Objective and Subjective Comparison of Two “Continuous Wear” Lenses: A Randomized 30-Day Study

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ABSTRACT
Continuous wear of contact lenses is a complex challenge to the physiological and immunologic ocular defense mechanisms, especially in extended wear. Practitioners have been reluctant to prescribe continuous wear lenses because of the adverse responses presumably associated with hypoxia caused by less optimal ocular responses with conventional hydrogel lens materials. Recent advances have provided soft contact lens materials with increased oxygen permeability by incorporating silicone into the hydrogel matrix. This study evaluates the comparative clinical performance of two silicone hydrogel lenses that are designated for continuous wear.

INTRODUCTION
Silicone hydrogel contact lenses were introduced in the late 1990’s heralding the re-emergence of 30-day continuous wear as a safe and viable option for lens wearers who seek the convenience of this modality. At the time this study was conducted, both the Bausch & Lomb PureVision ™ lens and the Ciba Focus Night & Day ™ lens had received approval by the United States Food and Drug Administration for lens wear up to 30-days of continuous wear. At the present time, however, patent issues have determined that only the Night & Day lens is currently prescribed in the U.S., whereas lenses are available in other parts of the world. Both lenses are made of a silicone hydrogel material which has demonstrated overnight overnight moister with resurfacing similar to those of non-wearing lenses during sleep. It is evident from previous reports that these products alleviate many of the complications previously observed with extended wear of conventional hydrogel materials. These include reduced limbal hyperemia and vasodilatation, reduced bacterial binding, fewer epithelial microlesions, as well as reduced corneal edema and polychromatophores. At the same time, a new phenomenon of post-lens debris, referred to as “mixin balls,” has also been reported. Although high Dk silicone hydrogel lenses have overcome most complications of a hydrogel design, many may be significant complications due to non-hygroscopic causes that still require careful professional assessment and significant treatment. Focus Night & Day (Optilens A) is characterized as a “true silicone hydrogel” with a Dk of 175, whereas Bausch & Lomb PureVision (silicon A) is a “silicone-hydrogel” with a Dk of 110. A plasma treatment is applied to the PureVision lens rendering the surface hydrophilic, whereas a plasma coating is applied to the Night & Day lens to enhance surface variability. Both companies claim their lenses minimize to no-smelling of the cornea, therefore allowing the lenses to be continuously worn for up to one month. The purpose of this study was to evaluate the comparative subjective and objective performances of the Focus Night & Day lens and the PureVision lens worn continuously on a 30-day continuous wear cycle.

METHODS AND MATERIALS
We report on a randomized, single-masked study in which each subject wore one Night & Day lens and one PureVision lens for 30 days continuously. Lenses were dispensed to be worn continuously, with required weekly follow-up care. Subjects were instructed not to routinely remove the lenses with consultation with the investigators. The only exceptions to this included immediate lens removal at any time there was pain, photophobia, or significant hypoxia.
The initial visit and the four weekly follow-ups were scheduled for the same general time of day (late afternoon) to control for effects of diurnal fluctuations. Table 1 is the examination record used to record findings during the initial visit. At the initial visit, keratometry readings were taken to determine which Night & Day base curve radius would be initially evaluated. Those subjects with corneal curvature more than 43.50 D were fit with the 8.66 mm base curve. All subjects wore the PureVision 8.6 mm base curve in one eye. Ultrasonic pachymetry was performed prior to insertion of the lenses, and again after the lenses were removed, to monitor for potential corneal edema caused by the lenses. Fitting characteristics as well as visual acuity was evaluated at the initial visit. Visual acuity, lens movement, debris buildup, corneal swelling, conjunctival hyperemia, dryness, subjective comfort, and corneal integrity were evaluated at weekly follow-up visits. Table 2 is the examination sheet used to record objective findings during each follow-up visit.
Dryness was addressed subjectively by slit lamp examination, and subjectively with questions inquiring about the additional use of moisturizing drops. Comfort was addressed subjectively by the patient answering a standardized questionnaire.

Table 3 is the standardized questionnaire in which dryness, comfort, and itching were subjectively evaluated. Edema was evaluated by slit lamp examination and ultrasonic pachymetry. Defects buildup and irritation of the cornea was evaluated by slit lamp exam and graded by a standardized scale. CCLRU grading scales were utilized to standardize grading of slit lamp observations.

RESULTS
All subjects were previously adapted daily soft lens wearers without ocular complications. These males and females were enrolled, with a mean age of 24 ± 3 years. All subjects had a manifest refraction between 20/20 and -3.00D, with less than 1.00D of astigmatism. All subjects wore the PureVision lens in one eye. Eleven subjects were fit with the Night & Day 8.4 mm lens and nine subjects wore the 8.6 mm lenses. Lenses were randomly assigned as to which eye wore a green band, and masked to the subjects.

Seventeen of the twenty subjects (85 per cent) completed the 30-day continuous wear study. The reasons for premature discontinuation of the three subjects were: one subject had a severe continuous headache for three days, another subject developed a contact lens peripheral ulcer (CLPU) in one eye, and one developed a perforated corneal secondary to a foreign body trapped under the contact lens. It was unsure exactly what the problem was with the first discontinuation. The second discontinuation was likely to have been related to the physical environment of club/disco lens wear. The eye that developed the CLPU was wearing the PureVision lens. The perforated corneal ulcer was unrelated to lens wear.

Week One Follow-Up
No significant vision problems or physiological complications were present in any of the subjects. Seventeen subjects (85 per cent) did not have any build-up on the lenses. Sixteen subjects (84 per cent) did not have any hypoxia of the bulbar conjunctiva.

Week Two Follow-Up
No significant vision problems, edema, or symptoms were present in any of the subjects. One subject had mosaic balls trapped under both lenses, greater with the Night & Day 8.4 base curve lens. Eleven subjects (58 per cent) did not have any build-up on the lenses.

Week Three Follow-Up
No significant vision problems, edema, or itching were present in any of the subjects. One subject still had mosaic balls trapped under both lenses, greater with the Night & Day 8.4 base curve lens. Eleven subjects (58 per cent) did not have any hypoxia of the bulbar conjunctiva.

Week Four Follow-Up
No significant vision problems, edema, or itching were present in any of the subjects. Eight subjects (43 per cent) did not have any build-up on the lenses. One subject still had mosaic balls trapped under the Night & Day 8.4 base curve lens. Thirteen subjects (70 per cent) did not have any hypoxia of the bulbar conjunctiva.

Pachymetry was taken before the lenses were inserted and at the conclusion of the study. Figure 1 is the comparison of the initial and final pachymetry readings for the PureVision lens. Figure 2 is the comparison of the initial and final pachymetry readings for the Night & Day lens. Figure 3 is the comparison of the differences of the initial and final pachymetry readings between both lenses. Overall, neither lens showed a significant difference between the initial and final pachymetry readings.

DISCUSSION
Overall, both lenses displayed good clinical performance and were well received by the subjects. Isomorphism signs, such as deposits on the lenses and injection of the conjunctiva, were similar for the two lenses. The contact lenses’ deposits along with injection of the conjunctiva began to develop at week one and continued to week four. The percentage of subjects with hypoxia was the highest at week two, 32 per cent. The percentage of subjects with deposits on their lenses continued to increase from 11 per cent at week one to 54 per cent at week four. Mosaic balls were an infrequent finding, and of no clinical consequence. The most severe complication was a CLPU in the eye wearing the PureVision lens. There were no cases of infiltrative keratitis, SCLAU (superior epithelial asteroid lesions), CLCPC (contact lens papillary conjunctivitis) or SCLAR (endothelial associated red eyes). Because this was a short-term 30- day study, it appears obvious that this is the reason that none of these complications were observed. Overall, this study indicates similar clinical performance with the two silicone hydrogel lenses evaluated and it is our view that both of these products can be successfully prescribed for continuous wear for up to 30 days. Close clinical monitoring, however, is essential for patients wearing lenses on a continuous wear basis.

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REFERENCES

ADDITIONAL READINGS