MANCHESTER

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Results cont.

Purpose

The University of Manchester

A single-centre, randomised, interventional clinical trial was carried out to evaluate the performance of two silicone hydrogel contact lenses when worn as bandage lenses after laser assisted epithelial keratomileusis (LASEK) refractive surgery.

Materials & Methods

Patient selection

Eighteen patients participated in this study: 10 males and 8 females, aged 34 \pm 10 years. IRB (Institutional Review Board) approval was obtained. Prior to the study informed consent was obtained from all the subjects. Subjects were also informed of the details of the study, commitment needed and possible risks involved.

Surgery procedure

All LASEK procedures were carried out by one surgeon (SJD) using 18% alcohol in water for 35 to 40 seconds. Both eyes were treated on the same day. The alcohol was applied to the cornea using a 9mm well. The alcohol was soaked up with a merecel spear and the cornea washed with BSS (Balanced Salt Solution) to wash off any excess alcohol. The epithelium was then pushed back with a

Materials & Methods cont.

Surgery procedure continued

blunt instrument, leaving a superior hinge. The laser ablation was then performed using a Technolas 217c excimer laser. The epithelium was repositioned and a single drop of g. exocin and g. predforte was placed onto the cornea. The contact lens was then placed onto the eye by the same surgeon.

Experimental protocol

After LASEK surgery each patient wore a PureVision silicone hydrogel lens in one eye and a Focus Night & Day silicone hydrogel lens in the contra-lateral eye for the post operative period (approximately 3 days). This protocol, in which each patient wore the two lenses in contralateral eyes, was chosen to minimise intersubject variation to sensations such as pain or discomfort.

Measurement techniques

Evaluation of the lenses was performed objectively using a slit lamp biomicroscope and subjectively by means of a questionnaire.

Results

Conjunctival redness and limbal redness were similar for the two lens types (p>0.05). Figure 1.

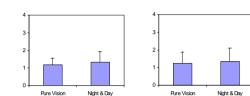


Figure 1. Conjunctival (left) and limbal (right) redness for the two lenses.

The PureVision lens was judged to have less deposition in comparison to the Night & Day lens. (Figure 2).

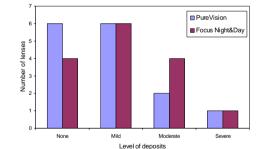


Figure 2. Level of deposition for the two lenses.

Eighty-nine per cent of eyes wearing the PureVision lens versus 82% of eyes wearing the Focus Night & Day lens had a completely healed epithelium on the evaluation day. In the few cases where the epithelium was not completely healed, eyes showed epithelial hyperplasia or epithelial strands.

Results cont.

Figure 3 (left) shows an eye with epithelial hyperplasia after contact lens removal and Figure 3 (right) shows an eye with large epithelial strands.

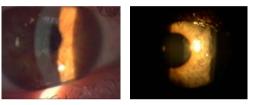


Figure 3. Epithelial hyperplasia (left). Large epithelial strands (right).

Subjectively, there were no differences between the two lens types for comfort (p = 0.30), foreign body sensation (p = 0.91), burning (p = 0.16), itching (p = 0.75), excess tearing (p = 0.66) and discharge (p = 0.61).

Conclusion

This study suggests similar clinical performance of the two silicone hydrogel lenses evaluated. In particular, both lenses achieved the therapeutical goal of a bandage lens; ' protection and healing of the corneal epithelium, and symptomatic relief'.

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