



OCULAR SIGNS AND SYMPTOMS IN PATIENTS COMPLETING 3 YEARS WITH SILICONE-HYDROGEL CONTACT LENSES IN 30-DAY CONTINUOUS WEAR

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Introduction

Extended wear of hydrogel lenses has been characterised by long-term physiological compromise of the cornea. The introduction of silicone-hydrogel lenses with their high oxygen transmissibility promises to alleviate such complications. In this study we analyse the case histories of subjects enrolled for 30 day continuous wear in our initial trials of PureVision contact lenses to determine whether there have been any notable changes in ocular physiology over time of wear.

Methods

- 56 subjects were enrolled at two sites at Melbourne (N=33) and Luzerne (N=23) during June and July, 1997.
- Subjects were initially enrolled in a funded study (by Bausch & Lomb) for one year in which the subjects wore PureVision lenses in one eye (30 day CW) and Acuvue lenses (7-day EW) in the contralateral eye.
- After one year, the subjects exited the study but were provided with free PureVision lenses bilaterally for a further 12 months by Bausch & Lomb.
- After the second year, the subjects were no longer provided with free lenses. However, the lenses were on the market by this stage and many chose to continue wear with this modality.
- Data presented in this report represents the status at July 2000.
- For the purposes of this comparison, data from the one eye which wore the PureVision lens over the course of this study was used.
- We compared the data at baseline (prior to lens wear), after 1 week of wear (initial adaptation) and after 3 years of wear.
- A standard set of grading criteria was used at all time points during the study.

Results

- Discontinuations are presented in Table 1, with the reasons for discontinuations presented in tables 2 and 3.
- 25 eyes continue with wear, although 2 have a modified wearing schedule, one due to an incidence of GPC and one with CLPU.

Results (cont.)

- The frequency of positive gradings and reported symptoms for a number of the key variables is presented in Table 4.
- There were insufficient cases of corneal epithelial edema, striae, and neovascularization at all three time points to undertake statistical analysis.
- There were insufficient cases of the symptoms of burning, blur, variable vision, handling, excess tearing, secretion and photophobia at both the 1 week and 3 year time points to undertake statistical analysis.

	Len srel ated	Non-len srel ated
Year 1	5	6
Year 2	0	4
Year 3	2	12

	N=
discomfort	3
GPC	2
CLPU	1
CLARE	1

lack of motivation	4
cost	12
unavailable liability parameters	3
loss to follow-up	1
change of residence	2
refractive surgery	1

	Baseline	1 week	3 years	p=
Epithelial microcysts	1	0	2	0.37
Corneal staining	2	4	0	0.14
				0.003
				0.12
				0.045
				0.02
				0.0001
				0.014
				0.002
				0.0001

Discussion

- Between-group assessment of the long term effects of contact lens wear requires a large sample size. Repeated measures is more efficient but difficult to achieve. In the Gothenburg study, unilateral contact lens wearers averaging over 5 years of wear were studied by comparing lens wearing corneas with the contralateral cornea.¹ In our study, the same eye was monitored over a period of greater than 3 years, with the assumption of consistency in grading scales over time.
- Unlike the Gothenburg study which found significant changes to corneal physiology induced by hydrogel lens wear,¹ this study found that silicone-hydrogels did not produce a significant effect on corneal physiology.
- Indeed, for some parameters, the subjects appeared to show improvement over 3 years, probably as a result of cessation of hydrogel lens wear.
- Variables under test associated with lens surface properties and the subsequent effect on the palpebral conjunctiva showed deterioration over time. This is clearly a cause for further research in optimizing lens surface coatings.
- Discontinuations are probably unrepresentative of a typical population because of the initial enrolment in the study and provision of free lenses and care.
- After 4 and a half years of wear, there have been few further dropouts and all ongoing subjects continue to report general satisfaction with silicone-hydrogel lenses.

References

- Holden BA, Sweeney, DF, Vannas A et al. *Invest Ophthalmol Vis Sci* 1985; 26: 1489