The impact of RGP care solutions on ISO measured lens parameters and the protein deposition on RGP lenses when managed with a hydrogen peroxide care solution

Alex Hui[1,2], Miriam Heynen[1], Vivian Chan[1], Parisa Mirzapour[1], Daryl Enstone[1], Manar Saad[1], Melanie George[3], William Ngo[4], Lyndon Jones[1,4]
[1]Centre for Ocular Research & Education, University of Waterloo, Canada
[2]School of Optometry and Vision Science, UNSW Sydney, Australia
[3]Coopervision, Pleasanton, USA, [4]School of Optometry & Vision Science, University of Waterloo, Canada

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Introduction

- Incompatibility of contact lenses with care solutions may lead to unacceptable changes to physical parameters. [1]
- ISO 11981:2017 details the criteria for assessing compatibility of contact lens care products with contact lenses. [1]
- The standard specifies acceptable changes to parameters such as base curve, back vertex power (BVP), physical appearance and spectral transmittance when contact lens care products are used. [1]
- Parameters which irreversibly change beyond specified tolerances would suggest an unacceptable combination of contact lens and care solution, but little published work has been detailed in the literature of this type of compatibility testing. [1]
- Contact lens care products are also expected to recondition lenses after use, including the removal of protein. [2]
- There have been relatively few studies quantifying protein deposition on rigid gas permeable (RGP) lenses, potentially due to the relatively low amount of deposition and the sensitivity of common techniques. [3]
- Tear film proteins such as lysozyme can be radiolabeled to quantify their deposition on rigid lenses when examined *in vitro*. [4]

Purpose

- To investigate the impact of several RGP care solutions on lens parameters of various RGP lens materials according to criteria in the ISO 11981:2017 standard, and the ability of a hydrogen peroxide-based RGP care solution to remove radiolabeled proteins from RGP lens materials.

Methods

- The ISO standard was followed for measuring lens curvature, BVP, spectral transmittance and examination of physical appearance, after equilibrating for 16 hours in phosphate buffered saline (PBS). [1]
- Lenses and solutions tested for compatibility are found in Tables 1 and 2.
- Lenses then underwent 31 cycles of 16 hours of soaking in PBS followed by 8 hours of soaking in one of four RGP solutions.
- The parameters were then remeasured and compared to the specified ISO tolerances in Table 3 [1] to determine if they passed or failed the criteria for compatibility.
- Cleaning efficacy of the solution containing 3% hydrogen peroxide, 0.00025% Poloxamer, phosphonic acid and phosphates in removing proteins was also evaluated. Thirty alternating cycles were performed of lenses soaking in an artificial tear solution containing radioactive lysozyme for 16 hours followed by 8 hours exposure to the care solution before quantifying lysozyme on the lenses using a radioactive method. Lenses examined are detailed in Table 4.

Methods (continued)

Contact Lens	Paragon CRT® HDS	Paragon CRT® 100	Menicon Z® Thin	Boston® XO	PMMA
Manufacturer	CooperVision Speciality EyeCare	CooperVision Speciality EyeCare	Menicon	Bausch & Lomb	New Phase Optics
USAN	paflufocon B	paflufocon D	tisilfocon A	hexafocon A	PMMA

Table 1: Lenses examined for compatibility with solutions.

Contact Lens Care Products	
Product Description	**Ingredients**
3% one step hydrogen peroxide solution	3% hydrogen peroxide, 0.00025% Poloxamer, phosphonic acid, phosphates
3% hydrogen peroxide solution with neutralizing tablet	3% hydrogen peroxide, phosphates
RGP cleaning and conditioning solution containing chlorhexidine	Chlorhexidine Digluconate, Disodium Edetate, Polyaminopropylbiguanide, Polyethylene Glycol, Polyvinyl Alcohol
RGP cleaning and conditioning solution containing polyhexanide	0.0001% Polyhexanide, EDTA, sodium phosphates, poloxamer, sodium chloride

Table 2: Solutions examined for compatibility with lenses.

Physical Parameter	Tolerance Limits		Relevant Method
Property	**PMMA**	**Gas Permeable**	**ISO 18369-3:2017 Section**
Curvature	±0.025 mm	±0.05 mm	4.2
Back Vertex Power (≤ 5D)	±0.12 D		4.3
Physical Appearance	None that would interfere with intended functional use		4.6, 4.7
Spectral Transmittance and Colour	±5 % absolute between 380-780 nm **Class 1 absorber** <1.0% between 280-315 nm <10.0% between 315-380 nm **Class 2 absorber** 5.0% between 280-315 nm <50.0% between 315-380 nm		4.8

Table 3: Acceptable range of parameter changes for rigid contact lenses after use of solutions as defined by ISO 11981:2017.

Proprietary Name	Optimum Extreme	Paragon CRT® HDS	Paraperm® O_2	Paragon CRT® 100	Boston® Equalens II	Boston® XO	Boston® XO_2
Manufacturer	Contamac	CooperVision Speciality EyeCare	CooperVision Speciality Eyecare	CooperVision Speciality EyeCare	Bausch & Lomb	Bausch & Lomb	Bausch & Lomb
USAN	roflufocon E	paflufocon B	pasifocon A	paflufocon D	oprifocon A	hexafocon A	hexafocon B

Table 4: Lenses assessed for protein removal by a representative 3% one step hydrogen peroxide solution

Results

Contact Lens		Paragon CRT® HDS	Paragon CRT® 100	Menicon Z® Thin	Boston® XO	PMMA
Material		paflufocon B	paflufocon D	tisilfocon A	hexafocon A	PMMA
Property	**Tolerance limits (ISO 18369-2:2017)**	**Difference in CL Measurements after Cycling in 3% One Step Peroxide Solution**				
Number of RGPs started		12	12	15	12	18
Number of RGPs completed		12	12	11	12	12
Curvature	RGP ± 0.05 mm PMMA ±0.025 mm	-0.01 ± 0.02 (-0.03, 0.02) 12/0	-0.01 ± 0.01 (-0.02, 0.00) 12/0	0.01 ± 0.02 (-0.03, 0.03) 11/0	0.00 ± 0.01 (-0.01, 0.02) 12/0	0.003 ± 0.013 (-0.016, - 0.020) 12/0
Back vertex power	±0.12 D	-0.01 ± 0.01 (-0.02, 0.00) 12/0	0.02 ± 0.00 (0.01, 0.02) 12/0	0.00 ± 0.01 (-0.01, 0.02) 12/0	0.00 ± 0.01 (-0.01, 0.02) 12/0	0.00 ± 0.01 (-0.01, 0.01) 12/0
Physical appearance (e.g. surface defects, colour)	Comparison of physical descriptors	12/0	12/0	11/0	12/0	12/0
Spectral transmittance	280-315 nm ±5.0% (Class 2)	N/A	N/A	-0.1 ± 0.1 (-0.4, 0.2) 11/0	N/A	N/A
	315-380 nm ±50.0% (Class 2)	N/A	N/A	0.0 ± 0.1 (-0.3, 0.3) 11/0	N/A	N/A
	380-780 nm ±5 %	1 ± 1 (0, 3) 12/0	0 ± 0 (-1, 1) 12/0	0 ± 1 (-2, 1) 11/0	0 ± 0 (0, 1) 12/0	0 ± 0 (-1, 1) 12/0
Colour	Δe<0.077	0.000 ± 0.000 (0.000, 0.001) 12/0	0.000 ± 0.000 (0.000, 0.001) 12/0	0.000 ± 0.000 (0.000, 0.000) 11/0	0.000 ± 0.000 (0.000, 0.000) 12/0	0.000 ± 0.000 (0.000, 0.000) 12/0

Table 5: Representative ISO compatibility data of examined lenses with a 3% one step hydrogen peroxide solution. All measurements were within tolerances specified after use and was similar to results seen with other solutions. No unacceptable change in parameters were observed. Data presented as mean difference ± SD, (min, max), number of CLs that passed / number of CLs that failed.

Results (continued)

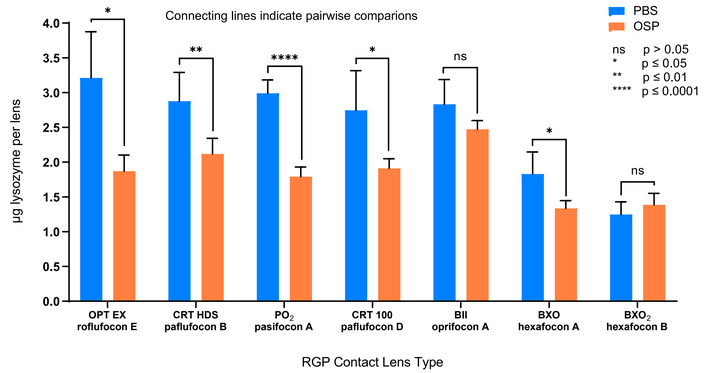

Figure 1: Radioactive lysozyme deposits from various RGP lenses when a representative 3% one step hydrogen peroxide (OSP,) solution is used compared to PBS over 30 alternating incubation/cleaning cycles.

Discussion and Conclusions

- All tested lens and solution combinations were deemed compatible with each other, with any changes in lens curvature, BVP, spectral transmittance and physical appearance within ISO specified tolerances, suggesting no significant physical changes occurred.
- The amount of lysozyme deposited on RGPs was comparatively small.
- A 3% one step hydrogen peroxide based solution was successful in significantly reducing the amount of radioactive lysozyme present on the majority of RGPs after being used for 30 alternating incubating and cleaning cycles, suggesting that it can be effective in removing protein deposits.

References

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 Email contact for correspondence: alex.hui@uwaterloo.ca