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Introduction:

Some types of contact lenses (CLs) can destabilize the tear film and increase evaporation, which may contribute to the feeling of dryness for CL wearers.¹ Wearer discomfort and lens dryness remain the most important factors for individuals discontinuing CLs.² These symptoms typically occur late in the day when dryness and discomfort symptoms are more prevalent with CL wearers.³ Improvements, such as the inclusion of moisturizing agents in the lens care solution, have increased comfort throughout the day for wearers.⁴

There remains a challenge with surface hydrophobicity of silicone hydrogel CLs, which may interfere with lens lubricity, vision quality, and wearer comfort.⁵⁻⁹ However, the incorporation of wetting enhancing agents can have a positive impact on the lens surface wettability. EOBO (polyoxyethylene-polyoxybutylene) is such a wetting agent which helps the lens surface to stay lubricious¹⁰ throughout the day¹¹ and to increase comfort and reduce dryness for wearers.

Purpose:

To determine pre-lens tear film stability and daily comfort of lotrafilcon B lenses packaged in blister solution containing the EOBO (polyoxyethylene-polyoxybutylene) wetting agent (lotrafilcon B+EOBO) in combination with lens care solutions formulated with EOBO (H₂O₂+EOBO; CLEAR CARE® PLUS; CCP) or MPS+EOBO; OPTI-FREE® PUREMOIST®, OFPM) after 30 days of wear.

Methods:

A multi-center, prospective, randomized, observer-masked study was conducted in which subjects (n=122) were fitted with lotrafilcon B+EOBO and randomized to either CCP (n=59) or OFPM (n=63) to care for their contact lenses. All subjects were habitual soft contact lenses wearers with a minimal wearing time of 8 hours a day at least 5 days per week.

Pre-lens tear film stability was determined by time (seconds) to first distortion analyzed from 25 seconds by non-invasive keratography break-up time (NIK BUT) (Keratograph 5, Oculus, Germany) videos over the right CL after Day 1/insertion, Day 1/8 hours, and Day 30/8 hours.

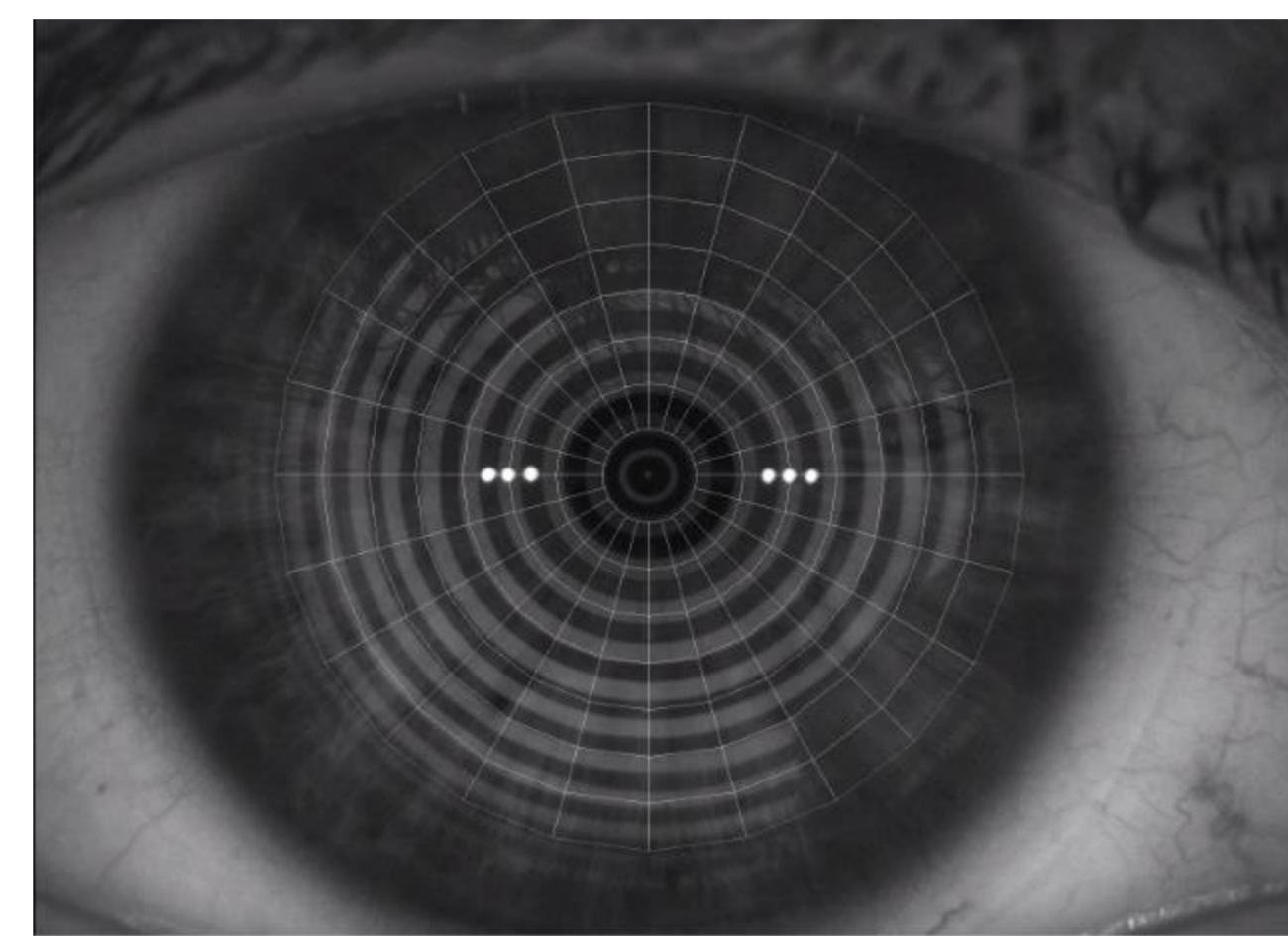


Figure 1: Investigator edited NIKBUT video

Captured videos were overlaid with a grid consisting of 192 segments. A trained investigator evaluated the video in steps of one second and marked segments which showed a dewetted area of the SCL. The analysis software plotted the number of marked segments over time starting from time point of first distortion.

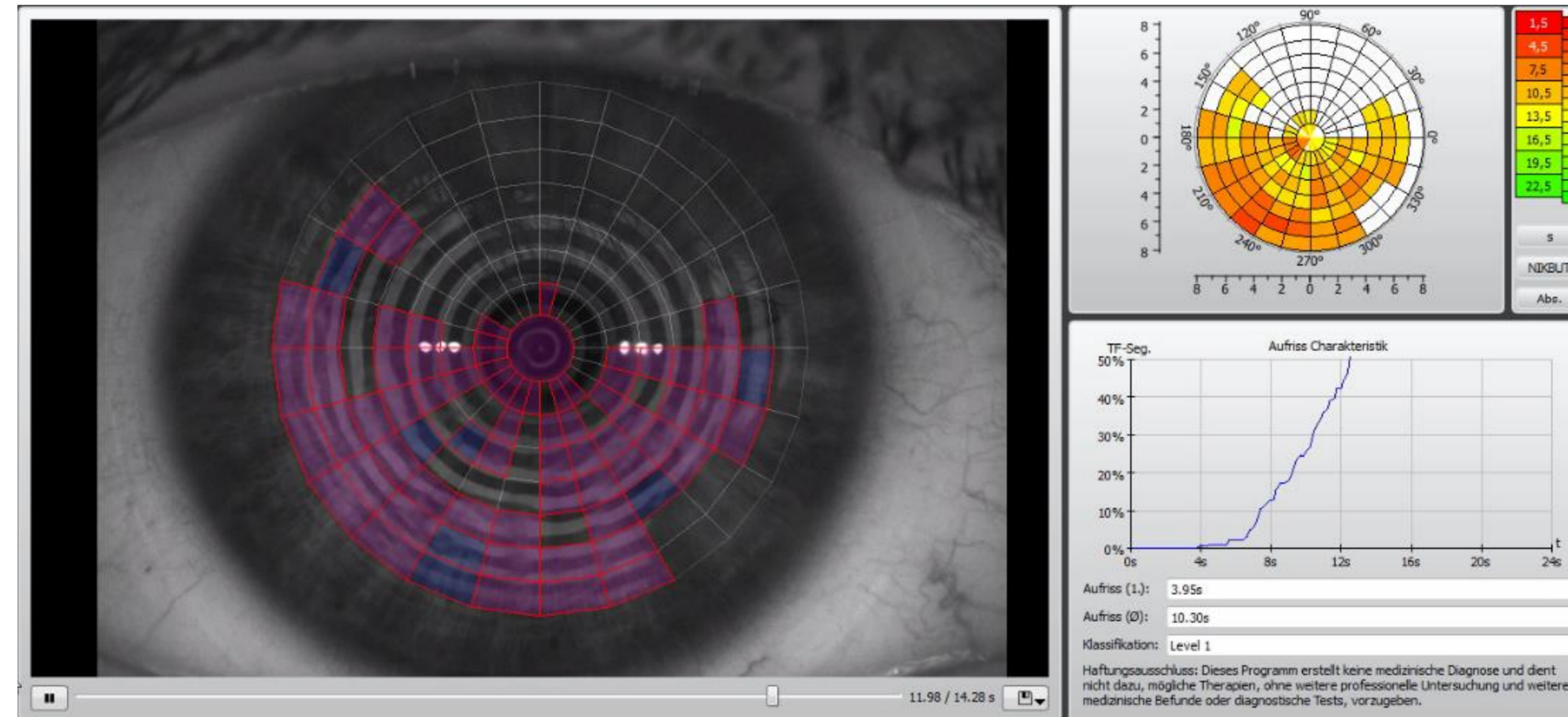
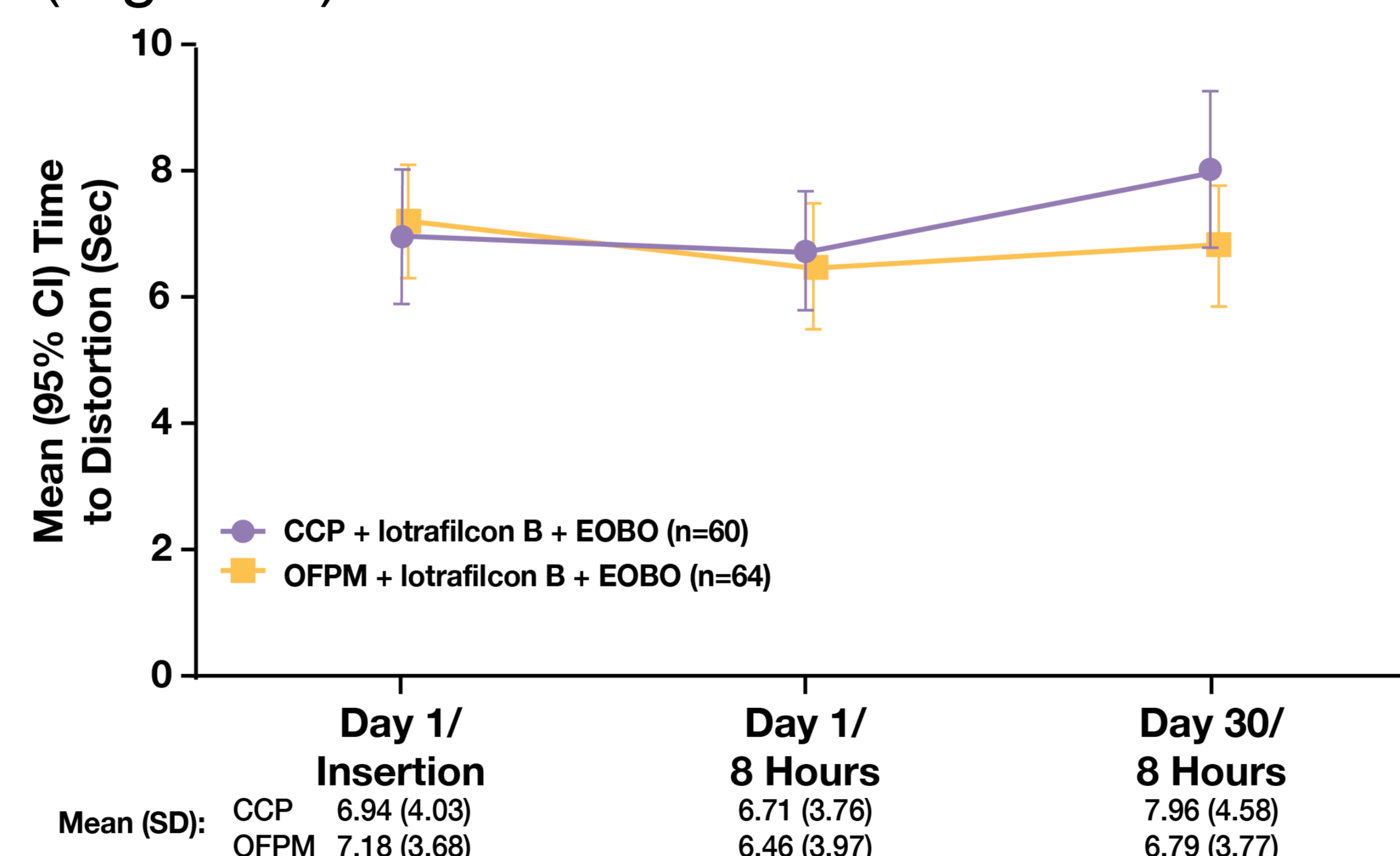


Figure 2: Investigator edited NIKBUT video

In addition to on site visits, subjects were asked to reply to text messages which were sent daily to their mobile phones. Text message questionnaires were completed on Day 1 to Day 30 after approximately 6 hours of CL wear. Subjects rated their experience in terms of comfort of their study CLs by texting the number (10-point scale; 1=poor, 10=excellent; whole numbers).

Results:

Time to first distortion was similar for subjects using each lens care solution and at each time point, (Figure 3).



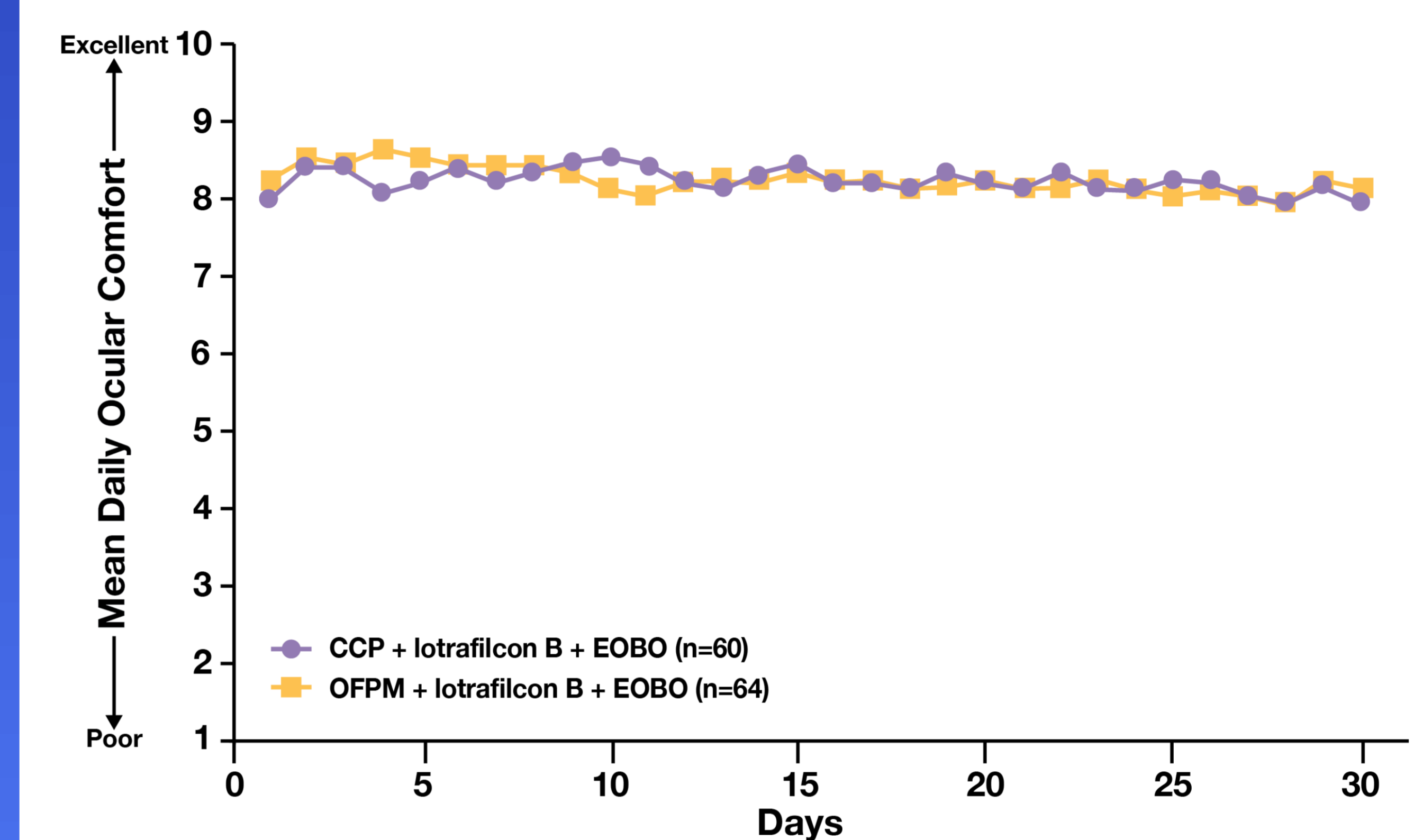
CCP, CLEAR CARE PLUS; CI, confidence interval; OFPM, OPTI-FREE PureMoist; SD, standard deviation

Figure 3. Mean (95% CI) time to first distortion (seconds) in wearers of lotrafilcon B+EOBO lenses cared for with CCP or OFPM lens care solution at Day 1/insertion, Day 1/8 hours and Day 30/8 hours.

Self-reported daily CL comfort after 6 hours of CL wear remained stable over 30 days in the CCP and OFPM group (Figure 4).

Mean (SD; 95% CI) daily CL comfort in the CCP group was 8.0 (1.7; 7.5-8.5) on Day 1 and 7.9 (1.6; 7.5-8.4) on Day 30 (-0.2 (1.8; -0.7-0.3) change in comfort)

Mean (SD; 95% CI) daily CL comfort in the OFPM group was 8.2 (1.6; 7.8-8.6) on Day 1 and 8.1 (1.3; 7.7-8.4) on Day 30 in the (-0.2 (1.7; -0.7-0.3) change in comfort).



CCP, CLEAR CARE PLUS; CI, confidence interval; OFPM, OPTI-FREE PureMoist; SD, standard deviation.

Figure 4. Mean daily CL comfort after 6 hours of wear on Days 1 through 30 in wearers of lotrafilcon B+EOBO lenses cared for with CCP or OFPM lens care solution.

Conclusion:

Both EOBO regimens were able to maintain the initial out of pack comfort and pre-lens tear film stability of lotrafilcon B+EOBO measured by the time to first distortion over 30 days of wear, suggesting that the EOBO solutions maintain long lasting lens surface wettability throughout this wearing period for a monthly replacement lens. This contributes to a constant comfortable wearing experience from day 1 to day 30.

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