



# Clinical performance of a peroxide-based care system and a multi-purpose care system formulated for use with silicone hydrogels

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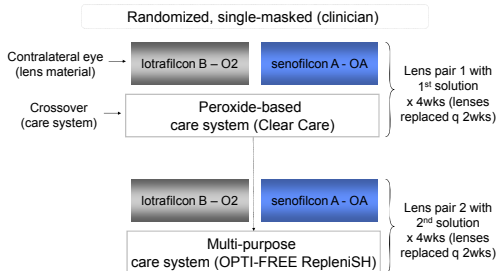
## Introduction

- Silicone hydrogel (SH) lenses have dramatically reduced lens-induced hypoxia in comparison to hydrogel lenses<sup>1,2</sup> and are quickly becoming the daily wear lens of choice for many practitioners.<sup>3</sup>
- Multipurpose solutions are used due to their convenience and low cost,<sup>3</sup> while hydrogen peroxide care systems are often recommended for the management of lens-solution incompatibilities.<sup>4</sup> Due to the unique characteristics of SH lens materials, many lens care systems are being reformulated in order to improve their compatibility and effectiveness.
- While studies continue to report less corneal staining with peroxide-based lens care systems compared to certain multi-purpose lens care systems;<sup>2,5</sup> there have been few studies comparing comfort (including comfortable wearing time (CWT)) and patient preference between these two options.

## Purpose

- To investigate the clinical performance of a peroxide-based lens care system (CIBA Vision, Clear Care) and a multi-purpose lens care system (Alcon, OPTI-FREE RepleniSH) which has been formulated for use with SH lenses.

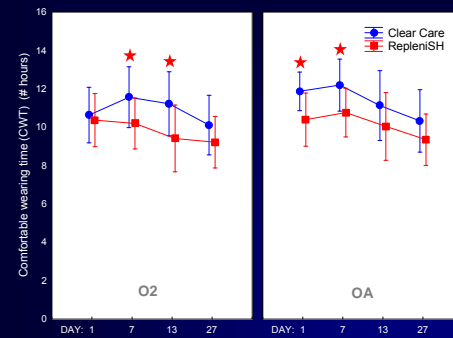
## Methods



**Subject Characteristics:** 26 subjects were enrolled into the study and 2 were discontinued. Results are reported for 24 subjects (see table below). Discontinuations were due to: 1) redness and discomfort while using RepleniSH and 2) lost study lenses.

Gender	9 males; 15 females	
Age (years)	31 ± 12 (range 17 to 59)	
Keratometry (diopres)	Horizontal	43.38 ± 1.40
	Vertical	44.21 ± 1.52
Refraction (diopres)	Sphere	-3.64 ± 2.10
	Cylinder	-0.18 ± 0.28

## Subjective ratings



	Clear Care O2	RepleniSH OA	No preference	Clear Care O2	RepleniSH OA	No preference
Comfort on lens insertion	12 (50%)	6 (25%)	6	8 (33%)	8 (33%)	8
Comfort at the end of the day	12 (50%)	6 (25%)	6	9 (38%)	7 (29%)	8
Overall comfort	12 (50%)	6 (25%)	6	10 (42%)	5 (21%)	9
Dryness later in the day	11 (46%)	7 (29%)	6	10 (42%)	7 (29%)	7
Maintaining clear vision	11 (46%)	4 (17%)	9	11 (46%)	3 (13%)	10
Redness at the end of the day	6 (25%)	4 (17%)	14	6 (25%)	2 (8%)	16
Irritation at the end of the day	7 (29%)	5 (21%)	12	9 (38%)	5 (21%)	10
Overall preference	13 (54%)	6 (25%)	5	11 (46%)	6 (25%)	7
Total	84	44	64	74	43	75

The hours of CWT were reported by phone in the evening to increase reliability and avoid missing data. Results are shown, with statistically significant differences marked. Overall, Clear Care resulted in significantly longer mean CWT than RepleniSH (10.8 1.7hrs vs 9.8 1.5hrs). Mean standard error comfort ratings on insertion, mid- and end-of-day, were 95.9 3.03, 93.8 3.8 and 88.3 8.8, respectively.

Prior to exiting the study a preference questionnaire was completed. Results are described above and indicate that Clear Care was preferentially rated over RepleniSH for maintaining clear vision, reducing end-of-day redness with OA, and for overall performance with O2 (all p<0.05).

## Clinical variables

	Clear Care O2	RepleniSH OA	Clear Care O2	RepleniSH OA
Wettability (grade 0=perfect; 4=severely reduced)	1.08 0.2	1.04 0.2	1.42 1.0	0.95 0.7
Deposits (grade 0=none; 4=severe)	0.33 0.1	0.38 0.1	0.60 0.7	0.33 0.5
PL NITBUT (seconds)	5.90 0.4	5.82 0.4	5.76 0.5	6.19 0.5
Confocal microscopy (peripheral basal cell density per mm <sup>2</sup> )	4794 193	4866 269	4904 274	4899 270
Epithelial permeability (nm/second; 2wks)	0.046 0.01	0.067 0.01	0.052 0.01	0.058 0.01
Conjunctival staining (0=none; 4=severe)	0.79 0.1	0.69 0.1	1.04 0.1	1.23 0.2
"non-solution sensitivity" corneal staining* (0=none; 4=severe)	0.52 0.2	0.46 0.1	0.35 0.1	0.60 0.1

\*one subject developed bilateral corneal staining that met the description used for "solution sensitivity" staining in the study (microprunctate staining in ≥ 3 peripheral corneal quadrants) while using RepleniSH.

The mean standard error for the clinical variables assessed at the four week visit for each cross-over phase are shown, with the exception of epithelial permeability which was measured at two weeks. Statistically significant findings (p<0.05) are shown in red. The majority of the clinical variables were similar across solutions, however front surface wettability and deposition were slightly better with RepleniSH compared to Clear Care with OA lenses (both p<0.05).

## Exit questionnaire

Question	Strongly agree	Somewhat agree	Neutral	Somewhat disagree	Strongly disagree
After using Clear Care I can't feel that I'm wearing my lenses	6	10	5	3	0
Clear Care cleans my lenses better than the other solution I used during the study	8	7	8	1	0
Clear Care is easy to use	12	6	1	5	0
Overall, Clear Care is superior to the other solution I used during the study	7	7	4	4	2
Total Responses	33	30	18	13	2

A study exit questionnaire was completed, which asked subjects whether they agreed to various statements. Responses that were statistically significant are marked in red (all p<0.01). The results show that subjects agreed that Clear Care made their lenses feel comfortable, cleaned their lenses better than RepleniSH and was easy to use.

## Discussion

- This study demonstrated that Clear Care resulted in a longer CWT, regardless of lens type. As clinical variables and subjective ratings do not always manifest what patients actually experience, CWT may prove to be a better assessment of lens performance and long term predictor of success.
- Slightly better graded wettability and fewer visible deposits seen on OA with RepleniSH were not associated with a longer CWT or better ratings, suggesting that these investigator assessed measures do not predict comfort.
- With the exception of one subject exhibiting corneal staining which was consistent with a solution sensitivity (with RepleniSH), both Clear Care and RepleniSH were compatible with the SH lens materials used in this study.
- Results from the preference and exit questionnaires suggest that a peroxide-based care system is a viable first choice lens care option for SH lenses.

## References

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