36 Months	Change	Baseline	36 Months	Change
Spherical Power Equivalent	-3.59 $\pm$ 1.99	-3.62 $\pm$ 2.16	-0.03	-2.10 $\pm$ 1.78	-2.50 $\pm$ 1.93	-0.40
Corneal Cylinder	0.79 $\pm$ 0.48	0.83 $\pm$ 0.47	+0.04	0.65 $\pm$ 0.48	0.71 $\pm$ 0.61	+0.06
Flat K	44.70 $\pm$ 1.52	44.52 $\pm$ 1.37	-0.18	43.48 $\pm$ 1.19	43.53 $\pm$ 1.40	+0.05
Steep K	45.48 $\pm$ 1.62	45.34 $\pm$ 1.49	-0.14	44.13 $\pm$ 1.32	44.24 $\pm$ 1.36	+0.11

The changes in SPE and steep K from baseline to 36 months were statistically different between the lotrafilcon A and low Dk daily wear arms.

Testing Differences Between Lotrafilcon A & Low Dk DW Arms For Change From Baseline To 36-Months		
Parameter	Least-Square Mean (SE)	P-Value
Spherical Power Equivalent	0.36 ( $\pm$ 0.131)	0.0070
Corneal Cylinder	-0.02 ( $\pm$ 0.098)	0.8534
Flat K	-0.23 ( $\pm$ 0.119)	0.0583
Steep K	-0.25 ( $\pm$ 0.112)	0.0305

## Discussion / Conclusion:

Myopia progression has been reported to continue into adult years<sup>1</sup> and it has been reported to be increased with soft contact lens wear<sup>2</sup>, although the data were from low Dk lenses. Dumbleton et al reported no increase in the spherical myopia component with lotrafilcon A wear and an increase of 0.30 diopters among low Dk contact lens wearers in a 9 month study.<sup>3</sup> The current trial over a period of 36 months shows that among age and sex matched arms ( $n=36$ ) there was a change in SPE over 36 months of -0.03 DS among lotrafilcon A wearers and -0.40 DS among low Dk wearers. This reduction in myopia progression adds to the benefits that have been reported elsewhere for lotrafilcon A lenses.

## References:

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