Investigators evaluated the patients for physiological response at 24 hours, 1 week, 1 month, 3 months, and 6 months. After beginning extended wear, follow-up visits were conducted every 14 days. The balafilcon A lenses were replaced every 30 days and the etafilcon A lenses were not more than six consecutive nights. The balafilcon A lenses overnight for a minimum of four consecutive nights, but no more than six consecutive nights. The balafilcon A lenses or had not worn contact lenses within the past 12 months, were enrolled in the study by 9 investigators. 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.

Methods

Introduction

Research has indicated that oxygen demands of the cornea vary from individual to individual. 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. 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. 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.

Traditionally, subjects in contact lens long-term performance studies are primarily adapted contact lens wearers. Thus, the swelling 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.

Results

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). The distribution of signs commonly associated with hypoxia, non-wear, daily wear and extended wear soft lens patients. Int Cont Lens Clin 1990; 17, 224-227.

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 Abfraction, Control - 1 Contact Lens Peripheral Ulcer. No loss of best corrected vision occurred as a result of any of the adverse events.

Surface Characteristics:

The distributions of graded deposits are illustrated in Figure 1. For the PureVision (Test) lenses, 88.8% of all visits were recorded as Grades 0-1 and for the Acuvue/Acuvue2 (Control) lenses, 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 (%). 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.

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

The authors wish to acknowledge the support of the investigators for this study: Jan Bergmannson, Noel Brennan, Scott Fine, Des Fonn, Jeffrey Hall, Joseph Hanes, Phillip Morgan, Jeffrey Smith, Steven Wigoder.

Acknowledgment

References