

Optometry Project

Study Protocol

Optical evaluation of this and that

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1. Introduction

A major cause of soft contact lens failure is Various factors can affect Contact lens manufacturers have tried to address this problem by developing ...

We plan to study The technique we plan to use to monitor the This is a novel application of

The instruments measure an eye's Each coefficient This is the basic objective data we will use.

2. Study objective

We specifically want to evaluate a We will evaluate the lens in comparison to another ..., and in comparison to

Hypothesis: The ...should show This effect may change over time. We are interested in seeing how ... will compare.

3. Study design and overview

We plan to evaluate ..., at different times during the day. Each of the ... will be tested on a different day, in the following order.

- First day:
- Second day:
- Third day:

We will test the right eye of each subject, who will be masked ...

During the one-minute measurement interval, the subject will ... We will collect about 60 measurements during a measurement session, and schedule measurement sessions at the following times.

- 1 hour
- 3 hours
- 6 hours

4. Investigators

This project will require the following investigators, who will carry out the study at the Northeastern State University Oklahoma College of Optometry.

- Co-principal investigators - two third year optometry students
- Coinvestigator/Faculty advisor - Associate professor, OD, PhD

5. Study population

The subject group will consist of approximately 10 subjects who meet the following inclusion criteria:

- Age 18 to 30
- Healthy eyes with normal tear films
- Currently wearing soft contact lenses with no problems
- 20/25 or better vision with contact lenses
- No history of refractive surgery or permanent optical distortion
- Spherical equivalent corneal-plane refractive error between -1.00 and -10.00 diopters
- Astigmatism less than or equal to -0.75 diopters

We will recruit subjects from among We will invite them to join this study by electronic mail, telephone or by personal contact.

6. Materials

6.1 Study lenses

We will use the following lenses in this study:

6.2 Equipment

Besides standard eye examination equipment available in the optometry clinics, we will use the This will allow non-invasive evaluation of

6.3 Pharmacological agents

During the preliminary exam, we will assess each subject's ... using ...

6.4 Lens care products

6.5 Lens inventory and accountability

We will order one box (30 lenses per box) for both of the following ...

1) Lens A

- Powers between -1.00 and -10.00 diopters (0.25-diopter steps) Base curves = 8.6 mm
- 29 boxes

2) Lens B

- New product packaged in ...
- Powers between -1.00 and -10.00 diopters (0.25-diopter steps) Base curves = 8.6 mm
- 29 boxes

6.6 Case report forms

We will prepare the following data forms.

- Baseline data
- Informed consent
- Subjective questionnaire
- Lens evaluation

7. Procedures

Obtain human subject's approval from the Northeastern State University Institutional Review Board before starting.

7.1 Visit schedule

Each subject will make four visits to the NSU Oklahoma College of Optometry as follows:

1. Preliminary exam. A 1.5-hour session will be necessary to measure baseline data, verify eligibility and for trial lens fitting, as detailed in Table 1 below.
2. Lens A evaluation. The subject will come in the morning of another day, be fitted with ..., and it will be evaluated throughout the day, as detailed in Tables 2 and 3 below.
3. Lens B evaluation. The subject will come in the morning of another day, be fitted with ..., and it will be evaluated throughout the day, as detailed in Tables 2 and 3 below.

7.2 Measurement procedures

We plan to conduct the sessions as outlined in the following tables.

Table 1. Preliminary exam procedures.

Major steps	Responsible person	Specific tasks
1. Pre-visit preparation	Principal investigator (PI) 1	1. Contact subject and schedule visit 2. Instruct subject to not wear contact lenses on that day. 3. Prepare subject's folder and data forms with baseline refraction and contact information.

2. Subject administration	PI1	<ol style="list-style-type: none"> 1. Verify all contact information (email, Facebook, cell phone, home phone, etc.) 2. Complete subject registration, informed consent, instructions, questions and answers 3. Introduce subject to the optometrist assistant and assist with translations, recording data, or other tasks.
3. Clinical optics evaluation	PI2	<ol style="list-style-type: none"> 1. Review history, medications, etc. for things that could adversely affect optics or the tear film. 2. If present, exclude from study. 3. Perform autorefraction/autokeratometry 4. Starting with available data, verify refraction for both eyes for infinity to the nearest 0.25 diopters for both sphere and cylinder. 5. Measure best-corrected visual acuity. 6. Calculate corneal-plane refraction 7. Calculate appropriate spherical contact lens power for both eyes. 8. Record results on baseline data form.
4. Slit lamp exam	PI	<ol style="list-style-type: none"> 1. Examine anterior segment of both eyes to rule out any contraindication to soft CL wear. 2. Evaluate tear film quality (debris, oil layer, tear prism, etc.). 3. Record tear break-up time (TBUT) 4. If TBUT is abnormally fast, or the subject shows consistent dry spots, exclude from study. 5. Evaluate and record corneal staining with yellow filter. 6. If abnormal staining, exclude from study. 7. Record results on baseline data form.
5. Schirmer tear test	PI 2	<ol style="list-style-type: none"> 1. Summarize procedure for subject 2. Perform Schirmer I tear test OU (no anesthetic) 3. If less than 5 mm, exclude from study. 4. Record results on baseline data form.
6. Select appropriate contact lenses from stock	PI1	<ol style="list-style-type: none"> 1. Copy contact lens powers from baseline exam form to another piece of paper. 2. Prepare tray with subject's name and lens data 3. Select One-Day Biomedics lenses with the appropriate powers. 4. Select One-Day Acuvue lens with the appropriate powers. 5. Put those lenses in the tray and take them to the optometrist assistant.
7. Verify Lens A contact lens fit	PI2	<ol style="list-style-type: none"> 1. Insert lenses trial lens. 2. Let the subject wait 10 minutes. 3. Evaluate the fit 4. Decide whether the fit is good enough to wear for this study. 5. Record results on baseline data form.
8. Verify Lens B	PI2	<ol style="list-style-type: none"> 1. Insert lenses trial lens. 2. Let the subject wait 10 minutes. 3. Evaluate the fit 4. Decide whether the fit is good enough to wear for this study. 5. Record results on baseline data form.
9. Dismiss subject	PI1	<ol style="list-style-type: none"> 1. Verify that all data has been collected. 2. Thank and dismiss subject.

Table 2. Lens evaluation exam procedures. Several subjects may be run in staggered parallel tracks.

Table 3.

8. Data management

All data will be stored in a secure location and identifiers or personal information will not be disclosed to persons outside the study or to those who do not have a need to see the data. Data will be destroyed when no longer needed. Subject names will be replaced with a code in all documents that may be seen by persons outside the study.

Raw objective data for each eye are the data files stored on

- 70 measurement files for each session.
- 5 measurement sessions (baseline, 1-hour, 3-hour, 6-hour) per lens
- 3 lenses will be evaluated
- Approximate number of data files per subject = $70 \times 5 \times 3 = 1050$ files.

A questionnaire will provide subject evaluations of each lens.

- Subject will answer questions during each measurement session
- Four measurement sessions (20-minute, 1-hour, 3-hour, 6-hour sessions) per lens
- One page includes questions for all sessions for that day.
- Three lenses will be evaluated, so each subject will complete 3 questionnaires.

Data processing after each lens measurement is complete.

- Open Data Viewer and verify that data was stored in the database.
- If not, load and process data for a 4-mm pupil.
- Arrange Data Viewer columns to include name, eye, date, time, pupil diameter, analysis pupil, sphere, cylinder, axis, 3rd-order, 4th-order, 5th-order, 6th-order, total RMS and
- Export these data to Excel for analysis. Each Excel spreadsheet will contain the complete data for one subject. Each row will have data from a single measurement. Columns will have the data for each measurement.
- Copy data for each session to a separate spreadsheet in that Excel workbook.

9. Data analysis

Follow the analysis methods used by ... the RMS value as a function of time for coma-like, spherical-like and total higher-order RMS values. Classify each pattern as being either

- Stable
- Small fluctuations
- Saw-toothed or
- Other

In addition, compute the following indices, as defined by

- Fluctuation index (FI) - standard deviation of
- Stability index (SI) - slope of linear regression fit to ...
- Time of minimum total higher-order aberrations ...

The subjective questionnaires will evaluate the following.

- Lens dryness
- Lens comfort
- Vision

Statistical analyses