24 Month Update of a Multicenter Trial of Silicone Hydrogel Soft Contact Lenses

Joseph T. Barr, MS, OD; Peter Bergenske, OD; Peter Donshik, MD; Glenda Secor, OD;
John Yoakum, OD; Sally M. Dillehay, MS, OD, EdD; Bill Long, BS

Abstract

To report findings through 24 months of a 36 month trial of signs of corneal health, subjective symptoms and safety with continuous wear of NIGHT&DAY (N&D) lenses and low Dk daily wear (DW) 2-week replacement soft contact lenses.

317 patients were dispensed to wear N&D for up to 30N CW and 81 neophyte patients were dispensed in a lens for DW. Clinical and subjective data were collected at follow-up visits for each group.

A cohort of 240 N&D and 58 DW patients completed all visits through 24 months. 30N CW was recommended for all N&D patients by the 24 month visit. For the N&D cohort, improvements in biomicroscopy grades were most dramatic within 1 week for limbal ($p<0.001$) and conjunctival ($p<0.001$) redness with 5 of 10 signs improving and 5 unchanged through 24 months. For the DW cohort, 4 of 10 signs worsened and 6 were unchanged through 24 months. For subjective symptoms, end of day dryness improved in both frequency ($p<0.001$) and severity ($p<0.001$) among 11% of patients in N&D, while 11% more patients in the DW group reported more frequent ($p=0.014$) and severe ($p=0.014$) end of day dryness. The percentage of eyes achieving 20/20 VA in the N&D cohort improved from 78% at dispensing to 86% at 12 months ($p=0.995$) and 86% at 24 months ($p=0.011$). For DW, 87%, 64% and 66% of eyes had 20/20 VA or better at dispensing, 12 ($p=0.001$), and 24 ($p=0.001$) months, respectively. Discontinuations totaled 24% for N&D and 27% for DW, with 1 discontinuation in each group from a potential adverse event. Microbial keratitis did not occur in either group.

N&D worn for 30N CW performed very well for biomicroscopy signs while DW results were mixed. In the N&D group, 5 signs of corneal health improved and none declined. In the DW group no signs improved and 4 signs declined. VA improved in the N&D group and declined in the DW group. N&D also showed improvement in end of day dryness symptoms. In these cohorts through 24 months, N&D worn for 30N CW may be healthier than DW lenses based on signs of corneal health, improvement in end of day dryness, and VA. It is an interesting finding that the prevalence of signs and symptoms in the DW cohort were generally greater than that in the CW cohort. Further research is warranted to clarify the impact of these findings on overall corneal health.

Investigators

Principal Investigator	Location
Joseph T. Barr, OD	Columbus, OH
Steve Bennett, OD	Ann Arbor, MI
Peter Bergenske, OD	Forest Grove, OR
Walter Choate, OD	Madison, TN
Bobby Christensen, OD	Midwest City, OK
DC Dean, OD	Albuquerque, NM
Peter Donshik, MD	Bloomfield, CT
Barry Eiden, OD	Deerfield, IL
Art Epstein, OD	Roslyn, NY
Michael Goldsmid, OD	San Diego, CA
Barry Kissack, OD	Honeoye Falls, NY
Lee Rigel, OD	East Lansing, MI
Ellen Rogers, OD	Jacksonville, FL
Joe Schwallie, OD	Holland, OH
Glenda Secor, OD	Huntington Beach, CA
Christine Sindt, OD	Iowa City, IA
Vivien Smith, OD	Lexington, KY
Joe Yager, OD	Orlando, FL

Patient profile at enrollment / dispensing

	FND group	DW group
Gender distribution (n, %)		
Female	211, 67%	54, 63%
Male	106, 33%	30, 35%
Not reported	0, 0%	2, 2%
Age (years)		
Average + sd	37.6 + 11.1	22.7 + 11.7
Maximum	72	54
Minimum	13	9
Spectacle refraction (average + sd, max, min)		
Sphere power in diopters	-3.36 + 2.71, -10.75, +6.50	-1.79 + 1.74, -7.75, +2.75
Cylinder power in diopters	-0.31 + 0.34, -1.50, 0.00	-0.30 + 0.36, -2.25, 0.00
Axis in degrees	64° + 69°, 0°, 180°	59° + 61°, 0°, 180°
Keratometry (average + sd, max, min)		
Horizontal power in diopters	44.09 + 1.45, 39.50, 49.13	43.60 + 1.41, 39.25, 47.00
Vertical power in diopters	44.66 + 1.50, 39.75, 49.62	44.16 + 1.41, 40.75, 47.75
Axis in degrees	92° + 37°, 0°, 180°	91° + 35°, 3°, 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%

Change in Average Biomicroscopy Signs Through 24 Months for N&D Cohort

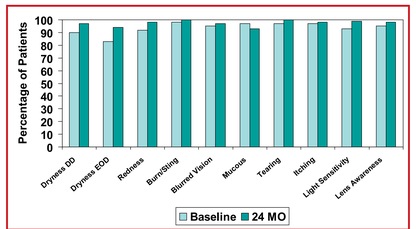
Bio Sign	Dispensing	1 week	1 month	12 months	24 months	p 1wk	statistical sig*
Limbal redness	0.4	improved	improved	improved	improved	0.001	SSD
Conjunctival staining	0.2	unchanged	unchanged	unchanged	improved	0.941	NSD
Corneal staining	0.2	improved	unchanged	unchanged	unchanged	0.095	NSD
Corneal infiltrates	0.0	unchanged	unchanged	unchanged	unchanged	0.149	NSD
Epithelial microcysts	0.1	unchanged	improved	improved	improved	0.819	NSD
Corneal edema	0.0	unchanged	unchanged	unchanged	unchanged	0.020	NSD
Conjunctival redness	0.5	improved	improved	improved	improved	0.001	SSD
Papillary conjunctivitis	0.3	unchanged	unchanged	unchanged	unchanged	0.020	NSD
Corneal ulcer	0.0	unchanged	unchanged	unchanged	unchanged	1.000	NSD
Corneal neovascularization	0.2	improved	improved	improved	improved	0.001	NSD
Average	0.2	improved	improved	improved	improved		

*$p < 0.005$, Bonferroni adjusted

Change in Average Biomicroscopy Signs Through 24 Months for DW Cohort

Bio Sign	Dispensing	1 week	1 month	12 months	24 months	p 1wk	statistical sig*
Limbal redness	0.0	worsened	worsened	worsened	worsened	0.670	NSD
Conjunctival staining	0.0	worsened	unchanged	worsened	worsened	0.487	NSD
Corneal staining	0.0	worsened	unchanged	worsened	worsened	0.098	NSD
Corneal infiltrates	0.0	worsened	unchanged	unchanged	unchanged	1.000	NSD
Epithelial microcysts	0.0	worsened	unchanged	unchanged	unchanged	1.000	NSD
Corneal edema	0.0	worsened	unchanged	unchanged	unchanged	1.000	NSD
Conjunctival redness	0.1	unchanged	improved	unchanged	unchanged	0.772	NSD
Papillary conjunctivitis	0.1	unchanged	worsened	worsened	worsened	0.770	NSD
Corneal ulcer	0.0	worsened	unchanged	unchanged	unchanged	1.000	NSD
Corneal neovascularization	0.0	worsened	unchanged	unchanged	unchanged	1.000	NSD
Average	0.0	worsened	worsened	worsened	worsened		

*$p < 0.005$, Bonferroni adjusted

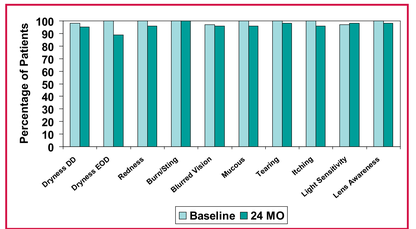


N&D Frequency of Symptoms (None or Sometimes) Through 24 Months

Percent of Subjects Reporting Symptom Frequency of None or Sometimes in N&D Cohort Through 24 Months

Symptom	p 24 mo	statistical sig*
Discomfort upon insertion		
Dryness during the day	0.001	SSD
Dryness at end of day	0.001	SSD
Redness	0.001	SSD
Burning or stinging	0.102	NSD
Blurred vision	0.225	NSD
Mucous in the morning	0.025	NSD
Tearing & watering	0.059	NSD
Itching	0.527	NSD
Sensitivity to bright lights	0.001	SSD
Lens awareness	0.046	NSD
Average		

*$p < 0.005$, Bonferroni adjusted

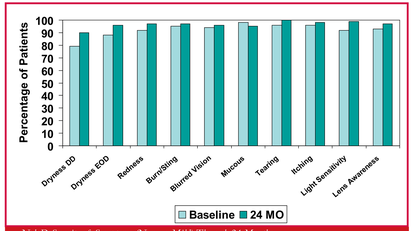


DW Frequency of Symptoms (None or Sometimes) Through 24 Months

Percent of Subjects Reporting Symptom Frequency of None or Sometimes in DW Cohort Through 24 Months

Symptom	p 24 mo	statistical sig*
Discomfort upon insertion		
Dryness during the day	0.317	NSD
Dryness at end of day	0.014	NSD
Redness	0.157	NSD
Burning or stinging	1.000	NSD
Blurred vision	0.999	NSD
Mucous in the morning	0.157	NSD
Tearing & watering	0.317	NSD
Itching	0.157	NSD
Sensitivity to bright lights	0.564	NSD
Lens awareness	0.317	NSD
Average	0.014	

*$p < 0.005$, Bonferroni adjusted

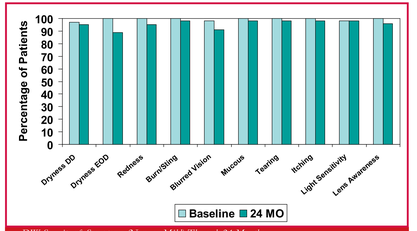


N&D Severity of Symptoms (None or Mild) Through 24 Months

Percent of Subjects Reporting Symptom Severity of None or Mild in N&D Cohort Through 24 Months

Symptom	p 24 mo	statistical sig*
Discomfort upon insertion		
Dryness at end of day	0.001	SSD
Dryness during the day	0.004	SSD
Redness	0.007	NSD
Burning or stinging	0.225	NSD
Blurred vision	0.371	NSD
Mucous in the morning	0.071	NSD
Tearing & watering	0.020	NSD
Itching	0.166	NSD
Sensitivity to bright lights	0.001	SSD
Lens awareness	0.022	NSD
Average		

*$p < 0.005$, Bonferroni adjusted

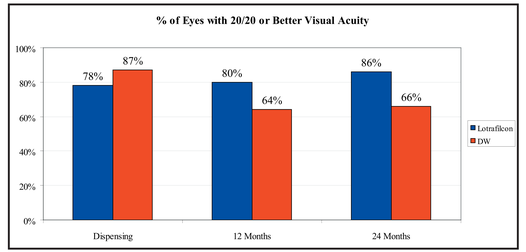


DW Severity of Symptoms (None or Mild) Through 24 Months

Percent of Subjects Reporting Symptom Severity of None or Mild in DW Cohort Through 24 Months

Symptom	p 24 mo	statistical sig*
Discomfort upon insertion		
Dryness during the day	0.564	NSD
Dryness at end of day	0.014	NSD
Redness	0.083	NSD
Burning or stinging	0.317	NSD
Blurred vision	0.102	NSD
Mucous in the morning	0.317	NSD
Tearing & watering	0.317	NSD
Itching	0.317	NSD
Sensitivity to bright lights	0.317	NSD
Lens awareness	1.000	NSD
Average		

*$p < 0.005$, Bonferroni adjusted



Discontinuations in CW Lotrafilcon A Group Through 24 Months

N&D Arm

	dispensing to 1-week	1-week to 1-month	1-month to 6-months	6-months to 12-months	12-months to 24-months	total
discomfort	3%	2%	1%	2%	0%	7%
disinterest	1%	1%	0%	1%	0%	3%
lost-to-follow up, relocated	1%	0%	3%	2%	1%	7%
unacceptable subjective vision	1%	0%	1%	0%	0%	2%
unacceptable fit	0%	0%	0%	0%	0%	0%
other	0%	0%	0%	1%	1%	3%
subjective symptoms	0%	0%	0%	1%	0%	1%
positive biomicroscopy	0%	0%	0%	0%	0%	0%
total	7%	3%	5%	6%	2%	24%

Discontinuations in Low Dk Group Through 24 Months

DW Arm, adjusted for inclusion/exclusion dc's

	dispensing to 1-week	1-week to 1-month		6-months to 12-months	12-months to 24-months	total
discomfort	0%	1%		2%	0%	4%
disinterest	1%	0%		1%	0%	2%
lost-to-follow up, relocated	14%	0%		2%	0%	16%
other	1%	0%		0%	2%	4%
handling	0%	0%		0%	1%	1%
total	16%	1%		6%	4%	27%

Summary

Biomicroscopy

- Lotrafilcon A: Continued improvement through 24 months
- Low Dk DW: Most signs worsened or unchanged

Visual acuity

- Lotrafilcon A: Improvements through 24 months
- Low Dk DW: Worsened through 24 months

Symptoms

- Lotrafilcon A: Improvements in frequency & severity. Fewer patients with c/o dryness
- Low Dk DW: Four of ten symptoms worsened

Discontinuations

- About equal between the groups

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