



Scleral Lens Surface Coating Improves Vision and Comfort

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INTRODUCTION

- Ocular surface discomfort is the leading cause of contact lens dropout, which occurs in approximately 50% of contact lens wearers.¹⁻²
- Contact lenses disrupt the natural tear film and can create ocular surface discomfort.³ In addition, lipid deposition on the surface of a lens can increase hydrophobicity of the lens.
- Tangible Hydra-PEG is a polyethylene glycol based polymer that covalently binds to the surface of a rigid or soft contact lens, to improve comfort and reduce negative interactions between a contact lens and the natural tear film.
- It has been previously shown that Tangible Hydra-PEG improves comfort in a soft and rigid contact lens wearing population.⁴⁻⁵

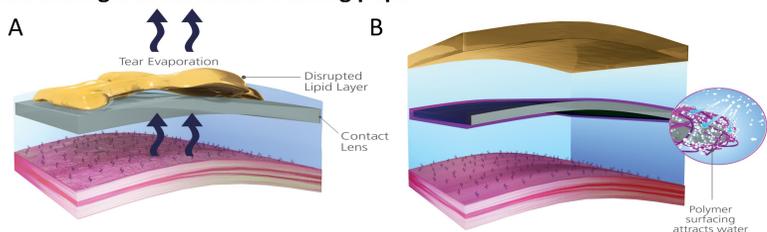


Figure 1. In a traditional contact lens/tear film interface (A), the tear film is often disrupted. Tangible Hydra-PEG is a 90% water, polyethylene glycol surface coating that acts to reduce the negative interactions between the tear layer and contact lens (B).

PURPOSE

This study evaluated the effects of Tangible Hydra-PEG contact lens coating on the comfort and vision of scleral lens wearers.

METHODS

Subject Recruitment

- Established scleral lens wearers were recruited from the University Eye Institute at the University of Houston College of Optometry.
- Subjects were asked to come into the clinic for a total of 4 visits, for evaluation of habitual lenses, uncoated lenses, and Hydra-PEG coated lenses. Subjects were dispensed uncoated and coated lenses and asked to wear them each for one week, and for at least 4 hours prior to coming in for each study visit. Clinical outcomes were measured at each study visit.
- Statistical analysis was done using Wilcoxon signed rank test.

Clinical Outcomes

- Visual Acuity** was measured with high contrast logMAR acuity testing.
- Subjective Lens Preference** was reported by each subject at the end of the study.
- End of Day comfort (EOD comfort)** was measured by a comfort survey, which included an analog (1-10) scale for grading comfort. The survey was completed at each visit for whichever lenses the patient was wearing.
- Midday fogging (MDF) score** was measured by grading the opacification level of the tear film layer during lens wear, using an anterior segment OCT.
- TFQS (tear film quality score)** was measured using the Medmont corneal topographer, which has a module for evaluating mire break up over a 10 second interval in which the subject holds their eye open.
- CL debris** on the surface of the lenses was rated on a scale of 1-5 by a masked examiner, from images taken with an anterior segment camera.

RESULTS

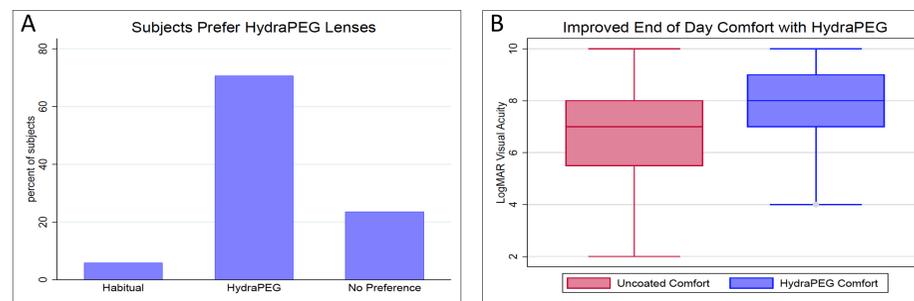


Figure 2. (A) 69% (n=11) of subjects preferred the Hydra-PEG coated lenses to the other lenses evaluated in the study. 25% of subjects had no preference between the three lens types (n=4), and 6% preferred their habitual lenses (n=1). **No subjects preferred the uncoated study lenses.** (B) There was a significant improvement in end-of-day comfort levels with Hydra-PEG lenses ($P < 0.05$). Median end-of-day comfort score was 7 with the uncoated lenses (IQR: 5.75-8), and 8 with the Hydra-PEG coated lenses (IQR: 7-9).

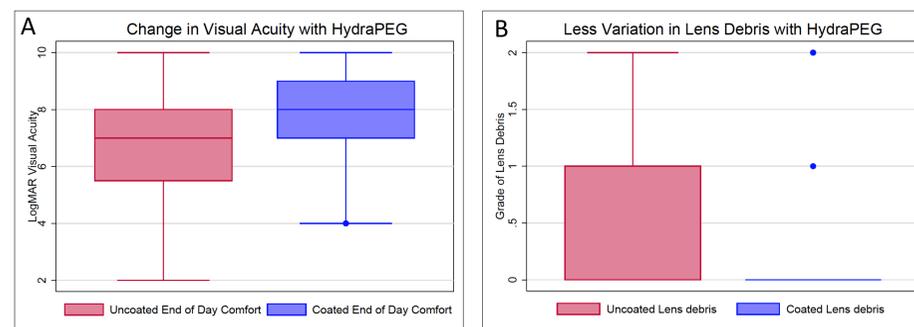


Figure 3. (A) Visual acuity significantly improved with the coated Hydra-PEG lenses ($p = 0.018$). (B) There was less variation in lens debris with the Hydra-PEG coating, which showed significantly lower debris scores when compared to the uncoated lenses ($p = 0.03$). (C) There was no difference in non-invasive tear break up scores between the coated and uncoated lenses ($p = 0.85$). Tear break up scores are measured through a module on the Medmont corneal topographer, on a scale of 0-1 (higher scores indicate greater tear breakup).

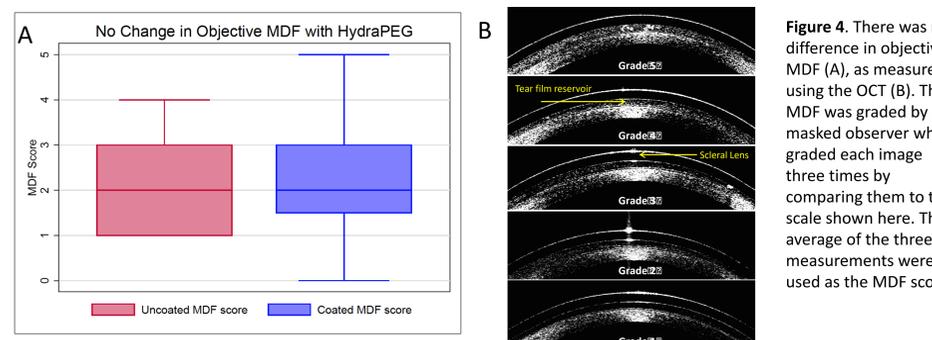


Figure 4. There was no difference in objective MDF (A), as measured using the OCT (B). The MDF was graded by a masked observer who graded each image three times by comparing them to the scale shown here. The average of the three measurements were used as the MDF score.

SUMMARY

- Subjects overall preferred the coated lenses to the uncoated lenses, or showed no preference for the uncoated and coated lenses. One out of sixteen subjects preferred their habitual lenses to the coated lenses (Figure 2A).
- There was a significant improvement in end-of-day comfort scores with the coated Hydra-PEG lenses, when compared to the uncoated lenses (Figure 2B).
- There was an improvement in visual acuity with the Hydra-PEG coating (Figure 3A).
- Lens Debris was reduced with the Hydra-PEG coating (Figure 3B).
- There were no changes in tear break up time with the coated Hydra-PEG versus uncoated lenses (Figure 3C).
- MDF occurs when precipitate matter accumulates within the tear film reservoir beneath the scleral lens during lens wear. The origin of the accumulate is unknown.
- No differences in MDF score were seen between the uncoated and coated lenses, as objectively measured using the OCT (Figure 4).
- Five subjects reported a subjective decrease in MDF when wearing the coated lenses, when compared to the uncoated lenses.

CONCLUSIONS

- Ocular discomfort is a leading cause of scleral lens drop-out for patients that require these medically necessary devices.
- The intent of this study was to evaluate the potential of a rigid lens coating to improve comfort and vision with a scleral lens.
- Our results show a statistically significant improvement in vision and end-of-day comfort with the coated lenses.
- The improved subjective fogging seen in some subjects is likely due to the improved surface quality that Hydra-PEG provides.
- Tangible Hydra-PEG is an effective technology, specifically for patients experiencing discomfort and reduced vision from lens deposition.

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