



Clinical Evaluation of Biotrue Hydration Plus Multipurpose Solution in Daily Use with Planned Replacement Soft Contact Lenses

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ABSTRACT

Introduction: Planned replacement soft contact lenses (PRSCLs) continue to remain a popular option for vision correction. Biotrue Hydration Plus (BHP) is a novel multipurpose solution (MPS) developed for PRSCLs, with a formulation informed by Tear Film & Ocular Surface Society (TFOS) International Dry Eye Workshop II insights. It contains hyaluronan (HA) for moisturizing, erythritol for antioxidant and osmoprotectant properties, and potassium to support ocular homeostasis. It also incorporates poloxamine 1107 and poloxamer 181 surfactants for lens cleaning and wettability, alongside a triple disinfectant system. A two-arm study evaluated the clinical performance of BHP MPS over 3 months; here, we present a subanalysis of the BHP MPS arm.

Methods: This study was conducted across 17 sites in the USA, with evaluations at 2 weeks,

1 month, 2 months, and 3 months of lens wear. BHP MPS was dispensed to habitual wearers of silicone hydrogel or conventional hydrogel PRSCLs (four and one prespecified types, respectively). Subjects rated 13 lens performance attributes (grouped into comfort, vision, handling, lens cleanliness, and overall impression). Performance ratings were compared across visits using statistical methods to confirm consistency and equivalence. Investigators performed slit lamp examinations and evaluated lens deposits at each follow-up visit to assess MPS biocompatibility.

Results: Mean scores for lens comfort, vision, handling, and cleanliness on removal, and also overall impression, were 80–100 across all visits (very good–excellent; $p \geq 0.05$). No subject presented with >Grade 2 slit lamp findings at any visit, and few ungraded slit lamp findings were noted, reflecting the biocompatibility of BHP MPS with respect to the ocular surface. Lens deposition, cleanliness, and wettability were clinically acceptable in almost all subjects, and no participants discontinued owing to an adverse event.

Conclusions: In this analysis, BHP MPS was associated with minimal lens deposition, excellent biocompatibility, and high-performance ratings, making it a promising option for PRSCL wearers and for eye care practitioners to recommend before switching symptomatic wearers to a different contact lens modality.

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Key Summary Points

Why carry out this study?

In addition to containing disinfectants, contact lens multipurpose solutions (MPS) also contain additional ingredients to maintain comfort during lens wear.

Biotrue Hydration Plus (BHP), a novel MPS containing ingredients reflecting insights from the Tear Film & Ocular Surface Society International Dry Eye Workshop II, was developed to help maintain ocular surface homeostasis and improve comfort during lens wear.

It was hypothesized that the combination of ingredients in BHP MPS (including moisturizers, antioxidant/osmoprotectants, surfactants, and potassium as an electrolyte) would lead to high satisfaction among habitual wearers of both silicone hydrogel and conventional hydrogel contact lenses.

Subjects in this 3-month analysis rated all performance attribute groups as “very good” to “excellent”, and all attribute group ratings remained consistent over the course of the study; lens deposition, cleanliness, and wettability were clinically acceptable in almost all subjects.

BHP MPS performed well on the basis of both subjective and objective criteria and may contribute to improved lens wearing outcomes, making it a promising option for PRSCL wearers, and also for eye care practitioners to recommend before switching symptomatic wearers to a different contact lens modality.

INTRODUCTION

An estimated 45 million people wear contact lenses (CLs) in the USA [1], with 150 million wearers worldwide [2]. Planned replacement soft CLs (PRSCLs) remain popular, despite the trend towards increased fitting of daily disposable soft CLs [3, 4]; PRSCLs account for 40% of all global CL fits [3], and 84% of 742 habitual soft CL wearers surveyed in the USA wore PRSCLs in 2023. [4]

Two primary CL disinfection regimens are available for PRSCLs—a multipurpose solution (MPS) or a hydrogen peroxide solution (HPS) [5, 6]—and globally, 91% of PRSCL wearers were prescribed an MPS in 2023 [3]. MPSs are formulated with a variety of components intended to improve the wear experience [7]. Functional components include antimicrobial agents for disinfection, surfactants for lens cleaning and conditioning to improve lens wetting, buffering agents, chelating agents to improve cleaning, nonsurfactant wetting agents to help maintain a stable lens tear film, and demulcents and lubricants for hydration and comfort [7–10]. Despite high reported satisfaction with contemporary lens care options, dryness remains the most common problem for soft CL wearers, reportedly experienced by nearly half (47%) in the their previous year of use. [11]

PRSCL wearers are typically motivated to continue with their preferred CL wear modality, and the choice of CL care solution for disinfecting their lenses can play an important role in CL comfort and maintaining successful CL wear. A real-world evaluation including more than 3000 PRSCL wearers demonstrated that Biotrue MPS (Bausch & Lomb Incorporated, Rochester, NY) [12] improved PRSCL comfort, with high eye care practitioner satisfaction [13, 14]. Additionally, 90% of PRSCL wearers on the verge of CL discontinuation owing to discomfort and dryness who switched from their habitual MPS to Biotrue MPS reported increased likelihood of continuing CL wear; 6 months later, 93% of responding subjects were still wearing CLs at least once per week [15].

The Tear Film & Ocular Surface Society (TFOS) International Workshop on Contact Lens

Discomfort highlighted research into wetting agents that could be included in CL solutions to sustain CL surface wettability [16]. Subsequently, the TFOS International Dry Eye Workshop II (TFOS DEWS II) identified various agents used to alleviate the symptoms of dry eye disease [17]. These include hyaluronan (HA), which acts as a lubricant [18, 19], erythritol, a four-carbon polyol which acts as an osmoprotectant [20], and potassium, a tear-native electrolyte that plays an important role in ocular homeostasis. [17, 21]

Applied learning from TFOS DEWS II and Biotrue MPS clinical performance informed the development of Biotrue Hydration Plus (BHP) MPS, which was formulated to maintain ocular surface homeostasis and improve comfort during CL wear [17, 22, 23]. The solution contains 25% more HA than Biotrue MPS to increase moisture, as well as poloxamine 1107 and poloxamer 181 surfactants [12, 22]. In addition, it includes potassium and erythritol to help maintain ocular surface homeostasis [22, 24] and a triple disinfection system of polyaminopropyl biguanide, polyquaternium-1, and alexidine dihydrochloride at concentrations to ensure good ocular compatibility and provide broad disinfection efficacy [22, 25]. The BHP MPS pH of 7.5 is in the middle of the range of healthy tears, which supports comfort during lens insertion [22, 26].

A multicenter two-arm study was conducted to assess the clinical performance and biocompatibility of BHP MPS with hydrogel and silicone hydrogel PRSCLs over 3 months of CL wear. Here, we present a subanalysis of the BHP MPS arm from this study.

METHODS

A total of 17 investigative sites in the USA participated in this multicenter 3-month, two-arm, randomized, masked, bilateral study (NCT03897751) for which results have already been posted to clinicaltrials.gov [27]. This study was approved by Western Institutional Review Board (Puyallup, WA) and was in accordance with the Helsinki Declaration of 1964 and its later amendments. All subjects were recruited as part of routine practice, and informed consent

was provided to participate in the study. The study also complied with the Health Insurance Portability and Accountability Act.

Informed consent was obtained from all potential participants at the screening/dispensing visit. To participate in the study, subjects 18 years of age or older were required to be adapted habitual wearers of either one of four silicone hydrogel, single-vision CLs, these being lotrafilcon B (Air Optix Aqua, Alcon, Fort Worth, TX), balafilcon A (PureVision2, Bausch + Lomb Incorporated), samfilcon A (Bausch + Lomb ULTRA, Bausch & Lomb Incorporated), and senofilcon C (Acuvue Vita, Johnson & Johnson Vision, Jacksonville, FL), or the hydrogel, single-vision CL etafilcon A (Acuvue2, Johnson & Johnson Vision). Additionally, they had to habitually use lens care systems for cleaning, disinfecting, and storage of their lenses. Subjects also agreed to wear their respective habitual lenses on a daily wear basis for approximately 3 months and to use only BHP MPS for cleaning, disinfecting, and storing their lenses. Potential subjects who were aphakic, amblyopic, or who habitually wore daily disposable, monovision, multifocal, or toric CLs, as well as those with $\geq$ Grade 2 finding during the eligibility slit lamp examination were excluded from the study.

Enrolled subjects were 18–67 years old; each received BHP MPS and three new pairs of PRSCLs for daily wear (one pair was dispensed at study start, with replacement pairs at the 1-month and 2-month follow-up visits). Subjects were instructed not to use any other cleaning and disinfecting solution during the study. Subjects returned to the clinic for follow-up visits after 2 weeks, 1 month, 2 months, and 3 months of lens wear, during which they rated 13 lens performance attributes (burning/stinging on insertion, comfort on insertion, overall comfort, comfort at end of day, dryness, vision on insertion, overall vision, vision in low light, vision at end of day, ease of handling/insertion, ease of handling/removal, lens cleanliness on removal, and overall impression) using a 0–100 scale, with higher scores being more favorable (e.g., 100=excellent, 80=very good, etc.). For each subject, the scores from both eyes were averaged to calculate a subject score for each attribute. At each visit, a “comfort” group score

was calculated as the average score of the five comfort-related attributes (burning/stinging on insertion, comfort on insertion, overall comfort, comfort at end of day, and dryness), a “vision” group score as the average score of the four vision-related attributes (vision on insertion, overall vision, vision in low light, and vision at end of day), and a “handling” group score as the average score of the two handling-related attributes (ease of handling/insertion, ease of handling/removal). Subjects were also asked to rate the degree to which their lenses needed cleaning using a 0–4 scale, where 0 indicates none, 1 indicates slight (felt occasionally), 2 indicates mild (noticeable but not irritating), 3 indicates moderate (moderately irritating and annoying), and 4 indicates severe (noticeable and irritating). A clinically acceptable need for lens cleaning was considered to be none to mild.

Subjects also underwent a thorough slit lamp examination performed by the investigators at the screening/dispensing visit, as well as each follow-up visit. Slit lamp signs of corneal infiltrates, bulbar injection, limbal injection, corneal staining, upper lid tarsal conjunctival abnormalities, corneal neovascularization, epithelial edema, and epithelial microcysts were graded using an ordinal, text-based scale, from which numeric grades in integer steps were assigned, 0 (no finding), 1 (trace), 2 (mild), 3 (moderate), and 4 (severe). Fluorescein corneal staining grades were computed as the maximum grade taken within each of five different corneal locations (central, inferior, nasal, superior, and temporal), and the worst case was used as the single corneal staining grade. Only those subjects who presented with 0 (no finding) or 1 (trace finding) at the screening/dispensing visit were enrolled in the study. Subjects presenting with persistent grade 3 or 4 slit lamp findings at any visit were subject to removal from the study at the discretion of the investigator. Slit lamp signs of external adnexa abnormalities, conjunctivitis, corneal striae, and new corneal scar were not graded but recorded as absent or present. All investigators and their site staffs were trained to ensure consistent standard procedures were used for grading the findings.

At each follow-up visit, the degree of lens deposits was assessed for each eye as none, light, medium, or heavy. Lenses were examined on the eye with a slit lamp using 7× to 15× magnification for this determination. Maximum deposits over all follow-up visits (none or light, medium or heavy) were summarized as a measure of cleaning performance. Optimal cleaning effectiveness was the proportion of lenses with clinically acceptable deposits (none or light). The wettability of the lens surface was assessed at each follow-up visit on a 0–4 scale, where 0 indicated that the anterior lens surface was 100% wettable; 1 indicated that small (<0.1 mm), individual discrete nonwetting areas were present; 2 indicated that a single area of nonwetting between 0.1 mm and 0.5 mm in size was present; 3 indicated that several areas of nonwetting between 0.1 mm and 0.5 mm in size were present; and 4 indicated that one or more nonwetting areas greater than 0.5 mm in size were present. Clinically acceptable wettability was considered to be no dewetting or a single area of nonwetting ≤ 0.5 mm.

Statistical Analysis

To determine if performance remained consistent over the course of the study, paired differences in performance parameter group ratings between visits were evaluated for “at least as good as” criterion using one-sided tests, with adjusted one-sided α risks of 0.05 and an equivalence margin of five points. This involved 30 pairwise comparisons (three attribute groups and two additional attributes, multiplied by six visit-pairs over four follow-up visits), with the one-sided *t*-test performed to determine if the mean score from the earlier visit to the later visit does not decrease by more than five scale units, and a conclusion that the score at the later visit is at least as good as at the earlier visit if the adjusted *p*-value is < 0.05. To address multiplicity when simultaneously considering the results of all 78 tests, *p*-values were adjusted by the Holm method. No statistical analysis was performed on the number of subjects presenting with clinically acceptable levels of lens

deposit, need for lens cleaning, or lens wettability, as these eye-wise measurements do not represent independent sampling units.

RESULTS

A total of 127 adapted PRSCL wearers were enrolled in this arm of the study; of these, 117 completed all follow-up visits. Of those who did not complete all follow-up visits, five did not attend the 3-month visit, three attended the 3-month visit outside of the required ± 7 day visit window, one violated inclusion/exclusion criteria, and one was excluded for “other” reason. No participants discontinued owing to an adverse event (AE). Enrolled subject demographics are shown in Table 1.

Table 1 Baseline demographics of enrolled subjects

Characteristic	
Age (<i>n</i> = 127)	Years (mean $\pm$ SD) 34.4 $\pm$ 9.7
Gender (<i>n</i> = 127)	% (<i>n</i>)
Female	69.3 (88)
Male	30.7(39)
Hispanic or Latino ethnicity (<i>n</i> = 127)	% (<i>n</i>)
Yes	7.9 (10)
No	92.1 (117)
Race (<i>n</i> = 126)	% (<i>n</i>)
American Indian or Alaska Native	0 (0)
Asian	8.7 (11)
Black or African American	10.3 (13)
Native Hawaiian or other Pacific Islander	0 (0)
White	80.2 (101)
Multiple	0.8 (1)

SD, standard deviation

Lens Performance Outcomes for Comfort, Vision, and Handling

The average ratings at each visit for five performance attributes (comfort, vision, handling, lens cleanliness on removal, and overall impression) are shown in Fig. 1. Overall, subjects rated each of these highly, with “very good” to “excellent” mean scores across all visits and parameters. All five parameters remained unchanged or improved between all visit pairs (all $p \geq 0.05$), demonstrating consistency in BHP MPS clinical performance over the course of the 3-month study.

Slit Lamp Assessment of BHP MPS Biocompatibility

After 22,962 exposures to BHP MPS, no subject presented with >Grade 2 slit lamp finding. There were no eyes with serious AEs, adverse device effects, or significant nonserious AEs, and there were no eyes discontinued from the study owing to an AE. Exclusive of the screening/dispensing visit, investigators performed 496 slit lamp examinations of 254 eyes over the course of the study. Ungraded slit lamp findings of conjunctivitis, corneal striae, or new corneal scar were not observed at any visit, while external adnexa abnormalities and other anterior segment abnormalities occurred in less than 1% of subjects at any visit.

Lens Deposits and Cleanliness

Only 1.3% of lenses had more than light deposit over all follow-up visits, and all lenses had clinically acceptable level of deposit at the 3-month follow-up visit (Fig. 2). Further, 97.6% of lenses had clinically acceptable need for cleaning at the 3-month visit (Fig. 2). There were no lens replacements for discomfort, deposits, or damage throughout the study.

Lens Wettability

Lenses remained wettable over the course of the study, with 98.2% of lenses having clinically

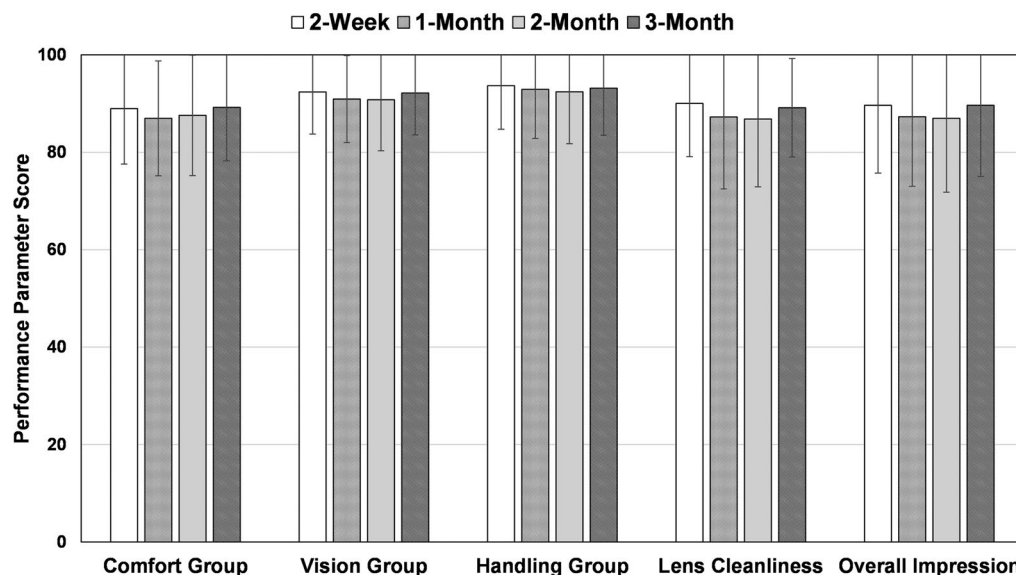


Fig. 1 Biotrue Hydration Plus MPS subjective performance ratings (average $\pm$ standard deviation) using a 0–100 scale, e.g., 100=excellent, 80=very good, etc. The comfort group represents the average score of the five comfort-related attributes (burning/stinging on insertion, comfort on insertion, overall comfort, comfort at end of day, and dryness); the vision group represents the average score of the four vision-related attributes (vision on insertion, over-

all vision, vision in low light, and vision at end of day); the handling group represents score as the average score of the two handling-related attributes (ease of handling/insertion and ease of handling/removal), and lens cleanliness is cleanliness on removal. For all attributes, no rating at any visit was worse than the rating at any other visit (all $p \geq 0.05$), reflecting the stability of the performance parameters over the 3-month duration of the study

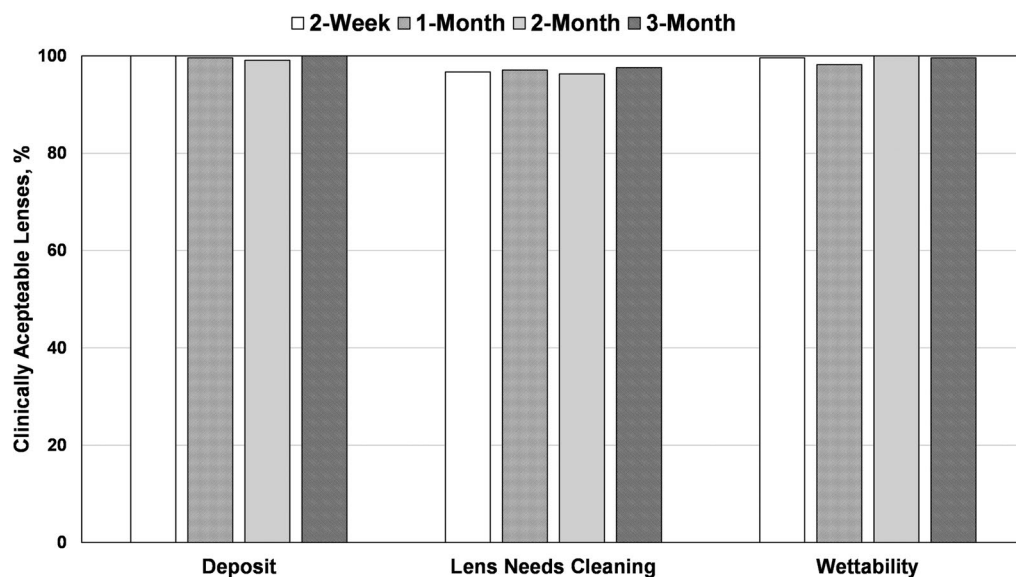


Fig. 2 Biotrue Hydration Plus MPS lens cleaning performance. Clinically acceptable lenses are those with none to light deposit, none to mild need for lens cleaning, and no dewetting or a single area of non-wetting ≤ 0.5 mm in size

acceptable wettability at the 1-month visit and 99.6% or greater at all other visits (Fig. 2).

DISCUSSION

CL wear satisfaction is driven by lens comfort and eye health; these can be affected by the CL material, design, and care system [28]. This subanalysis provides insight from the first large-scale evaluation of the clinical performance of BHP MPS among habitual wearers of both hydrogel and silicone hydrogel lenses. BHP MPS performed admirably on the basis of both objective and subjective assessments.

BHP MPS achieved consistently high subjective ratings for performance parameters of lens comfort, vision, handling, cleanliness, and overall impression. Performance parameter ratings remained consistent for this study arm over the 3 months of the study, with no decrease in rating noted for any parameter over all follow-up visits. Notably, lens comfort group scores remained between “very good” and “excellent” at all follow-up visits, suggesting that ocular homeostasis was maintained in this arm over the course of the study. This finding is of utmost clinical importance, as eye care practitioners and the CL industry have come to better appreciate the importance of ocular surface homeostasis during CL wear, which involves several key processes, including the maintenance of a stable tear film in addition to the maintenance of lens cleanliness [28, 29].

Investigator slit lamp evaluations for solution biocompatibility found no subject presenting with >Grade 2 slit lamp findings at any visit. Absence of any serious, clinically significant AE or adverse device effect in either eye at any of the 496 follow-up visits after nearly 23,000 exposures to the MPS, as well as no subject discontinuation from the study arm due to an AE, reflect maintenance of ocular surface homeostasis in the study arm population. In addition, the absence of ungraded slit lamp findings of conjunctivitis, corneal striae, or new corneal scar and the infrequency of external adnexa abnormalities and other anterior segment abnormalities at any visit reflect good biocompatibility of BHP MPS.

Preventing buildup of lens deposits by using an MPS contributes to maintenance of ocular surface homeostasis. In this study arm, optimal cleaning effectiveness was demonstrated with 100% of lenses having clinically acceptable deposit at the 3-month follow-up visit. BHP MPS effectively maintained lens cleanliness, with 97.6% of lenses acceptably clean at the 3-month follow-up visit. Excessive surface deposits can lead to decreased lens wettability and disrupted homeostasis. BHP MPS effectively maintained lens wettability, with 99.6% of lenses acceptably wettable at the 3-month follow-up visit.

In vitro studies of the performance of BHP MPS described in the literature support the findings of the current study subanalysis [30–32]. CLs soaked overnight in BHP MPS were found to retain and release HA over 20 h of simulated wear, and more HA was released in the first 12 h of simulated wear from BHP MPS-soaked CLs than from Biotrue MPS-soaked CLs, which is meaningful as 12h can represent a full day of CL wear for most users [31, 32]. Previously, CLs soaked overnight in Biotrue MPS were also reported to retain HA and release it over 20 h of simulated wear [32], and at least 2 h of clinical wear [33]. With respect to antimicrobial efficacy, BHP MPS was found to be as effective as HPS and more effective than four competitive MPSs at disinfecting compendial organisms in the presence of organic soil [25], when evaluated using the International Organization for Standardization (ISO, Geneva, Switzerland) ISO 14729 stand-alone test protocol [34].

The findings presented here should be considered in the context of the limitations intrinsic to the single-arm subanalysis and study design, including the subjective nature of wearers self-reporting BHP MPS performance. While the findings demonstrate the effectiveness of BHP MPS, the current study did not specifically assess its performance in wearers with severe dryness or other ocular conditions, which may limit its generalizability and would be of interest for further study.

Clinical studies suggest that in symptomatic populations, modification to lens material, design, and care system, as well as wear modality can potentially improve comfort [6]. Of note, a portion of CL wearers may even be unaware that

they experience signs or symptoms, with half of apparently “asymptomatic” PRSCL wearers being found to have an undiagnosed condition in a study of CL wearers undergoing routine eye examination [35]. Meanwhile, CL-related dryness persists as a common symptom reported by wearers of all types of lenses and remains one of the main reasons for discontinuation of CL wear [36]. Strategies reported to address CL dryness include fitting with daily disposable lenses, use of wetting agents (both topical and internal to the CL), ophthalmic inserts, punctal plugs, omega fatty acids, antibiotics, reducing CL wear time, or dropping out of lens wear altogether [37]. In the case of PRSCLs, manufacturers have included components in MPSs that sorb onto the CL during storage, then either remain localized at the lens surface or passively elute from the lens during wear or both [6, 38, 39]. Among these are surfactants such as poloxamers, poloxamines, and polyoxyethylene-polybutylene (EOBO) copolymer intended to improve wetting while also acting as moisturizers [6, 38]. For example, poloxamine 1107 sorbed on etafilcon A lenses was shown to increase lens wettability over at least the first 4 h of wear and was retained by the lens over at least 8 h of wear, manifesting as improved subjective comfort [40].

In addition to surfactants, manufacturers sometimes include other humectants and wetting agents in an MPS to address dryness, such as polysaccharides (e.g., HA) and other polyols (e.g., sorbitol and propylene glycol) [8, 16]. In a study of test subjects who wore senofilcon A lenses that had been soaked 14 h in Biotrue MPS prior to wear, HA concentrations in the subjects’ tear films remained elevated relative to baseline after 2 h of lens wear [33]. The addition of ingredients to BHP MPS and other CL solutions, informed by evidence-based insights from TFOS DEWS II, suggests that modification of MPS formulations can lead to high PRSCL user satisfaction [16, 17, 22].

In one study, PRSCL wearers intending to drop out of CL wear altogether within 6 months owing to CL discomfort and dryness switched from using their habitual MPS to using BHP MPS; 90% of study subjects reported improved comfort after using the BHP MPS for 7 days, and

86.6% were more likely to continue CL wear [22]. The specific lens properties and solution components that most contributed to BHP MPS user satisfaction and homeostasis remain to be confirmed, but similar high satisfaction among users of Biotrue MPS suggest that HA plays a key role [13–15]. Further, high satisfaction among CL wearers with habitual lens-related dryness who wore a daily disposable silicone hydrogel CL with a blister package solution containing several of the same ingredients as found in BHP MPS suggests that poloxamine 1107, poloxamer 181, erythritol, and potassium may also count as contributing factors to a more satisfying wear experience for lens wearers experiencing CL discomfort [41].

Several MPS components can serve multiple functions. Surfactants, while recognized as lens-wetting agents through interaction with lens polymer, also interact with proteins deposited on the lens [38]. The dual-surfactant system comprising highly hydrophilic poloxamine 1107 in combination with hydrophobic poloxamer 181 in BHP MPS contributes to the maintenance of tear proteins in their natural state by interaction with both hydrophilic and hydrophobic regions of protein molecules [38, 42, 43]. This was demonstrated previously in a study of daily disposable soft CL packaging solutions, in which the tear protein lysozyme, when challenged with the protein denaturant sodium lauryl sulfate, retained over 90% of its enzymatic activity in the presence of the solution containing the dual surfactants, compared with less than 5% in the presence of eight other packaging solutions or saline [39]. In a similar study of BHP MPS, the protein retained over 87% of its enzymatic activity in the presence of the MPS, compared with 88% in the presence of Biotrue MPS and less than 4% in the presence of four other MPSs, two HPSs, or saline [30]. Erythritol, while recognized as an osmoprotectant, further acts as an antioxidant [44], which may protect HA from free radical degradation [45]. HA, while recognized as a humectant, lubricant, and wetting agent, is also reported to have antioxidant properties itself [46]. Which of these functions are critical to ocular surface homeostasis remains to be elucidated.

CONCLUSIONS

BHP MPS, a unique formulation that includes ingredients informed by TFOS DEWS II, performed well in habitual hydrogel and silicone hydrogel PRSCL wearers with respect to comfort, vision, and handling. High ratings for these parameters were consistent and persisted over the 3-month time course of the study. Slit lamp examinations demonstrated the solution to be biologically compatible with the eyes. Lenses remained clean and wettable, with minimal deposit accumulation throughout the study. BHP MPS provides PRSCL wearers with a favorable lens wearing experience and represents a promising option for eye care practitioners to recommend before switching symptomatic PRSCL wearers to a different CL wear modality.

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Data Availability. Relevant data are within the manuscript. Clarification requests around the manuscript and its data can be made to the corresponding author.

Declarations

Conflict of Interest. Mark Schaeffer is a consultant to Bausch & Lomb Incorporated. All other authors are employees of Bausch & Lomb Incorporated.

Ethical Approval. This study was approved by Western Institutional Review Board (Puyallup, WA) and was in accordance with the Helsinki Declaration of 1964 and its later amendments. All subjects provided informed consent to participate in the study. The study also complied with the Health Insurance Portability and Accountability Act.

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REFERENCES

- Cope JR, Collier SA, Nethercut H, Jones JM, Yates K, Yoder JS. Risk behaviors for contact lens-related eye infections among adults and adolescents—United States, 2016. *MMWR Morb Mortal Wkly Rep*. 2017;66(32):841–5. <https://doi.org/10.15585/mmwr.mm6632a2>.
- Moreddu R, Vigolo D, Yetisen AK. Contact lens technology: from fundamentals to applications. *Adv Healthc Mater*. 2019;8(15): e1900368. <https://doi.org/10.1002/adhm.201900368>.
- Morgan PB, Efron N, Woods CA, Jones D, Jones L, Nichols JJ. International trends in daily disposable contact lens prescribing (2000–2023): an update. *Cont Lens Anterior Eye*. 2024;47(6): 102259. <https://doi.org/10.1016/j.clae.2024.102259>.
- Multi-Sponsor Surveys, Inc. (Princeton, NJ). Study of the U.S. consumer contact lens market (MS2314). 2023. Accessed March 2025. <https://www.multisponsor.com/wp-content/uploads/2024/02/US-Consumer-Contact-Lens-Market-MS2314.pdf>.
- US Centers For Disease Control and Prevention. About cleaning, disinfecting, and storing contact lenses. 2024. Accessed March 2025. <https://www.cdc.gov/contact-lenses/about/about-cleaning-disinfecting-and-storing-contact-lenses.html>.
- Willcox M, Keir N, Maseedupally V, et al. CLEAR—Contact lens wettability, cleaning, disinfection and interactions with tears. *Cont Lens Anterior Eye*. 2021;44(2):157–91. <https://doi.org/10.1016/j.clae.2021.02.004>.
- Jones L, Brennan NA, Gonzalez-Meijome J, et al. The TFOS International Workshop on Contact Lens Discomfort: report of the contact lens materials, design, and care subcommittee. *Invest Ophthalmol Vis Sci*. 2013;54(11):TFOS37–70. <https://doi.org/10.1167/iovs.13-13215>.
- Capote-Puente R, Sanchez-Gonzalez JM, Bautista-Llamas MJ. Multipurpose lens care systems and silicone hydrogel contact lens wettability: a systematic review. *Eye Contact Lens*. 2022;48(9):356–61. <https://doi.org/10.1097/ICL.0000000000000914>.
- Gromacki SJWM. Understanding contemporary contact lens care products. *Cont Lens Spectr*. 2013;28(6):20–5.
- Gulmiri A and Liao J. Contact lenses & solutions summary (CLASS). *Contact Lens Spectr*. 2023;38(9S).
- Multi-Sponsor Surveys, Inc. (Princeton, NJ). The 2023 Study of Contact Lens Cleaning & Care (MS2307). 2023. Accessed March 2025. <https://www.multisponsor.com/wp-content/uploads/2023/08/Contact-Lens-Cleaning-and-Care-MS2307.pdf>.
- Bausch & Lomb Incorporated (Rochester NY) Biotrue® multi-purpose solution [package insert]. 2010. Accessed January 2025. <https://www.biotrue.com/siteassets/pdf/biotrue-solution-package-insert.pdf>.
- Merchea MM, Bednar K, Doktor M, Bateman K. Patient satisfaction with multipurpose solutions in over 3000 subjects. presented at: American Academy of Optometry meeting; October 24–27 2012; Phoenix, AZ. Session Program Number 23960. Accessed March 2025. <https://aaopt.org/past-meeting-abstract-archives/?SortBy=&ArticleYear=2012&PROGRAMNUMBER=23960>.
- Reindel W, Cairns G, Merchea M. Assessment of patient and practitioner satisfaction with Biotrue multi-purpose solution for contact lenses. *Cont Lens Anterior Eye*. 2010;33(Suppl 1):S12–7. <https://doi.org/10.1016/j.clae.2010.06.013>.
- Rah MJ, Merchea MM, Doktor MQ. Reducing drop-out of contact lens wear with Biotrue multipurpose solution. *Clin Ophthalmol*. 2014;8:293–9. <https://doi.org/10.2147/OPTH.S54521>.
- Craig JP, Willcox MD, Argueso P, et al. The TFOS International Workshop on Contact Lens Discomfort: report of the contact lens interactions with the tear film subcommittee. *Invest Ophthalmol Vis Sci*. 2013;54(11):TFOS123–56. <https://doi.org/10.1167/iovs.13-13235>.
- Jones L, Downie LE, Korb D, et al. TFOS DEWS II management and therapy report. *Ocul Surf*. 2017;15(3):575–628. <https://doi.org/10.1016/j.jtos.2017.05.006>.
- Hynnekleiv L, Magno M, Vernhardsdottir RR, et al. Hyaluronic acid in the treatment of dry eye disease. *Acta Ophthalmol*. 2022;100(8):844–60. <https://doi.org/10.1111/aos.15159>.
- Rah MJ. A review of hyaluronan and its ophthalmic applications. *Optometry*. 2011;82(1):38–43. <https://doi.org/10.1016/j.optm.2010.08.003>.
- Yang W, Zhao X, Han M, et al. Recent advances in biosynthesis mechanisms and yield enhancement strategies of erythritol. *Crit Rev Food Sci Nutr*. 2024;64(33):13112–32. <https://doi.org/10.1080/10408398.2023.2260869>.

21. Bachman WG, Wilson G. Essential ions for maintenance of the corneal epithelial surface. *Invest Ophthalmol Vis Sci.* 1985;26(11):1484–8.
22. Bausch & Lomb Incorporated (Rochester NY) Biotrue® Hydration Plus Multi-Purpose Solution [package insert]. 2021. Accessed March 2025. <https://pi.bausch.com/globalassets/pdf/packageinserts/vision-care/biotrue-hydration-plus-package-insert.pdf>.
23. Rah MSJ, Shahidi A, Reindel W. In-home use test of a novel contact lens solution in contact lens wearers on the verge of dropout. *Invest Ophthalmol Vis Sci.* 2024;65:2687.
24. Van Der Meid KR, Byrnes MG, Millard K, Scheuer CA, Phatak NR, Reindel W. Comparative analysis of the osmoprotective effects of daily disposable contact lens packaging solutions on human corneal epithelial cells. *Clin Ophthalmol.* 2024;18:247–58. <https://doi.org/10.2147/OPTH.S437841>.
25. Corwin-Buell J, Callahan D, McGrath D, Millard K, Mosehauer G, Phatak NR. Biocidal efficacies of contact lens disinfecting solutions against international organization for standardization (ISO) compendial organisms. *Clin Ophthalmol.* 2024;18:337–45. <https://doi.org/10.2147/OPTH.S445870>.
26. Moses RA HW. Adler's physiology of the eye, clinical application. St. Louis, MO: C.V. Mosby; 1981.
27. Bausch & Lomb Incorporated (Rochester NY) A safety and effectiveness study of BL-ABT12 multi-purpose solution for use by participants with soft contact lenses. <https://clinicaltrials.gov/study/NCT03897751>.
28. Pucker AD, Tichenor AA. A review of contact lens dropout. *Clin Optom (Auckl).* 2020;12:85–94. <https://doi.org/10.2147/OPTO.S198637>.
29. Efron NBN, Bright FV, et al. 2. Contact lens care and ocular surface homeostasis. *Cont Lens Anterior Eye.* 2013;36(Suppl 1):S9–13.
30. Scheuer CA, Barniak VL. Impact of a new contact lens multi-purpose solution on maintaining the native state of a tear film protein. ePoster 1697. presented at: Optometry's Meeting: American Optometric Association Virtual Event; June 7–8 2022.
31. Scheuer CA, Barniak VL, Rah MJ. Hyaluronan release from contact lenses soaked in a new hyaluronan-containing multi-purpose solution. ePoster 1560. presented at: Optometry's Meeting: American Optometric Association Virtual Event; June 7–8 2022.
32. Scheuer CA, Fridman KM, Barniak VL, Burke SE, Venkatesh S. Retention of conditioning agent hyaluronan on hydrogel contact lenses. *Cont Lens Anterior Eye.* 2010;33(Suppl 1):S2–6.
33. Scheuer CA, Rah MJ, Reindel WT. Increased concentration of hyaluronan in tears after soaking contact lenses in Biotrue multipurpose solution. *Clin Ophthalmol.* 2016;10:1945–52. <https://doi.org/10.2147/OPTH.S115705>.
34. International Organization for Standardization. ISO 14729:2001: Ophthalmic optics—Contact lens care products—Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses—Amendment 1. 2010. Accessed March 2025. <https://www.iso.org/standard/51069.html>.
35. Chen EY, Myung Lee E, Loc-Nguyen A, Frank LA, Parsons Malloy J, Weissman BA. Value of routine evaluation in asymptomatic soft contact lens wearers. *Cont Lens Anterior Eye.* 2020;43(5):484–8. <https://doi.org/10.1016/j.clae.2020.02.014>.
36. Markoulli M, Kolanu S. Contact lens wear and dry eyes: challenges and solutions. *Clin Optom (Auckl).* 2017;9:41–8. <https://doi.org/10.2147/OPTO.S111130>.
37. Gomes JAP, Azar DT, Baudouin C, et al. TFOS DEWS II iatrogenic report. *Ocul Surf.* 2017;15(3):511–38. <https://doi.org/10.1016/j.jtos.2017.05.004>.
38. Burke SE, Barniak VL, Scheuer CA, Fridman KM. The influence of commonly used surfactants of multi-purpose solutions on the native state of a tear film protein. *Invest Ophthalmol Vis Sci.* 2012;53:4245.
39. Scheuer CA, Barniak VL, Phatak NR, Rah MJ, Reindel W. Effect of contact lens solutions in stabilizing the activity of tear lysozyme. *Clin Optom (Auckl).* 2023;15:119–27. <https://doi.org/10.2147/OPTO.S404261>.
40. Tonge S, Jones L, Goodall S, Tighe B. The ex vivo wettability of soft contact lenses. *Curr Eye Res.* 2001;23(1):51–9. <https://doi.org/10.1076/ceyr.23.1.51.5418>.
41. Reindel WSR, Mosehauer G, et al. Performance of a silicone hydrogel daily disposable contact lens among wearers with lens-related dryness. *Open J Ophthalmol.* 2023;17: e187436412303021.
42. Almeida M, Magalhães M, Veiga F, Figueiras A. Poloxamers, poloxamines and polymeric micelles: definition, structure and therapeutic applications in cancer. *J Polym Res.* 2017;25(1):31. <https://doi.org/10.1007/s10965-017-1426-x>.

-
43. Mustafi D, Smith CM, Makinen MW, Lee RC. Multi-block poloxamer surfactants suppress aggregation of denatured proteins. *Biochim Biophys Acta*. 2008;1780(1):7–15. <https://doi.org/10.1016/j.bbagen.2007.08.017>.
 44. den Hartog GJ, Boots AW, Adam-Perrot A, et al. Erythritol is a sweet antioxidant. *Nutrition*. 2010;26(4):449–58. <https://doi.org/10.1016/j.nut.2009.05.004>.
 45. Soltes L, Mendichi R, Kogan G, Schiller J, Stankovska M, Arnhold J. Degradative action of reactive oxygen species on hyaluronan. *Biomacromol*. 2006;7(3):659–68. <https://doi.org/10.1021/bm050867v>.
 46. Galvez-Martin P, Soto-Fernandez C, Romero-Rueda J, et al. A novel hyaluronic acid matrix ingredient with regenerative, anti-aging and antioxidant capacity. *Int J Mol Sci*. 2023;24(5):4774. <https://doi.org/10.3390/ijms24054774>.