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Purpose

To compare the frequency of post-lens "tear microspheres" (TMS's), previously referred to as "lipid plugs" or "mucin balls", seen with high Dk and low Dk hydrogel lenses during 12 months of extended wear
 To determine whether TMS's are correlated with physiological responses, lens performance or patient subjective responses

Methods

186 subjects
 Random assignment to two lens wearing groups:

	Low Dk	High Dk
Lens material	etafilcon A	lotrafilcon A
FDA group	Group IV	Group I
Water content (%)	58	24
Dk/t (barriers at -3.00D)	40	175
Extended wear schedule	6N	30N
Replacement schedule	Weekly	Monthly
	Low Dk (n = 96)	High Dk (n = 90)
Mean age (years)	32 ± 8	31 ± 8
Sex distribution (%M:F)	41:59	47:53
Spherical Rx (DS)	-2.73 ± 1.56	-2.65 ± 1.31

Table 1: Lens and subject characteristics for each group
 Subjects monitored at baseline (BL), 1, 3, 6, 9 and 12 months of extended wear
 Eighty-six subjects completed the 12 month visit
 Variables assessed:

Prior to lens removal:

- TMS's counted using a biomicroscope under direct white light illumination (16x)
- Visual acuity
- Lens surface (front and back surface deposits, back surface debris, front surface wettability)
- Fitting performance (centration, primary gaze movement, primary gaze lag, tightness)
- Subjective ratings for comfort and symptoms

Upon lens removal:

- Physiological variables (bulbar and limbal redness, microcysts, vacuoles, corneal staining, infiltrates)

Statistical Analysis

Pearson's correlation:

TMS numbers highly correlated for right and left eyes ($p < 0.01$)
 For analysis, results for both eyes meaned for each subject for each visit

Two-way ANOVA; Multiple comparison (Bonferroni):

To compare the number of TMS's in each lens wear group at each visit

Multiple regression:

To determine relationships between physiological responses, lens fitting and surface performance, visual acuity and subjective responses and the number of TMS's

Results

Characteristics

- Typically spherical bodies
- 40 to 120µm in diameter (Figure 1 and 4)
- More commonly observed on the superior cornea
- Immobile under the lens
- Dislodged on lens removal and with subsequent blinks
- Leave a corneal indentation which pools with fluorescein (Figure 2 and 3)
- Occur more frequently and in higher numbers with certain patients

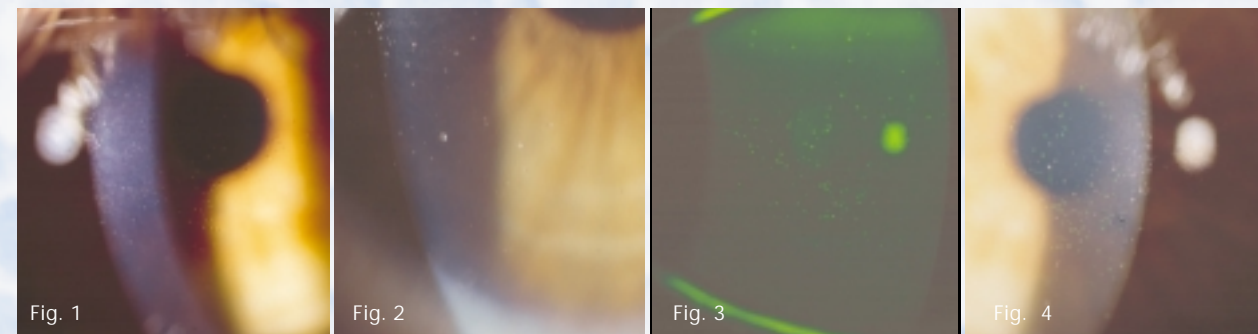


Fig. 1 TMS's viewed with direct white light illumination (mag 16x)
 Fig. 2 TMS's viewed with high magnification white light (mag 40x)
 Fig. 3 Corneal indentations pooling with fluorescein (mag 16x)
 Fig. 4 Corneal indentations pooling with white light (mag 25x)

Incidence

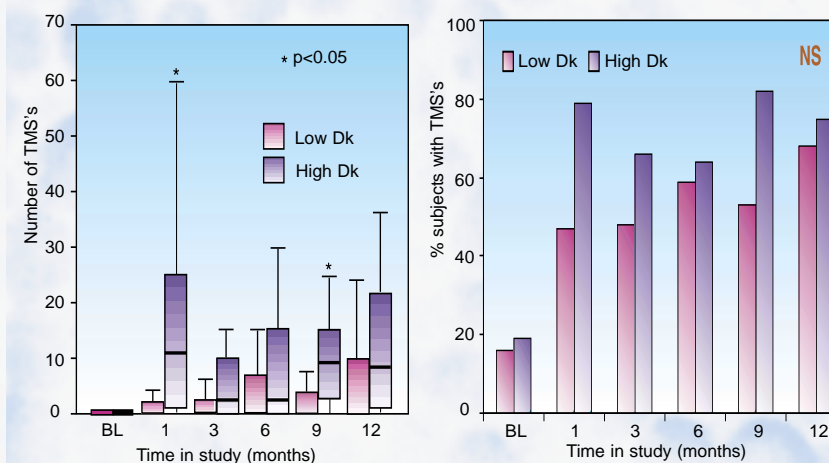


Fig. 5: Number of TMS's for each lens type across 12 month wearing period. Values expressed as median ± interquartile range
 Fig. 6: Percentage of subjects with TMS's with each lens type

No relationship between TMS's and:

Physiological responses bulbar redness limbal redness corneal microcysts corneal vacuoles corneal staining corneal infiltrates adverse responses	Lens fitting performance centration primary gaze movement primary gaze lag tightness	Lens surface performance front surface deposits back surface deposits back surface debris front surface wettability	Visual acuity and subjective responses visual acuity comfort and symptoms
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Discussion

TMS's are observed in higher numbers with high Dk hydrogels not associated with adverse responses; no effect on visual acuity, comfort or symptoms; not related to lens fitting or surface performance
 patient specific, but as they are innocuous, no special management is required
 important to differentially diagnose from microcysts, vacuoles and macropunctate staining which are similar in appearance but indicate the cornea is under hypoxic or other types of stress
 no definite etiology – one hypothesis is that the interaction between the contact lens surface and the ocular surface can create shear and tension forces within the tear film that result in the formation of TMS's

Conclusion

TMS's occur in higher numbers with high Dk lens wear but are not of clinical concern

References

- Bourassa and Benjamin. Transient corneal surface "micro deposits" and associated epithelial surface pits occurring with gel contact lens extended wear, *ICLC* 1988, 15:339-340
- Fleming et al. Pre-corneal "deposits" during soft contact lens wear, *OVS* 1994 (suppl), 71:152-153

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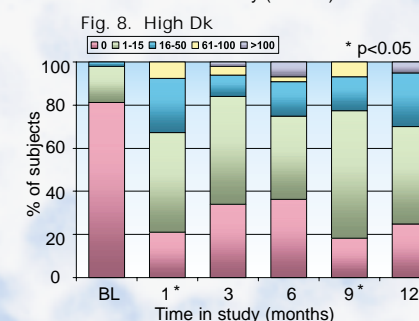
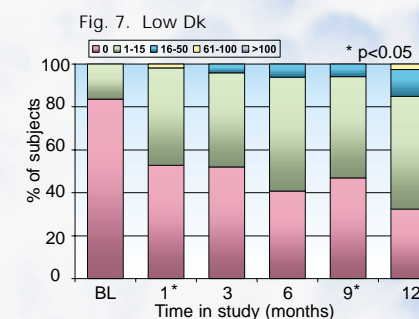


Fig. 7 and 8: Frequency distribution of subjects with TMS's for each lens type across 12 month wearing period