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The Evaluation of Silicone Hydrogel and Traditional Hydrogel Materials for 7 Day Continuous Wear Among New Contact Lens Wearers.

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TL Comstock, OD, MS, WT Reindel, OD, MS, D Dey, MS

Rochester, NY

Introduction

Research has indicated that oxygen demands of the cornea vary from individual to individual.[1] The swelling response of the cornea to overnight wear of contact lenses also varies depending on the degree to which an individual is adapted to contact lenses.[2,3] Studies have demonstrated that the overnight corneal swelling response decreased as the patient's exposure to different levels of soft contact lens induced hypoxia increased.[2-4] Although the corneal swelling response investigations are of limited duration (i.e. overnight wear), non-adapted wearers had the most dramatic corneal response to hypoxia.[2,3]

Traditionally, subjects in contact lens long-term performance studies are primarily adapted contact lens wearers. Thus, the ocular response to long-term wear may be understated. The purpose of this study was to assess the long-term performance of two extended wear contact lens materials among a population of new contact lens wearers.

Methods

A total of 498 eyes (249 patients, that had never worn contact lenses or had not worn contact lenses within the past 12 months, were enrolled in the study by 9 investigators. Patients that met the eligibility criteria were dispensed a Test lens (balafilcon A - PureVision) and a Control lens (etafilcon A - Acuvue/Acuvue2) on the contralateral eye for one eye according to a randomization table. Patients were instructed to wear both lenses overnight for a minimum of four consecutive nights, but no more than six consecutive nights. The balafilcon A lenses were replaced every 30 days and the etafilcon A lenses were replaced every 14 days.

After beginning extended wear, follow-up visits were conducted at 24 hours, 1 week, 1 month, 3 months, and 6 months. Investigators evaluated the patients for physiological response and the lenses for fitting performance and lens surface characteristics.

Results

Patient Accountability:

Of the 498 eyes (249 patients) enrolled, 312 eyes (156 patients) completed the study, 6 eyes (3 patients) were non-dispensed and 180 eyes (90 patients) were discontinued from the study. (Table 1)

Table 1: Reason for discontinue from study. (Reported as eyes.)

Reason	Test	Control
Positive Slit Lamp Finding	10	10
Adverse Effect	1	0
Study related Signs/Symptoms	13	11
Unacceptable VA	9	8
Wearing Schedule	12	13
Non-Lens Related	45	48

Physiological Data:

Over all visits, the distribution of graded slit lamp findings are illustrated in Table 2. Chi-Square analysis of the distribution indicated a significant difference between the eyes wearing the PureVision (Test) lens when compared to the eyes wearing the Acuvue/Acuvue2 (Control) lens for Epithelial Microcysts, Limbal Injection, Bulbar Injection, and Neovascularization. As reported in Table 2, such findings were lower in the PureVision wearing eyes. There were no significant differences between Test and Control eyes for Epithelial Edema, Corneal Staining, Tarsal Conjunctival Abnormalities, or Infiltrates. (Table 2)

Table 2: Distribution of graded slit lamp findings that occurred over all visits. (Percent)

Events*	Test					Control				
	0	1	2	3	4	0	1	2	3	4
Epithelial Edema	98.7	1.0	0.2	0.1	-	97.7	1.8	0.4	0.1	-
Epithelial Microcysts	97.9	2.0	0.1	-	-	92.4	7.1	0.4	0.1	-
Corneal Staining	68.4	26.0	5.4	0.1	0.1	71.3	24.6	4.0	0.1	0.1
Limbal Injection	68.9	26.9	3.7	0.5	-	54.5	25.4	18.8	1.3	-
Bulbar Injection	66.7	25.6	7.1	0.6	-	61.3	26.0	11.3	1.4	-
Tarsal Conj. Abnormalities	57.2	34.1	8.0	0.8	-	57.4	36.4	5.7	0.6	-
Neovascularization	96.9	3.0	0.1	-	-	94.6	5.0	0.4	-	-
Infiltrates	98.8	0.7	0.3	0.2	0.1	98.3	1.0	0.5	0.2	-

*** Shading represents events where the distribution of graded slit lamp findings were significantly different.**

During the study, there were 12 eyes (6 Test, 6 Control) of 8 patients that required treatment for slit lamp findings and/or symptoms. There were 6 eyes from 5 patients (5 Test, 1 Control) reported to have "adverse events" that occurred during the study, Test - 2 Contact Lens Peripheral Ulcer, 2 Infiltrative Keratitis, 1 Foreign Body Abrasion, Control - 1 Contact Lens Peripheral Ulcer. No loss of best corrected vision occurred as a result of any of the adverse events.

Lens Fit:

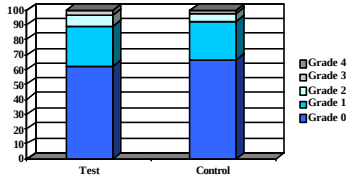
Over all visits, there was no significant difference in lens centration. Lens centration was described as good or excellent for 97.3% of the eyes wearing the Test (PureVision) lenses and at 95.1 % of the eyes wearing Control (Acuvue/Acuvue2) lenses.

Lens movement was significantly better with the Test (PureVision) lenses than with the Control (Acuvue/Acuvue2) lenses over all visits. Lens movement was described as adequate at all visits for 83.3% of the eyes wearing the Test (PureVision) lenses and for 69.4% of the eyes wearing the Control (Acuvue/Acuvue2) lenses.

Surface Characteristics:

The distributions of graded deposits are illustrated in Figure 1. For the PureVision (Test) lens, 88.9% of all visits were recorded as Grades 0-1 and for the Acuvue/Acuvue2 (Control) lens, 91.8% of all visits were recorded as Grade 0-1. Chi-square analysis indicated that there was no statistical difference between the distributions of lens deposits over all visits.

Figure 1: Distribution of graded deposit findings over all visits (Percent).



Optimal lens wettability was reported at 95.5% of the eye exams for the PureVision (Test) lenses and at 95.8% of the Acuvue/Acuvue2 (Control) lens eye exams. There were no significant differences in lens wettability reported between the Test and Control lenses.

Discussion

Improving the probability of success when designing a soft contact lens for continuous overnight wear requires a good balance between the material's oxygen transmissibility, physical/mechanical properties, and the lens design. While overnight swelling studies have demonstrated that non-adapted wearers have more corneal swelling, these studies are limited because of their short duration. Among daily wear adapted patients, previous research has shown that the oxygen transmissibility of the silicone hydrogel lens was sufficient to limit overnight swelling to an average of 4.1% when PureVision lenses are worn overnight. This compares to a an average of 9.1% swelling for Acuvue lenses.[5]

The distribution of signs commonly associated with hypoxia, epithelial microcycsts, injection and neovascularization, are reported more frequently among non-adapted eyes wearing the Acuvue/Acuvue 2 (Control) lens when compared to the non-adapted eyes wearing the PureVision (Test) lens. These outcomes are likely related to the higher oxygen transmissibility of the Test lens.

Other factors that may contribute to these outcomes are the fitting characteristics of the lens. In this evaluation, lens movement was significantly better with the PureVision (Test) lenses. Lens movement may play a role in the exchange of tears between the lens and cornea interface. Adequate movement upon awakening is recognized as an important factor in successful continuous wear of contact lenses.

Although the Test (PureVision) lenses were replaced on a monthly basis and the Control (Acuvue/Acuvue2) lenses were replaced every 2 weeks, the deposit distributions were not significantly different. Additionally, there was no significant difference in the distributions of Tarsal Conjunctival Abnormalities. Together with the lens wetting findings, these results indicate that the 30 day replacement schedule for the Test lens is also appropriate.

Conclusion

The results indicate that practitioners should observe fewer clinical signs among new patients fitted with PureVision (balafilcon A) lenses versus Acuvue/Acuvue2 (etafilcon A) lenses for extended wear. This difference appears to be related to the oxygen permeability of the material and the fitting characteristics of the lens.

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