Initial Correction Keratoconus: Scleral vs Corneal Gas Permeable Lenses

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LIST OF ABBREVIATIONS

COI	Conflict of Interest
DHHS	Department of Health and Human Services
DMC	Data Monitoring Committee
DSMB	Data and Safety Monitoring Board
DSMP	Data and Safety Monitoring Plan
FERPA	Family Educational Rights and Privacy Act
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IBC	Institutional Biosafety Committee
ICD	Informed Consent Document
ICH	International Conference of Harmonization
IDE	Investigational Device Exemption
IDS	Investigational Drug Service
IND	Investigational New Drug
IRB	Institutional Review Board
LAR	Legally Authorized Representative
OHRP	Office of Human Research Protections
OPRS	Office for the Protection of Research Subjects
PHI	Protected Health Information
PI	Principal Investigator
PPRA	Protection of Pupil Rights Amendment
QA/QI	Quality Assurance/Quality Improvement
SAE	Serious Adverse Event
SOP	Standard Operating Procedure

1.0 Project Summary/Abstract

- This is a multi-center, randomized interventional clinical trial with a 2x2 crossover design of patients with keratoconus fit with corneal and scleral gas permeable contact lenses.
- While both corneal gas permeable and scleral lenses have been show to improve visual acuity in individuals with keratoconus, it has yet to be determined if one option has superior comfort and overall patient satisfaction in patients new to gas permeable lens use.

2.0 Background/Scientific Rationale

- Keratoconus is a non-inflammatory, progressive disease in which corneal irregularity increases and thickness decreases. It is thought to occur in approximately 1 of 2,000 individuals[1] and has been associated with contact lens wear, eye rubbing, Down's syndrome, atopic disease, connective tissue disease, and family history of corneal ectatic disease.[2] As the condition develops, progressively more advanced forms of optical correction are needed to provide functional visual acuity for patients. Until recently, corneal rigid gas permeable lenses were considered the primary mode of correction for patients with keratoconus. Now, however, practitioners have multiple options for reducing the optical aberrations caused by keratoconus, including custom hydrogels, hybrid lenses, and scleral lenses. As a consequence patients who previously could not be fit with lenses are able to wear them, decreasing the need for surgical intervention such as keratoplasty. However, being able to use non-surgical strategies for keratoconus management may lead to an increased number of visits and complexity of decision-making during the contact lens fitting process. As of yet, no single option for optical correction has been identified as the preferred mode of correction in terms of overall patient satisfaction with vision, comfort, and ease of use. The order in which various forms of optical correction would be most logically introduced has yet to be determined.
- Keratoconus is known to impact overall quality of life, as well as vision-related quality of life.[3-5] We hypothesize that patient-reported quality of life may vary depending upon the prescribed form of contact lens correction. Most studies, which investigate quality of life, are relatively small, and assess change in quality of life following a specific intervention.

- In this study, patients will be prospectively fit with both corneal gas permeable and scleral lenses according to standard clinical practice. Both corneal gas permeable and scleral lenses are considered standard of care for patients with keratoconus. In a previous study by Kumar et al, patients with keratoconus who were naiive to contact lens wear reported comparable improvement in visual function (including logMAR acuity, contrast sensitivity function, steroacuity using Howard-Dolman apparatus and higher-order wavefront abberations) for both corneal gas permeable and scleral lenses.[6] The authors suggest that non-visual factors such as quality of lens fitting, wearing comfort and cost may be more important for determining lens preference among patients than visual performance. Corneal gas permeable lenses were more difficulty to fit, and were not as comfortable, but were less expensive than scleral lenses.[6]

  An additional study evaluated subjective comfort between corneal gas permeable and scleral lenses in patients with keratoconus who were stable corneal gas permeable lens users .[7] Subjective comfort scores were significantly higher in

scleral lens wearers, however the final lens of choice in the study were similar with 53% opting to continue with their habitual corneal gas permeable lens and 47% choosing the scleral lens instead.[7] Similar to the study by Kumar et al., there was no significant difference in best corrected visual acuity or contrast sensitivity function between the two lens modalities.[7]

3.0 Objectives/Aims

- Specific Aim;
- This study will prospectively compare visual satisfaction and ease of use between corneal gas permeable and scleral lenses for patients with mild to moderate keratoconus who are naiive to lens use.

- Hypotheses to be tested:
  1. Participants will select scleral lens over corneal gas permeable lens as their preferred final lens type. Scleral lens comfort will be rated higher than corneal gas permeable lenses.

- Primary Outcome Measure:
- 1. The Primary outcome of this study is participant selected final lens choice for continued use for the management of keratoconus.

- Secondary Outcome Measures:
- 1. Best corrected Snellen visual acuity converted to logMAR
- 2. Practitioner ease of lens fitting including number of visits, number of trial lens required for fitting and number of lenses ordered.
- 3. Patient burden including time required to learn safe application and removal as well as daily time require for lens application and removal.
- 4. Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable)
- 5. Dry eye symptoms assessed using the validated OSDI and CLDEQ do we get baseline meibography on each patient.
- 6. Impact of lens cost on lens choice.

Methods:

- Patients will be consented and enrolled in the study during routine clinical visits.
- At the first study visit, participants will be fit with corneal gas permeable and scleral lenses in both eyes. The OSDI and CLDEQ questionnaires will be assessed.
- The patient will return for regularly scheduled fitting visits to maximize lens fitting and visual acuity.
- At the 2nd study visit, patients will be randomized to receive lens application and removal training with lens type #1. Patients will begin daily wear of lens type #1.

- At the 3rd study visit (2-4 weeks after dispensing of lens #1), visual acuity, ease of use and subjective comfort of lens #1 will be assessed. The OSDI and CLDEQ questionnaires will be repeated.
- The participant will be trained in lens application and removal with lens #2. Lens #1 will be returned to the study clinician unless the patient refuses (thus ending the study).
- At the 4th study visit (2-4 weeks after dispensing lens #2), visual acuity, ease of use and subjective comfort of lens #2 will be assessed. The OSDI and CLDEQ questionnaires will be repeated. Participants will be asked to select their final lens of choice. Participants unable to return for a study visit will be contacted to complete the surveys and final lens preference,

4.0 Eligibility

- Potential participants will be identified and recruited from ophthalmology and optometry clinics at study sites during routine visits.
- Individuals must have a diagnosis of keratoconus confirmed by clinical examination and topography.
- Wiliness to return for a minimum of 4 study visits.
- The principal and co-investigators will determine subject eligibility using study eligibility checklist.

4.1 Inclusion Criteria

- Age 18 or older.
- Diagnosis of keratoconus.
- Available baseline corneal topography and pachymetry.
- Amsler-Krumeich keratoconus classification[9] of stage 1 or higher

Table 1 Standard Amsler-Krumeich keratoconus classification.

Stage I	Eccentric steepening Myopia/astigmatism < 5.00 D Mean K < 48.0 D
Stage II	Myopia/astigmatism > 5.00 D but < 8.00 D Mean K < 53.0 D Absence of scarring Minimal apical corneal thickness > 400 µm
Stage III	Myopia/astigmatism > 8.00 D but < 10.00 D Mean K > 53.0 D Absence of scarring Minimal apical corneal thickness < 400 µm but > 300 µm
Stage IV	Refraction not possible Mean K > 55.0 D Central corneal scarring Minimal apical corneal thickness < 300 µm

-

4.2 Exclusion Criteria

- No prior corneal transplantation or INTACTS.
- No prior use of hybrid, corneal or scleral gas permeable lenses.
- Presence of corneal scarring.

4.3 Excluded or Vulnerable Populations

- No vulnerable populations will be enrolled.
- Non-English speaking subjects can be enrolled with the use of translation services.

5.0 Subject Enrollment

- After identification, potential participants will be asked if they would like to hear more about the study during routine clinical visits.
- A standardized recruitment script will be used by study investigators.
- The informed consent document will be reviewed with potential participants.
- Individuals with a diagnosis of keratoconus meeting all inclusion and exclusion criteria and willing to participate will be enrolled by the principle and co-investigators.
- Participants will be compensated $40 (Visa gift cards) for each of the four study visits at the completion of the study. The patient will receive their final selected lens of choice at no cost.

6.0 Study Design and Procedures

- Multi-center study sites will include:

.1 Illinois Eye and Ear Infirmary, Chicago IL.(UIC)
.2 Millennium Park Eye Center, Chicago, IL. (UIC)
.3 The Mayo Clinic, Rochester MN.
.4 The Ohio State University, Columbus OH.
.5 The Illinois College of Optometry, Chicago IL.

- This is a prospective, multi-center, randomized interventional clinical trial with a 2x2 crossover design of patients with keratoconus fit with corneal and scleral gas permeable contact lenses. The crossover design allows intra-subject differences between two randomized groups with participants serving as their own controls.
- This is a pilot study to determine sample size and feasibility of study protocol for a larger randomized study.
- Each clinic will enroll up to 25 participants with a maximum of 125 participants.

- Screening eligibility
  .1 Patients age 18 or older with a diagnosis of keratoconus will be recruited during routine clinical exams at the Illinois Eye and Ear Infirmary.
  .2 Available baseline corneal topography and pachymetry.
  .3 Willingness to return for 4 study visits.
- Informed consent will be obtained by the principal investigator or co-investigators.

- Study visit number 1 (estimated 45-90 minutes)
  .1 Patient demographics (age, race, age diagnosed with keratoconus) [standard of care]
  .2 Past ocular and medical history including ocular procedures such as corneal collage crosslinking and corneal surgery. [standard of care]
  .3 Best corrected visual acuity with manifest refraction [standard of care]
  .4 Corneal curvature using topography [standard of care]
  .5 Corneal pachymetry (thickness) [standard of care]
  .6 Meibography [standard of care] ifalready performed and present in the patient's medical record, the data will be gathered. However, it will not be completed solely for the purpose of this study. .
  .7 Dry eye symptoms and contact lens comfort assessed using the validated 12-item OSDI and CLDEQ questionnaire. [for research purposes]
  .8 Research intervention: Fitting for keratoconus [standard of care]
    .8.1 Both eyes will be fit according to standard practices with the RoseK 2 corneal gas permeable and Synergeyes VS scleral lenses following manufacturer's recommendations.

.8.1.1 Over refraction and best corrected visual acuity.

.8.1.2 Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable).

- Routine Follow up visits to evaluate lens fit and visual acuity according to standard practice until lenses are deemed adequate for dispensing. [standard of care].

- Study visit number 2 (estimated 30-60 minutes)
  - .1 Randomize to dispense lens #1 vs lens #2. [for research purposes]
  - .2 Lens application and removal handling [standard of care].
  - .3 Instructions on lens disinfection procedures.
  - .4 Best corrected visual acuity with lens #1 [standard of care]
  - .5 Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable) [for research purposes].

- Study visit number 3- wearing lens #1 between 2-4 weeks for minimum of 3 hours (estimated 45-75 minutes)
  - .1 Best corrected visual acuity with lens #1 [standard of care]
  - .2 Hours of lens wear today, average hours of lens wear time, days per week of per week and daily time spent on lens application and removal (general question – patients will not need to keep track or a log) [standard of care]
  - .3 Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable) [for research purposes].
  - .4 Dry eye symptoms assessed (OSDI questionnaire), contact lens comfort assessed (CLDEQ). [for research purposes]
  - .5 Lens #2 application and removal training [for research purposes].
  - .6 Best corrected visual acuity with lens #2 [standard of care].
  - .7 Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable) [for research purposes].
- Study visit number 4- wearing lens #2 between 2-4 weeks for minimum of 3 hours (estimated 15-45 minutes)
  - .1 Best corrected visual acuity with lens #2 [standard of care]
  - .2 Hours of lens wear today, average hours of lens wear time, days per week of per week and daily time spent on lens application and removal (general question – patients will not need to keep track or a log) [standard of care]
  - .3 Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable) [for research purposes].
  - .4 Dry eye symptoms assessed (OSDI questionnaire), contact lens comfort assessed (CLDEQ). [for research purposes]

.5 Participant final selection of lens of choice #1 or #2 [for research purposes].
.6 Participant final selection of lens of choice #1 or #2 given average self-pay cost of annual replacement [for research purposes].

- Final participant preferences- participants can be contacted to complete the surveys and final lens preference,
  .1 Dry eye symptoms assessed (OSDI questionnaire), contact lens comfort assessed (CLDEQ). [for research purposes]
  .2 Participant final selection of lens of choice #1 or #2 [for research purposes].
  .3 Participant final selection of lens of choice #1 or #2 given average self-pay cost of annual replacement [for research purposes].

- Unscheduled visits
  Will tally unscheduled visits and current lens type. [standard of care]

For Studies that Collect Prospective Data

- Data will be collected prospectively from the electronic medical record using paper care report forms and RedCAP by the primary and co-investigators at all study sites.
- A master list will be used to code participants and maintain study documents with study ID only. The list will be maintained by the investigator at each study site. De-identified data only will be shared with co-investigators listed on the study and with the locations listed on this study. The list will be stored in a locked cabinet of a locked office.
- At the completion of the study, the lists will be destroyed.
- De-identified data only will be maintained for future research use.

Survey studies

- Participants will complete the validated 12-item OSDI[10] and the Contact lens dry eye questionnaire-8 (CLDEQ-8) [11] and comfort scale of contact lens performance to assess dry eye symptoms at each study visit.
- The OSDI Score is assessed on a scale of 0 to 100 with higher scores representing greater disability.

Studies involving use of product

- Two products will be used in this study.
  - Contact lens #1: SynergEyes VS (Synergeyes, Inc., Carlsbad CA) which features bi-tangential toric peripheries with linear landing zones. The standard lens is 16.0mm and is available from 14.5 to 17.5mm diameters.
  - Contact lens #2: RoseK2 corneal gas permeable lens (Blanchard Contact Lens, Inc. Manchester, NH). The lens is available in with a base

curve range from 4.30 to 8.60 mm, diameter of 7.90 to 10.40mm.

- · Product information including lens order number, lens parameters, lens materials and verification will be tracked and maintained in the case report form and on RedCAP.
- · Adverse events will be recorded and immediately reported to the clinic PI.
    - Potential adverse events include corneal scratch or abrasion related to lens handling, blurred vision, red or irritated eyes, pain in and around the eyes and excessive tearing.

7.0 Expected Risks/Benefits

- There are potential benefits for participants including improved visual clarity. Contact lens prescription is the current standard of care for keratoconus. There are associated risks associated with contact lens use including eye pain, epithelial defects, microbial keratitis, corneal scarring and neovascularization.
- There are potential risks associated with new contact lens wear including handling issues and loss of contact lens. This may result in eye pain, epithelial defects, microbial keratitis, corneal scarring and neovascularization. These issues are not specific to the study but with wearing/using new contact lens in general.

8.0 Data Collection and Management Procedures

- Paper case report forms will be completed at each site.
- De-identified data only will be entered into the RedCAP database by each investigator.
- De-identified data will be stored in RedCAP for future analysis and publication.

9.0 Data Analysis

- Final lens selection will be calculated for each randomization group.

- Descriptive statistics will be used to compare logMAR visual acuity, comfort (OSDI and CLDEQ) and number of lenses ordered to achieve fitting for lens #1 and lens #2. Meibography will be analyzed.

10.0 Quality Control and Quality Assurance

- The principal investigator will provide training for all co-investigators on recruitment, obtaining informed consent and proper filling out of case report forms.
- The principal investigator will review de-identified data entered into RedCAP after every 5 participants for completeness. REDCap limits will be used to ensure responses fall within appropriate ranges.

- The principal investigator will review de-identified data from each study sites to ensure data completeness and accuracy.

11.0 Data and Safety Monitoring

- There will not be a data and safety monitoring committee for this study. All study related problems will be identified and reported to the principal investigator. All co-investigators will be responsible for reporting safety concerns to the PI within 48 hours of occurrence.
- Adverse Events (AEs) will be collected and reviewed by the principal investigator within one business day.
- Unanticipated problems (UPs) will be detailed by co-investigators and reported to the principal investigator within one business day. Any study related AEs or UPs outside of usual contact lens related or contact lens handling problems will be reported to the IRB.
- A participant may elect to withdraw or stop participating in the study at any time.

12.0 Statistical Considerations

- This is a pilot study to determine feasibility for a future randomized clinical trial. Descriptive statistics will be compiled.

13.0 Regulatory Requirements

13.1 Informed Consent

- Informed consent will be obtained by the investigators at each site during routine ophthalmology or optometry visits.
- The principal investigator will train the co-investigators to use a script to obtain informed consent.
- Paper copies of informed consent documents will be provided to the study participant and maintained by the principal investigator in a locked file cabinet of locked office.
- No minors will be enrolled in this study.
- In person translators will be used to enroll non-English speaking participants if applicable. If in person translators are unavailable, the study visit can be rescheduled until an in person translator is available.

13.2 Subject Confidentiality

- Study participants will be recruited and complete informed consent in a clinical exam lane with a closed door by the principal investigator or co-investigator.
- Only the principal and co-investigators will have access to the study data for each participant at their individual site.

- Study data will be de-identified and entered into the REDCap database.
- After completion of the study, the master list linking participants to their study will be destroyed.
- De-identified data only will be maintained in RedCAP for analysis and publication.
- PHI will be viewed during routine clinical visits while viewing the electronic medical record.

13.3 Unanticipated Problems

- Adverse Events (AEs) and unanticipated problems (UPs) will be collected and reviewed by the principal investigator within one business day.
- Any study related AEs or UPs outside of the usual contact related or contact lens handling problems will be reported to the IRB.

- **14.0 References**

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APPENDICES

A. Eligibility Checklist

-Diagnosis of keratoconus confirmed by slit lamp and topography.

-No history of corneal surgery or INTACS (history of CXL okay)

-No prior history of prior hybrid, corneal or scleral gas permeable lens use.

-Age 18 or older

-Willing to return for 4 study visits.

Recruitment script:

"You may qualify to participate in a research study for patients with keratoconus with corrective contact lenses. As part of the study, participants are fit with two types of contact lenses and asked questions about their experience with each lens type. If you are interested in hearing more about the study I can provide more information and a copy of the written informed consent which outlines more details of the study. If you are not interested in participating in the study there will be no negative impact on your ongoing care.

B. Data Collection Forms

Study ID #

Date of signed informed consent

Randomization lens #1→#2 or lens #2→#1

**Odd # study id will begin with lens #1.*

- *Study visit number 1*
  - *.1 Patient demographics*
    - *.1.1 Age*
    - *.1.2 Race*
    - *.1.3 Age diagnosed with keratoconus*
  - *.2 Past ocular and medical history including ocular procedures such as corneal collage crosslinking and corneal surgery.*
  - *.3 Best corrected visual acuity with manifest refraction*
  - *.4 Corneal curvature using topography*
  - *.5 Corneal pachymetry (thickness)*
  - *.6 Meibography*

.7 OSDI questionnaire
.8 CLDEQ questionnaire
.9 Lens fitting data
.9.1 Trial lens
.9.2 CL fitting evaluation
.9.3 Over refraction and best corrected visual acuity.
.9.4 Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable)

- *Study visit number 2*
  .1 Randomization: lens type corneal gas permeable or scleral lens
  .2 Time started/finished lens application and removal handling
  .3 Best corrected visual acuity with lens #1
  .4 Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable)

- *Study visit number 3*

  .1 Best corrected visual acuity with lens #1
  .2 Hours of lens wear today, average hours of lens wear time, days per week of per week and daily time spent on lens application and removal
  .3 Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable)
  .4 OSDI questionnaire
  .5 CLDEQ questionnaire
  .6 Time started/finished application and removal handling
  .7 Best corrected visual acuity with lens #2
  .8 Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable)

- *Study visit number 4*
  .1 Best corrected visual acuity with lens #2
  .2 Hours of lens wear today, average hours of lens wear time, days per week of per week and daily time spent on lens application and removal
  .3 Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable)
  .4 OSDI questionnaire
  .5 CLDEQ questionnaire
  .6 Participant final selection of lens of choice #1 or #2
  .7 Participant final selection of lens of choice #1 or #2 given average self-pay cost of annual replacement.

Non-study visits

Lens #1- number of lenses needed to finalize

Lens #2- number of lenses needed to finalize

Unscheduled visits

.1 Study ID

Date

Reason for unscheduled visit

Lens type unscheduled visit is related to (corneal gas permeable or scleral lens)

Lens loss

Lens breakage

Other problem (describe)

Len cessation advised? Yes/No

Adverse Event reporting

Study ID

Date

Type of adverse event:

Medical treatment required:

Len cessation advised? Yes/No

Questionnaires

OSDI 12

CLDEQ-8

Ocular Surface Disease Index© (OSDI©)[2]

Ask your patients the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

Have you experienced any of the following *during the last week*?	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light? . .	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5 (A)

Have problems with your eyes limited you in performing any of the following *during the last week*?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9 (B)

Have your eyes felt uncomfortable in any of the following situations *during the last week*?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned? . . .	4	3	2	1	0	N/A

Subtotal score for answers 10 to 12 (C)

Add subtotals A, B, and C to obtain D
(D = sum of scores for all questions answered) (D)

Total number of questions answered
(do not include questions answered N/A) (E)

Please turn over the questionnaire to calculate the patient's final OSDI© score.

Patient/Subject #:_____

Date:__/___/____Time:_____

CONTACT LENS QUESTIONNAIRE-8 (CLDEQ-8)

1. Questions about **EYE DISCOMFORT**:

   a. During a typical day in the past 2 weeks, **how often** did your eyes feel discomfort while wearing your contact lenses?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

   When your eyes felt discomfort with your contact lenses, **how intense was this feeling of discomfort…**

   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	**1**	**2**	**3**	**4**	**5**

2. Questions about **EYE DRYNESS**:

   a. During a typical day in the past 2 weeks, **how often** did your eyes feel dry?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

   When your eyes felt dry, **how intense was this feeling of dryness**…

   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	**1**	**2**	**3**	**4**	**5**

3. Questions about **CHANGEABLE, BLURRY VISION**:

   a. During a typical day in the past 2 weeks, **how often** did your vision change between clear and blurry or foggy while wearing your contact lenses?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

   When your vision was blurry, **how noticeable was the changeable, blurry, or foggy vision** …

   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	**1**	**2**	**3**	**4**	**5**

4. Question about **CLOSING YOUR EYES**:
   During a typical day in the past 2 weeks, **how often** did your **eyes bother you so much that you wanted to close them**?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

5. Question about **REMOVING YOUR LENSES**:
   How often during the past 2 weeks, did your eyes *bother you so much* while wearing your contact lenses that you felt as if you needed to stop whatever you were doing and **take out your contact lenses**?

   1 Never
   2 Less than once a week
   3 Weekly
   4 Several times a week
   5 Daily
   6 Several times a day