Minimal Cholesterol Extraction and Maintenance of Pre-lens Tear Film Stability
Associated with an EOBO-Containing Lens and Lens Care Regimen

Christopher Lievens¹, Sebastian Marx², Wolfgang Sickenberger², Stefan Schwarz³, Amanda Shows⁴, Jessie Lemp⁴
Southwestern College of Optometry, Memphis, TN, USA; JENVIS Research, Ernst Abbe University Jena, Jena, Germany; Private Practice, Hildesheim, Germany; Alcon, Fort Worth, TX, USA

Introduction

● This study focused on evaluation of cholesterol deposition onto contact lenses (CLs) and the wettability of CLs.

● Cholesterol is the most abundant lipid component of tears deposited onto contact lenses (CLs), and can negatively impact CL comfort and visual performance. Overall, significantly higher amounts of cholesterol are deposited onto silicone hydrogel lenses than onto conventional hydrogel lenses.

● One aim in the development of silicone hydrogel contact lenses was to enhance the wettability of CL surface; the ability of fluid to spread and the tear film to be maintained over the surface. Silicone hydrogel CLs made of lotrafilcon B are manufactured with hydrophobic surface technology and have been shown to resist lipid deposition and maintain good surface wettability through 30 days of wear.

● The addition of the substantive wetting agent polyoxyethylene-polyoxybutylene (EOBO) to the packaging solution of spherical lotrafilcon B lenses has been shown to result in longer retention of moisture on the lens surface on the first day of wear.

● EOBO is also used in two lens care solution products, one containing hydrogen peroxide (H₂O₂) CLEAR CARE® PLUS with Hydraglyde® Matrix (CCP) and the other non-peroxide solution (OFPM) that includes Polyoxyethylene-polyoxybutylene (EOBO)-containing solution (OFPM) to provide longer lasting lens surface wettability, further reducing lipid deposition.

Objective

To determine the total cholesterol extracted from lotrafilcon B lenses and pre-lens tear film stability (PLTF) of lotrafilcon B lenses packaged in blister solution containing the EOBO wetting agent (ECOBO®) and care solutions formulated with EOBO (H₂O₂+EOBO®) or MPS+EOBO® (OFPM) after 30 days of wear.

Methods

Subjects

● Subjects were current, full-time (habitual) wearers of four other reusable silicone hydrogel contact lenses: confoflex® A, serriflex® A, senofilcon C monthly replacement, or senofilcon A two-week replacement lenses and were currently using an MPS not containing EOBO.

Study Design

Overall

This was a multicenter, prospective, randomized, observer-masked, controlled, parallel group study conducted at eight sites: five in the USA, two in Germany, and one in Canada.

The study protocol was approved by the institutional review board/ethics committee of each site, was conducted in accordance with the principles of the Declaration of Helsinki, and all subjects provided written informed consent.

The trial was registered at clinicaltrials.gov as NCT010292657.

At their initial visit, subjects were randomized 1:1 to either lotrafilcon B lenses packed in solution containing ECOBO (AIR OPTIX® with Hydraglyde®, Alcon Laboratories, Fort Worth, TX, USA) or to their habitual silicone hydrogel contact lenses.

Subjects randomized to lotrafilcon B CLs were further randomized 1:1 to either of two solutions containing ECOBO: CLEAR CARE PLUS® (CCP) with Hydraglyde® Matrix, which contains H₂O₂, or OPTI-FREE® PureMoist® (OPFM)+EOBO® MPS. This analysis was restricted to subjects who were fitted on Day 1 with lotrafilcon B+EOBO® CLs and randomized 1:1 to care solutions containing ECOBO, either CCP or OPFM.

After 30 ± 3 days of wear, right contact lenses were collected from all subjects, lenses frozen at -20 °C and sent to the laboratory for analysis.

Cholesterol Extraction

A subset of lenses were thawed and lipids were extracted using a two-step chloroform/methanol (1:1) method.

Free cholesterol and cholesterol ester (total cholesterol) concentrations obtained from each contact lens/care regimen were measured using a fluorometric enzymatic assay.

PLTF Stability

The tear film was assessed by measuring non invasive keratograph break-up time (NKBUT) using the Keratograph 5 (Zucal Eye, Germany) without lenses at baseline.

Subjects were then classified as having marginal (≥6 and <12 seconds) or optimal (≥12 seconds) NKBUT, and randomized was stratified by NKBUT category (marginal or optimal).

NKBUT video software was used to determine the percentage of the total tear film in contact lens wearers.

Percent area of distortion (PAD) at each timepoint was determined at 15 seconds.

Statistical Analysis

Descriptive statistics (means and standard deviations [SD]) are depicted in Table 1. 5

Descriptive statistics (means and standard deviations [SD]) and geometric coefficients of variation were calculated for the total cholesterol extraction data.

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Results

Subject Characteristics

● Characteristics of subjects is presented in Table 1.

● Most of the subjects were female and white.

● Subgroups were generally balanced with respect to age, sex, and race.

Table 1. Demographic characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean ± SD</th>
<th>Median</th>
<th>5th percentile</th>
<th>95th percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr (mean ± SD)</td>
<td>39.9 ± 5.1</td>
<td>39.3</td>
<td>35.0</td>
<td>43.0</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>White</td>
<td>40 (48.7)</td>
<td>39 (60)</td>
<td>40 (60)</td>
</tr>
<tr>
<td>Oriental-American</td>
<td>4 (6.2)</td>
<td>4 (6.2)</td>
<td>4 (6.2)</td>
<td>4 (6.2)</td>
</tr>
<tr>
<td>Asian</td>
<td>6 (24.0)</td>
<td>6 (24.0)</td>
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<td>6 (24.0)</td>
</tr>
<tr>
<td>Other/Mixed race</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
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</tr>
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Table 2. Total cholesterol extracted from individual combinations of contact lenses/lens care regimens

<table>
<thead>
<tr>
<th>Total cholesterol extracted, pg/lens</th>
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<tr>
<td>lotrafilcon B*+CCP**</td>
<td>32</td>
<td>0.28 ± 0.18</td>
<td>0.30</td>
<td>0.20</td>
<td>0.40</td>
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<tr>
<td>lotrafilcon B*+OFPM**</td>
<td>32</td>
<td>0.28 ± 0.48</td>
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</tr>
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Cholesterol Extraction Analysis

The mean ± SD amount of total cholesterol extracted from lotrafilcon B CLs maintained with the ECOBO-containing solutions CCP and OPFM was 0.28 ± 0.18 µg/lens and 0.28 ± 0.48 µg/lens, respectively (Table 2, Figure 1).

There was no significant difference between the amount of cholesterol extracted from lotrafilcon B CLs maintained with the ECOBO-containing solutions CCP and OPFM.

Cholesterol Extraction Analysis - Individual Combinations

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PLTF Stability

● PAD was similar in the CCP and OPFM groups and across timepoints (Figure 2).

● PAD was larger in subjects with marginal NIKBUT than in those with optimal NIKBUT at baseline. PAD remained stable across timepoints through Day 30 in the optimal NIKBUT group and increased slightly with time in the marginal NIKBUT group (Figure 3).

Conclusions

● The combination of lotrafilcon B contact lenses with packaging solution containing ECOBO and the use of CCP and OPFM lens care solutions regimens containing ECOBO resulted in similar low levels of extracted cholesterol and cholesterol esters.

● Both ECOBO regimens were able to maintain a constant PAD from Day 1 (insertion) and Day 1 (8 hours) to Day 30 (8 hours) of CL wear, suggesting that the ECOBO solutions maintain long-lasting lens surface wettability throughout the wearing period of 30 days.

● In addition, PLTF stability was similar over time in subjects who initially had optimal NIKBUT or marginal NIKBUT. Thus, the PLTF did not degrade over 30 days even among subjects who had less optimal tear film characteristics assessed at baseline.

● Low levels of cholesterol deposition observed in this study may have contributed to, or reflected, the maintenance of a stable PLTF.

Table 2. Total cholesterol extracted from individual combinations of habitual SfHy and lotrafilcon B contact lenses with solutions

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References


Disclosures

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