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Open-eye clinical performance of etafilcon A multifocal daily disposable hydrogel contact lenses compared to habitual silicone hydrogel lens wear

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Purpose: To evaluate ocular physiological responses to etafilcon A multifocal (etMF) daily disposable (DD) lenses after 4 weeks of switching from habitual silicone hydrogel (SiHy) daily wear.

Method: A single-arm, open-label, bilateral dispensing study was conducted in 39 habitual spherical SiHy wearers (14 hyperopes; 25 myopes). Clinical visits occurred after 6 hours of open-eye lens wear with habitual SiHy (control) at baseline and after 4 weeks of etMF DD at exit. Objective limbal/bulbar hyperemia using the Oculus K5M (0-4) and subjective grading of upper lid margin staining (ULMS) (0-4) were tested for non-inferiority (NI), using a margin of 1 grade. Corneal thickness along a 10 mm cord was measured using the Visante™ OCT and tested for NI using a 30 µm margin. Corneal staining area was graded (0-100%).

Results: The least-square mean differences (LSMD) and 95% confidence interval (95% CI) between etMF DD and habitual SiHy in central and peripheral corneal thickness (µm) were 3.64 (-2.0, 9.29) and 3.0 (-7.72, 13.72) in hyperopic, and 3.56 (-0.66, 7.78) and 6.40 (-1.62, 14.42) in myopic subjects. The LSMD (95% CI) for bulbar and limbal hyperemia were -0.08 (-0.19, 0.02) and -0.01 (-0.12, 0.09) in hyperopes, and 0.04 (-0.03, 0.12) and 0.04 (-0.04, 0.11) in myopes. The LSMD (95% CI) for ULMS were 0.11 (-0.39, 0.60), and 0.30 (-0.07, 0.67) for hyperopes and myopes, respectively. There was no corneal staining in 59% of eyes at baseline or the final visit. The maximum grades of mean corneal staining area were 17% in hyperopes and 5% in myopes at baseline, and ≤ 8% at exit. No significant differences between any of the variables were determined for patients switching into the etMF DD.

Conclusions: No clinically significant differences in a variety of ocular physiological responses to CL wear were found between habitual reusable SiHy wear and after 4 weeks of open-eye DD wear of 1-DAY ACUVUE MOIST MULTIFOCAL lenses, in either hyperopes or myopes may impact lens performance over time.

