

# Efficacy and Safety of Two Peroxide Based Lens Care Solutions in Wearers of Gas Permeable Contact Lenses

Sruthi Srinivasan and Manoj Venkiteshwar  
Alcon Research, LLC, Johns Creek, GA, USA

## Purpose

- To assess the efficacy and safety of two peroxide based AOSEPT PLUS (AOSP) and AOSEPT PLUS with HydraGlyde (AOSP-HG) contact lens (CL) care solutions to other CL care solutions in gas permeable (GP) CL wearers.

## Methods

- Two prospective, multicenter, randomized, single masked, parallel group studies were conducted.

### Study 1

- (n=36 subjects, 3 month study) assessed the insertion and overall comfort, discomfort symptoms and safety parameters (corneal fluorescein staining, conjunctival injection and papillary response) with AOSP and SOLO-CARE HARD (SCH) (CIBA Vision®).

### Study 2

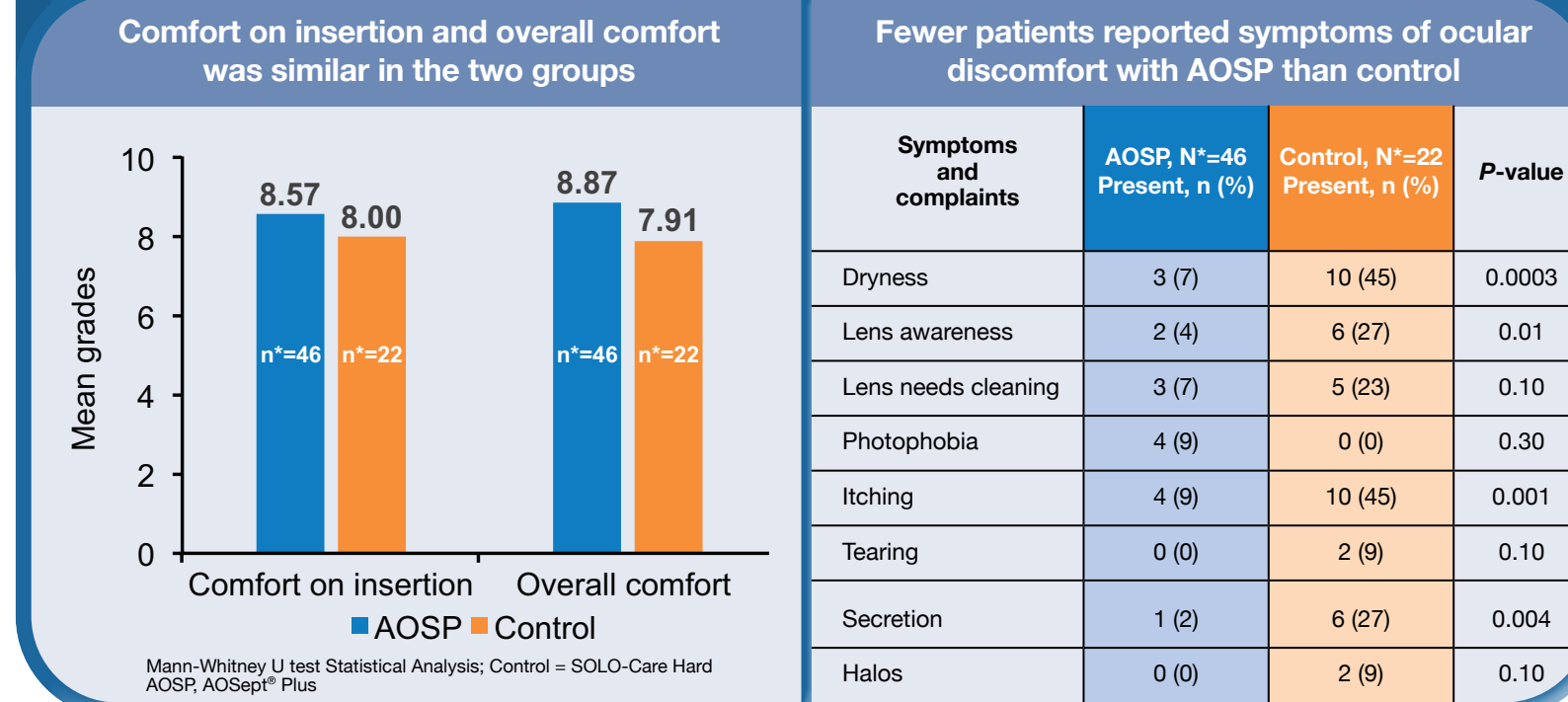
- (n=106 subjects, 90 day study) evaluated CL cleanliness, visual acuity, average lens wear time, unscheduled lens replacement incidence and causality, and symptoms/problems/complaints related to comfort, vision, and handling of AOSP-HG when compared to Boston Simplus Multi-Action Solution (BOS) (Bausch & Lomb).

## Results

### Study 1:

- No significant differences were noted between the groups for initial and overall comfort ( $p>0.05$ ). Subjects using AOSP reported statistically significantly fewer symptoms, problems and complaints for dryness, lens awareness, lens needs cleaning and photophobia (all  $p<0.05$ ). AOSP subjects had low incidence of symptoms and/or slit lamp findings compared with those wearing lenses treated with SCH.

### Study 1: Comfort on insertion/overall comfort and proportion of patients with symptoms and complaints at Day 30 with AOSP and control



\*N, total number of eyes

### Study 2:

- No clinically significant differences between the solutions for CL cleanliness, visual acuity, average lens wear time, lens replacements, and some symptoms/problems/complaints.

### Study 2: A nominal difference between AOSP-HPG and BOS for few symptoms/problems/complaints related to comfort and vision was reported

Likert Statement	AOSP-HPG, N=71 (%)	BOS, N=35 (%)
<b>My lenses are comfortable all Day (Day 90)</b>		
Strongly agree or agree	81.2	82.9
Undecided	1.4	2.9
Strongly Disagree or Disagree	17.4	14.3
<b>My vision is clear at end of the Day (Day 90)</b>		
Strongly agree or agree	78.3	80.0
Undecided	7.2	5.7
Strongly Disagree or Disagree	14.5	14.3

AOSP-HG, AOSep<sup>®</sup> Plus with HydraGlyde<sup>®</sup>; BOS, Boston<sup>®</sup> Simplus Multi-Action Solution; N, total number of subjects

## Safety

### Study 1

- No undesirable side-effects were reported
- Two patients with AOSP required treatment (one for conjunctivitis, other for discomfort on insertion of CL)
- One patient with control required treatment for inferior lid chalazion
- Significant events (slit lamp findings)**
  - AOSP: 1 patient: grade 3 bulbar hyperemia
  - Control: 3 patients:
    - grade 3 limbal and bulbar hyperemia
    - grade 3 bulbar hyperemia
    - grade 2/3 bulbar hyperemia and conjunctival staining at baseline and first follow-up visit

### Study 2

- No serious adverse events (AEs)** or significant non-serious AEs were reported
- Ocular AEs:** AOSP-HPG: 21 (7 patients), BOS: 3 (2 patients)
- Non-ocular AEs:** AOSP-HPG: 10 (5 patients), BOS: 3 (2 patients)
- Device deficiencies** - none associated with an AE
  - AOSP-HPG: 2 (lack of efficacy, user error), BOS: 1 (suspected dilution of solution)

## Conclusions

- Overall, AOSEPT PLUS and AOSEPT PLUS with HydraGlyde hydrogen peroxide lens care solutions are effective gas permeable care systems.
- AOSEPT PLUS also appeared to be a more effective lens care regimen than SOLO-CARE HARD for certain aspects of performance.