Patient Experience and Management in HDk Silicone Hydrogel Soft Contact Lenses

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Introduction

High oxygen permeable silicone hydrogel soft contact lenses were first launched in 1998 in Mexico, in 1999 in Europe, Latin America and Asia, and in 2002 in the USA. Clinical benefits with high oxygen permeable silicone hydrogel soft contact lenses have been reported from research centers and clinical practices and the lenses are being fitted in increasing numbers. With the demonstrated clinical benefits of high oxygen permeable lenses, managing patients expectations and their compliance with wearing schedules remain important issues for acceptance of the continuous wear modality.

Objective

To report patient and practitioner experiences through 12 months of a 36 month trial with a high oxygen permeable silicone soft contact lens (lotrafilcon A, Focus NIGHT&DAY, CIBA Vision Corp., Duluth, GA, USA).

Methods

Nineteen sites in the US dispensed 317 patients to wear lotrafilcon A lenses in a 36 month prospective, in-practice trial. Inclusion / exclusion criteria allowed sites wide latitude that the patient sample would represent the normal population of patients who wear soft contact lenses. Lens characteristics are reported in Table 1 and the profile of patients at dispensing is summarized in Table 2.

Clinical and subjective data were collected at follow-up visits at 1-week and 1, 6, and 12 months to date.

Table 1: Lotrafilcon A Lens Characteristics

Brand name	Focus® NIGHT & DAY®
USAN material	lotrafilcon A
% water	24%
Dk	140 barrers
Base curve	8.4 & 8.6 mm
Diameter	13.8 mm
Rx range	-8.00 to +6.00 in 0.25 diopter steps -8.50 to -10.00 in 0.50 diopter steps

Table 2: Patient Profile at Enrollment / Dispensing

Gender distribution (n, %)	
Female	211, 67%
Male	106, 33%
Age (years)	
Average ± sd, minimum to maximum	37.6 ± 11.1, 13 to 72
Spectacle refraction (average ± sd, max - min)	
Sphere power in diopters	-3.36 ± 2.71, -10.75 - +6.50
Cylinder power in diopters	-0.31 ± 0.34, -1.50 - 0.00
Axis in degrees	64° ± 69°, 0° - 180°
Keratometry (average ± sd, max - min)	
Horizontal power in diopters	44.09 ± 1.45, 39.50 - 49.13
Vertical power in diopters	44.66 ± 1.50, 39.75 - 49.62
Axis in degrees	92° ± 37°, 0° - 180°
Contact lens experience (n, %)	
Current SCL wearer.	286, 90%
Former SCL wearer.	26, 8%
New SCL wearer.	5, 2%

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Clinical Management

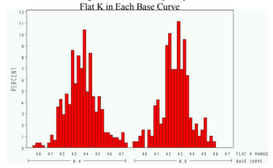
Lenses

- 30% of eyes were dispensed in 8.6 and 70% in 8.4 base curve. The flat K profile is summarized in Table 3 and Figure 1.
  - 97% of eyes remained in the 1st base curve in which they were dispensed.
- Lens power changes were made for 8% of eyes through 12 months.

Table 3: Flat K Distribution For Each BC Dispensed

BC	N	%	Mean	Std Dev	Minimum	Maximum	25th Percentile	75th Percentile
8.6	188	30%	43.27	1.26	39.50	46.50	42.50	44.00
8.4	442	70%	44.32	1.36	40.25	48.25	43.50	45.12
Not reported	2	<1%	44.25	0.00	44.25	44.25	44.25	44.25

Figure 1: Percent of Eyes By Flat K in Each Base Curve



Wear Schedule

- At dispensing, investigators recommended 6 night continuous wear for 40%, 30 night continuous wear for 46%, daily wear for 4%, and other continuous wear periods for 10% of their patients.
- At 6 months, 89% of practitioners recommended 30 night continuous wear and 85% of patients reported that they were compliant with the recommended wear schedule at the 12 month visit.

Complications

- 31 complications were reported among 25 patients.
  - 18 complications were reported among 17 patients, or 5.4% of patients, as lens-related.
- There were no reports of microbial keratitis (MK).

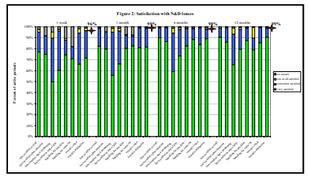
Table 4: Complications Through 12 Months

Lens-Related	Count	Non-Lens Related	Count
Corneal infiltrates/ulcer	4	Allergic conjunctivitis	1
CLPU	1	Abrasion	2
Infiltrative keratitis	3	Viral conjunctivitis	1
Bacterial corneal ulcer	1	Conjunctivitis	5
Keratitis/CLARE	3	Not indicated	1
GPC	1	Bacterial conjunctivitis/keratoconjunctivitis	1
SEAL	1	Upper respiratory infection	1
CL abrasion	1	Inflammation	1
Conjunctival epithelial split	1		

Patient Experience

Satisfaction

- At 1-week 96% and at 12-months 99% of patients were somewhat or very satisfied with the lotrafilcon A lenses.
- Satisfaction with lens handling for insertion and removal were at 88% and 82% at 1-month, respectively, and improved to 99% of patients by 12 months for both insertion and removal.



Problems

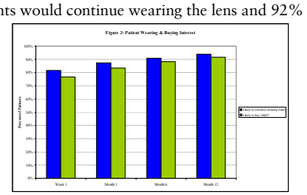
- Handling for insertion was reported as a moderate problem by 2% of patients.
- Handling for removal was reported as a moderate problem by 3% of patients.
- No patients reported any severe problems.

Table 5: Percent of Patients Reporting Moderate Problems Through 12 Months

	week 1	month 1	month 6	month 12
difficulty disinfecting lenses	0%	0%	0%	0%
difficulty inserting lenses	2%	1%	1%	2%
difficulty removing lenses	1%	1%	3%	3%
lost lenses	0%	0%	0%	0%
torn lenses	0%	0%	1%	2%

Wearing and Buying Interest

- At 12 months, 94% of patients would continue wearing the lens and 92% would continue to purchase it.



Discussion

The 2 base curve option for lotrafilcon lenses was successfully fitted for a wide range of flat Ks and required few adjustments in lens power through 12 months. Practitioners increased their recommendations for continuous wear as they gained experience with the lens and patients were compliant with their wear schedule recommendations. The overall, lens-related complication rate of 5.4% was well below the range of 35% to 41% that has been reported with 2-week replacement contact lenses[Solomon, 1996; Suchecki, 2000]. Patients were highly satisfied with the lenses early in their experience and satisfaction increased as they wore them through 12 months. Problems were infrequent and not severe when they occurred.