

# Ex Vivo Analysis of Lipid Deposition with Silicone Hydrogel Contact Lenses and EOBO-Based Lens Care Solutions

Rachel L. Redfern<sup>1</sup>; Jason J. Nichols<sup>2</sup>; Wolfgang Sickenberger<sup>3</sup>; Jennifer S. Fogt<sup>4</sup>; Marc Schulze<sup>5</sup>; Christopher Lievens<sup>6</sup>; Loretta Szczotka-Flynn<sup>7</sup>; Stefan Schwarz<sup>8</sup>; Amanda Shows<sup>9</sup>; Jessie Lemp-Hull<sup>9</sup>

<sup>1</sup>College of Optometry, University of Houston, Houston, TX, USA; <sup>2</sup>University of Alabama, Birmingham, AL, USA; <sup>3</sup>University of Applied Sciences, Jena, Germany; <sup>4</sup>The Ohio State University, Columbus, OH, USA; <sup>5</sup>University of Waterloo, Waterloo, ON, Canada; <sup>6</sup>Southern College of Optometry, Memphis, TN, USA; <sup>7</sup>Case Western Reserve University, Cleveland, OH, USA; <sup>8</sup>Private Practice, Hildesheim, Germany; <sup>9</sup>Alcon, Fort Worth, TX, USA

## Introduction

- Lipid deposition is of particular concern with silicone hydrogel (SiHy) contact lenses because the silicone in the material is hydrophobic. Over time, the silicone can reach the contact lens surface, enhancing its affinity for lipids from the tears.<sup>1,2</sup>
- The major lipid deposited on contact lenses is reported to be cholesterol.<sup>3</sup>
- Lipid deposition can have a negative effect on contact lens comfort and visual performance.<sup>4</sup>
- Lotrafilcon B lenses are manufactured with hydrophilic technology, which provides an ultra-thin shield around the outer surface to minimize the amount of exposed silicone.<sup>3</sup>
- Lotrafilcon B lenses have been shown to better resist lipid deposition than other types of SiHy contact lenses and to maintain good surface wettability through 30 days of wear.<sup>3</sup>
- Addition of the substantive wetting agent EOBO (polyoxyethylene-polyoxybutylene) to the packaging solution of spherical lotrafilcon B lenses (AIR OPTIX<sup>®</sup> plus HydraGlyde<sup>®</sup>, AOHG) has been shown to result in longer retention of moisture on the lens surface on the first day of wear.<sup>5,6</sup>
- EOBO is included in OPTI-FREE<sup>®</sup> PureMoist<sup>®</sup> multi-purpose disinfecting solution (OFPM) and CLEAR CARE<sup>®</sup> PLUS with HydraGlyde<sup>®</sup> Moisture Matrix (CCP), for longer lasting lens surface wettability to further reduce lipid deposition.<sup>7</sup>

## Purpose

- To compare the total cholesterol extracted from worn lotrafilcon B + EOBO contact lenses and cared for with EOBO-containing lens care solutions (OFPM and CCP) with the total cholesterol extracted from other worn SiHy contact lenses and cared for with multipurpose solutions (MPS) that do not contain EOBO.

## Methods

### Subjects

- This was a multicenter, prospective, randomized, observer-masked, controlled parallel-group study in which subjects were also masked to study lens and test solution (OFPM or CCP).
- Current full-time wearers of senofilcon C monthly or senofilcon A 2-week replacement lenses, comfilcon A, or samfilcon A lenses and who were currently using MPS that did not contain EOBO were recruited at eight sites, five in the USA, two in Germany, and one in Canada.

### Study Design

- Randomized 1:1 to lotrafilcon B lenses packaged in solution containing EOBO or to their habitual SiHy contact lenses (senofilcon C, senofilcon A, comfilcon A, or samfilcon A).
- Subjects randomized to lotrafilcon B contact lenses were further randomized 1:1 to EOBO-containing CCP or OFPM.
- Subjects randomized to their habitual SiHy lenses continued to use their habitual MPS (HMPS).
- Senofilcon A lenses were replaced after 15 ± 1 days.
- Right contact lenses were collected after 30 + 3 days of wear, frozen at ≤-20 °C, and sent to the laboratory for analysis.

### Cholesterol Extraction

- Lipids were extracted using a two-step chloroform:methanol (1:1) method.<sup>8</sup> Free cholesterol and cholesterol ester concentrations obtained from each contact lens/lens care solution group were measured using a fluorometric enzymatic assay.
- To compare total cholesterol extraction by groups of lenses, the geometric least squares mean (LSM) and upper confidence limit were calculated for each contact lens/lens care solution combination based on a general linear model.
- Results for lotrafilcon B+EOBO lenses and each EOBO-containing solution (CCP or OFPM) were compared with habitual SiHy lens/HMPS regimens by Dunnett's method, with all reported p-values being one-sided.

## Results

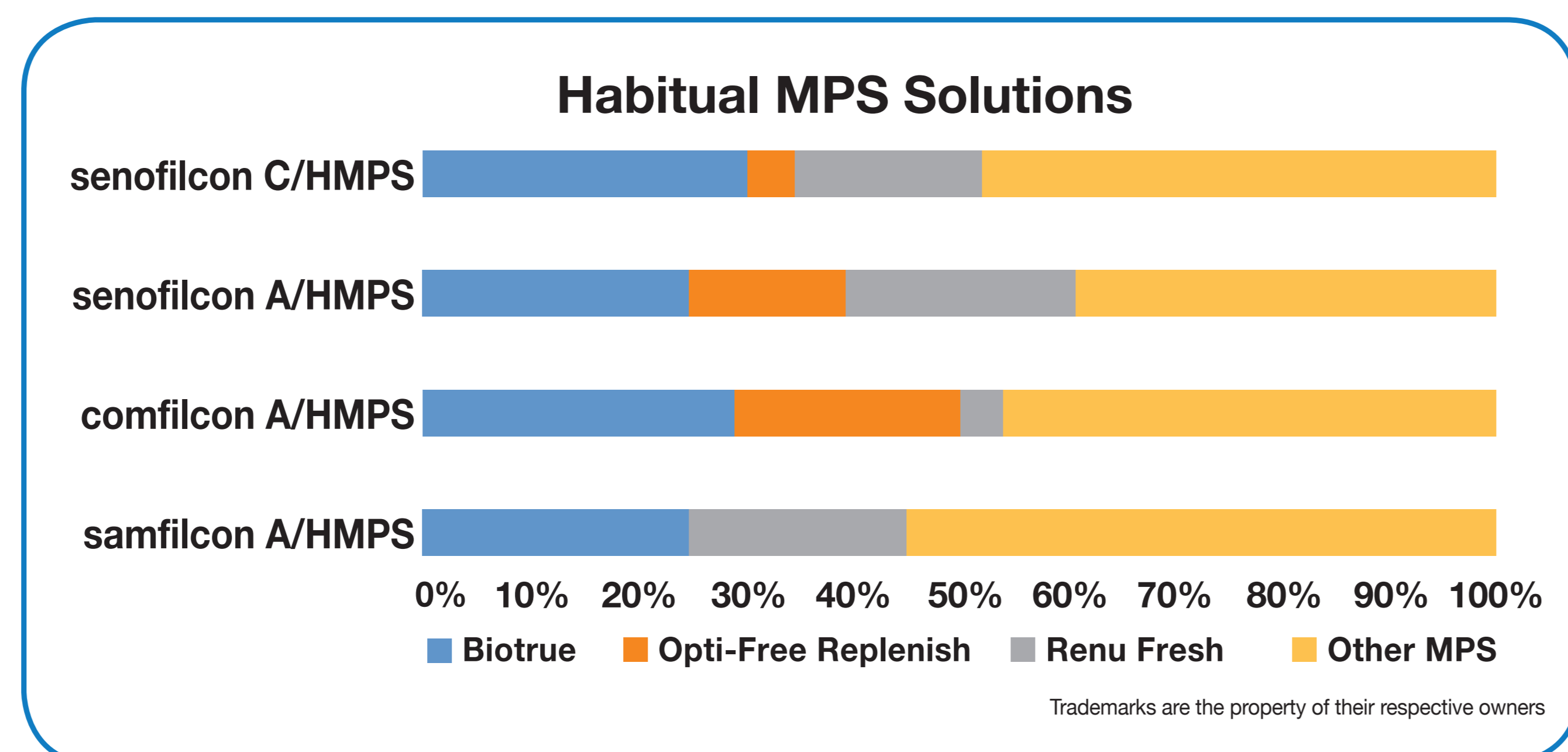
- The demographic characteristics of the six subgroups were well balanced (Table 1)

Table 1. Demographic characteristics of the study subgroups

	senofilcon C/HMPS (n=23)	senofilcon A/HMPS (n=28)	comfilcon A/HMPS (n=24)	samfilcon A/HMPS (n=20)	lotrafilcon B*/CCP** (n=23)	lotrafilcon B*/OFPM** (n=25)	Total (N=143)
Age, yr (mean ± SD)	27.8±5.6	30.1±8.1	27.8±5.0	29.1±7.2	26.5±5.4	27.8±5.9	28.2±6.3
Sex, female, n (%)	15 (65.2)	19 (67.9)	16 (66.7)	14 (70.0)	18 (78.3)	21 (84.0)	103 (72.0)
Race, n (%)							
White	16 (69.6)	16 (57.1)	21 (87.5)	17 (85.0)	16 (69.6)	20 (80.0)	106 (74.1)
African-American	1 (4.3)	2 (7.1)	2 (8.3)	1 (5.0)	1 (4.3)	2 (8.0)	9 (6.3)
Asian	5 (21.7)	7 (25.0)	1 (4.2)	2 (10.0)	6 (26.1)	3 (12.0)	24 (16.8)
Other/ Multiracial	1 (4.3)	3 (10.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (2.8)

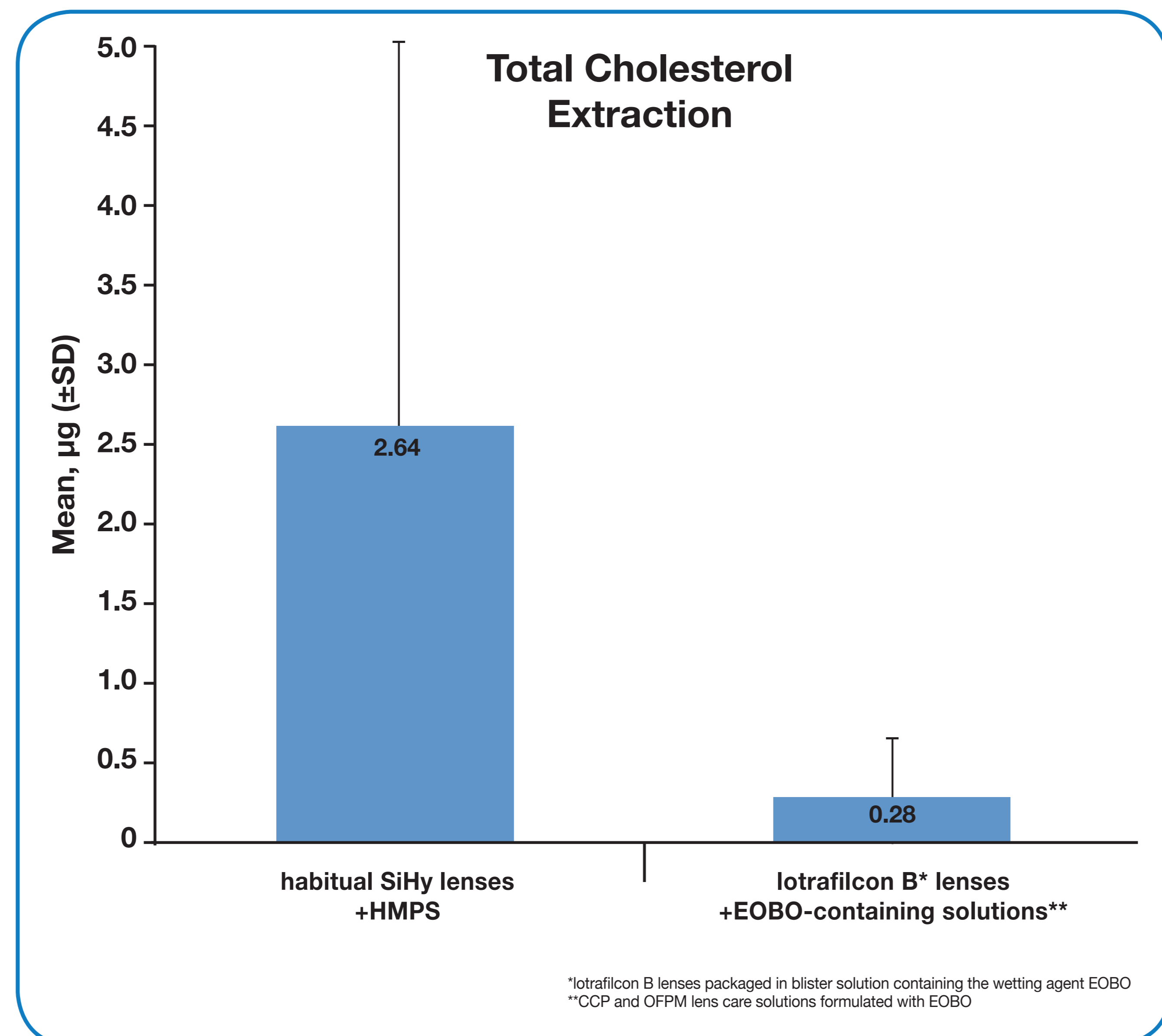
\*lotrafilcon B lenses packaged in blister solution containing the wetting agent EOBO  
 \*\*Clear Care Plus (CCP) and OPTI-FREE PureMoist (OFPM) lens care solutions formulated with EOBO  
 HMPS, habitual multi-purpose solution  
 \*senofilcon A lenses worn for 2 weeks

Figure 2. Habitual MPS used per lens by study subjects during enrollment



- A comparison of lotrafilcon B+EOBO lenses and cared for with EOBO lens care solutions versus all combinations of habitual SiHy contact lenses and HMPS showed that total cholesterol extraction was numerically lower in the lotrafilcon B group (Figure 3, Table 2)

Figure 3. Total cholesterol extraction of habitual SiHy and lotrafilcon B contact lenses



\*lotrafilcon B lenses packaged in blister solution containing the wetting agent EOBO  
 \*\*CCP and OFPM lens care solutions formulated with EOBO

Table 2. Total cholesterol extraction by lotrafilcon B+EOBO contact lenses and both EOBO-containing lens care solutions and by all combinations of habitual contact lenses/lens care solutions

	Habitual SiHy MPS	lotrafilcon B* + EOBO solutions
n	95	48
Mean ± SD	2.64 ± 2.51	0.28 ± 0.37
Median	2.00	0.20
(Min, Max)	(0.0, 14.0)	(0.0, 2.5)
95% CI	(2.13, 3.15)	(0.17, 0.39)
Difference (SE)		-2.36 (0.364)
95% CI of Difference		(-3.08, -1.64)

\*lotrafilcon B lenses packaged in blister solution containing the wetting agent EOBO

- Comparisons of individual combinations showed that ex vivo cholesterol extraction was significantly lower for lotrafilcon B+EOBO contact lenses cared for with both EOBO-containing lens care solutions than for any other contact lens/MPS combination (p < 0.0001, Figure 4, Table 3)

Figure 4. Total cholesterol extraction by each combination of habitual SiHy and lotrafilcon B contact lenses with solutions

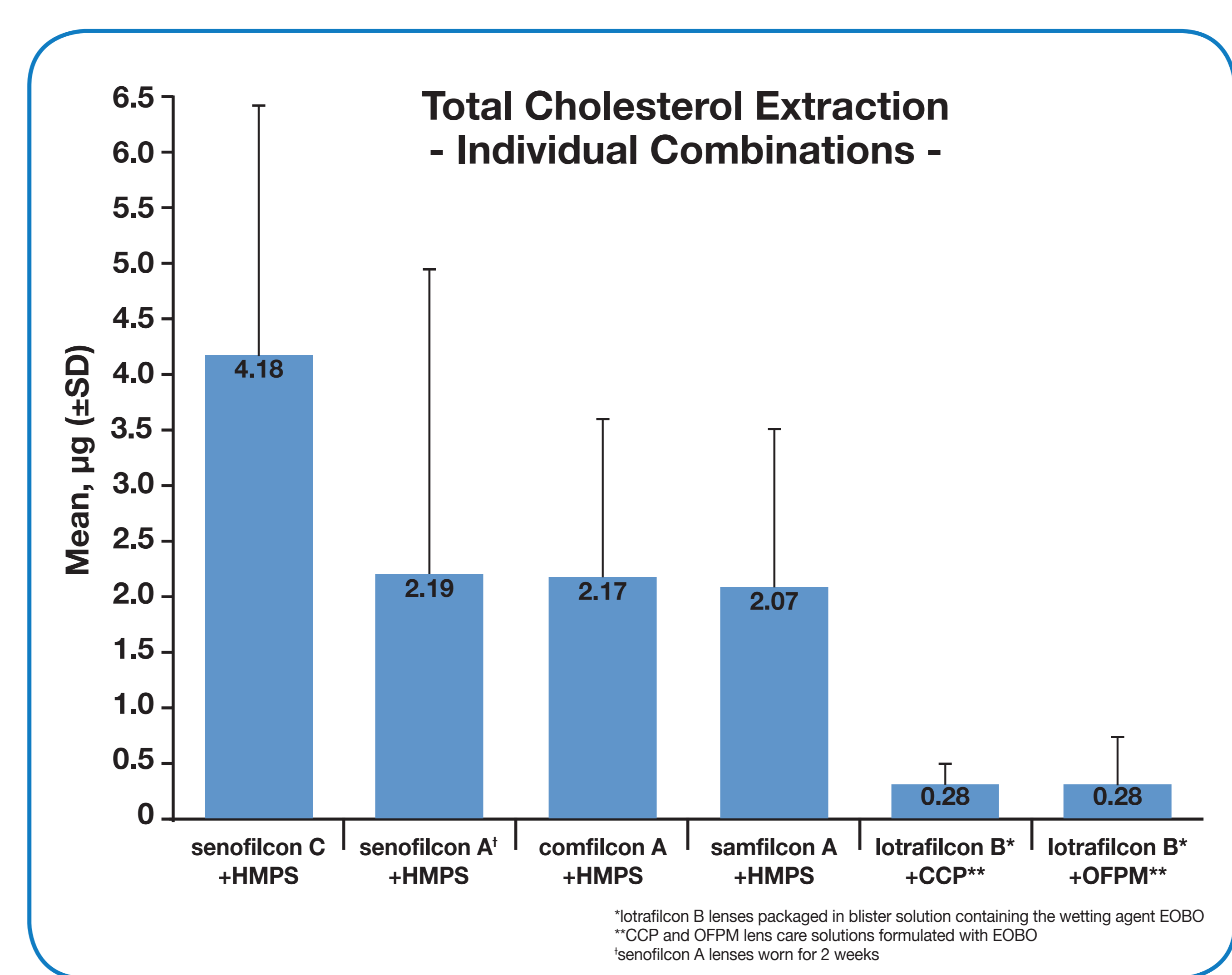


Table 3. Total cholesterol extraction by individual contact lens/lens care group

	senofilcon C/HMPS	senofilcon A/HMPS	comfilcon A/HMPS	samfilcon A/HMPS	lotrafilcon B*/CCP**	lotrafilcon B*/OFPM**
n	23	28	24	20	23	25
Mean ± SD	4.18 ± 2.25	2.19 ± 2.69	2.17 ± 1.47	2.07 ± 1.48	0.28 ± 0.18	0.28 ± 0.48
Median	4.20	1.55	1.55	1.90	0.30	0.10
(Min, Max)	(0.3, 14.0)	(0.0, 10.8)	(0.3, 6.9)	(0.6, 7.1)	(0.0, 0.8)	(0.0, 2.5)
95% CI	(2.78, 5.59)	(1.14, 3.23)	(1.54, 2.79)	(1.37, 2.76)	(0.20, 0.36)	(0.08, 0.48)
Geo Mean (CV%)	4.38 (65.97)	2.49 (76.21)	2.90 (43.39)	2.83 (40.46)	1.27 (13.94)	1.23 (24.77)
lotrafilcon B* vs. each habitual SiHy						
Geo LSM	4.38	2.49	2.90	2.82	1.27	1.23
p-value	<0.0001	<0.0001	<0.0001	<0.0001		

Geo. = Geometric; CV = Coefficient of Variation; LSM = Least Squares Mean  
 \*lotrafilcon B lenses packaged in blister solution containing the wetting agent EOBO  
 \*\*Clear Care Plus (CCP) and OPTI-FREE PureMoist (OFPM) lens care solutions formulated with EOBO  
 \*senofilcon A lenses worn for 2 weeks

## Conclusions

- The combination of lotrafilcon B contact lenses with packaging solution containing EOBO and the use of CCP and OFPM lens care solution regimens containing EOBO resulted in lower cholesterol extraction than each of the habitual SiHy/HMPS regimens tested.
- Both EOBO-containing lens care solutions (CCP and OFPM) showed similar low cholesterol deposition with lotrafilcon B lenses.
- Lipids are commonly extracted from contact lens materials using the solvents chloroform and methanol as used in this study. However, the efficiency of these solvents across a broad range of contact lens materials is not known, and therefore could have contributed to differences found here.

## References

- Keir N, Jones L. Wettability and silicone hydrogel lenses: a review. *Eye Contact Lens*. 2013;39:100-8.
- Ketelson H, Meadows DL, Stone RP. Dynamic wettability properties of a soft contact lens hydrogel. *Colloids Surf B Biointerfaces*. 2005;40:1-9.
- Nash WL, Gabriel MM. Ex vivo analysis of cholesterol deposition for commercially available silicone hydrogel contact lenses using a fluorometric enzymatic assay. *Eye Contact Lens*. 2014;40:277-82.
- Zhao Z, Naduvilath T, Flanagan JL, et al. Contact lens deposits, adverse responses, and clinical ocular surface parameters. *Optom Vis Sci*. 2010;87:669-74.
- Lemp J, Muya L, Driver-Scott A, Alvord L. A comparison of two methods for assessing wetting substantivity. Poster presented at: Global Specialty Lens Symposium; 2016 Jan 26-29; Las Vegas, NV.
- Muya L, Lemp J, Kern JR, Sentell KB, Lane J, Perry SS. Impact of packaging saline wetting agents on wetting substantivity and lubricity. Poster presented at the ARVO Annual Meeting 2016; May 1-6; Seattle, WA.
- Huo Y, Rudy A, Wang A, Ketelson H, Perry SS. Impact of ethylene oxide butylene oxide copolymers on the composition and friction of silicone hydrogel surfaces. *Tribol Lett*. 2012;45:505-13.
- Jones L, Senchyna M, Glasier MA, et al. Lysozyme and lipid deposition on silicone hydrogel contact lens materials. *Eye Contact Lens*. 2003;29:S75-79.

## Disclosures and Acknowledgments

This study was sponsored by Alcon Research, Ltd. Amanda Shows and Jessie Lemp-Hull are employees of Alcon. Editorial support was provided by BelMed Professional Resources, Inc. and was funded by Alcon.