Open Eye Corneal Swelling with 1-DAY ACUVUE® DEFINE™ and 1-DAY ACUVUE® DEFINE™ with Lacreon® compared to 1-DAY ACUVUE® MOIST®

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Introduction

- For hydrogel lenses, oxygen permeability (Dk) is dependent on the water content of the lens material.[1]
- Previous studies showed minimal (~2%) corneal swelling with daily wear (DW) of conventional low Dk hydrogel lenses.[2-3]
- 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 (but the differences were not considered clinically significant).[4]
- In vitro, it has been shown that the colorants used in the fabrication of 1DAY ACUVUE® DEFINE™ Brand contact lenses do not affect the Dk of the contact lens.[5] Additionally, adding PVP to 1DAY ACUVUE® MOIST® does not affect the Dk of etafilcon A.[6]
- To-date, this impact of lens pigments on Dk has not been shown in vivo.

Purpose

To determine if the use of pigments or adding PVP during the fabrication of 1-DAY ACUVUE® DEFINE™ contact lenses impacts open eye corneal swelling.

Materials & Methods

- This was a double-masked, randomized, crossover study with bilateral lens wear.
- 24 Asian subjects (19 female and 5 male, mean age 21.1 ± 2.4 years, range 18 - 28 years) wore the study lenses (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).
- Both limbal ring lenses had pigment in the same areas in the periphery of the lens.
- 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.[7-9]
- 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 contralateral eye along the horizontal meridian (0-2 mm central cornea, and 2-5 mm peri-central, 5-7 mm mid-peripheral and 7-10 mm peripheral zones) using the Visante™ OCT (Fig 1).

Table 1: Study contact lenses

	Test lens (AD)	Test lens (AL)	Control lens
Name	1DAY ACUVUE® DEFINE™ Vivid (AD)	1DAY ACUVUE® DEFINE™ with Lacreon ®	1-DAY ACUVUE® MOIST®
Manufacturer	Johnson & Johnson Vision Care, Inc.	Johnson & Johnson Vision Care, Inc.	Johnson & Johnson Vision Care, Inc.
Lens Material	etafilcon A	etafilcon A	etafilcon A
Nominal Base Curve (mm)	8.5	8.5	8.5
Nominal Diameter (mm)	14.2	14.2	14.0
Lens Powers	-1.00 D to -6.00 D in 0.25 steps	-1.00 D to -6.00 D in 0.25 steps	-1.00 D to -6.00 D in 0.25 steps
Water Content	58 %	58 %	58 %
Nominal Center Thickness (mm) (at -3.00 D)	0.084	0.084	0.084
Oxygen Transmissibility* (Dk/t) (Barrer/cm)	25.5	25.5	25.5
Modality/Intended Use	Daily disposable	Daily disposable	Daily disposable

* *Dk/t @ center - 3.00 D lens using boundary-corrected, edge-corrected Dk values. Unit: (Barrer/cm) at 35° C*

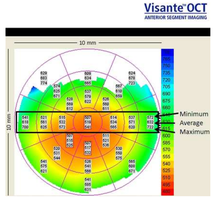


Fig 1. Topographical corneal thickness

Methods

- The corneal endothelial bleb response was measured at baseline and 20 minutes after lens insertion.
- 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%.
- High contrast VA (HCVA) and subjective grading of limbal and bulbar hyperemia and corneal staining were monitored at each visit.
- Efron grading scale was used to grade slit-lamp biomicroscopy variables.

Results

- After 8 ± 1 hours open eye wear, the LS mean differences in central corneal swelling induced by AD and the control were -0.05% (95% CI: -0.28, 0.18%) and 0.17% (95% CI: -0.29, 0.63%), and between AL and control lens were -0.16% (95% CI: -0.39, 0.08%) and -0.13% (95% CI: -0.59, 0.34%) measured with OP and OCT respectively (Figures 2-3).

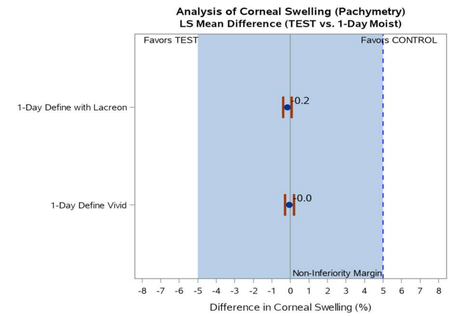


Fig 2. Central corneal swelling (Δ%) by Optical pachymetry

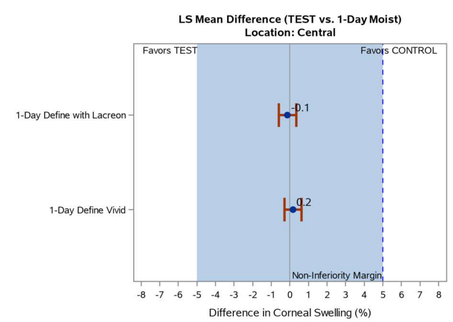
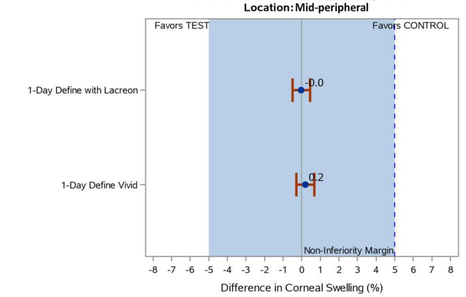


Fig 3. Central corneal swelling (Δ%) by OCT

Results

- OCT measurements along the horizontal meridian showed corneal swelling LS mean differences of 0.27% (95% CI: -0.14, 0.67%) and 0.04% (95% CI: -0.37, 0.45%) in peri-central, 0.20% (95% CI: -0.28, 0.67%) and -0.02% (95% CI: -0.50, 0.45%) in mid-peripheral, and -0.03 % (95% CI: -0.65, 0.58%) and -0.26 % (95% CI: -0.87, 0.36%) in peripheral zone between each AD and AL and control lens respectively.



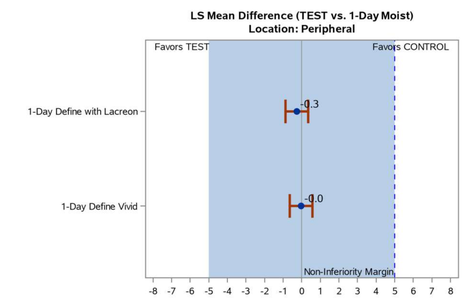


Fig 4. Peri-central ,mid-peripheral and peripheral swelling (Δ%)

- No endothelial blebs were found in this study.
- After 8 ± 1 hours open eye wear, the differences between the study lenses in HCVA, limbal and bulbar hyperemia (Fig 5) and corneal staining (Fig 6) were unremarkable.

Results

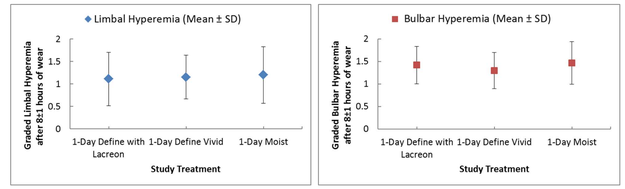


Fig 5. Graded max. limbal and bulbar hyperemia across conjunctiva

Fig 6. Graded max. staining type and area across cornea

Conclusions

- After 8 ± 1 hours open eye wear, central and peripheral corneal swelling along horizontal meridian with each AD and AL lens were equal to that observed with the control lens.
- These results confirm that the addition of PVP or pigments to obtain a limbal ring design have no impact on corneal swelling during normal open eye wear.
- The study lenses showed minimal impact on corneal physiology, as shown by the complete absence of any endothelial blebs at twenty minutes after lens wear, and the presence of clinically insignificant levels of graded corneal staining[10] or graded limbal and bulbar hyperemia[11-12] at 8 ± 1 hours after lens wear.

References

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