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 physiologic and immunologic mechanisms of the ocular tissues, especially the cornea. Practitioners have been reluctant to prescribe continuous wear lenses because of the adverse responses presumably associated with hypoxia caused by less than optimal oxygen permeability 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 designed 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 both lenses are used throughout other parts of the world. Both lenses are made of a silicone hydrogel material which has demonstrated overnight corneal swelling responses similar to those of eyes not wearing lenses during sleep.[1] 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 vascularization, reduced bacterial binding, fewer epithelial microcysts, as well as reduced corneal edema and polymegathism. At the same time, a new phenomenon of post-lens debris, referred to as 'mucin balls,' has also been reported.[2] Although high Dk silicone hydrogel lenses have overcome most complications of a hypoxic origin, there may be significant complications due to non-hypoxic causes that still require careful professional assessment and significant treatment.

Focus Night & Day (lotrafilcon A) is characterized as a 'fluoro-silicone hydrogel' with a Dk/t of 175, whereas Bausch & Lomb Purevision (balafilicon A) is a 'silicone-hydrogel' with a Dk/t 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 wettability.[2]

Both companies claim their lens causes minimal to no swelling 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 when worn specifically 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 without consultation with the investigators. The only exceptions to this included immediate lens removal if at any time there was pain, photophobia, or significant hyperemia.

The initial visit and 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 curvatures of 43.50 D and steeper were fit with the 8.4-mm base curve. Those subjects with curvatures flatter than 43.50 D were fit with the 8.6-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 build-up, 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 objectively by slit lamp examination, and subjectively with questionnaires inquiring about the additional use of rewetting 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. Debris build-up and injection of the conjunctiva was evaluated by slit lamp exam and graded by a standardized scale. CCLRU grading scales were utilized to help standardize grading of slit lamp observations.

SUBJECTS

All subjects were previously adapted daily soft lens wearers without ocular complications. Three males and seventeen females were enrolled, with a mean age of 24 ± 4 years. All subjects had a manifest refraction between –1.00 and –7.50 D, with less than –1.00 D of astigmatism. All subjects wore the Purevision lens in one eye. Eleven subjects were fit with the Night & Day 8.4 lens and nine subjects wore the 8.6 lens. Lenses were randomly assigned as to which eye wore a given brand, and were masked to the subjects.

RESULTS

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 preseptal cellulitis 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 physiological environment of closed-eye lens wear. The eye that developed the CLPU was wearing the Purevision lens. The preseptal cellulitis 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 (89 per cent) did not have any build-up on the lenses. Sixteen subjects (84 per cent) did not have any hyperemia 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 mucin 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 mucin balls trapped under the Night & Day 8.4 lens. The mucin balls were no longer seen under the Purevision lens. Fifteen subjects (79 per cent) did not have any hyperemia of the bulbar conjunctiva.

Week Four Follow-Up

No significant vision problems, edema, or itching were present in any of the subjects. Eight subjects (47 per cent) did not have any build up on the lenses. One subject still had mucin balls trapped under the Night & Day 8.4 base curve lens. Thirteen subjects (76 per cent) did not have any hyperemia 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.

Figure 1: Initial/Final Pachymetry Readings for the Purevision lens

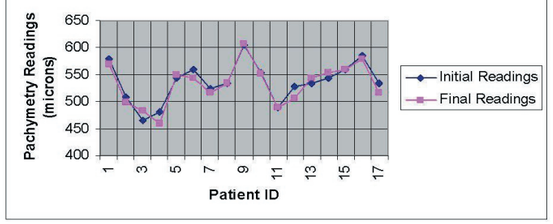


Figure 2: Initial/Final Pachymetry Readings for the Night & Day Lens

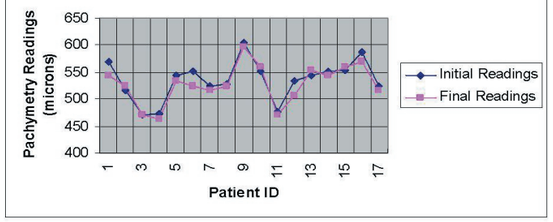
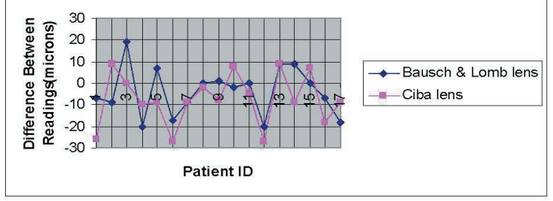


Figure 3: The Comparison of the Differences of the Initial/Final Pachymetry Readings Between Two Lenses



DISCUSSION

Overall, both lenses displayed good clinical performance and were well received by the subjects. Biomicroscopic 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 hyperemia 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 53 per cent at week four. Mucin 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, SEALs (superior epithelial arcuate lesions), CLPC (contact lens papillary conjunctivitis) or CLARE reactions (contact lens 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 performances 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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ADDITIONAL READINGS

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