

Hydrogen Peroxide Disinfecting Solution for Gas Permeable Contact Lenses: A Review of the Antimicrobial Efficacy, Compatibility, and Safety Performance of a One-Step Lens Care System

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Abstract: CLEAR CARE PLUS (CCP), also known as AOSEPT PLUS with HydraGlyde, is approved for use with gas permeable (GP) lenses, and the indication is supported by the scientific evidence that is reviewed in this article. Antimicrobial efficacy testing of CCP both as a stand-alone disinfectant and as part of a regimen shows that CCP exceeds the ISO 14729 criteria against bacteria, yeast, and mold. In real-world conditions, it is effective against clinically relevant bacterial strains isolated from adverse events and against the two forms, trophozoites and cysts, of resilient *Acanthamoeba* species. Compatibility tests of CCP with two types of GP lenses indicate that the physical and/or optical parameters of lenses are unaffected through 30 cycles of simulated use with CCP, and a clinical trial shows substantial equivalence of clinical performance with a commonly used GP multipurpose solution. These results indicate that CCP is well suited for cleaning and disinfection of GP contact lenses.

Keywords: antimicrobial efficacy, CLEAR CARE PLUS, AOSEPT PLUS with HydraGlyde, gas permeable contact lenses, lens care

Introduction

Gas permeable (GP) contact lenses are used in the form of scleral and corneal lenses and for orthokeratology (ortho-k) for the correction of myopia, for other refractive disorders, and for the slowing of myopia progression.¹⁻³ They account for about 10% of fits worldwide (with considerable intercountry variation) and hold a steadily increasing share of ortho-k lenses.⁴ CLEAR CARE (also known as AOSEPT PLUS) is a 3% hydrogen peroxide cleaning and disinfecting solution for contact lenses (Alcon Laboratories, LLC, Fort Worth, TX, USA) in which, simultaneously with disinfection, a catalytic “disc” inside the case gradually reduces the peroxide to water and oxygen over six hours, leaving the lenses stored in phosphate buffered saline and ready for use. A more recent version, CLEAR CARE PLUS (CCP), also known as AOSEPT PLUS with HydraGlyde, has an additional wetting agent. Both solutions are indicated for the cleaning, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) and GP contact lenses.

In light of the increasing use of GP scleral and ortho-k lenses for myopia and other refractive disorders and/or for the control of myopia progression, this article reviews the scientific data pertaining to the use of CCP with GP lenses. Two types of commonly used GP lens materials were assessed: silicone acrylate (Boston[®] II

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[itafocon A]; Bausch + Lomb, Rochester, NY) and fluorosilicone acrylate (Boston[®] XO [hexafocon A]; Bausch + Lomb, Rochester, NY). These two types of lens materials are required by the International Standard Organization (ISO) for standard regimen and lens compatibility testing.^{5,6} Three main areas will be examined in the paper: effectiveness as a disinfectant, compatibility with GP lens material, and indications for use by contact lens wearers.

Antimicrobial Efficacy

A contact lens solution must comply with the requirements of ISO 14729, Ophthalmic optics – Contact lens care products – Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses.⁵ In the ISO 14729 antimicrobial activity test (Stand-alone), a solution challenged with 10^5 – 10^6 colony forming unit (CFU)/mL of five ISO representative microorganisms is assessed for microbial load at 25%, 50%, 75%, and 100% of the recommended disinfection time (DT). The ISO panel of microorganisms includes one Gram-positive and two Gram-negative bacteria, a yeast, and a mold (Table 1).

To meet the highest requirement (primary criteria), a solution is required to reduce the microbial load for each of three bacteria by 3 logs, yeast by 1 log, and mold by 1 log at DT (with no increase >0.5 log for yeast or mold at 400% DT). A product may be labeled as a disinfecting solution when it meets the primary criteria. For “no rub” solutions, organic soil is required in the Stand-alone and Regimen tests. Organic soil mimics organic matter and deposits on lenses that may be present in actual patient wear situations.⁵ The Regimen test is designed to evaluate the effectiveness of the solution regimen (eg, rubbing, and/or rinsing, soaking steps) at reducing microorganisms and organic matter on contact lenses. A solution passes the Regimen test if the average CFU per lens and soaking solution recovered at DT is <10 for all

five ISO microorganisms per contact lens type (Table 2). ISO 14729 does not require Stand-alone or Regimen testing with clinically relevant bacteria from adverse events (AE) or *Acanthamoeba* species (spp).

Gabriel et al^{7,8} reported on the antimicrobial efficacy of CCP in the Stand-alone and Regimen tests. Solutions in CCP lens cases with neutralizing discs were inoculated with organisms and evaluated for microbial loads at DT. The Stand-alone tests were carried out with and without organic soil (the results with organic soil are considered the worst-case scenario for disinfection, as organic soil can interfere with disinfecting agents in the solution⁵). Figure 1 shows the results for the Stand-alone at DT. The antimicrobial efficacy of CCP exceeds the primary criteria of the ISO Stand-alone requirements.

For the Regimen test, GP lenses inoculated with ISO microorganisms were placed in basket lens holders, rinsed for five seconds with CCP solution, and soaked in CCP solution in the lens case with the neutralizing disc for at least 6 hours. Lenses and solutions were evaluated for microbial loads at DT. Table 3 shows the results of the Regimen tests with GP lenses at DT.

The antimicrobial efficacy of a disinfecting solution can be further challenged using clinically relevant ocular strains isolated from patients with adverse events (AEs), as these strains may be more resistant to disinfection than laboratory strains. Gabriel et al⁷ tested CCP against two clinically relevant ocular isolates from infections of *P. aeruginosa* and one strain each of *Stenotrophomonas maltophilia* and *S. aureus*. CCP reduced all clinically relevant bacterial strains by >4.5 logs, therefore exceeding the ISO 3-log reduction requirement for bacteria (Figure 2).

The most rigorous test of antimicrobial efficacy is to challenge the solution with *Acanthamoeba* spp, as *Acanthamoeba* are resilient in both their trophozoite and particularly their cyst form. CCP was evaluated by a modified Stand-alone test using strains of the T4 genotype isolated from keratitis cases, *A. castellanii* ATCC 50370 and *A. polyphaga* ATCC 30461. Strains belonging to the T4 genotype are most commonly associated with *Acanthamoeba* keratitis.⁷ While there are no standards for determining lens care solution efficacy against *Acanthamoeba* spp, Figure 3 shows that CCP reduces trophozoites by ≥ 4.0 logs (99.99%) and cysts by >2.0 logs (99%) at DT. The superior efficacy of the CCP hydrogen peroxide lens care system compared with multipurpose solutions (MPS) against *Acanthamoeba* spp is supported by previous studies.^{9,10}

Table 1 Microorganisms Required in the ISO 14729 Stand-Alone and Regimen Tests

Microorganism	Type	ATCC Strain
<i>Staphylococcus aureus</i>	Bacteria	6538
<i>Pseudomonas aeruginosa</i>	Bacteria	9027
<i>Serratia marcescens</i>	Bacteria	13880
<i>Candida albicans</i>	Yeast	10231
<i>Fusarium keratoplasticum</i> (formerly known as <i>F. solani</i>)	Mold	36031

Table 2 ISO 14729:2001 Antimicrobial Activity Test Criteria

Test	Average Log Reduction at Soaking Time				
	Bacteria			Fungi (Yeast and Mold)	
	<i>S. aureus</i> ATCC 6538	<i>P. aeruginosa</i> ATCC 9027	<i>S. marcescens</i> ATCC 13880	<i>C. albicans</i> ATCC 10231	<i>F. keratoplasticum</i> ATCC 36031
Stand-alone test: Primary Criteria	3	3	3	1	1
Stand-alone test: Secondary criteria	Minimum for all three combined = 5 Minimum for any single bacterial type = 1			Stasis at soaking time	
Regimen test	4 to 5	4 to 5	4 to 5	4 to 5	4 to 5
Regimen end-point criteria	Average of not more than 10 colony forming units (CFU) per lens type/storage solution combination				

Compatibility

One concern with exposing contact lenses to any form of disinfection system is whether the solution might have an effect on the lens material or cause changes in lens parameters. Lens compatibility testing with the indicated types of lenses is a standard part of the regulatory review and approval process for any contact lens care solution.

Lens compatibility testing was conducted in accordance with ISO 11981.⁶ CCP was tested over 30 cycles with two GP contact lenses, Boston II (silicone acrylate) and Boston XO (fluorosilicone acrylate). Sixteen lenses of

each type covering the power range from -10.25D to +11.50D were used in this study. Initially all lenses were soaked in ISO saline (isotonic standard saline solution) for at least one hour to equilibrate them before being inspected. Lenses were inspected for physical appearance to ensure they were free of nicks, cuts, and visual discoloration. For all lenses, the base curves, diameters, and powers were measured at baseline. Before each disinfection cycle, all lenses were incubated for 30 minutes at 37 °C in an artificial tear solution containing salts, lysozyme, albumin, and immunoglobulin. The lenses were then

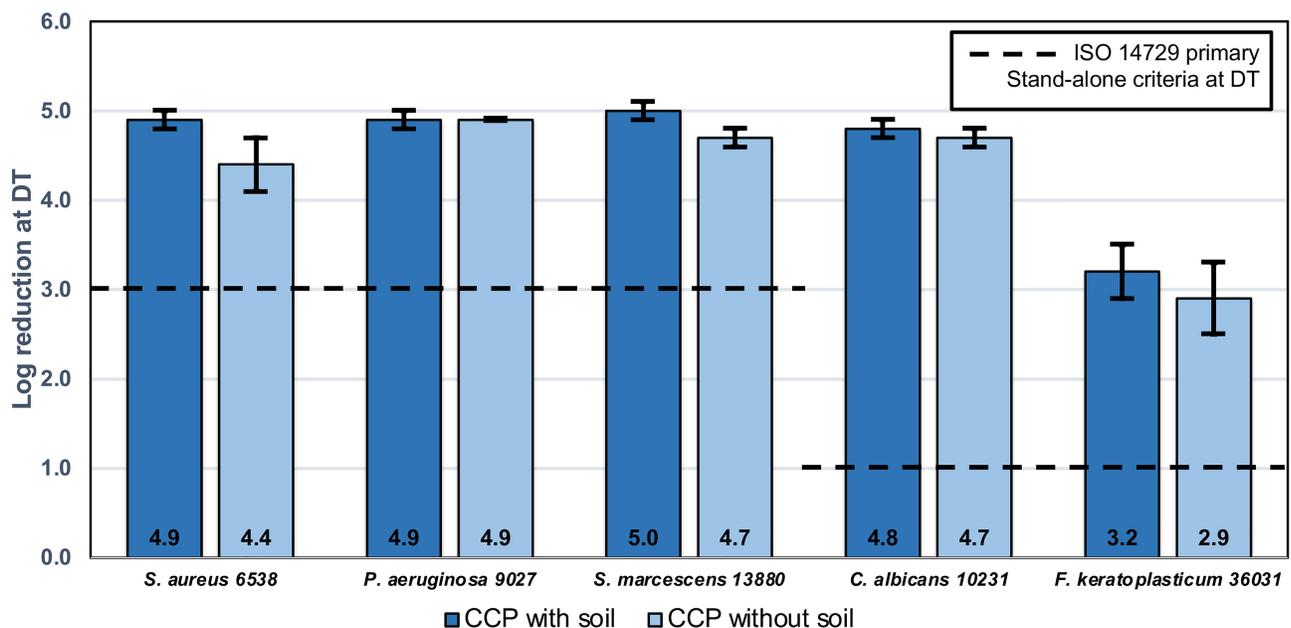


Figure 1 Antimicrobial efficacy of CCP against ISO 14729 microorganisms. CCP exceeds the primary Stand-alone criteria against bacteria, yeast and mold. Adapted with permission from Wolters Kluwer Health, Inc.: Gabriel MM, McAnally C, Bartell J, et al. Biocidal efficacy of a hydrogen peroxide lens care solution incorporating a novel wetting agent. *Eye Contact Lens*. 2019;45(3):164–170. © 2018 Contact Lens Association of Ophthalmologists.⁷

Abbreviations: CCP, CLEAR CARE PLUS; ISO, International Standard Organization.

Table 3 Results of the Regimen Test for CCP Used with GP Lenses

Lens Material	Microorganism	Initial CFU/Lens	CFU/Lens and Soaking Solution After 6 Hours (n=12)
Silicone acrylate	<i>S. aureus</i>	1.0×10^6	<1
	<i>P. aeruginosa</i>	7.4×10^5	0
	<i>S. marcescens</i>	6.3×10^5	<1
	<i>C. albicans</i>	5.0×10^5	0
	<i>F. keratoplasticum</i>	4.1×10^5	0
Fluorosilicone acrylate	<i>S. aureus</i>	1.4×10^6	0
	<i>P. aeruginosa</i>	8.4×10^5	0
	<i>S. marcescens</i>	5.7×10^5	0
	<i>C. albicans</i>	5.6×10^5	0
	<i>F. keratoplasticum</i>	4.1×10^5	<1

Notes: Data reflect an average CFU from 4 lenses and 3 lots of solution for each lens type. Regimen test criteria is an average of <10 CFU per lens and soaking solution. For results of the soft (hydrophilic) and silicone hydrogel lenses tested, see Gabriel et al.⁷

placed in basket lens holders, rinsed for five seconds with CCP solution, and soaked in CCP solution in the case with the neutralizing disc for at least 6 hours. Thirty (30) treatment cycles were conducted to represent a full month of daily use of the CCP lens care solution. After 30 cycles, the lenses were soaked in ISO saline for at least one hour for post-cycle testing. Then a final measurement of all lens parameters was performed. The baseline and final measurements were compared to determine the average change in each measurement. After 30 disinfection cycles, it was determined that the lenses were still free of nicks, cuts, and visual discoloration, and that all lens parameter measurements were within acceptable limits (Table 4). CCP solution did not affect the physical and optical parameters of GP lenses evaluated in the study, indicating that CCP solution is compatible with silicone acrylate and fluorosilicone acrylate GP lenses.

Safety Performance

After demonstrating CCP antimicrobial efficacy as a disinfecting solution and its compatibility with GP contact lenses, the final test is to examine its performance with patients in clinical use. A 3-month, prospective, randomized, multicenter, single (observer)-masked, parallel-group study was conducted with 106 volunteer subjects with normal eyes (apart from a corrected refractive error) with a history of successful wear of either Boston II

(silicone acrylate) or Boston XO (fluorosilicone acrylate) GP contact lenses. Subjects were randomized to use either the test solution, CCP (n=71 subjects) or the control solution, Boston Simplus Multi-action Solution (MAS) (n=35 subjects) daily for at least 8 hours a day for 90 days. The bottles of the test and control solutions were labeled as “Disinfecting Solution” including subject number, protocol number, fill volume, storage conditions, and the product is for investigational use only. Following the baseline visit, at which subjects were given the solutions and instructions for use, subjects were followed up at 7, 30, 60, and 90 days. At each visit, wear time and symptoms (comfort, vision, and handling) were recorded and visual acuity, contact lens fit, and lens over-refraction were evaluated. The contact lenses were inspected using a modified Rudko lens classification system and an anterior segment slit lamp examination including fluorescein staining was carried out. At the end of the study, the collected lenses were analyzed for level of lysozyme deposition using liquid chromatography. Procedures were in place for the reporting and management of any potential AEs.

There were no significant differences in wear times from day 0 in either group, except for the control MPS at 60 days, where it was longer (13.3 hours vs 11.8 hours) (Figure 4). Visual acuities did not change significantly for either group during the study. There were no biomicroscopy findings greater than mild (grade 2) in either group.

A total of 21 ocular AEs in 7 of the total 71 subjects were reported in the test group and 7 AEs in 2 of 35 subjects in the control group (p=NS). The most frequently reported AE was eye irritation; all were mild to moderate and all resolved/recovered. Two subjects discontinued voluntarily from the test group during the first week. Four lenses in the test group were replaced (three lost, one damaged) as were two in the control group (one lost, one damaged).

The percentage of lenses that were visibly clean was not significantly different between the test and control groups at the p = 0.05 level, nor were the levels for film deposits, crystalline deposits, and area of the lens covered by deposits (Figure 5). The average amount of residual lysozyme per lens at day 90 was 0.2 µg for both lens care systems.

In this study, CCP performed similarly to and was found to be as effective as Boston Simplus MAS based on the assessments of cleanliness, visual acuity, average lens wearing time, lens replacements, and symptoms/problems/complaints related to comfort, vision, and handling.

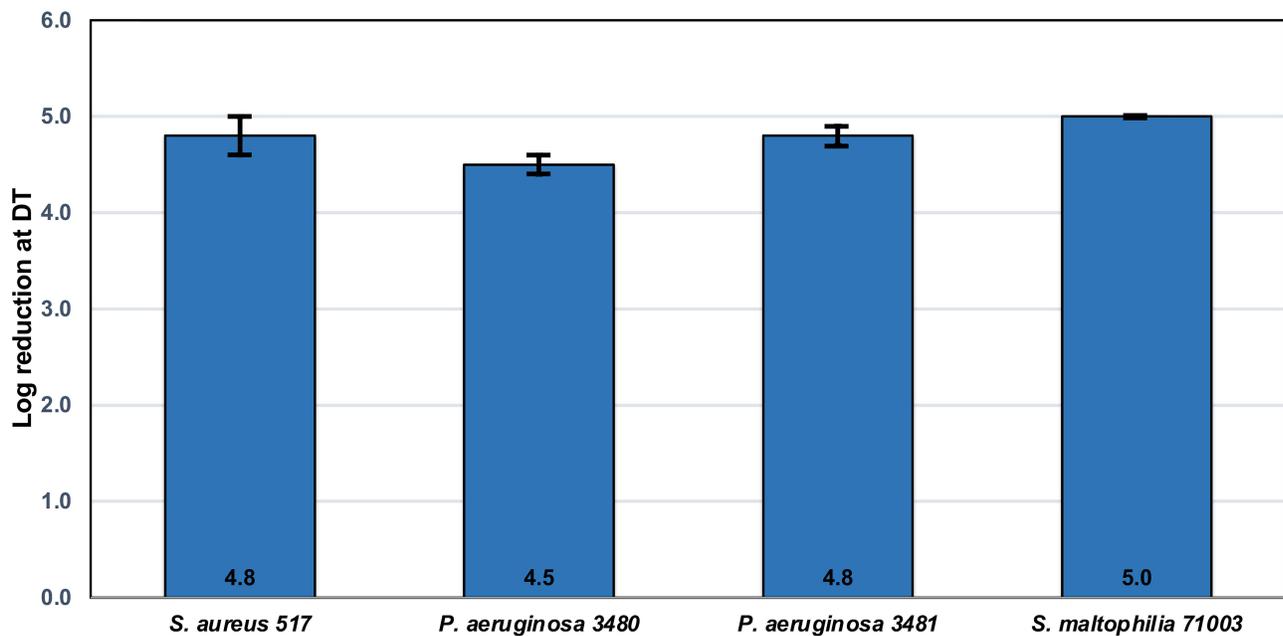


Figure 2 Antimicrobial efficacy of CCP against clinically relevant microorganisms. CCP exceeds the primary Stand-alone criteria against bacteria. Adapted with permission from Wolters Kluwer Health, Inc.: Gabriel MM, McAnally C, Bartell J, et al. Biocidal efficacy of a hydrogen peroxide lens care solution incorporating a novel wetting agent. *Eye Contact Lens*. 2019;45(3):164–170. © 2018 Contact Lens Association of Ophthalmologists.⁷
Abbreviation: CCP, CLEAR CARE PLUS.

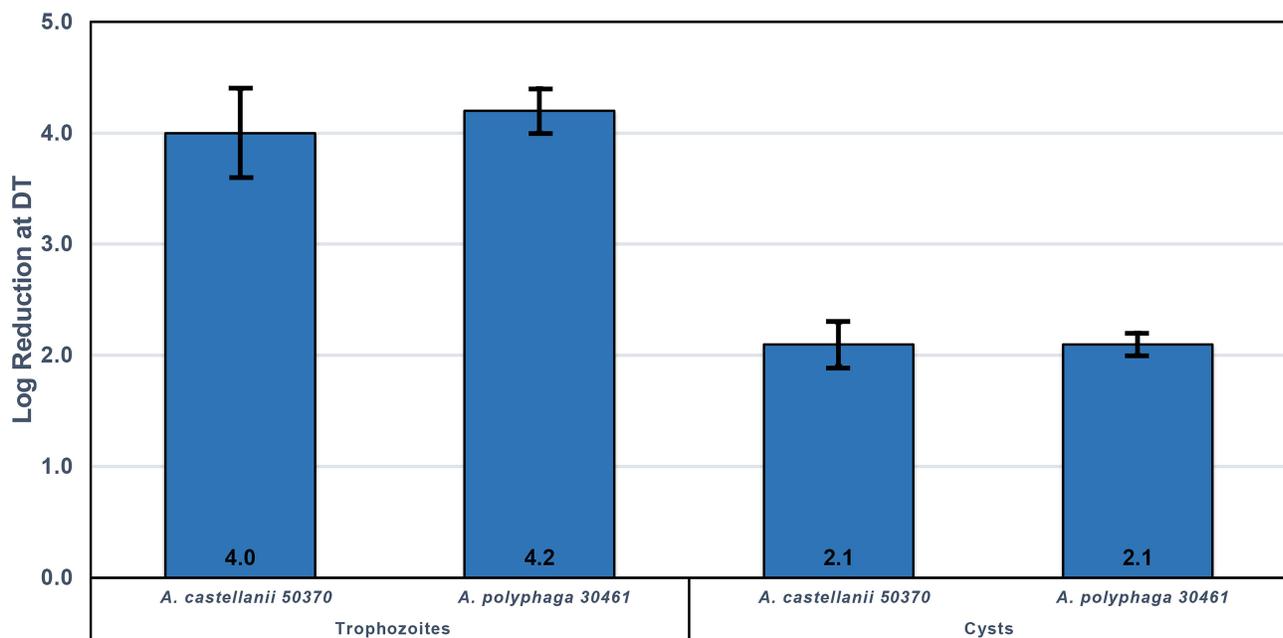


Figure 3 Antimicrobial efficacy of CCP against trophozoites and cysts for two strains of *Acanthamoeba*. CCP reduces trophozoites of two *Acanthamoeba* strains by $\geq 99.99\%$ and cysts of two *Acanthamoeba* strains by $>99\%$. Adapted with permission from Wolters Kluwer Health, Inc.: Gabriel MM, McAnally C, Bartell J, et al. Biocidal efficacy of a hydrogen peroxide lens care solution incorporating a novel wetting agent. *Eye Contact Lens*. 2019;45(3):164–170. © 2018 Contact Lens Association of Ophthalmologists.⁷
Abbreviation: CCP, CLEAR CARE PLUS.

Discussion

Hydrogen peroxide lens care solutions kill microorganisms by producing free radicals that destroy cell membranes and

essential cell components.^{11,12} This contrasts with MPS systems that use polyhexamethylene biguanide (PHMB), which acts on bacterial chromosomes^{12,13} or with

Table 4 Results of Parameter Measurements for Two GP Lenses After 30x Disinfection Cycles with CCP

Lens Material	Test	Difference After Cycling vs Before (n=16) Mean/SD	ISO Measurement Tolerance*	Conclusion
Silicone acrylate	Inspection	No appearance change	Not Applicable	PASS
	Base curve	0.00 mm/0.035 mm	±0.05 mm	PASS
	Diameter	0.00/0.00 mm	±0.10 mm	PASS
	Power	0.08/0.285D	±0.12D*	PASS
Fluorosilicone acrylate	Inspection	No appearance change	Not Applicable	PASS
	Base curve	0.01/0.016 mm	±0.05 mm	PASS
	Diameter	0.01/0.025 mm	±0.10 mm	PASS
	Power	-0.09/0.155D	±0.12D*	PASS

Notes: *Tolerance dependent on lens power range: ≤5.00D = ±0.12D; 5.00D to 10.00D = ±0.18D; 10.00D to 15.00D = ±0.25D.

Abbreviations: ISO, International Standard Organization; SD, standard deviation.

alexidine and polyquaternium-1 (PQ), which interact with cell membranes and disrupt the membrane structure.^{12–14} Irrespective of mechanism, the disinfecting solutions must be capable of killing a broad range of microorganisms as prescribed by ISO and FDA standards.^{5,15} The disinfection tests are typically carried out against planktonic (floating in liquid) microorganisms, whereas it is known that, once adherent to a surface, bacteria will cover themselves with a protective biofilm that renders them more difficult to kill. Testing against bacterial and fungal biofilms showed that hydrogen peroxide disinfection performs better than a range of MPS.^{16–18}

One concern with the use of hydrogen peroxide systems for contact lens disinfection is that the H₂O₂ may not be fully neutralized, which might lead to ocular irritation for contact lens wearers. Neutralization of CCP by the catalytic disc results in residual peroxide levels of 5 to 20 ppm of hydrogen peroxide,¹⁹ well below the human detection thresholds of 267–282 ppm in hydrogel lenses and 812 ppm when instilled as a drop into the eye.²⁰ As the water content of GP lenses is typically less than 1%, exposure would be restricted to the small volume of solution on the surface of the lenses. Furthermore, hydrogen peroxide is a common by-product of normal physiological

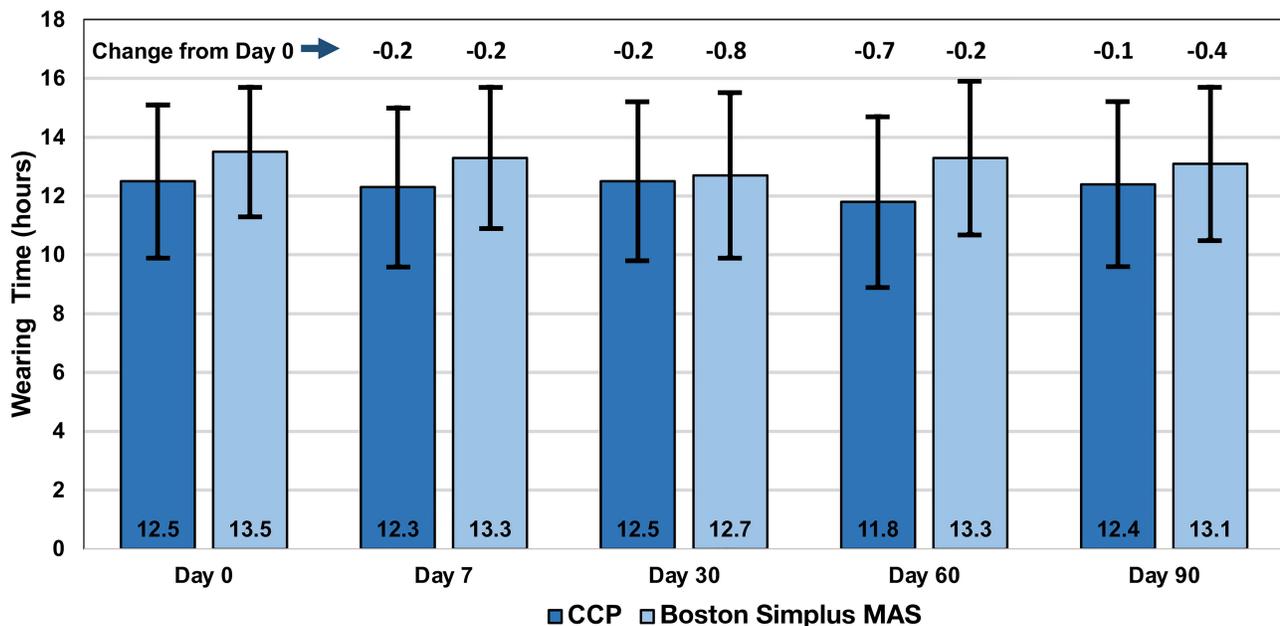


Figure 4 Difference in wearing times for CCP and the control MAS over 90 days. One result at day 60 was statistically significant ($p < 0.05$), but the overall changes over time were comparable.

Abbreviations: CCP, CLEAR CARE PLUS; MAS, multi-action solution.

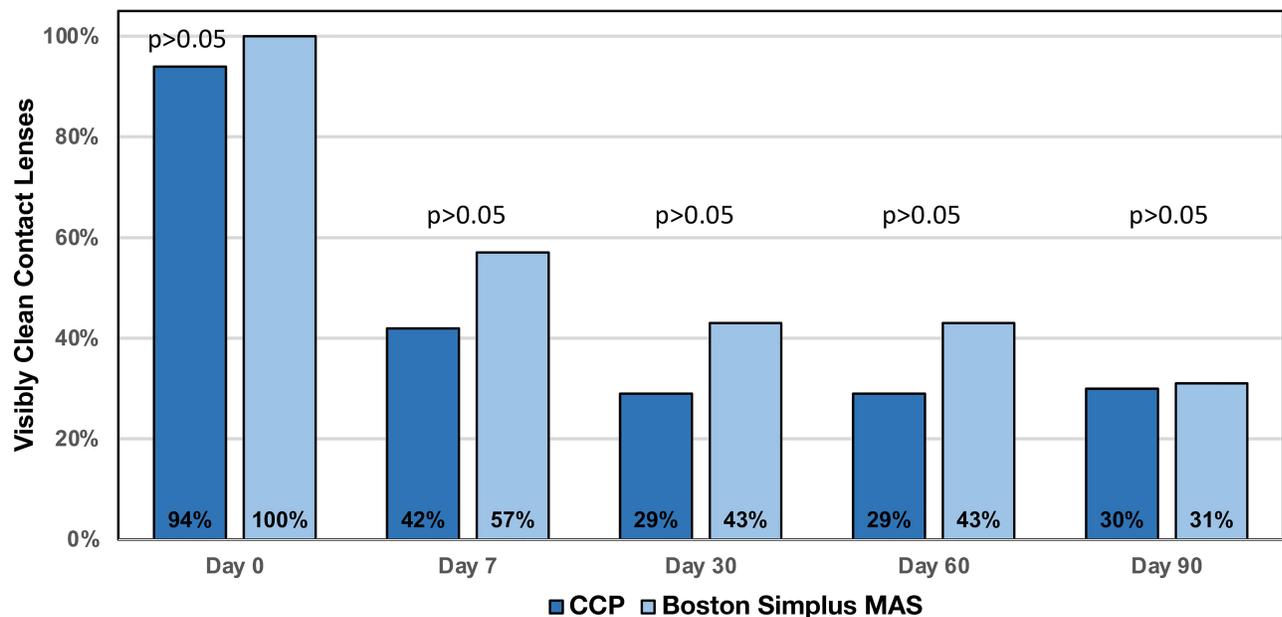


Figure 5 Percent of visibly clean contact lenses at each visit over 90 days. The percentage of lenses that were visibly clean was not significantly different between the CCP/AOSEPT with HydraGlyde and the MAS control groups at the $p = 0.05$ level, nor were the levels for film deposits, crystalline deposits, and area of the lens covered by deposits.

Abbreviations: CCP, CLEAR CARE PLUS; MAS, multi-action solution.

processes and a part of the body's normal defenses against microbes. The conjunctival sac is well equipped with enzymes such as catalase, superoxide dismutase, and glutathione peroxidase to rapidly neutralize any low levels of peroxide residuals on the lenses.²¹

Hydrogen peroxide cleaning and disinfecting systems have been widely trusted and used by contact lens wearers since the 1970s¹⁹ and they still have a strong presence in the market because of their combination of a strong disinfection capability with low sensitivity from the absence of disinfectant after neutralization.

A recently published review of scientific and clinical evidence provides an overview of the ease of use and compliance, lens and ocular tissue compatibility, disinfection efficacy, and ocular surface safety of hydrogen peroxide systems. The publication suggested that hydrogen peroxide maybe particularly relevant for GP lens wearers due to its ability to remove deposits and penetrate biofilms.²²

Conclusion

CCP has been subjected to a large variety of tests to assess cleaning, disinfection, compatibility, and safety performance when used with GP contact lenses. CCP satisfies ISO 14729 and FDA lens care solution efficacy requirements for the Stand-alone test, and the Regimen test with GP lenses, and

has been shown to be effective against clinically relevant isolates from AEs and *Acanthamoeba* trophozoites and cysts. Compatibility of CCP for use with GP lenses has been demonstrated. Clinical trials have established safety when used with GP lenses, and these are supported by additional studies reported in the literature, confirming its competence for the labeled indication with these lenses.

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Disclosure

The authors are employees of Alcon Research, LLC, Johns Creek, GA, and Fort Worth TX, USA. The authors report no other conflicts of interest in this work.

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