Higher Order Aberration and Relationship with Soft Contact Lens Modulus

IRB approved 05/13/2024

Background and Rationale:

Corneal diseases, injuries, or surgeries may induce irregular astigmatism, which cannot be corrected by spectacles alone. The standard of care for managing irregular astigmatism are non-flexible rigid gas permeable lenses, hybrid lenses, piggy-back system, or scleral lenses.[1] These lenses correct the residual higher order aberrations (HOAs) induced by irregular astigmatism. However, patients may find these lenses inconvenient, cost prohibitive, difficult to insert and remove, or difficult to adapt due to increased lens awareness. When the irregular astigmatism is mild, soft contact lens can be a viable alternative.[2]

Custom soft contact lenses that are designed to mask mild to moderate amount of irregular astigmatism work by two ways. One is by increasing the center thickness to mimic the non-flexing nature of the GP material.[3] Another way is by increasing its asphericity to limit aberrations.[1,4,5] Still, these lenses are not readily available; most have low oxygen permeability, and their longer replacement schedule is not ideal for patients with dry eyes.[6] Therefore, when patients have acceptable spectacle vision with low amount of irregular astigmatism, they may want to be fit in disposable soft contact lenses readily available off the shelf. Disposable soft contact lenses also have additional benefits, such as options for daily replacement, colors or tinting, and different lens materials optimized to reduce dry eye symptoms.

The modulus of a contact lens material is a measurement of its stiffness,[4] or the material's ability to maintain its shape and resist deformation. A contact lens with a higher modulus does not mold to the eye's anatomy as readily as a contact lens with a lower modulus. To our knowledge, no studies have evaluated the correlation between soft lens modulus and HOA changes with soft contact lens wear. Previous studies on HOA and soft contact lenses have found conflicting data on whether soft contact lens wear increase or decrease HOA,[7–10] and the most recent study was conducted in 2010 using older technology and lens design.[11]

The purpose of this study is to determine whether the lens modulus affects the amount of HOAs in subjects wearing soft contact lenses. OVITZ xwave is a novel aberrometer that is currently used to measure HOAs in an eye. Its data is used to manufacture scleral lenses with optics to correct HOA and improve patients' vision. In this study, we will use OVITZ xwave to measure the HOA of an eye with and without soft contact lens wear. The difference in HOA will then be evaluated for its correlation with soft lens modulus.

Specific Aim:

Determine whether there is a correlation between HOAscorrection and soft contact lens modulus

Hypothesis: Soft contact lenses with stiffer modulus are more effective in reducing HOAs compared to those with softer modulus.

Primary end point: HOA of an eye with and without soft contact lens wear

Exploratory end point: Specific HOA corrected/worsened with soft contact lens.

Study Design:

This one-visit, single-arm observational study will be conducted at the Southern College of Optometry (Memphis, TN, USA). Subjects will be recruited via emails, fliers, and word of mouth. Adults (>18 years old) who are wearing single-vision soft contact lenses will be recruited.

Inclusion Criteria:

- Willing and able to provide informed consent
- Adults > 18 years old regardless of gender, race, or ethnicity
- Habitual single vision soft CL wearer for at least 1 week in any modality.

Exclusion Criteria:

- Multifocal soft CL wear
- GP or ortho K wear in the last 3 months.
- Active eye infections and inflammations.
- Current use of ocular medication.

Materials needed:

CL cases and solution. OVITZ wave system.

Sample size:

The lens modulus and HOA distribution will be used to determine sample size. The number of subjects tentatively estimated is 100.

Methods:

This will be a prospective, single-arm clinical trial, which will be registered with ClinicalTrials.gov. Subjects who meet all study criteria will be enrolled into the study. Clinical measurement will be obtained from both eyes of each subject and testing will be performed in the below order. Testing order was designed to allow for adequate time for contact lens settling. Subjects will be randomized to two groups. One group will be asked to come to the visit wearing their habitual contact lenses for at least 2 hours on the day of the visit. The other group will be asked to refrain from CL wear the day of the visit and to come wearing habitual spectacles.

1. Subject History, Eligibility, Informed Consent: Subjects will be asked to complete a screening survey to verify that they are eligible for the study. All relevant ocular, systemic, and surgical history will be gathered via a questionnaire developed by the investigators. Non-eligible subjects will be dismissed at this time or rescheduled depending upon the reason for ineligibility. Eligible subjects will be enrolled, consented, and requested to sign a privacy document.

Group 1: (presenting wearing CLs)

2. HOA with CLs: The investigator will use OVITZ xwave system to measure the amount of HOA in both the right and the left eye. The subjects will be asked to blink immediately prior to each measurement. The measurements will be repeated 3 times for each eyes.

3. CL removal: The subject will be asked to remove their contact lens. The subjects will be asked to wait for 15 minutes while their ocular system returns to homeostasis.

4. HOA without CLs: The investigator will use OVITZ xwave system to measure the amount of HOA in both the right and the left eye. The subjects will be asked to blink immediately prior to each measurement. The measurements will be repeated 3 times for each eye.

Group 2: (presenting wearing spectacles)

2. HOA without CLs: The investigator will use OVITZ xwave system to measure the amount of HOA in both the right and the left eye. The subjects will be asked to blink immediately prior to each measurement. The measurements will be repeated 3 times for each eye.

3. CL insertion: The subject will be asked to insert their habitual contact lens. The subjects will be asked to wait for 15 minutes while their contact lenses settle.

4. HOA with CLs: The investigator will use OVITZ xwave system to measure the amount of HOA in both the right and the left eye. The subjects will be asked to blink immediately prior to each measurement. The measurements will be repeated 3 times for each eyes.

References:

1. Rathi, V. M., Mandathara, P. S. & Dumpati, S. Contact lens in keratoconus. in *Indian Journal of Ophthalmology* vol. 61 410–415 (2013).

2. Sabesan, R. *et al. Vision Improvement by Correcting Higher-Order Aberrations with Customized Soft Contact Lenses in Keratoconic Eyes*. (2007).

3. Lampa, M. *Leadership in Clinical Care Custom So Lenses for Irregular Astigmatism Contact Lens Close-Up*. https://www.reviewofoptometry.com/article/custom-soft-lenses-for-irregular-astigmatism.

4. Bennett, E. S. & Henry, V. A. *Clinical Manual of Contact Lenses*. (Wolters Kluwer, Philadelphia, 2019).

5. The Comfortable Side of Keratoconus.

6. Managing Irregular Corneas With Soft Lenses.

7. Hong, X., Himebaugh, N. & Thibos, L. N. *On-Eye Evaluation of Optical Performance of Rigid and Soft Contact Lenses*. *Optometry and Vision Science* vol. 78 http://journals.lww.com/optvisscibyBhDMf5ePHKav1zEoum1tQfN4a+kJLhEZgbsIHo4XMi0hCyw (2001).

8. Roberts, B., Athappilly, G., Tinio, B., Naikoo, H. & Asbell, P. Higher order aberrations induced by soft contact lenses in normal eyes with myopia. *Eye Contact Lens* **32**, 138–142 (2006).

9. Lu, F., Mao, X., Qu, J., Xu, D. & He, J. C. *Monochromatic Wavefront Aberrations in the Human Eye with Contact Lenses*. *OPTOMETRY AND VISION SCIENCE* vol. 80 http://journals.lww.com/optvisscibyBhDMf5ePHKav1zEoum1tQfN4a+kJLhEZgbsIHo4XMi0hCyw (2003).

10. Jiang, H., Wang, D., Yang, L., Xie, P. & He, J. C. *A Comparison of Wavefront Aberrations in Eyes Wearing Different Types of Soft Contact Lenses*. *Optometry and Vision Science* vol. 83 http://journals.lww.com/optvisscibyBhDMf5ePHKav1zEoum1tQfN4a+kJLhEZgbsIHo4XMi0hCyw (2006).

11. Berntsen, D. A., Merchea, M. M., Richdale, K., MacK, C. J. & Barr, J. T. Higher-order aberrations when wearing sphere and toric soft contact lenses. in *Optometry and Vision Science* vol. 86 115–122 (2009).