



Refractive and Keratometric Changes Following Extended Wear.



K Dumbleton¹, D Richter¹, D Fonn¹, R. Chalmers².

Centre for Contact Lens Research, School of Optometry, University of Waterloo, Canada¹. CIBA Vision, Atlanta, GA²

Introduction

Early studies have reported a small increase in myopia and in some cases a concurrent steepening of the cornea following daily wear of "thick" (? 0.1mm) hydrogel lenses^{1,2,3}. Since these changes were not reported to occur with thin (0.06mm) hydrogel lenses⁴, they have generally been attributed to edema and possibly the steep fitting characteristics of the lenses worn. Similar results have also been reported with extended wear⁵. In a more recent study, a small but significant increase in myopia following extended wear of low DK hydrogel lenses has been reported⁶; however, the specific impact of hypoxia on refractive status and corneal curvature with extended wear are not well documented.

Aims

- To compare the refractive and keratometric changes induced over a period of 9 months of extended wear with conventional low DK (LDK) lenses and an experimental high DK silicone hydrogel lens (HDK).
- To determine whether the degree of refractive change is related to the initial level of myopic correction.

Methods

Study Design

- Subject eligibility confirmed.
- 62 adapted contact lens wearers completed study.
- Random group assignment.
- Bilateral lens design.
- 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: Sphere	-3.37 ± 1.65DS	-2.70 ± 1.18DS
Cylinder	-0.42 ± 0.22DC	-0.42 ± 0.22DC
Keratometry: H	44.02 ± 1.14D	43.70 ± 1.21D
V	44.54 ± 1.13D	44.33 ± 1.17D

Refraction

Refractive error: Nikon AutoRef Keratometer (NRK-8000)
Baseline, 3M, 6M, 9M

Keratometry

Central Corneal Curvature: Nikon AutoRef Keratometer (NRK-8000)
Baseline, 3M, 6M, 9M

Analysis

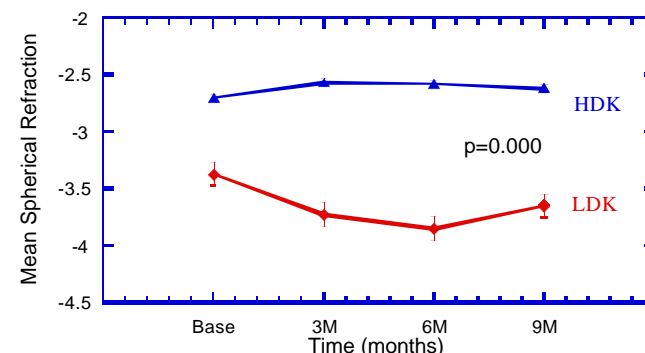
The refraction and keratometry data from all visits were analysed using a repeated measures ANOVA and paired t-tests. For the pairwise *post hoc* comparisons ? was chosen to be 0.005 in order to preserve a comparison-wise ? of 0.05.

A stratified analysis to determine how changes in spherical refraction depended on degree of myopia - "low" (<-3.00D) or "moderate" (-3.00 to -6.00D) - was also conducted. A Tukey HSD *post hoc* test was used in these analyses (? = 0.05)

Results

Since there was no change in cylindrical refraction over time in either lens wearing group (p=0.861, LDK; p=0.724, HDK), only the spherical refraction data are presented.

Figure 1: Spherical Refraction



Spherical myopic refraction increased significantly with the LDK lenses and did not change with the HDK lenses following 9 months extended wear. Spherical refractive error in this group increased most over the first 3 months of wear (p=0.006), but did not change significantly between subsequent visits.

Figure 2: Subject Change in Spherical Refraction

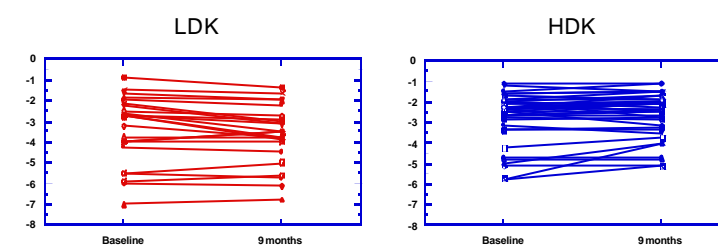
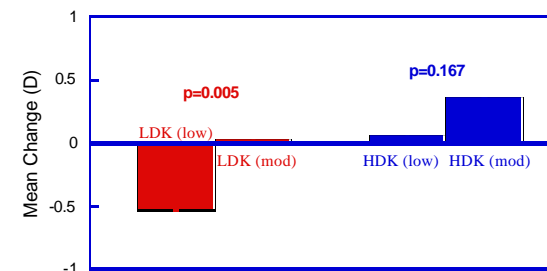
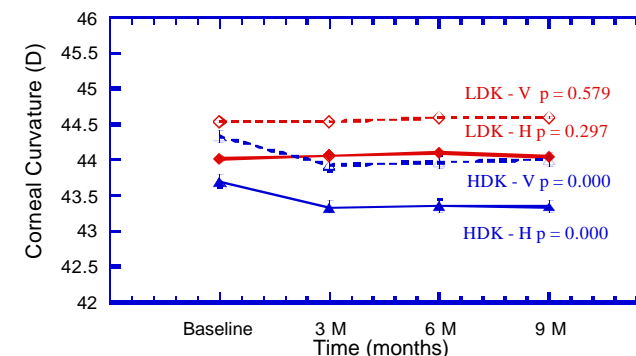


Figure 3: Change in Spherical Refraction by Degree of Myopia 9M vs. Baseline



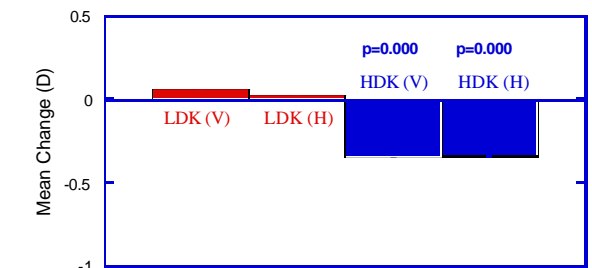
Spherical myopic refraction increased to a greater extent in LDK subjects with low myopia when compared to LDK subjects with moderate myopia. There was a small decrease in spherical refractive error in HDK subjects with moderate myopia, but this was not significantly different to the change in refractive error in the subjects with low myopia wearing the same lens.

Figure 4: Central Corneal Curvature



Central corneal curvature in both major meridians decreased significantly with the HDK lenses but did not change with the LDK lenses following 9 months extended wear. The curvature in the HDK group changed most over the first 3 months of wear (p=0.006), but did not change significantly between subsequent visits.

Figure 5: Mean Change in Corneal Curvature 9M vs. Baseline



Conclusions

- Hypoxia following 9M extended wear with conventional lower DK (LDK) lenses resulted in a myopic progression of 0.3D.
- The myopic shift was greatest for the low (<-3.00D) myopes wearing the lower DK lenses.
- 9M extended wear with the experimental high DK (HDK) lenses did not result in any significant change in refractive status.
- The myopic shift in the LDK group was not associated with central corneal steepening, however 9M EW resulted in a small degree of central corneal flattening with the high DK lenses.

References

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