# 117

# Subjective Dryness Symptoms Improve When Adapted HEMA Soft Contact Lens Wearers Change to Lotrafilcon Silicone Hydrogel Soft Contact Lenses

**Bill Long[1], BS, FAAO; Sally M. Dillehay[1], OD, EdD, FAAO; John McNally[1], OD, FAAO; Joseph T. Barr[2], OD, MS, FAAO**
**Peter Bergenske[1, 3], OD, FAAO; Peter Donshik[4], MD; Glenda Secor[5], OD, FAAO; John Yoakum[6], OD**
[1]CIBA Vision Corp, Duluth, GA, USA; [2]College of Optometry, The Ohio State University, Columbus, OH, USA; [3]College of Optometry, Pacific University, Forest Grove, OR, USA
[4]University of Connecticut Health Center, Bloomfield, CT, USA; [5]Private Practice, Huntington Beach, CA, USA; [6]Groate Eyecare Associates, Greensboro, NC, USA

## Purpose:

Dry eye symptoms among contact lens wearers have been reported as a leading cause of discontinuation of contact lens wear.[1] Patient reported symptoms of dryness are often the only diagnostic criteria used by practitioners for diagnosing and managing dry eye.[2, 3, 4] Some investigators have reported improvement in contact lens-related dry eye symptoms when adapted HEMA hydrogel wearers change to silicone hydrogel (SiHy) lenses.[5, 6] Five trials with lotrafilcon A and B lenses were analyzed retrospectively to investigate the performance of this material for improvement of dryness symptoms.

## Methods:

Five trials involving 1,279 adapted HEMA wearers who were changed to lotrafilcon A or B SiHy lenses were analyzed for subjective patient evaluations of dryness during the day (DD) and dryness at the end of day (ED): 1 trial with lotrafilcon A for up to 30 night wear, 3 trials with lotrafilcon A for daily wear, and 1 trial with lotrafilcon B lenses for daily wear. Subjective evaluations with habitual HEMA lenses were compared to evaluations after wearing lotrafilcon SiHy lenses.

## Results:

At 1 month, statistically significant improvements with lotrafilcon A for up to 30 night continuous wear were found for DD ($p<0.0001$, n=282) and ED ($p=0.002$, n=282). At 1 month, statistically significant improvements with lotrafilcon A for daily wear were found for DD ($p<0.001$, n=81; $p<0.0001$, n=60; $p<0.0001$, n=96) and ED ($p=0.0017$, n=81, $p=0.0001$, n=60, $p<0.0001$, n=96). At 2 weeks, statistically significant improvements with lotrafilcon B for daily wear were found for DD ($p<0.0001$, n=750) and ED ($p<0.0001$, n=750). On average, 46% (range 33% to 51%) of subjects reported improved DD and 32% (range 28% to 51%) improved ED.

## Conclusions:

Changing to lotrafilcon A or B silicone hydrogel contact lenses provides improvment for some adapted HEMA wearers from symptoms of contact lens-related dryness during the day and dryness at the end of day.

## Profile of Subjects in Trials:

| Trial | Polymer | Subject Profile |
|---|---|---|
| 3 Year US Trial | Lotrafilcon A | 67% females<br>37.6 ± 11.1 years old<br>90% were adapted CL wearers |
| 1 Month Asian US Trial | Lotrafilcon A | 66% females<br>31 ± 10 years old<br>All were adapted SCL wearers |
| 1 Month Italy Trial | Lotrafilcon A | 68% females<br>31.7 ± 10.9 years old<br>70% were adapted CL wearers |
| 1 Month Nordic Trial | Lotrafilcon A | 74% females<br>32.3 ± 9.3 years old<br>53% were adapted CL wearers |
| 2 Week US Trial | Lotrafilcon B | 70% females<br>28.8 years old<br>All adapted SCL wearers |

## Profile of Wearing Schedules in Trials:

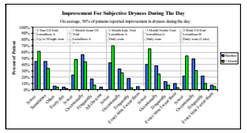
| Trial | Polymer | Wearing Schedules in Trial |
|---|---|---|
| 3 Year US Trial | Lotrafilcon A | Up to 30 night continuous wear |
| 1 Month Asian US Trial | Lotrafilcon A | Daily wear |
| 1 Month Italy Trial | Lotrafilcon A | Daily wear |
| 1 Month Nordic Trial | Lotrafilcon A | Daily wear |
| 2 Week US Trial | Lotrafilcon B | Daily wear |

## Summary of Results:

| Trial & Polymer | Visits Analyzed | Symptoms Analyzed | N | Wilcoxon Signed-Rank Test Results |
|---|---|---|---|---|
| 3 Year US Trial<br>Lotrafilcon A | Baseline &<br>1 Month | Dryness during the day<br>Dryness at end of day | 292<br>292 | -0.23 change ($p<0.0001$)<br>-0.18 change ($p=0.0020$)) |
| 1 Month Asian US Trial<br>Lotrafilcon A | Baseline &<br>1 Month | My eyes feel dry during the day<br>My eyes feel dry at the end of the day | 81<br>81 | -0.42 change ($p.<0.001$)<br>-0.37 change ($p=0.0017$) |
| 1 Month Italy Trial<br>Lotrafilcon A | Baseline &<br>1 Month | My eyes feel dry during the day<br>My eyes feel dry at the end of the day | 60<br>60 | -0.52 change ($p<0.0001$)<br>-0.55 change ($p<0.0001$) |
| 1 Month Nordic Trial<br>Lotrafilcon A | Baseline &<br>1 Month | My eyes feel dry during the day<br>My eyes feel dry at the end of the day | 96<br>96 | -0.45 change ($p<0.0001$)<br>-0.61 change ($p<0.0001$) |
| 2 Week US Trial<br>Lotrafilcon B | Baseline &<br>2 Weeks | My eyes feel dry during the day<br>My eyes feel dry at the end of the day | 750<br>750 | -0.46 change ($p<0.0001$)<br>-0.53 change ($p<0.0001$) |
| Pooled | | My eyes feel dry during the day<br>My eyes feel dry at the end of the day | 1279<br>1279 | -0.41 change ($p<0.0001$)<br>-0.45 change ($p<0.0001$) |

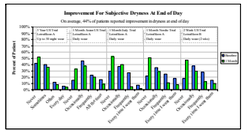
## Summary For Dryness During The Day:

| Percent of Patients With Improvement in Dryness During The Day | | |
|---|---|---|
| Trial | Polymer | % of Patients With Improved Symptoms |
| 3 Year US Trial | Lotrafilcon A | 32% |
| 1 Month Asian US Trial | Lotrafilcon A | 50% |
| 1 Month Italy Trial | Lotrafilcon A | 54% |
| 1 Month Nordic Trial | Lotrafilcon A | 50% |
| 2 Week US Trial | Lotrafilcon B | 62% |
| Average | | 50% |




## Summary For Dryness At The End of The Day:

| Percent of Patients With Improvement in Dryness at the End of Day | | |
|---|---|---|
| Trial | Polymer | % of Patients With Improved Symptoms |
| 3 Year US Trial | Lotrafilcon A | 21% |
| 1 Month Asian US Trial | Lotrafilcon A | 37% |
| 1 Month Italy Trial | Lotrafilcon A | 47% |
| 1 Month Nordic Trial | Lotrafilcon A | 58% |
| 2 Week US Trial | Lotrafilcon B | 57% |
| Average | | 44% |




## Conclusions:

Contact lens wearers may experience improvement in symptoms of dryness when wearing either lotrafilcon A or B lenses. On average, 50% of patients noted improvement in symptoms of dryness during the day and 44% noted improvement in symptoms of dryness at the end of the day.

## References

1. Begley, C., et al., Characterization of ocular surface symptoms from optometric practices in North America. Cornea, 2001. 20(6): p. 610-618.
2. Korb, D., Survey of preferred tests for diagnosis of the tear film and dry eye. Cornea, 2000. 19(4): p. 483-486.
3. Nichols, K., J. Nickols, and K. Zadnik, Frequency of dry eye diagnostic test procedures used in various modes of ophthalmic practice. Cornea, 2000. 19(4): p. 477-482.
4. Turner, A., C. Layton, and A. Bron, Survey of eye practitioners' attitudes towards diagnostic tests and therapies for dry eye disease. Clin Exp Opthal, 2005. 33: p. 351-355.
5. Chalmers, R., et al., Impact of previous extended and daily wear schedules on signs and symptoms with high Dk lotrafilcon A lenses. Optom Vis Sci, 2005. 82(6): p. 549-554.
6. Schafer, J., J. Barr, and C. Mack, A characterization of dryness symptoms with silicone hydrogel contact lenses. Opt Vis Sci, 2003. 80(12s): p. 187.

## Acknowledgement

Portions of this material were presented at the 2006 British Contact Lens Association Clinical Conference.