

Comparison of biomicroscopy signs between new and experienced contact lens wearers when dispensed in a high Dk fluorosilicone soft contact lens

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Abstract
Changes in many biomicroscopy signs have been reported with contact lens wear. These reports have been with low Dk lenses. With the introduction of highly oxygen permeable soft contact lens materials (high Dk lenses), there is an opportunity to examine the contribution of increased oxygenation to corneal health via biomicroscopy.

PURPOSE: To determine the impact of high Dk extended wear on the corneal health via biomicroscopy signs. We analyzed the biomicroscopy data from a multi-national, in-practice clinical trial of patients dispensed for up to 30 night extended wear of a high Dk (DKA = 175) fluorosilicone soft contact lens (lotrafilcon A, CIBA Vision).

METHODS: 322 patients in Argentina, Brazil, and Spain were dispensed in a 6 month, in-practice clinical trial. 273 (85%) were experienced contact lens wearers and 48 (15%) were new contact lens wearers. Biomicroscopy signs were graded as dispensing, 1 week, 1 month, 3 months, and 6 months using a 0 (absent) to 4 (severe) scale with integer steps. Biomicroscopy signs were analyzed individually, overall and grouped into signs indicating hypoxic, vascular, and surface response and compared using Student's unpaired t-test.

RESULTS: All biomicroscopy signs for both experienced or new wearers at all visits averaged below 0.5. At baseline, experienced wearers showed higher average signs than new wearers for overall average (p=0.0001), hypoxic (p=0.0002), vascular (p=0.0014), ocular surface (p=0.0057) and microcysts (p=0.0268) signs. At 6 months, differences between experienced and new wearers were very minimal although statistically significant differences were found for overall (p=0.0385), hypoxic (p=0.0001) and surface (p=0.0104) signs. The signs for experienced wearers improved from baseline to 6 months. On average, signs for new wearers were lower than for experienced wearers throughout the study.

CONCLUSIONS: The results indicate that there is an improvement in corneal health as seen in biomicroscopy signs among experienced wearers and that with new wearers minimal changes in corneal signs occur compared to baseline observations.

Introduction

Studies that report changes in biomicroscopic signs with extended wear of low Dk lenses include:

- Cystic formations in the corneal epithelium during extended wear of contact lenses. Zantos. ICLC 1983, v. 10, p. 128-146.
 - Changes in corneal thickness and circumferential vascularization with contact lens wear. Tomlinson & Haas. ICLC 1980, v. 7, January / February, p. 45-56.
 - Corneal infiltrates with red eye related to duration of extended wear. Crook. J. of the Am. Optometric Assoc. 1985, v. 56, n. 9, p. 698-700.
- More recent studies reporting biomicroscopic signs with high Dk soft lenses include:
- High oxygen transmissibility soft contact lenses do not induce limbal hyperaemia. Papas, Vajdic, Austen, Holden. Current Eye Research 1997, v. 16, n. 9, p. 942-948.
 - Microcyst response to high Dk silicone hydrogel contact lenses. Keay, Sweeney, Jalbert, Skotnisky, Holden. OVS 2000, v. 77, n. 11, p. 582-585.
 - A comparison of the vascular response to extended wear of conventional lower Dk and experimental high Dk hydrogel contact lenses. Dumbleton. OVS 1998, v. 75, n. 12s, p. 170.
 - Six months of in-practice experience with a high Dk lotrafilcon A soft contact lens. Long, Robirds, & Grant. Contact Lens & Anterior Eye 2000, v. 23, n. 4, p. 112-118.

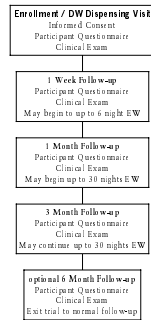
This is a report of a post hoc analysis of biomicroscopy data that was previously reported by Long et al.

Methods

Biomicroscopy signs were collected during this 6 month study and patients were grouped according their pre-study contact lens wearing history of being experienced or new contact lens wearers. Averages were calculated for each sign, for all signs, and for grouped hypoxic, vascular, and surface response signs. Microcyst grades were analyzed separately as there has been recent interest in the response of this sign while wearing high Dk lenses. Student's unpaired t-test was used to compare the groups. Biomicroscopy signs collected and the groupings were as follows:

Sign	Group
Microcysts	Hypoxic signs
Stria	
Limbal redness	
Bulbar redness	Vascular signs
Palpebral redness	
Corneal vascularization	Ocular surface signs
Epithelial staining	
Conjunctival staining	
Tarsal abnormalities	
Infiltrates	

Study visit schedule



Patient profile

	Overall sample		Experienced CL wearers		New CL wearers	
	n	%	n	%	n	%
Sex						
Females	207	64%	179	66%	28	58 %
Males	114	36%	93	34%	20	42 %
Missing	1	<1%	1	<1%	0	**

Age	Overall sample		Experienced CL wearers		New CL wearers	
	Average + 1 sd	range	Average + 1 sd	range	Average + 1 sd	Range
Years	28.2 ± 9.5	12.5-82.7	29.5 ± 9.5	12.5-82.7	25.2 ± 8.2	12.8-51.3

Refraction	Overall sample		Experienced CL wearers		New CL wearers	
	Right	Left	Right	Left	Right	Left
Sphere	-0.10 ± 0.40	-0.23 ± 0.39	-0.28 ± 0.38	-0.29 ± 0.34	-0.06 ± 0.28	-0.08 ± 0.26
Cylinder	-0.50 ± 0.20	-0.49 ± 0.33	-0.48 ± 0.38	-0.51 ± 0.32	-0.64 ± 0.22	-0.41 ± 0.41
Axis	111 ± 65	116 ± 67	111 ± 65	122 ± 64	106 ± 66	88 ± 71

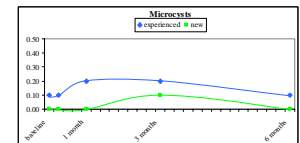
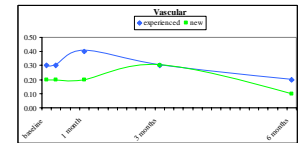
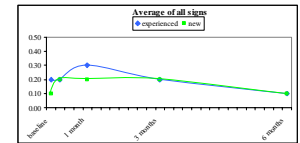
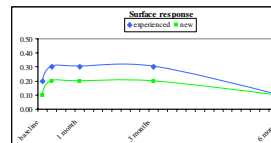
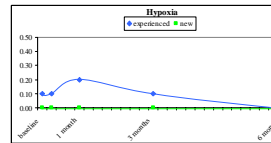
Item	n	%
Experienced wearers	273	85%
New wearers	48	15%

Lenses

brand name	Focus® NIGHT & DAY™
material	lotrafilcon A
% water	24%
Dk	140 barreres
Dk / t	17.5 barreres/cm
modulus	1.2 Mpa
base curve	8.6 mm
diameter	13.8 mm
rx range for trial	-1.00 to +5.00 / -1.0, 2.5, -5.50, +6.00 diopters

Results

	baseline	1 week	1 month	3 months	6 months
Overall	0.07	0.07	0.07	0.07	0.07
Dispensing	0.02 ± 0.01	0.02 ± 0.01	0.02 ± 0.01	0.02 ± 0.01	0.02 ± 0.01
Hypoxic	0.07	0.07	0.07	0.07	0.07
Vascular	0.02 ± 0.01	0.02 ± 0.01	0.02 ± 0.01	0.02 ± 0.01	0.02 ± 0.01
Surface response	0.07	0.07	0.07	0.07	0.07
Microcysts	0.02 ± 0.01	0.02 ± 0.01	0.02 ± 0.01	0.02 ± 0.01	0.02 ± 0.01



- On average, experienced contact lens wearers had higher biomicroscopy signs at baseline than did new wearers.
- Both experienced and new wearers showed transient increases in biomicroscopy signs as they wore high Dk, lotrafilcon A fluorosilicone lenses.
- Average biomicroscopy signs for experienced wearers increased after 6 months in high Dk, lotrafilcon A lenses were better than at baseline.
- Average biomicroscopy signs for new wearers returned to baseline levels after 6 months of wearing the high Dk, lotrafilcon A lens.

Discussion

Several research studies have reported improvements in one or two biomicroscopy signs among patients wearing high Dk silicone hydrogel contact lenses. This in-practice study has found a difference in response between experienced and new wearers for many signs. Results indicate that experienced wearers will show improvement in biomicroscopy signs and that new wearers will return to their pre-lens levels soon after starting to wear lenses. These results support the benefit of high Dk lenses for corneal health.

Different physiologic processes beyond the scope of this presentation may be involved for the different signs monitored in this study. The responses seen were small and the discriminating the overall effect was aided by the large number of patients dispensed. Although delivering more oxygen to the cornea results in measurable benefits, the effect may be difficult to detect for individual patients in routine practice.