Tolerability of 24-Hour Intraocular Pressure Monitoring of a Pressure-sensitive Contact Lens

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ABSTRACT:
Purpose: To investigate tolerability and safety of a new diagnostic device for 24-hour intraocular pressure monitoring in healthy subjects and age-matched glaucoma patients.
Patients and Methods: Twenty healthy subjects (group 1) and 20 age-matched glaucoma patients (group 2) were included in this prospective, single-center, open, observational parallel group study. The SENSIMED Triggerfish Sensor is a soft disposable contact lens embedding a telemetry chip and strain gauge sensor for continuous intraocular pressure monitoring. The Sensor was placed in 1 eye for 24 hours. Tolerability was evaluated using a visual analog scale (range, 0 to 100; 0=no discomfort; 100=very severe discomfort). Safety parameters included best corrected visual acuity, pachymetry, epithelial defects, conjunctival erythema, and corneal topography.
Results: Mean age was 61.7 years in group 1 and 65.0 years in group 2. Nineteen healthy subjects and 19 glaucoma patients (95%) completed the 24-hour wearing period. Early discontinuation resulted from pain (n=1) or inappropriate fitting of the sensor due to steep corneal radii (n=1). Mean tolerability was 21.8 in group 1 (range, 7 to 67) and 26.8 in group 2 (range, 0 to 71). Corneal epithelial staining (Modified Oxford scale, grade 0 to 4) changed from 0.4 (group 1) and 1.0 (group 2) at baseline to 1.8 (group 1) and 2.8 (group 2) after monitoring. No statistically significant differences could be detected between both groups.
Conclusions: This new pressure-sensitive contact lens is tolerable and safe over a 24-hour wearing period in healthy subjects and glaucoma patients. Both normals and glaucoma patients had a similar safety and tolerability profile.