Open-eye corneal swelling with etafilcon A with PVP daily disposable limbal ring and clear hydrogel contact lenses compared to no lens wear

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Introduction

- For hydrogel lenses, oxygen permeability (Dk) is dependent on the water content of the lens.
- Previous studies showed minimal (2%) corneal swelling with daily wear (DW) of conventional low Dk hydrogel lenses.1,2
- A recent study showed statistically significantly greater corneal swelling and limbal hyperemia induced by DW of a low Dk hydrogel lens (Dk = 8.4) compared to silicone hydrogel lenses, however the differences were not considered clinically significant.3
- In vitro, it has been shown that the colors used in the fabrication of 1-DAY ACUVUE® DEFINE™ Brand contact lenses do not affect the Dk of the contact lens.
- To date, this impact of lens pigments on Dk has not been shown in vivo.

Purpose

To determine the impact of adding pigments to etafilcon A with PVP daily disposable (DD) hydrogel lenses on open-eye corneal swelling and compared to no lens wear (NLW).

Materials & Methods

- This was a double-masked, randomised, crossover study with bilateral lens wear in Asian eyes, which have been reported in the literature to be more susceptible to hypoxic effects of contact lens wear than Caucasian eyes.4
- 24 subjects (19 female and 5 male, mean age 21.1 ± 2.4 years, range 18-28 years) were the study lens-wearers (Table 1) according to a randomization schedule, on separate days with a minimum of 24 hours of no lens wear prior to each visit (washout period).
- Each participant was instructed to wake at least 3 hours before attending each baseline visit to ensure that any residual corneal swelling from overnight eye closure had dissipated.5
- Central corneal thickness (CCT) was measured before lens insertion and immediately after lens removal following an 8 ± 1 hour open eye period in one eye, using an optical pachymeter (OP).
- Topographical corneal thickness was measured along a 10 mm chord in the corneal meridian at the horizontal meridian (0-2 mm central cornea, and 2.5 mm peripheral, 5.7 mm mid-peripheral and 7.10 mm peripheral zones) using the Visante® OCT (Fig. 1).
- The corneal endothelial bleb response was measured at baseline and 20 minutes after lens insertion.6,7
- Examination of corneal endothelial cells was conducted using the Topcon SP-3000P Specular Microscope (Topcon Corporation, Tokyo, Japan) and was analysed with ImageNet™ software (Topcon Corporation, Tokyo, Japan). A test for non-inferiority for each lens relative to the control was carried out for corneal swelling using a margin of 5%.
- Subjective grating of limbal and bulbar hyperemia and corneal staining were monitored at each visit.
- Eltor grading scale was used to grade slit-lamp biomicroscopy variables.

Methods

- After 8 ± 1 hours open eye wear, the mean central corneal swelling values were 0.03%, 0.13% and 0.17% for etDdL, etDDP and NLW respectively as measured by optical pachymetry. (Fig 2).
- After 8 ± 1 hours open eye wear, the least square mean differences (LSMD) in central corneal swelling induced by etDdL and etDDP were -0.16% (95% CI: -0.39%,0.08%) and -0.13% (95% CI: -0.59%, 0.34%), and between etDdL and NLW were 0.04% (95% CI: -0.20%, 0.27%) and 0.07% (95% CI: 0.01%, 1.13%), and between etDDP and NLW were 0.19% (95% CI: 0.04%, 0.43%) and 0.80% (95% CI: 0.33, 1.26%) measured with OP (Table 2) and OCT (Table 3) respectively.
- OCT measurements along the horizontal meridian showed corneal swelling LSMD of -0.26% (95% CI: -0.36%, 1.45%) (95% CI: 0.84%, 2.06%), and 1.70% (95% CI: 1.09%, 2.32%) in the peripheral zone between each etDdL/etDDP, etDdL-NLW, and etDDP-NLW respectively (Table 3).

Results

- No endothelial blebs were found in this study.
- After 8 ± 1 hours open eye wear, the differences between the lenses and no lens wear in hyperemia (Fig. 4) and corneal staining (Fig. 5) were unremarkable.

Conclusions

- After 8 ± 1 hours open eye wear, central and peripheral corneal swelling along the horizontal meridian with 1-DAY ACUVUE® DEFINE™ with LARCEON® and 1-DAY ACUVUE® MOIST® were equivalent within the pre-stated margin of 5%.
- Those results confirm that the addition of pigments to obtain a limbal ring design had no impact on corneal swelling during normal open eye wear.
- After 8 ± 1 hours open eye wear, central and peripheral corneal swelling along the horizontal meridian with 1-DAY ACUVUE® DEFINE™ with LARCEON® and 1-DAY ACUVUE® MOIST® were equivalent to no lens wear within a margin of 5%.
- Those results confirm that 1-DAY ACUVUE® DEFINE™ with LARCEON® and 1-DAY ACUVUE® MOIST® provide sufficient oxygen to the cornea during normal open-eye wear.
- The study lenses showed minimal impact on corneal physiology in daily disposable regimen, as shown by the complete absence of any endothelial blebs at twenty minutes after lens wear and the presence of clinically insignificant levels of corneal staining5 6 and limbal and bulbar hyperemia10-11 at 8 ± 1 hours after lens wear.
- Both lens types can be used in open eye DD wear with minimal differences in their physiological performance or no from lens wear.

References


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