A Comparison of the Vascular Response to Extended Wear of Conventional Lower DK and Experimental High DK Hydrogel Contact Lenses.

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Introduction

There is a wide variation in the level of hyperemia observed in contact lens patients. One of the most common complications induced by contact lens wear is increased bulbar and limbal hyperemia[1,2]. Reduction in hyperemia[3,4,5] and faster recovery from induced hyperemia[6] have been reported with the short term wear of silicone hydrogel high oxygen transmissibility contact lenses. The longer term effects of oxygen transmissibility on the vascular response are not as well documented. It is also not clear whether patients presenting with greater levels of baseline hyperemia and neovascularization are more or less affected by the oxygen transmissibility of the contact lenses worn.

Aims

- To compare changes in bulbar and limbal hyperemia and neovascularization following 9 months of extended wear with conventional low Dk (LDK) lenses and an experimental high Dk silicone hydrogel lens (HDK).
- To determine how patient specific the effect of hypoxia is on hyperemia and neovascularization.

Methods

Study Design

- Subject eligibility confirmed.
- 62 adapted contact lens wearers completed study.
- Random group assignment.
- Same lens type worn in both eyes.
- Single (Investigator) masked.
- Baseline, 1M, 2M, 3M, 6M, 9M visits.

Lenses

	LDK	HDK
Material	Etafilcon A	Lotrafilcon A
Water	58%	24%
DK	28	140
Base Curve	8.4, 8.8	8.8
Diameter	14.0	14.0
Wear Schedule	Max 7D/6N	Max 30D/29N

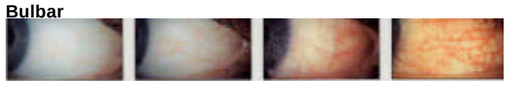
Subjects

	LDK	HDK
Number	23 (11M, 12F)	39 (13M, 26F)
Age	24.5 ± 5.4	25.2 ± 5.6
Rx	-3.37 ± 1.65DS	-2.70 ± 1.18DS
	-0.42 ± 0.22DC	-0.42 ± 0.22DC

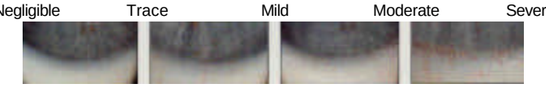
Grading

Hyperemia: Bulbar and limbal
0 - 100 point scale
Verbal anchors
CCLRU grading scales photographs
4 quadrants

Bulbar



0----------25----------50----------75----------100
Negligible Trace Mild Moderate Severe



Limbal

Neovascularization: 0 - 4 point scale with 0.5 increments
4 quadrants

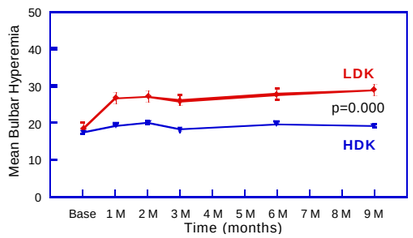
Analysis

The data from all visits were analysed using a repeated measures ANOVA and paired t-tests. For the pairwise *post hoc* comparisons ? was chosen to be 0.001 in order to preserve an ? of 0.05.

A stratified analysis to determine how changes in hyperemia and neovascularization depended on initial presentation ("low" or "high" levels at baseline) was also conducted. A Tukey HSD *post hoc* test was used in these analyses (? = 0.05)

Results

Figure1: Bulbar Hyperemia



Bulbar hyperemia increased significantly with the LDK lenses and did not change with the HDK lenses following 9 months extended wear. The level in this group increased most over the first month of wear (p=0.000) and remained significantly higher than for the HDK group, but did not change between subsequent visits.

Figure 2: Subject Change in Bulbar Hyperemia

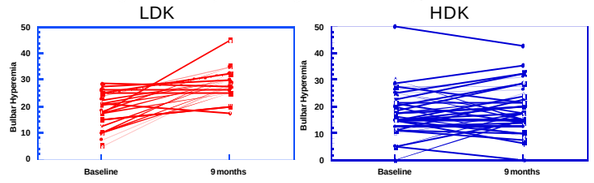
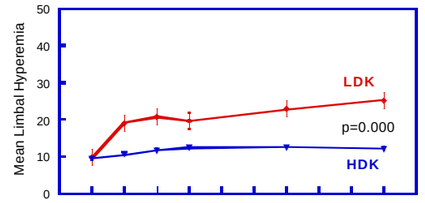


Figure 3: Limbal Hyperemia



Limbal hyperemia increased significantly with the LDK lenses and did not change with the HDK lenses following 9 months extended wear. The level in this group increased most over the first month of wear (p=0.000) and remained significantly higher than for the HDK group, but did not change between subsequent visits.

Figure 4: Subject Change in Limbal Hyperemia

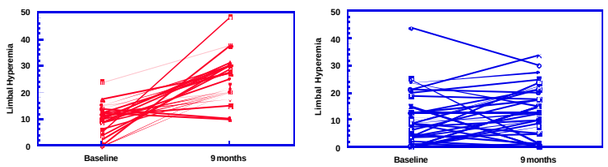
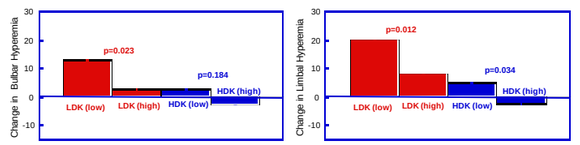
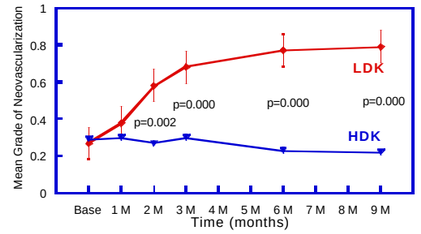


Figure 5: Change in Bulbar and Limbal Hyperemia by Initial Presentation Level



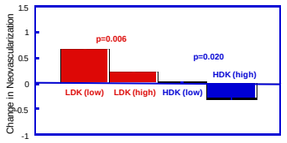
Bulbar and limbal hyperemia increased to a greater extent in LDK subjects initially presenting with lower levels of hyperemia. There was a decrease in limbal hyperemia in HDK subjects with higher levels of baseline hyperemia.

Figure 6: Neovascularization



Neovascularization increased significantly with the LDK lenses and did not change with the HDK lenses. The level was significantly greater in the LDK group at the 2 month and all subsequent visits.

Figure 7: Change in Neovascularization



Neovascularization increased to a greater extent in LDK subjects initially presenting with lower levels of neovascularization. There was a decrease in HDK subjects with higher levels of baseline vascularization.

Conclusions

- Hypoxia following 9M extended wear with conventional lower Dk (LDK) lenses resulted in an increase in bulbar and limbal hyperemia and an increase of 0.5 units (0-4 scale) in neovascularization.
- The increase in bulbar and limbal hyperemia and neovascularization was greatest for LDK subjects initially presenting with low levels of hyperemia or neovascularization.
- 9M wear with the experimental high Dk (HDK) lenses did not result in an increase in hyperemia or neovascularization.
- Wearers of HDK initially presenting with high levels of hyperemia or neovascularization showed a decrease in bulbar and limbal hyperemia and neovascularization.

References

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