Patient reported vision outcomes for two daily disposable toric soft contact lenses containing HEV Filters

Giovanna Olivares OD FAAO[1], Ben Straker BAppScOptom[1], Ross Franklin BAppScOptom[1], Ryan Sherrill MBA[1], Jessica Cannon-Hill MSc[1]
[1]Johnson & Johnson Vision, Inc., Jacksonville, FL

INTRODUCTION

High energy visible (HEV) light filters in contact lenses (CLs) are relatively new. Reported benefits include reduced light scatter and reduction in time to recover from glare-associated temporary loss in visual function and discomfort.[1] Currently, only two daily disposable (DD) CLs for astigmatism contain HEV filters, though their transmission spectra and HEV blocking percentages vary considerably.[1,2] This work presents vision-related findings from a head-to-head study and a 6-study meta-analysis involving these 2 lenses.

STUDY DESIGN

		Visit 2 (7 ± 2 days)	*Washout (1 week)*	*Visit 3 (7 ± 2 days)*	*Visit 4 (7 ± 2 days)*
	Fit/Dispense	Follow-up		Fit/Dispense	Follow-up
Arm 1	senABSD	Assessments	WASHOUT	delAPB8-4	Assessments & Final eval
Arm 2	delAPB8-4			senABSD	

A total of 133 non-presbyopic myopic astigmatic subjects were enrolled in a 4-visit prospective multi-site randomized double-masked controlled 2X2 crossover study of the 2 DD toric silicone hydrogel CLs: senofilcon A (senABSD) or delefilcon A (delAPB8-4) materials. The senABSD features a horizontally and vertically symmetrical design with peripheral stabilization zones at 3 and 9 o'clock (Blink Stabilized design "BSD") and the delAPB8-4 design is a modified prism ballast design (Precision Balance 8|4 "PB8-4"). Subjects were randomized to wear one CL pair for 7±2 days, followed by a 7±2 days washout period before the second pair wear for 7±2 days. CLs were assessed after insertion, settling, and at the follow-up visit. The CLUE™ (Contact Lens User Experience) questionnaire was used to capture subjective vision feedback at dispensing and follow-up visits. A generalized linear mixed model with a binary distribution was used with CL wear sequence, period and study/test lens included in the model as fixed effects. CL fitting, visual acuity and CL preference were assessed. An additional meta-analysis involving 6 studies (senABSD n=228, delAPB8-4 n=119) was performed to assess additional vision-related patient-reported outcomes. Proportion estimates and odds ratio (95% CIs) for Top-2 Box responses were analyzed.

Subject Numbers		
	Control (delAPB8-4)	**Test** (senABSD)
Study 1	-	37
Study 2	-	41
Study 3	29	-
Study 4	-	66
Study 5	20	21
Study 6	70	63

STUDY ARTICLES

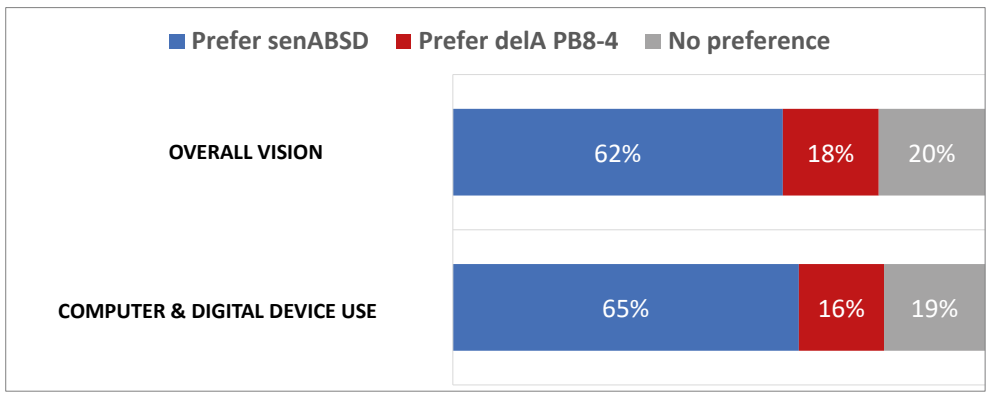
	Control	**Test**
Manufacturer	Alcon	Johnson & Johnson Vision
Trade name	Dailies Total 1® for Astigmatism (delAPB8-4)	OASYS® MAX 1-Day for Astigmatism (senABSD)
Material	delefilcon A	senofilcon A
Water content	33%	38%
Design	Precision Balance 8|4 "PB8-4"	Blink Stabilized design "BSD"
% Blue-violet light filtering	33%	60%

STATISTICS

- A generalized linear mixed model with a binary distribution was used with lens wear sequence, period & study/test lens included in the model as fixed effects.
- The primary outcome variables were related to comfort (not reported here).
- Toric fitting, visual acuity & study lens preference were additional efficacy variables.
- An additional meta-analysis was performed over 6 studies to look at additional vision-related patient-reported outcomes

RESULTS

Crossover Study Preference



Integrated Analysis of six studies

The meta-analysis show that senABSD demonstrates statistical superiority (2 to 4X higher odds of achieving positive results) over delAPB8-4 in several patient reported vision-related outcomes.

Patient Reported Outcome	**Odds Ratio**	
Fluctuating vision (vision going in and out of focus)	4.0	senABSD is 4x less likely to have fluctuating vision
Need To Blink Hard To Clear Vision	3.4	senABSD is 3.4x less likely to need to blink hard to clear vision
Clarity of vision when performing activities that involve head movement	2.9	senABSD is 2.9x more likely to have clarity of vision when performing activities that involve head movement
Eye fatigue	2.8	senABSD is 2.8x less likely to have eye fatigue
Clarity of vision with computer screen or digital devices	2.4	senABSD is 2.4x more likely to have clarity of vision with computer screens and digital device
Clarity of vision while performing activities involving tilting your head	2.2	senABSD is 2.2x more likely to have clarity of vision while performing activities involving tilting your head
Reduction in the feeling of tired eyes from using a computer or digital device	2.1	senABSD is 2.1x more likely to have reduction of feeling of tired eyes from using computer or digital device
Ability to see comfortably while driving at night	2.0	senABSD is 2.0x more likely to have reduction of feeling of tired eyes from using computer or digital device

CONCLUSIONS

The senABSD demonstrated statistically significant superiority over delAPB8-4 across the evaluated visual performance metrics. This enhanced performance may be attributed to the synergistic combination of three advanced technologies: OPTIBLUE™ Technology, which provides 60% high-energy visible (HEV) light filtration; TEARSTABLE™ Technology, which reduces tear film evaporation and promotes tear film stability; and the Blink Stabilized Design, which minimizes dependence on gaze and head position, thereby potentially improving visual stability and quality. The integration of these technologies likely contributed to the overall superior visual outcomes observed with the senABSD.

References:
1. Renzi-Hammond LM, Buch J, Xu J, Hammond BR. The influence of HEV-filtering contact lenses on behavioral indices of glare. Eye & Contact Lens. 2022 Dec 1;48(12):509-15.
2. Renzi-Hammond, LM, Buch J, Xu J,Hammond, BR. Reduction of Glare Discomfort and Photostress Recovery Time Through the Use of a High-Energy Visible–Filtering Contact Lens. Eye & Contact Lens: Science & Clinical Practice . 2022 Dec; 48(12):516-520.

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