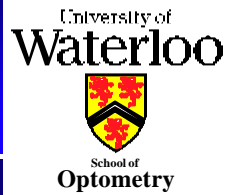




MUCIN BALL POST-LENS DEBRIS IN HIGH Dk SILICONE HYDROGEL WEARERS



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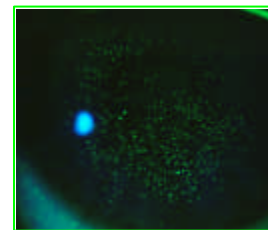
Introduction

- ? Experience with high Dk silicone hydrogel lenses indicates that some subjects are prone to the development of a unique form of tear-film derived debris between the back surface of these lenses and the corneal epithelium.
- ? This translucent debris (so-called "mucin balls") commonly occurs after overnight wear, forming as a number of spherical bodies between the cornea and back surface of the lens. The size of the debris particles ranges from 20 to 200µm.
- ? Following lens removal, the mucin balls are easily blinked away, leaving depressions or imprints on the ocular surface (Figure 1), which display unreversed illumination.
- ? These imprints are more visible when fluorescein is instilled into the eye due to accumulation of fluorescein within the depression (Figure 2). There is no fluorescein penetration into the epithelium.
- ? Little information is known about these spherical bodies, particularly in respect of their incidence, time to develop and any associated complications.

Fig 1 - Mucin Ball Imprints



Fig 2 - Fluorescein Accumulation



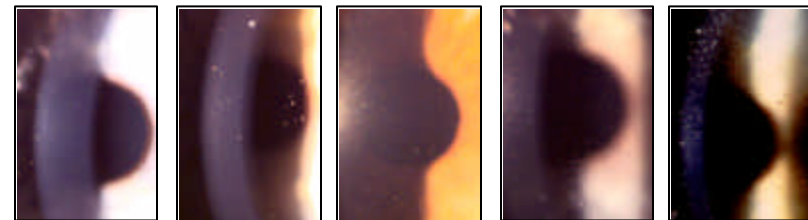
Aims

- ? To determine the incidence and severity of mucin ball observation in a large group of subjects using high Dk silicone-hydrogel lenses (Lotraficon A) on an extended-wear basis.
- ? To determine if the presence of mucin balls is in any way associated with ocular symptoms.

Materials & Methods

- ? Subjects: 92 myopic subjects wore a pair of Lotraficon A lenses (Focus Night & Day?) on an overnight basis for up to 6 nights (n=30) or up to 30 nights (n=62).
- ? Visits: subjects were evaluated at dispensing and after 1, 3 and 6 months.
- ? Mucin ball observations: a 0-4 severity grading scale in 0.5 increments was developed, in which a higher number represented a greater mucin ball response. This scale is photographically represented in Figure 3.
- ? Pre-lens non-invasive tear break-up time (NIBUT - Tearscope), biomicroscopic response, subjective responses, and lubricant-drop usage were recorded throughout the period of the study.

Fig 3 - Mucin Ball Severity Grading Scale



Grade 0.5 Grade 1.0 Grade 2.0 Grade 3.0 Grade 4.0

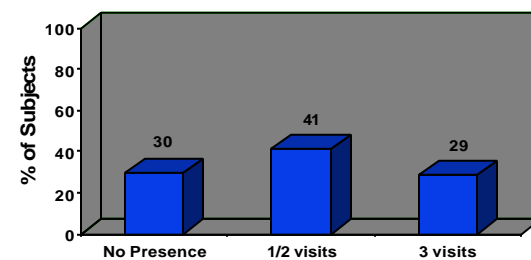
Statistical Analysis

- ? SAS and Systat 8.0
- ? Pairwise comparisons using Students paired t-test
- ? Right eye only data used for analyses
- ? Composite analyses using GENMOD to take into account repeated measures on the same subject over time

Results

? **Incidence:** Fig 4 indicates that 70% of subjects exhibited mucin balls: 41% exhibited them on 1 or 2 of the visits and 29% exhibited them at each of the 3 visits.

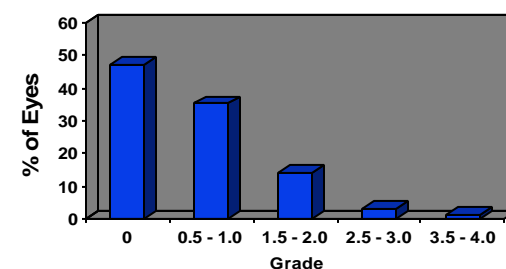
Fig 4 - Incidence of Mucin Ball Observations



? **Concordance:** There was a 71% concordance between eyes. Therefore, the following results represent data from the right eye only.

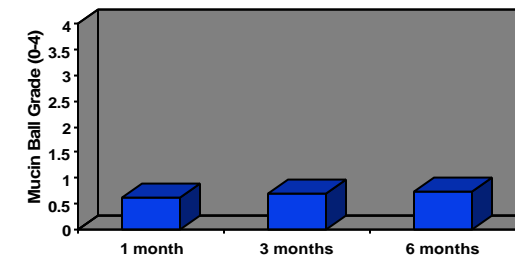
? **Severity:** Fig 5 indicates that almost 50% of eyes did not exhibit mucin balls at any visit and mucin balls were graded at > grade 1 in 18% of eyes, > grade 2 in 4% of eyes and > grade 3 in 1% of eyes.

Fig 5 - Severity of Mucin Ball Observations



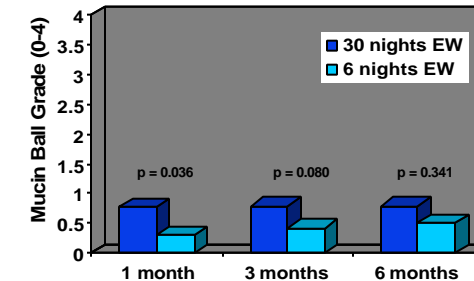
? **Variation over time:** Figure 6 shows no change in mean grade of mucin ball appearance over time (p = 0.237).

Fig 6 - Mucin Ball Mean Scores by Visit



? **Variation with wearing time:** Figure 7 shows a higher mean grade for mucin balls in the subjects wearing their lenses for up to 30 nights extended wear.

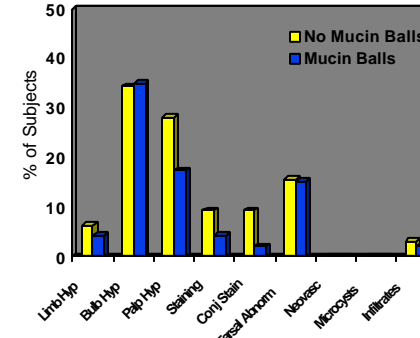
Fig 7 - Mucin Ball Mean Scores by EW Wearing Time



? **Pre-lens NIBUT:** The mean NIBUT was 6.6 ± 2.7, 5.8 ± 2.7 and 6.4 ± 2.7 seconds for the 1, 3 and 6 month visits respectively. There was no correlation between mucin ball score and NIBUT at any of the visits (r = -0.12, 0.24, 0.06).

? **Association with biomicroscopic appearance:** Fig 8 represents the percentage of subjects with biomicroscopic findings ? 2 (0-4 scale) at the 6 month visit and indicates that there was no association between biomicroscopic response and mucin ball observation (p=NS). This was also the case at the 1 and 3 month visits.

Fig 8 - Biomicroscopy Findings (? grade 2)



? **Subjective ratings:** Table 1 shows mean subjective ratings by mucin ball appearance. With the exception of handling on removal, the presence of mucin balls does not affect subjective ratings.

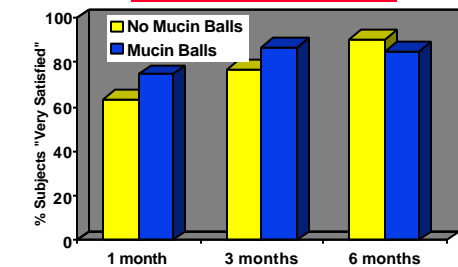
Table 1 - Mean Subjective Ratings by Visit

Mean Rating (0-10)	1 month		3 months		6 months	
	No MB	MB	No MB	MB	No MB	MB
Overall Comfort	8.9	8.8	8.8	8.9	8.9	9.0
Waking Comfort	7.2	7.7	6.9	7.8	7.2	7.6
Removal Handling	9.2	8.9	9.2*	9.1*	9.2*	8.8*
Vision	9.1	9.1	9.0	9.2	9.0*	9.2*
Waking Dryness	6.3	7.3	6.2	7.2	6.2	6.5
Day End Dryness	7.6	7.9	7.3	7.8	7.6	7.9

* p = 0.0043, † p = 0.04, ‡ p = 0.029 (higher rating in subjects with mucin balls)

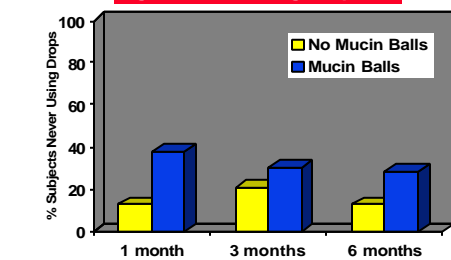
? **Subject Satisfaction:** Figure 9 shows that there were no significant differences in overall satisfaction between the subjects with and without mucin balls (p = 0.27, 0.27, 0.48).

Fig 9 - Subject Satisfaction



? **Lubricating Drops (Figure 10):** The percentage of subjects "never" using lubricating drops was higher in the subjects with mucin balls (p = 0.0014).

Fig 10 - Lubricating Drop Use



Conclusions

- ? Approximately one-third of all subjects exhibit mucin balls at all visits with Lotraficon A lenses.
- ? Approximately one-third of all subjects never exhibit mucin balls when wearing Lotraficon A lenses.
- ? Only 5% of subjects demonstrate a clinically significant degree of mucin ball debris.
- ? The presence of mucin balls does not appear to be detrimental to contact lens wear.
- ? Future investigation into the relationship between mucin ball observation and the use of rewetting drops is warranted.

Acknowledgement

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