Contact Lens Adaptation in Neophytes (CLAN)

Study Protocol & Analysis Plan

NCT02148263

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Birmingham, AL 35294

CONSENT FORM

Title of Research:	Contact Lens Adaptation in Neophytes (CLAN)
UAB IRB Protocol #:	170324011
Principal Investigator:	Andrew D. Pucker, OD, PhD
Sponsor:	National Eye Institute, The Ohio State University College of Optometry, University of Alabama at Birmingham

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with the University of Alabama at Birmingham. If you are a student or employee at the University of Alabama at Birmingham, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

Eye doctors often instruct new contact lens patients to gradually increase the amount of time that they wear their contact lenses each day until they are wearing their contact lenses for an entire day. This study will determine if that is necessary.

2. How many people will take part in this study?

Approximately 30 people will participate in this study.

3. What will happen if I take part in this study?

You will be placed by chance into one of two study groups. After a successful contact lens fit and instruction of care, one group of subjects will slowly increase their wearing time and the other group of subjects will wear their contact lenses for a full day starting with day one. Your eye health will be evaluated with a microscope and your eye comfort will be assessed with surveys at the first visit and at the one and two week visit. You will also keep a daily diary of your eye comfort. This diary will be provided to you.

4. How long will I be in the study?

You will be in this study for two weeks. The first visit will last approximately two hours and subsequent visits will last about 30 minutes each.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with the University of Alabama at Birmingham.

6. What risks, side effects or discomforts can I expect from being in the study?

New contact lens wearers may have mild discomfort during the first few days of contact lens wear. Contact lens wear may lead to red eyes, uncomfortable eyes, or decreased vision, and the contact lens care solution used in this study could cause a mild allergic reaction. These problems don't happen often and usually get better without any treatment. Very rarely, contact lens wearers may get an eye infection, which can lead to permanent vision loss. You will be assigned to a wear schedule group by chance, which may prove to be less effective for initial contact lens use or to have more side effects than the other study group.

7. What benefits can I expect from being in the study?

You will get to wear contact lenses free of charge with no commitment to continue wearing contact lenses. If you like the contact lenses, you will receive a prescription at the end of the study.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. You may also be fit with contact lenses by an eye care practitioner, or you may continue to wear glasses.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices. An IRB is a group that reviews the study to protect the rights and welfare of research participants;
- The UAB Institutional Review Board (IRB);
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized University of Alabama at Birmingham staff not involved in the study may be aware that you are participating in a research study and have access to your information.

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 website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

There will be no cost to subjects in this study.

11. Will I be paid for taking part in this study?

By law, payments to subjects are considered taxable income. Subjects will be paid $10.00 for each study visit.

12. What happens if I am injured because I took part in this study?

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at the University of Alabama at Birmingham reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Andrew D. Pucker, OD, PhD at 205-934-3093 or email apucker@uab.edu.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Andrew D. Pucker, OD, PhD at 205-934-3093 or email apucker@uab.edu.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time

University of Alabama at Birmingham

AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: Contact Lens Adaptation in Neophytes (CLAN)

UAB IRB Protocol Number: 1704100001
Principal Investigator: Andrew D. Pucker, OD, PhD
Sponsor: National Eye Institute, The Ohio State University, University of Alabama at Birmingham

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? *Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.*

Can I cancel this Authorization? *You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.*

Can I see my protected health information? *You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.*

Signature of participant: _____ *Date:* _____
or *participant's legally authorized representative:* _____ *Date:* _____
Printed Name of participant's representative: _____
Relationship to the participant: _____

CLAN STUDY METHODS

BEFORE THE STUDY VISIT

Recruitment

You can recruit subjects via word of mouth or any of the IRB approved recruitment methods (fliers, postcards, email). The easiest method will likely be via word of mouth from your clinic schedules. Fliers have not been very helpful but can be used. Post cards seem to work. If you want to use this method, you will need to contact Alex Vu for a list of subjects who have been seen in our clinic in the last six months (patients with diagnosed myopia or hyperopia without astigmatism); Keri can then print the post cards for you using the patient contact information and IRB approved postcard. Email works well. If you use email, you should consider contacting optometry, dentistry, medicine, and nursing (not on the same day). Once you have found subjects, you should then screen them with the phone screen survey (can be done in person). If they pass, you need to make sure that they can come in three weeks in a row on the same day of the week (+/- 1 day). You also need to tell them to bring in their glasses prescription. If you pull it for them from Compulink, you need to record that you pulled it on the records review form in the main documents folder.

Rooms

You should open each room and setup the rooms prior to each visit (make sure things turn on). Room 452 has the autorefractor and Baily-Lovie eye chart; you can use other autorefractors or logMAR eye charts if they are more convenient for you. Don Mutti or Kimberly Shaw can open this room for you. Room 446 has the Keratograph 5M (TMH and bulbar redness), and Room 546 has the Medmont (NITBUT). You should coordinate with Matt (kowalski.145@osu.edu) and Erin to schedule to use these rooms; they can also you help you open these rooms. You will conduct the rest of the study visit in the pre-clinic area (2nd Floor Fry). Make sure that you have a study folder prepared for the subject (all documents are up to date). Use an old folder as a reference.

STUDY VISIT

Informed Consent for Study Participation (Unmasked Examiner)

The phone screen questionnaire should be used again to verify that the subjects are still eligible to participant in the study before they can be enrolled into the study. A study representative should then discuss the study with the patient and give him/her an opportunity to answer questions. Consent will be documented when the patient and investigator have both signed the IRB approved consent form. Make sure everything is signed and dated at the visit. It is an ethics violation if you do not do this! The subject should be given a copy of the signed consent form. Consent should be obtained prior to completion of any of the study surveys or clinical test. If the patient is younger than eighteen years old, they will need to sign an IRB approved assent form, and their guardian will need to sign the IRB approved parental permission form. Copies of these documents should also be provided to the subject. The subject should then be asked to sign a HIPAA form. After these forms are done, testing can begin.

Assignment of Subject ID Number (Unmasked Examiner)

Once consent has been obtained, the study investigator will assign the subject a unique ID number ranging from 301 to 330. These numbers should be given out consecutively.

Habitual Spectacle Prescription (Unmasked Examiner)

The subjects will be asked to provide a valid spectacle prescription at the start of the study. The potential subject will be asked to reschedule their exam if they are unable to provide this information.

Questionnaires (Unmasked Examiner)

Subjects will be asked to complete the OSDI questionnaire at the start of each visit. They will also be asked to complete the CLDEQ at the start of the second and third study visits. You should enter the subject's ID number into the form for them, so we know for sure that the ID number is entered correctly. The questionnaires will be administered electronically; however, paper forms may be used if Internet access is not available. All paper forms must be entered electronically within one day of the study visit by the unmasked examiner (really, just make sure the online version works).

OSDI Link: https://survey.qualtrics.com/SE/?SID=SV_8B0PMcLP2smXMX3
CLDEQ Link: https://survey.qualtrics.com/SE/?SID=SV_3pA88YmNqnBLX4V

Note that you may want to have these links on the computer desktop, and you should check to make sure that they work before the visit. Also, just tell patients to answer the questions to the best of their ability.

Visual Acuity (Unmasked Examiner)

1. The subject will be comfortably seated and asked to wear their habitual spectacle correction.
2. The examiner will then have the subject read the Bailey-Lovie eye chart (LogMAR). The examiner should encourage the subject to do their best while performing the test. Habitual room lighting conditions are acceptable for this study.
3. The examiner should then record right and left eye visual acuity (LogMAR & Snellen Equivalent).

LogMAR conversion chart by row (when tested at 6-meters)

LogMAR	Snellen Equivalent
0.8	20/125
0.7	20/100
0.6	20/80
0.5	20/63
0.4	20/50
0.3	20/40
0.2	20/32
0.1	20/25
0.0	20/20
-0.1	20/16

-0.2	20/12.5
-0.3	20/10
-0.4	20/8
-0.5	20/6.3

Auto Refraction & Keratometry (Unmasked Examiner)

1. Comfortably seat participant with their head supported by the forehead and chin rest.
2. Instruct participant to look straight ahead.
3. Center the auto-refractor mires with the pupil center - right eye.
4. Instrument takes automated readings (3 per eye).
5. Switch to left eye and repeat steps 2 to 4.
6. Record the average values for each eye: sphere/cylinder X axis with power and Ks. If the machine does not provide K readings, do not worry about it.

TMH with K5M (Unmasked & Masked Examiners)

Note: Notify the masked examiner that they will be needed in about five minutes.

Unmasked Examiner

1. Double click the Oculus program.
2. Enter participants details
   - Last Name: Study name (CLAN)
   - First Name: ID number
   - Enter 01/01/1990 for DOB. Make sure that age in years and months was recorded on the subject's history form.
3. Select "examination"
4. Click "new"
5. On the panel in the left - Locate TF scan.
6. Click on TMH.
7. Comfortably seat participant with their head supported by the forehead and chin rest.
8. Focus the TMH in white light mode.
9. Capture image.
10. Repeat for left eye.
11. Move on to next test

Masked Examiner (Completed after Exam)

12. Open the captured image
13. The ruler should just automatically be on.
14. Obtain the height (temporally below the most temporal part of iris) of the meniscus by using the ruler tool three times (Masked Examiner must do the measurements).
15. Measurements for each eye will be averaged and used in analysis.

Bulbar and Limbal Redness with K5M (Unmasked & Masked Examiners)

Unmasked Examiner

1. Double click the Oculus program icon.
2. Select participant name from the list (participant details will be saved - see TMH for details).
3. Select “examination”
4. Click “new”
5. On the panel in the left - locate R-scan bulbar redness.
6. Seat patient and ask them to look straight ahead.
7. Focus and capture an image.
8. The instrument provides redness reading automatically in 0.1 steps.
9. Move on to next test

Masked Examiner (Completed after Exam)

10. Record the following on the data collection form
    - Temporal and nasal bulbar conjunctival redness
    - Temporal and nasal limbal redness
    - Overall bulbar conjunctival redness
    - Overall bulbar conjunctival redness area (mm^2).

NITBUT – Medmont (Masked Examiner)

1. Comfortably seat participant with their head supported by the forehead and chin rest.
2. The instrument has a keratoscope unit that produces concentric rings of light, which are reflected off the cornea and imaged in a CCD camera.
3. Ask the participant to look at a fixation light at the center of the concentric rights of light.
4. Ask participants to blink 3 times before each measurement.
5. NITBUT can be determined by measuring the time taken for distortions or discontinuities to appear in the reflected image of the concentric ring pattern.
6. Measure the time (in seconds) for the tear-film to rupture (and thus distort the rings) using a stopwatch, to the nearest 0.1 of a second (phone or stopwatch in box).
7. Three measurements should be taken of each eye and recorded on the exam sheet. Make sure to pull the instrument back between each measurement in order to allow the subject to have a break between readings (~10s).
8. The mean values obtained in both eyes will then be averaged and used for data analysis.

Anterior Segment Assessment (Masked Examiner)

1. Position the slit lamp (white light) at the cornea using medium magnification.
2. Assess for the presence or absence of pingecula/pterygium, lid notching, and corneal scarring. If corneal scarring is present, draw location of scar in the designated area of the data collection sheet.
3. Assess/grade blepharitis using the scale provided in the data collection sheet.
4. Assess/grade corneal vascularization using the scale provided in the data collection sheet.
5. Record all values on the data collection sheet.

Fluorescein Corneal Staining (Masked Examiner)

1. Wet the fluorescein strips (Bio Glo) with 2-3 drops of Unisol (or equivalent) and shake off the excess solution.
2. Wait for 3 seconds to ensure that the fluorescein in particles dissolve before applying the strip.

3. Instill a small amount by touching the superior bulbar conjunctiva; make sure to avoid touching the eyelids with the strip.
4. Instruct participant to blink several times.
5. Staining will be evaluated 2.0 - 2.5 minutes following fluorescein dye instillation (use the stopwatch).
6. This procedure should be conducted at a magnification of 8X to 12X using cobalt blue illumination. A yellow barrier filter should be used.
7. Use a 0-4 scale (0.5 increments) to grade the type of staining, and a 0-4 scale (1.0 increment) to grade the extent/area and depth of staining. Make sure to have the subject blink to verify that staining is truly present. The grades for staining should be standardized to the CCLRU grading scale. There is a better explanation of the back of the grading card.
8. Record staining, type and extent in the 5 regions of the cornea for each eye.

Lissamine Green Conjunctival Staining

1. Not tested. Just cross it out.

Schirmer Test 1 (Masked Examiner)

1. Prepare the strips in the package by folding the rounded end at the indentation, approximately 5 mm from the tip.
2. Position the strips into the inferior cul-de-sac at the lateral third of the eyelid
3. After inserting the remaining strip into the eye, instruct the participant to gently close their eyes (both eyes tested at same time).
4. Leave the strips in place for 5 minutes (stopwatch). The subjects will be instructed to lightly close their eyes during the test to make it more comfortable. The measurements should be made to the nearest millimeter. Subjects are allowed to stop the test early if they completely wet the strips.
5. Record values for each eye.

Contact Lens Fitting (Unmasked Examiner)

Contact lenses should be selected based upon the patient's spectacle prescriptions (compensated for cylinder) and Ks. Ks flatter than 44.5 will be first given the 8.8 BC lens and Ks steeper than 44.5 will be given that 8.4 BC lens. Just use your best judgement. You will get the trial contact lenses from the contact lens clinic; you may want to get the contacts before the start of the visit. All prescriptions greater than ± 4.00 DS should be appropriately vertexed. The unmasked examiner will apply all contact lenses during the fitting process. Acuity will then be measured with electronic eye chart, and spherical over-refraction will be performed to determine if a power adjustment is needed. Subjects who are unable to accept spherical Acuvue Oasys contact lenses will be excluded from the study. Once subjects are able to obtain acceptable, comfortable vision, the contact lenses will be assessed (centration, movement, coverage). The alternative BC lens may be used if it allows for improved fit. All trialed lenses should be recorded on the last page. You can use the back of a page if needed.

Contact Lens Insertion & Removal Training (Unmasked Examiner)

The subject will then be taught how to use their contact lenses, and they will be provided with care information. The participant must demonstrate that they can remove the lens at least 3 times before they will be allowed to take home their contact lenses. This will be done to assure the safety of the participant. If the participant is unable to do so, they will be asked to return at a later date for more

training before they can continue with the study. Subjects should not start wearing their contact lenses until the next day.

Subject Randomization, Scheduling, and Take Home Materials (Unmasked Examiner)

Fully qualifying subjects will then be randomly placed into one of two groups (only subjects who have completed I&R and still want to try the contact lenses). One group will consist of gradual wear participants, and the other full-time wear participants. The randomization will be done by the unmasked examiner. Randomization will be done in a closed room away from the masked examiner. All questions about the treatment will be answered at this time. If it is the patient's first visit, then their second visit should be confirmed at this time. The next visit will be scheduled one week from the first visit (+/- 1 day). If the patient is at their second visit, then their third and final visit will be conformed and scheduled for the following week; an additional visual analog diary will be given at this time. Upon leaving the subjects will be provided with their prescribed contact lenses, a contact lens case, solution, a visual analog survey to complete throughout the week, and wear schedule directions. Subjects should be paid $10/visit and offered a parking pass. Subjects need to sign a payment form at each visit after receiving their money. If a parking pass is given, it should be noted on the payment form.

FUTURE VISITS

The subject will be asked to return for two follow up visits. The subject will provide us with their visual analog survey at each follow up visit, and they will complete the OSDI and CLDEQ surveys again at each visit. The following testing will also be completed during each follow up visit: visual acuity, NITBUT, TMH, bulbar and limbal redness, anterior segment (all slit-lamp tests even if they are unlikely to change) assessment, fluorescein corneal staining, and Schirmer's test. When the masked examiner arrives to the room, they should explicitly say that they are the masked examiner. They should also tell the patient that they cannot know which study group they are in. Scheduling will be done as described above. Subjects completing their third study visit will be released from the study and will be provided with a contact lenses prescription from the study doctor at this time if they are happy with their contact lenses (paper prescription). If a prescription is released, it should be recorded in the chart.