

Longterm Results with High Dk Soft Contact Lenses from a Prospective Clinical Trial

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Purpose

High Dk soft lenses that meet the Holden-Mertz criteria¹ for the oxygen requirements of the cornea to avoid overnight edema are now available.

Microcysts² and limbal redness³ have been established as excellent clinical markers of hypoxic stress.

In a long term prospective clinical trial of high Dk soft prototype lenses, patients were monitored for their levels of both microcysts and limbal redness. Results for conventional low Dk soft lenses worn on a 6 night extended wear schedule are presented for comparative purposes.

Methods

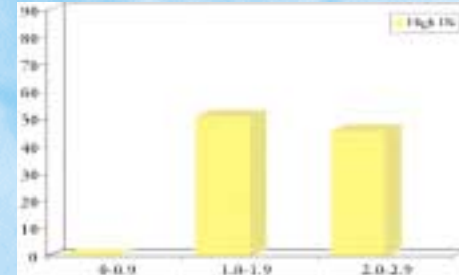
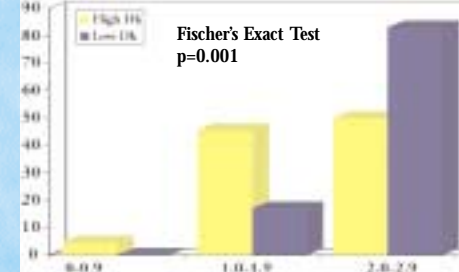
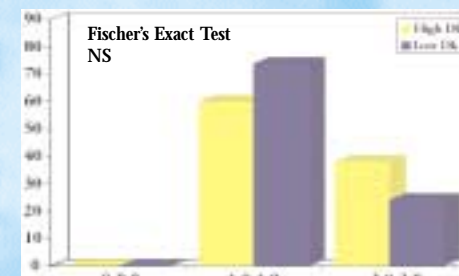
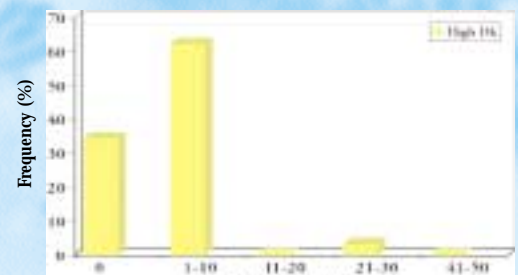
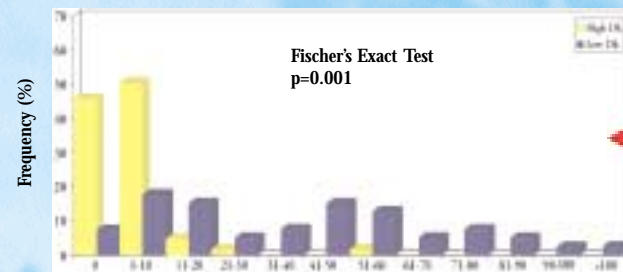
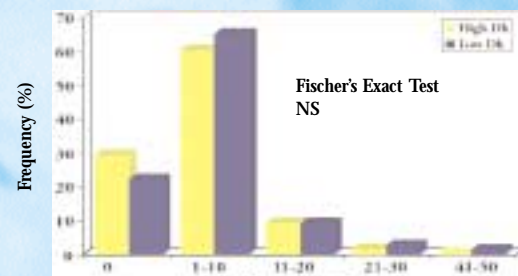
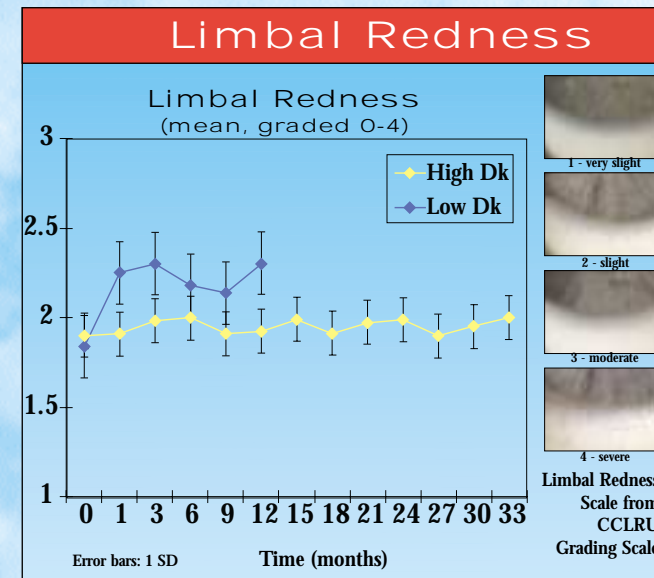
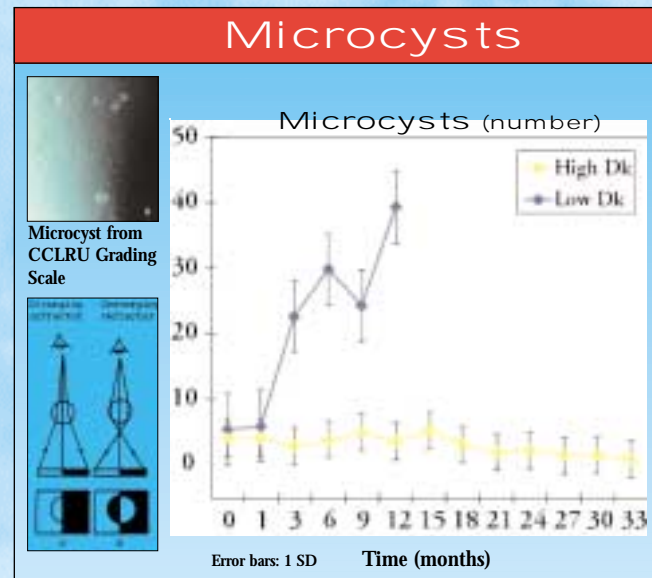
Lenses	High Dk	Low Dk
Type	Prototypes	Marketed
H ₂ O (%)	24, 35	58
Wear schedule	30N	6N
Replacement schedule	monthly	weekly

Subjects	High Dk	Low Dk
n	68	77
Male : Female	33 : 35	33 : 44
Age (years)	32 ± 7	32 ± 10
% previous DW	27	33
% neophytes	34	31
Rx - sphere (D)	-2.42 ± 0.29	-2.74 ± 1.32
- cyl (D)	-0.30 ± 0.25	-0.37 ± 0.27
Length of wear (years)	2.4 ± 0.3 (2 - 3.7 yrs)	0.8 ± 0.3 (up to 1 yr)

Study Design

- ▶ Prospective clinical trial
- ▶ All observers concordant⁴
- ▶ Visit schedule: baseline, 1, 3 months and every 3 months thereafter.

Results



Discussion

Across the study period there were no significant increases in numbers of microcysts, or levels of limbal redness with the high Dk group.

In comparison, significant increases with time in both microcysts and limbal redness were observed with the low Dk group. Significantly higher numbers of microcysts were observed in the low Dk group, with over 95% of the high Dk group having <10 microcysts at all visits.

Levels of limbal redness were also significantly higher in with the low Dk group compared to the high Dk group.

Conclusion

The oxygen transmissibility provided by the high Dk soft lenses alleviates the hypoxic stress normally associated with extended wear of contact lenses. No effects of hypoxia were evident after three years wear of high Dk soft lenses. To date there have been no reports of microbial keratitis. The ramifications of a normally functioning epithelium on the success of these high Dk products is being assessed in ongoing studies.

References

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