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IRB Approved at the
Protocol Level
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Corneal Oxygen Uptake with Apioc Contact Lenses

Protocol Len-003

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Columbus, OH

Revision	Originator	Description of Changes	Date
0.0	J Barr, N Satiani	New Protocol	12/22/2018

Background and Introduction

The human cornea is an avascular tissue that receives its oxygen through the tear film. It is well accepted that contact lens wear interrupts this oxygen diffusion and results in physiologic changes (Smelser GK, 1955). Contact lens and oxygen metrics to prevent these physiologic changes due to contact lens wear like corneal swelling, limbal injection, and neovascularization have been calculated (Brennan NA, 1987; Papas, 1998; Yeung KK, 2018). The Apioc lens design differs from commercially available lenses primarily because it has greater on-eye movement. It is proposed that this greater movement allows for greater tear flow and thus greater oxygen diffusion to the cornea.

Human corneal oxygen uptake rate is measured by gently placing a polarographic oxygen sensor against the central cornea while the subject is seated in a chair and fixating a target straight in front of the subject on the wall. A Dual Channel oxygen meter with automated respirometry software amplifies the current output of the sensor and displays the oxygen tension in torr. The sensor has a flat, non-recessed 25 um diameter silver anode covered by a nominal 12.5-um polyethylene membrane. To maintain proper sensor function, as well as sanitary conditions, the membrane covering the sensor tip which contacts the cornea is changed between subjects.

Calibration of the sensor allows for accurate measurements. The output of the sensor is zeroed by immersing the sensor into a 0.9 percent saline bath which has been bubbled with nitrogen from a compressed nitrogen gas cylinder for at least 60 minutes. Though dissolving sodium sulfite would create a more stable zero oxygen solution, this method is not safe for measurements being done on the human cornea *in vivo*. Nitrogen purging is considered the most effective method to remove dissolved oxygen for the stated purpose (Butler IB, 1994). The gain of the sensor's output is adjusted after immersion in a second bath of 0.9 percent saline bubbled with room air to establish an oxygen tension of approximately 154.3 torr (or, 20.9% of the average barometric pressure less the partial pressure of humidity). The temperature of both baths is controlled at 35.9°C, the average human corneal temperature (Purslow C, 2005).

Corneal oxygen uptake rates are derived by rapid transfer of the sensor from the 154.3-torr bath to gentle contact with mild consistent pressure against the central cornea. This transfer takes less than 2 sec. There is an initial upward burst of the sensor output to approximately 160 torr, after which the partial pressure of oxygen falls monotonically as the cornea depletes oxygen from the reservoir of the sensor (i.e., oxygen dissolved in the polyethylene jacket). Contact with the normal open-eye cornea is discontinued within approximately 28-40 seconds– when the cornea has depleted the oxygen reservoir below 40 torr. The corneal oxygen uptake rate is defined in mmHg/sec as the average depletion rate over the 100-mmHg range from 140 to 40 mmHg. It is important to note this difference in units (torr vs. mmHg) is negligible as one torr is equivalent to 0.9999998575337 mmHg. The resting oxygen uptake rate of the normal open-eye human cornea measured in this manner will therefore vary from 3.5 to 4.5 mmHg/sec.

According to Benjamin (1982) (1979) measurements of corneal oxygen uptake rate can also be made immediately after 5-min periods of eye closure, 5-min non-blinking periods of open-eye contact lens wear, and 5-min periods of open-eye contact lens wear in which blinking occurs. Each of these conditions will lower the concentration of oxygen available to the cornea and create an oxygen uptake rate that is greater than that of the resting open-eye cornea. The degree to which the oxygen uptake rate is greater is related to the degree to which the conditions lower the concentration of oxygen at the corneal surface below that of the resting condition, 20.9%.

The study objective is to compare the corneal oxygen uptake rates of the standard conditions (normal open and closed eyes) and test conditions.

Tear Flow Under Hydrogel Contact Lenses

Polse measured the tear replenishment rate under three different hydrogel lenses and determined with a slit lamp modified to serve as a fluorophotometer. He found that fractional tear volume replenishment rates under these lenses averaged 0.011 per blink, which was significantly lower than the 0.10 to 0.20 per blink reported for rigid lenses. These data suggest that the amount of oxygen delivered to the cornea by tear pumping for common hydrogel lenses is relatively small and that oxygen received by the cornea covered by a hydrogel lens comes principally by diffusion through the material (Polse, 1979).

Using hypothetical tear mixing rates, Fatt and Lin (1976) calculated the amount of oxygen under the lens attributable to tear pumping. Their results show that if the mixing efficiency (fractional replacement of the tear-lens volume per blink) is 0.05 or greater, the partial pressure contributed by tear pumping can range from 5 to 10 mmHg, depending on the oxygen transmissibility of the lens. They theorized that increasing the oxygen tension under the lens by 5 to 10 mmHg would likely reduce much of the corneal edema resulting from corneal hypoxia seen with the low-transmissibility soft lenses of their day.

The low tear interchange rate reported by Polse suggests that if corneal edema is to be prevented with contact lens wear, the material must have high enough oxygen transmissibility to meet the oxygen needs of the cornea. This observation is consistent with the predictions by Fatt and Lin (Fatt I L. D., 1976) and Fatt and Hill (Fatt I H. R., 1970), who have shown that the contribution of tear flow to the oxygen tension at the anterior cornea for most low Dk/t hydrogel lenses would be as low as 4 mmHg. Many currently used hydrogel contact lenses can only supply adequate oxygen to the cornea directly by diffusion if the lens thickness is less than 0.10 mm (Decker M, 1978).

Study Objective

I. Evaluate corneal oxygen uptake of a new translating contact lens design with comparison to published data and commercially available designs.
II. Evaluate subjectively reported comfort of a new translating contact lens design with comparison to commercially available designs.

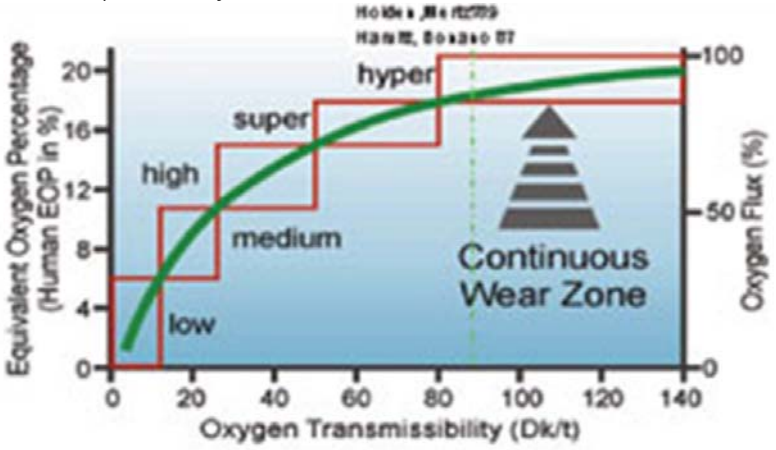
Hypothesis

We hypothesize that the Apioc lens design will provide greater tear exchange behind this novel soft contact lens than a standard soft contact lens. Its patented design suspends the lens from the upper eyelid thus allowing a looser fit and greater movement of the contact lens over the ocular surface than standard thickness soft contact lenses. These design aspects should lead to an increase in tear exchange behind the contact lens. Because tear exchange behind a soft contact lens is very difficult to measure on the human eye, and there is no tear exchange rate benchmark that is correlated with direct clinical benefits, the impact of the Apioc contact lens design will be assessed indirectly by measuring corneal oxygen uptake, as the cornea receives its oxygenation through the tears. Thus, our experimental hypothesis is that the cornea wearing the Apioc contact lens will have an oxygen uptake rate of >=10 mm Hg.

Apioc is manufactured in Definitive 74 contact lens material (Dk/t = 44) (Benjamin, 2018). If the Apioc contact lens and standard contact lens have center thickness of 0.20 mm, then the Dk/t of the lenses is 22 which correlates with 9 percent EOP. If the Apioc lens movement with blinking at a normal blink rate allows greater oxygen delivery by 30 percent to 12 percent EOP, (See illustration by Benjamin below) it will allow normal corneal thickness, (prohibit corneal swelling) in daily wear. This provides a clinical benchmark demonstrating

that the Apioc contact lens design will provide an improvement in corneal physiology over the standard soft contact lens design.

Note, lenses having an Equivalent Oxygen Percentage (EOP) of 9.9%, do not induce corneal edema. Holden and Mertz (Holden BA, 1984) state an oxygen transmissibility of at least 24.1 ± 2.7 X 10~9 (cm X ml C>2)/(sec X ml X mmHg) which correlates closely with Benjamin, above.



Study Lenses

The Apioc contact lens is a daily wear soft contact lens, which is classified under 21 CFR 886.5925 (product code: LPL). The FDA has previously made risk determinations (class II, non-significant risk) for devices classified under 21 CFR 886.5925. The Apioc-A contact lens has the same actions and indications for use as other contact lenses classified under 21 CFR 886.5925. As a non-significant risk device, the Apioc contact lens is exempt from the IDE regulation (21 CFR 812).

Subject Qualification

Number of Subjects

The total number of enrolled subjects will be 10. This is a common sample size for corneal oxygen uptake studies.

Inclusion Criteria

Prior to enrollment in the study, the following criteria must be met by each prospective subject:

1. Provide informed consent.
2. Appear willing and able to adhere to instructions set forth in the protocol.
3. Be between the ages of 18 and 45.
4. Be an experienced contact lens wearer.
5. Be an eyecare clinician or clinician-in-training.
6. Flat and steep keratometry readings within 40 to 50D.
7. Clear, healthy corneas with no irregular astigmatism.
8. Normal, healthy conjunctiva in both eyes.
9. Be able to provide corneal topography measurements.
10. Be able to provide manifest refraction measurements.

Exclusion Criteria

1. Irregular corneal astigmatism.
2. Use of topical or systemic antihistamines within the previous week.
3. Use of topical ophthalmic drops within the previous two days.
4. History of corneal surgery.
5. Currently pregnant or lactating.
6. Systemic disease that would interfere with contact lens wear.
7. Previous diagnosis of dry eye syndrome.

Study Design and Procedures

Study Design

Structure: Single center, serially recruited

Duration: approximately one month from consent to study completion

Visit Schedule: up to three study visits separated by a minimum of 48 hours

Clinical Study Methods

In this study, an experienced clinician will apply the oxygen electrode as described above to one eye of up to 10 subjects who are experienced contact lens wearers, eyecare clinicians or clinicians-in-training, and have no active ocular conditions that would preclude short term contact lens wear.

There will be up to five scenarios that will be examined at each visit: cornea with no stimulus to represents the high oxygen condition; immediately after gently closing their eyes for 5 minutes to represent the low oxygen condition; and after contract lens wear. Lens options include Apioc lens design with lenticular, Apioc lens design without lenticular, and commercially available contact lenses. The contact lens conditions will be worn with normal blinking – every four seconds for five minutes prior to oxygen uptake measures. The scenarios will be randomized to minimize bias.

Each of these measurements lasts less than one minute and are repeated at two additional visits.

A rest period of at least ten minutes of normal open eye blinking should be allowed between measurements of the same eye.

The conjunctiva of the subject will be examined prior to probe applications and between probe applications to assess ocular irritation induced by the probe. An increase in two grades on to the Brien Holden Vision Institute Grading Scales (see appendix) will indicate a need to discontinue measurements for the day.

Screening

I. Statement of Informed Consent
    A. Prior to enrollment, each subject must read, understand, and sign the informed consent document. It must also be signed by a study team member who is authorized to consent subjects.
    B. Each subject must be given a signed version of this document.

II. Eligibility
    A. All criteria must be met.
    B. All responses to Inclusion Criteria must be “yes.”
    C. All responses to Exclusion Criteria must be “no.”

III. Demographics – Age (in years and months)

Baseline Visual and Ocular Assessment

I. Measure presenting visual acuities: OD, OS
II. Anterior segment slit lamp examination
    A. Ocular abnormalities noted
    B. Eligibility – examiner will determine if subject continues to meet inclusion/exclusion criteria

Oxygen Consumption of the Cornea Measurement

I. Setup equipment in accordance with the procedure manual.
II. Instill 1 drop of artificial tears into the eye that will not be measured.
III. Experimental Conditions
    A. High oxygen conditions: normal open eye conditions with normal blinking
    B. Low oxygen conditions: close both eyes for 5 minutes prior to testing
    C. Soft contact lens conditions: apply contact lens to test eye and wait at least 5 minutes. Blink to a metronome set at 15 blinks per minute. Remove the contact lens immediately before the probe is applied in step IV below. In one visit, measure up to three different contact lens designs in a randomized order:
        i. Apioc lens design with lenticular
        ii. Apioc lens design without lenticular
        iii. Standard lens design with a thickness equivalent to the mean thickness of the Apioc design with lenticular
        iv. Commercially available contact lenses
IV. Collect measurements in accordance with the procedure manual.
    A. Measurements will be randomized to minimize bias.
    B. Measurements will be repeated if initial review of data indicates poor quality.
V. Determine whether the study visit is complete.
    A. Visually assess conjunctival redness. An increase of two grades in bulbar or limbal redness on the reference grading scales indicates the current study visit is complete.
    B. Ask the subject to complete the comfort assessment (see Appendix). An answer of “no” to question 2 indicates the current study visit is complete.
    C. A completion of all measurements listed in the conditions above (A, B, and up to three contact lenses for condition C) indicates the current study visit is complete.
VI. If another measurement will be collected in the current study visit, a rest period of at least ten minutes of normal open eye blinking will be allowed between measurements of the same eye.

Concluding Visual and Ocular Assessment

I. Measure visual acuities with presenting correction in place: OD, OS
II. Anterior segment slit lamp examination
    A. Ocular abnormalities noted

Corneal Oxygen Uptake Calculation

Calculate the slope over a 100 torr drop in oxygen uptake – from 140 torr to 40 torr.

Data Analysis

The study objective is to compare the corneal oxygen uptake rates of the standard conditions (normal open and closed eyes) and test conditions. Paired t-tests will be performed to determine if this objective is met.

The individual performing data analysis will be masked to minimize bias.

Safety and Adverse Events

Subjects in this study are exposed to a test contact lens. Adverse events reported before the use of the test lens should be recorded as medical history. Untoward medical events reported after the subject's exit from the study will be recorded as adverse events at the discretion of the Investigator.

All adverse events either observed by the Investigator, one of his/her medical collaborators, or reported by the subject spontaneously or in response to direct questioning, will be recorded on an adverse event form. Documentation will include a description of the adverse event, time of onset, duration of event, treatment regimen instituted, any referral to other health care providers (if needed), outcome, prognosis, and likely etiology. Habitual visual acuity will be recorded prior to the report of an adverse event (as part of the examination), upon report of the subject's report of the adverse event, and after the adverse event has resolved. All adverse events will be followed in accordance with standard of care.

The Investigator will evaluate adverse events to ensure the events are categorized correctly. Elements of categorization will include (definitions provided in following section):

- Causality - i.e. the relationship between the test lens and the adverse event (not related; doubtful; possible; probable; very likely)
- Severity - i.e. the degree of intensity of the adverse event (mild, moderate, severe)

Adverse Event (AE) Definitions

An AE is any untoward (unwanted) medical occurrence in a patient or clinical investigation subject administered a test lens, if caused by the test lens. An AE can therefore be any unfavorable or unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of the test lens if related to the test lens.

An AE includes any condition (including a pre-existing condition) that: 1) was not present prior to study treatment, but appeared or reappeared following initiation of study treatment; or 2) was present prior to study treatment but worsened during study treatment. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states. Pregnancy should be documented as an adverse event and should be reported to the clinical monitor and to the Sponsor immediately upon learning of the event.

Causality Assessment

A determination of the relationship between an adverse event and the test lens. The test lens relationship for each adverse event should be determined by the investigator using these explanations:

Not Related

An adverse event that is not related to the use of the test lens.

Doubtful

An adverse event for which an alternative explanation is more likely, e.g. concomitant treatment, concomitant disease(s), or the relationship of time suggests that a causal relationship is not likely.

Possible

An adverse event that might be due to the use of the test lens. An alternative explanation, e.g. concomitant treatment, concomitant disease(s), is inconclusive. The relationship in time is reasonable. Therefore, the causal relationship cannot be excluded.

Probable

An adverse event that might be due to the use of the test lens. The relationship in time is suggestive (e.g. confirmed by de-challenge). An alternative explanation is less likely, e.g. concomitant treatment or concomitant disease(s).

Very Likely

An adverse event that is listed as a possible adverse effect (device) and cannot be reasonably explained by an alternative explanation, e.g. concomitant treatment of concomitant disease(s). The relationship in time is very suggestive, ex: it is confirmed by de-challenge and re-challenge.

Severity Assessment

A qualitative assessment of the degree of intensity of an adverse event as determined by the investigator or reported to him/her by the subject. The assessment of severity is made irrespective of test lens relationship or seriousness of the event and should be evaluated according to the following scale:

Mild

Event is noticeable to the subject but is easily tolerated and does not interfere with the subject's daily activities. These conditions are usually asymptomatic and usually do not warrant discontinuation (temporary or permanent) of the test lens. Nonetheless, the Investigator may choose to treat the condition as a precautionary measure.

Diagnoses and conditions that are considered Mild Adverse Events include the following:

- Non-significant Infiltrative Event
- Contact Lens Papillary Conjunctivitis
- Superficial Punctate Keratitis
- Conjunctivitis: Bacterial, Viral, Allergic
- Blepharitis
- Meibomianitis
- Contact Dermatitis
- Localized Allergic Reactions
- Any corneal event not explicitly defined as serious or significant adverse event, which necessitates temporary lens discontinuation < 2 weeks

Moderate

Event is bothersome, possible requiring additional therapy, and may interfere with the subject's daily activities. Those events that are usually symptomatic and warrant discontinuation (temporary or permanent) of the test lens (excluding Serious Adverse Events).

Diagnoses and conditions that are considered Moderate Adverse Events include the following:

- Contact Lens Induced Peripheral Ulcer (CLPU)
- Significant Infiltrative Events (SIE)
- Superior Epithelial Arcuate Lesions (SEALs)
- Any Temporary Loss of 2 Lines of BSCVA
- Other grade 3 or higher corneal findings, such as abrasions or edema
- Any corneal event which necessitates temporary lens discontinuation for ≥ 2 weeks
- Non-contact-lens-related-corneal-events – ex: EKC (Epidemic Keratoconjunctivitis)

- Asymptomatic Corneal Scar

Severe

Event is intolerable, necessitates additional therapy or alteration of therapy and interferes with the subject's daily activities. A serious AE is any untoward medical occurrence that:

- Results in death
- Is life threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Has potential to cause permanent impairment of a body function
- Has potential to cause damage to a body structure and may necessitate medical or surgical intervention

Diagnoses and conditions that are considered Serious Adverse Events include:

- Microbial Keratitis (MK)
- Iritis
- Permanent decrease in best spectacle corrected visual acuity equivalent to 2 acuity lines or greater
- Central Corneal Opacity
- Central Corneal Neovascularization
- Uveitis
- Endophthalmitis
- Hypopyon
- Hyphemia
- Penetration of Bowman's Membrane
- Persistent Epithelial Defect
- Limbal cell damage leading to conjunctivalization

Upon finding an adverse event, the Principal Investigator will document the condition on the follow-up visit examination form using photos or drawings (where appropriate) that detail size, location, and depth. He/she will also complete the Adverse Event Classification (AEC) Discovery Form.

Adverse Event Follow-up

It is the Investigator's responsibility to maintain documentation of each reported adverse event. All adverse events will be followed in accordance with standard of care. Such documentation will include the following:

- Diagnosis
- A description of the adverse event or ocular complication
- Detailed drawings or photographs, when appropriate
- Time of onset
- Duration of event
- Treatment regimen instituted, in accordance with state/national licensing requirements
- Any referral to another health care provider if needed
- Outcome, ocular damage (if any)
- Likely etiology
- Best corrected visual acuity at the discovery of the event and upon conclusion of the event

Subjects who present with an adverse event should be followed by the Investigator, within licensure, until all signs and symptoms have returned to pre-treatment status, stabilized, or been satisfactorily explained. If further treatment (i.e. beyond licensure) is required, the patient will be referred to the appropriate health care provider. The Investigator should use his/her clinical judgment as to whether a subject reporting with an

adverse event should continue in the study. If a subject is discontinued from the study, it will be the responsibility of the Investigator to record the reason for discontinuation. The investigator will also complete the Adverse Event Classification (AEC) Outcome Form.

Adverse Event Reporting Timeline

The investigator will notify the Sponsor of an adverse event by e-mail, facsimile, or telephone as soon as possible and no later than 24 hours from discovery of a serious adverse event, and no later than 3 working days from discovery of any non-serious potentially related adverse event. In addition, the study Sponsor will submit notification to the IRB according to their requirements. Such a report should comment on whether the adverse event was considered test lens related.

All adverse events will be recorded on the Adverse Event Classification (AEC) Outcome Form and evaluated by the investigator – see appendix, page 12.

Serious Adverse Events:

The Investigator will inform the sponsor of all serious adverse events occurring during the study period as soon as possible by e-mail, fax, or telephone, but no later than 24 hours following discovery of the event. All subjects experiencing a serious adverse event must be followed and all outcomes must be reported.

In the event of a serious adverse event, the investigator must:

1. Notify the Sponsor immediately
2. Obtain and maintain in the subject's file all pertinent medical records, information, medical judgment and follow-up of the subject
3. Provide the Sponsor with a complete case history which includes a statement as to whether the event was or was not related to the use of the investigational test lens
4. Notify the IRB as required by the IRB reporting procedure and by federal, state and local regulations

Non-Serious Adverse Events:

All non-serious adverse events will be reported to the sponsor no later than 3 working days from discovery for review by the sponsor's medical officer.

Unanticipated (Serious) Adverse Device Effect (UADE):

In the event of an Unanticipated (Serious) Adverse Device Effect (UADE), the Investigator will submit a report of the UADE to the Sponsor and IRB as soon as possible, but no later than 10 working days after the Investigator first learns of the effect.

The Sponsor must conduct an evaluation of the UADE and must report the results of the evaluation to FDA, the IRB and participating investigators within 10 working days after the Sponsor first receives notification of the effect.

Protocol Deviations

In the event of an unintentional protocol deviation, the Investigator will notify the sponsor's Chief Medical Officer who will decide whether the deviation was significant enough to notify the IRB. No changes in the protocol can be put into effect without prior authorization by the IRB unless the change is required to reduce the risk or eliminate immediate hazard to the study subjects. This includes all advertising for subject recruitment which must be approved by the IRB prior to dissemination.

Appendix

Comfort Assessment

1. Please make a mark on the line to tell us your answer. How much discomfort did you feel with the contact lens on your eyes?

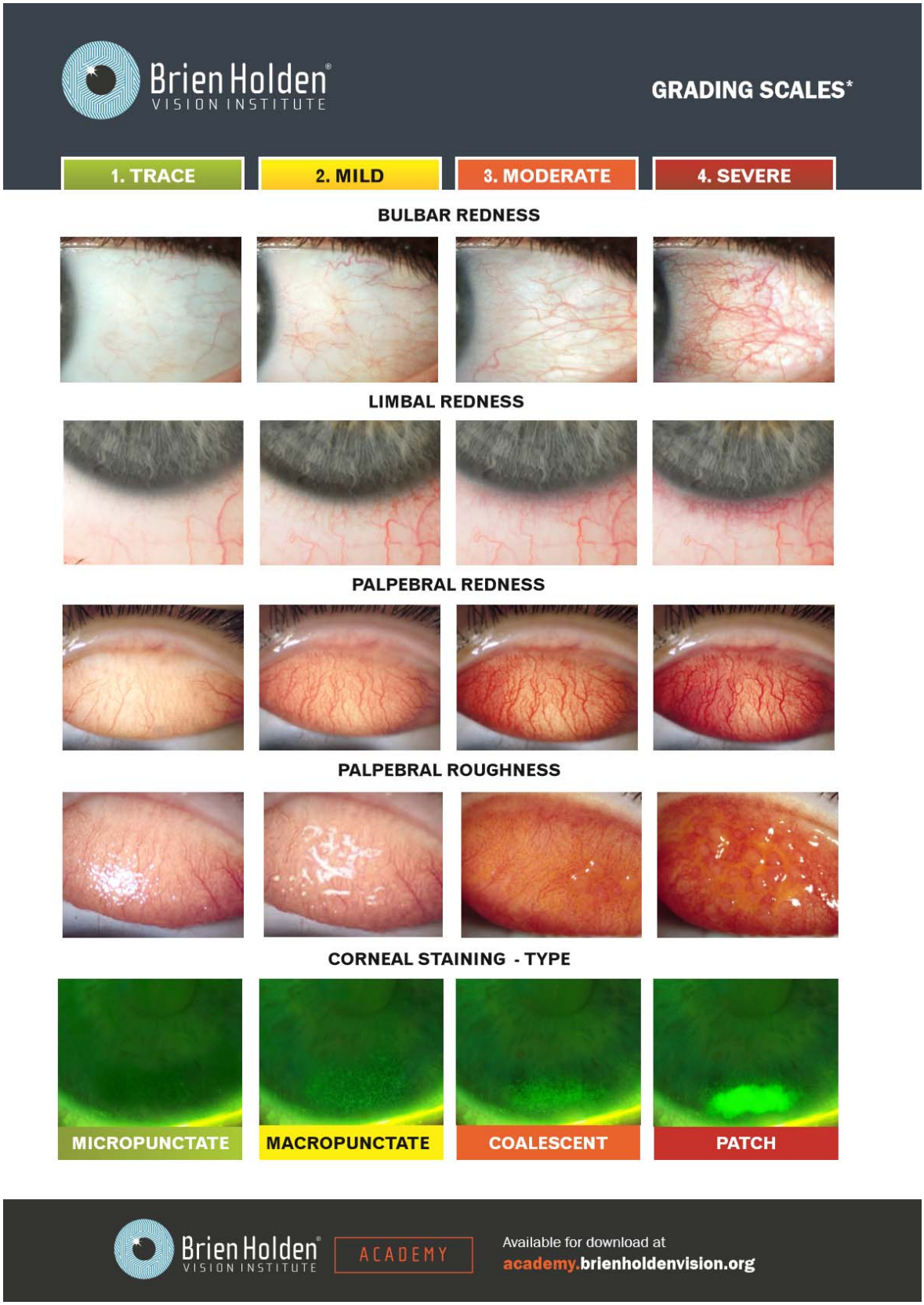
   N/A

pain, must remove lenses now 0 _____ no sensation 100

2. Please circle your answer. Subjectively, do you feel comfortable doing another measurement today?

   Yes No

Brien Holden Vision Institute Grading Scales



Adverse Event Classification (AEC) Form

Adverse Event Onset Date (MMM/DD/YYYY): ___ ___ ___ /___ ___ / ___ ___ ___ ___	
Eye:	OD OS OU N/A (mark N/A if AE is not related to the eyes)
AE Number	___ ___ ___ Subject Number ___ ___ AE Number
Specify Adverse Event	_____ _____ _____ _____
Causality	Not Related - An adverse event that is not related to the use of the test lens. Doubtful - An adverse event for which an alternative explanation is more likely, e.g. concomitant treatment, concomitant disease(s), or the relationship of time suggests that a causal relationship is not likely. Possible - An adverse event that might be due to the use of the test lens. An alternative explanation, e.g. concomitant treatment, concomitant disease(s), is inconclusive. The relationship in time is reasonable. Therefore, the causal relationship cannot be excluded. Probable - An adverse event that might be due to the use of the test lens. The relationship in time is suggestive (e.g. confirmed by de-challenge). An alternative explanation is less likely, e.g. concomitant treatment or concomitant disease(s). Very Likely - An adverse event that is listed as a possible adverse effect (device) and cannot be reasonably explained by an alternative explanation, e.g. concomitant treatment of concomitant disease(s). The relationship in time is very suggestive, ex: it is confirmed by de-challenge and re-challenge.
Severity	Mild - Event is noticeable to the subject but is easily tolerated and does not interfere with the subject's daily activities. Moderate - Event is bothersome, possibly requiring additional therapy, and may interfere with the subject's daily activities. Severe - Event is intolerable, necessitates additional therapy or alteration of therapy and interferes with the subject's daily activities.
Treatment Implemented and Recommended Follow-up	_____ _____ _____
Signature of Examiner	_____ Signature ___ ___ ___ / ___ ___ /___ ___ ___ ___ (MMM/DD/YYYY)

Adverse Event Follow-up Form

Adverse Event Follow-up Date (MMM/DD/YYYY): ___ ___ ___ /___ ___ / ___ ___ ___ ___	
Eye:	OD OS OU N/A (mark N/A if AE is not related to the eyes)
AE Number	___ ___ ___ (Subject Number) ___ ___ (AE Number)
Brief Summary of Pertinent Findings	_____ _____ _____ _____
Action Taken and Recommended Follow-up	_____ _____ _____
Signature of Examiner	_____ (Signature) ___ ___ ___ / ___ ___ /___ ___ ___ ___ (MMM/DD/YYYY)

Adverse Event Outcome Form

Adverse Event Resolution Date (MMM/DD/YYYY): ___ ___ ___ /___ ___ / ___ ___ ___ ___	
AE Number	___ ___ ___ (Subject Number) ___ ___ (AE Number)
Final Outcome	Recovered without sequelae Recovered with sequelae Describe sequelae: _____ Ongoing Ongoing but stable Death Date of death (MMM/DD/YYYY): ___ ___ ___ / ___ ___ / ___ ___ ___ ___ Other. Describe: _____
Signature of Examiner	_____ (signature) ___ ___ ___ / ___ ___ /___ ___ ___ ___ (MMM/DD/YYYY)

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