Title: Toric Contact Lens Performance Study

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FULL PROTOCOL TITLE: Toric Contact Lens Performance Study

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1.0 Objectives

This study seeks to quantify the near visual performance and subjective visual acceptance of toric contact lenses as compared to spherical lenses in an astigmatic cohort of patients.

Study Hypotheses: Subjects will have better near visual acuity and near visual performance with toric, as opposed to spherical, contact lens correction. As such, the following hypotheses will be tested:

- H_{01}: There is no statistically significant difference in near visual acuity or near vision performance between contact lenses corrections
- H_{a1}: There is a statistically significant difference in visual acuity or vision performance between contact lenses corrections

2.0 Background

Americans spend over 10 hours a day consuming media on smartphones, digital tablets and home computers.[1] The visual demands of this type of work require the use of sustained clear near and intermediate vision. Previous work in our labs has shown small but measureable improvements in visual acuity for multifocal contact lenses as compared to monovision[2, 3] and toric lenses[4] as compared to spherical correction; especially in low lighting or low contrast conditions. Unfortunately standard in office high contrast, high luminance testing is often not helpful in demonstrating potential improvement in real-world tasks afforded by toric lenses.

Woods et al began exploring patients' preferences conducting real-world tasks such as the ability to locate a web page, read a newspaper or use a computer.[5] They showed that while the difference in standard acuity testing were small, patients reported significant subjective improvements in driving, watching a television, and using a desktop computer, among others.[5]

Wolffsohn and colleagues recently developed iPad based applications that can quantify reading performance on digital devices while the user performs reading tasks (see also Appendix).[6] The user's face is analyzed in real-time by the front facing camera to allow working distance and blinks to be tracked. Swipes, changes in magnification and the time to complete the task are also assessed. This group also developed a Near Activity Visual Questionnaire (NAVQ) to quantify subjective near visual function.[7]

The purpose of the proposed study it to quantify subjective and objective benefits of toric corrections in astigmatic patients, , using the latest digital and patient reported outcomes tools.

3.0 Inclusion and Exclusion Criteria

ALL SUBJECTS

- Able to read and understand the study informed consent

- +0.50 to +4.00 or -0.50 to -6.00 D vertex corrected sphere power
- Best corrected acuity of 20/25 or better in each eye
- Self report of at least 5 hrs/day using digital devices
- No history of ocular pathology or surgery
- No active ocular infection or clinically significant ocular inflammation
- No significant binocular vision abnormality
- No gas permeable lens wear for at least 3 months
- Not an optometrist or optometry student
- Not pregnant/lactating (by self-report)
- 18 to 39 years of age (inclusive)
- 0.75 to 1.50 D vertexed refractive cylinder OD and OS

Potential subjects will be initially screened for study eligibility by phone/in person discussion and through collection of baseline data at visit 1.

Vulnerable Populations

The following vulnerable populations will be excluded from the study:

1. Adults unable to consent
2. Individuals who are not yet adults (infants, children, teenagers under age 18)
3. Prisoners
4. Students for whom the principal investigators have direct access to/influence on grades.
5. Pregnant/lactating women (by self-report)

4.0 Number of Subjects

The proposed single-site study will be conducted at The Ocular Surface Institute at the University of Houston College of Optometry. Up to 76 subjects will be screened for study inclusion, with the goal of completing 34 subjects.

Source data will be collected on paper case report forms and then doubly entered electronically into a database by trained personnel. Source data will be quality assured at the levels of coding, scoring, and entry prior to locking the dataset for analysis.

In this within-subject crossover design, a paired t-test will be used to compare primary outcome visual acuity performance of study treatment lens wear to standard spherical contact lens wear among astigmats. We will use a two-sided independent t-test to ensure there are no carry over or period effects in our cross-over design, although it is not anticipated. As a secondary outcome, subjects will be asked their preference of contact lenses in a two-alternative forced choice format. A one-sample binomial test will be used to test the hypothesis that the probability of preference to treatment lens and standard lenses are equally likely ($H_0: p=.5$ v.$H_1: p\neq.5$).

We aim to test the hypothesis that H_0: $\Delta=0$ v.H_1: $\Delta\neq0$ using a two-sided test with significance level $\alpha=0.05$, where Δ is the underlying benefit for treatment contact lenses versus spherical contact lenses in this cross-over design. Based on previous studies reported average photopic low contrast visual acuity ranged from 0.3 to 0.4 logMAR with various brands of toric contact lenses and under the same conditions from 0.51 to 0.56 with spherical contact lenses among low-to-moderate astigmatic eyes. An estimated improvement with toric lenses has been reported as 0.07±-0.14 among those with low astigmatism with the magnitude of improvement increasing among those with high levels of astigmatism. It is reasonable to expect a detectable range of 2 letters to half-line of improvement with the treatment contact lenses versus the standard sphere lenses. If we expect a half-line treatment benefit and the within-subject variance of the difference in mean visual acuity between the two periods to be a line (0.1 logMar), then based on pilot-study results, and a required 80% power we need 34 participants overall for each study population (68 total). We will randomize an equal number of subjects to each group (i.e., group A receives treatment 1 in period 1 and treatment 2 in period 2; group B receives treatment 2 in period 1 and treatment 1 in period 2). Depending on the variability, a sample size of 34 in each sampled population allows us to detect a smaller effect size (e.g., high contrast tests) as low as 2.5 letters with a within-subject variability of 0.06 logMar. The visual function testing is novel and has not been used on a population of astigmatic contact lens wearers. So sample size planning cannot be done for these tests. We plan to screen up to 38 participants from the study population to allow for attrition.

5.0 Recruitment Methods

Potential subjects will be recruited from the patients and staff of the University Eye Institute/University of Houston College of Optometry, as well as the surrounding community via verbal communication, print media (e.g. study fliers, newspaper adverts), telephone and electronic media (e.g. email, The Ocular Surface Institute Website, social media). Additionally, potential subjects will be identified and recruited via The Ocular Surface Institute's research database.

The total duration of an individual subject's participation in the study will be less than 1 month. The study will consist of 5 visits. Visit 1 will be a baseline evaluation, pre-fitting assessment, randomization, and contact lens fitting. Visits 2 and 4 will be contact lens follow-ups. Visits 3 and 5 are outcome visits. Expected visit timing is summarized in the table below:

Anticipated Visit Timing and Duration		
Study Window	Study Visit	Duration
Day 1	Visit 1: Baseline, randomization, contact lens fitting	120 minutes
Day 4 ± 2	Visit 2: Contact lens follow-up	30-50 minutes
Day 10 ± 2	Visit 3: Outcome lens #1, re-fit to lens #2	75 minutes
Day 13 ± 2	Visit 4: Contact lens follow-up	30-50 minutes

Day 20 ± 2	Visit 5: Outcome lens #2	55 minutes

The anticipated duration to enroll and complete all study subjects is approximately 6 months. The estimated date for the investigators to complete analyses for this study is August 2018.

6.0 Study Endpoints

The primary study endpoints will compare toric to spherical lenses for:

- Binocular near visual acuity

The secondary study endpoints will compare toric to spherical lenses for:

- Binocular near visual performance
    - Reading speed, errors, etc.
- Contrast
    - Binocular low contrast acuity, contrast sensitivity at near

7.0 Procedures Involved

The study is a clinical trial. Subjects will be randomized to start with either toric lenses or spherical correction. Patients will be seen for 5 visits over a period of approximately 1 month. Visit l will determine subject eligibility for the study. Visits 2 and 4 are contact lens follow-up visits. Visits 3 and 5 are study outcome visits. Tests of visual performance at a near reading distance will be evaluated with an iPad application (Optom Central) developed by Dr. James Wolffsohn. This application can measure reading speed, near contract sensitivity and can provide information on how a subject interacts with the electronic device (e.g. blink rate, working distance from the device, scrolling and zooming on the page, etc.). This application is designed for research purposed only and is not commercially available in the Apple App Store.

Visit 1: Screening, Enrollment and Baseline		
Step	**Item**	**Details**
1.1.1	Informed Consent	Review and complete the informed consent form
1.1.2	Subject Demographics	Collect subject demographic data
1.1.3	Medical/Ocular History	Collect subject history including contact lens history
1.1.4	Concomitant Medications	Collect information on concomitant medications
1.1.5	Distance and Near Visual Acuity	Perform Distance and Near Snellen and LogMAR acuity OD/OS with the patient's habitual correction.
1.1.6	Questionnaires	Administer the NAVQ to the subject

1.1.7	Contrast Sensitivity	Perform the contrast sensitivity test on the iPad
1.1.8	Radner reading test	Perform the Radner reading speed test on the iPad
1.19	Functional Vision testing with iPad	Perform the functional vision test on the iPad
1.1.10	Auto-Refraction / Auto-keratometry	Perform autorefraction/keratometry with open field machine
1.1.11	Refraction	Perform Manifest Refraction using maximum plus to best visual acuity
1.1.12	Accommodation, binocular vision	Conduct negative relative accommodation and positive relative accommodation test, Modified Thorington Test at distance and near
1.1.13	Pupil size	Measure pupil size OD/OS in dim and bright light settings
1.1.14	Slit Lamp Exam with NaFl staining	Instill 1 drop of NaFL and evaluate slit lamp findings using the CCLRU grading scale
1.1.15	Check of eligibility and lens order randomization	Confirm eligibility criteria are met. If so, use randomization table to determine order of lens wear
1.1.16	Contact Lens Fitting	Fit subject in the first set of contact lenses based on randomization schedule. • The toric lens parameters should be selected based on the manufactures fitting guide. • The powers for the spherical lenses should be the vertexed spherical equivalent. After allowing the lens to settle for 10 minutes, assess the fit using slit lamp biomicroscopy.
1.1.17	Contact Lens Over-Refraction	Perform over-refraction using maximum plus to best visual acuity • Perform best sphere and sphero-cylindrical over-refraction
1.1.18	Contact Lens Power Adjustment (if necessary)	Follow the manufactures fitting guide and modify contact lens power, based upon the Contact Lens Over-Refraction, if the subject gains more than 3 letters of acuity with over-

		refraction

Visit 2: Contact Lens Follow Up Lens #1 Note: Subjects should report wearing their assigned study contact lenses at least 2 hours.		
2.1	Visual Acuity	Perform Distance Snellen acuity OD/OS with the patient's study lens correction.
2.2	Contact Lens Assessment	Assess the fit using slit lamp biomicroscopy.
2.3	Contact Lens Over-Refraction	Perform over-refraction using maximum plus to best visual acuity
2.4	Contact Lens Power Adjustment (if necessary)	Follow the manufactures fitting guide and modify contact lens power, based upon the Contact Lens Over-Refraction, if the subject gains more than 3 letters of acuity with over-refraction • Perform best sphere and sphero-cylindrical over-refraction
2.5	Slit Lamp Exam with NaFl	Remove the contact lens and instill NaFL then evaluate slit lamp findings using the CCLRU grading scale

Visit 3: Outcome Lens #1 Note: Subjects should report wearing their assigned study contact lenses at least 2 hours.		
3.1	Visual Acuity	Perform Distance Snellen acuity OD/OS with the patient's study lens correction.
3.2	Questionnaires	Administer the NAVQ to the subject
3.3	High and Low Contrast Near Visual Acuity	Measure logMAR high and low contrast acuity at near OU with high luminance
3.4	Contrast Sensitivity	Perform the contrast sensitivity test on the iPad
3.5	Radner reading test	Perform the Radner reading speed test on the iPad
3.6	Functional Vision testing with iPad	Perform the functional vision test on the iPad
3.7	Slit Lamp Exam with NaFl	Remove the contact lens and instill NaFL then evaluate slit lamp findings using the CCLRU grading scale
3.8	Contact Lens Fitting	Fit subject in the second set of contact lenses based on randomization schedule. • The toric lens should be selected based on the manufactures fitting guide. • The powers for the spherical

		lenses should be the vertexed spherical equivalent. • After allowing the lens to settle for 10 minutes, assess the fit using slit lamp biomicroscopy.
3.9	Contact Lens Over-Refraction	Perform over-refraction using maximum plus to best visual acuity
3.10	Contact Lens Power Adjustment (if necessary)	Follow the manufactures fitting guide and modify contact lens power, based upon the Contact Lens Over-Refraction, if the subject gains more than 3 letters of acuity with over-refraction

Visit 4: Contact Lens Follow Up Lens #2 Note: Subjects should report wearing their assigned study contact lenses at least 2 hours.		
4.1	Visual Acuity	Perform Distance Snellen acuity OD/OS with the patient's study lens correction.
4.2	Contact Lens Assessment	Assess the fit using slit lamp biomicroscopy.
4.3	Contact Lens Over-Refraction	Perform over-refraction using maximum plus to best visual acuity
4.4	Contact Lens Power Adjustment (if necessary)	Modify contact lens power, based upon the Contact Lens Over-Refraction, if the subject gains more than 3 letters of acuity
4.5	Slit Lamp Exam with NaFl	Remove the contact lens and instill NaFL then evaluate slit lamp findings using the CCLRU grading scale

Visit 5: Outcome Lens #2 Note: Subjects should report wearing their assigned study contact lenses at least 2 hours.		
5.1	Visual Acuity	Perform Distance Snellen acuity OD/OS with the patient's study lens correction.
5.2	Questionnaires	Administer the NAVQ to the subject
5.3	High and Low Contrast Near Visual Acuity	Measure logMAR high and low contrast acuity at near OU with high luminance
5.4	Contrast Sensitivity	Perform the contrast sensitivity test on the iPad
5.5	Radner reading test	Perform the Radner reading speed test on the iPad
5.6	Functional Vision testing with iPad	Perform the functional vision test on the iPad
5.7	Slit Lamp Exam with NaFl	Remove the contact lens and instill NaFL then evaluate slit lamp findings using the CCLRU grading scale
5.8	Study Exit	Ensure all paperwork is complete and

		exit the subject from the study.

Layman's Description of Procedures	
Patient demographics	The subjects will be asked questions about their age, sex, race and ethnicity.
History	The subjects will be asked questions about their systemic and eye health and surgical history. The subjects will be asked questions about how they use their current contact lenses, such as their current contact lens brand and wear time, as performed during a normal eye exam.
Concomitant Medications	The subjects will be asked questions about their current ocular and systemic medications.
Visual acuity and contrast sensitivity	Measurements of how well subjects can detect letters/lines and with varying levels of contrast (black versus grey on light background)
Auto-refraction/keratometry	A machine will shine light into a subject's eye and will estimate their prescription and curvature of the eye without making contact with the eye.
Slit Lamp Exam	A specialized microscope is used to shine light on the eye and to examine the health of the front of the eye. Sodium fluorescein (NaFl) is a temporary dye that is used in routine contact lens exams to evaluate the health of the front surface cells.
Refraction	The subject's prescription is determined by placing different power lenses in front of the subject's eye, and modified according to the subject's responses.
Contact Lens Fitting	A contact lens is placed on the eye and the fit is assessed (how much is moves, where it sits on the eye, etc.). This is done using a slit lamp biomicroscope.
Contact Lens Over-Refraction and Power Adjustment	Lenses will be placed in front of the subject's eye while wearing the study contact lenses to determine if the prescription needs to be changed according to the subject's responses. The contact lens power will be adjusted if needed based on standard clinical fitting guidelines.
Questionnaires	Asks the subject about his/her vision
Radner Reading and functional vision tests	Measure reading performance (speed, accuracy, etc.) using an iPad based app.

8.0 Setting

All study visits will be conducted at the University of Houston College of Optometry in The Ocular Surface Institute (TOSI).

9.0 Drugs or Devices

No investigational drugs or devices will be used in this study. The contact lenses fit in the study are commercially available, FDA approved contact lenses that will be worn on a daily wear, daily disposable basis. An assistant will mask (over-label) contact lenses so that the subject and outcome examiner remain masked. The primary examiner will follow the manufacturer's fitting guide to determine the initial lens powers. Lens powers will be modified, as needed for best vision, according to the manufactures fitting guide.

The ophthalmic dye used in the trial to evaluate the health of the front surface (sodium fluorescein) is a commercially available ocular diagnostic agent commonly used in routine clinical assessment of contact lenses in optometry.

Study Arm	Study Contact Lenses (Alcon)	Base Curve	Diameter
Toric/Astigmatic	Dailies Aqua Comfort Plus Toric	8.8	14.4
	Dailies Aqua Comfort Plus Sphere	8.7	14.0

10.0 Risks to Subjects

The risks to the subjects in the trial are the same risks found in standard clinical practice and patients wearing contact lenses outside of a controlled trial. During study procedures, there is the risk of mild discomfort due to light being shined on the eye or through the use of topical ophthalmic diagnostic agents (sodium fluorescein) or insertion of contact lenses. Potential discomfort from these procedures is transient and self-limiting.

Contact lenses will be fit as part of this study. The US Food and Drug Administration consider daily wear contact lenses Class II medical devices. While most individuals wear contact lenses without problems, there are some risks associated with wearing contact lenses. Ulcerative keratitis (infection of the clear front part of the eye), is the most severe risk and can lead to loss of vision. Ulcerative keratitis is estimated to happen to about 1-2 out of 10,000 people who use daily wear, daily disposable contact lenses. The risk for ulcerative keratitis in this study is no different than the risk found with contact lens fitting in standard clinical practice. The risk of ulcerative keratitis may be reduced by educating subjects to carefully following the study doctor’s directions for lens care, including throwing out your contact lenses each night, never sleeping or napping in contact lenses, and never exposing the contact lenses to water. These study instructions are the same as those provided to subjects in clinical practice

In addition to ulcerative keratitis, the following problems may occur when wearing contact lenses:

- Other, less serious, infections or inflammation of the eye(s)
- Burning, stinging, itching, dryness or general irritation of the eye(s)
- Corneal neovascularization (small blood vessels growing into the cornea)
- Excessive watering, unusual eye secretions, or redness of the eye
- Reduced or blurred vision (compared to glasses)
- Seeing rainbows or halos around bright lights (compared to glasses)

Many of the potential problems associated with contact lens wear are self-limiting and can be resolved with discontinuation of lens wear. These problems can be minimized or avoided with proper contact lens fitting and follow-up. Subjects in the study will be examined approximately 3-7 days after contact lens fitting, which is a typical follow-up schedule seen in clinical practice for contact lenses worn in a daily wear modality.

Subject safety will be monitored in the trial through slit lamp evaluation of the ocular surface. Subjects will be educated to potential risk with contact lens wear and instructed to discontinue contact lens wear and contact the study investigators immediately if they experience any eye discomfort, excessive tearing, vision changes, redness of the eye, or other problems.

Subjects will be instructed that in the event they experience signs or symptoms associated with a potential adverse event, they should contact the study personnel immediately for evaluation.

11.0 Potential Benefits to Subjects

While there are few direct benefit to the study subjects, subjects will be unmasked (told what each of their study lenses were) at the end of the study. Through this they may learn more about their vision and visual performance with different types of contact lenses. Participation in the study may also improve the fitting of multifocal and toric contact lenses for future patients.

12.0 Withdrawal of Subjects

Subjects may withdraw consent to participate in the study at any time. Subjects may be withdrawn from the trial by the study investigators if they fail to return for study visits or follow study instructions, have unacceptable vision or fit with the contact lenses, become pregnant during the trial, or have a study-related adverse event that warrants study withdrawal.

13.0 Costs/Payments to Subjects

There are no expected additional costs to subjects that participate in the study. There is no cost to subjects for contact lens fitting in this study. Subjects will be provided with daily disposable contact lenses for the duration of the study at no charge. Subjects will be provided with a token for parking at each study visit (if necessary). Subjects will be

compensated $40 for completion of each study visit (a total of up to $200 for 5 visits). Subjects will be compensated with an Amazon gift cards after completion of the last study visit or exit from the study (if early exit due to withdrawal).

14.0 Compensation for Research-Related Injury

The risks to subjects from participation in the study are minimal. The clinical procedures used in the study are commonly used clinical procedure in optometry and ophthalmology. In the rare case that a subject is injured as part of their participation in the study, the subject will be responsible for any associated medical bills.

15.0 Confidentiality

Subjects will be assigned a unique subject ID. Subjects IDs are two digits and should start at 01 and continue in the order of enrollment. No one outside of the research team will have access to the subject identifiers. A key to the study code will be maintained for 3 years at the time of study completion (i.e. Last Subject, Last Visit).

Any source documents with patient identifiable information will be kept only at the local site (informed consent form, linking log). Individual documents will be kept in a locked room in The Ocular Surface Institute.

16.0 Provisions to Protect the Privacy Interests of Subjects.

Those who are potentially eligible and interested in the study will be referred to a study team member who will discuss the study with the patient. This discussion will take place in a quiet, private area and as much time as necessary will be spent discussing the details of the study.

17.0 Informed Consent Process

This trial will follow the University of Houston Division of Research SOP: Informed Consent Process for Research (HRP-090). The participant will be provided an opportunity to read the informed consent and to have any questions answered before agreeing to participate. Prior to any testing, the investigator or study coordinator will obtain written informed consent from all participants. The consent form will be signed and dated by both the participant and a member of the study personnel who has been approved to obtain consent. The participant will receive a copy of the signed consent documents and the originals will be filed in the subject binder on site in a secure location.

18.0 Process to Document Consent in Writing

The clinical trial will follow the University of Houston Division of Research standard operating procedure regarding written documentation of informed consent (SOP: Written Documentation of Consent (HRP-091)). The consent form will be signed and dated by both the participant and a member of the study personnel who has been approved to obtain consent. The participant will receive a copy of the signed consent documents and the originals will be filed in the subject binder on site in a secure location. A copy of the informed consent document is included in the study related documents.

19.0 HIPAA

We will be collecting demographic information and general medical and eye health information. Since protected health information will be collected, the Health Insurance Portability and Accountability Act (HIPAA) authorization form will be included as part of the Informed Consent process.

The linked PHI will be destroyed upon completion of the study and final analysis/report. PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

20.0 Data Management

Paper source documents (i.e. case report forms) will only be associated with a subject ID number and will not contain direct subject identifiers.

21.0 Specimen Use and Banking

No specimens will be collected in this study.

22.0 Sharing of Results with Subjects

Subjects will be unmasked at the end of the study and informed of their contact lens parameters. The subject may choose to share this information with their eye doctor to inform future contact lens fitting needs.

23.0 Resources

The study team completed all necessary ethics training requirements. The co-PIs (Eric Ritchey, OD, PhD and Kathryn Richdale, OD, PhD) each have over a decade of experience conducting clinical care and research and will oversee all study personnel.

With an abundance of contact lens wearers in the surrounding community, we believe that we should be able to complete enrollment within 6 months.

This study utilizes the clinics of The University Eye Center and The Ocular Surface Institute to recruit study subjects on the campus of the University of Houston.

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Consent to Take Part in a Human Research Study

Title of research study: Toric Contact Lens Performance Study

Investigators: Kathryn Richdale OD PhD, Eric Ritchey OD PhD

Why am I being invited to take part in a research study?

You are being asked to participate in a research study to help us evaluate the vision and performance of different types of contact lenses when used with digital devices. You may be eligible to be in the study because you have a certain amount of astigmatism (due to the curvature of the front of your eye)..

We will be testing different types of soft contact lenses to see how they perform when using digital devices. As such, you may get slightly different vision with each set of contact lenses. At the end of the study, the study doctors will explain the differences in the contact lenses to you.

Taking part in this study is entirely voluntary, meaning that you may or may not choose to participate. To decide whether or not you want to be part of this research, the risks and possible benefits of the study are described in this form so you can make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study. This form also explains how your medical information will be used and who may see it. You may have a copy of this form to take home to review and ask advice from others.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide, and can ask questions at any time during the study.

Why is this research being done?

The purpose of this research is to better understand how different types of contact lens corrections may improve vision and performance, like the ability to read on digital devices.

How long will the research last?

Each subject should complete the study in less than one month. The study requires 5 visits. Visit 1 will last about 2.0 hours and is a baseline screening for eligibility and includes tests to determine which contact lens powers you will wear during the study. You will be randomized (like flipping a coin) to

which lens design you wear first. All subjects will wear two different designs of contact lenses – each for about 1 week. Visit 2 will take less than 1 hour and should be done within 2-5 days from Visit 1. At Visit 2 we will check to make sure you are doing well with your contact lenses and make changes to the power, if needed, to give you your best vision. Visit 3 will take less than 1.5 hours and should be done about 8-12 days after Visit 1. At Visit 3 we will assess your vision and performance with the contact lenses and then fit you with the other contact lens design. Visits 4 is the same as Visit 2 but with the second design of contact lenses (also a 1 hour visit). At visit 5 we will assess your vision and performance with the second contact lens design.

See the tables below for a detailed breakdown of the procedures and estimated study visit timing.

Visit 1 – You can come to this visit wearing your glasses or your current contact lenses		
Procedure	***Description***	***Duration***
Informed Consent	Review risks, benefits, and purpose of study	20 mins
Demographics & Medical History	Collect info on medical history, current medications, contact lens information and demographics	5 mins
Visual Acuity	Measure your vision with your current prescription using an eye chart designed for regular eye examinations	5 mins
Auto-refraction and auto-keratometry	A machine will be used to estimate your prescription and the shape of your eye	5 mins
Questionnaire	Answer questions about your vision with the contact lenses	5 min
High and Low Contrast Near Visual Acuity and Contrast Sensitivity	Measure your vision at near using special charts with more and less contrast (black or grey letters/lines on a white background)	10 mins
Radner Reading Test and Functional Vision testing with iPad	Measure how quickly and easily you are able to read on an iPad	15 min
Refraction	Determine your prescription	10 mins
Accommodation, Binocular Vision	Measure how well you focus your eyes and use them together as a team.	10 min
Pupil size	An instrument will measure how big your pupils are in dim and bright light	5 min
Slit Lamp Exam	A microscope will be used to make sure the front surface of your eyes are healthy and able to wear contact lenses	5 mins
Study Contact Lens Order Randomization	You will be randomized (like a flip of a coin) to which lens design you wear first. All subjects will wear both lens designs if they complete the study.	5 min
Contact Lens Fitting & Over-Refraction	Make sure the first contact lenses fit your eyes well and the prescription works well	20 mins

	Total Estimated Duration:	2.0 hours

Visit 2 – You should come to this visit wearing your study contact lenses for at least 2 hours

Procedure	*Description*	*Duration*
Visual Acuity	Measure vision with your contact lenses using a standard eye chart for regular eye examinations	5 min
Contact Lens Assessment & Over-Refraction	Make sure the contact lenses still fit your eyes well and the prescription works well after you adapted to them for a few days If the vision can be improved, new lenses will be put on the eye(s) and allowed to settle, and the vision will be checked again. If the fit or vision are not acceptable you will be exited from the study.	20-40 min
Slit Lamp Exam	A microscope will be used to make sure the front surface of your eyes are healthy and able to continue wearing contact lenses	5 mins
	Total Estimated Duration:	30-50 mins

Visit 3 - You should come to this visit wearing your study contact lenses for at least 2 hours

Procedure	*Description*	*Duration*
Visual Acuity	Measure vision with your contact lenses using a standard eye chart for regular eye examinations	5 min
Questionnaire	Answer questions about your vision with the contact lenses	10 min
High and Low Contrast Near Visual Acuity and Contrast Sensitivity	Measure your vision at near using special charts with more and less contrast (black or grey letters/lines on a white background)	15 mins
Radner Reading Test and Functional Vision testing with iPad	Measure how quickly and easily you are able to read on an iPad	20 min
Slit Lamp Exam	A microscope will be used to make sure the front surface of your eyes are healthy and able to continue wearing contact lenses	5 mins
Contact Lens Fitting & Over-Refraction	Make sure the second contact lens design fits your eyes well and the prescription works well If the fit or vision are not acceptable you will be exited	20 mins

	from the study.	
	Total Estimated Duration:	75 mins

Visit 4 – You should come to this visit wearing your study contact lenses for at least 2 hours

Procedure	*Description*	*Duration*
Visual Acuity	Measure vision with your contact lenses using a standard eye chart for regular eye examinations	5 min
Contact Lens Assessment & Over-Refraction	Make sure the contact lenses still fit your eyes well and the prescription works well after you adapted to them for a few days If the vision can be improved, new lenses will be put on the eye(s) and allowed to settle, and the vision will be checked again. If the fit or vision are not acceptable you will be exited from the study.	20-40 min
Slit Lamp Exam	A microscope will be used to make sure the front surface of your eyes are healthy and able to continue wearing contact lenses	5 mins
	Total Estimated Duration:	30-50 mins

Visit 5 - You should come to this visit wearing your study contact lenses for at least 2 hours

You should bring your glasses or contact lenses to wear home from the study.

Procedure	*Description*	*Duration*
Visual Acuity	Measure vision with your contact lenses using a standard eye chart for regular eye examinations	5 min
Questionnaire	Answer questions about your vision with the contact lenses	10 min
High and Low Contrast Near Visual Acuity and Contrast Sensitivity	Measure your vision at near using special charts with more and less contrast (black or grey on white)	15 mins
Radner Reading Test and Functional Vision testing with iPad	Measure how quickly and easily you are able to read on an iPad	20 min
Slit Lamp Exam	A microscope will be used to make sure the front surface of your eyes are healthy and able to continue wearing contact lenses	5 mins

	Total Estimated Duration:	55 mins

How many people will be studied?

We expect to start about 38 people.

We expect 34 people to complete the study.

What happens if I say yes, I want to be in this research?

All of the tests done during the study are described above. All of the contact lenses used in the study are FDA approved. The eye examination and contact lens fitting are the same as what is done in standard clinical care. The questionnaires and special vision and reading testing are done for research purposes to get a better idea of how subjects are performing with the contact lenses.

An iPad app will be used to measure your reading performance. This iPad App used the FaceTime camera to track your blinks and eye movements, as well as to make sure that you are properly lined up with the device,

This research study will be conducted at The Ocular Surface Institute by trained study personnel. Optometrists (eye doctors) will fit the contact lenses and conduct the eye examination portion. A research assistant may help with the questionnaire and visual performance testing.

The contact lens design you wear first will be chosen by chance, like flipping a coin. You will have equal chance of starting with either lens design treatment. Neither you nor the study doctor evaluating your performance will know which lens design you are using.

What are my responsibilities if I take part in this research?

If you agree to be a part of this research, you will be responsible for wearing the assigned contact lenses at least 8 hours a day on the days between the study visits. You will also need to adhere to the dates and times for study visits and wear the assigned contact lenses for at least two hours before coming to the study visits (Visit 2-5).

What happens if I do not want to be in this research?

You can choose not to take part in the research and it will not be held against you. Choosing not to take part will involve no penalty or loss of benefit to which you are otherwise entitled.

If you are a student, a decision to take part or not, or to withdraw from the research will have no effect on your grades and/or standing with the University of Houston. If you are receiving clinical care, a decision to take part or not will have no effect on what would be offered to you as part of routine care. If you are an employee of the University of Houston, a decision to take part or not, or to withdraw from the research will have no effect on your employment with the University of Houston

If you chose not to be in this study, you can ask your eye doctor if you can be fitted or toric contact lenses.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

If you decide to leave the research, you will not be compensated for your study visits after you exit the study and the data collected up to the point of study exit may still be used. If you decide to leave the study, contact the investigator. The study investigator will want to talk to you or see you to make sure that you are okay and your eyes are still healthy.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me?

The risks to subjects from participation in the study are minimal. The procedures in the study (slit lamp exam, contact lens fitting, etc.) are commonly used clinical procedures in optometry and ophthalmology.

Commercially available (FDA approved) contact lenses will be fit as part of this study. While most individuals wear contact lenses without problems, there are some risks associated with wearing contact lenses. Ulcerative keratitis (infection of the clear front part of the eye), is the most severe risk and can lead to loss of vision. Ulcerative keratitis is estimated to happen to about 1-2 out of 10,000 people who use daily wear daily disposable contact lenses. The risk in this study is no different than the risk if your eye care provider fit you in contact lenses. The risk of ulcerative keratitis may be reduced by carefully following the study doctor's directions for lens care including throwing out your contact lenses each night, never sleeping or napping in contact lenses, and never exposing your contact lenses to water.

The following problems may also occur when wearing contact lenses:

- Other, less serious, infections or inflammation of the eye(s)
- Burning, stinging, itching, dryness or general irritation of the eye(s)
- Corneal neovascularization (small blood vessels growing into the cornea)
- Excessive watering, unusual eye secretions (such as mucus), or redness of the eye(s)
- Reduced or blurred vision (compared to glasses)
- Seeing rainbows or halos around bright lights (compared to glasses)

In the event you experience signs or symptoms associated with one of the problems listed above, you should immediately contact the The Ocular Surface Institute at 713-743-2849 (during regular business hours) or the study Principal Investigator, Dr. Kathryn Richdale, at 917-755-4548 or Dr. Eric Richey at 614-596-7477 (outside business hours).

Will I get anything for being in this study?

If you are eligible for the study and complete all 5 study visits you will receive a $200 Amazon gift card ($40/visit for 5 visits). If you attend the first visit but are not eligible (screen fail), you will receive a $40 Amazon gift card for Visit 1. If you are exited from the study at a later visit (due to problems with the fit or vision of the contact lenses, or not attending the study visits as assigned), you will only be paid for the study visits that you completed on time. You will be paid when you complete or otherwise exit the study.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. Subjects may be unmasked (told what each of their study lenses were) at the end of the study. Through this they may learn more about their vision and visual performance with different types of contact lenses. Participation in the study may also improve the fitting of toric contact lenses for future patients.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. Each subject's name will be paired with a code number, which will appear on all written study materials. The list pairing the subject's name to the assigned code number will be kept separate from these materials. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization, as well as collaborating institutions and federal agencies that oversee human subjects research. The sponsor of the research (Alcon) may also review research records upon request. This research uses or discloses Protected Health Information as defined by the Health Insurance Portability and Accountability Act (HIPAA), and you will be asked to sign an additional document to authorize the use of this information.

We may publish the results of this research. However, unless otherwise detailed in this document, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you do not attend the study visits or the do not have acceptable vision or fit with the contact lenses.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. The University of Houston has no program to pay for medical care for research-related injury.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can email Dr. Richdale (Richdale@uh.edu) or Dr. Ritchey (erritche@Central.UH.EDU) or call and ask to speak to one of them (713-743-2849).

This research has been reviewed and approved by the University of Houston Institutional Review Board (IRB). You may also talk to them at (713) 743-9204 or cphs@central.uh.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Consent to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your consent to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

In the future, our research team may be interested in contacting you for other research studies we undertake, or to conduct a follow-up study to this one. ***There is never any obligation to take part in additional research.*** Do we have permission to contact you to provide additional information?

- ☐ Yes
- ☐ No