Title
Toric Contact Lens Digital Performance and Comfort Study

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FULL PROTOCOL TITLE: Toric Contact Lens Digital Performance and Comfort Study

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Table of Contents

1.0 Objectives

1.1 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. We also aim to explore associations between tear LTB4 concentration, eye comfort, visual performance, and subjective visual quality after 6-8 hours (full day of wear) toric and spherical contact lens wear.

1.2 Primary 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:
H01: There is no statistically significant difference in near visual acuity or near vision performance between contact lenses corrections
Ha1: There is a statistically significant difference in visual acuity or vision performance between contact lenses corrections

2.0 Background

2.1 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 measurable improvements in visual acuity for toric lenses[2] as compared to spherical correction. 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.

2.2 Dynamic visual acuity has been used in sports vision assessment and training in the past, but little is published on the topic. It is more robust than traditional visual acuity measures in being a detection rather than recognition task, is always of equal difficulty, there is limited time for observer adjustments such as blinking/squinting, and a staircase procedure ensures a definitive endpoint. Wolffsohn's lab has recently developed an iPad-based application to assess dynamic visual acuity **(see Appendix A).**

Woods et al[3] began exploring patients' preferences conducting real-world tasks such as the ability to locate a web page, read a newspaper or use a computer. They showed that while the difference in standard acuity testing was small, patients reported significant subjective improvements in driving, watching a television, and using a desktop computer, among others.[3] 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 B**).[4] 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) **(Appendix C)** to quantify subjective near visual function.[5]

The Richdale lab recently utilized these applications to assess near visual performance with spherical vs. toric soft contact lenses and found that toric correction improved near high-and low-contrast visual acuity by 0.5 to 1 full line, and enabled individuals to read one line smaller text on the iPad (STUDY00000682). The majority of subjects preferred the toric correction, though this was based on visual performance alone, and not ocular comfort.[6]

2.3 Contact lens discomfort can affect wearing time and potentially lead to dropout, particularly in the first year of wear.[6,7] According to the Tear Film Ocular Surface (TFOS) Contact Lens Discomfort report, lens design, material and the interaction between the contact lens and ocular surface are potential factors associated with contact lens discomfort.[7] Toric lenses have been reported to be less comfortable than spherical lenses; however previous studies mainly explored older lens materials and designs.[7] Additionally, it is thought that contact lens discomfort may be more related to subjective visual quality (Questions 3a and 3b in Contact Lens Dry Eye Questionaire-8**) (Appendix D)**.[8] However, the effect of modern toric and spherical daily disposable soft contact lenses on the association between contact lens discomfort, subjective visual quality and visual function has not been investigated. Symptomatic lens wearers usually report discomfort prior to reducing lens wear time.[9] Recently, it has been shown that contact lens discomfort was related to upregulation of tear eicosanoid biomarkers. Masoudi et al found a higher tear concentration of Leukotriene B4 (LTB4) at the end of the day in symptomatic soft contact lens wearers compared to asymptomatic contact lens wearers.[9]

The purpose of this study is to quantify digital visual performance and subjective visual acceptance and its association with ocular comfort and subjective visual quality, during toric contact lens wear as compared to spherical lens wear in low to moderate astigmatic patients after a full day of contact lens wear. We also aim to explore the association between tear LTB4 concentration, eye comfort, visual performance, and subjective visual quality after 6-8 hours (full day) of toric and spherical contact lens wear.

3.0 Inclusion and Exclusion Criteria

3.1 ALL SUBJECTS must be/have:

- Able to speak and read English at a high school level / have at least a high school diploma or equivalent (by self-report)18 to 39 years of age (inclusive)
- Plano to -6.00 D vertex corrected sphere power and -0.75 to -1.50 vertexed cylinder power in each eye
- Best corrected acuity of 20/25 or better in each eye
- Self-report of at least 4 hrs/day using digital devices
- Willing not to wear their habitual contact lenses or use artificial tears or other solutions for at least 24 hours
- No history of ocular pathology or surgery
- No active ocular infection or clinically significant ocular inflammation
- Current/established full time (>6 days per week, >8 hours per day) soft contact lens wearer

- Asymptomatic soft contact lens wearer (CLDEQ-8 score <12 at baseline)
- No significant binocular vision abnormality (i.e., tropia, convergence or accommodative insufficiency)
- No gas permeable lens wear for at least 3 months
- Not an optometrist
- Not pregnant/lactating (by self-report)
- Willing to wear lenses at least 8 hours each day during the study period

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

3.3 *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. Pregnant/lactating women (by self-report) will not be enrolled as hormone changes can affect the ocular surface and comfort with contact lenses
5. Students for whom the principal investigator has direct access to/influence on grades will only be consented and examined by other investigators.

4.0 Vulnerable Populations

Students for whom one of the principal investigators has direct access to/influence on grades would be consented and seen by another investigator for all visits. The following vulnerable populations will be excluded from the study:

1. Pregnant women
2. Neonates of uncertain viability or non-viable neonates
3. Prisoners
4. Children
5. Cognitively impaired adults

5.0 Number of Subjects

5.1 The proposed single-site study will be conducted at the University of Houston College of Optometry. Up to 30 subjects will be screened for study inclusion, with the goal of completing 24 subjects.

Source data will be collected on paper case report forms and then double entered electronically into a database by trained personnel prior to locking the dataset for analysis.

5.2 In this within-subject crossover design, a paired T-test will be used to compare visual acuity performance, contact lens discomfort, subjective visual quality and LTB4 concentration following toric lens wear to spherical contact lens wear. 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.

One-sample binomial tests will be used to test the hypothesis that the probability of preference to toric lens and spherical lenses are equally likely. Linear mixed model or generalized linear model, as appropriate, will be carried out to examine the associations between eye comfort, visual performance, subjective visual quality and LTB4 concentration during toric and spherical contact lens wear.

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. Our previous work found that toric correction improved visual acuity compared to spherical correction by 6 and 11 letters for high and low contrast logMAR, respectively ($P<0.001$).[10] To demonstrate an improvement of this amount or more it will require at least 24 and 15 subjects with a P=0.05 and 80% power. The dynamic visual acuity test is novel and has not been used previously to allow sample size estimates. A total of 30 subjects will be enrolled to allow for up to 20% dropout/screen-failure/missing data and have 24 subjects complete. 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).

6.0 Recruitment Methods

6.1 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,), telephone and electronic media (e.g. email or posting of study flyer).
6.2 Potential subjects will be screened via phone call.
6.3 Verbal communication, print media (e.g. study flyer), telephone and electronic media (e.g. flyer sent by email, or posted to social media) will be used. (Flyer and phone script are included in this application)

7.0 Multi-Site Research Communication

N/A

8.0 Study Timelines

8.1 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 and will be performed after 6-8 hours of contact lens wear to provide consistent duration of lens wear between subjects and lens types. The 6-8 hours of wearing time also allows a better understanding of end of day visual performance and the changes in LTB4. 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, tear collection	140 minutes
Day 3 ± 1	Visit 2: Contact lens follow-up	30-50 minutes
Day 10 ± 2	Visit 3: Outcome lens #1, subjective and objective visual assessments and tear collection, re-fit to lens #2	95 minutes
Day 13 ± 2	Visit 4: Contact lens follow-up	30-50 minutes
Day 20 ± 2	Visit 5: Outcome lens #2, subjective and objective visual assessments and tear collection and tear collection	75 minutes

The anticipated duration to enroll and complete all study subjects is approximately 9-12 months. The estimated date for the investigators to complete analyses for this study is Fall/Winter 2021.

9.0 Study Endpoints

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

- Near visual acuity

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

- Other near visual performance outcomes
    - Reading speed, reading sentences acuity, digital device interaction, dynamic visual acuity
- Subjective eye comfort and visual acceptance during contact lens wear
    - Association between subjective comfort surveys and tear TLB4 concentration

*9.*2 This is a minimal risk study so safety endpoints are not required

10.0 Procedures Involved

10.1 The study is a clinical trial and will be registered on ClinicalTrials.gov prior to subject enrollment.

10.2 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 developed by Prof. James Wolffsohn. These applications are designed for research purposes only and are not commercially available. The applications can measure reading speed and 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.).

10.3 Subjects will be randomized to start with either toric lenses or spherical correction (FDA approved lenses will be utilized).

Overview of Visit Procedures (Assessments)

A masked examiner will perform all outcome measures.

	Visit 1 Baseline and Fit Lens 1	Visit 2 day 3±1	Visit 3 – day 10±2		Visit 4 day 13±1	Visit 5 day 20±2
		Follow-up Lens 1	Outcomes Lens 1	Fit Lens 2	Follow-up Lens 2	Outcomes Lens 2
Informed consent	X					
Ocular/medical/contact lens history	X					
Ocular symptoms (CLDEQ-8)[8]	X		X			X
Auto-refraction and keratometry	X					
Slit lamp exam with NaFl staining	X					
Manifest refraction	X					
Accommodation and phoria	X					
Near logMAR HCHL & LCHL acuity OU	X		X			X
NAVQ survey[5]	X		X			X
Radner reading sentences, dynamic acuity measurement and functional vision test with iPad[4]	X		X			X
Tear collection	X		X			X
Study lens order randomization	X					
Insertion of CL and settling (15 min)	X			X		
Clinical CL vision and fit assessment, over-refraction, and power adjustment if indicated	X	X		X	X	
Removal of study lens and slit lamp exam with NaFl staining		X	X		X	X

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 and medications. 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.
Questionnaires	Asks the subject about his/her vision and comfort during contact lens wear
Visual acuity	Measurements of how well subjects can detect letters or symbols at a given distance
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, including conjunctival and limbal redness using Cornea and Contact Len Research Unit (CCLRU) grading scale. Sodium fluorescein (NaFl) and lissamine green are temporary dyes that are used in routine contact lens exams to evaluate the health of the front surface of the eye using modified Oxford Scale.
Tear collection	Tears will be collected from both eyes using glass microcapillary tubes (BLAU_BRAND, Intramark, Werthein, Germany) and pooled together in a low adhesion Eppendorf tube. The collected tears will be kept on ice and transferred to a -80°C freezer within half an hour and stored until batch analysis using Leukotriene B4 ELISA kits (dilution factor 1:10, Assay Designs, Ann Arbor, MI).[9]
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.
Radner Reading, functional vision tests, and dynamic acuity measurement	An iPad application will be used to assess reading performance (speed, accuracy, etc.). The dynamic acuity measurement (detection rather than a recognition task) involves a Landolt C surrounded by crowding bars presented for a limited duration

	(300ms) and the observer identifies which of the 4 possible directions it is orientated on a response keypad. An incorrect response leads to an increase in presentation size and correct response a decrease, with the endpoint being when there have been 3 reversals in the staircase procedure.

11.0 Setting

11.1 All study visits will be conducted at the University of Houston College of Optometry in the Richdale lab

12.0 Drugs or Devices

12.1 No investigational drugs or devices will be used in this study. The contact lenses used 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 dyes used in the trial to evaluate the health of the front surface (sodium fluorescein and lissamine green) are a commercially available ocular diagnostic agents commonly used in routine clinical assessment of ocular health in optometry.

Study Contact Lenses (Alcon)	Starting Sphere Power	Starting Cyl Power
Precision1 for Astigmatism	Vertexed manifest refraction	Per the fitting guide
Precision1 Sphere	Vertexed spherical-equivalent of manifest refraction	N/A

13.0 Risks to Subjects

13.1 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, through the use of topical ophthalmic diagnostic agents, or insertion of contact lenses. The usual risks which exist during the performance of tear collection may include minor eye discomfort, irritation, and temporary redness of the eyes. The discomfort is usually self-limiting and can be resolved with the use of over the counter artificial tears. A break will be given if the subjects experience any discomfort or irritation during tear collection.

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 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 within a week after initial 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

14.0 Potential Benefits to Subjects

14.1 While there are few direct benefits 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.

15.0 Provisions to Monitor Data to Ensure the Safety of Subjects

N/A

16.0 Withdrawal of Subjects

16.1 Subjects may withdraw consent to participate in the study at any time.
16.2 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, are unable to complete the study outcomes, become pregnant during the trial, or have a study-related adverse event that warrants study withdrawal.

17.0 Costs/Payments to Subjects

17.1 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.
17.2 Subjects will be provided with daily disposable contact lenses for the duration of the study at no charge. Subjects parking at each study visit will be validated (if necessary). Subjects will be compensated $50 for completion of each study visit (a total of up to $250 for 5 visits). Subjects will be compensated with an Amazon gift card after completion of the last study visit or exit from the study (if early exit).

18.0 Compensation for Research-Related Injury

18.1 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.

19.0 Confidentiality

19.1 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.
19.2 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 Richdale lab.
19.3 No one outside of the research team will have access to the subject identifiers.
19.4 A key to the study code will be maintained for 3 years at the time of study completion (i.e. Last Subject, Last Visit).
19.5 No audio or video will be saved in this study. The video recorded during the digital performance testing is only used to verify blinks and test distance/alignment and will be deleted once testing is verified. Only the numerical data will be saved.

20.0 Provisions to Protect the Privacy Interests of Subjects

20.1 Those who are potentially eligible and interested in the study will be referred to a study team member who will discuss the study with them. 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.

21.0 Informed Consent Process

21.1 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.

21.2 Potential individuals who cannot understand English, or who are unable to consent, will not be included in this study.

22.0 Process to Document Consent in Writing

22.1 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.

22.2 Template Consent Document HRP-502c will be used for consented adults

22.3 A copy of the informed consent document is included in the study related documents.

23.0 HIPAA

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

23.2 The link to 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.

24.0 FERPA

N/A

25.0 Data Management

25.1 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 Richdale lab. Paper source documents (i.e. case report forms) will only be associated with a subject ID number and will not contain direct subject identifiers. Data will be entered in Excel for analysis and no patient identifiers will be entered in the data analysis spreadsheets.
25.2 Data Entry will be conducted by study team members and data will be doubled checked for any errors.
25.3 Electronic data will only be stored in a limited access shared folder on the college directory.
25.4 Copy of the data will be stored on campus for 3 years following completion of the research.
25.5 Only study team members will have access to the study data.
25.6 Data can only be accessed remotely via the secure UH VPN system.

26.0 Specimen Use and Banking

26.1 Tear samples will be stored at College of Optometry, JDA building until batch analysis.
26.2 The samples will be stored until analysis.
26.3 Only the investigators in this study will have access to the specimens.
26.4 The investigators in this study will be responsible for the transportation of the specimens from Health 1 to JDA building in College of Optometry.
26.5 The samples will be transported in a tripled sealed container on ice.
26.6 Tear samples will be stored in the lab until analyses.
26.7 There will not be enough specimens to save or store for future use.

27.0 Community-Based Participatory Research

N/A

28.0 Sharing of Results with Subjects

28.1 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.

29.0 Resources

29.1 The study team completed all necessary ethics training requirements. The PI (Kathryn Richdale, OD, PhD) has nearly two decades of experience conducting clinical care and research and will oversee all study personnel.

29.2 With an abundance of contact lens wearers in the surrounding community, and based on our recruitment with previous contact lens studies we believe that we should be able to complete enrollment within 6-9 months.

30.0 Additional Approvals

N/A

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UNIVERSITY of HOUSTON
A CARNEGIE-DESIGNATED TIER ONE PUBLIC RESEARCH UNIVERSITY

Consent to Take Part in a Human Research Study

Title of research study: Toric Contact Lens Digital Performance and Comfort Study

Investigator: Kathryn Richdale OD PhD

Key Information:

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. In addition, we will be evaluating the composition of the tears on the front of your eye after wearing the different types of lenses. 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.

We invite you to take part in a research study about testing different types of soft contact lenses to see how they perform when using digital devices because you meet the following criteria

- Able to read and understand the study informed consent
- 18 to 39 years of age (inclusive)
- Pl to -6.00 D vertex corrected sphere power and -0.75 to -1.50 vertexed cylinder power in each eye
- Best corrected acuity of 20/25 or better in each eye
- Self-report of at least 4 hrs/day using digital devices

- Willing not to wear their habitual contact lenses or use artificial tears or other solutions for at least 24 hours
- No history of ocular pathology or surgery
- No active ocular infection or clinically significant ocular inflammation
- Current/established full time (>6 days per week, >8 hours per day) soft contact lens wearer
- Asymptomatic soft contact lens wearer (CLDEQ-8 score <12 at baseline)
- No significant binocular vision abnormality
- No gas permeable lens wear for at least 3 months
- Not an optometrist
- Not pregnant/lactating (by self-report)
- Willing to wear lenses at least 8 hours each day during the study period

This research is being funded by Alcon Laboratories.

In general, your participation in the research involves 5 visits over a period of one month.Visit 1 will last about 2 hours and is a baseline screening for eligibility and includes tests to determine which contact lens powers you will wear during the study. We will also obtain a sample of your tears. 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 2-4 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, obtain a tear sample, and then fit you with the other contact lens design. Visit 4 is the same as Visit 2 but with the second design of contact lenses (also less than 1 hour visit). At visit 5 we will assess your vision and performance with the second contact lens design and take a third and final tear sample (less than 1 hour).

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 min
Demographics & Medical History	Collect info on medical history, current medications, contact lens information and demographics	5 min
Visual Acuity	Measure your vision with your current prescription	5 min
Auto-refraction and auto-keratometry	A machine will be used to estimate your prescription and the shape of your eye	5 min
Questionnaires	Answer questions about your vision with the contact lenses	10 min
Radner Reading Test, dynamic acuity, and Functional Vision testing	Measure how quickly and easily you are able to read on an iPad	15 min

with iPad		
Refraction	Determine your prescription	10 min
Accommodation, Binocular Vision	Measure how well you focus your eyes and use them together as a team.	10 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 min
Tear Collection	A small tube will be used to collect a small amount of your tears.	5-10 min
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 min
	Total Estimated Duration:	2 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 min
	Total Estimated Duration:	0.5 to 1 hr

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	5 min
Questionnaires	Answer questions about your vision with the contact lenses	10 min
Radner Reading Test, dynamic acuity, 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 min
Tear Collection	A small tube will be used to collect a small amount of your tears.	5-10 min
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 from the study.	20 min
	Total Estimated Duration:	1 hour

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 min
	Total Estimated Duration:	0.5 to 1 hr

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
Radner Reading Test, dynamic acuity, 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 min
Tear Collection	A small tube will be used to collect a small amount of your tears.	5-10 min
	Total Estimated Duration:	0.5 to 1 hour

The primary risk to you during study procedures, there may be minor eye irritation, allergic reactions (to the anesthetic drop), and redness of the eyes due to the use of sodium fluorescein, or collection of tears. The discomfort is self-limiting and can be resolved with the use of over the counter artificial tears.
There are no direct benefits for the participants. You will receive compensation for your time to participate.

Detailed Information:

The following is more detailed information about this study, in addition to the information listed above.

Why is this research being done?

The purpose of this research is to better understand how different types of contact lens corrections may affect your tears, eye comfort, and visual performance, like the ability to read on digital devices.

How long will the research last?

We expect that you will be in this research study for about one month.

How many people will be studied?

We expect to start about 30 people in the study. We expect 24 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 uses the front camera to track your blinks and eye movements, as well as to make sure that you are properly lined up with the device. The video/images will be deleted after they are checked for accuracy at the end of each study visit.

This research study will be conducted at Richdale Lab 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.

Audio, video or photograph will be not be taken during the study.

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 during the study. You will also need to adhere to the dates and times for study visits and wear the assigned contact lenses for at least six hours before coming to the outcome visits (Visits 3 and 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, or withdraw from the research, 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 for 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 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 a study 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.

The usual risks which exist during the performance of tear collection may include minor eye discomfort, irritation, and temporary redness of the eyes. The discomfort is usually self-limiting and can be resolved with the use of over the counter artificial tears. A break will be given if you experience any discomfort or irritation during tear collection.

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 lab at 713-743-7908 (during regular business hours) or the study Principal Investigator, Dr. Kathryn Richdale, at 917-755-4548 (outside business hours).

Will I receive anything for being in this study?

If you are eligible for the study and complete all 5 study visits you will receive a $250 Amazon gift card ($50/visit for 5 visits) and parking validation at any study visit(s) for the patient parking lot. If you attend the first visit but are not eligible (screen fail), you will receive a $50 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 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 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.

Your information and/or biological samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

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.

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.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found.

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 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.

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.

May we contact you regarding future research opportunities?

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

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	